Investigation of Storytelling as a Requirements Elicitation Method for Medical Devices

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ABSTRACT

Medical device usability directly impacts the practitioner's ability to perform their diagnostic task in an effective, efficient, and safe manner. A device with poor usability may frustrate the practitioner, increasing the worker's stress level in a high-stress work environment. In addition, a device with poor usability may facilitate operator error, increasing the patient's risk of injury.

Designers of healthcare systems and devices face a unique conundrum that has been documented in the literature (Martin, Murphy, Crowe, & Norris, 2006; Martin, Norris, Murphy, & Crowe, 2007; Ward & Clarkson, 2007). Standards require the use of user research techniques, yet patient privacy standards prevent designers from observing users in context. The inability to observe users in their work environment impedes understanding the context-of-use. Since understanding context-of-use is required to ensure usability, further exploration into alternative methods for requirements gathering is needed.

This study explored the storytelling as an elicitation method for medical device requirements by comparing the information elicited from nurses during requirements gathering for an infusion pump by two methods: focus groups followed by interviews (Group #1) and focus groups followed by storytelling sessions (Group #2). Results suggest further exploration of storytelling is warranted as Group #2 contributed similar quantity and breadth of information in significantly less time. Results also indicate potential support for the efficacy of storytelling within the healthcare domain as Group #2 participants contributed more distinct context-of-use information with an emphasis on the social context. Contributions of this study include a plan for mixed-method data analysis, a protocol for conducting a storytelling session, and a framework for defining requirements within the healthcare domain.

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CHAPTER 1. INTRODUCTION

Present day healthcare workers must contend with various stressful job conditions throughout a typical workday. Stressful job conditions include demanding patients, understaffing, interruptions, and the increased use of technological equipment (Williams, McMurray, Baier-Manwell, Schwartz, & Linzer, 2007). Consider the following hypothetical story:

> *Edward, an anesthesiologist, starts prepping the first patient of the morning for surgery. Edward refers to the patient's chart to determine the patient's anesthesia prescription. The young patient is visibly upset and starts to cry on the gurney. Edward consoles the patient until she stops crying and returns to the IV preparation. Edward starts to enter the prescription into the infusion pump and is interrupted by the patient with a question as he chooses the dosage amount. After answering the patient's question, Edward resumes programming the prescription into the infusion pump. Edward notices that he had entered a program for 12ml instead of 125ml because he was interrupted. Edward fixes the mistake and completes the program. After programming the infusion pump, Edward attempts to insert the IV into the patient's arm but the patient begins to thrash and cry. Edward spends 15 minutes consoling the patient and after several attempts Edward is able to insert the IV. Edward thinks to himself: "It is going to be a long day".*

As demonstrated in the above story, conflicting demands between the infusion pump, the patient, and the healthcare worker resulted in a stressful day for Edward and a potential sentinel event for the patient. Thankfully, Edward caught the dosage mistake in time. However, the story reveals a gap between the usability of the medical device and the high-stress and interruptive hospital environment.

The selection of the healthcare domain as the focus for World Usability Day 2007 events emphasizes the importance of usability in medical devices. Designing for usability has the potential for a huge impact within the healthcare domain considering the high stress and high risk work environment in which the devices are used. For example, the usability of a medical device directly impacts the practitioner's ability to perform their diagnostic task in an effective

and efficient manner. A device with poor usability may frustrate the practitioner, increasing the worker's stress level in an already high-stress work environment.

In addition, poor usability can cause errors that can negatively impact patient safety. For example, analysis of a computerized physician order entry (CPOE) system, which was intended to assist doctors in ordering correct medications for their patients, revealed that poor system usability contributed to 22 medication error risks (Koppel et al., 2005). Patient safety is a common concern for healthcare organizations and the desire for continued improvement in safety is indicated by the annual development of patient safety goals developed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In addition, a recent trend in healthcare organizations is increased interest in human factors engineering, as demonstrated by the 2007 Mayo Clinic continuing education course "Human Factors in Healthcare: Practical Applications to Improve Patient Safety". Recent publications highlight the use of human factors engineering methods to analyze causal factors for medication errors in hospitals (Coombes, Stowasser, Coombes, & Mitchell, 2008; Kunac & Reith, 2005; Liu, Osvalder, & Dahlman, 2005). As a result of these interventions, hospitals have received recommendations for changes to the organization, tasks, and equipment as a means to reduce medication errors.

The design of medical devices is complex because non-functional requirements, such as usability and safety requirements, are essential design characteristics when considered within the high stress and life critical context-of-use within a healthcare setting. Scholtz and Shneiderman (1999) acknowledge the potential impact of usability on medical and air traffic control applications since they are both used in life-critical contexts. Unfortunately, non-functional requirements required for usability are notoriously difficult to manage within the requirements engineering process as they are difficult to elicit from stakeholders (Christel & Kang, 1992). In addition, non-functional requirements are difficult to specify because they are subjective quality characteristics and not objective functional characteristics (Davis, 1993).

Usability challenges for medical device designers have been identified in the literature. Drews & Westenskow (2007) recognize the potential difficulty in understanding complex high-stress, high-risk, and high-stake healthcare work environments. For example, how can a medical device designer ensure that a product is usable within a certain context-of-use if the designer does not fully understand the intended work environment? Ward & Clarkson (2007) also

recognize context-of-use complexity as a design challenge. Other challenges identified by Ward & Clarkson (2007) include the:

- High-risk and life-critical nature of tasks in healthcare compounded by environmental and task factors, such as, "high workload, inexperience, understaffing, and haste"
- Requirement to adhere to vague federal regulations during design process
- Increased use of medical devices outside of clinical setting (e.g., at home)

Based on these identified design challenges, further research is needed to explore the following issues related to the design of medical devices:

- How does a requirements engineer analyze vague usability statements such as "the infusion pump will be easy to use" and "the infusion pump will not frustrate users"?
- How does a requirements engineer elicit non-functional usability requirements from healthcare stakeholders?
- How does a requirements engineer ensure that the context-of-use is considered during the elicitation of requirements?

1.1 Healthcare Worker Stress

The Occupational Safety and Health Administration (OSHA) recognizes stress as a workplace hazard in the healthcare domain (OSHA, 2007). In addition to workplace characteristics such as overwork, understaffing, and the need to care for demanding patients with potentially life-threatening illnesses, OSHA recognizes "dealing with intricate and malfunctioning equipment" as a contributor to healthcare worker stress. Since worker interactions with medical devices can exacerbate an already stressful work environment (OSHA, 2007), designing for usability during the medical device development process has the potential to directly impact the worker's perceived stress and resulting job satisfaction.

Healthcare worker job stress is a concern due to the negative impact on worker health. NIOSH (2007) identifies the following health issues which are associated with job stress:

- Cardiovascular disease
- Musculoskeletal disorders
- Mental health problems
- Injuries due to work-related accidents

Since medical device usability impacts worker stress it also impacts worker health. Aviation is another domain in which usability of work systems impacts stress and resulting worker health. For example, air traffic control (ATC) workers' use of cluttered and confusing workstation displays while making life-critical decisions has been identified as a contributing factor to ATC worker stress (ILO, 2008). Research in ATC workstation redesign has focused on reducing operator stress through usability improvements (Paterno, Santoro, & Tahmassebi, 1999). Similarly, including usability throughout all stages of the medical device design process has the potential to reduce worker stress and subsequent health-related issues. The benefits of human factors techniques initially developed for aviation safety have been recognized by healthcare professionals. For example, surgery checklists have been modeled after aviation checklists designed to assist aircraft pilots (KSPR, 2008).

1.2 Usability in the Healthcare Domain

Standards for medical device design provide guidance for the meaning of usability within the healthcare domain. The national standard ANSI/AAMI HE74 (2001) defines usability as a "measure of the ease with which one can use or learn how to use a device". The standard does not provide any further definition for "ease of use", which may result in different interpretations by different medical device designers.

However, the international standard for the application of usability engineering to medical devices, IEC 62366 (2007), provides a more detailed definition for usability. IEC 62366 defines usability as a "characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction". The standard further defines effectiveness as a "measure of accuracy and completeness with which users achieve specified goals". The standard defines efficiency as dependent on "effectiveness in relation to the resources expended".

Although IEC 62366 does not include context-of-use within the definition of usability, the standard requires an understanding of the context-of-use during hazard analysis. Context-of-use is further explained in the standard as the characteristics of the clinical environment in which the device is used. The standard identifies six categories of contextual factors that must be considered during medical device design: spatial context, social context, technological context, hygienic context, physical context, and activity context. For example, spatial context factors

include architectural design components, such as the smoothness and inclination of the floor. A full listing of context-of-use factors defined by IEC 62366 is provided in Appendix C.

According to IEC 62366 an understanding of the context-of-use is necessary to prevent latent design hazards. Consideration of the high stress and life-critical context-of-use is necessary to ensure that the resulting medical device design is usable and safe in the real world. The emphasis within both standards on user research reinforces the need for elicitation of usability requirements from stakeholders to ensure that the context-of-use is considered during the design process.

1.3 Need for User-centered Design Model for Medical Devices

One way to incorporate usability into the design process is to apply human factors techniques and methods to the design of products in the healthcare domain. User-centered design is an approach to design which factors in the needs and limitations of end users into all stages of the design process. The international standard for human centered design processes for interactive systems, ISO 13407 (1999), defines a generic human centered design process. (Note that "human centered design" and "user-centered design" are commonly used interchangeably in the literature and will be used interchangeably here as well). The human centered iterative design process is grounded in the user's work context. Requirements are identified within the context-of-use, design solutions are proposed that meet the requirements within the context-of-use, and the design is evaluated by end users within the context-of-use. The design iterations continue until the resulting system design satisfies all identified requirements.

Application of the human centered design activities to the healthcare domain reveals opportunities within activities to incorporate usability and safety into the overall design process as shown in Table 1 below, which is compiled from a synthesis of the literature.

Table 1: Application of human-centered design activities to the healthcare domain

Human Centered Design Activities	Healthcare Domain Characteristics
Identify need for human centered design	-need for error reduction (Coombes et al., 2008; Williams et al., 2007) -need for stress reduction (HRSA, 2004; Williams et al., 2007) -need for patient safety (Purcell, 2007)
Specify context-of-use	-life critical (Ward & Clarkson, 2007) -stressful (HRSA, 2004; McVicar, 2003; Williams et al., 2007) -interruptive (Brixey et al., 2005) -requires collaboration between HFE and medical stakeholders (Garmer, Ylven, & Karlsson, 2004; Martin et al., 2007)
Specify requirements	-requires emphasis on non-functional requirements, such as usability and safety requirements (Martin et al., 2006) ***-how to elicit non-functional requirements?*** ***-how to specify non-functional requirements?*** -requires collaboration between HFE and medical stakeholders (Garmer et al., 2004; Martin et al., 2007)
Produce design solutions	-requires collaboration between HFE and medical stakeholders (Garmer et al., 2004; Martin et al., 2007)
Evaluate design	-requires collaboration between HFE and medical stakeholders (Garmer et al., 2004; Martin et al., 2007)
System satisfies specified requirements	***-how to verify and validate usability and safety requirements?***

As noted by Martin et. al. (2007), although design standards for medical devices recommend iterative design and development with an emphasis on usability, recommendations for design models specific to medical devices are lacking. ***Therefore, there is an existing need for user-centered design model for medical devices***. The development of a new UCD model for healthcare is also needed to demonstrate how human factors professionals can work with medical stakeholders in the design of new products, which has been identified as a barrier to medical device development by Martin et. al. (2007).

1.4 Need for Elicitation Technique for Non-functional Requirements

Since a UCD model for medical devices requires elicitation methods for non-functional requirements, investigation in non-functional requirements elicitation techniques within the healthcare domain is also needed. As Martin et. al (2007) argue, requirements gathering techniques currently used in healthcare, such as, contextual inquiry, cognitive task analysis,

focus groups, usability tests, and cognitive walkthroughs, lack ability to capture the full range of requirements needed during medical device design. In addition, an identified cultural problem within the healthcare domain is the reluctance of workers to report errors or near-errors due to fear of professional repercussions (Geller & Johnson, 2007). This reluctance to discuss all aspects of the context-of-use is problematic during requirements elicitation. How can usability and safety requirements be determined if stakeholders are reluctant to talk about issues with medical devices?

Investigation of novel elicitation techniques specific to the healthcare domain is necessary due to barriers preventing ethnographic research within real-world healthcare settings. For example, it might not be appropriate due to safety and legal reasons for requirements engineers and system designers to shadow a physician using a laparoscope during surgery. If designers are unable to observe the work environment directly, traditional techniques such as cognitive task analysis and contextual inquiry may not be appropriate for determining user requirements as noted by Martin et. al. (2007).

A potential solution to these problems which requires further research is the use of storytelling as an elicitation technique which focuses on the identification of non-functional requirements, as detailed in Section 2.5.2.3. Stakeholders might be more likely to discuss workplace if their experiences are placed in a hypothetical storytelling context where they are asked to identify stressful situations, usability issues, accidents, and/or errors that *could* occur. Storytelling has the potential to elicit elusive information, such as context-of-use information, from healthcare practitioners, due to the pre-existing use of narrative within the healthcare domain. For example, Coombes et. al. (2008) used storytelling to identify contributing factors to prescribing errors and provided practical recommendations for barriers to errors to hospital administrators.

As noted by (Hunter, 1991), stories are used extensively within healthcare to communicate knowledge. For example, patients relate their illness to the practitioner in a story (I started feeling the pain last night after soccer practice….), the practitioner interprets the story for meaningful information to determine a diagnosis, and the practitioner relates the diagnosis back to the patient in story form as well (It seems when you rotated your ankle during that kick you sprained a ligament….).

In contrast to functional requirements which specify the operations of the system, non-functional requirements specify quality attributes, goals, and constraints of the system (Chung, Nixon, Yu, & Mylopoulos, 1999). Simply, functional requirements specify "what" is to be done; non-functional requirements specify "how well" the system performs.

Elicitation of non-functional requirements from stakeholders is often challenging because quality goals of the system are subjective. The subjective nature of non-functional requirements introduces opportunities for miscommunication between the development team and system stakeholders (Chung et al., 1999). Elicitation techniques specific to the complexities of non-functional requirements are needed to ensure that broad stakeholder statements such as "The infusion pump will be easy to use" are fully discussed. Elicitation techniques for non-functional requirements should facilitate mutual understanding between the development team and stakeholders (Cleland-Huang, Settimi, Zou, & Sole, 2006).

Landry & Guzdial (2006) suggest that novice untrained storytellers begin stories with either an actual or an abstract event. An actual event is an experience, such as "I went to take my driver's test". An abstract event is a retrospective emotional feeling, such as "I was nervous about passing my driver's test". Storytelling could also be used in this retrospective manner by first prompting stakeholders with abstract statements such as "You were feeling stressed at work" to frame their story from an emotional context. If the stakeholder story is framed in a stressful context, stressors in the workplace might be easier to elicit.

1.5 Research Objectives

Research in the development of usable healthcare products has great impact on patient and medical practitioner health and safety. The research objective of this proposal is to investigate storytelling as an elicitation method for medical device requirements, as discussed in Section 2.5.2.3. This research is a first step within the overall goal of the development of a user-centered design methodology for medical devices.

A literature review follows.

CHAPTER 2. LITERATURE REVIEW

2.1 Job stress in healthcare

Anyone who has visited a doctor's office or hospital recently can empathize with the daily job demands of healthcare workers. The healthcare domain is generally classified as "people work", but the demands within this particular service industry are exacerbated by the life-critical nature of the work. Other common "people-work" domains, such as retail customer service, are notoriously stressful due to the demands of satisfying dissatisfied customers. If a retail customer service agent is unable to fulfill their job demands, the company might lose a customer or the worker might lose his or her job. In contrast, healthcare workers must successfully treat and satisfy patients who are physically and/or psychologically unwell while operating under the constraint that any mistake or errors committed might result in patient harm or loss of life. These constant job demands contribute to job stress.

2.1.1 Definition of job stress

The NIOSH definition of job stress is "the harmful physical and emotional responses that occur when the requirements of the job do not match the capabilities, resources, or needs of the worker". The NIOSH model of job stress illustrates the effect of stressful job conditions combined with individual and situational factors on the risk of injury and illness. In this model all workers are exposed to the same stressors. Stressors are events or conditions that cause stress. The combination of the stressful job conditions with individual and situational factors results in the risk of injury and illness. Since individual factors contribute to the risk of injury and illness, job stress is subjective. Individual factors include personality traits, such as trait anxiousness. Situational factors include aspects of the work environment, such as a supportive teamwork environment.

For example, the NIOSH Model of Job Stress can be used to analyze the following scenario:

> *Mary, a nurse at Carilion Family Medicine, Blacksburg, VA, experiences a headache after meeting with a patient for an initial patient interview. During the interview Mary asks the patient for his medical history and his current symptoms. The patient is very agitated because the patient had to wait 30 minutes past the appointment time before being called into the office. Mary uses the clinic's computer system to update the*

patient's medical record. Initially, Mary is unable to find the patient's record, but then realizes that she is conducting the patient search in the wrong computer screen. After locating the record, Mary continues to enter the patient's information. Mary mistakenly enters the patient's allergy to penicillin in the "prescription order" area. Halfway through the interview Mary is interrupted by a physician who needs assistance giving a shot to an unruly child. The physician's regular nurse is out today so Mary must cover for her. Mary is tired because she had to work an extra shift yesterday to cover for the nurse as well. Mary sighs deeply, excuses herself from the interview,, assists with the injection, and returns to complete the interview. After the interview is complete, Mary starts to get a headache.

Application of the NIOSH Model of Job Stress to the above scenario reveals the following stressful job conditions, individual and situational factors:

Stressful job conditions:

- Poor usability of clinic's patient medical record system
- Interruptions
- Understaffing

Individual factors:

- Fatigue

Situational factors:

- Agitated patient

Injury or Illness:

- Headache

Another model used in occupational settings, is the Lazarus and Folkman (1984) conceptual model of job stress. In this model, stress is a result of a worker's perception of the demands placed on them and their perceived ability to meet those demands. Williams et. al. (2007) modified the Lazarus and Folkman model to apply to the healthcare domain. This conceptual model of job stress in healthcare consists of five linear stages: 1) antecedents, 2) stress appraisal/ coping process, 3) worker reactions, 4) clinical encounter quality, and 5) patient outcomes.

Similar to the NIOSH Model of Job Stress, in this model workers' reactions to stressors (antecedents) are influenced by a worker's individual capability to cope with the stressors. This model extends the NIOSH Model of Job Stress beyond the worker's reaction to include patient outcomes. In the Williams et. al. model, worker reactions, such as job satisfaction and burnout, impact the quality of patient care which directly impacts the patient. Application of the Williams et. al. conceptual model of job stress to the previous scenario reveals the following factors:

Antecedents:

- Poor usability of clinic's patient medical record system
- Interruptions
- Understaffing

Coping Process:

- Attempts to relax by sighing

Worker Reactions:

- Headache
- Job dissatisfaction

Clinical Encounter Quality:

- Poor

Patient Outcomes:

- Dissatisfied Patient
- Patient prescribed penicillin when allergic

2.1.2 Impact of job stress

According to the Williams et. al. conceptual model of job stress in healthcare, the healthcare organization, worker, and patient are all involved in the process. The impact of job stress on the organization, the worker, and the patient are explored in more detail below.

2.1.2.1 Impact on worker

McVicar (2003) provides a comprehensive review of stress in the workplace. McVicar notes that stress results in both psychological and physiological responses and that stress can be either positive or negative. The term for positive stress, such as excitement due to the first day of work, is eustress. The term for negative stress, such as the fear of being fired, is distress. Prolonged exposure to distress results in severe distress. When workers experience distress and severe distress they have negative physiological experiences as well. For example, workers under distress may experience indigestion, high blood pressure, and constipation or diarrhea. Workers experiencing severe distress may develop clinical hypertension, gastric disorders, or coronary heart disease.

In addition to the negative physiological reactions, workers exposed to prolonged stress experience negative psychological phenomena. McVicar collectively refers to these negative

psychological factors as burnout. McVicar defines burnout to include emotional exhaustion, depersonalization and disengagement, and feelings of decreased personal accomplishment.

Definitions of burnout vary in the literature. Schaufeli (2007) expands upon McVicar's definition to include physical, behavioral, and motivational symptoms. For example, Schaufeli identifies headaches as a physical symptom, absenteeism as a behavioral symptom, and disillusionment as a motivational symptom. Schaufeli also views burnout as a result of prolonged job stress and believes that healthcare workers are more susceptible to burnout due to healthcare workers' high expectations prior to entrance into the workforce. Schaufeli refers to previous work by Pines (1993) which argues that burnout is a result of a mismatch between expectations upon entering a job and the realities of the job. Schaufeli posits that workers choose to work in the healthcare domain because they believe that their efforts will have an impact on patients' well-being. In Schaufeli's view, when realities of a job within the healthcare domain, such as understaffing, prevent workers from having the impact envisioned, workers become susceptible to burnout.

2.1.2.2 Impact on patient

Worker stress and burnout also have the potential to negatively affect patients in the healthcare domain. As mentioned earlier, the healthcare domain is a life-critical domain and any errors may result in patient harm or loss of life. The close physical interactions between practitioner and patient provide many opportunities for patient harm. Common tasks in healthcare involve the worker either diagnosing or providing some treatment to the patient. Consider the following scenario:

> *Angela is a nurse who typically works in the birthing center. However, she is reassigned to the chemotherapy unit when chemotherapy patients are admitted. This hospital does not have many chemotherapy patients so Angela is rarely transferred to the chemotherapy unit. Although Angela finds her work in both wards rewarding, she feels anxious when she is reassigned to chemotherapy. She is aware that any mistake can result in significant damage for the patient due to the strength of the chemotherapy drugs. When Angela works in the birthing center she feels confident, but she feels hesitant in the chemotherapy unit and finds herself frequently checking her work. Angela also finds working in the chemotherapy unit to be stressful because she is not as*

familiar with the staff and equipment as she is in her normal ward. While setting up a patient's chemotherapy line, Angela is distracted by the announcement of a code blue down the hallway. Angela finishes the setup and sits with the patient for the required 15 minutes to monitor the infusion. After a few minutes Angela realizes that she forgot to start the machine so the patient has not yet received the medication. Angela starts the machine and the infusion starts correctly.

As shown in the above example, most tasks within the healthcare domain are complex in nature because the tasks involve simultaneous interactions with a patient and a medical device, not to mention interactions with other staff members. The potential for patient harm resulting from poor worker performance is reinforced by the application of the Yerkes Dodson Law. The Yerkes Dodson Law compares an individual's arousal with performance for both complex and simple tasks (Yerkes & Dodson, 1908). For each type of task, there exists an optimal level of arousal that will result in optimal performance. Since one of the psychological effects of stress is arousal, the Yerkes Dodson Law applies to performance under stress as well. This is inline with the earlier segmentation of stress into positive (eustress) and negative (distress) categories.

The implication of the Yerkes Dodson Law when applied to healthcare worker performance is that the optimal worker performance occurs at a lower level of arousal compared to other domains with simpler tasks. In addition, the degradation of worker performance occurs more rapidly as arousal increases than in other domains with simpler tasks. Application of the Yerkes Dodson Law to the healthcare domain by the author results in a potential model for worker stress in healthcare. The implication for the patient could be that unusable technologies → increased worker stress → increased worker arousal → decreased worker performance → increased risk of patient harm. This is similar to the Williams et. al. conceptual model of job stress where the patient is the unfortunate entity at the receiving end of a series of events.

2.1.2.3 Impact on organization

From an organizational perspective, the potential impact of work-related stress and burnout is concerning. In addition to costs for worker compensation claims for injuries and illnesses associated with job stress, organizations must also burden costs for consequences of job stress, such as turnover, absenteeism, and poor performance. Workers might choose to leave the

healthcare profession altogether. For example, findings of the 2004 National Sample Survey of Registered Nurses revealed that 41% of nurses who left the healthcare industry reported that stress and/or burnout was a factor in the decision to leave the profession (HRSA, 2004). The potential impact of employee turnover is especially problematic in healthcare due to a shortage of nurses. The healthcare industry has a 4.5% annual growth rate and over 1 million new nurses will be needed by 2016 to meet this growth (BLS, 2007).

As suggested by McVicar (2003), healthcare organizations must take a proactive approach to job stress reduction in order to avoid the negative consequences associated with job stress. A first step towards a proactive approach is the identification of factors contributing to job stress and associated burnout. Schaufeli (2007) identifies potential correlates, causes, and consequences of job stress. Potential correlates include demographic information such as age and gender. Causes include job demands, such as work overload and time pressure, as well as poor job resources, such as lack of participation in decision making. The consequences of these correlates and causes are detriments to individual health and work-related attitudes. For example, an individual's health may be impacted by the development of cardiovascular disease. In addition, workers' attitudes may be negatively impacted resulting in job dissatisfaction, increased turnover, and absenteeism.

From a human factors perspective, the identified job demands and resource limitations associated with job stress provide guidance for potential areas to target for redesign. For example, if work overload and time pressure contribute to job stress, analysis of healthcare workers' tasks and use of equipment might reveal opportunities for optimization.

Recent research in healthcare has focused on factors contributing to medication errors. Coombes et. al. (2008) interviewed 14 medical interns involved in 21 prescribing errors at a teaching hospital in Brisbane, Queensland, Australia. Based on thematic analysis of interview transcripts and questionnaire results, the researchers identified environment, task, individual, team, and patient factors contributing to the prescribing error. Environmental factors, such as staffing levels, high workloads, and long working hours were the most prevalent contributing factors. Task factors, including medical chart layout and ambiguous medication guidelines, were also identified as contributing factors to medication errors. As a result of these findings, the researchers suggest reduced workload, increased staffing, and a redesigned medical chart as potential defenses against medical errors at the hospital.

In addition to the job demands identified by Schaufeli above, a review of the literature reveals several other factors contributing to job stress. These factors are discussed in more detail below.

2.1.3 Types of stressors

The Williams et. al. (2007) conceptual model of job stress identifies intraorganizational and extraorganizational stressors which are antecedents to worker stress. The intraorganizational categories identified in this model are:

- Physical environment
- Individual level
- Group level

Physical environment stressors are characteristics of the environment, such as temperature and noise, which might induce stress. Individual level stressors in this model are factors of the individual worker's job which might induce stress. These individual level stressors include workload, task complexity, and patient demands. Group level stressors are factors within the team which might contribute to stress, such as poor communication and understaffing.

The model identifies one extraorganizational category of job stressors:

- Organizational level

Organizational level stressors include factors of the organization which may contribute to stress, such as the organizational design, work processes, organizational culture, and the technology used to complete the work.

Of these organizational level stressors, only a redesign of the technology used in the workplace can be attempted without a holistic macroergonomic intervention of the entire healthcare organization. Technology in the healthcare domain includes medical devices, such as syringes, x-ray machines, infusion pumps, and thermometers.

Due to the relative ease of performing a microergonomic intervention on the technology used in the workforce compared to a macroergonomic intervention on the entire organization, an opportunity exists in the redesign of medical devices with an emphasis on usability as an effort to reduce worker stress.

2.2 Usability

OSHA (2007) recognizes "dealing with intricate and malfunctioning equipment" as a contributor to healthcare worker stress. Since worker interactions with medical devices can exacerbate and already stressful work environment, designing for usability during the medical device development process has the potential to directly impact the worker's perceived stress and resulting job satisfaction.

2.2.1 Definition

The international standard for the ergonomic requirements for office work with visual display terminals, ISO 9241-11 (1998), defines *usability* as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context-of-use". Figure 1 below provides a comparison of the ISO definition of usability with an interpretation of this definition within the healthcare domain. In this generic definition of usability, *effectiveness* is the level of accuracy and completeness in which a user is able to satisfy the goals. *Efficiency* describes the amount of resources used to achieve the goals, and *satisfaction* is viewed as the user's perceived comfort level and acceptability of the product while working towards the goals.

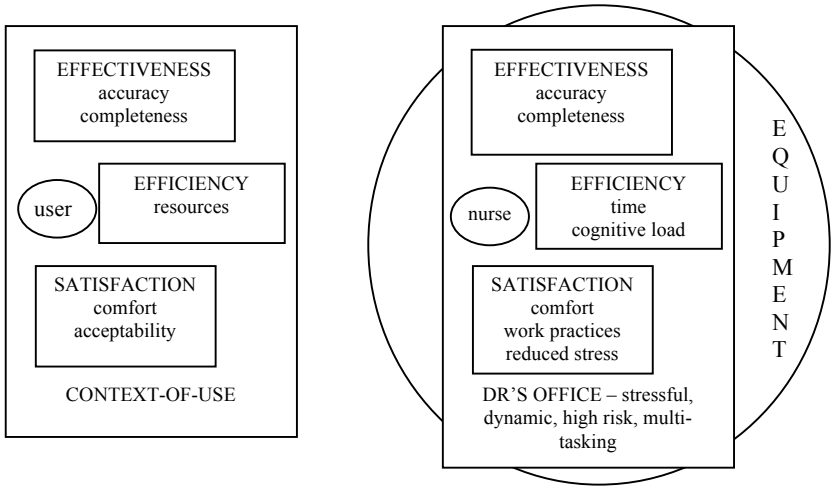

Figure 1: Comparison of generic usability definition with usability within the healthcare domain

How does this definition apply to the dynamic healthcare domain? For example, what does this definition imply when applied to a common healthcare scenario such as a nurse entering a patient's symptoms into a computer system during the initial patient interview? The context-of-

use in a doctor's office is often dynamic, stressful, interruptive, and requires multi-tasking. *Efficiency* in this scenario is the amount of time the nurse takes in entering the relative information, and the amount of cognitive resources required to enter the information. For example, can the nurse continue a conversation with the patient while entering the information or must the nurse stop conversation to concentrate on the data entry? S*atisfaction* in this context is impacted by how the computer system aligns with existing workflows. For example, if the nurse's daily work practice is to collect the patient's insurance information first and then enter the symptoms, the nurse's satisfaction will most likely decrease if the computer system requires the entering of symptoms first. The *effectiveness* of the system can be viewed by how closely the patient's description of the information matches with what the nurse entered – the completeness and accuracy of what was entered. Note that usability in the medical domain implies safety, but the connection between usability and safety is not made explicit. As shown in Section 2.3, medical device design standards contain conflicting definitions of usability that neglect to include a direct connection between usability and safety. Safety could be viewed as a "specified goal" which is ever present in all situations. Perhaps a more accurate definition for usability in the healthcare domain is:

> "the extent to which a medical device can be used by practitioners to perform safe diagnostic treatment with effectiveness, efficiency, and satisfaction in **a high stress and life critical work environment**"

Consideration of the high stress and life-critical context-of-use is necessary to ensure that the resulting medical device design is usable and safe in the real world.

2.2.2 Usability engineering lifecycle models

Since usability is a design goal of medical devices, how do medical device designers ensure that usability is considered throughout the design process? One solution is to follow the usability engineering process during product development. The usability engineering process integrates usability throughout the entire design lifecycle. Usability engineering in this context is also known as formative usability. Formative usability occurs when usability issues are addressed throughout the product lifecycle. The goal of formative usability is to form the design based on usability goals. In contrast to formative usability, summative usability is the evaluation of a product after its design to determine if usability goals have been met (Hix & Harston, 2006).

Although usability engineering is a relatively new discipline, its success within the software industry suggests similar benefits can be achieved by other domains, such as healthcare. A review of the usability engineering process in software development will aid the designer in understanding how usability engineering may be applied to medical device design and development. A review of usability engineering models used in software development follows.

2.2.2.1 Nielsen's usability engineering lifecycle model

Jakob Nielsen developed one of the earliest usability engineering lifecycle models. Nielsen's (1993) 11-stage usability engineering lifecycle model begins with understanding of the user and ends with feedback from field studies. In Nielsen's model, usability can only be achieved by a design emphasis on user needs. This view is emphasized by the first stage directive: "Know the user", which can be considered a mantra for usability in general. To understand the user, Nielsen recommends that designers identify characteristics of the targeted user. These individual characteristics include information such as age, gender, education level, and collectively they define user profiles. To further understand user needs the designer must learn what tasks the user performs, how they perform the tasks, and why they perform the tasks.
The separation of the "what" and the "why" during task analysis allows the designer to understand the motivations behind the task performance and to identify alternative ways to complete the task. Nielsen's model also recognizes that users are dynamic and that their needs may change over time. Nielsen's model set the standard for up-front and iterative user analysis in product development as a means to inform design around user needs.

Nielsen notes that the designer must not complete all stages of the model to achieve usability. Based on subsequent model revisions by other researchers (Carlshamre & Karlsson, 1996; Hix & Harston, 2006; Rosson & Carroll, 2002) which further reduce Nielsen's model, the following stages appear to be fundamental to the usability process:

- Know the user
- Setting usability goals
- Apply guidelines and heuristic analysis
- Prototyping
- Empirical testing
- Iterative Design
- Collect feedback from field of use

These stages will be discussed further in the context of Hix & Hartson's (2006) lifecycle for usability engineering. Interested readers in the other stages of Nielsen's model are referred to Nielsen (1993) for a comprehensive overview.

2.2.2.2 Hix & Hartson (2006) usability engineering lifecycle

The Hix & Hartson usability lifecycle model is an iterative model where any stage can be revisited as needed as the result of formative user-based evaluation. Similar to the Nielsen model, user needs are considered up-front during systems analysis. Although the systems analysis stage employs ethnographic techniques such as field visits, observations, and interviews to analyze users' needs, the focus of the requirements gathering is typically task focused with outputs such as task-based scenarios and business process models used to guide the design.

In this model the output of each stage becomes the input to the subsequent stage. For example, during systems analysis user needs, such as tasks and interaction design requirements, are developed. This information is then used during user interaction design to develop usage scenarios and associated screen mock-ups. Usability specifications, such as "95% of users will complete the prescription order within 3 minutes" are then created based on the usage scenarios. Prototypes are then created based on the usage scenarios and usability testing on the prototypes determines if the usability specifications have been achieved or not. If the specifications have not been achieved, designers can return to any previous stage for further analysis of the problem.

Although the Hix & Hartson model consists of fewer stages than the Nielsen model, many similarities exist. Comparisons of the stages within each model are detailed in Table 2 below. Stages within the Hix & Harston correspond to one or more stages within the Nielsen model. For example, the formative user-based evaluation stage within the Hix & Hartson model incorporates the heuristic evaluation, empirical testing and feedback collection stages within the Nielsen model.

Table 2: Comparison of Hix & Hartson (2006) and Nielsen (1993) usability lifecycle stages

Hix & Hartson (2006) stage	Nielsen (1993) stage
Systems analysis	Know the user Guidelines
User interaction design	Iterative design
Usability specifications	Setting usability goals
Rapid prototyping	Prototyping
Formative user-based evaluation	Heuristic evaluation Empirical testing Collect feedback from field of use

Another similarity between the two models is the use of scenarios to model user tasks. Hix and Hartson (2006) define scenarios as "stories about people and their work activities". Scenarios reveal system requirements because they include information regarding what tasks need to be completed, how they need to be completed, and why they need to be completed.

2.2.2.3 Scenario-based usability engineering

Rosson & Carroll (2002) developed a usability engineering framework, scenario-based development (SBD), "wherein user interaction scenarios play a central role in responding to users' needs during system development". Rosson & Carroll define scenarios as "a narrative or story that describes the activities of one or more persons, including information about goals, expectations, actions, and reactions".

This framework begins consists of three stages: 1) Analyze, 2) Design, 3) Prototype and Evaluate. Similar to the previously discussed models, design begins with careful analysis of user needs. The design process is also iterative and redesigns are based on prototypes. However, in contrast to the previously discussed models, this model distinguishes between different types of scenarios, such as, problem scenarios, activity scenarios, information scenarios, and interaction scenarios. Problem scenarios are stories about the stakeholders' current activities and needs. Activity scenarios are generated from problem scenarios and contain possible system functions to address user needs identified in the problem scenarios. Activity scenarios also include context-of-use information. Activity scenarios act as input into the development of information scenarios. Information scenarios are stories about the information presented to the user by the system during use and possible user reactions. Interaction scenarios are then created which describe how the user will manipulate the interface and interact with the system. This refinement

of scenarios from problem scenarios to interaction scenarios guides the designer from the problem space to the solution space.

What can the medical device designer learn from these usability engineering lifecycle models? These models stress the importance of:

- Consideration of user needs at the beginning and throughout the product development process
- Development of scenarios
- Iterative design based on user evaluation of prototypes

2.3 Medical device usability

The importance of usability engineering in the medical device design process is emphasized by the inclusion of usability engineering practices in medical device regulations and standards. Two standards which emphasize the importance of addressing user needs throughout the design process are:

- IEC 62366 – Medical devices – Application of usability engineering to medical devices
- ANSI/AAMI HE74 – Human factors design process for medical devices

In addition, interest in design processes for medical devices is expected to increase as indicated by the results of a "Future of Ergonomics" survey of Human Factors and Ergonomics Society (HFES) members. The healthcare domain was identified in this survey as the top domain for a potential increase in ergonomic jobs within the next 5 years (Hedge & Spier, 2008).

A review of current guidelines for medical devices and identified limitations within the existing guidelines follows.

2.3.1 Definition

IEC 62366 (2007) provides the following definition for a medical device:

> "Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator software, material or other similar related article, intended by the MANUFACTURER to be used, alone, or in combination, for human beings for one or more of the specific purpose(s) of:
>
> - diagnosis, prevention, monitoring, treatment, or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
> - investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
> - supporting or sustaining life,

- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its function by such means."

By this definition, medical devices include simple healthcare items (ex., cotton swabs, thermometers, condoms) and complex items (ex., x-ray machines, endoscopes, patient monitoring devices).

IEC 62366 provides the following definition for medical device usability:

> "Usability is a measure of the EFFECTIVENESS, EFFICIENCY, and satisfaction with which specified USERS achieve specified goals in particular environments, within the scope of the INTENDED USE of the MEDICAL DEVICE. Many of these factors can influence SAFETY to various extents."

This definition for medical device usability expands upon the generic ISO 9241-11 (1998) definition of usability. For example, both definitions consider usability to be a measure of effectiveness, efficiency and satisfaction. Both definitions consider the usage environment, which is referred to as "context-of-use" in ISO 9241-11. IEC 62366 includes references to both "intended use" and safety which are not mentioned in ISO 9241-11. The inclusion of safety emphasizes the life-critical nature of the domain. The inclusion of "intended use" suggests that acceptable designs can result in patient or practitioner harm if used in an incorrect manner.

2.3.2 Design guidelines

Since medical device usability is required, suggestions for the inclusion of usability throughout the product development lifecycle are found in the standards and in the literature. A review of design guidelines follows.

2.3.2.1 ANSI/AAMI HE74

ANSI/AAMI HE74 (2001) suggests the use of a user-centered design process to incorporate usability needs throughout the design process. This design cycle identifies distinct phases for user research, conceptual design, criteria and requirement development, detailed

design and specification, evaluation, and deployment. The human factors engineering (HFE) design cycle is a systems approach to design, meaning that characteristics of the users, the environment, and the interactions between them are considered during the design process. Similar to software usability engineering models discussed previously, the HFE process begins with user research. The process is iterative and earlier stages can be re-visited for further analysis based on user evaluation results. The standard emphasizes that early user involvement is critical for successful design and that "input from users is typically obtained at nearly every stage in the cycle". The standard does not make any particular recommendations for user research techniques specific to medical devices, however, the standard does advise designers to observe users in their work environment. Medical device designers are encouraged to use any or all of the following user research methods as they see fit:

- Contextual inquiry and observation
- Functional analysis
- Interviews
- Participatory design
- Questionnaires and surveys
- Task analysis
- Time and motion studies
- Cognitive task analysis

The HFE process is similar to the software usability engineering lifecycle models discussed previously since the HFE process also recognizes the importance of:

- Consideration of user needs at the beginning and throughout the product development process
- Iterative design based on user evaluation of prototypes

However, unlike the software usability lifecycle models, the HFE process recommended by ANSI/AAMI HE74 does not stress the development of scenarios to capture the context-of-use.

2.3.2.2 IEC 62366

The HFE process recommended by ANSI/AAMI HE74 is also referenced within IEC 62366 (2007), the International Standard for the Application of Usability Engineering to Medical Devices. However, IEC 62366 also provides a framework for the usability engineering design and development process, which is compared with the risk management process. Readers

interested in a comprehensive overview of this usability engineering framework and it's comparison to the risk analysis are referred to IEC 62366 for more information.

As shown below, the IEC 62366 usability engineering process is an iterative process which emphasizes early user research and continuous user input throughout the development process. Similar to the software usability lifecycles discussed previously, the IEC 62366 usability engineering process recognizes the importance of:

- Consideration of user needs at the beginning and throughout the product development process
- Development of scenarios
- Iterative design based on user evaluation of prototypes

Similar to ANSI/AAMI HE74, this standard does not recommend particular user research methods specific to medical devices. Designers are expected to choose the appropriate user research method appropriate for the project. However, the standard does emphasize the importance of the consideration of the context-of-use during product development. The IEC 62366 standard states:

> "The context-of-use can have a significant impact on USABILITY of the MEDICAL DEVICE USER INTERFACE. For SAFETY reasons the context-of-use needs to be analyzed and considered…"

Due to the apparent importance of the context-of-use and the lack of suggestions from standards regarding user research methods which capture the context-of-use, one wonders: How do medical device designers ensure that they elicit context-of-use information during user research? This gap is the focus of this proposed research.

A review of the literature suggests that this problem has not yet been resolved in industry (Martin et al., 2006; Martin et al., 2007; Shefelbine, Clarkson, Farmer, & Eason, 2002). A review of requirements engineering, with an emphasis on limitations of existing elicitation methods for use in the healthcare domain, follows.

2.4 Requirements

Eliciting correct information from users is critical because system requirements are based on user needs. If the user needs and problems are not fully understood, the system requirements

specification will be incorrect. The end result is that the medical device designer creates a product that does not address the users' needs.

2.4.1 Definition

What exactly is a requirement? Definitions available in medical device and software development standards provide guidance.

ANSI/AAMI HE74 defines a requirement as:

> "description of general or specific device characteristics that must be accounted for in the development of a device or product"

IEEE 729 (1983) provides the following definitions of requirements:

> "a condition or capability needed by the user to solve a problem or achieve an objective"
> AND
> "a condition or capability that must be met or possessed by a system or system component to satisfy a contract standard, specification or other formally imposed document"

In general, a requirement is a specification of user need. According to Ravichandar et. al (2007), user needs are part of the problem space and requirements are part of the solution space. Stated in another way, user needs are stated in the users' language and contain information relative to the problem being solved. Requirements are stated from the designers' point of view and contain information relative to the solution to the problem.

2.4.2 Types of requirements

As shown in Figure 2 below, requirements are typically divided into two categories: functional and non-functional.

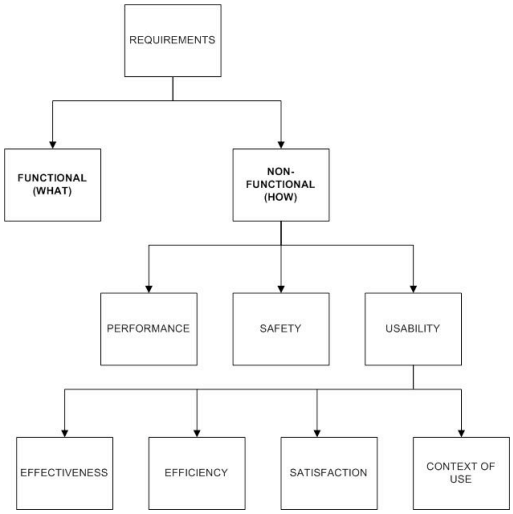

Figure 2: Functional and non-functional requirements

2.4.2.1 Functional

Functional requirements specify *what* the system needs to do (Arthur, 2007). Example functional requirements for an infusion pump could include:

- The infusion pump shall deliver intravenous medication to the patient
- The infusion pump shall store prescription programs
- The infusion pump shall allow users to edit prescription programs
- The infusion pump shall provide auditory feedback

2.4.2.2 Non-functional

Non-functional requirements specify *how well* the system performs its functions (Arthur, 2007). Example non-functional requirements could include:

- The infusion pump shall be usable
- The infusion pump shall not allow for delivery of unsafe doses of medication
- The infusion pump shall not harm the patient
- The infusion pump shall not harm the practitioner

Elicitation of non-functional requirements from stakeholders is often challenging because quality goals of the system are subjective. The subjective nature of non-functional requirements

introduces opportunities for miscommunication between the development team and system stakeholders (Chung et al., 1999). Elicitation techniques specific to the complexities of non-functional requirements are needed to ensure that broad stakeholder statements, such as "The infusion pump will be easy to use" are fully discussed. Elicitation techniques for non-functional requirements should facilitate mutual understanding between the development team and stakeholders (Cleland-Huang et al., 2006).

2.4.3 Effects of poor understanding of users' needs

Davis (1993) illustrates the repercussions of a misunderstanding between stakeholders and designers through a model representing the cumulative effects of error. In this model, errors are possible within he requirements specification, design, implementation, and testing stages of a product. This model demonstrates the additional errors that occur as a result of errors within the requirements specification stage. For example, if the designers are not able to correctly understand the real problem the users' are trying to convey, the designers will create an incorrect system requirements specification. This error results in a design based on the erroneous specification, which end result is an imperfect product. Readers interested in the errors possible in other stages of the design lifecycle are referred to Davis (1993) for more information.

2.5 Elicitation methods

Since mutual understanding between stakeholders and designers is necessary for the successful creation of a medical device, the information elicited during the user research stage of medical device design has great impact on the overall design of the device. However, a review of literature in the healthcare industry reveals limitations of traditional elicitation techniques in the healthcare domain.

2.5.1 Complexity of understanding user needs in healthcare

Martin et. al. (2006, 2007) identify the following issues which complicate the ability of medical device designers to understand stakeholder needs:

- Difficulty understanding context-of-use
    - Inability to gain access to all device users
    - Inability for designers to conduct field research

- Difficulty understanding conflicting stakeholder needs
    - Potential conflicting needs between practitioners and patient

For example, the design of a medical device is inherently more complicated than the design of a consumer device because the designer's access to end users is limited. To even begin user research in a hospital setting the designer must complete the hospital's lengthy IRB approval process (Martin et al., 2006). Even if IRB approval is achieved, field research might not be practical. For example, it might not be safe for a researcher to shadow the use of an x-ray machine due to the exposure hazard.

Medical devices, such as anesthesia delivery systems, are also unique from consumer products due to the role of the device in the interaction between practitioner and patient (Dalley, Robinson, Weller, & Caldwell, 2004). Medical devices are used by the practitioner to perform an act, such as a diagnostic treatment, on a patient. This type of interaction may result in conflicting user needs between practitioner and patient. For example, to ensure the safety of the patient, the safety of the practitioner might be compromised.

These problems are exacerbated by the lack of design guidance from standards recommending techniques to "capture the full range of requirements" and the current lack of elicitation methods specific to the healthcare domain (Martin et al., 2006). In an effort to assist with the provision of recommendations to medical device designers, Martin et. al. (2007) provide a comparison of existing elicitation techniques. According to the researchers' comparisons, both focus groups and usability tests have been identified as methods which can be used from the concept stage of a product through evaluation of a product. Since both the usability engineering process and models suggested by medical device standards require user involvement throughout these stages, focus groups and usability tests have potential as methods to use during an iterative design process. Another benefit of these methods when compared to the others is that real users and proxies (actors modeling users) can be used. Readers interested in a comprehensive comparison of the elicitation methods are referred to Martin et. al. (2007).

2.5.2 Self-report methods

How do medical device designers elicit user needs when designers cannot observe users in the hospital setting due to IRB, safety, and/or ethical restrictions? In addition, how do medical

device designers ensure that context-of-use information necessary to achieve usability is elicited outside of the use environment? The use of self-report elicitation methods, such as focus groups and interviews, may assist the designer in understanding user needs. However, as detailed below, these techniques have some limitations.

2.5.2.1 Interviews

Requirements can be elicited from users during individual interviews. During an interview, the designer asks the user a series of questions in an effort to elicit user needs and to gain further understanding of the problem. Interviews can be structured, semi-structured, or unstructured. In structured interviews, the designer follows a set of questions and does not deviate from the question list. In unstructured interviews, the designer does not have a set question set and asks question "on-the-fly". A semi-structured approach is a combination of structured and unstructured, where the designer follows a pre-determined question list but asks follow-up questions when needed (Hendrick & Kleiner, 2001).

Although interviews are referenced as potential user research methods for medical devices in IEC 62366 and ANSI/AAMI HE74, designers need to consider the following advantages and disadvantages of interviews:

Advantages of interviews:

- Observe both oral and non-verbal responses
- Users can be probed for more in-depth responses
- Additional follow-up questions can be addressed
- Can be used when field studies are inappropriate

Disadvantages of interviews:

- Interviewees lose anonymity
- Difficult to access tacit knowledge (Goguen & Linde, 1993)
- Context-of-use information may be lost

The disadvantages of interviews are important when considering the healthcare domain. Anonymity within healthcare, especially during discussions relating to accidents, is important as workers may fear repercussions if they reveal information that may implicate any negligence on their part. In addition, difficulty eliciting context-of-use information from users will negatively

impact usability, which is critical for medical device design. Context-of-use information is more difficult to obtain during interviews than other techniques, such as contextual analysis, because the user is removed from the environment where they perform the task. Users may have problems recalling

2.5.2.2 Focus groups

Focus groups are commonly used during medical device design (Garmer et al., 2004; Koppel et al., 2005; Martin et al., 2006; McAlearney, Schweikhart, & Medow, 2004; Muller et al., 2007; Wiklund, 1995a). A focus group is similar to an interview, but focus groups contain multiple users. During a focus group, the designer asks the group a series of questions in an effort to understand the problem and the user needs. In addition to advantages & disadvantages of interviews, focus groups have the following advantages and disadvantages:

Advantages

- Discussion between focus group members may reveal more requirements
- Less time consuming than individual interviews

Disadvantages

- Group think – users may feel uncomfortable stating their opinions if they differ from the group (Janis, 1972)

The problem of anonymity might be more severe in focus groups because individuals may feel more self-conscious stating their opinions in front of their peers than in front of a designer alone. If the worker does not feel comfortable sharing past experiences relating to safety and errors, the designer will be unable to elicit all necessary safety requirements.

2.5.2.3 Storytelling

Due to its extensive use as a method to capture and communicate culture in anthropology (Patton, 2002), storytelling warrants further investigation as a self-report method for requirements gathering in healthcare. For example, the purpose of anthropological research is to create and understand the story of humankind (Grindal, 1978). A framework used in anthropology to collect and understand the story of humankind is narratology. As discussed below, narrative research is used within medical anthropology to further understanding of

experiences of medical practitioners, patients, and patients' families within the healthcare domain.

Oral histories are used in anthropology as a means to gather, understand, and share the personal experiences of an identified group. For example, Gunther & Thomas (2006) used a phenomenological framework to collect oral histories from nurses to understand how nurses make meaning of their role as patient caregiver. The researchers analyzed the nurses' stories using thematic analysis and identified four common themes. The identified themes were 'extraordinary patient events', 'incomprehensibility', 'questioning whether anything else could have been done', and 'alone or together'. The identification of these themes facilitated the understanding of the nurses' daily stressors and their associated reactions.

Narrative research is also used within medical anthropology during safety interventions. Coombes et. al. (2008) collected stories from medical students who recently committed a prescribing error to determine common attributes among the students' mistakes. The researchers' identification of potential error antecedents resulted in practical recommendations to the hospital for error avoidance. For example, the researchers recommended the hospital adopt a consistent prescription form throughout the hospital.

A review of design literature reveals that industry has attempted to capitalize on the benefits of stories during the design process (Erickson, 1995; Moggridge, 1993; Suri & Marsh, 2000). However, the literature suggests that stories are defined differently by different designers. Some design teams view stories as outputs of traditional user analysis techniques. For example, Suri and Marsh (2000) view stories as scenarios which are created by the analyst through synthesis of results from task analysis, user profiling, and interviews. Suri and Marsh (2000) note that one benefit of scenarios is that they allow for the analysis of the "less celebrated characteristics of people", such as drug use, in a hypothetical context which allows participants to freely discuss these topics in a non-threatening and non-judgmental manner. Suri and Marsh (2000) utilized scenarios in the design process for home-use diabetic equipment and recognized the importance of factoring in real non-idealized human behavior, such as consumer's re-use of needles to save money, during the design process.

Some design teams view stories as scenarios created by both the user and the analyst. For example, IDEO, a design firm which provides consulting services to Fortune 500 companies,

integrates scenario-building into the design process (Moggridge, 1993). Storytelling is an integral part of IDEO's 4 part design process, which consists of the following steps:

1. understand
2. observe
3. visualize
4. evaluate

In the first step, designers attempt to understand the needs of others through empathizing with the subject population. The next step in gaining further understanding of potential users is to observe users performing tasks in real-life. In step #3 in the design process, designers "visualize" alternate realities through the creation of scenarios. Designers can create these scenarios themselves or ask targeted end users to "tell stories" about their perceived ideal experience with a product. In the final step, design solutions are evaluated against the full range of potential users.

In Erickson's (1995) communication-oriented model of design, stories are viewed as design artifacts which facilitate communication between designers, users, and stakeholders. Unlike other design teams which use the terms *scenarios* and *stories* interchangeably, Erickson (1995) distinguishes between the terms. Erickson (1995) defines stories as "concrete accounts of particular people and events, in particular situations" and defines scenarios as "abstract scripts of events that may leave out detail of history, motivation, and personality". Stories are created by users; scenarios are created by analysts.

Muller (2008) also recognizes the potential use of stories during the design of medical devices in his example of using stories to understand user needs for a medical imaging workstation. In Muller's (2008) CAFCR model for architecture description, the product is represented in five views: Customer objectives, Application, Functional, Conceptual, and Realization. The customer objectives and application views represent the customer views of the model, representing what the customer needs and how the customer envisions the solution. The functional, conceptual and realization views represent the solution to the customer's problem. The functional view represents what the product needs to do, and the conceptual and realization views represent how the product will function. In this model, stories represent the customer's view of the product and cases are created by designers as a means to transition from customer's

problem to the design solution. Unlike Erickson's model, which looks to user's stories for design inspiration, Muller's model looks to synthesized use cases for design solutions.

As demonstrated in the above sampling of literature referencing the use of stories during the design process, the potential value of stories is recognized among designers among various domains, including those in the medical field. However, research into the use of storytelling as a requirements elicitation technique is lacking. In addition, as suggested by Martin et. al. (2007) elicitation techniques must be modified to suit the specific needs of medical device designers. Investigation into storytelling as a novel elicitation method is needed as a first step in the development of a user-centered design methodology for medical devices. An initial research emphasis on user research is logical considering the overall impact of successful user research on the resulting design.

Why investigate storytelling as an elicitation method for medical device requirements? :

- Potential to capture a full-range of requirements including requirements specific to context-of-use needed to ensure usability
- Elicitation of stories results in scenarios which can be used during the usability engineering process
- Storytelling capitalizes on the inherent narrative nature of the healthcare domain

Current research in medical device design methods provides support for a new elicitation method such as storytelling. Shefelbine et. al. (2002) recommend in *Good Design Practice for Medical Devices and Equipment* that designers address "who, what, why, where, when" questions during problem definition as a means to determine device requirements. Note that these identified questions are also factors found within a story.

The addition of "How?" to Shefelbine et. al.'s existing list, results in an elicitation technique which has potential to elicit both functional and non-functional requirements from users as shown in Table 3.

Table 3: Potential information elicited during novel storytelling method

Question	Potential Information Elicited during Storytelling
Who?	User classes
What?	Functional requirements
Why?	Motivation Constraints
Where?	Context-of-use
When?	Context-of-use
How?	Context-of-use Process requirements Non-functional requirements, such as safety

The elicitation of stories also provides designers with direct access to usage scenarios. Scenarios are typically created by the designer through the piecing together of disparate information elicited from focus groups and interviews. In contrast, storytelling empowers the end users by allowing them to create their own scenarios of device usage. Perhaps scenarios created by the users will provide a more holistic view of device usage and will provide a more accurate representation of actual usage than scenarios created by the designer.

Another strength of storytelling as an elicitation technique within the healthcare domain is that it capitalizes on the inherent narrative nature of healthcare. As noted by (Hunter, 1991), stories are used extensively within healthcare to communicate knowledge. For example, patients relate their illness to the practitioner in a story (I started feeling the pain last night after soccer practice….), the practitioner interprets the story for meaningful information to determine a diagnosis, and the practitioner relates the diagnosis back to the patient in story form as well (It seems when you rotated your ankle during that kick you sprained a ligament…). According to Ravichandar et. al's (2007) view of requirements in terms of spaces, an emphasis on the problem domain is needed to transfer user needs into system requirements. The use of an elicitation technique that corresponds with existing practices within the problem domain aids in the transition from user needs to requirements.

One potential weakness of storytelling as an elicitation method is the challenge of ensuring confidentiality to healthcare workers. As noted by Geller & Johnson (2007), healthcare workers typically avoid admitting errors for fear professional repercussions. Lutters (2002) views stories in the workplace as an "an intensely personal form of communication" since the

storyteller's "experience, personality, biases, and interpretive views" are revealed during the communicative process. Due to the revealing nature of stories, healthcare workers may not feel comfortable with the use of storytelling as an elicitation technique. Another potential challenge is that storytelling in the workplace is a social exchange (2002) and the natural interaction between storyteller and listener may be difficult to replicate in a storytelling elicitation method.

Investigation of the efficacy of storytelling as an elicitation method specific to medical device design is needed. The results for an exploratory study investigating the efficacy of storytelling combined with focus groups within the healthcare domain follows.

CHAPTER 3. RESEARCH QUESTIONS AND HYPOTHESES

This study was an exploratory study to determine the efficacy of storytelling as an elicitation method for medical device requirements. This study examined each of four research questions and tested the following research hypotheses. Since this study was exploratory in nature, a large number of hypotheses were appropriate. As detailed in the hypotheses below, the focus of this research was "requirement THEMES" and not "requirements". In this study, "requirements themes" were operationally defined as "a participant's statement(s) of a user need which contributes to the development of a requirement". The distinction between "requirements themes" and "requirements" was appropriate since the proposed research did not attempt to address the transformation from elicited user needs to specified requirements. The transformation process from user needs to specified functional requirements will be addressed in future work.

This study was bounded by the definition of medical device usability provided by IEC 62366. This definition was used to create a requirements ontology for medical devices (Figure 6), which defines categories of usability requirements in which the identified themes were systematically categorized. These usability categories are efficiency, effectiveness, satisfaction, and context-of-use. Context-of-use was further defined as spatial context, social context, technological context, hygienic context, physical context, and activity context.

The focus of the following research questions allowed for determination of the 'better' set of information elicited by each group. For the purposes of this study, 'better' was operationally defined as greater in quantity, breadth and depth. Quantity was considered to be a factor of a 'better' set of requirements since it would indicate how many themes the individual

discussed as a result of the elicitation method. In this respect, greater quantity was directly proportional to greater quality. Breadth and depth were included as factors while judging the set of requirements per group. Breadth was considered to be a factor of a 'better' set of requirements since it would indicate the group's coverage of all possible requirements categories. In this respect, greater breadth was directly proportional to greater quality. Depth was considered to be a factor of a 'better' set of requirements since it would indicate how many themes a group identified within each possible requirements category. In this respect, greater depth was directly proportional to greater quality.

RQ1 addressed the quantity of information elicited from each group. RQ2 addressed the breadth of information, where breadth was operationally defined as the ratio between the number of categories addressed and the number of possible categories. RQ3 addressed the depth of information, where depth was operationally defined as the number of distinct themes collectively identified per group per category. RQ4 addressed the participant time required by each elicitation method. For the purposes of this study, "better" time was considered to be the least time required due to the warnings in the literature regarding the difficulty gaining access to medical device practitioners (Martin et al., 2006).

RESEARCH QUESTION 1: What are the differences in the number of themes addressed per participant via the different elicitation method combinations of

Group 1) focus group & interview and

Group 2) focus group & storytelling?

The hypotheses for the first research question are detailed in Table 4.

Table 4: Hypotheses for research question #1

	Hypothesis
1a	*Group #2 participants will identify more **usability themes** than Group #1 participants*
1b	*No expected difference for the number of **efficiency themes** identified by participants in each group*
1c	*No expected difference for the number of **effectiveness themes** identified by participants in each group*
1d	*No expected difference for the number of **satisfaction themes** identified by participants in each group*
1e	*Group #2 participants will identify more **context-of-use themes** than Group #1 participants*
1f	*No expected difference for the number of **spatial themes** identified by participants each group*
1g	*Group #2 participants will identify more **social themes** than Group #1*
1h	*Group #2 participants will identify more **technological themes** than Group #1 participants*
1i	*No expected difference for the number of **hygienic themes** identified by participants in each group*
1j	*No expected difference for the number of **physical themes** identified by participants in each group*
1k	*Group #2 participants will identify more **activity themes** than Group #1 participants*

RESEARCH QUESTION 2: What are the differences in the breadth of requirement themes per person?

Hypothesis 2: There will be differences between the breadth of requirements categories addressed per group

RESEARCH QUESTION 3: What are the differences in the depth of compiled requirement themes per group?

The hypotheses for the third research question are listed in Table 5.

Table 5: Hypotheses for research question #3

	Hypothesis
3a	*Group #2 participants will **collectively** identify more **distinct usability themes** than Group #1 participants*
3b	*No expected difference for the number of **distinct efficiency themes collectively** identified by participants in each group*
3c	*No expected difference for the number of **distinct effectiveness themes collectively** identified by participants in each group*
3d	*No expected difference for the number of **distinct satisfaction themes collectively** identified by participants in each group*
3e	*Group #2 participants will **collectively** identify more **distinct context-of-use themes** than Group #1 participants*
3f	*No expected difference for the number of **distinct spatial themes collectively** identified by participants each group*
3g	*Group #2 participants will **collectively** identify more **distinct social themes** than Group #1*
3h	*Group #2 participants will **collectively** identify more **distinct technological themes** than Group #1 participants*
3i	*No expected difference for the number of **distinct hygienic themes collectively** identified by participants in each group*
3j	*No expected difference for the number of **distinct physical themes collectively** identified by participants in each group*
3k	*Group #2 participants will identify more **activity themes** than Group #1 participants*

RESEARCH QUESTION 4: What are the differences between the time used by each elicitation method during the experiment?

Hypothesis 4: No expected difference between the time used for each elicitation method.

CHAPTER 4. METHOD

The goal of this study was to investigate storytelling as an elicitation method for medical device requirements to determine if storytelling elicited more context-of-use usability requirements than a traditional interview technique. An infusion pump was chosen as the specific medical device for this research based on the prevalence of infusion pump design research (Amoore & Adamson, 2003; Garmer, Liljegren, Osvalder, & Dahlman, 2002a, 2002b;

Lane, Stanton, & Harrison, 2006) and the inclusion of infusion pump examples within design standards (ANSI/AAMI, 2001; IEC, 2007).

4.1 Summary of Design

The research design was a between-subjects design to allow for comparisons between treatments. Garmer et. al. (2004) also used a between-subjects design to compare the medical device requirements gathered via focus groups with requirements gathered during usability tests. Participants were randomly assigned to one of two groups:

Group #1 – Focus Group and Individual Interviews
Participants randomly assigned to Group #1 participated in a focus group consisting of all Group #1 participants. The purpose of the focus group was to discuss requirements for a new design of a "hypothetical" infusion pump. Group #1 participants also participated in follow-up individual interview sessions as part of the requirements gathering process.

Group #2 – Focus Group and Storytelling Sessions
Participants randomly assigned to Group #2 participated in a focus group consisting of all Group #2 participants. The purpose of the focus group was to discuss requirements for a new design of a "hypothetical" infusion pump. Group #1 participants also participated in follow-up individual storytelling sessions as part of the requirements gathering process.

Focus groups and individual interviews were chosen as elicitation methods to compare with the new storytelling sessions method since they were often cited in the literature (Garmer et al., 2004; Wiklund, 1995a) and recommended in the standards (ANSI/AAMI, 2001; IEC, 2007). Sizes for focus groups were bounded by recommendations in the literature for the restriction of focus group size to 4-8 participants (Wiklund, 1995a). Participants in each group were exposed to more than one type of elicitation technique to adhere to recommendations for the use of multiple techniques to gather a broad range of user requirements (Garmer et al., 2004; Martin et al., 2007). Focus groups were conducted first for both sets of participants since focus groups are typically used in industry as an initial method to bring project stakeholders together to talk about their user needs (Wiklund, 1995a).

The study was a mixed methods study. Transcripts of the focus groups, individual interviews, and individual storytelling sessions were analyzed using thematic analysis. User

statements were associated with an ontology of requirement types through thematic analysis. complete copy of the instructions for data coders is available in Appendix C.

4.2 Participants

After collection of 15+ background questionnaires, 2 focus groups were scheduled in cooperation with the Director of Staff Development. To accommodate both day & night shifts, one focus group was scheduled for the end of day shift while the other was scheduled for the end of night shift. To allow for homogeneity between groups, participants were assigned to groups based on information provided in their background questionnaire. Age, gender, years of experience, and work location were factors considered during group assignment. 8 potential participants accepted invitation to the first focus group. However, one cancelled the day before and 2 did not attend. Since focus groups in the medical industry operate with as few as 4 participants, the focus group proceeded with a total of 5 participants (Wiklund, 1995b).

Demographic information for participants in Group 1 and 2 are shown in Tables 6 and 7 below, respectively. Demographic information for each group was compared with national demographic information obtained from the Infusion Nurses Society (INS), the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), and Montgomery Regional Hospital (MRH) (HRSA, 2004; INS, 2008; Linkenhoker, 2008). Neither group matched the national demographic information for age or for years of experience. Since age is logically related to years of experience, there were two possible causes for the discrepancy between the research sample demographics and the national demographics. Since MRH nurses were able to use participation in this study towards their clinical ladder of promotion, less experienced nurses had a greater motivation to participate in the study than more experienced and older nurses. Also, as shown in Table 6 below, the nursing staff at MRH was younger and less experienced than the national average. 52% of MRH nursing staff was under 40 years of age, which was double the 26% found in the HRSA survey. 30% of MRH nursing staff had less than 5 years of experience, which was double the 15% found by the INS survey.

Table 6: Group #1 demographic information

Age (years)	n	Group 1 %	HRSA %	MRH %	Gender	n	Group 1 %	HRSA %	MRH %	Experience (years)	n	Group 1 %	INS%	MRH %
< 40	2	40	26	52	***Male***	1	20	6	13	**< 5**	2	40	15	30

40-50	2	40	32	30	***Female***	4	80	94	87	**5-20**	2	40	70	50
> 50	1	20	41	18						**>20**	1	20	15	20

Table 7: Group #2 demographic information

Age (years)	n	Group 1 %	HRSA %	MRH %	Gender	n	Group 1 %	HRSA %	MRH %	Experience (years)	n	Group 1 %	INS%	MRH %
< 40	4	80	26	52	***Male***	1	20	6	13	**< 5**	2	40	15	30
40-50	1	20	32	30	***Female***	4	80	94	87	**5-20**	2	40	70	50
> 50	0	0	41	18						**>20**	1	20	15	20

Table 8 compares demographic information for Groups 1 and 2. Average age of participants in Group 1 and Group 2 was 42 years of age and 35 years of age, respectively. Although Group 1 participants were slightly older than Group 2 participants, total years of experience for each group was very similar. Group 1 participants had a total of 52 years of nursing experience and Group 2 participants had a total of 53 years of nursing experience.

Table 8: Demographic comparison of Group 1 and Group 2 participants

Age (years)	Group 1 n	Group 2 n	Gender	Group 1 n	Group 2 n	Experience (years)	Group 1 n	Group 2 n
< 40	2	4	***Male***	1	1	**< 5**	2	2
40-50	2	1	***Female***	4	4	**5-20**	2	2
> 50	1	0				**>20**	1	1

Table 9 below details the primary work locations for Group 1 and Group 2 participants, which were obtained via the background questionnaire. Although control for work location was attempted through restricted invitations to particular focus group times, participants "heard-through-the-grapevine" of the other focus group date and time and attended the session most convenient to them.

In general, recruitment of participants was challenging due to the standard 12-hour daily work schedules of nurses. Several potential participants stated disinterest once they learned of the time commitment since it required adding an extra hour to an already long workday. Due to the limited participant pool and day/night shift constraints, work locations for each group could not be matched exactly.

Table 9: Primary work locations for Group #1 and Group #2 participants

	Group 1	**Group 2**
Wards	Emergency (3) Birthing Center (1)	Emergency (1) Birthing Center (1)

	Pediatrics (1)	Cardio-Pulmonary (1) Orthopaedics (2)

However, although nurses indicated a primary work location on the demographic form, the practice of "floating" was revealed through the focus group, interview, and storytelling discussions. Based on the information provided by participants, it became apparent that floating was a practice at MRH where nurses at one ward occasionally worked in another ward. According to the Assistant Chief Nursing Officer, unit staffing was based on the number of patients in the unit. When the patients assigned to the ward exceed the desired staff : patient ratio for the unit, an additional staff member with comparable skills from another unit was assigned to the unit in need. Floating was considered to be a rare occurrence which was "used to equal the work environment in regards to the nurse workload and the patient's [sic] needs" (Lindsey, 2008). The participants' familiarity with other wards was important since the focus of this study was context-of-use, which is associated with work location. For example, a worker familiar with 3 wards may have had a greater understanding of different work contexts than a worker familiar with 1 ward.

An analysis of the transcripts from the focus group, interview, and storytelling sessions revealed that workers were experienced with more than their main ward. Table 10 below details the wards worked by Group 1 and Group 2 participants.

Table 10: All work locations for Group #1 and Group #2 participants

	Group 1 (n)	**Group 2 (n)**
Wards	Emergency (4) Birthing Center (1) Pediatrics (1) Critical Care (2)	Emergency (2) Birthing Center (1) Cardio-Pulmonary (1) Orthopaedics (2) Oncology (1)

4.3 Procedure

4.3.1 Focus Groups

The participants in each group initially participated in a focus group consisting of all members of the assigned group. The purpose of the focus group was to discuss requirements for a new design of a "hypothetical" infusion pump. Sizes for focus groups were bounded by

recommendations in the literature for the restriction of focus group size to 4-8 participants (Wiklund, 1995a).

The primary researcher conducted each focus group using a pre-determined script, which provided an over-arching structure to the focus group. The script format was adapted from McAlearney et. al. (2004), with permission. Focus group questions were created following the guidelines for process-focused and product-focused questions within an initial problem and needs identification meeting (Arthur, 2007). As the goal of the initial meeting was to identify "global properties of the design problem and potential solutions", the majority of questions within the focus group were high-level context-free questions (Gause & Weinberg, 1989). The complete focus group script is included in Appendix A.

Focus groups were conducted in the Nurses Reading Room (335) located on the Montgomery Regional Hospital campus shown in Figure 3 below. During the focus groups, the researcher and participants sat in a circle around the coffee table.

Figure 3: MRH Nurses Reading Room (335)

Proceedings of each focus group were recorded using an Olympus Digital Voice Recorder (Model #DS-2). Focus groups were scheduled to last one hour. At the end of each session, participants were compensated $25 for their time and their next session (either interview or storytelling session) was scheduled.

4.3.2 Interviews

After Focus Group #1, Group #1 participants participated in one individual interview session. Interview dates and times were scheduled at the end of the focus group at the convenience of each participant. Interviews were scheduled to last 60 minutes.

The primary researcher conducted the interviews following a pre-determined interview question list (Appendix A), which provided an over-arching structure to the interview. The interview questions were developed following recommendations for the types of requirements needed for infusion pumps (Drews & Westenskow, 2007) and suggestions for following a "who, what, where, when, why" question format for medical device requirement gathering (Shefelbine et al., 2002). An additional question category ("how") was added to ensure that usability issues would be discussed since functional requirements are typically discussed as the "what" and non-functional requirements are discussed as the "how". Interview questions were designed to be open-ended as not to direct the participant towards a particular response (Genzuk, 2003).

The pre-determined list of questions allowed for similarity of discussion between participants. However, interviews were semi-structured to allow for a more conversational interview and to allow for investigation of responses. A complete interview script is included in Appendix A.

All interviews were conducted in the MRH Nurses Reading Room (Figure 3) at the circular table. To control for bias among positive and negative themes, participants were randomly assigned to start with either positive or negative themes. 3 participants started with a positive theme and 2 participants started with a negative theme. Proceedings of each interview were recorded using an Olympus Digital Voice Recorder (Model #DS-2).

At the end of each session, participants were compensated $25 for their time and thanked for their participation in the research project. The primary researcher also emailed each participant a PDF copy of a letter on Virginia Tech letterhead thanking the participant. This letter was requested by some participants as documentation to be used towards the MRH clinical ladder of promotion.

4.3.3 Storytelling Sessions

Group #2 participants participated in one individual storytelling session after Focus Group #2. Storytelling session dates and times were scheduled at the end of the focus group at the convenience of each participant. Storytelling sessions were scheduled to last 60 minutes.

The researcher conducted each storytelling session by following the pre-determined script (Appendix A). Each participant was asked to tell 6 different stories relating to the use of an infusion pump. The participant was instructed that their stories could be either:

1) reflective: based on something that actually happened

2) hypothetical: based on something that could happen

3) second-hand: based on something that happened to an acquaintance

As not to bias the stories towards either pleasant or negative events, 3 of the requested stories had a positive theme and 3 of the stories will had a negative theme.

Positive themes:

- Job satisfaction
- Successful patient treatment
- Efficiency

Negative themes:

- Stress
- Inefficiency
- Error

Expanding upon Shefelbine et. al.'s (2002) recommendation to include "who, what, where, when, why" questions within interviews, participants were reminded at the start of each story to include the "who, what, where, when, why, how" factors within their stories. Similar to the interview protocol, the extra "how" category was added to ensure inclusion of usability issues since usability is typically considered to address the "how" characteristics of a product.

In an effort to allow for comparison between the information elicited via storytelling sessions and individual interviews, the instruments were designed to allow for equal elicitation of "who, what, where, when, why, & how" factors. For example, each interview consisted of 6 questions per category for a total of 36 prompts for "who, what, where, when, why & how" information. Similarly, each storytelling session consisted of 6 stories with prompts to include "who, what, where, when, why & how" factors in each story.

All storytelling sessions were conducted in the MRH Nurses Reading Room (Figure 3) at the circular table. To control for bias among positive and negative themes, participants were randomly assigned to start with either positive or negative themes. 3 participants started with a positive theme and 2 participants started with a negative theme. Proceedings of each interview were recorded using an Olympus Digital Voice Recorder (Model #DS-2)

At the end of each session, participants were compensated $25 for their time and thanked for their participation in the research project. The primary researcher also emailed each participant a PDF copy of a letter on Virginia Tech letterhead thanking the participant. This letter was requested by some participants as documentation to be used towards the MRH clinical ladder of promotion.

A complete storytelling script is available in Appendix A.

CHAPTER 5. RESULTS

This section first describes the data analysis method used for the identification of themes within the participants' transcripts and the subsequent categorization of themes into a pre-existing ontology of usability requirements. This section then details the analyses for each of the research questions and hypotheses. A summary of the people involved in this study is shown in Table 11 below.

Table 11: Groups of people involved in the study

Group	Description
5 Group #1 participants	MRH nurses who participated in one focus group followed by an individual interview session
5 Group #2 participants	MRH nurses who participated in one focus group followed by an individual storytelling session
2 Coders	Identified themes within the focus group, interview, and storytelling session transcripts. Categorized identified themes into a pre-existing ontology of usability requirements.
1 Judge	Determined which identified themes were valid and determined final categorization of themes.

This study was a mixed methods study utilizing both qualitative and quantitative analysis techniques. A summary of the steps required prior to theme identification for each transcript is given in Figure 4. As shown below, the majority of the analysis for this study involved identifying requirements themes within each transcript.

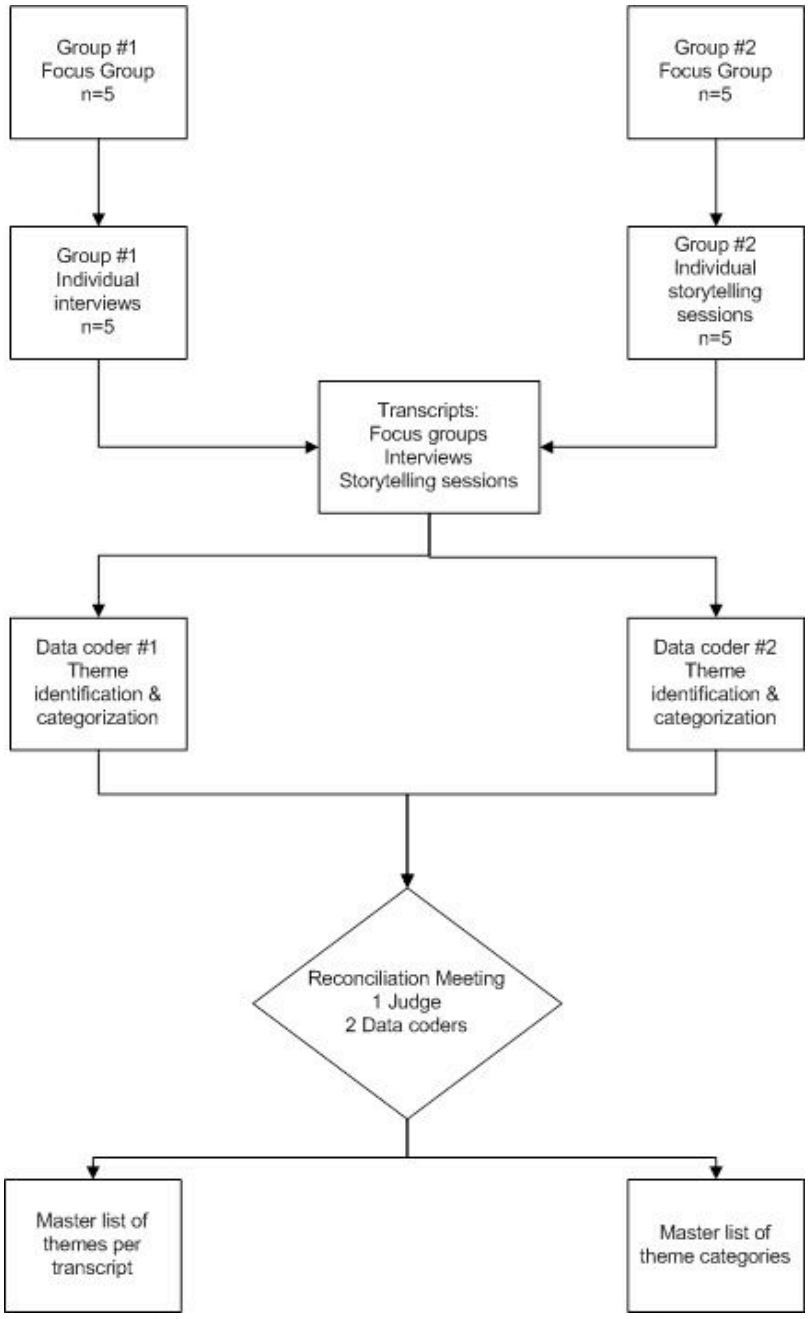

Figure 4: Summary of steps leading to theme identification

Table 12 below summarizes the research hours involved for this study. As shown below, the majority of time spent during this study was during the qualitative analysis of the transcripts, which involved the identification of themes within the transcripts and the reconciliation of those themes with the other coder during the reconciliation meetings. The use of a reconciliation

meeting to compile results from independent coders in this study was based on procedures developed by Capra (2006).

Table 12: Summary of research hours involved in this study

Tasks	People Involved	Hours	Total Hours
Focus Group #1	5 participants 1 researcher	1 hr each	6 hrs
Focus Group #2	5 participants 1 researcher	1 hr each	6 hrs
Interviews	5 participants 1 researcher	1 hr each 5 hrs	10 hrs
Storytelling sessions	5 participants 1 researcher	1 hr each 5 hrs	10 hrs
Data coding	Coder #1 Coder #2	28 hrs 41 hrs	69 hrs
Reconciliation meetings	2 coders 1 judge	17 hrs	51 hrs
		Total Hours	**152 hrs**

5.1 Theme identification

A professional transcription service, eScriptionist.com, was contracted to transcribe the audio from all sessions. Two data coders coded statements within the transcripts into requirement themes following the block and file approach to thematic analysis described in Grbich (2007). Thematic analysis is a technique used in content analysis where themes emerge from participant transcripts after repeated readings and iterative comparisons. In the block and file approach, coders tag statements into chunks and then categorize these chunks into meaningful groupings. In this study, the data coders tagged statements into "requirement themes" (chunks) and then categorized these themes into the meaningful groupings already described by a pre-existing requirements ontology.

Figure 5 below depicts the ontology for requirements that was used during data analysis. This ontology provided a framework for categorization of requirements themes into requirements categories specific to medical devices. It is important to note that one requirement theme can be associated with more than one requirement category. For example, the theme "Certain drugs are weight based" was categorized in both activity context and effectiveness context. It was associated with activity context since dealing with a weight-based drug impacted the nurses' strain and stress. It was also associated with effectiveness because the accuracy level of the treatment depended upon the correct dosage for a patient's weight.

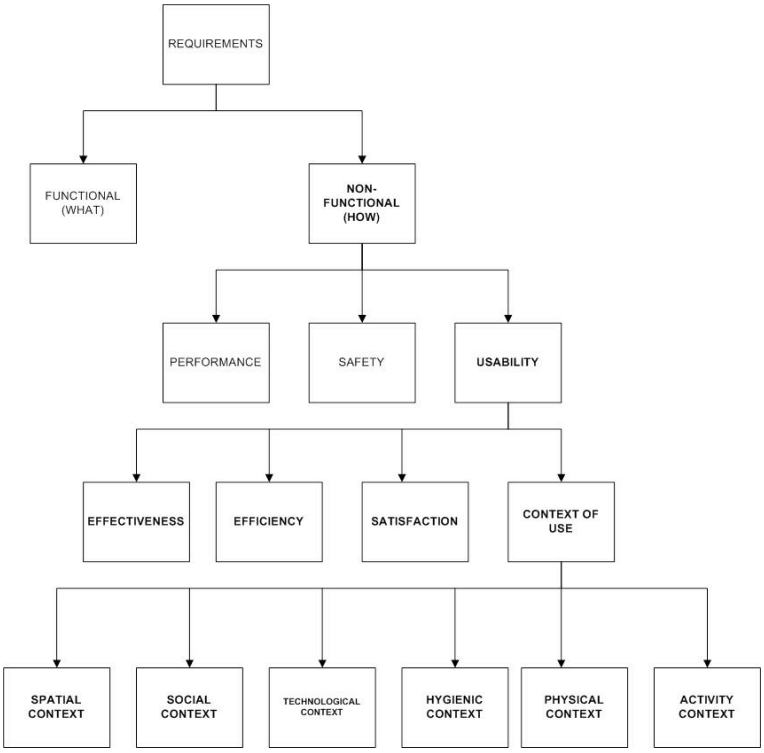

Figure 5: Requirements ontology used during data analysis

This ontology was adapted by expanding requirements categories identified in the literature (Arthur, 2007; Chung et al., 1999) to include context-of-use requirements specific to medical devices identified in IEC 62366. Since the focus of the research project was the elicitation of usability requirements, the ontology was expanded to further categorize usability requirements using both the ISO 9241-11 definition of usability and the definition within ANSI/AAMI HE74.

5.1.1 Data coding

A process flow for the data coding is detailed in Figure 6. The first stage of the data coding process was independent coding of the transcripts by two data coders who utilized thematic analysis to identify themes within the transcripts. Identified themes were then sorted into categories based on the requirements ontology for medical device requirements developed for this study. A detailed explanation of the independent coding process follows.

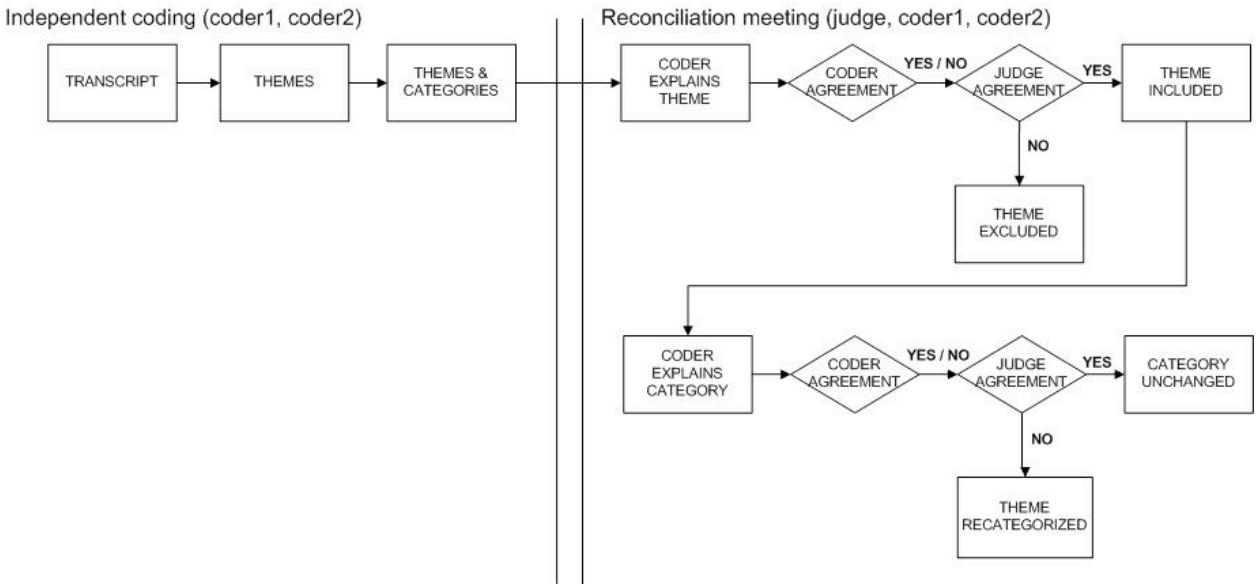

Figure 6: Process flow for data coding process

Two graduate students enrolled in the Human Factors option within the Industrial and Systems Engineering program at Virginia Tech acted as data coders. The primary researcher acted as a data coder due to resource constraints. Both data coders used ATLAS.ti 5.2 qualitative analysis software to code participant statements into requirements themes. Both data coders also categorized identified themes into the appropriate category or categories following the usability requirements ontology depicted in Figure 5. A full copy of the coding instructions is available in Appendix C.

An example analysis for a participant's story is shown in Figure 7 below. The left pane contains the participant's transcript and the right pane contains the themes identified by the data coder.

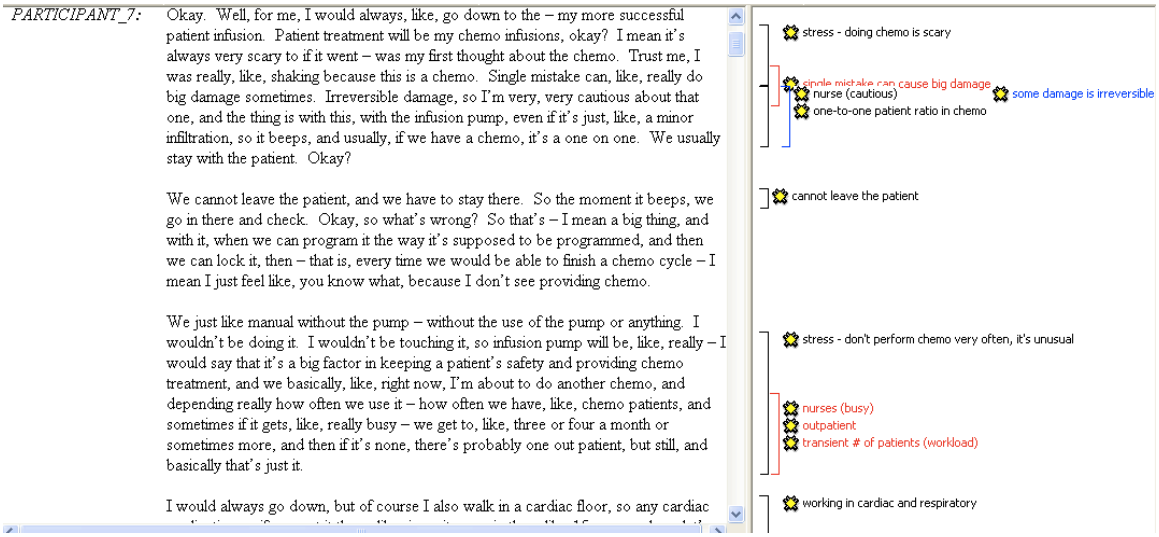

Figure 7: Example transcript coding in ATLAS.ti

After theme identification, each data coder independently categorized all themes according to the requirements ontology. For example, Table 13 below lists the categories assigned by the data coder for the themes identified above.

Table 13: Example categorization of identified themes by data coder

Theme	Categories
Stress – doing chemo is scary	Activity context Satisfaction
Single mistake can cause big damage	Activity context
Nurse(cautious)	Activity context Satisfaction
One-to-one patient ratio in chemo	Activity context
Some damage is irreversible	Activity context
Cannot leave the patient	Activity context
Stress – don't perform chemo very often, it's unusual	Activity context
Outpatient	Social context
Transient # of patients (workload)	Activity context
Working in cardiac and respiratory	Spatial context

As shown in Figure 7, the second phase of the data coding process was the reconciliation of the independent coding results. During the reconciliation meetings each coder presented his or her findings to the other data coder and the data coding judge. The purpose of the reconciliation meetings was to create a final list of themes and associated categories for each transcript. A detailed explanation of the reconciliation meetings follows.

Data coding results from the two coders were combined during three reconciliation meetings, totaling 17 hours, which were moderated by a data coding judge to reduce experimenter bias. A doctoral student in the Computer Science department at Virginia Tech with expertise in requirements engineering acted as the data coding judge. In preparation for the meetings, the data coding judge reviewed the following materials:

- Data coding instructions (Appendix C)
- All transcripts (Appendix A)
- Data judge instructions (Appendix C)

During the meetings, an excel spreadsheet that compared the results from the two coders for each transcript was projected on a large screen for easier discussion. Following the reconciliation meeting protocol (Appendix C) each data coder individually explained each identified theme and why it was categorized into the category. After each explanation, the other data coder expressed either agreement or disagreement. The data coding judge then recorded her decision on the master Excel spreadsheet. During the meeting the data coding judge also combined similar themes. In the example above, the theme "Stress – don't perform chemo very often – it's unusual" was deemed to be redundant with "Stress – doing chemo is scary" so the two themes were combined into one.

Tables 14 and 15 below summarize the results of the reconciliation meeting for the transcript section displayed in Figure 7. Themes that were changed as a result of the reconciliation meeting are italicized in Table 14. For example, the theme "Some damage is irreversible" was moved from the "activity context" category into the "effectiveness" category.

Table 14: Themes and categories after reconciliation meeting

Included themes	**Categories**
Stress – doing chemo is scary	*Activity context* *Satisfaction*
Nurses (cautious)	Activity context
One-to-one patient ratio in chemo	Activity context
Some damage is irreversible	*Effectiveness*
Cannot leave the patient	Activity context
Working in cardiac and respiratory	Spatial context

As shown in Table 15 below, several themes in the above example were excluded as a result of the reconciliation meeting. One theme was excluded because it was considered to be a user profile, two themes were excluded because they were considered redundant with another themes, and one theme was excluded because it was judged to be invalid.

Table 15: Themes excluded after reconciliation meeting

Excluded themes	**Reasoning**
Outpatient	Considered to be a user profile – type of patient
Single mistake can cause big damage	Redundant with "Some damage is irreversible"
Stress – don't perform chemo very often, it's unusual	Redundant with "Stress – doing chemo is scary"
Transient # of patients (workload)	Not a valid theme based on a re-reading of the transcript.

An unexpected challenge during the reconciliation meetings was the inability to categorize identified themes into the pre-existing categories within the requirements ontology. Table 16 below lists the themes that were considered valid, but which did not match with a pre-existing category. These themes were discarded since they did not fit within any of the requirements categories. The implication of this finding is that the requirements ontology used, which was based on the usability definitions available in the standards IEC 62366 (2007) and ANSI/AAMI HE74 (2001), may have been too restrictive.

Table 16: Themes discarded during theme reconciliation

Discarded themes	**Source**
Thinking of the IV pump as a worker (personification)	P10
Some situations are comical	P8
Some situations are crazy	P7
Everybody has own standards	P5

The main purpose of the reconciliation meeting was to improve the percent agreement among coders. Percent agreement represents the ratio of agreement to total decision items and was calculated as:

$$\text{Percent agreement} = \frac{\#\,agreements}{\#\,agreements + \#\,disagreements}$$

Prior to the reconciliation meeting the average percent agreement between the two coders was 9% (*SD*=0.03). After the reconciliation meeting the average percent agreement between the two coders was 91% (*SD*=0.02).

5.1.2 Data handling

Immediately following the last reconciliation meeting, the primary researcher compiled the identified valid themes per transcript and valid theme categories into a master Excel spreadsheet. In an effort to identify any redundant codes missed during the reconciliation meeting, the primary researcher used SAS statistical software to create lists of unique themes per participant. Redundant themes were identified by visually comparing the two lists. Redundant themes, such as "insufficient training" and "training insufficient", were combined. An additional column entitled "Traceablity" was added to the Excel spreadsheet to provide a record of all changes.

5.2 RQ1: What are the differences in the number of themes addressed per participant via the different elicitation method combinations?

The purpose of the first research question was to determine if participants focused on different usability categories as a result of the differences in treatment. The total number of themes identified per participant, per category was calculated as the union between the results of the focus group and individual follow-up session, as represented in Figure 8 below.

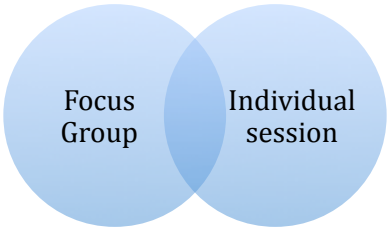

Figure 8: Total themes per participant per category was the union of all themes identified in the focus group and follow-up session

For example, the total usability themes for P1 was calculated as:

$$\text{Total\_Usability\_Themes}_{P1} = \text{Total\_Usablity\_Themes\_FG1}_{All} \cup \text{Total\_Usability\_Themes\_Interview}_{P1}$$

All participant statements during each focus group were considered to be owned by all focus group participants since the requirements collection was a group effort.

A two-sample t-test was used to test for significant differences in the quantities of themes addressed per participant since the groups represented independent samples. Due to the small sample size, data was initially tested for normality using the Shapiro-Wilk test with an alpha level of 0.05. The appropriate parametric or nonparametric test was then chosen based on the results of the Shapiro-Wilk test. The parametric test used was the Satterthwaite t-test and the nonparametric test used was the Mann Whitney U test. The SAS code and relevant output are available in Appendix D. Since this study is exploratory and contains multiple hypotheses, an alpha level for the entire experiment was set at 0.2 to account for experimentwise Type I error (Ott & Longnecker, 2001) . The alpha level for each test was calculated using the Bonferroni inequality, where m is the number of statistical tests on the data set

$$\alpha 1 = \frac{\alpha}{m} = \frac{0.2}{11} = 0.02$$

Although the purpose of several tests was to confirm that no differences existed (1b, 1c, 1d, 1f, 1i, 1j), all statistical tests on the data set must be included when calculating the alpha level using the Bonferroni inequality.

5.2.1 Hypotheses 1a – 1k

The results for the tests for all RQ1 hypotheses are listed in Table 17 below. No significant differences were found for any of the hypothesis tests. However, the test statistic for hypotheses 1e, 1f, 1g, and 1i was negative which indicates that the Group 2 mean was larger than the Group 1 mean for these tests.

Table 17: RQ1 findings

Hypothesis	Test Hypothesis	*t(n-2)*	*p*	Finding
1a	H_0: $\mu_{USABILITY(GROUP\ 1)} \geq \mu_{USABILITY(GROUP2)}$ H_1: $\mu_{USABILITY(GROUP\ 1)} < \mu_{USABILITY(GROUP2)}$	$t(8)=0.71$	0.25	No significant difference
1b	H_0: $\mu_{EFFICIENCY(GROUP\ 1)} = \mu_{EFFICIENCY(GROUP2)}$ H_1: $\mu_{EFFICIENCY(GROUP\ 1)} \neq \mu_{EFFICIENCY(GROUP2)}$	$z=1.48$	0.17	No significant difference
1c	H_0: $\mu_{EFFECTIVENESS(GROUP\ 1)} = \mu_{EFFECTIVENESS(GROUP2)}$ H_1: $\mu_{EFFECTIVENESS(GROUP\ 1)} \neq \mu_{EFFECTIVENESS(GROUP2)}$	$t(8)=1.57$	0.16	No significant difference
1d	H_0: $\mu_{SATISFACTION(GROUP\ 1)} = \mu_{SATISFACTION(GROUP2)}$ H_1: $\mu_{SATISFACTION(GROUP\ 1)} \neq \mu_{SATISFACTION(GROUP2)}$	$t(8)=1.57$	0.16	No significant difference
1e	H_0: $\mu_{CONTEXT\ (GROUP\ 1)} \geq \mu_{CONTEXT(GROUP2)}$ H_1: $\mu_{CONTEXT\ (GROUP\ 1)} < \mu_{CONTEXT(GROUP2)}$	$t(8)=-0.14$	0.45	No significant difference
1f	H_0: $\mu_{SPATIAL(GROUP\ 1)} = \mu_{SPATIAL(GROUP2)}$ H_1: $\mu_{SPATIAL(GROUP\ 1)} \neq \mu_{SPATIAL(GROUP2)}$	$t(8)=-1.01$	0.35	No significant difference
1g	H_0: $\mu_{SOCIAL(GROUP\ 1)} \geq \mu_{SOCIAL(GROUP2)}$ H_1: $\mu_{SOCIAL(GROUP\ 1)} < \mu_{SOCIAL(GROUP2)}$	$z=-1.89$	0.05	No significant difference
1h	H_0: $\mu_{TECH\ (GROUP\ 1)} \geq \mu_{TECH(GROUP2)}$ H_1: $\mu_{TECH\ (GROUP\ 1)} < \mu_{TECH(GROUP2)}$	$z=2.63$	0.03	No significant difference
1i	H_0: $\mu_{HYGIENIC(GROUP\ 1)} = \mu_{HYGIENIC\ (GROUP2)}$ H_1: $\mu_{HYGIENIC(GROUP\ 1)} \neq \mu_{HYGIENIC\ (GROUP2)}$	$z= -0.39$	0.70	No significant difference
1j	H_0: $\mu_{PHYSICAL\ (GROUP\ 1)} = \mu_{PHYSICAL(GROUP2)}$ H_1: $\mu_{PHYSICAL\ (GROUP\ 1)} \neq \mu_{PHYSICAL(GROUP2)}$	$z=2.31$	0.05	No significant difference
1k	H_0: $\mu_{ACTIVITY(GROUP\ 1)} \geq \mu_{ACTIVITY(GROUP2)}$ H_1: $\mu_{ACTIVITY(GROUP\ 1)} < \mu_{ACTIVITY(GROUP2)}$	$t(8)=2.45$	0.02	No significant difference

Table 18 below summarizes the mean and medians of themes identified per category by group. Means are supplied for parametric tests and medians are supplied for nonparametric tests. The median is supplied when the standard deviation exceeds the mean, as the median is a more accurate representation of central tendency. The means, medians, minimums, and maximums are represented as integers since the data represents themes.

Table 18: Mean themes identified per category per group

Category	**Group**	***M***	***SD***	**Min**	**Max**
Usability	1	232	13.27	214	246
	2	225	16.91	204	251
Efficiency	1	53	1.41	53	56
	2	50	7.23	41	61
Effectiveness	1	57	6.52	49	66
	2	52	2.92	49	56
Satisfaction	1	101	4.22	101	112
	1	98	9.68	86	113
Context-of-use	1	112	9.71	102	127
	2	113	8.04	103	124
Spatial Context	1	13	1.64	12	16
	2	14	1.48	12	16
Social Context	1	28	5.58	26	40
	2	38	5.93	35	49
Technological Context	1	9	0.48	8	9
	2	7	0.55	6	7
Hygienic Context	1	2	0.89	2	4
	1	2	0.89	2	4
Physical Context	1	1	0.45	1	2
	2	0	0.45	0	1
Activity	1	65	6.22	58	73
	2	57	5.08	50	63

As this study was exploratory in nature, the distribution of central tendency for each requirement category was analyzed to identify trends in the data. The following section details the analysis of the graphs for each requirement category. Figures for parametric data include graphs of the distributions in addition to box plots of the means. Figures for nonparametric data include box plots of the Wilcoxon scores for each group since the Wilcoxon scores represent the central tendency. Graphs for hygienic and physical context were not analyzed, as these categories lacked necessary data points to produce a conclusive distribution.

5.2.1.1 Hypothesis 1a: Group #2 participants will identify more **usability themes** than Group #1 participants

As shown in Figure 9 below the data distribution indicated a potential trend for Group 1 to identify more usability themes. Although no significant differences were found between the two groups, this lack of finding may be caused by the small sample size of the study.

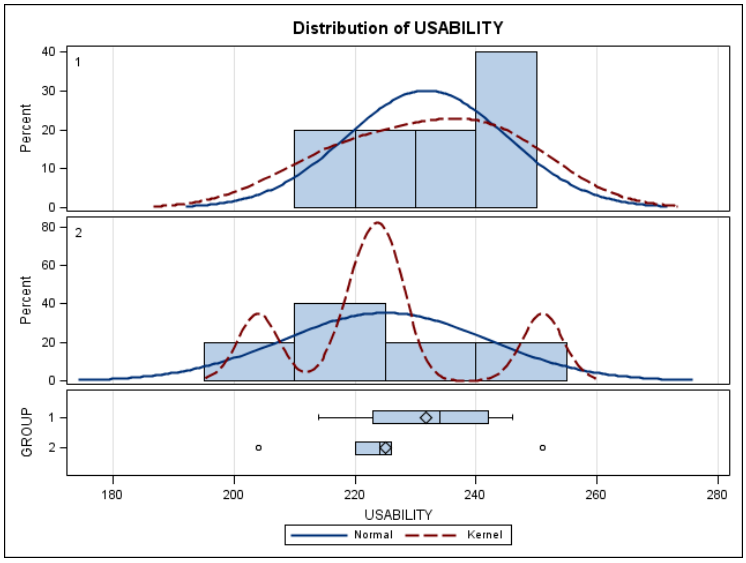

Figure 9: Distribution of usability themes for each group

5.2.1.2 Hypothesis 1b: No expected difference for the number of **efficiency themes** identified by participants in each group

As shown in Figure 10 below the data distribution indicated a potential trend for Group 1 to identify more efficiency themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

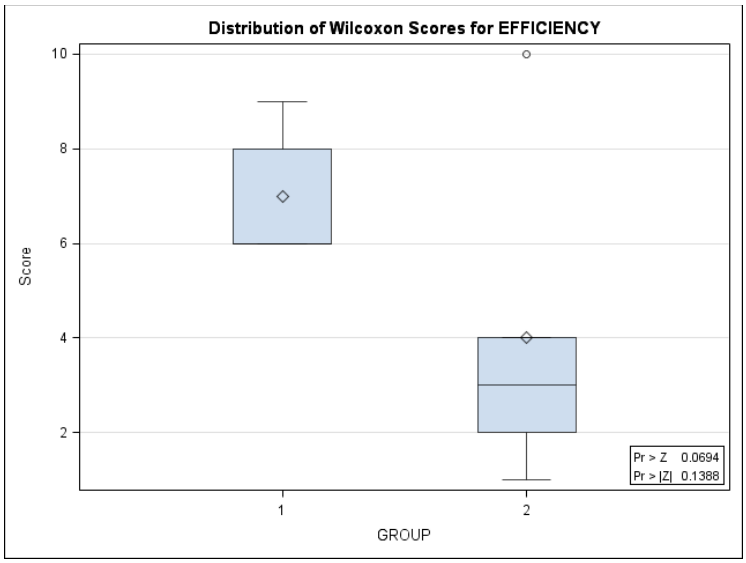

Figure 10: Distribution of efficiency Wilcoxon scores for each group

5.2.1.3 Hypothesis 1c: No expected difference for the number of **effectiveness themes** identified by participants in each group

As shown in Figure 11 below the data distribution indicated a potential trend for Group 1 to identify more effectiveness themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

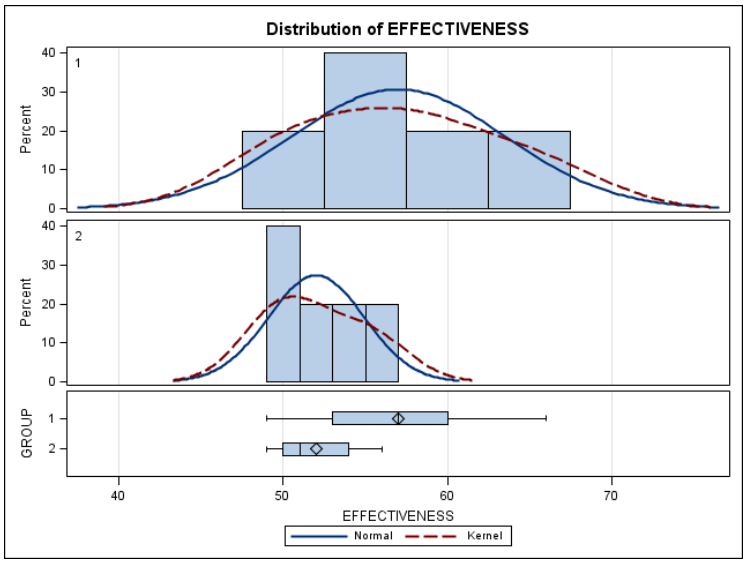

Figure 11: Distribution of effectiveness themes for each group

5.2.1.4 Hypothesis 1d: No expected difference for the number of **satisfaction themes** identified by participants in each group

As shown in Figure 12 below the data distribution indicated a potential trend for Group 1 to identify more satisfaction themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

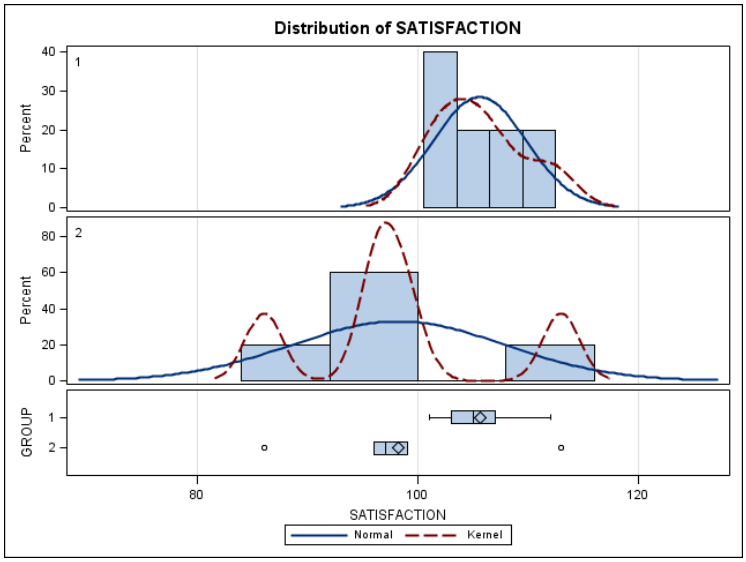

Figure 12: Distribution of satisfaction themes for each group

5.2.1.5 Hypothesis 1e: Group #2 participants will identify more **context-of-use themes** than Group #1 participants

As shown in Figure 13 below the data distribution indicated a potential trend for Group 2 to identify more context-of-use themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

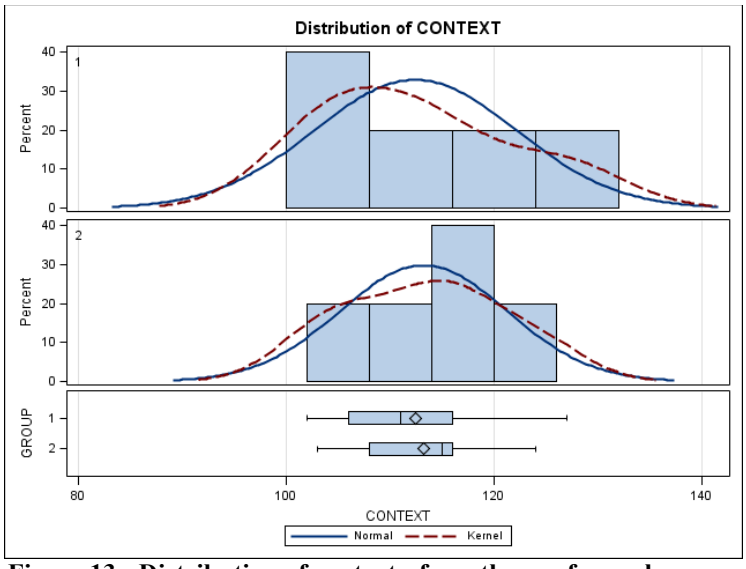

Figure 13: Distribution of context-of-use themes for each group

5.2.1.6 Hypothesis 1f: No expected difference for the number of **spatial themes** identified by participants each group

As shown in Figure 14 below the data distribution indicated a potential trend for Group 2 to identify more spatial themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

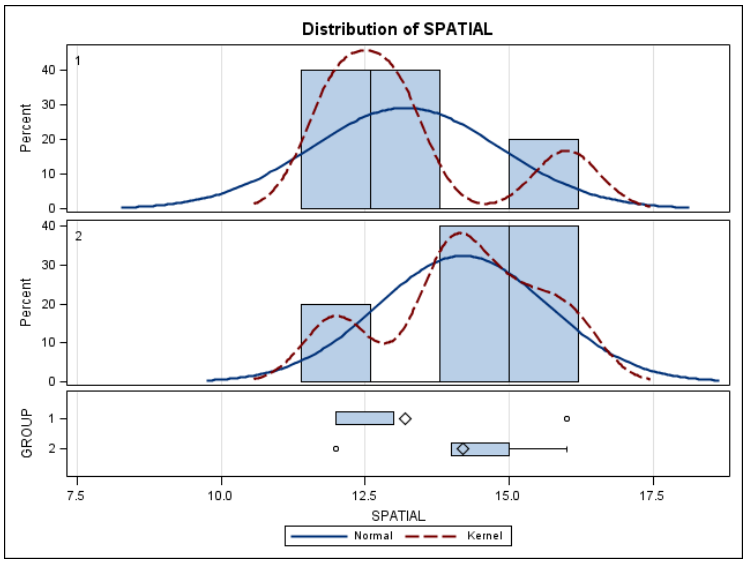

Figure 14: Distribution of spatial context themes for each group

5.2.1.7 Hypothesis 1g: Group #2 participants will identify more **social themes** than Group #1

As shown in Figure 15 below the data distribution indicated a potential trend for Group 2 to identify more social themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

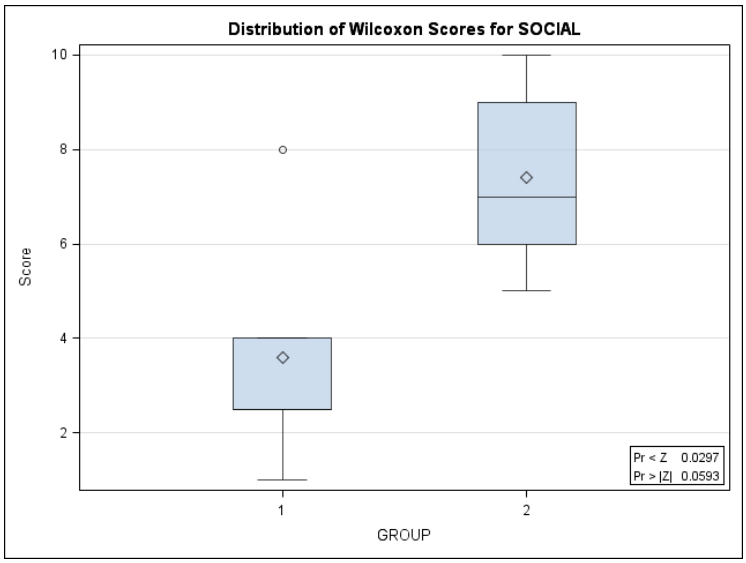

Figure 15: Distribution of social context Wilcoxon scores for each group

5.2.1.8 Hypothesis 1k: Group #2 participants will identify more **activity themes** than Group #1 participants

As shown in Figure 16 below the data distribution indicated a potential trend for Group 1 to identify more activity themes. Although no significant differences were found between the two groups, this lack of finding may have been caused by the small sample size of the study.

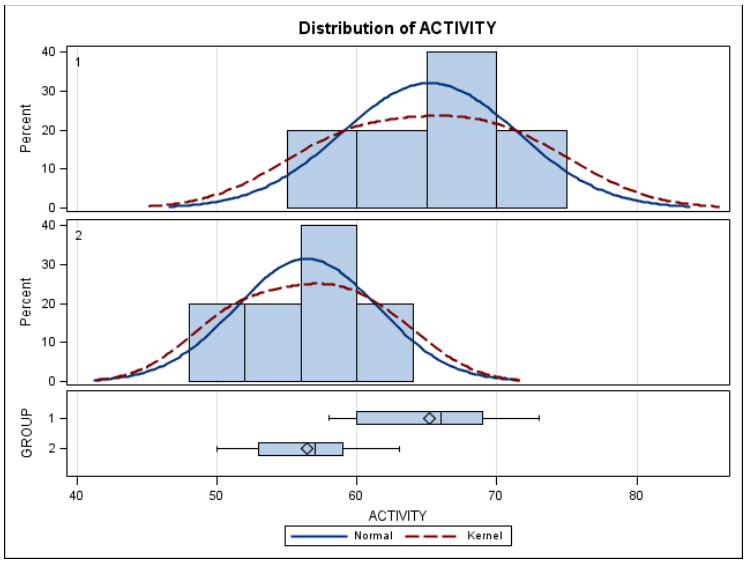

Figure 16: Distribution of activity themes for each group

5.3 RQ2: What are the differences in the breadth of requirement themes per person?

The purpose of the second research question was to investigate if participants discussed a broader range of themes as a result of the differences in treatments. Breadth was considered to be a factor of a 'better' set of requirements since it would indicate the group's coverage of all possible requirements categories. In this respect, greater breadth was directly proportional to greater quality. Breadth per person was calculated as:

$$\text{Breadth} = \frac{\#categories\_discussed}{total\_\#\_categories} = \frac{\#categories\_discussed}{11} =$$

A two-sample t-test was used to test for significant differences in the breadth of themes addressed per participant since the groups represented independent samples. Data was initially tested for normality using the Shapiro-Wilk test with an alpha level of 0.05. Since the data was nonparametric the test used was the Mann Whitney U test. The SAS code and relevant output are available in Appendix D. As stated previously in Section 5.2, an alpha level for the entire experiment was set at 0.2 using the Bonferroni inequality to account for experimentwise Type I error (Ott & Longnecker, 2001) .

5.3.1 Hypothesis 2: There will be significant differences between the breadth of requirements categories addressed per group

All participants except for P8 covered all categories as a result of the combination of focus group and the follow-up session so the breadth between groups was not significantly different ($z = 0.8$, $p = 0.44$) where $M_{Group1} = 1$ and $M_{Group2} = 1$.

Since the breadth of the focus groups may have skewed each individual's total breadth score, additional analysis was done to investigate the breadth of the requirement themes obtained per participant solely as a result of the individual follow-up session (interview OR storytelling session). Participants in both groups addressed themes associated with all categories except for hygienic and physical during the follow-up sessions. As shown in Table 19 below, only P1 and P7 addressed all usability categories.

Table 19: Participants in both groups neglected to mention hygienic and physical themes

PARTICIPANT	HYGIENIC	PHYSICAL
P1	√	√
P2	0	0
P3	0	0
P4	0	√
P5	0	√
P6	√	0
P7	√	√
P8	0	0
P9	0	0
P10	0	0

No significant difference ($z = 0.34$, $p = 0.74$) was found between the breadth of requirement categories addressed by either participants in interviews (*M*breadth=1 (*SD*=0.08)) or participants in storytelling sessions (*M*breadth=0.82 (*SD*=0.08)) . The SAS code and relevant output are included in Appendix D.

5.4 RQ3: What are the differences in the depth of compiled requirement themes per group?

The purpose of the third research question was to investigate differences in the compiled results for each group. The compiled results for each group was of interest because the value of the information obtained was ultimately judged by the set of responses and not by the individual

responses. For example, if a requirements engineer interviews 5 people who all express the same 20 user needs, the requirements engineer has only identified 20 user needs across all 5 participants. However, if the 5 people revealed 20 distinct user needs each, the requirements engineer has collected 100 (5x20) distinct user needs.

The total number of themes identified per group was calculated as the union between the results of the focus group and all individual follow-up sessions. For example, the total number of usability themes identified by Group #1 is represented in Figure 17 below.

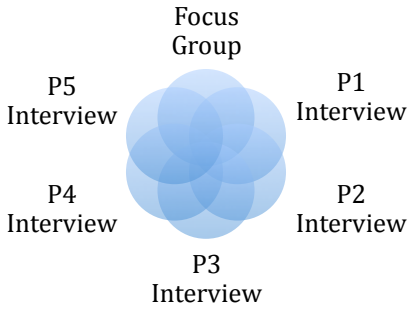

Figure 17: Total usability themes for Group #1 (Focus group & interviews)

For example, the total usability themes for Group #1 was calculated as:

$$\begin{aligned} \text{Total\_Usability\_Themes}_{\text{GROUP\_1}} = \; & \text{Total\_Usablity\_Themes\_FG1}_{\text{All}} \cup \\ & \text{Total\_Usability\_Themes\_Interview}_{\text{P1}} \cup \\ & \text{Total\_Usability\_Themes\_Interview}_{\text{P2}} \cup \\ & \text{Total\_Usability\_Themes\_Interview}_{\text{P3}} \cup \\ & \text{Total\_Usability\_Themes\_Interview}_{\text{P4}} \cup \\ & \text{Total\_Usability\_Themes\_Interview}_{\text{P5}} \end{aligned}$$

For the hypotheses below, any discrepancy greater than or equal to 10% was considered to demonstrate potential support for the hypothesis. Since this study was exploratory in nature a 10% increase was considered to be a significant increase. This 10% cutoff was based on the primary researcher's work experience gathering user requirements for Virginia Tech computer systems. However, any hypothesis with less than 50 data points was considered to be inconclusive (eg, 3f, 3h, 3i, 3j). The cutoff was set at 50 data points to account for a minimum average of 5 identified themes per participant (5 themes x10 participants).

The SAS code and relevant output are included in Appendix D.

5.4.1 *Hypothesis 3a: Group #2 participants will **collectively** identify more **distinct usability themes** than Group #1 participants*

As shown in Figure 18 below, Group 2 identified 18 more usability themes than Group 1. However, this was only a 4% increase over Group 1 so this hypothesis was not supported.

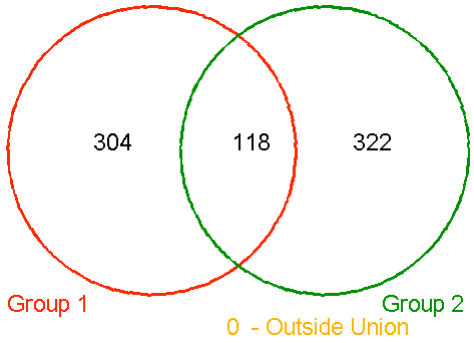

Figure 18: Distinct usability themes per group

A list of all identified usability themes per group is available in Appendix E.

5.4.2 *Hypothesis 3b: No expected difference for the number of **distinct efficiency themes collectively** identified by participants in each group.*

As shown in Figure 19 below, Group 2 identified 2 more efficiency themes than Group 1. However, this was only a 2% increase over Group 1 so this hypothesis was supported.

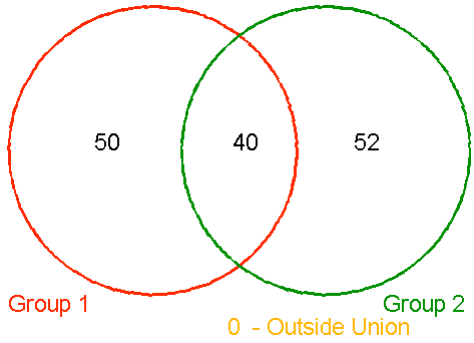

Figure 19: Distinct efficiency themes per group

A list of all identified efficiency themes per group is available in Appendix E.

5.4.3 *Hypothesis 3c: No expected difference for the number of **distinct effectiveness themes collectively** identified by participants in each group.*

As shown in Figure 20 below, Group 1 identified 2 more effectiveness themes than Group 2. However, this was only a 2% increase over Group 2 so this hypothesis was supported.

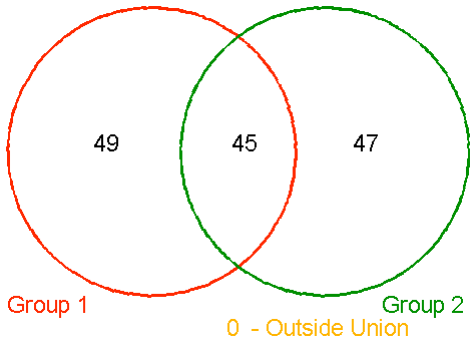

Figure 20: Distinct effectiveness themes per group

A list of all identified effectiveness themes per group is available in Appendix E.

5.4.4 *Hypothesis 3d: No expected difference for the number of **distinct satisfaction themes collectively** identified by participants in each group*

As shown in Figure 21 below, Group 1 identified 18 more satisfaction themes than Group 2. Since this was a 10% increase over Group 2 this hypothesis was rejected.

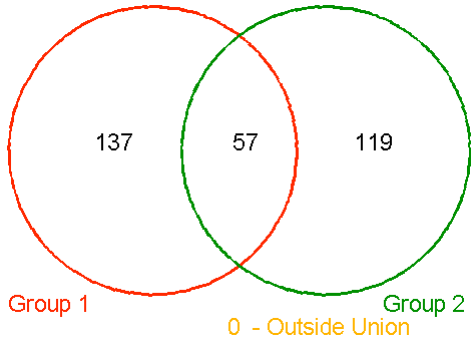

Figure 21: Distinct satisfaction themes per group

A list of all identified satisfaction themes per group is available in Appendix E.

5.4.5 *Hypothesis 3e: Group #2 participants will **collectively** identify more **distinct context-of-use themes** than Group #1 participants*

As shown in Figure 22 below, Group 2 identified 50 more context-of-use themes than Group 1. Since this was a 27% increase over Group 2 this hypothesis was supported.

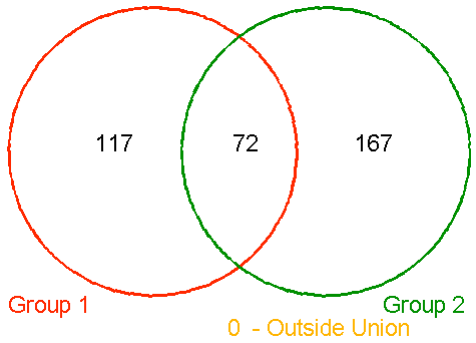

Figure 22: Distinct context-of-use themes per group

A list of all identified context-of-use themes per group is available in Appendix E.

5.4.6 *Hypothesis 3f: No expected difference for the number of **distinct spatial themes collectively** identified by participants each group*

As shown in Figure 23 below, Group 2 identified 2 more spatial themes than Group 1. Although this represented a 14% increase over Group 1, the data set did not meet the minimum cutoff. The results for this hypothesis were inconclusive.

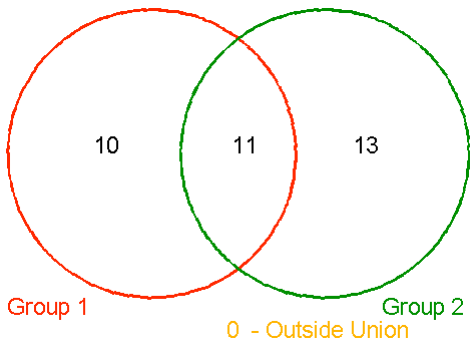

Figure 23: Distinct spatial themes per group

A list of all identified spatial themes per group is available in Appendix E.

5.4.7 *Hypothesis 3g: Group #2 participants will **collectively** identify more **distinct social themes** than Group #1*

As shown in Figure 24 below, Group 2 identified 35 more social themes than Group 1. Since this represented a 60% increase over Group 1 this hypothesis was supported.

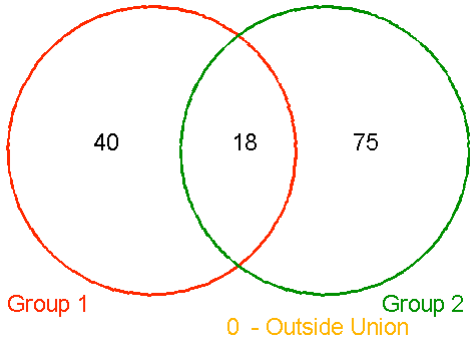

Figure 24: Distinct social themes per group

A list of all identified social themes per group is available in Appendix E.

5.4.8 *Hypothesis 3h: Group #2 participants will **collectively** identify more **distinct technological themes** than Group #1 participants*

As shown in Figure 25 below, Group 2 identified 2 more technological themes than Group 1. Although this represented a 20% increase over Group 1, the data set did not meet the minimum cutoff. The results for this hypothesis were inconclusive.

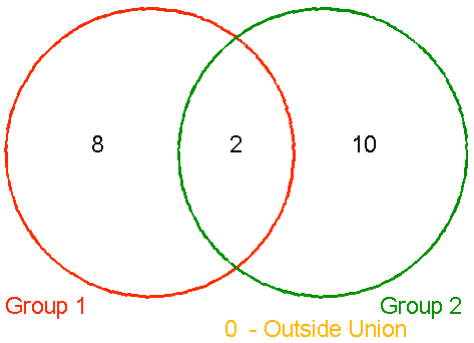

Figure 25: Distinct technological themes per group

A list of all identified technological themes per group is available in Appendix E.

5.4.9 *Hypothesis 3i: No expected difference for the number of **distinct hygienic themes collectively** identified by participants in each group*

As shown in Figure 26 below, Group 2 identified 1 more technological theme than Group 1. Although this represented a 25% increase over Group 1, the data set does not meet the minimum cutoff. The results for this hypothesis were inconclusive.

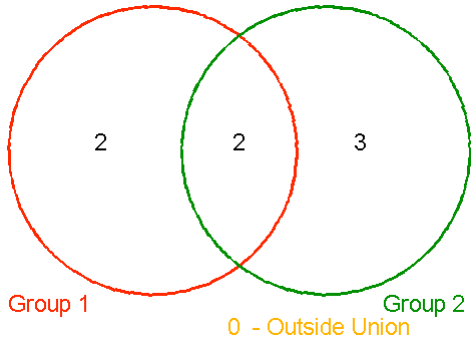

Figure 26: Distinct hygienic themes per group

A list of all identified hygienic per group is available in Appendix E.

*5.4.10 Hypothesis 3j: No expected difference for the number of **distinct physical themes collectively** identified by participants in each group*

As shown in Figure 27 below, Group 1 identified 1 more physical theme than Group 1. Although this represented a 50% increase over Group 1, the data set does not meet the minimum cutoff. The results for this hypothesis were inconclusive.

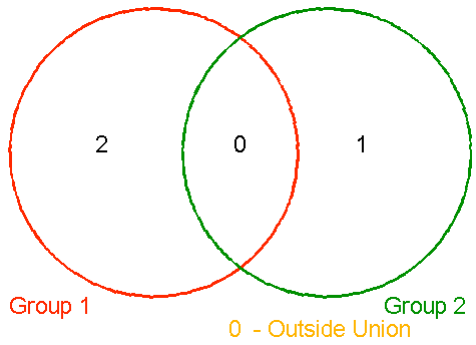

Figure 27: Distinct physical themes per group

A list of all identified physical themes per group is available in Appendix E.

5.4.11 *Hypothesis 3k: Group #2 participants will identify more **activity themes** than Group #1 participants*

As shown in Figure 28 below, Group 2 identified 9 more activity themes than Group 1. Since this represented an 8% increase over Group 1 this hypothesis was not supported.

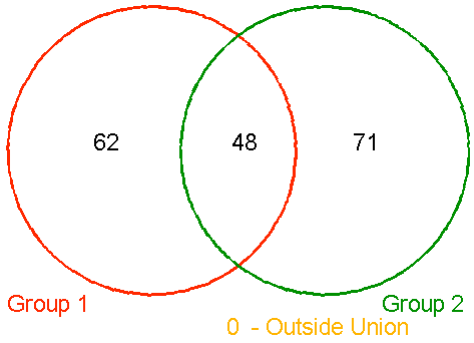

Figure 28: Distinct activity themes per group

A list of all identified activity themes per group is available in Appendix E.

5.4.12 *Summary of RQ3 data*

Table 20 below summarizes the data used for RQ3.

Table 20: Summary of distinct themes identified per category per group

Category	Group #1 Themes	Group #2 Themes	Overlap
Usability	422	440	118
Efficiency	90	92	40
Effectiveness	94	92	45
Satisfaction	194	176	57
Context-of-use	189	239	72
Spatial	21	24	11
Social	58	93	18
Technological	10	12	2
Hygienic	4	5	2
Physical	2	1	0
Activity	110	119	48

5.5 RQ4: What are the differences between the time used by each elicitation method during the experiment?

The purpose of the fourth research question was to determine if some of the elicitation methods used in the study involved more participant time than other elicitation methods. For the purposes of this study, "better" time was considered to be the least time required due to the warnings in the literature regarding the difficulty gaining access to medical device practitioners (Martin et al., 2006). Data was initially tested for normality using the Shapiro-Wilk test with an alpha level of 0.05. An ANOVA was used to compare participant's time for focus groups, interviews, and storytelling sessions with an alpha level of 0.05. Since the data was nonparametric the npar1way procedure in SAS was used, which uses the Kruskal-Wallis test. The SAS code and relevant output is available in Appendix D.

5.5.1 Hypothesis 4: No expected difference between the time used for each elicitation method.

Time spent during each of the elicitation methods was significantly different ($F_{(2,9)} = 14$; p=0.0017). Focus groups took the most amount of time (Mfocus_group=48.2 (SD=1.1) min), followed by interviews (Minterview=39.4 (SD=5.8) min) and storytelling sessions (Mstory=30 (SD=4.5) min).

Combined times per participant (e.g., Focus group + follow up session) between each group was also significantly different ($F_{(1,8)}$=9.1;p=0.02). Participants in Group 1 (MGroup_1=86.8 (SD=5.8) min) spent significantly more time in requirements capturing sessions than those in Group 2 (MGroup_2=76.9 (SD=4.6) min).

This hypothesis was rejected.

5.6 Summary of results

A summary of the above findings is compiled in Table 21 below.

Table 21: Summary of results

Research Question	Finding	Interpretation
RQ1	For all requirement categories: • No significant differences in the amount of information obtained per participant per group	In terms of the amount of information obtained per participant, the results suggest that using either Focus Groups & Interviews or Focus Groups & Storytelling Sessions results in similar **quantity** of information.
RQ2	For all requirement categories: • No significant difference in the breadth of requirements covered per participant per group • No significant difference in the breadth of requirements covered per participant per follow-up session • Both groups neglected to discuss hygienic and physical themes	In terms of the numbers of categories addressed per participant, the results suggest using either Focus Groups & Interviews or Focus Groups & Storytelling Sessions results in similar **breadth** of information. In terms of the numbers of categories addressed per participant, using either interviews or storytelling sessions results in the similar **breadth** of information.
RQ3	Potential support for: • Significant difference between the distinct context-of-use themes collectively identified by each group • Significant difference between the distinct social themes collectively identified by each group • Significant difference between the distinct satisfaction themes collectively identified by each group	In terms of eliciting context-of-use information, the results suggest that the combination of Focus Group & Storytelling Sessions demonstrates efficacy as a better elicitation choice than Focus Group & Interviews In terms of eliciting social information, the results suggest that the combination of Focus Group & Storytelling Sessions demonstrates efficacy as a better elicitation choice than Focus Group & Interviews In terms of eliciting satisfaction information, the results suggest that the combination of Focus Group & Interviews demonstrates efficacy as a better elicitation choice than Focus Group & Storytelling Sessions
RQ4	Focus_Group_Time > Interview_Time > Storytelling_Time Group1_Time > Group2_Time	In terms of time used during each elicitation method, the results suggest that: • Storytelling takes less time than interviews • Combination of Focus Group & Storytelling Sessions takes less time than Focus Group & Interviews

CHAPTER 6. DISCUSSION

6.1 RQ1: Requirement themes per participant

The purpose of the first research question was to determine if participants focused on different usability categories as a result of the differences in treatment. Although none of the hypotheses were supported, the results for RQ1 were not entirely negative. Since no significant difference was found between the two treatments, the results suggest that the use of Focus Group & Storytelling Sessions instead of Focus Groups & Interviews did not negatively affect the quantity of information obtained per participant per category. This finding does have positive implications in the support of the use of Focus Group & Storytelling Sessions over Focus Group & Interviews. For example, the amount of preparation for a storytelling session is less than for an interview since multiple questions need not be developed in advance. The results of this research question suggest that the same quantity of information is expected from either elicitation combination.

Although no significant differences were found, trends in the data distributions suggest potential tradeoffs between methods. Future researchers should be aware of these potential trends as they may be result in a finding of differences in quality in a study with a larger sample size. For example, graphs of the central tendencies indicated a Group #1 trend to discuss more usability, efficiency, effectiveness, and activity context themes. Graphs of the central tendencies indicated a Group #2 trend to discuss more context-of-use, spatial context, and social context themes. Distributions for technological, hygienic, and physical context were inconclusive due to a lack of data points.

However, this research question only addressed the quantity of information elicited and not the quality of the information. The difference in the quality of information (as defined by the breadth and depth of information) was explored in research questions 2 and 3 below. The original rationale for investigating the quantity of information elicited was the assumption that storytelling would prompt participants to talk more, which would result in the identification of more requirements themes within the group. However, as discussed in Section 6.3, while storytelling did not prompt participants to talk more, it did prompt participants to discuss a more diverse set of topics.

6.2 RQ2: Breadth of requirement themes

This purpose of the second research question was to investigate if participants discussed a broader range of themes as a result of the differences in treatments. The breadth of requirement themes, along with the depth of requirement themes (RQ3), constituted the perceived quality of the information elicited.

Although none of the hypotheses were supported, the results for RQ2 were not entirely negative. Since no significant difference was found between the two treatments, the results suggest that the use of Focus Group & Storytelling Sessions instead of Focus Group & Interviews did not negatively affect the breadth of information obtained per participant per category.

Participants in both groups neglected to discuss themes related to hygienic context and physical context in both interviews and storytelling sessions. This finding suggests that medical device designers should include specific questions relating to these context categories in their elicitation protocol to ensure that participants address these areas. This finding was not unexpected, as it seems logical that participants would neglect to discuss these topics without specific prompting.

6.3 RQ3: Depth of requirement themes

The purpose of the third research question was to investigate differences in the *compiled* results for each group. The depth of requirement themes, along with the breadth of requirement themes (RQ2), constituted the perceived quality of the information elicited.

Although statistical tests could not be conducted on this data as the data represents only 2 data points, investigation of the union and intersections between each group indicated some differences between the depth of information obtained per category between the two groups. For example, the overarching research question of the efficacy of storytelling as an elicitation method for context-of-use requirements gains support from the results of Hypothesis 3e. As shown in Figure 22 above, participants in Group # 2 discussed 50 more distinct context-of-use themes than participants in Group #1, which was a 27% increase over Group # 1. Due to the documented difficulties gaining understanding of the context within a complex domain such as

healthcare (Martin et al., 2007; Ward & Clarkson, 2007), this result suggests that storytelling has potential addressing this need.

Analysis of the categories that encompass context-of-use indicated that the main benefit of Focus Group & Storytelling over Focus Groups & Interviews was the increased understanding of the social context. As shown in Figure 24 above, Group #2 participants discussed 35 more distinct social themes than Group #1, which was a 60% increase over Group #1. As shown in the list of social themes for each group (Appendix E), Group #2 participants gave a more holistic view of all those involved during patient care, including the interactions between employees, the responsibilities of employees, and the hospital's organizational culture. For example, participants in Group #2 discussed "calling" other employees as part of their daily operations within patient care. Group #1 participants did not address this type of interaction.

A potential benefit of storytelling, which requires further analysis outside of the scope of this study, is the efficacy of storytelling when used to elicit more sequential information from participants. For example, while relating a story about a blood transfusion, P9 revealed how patient information is transferred between employees and departments:

> *"I work on surgery floor, so typically after surgery blood levels are checked and make sure they're maintained at a safe level. Usually checked every morning around 5:00, so the lab comes in, draws labs, specifically H and H for people who've had joint surgeries, and the lab will call us for a critical value….one particular lady one day who had a critical H and H of seven, which is very low. I got the order from the doctor after I called him, after the lab called me. And I got the order to transfuse three units of packed red blood cells".*

As shown in the transcripts, participants in Group #1 did not match this level of detailed description. Perhaps one of the benefits of storytelling is accessing this rich description.

An unexpected finding was the discrepancy in distinct satisfaction themes between groups. Group #1 discussed 18 more distinct satisfaction themes than Group #2, which was a 10% increase. A possible explanation for this discrepancy, which requires further research, may be a tendency for participants to focus on their desires for the future during interviews. Perhaps one of the benefits of storytelling is that the focus is shifted away from "what could be" and is grounded in "what is" so that designers can identify the best solution for the current real-life situation.

Another unexpected finding was a lack of a significant difference for the distinct usability themes between groups. It was originally hypothesized that the combination of Focus Group & Storytelling Sessions would result in more distinct usability themes than the combination of Focus Group & Interviews. One possible implication, which requires further analysis outside the scope of this study, is the possibility that the concentration on context-of-use requirements by participants negatively impacts the collection of requirements from other categories, such as satisfaction.

6.4 RQ4: Time used by each elicitation method

The purpose of the fourth research question was to determine if some of the elicitation methods used in the study involved more participant time than other elicitation methods. It was originally hypothesized that each elicitation method would involve the same amount of participant time since each elicitation meeting was scheduled for 60 minutes. However, on average participants in Group #1 spent 12 more minutes in interviews than participants in Group #2 spent in storytelling sessions. This means that Group #1 participants spent 30% more time in their follow-up session than Group #2 participants.

This finding has several implications. First, since no significant difference was found between the quantity and breadth of themes identified between Group #1 and Group #2, the logical conclusion is that Group #2 was able to achieve similar results in quantity and breadth to Group #1 in less time. This finding is significant considering the difficulty obtaining access to healthcare workers who work 12-hour shifts multiple days in a row. For example, one of the difficulties in participant recruitment for this study was convincing nurses to volunteer for a 2-hour commitment. Any method that reduces the time required by healthcare practitioners also has the potential to assist medical designers in recruiting stakeholders for the requirements gathering process.

Another implication of this finding is that the effects of storytelling were not revealed fully in this study since this study compared two groups who spent significantly different amounts of time involved in the requirements gathering process. One possible explanation for this discrepancy was the "newness" of the storytelling technique and the lack of prompts during storytelling. For example, the interview script guide allowed for follow-up questions and prompts to encourage participant discussion. The only prompts within the storytelling protocol

included reminders to include "who, what, where, when, why, and how" information and the prompt "Any other stories". Perhaps if participants were prompted to provide more information during storytelling sessions, the sessions would have lasted as long as the interviews.

CHAPTER 7. CONCLUSION

7.1 Does storytelling warrant further investigation?

Based on the preliminary findings of this study, further investigation into the use of storytelling as an elicitation method for medical device requirements is warranted. An implication of this study was that the combination of Focus Group and Storytelling Sessions results in similar quantity and breadth of information as Focus Group and Interviews, but the quality of the information obtained (as judged by depth) was higher.

7.2 How does this work relate to worker stress?

Participant statements during all elicitation sessions provided support for Williams et.al's (2007) conceptual model of job stress where the technology used in the workplace is viewed as an organizational level stressor. For example, all participants expressed frustration in relation to "pump failure", which was described by P7 as "Now that's another stress. When it says failure and it makes this high-pitch sound. It's – we cannot turn it off. We cannot turn it off. We try to cover it with towels…." Pump failure was frequently referred to as "crazy" and participants expressed disbelief at the actions required of them during these events, such as hiding the pump in a staircase or covering the device with towels.

Another common theme among participants was the impact poor battery life had on their ability to transfer patients between wards within the hospital. For example, P8 described frustration when a battery died during patient transport: "….we've had critical patients on multiple drips, on a triple-channel, and we roll out of the E.R. and then you're on that elevator, and that battery dies, and it alarms obnoxiously. And, you know, you've had a Nitro drip – things that you don't want to stop, and so it's very frustrating."

The overall motivation for this work was the belief that a greater understanding of the context-of-use will positively impact the ability of medical device designers to develop usable products. According to the conceptual model of job stress, the improved usability of workplace

technology results in reduced organizational level stressors for the healthcare practitioner. Since the results of this study provided support for storytelling's efficacy in understanding the context-of-use, the study also provided support for storytelling's efficacy in the reduction of healthcare worker stress.

7.3 Limitations and assumptions of study

A limitation of this study was the small sample size (n=10). However, the purpose of this study was to explore the efficacy of storytelling as an elicitation method for medical device requirements and not to prove that the use of focus groups combined with storytelling sessions was a better elicitation method than focus groups combined with interviews.

Another limitation in this study was the inclusion of the primary researcher as one of the data coders. Unfortunately, this could not be avoided due to resource constraints. Since the primary researcher knew the hypotheses of the study, it was possible that the primary researcher found more context-of-use themes because she knew what to look for. This might explain the initial low percent agreement of 9% between the two coders. However, this research did include steps to reduce investigator bias, such as the inclusion of a second data coder and data coding judge who were unaware of the research hypotheses. The use of the data coding judge during the reconciliation meeting was another method employed during this study to reduce investigator bias.

Another limitation of this study was the unit of analysis. As mentioned previously, the focus of this study was "requirement themes" and not requirements. Although the results of this work indicated efficacy in the use of Focus Groups and Storytelling Sessions in identifying requirement themes, future work is needed to investigate if this potential extends when requirement themes are translated into requirements.

Another limitation of this study was the restriction of the definition of medical device usability to the IEC 62366 definition where usability is comprised of effectiveness, efficiency, satisfaction and context-of-use. In this definition context-of-use is comprised of spatial context, social context, technological context, hygienic context, physical context, and activity context. The initial low inter-coder percent agreement (9%) and the resulting 17 hours of reconciliation meetings may be a result of a mismatch between the information obtained from participants and the pre-determined categories in which the information was to be categorized.

Another limitation of this study was the lack of addressing safety as its own category of requirements. Future work might explore the development of a framework specific to medical device usability that incorporates safety. Usability of medical devices is unique in the respect that usability is judged at a minimum by two user classes (the healthcare practitioner and the patient) with potentially conflicting safety requirements.

Another limitation of this study was a lack of control for time during each elicitation method, which may have resulted in the time discrepancies found between focus groups, interviews, and storytelling sessions. Although interviews took more time than storytelling sessions, this discrepancy may have been caused by a lack of prompts within the storytelling protocol. During the course of the study the primary researcher found it awkward to interrupt participants during a story to request more information, as the interruption seemed to divert the participant's response away from the story.

7.4 Study contributions

Several challenges relating to study design were encountered during the course of the study. The first challenge was the development of a plan for a mixed-methods data analysis since the literature provided little guidance. The second challenge was the development of a protocol for a storytelling session. Although a review of the literature indicated the use of storytelling within healthcare (Coombes et al., 2008; Gunther & Thomas, 2006), the literature lacked specific information, such as elicitation scripts and protocols. The third challenge was synthesizing the meaning of usability within the healthcare domain from diverse definitions within the standards into a requirements ontology that could be used during data coding. Contributions of this study include a plan for mixed-method data analysis, a protocol for conducting a storytelling session, and a framework for defining requirements within the healthcare domain.

7.4.1 Systematic analysis method

An additional contribution of this study is the systematic plan for mixed-method data analysis. A disturbing trend within published qualitative and mixed-methods studies is the author's omission of the design reasoning and methodology. The design reasoning and methodology must be transparent to the reader for a study to be considered systematic and

rigorous. Table 22 below summarizes how rigor was addressed throughout the study. Rigor was addressed during all phases of this study. For example, the storytelling and interview scripts were created following recommendations in the literature (Shefelbine et al., 2002). During the data coding phase bias was reduced through the use of two independent data coders. Rigor was addressed during the hypothesis testing phase through the use of a triangulation of techniques, such as statistical tests, Venn diagrams, and analysis of data distributions.

Table 22: Summary of decisions to ensure rigor throughout the study

Study phase	Decisions to ensure rigor
Materials creation	Creation of requirements ontology based on usability definitions available in medical device standards Creation of storytelling and interview scripts based on recommendations for who, what, why, where, when, how questions during medical device requirements gathering (Shefelbine et al., 2002)
Data coding	Selection of "requirements themes" as the unit of analysis allowed for the use of thematic analysis as the qualitative data analysis technique Use of requirements ontology for theme categorization Use of two independent coders Use of judge during reconciliation meeting Reduction of transcripts into themes allowed for statistical analysis of results
Hypothesis testing	Focus on quantity and quality of requirement themes provided a comprehensive view of results Use of parametric two-sample t-test and nonparametric equivalent to test for differences between groups. Use of Venn diagrams to compare and analyze the requirement sets Analysis of central tendency distributions identified potential data trends

7.4.2 Method for conducting a storytelling session

Another contribution of this study is the method for conducting a storytelling session, which is detailed in Section 4.3.3. Although storytelling has been used as data gathering technique within medical anthropology (Coombes et al., 2008; Gunther & Thomas, 2006), researchers utilizing this technique typically do not publish details of the method used.

7.4.3 Framework for defining requirements in the healthcare domain

Another contribution of this study is the framework for defining requirements within the healthcare domain, which is shown in Figure 5. This framework was developed from definitions of usability in design standards IEC 62366 (2007) and ANSE/AAMI HE:74 (2001), which are specific to medical devices. The creation of the framework prior to data analysis allowed for a deductive approach where identified themes were categorized into pre-determined categories. However, an inductive approach, such as grounded theory, could be used to reverse engineer a requirements framework based on the participants' statements. The use of an inductive approach may result in a more accurate ontology of medical device requirements. For example, the complex connection between usability and safety may be further understood as a result of this type of analysis. This is a promising area for future work since the definition of usability is inconsistent among adopted design standards.

7.5 Observations and Recommendations

The following section details the primary researcher's observations during the course of the study as well as recommendations for future researchers starting work in the healthcare domain.

7.5.1 Storytelling

The following section details anecdotal observations during the use of storytelling as an elicitation method for medical device requirements. For each observation, corresponding recommendations for future healthcare researchers are offered.

7.5.1.1 Experience Adversely Affects Elicitation

The primary researcher purposefully included participants with varying years-of-experience levels in both of the treatment groups following recommendations from the literature (Garmer et al., 2002a). Although years-of-experience was to have an effect of the types of information elicited, the difficulty more-experienced nurses expressed recalling specific events after prompts, such as "Tell me a story about frustration and infusion pumps" was surprising.

One participant summarized her difficulty at the end of the session: "I feel like I'm using the same. It's hard to be really specific. Especially when you've been a nurse for awhile, it's like, Oh God, I could think of a million. I'll go home and think of a million examples." In contrast, less-experienced nurses exhibited less hesitation recalling stories and provided more detailed stories than more-experienced nurses. Although further investigation is needed, the preliminary findings suggest that storytelling may be better suited as an elicitation method when working with less-experienced nurses. One potential cause of this effect may be that day-to-day work experiences are more salient to workers with less experience.

7.5.1.2 Storytelling Can Improve Rapport

The primary researcher also observed that participants in the storytelling group tended to linger after the session to chat whereas participants in the interview group tended to leave soon after reimbursement. Based on these initial observations, a potential strength of storytelling is the ability to maintain a more natural conversational tone throughout the data gathering session in contrast to the more rapid question/answer pace of interviews. One potential benefit of a more natural discourse between designer and user may be improved rapport. Further investigation is needed to determine if storytelling facilitates more rapport between designer and user than traditional interview techniques.

7.5.1.3 Participants Do Not Want Some Stories Audio-recorded

Although participant reluctance to discuss certain issues, such as errors (Geller & Johnson, 2007), while audio-taped was anticipated, the primary researcher observed a greater effect during storytelling sessions than with either focus groups or interviews. Several storytelling participants offered additional stories and anecdotes after the primary researcher turned off the audio recorder while participants in the interview group tended to use the opportunity to inquire about the purpose of the research. One storytelling participant revealed that she purposefully waited until the recording was turned off to relate a personal story. Researchers should come prepared with a field notebook to make note of such occurrences.

The primary researcher's observations also suggest that there may also be an interaction effect between rapport and audio recording effects. Unlike traditional techniques, such as focus groups and interviews where the end of the session is made clear by the cessation of questions,

the boundaries of the storytelling session may not be as clear. Perhaps storytelling participants continued to relate stories because they did not realize the session was over.

7.5.1.4 Participants Speak More Freely with Each Other

The primary researcher observed that participants engaged in more natural conversation with each other during focus group sessions than with us individually during storytelling sessions. For example, prior to the start of each focus group participants chatted with each other about their use of infusion pumps without any prompting.

Future studies may investigate the use of paired participants in storytelling. Participants may provide more detailed accounts when paired because they are speaking to another person intimately familiar with the domain. The use of pairs may also assist with participant recruitment as participants may prefer to volunteer with a friend or colleague (Macpherson, 2008).

7.5.2 Recruitment

Although the initial literature review provided insight into potential recruitment barriers, in retrospect the primary researcher was still naive during the development of the recruitment strategy. The greatest difficulty encountered in the study was the recruitment of participants in a timely manner.

The following section details observations during the recruitment process. For each observation, recommendations for future healthcare researchers are offered.

7.5.2.1 Locate Champions for Research within the Organization

The initial barrier faced was locating a healthcare organization that would allow researcher access to the facility to perform the study. Due to unfamiliarity with hospital administration, the primary researcher targeted nursing school programs since she was more comfortable and familiar with university policies and procedures. The primary researcher initially contacted a nursing program director at a local university and she referred the primary researcher to the chair of the hospital's Nursing Research Council since the study involved nurses. This council fosters staff education through collaborative research efforts. Council

members quickly became champions for this research within the organization. Members disseminated study advertisements throughout the hospital wards and encouraged ward managers to promote staff participation. Members also introduced the primary researcher to hospital administrators who had the power to assist with the study, expanding the network of champions for this work.

Working with the council simplified this study in several ways. First, the hospital's IRB board requires approval from the council prior to IRB approval for any study involving nurses. Since the primary researcher collaborated with the council prior to submitting IRB paperwork, additional delays waiting for approval were avoided. Second, the primary researcher was given the opportunity to present and advertise the study at the council's monthly meetings, improving access to potential participants.

Since it is difficult to identify potential research champions in an unfamiliar organization, consult the hospital's published phone directly and contact the department most relevant to your study. If research organizations exist, the department should be able to refer you to them. Also, ask the department for referrals to hospital administrators who may be interested in your study's topic.

7.5.2.2 Offer Multiple Forms of Reimbursement

Members of the Nursing Research Council also suggested means to improve recruitment. Although the original reimbursement plan of $25 per session per participant was considered adequate, members suggested including clinical ladder credit as an additional enticement. The hospital's clinical ladder program is the advancement system for registered nurses. Nurses "move up the ladder" by accumulating points through continuing formal education, experience, continuing education, involvement in professional activities, and professional role modeling (Committee, 2002). The primary researcher was able to provide participants with clinical ladder credit by providing a letter of appreciation to each participant at the study's conclusion. Clinical ladder credit proved to be a greater motivator for participation than monetary reimbursement. However, since less-experienced nurses are more likely to need clinical ladder credit, monetary compensation should be offered as well to ensure participation by more-experienced nurses.

7.5.2.3 Utilize Radial Sampling Strategy

The primary researcher also observed that participants tended to join the study with a friend or co-worker from the same nursing ward. Preliminary analysis of transcripts from the focus groups, interviews, and storytelling sessions reveals a highly social work environment. For example, one participant when describing her work environment stated "I know when I think of my co-workers, I think family, friends, support, caring." In addition, the primary researcher noted during the focus groups that introductions were not necessary, as all participants already knew each other even when they did not work in the same ward. Future studies should utilize the social nature of the nursing environment by using a radial sampling strategy. For example, after recruitment of a participant the participant can then assist in the recruitment of friends and colleagues. A radial sampling strategy utilizing a participant's current social network may mitigate the initial issue of restricted access to potential participants. However, one potential drawback of a radial sampling strategy is a lack of diversity among participants. For example, nurses may be of similar age and may work in the same ward as their friends.

7.5.2.4 Schedule for Convenience

The Nursing Research Council also provided recommendations for scheduling the sessions in a manner convenient for participants. The original research plan provided for a room located on the university's campus if a suitable hospital room was not available. However, several council members thought that nurses would not want to drive an additional 10 minutes after working a 12-hour shift to participate in our study. The council suggested the use of the Nurses Reading Room, which is a newly designated quiet learning space on the hospital's campus. The council also benefited by the use of this room for our study since they were able to promote the room among nursing staff.

The scheduling of focus groups presented a unique challenge because the date and time needed to be convenient for 5-8 participants. The council suggested scheduling sessions at the end of both day and night shifts to accommodate both shifts. Sessions were scheduled to begin 30 minutes after the end of each shift to provide participants time to relax.

The primary researcher also observed that willingness to be flexible was appreciated by participants. When scheduling individual follow-up sessions the motto was "If the best time for

you is 2AM on a Tuesday, I can make that work." Several participants expressed appreciation for this willingness to work around their schedule..

7.6 Future research

Future work should investigate the effect of practitioner's years-of-experience on story detail since more-experienced nurses in this study expressed difficulty recalling specific instances of an event.

Future work should also investigate paired storytelling to determine if the elicitation method is more effective when nurses tell stories to each other, rather than to the researcher.

Since the focus of the current work was restricted to "requirements themes", future work should explore the transformation process of stakeholders' expressions of user needs into a requirements specification document.

Future work should further explore the quality of requirements elicited during storytelling sessions and interviews. For example, the criterion method (Hartson, Andre, & Williges, 2003) could be used to compare the ideal requirements set for a medical device obtained from experts with the actual requirements set obtained via the different elicitation methods.

7.7 Overall Conclusion

The results of this study provided support for the efficacy of storytelling as an elicitation method for medical device requirements. Although no significant differences were found for the quantity of information elicited by either method, analysis of the data distribution for Group #2 indicated a potential trend for individual participants to discuss more context-of-use, spatial context, and social context themes. Although this analysis provided more support for the efficacy of storytelling as a method for eliciting more context-of-use information, the analysis indicated a potential trade-off between methods, as there was a Group #1 trend to obtain more usability, efficiency, effectiveness, satisfaction, and activity context themes.

However, the results of the study provided more support for the efficacy of storytelling in the elicitation of a higher quality requirement set. Although no significant differences were found for the breadth of requirements, differences were found in the depth of requirements in the collective set for both groups. A synthesis of the findings for both quantity and quality indicated

that while storytelling elicited fewer themes per individual, storytelling also elicited a more diverse set of themes across individuals.

While future work is needed to replicate the findings of this study, the findings should be generalizable to requirements elicitation for medical devices other than an infusion pump. The efficacy of storytelling to elicit social and spatial themes should not be dependent upon the medical device investigated since these topics are independent of the medical device. For example, the social structure within a hospital is not dependent upon the medical device used.

There are ample opportunities for future research of elicitation methods for medical devices considering the need for usability within the healthcare domain (Martin et al., 2007) and the requirement for a triangulation of methods during user research (Garmer et al., 2002b). As has been demonstrated in other domains, such as aviation (Paterno et al., 1999), improvements in the understanding of usability requirements will positively impact the design of the medical device, thereby improving the health and safety of medical practitioners and patients.

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APPENDIX A: Data Collection Documents

A.1 VT IRB Approval

VirginiaTech

Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu

FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: May 16, 2008

MEMORANDUM

TO: Woodrow Winchester
James D. Arthur
Tonya L. Smith-Jackson

Approval date: 5/16/2008
Continuing Review Due Date:5/1/2009
Expiration Date: 5/15/2009

FROM: David M. Moore

SUBJECT: **IRB Expedited Approval:** "Elicitation Techniques for Medical Device Requirements" , IRB # 08-313

This memo is regarding the above-mentioned protocol. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. As Chair of the Virginia Tech Institutional Review Board, I have granted approval to the study for a period of 12 months, effective May 16, 2008.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

Important:
If you are conducting **federally funded non-exempt research**, please send the applicable OSP/grant proposal to the IRB office, once available. OSP funds may not be released until the IRB has compared and found consistent the proposal and related IRB applicaton.

cc: File
Department Reviewer:Maury A. Nussbaum
T. Coalson 0118

A.2 MRH IRB Approval

Montgomery Regional Hospital
HCA Virginia

3700 South Main Street
Blacksburg, Virginia 24060
P.O. Box 90004
Blacksburg, Virginia 24062-9004
Telephone 540.951.1111 / Fax 540.953.5295
www.mrhospital.com

June 24, 2008

Ms. Kimberley Ann Gausepohl
Industrial Systems Engineering
Virginia Tech
536F Whittemore Hall
Blacksburg, VA 24061

RE: Investigation of Storytelling as a Novel Elicitation Method for Medical Device Requirements"

Dear Ms. Gausepohl,

The Institutional Review Board of Montgomery Regional Hospital reviewed your application for the above named study. After the Nursing Research Council approved your approach to enrolling nurses for this study, the IRB approved the study as of June 16, 2008 through June 15, 2009.

Each year that Continuing Review is requested, please provide

1. **The Co-Investigator and Medical Director's Assurance Forms**
2. **A report of the number of subjects in the study,**
3. **The number of subjects in each section and**
4. **A total report of Adverse Events.**

Additionally, Adverse Events should be reported to the IRB immediately after they happen.

We look forward to our continued relationship and the findings of your studies once they are concluded.

Sincerely,

Chris Riegert, R.Ph.
Chair, Institutional Review Board

A.3 Recruiting Flyer

Infusion Pump Study

Call for participation in infusion pump requirements development

Are you:
- A healthcare practitioner who uses infusion pumps during your work?
- Interested in collaborating with colleagues?
- Interested in participating in the design process?

If so, please consider participating as a stakeholder in this research project.

Participation includes:
- a 2-hour focus group with colleagues
- a 1-hour individual follow-up session

If interested, please contact:
Kim Gausepohl
kgausepo@vt.edu
540-448-4769

Kim Gausepohl **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**	**Kim Gausepohl** **infusion@vt.edu** **540-449-4769**

A.4 Participant Background Questionnaire

Participant Background Questionnaire

Name: _____

Preferred Contact Method (circle one):

Email: _____

Phone: _____

Work Location: _____

Work Title: _____

Age:_____

Gender: _____

Nursing experience (years & months) _____

Infusion pump experience (years & months) _____

A.5 Virginia Tech Informed Consent Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants in Research Projects Involving Human Subjects

Title of Project: **Elicitation Techniques for Medical Device Requirements**

Investigator(s) Kim Gausepohl, Dr. Woodrow Winchester III, Dr. James Arthur, Dr. Tonya Smith-Jackson

I. Purpose of this Research/Project

Medical device design impacts both the medical practitioner as well as the patient receiving treatment via the device. The purpose of this study is to investigate the efficacy of different requirements elicitation methods for medical devices in an effort to improve communication between healthcare workers and medical device designers.

12-16 participants will participate in this research project. Participants will be adult healthcare workers of Carillion New River Valley Medical Center (CNRVMC) who interact with an infusion pump during their normal work life.

II. Procedures

Focus Group:
All participants will participate in a 2 hour focus group session with 5-7 other participants. The focus group session will be led by the primary researcher who will pose several high-level questions regarding participants' needs and expectations for an infusion pump. During the focus group all participants will be allowed an opportunity to speak and will be encouraged not to interrupt or judge others. The proceedings of the focus group will be audio-taped for later analysis. However, nothing will be released which could potentially identify participants with their responses. Participants are free to not answer questions and to leave the focus group at any time without penalty.

If possible, focus group sessions will be conducted in a private room on the CNRVMC campus. If accommodations are not available at CNRVMC, the focus group will be conducted in a private room located on the Virginia Tech (VT) campus.

Following the focus group, each participant will be asked to schedule a 1 hour individual session with the primary researcher. Participants will be randomly chosen to participate in either a) an interview or b) a storytelling session.

Interview:
If selected for an interview, each participant will meet individually with the researcher at a

later date following the focus group for approximately one hour. During the interview, participants will be asked 36 questions relating to their experiences, attitudes, and beliefs regarding infusion pump usage. The proceedings of the interview will be audio-taped for later analysis. However, nothing will be released which could potentially identify participants with their responses. Participants are free to not answer questions and to leave the interview at any time without penalty.

If possible, interviews will be conducted in a private room on the CNRVMC campus. If accommodations are not available at CNRVMC, the interview will be conducted in a private room located on the Virginia Tech (VT) campus.

Storytelling Session:

If chosen for a storytelling session, each participant will meet individually with the researcher at a later date for approximately one hour. During the interview, participants will be asked to tell 6 stories relating to infusion pump usage. Each story will be framed within a certain theme (e.g., frustration, job satisfaction, etc…) The proceedings of the storytelling sessions will be audio-taped for later analysis. However, nothing will be released which could potentially identify participants with their responses. Participants are free to refuse to tell a story and to leave the storytelling session at any time without penalty.

If possible, storytelling sessions will be conducted in a private room on the CNRVMC campus. If accommodations are not available at CNRVMC, the interview will be conducted in a private room located on the Virginia Tech (VT) campus.

III. Risks

No more than minimal risk. Participants may feel uncomfortable sharing their opinions and experiences with colleagues during the focus group. To minimize this distress the researcher will establish guidelines for the discussion. For example, participants will be instructed not to interrupt or judge others during the group discussion.

Participants may feel self conscious creating stories during the storytelling sessions. To minimize this distress the researcher will advise participants that they can refrain from telling a story for any theme which makes them uncomfortable.

Participants may feel uncomfortable during the interview if they are asked a question to which they do not have a response. To minimize this distress the researcher will advise participants that they can refuse to answer any question without penalty.

The researcher will also reinforce that there are no right or wrong answers and that all information they give is valuable.

IV. Benefits

Potential benefits include the opportunity to discuss requirements with colleagues and the opportunity for greater understanding of your own use of infusion pumps.

Please note that no promise or guarantee of benefits have been made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

All information gathered from participants is confidential. Information gathered from participants will be de-identified. Each participant will be assigned a participant number, such as P1, which will be used as identifiers in lieu of names. Information that associates participants and their assigned numbers will be stored in a locked drawer in Whittemore 536F.

Audio from the focus groups, interviews, and storytelling sessions will be digitally recorded. Within one hour of the session, the digital file will be transferred from the recording device to a fire-walled and password protected laptop. The digital file will then be deleted from the recording device. The audio files will be stored on the laptop in a locked office (Whittemore 536F) under the supervision of the primary researcher. The primary researcher will transcribe the audio recordings. All audio recordings will be deleted from the laptop within 90 days from the date of the last recording.

It is possible that the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

In some situations, it may be necessary for an investigator to break confidentiality. If a subject is believed to be a threat to herself/himself or others, the investigator will notify the appropriate authorities. For example, if a participant threatens another participant during the focus group, the police will be called.

VI. Compensation

There is no compensation for participation in this study.

VII. Freedom to Withdraw

Subjects are free to withdraw from a study at any time without penalty. Subjects are free not to answer any questions or respond to experimental situations that they choose without penalty.

VIII. Subject's Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

- Participation in one 2-hour focus group
- Participation in one 1-hour individual follow-up session (either storytelling or an interview)

IX. Subject's Permission

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ Date_____

Subject signature

Should I have any pertinent questions about this research or its conduct, and research subjects' rights, and whom to contact in the event of a research-related injury to the subject, I may contact:

Investigator(s) Telephone/e-mail
Kim Gausepohl
kgausepo@vt.edu
540-449-4769

Faculty Advisor Telephone/e-mail
Dr. Woodrow Winchester
wwwinche@vt.edu
540-231-5936

Departmental Reviewer/Department Head Telephone/e-mail
David M. Moore
Chair, Virginia Tech Institutional Board for the Protection of Human Subjects
Office of Research Compliance
2000 Kraft Drive, Suite 2000 (0497)Blacksburg, VA 24060
540-231-4991
moored@vt.edu

[NOTE: Subjects must be given a complete copy (or duplicate original) of the signed Informed Consent.]

A.6 Focus Group Script

Focus Group Guide

adapted from McAlearney et. al. (2004) with permission

First, let me thank you for agreeing to participate in this research project. My name is Kim Gausepohl and I am currently a master's student in Industrial Systems Engineering at Virginia Tech.

As you may know, I am studying the use of infusion pumps. We have scheduled the next 2 hours for this discussion.

Before we begin the discussion, let me make sure that you understand that:

a. Your participation is completely voluntary. If you do choose to stay and talk with us, you may decide to leave at any time during this focus group.

b. We consider this discussion to be confidential. Your participation is confidential in the sense that your name will not be used in any reports or articles.

- We would like you to read this Informed Consent Form from Virginia Tech.
- Do you have any questions about this form or about our study?
- If you agree to proceed, please sign and date the form.
- Also, please note that we would like to record this conversation, but we need your consent in order to do so. You must indicate your agreement, or non-agreement, with audio taping on the consent form.

If the participant does not sign the form or chooses to leave before starting the interview: thank you very much for your time and willingness to hear about our work.

If the participant signs the form: thank you for signing this form. Please remember that this is a voluntary interview, which you may leave at any time.

I will ask you several open-ended questions about your experience and opinions regarding infusion pumps. Essentially, I will be facilitating a discussion, but you all will do most of the talking. Some quick ground rules:

- Everyone will have a chance to speak
- Please do not interrupt each other.
- Do not criticize the views of others (Wiklund, 1995)

Are there any questions before we begin?

Focus Group Questions

What we are interested in is obtaining perspectives about needs, attitudes, behaviors, and expectations about using infusion pumps. So, as medical practitioners, we turn to you to get the answers to these questions…

Now, to get going, let's have everyone introduce themselves and describe how infusion pumps are part of their daily work life. (1. How are infusion pumps part of your daily work life?)

2. What problems do infusion pumps solve?

3. Can you describe the environment in which the infusion pump will be used?

4. How would you characterize good output that would be generated by the infusion pump?

5. What problems could the infusion pump create?

6. Have you encountered any specific barriers or challenges using infusion pumps?
   - Do you have any fears/concerns so far, based on your own experiences of those of others?

7. Is there anything you need from your organization with respect to support, resources, etc. to make using infusion pumps easier?

8. What do you expect with this technology?
   - Have there been any surprises?
   - What did you expect that didn't happen/you didn't get?
   - What did you get/what happened that you did not expect?

9. Is your use of infusion pumps changing how you feel about and/or use other technologies or medical devices?

   - Do you have more confidence with other technologies you use or might use in the future?

Wrap Up:

Make sure everyone has the opportunity to make a final statement, answering the question…

10. What would you like to be able to do with infusion pumps?

In Conclusion…

11. Is there anything else I should be asking you?
12. Is there anyone else I should be asking for answers?
13. Is there anything else you want to ask me?

A.7 Interview Script

Individual Interview Script

Guidelines for interviewer:

- *Read the questions exactly*
- *Repeat a question, if asked*
- *Allow participants to choose not to answer a question*
- *Use neutral language while probing for more information as not to direct participants towards any particular response*
- *"The aim is for bland, social neutrality" (Gray, 2004)*

Introduction:

Nice to see you again. Thank you again for participating in this research project.
Just as a reminder, here is the informed consent form which you signed prior to the focus group. Please look it over. Do you have any questions before we proceed?

Today's interview is a follow-up discussion to the infusion pump focus group. The goal of the interview is to determine requirements for the design and development of an infusion pump. I'll ask a series of questions about your use of infusion pumps. Please note that there are no right or wrong answers. Your opinions and experience will be very helpful.

Please speak freely during the discussion. The discussion will be audio-taped. However, nothing that could identify you personally will be released from this discussion. For confidentiality of others, please remember not to use identifiers such as names of co-workers or patients. You are free to choose not to respond to a question. In addition, you can choose to leave the interview at any time without penalty. The interview should last approximately 60 minutes. Let us begin with some general questions about the users of infusion pumps.

INTERVIEW QUESTIONS

1.0 **EFFECTIVENESS (+)**

level of accuracy and completeness in which a user is able to satisfy the goals

WHO	Who is affected by the effectiveness of the infusion pump?
WHAT	What functions, features, or qualities impact the effectiveness of the infusion pump?
WHY	Why is using an infusion pump more effective than other types of medication delivery?
WHERE	In which locations or contexts are infusion pumps the most effective?
WHEN	When do you determine if your use of the infusion pump has been effective or not?
HOW	How should an infusion pump work so that your work is as effective as possible?

2.0 **EFFECIENCY (+)**

amount of resources used to achieve the goals

WHO	Who is affected by the efficiency of the infusion pump?
WHAT	What functions, features or qualities impact the efficiency of the infusion pump?
WHY	Why is using an infusion pump more efficient than other types of medication delivery?
WHERE	In which locations or contexts are infusion pumps more efficient?
WHEN	When do you determine if your use of the infusion pump has been efficient or not?
HOW	How should and infusion pump work so that your work is as efficient as possible?

3.0 SATISFACTION (+)

the user's perceived comfort level and acceptability of the product while working towards the goals

WHO	Who needs to be satisified by the design of the infusion pump?
WHAT	What functions, features or qualities impact the perceived satisfaction level of the infusion pump?
WHY	Why do you prefer to use an infusion pump instead of other types of medication delivery?
WHERE	Where do you prefer to use an infusion pump?
WHEN	When do you prefer to use an infusion pump?
HOW	How should an "ideal" infusion pump work?

4.0 ERROR (-) [opposite of efficiency]

mistakes: level of INaccuracy and INcompleteness in which a user is able to satisfy the goals

WHO	Who typically makes mistakes while using an infusion pump?
WHAT	What types of errors are possible while using an infusion pump?
WHY	In terms of error protection, why would you rate one infusion pump as being better than another infusion pump?
WHERE	In what locations or contexts do you think that the most infusion pump mistakes occur?
WHEN	When do you think that the most infusion pump mistakes occur?
HOW	How should and infusion pump work so that your likelihood to make a mistake is as low as possible?

5.0 **INEFFECIENCY (-) [opposite of effectiveness]**
TOO MANY resources used to achieve the goals

WHO	Who is impacted when infusion pump use is inefficient?
WHAT	What functions, features or qualities cause an infusion pump to be inefficient?
WHY	Why would you rate one infusion pump as less efficient than another infusion pump?
WHERE	In what locations or contexts is infusion pump usage inefficient?
WHEN	When does infusion pump inefficiency have the most impact?
HOW	How should and infusion pump work so that inefficiency is as low as possible?

6.0 STRESS (-) [opposite of satisfaction]

WHO	Who typically gets frustrated or stressed while using an infusion pump?
WHAT	What functions, features or qualities stress users of an infusion pump?
WHY	In terms of your perceived stress level, why would you rate one infusion pump as more frustrating to use than another infusion pump?
WHERE	In what locations or contexts do you find yourself most stressed when using an infusion pump?
WHEN	When do you think that the most infusion pump frustrations occur?
HOW	How should and infusion pump work so that your stress level is as low as possible?

Closing Questions:

I think that covers all of the questions that I have. Please excuse me while I double check that we have covered all areas. [If not, ask any remaining questions before proceeding]

Yes, I think we have covered every question.

Do you have any questions or final comments?
That concludes the interview. Thank you again for your participation in this research project.

A.8 Storytelling Script

Storytelling Sessions Script

Introduction:
Nice to see you again. Thank you again for participating in this research project.
Just as a reminder, here is the informed consent form which you signed prior to the focus group. Please look it over. Do you have any questions before we proceed?

Today's storytelling session is a follow-up to the infusion pump focus group. The goal of the storytelling session is to improve our understanding of requirements for the design and development of an infusion pump. I'll provide prompts prior to each story to help you get started. Please note that there is no right or wrong way to tell a story. Your stories will be very helpful in helping us understand infusion pump usage.

Please speak freely during the storytelling sessions. The session will be audio-taped. However, nothing that could identify you personally will be released from this session. For confidentiality of others, please remember not to use identifiers such as names when referring to co-workers or patients. You are free to choose not to respond to a storytelling prompt. In addition, you can choose to leave the session at any time without penalty.

I'll ask you to tell me 6 stories with different themes about the use of infusion pumps. The stories can be:

- Based on something that actually happened
- Based on something that could happen
- Based on something you heard happened to an acquaintance (eg, second hand)

After each prompt, feel free to think about the story as long as necessary before beginning. When you feel comfortable starting the story, say "Ready". Try to keep the story as conversational as possible. Pretend that you are relaying the story to one of your co-workers or friends.

For each story, please try to include the following in your story:

- Who
- What
- Why
- Where
- When
- How

[*Hand participant reminder sheet that contains the words "who, what, why, where, when, how"*]

The storytelling session should last approximately 60 minutes. Feel free to use the provided paper to take any notes on your story or to write down ideas.

Any questions?

Let us begin.

[To avoid bias, half of the participants will start off with a "negative" story while the other half starts with a "positive" story. All participants will alternate between negative & positive stories]

Storytelling Session:
Please tell me a story about:

1. inefficiency & infusion pumps [negative]
2. errors and infusion pumps [negative]
3. stress and infusion pumps [negative]
4. job satisfaction & infusion pumps [positive]
5. successful patient treatment & infusion pumps [positive]
6. efficiency & infusion pumps [positive]

At the end of each prompt, remind the participant to:

- *keep the story as conversational as possible*
- *include who, what, why, where, when, how in the story*

Wrap-up:
That concludes our storytelling session. Do you have any questions or final comments?

Thank you again for your participation in this research project.

Appendix B: Example Transcripts

B.1 Focus Group 1 Transcript

RESEARCHER: Okay. So, as part of this focus group, what I'm really interested in is obtaining your perspectives about your needs, your attitudes, your behaviors, regarding I.V. pumps. So, as medical practitioners, we turn to you to get those kinds of answers. So, to get going, if we could just go around in a circle, and if you could just talk about where you work and how I.V. pumps are part of your daily workplace. And, can we talk – start with you?

PARTICIPANT_5: I work in the Emergency Department. I've also worked in critical care, which probably uses more I.V. pumps than the E.D. does, and basically it's to manage medication infusions to patients, safely, and at an accurate dose.

RESEARCHER: Okay.

PARTICIPANT_2: I work in E.R., and I have also worked in critical care areas, and used pumps mostly to help regulate rates for elderly patients that'll get fluid overload, and medication rates to make sure they get the right dose, at the right time, and the right strength that the doctor ordered.

PARTICIPANT_1: I work in the Emergency Room as well, and it's pretty much the same thing that they say. You know, it's just to regulate what we're giving the patients.

RESEARCHER: Okay.

PARTICIPANT_3: I work in the Birthing Center, and sometimes in the E.R., but mainly the Birthing Center, and ours is basically the same thing. Ours is more so with our standard fluids is not so much to control the least amount, but to really overload them for labor and delivery. And, again, we have certain medications that we have to regulate closely, for labor or to stop labor.

RESEARCHER: Okay.

PARTICIPANT_4: I work on med-search pedes, and I use the I.V. pumps to regulate fluids and – medication administration, safely.

RESEARCHER: Okay. Now, what is regulate fluids? That's just not something I'm familiar with, as well.

PARTICIPANT_2: It's like, the doctor orders three red tickets an hour, and unless you sit there and calculate by hand – you know, you could put, you know - 250 an

hour, divided by 500-cl. At one hour they'll get 250-ml _____. That's what, you know, regulating fluids.

RESEARCHER: Okay. Great. The next question is an open-ended question. What problems that infusion pumps solve in your work?

PARTICIPANT_2: They prevent, like, if you don't regulate the rate by, by manually, you could give someone too much fluid quickly, and make them go into CHF. Or, just – probably the biggest one is that. And, that way – and then certain antibiotics you supposed to give over a certain amount of time, and they could get it too quickly, which may cause a problem. Like Levaquin is one drug that you have to give over an hour, or an hour and a half, depending on the strength, and you don't wanna get it too fast.

PARTICIPANT_4: And it also allows you to give fluid fast, if you want – need to give them a Bolus, and you do their _____. Get it quickly in, and it allows you to pump it in as fast as it can go.

RESEARCHER: Okay.

PARTICIPANT_5: It also allows us to make sure that we're giving the proper dosage, that we're not overdosing, or under-dosing someone on a maintenance medication that you'd be giving over hours. Because there's so many things that can affect how fast an I.V. runs, that could change from time to time, even though you've adjusted it manually, there are things that can make it just run away from you or not drip, so the pump eliminates that error – that would occur.

RESEARCHER: As far as, like under-dosing, and overdosing goes, is one more serious than the other?

PARTICIPANT_5: I would think overdosing is probably – well, again, it would probably depend on the medication. Some medications, if you under-dose, you're not gonna get your therapeutic effect. Some medications, if you overdoes them, you're gonna get bad effects from. So, one's probably as bad as the other, depending on the medication.

PARTICIPANT_1: And depending upon the patient.

PARTICIPANT_5: Yeah, true.

RESEARCHER: Are there any other problems that you can think of, where an I.V. pump would solve that problem?

PARTICIPANT_3: I know for us, if we have, like a triple-chamber pump, which means that you can have several medications running at the same time, without it you'd have to – it helps you regulate different medications at the same

time, rather than using two different ports or two different I.V. lines, and trying to regulate it. You've got one I.V. line that can regulate three different medications at the same time, and actually even four, if you have – if you hang something, what we call by piggy-back, which is typically the antibiotic, that you could run it on your standard line or your maintenance line. So, it just kinda helps control all of those, so that you're getting the proper dose of each one without complicating things.

RESEARCHER: Okay.

PARTICIPANT_5: And it also stops the people from – patients or families, or visitors from adjusting things that don't need to be adjusted. You know, playing with the clamp, or – *[imitating patient] Oh, I don't think it's running fast enough, so I'm gonna turn it up for ya. Thanks! [Laughter]* – kinda thing, so it's a safety mechanism there also.

RESEARCHER: Okay. Is there anything else that you can think of?

PARTICIPANT_3: Oh, I can think of – it really catches, like if you just have a free-hanging I.V., versus a pump. The pump will catch if you have air in your tubing, so your patient doesn't get air. And, you can either adjust it out, or if you can't adjust it out you could fix it without giving somebody this much in your tube of air. So, that catches it for you. Whereas if you just have it hanging, you're not gonna know that.

RESEARCHER: Okay. So, on to the next question. Can you describe the environments in which an I.V. pump will be used? And this can be from your own work and experience, or where you've seen them used.

PARTICIPANT_5: Probably anyplace in the hospital. I mean, the only place I can think that you wouldn't probably find them would be the laboratory, or – probably that'd be it. You know, for a patient care area. Outpatient would have them, surgery would have them, the floors, any of the specialty units, X-ray – they can come down with patients, so probably the Lab, I think, would probably be the only place patient-care wise you wouldn't find them.

RESEARCHER: How is it home health-care – some patients that are regulated, mostly, could potentially – but I'm not really familiar with home health-care.

PARTICIPANT_1: Yeah, that's true.

PARTICIPANT_5: Well, there are home-health pumps that they use, and there's also delivery systems for home-health that don't require a machine. They're like a ball, pressurized that gives the medication.

RESEARCHER: And then, how would you describe the hospital environment. What are some adjectives you would use to describe the hospital? And, again, your names will not be used. *[Laughter]*

PARTICIPANT_5: Stressful, busy, chaotic at times.

PARTICIPANT_1: Like, what are you asking? Can you clarify it more, what you're looking for?

RESEARCHER: If you were going to explain, I guess to your friend, where you worked and what your work environment was like, how would you describe your work environment?

PARTICIPANT_2: Small patient-room with a stretcher. *[Laughter]*

PARTICIPANT_5: Usually, a patient. *[Laughter]*

PARTICIPANT_2: There's a patient. You may have a monitor, and an I.V. pole with a pump on it. Our four main rooms have a crash-cart in it, so you have to walk around those. And there's chairs, there's stools, there's trash-cans. *[Laughter]*

PARTICIPANT_5: Is that what you're talking about, or are you –

RESEARCHER: I think more toward [PARTICIPANT 5]'s description of the environment –

PARTICIPANT_4: She pretty much described the whole –

PARTICIPANT_5: Yeah, chaotic.

PARTICIPANT_3: I think it can be therapeutic, or not, you know. Therapeutic, comforting – you know, I think some people come to the hospital for the idea to be – have the attention. You know, to have people fuss over you, and to them that's comforting.

PARTICIPANT_5: I know when I think of my co-workers, I think family, friends, support, caring.

PARTICIPANT_2: In the E.R. we describe – when we're burning down, like we're on fire *[Laughter]*. So they called me one day, and it's – they said, "Can you come in to work early, 'cause we're burning down." So, I told my mother-in-law, "Yes, I'll come in. But, the E.R.'s on fire. Burning down." She went, "It's on fire?!" *[Laughter]* She had no idea what it meant, that – what burning down meant. And, in the E.R. that's like, you know, when you've got ten people in the hall, the rooms are all full,

squads are coming in, you got 12 people to triage, and you've got no place to put anybody, but everybody needs a room. So, kinda chaotic, and it can seem out of control sometimes. Then, at some point during the day it gets back to normal, at least for the E.R., anyway.

RESEARCHER: And then what is normal, in quotes?

PARTICIPANT_2: Three or four patients that, you know, under control. A nice, even pace, nobody's running around and like, their heads cut off. Patients are getting see quickly, and efficiently –

PARTICIPANT_5: I'd say, relaxed.

PARTICIPANT_2: Relaxed. There's not a lot of stress in the air, there's no squads coming in.

PARTICIPANT_5: You actually have time to –

PARTICIPANT_2: Sit down and eat.

PARTICIPANT_5: Talk to your patient a little bit, as opposed to just running in and doing what you need to do, and running out, because you gotta run to the next room. And then, you can actually have a little bit of rapport.

RESEARCHER: Any other comments on the work environment. Okay, back to infusion pumps. When you talk about like, the outfit that you receive from an infusion pump, how would you characterize good output?

PARTICIPANT_5: Information wise, or volume wise? I'm not sure what you're referring to when you say output.

RESEARCHER: It's really how you interpret output, so it could be the display, it could be whatever sort of feedback you get back.

PARTICIPANT_4: Are you saying, like if it's running good, then – you know, we'd be happy. You know, but sometimes like, the air, or maybe –

PARTICIPANT_2: Occlusion.

PARTICIPANT_5: Occlusion.
PARTICIPANT_4: Occlusion, and there's no occlusion.

PARTICIPANT_2: Like, on our screens, there's four or five little arrows that are usually clear, and not white. When they're white, that means it's either stopped-up, it's got air, it's not running, the patient's bending their arm – so good output means the arrows are empty, and it's flowing good. On the screen you see like, you're giving 250 an hour, and you got, you know 400 left, you know

– about an hour, so you'll have to hang a new bag. And then, when you hit the button for – you can tell how much total has gone in, than trying to calculate it yourself. And, I guess that's, for me, good output for a pump. That it's working.

RESEARCHER: And you talked about beeping? Do you get other feedback, or just the beep?

PARTICIPANT_4: That's the only feedback you get. We – it says on the screen, air, downward occlusion, upstream occlusion.

RESEARCHER: Is there anything that you would change about that kind of feedback that you get?

PARTICIPANT_1: It would be nice, I think to have different sounds or something that indicate diff – you know, if they just start beeping, you don't know why they're beeping. You know, they even beep when they go to KVO. If you've given a Bolus of fluid, and then it goes to just a slow drip, so that it's just keeping the vein open is what KVO is, and then it'll just beep that it's going to keep KVO.

PARTICIPANT_2: Yeah, I can see that – different beeps. You know, like, this beep – oh, I gotta go hang a new bag.

PARTICIPANT_1: Yeah, that –

PARTICIPANT_5: Right, that would be nice.

PARTICIPANT_2: Or the – and the antibiotic's now in, you go – gotta get a flush to flush the line, or if it's staff locked or something. That'd be kinda neat.

PARTICIPANT_4: Yeah.

RESEARCHER: Any other thoughts? Okay. So, the next question. What problems do you think that I.V. pumps could create, possibly?

PARTICIPANT_5: I think, sometimes, they present a false sense of security, because you're assuming they're working correctly, and they're not always. You know, you go in and you have programmed the patient to get 500 cc's and there's 100 going out of the bag, but it says it's giving the 500. So, I think sometimes there's a false sense of security with them, that it's doing what it's supposed to do.

RESEARCHER: Okay.

PARTICIPANT_5: And that's not always the case.

RESEARCHER: Now, how can you recti – how can you tell if the display is saying 500? Can you visually see if only 100 –

PARTICIPANT_5: Well, you can look at the bag, and – I mean, you can guestimate. You know, if half the bag's supposed to be gone, and there's this much gone, you know it's not working correctly. But, you may not notice that right away, because you're making an assumption that this piece of equipment is working properly.

RESEARCHER: Okay.

PARTICIPANT_5: You know, or you're making the assumption that someone hasn't turned it off on you, or you're making an assumption that the I.V.'s okay because the pump's still running. So, I think sometimes it's a false sense of security with them.

RESEARCHER: Okay.

PARTICIPANT_2: You know, our pumps have what's called Colleague-Guardian. It has a drug database in it. You can program the certain rate, based on the weight, or whatever. And, if it's not programmed up to date by the pharmacy, or whoever, you could have the wrong strength, program the wrong dose or route while thinking you're doing the right thing, but you're not. Because you didn't take the few seconds to double-check. Because, you think, oh that's just – it's Heparin, but it's maybe a different strength, or you know, you just gotta double check. And people might not do that, and put in the wrong route, or the wrong amount.

RESEARCHER: Okay. And you mentioned like, in "our" infusion pumps. Are there different types of infusion pumps used throughout the hospital?

PARTICIPANT_5: This hospital has, I think one type, I've never seen anything –

PARTICIPANT_2: Baxter.

PARTICIPANT_5: The Baxter. But, there are a bagillian *[sic]* out on the market. So, depending on what institution you're with –

PARTICIPANT_2: I think I've only ever experienced Baxter here, at the hospital.

PARTICIPANT_5: I've worked with several others, but I mean the issues are pretty much the same. It's the controls are just, generally different.

PARTICIPANT_3: You know what'd be nice, is when you piggy-back an I.V. and I can't tell you – I'm sure it's happened to everybody – is if you forget to undo your

clamp, there's no way of knowing unless you stand there and make sure that you're watching it drip. I mean, I can't tell you how many times people are like, "Oh, I went back in a room, and I forgot to unclamp." You know, and it's been an hour, and it was due an hour ago. But, it still runs as if you're giving that antibiotic. So, it would be nice, when you piggy-back that in, it's just something to flag it like, it's not – that's occluded. Instead of just turning to your main line.

PARTICIPANT_2: 'Cause it'll draw off the big-bag, the amount of the piggy-back, and never say you didn't unclamp it.

RESEARCHER: So, really, the only way to figure out if that's happened is just to visually see it, and –

PARTICIPANT_3: And, to go back in your room and the whole thing is still full. You think that your antibiotic has run-in, and it hasn't.

RESEARCHER: Okay. Can you think of any other kind of problems that can be associated with I.V. pumps?

PARTICIPANT_2: I guess what she sorta said was, you know, in the E.R. if it's busy, you don't really check, and then all of the sudden the battery dies, and you don't have time to go back in your room for a while, which can happen in the E.R. sometimes, and it's shut-off. 'Cause, with it plugged in, or the battery's died or whatever, you think it's working, but it's not. 'Cause you've been too busy to go back and check. So they might not get whatever medicines for you know, who knows – a little while. 'Cause it died.

PATICIPANT_5: I think [PARTICIPANT 2] touched on it, but didn't finish. But, like, if it's running, you're assuming it's running fine. And, that I.V. may be infiltrated. And, if you don't catch it, like when you first hook it up, that it's infiltrated, you could give somebody a nice Bolus right into the skin, and then you're not even giving it.

PARTICIPANT_2: Yeah, it doesn't – it'll keep pumping, up into the arm.

PARTICIPANT_5: It'll keep pumping. It's pumping, it'll keep pump – and it'll just pump it into the –

PARTICIPANT_2: Their arm.

PARTICIPANT_5: You know, into this interstitial space, rather than into the vein.

RESEARCHER: Oh, okay. So, that's what you mean by infiltrated? That's what that means?

PARTICIPANT_2: And it won't alarm that, hey this isn't working right. It'll just keep pumping.

RESEARCHER: Oh.

PARTICIPANT_5: I've seen people, and their arm just gets huge, because they haven't noticed that it infiltrated.

RESEARCHER: Oh.

PARTICIPANT_2: Another thing I just thought of, we have – it's called alligator-clips, and if you clip it onto your – into your little hep-lock, and it becomes disconnected, it'll still keep pumping because it's flowing. It could be on the bed, or the floor – the patient won't be getting the medicine because it has somehow become disconnected, and it won't – the machine doesn't know it.

RESEARCHER: Any other thoughts about problems? Okay. So, the next question is: have you encountered specific barriers or challenges using infusion pumps?

PARTICIPANT_2: On the pumps we have here, there's a little catch on the side that allows you – it's like a quick-release, if it comes off, you can twirl it – it'll get your line out, there on the pole, and you can hit it by accident, and you have to like, reset it a couple times. And sometimes it doesn't reset, and you gotta send the pump back to get reset by the bio-med guys who fix our pumps. You could but hit that, knock it off-kilter, and must've spent a few minutes trying to line it back up, to get it back to where it'll work. On the triple-channel, there's three channels, and sometimes line-A might just quick working. So, you have to take it off, and put it on line-B, or line-C, or –

PARTICIPANT_4: A new pump.

PARTICIPANT_2: A new pump. Or, you turn it on, it just goes – it just makes this god-awful screeching noise that will not stop. *[Laughter]*

PARTICIPANT_1: Oh gosh.

RESEARCHER: Is that a failure?

PARTICIPANT_1: Yes, a failure screech.

PARTICIPANT_2: Yep, a failure screen.

RESEARCHER: And what is the failure screen?

PARTICIPANT_3: Failure is what happens – sometimes it's because the battery could be dead, or it could just be because it just won't work, and it'll go into failure, and it will not quit screeching. You can try turning them off, it doesn't turn off.

PARTICIPANT_4: Unplug it, it's still screeching. *[Laughter]*

PARTICIPANT_2: Still screeching.

PARTICIPANT_5: Still screeching.

PARTICIPANT_2: I mean, it's like, make the guard –

PARTICIPANT_5: So, we sit them in the dirty utility room and shut the door, so we don't have to listen to it. *[Laughter]*

PARTICIPANT_2: Or, you know, get the guard – make the guard take it down to central – or central stair, where they clean them, and just hide them in there, just to get them away from us. They are so loud, and so obnoxious, they will not be quiet.

RESEARCHER: Oh, my goodness. How do the patients react when this thing starts screeching? *[Laughter]*

PARTICIPANT_4: Well, the worst part is when you're transporting a patient upstairs, and it's like, sorry we're gonna have to deal with this until we get back. *[Laughter]* You know, you're in the elevator and it starts.

PARTICIPANT_2: Some of the people it frightens.

RESEARCHER: Yeah.

PARTICIPANT_2: 'Cause they're like, "What's this noise?" 'Cause they hear that noise thinking oh, their heart's stopped, they're in front of the monitor.

PARTICIPANT_4: Yeah, 'cause a noise like that usually is not good.

PARTICIPANT_2: Yeah. It's not a pleasant sound.

PARTICIPANT_5: And, I think every pump, depending upon what brand it is, has their own little idiosyncrasies that make you just want to throw them out the window sometimes, because you're doing everything the way you're supposed to, and it won't reset, or it won't run, or it won't stop that screeching, or whatever. And, it's frustrating to you because, or to me, because you don't have the time for this nonsense. It's frustrating for the patient,

because they see this nurse who's like ready to kick this thing out the room, and they're in a panic, because - "Oh my God, what's wrong? Am I gonna be okay?" Well, yeah, you're fine. It's this damned piece of machinery! So, there are times when they're not particularly user-friendly, and you can't predict when that's gonna happen, and when it's gonna let you do what you need to do with it. And then, sometimes, it just won't let you, and it won't tell you why it won't let you, and that's when you take it – and you just take it and put it in a closet somewhere to get them to fix it. And that's a waste of time, and energy, and you know, if it's a critical medication then it's an interruption of the administration, and it just becomes a whole, like cascade of events – that's time consuming.

PARTICIPANT_2: There was a few time where like, there'd be a pump sitting in the back, and you go to grab one, and you hook – hook to the pole, turn it on, it doesn't come on. It's plugged in the wall, it will not come on. I've had like five or six pumps that you just – it will not come on, no matter what – even plugged-in, so. And, it's not screaming failure, it just won't come on.

RESEARCHER: Can you think of any other challenges that you've had?

PARTICIPANT_3: I think, availability, sometimes. You know, just – you really need one, and you just – they're all in use, or you can't find one, or you ended up having to clean one when you're, you know, it's just – I think the availability, sometimes, is an issue.

RESEARCHER: Okay. Having enough.

PARTICIPANT_3: And, you know, for us in the Nic-U, we have to have certain ones for our babies. So, if somebody has put an adult pump in the Nic-U, we can't use that. We have to use one that's programmed for babies, so that they don't get too many fluids.

RESEARCHER: Okay.

PARTICIPANT_3: It's programmed that they can't get more than x-number of ml's an hour, which is, I think like 100, and that's really – that might even be too much. It might be 50.

RESEARCHER: Now, is that programmed with the prescription thing that [PARTICIPANT 2] was talking about?

PARTICIPANT_2: I've not seen those pumps. I don't know.

PARTICIPANT_3: No, it's a new-born pump, and it actually has an N on it.

RESEARCHER: Okay.

PARTICIPANT_3: So, if you try to give somebody a 500-ml Bolus on those, you cannot do it.

RESEARCHER: Okay. Do those infusion pumps ever get swapped around, where they can –

PARTICIPANT_3: Yes. We've had a girl – I mean, of course, 4th floor get's them, because of the pedes, and we have them because of our Nic-U. So, you know, if they have three babies upstairs and we need one, it's not necessarily always that we have one. I think we try to keep one in our unit, but we really try not to use an adult one for babies.

RESEARCHER: Okay. Any other thoughts on this question? Do you have any fears or concerns, based on your own experiences using an infusion pump, or those of others that you've seen?

PARTICIPANT_3: My fear's not so much with the pumps as it is making sure with our critical meds that they're being hung right, and at the right dose. You know, checking and double-checking, and not mixing-up your main-line with a different one, you know. It's a different line, and I'm not sure if that's so much the pump, or the nurse looking at it, but at the same time – you know, it would be nice if you could, on your – where you can label the lines, that it's programmed that you can only give a maximum amount. So, like when we tap mag patients, you cannot give more than 100, or you know, 150 ml's an hour and it stops you if you try to program something higher. So, if you need to give them a mainline Bolus, and you accidently hit your mag, then it's not going to let you open that up. Because you can –

RESEARCHER: Okay.

PARTICIPANT_3: So, you know, I think that would be nice. That, only if you labeled your line maintenance-line, then you can give Boluss through that, but if you had something else – it would be nice if it was programmed that way. But, I don't know if that's a nursing thing, but that would be – that's one of my fears with using an I.V. pump, that my – I triple check. You know, if I'm –

RESEARCHER: Okay.

PARTICIPANT_5: See in my year in the E.D., and not only this one but others I've worked in, is the same kinda thing, but with pediatric patients. Because, if the pump runs away, and there's liter bag hanging there, which is generally what's hung, now I've given them a lot more fluid and overloaded them, possibly, than – maybe the 100-cc's I wanted to give them, I've given

them 500 or 600 because the pump's gotten away from us. And that – I didn't even realize we had special neo-natal pumps, I mean, that would be ideal to prevent that. But, even so, I'm wary with the pediatrics particularly, 'cause I don't do a lot of pedes, and it makes me very nervous giving medicines and fluids to pediatrics, because they – you know, the volume and the medication doses are so much more critical with a child, because of the weight, than they are with an adult. You know, you've got a lot more leeway with an adult, than you do with a child, for safety, and I think – I've seen pumps run away, and, you know, give a child a big Bolus.

RESEARCHER: Okay.

PARTICIPANT_5: And that makes me very unsettled.

PARTICIPANT_3: It'd be nice to kinda be able to almost program your patient –

PARTICIPANT_5: Like be able to put their weight in, or something.

PARTICIPANT_3: Like their weight. And, then it triggers something that says, "Are you sure you want to give" – let's say if you were gonna give a 50-ml Bolus, and you put in 500, "Are you sure you want to give 500?" You know, just something to trigger you, just as a catching mechanism. But, I think giving anybody too many fluids, or you know – I think that's probably a fear of anybody. You know, if it's a particular medication, I think it's – I would be worried if someone was not fearful of giving too much of a particular medication.

RESEARCHER: Are there any other concerns with respect to I.V. pumps? Is there anything that you need from your organization, with respect to support, resources, etc. to make using I.V. pumps easier?

PARTICIPANT_4: More pumps.

PARTICIPANT_2: More of them. Because in the E.R. we're always struggling, or calling somebody, "I need another pump, I need another pump." Who – go find a pump, 'cause sometimes if the one malfunctions, people don't tag it. They'll stick it in the back, and they don't put a tag on it that says, "Don't use this." So, you grab the same pump, go to a room, it don't work, it's failed, or it won't come on. So, you have to just walk out, try to find another pump. Just more pumps, at least for the E.R., more pumps.

PARTICIPANT_1: Yeah, we've only got like four.

PARTICIPANT_4: On a good day.

PARTICIPANT_1: Yeah, on a good day.

PARTICIPANT_5: And I think that that – the more pump thing is even when patients leave the E.R., if we have to take them up on a pump, then the floor we're taking them to has to find a pump, because we've gotta take ours back, because we don't have any extras. And, sometimes, that becomes an issue and can cause conflict between the units, because, I understand you need this pump, but I need it, too, and I can't give it to you. So, I think, sometimes not having enough affects your working relationship among your co-workers, too. You know, I mean even in the E.R., "Do you really need that patient on the pump? I need it for something." You know, we're stealing pumps from one patient to another, and I'm sure it happens on the floor, too. And, it's a volume issue, opposed to, maybe, the type of pump, but it's the number of pumps.

RESEARCHER: Can you think of anything else that the organization could do for you, to support your work with the I.V. pumps? Besides giving you more of them.

PARTICIPANT_2: I guess the Colleague-Guardian thing, just make sure that the strength of the medicine is what the pharmacy currently has – I don't know, I don't know who updates those, or if that's ever checked, or how it's even updated.

PARTICIPANT_4: The Guardian? Do you know about Guardian?

PARTICIPANT_3: It's where you can go in the I.V. pump, and you can – like, if you're giving Heparin, or something like that, you can program it to – by weight, and all that.

PARTICIPANT_5: And it comes-up, but you know –

PARTICIPANT_4: I guess we've just never had to do that.

PARTICIPANT_5: On your main –

PARTICIPANT_4: Yeah.

PARTICIPANT_2: You just put Nitro, or –

PARTICIPANT_5: There's a thing that'll say Guardian college, or Guardian something –

PARTICIPANT_2: And you can scroll down and hit Nitro, and –

PARTICIPANT_5: Yeah, and you hit that, and it'll come up with a list of medications that you program –

PARTICIPANT_3: It's not very user-friendly, though.

PARTICIPANT_5: It's not user-friendly, at all. But, then, say if you're gonna do Heparin, you pull out the Heparin and it'll give you a concentration, and then you them how many units an hour you wanna give, and it'll tell you the volume you should be infusing at.

PARTICIPANT_2: It'll set the rate for you.

PARTICIPANT_5: It'll set the rate, but it should be on. It should say, Colleague?

PARTICIPANT_2: Colleague-Guardian.

PARTICIPANT_5: Something Guardian. It starts with a C, I don't know.

PARTICIPANT_4: I guess I've just never had to use that before.

RESEARCHER: [PARTICIPANT 5], you mentioned that it wasn't user-friendly, what do you mean by that?

PARTICIPANT_3: It's hard to find. And then, once you do find it, then you have to really – you have to find somebody who knows how to use it.

PARTICIPANT_1: Just pulling it up is difficult, and some of them don't have it, or something. 'Cause I've run –

PARTICIPANT_3: Yeah, some of them don't have it. It's not on every pump.

RESEARCHER: Okay.

PARTICIPANT_3: I don't know what it is about it, but can be difficult, yeah.

PARTICIPANT_2: And the med-list is like, you know, this long. And you have to like, page-down, page-down, page-down, then scroll up or scroll down to get the right medicine.

PARTICIPANT_3: You just keep going up and down, up and down. It's not, you know, you can't type-in, okay – Heparin, and –

RESEARCHER: Or, like, go straight to H, or –

PARTICIPANT_5: No.

PARTICIPANT_2: With my – on our – above the line, there's a little screen that'll say, Heparin, or Nitro, or Dubutimine, or whatever, so you know what that line is without actually putting a tag on the line.

PARTICIPANT_5: And the print on it, for those of us who are blind, is very small. And, the lighting on the pumps, depending on the lighting in your room, the back-lighting's not always good. So, sometimes you have a hard time reading it. And, sometimes the dosage isn't the standard concentration that we get, and there really isn't a big – I don't know if there's a way to change it.

PARTICIPANT_2: There's a way to program like, a generic one, but it's like, buried in that list.

PARTICIPANT_5: Yeah, so unless it's the proper concentration, it really isn't gonna give you the accurate dosage. And, my fear with it is, also, that maybe because I'm not tech-savvy and I don't trust a lot of technical stuff is, I don't know that the person that programmed that dosage in there put it in correctly.

PARTICIPANT_1: Yeah.

PARTICIPANT_5: So, I feel like, a lot of times I have to re-check that myself to make sure that the pump's giving me the correct information. Now, I've never found one that didn't, but, you know, it's like everything else. I just don't trust it, because I'm an old nurse and used to doing it myself.

RESEARCHER: Okay. Now, the person who programs that in, do you know who that person is at the hospital, or is that just kind of a mystery?

PARTICIPANT_4: It's a mystery.

PARTICIPANT_2: I guess it's –

PARTICIPANT_4: I don't know if they even come programmed – I don't know.

PARTICIPANT_5: See, I don't know if it's from the company, or a pharmacy does it –

PARTICIPANT_2: Or if it's our bio-men do it. I don't know who does it.

PARTICIPANT_5: Or if our bio-people do it. And, I don't know if it's a case of, you know, they put the concentration of the drug in and there's a program in the computer that says – and figures it out, or if there's a person that manually figures it out and enters it in.

RESEARCHER: Would you feel more comfortable if it was the computer making that calculation, or the person, the pharmacist, or –

PARTICIPANT_5: I don't know. Because, again, these pumps are not fool-proof, you know, or am I sure that that's correct?

PARTICIPANT_3: I would think that, you know, you have the computer calculate it but the pharmacist looking at it and saying, "Okay, that's right." Or, "Oh, that's not right."

RESEARCHER: Okay.

PARTICIPANT_3: I think a system that double-checks is always –

PARTICIPANT_5: Absolutely.

PARTICIPANT_3: Especially when you're talking about Heparin, and Nitro, and you know, things like Stimine –

PARTICIPANT_1: Yeah, drugs that if you screw it up it could kill you.
PARTICIPANT_5: Yeah, I mean, we're not talking about an antibiotic.

PARTICIPANT_3: Right.

RESEARCHER: Any other comment for this question before we move on? So, as far as looking at infusion pumps as a technology, what are your expectations with using an I.V. pump?

PARTICIPANT_5: I want it to be easy, I want it to be accurate, and I want it to be user-friendly. I don't wanna have to spend 20 minutes hanging an I.V. I don't have that time.

PARTICIPANT_2: I would say, like, if it does the doses, we should know about how updates it, and how often it gets updated, and it meets current pharmacy – whatever they've got on stock, and that those screens are easy to find, easy to use, and there's some – and obviously double check with a real person, to make sure that you're giving the right dose.

PARTICIPANT_1: And to be able to read it.

PARTICIPANT_2: The wear on there – it can be pretty bad sometimes. If you don't _____ you're like, trying to squint at it to – or adjust the contrast on it to see – to be able to read it.

RESEARCHER: Okay, so there's a problem with the size, the glare, the backlight. Are there other issues?

PARTICIPANT_4: Yeah, it's like the lighting on them. They're green, with like a yellow kind of light behind it, and I think the plastic screen distorts stuff, because it's plastic.

PARTICIPANT_2: The plastic kinda protects the screen, but it –

PARTICIPANT_5: It's like an old-timey computer screen color. *[Laughter]*

PARTICIPANT_3: I think I'd like to just see the systems of checks – the checks and balances, you know. Like I said earlier, "Are you sure you want to –" I mean, yes, it's an extra step, and yes, it may be cumbersome, but like with the pedes patients and our Nic-U babies and things like that, I'd rather take that extra step of, "Oh, crap, yes I meant to put 5 and not 50" in my pump, you know. A system of being able to enter-in your patient information, and going from there. And that's an extra step, and not everybody's gonna need it, but I think in the situations that you do need it, it'll be worth it.

PARTICIPANT_4: Or we could take out the – where when you turn it on it says, "Can you hear the noise?" *[Laughter]*

PARTICIPANT_5: *[Laughter]* Input patient weight.

PARTICIPANT_1: Is this a new patient? Yes. You know, and can you speaker-check, you know. You have to check. Can you hear it? Yes.

PARTICIPANT_3: Your patients would really think you're crazy, when you're making it beep, and they're going, "Why is that – why are you beeping that thing?"

PARTICIPANT_4: And it beeps when you first turn it on, anyway.

PARTICIPANT_5: Right.

PARTICIPANT_2: I'd do it and just tell people, "It's programmed just to beep." *[Laughter]*

PARTICIPANT_5: It's to make us crazy. It's working.

RESEARCHER: Have you had any surprises while using an I.V. pump?

PARTICIPANT_3: I guess probably my biggest surprise is like Tony was saying, the – you go in, and you're disconnected, and your bed is soaking wet, and you're just like, "I had it screwed-in tight. What happened?" Or, you know. Those are probably my biggest –

PARTICIPANT_5: Mine are the empty piggy-backs, or the not-empty piggy-backs. You know, I go back and I think it's gone, and it's still sitting there.

PARTICIPANT_2: I remember one nurse telling me that they didn't have to program it because once you plugged it in like that, it automatically detected it as a piggy-back. I said, "No. It don't work like that." *[Laughter]* It just lets the big bag draw, not the little one.

PARTICIPANT_3: My biggest surprise is to go in, you know, and find your rate is something astronomical when you know you didn't set it at that. Because the patient has messed with it, and is –

PARTICIPANT_2: Or the patient's family member is a nurse.

PARTICIPANT_1: You can lock your pump.

PARTICIPANT_3: Yeah, but you don't always know which patients are – you know, some of your best patients, you don't think that they're gonna do that.

PARTICIPANT_5: It would be nice to have a door on them, like the PCA pumps do, that you can – you know, you can't mess with it unless you open the door and the door's locked.

PARTICIPANT_2: Yeah, 'cause – 'cause the lock button's in the back of it, and anybody can have access to it.

PARTICIPANT_3: They have _____ about that. I mean, you're a really good patient, you're really good –

PARTICIPANT_5: Yeah, 'cause they watch what you're doing.

PARTICIPANT_3: Yeah, and they're so – you know, they come-in every other week. They know how to – *[Laughter]*

PARTICIPANT_2: And, the lock button isn't locked. It's open. Anybody can just touch it. The screen'll tell you if it's locked.

PARTICIPANT_5: I'll have to look at that, anyhow.

RESEARCHER: Why do you think that patients do that?

PARTICIPANT_3: Because they want their medication faster. They want their pain medicine as fast as they can get it, so they can get that – that jolt.

PARTICIPANT_2: Or their family member is a nurse – thinking they're helping out grandma or grandpa by making them – more fluid makes them better, which sometimes won't work.

PARTICIPANT_5: And sometimes, I think they just do it because they can. I don't think there's a particular reason why they do it, or they do it because they know it'll alarm.

PARTICIPANT_3: They want the attention. They want somebody to come back into their room.

PARTICIPANT_5: They want the attention. Or, just 'cause they can.

RESEARCHER: Any other surprises you can think of? Are there any sort of instances where what you expected to happen didn't happen?

PARTICIPANT_1: I think we've kinda hit that.
RESEARCHER: Aside from the piggy-backing and not having the right amount of fluid go in.

PARTICIPANT_2: That's probably about the two that I would think of.

RESEARCHER: So, is your use of I.V. pumps changing how you feel about, and/or use other technologies or medical devices?

PARTICIPANT_3: I just think that there's a lot of stuff they keep changing and updating and things, and I think some of the I.V. pumps just kinda need their own re-vamping, the same as the blood-pressure cuffs, and equipment is changing and all that. I just think that the I.V. pumps are probably gonna be coming to that same level.

RESEARCHER: Do you feel that other technologies are advancing faster than I.V. pumps?

PARTICIPANT_2: Yeah.

PARTICIPANT_5: Oh, yeah.

PARTICIPANT_2: Most of the triple-channels are kinda heavy, and if you get an I.V. pole that's kinda weak, it'll bend. Or, the grip on the pole doesn't always hold, and it slides down. I think they could be a little smaller. Not making the screens smaller, but making them weigh less, at least on the triple-channels, 'cause if the pole hits the patient it's gonna hurt 'em.

PARTICIPANT_1: I have had that happen.

RESEARCHER: Really?

PARTICIPANT_4: We haven't talked about that, oh gosh.

PARTICIPANT_5: And I don't think pumps, over the last, oh – yea-many years that I've been doing this, have really changed a lot. Other equipment has. Defibrillators have, charting computers have, monitoring computers have, even I.V. catheters have changed. But, your basic I.V. pump is probably – maybe it's a different shape, maybe it's a different color, but it's probably the same as it was 20 years ago.

PARTICIPANT_2: I'd have to agree. When I was here as an orderly, I think they were, not technically the same pumps, but almost the same pumps.

PARTICIPANT_5: Well, and the same problems, and the same programming, and I don't think that – I mean, look at your computer module – monitors, how small they've gotten over the last 10 years, or even 5 years. The pumps haven't changed. I mean, we've got ventilators on ambulances that are the size of a lunch-box, and our pumps are still – weigh 20 pounds, and they're still heavy, and they're still bulky, and they're still using screw-clamps on the back, and they're still using the same button technology. You're not seeing that change in the pumps that you're seeing in other equipment that, even our accu-checks, and stuff, have changed dramatically over the last 10 years. But, the pumps don't. They stay the same way.

PARTICIPANT_2: The only thing I think they've changed, is they've added the Colleague-Guardian. That's pretty-much – probably the only thing I can think of.

PARTICIPANT_5: Yeah, and that's been around for, probably the mid-80's.

PARTICIPANT_2: Yeah.

PARTICIPANT_5: Because we had that when I worked in the '80, we had that.

PARTICIPANT_2: 'Cause there are actually machines now – it's a palm-pilot.

PARTICIPANT_5: Well, I mean, even that. Look at our phones and stuff, how small they've gotten in the last 10 years. But, this pump that's so crucial to what we do every day, is still a dinosaur.

RESEARCHER: Okay. Any other thoughts? Do you feel that you have more confidence with other technologies that you use, or might use in the future, based on your work with the I.V. pumps, now?

PARTICIPANT_5: Not at all. If they were changing and advancing, maybe. But, I don't see that they impact how I do other stuff.

RESEARCHER: Okay. I guess everyone agrees with that. Okay. So, this is our final wrap-up question, and again, we'll just go around the room and just answer this one question. And, we may have touched on some of this

already, but what would you like to be able to do with infusion pumps? And we'll start with you.

PARTICIPANT_5: I would like them to be less – I want them to be accurate, I want them to be easy to use, I want the screens to be able to be seen well, I'd like them to be safer in that patients can't change them. I'd like to see them be smaller, light-weight, not as bulky to work with.

PARTICIPANT_2: I would say the same thing, but on the back of the current pumps the lock-key is actually open. Anybody could hit it. There's no pass-code, there's no – you know, you just – off and on. So, anybody could hit it. I mean, you might set it locked, but if someone's a nurse, or a CNA who works for the hospital, and – oh, I can just do this and change it. Like [PARTICIPANT 5] says, smaller, a little more compacter, the Colleague-Guardian could be a little more user-friendly, and make sure that – you know, who updates it, when it's updated, and that's pretty-much it.

PARTICIPANT_1: I would think, as [PARTICIPANT 3] said earlier, as having some – another check in there, you know. So that you're not gonna end up giving somebody, you know, 50-mikes of Nitro *[Laughter]* –

PARTICPANT_5: You only wanted to give them 5.

PARTICIPANT_1: Yeah, and you wanted to give them 5. So, when you punch-in the 50, it says, "Are you sure you really want this?"

RESEARCHER: Okay.

PARTICIPANT_3: I don't think I have anything to add to what everybody's already said. I mean, I think just updating them, in all aspects.

RESEARCHER: Okay.

PARTICIPANT_4: I don't think I have anything to add, either.

RESEARCHER: So, in conclusion, I just have three other questions. Is there anything else I should be asking you? Are there any questions that I didn't bring up that you were expecting?

PARTICIPANT_2: I can't think of anything.

RESEARCHER: Okay. Is there anyone else I should be asking for answers?

PARTICPANT_1: Bio-Med.

PARTICIPANT_5: Bio-Med, yeah.

PARTICIPANT_2: 'Cause they're the guys who fix the pump, repair 'em. Like I said, I don't know if they update -

PARTICIPANT_4: They may update them.

PARTICIPANT_2: With the drugs in it, I don't know.
PARTICIPANT_4: Maybe talk to pharmacy.

RESEARCHER: How about like, physicians? Do anything with them?

PARTICIPANT_4: Oh gosh, no. *[Laughter]*

PARTICIPANT_2: [Doctor X] might change – [Doctor X] and [Doctor Y] will change the rate on stuff without telling you – at least, [Doctor X] will, on some medicines. And, [Doctor X], I don't know if he messes with them or not. I know, one doc – one cardiologist will mess with it. [Doctor Y]. It's few and far between that he ever does that, but I've seen him do it.

RESEARCHER: Is that confusing when –

PARTICIPANT_2: Yeah, 'cause the nurse came to me and goes, "Tell me, did you set this rate at X?" I said, "Yes." Go back there, it was not at what I set it at. 'Cause I had even charged – you know, I put it at 10-mikes, or whatever it was, and he had went in the room, and he had upped-it to like 15 or 20, and didn't tell anybody. And, the nurse thought I was at fault. I said, "No, no, no. I made sure – 'cause if you were in the room when I set it at 10 – *[Laughter]* Then, we kinda figured out that he had messed with it, and didn't tell us.

PARTICIPANT_5: Let his fingers do the walking. *[Laughter]*

RESEARCHER: Is there anything that you wanna ask me?

PARTICIPANT_5: What are you trying to come away with for this? What is the focus that your – I mean, I would assume you're trying to document a point or an outcome – what is it that you are trying to –

RESEARCHER: Well, I don't wanna bias, since there's another part of it, I don't wanna bias you.

PARTICIPANT_5: Okay.

RESEARCHER: But, the role that I'm trying to play is a person who's working for an infusion pump company, who's just getting into the infusion pump

business and is trying to learn about it. But, then, at the end of our next session I can reveal my topic, and what my thesis is.

PARTICIPANT_5: Okay. That's fair enough.

RESEARCHER: Anything else? Okay. Again, I wanna thank you so much for coming today. It's such a relief to get this out, and I think we got a lot of really good information, so I'm excited about that. So, I think that's it. The last thing I need to do, is schedule your follow-up sessions, and for this group it'll be an interview, just with me, more about infusion pumps, but just coming from a different direction. So, let me stop the recorder.

[End of Audio]

B.3 P1 Interview Transcript

Researcher: So, the first series of questions that I'm going to talk about is about inefficiency, using too many resources when you're trying to use the infusion pump. So my first question is who do you think is impacted when infusion pump use is inefficient?

Participant_1: Well, everybody would be who's dealing with the patient from the doctor all the way to the patient.

Researcher: Okay, so who does that include, the doctor, the patient?

Participant_1: The nurse and even the patient and the family because even the family members that are sitting there and getting anxious.

Researcher: Okay. What functions, features or qualities cause an infusion pump to be inefficient?

Participant_1: Hmm. Well, I guess when they don't work, when they – you know, when they tell you that it's not infusing, that it's occluded upstream or downstream. When they go into failure, pump failure, for whatever they go into failure for and then you've got the pump that won't quit beeping and it's obnoxious. What was – again remind me?

Researcher: The functions, features or qualities that would cause an infusion pump to be inefficient.

Participant_1: You know, I guess when it comes to the functions and features, it would be, you know, if you can't read it, if the backlight is the wrong color of if it's not bright enough and you're having to constantly scroll around it and figure it out and you can't see it, that's gonna decrease efficiency just in the nurse's time in the room and spending trying to get the thing going.

Researcher: Okay, and you mentioned occlusions. What causes occlusions?

Participant_1: It just varies. I mean, if it's – if the IV has been started in the AC and the patient bends their arm, that'll cause an occlusion and the pump will be – but it – I've had them say that they're occluded and I can't find anything wrong with it.

Researcher: Okay.

Participant_1: And sometimes I just stop it, open it up, pull the line out, put it back in and push start again and it works.

Researcher: Okay.

Participant_1: And I just don't know why.

Researcher: Okay. If you were going to compare two infusion pumps, why would you rate one infusion pump as being less efficient than another?

Participant_1: The time – it would be on the time that it takes me to deal with it.

Researcher: Okay.

Participant_1: 'Cause that affects how much time it takes me personally dealing with the one patient, dealing – giving one drug.

Researcher: Okay, and with the Baxter pump, how – what's an average time just an add up or is there an average time?

Participant_1: I don't know, it just depends. It depends on – you know, if you're setting it up for – for just normal saline infusing, it doesn't take very long at all. But if you're having to use, like we were telling you the last time, the Guardian and going through that and looking for the med and, you know, that takes more time.

Researcher: Okay. In what locations or context do you find that infusion pump usage is inefficient?

Participant_1: I really don't think there would be a time, I mean, I can't – I guess the only time would be if you had to give something really fast, sometimes by gravity it goes in faster.

Researcher: Okay. Do you find like between different wards, do you prefer – do you find that they're more efficient in different places?

Participant_1: I wouldn't know, I only work in the ER.

Researcher: Okay.

Participant_1: I've only worked in the ER.

Researcher: Okay. When do you think that infusion pump inefficiency has the most impact?

Participant_1: When it doesn't work. I mean, when you're giving a – you know, if you're doing something critical on a patient that's in critical condition and you've got to, you know, you've got to do it now and you need it to work and you need to do it quickly, that's where – with really critical patients when they're not efficient.

Researcher: Now, in the ER do you have – are they mainly critical patients?

Participant_1: No. I would say they're mainly not critical patients, what we mostly see but there are those times where –

Researcher: And how do you think an infusion pump should work so that inefficiency is as low as possible?

Participant_1: They should work. They should be easily *[sic]* to read and to set 'cause that's really the only inefficiency it's gonna, in my opinion, have. I mean, people – other people might be able to tell you more but I feel like that's – you know, otherwise they're efficient.

Researcher: Okay.

Participant_1: You know if they're – you know, except for when say that they're occlusion but they're not or you have pump failure. But for the most part, you know, it's just the – you know, getting it set up, being able to utilize the buttons easily and quickly and just being able to read it.

Researcher: Okay. The next set of questions is about stress. So the first question is who do you think typically gets frustrated or stressed while using an infusion pump?

Participant_1: Nurses. They're pretty much the only people that really use them, so, yeah.

Researcher: Do you think there's different types of nurses or different characteristics of nurses that would make them more prone to being frustrated?

Participant_1: Well because typically it's the nurse that's hanging the fluid that has to go through the pump and so that would, you know – I mean, I guess if a doctor was standing there and knew and saw how frustrating it was when they're not working properly and then the patient, but I think for the most part, it's the nurses.

Researcher: Okay. What functions, features or qualities do you think that stress users of an infusion pump?

Participant_1: When you can't read it, when you can't see it, when it's – pump failure is probably the most frustrating, particularly when you get the three-channeled ones and one channel for some reason fails and you do the little twisty thing on the side that it says to do to release the – I guess it's releasing the tubing, what clamps the tubing in and then that still doesn't work and the thing's beeping and it's just loud and it's very frustrating.

Researcher: So if you have a failure in one channel, does that make all three –

Participant_1: No, no. On a three channel – and I'm trying to recall, I don't even think on a three-channel if the pump failure beeps all the whole time. But on a one-channel, definitely just obnoxiously beeps and then – no but you could still use the other two channels on the three-channel pump.

Researcher: Okay.

Participant_1: But it's just, you know, again, if you've got somebody whose got two or three lines going in and you need 'em on pumps, then you've gotta get another pump and the three-channel pumps are very large and so then you've got to fit it on another pump on the pole.

Researcher: And these are the poles that are attached to the beds?

Participant_1: Some of them are attached to the beds and some of them aren't.

Researcher: Okay. And then again, if you were gonna compared two infusion pumps, in terms of your perceived stress level, why would you rate one infusion pump as being more frustrating to use than another?

Participant_1: I think – isn't that the same question as earlier?

Researcher: They're similar.

Participant_1: Again, you know, just being able to see, being able to use it easily. If it does go into failure, I just wish it wouldn't beep. So, I would think one that doesn't beep all the time – you know, it's one thing to notify you like when your med's in and it's gone KVO (keep vein open) or something, but that pump failure beep is just – if you've ever heard it, it's really annoying.

Researcher: Okay. And it doesn't stop?

Participant_1: And it does not stop. In fact, we just put it in another room and close the door because it will not stop beeping.

Researcher: Okay.

Participant_1: And it's not even really a beep, it's just a noise. It's just a loud constant noise. It's very, very obnoxious.

Researcher: Okay. Following up on that, what locations or contacts do you find yourself more stressed out when using an infusion pump? Are there any situations or scenarios where –

Participant_1: Probably the most stressful is when the battery dies and you're transporting a patient to another floor and you're kind of stuck and, you know, you can't plug it in 'cause you're on the elevator and so battery – you know, the length of time that the battery lasts.

Researcher: So what do you do in that situation if it failed?

Participant_1: You just have to say, "Sorry," you know, "We'll be to a place we can plug this in in a minute."

Researcher: Okay.

Participant_1: Yeah, there's really nothing you can do.

Researcher: So when in the process do you think that most frustrations occur when using an infusion pump?

Participant_1: I guess when you're in a hurry.

Researcher: Okay. And what would impact being in a hurry?

Participant_1: What would cause one to be in a hurry?

Researcher: Mm-hmm.

Participant_1: Again, if you have somebody critical and you're gotta get it hung and you're – like if you're working a code and you gotta get something going and you can't get the pump to work.

Researcher: What is working a code?

Participant_1: Somebody who's basically dead.

Researcher: Oh, okay like a code blue?

Participant_1: Yeah, a code blue.

Researcher: Okay. So if you were going to redesign the pump or any pump, how do you think it should work so that your stress level is as low as possible?

Participant_1: Well, it should work. It doesn't need to be putting this into pump failure. It should be easy to read. I don't know, like ours right now I think have like either a yellow or a green background and it's just very difficult to read, particularly if the light is hitting it at a certain angle. So, having so that the lights don't affect – get reflected in it too much that you can read it. Having buttons big enough. If it's gonna have – I think the Guardian is

a great thing. I really like that. I would like that feature on a pump but again, it needs to be user friendly rather than this – it's very un-user friendly.

Researcher: Now, for the Guardian, what are the things that you don't like about it?

Participant_1: Just the way it scrolls because it's like this little touch pad and it's just difficult to scroll between the medications.

Researcher: Okay.

Participant_1: I mean, I don't know. I doubt you could have something with a keyboard but, you know, I don't know what would make – what could be designed to make it easier but if there was just the way it scrolls through the medications and the little keypad that you have to use 'cause it's like a little – it's kinda rubbery.

Researcher: Mm-hmm. The next group of questions is about error and the mistakes that could be made when using a pump. Who do you think typically makes mistakes while using an infusion pump?

Participant_1: I guess, again, the nurse or whoever is setting the pump up.

Researcher: Do you think there is anyone who is more susceptible to making a mistake or an error?

Participant_1: I don't know on the floors who all runs the pumps. Like I know when I was a tech in the ER at Lewis-Gale, we didn't mess with the pumps too much because that was considered a nursing duty, so we didn't mess with them. And I don't know if on the floors CNAs or anybody could use – can do anything with the pumps.

Researcher: Okay.

Participant_1: But basically, in the ER it's the nurses.

Researcher: Do you think that there is anyone in the ER that's more susceptible to making an error than anyone else or is it kind of even?

Participant_1: New nurses.

Researcher: Okay. And why do you think that it?

Participant_1: Just because they're not as familiar and haven't done it as much.

Researcher: Okay. They don't have the experience?

Participant_1: Mm-hmm.

Researcher: Okay. What types of errors are possible while using the pump?

Participant_1: Well, you can set – you know, like we were saying the other night, you could punch in – say you're starting a drip that supposed to start at 50 mls an hour and you accidentally punch in 500 or vice versa, you're supposed to give 500 and you give 50. Those kind of mistakes where you're physically putting the numbers in. That's the nice thing about Guardian 'cause typically all you put in is the weight because most of those meds are weight-based and then it calculates it through.

Researcher: Okay.

Participant_1: And then if the doctor is there and if they want like nitro running at 5 mics, you know, then you just say okay, it's 5 mics per kilogram and then you tell the pump what the kilogram is and then it just does it.

Researcher: Okay, so other than entering the wrong rate, are there other types of errors that could be made?

Participant_1: Well, I guess, you know, you could think you've started it and you haven't. You know, there's nothing that really confirms that it's started.

Researcher: Okay. And so really the only way to view that, is that usually through visual?

Participant_1: Mm-hmm.

Researcher: Looking to see if the fluid is gone?
Participant_1: Mm-hmm.

Researcher: Okay. The next question is, in terms of error production, why would you rate one infusion pump as being better than another?

Participant_1: Again, it goes back to the, you know, being able to see it, user friendly, light-weight, a long-lasting battery so that when they do get unplugged that you're not listening to them beep. You know, having the – I think – I would not want one that didn't have the Guardian, the drug thing in there. I just think that's very useful and very helpful.

Researcher: Okay. And you mentioned user friendliness. What does that mean to you?

Participant_1: That you can see it, that you can – that the dials or however you're punching in stuff is easy to see, easy to get to. Like some of the things like the lock, for instance, on ours is like on the back in some weird location and so if you want to lock it so people can't mess with it, you know, you have to reach around behind. Then if you can't see it, you gotta turn the pump around, so having things that are just user friendly, that are easy to find, you don't have to hunt around for it.

Researcher: Okay. So when in the process do you think that most mistakes occur? So, throughout the process of using the pump, when is it more likely to make a mistake?

Participant_1: When you initially start it, when you're hanging something initially.

Researcher: Okay, and is that for like part of entering the rate and all that?

Participant_1: Mm-hmm.

Researcher: Okay. So how do you think an infusion pump should work so that your likelihood to make a mistake is as slow as possible?

Participant_1: You need to figure that out.

Researcher: I'm going to the experts.

Participant_1: Yeah. I don't – I don't know. Say it again, how –

Researcher: So if you were going to make your own pump, how do you think it should work so that your likelihood to make a mistake is as low as possible?

Participant_1: I think having a check, you know, something where you actually confirm that that's what you want. Luckily when we do use Guardian, that does make you confirm what you're doing so you go through and check it and then you confirm it. But typically when you're just putting in rate and you're not, you know, naming the line and everything, you can just put it in and go and hit start. So probably having a check, just to make you confirm is this really what you want.

Researcher: Okay, now is it standard procedure when you use a critical drug that you always have to use Guardian?

Participant_1: I do.

Researcher: Okay.

Participant_1: I mean, not – it isn't – I don't think anything is completely standard like that because I mean I've seen people who don't but I do 'cause I just feel more comfortable knowing that it's set, it's going in at the rate that I'm expecting it to go in, that nothing happens to make it go in faster or slower and so that – yeah.

Researcher: Okay.

Participant_1: So for me, yeah, I would never not use it.

Researcher: Okay.

Participant_1: But then there are so many drugs that you can't use it for, too, you know, because they're not in there and I can't – I could not even begin to name what's not in there, but, you know, there are some that aren't.

Researcher: But it's just really just the critical drugs that are in Guardian?

Participant_1: Like yeah, like dopamine and not nitro and Nitropress and, you know, things like that.

Researcher: Okay, the next round of questions is about effectiveness, accuracy and completeness when using it. So who do you think is affected by effectiveness of a pump?

Participant_1: Everybody. The doctors, nurse, the patient, the patient's family.

Researcher: Okay. How do you think the patient's family is affected?

Participant_1: Well, I mean if you think about a patient family sitting there at the bedside and you know, say something happens that shouldn't happen, then they've got added stress and anxiety. So to just keep kind of everything going smoothly.

Researcher: Okay. So what functions, features or qualities impact the effectiveness of the pump? And some of these are kind of repetitive.

Participant_1: Yeah. I mean, I think it goes back to the being able to see it, being able to lock it out easily so that people can't change it.

Researcher: And why do you think that people change the pump settings?

Participant_1: I don't think people know – I think people are bored, particularly – when they're in the hospital, particularly if they're in a room without a TV and they get bored and they start messing with stuff. You know, not necessarily to say, "Oh, I want to get this drug faster." I think maybe

some people do that but I think probably most of them, "I wonder what this button is for, wonder what that button does," you know.

Researcher: And do you find that it's the patients or the patient's family who do that or –

Participant_1: Both.

Researcher: Okay. Why is using an infusion pump more effective than other types of medication delivery?

Participant_1: Because you know that you're giving what you say that – you know, as long as you trust the pump and the pump is working properly, then you know what you're giving and how much you're giving so you can document this person got 200 ml bolus and then it was running at 100 an hour and so you can vary document and you know what the patient is getting.

Researcher: Okay. In what locations or context are infusion pumps the most effective?

Participant_1: The most effective. Definitely when you're doing anything critical.
Researcher: Okay.

Participant_1: Now, in our facility, they ideally like us to put everybody on a pump, particularly young and old patients but –

Researcher: And why is that for the young and the old?

Participant_1: Because fluid overload is more critical. It affects them more than it does somebody young and healthy like you and I could get too much of normal saline and it's not gonna affect us 'cause our bodies can compensate for it whereas somebody who is real old, it might put them into flash pulmonary edema or something else and their bodies just can't compensate and same with young children.

Researcher: Okay. So when does fluid overload happen?

Participant_1: When they get too much fluid.

Researcher: Oh, okay.

Participant_1: You know, and it varies, it's different for everybody.

Researcher: Okay. So other than critical patients and the young and the old, are there other locations or context where the use of the infusion pump would be the most effective?

Participant_1: Well, in transporting patients as well. You know, like particularly when somebody is being transported out of our facility to another facility, you know, you set the – if they're getting medications and they're out, then you set it and you know that they're getting what they're supposed to be getting.

Researcher: Okay. And what happens – does that infusion pump go with the person?

Participant_1: Mm-hmm. Sometimes. I would say – I don't know how, I mean I'm not sure how many times. I mean, there's probably just as many times we ship people out without infusion pumps because they're not on a critical med as we do people with critical meds.

Researcher: Okay.

Participant_1: And then we eventually just get the pump back. Usually what happens is that the EMS agency that's taking them somewhere, they usually originated in this area. So they take them, say, to Roanoke and they switch over the pump when they get there and then the bring our pump back.

Researcher: Oh, okay. So when in the process do you determine if your use of the IV pump has been effective or not? How do you know that it's working the way that you expected it to?

Participant_1: Well, when you've given – say you set it to give a certain amount of fluid within a certain time period and you go in and that amount is gone, then you know that it's worked. You know, you can count the drip rate if you want to calculate what it – because it used to be you just did it by hand. On the back of an ambulance because I also run rescue, we just do it and we count the drop rate and figure out what our drip rate should be and then count the drops going into the ten-drop set. And so you could sit there and count the drops to make sure it's going in at the rate that you're expecting it to go in.

Researcher: Is that a common thing to do?

Participant_1: I think probably most nurses just trust that the machine is working properly.

Researcher: Okay.

Participant_1: Of course, if you went in there and a whole bag of fluid is gone and you had set it for 100 an hour – and see that's where if you had a check, 'cause you know, you might have set it for 1000 and it went in in an hour and you

were supposed to have only given 100, then you know something has gone wrong.

Researcher: And you don't really notice it, you don't –

Participant_1: You don't – yeah, yeah, right, unless you double-check yourself. And I would say most nurses probably do double-check themselves but you just assume that if you've double-checked and you know that you've set it up correctly that it's doing what it's supposed to do.

Researcher: Okay. So, if you're going to redesign a pump, how do you think a pump should work so that your work is as effective as possible?

Participant_1: Well, it should be easy to read. It should – you know, the tubing, it should be easy to put the tubing in, light-weight, easy to clean. I don't know anything about cleaning them.

Researcher: Oh, okay. Do you know who cleans them?

Participant_1: Sterile – central sterile.

Researcher: And how often are they cleaned?

Participant_1: You'd have to ask somebody else about that.

Researcher: The next group of questions is about efficiency. So who do you think is affected by the efficiency of a pump?

Participant_1: Again, I think it would be all involved, you know, because if it's efficient, it's doing what it's supposed to do, then they're getting the medication at the time that they're supposed to get it so then the doctor knows that – you know, can see what the effect of the medication is in a timely manner and so I would say everybody is, the nurses, the patients.

Researcher: And the family and –

Participant_1: Right. Family is kind of like secondary but yeah.

Researcher: But they would still be affected.

Participant_1: Mm-hmm.

Researcher: What functions, features or qualities do you think impact the efficiency of an infusion pump?

Participant_1: It goes back to – I mean, I don't know how mechanically they really work so I don't know, you know if anything different there, but when it comes to efficiency, it goes back to the nurse efficiency, you know, being able to do it in a timely manner and not have to feel like you want to drop-kick it across the room.

Researcher: So what are those things that make you want to drop-kick it?

Participant_1: When it won't – like when it goes into its failure mode, when you just can't get – like there's been times, you know, like you can't get the gate or whatever catches the tubing in to release so that you can get it in there or so you can get it out.

Researcher: So sometimes it's like mechanical misuse of the pump?

Participant_1: Mm-hmm.

Researcher: Okay. Why do you think infusion pump use is more efficient that other types of medication delivery?

Participant_1: Because you know what the patient is getting and you know how much they're getting.

Researcher: Okay, so that you don't have to do the manual calculation?

Participant_1: Well, even if you have to do the manual calculation to know how to set it up, you just know that if it's working properly, the patient is getting what they're supposed to get.

Researcher: Okay. Are there any locations or contacts where using an infusion pump is more efficient that somewhere else?

Participant_1: I mean, I guess – I mean really anywhere you hang a line, it's gonna be more efficient to use a pump. You know, whether it's a critical patient or not, you know, because otherwise you're just eyeballing and counting the drips and you don't have quite the control over if the little – on the IV sets, you know, they've just got that little wheel that cranks up and down – if that should get bumped in some way that causes it to open up, you know, you don't have a way to lock that down in the position that you want it. So really, ideally every place it would make it more efficient and better. But it's unrealistic 'cause you can't have a pump for every single patient.

Researcher: Okay. And why is that? Why can't you have pumps for everybody?

Participant_1: I mean you could. That would be great but I don't think anybody's gonna pay for it.

Researcher: So when do you determine your use of the pump? When do you determine if your use of the infusion pump has been efficient or not?

Participant_1: When it works.

Researcher: And when do you know that it works?

Participant_1: When you don't have to keep going in 'cause it keeps beeping or it doesn't go into failure. You know, it doesn't say it's occluded all the time.

Researcher: Okay.
Participant_1: The medication goes in in the time it's supposed to go in.

Researcher: Okay. So how do you think an infusion pump should work so that your work is as efficient as possible?

Participant_1: It should just work.

Researcher: Okay. And by just work –

Participant_1: I mean when you go in and you turn them on, they should turn on. Like I said, if they were light-weight, if they had a good battery, if – like I said, I don't mind 'em beeping but when it goes into the pump failure beep, that not really – I mean I guess you know if it just beeped to let you know that it was doing it and then stopped, you know. So you could go in there and deal with it but not have it have to be locked in a room by itself.

Researcher: Okay. Because when it goes into failure mode, can you do anything other than –

Participant_1: Sometimes you can't do anything. You can get the line out and then you cannot do anything else. You cannot even turn 'em off.

Researcher: Okay.

Participant_1: They just go into this, you know, they will not function at all.

Researcher: Okay. And then the last group of questions are about satisfaction, your comfort level and acceptance while using the pump. So who do you think needs to be satisfied by the design of an infusion pump?

Participant_1: I would say more than anybody, the nurses. Then whoever or whatever person is using, whether it be a CNA – whoever is using it, those people should be the ones.

Researcher: Okay. And doctors, they don't really use the pumps?

Participant_1: Shoot, they probably wouldn't even know how to turn it on.

Researcher: Okay. So what functions, features or qualities impact the perceived satisfaction level of the infusion pump?

Participant_1: It goes back to being able to see it, having it lit well, the type to be something that you can actually read, the buttons to be user friendly.

Researcher: Okay. So as far as being able to see if there is a contrast issue, size issue, anything else with the –

Participant_1: That's probably it is size of –

Researcher: Is it an issue when you move the pump around to different places?

Participant_1: Well, sometimes the reflection of the light hits – it's got like a little plastic coating over the front of it, that's – and maybe that's just because they're old and they've – the plastic has degraded some, but sometimes that's hard. And then to be able to – you can actually adjust the backlight on it but it's – it is easy enough to use. It's on the back of the handle but it's just – it doesn't make a huge, huge adjustment. Or at least it doesn't make it bright enough for me or the contrast is not right, or if I feel like it's bright enough, you have to almost get right down on it and you have to be even with it to see it.

Researcher: Oh, okay. So you have to kind of like stoop down and look at it?

Participant_1: Yeah, mm-hmm and be at the same level to see – to really see it well.

Researcher: Okay. Why do you prefer to use an infusion pump instead of other types of medication delivery?

Participant_1: Because for the most part, I think they're the most accurate.

Researcher: And so accurate in terms of –

Participant_1: You're getting what you say – what you've put in that you're getting.

Researcher: Okay. Where do you prefer to use an infusion pump?

Participant_1: Well, I only work in the emergency room, so I guess the emergency room.

Researcher: Yeah, are the any like types of scenarios where you would – you're like, "Oh, I really need to use an infusion pump now," or "I'd really like to use one."

Participant_1: I usually try, like if I'm giving an antibiotic, particularly that I want to go in over a certain period of time like Levaquin, you can't put in quite as fast as you can other antibiotics. So I would prefer to put that on a pump. I don't like to eyeball that. Anytime I'm giving anything other than saline or Zantac, I prefer to put it on a pump.

Researcher: What is Zantac?

Participant_1: It's an H2 blocker.

Researcher: Okay.

Participant_1: It's like an antacid and that you could just let it run in.

Researcher: Okay. Let's see, the other question is when in the process do you prefer to use an infusion pump? It would just have to be similar to –

Participant_1: I guess, yeah, when I'm hanging a medication. Not so much when I'm hanging fluids but when I'm hanging a medication. And I'm even – you know, I prefer to put it on like an older person with fluids but I'm not as concerned as I am when I'm giving a medication.

Researcher: Okay. With younger people, with children, do you try to do fluids as well on an infusion pump?

Participant_1: Mm-hmm.

Researcher: Okay. And then the last question is how should the ideal infusion pump work? So if you could have your way about how the infusion pump should work?

Participant_1: Well, I think that, you know, the screen, like I said, it should be easy to read and – but I really think it's a good idea to have a confirm button so that like if you want to put in – and you're putting in 100 mls an hour, then you have to confirm that's what you want.

Researcher: Okay.

Participant_1: And then, you know, then you would just hit confirm it, hit start and go.

Researcher: Okay.

Participant_1: Does that make sense?

Researcher: I think so. So as far as like the task goes, is there anything – like how would you like the task to go as far as entering the rate in and then entering the time frame. Is there anything that you would change of the current pump that you don't like?

Participant_1: I mean, it automatically comes up as entering it by the hour, how many – you know, how much you want to give per hour.

Researcher: Okay.

Participant_1: I mean, and you can go in, I think – I've never done it but I think you can go in and change it like if you want to go milligrams per hour versus mls per hour and of course the pump needs to be able to do that, even though that might not be simple, we all use that regularly.

Researcher: Okay. When do you – when would you use milligrams versus millimeters?

Participant_1: When you're giving a medication that that's how it's dosed.

Researcher: Okay.

Participant_1: Some of them, they just dose them in milligrams per hour versus mls per hour.

Researcher: Oh, okay. So could that be a mistake that you would make if you were doing something that was milligrams and you put it in as millimeters?

Participant_1: Mm-hmm.

Researcher: So you kind of have to know it ahead that there's a change there?

Participant_1: Mm-hmm.

Researcher: Any other thoughts on how the perfect pump would work?

Participant_1: Have the Guardian or something like it.

Researcher: Okay. And that's important for –

Participant_1: In fact, I was just thinking most of the meds I've ever given that are by like milligrams or micrograms, they are in Guardian so that – 'cause a lot of them are weight-based anyway so they're based on the patient's weight.

Researcher: Okay.

Participant_1: So it's like 5 milligrams per kilogram per hour for that, you know.

Researcher: Well, I think those are all the questions that I have, and do you have any questions for me?

Participant_1: No, I don't think so.

[End of Audio]

B.8 P6 Storytelling Session Transcript

Researcher: So the first story is about – the theme would be inefficiency in infusion pumps. This is something where perhaps using an infusion pump, you didn't feel it was very efficient to use, where inefficiency is really defined as the resources needed – that too many resources are needed to use it or to accomplish what you're trying to accomplish.

Participant_6: Okay. I would say some examples of inefficiency with the infusion pumps would be sometimes we have a problem with the availability. I don't know if that falls into this category.

Researcher: Yeah.

Participant_6: I feel sometimes we're kind of scrambling around like looking for pumps. And I work night shift, so a lot of times we don't have the ancillary staff here to put their hands on the pumps. So I would say availability can be an issue.

Researcher: Can you think of a specific instance where that happened?

Participant_6: We very often need triple channel pumps for our patients. I work in labor and delivery, and whenever we hang more than one of any – if we hang Pitocin, we need to have a triple channel and there have been times where I will go need to hang this medicine on my patient and the doctor is waiting and feeling impatient. I'm feeling frustrated and I go into the room to start this medicine and I have the single channel pump and we maybe have a full census and I can't right then put my hands on the triple channel and I can't for safety reasons start this medicine on this single channel pump. I have to have the triple channel.

Researcher: Okay.

Participant_6: So I can think of probably a handful of times that that's happened and then I'm having to leave the patient's bedside and go and either try to go to other rooms and get and clean a pump myself, or walk over to the operating room to central sterile to find the pump, or even call the nursing supervisor which causes a delay for the patient's care, and just a bump in the road for the night, and causes the doctor to feel frustrated and me to feel frustrated.

Researcher: Oh, okay.

Participant_6: Let's see – effectiveness. Sometimes I feel – I can think of specific examples where –

Researcher: Well this is about inefficiency.

Participant_6: Oh, inefficiency. Well this would be inefficiency actually.

Researcher: Okay.

Participant_6: Where especially when it comes to your secondary, your antibiotic that you hang, I feel that sometimes the pump can be inefficient. It doesn't pick up very well on user error.

Researcher: Okay.

Participant_6: Because you can hang the medication and forget to unclamp it and the pump does not pick up on – is this along this?

Okay.

The pump doesn't pick up that you forgot to unclamp, and you can come back an hour or two or three hours later and realize that a very important antibiotic hasn't infused. I feel – I wish sometimes that the pump had the ability to pick up on – cause sometimes you're busy.

And then these pumps – the particular Baxter pumps that we're using right now I feel can be inefficient sometimes because they're very specific with the way in which you hang your bigger fluid and your smaller fluid. It works by gravity and it can be very specific to how you hang it. And if you don't hang it lower, then it won't pull from the smaller, from the secondary.

Researcher: Can you think of a particular instance where that happened with a patient?

Participant_6: It's been awhile since that. There have been, you know, probably in all the years that I've been a nurse, which has been twelve years, maybe two times I've come back or have walked in upon another nurse and their medication has not infused.

Researcher: Okay.

Participant_6: Maybe two or three specific examples I can think of all along those same lines.

Researcher: Okay. Anything else about inefficiency?

Participant_6: I feel that possibly sometimes I think the pumps can cause you to be inefficient because they don't have very distinctive alarms on them. Sometimes you can save yourself steps if you can hear the audible alarm and you know that that means your fluid is out or that means that it's occluded. You know, sometimes you go to the room to troubleshoot the problem, and then you have to come out to get another liter when really it's only an empty. So sometimes – our PCA pumps have very specific alarms. Like you can tell when it's empty, so you kind of can save a lot of time and energy and effort by having more distinctive audible alarms. I think that can cause some inefficiency sometimes.

Researcher: Can you think of a specific instance where the alarm was a problem when you were working?

Participant_6: No.

Researcher: Okay. Thank you.

Participant_6: You're welcome.

Researcher: The next one is about job satisfaction and infusion pumps. So again, just try to keep the story as conversational as possible to try to include the who, the what, the why, the when, the how.

Participant_6: Okay.

Researcher: So something where your use of the infusion pump positively affected your job positively.

Participant_6: Okay. I feel everyday that the infusion pump positively satisfies me and keeps me satisfied in my job. I get a comfort level from having the pump. And we've talked before where it wasn't ever the standard, you know, to really have pumps unless you had a patient that had heart problems. But I say everyday I have a certain – I feel very comfortable using the pumps. I feel very satisfied when there are plenty of them and I don't have to go running around trying to find them and clean them. I feel happy that it helps deliver safe medication to the patient, and especially we have babies on our unit that have IVs, and I have a lot of comfort in them. That makes me feel very happy that we have the pumps to use for our babies.

Researcher: Can you think of a particular instance at work where your use of the infusion pump made you satisfied? Like a situation or scenario?

Participant_6: I can think of a particular scenario where we had, you know, a more critical patient that was having some blood pressure issues, so she was on Magnesium Sulfate for her blood pressure. And she also was a diabetic

and was on Insulin for her diabetes, so it was very, very important that I had a high functioning pump to help control her medication and it helped me stay very organized and take much better care of her, because the pump was a three channel pump and I could control her fluid volume and I could very, very specifically titrate the dose of medication that I gave her.

Researcher: Okay.

Participant_6: And that made me feel very satisfied and I felt at the end of the day like I did a really good job.

Researcher: Okay.

Participant_6: And the pump allows you to give very, very minute like 12.5, or whatever, cc's an hour and so I felt like I knew exactly what I was giving, and I felt that I gave her good care at the end of the day and that a large part because of the IV pump.

Researcher: Okay. Great. Next one is about errors and infusion pumps. So perhaps, an instance where you nearly made an error, you made an error, or you heard about someone else making an error while using an IV pump.

Participant_6: I'm trying to think if this is a pump issue. We – I don't know if this really relates, but when we give Pitocin to induce a patient's labor, the dose we give is in milliunits and it used to be – this was more a pharmacy issue – the way the medicine was diluted, we had to come up with a conversion in our head.

Researcher: Okay.

Participant_6: That if we wanted to give two milliunits of Pitocin, we had to start it at 12mm an hour.

Researcher: Okay.

Participant_6: I don't know if this is really IV, but we now have it to where the ratio is 1:1. 1 milliunit equals 1 milliliter, so we don't really have to – but that's not really an infusion pump. That's more of like what we troubleshoot on the pharmacy end.

Researcher: So now you no longer have to do that?

Participant_6: We don't have to do the conversion. It's like just a 1:1 ratio and so I think that's more of a thing –

Researcher: So can you think of any other type of –

Participant_6: Some errors that I can think of maybe that I've made the mistake before is if I've been in a hurry, you can program on the pump your rate or your volume to be infused, and I have made a specific mistake before where maybe the volume is 200, but I accidentally set the rate for 200.

Researcher: Okay.

Participant_6: But I mean that is a possible mistake to make on the pump.

Researcher: And when do you notice that you've made that kind of mistake?

Participant_6: When it's all infused and half the time. Or you know, if it's gone in too fast. Sometimes if you infuse things too quickly, the patient can feel discomfort at their IV site.

Researcher: Okay. So do they complain about that?

Participant_6: Yeah, they might complain about that and that might cause you to pay closer attention. And then again, the error with the hanging the antibiotic and forgetting to unclamp it. Forgetting to hit secondary and then you come back and you're medicine hasn't gone in. I can think of a couple of specific examples where that's happened to myself or other nurses.

Researcher: Okay. Can you describe that particular instance? Like what was happening that day and –

Participant_6: The patient just would maybe – I can think of a patient that had a post-op infection and had to have, you know, a couple of different antibiotics to heal the infection. I went in and hung the antibiotic and selected at the end of me hanging it and hooking it up, I hit back to primary and did not hit to secondary. Or a second example is just did not simply unroll the roller clamp and the antibiotic did not go in. One occasion I can think of, I realized it was in thirty minutes and then I just fixed it. Another occasion, you know, maybe two or three hours past by and the patient missed a dose.

Researcher: Okay.

Participant_6: And there's probably been three or four times where I've come on after a nurse and their medication hasn't infused for the same scenario.

Researcher: Okay, so kind of like after a shift change in a unit?

Participant_6: Yeah. Shift change. You go in to round on your patient and you look up and the whole bag is full.

Researcher: Okay.

Participant_6: And sometimes – I guess this would go along the line of errors – is neglecting to plug it in. And then if you have a battery failure, then that can cause your medication to not go in. I mean I can think of multiple times where somebody hasn't plugged in the IV pump and then the whole thing is just completely shut down, and then you have to manually release your tubing and it makes a really loud racket and then you have to find another pump.

Researcher: Okay. Can you think of a particular instance with a patient where you had that problem with a battery?

Participant_6: Maybe one or two times where the battery is like severely depleted and then it'll alarm low battery, but then it doesn't give you much warning, or it didn't give you much warning and then all of a sudden, it just was like system failure and the whole pump shut off. But then you're tubing – the pump has to be on in order to get your tubing out. Otherwise you have to do this thing on the side where you twist it, and if you don't realize it, then the patient won't be getting any medication which could also affect their IV site. In this instance, the pump went out. I realized it and remedied it. Got another pump. But I guess it could – your IV could clot off. It could ruin the IV site if you didn't realize it if no fluid was infusing.

Researcher: Okay. Thank you.

The next one is about efficiency in infusion pumps. So an instance where you felt that your use of an infusion pump was efficient in that particular scenario.

Participant_6: Okay. I had a patient that was in labor – came in in active labor and wanted her epidural. And one of the criteria for epidurals is that they have to have a whole liter of IV fluid before they can have it so they can get the IV bolus. And sometimes, or often, we'll just run it by gravity so it'll go in quickly. The patient was

very uncomfortable and restless in the bed and was hurting, and her IV was in place, and with her position, the IV was not flowing but gravity. So in that instance, I put it on the pump and could run in a whole liter of fluid and vary – you know, you could set it at 9 – I set it at 999 and it ran in very quickly over an hour, which is safe for our patients and then therefore got her epidural in a more timely manner which made her happy and made me more efficient.

Researcher: That's great. Can you think of any other scenarios or stories?

Participant_6: Can I use the same?

Researcher: Sure.

Participant_6: Okay, back to the patient who was on the Magnesium for her blood pressure and the Insulin for her diabetes. Having a triple chamber pump made me very efficient that day. I could keep up with what was where and it helped me keep up with my medications and the rates. And then it also helps you keep up with the amount of fluid that has infused. It keeps you very accurate, which is much safer for the patients. So that day it made me more efficient.

Researcher: Okay.

Participant_6: I guess that's all.

Researcher: Okay. Great.

The next one is about stress and infusion pumps. So a particular situation where you felt a little stressed or frustrated while using it.

Participant_6: Sometimes, you know, when we have our patients that are in labor, we're dealing with the mom and then the baby, so we've got two patients that we have to worry about. And when things get stressful, you need to be able to act quickly. So there has been a time where I felt like I've been a step ahead of the IV pump and I've needed to do something even quicker than the IV pump would let me just with the loading or unloading of the tubing. So that has caused me stress before.

Researcher: Okay.

Participant_6: If, you know, in a particular instance where the baby was having distress and it was like an emergency C-section situation, and I just felt like I was a step ahead and it just made me feel stressed toward the pump.

Researcher: Oh okay. So did you use the pump in that situation? Or did you decide not to use it?

Participant_6: I guess I was taking the patient off the pump.

Researcher: Okay.

Participant_6: So I was not needing it anymore. I was like trying to stop it and unload the tubing and I was just a little bit quicker.

Researcher: Okay.

Participant_6: But it didn't have an action that caused me stress. Back to the instance where my antibiotic didn't infuse, if we don't give our patient our medications, that from a nursing standpoint makes you feel very stressed if they miss a dose. And also as a responsible nurse, you need to report that in an occurrence reporting setting, so you're actually kind of writing yourself up that your patient didn't get your medication. So there has been a time before where I haven't infused or I had to do a report on another nurse based on the patient not receiving their medication. And that has caused me stress.

Researcher: Okay, so like from the shift change –

Participant_6: Yeah. The shift change thing. Uh hum.

Researcher: Then it's your responsibility –

Participant_6: Yeah. This was supposed to go on four or five hours ago and it didn't. Then the patient in fact missed a dose, which isn't good. So that's had to be reported and it makes you feel uncomfortable and stressed.

Researcher: And does that affect your kind of relationship with your co-workers?

Participant_6: No, not really. It ends up, you know – it's all kind of – usually you verbally kind of approach that it didn't infuse and then people understand what the rules are. And it's all confidential anyways, so if you didn't verbally report – if you didn't tell them – and we here at this hospital have a non-punative approach to any kind of medication errors, so no one really gets in trouble. They just try to troubleshoot what the problem was.

Researcher: Okay.

Participant_6: Stress. Let me think about that. Of course back to the instance where I had to find, you know, we didn't have enough pumps. That caused me stress, cause when you don't have enough time, you know, and you're trying to find the pump so you can take care of your patient, that causes me a lot of stress.

Researcher: Okay. Can you think of a particular situation you had where time was a factor?

Participant_6: Well, where the patient – the doctor's kind of tapping his foot with that one patient who's ready to start the Pitocin and then I didn't have the right pump and I kind of had to go find, and he's ready for it to be started thirty minutes ago and there's a delay.

Researcher: Okay.

Participant_6: And that makes you feel under stress. I can't think of anything else under this category.

Researcher: Okay. So the next one is about successful patient treatment and infusion pumps. So an instance that – either real or hypothetical – where you felt that using an infusion pump allowed you to give successful treatment to a particular patient.

Participant_6: Okay. I would say every patient that I have that we have to give Pitocin on in order to get their baby here, that I feel a very much sense of accomplishment at the end of the day when their baby is here and we've used the IV pump to titrate their Pitocin, cause it's all day long you're working with the IV pump to get the right dosage for that patient. So it gives you a huge sense of success when the baby gets here safely and it's all really because of the IV pump. I couldn't imagine a day where you just kind of fiddled with it without an IV pump. So I feel success every day with that.

Researcher: Is there one situation that stands out more than another? Any particular patient or situation where –

Participant_6: No. I just feel every – I mean, I feel like I'm using the same examples all the time, but I could think of different times where we've had patients who were on Magnesium for blood pressure issues, or Magnesium for – I can think of a patient that we had recently that was in preterm labor. Like her baby was trying to come too soon and we put her on Magnesium for preterm labor. And again, it's a very _____. You know, you have to have a very specific dose that works differently for each patient. So we kind of were fiddling, particularly with her, all night long with the

right dose for her, and when we left in the morning, she was still – her baby did not come. And without that very specific IV titration of that dosage, the outcome might have been different.

Researcher: Okay.

Participant_6: And then – or the patient that I used earlier that was on the Magnesium and the Insulin, at the end of that day I felt a huge feeling of success that I kept her safe and the baby safe and it had a good outcome.

Researcher: Okay.

Participant_6: And I don't feel like it would have been if I was kind of winging it without an IV pump.

Researcher: Okay.

Participant_6: I don't know what we did in those days. *[Laughing]* I can't think of anything really very specific.

Researcher: Okay. Well just in general, if you can think of anything else.

Participant_6: Okay. I can think of a specific example where we've had to give a blood transfusion for a patient that was declining.

Researcher: Uh hum.

Participant_6: And the IV pump helps you give the blood in a safe and controlled manner.

Researcher: Okay.

Participant_6: And in a timely manner to help the patient.

Researcher: Okay.

Participant_6: And I can think of a specific example where that caused, you know, helped us have a successful patient outcome. That made me feel satisfied.

Researcher: Okay.

Participant_6: We use a different – it's a Baxter. We have a syringe pump. I don't know if that falls into your criteria. We use it to give antibiotics to babies.

Researcher: Okay.

Participant_6: Is that something you're interested in hearing about?

Researcher: Sure. I'll hear about anything.

Participant_6: We've always, until like the last two years, whenever we have to give an antibiotic to a baby, we would have it in a syringe, and a lot of antibiotics have to go in over thirty minutes to an hour, and we would just kind of go in the room and give a little bit. Come back out. Go in the room five or ten minutes later and give a little bit. And we have gotten a Baxter syringe

pump, which holds the syringe. And you hook it into your tubing, and it seems so far pretty much to be error proof. I mean, we don't have any of the same issued with the other Baxter pump where we piggy back the tubing in for the antibiotics.

Researcher: Okay.

Participant_6: But this gives very controlled amounts of fluid to the baby, and all you do is have to hook the syringe into the pump and then it gives the medication timely. So we've – and it has helped with time management, because we're not having to run back and forth. So that's been very successful – this new syringe pump that we've gotten within the last two years.

Researcher: Okay. Now as far as the control of the medication, is that as important for the mother as for the baby?

Participant_6: Certain things have to infuse over a certain period of time. I would say no, it's not. It depends on what it is.

Researcher: Okay.

Participant_6: But if you're giving Gentomycin or something to the baby, then it's very important that you deliver it – I mean, if something were to malfunction – you were to give the baby a large amount – it could cause them to be deaf. You know, you have to be very careful with the toxicity.

Researcher: Okay.

Participant_6: But, that is also a risk with any adult too, but it's much less – you know, it would take a much larger amount to cause the same damage.

Researcher: Okay.

Participant_6: So I think that's helped us be successful with our treatment.

Researcher: Okay. Any other thoughts?

Participant_6: I can't think of anything.

Researcher: Okay. That's the end.

Participant_6: That's the end? I feel like I'm using the same. It's hard to be really specific. Especially when you've been a nurse for awhile, it's like, Oh God, I could think of a million. I'll go home and think of a million examples.

Researcher: Okay. *[Laughing]*

[End of Audio]

Appendix C: Data Coding Materials

C.1 Data Coding Instructions

CODING INSTRUCTIONS:

Thank you for your participation in this research study. Please read below for information to guide your coding process. Your assistance in this project consists of the following steps:

1) Code individual transcripts using thematic analysis
2) Reconcile your coding results with other coder
3) Assign identified themes to existing requirements categories
4) Create excel spreadsheet of category counts
    a. Per participant
    b. Per focus group
    c. Total

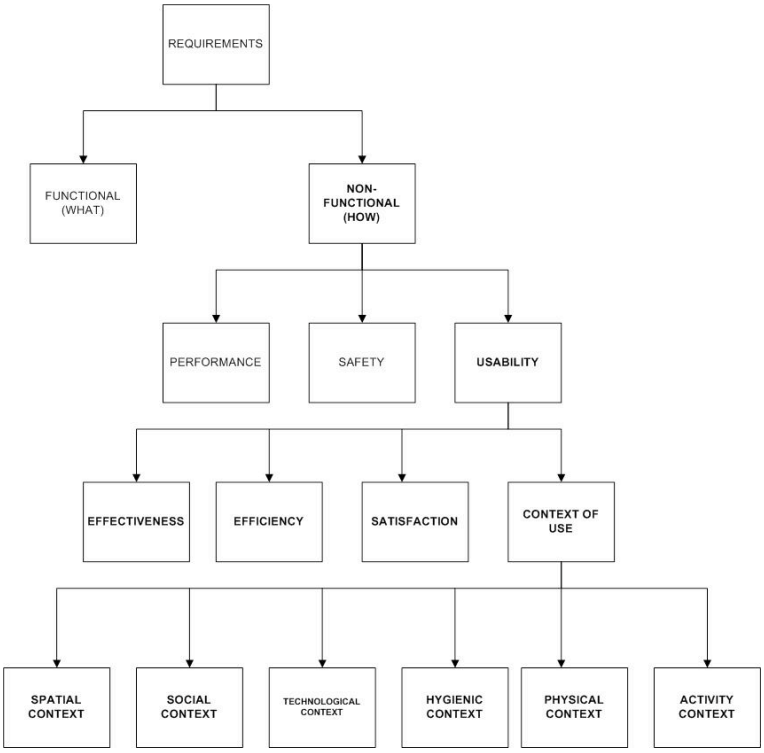
Note:

Coding is an iterative process. Whenever you identify a new theme, you must go back to all previously coded transcripts and code for that theme. For example, if on transcript #6, you discover a new theme (eg, "pressure from management"), you must go back to all previously coded transcripts (1-5) to see if you can apply that code to any participant statements in those transcripts.

Scenario:

You are a requirements engineer for a medical device company. Your company, which has already designed, manufactured, and marketed several successful products, is interested in including infusion pumps used in a hospital setting in the company's product offering. Following recommendations for conducting user research as the first step of device development in ANSI/AAMI HE74:2001, the company conducted focus groups, individual interviews, and individual storytelling sessions to gather initial user needs for an infusion pump. You have the transcripts of all of these sessions and your boss has asked you to categorize statements in the transcripts into requirements categories as the first step of analysis. To do this categorization you will use Atlas TI software. Atlas TI software is located in 536E Whittemore Hall.

You will be coding transcripts looking for themes that relate to usability. The overall goal of the coding is to take the identified themes and associate them with existing requirements categories as shown below. So look over the definitions of requirements themes (at the end of the document) and keep these in you mind as you identify themes in the transcripts. Since safety might also impact usability be sure to consider those topics in your coding.



Usability themes
- Efficiency themes
- Effectiveness themes
- Satisfaction themes
- Context-of-use themes
  - Spatial context
  - Social context
  - Technological context
  - Hygienic context
  - Physical context
  - Activity context

Infusion pump definition:
"Infusion pumps regulate the volume and rate of fluid or medication delivered to the patient and notify care providers of events or problems in the process. Depending on where the system boundaries are drawn, other system elements might include the care providers who use the device, the patient, patient visitors, other patients, environment (which is relevant to device design because of issues such as illumination and noise level)….The boundaries of the system might include the prescribing physician, the pharmacy, the transcriptionist, other hospital personnel (e.g., aides, bioengineers, maintenance personnel, technicians), hospital administrative procedures, the social and cultural environment of the people in the system, and the cultural environment of the hospital. One might even include other device manufacturers and the

services they provide, the patient's visitors, the drug manufacturers, because their products and actions affect or define system elements" (ANSI/AAMI, 2001).

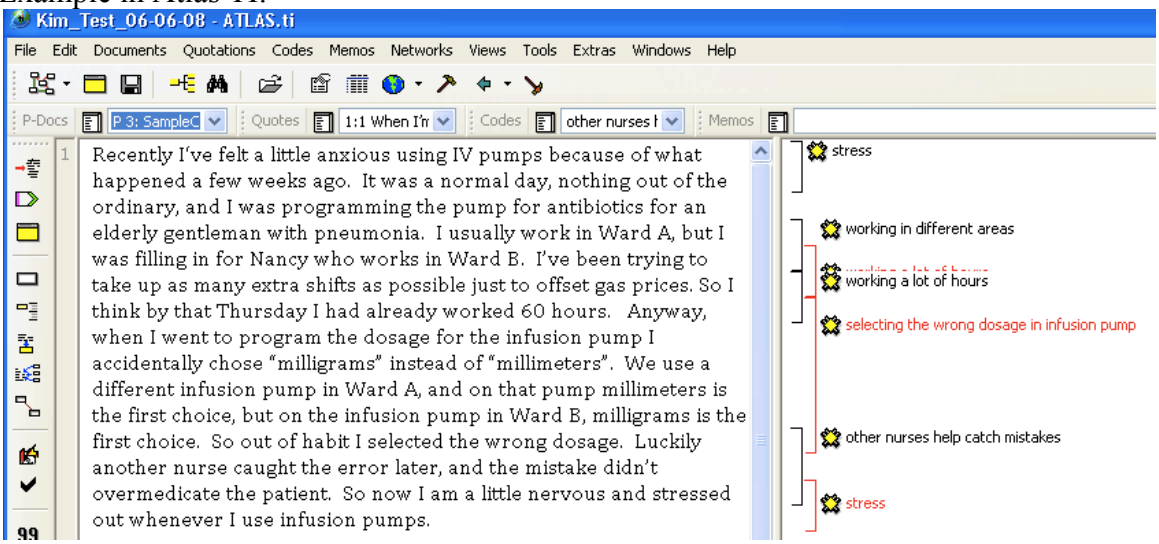
TO GET STARTED:

- Read over thematic analysis section from Gribch (handout)
- Familiarize yourself with the Atlas TI software.
    - Manual is available at http://www.atlasti.com/downloads/atlman.pdf ; See me if you would like a printed version.
    - I am new to Atlas Ti myself, but it seems we will mainly be using:
        - Hermetic unit (fancy name for project)
        - Assign document (how you load a transcript into the project)
        - Open coding (right click on a sentence and then type the code in)
        - Code by list (choose an already existing code)
        - Code manager (view the codes)
    - You can also download a free trial of Atlas TI from http://www.atlasti.com/

EXAMPLES:
EXAMPLE TRANSCRIPT1:
Recently I've felt a little anxious using IV pumps because of what happened a few weeks ago. It was a normal day, nothing out of the ordinary, and I was programming the pump for antibiotics for an elderly gentleman with pneumonia. I usually work in Ward A, but I was filling in for Nancy who works in Ward B. I've been trying to take up as many extra shifts as possible just to offset gas prices. So I think by that Thursday I had already worked 60 hours. Anyway, when I went to program the dosage for the infusion pump I accidentally chose "milligrams" instead of "millimeters". We use a different infusion pump in Ward A, and on that pump millimeters is the first choice, but on the infusion pump in Ward B, milligrams is the first choice. So out of habit I selected the wrong dosage. Luckily another nurse caught the error later, and the mistake didn't overmedicate the patient. So now I am a little nervous and stressed out whenever I use infusion pumps.
So by using the block & file coding approach, the following themes might be identified.

THEME	**stress**	**Working in different areas**	**Working a lot of hours**	**Selecting the wrong dosage in infusion pump**	**Other nurses help catch mistakes**
PARTICIPANT STATEMENT	Recently I‘ve felt a little anxious using IV pumps because of what happened a few weeks ago. So now I am a little nervous and stressed out whenever I use infusion pumps.	I usually work in Ward A, but I was filling in for Nancy who works in Ward B.	So I think by that Thursday I had already worked 60 hours. I’ve been trying to take up as many extra shifts as possible just to offset gas prices.	Anyway, when I went to program the dosage for the infusion pump I accidentally chose “milligrams” instead of “millimeters”. We use a different infusion pump in Ward A, and on that pump millimeters is the first choice, but on the infusion pump in Ward B, milligrams is the first choice. So out of habit I selected the wrong dosage.	Luckily another nurse caught the error later, and the mistake didn’t overmedicate the patient.

Example in Atlas TI:



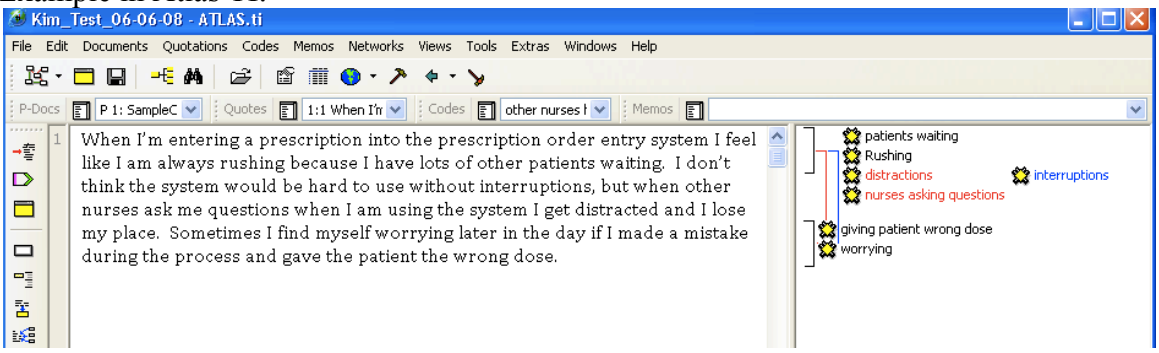
Now if we were to apply these themes to Requirements Ontology, our categorization might be:
Stress: USABILITY, SATISFACTION
Working in different areas: USABILITY, CONTEXT, SPATIAL CONTEXT:
Working a lot of hours: USABILITY, CONTEXT, ACTIVITY CONTEXT:
Selecting the wrong dosage in infusion pump: USABILITY, EFFECTIVENESS
Other nurses help catch mistakes: USABILITY, CONTEXT, SOCIAL CONTEXT

Note that a theme can fall in more than one category. Also, if a theme falls in in a subcategory (eg, social context) it also falls in the parent categories (context, usability)
//
EXAMPLE 2:
¨When I'm entering a prescription into the prescription order entry system I feel like I am always rushing because I have lots of other patients waiting. I don't think the system would be hard to use without interruptions, but when other nurses ask me questions when I am using the system I get distracted and I lose my place. Sometimes I find myself worrying later in the day if I made a mistake during the process and gave the patient the wrong dose.

So coding this using block and file might reveal the following themes:

THEMES	rushing	Patients waiting	Interruptions from other nurses
PARTICIPANT STATEMENT	When I'm entering a prescription into the prescription order entry system I feel like I am always rushing because I have lots of other patients waiting.	When I'm entering a prescription into the prescription order entry system I feel like I am always rushing because I have lots of other patients waiting	I don't think the system would be hard to use without interruptions, but when other nurses ask me questions when I am using the system I get distracted and I lose my place.

Example in Atlas TI:



And finally, assigning these themes to the requirements categories might result in:
Rushing: USABILITY, CONTEXT, ACTIVITY CONTEXT
patients waiting: : USABILITY, CONTEXT, ACTIVITY CONTEXT
interruptions from other nurses: : USABILITY, CONTEXT, ACTIVITY CONTEXT, SOCIAL CONTEXT
worrying: USABILITY, CONTEXT, ACTIVITY CONTEXT
distractions
SOCIAL CONTEXT: nurses asking questions
EFFECTIVENESS & SAFETY: giving patient the wrong dose

DEFINITIONS OF REQUIREMENT TYPES

Requirement type	Definition	Example
Non-functional	How well the system does it (Arthur, 2007)	-performance & reliability -interface requirements -constraints (e.g., safety, security) (Arthur, 2007)
Usability	"The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use." (ISO, 1998)	
Effectiveness	The level of accuracy and completeness in which a user is able to satisfy the goals (ISO, 1998)	
Efficiency	Amount of resources used to achieve the goals (ISO, 1998)	
Satisfaction	User's perceived comfort level and acceptability of the product while working towards the goals (ISO, 1998)	
Context-of-use	Overall ambience and environment of user's work (Hix & Hartson, 2006) user characteristics, tasks, equipment, and a physical and social environment in which a product is used (ISO, 1999)	
Spatial context		-architecture: type of

		building and location in the building, e.g., hospital (e.g., ward, operating theatre, intensive care unit), office, cinema, home, -outdoors -patient transport (e.g., airplane, ship, ambulance, car) -smoothness and inclination of floor -location of emergency or accident (IEC, 2007)
Social context		-organization -transition of care (e.g., requirement to receive / forward inputs / outputs for the medical device at change of users -presence of: unattended children; untrained or curious adults -responsibility (e.g., shared, alone) (IEC, 2007)
Technological context		-other technological devices which are required for the use of the medical device -other technical devices which might influence the use of the medical device -effect of other devices on the medical device

		(IEC, 2007)
Hygienic context		-requirements for cleanliness, sterile conditions -facilities for cleaning -facilities for waste disposal (IEC, 2007)
Physical context		-climate conditions (e.g., altitude, ambient pressure, temperature, humidity, precipitation, wind) -acceleration, movement of frame of reference (e.g., car, ship) -light level -ambient noise (IEC, 2007)
Activity context		-distractions -other tasks which can interfere with the operation of the medical device -surprise/startle effect -strain and stress -influence on the working environment (e.g., inability to communicate with the patient over the noise of MRI equipment) -alterations of the work environment that could affect other medical devices (e.g., low general lighting during ophthalmic surgery)

		-workload and fatigue (e.g., the effects of shift work, such as cognitive degradation, on task performance) (IEC, 2007)

WORKING WITH ATLAS TI –

CODING THE DOCUMENT

-each transcript should be it's own Hermeneutic Unit (eg, separate project file)

STEP 1: CREATE HERMENEUTIC UNIT

File->New Hermeneutic Unit (save the file as the same as the transcript, eg. P1_Interview)

STEP 2: LOAD THE TRANSCRIPT FILE

Document->Assign->Select file->Open

STEP 3: VIEW THE TRANSCRIPT FILE

I'm not sure why, but you need to select the file in the dropdown within Atlas TI to view it. (the dropdown at the left-hand side of the screen)

STEP 4: READ & CODE:

-NOTE: Only code the Participant's responses, not the Researchers. However, the researcher's questions (eg, tell me about efficiency) will help with the coding.

NOTE: The smallest possible quotation for a code is a full sentence.

NOTE: When getting started you'll mainly use free codes (CTRL SHIFT O) but once you get a bunch of codes you can code by list (CTRL SHIFT L)

TO CODE:

Highlight the quotation (should be at least 1 sentence long) -> Codes->Coding->Open Coding ->type the code(s)

OR

Highlight the quotation (should be at least 1 sentence long) -> Codes->Coding->code by list ->select the code(s)

ASSIGNING THEMES TO REQUIREMENTS CATEGORIES

STEP 1: CREATE FAMILIES FOR THE REQUIREMENT CATEGORIES

CODES->Edit Families->Open family manager->Create a new family

-create families for: usability, efficiency, effectiveness. Satisfaction, cotext, spatial context, social context, technological context, hygienic context, physical context, activity context.

STEP 2: GO THROUGH TRANSCRIPT AND SELECT EACH CODE INDIVIDUALLY.

Highlight code with mouse/cursor->Codes->Edit Families->Assign families->choose the categories you think that excerpt fits into and click OK. You will only be able to see categories that haven't yet been assigned to that code.

STEP 3: EXPORT FAMILY INFORMATION TO EXCEL

Codes->Edit Families->Open Family Manager

Families->Output all families->Editor
Copy & paste information into the appropriate worksheet (eg, Focus_Group_1) in the provided Excel files following the example worksheet

STEP 4: PROCEED WITH NEXT TRANSCRIPT
You can re-use the list of codes you created in the previous transcript:
Go to original transcript: Code->Export-->selected codes XML (be sure to select all codes)
In the hermeneutic unit for the other transcript, go to the Code->Import Codes (XML)

C.2 Data Coding Judge Instructions

Thank you for agreeing to act as the data coding judge for this research project. Some quick background:

- The data for this research project consists of 12 transcripts (2 focus groups, 5 interviews, and 5 storytelling sessions).
- 2 independent data coders (an ISE graduate student and the primary researcher) have read the information about thematic analysis and have used the data coding instructions to code the transcripts into usability themes. Each data coder also independently associated these themes into the appropriate requirement categories. A theme can be associated with more than one category
- The role of the data coding judge is to reconcile the data coding results. For each transcript, the data coders identified themes which overlap. However, the data coders each identified themes that the other data coder did not identify. For each theme that was not identified by both coders, your role is to hear the coder's argument for inclusion of the theme and to judge if it should be included, excluded, or combined into another theme.
- You are the final deciding authority. Rely on your expertise in requirements and usability engineering while making decisions.

In preparation for the meeting on 11/08:

- Read the thematic analysis handout
- Read the data coding instructions
- Read and familiarize yourself with the transcripts

What to expect during the meeting:

- The data coding results for each transcript will be compiled into separate Excel worksheets. Overlapping themes will have already been identified. Themes up for debate will be identified
- Each coder will be limited to 2 minutes to present their argument about the theme. The coders' Atlas TI files, which contain their individual coding, will be displayed on the overhead so it will be easy to locate participant quotations which relate to themes.
- You will update the master excel file on your computer to either exclude, include or combine the theme with another.

C.3 Reconciliation Meeting Instructions

Data Coding Meeting Agenda 11/08/08

Thank you for your help with this research project! Here's a quick overview for the day:

9AM – 9:30	Set-up and overview
9:30 -11	Compilation
11-11:15	Break
11:15-1PM	Compilation
1PM-1:30PM	Lunch (pizza?)
1:30PM-3:30PM	Compilation
3:30-3:45PM	Break
3:45-5:45	Compilation

1. Review Data Coding Instructions, Checklist, & Requirements Ontology
2. Procedure for the day
    a. Themes need to be compiled for 12 transcripts. Each transcript has its own worksheet in an Excel file.
        i. Excel file (Coding_to_be_judged.xlx)
            1. Judge
                a. This is YOUR working file. To include a theme, simply **bold** the theme. If you choose not to include the theme, do nothing to it.
                b. You are also free to move themes to different categories as you see fit and based on the arguments of the coders. Be sure to bold the theme after moving it to the desired category
                c. You do not need to show your decisions to the coders
                d. Be sure to SAVE OFTEN
            2. Coders
                a. Use this file to follow along
    b. The files will be done in the following random order. Each coder will take turns starting first. For example, for P8, Kim starts first for all categories.
        - P8_STORY (kim starts)
        - FG1 (sudipto starts)
        - FG2 (kim starts)
        - P10_STORY (sudipto starts)
        - P2_INTERVIEW (kim starts)
        - P5_INTERVIEW (sudipto starts)
        - P7_STORY (kim starts)
        - P6_STORY (sudipto starts)
        - P3_INTERVIEW (kim starts)
        - P1_INTERVIEW (sudipto starts)
        - P9_STORY (kim starts)
        - P4_INTERVIEW (sudipto starts)

3. Procedure for presenting each identified theme (that you found & the other coder did not)
    a. Original Coder Presentation
        i. Pull up on Atlas TI where you found the theme
        ii. Talk BRIEFLY about why you think the theme exists and why you assigned it to the category. You will be limited to 2 minutes
    b. Other Coder Rebuttal
        i. State why you think the theme does / does not exist and what category you think it should belong in. You are limited to 1 minute
        ii. Groundrule: No disrespect to other coder or judge if they do not agree with you
    c. Judge makes decision privately in Excel spreadsheet
        i. Keep in mind:
            1. Data coding instructions
            2. Checklist

Appendix D: Detailed Analysis Outputs

D.1 RQ1 t-test

Hypothesis 1a – USABILITY

```
/*first test for normality*/
proc univariate
var USABILITY;
where GROUP=1;
run;
```

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.948417	Pr < W		0.7259
Kolmogorov-Smirnov	D	0.17888	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.031262	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.209378	Pr > A-Sq		>0.2500

```
proc univariate
var USABILITY;
where GROUP=2;
run;
```

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.933906	Pr < W		0.6232
Kolmogorov-Smirnov	D	0.276424	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.056849	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.313611	Pr > A-Sq		>0.2500

```
/*the data is normal since cannot reject null hypothesis for either group */
proc ttest data=RQ1;
 var USABILITY;
 class group;
 run;
```

Method	Variances	DF	t Value	Pr > |t|	
Pooled	Equal	8	0.71		0.4995
Satterthwaite	Unequal	7.5726	0.71		0.5006

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	1.62	0.6504

```
proc means;
 var USABILITY;
 class group;
 run;
```

The MEANS Procedure

Analysis Variable : USABILITY

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	231.8000000	13.2740348	214.0000000	246.0000000
2	5	5	225.0000000	16.9115345	204.0000000	251.0000000

Hypothesis 1b - EFFICIENCY

```
/*first test for normality*/
proc univariate
var EFFICIENCY;
where GROUP=1;
run;
```

```
Tests for Normality

                    Test                 --Statistic---    -----p Value------

                    Shapiro-Wilk         W     0.766717    Pr < W      0.0422
                    Kolmogorov-Smirnov   D      0.36025    Pr > D      0.0317
                    Cramer-von Mises     W-Sq  0.111643    Pr > W-Sq   0.0573
                    Anderson-Darling     A-Sq  0.618582    Pr > A-Sq   0.0469
```

```
proc univariate
var EFFICIENCY;
where GROUP=2;
run;
```

```
Tests for Normality

                    Test                 --Statistic---    -----p Value------

                    Shapiro-Wilk         W     0.971783    Pr < W      0.8866
                    Kolmogorov-Smirnov   D     0.212452    Pr > D     >0.1500
                    Cramer-von Mises     W-Sq  0.035528    Pr > W-Sq  >0.2500
                    Anderson-Darling     A-Sq  0.219082    Pr > A-Sq  >0.2500
```

```
/*distribution for group 1 is not normal since we can reject the null hypothesis for the Shapiro-
Wilk test*/
proc npar1way data=RQ1;
 var EFFICIENCY;
 class group;
 run;
```

```
Wilcoxon Two-Sample Test

                                    Statistic             35.0000

                                    Normal Approximation
                                    Z                      1.4803
                                    One-Sided Pr >  Z      0.0694
                                    Two-Sided Pr > |Z|     0.1388

                                    t Approximation
                                    One-Sided Pr >  Z      0.0865
                                    Two-Sided Pr > |Z|     0.1729

                                Z includes a continuity correction of 0.5.
```

Kruskal-Wallis Test

Chi-Square	2.5155
DF	1
Pr > Chi-Square	0.1127

The MEANS Procedure

Analysis Variable : EFFICIENCY

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	54.0000000	1.4142136	53.0000000	56.0000000
2	5	5	50.4000000	7.2318739	41.0000000	61.0000000

Hypothesis 1c – EFFECTIVENESS

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.992342	Pr < W	0.9872
Kolmogorov-Smirnov	D	0.130251	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.01846	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.141313	Pr > A-Sq	>0.2500

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.928264	Pr < W	0.5846
Kolmogorov-Smirnov	D	0.2342	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.043332	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.260414	Pr > A-Sq	>0.2500

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	8	1.57	0.1561
Satterthwaite	Unequal	5.5385	1.57	0.1726

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	5.00	0.1481

The MEANS Procedure

Analysis Variable : EFFECTIVENESS

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	57.0000000	6.5192024	49.0000000	66.0000000
2	5	5	52.0000000	2.9154759	49.0000000	56.0000000

Hypothesis 1d – SATISFACTION

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.962078	Pr < W		0.8224
Kolmogorov-Smirnov	D	0.170008	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.028413	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.200453	Pr > A-Sq		>0.2500

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.929947	Pr < W		0.5960
Kolmogorov-Smirnov	D	0.267067	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.060507	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.327889	Pr > A-Sq		>0.2500

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	8	1.57	0.1557
Satterthwaite	Unequal	5.4668	1.57	0.1729

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	5.26	0.1366

The MEANS Procedure

Analysis Variable : SATISFACTION

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	105.6000000	4.2190046	101.0000000	112.0000000
2	5	5	98.2000000	9.6798760	86.0000000	113.0000000

Hypothesis 1e – CONTEXT-OF-USE

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.960034	Pr < W	0.8082
Kolmogorov-Smirnov	D	0.157317	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.027958	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.199315	Pr > A-Sq	>0.2500

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.975418	Pr < W	0.9087
Kolmogorov-Smirnov	D	0.188536	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.03038	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.189898	Pr > A-Sq	>0.2500

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	8	-0.14	0.8907
Satterthwaite	Unequal	7.732	-0.14	0.8908

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	1.46	0.7240

The MEANS Procedure

Analysis Variable : CONTEXT

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	112.4000000	9.7108187	102.0000000	127.0000000
2	5	5	113.2000000	8.0436310	103.0000000	124.0000000

Hypothesis 1f – SPATIAL

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.778659	Pr < W		0.0537
Kolmogorov-Smirnov	D	0.348438	Pr > D		0.0445
Cramer-von Mises	W-Sq	0.105975	Pr > W-Sq		0.0714
Anderson-Darling	A-Sq	0.588343	Pr > A-Sq		0.059

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.955627	Pr < W		0.7773
Kolmogorov-Smirnov	D	0.246369	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.04211	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.24664	Pr > A-Sq		>0.2500

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	8	-1.01	0.3420
Satterthwaite	Unequal	7.9176	-1.01	0.3423

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	1.23	0.8475

The MEANS Procedure

Analysis Variable : SPATIAL

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	13.2000000	1.6431677	12.0000000	16.0000000
2	5	5	14.2000000	1.4832397	12.0000000	16.0000000

Hypothesis 1g – SOCIAL

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.730225	Pr < W	0.0193
Kolmogorov-Smirnov	D	0.385052	Pr > D	0.0159
Cramer-von Mises	W-Sq	0.143101	Pr > W-Sq	0.0203
Anderson-Darling	A-Sq	0.746466	Pr > A-Sq	0.0201

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.896618	Pr < W	0.3915
Kolmogorov-Smirnov	D	0.281515	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.059188	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.335518	Pr > A-Sq	>0.2500

Wilcoxon Two-Sample Test

Statistic	18.0000
Normal Approximation	
Z	-1.8858
One-Sided Pr < Z	0.0297
Two-Sided Pr > |Z|	0.0593
t Approximation	
One-Sided Pr < Z	0.0460
Two-Sided Pr > |Z|	0.0920

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	3.9622
DF	1
Pr > Chi-Square	0.0465

The MEANS Procedure

Analysis Variable : SOCIAL

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	30.2000000	5.5856960	26.0000000	40.0000000
2	5	5	40.8000000	5.9329588	35.0000000	49.0000000

Hypothesis 1h – TECHNOLOGICAL

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.552182	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.47264	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.241765	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.204711	Pr > A-Sq	<0.0050

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.684029	Pr < W	0.0065
Kolmogorov-Smirnov	D	0.367396	Pr > D	0.0245
Cramer-von Mises	W-Sq	0.138317	Pr > W-Sq	0.0229
Anderson-Darling	A-Sq	0.799546	Pr > A-Sq	0.0140

Wilcoxon Two-Sample Test

Statistic	40.0000
Normal Approximation	
Z	2.6291
One-Sided Pr > Z	0.0043
Two-Sided Pr > |Z|	0.0086
t Approximation	
One-Sided Pr > Z	0.0137
Two-Sided Pr > |Z|	0.0274

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	7.5000
DF	1
Pr > Chi-Square	0.006

The MEANS Procedure

Analysis Variable : TECHNOLOGICAL

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	8.8000000	0.4472136	8.0000000	9.0000000
2	5	5	6.6000000	0.5477226	6.0000000	7.0000000

Hypothesis 1i – HYGIENIC

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.552182	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.47264	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.241765	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.204711	Pr > A-Sq	<0.0050

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.770908	Pr < W	0.0460
Kolmogorov-Smirnov	D	0.348833	Pr > D	0.0441
Cramer-von Mises	W-Sq	0.10627	Pr > W-Sq	0.0707
Anderson-Darling	A-Sq	0.602789	Pr > A-Sq	0.0519

Wilcoxon Two-Sample Test

Statistic	25.5000
Normal Approximation	
Z	-0.3873
One-Sided Pr < Z	0.3493
Two-Sided Pr > |Z|	0.6985
t Approximation	
One-Sided Pr < Z	0.3538
Two-Sided Pr > |Z|	0.7075

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.2667
DF	1
Pr > Chi-Square	0.6056

The MEANS Procedure

Analysis Variable : HYGIENIC

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	2.4000000	0.8944272	2.0000000	4.0000000
2	5	5	2.6000000	0.8944272	2.0000000	4.0000000

Hypothesis 1j – PHYSICAL

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.552182	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.47264	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.241765	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.204711	Pr > A-Sq	<0.0050

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.552182	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.47264	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.241765	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.204711	Pr > A-Sq	<0.0050

Wilcoxon Two-Sample Test

Statistic	38.0000
Normal Approximation	
Z	2.3094
One-Sided Pr > Z	0.0105
Two-Sided Pr > |Z|	0.0209
t Approximation	
One-Sided Pr > Z	0.0231
Two-Sided Pr > |Z|	0.0463

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	5.8800
DF	1
Pr > Chi-Square	0.0153

The MEANS Procedure

Analysis Variable : PHYSICAL

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	1.2000000	0.4472136	1.0000000	2.0000000
2	5	5	0.2000000	0.4472136	0	1.0000000

Hypothesis 1k – ACTIVITY

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.952351	Pr < W		0.7540
Kolmogorov-Smirnov	D	0.198391	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.030406	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.204925	Pr > A-Sq		>0.2500

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.986214	Pr < W		0.9648
Kolmogorov-Smirnov	D	0.148372	Pr > D		>0.1500
Cramer-von Mises	W-Sq	0.02126	Pr > W-Sq		>0.2500
Anderson-Darling	A-Sq	0.151274	Pr > A-Sq		>0.2500

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	8	2.45	0.0399
Satterthwaite	Unequal	7.6923	2.45	0.0411

Equality of Variances

Method	Num DF	Den DF	F Value	Pr > F
Folded F	4	4	1.50	0.7040

The MEANS Procedure

Analysis Variable : ACTIVITY

GROUP	N Obs	N	Mean	Std Dev	Minimum	Maximum
1	5	5	65.2000000	6.2209324	58.0000000	73.0000000
2	5	5	56.4000000	5.0793700	50.0000000	63.0000000

D.2 RQ2 t-test

/* this tested the breadth of (Focus Group + Interviews) vs (Focus Group + Storytelling Sessions) */

```
Tests for Normality

                  Test                 --Statistic---    -----p Value------

                  Shapiro-Wilk         W     0.552182    Pr < W      0.0001
                  Kolmogorov-Smirnov   D      0.47264    Pr > D     <0.0100
                  Cramer-von Mises     W-Sq  0.241765    Pr > W-Sq  <0.0050
                  Anderson-Darling     A-Sq  1.204711    Pr > A-Sq  <0.0050
```

```
proc npar1way data=RQ2;
 var BREADTH;
 class group;
 run;
```

```
Wilcoxon Two-Sample Test

                                   Statistic             30.0000

                                   Normal Approximation
                                   Z                      0.8000
                                   One-Sided Pr >  Z      0.2119
                                   Two-Sided Pr > |Z|     0.4237

                                   t Approximation
                                   One-Sided Pr >  Z      0.2222
                                   Two-Sided Pr > |Z|     0.4443

                              Z includes a continuity correction of 0.5.


                                        Kruskal-Wallis Test

                                   Chi-Square             1.0000
                                   DF                          1
                                   Pr > Chi-Square        0.3173
```

/* this tested the breadth of Interviews vs Storytelling Sessions) */

```
proc npar1way data=RQ2;
 var BREADTH;
 class group;
 run;
```

Wilcoxon Two-Sample Test

Statistic	29.5000
Normal Approximation	
Z	0.3402
One-Sided Pr > Z	0.3669
Two-Sided Pr > |Z|	0.7337
t Approximation	
One-Sided Pr > Z	0.3708
Two-Sided Pr > |Z|	0.7415

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.2057
DF	1
Pr > Chi-Square	0.650

D.3 RQ3 Venn diagrams to investigate depth of requirement categories

```
/*****************************************************************
 Author: Kriss Harris
 Date: 08 August 2007
 *****************************************************************/

 /* The main macro to produce the graphic */

 %macro venn( data =
          ,venn_diagram = 2 ,cutoff = > 0
          ,GroupA = Group 1
          GroupB = Group 2                                    ,
          ,out_location = C:\Venn Diagrams                    ,
          outputfilename = Venn diagram
          ,drilldownfilename = Drilldown
           );
```

D.4 RQ4 Time ANOVA

/*comparing times for focus groups, interviews, and storytelling sessions */

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.733204	Pr < W	0.0206
Kolmogorov-Smirnov	D	0.350981	Pr > D	0.0418
Cramer-von Mises	W-Sq	0.128804	Pr > W-Sq	0.0322
Anderson-Darling	A-Sq	0.69719	Pr > A-Sq	0.0268

```
proc npar1way;
 CLASS GROUP;
 run;
```

The NPAR1WAY Procedure

Analysis of Variance for Variable TIME
Classified by Variable GROUP

GROUP	N	Mean
1	2	48.150
2	5	39.360
3	5	27.980

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Among	2	673.211667	336.605833	13.9990	0.0017
Within	9	216.405000	24.045000		

/*comparing combined time per participant*/

```
proc npar1way;
 CLASS GROUP;
 run;
```

The NPAR1WAY Procedure

Analysis of Variance for Variable TIME
Classified by Variable GROUP

GROUP	N	Mean
1	5	86.760
2	5	76.880

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Among	1	244.0360	244.0360	9.0686	0.0168
Within	8	215.2800	26.9100		

Appendix E: Identified Requirement Themes

E.1 Usability Themes by Group

Group 1 only

"get in there and do it" (satisfaction)
3 channel pumps are used even when single channel not available
Always prefer to use an IV pump
CNAs (certified nurse assistant)
CNAs (certified nursing assistant) locate replacement for defective IV pump
ER ward - burning down!
ER ward is busy
Effectiveness important when giving controlled medication
IV backlighting / visibility depends on lighting in room
IV pump eliminates human error
IV pump helps with documenting what patient is getting
IV pump is efficient
IV pump is faster than manual delivery
IV pump is safer than doing it manually
IV pump more accurate than other types of delivery
IV pump not as efficient in ER
IV pump prevents you from doing what you need to do
IV pump provides false sense of security
IV pump should have less room for error (desired feature)
IV pump used in home health care (chemo)
IV pump will not turn on
IV pumps more available on floor wards
IV pumps more efficient in wards since more controlled environment
IV pumps should be smaller / less bulky
Techs locate replacement for defective IV pump
Touch system would help
You think an IV pump is working but it's not (surprise)
ability to load tubing (satisfaction)
accidental bumps can disrupt IV settings
accuracy
accuracy - regulate several medications at the same time
adult pump not used for babies
alarm-while dose is administered
alert needed for IV infiltration
alerts provide nurses time to change bag
ambulance
antibiotics infusion - pump useful
availability more in OB
average number of patients
battery charges too slowly
battery operative - increased risk
beeping only indicator
blood pressure cuffs
can't be quick & fast if pump not working
can't be quick & fast if you have to constantly reprogram
can't predict what IV pump is going to do
charting computers
check patient every hour or so
condition of patients changing
confidence low
confirmation of start (desired feature)
conflict between wards due to pump availability
confused nurse
control - more control over the process by user
crash cart
database for medication
defibrillators
delivering safe levels of medication
demands of doctors
different dosage required for different people
different patient scenarios in different wards
different patient tolerances for medication error
difficult to scroll using tiny touch pad (satisfaction)
display - not readable
display-what is the problem
do not make nurses lives more complicated (desired feature)
doctors change pump settings without telling anyone
doctors unfamiliar with pump

does what its suppossed to do (satisfaction)
door on the pumps
double checks are an extra step
double checks provide comfort
dreaded paperwork for errors mistakes (organization)
ease of use (satisfaction)
easy to set up (desired feature)
effectiveness - IV pumps effective when doing anything critical
effectiveness - accuracy important when dispensing weight based drugs (eg, pediatrics)
effectiveness - dispensed in correct time
effectiveness - make less mistakes if it is not complicated - easy to use
effectiveness - medication going in vein
effectiveness - need pump output that it is working / flowing
effectiveness - when the correct amount of fluids has been dispensed
efficent - if pump works
efficiency - can tell working by drops in chamber (feedback)
efficiency - capable of doing what I need it to do?
efficiency - critical drugs take more time to prepare than normal drugs
efficiency - different pumps are programmed differently
efficiency - difficult to move equipment from dept to dept
efficiency - dispensing drugs over a long time (eg, nutrition for 18 hours)
efficiency - dispensing multiple medications
efficiency - doctor knows patient is getting medication at the right time
efficiency - easier to regulate than calculating manually
efficiency - getting it set up
efficiency - need to dispense critical drugs quickly
efficiency - not efficient for EMS
efficiency - not having to start all over
efficiency - nurse doesn't have to keep checking on it
efficiency - nurses being able to use pump in a timely manner
efficiency - pump not efficient working a code (need to give drugs quickly)
efficiency - pump not effiicient if just giving drugs over a couple of minutes (syringe)
efficiency - quick to use
efficiency - using buttons easily
equipment problems are time consuming (frustration)
error - mixing up generic and trade drug names
error- equipment
error- operator
errors are caused by hectic situations
errors create additional tasks for nurses
estmation by user
faster pumping - still faster expected
features need to be easy to find
feedback- incorrect< occlusion>
fiddling with defective pump trying to make work
finding someone who knows how to do something when you don't
fluids gone faster than expected (surprise)
forgetting to turn back on
free time allows you to talk with patient / build rapport
frustration - alerts when there isn't anything wrong
frustration - doctor
frustration - having to do same thing twice
frustration - patient
guard takes broken screeching pumps to central sterile
guardian - stress
having programs available (satisfaction)
hectic situation
hospital is chaotic
hurry - depends on patients condition
ideally want a pump for every patient (satisfaction)
improvement needed on current pumps
indicator - to show pump started
insecurity
interface - improvement
interface- should be easy to scroll
iv pumps are crucial to what nurses do everyday
iv pumps haven't advanced as much as other medical devices
key pads hard to use (satisfaction)
keyboard for data entry (desired feature)
label lines so you don't mix them up (desired feature)
lack of standards to handle malfunctioning equipment (organization)
locating equipment
lock mechanism-improvement required

logical steps
long medicinne list
mag infusions are different on different floors - wards (organization)
making do when a pump is not available (organization)
medication infusing at wrong rate (surprise)
mistake prone- short staffed
mistakes happen during changing of bags / medication
mistakes happen on new equipment
monitor strip used to monitor baby in OB ward
monitoring computers
most nurses trust pumps
multiple pumps needed for multiple medications
need balance between security and ease of use
needed pump available
new admitted patient - busy determinant
new nurse - more frustrated]
newer nurses aren't as familiar with the pumps
no patience for equipment issues when have several patients
noise-beeping-pump, really annoying
noisy work environment makes it hard to find beeping iv pump]
normal pace in ER is patients seen quickly & efficiently
not all pumps have colleague guardian installed
not having enough equipment affects co-workers relationships
not loading tube properly
not trusting pump (satisfaction)
notification-task ending
number of patients varies by hospital (organization)
number of patients varies by unit (organization)
nurse - annoyed
nurse - extra to check behind another nurse
nurse - impatient
nurse - mostly trust the machine
nurses (unsettled by what's going on)
nurses feel guilty when make a mistake
nurses from different facility aren't as familiar with pumps
nurses not aware of all iv pump features (eg, colleague guardian)
nurses question accuracy of the pump
nurses unaware of special neo natal pumps in hospital
operator should have more controls on pump
other patient's distrurbed by patient's pump
outpatient
overload - lethal for babies
pace of hospital varies (organization)
pace of unit varies (organization)
patient - annoyed
patient adverse reaction (surprise)
patient can't move around with low battery
patient frightened
patient satisfaction important
patient workload impacts nurse time
patient's family attempts to reprogram pump
patient's family disrupted by noisy pump
patient's family is anxious
patients are frustrated when they see nurse frustrated
patients frighted by IV alarms
patients rely on nurses
patients watch nurses program pump to learn how to use it
pharmacy provides double checks
piggyback not infusing at all
plastic screen distorting
pole of 3 channel pumps are not able to hold
preference- medication over saline, in using pump
previous pumps worked better (organization)
priming of the pump a problem
program pump based on patient info (weight, height, age) (desired feature)
programming error
programming wrong amount of fluids available
proper programming required
pump - comfortable to use
pump - conflict between departments to get it
pump - easy
pump - expanded capabilities
pump - fragile

pump always efficient
pump availability affect efficiency
pump is less complicated
pump keeps pumping when out of vein and medication goes to floor (surprise)
pump needs to be dependable
pumps - effective everywhere
pumps - multiple channel
pumps are not fool proof
quiet functioning expected
radiology
rate running higher than what you programmed
responsibility: nurse responsible for life of every patient your take care of
safety hazard: IV pole tipping (too heavy)
screen glare is a problem
screen visibility
screen visibility impacted by backlight
screen visibility impacted by brightness
screen visibility impacted by text size
setup - periodic checks
shift change-wrong dosage
should not need training to use
simple (satisfaction)
single channel more annoying
staff -number present
standard to always put young & old patiens on pumps (organization
standardized tubing (organization)
stoop to see the display
stress - family stress increases nurse stress
stress - fear of overdosing patient
stress - fluid overload
stress - patient's family is anxious
stress - running in & out of patient's room
stress - working a code (somebody who is almost dead)
stress caused by not knowing all of pump features
stress caused by not knowing what's going on
stress during initial set-up period
stress when can't get pump to work
stress when working on children
stress when working on patient type not usually working with
stressed when working with babies
stressed when working with labor patients
stressed when working with preterm moms
support staff efficiency - determinant
tag - pumps not working
taking one patient off pump so another can have it
taking over a patient who already has an IV pump running
taking patient to CT scan
the rate you set is not the rate the IV pump is at now (surprise)
thinking you are doing the right thing but you aren't (surprise)
too busy to double check things
too many screens (satisfaction)
tradeoff between efficiency and safety
transfering patient BACK to ER
transferring patient - iv pump is switched out to their facility's IV pump]
transferring patient with EMS
transportation patient outside hospital
transporting patient - pump useful
trusting other nurse set up IV correctly when you take over for them
tubing - easy to clean
tubing - lightweight
tubing- easy to put in
unable to turn off pump and it contintues to beep
unexpected problem
unsure about how to clean pumps (organization)
unsure how often the pumps are cleaned (organization)
unsure how other wards dispense drugs (organization)
unsure of standards for dispensing critical drugs (organization)
unsure of working- nurse
unsure who is able to program pumps (organization)
useful
user control - more
ventillators
visual conformation-infusion

visually looking is only way to detect some problems
wandering around trying to find beeping pump
when you don't use a feature a lot it seems hard to use
work place -trauma room
working determinant - by looking and estimating
working determinant - count drip rate
working determinant-when fluid consumed on time
working in an ambulance
working in birthing center
working in critical care
working in medical services - pediatrics
working in the cath-lab
working on your own
workload - doing multiple things at once
workload - see many different patients quickly
you are doing everything you are suppossed to and it is still not working
you think you've started the pump but you haven't

Group 2 only

3 channel pump can be more helpful
IV pump allows for setup of preventive safety measures (eg, adverse patient reaction)
IV pump allows nurses to leave & come back later
IV pump as fool proof
IV pump failure: IV changing rate leads to patient overdose/overload
IV pump has features I don't know about that would help me with my job
IV pump helps newer nurses
IV pump helps with blood transfusion
IV pump helps with continuity of patient care
IV pump helps with organization
IV pump is essential
IV pump is really effective
IV pump keeps beeping after you think you fixed it
IV pump makes job easier
IV pump makes nurses feel confident
IV pump not fast enough
IV pump reduces nurses worry
IV pump should provide double checks for all drugs, not just the critical ones
IV pump should receive updates of drug information
IV pump too sensitive to air
IV pumps are easy
IV pumps as second line in monitoring patients' safety
IV pumps makes nurses feel comfortable
IV pumps makes nurses feel satisfied with job
IV pumps malfunction
IV pumps would be better if you didn't have to plug them in
KVO functionality in pump
OR calls ward to say battery died
Recovery room
ability to add channels to a pump (desired feature)
ability to adjust rate to a safe level depending on patient's needs
ability to remove channels from a pump (desired feature)
accident- learning from mistakes
accuracy - higher expected
accuracy: precise control of medication
add fluid to the bag-nurse
all information lost during battery failure
alter treatment based on patient's response
availability- nurse, not always there
baby in distress
bar code scanner
battery - emergency battery would be helpfull
battery - frequent checking
battery failure
battery low - even when its plugged
bladder scanner
blood pressure flow sheet (technological)]
call nursing supervisor to get correct pump
call pharmacy to check drug compatibility
calling doctor to get order
calling doctor to interpret results of test (eg, PPT)
calling equipment people when pump dies
calling pharmacy to place order

calling surgery
cancel patient procedure when patient reaction to medication not achieved
cannot leave the patient
cardiac monitors
cell phone interaction with pump - may lead to failure
central sterile - stores clean pumps]
clean pumps are in supply room
clear button helps when you've made a mistake
color code pumps by ward (desired feature)
color code pumps to distinguish between single, triple, and NICU (desired feature)
concentration - vary
concentrations for all drugs programmed in IV pump
confidentiality of incidents
conformation - pump should ask the operator
contact anesthesiologist about drug
critical drugs are always put on colleague guardian (safety)
critical drugs need to be checked by two licensed staff
damage - patient ripped pump of the stretcher pole
delivering medication in a timely manner
did a good job
different patient tolerances for air in tube young & old
different rate tolerances for older & younger patients
difficlult for patients to move when hooked to pump
difficult moving IV pump from one pole to another
difficulty in locating equipment
dispensing non-routine medications
distance from nurses station
doctor - impatient
doctor - waiting
doctor trusts pump warning over nurse warning
doctor will think that more infused than really did if previous shift forgot to clear
doublechecking with doctor that the order is what they want
drip stops when battery dies - frustrating
drug compatibility an issue
drug standards are changing
easy to adapt and learn expected
effectiveness - alerts help
effectiveness - pump puts in right amount in right time
effectiveness: important to match concentration in pump with concentration in bottle
efficiency - IV pump can sometimes make treatment quicker (eg, chemo)
efficiency - IV pump helps OTHER NURSES know what / how much patient is getting
efficiency - call back feature
efficiency - don't need to track down a nurse to find out dose
efficiency - easy to check what a patient is getting on IV screen
efficiency - easy to increase or decrease medication
efficiency - have to stop procedure when pump failure / battery dies
efficiency - too many steps to advance air
efficiency - wasting medicine
efficiency important with critical patients
efficiency: know rates off top of head for common medications
emergency backup battery (desired feature)
error - mistake between primary and secondary line
error recovery depends on time to notice mistake
errors are nurse errors (organization)
expectation - not a lot of deviation between pumps
experience - helps in learning the operation fast
experience with pumps helpful
fast paced work environment
faster air advance needed (desired feature)
feedback unavailable
feeling of success
feeling of success when keeping patient safe
forgetting a step when you are in a hurry
frustration - patient eating causes IV occlusions (bending of arm)
good patient care
hard to carry pumps around (too heavy)
hard to swtich pumps from bed to bed (too heavy)
have a pump for every room (desired feature)
humans are error prone
icon displaying how much battery left (desired feature)
ideal workload is 4 patients to one nurse
important to control fluid volume
in surgery fluids are given quickly (bolus)

incident report (colleague)
incident report (self)
interface - more friendly and easy is expected
job satisfaction: time management
lab calls with critical value
lab results say medication needs to be changed
learning one technology helps with other technologies
locate pump at central sterile
lock - for drip
lock mechanism required
making use when run out of proper bags - supplies (organization)
managing multiple critical patients
manual - would be helpful
manual calculations
manual tube release is aggravating
manually fix pump during failure
manufacturer - teaching about all the functions, helpful
many things going wrong
medication bin
medication delivered in specific order
medication wont' scan (surprise)
memory would provide record of care (desired feature)
mistakes happen when you are in a hurry
mistakes happen when you are tired
mixing up or programming wrong volume and rate
mixing- not dangerous, but dilutes medication
monitoring
more experienced nurses have higher tolerance for not knowing how to use equipment
multiple nurses work on one patient
multiple pump- difficult to handle
must be careful hanging piggyback or it won't work
necessary equipment not available
necessary sterile equipment available]
need to act quickly
need to be careful with toxicity
need to draw blood if you don't have blood in stock
new technology changing work practices
new tubing system at hospital
newer nurses practice more than more experienced nurses
next shift check IV settings of previous shift
no beeping- when error is made
non-punitive approach to incidents
notebooks-previously used for keeping drip rates
notice not infusing since bag still full
nurse (experienced)
nurse - dont rely on pump
nurse - headache
nurse - nervous
nurse and doctor disagree on medication order
nurses (cautious)
nurses (mad)
nurses (not always paying attention)
nurses aren't taught all of the features (organization)
nurses can program pump faster than pump can respond
nurses catch mistakes of other nurses (eg, bag not infusing)
nurses create workarounds when pump doesnt act as expected
nurses don't notice beeps/alarms when busy
nurses feel not necessary to learn all features (organization)
nurses figure out pump features on their own
nurses go to other wards to find pumps
nurses go with patients when transfered to other wards because other staff isn't trained on iv pumps (eg, radiologists)
nurses in ER monitoring IVS for short period of time (few hours)
nurses learn from each other
nurses need to be accountable for actions
nurses need to keep up with technology changes
nurses need to know when pharmacy info is updated into pumps (organization)
nurses need to troubleshoot
nurses on floor monitoring IVs for long time - 12 hours
nurses stay in room with patient to monitor first 15 min of transfusion
nurses train other nurses on IV pump
older versions of infusion pumps
one-to-one patient ratio in chemo

organized - helps the nurse to stay
patient barcoding (desired feature)
patient crashing
patient discomfort at IV site
patient disturbed by beeping pump
patient happy
patient has difficulty walking around when attached to infusion pumps
patient has to be restuck when IV infiltrated
patient kept on pump (KVO) when not getting medicine (organization)
patient lost a lot of blood during surgery
patient missing a dose
patient negatively affected if don't get medicine at right time
patient safe
patient walking
patients transferred from OR (surgery) to wards
patients who don't complain are forgotten about during high patient loads
pca pumps have different alarms
people understand incident rules (organization)
perfect timing needed
pharmacy (busy)
pharmacy does the drug calculations
pharmacy mixed up bin and medication
pole - only one pump can be attached
possibility of drug companies changing concentration levels
possibility of pump failure at back of mind
poster -guide to the pump
poster-letters too small to read
pre- set- pumps
pretending to be calm when really frustrated
previous shift sometimes forgets to clear
primary used- though secondary is selected
print out would provide record of care
procedure-pump operation tedious
pump - could be more efficient
pump - easy to learn and adapt
pump failure doesn't happen very often
pump failure is frustrating
pump failure makes patients panic
pump takes too long to load tubing
pump-helpful
pump-pulls out last information
pumps prime tubing (desired feature)
rate - easy to increase rate of drug in pump
rates for all drugs (including uncommon) programmed in IV pump
rates for common drugs ingrained in nurses' brains
ratio - better nurse to patient ratio expected
reaction to incidents - troubleshoot problem (organization)
reading order wrong
recovery nurse tells ward about patient
relationship- good with co-workers]
remove pump from patient's room during pump failure
rescue and transport people unfamiiiar with pump (organization)
responsibility: check concentration in bag and concentration in pump (organization)
responsibility: nurse responsibility to check settings against medication order
responsibility: nurse takes on additional responsibility to make life easier for patient
responsibility: pharmacy update pump information
restart an IV because it is beeping too much
reveal mistake to patient (organization)
satisfaction - IV pump saves time
satisfaction - following doctors orders accurately
satisfaction - patient has to reschedule procedure when iv pump fails during it
satisfaction when baby delivered successfully
scan medication prior to dispensing it (organization)
select between primary or secondary
shift change
shift work
shifting beds - so pumps are unplugged
shortcuts (desired feature)
silent operation expected
simple
some damage is irreversible
some work is tedious
standard procedure - always put certain medications on IV pump (organization)

standby button for triple channel pumps (desired feature)
stress - can't turn off pump failure noise - beeps for days
stress - difficulty monitoring symptoms of unresponsive patient
stress - doing chemo is scary
stress - everything seems to go wrong when you are busy
stress - exposure to a lot of hospital sounds
stress - handling multiple pumps at a time
stress - in a situation where you can't anticpate what is going to happen next
stress - nurse scared when makes a mistake
stress - patient's family has too high expectations of your standard of care
stress - unsure what will happen to patient
stress - unusual medication order
stretcher pole- pump
switch - between primary - piggyback
syringe pump
taught to investigate if pump alarms (organization)
time - pump less time consuming
time consuming-figuring out the pump
time-wise
timely dosage to patients
trained- all departments not trained
transfer patient from nursing home into hospital
transfer patient to OR
transferring patient for a procedure
transposed function - difficult for operator
troubleshooting-improved with the use of pump
unexpected medical situation
unfamiliar with pumps in different ward NICU (organization)
unsure of proper dose (organization)
using one channel on a triple channel pump is frustrating
walking around - patient
ward closed on weekends (organization)
with IV pump you know that the patient is getting medicine
workers in next shift find errors of previous shift (organization)
working in a hospital in another country
working in cardiac and respiratory
working in hospital wards (on on of the floors, not ER)
working in labor and delivery (ward)
working in oncology
working in orthopedics
working with admitting doc
working with aides
working with an inexperienced nurse / coworker
working with anesthesiologist
working with efficient nurses
working with nursing supervisor
working with pump representative
working with recovery nurse
working with senior nurse
wrong fluid given
wrong rate leads to poor patient outcomes

Group 1 and Group 2

3 channel can be used even if one channel not working
Critcal work
IV provides double checks
IV pump helps nurses perform their job
IV pump helps with labeling channels (A, B, C)
IV pump helps with safety of critical patients
IV pump is more convenient than manual delivery
IV pump is quicker than calculating concentration yourself
IV pump prevents air in line (air bolus)
IV pump provides controlled environment
IV pump should be smarter
IV pump should help with calculations & measurements
IV pumps are too heavy
accuracy - adverse patient reaction to under over dose
accuracy of dosage
alarm - distinctive
alarm constantly
alarm is obnoxious (too loud)
alerts are a distraction
anesthesiologist

babies - pump functioning critical for them
battery life is a problem
big buttons are easier to read (desired feature)
certain drug mistakes can kill patients (stress)
certain drugs are weight based
certain medications can't go in too fast - adverse patient reaction
certain medications need to go in fast (like a bolus)
conflict between pharmacy dose and what is needed in ward
critical patient
different volume tolerances for old & young patients
difficult to control IV with manual calculations
difficulty finding desired medication in iv pump medication list
dispensing critical drip
display - smaller fonts
display is confusing
distracton - hiding broken/failed pump in another room / stairwell
do not have time for equipment issues (frustration)
effectiveness - accuracy important when dispensing critical drugs
effectiveness - punching in wrong numbers for rate or volume
effectiveness determined by patient response
efficiency - IV helps nurses get work done faster
efficiency - IV pump helps know what / how much patient is getting (awareness)
efficiency - alerts help
efficiency - time spent messing with pump takes away time with patient
equipment helps with time management
floor nurses have to keep checking IV so it doesn't run out
forget a step
full census (lots of patients)
giving multiple infusions
guardian - cant be used for all drugs- only critical drugs
guardian helpfull
in nighttime you don't want the screen bright because it keeps patients up
in nighttime you want to be quiet so you don't disrupt patient
infiltration
lock is a safety precaution
lock is too easy for patients to access
lock prevents patient access
medication - correct or not
medication not infusing at all (surprise)
mistakes happen when you are busy & trying to do things quickly
most mistakes occur during initial set up period
new nurses more likely to make errors
no malfunction alarm
nurse - worried
nurses (busy)
nurses (frustrated)
nurses (in a hurry)
nurses (stress)
nurses (tired)
nurses clean pumps
nurses know about mistakes of other nurses (organization)
nurses provide double checks
occlusion
older nurses have problems seeing
overload of medication
patient attempts to reprogram pump
patients transferred from ER to wards
pca pumps
piggyback medication
problems distinguishing between different alarms
programming wrong rate
pump - good tool to have
pump availability is a problem
pump failure
pump failure during patient transfer
pumps sent to central sterile to get cleaned
pumps set to biomed to get fixed
safety - feeling of safety
safety paramount
same IV pump brand (Baxter) used in all hospital wards
satisfied with pump
screeching noise-annoying
stress - everything is happening all at once

stress - patient anxious
stress - patients stress increases nurses stress
time constraints
too many steps/ buttons (frustration)
training is insufficient (organization)
transfer patient to radiology
transferring patient in elevator
transferring patient to another facility
transferring patient to different ward
unable to figure out problem
unable to fix problem (satisfaction)
understaffed / shortstaffed
unsure who programs pharmacy information into pumps
user-friendliness
vital signs machine
what you thought was happening is not happening
working in ER ward
working in NICU (ward)
working in OB ward
working in PCU
working in different wards
working in the ICU
working in the OR (ward)
working night shift
working with doctor

E.2 Efficiency Themes by Group

Group 1 only

3 channel pumps are used even when single channel not available
IV backlighting / visibility depends on lighting in room
IV pump is faster than manual delivery
IV pump not as efficient in ER
IV pumps more efficient in wards since more controlled environment
accuracy - regulate several medications at the same time
alerts provide nurses time to change bag
availability more in OB
average number of patients
battery operative - increased risk
can't be quick & fast if pump not working
can't be quick & fast if you have to constantly reprogram
conflict between wards due to pump availability
confused nurse
database for medication
display - not readable
double checks are an extra step
ease of use (satisfaction)
easy to set up (desired feature)
efficent - if pump works
efficiency - can tell working by drops in chamber (feedback)
efficiency - capable of doing what I need it to do?
efficiency - critical drugs take more time to prepare than normal drugs
efficiency - different pumps are programmed differently
efficiency - dispensing drugs over a long time (eg, nutrition for 18 hours)
efficiency - dispensing multiple medications
efficiency - doctor knows patient is getting medication at the right time
efficiency - easier to regulate than calculating manually
efficiency - getting it set up
efficiency - need to dispense critical drugs quickly
efficiency - not having to start all over
efficiency - nurse doesn't have to keep checking on it
efficiency - quick to use
equipment problems are time consuming (frustration)
feedback- incorrect< occlusion>
finding someone who knows how to do something when you don't
mistake prone- short staffed
multiple pumps needed for multiple medications
new admitted patient - busy determinant
newer nurses aren't as familiar with the pumps
nurses from different facility aren't as familiar with pumps
plastic screen distorting
pump - conflict between departments to get it
pump availability affect efficiency
staff -number present
support staff efficiency - determinant
too busy to double check things
too many screens (satisfaction)
tradeoff between efficiency and safety
unexpected problem

Group 2 only

3 channel pump can be more helpful
IV pump has features I don't know about that would help me with my job
IV pump helps with continuity of patient care
IV pump makes job easier
IV pump not fast enough
IV pump too sensitive to air
KVO functionality in pump
availability- nurse, not always there
bar code scanner
concentrations for all drugs programmed in IV pump
critical drugs need to be checked by two licensed staff
delivering medication in a timely manner
difficulty in locating equipment
doctor - impatient
doctor - waiting

efficiency - IV pump can sometimes make treatment quicker (eg, chemo)
efficiency - IV pump helps OTHER NURSES know what / how much patient is getting
efficiency - call back feature
efficiency - don't need to track down a nurse to find out dose
efficiency - easy to check what a patient is getting on IV screen
efficiency - easy to increase or decrease medication
efficiency - have to stop procedure when pump failure / battery dies
efficiency - too many steps to advance air
efficiency - wasting medicine
efficiency important with critical patients
efficiency: know rates off top of head for common medications
experience with pumps helpful
learning one technology helps with other technologies
lock mechanism required
mistakes happen when you are tired
multiple pump- difficult to handle
notebooks-previously used for keeping drip rates
notice not infusing since bag still full
nurses figure out pump features on their own
nurses go to other wards to find pumps
nurses need to keep up with technology changes
nurses need to troubleshoot
organized - helps the nurse to stay
pole - only one pump can be attached
poster -guide to the pump
poster-letters too small to read
pre- set- pumps
procedure-pump operation tedious
rates for common drugs ingrained in nurses' brains
ratio - better nurse to patient ratio expected
satisfaction - IV pump saves time
time - pump less time consuming
time consuming-figuring out the pump
time-wise
timely dosage to patients
transposed function - difficult for operator
working with an inexperienced nurse / coworker

Group 1 and Group 2

3 channel can be used even if one channel not working
IV provides double checks
IV pump helps with labeling channels (A, B, C)
IV pump is quicker than calculating concentration yourself
IV pump prevents air in line (air bolus)
IV pump should help with calculations & measurements
IV pumps are too heavy
certain medications need to go in fast (like a bolus)
critical patient
difficult to control IV with manual calculations
difficulty finding desired medication in iv pump medication list
display - smaller fonts
display is confusing
distracton - hiding broken/failed pump in another room / stairwell
efficiency - IV helps nurses get work done faster
efficiency - IV pump helps know what / how much patient is getting (awareness)
efficiency - alerts help
efficiency - time spent messing with pump takes away time with patient
equipment helps with time management
full census (lots of patients)
giving multiple infusions
guardian - cant be used for all drugs- only critical drugs
guardian helpfull
lock prevents patient access
mistakes happen when you are busy & trying to do things quickly
new nurses more likely to make errors
no malfunction alarm
nurse - worried
nurses (busy)
nurses (in a hurry)
nurses (stress)
nurses clean pumps
older nurses have problems seeing

problems distinguishing between different alarms
pump availability is a problem
pump failure
pump failure during patient transfer
time constraints
too many steps/ buttons (frustration)
user-friendliness

E.3 Effectiveness Themes by Group

Group 1 only

Effectiveness important when giving controlled medication
IV pump eliminates human error
IV pump helps with documenting what patient is getting
IV pump is safer than doing it manually
IV pump more accurate than other types of delivery
Touch system would help
ability to load tubing (satisfaction)
accuracy
alert needed for IV infiltration
beeping only indicator
control - more control over the process by user
delivering safe levels of medication
different dosage required for different people
different patient tolerances for medication error
display - not readable
display-what is the problem
effectiveness - IV pumps effective when doing anything critical
effectiveness - accuracy important when dispensing weight based drugs (eg, pediatrics)
effectiveness - dispensed in correct time
effectiveness - make less mistakes if it is not complicated - easy to use
effectiveness - medication going in vein
effectiveness - when the correct amount of fluids has been dispensed
error - mixing up generic and trade drug names
error- equipment
error- operator
errors are caused by hectic situations
estmation by user
forgetting to turn back on
having programs available (satisfaction)
medication infusing at wrong rate (surprise)
mistakes happen during changing of bags / medication
mistakes happen on new equipment
newer nurses aren't as familiar with the pumps
not loading tube properly
nurses question accuracy of the pump
overload - lethal for babies
pharmacy provides double checks
programming error
programming wrong amount of fluids available
proper programming required
pump keeps pumping when out of vein and medication goes to floor (surprise)
rate running higher than what you programmed
too busy to double check things
unexpected problem
visually looking is only way to detect some problems
working determinant - by looking and estimating
working determinant - count drip rate
working determinant-when fluid consumed on time
you think you've started the pump but you haven't

Group 2 only

IV pump allows for setup of preventive safety measures (eg, adverse patient reaction)
IV pump failure: IV changing rate leads to patient overdose/overload
IV pump should receive updates of drug information
IV pumps malfunction
ability to adjust rate to a safe level depending on patient's needs
accuracy: precise control of medication
battery failure
cancel patient procedure when patient reaction to medication not achieved
clear button helps when you've made a mistake
concentration - vary
concentrations for all drugs programmed in IV pump
critical drugs are always put on colleague guardian (safety)
critical drugs need to be checked by two licensed staff
different rate tolerances for older & younger patients
doctor will think that more infused than really did if previous shift forgot to clear
effectiveness - alerts help
effectiveness - pump puts in right amount in right time

effectiveness: important to match concentration in pump with concentration in bottle
error - mistake between primary and secondary line
error recovery depends on time to notice mistake
forgetting a step when you are in a hurry
important to control fluid volume
manual - would be helpful
manual calculations
medication delivered in specific order
mistakes happen when you are in a hurry
mistakes happen when you are tired
mixing up or programming wrong volume and rate
mixing- not dangerous, but dilutes medication
no beeping- when error is made
notice not infusing since bag still full
nurses aren't taught all of the features (organization)
nurses don't notice beeps/alarms when busy
nurses need to know when pharmacy info is updated into pumps (organization)
patient missing a dose
patient negatively affected if don't get medicine at right time
pharmacy mixed up bin and medication
possibility of drug companies changing concentration levels
primary used- though secondary is selected
rate - easy to increase rate of drug in pump
rates for all drugs (including uncommon) programmed in IV pump
rates for common drugs ingrained in nurses' brains
reading order wrong
satisfaction - following doctors orders accurately
some damage is irreversible
wrong fluid given
wrong rate leads to poor patient outcomes

Group 1 and Group 2

Critcal work
IV provides double checks
IV pump helps with labeling channels (A, B, C)
IV pump helps with safety of critical patients
IV pump prevents air in line (air bolus)
IV pump provides controlled environment
IV pump should help with calculations & measurements
accuracy - adverse patient reaction to under over dose
accuracy of dosage
alarm - distinctive
babies - pump functioning critical for them
certain drug mistakes can kill patients (stress)
certain drugs are weight based
certain medications can't go in too fast - adverse patient reaction
certain medications need to go in fast (like a bolus)
conflict between pharmacy dose and what is needed in ward
different volume tolerances for old & young patients
difficult to control IV with manual calculations
dispensing critical drip
effectiveness - accuracy important when dispensing critical drugs
effectiveness - punching in wrong numbers for rate or volume
effectiveness determined by patient response
forget a step
guardian helpfull
infiltration
lock is a safety precaution
medication - correct or not
medication not infusing at all (surprise)
mistakes happen when you are busy & trying to do things quickly
most mistakes occur during initial set up period
new nurses more likely to make errors
nurses provide double checks
occlusion
overload of medication
patient attempts to reprogram pump
problems distinguishing between different alarms
programming wrong rate
pump availability is a problem
pump failure
pump failure during patient transfer

safety paramount
too many steps/ buttons (frustration)
unable to figure out problem
user-friendliness
what you thought was happening is not happening

E.4 Satsifaction Themes by Group

Group 1 only

"get in there and do it" (satisfaction)
Always prefer to use an IV pump
IV pump eliminates human error
IV pump helps with documenting what patient is getting
IV pump is efficient
IV pump prevents you from doing what you need to do
IV pump provides false sense of security
IV pump should have less room for error (desired feature)
IV pump will not turn on
IV pumps should be smaller / less bulky
ability to load tubing (satisfaction)
accuracy
alarm-while dose is administered
alert needed for IV infiltration
antibiotics infusion - pump useful
battery charges too slowly
can't be quick & fast if pump not working
can't be quick & fast if you have to constantly reprogram
can't predict what IV pump is going to do
confidence low
confirmation of start (desired feature)
conflict between wards due to pump availability
database for medication
difficult to scroll using tiny touch pad (satisfaction)
display - not readable
display-what is the problem
do not make nurses lives more complicated (desired feature)
does what its suppossed to do (satisfaction)
door on the pumps
double checks provide comfort
dreaded paperwork for errors mistakes (organization)
ease of use (satisfaction)
easy to set up (desired feature)
effectiveness - need pump output that it is working / flowing
efficiency - can tell working by drops in chamber (feedback)
efficiency - capable of doing what I need it to do?
efficiency - different pumps are programmed differently
efficiency - difficult to move equipment from dept to dept
efficiency - dispensing drugs over a long time (eg, nutrition for 18 hours)
efficiency - dispensing multiple medications
efficiency - getting it set up
efficiency - not efficient for EMS
efficiency - not having to start all over
efficiency - nurse doesn't have to keep checking on it
efficiency - nurses being able to use pump in a timely manner
efficiency - pump not efficient working a code (need to give drugs quickly)
efficiency - pump not effiicient if just giving drugs over a couple of minutes (syringe)
efficiency - quick to use
efficiency - using buttons easily
equipment problems are time consuming (frustration)
faster pumping - still faster expected
features need to be easy to find
fluids gone faster than expected (surprise)
free time allows you to talk with patient / build rapport
frustration - alerts when there isn't anything wrong
frustration - doctor
frustration - having to do same thing twice
frustration - patient
ideally want a pump for every patient (satisfaction)
improvement needed on current pumps
indicator - to show pump started
interface - improvement
interface- should be easy to scroll
iv pumps are crucial to what nurses do everyday
iv pumps haven't advanced as much as other medical devices
key pads hard to use (satisfaction)
keyboard for data entry (desired feature)

label lines so you don't mix them up (desired feature)
locating equipment
lock mechanism-improvement required
logical steps
most nurses trust pumps
need balance between security and ease of use
needed pump available
new nurse - more frustrated]
no patience for equipment issues when have several patients
noise-beeping-pump, really annoying
not trusting pump (satisfaction)
notification-task ending
nurse - annoyed
nurse - extra to check behind another nurse
nurse - impatient
nurse - mostly trust the machine
nurses (unsettled by what's going on)
operator should have more controls on pump
other patient's distrurbed by patient's pump
patient - annoyed
patient can't move around with low battery
patient satisfaction important
patient workload impacts nurse time
patient's family disrupted by noisy pump
patients are frustrated when they see nurse frustrated
patients frighted by IV alarms
pharmacy provides double checks
piggyback not infusing at all
pole of 3 channel pumps are not able to hold
previous pumps worked better (organization)
priming of the pump a problem
program pump based on patient info (weight, height, age) (desired feature)
pump - comfortable to use
pump - easy
pump - expanded capabilities
pump - fragile
pump always efficient
pump is less complicated
pump needs to be dependable
pumps - effective everywhere
pumps - multiple channel
pumps are not fool proof
quiet functioning expected
safety hazard: IV pole tipping (too heavy)
screen glare is a problem
screen visibility
screen visibility impacted by backlight
screen visibility impacted by brightness
screen visibility impacted by text size
should not need training to use
simple (satisfaction)
single channel more annoying
stoop to see the display
stress - fluid overload
stress - patient's family is anxious
stress caused by not knowing all of pump features
stress when can't get pump to work
tag - pumps not working
the rate you set is not the rate the IV pump is at now (surprise)
too many screens (satisfaction)
transporting patient - pump useful
tubing - easy to clean
tubing - lightweight
tubing- easy to put in
unable to turn off pump and it contintues to beep
unsure of working- nurse
useful
user control - more
when you don't use a feature a lot it seems hard to use
you are doing everything you are suppossed to and it is still not working

Group 2 only

IV pump allows for setup of preventive safety measures (eg, adverse patient reaction)
IV pump allows nurses to leave & come back later
IV pump as fool proof
IV pump helps newer nurses
IV pump helps with blood transfusion
IV pump helps with continuity of patient care
IV pump helps with organization
IV pump is essential
IV pump is really effective
IV pump keeps beeping after you think you fixed it
IV pump makes job easier
IV pump makes nurses feel confident
IV pump not fast enough
IV pump reduces nurses worry
IV pump should provide double checks for all drugs, not just the critical ones
IV pump should receive updates of drug information
IV pump too sensitive to air
IV pumps are easy
IV pumps as second line in monitoring patients' safety
IV pumps makes nurses feel comfortable
IV pumps makes nurses feel satisfied with job
IV pumps malfunction
IV pumps would be better if you didn't have to plug them in
ability to add channels to a pump (desired feature)
ability to adjust rate to a safe level depending on patient's needs
ability to remove channels from a pump (desired feature)
accident- learning from mistakes
accuracy - higher expected
battery - emergency battery would be helpfull
battery low - even when its plugged
clear button helps when you've made a mistake
color code pumps by ward (desired feature)
color code pumps to distinguish between single, triple, and NICU (desired feature)
confidentiality of incidents
conformation - pump should ask the operator
did a good job
difficlult for patients to move when hooked to pump
difficult moving IV pump from one pole to another
doctor - impatient
drug compatibility an issue
easy to adapt and learn expected
efficiency - IV pump can sometimes make treatment quicker (eg, chemo)
efficiency - call back feature
efficiency - easy to check what a patient is getting on IV screen
efficiency - easy to increase or decrease medication
efficiency - too many steps to advance air
emergency backup battery (desired feature)
expectation - not a lot of deviation between pumps
experience - helps in learning the operation fast
faster air advance needed (desired feature)
feedback unavailable
feeling of success
feeling of success when keeping patient safe
frustration - patient eating causes IV occlusions (bending of arm)
good patient care
hard to carry pumps around (too heavy)
hard to swtich pumps from bed to bed (too heavy)
have a pump for every room (desired feature)
icon displaying how much battery left (desired feature)
incident report (colleague)
incident report (self)
interface - more friendly and easy is expected
job satisfaction: time management
lock - for drip
manual - would be helpful
manual tube release is aggravating
manufacturer - teaching about all the functions, helpful
memory would provide record of care (desired feature)
more experienced nurses have higher tolerance for not knowing how to use equipment
multiple pump- difficult to handle
must be careful hanging piggyback or it won't work

necessary equipment not available
new technology changing work practices
non-punitive approach to incidents
nurse - dont rely on pump
nurses (mad)
nurses aren't taught all of the features (organization)
nurses go with patients when transfered to other wards because other staff isn't trained on iv pumps (eg, radiologists)
patient barcoding (desired feature)
patient discomfort at IV site
patient disturbed by beeping pump
patient happy
patient has difficulty walking around when attached to infusion pumps
patient has to be restuck when IV infiltrated
patient safe
pole - only one pump can be attached
possibility of pump failure at back of mind
poster -guide to the pump
poster-letters too small to read
pre- set- pumps
print out would provide record of care
pump - could be more efficient
pump - easy to learn and adapt
pump failure doesn't happen very often
pump failure is frustrating
pump failure makes patients panic
pump takes too long to load tubing
pump-helpful
pump-pulls out last information
pumps prime tubing (desired feature)
ratio - better nurse to patient ratio expected
satisfaction - following doctors orders accurately
satisfaction - patient has to reschedule procedure when iv pump fails during it
satisfaction when baby delivered successfully
shortcuts (desired feature)
silent operation expected
simple
standby button for triple channel pumps (desired feature)
stress - can't turn off pump failure noise - beeps for days
stress - difficulty monitoring symptoms of unresponsive patient
stress - doing chemo is scary
stress - nurse scared when makes a mistake
stress - unusual medication order
stretcher pole- pump
troubleshooting-improved with the use of pump
unsure of proper dose (organization)
using one channel on a triple channel pump is frustrating
with IV pump you know that the patient is getting medicine
working with pump representative

Group 1 and Group 2

3 channel can be used even if one channel not working
IV provides double checks
IV pump helps nurses perform their job
IV pump helps with labeling channels (A, B, C)
IV pump helps with safety of critical patients
IV pump is more convenient than manual delivery
IV pump is quicker than calculating concentration yourself
IV pump prevents air in line (air bolus)
IV pump provides controlled environment
IV pump should be smarter
IV pump should help with calculations & measurements
IV pumps are too heavy
alarm - distinctive
alarm is obnoxious (too loud)
battery life is a problem
big buttons are easier to read (desired feature)
certain drug mistakes can kill patients (stress)
conflict between pharmacy dose and what is needed in ward
difficult to control IV with manual calculations
difficulty finding desired medication in iv pump medication list
display - smaller fonts

display is confusing
distracton - hiding broken/failed pump in another room / stairwell
do not have time for equipment issues (frustration)
efficiency - IV helps nurses get work done faster
efficiency - IV pump helps know what / how much patient is getting (awareness)
efficiency - alerts help
efficiency - time spent messing with pump takes away time with patient
equipment helps with time management
floor nurses have to keep checking IV so it doesn't run out
guardian helpfull
in nighttime you don't want the screen bright because it keeps patients up
in nighttime you want to be quiet so you don't disrupt patient
lock is a safety precaution
lock is too easy for patients to access
lock prevents patient access
no malfunction alarm
nurse - worried
nurses (frustrated)
nurses (stress)
nurses (tired)
patient attempts to reprogram pump
problems distinguishing between different alarms
pump - good tool to have
pump availability is a problem
pump failure
pump failure during patient transfer
safety - feeling of safety
safety paramount
satisfied with pump
screeching noise-annoying
stress - patient anxious
too many steps/ buttons (frustration)
unable to figure out problem
unable to fix problem (satisfaction)
unsure who programs pharmacy information into pumps
user-friendliness

E.5 Context-of-Use Themes by Group

Group 1 only

3 channel pumps are used even when single channel not available
CNAs (certified nurse assistant)
CNAs (certified nursing assistant) locate replacement for defective IV pump
ER ward - burning down!
ER ward is busy
IV backlighting / visibility depends on lighting in room
IV pump used in home health care (chemo)
IV pumps more available on floor wards
Techs locate replacement for defective IV pump
You think an IV pump is working but it's not (surprise)
accidental bumps can disrupt IV settings
adult pump not used for babies
ambulance
availability more in OB
blood pressure cuffs
charting computers
check patient every hour or so
condition of patients changing
crash cart
defibrillators
demands of doctors
different patient scenarios in different wards
doctors change pump settings without telling anyone
doctors unfamiliar with pump
double checks provide comfort
dreaded paperwork for errors mistakes (organization)
errors create additional tasks for nurses
feedback- incorrect< occlusion>
fiddling with defective pump trying to make work
fluids gone faster than expected (surprise)
frustration - alerts when there isn't anything wrong
frustration - doctor
frustration - having to do same thing twice
frustration - patient
guard takes broken screeching pumps to central sterile
guardian - stress
hectic situation
hospital is chaotic
hurry - depends on patients condition
insecurity
lack of standards to handle malfunctioning equipment (organization)
locating equipment
long medicinne list
mag infusions are different on different floors - wards (organization)
making do when a pump is not available (organization)
medication infusing at wrong rate (surprise)
monitor strip used to monitor baby in OB ward
monitoring computers
multiple pumps needed for multiple medications
noise-beeping-pump, really annoying
noisy work environment makes it hard to find beeping iv pump]
normal pace in ER is patients seen quickly & efficiently
not all pumps have colleague guardian installed
not having enough equipment affects co-workers relationships
number of patients varies by hospital (organization)
number of patients varies by unit (organization)
nurse - impatient
nurses (unsettled by what's going on)
nurses feel guilty when make a mistake
nurses not aware of all iv pump features (eg, colleague guardian)
nurses unaware of special neo natal pumps in hospital
outpatient
pace of hospital varies (organization)
pace of unit varies (organization)
patient adverse reaction (surprise)
patient frightened
patient's family attempts to reprogram pump
patient's family is anxious
patients rely on nurses

patients watch nurses program pump to learn how to use it
pharmacy provides double checks
preference- medication over saline, in using pump
pump keeps pumping when out of vein and medication goes to floor (surprise)
radiology
responsibility: nurse responsible for life of every patient your take care of
setup - periodic checks
shift change-wrong dosage
standard to always put young & old patiens on pumps (organization
standardized tubing (organization)
stress - family stress increases nurse stress
stress - fear of overdosing patient
stress - running in & out of patient's room
stress - working a code (somebody who is almost dead)
stress caused by not knowing what's going on
stress during initial set-up period
stress when working on children
stress when working on patient type not usually working with
stressed when working with babies
stressed when working with labor patients
stressed when working with preterm moms
taking one patient off pump so another can have it
taking over a patient who already has an IV pump running
taking patient to CT scan
thinking you are doing the right thing but you aren't (surprise)
too busy to double check things
transfering patient BACK to ER
transferring patient - iv pump is switched out to their facility's IV pump]
transferring patient with EMS
transportation patient outside hospital
trusting other nurse set up IV correctly when you take over for them
unexpected problem
unsure about how to clean pumps (organization)
unsure how often the pumps are cleaned (organization)
unsure how other wards dispense drugs (organization)
unsure of standards for dispensing critical drugs (organization)
unsure who is able to program pumps (organization)
ventillators
wandering around trying to find beeping pump
work place -trauma room
working in an ambulance
working in birthing center
working in critical care
working in medical services - pediatrics
working in the cath-lab
working on your own
workload - doing multiple things at once
workload - see many different patients quickly

Group 2 only

IV pump too sensitive to air
OR calls ward to say battery died
Recovery room
add fluid to the bag-nurse
all information lost during battery failure
alter treatment based on patient's response
baby in distress
battery - frequent checking
bladder scanner
blood pressure flow sheet (technological)]
call nursing supervisor to get correct pump
call pharmacy to check drug compatibility
calling doctor to get order
calling doctor to interpret results of test (eg, PPT)
calling equipment people when pump dies
calling pharmacy to place order
calling surgery
cannot leave the patient
cardiac monitors
cell phone interaction with pump - may lead to failure
central sterile - stores clean pumps]

clean pumps are in supply room
confidentiality of incidents
contact anesthesiologist about drug
critical drugs are always put on colleague guardian (safety)
critical drugs need to be checked by two licensed staff
damage - patient ripped pump of the stretcher pole
different patient tolerances for air in tube young & old
different rate tolerances for older & younger patients
difficlult for patients to move when hooked to pump
difficult moving IV pump from one pole to another
dispensing non-routine medications
distance from nurses station
doctor - impatient
doctor trusts pump warning over nurse warning
doctor will think that more infused than really did if previous shift forgot to clear
doublechecking with doctor that the order is what they want
drip stops when battery dies - frustrating
drug standards are changing
errors are nurse errors (organization)
experience - helps in learning the operation fast
fast paced work environment
frustration - patient eating causes IV occlusions (bending of arm)
hard to carry pumps around (too heavy)
hard to swtich pumps from bed to bed (too heavy)
humans are error prone
ideal workload is 4 patients to one nurse
in surgery fluids are given quickly (bolus)
incident report (colleague)
incident report (self)
lab calls with critical value
lab results say medication needs to be changed
learning one technology helps with other technologies
locate pump at central sterile
making use when run out of proper bags - supplies (organization)
managing multiple critical patients
manually fix pump during failure
many things going wrong
medication bin
medication wont' scan (surprise)
mistakes happen when you are in a hurry
monitoring
multiple nurses work on one patient
necessary sterile equipment available]
need to act quickly
need to be careful with toxicity
need to draw blood if you don't have blood in stock
new tubing system at hospital
newer nurses practice more than more experienced nurses
next shift check IV settings of previous shift
non-punitive approach to incidents
nurse (experienced)
nurse - headache
nurse - nervous
nurse and doctor disagree on medication order
nurses (cautious)
nurses (not always paying attention)
nurses aren't taught all of the features (organization)
nurses can program pump faster than pump can respond
nurses catch mistakes of other nurses (eg, bag not infusing)
nurses create workarounds when pump doesnt act as expected
nurses feel not necessary to learn all features (organization)
nurses figure out pump features on their own
nurses go to other wards to find pumps
nurses go with patients when transfered to other wards because other staff isn't trained on iv pumps (eg, radiologists)
nurses in ER monitoring IVS for short period of time (few hours)
nurses learn from each other
nurses need to be accountable for actions
nurses need to know when pharmacy info is updated into pumps (organization)
nurses need to troubleshoot
nurses on floor monitoring IVs for long time - 12 hours
nurses stay in room with patient to monitor first 15 min of transfusion
nurses train other nurses on IV pump

older versions of infusion pumps
one-to-one patient ratio in chemo
patient crashing
patient kept on pump (KVO) when not getting medicine (organization)
patient lost a lot of blood during surgery
patient walking
patients transferred from OR (surgery) to wards
patients who don't complain are forgotten about during high patient loads
pca pumps have different alarms
people understand incident rules (organization)
perfect timing needed
pharmacy (busy)
pharmacy does the drug calculations
pharmacy mixed up bin and medication
poster -guide to the pump
pretending to be calm when really frustrated
previous shift sometimes forgets to clear
ratio - better nurse to patient ratio expected
reaction to incidents - troubleshoot problem (organization)
recovery nurse tells ward about patient
relationship- good with co-workers]
remove pump from patient's room during pump failure
rescue and transport people unfamiiiar with pump (organization)
responsibility: check concentration in bag and concentration in pump (organization)
responsibility: nurse responsibility to check settings against medication order
responsibility: nurse takes on additional responsibility to make life easier for patient
responsibility: pharmacy update pump information
restart an IV because it is beeping too much
reveal mistake to patient (organization)
scan medication prior to dispensing it (organization)
select between primary or secondary
shift change
shift work
shifting beds - so pumps are unplugged
some work is tedious
standard procedure - always put certain medications on IV pump (organization)
stress - difficulty monitoring symptoms of unresponsive patient
stress - doing chemo is scary
stress - everything seems to go wrong when you are busy
stress - exposure to a lot of hospital sounds
stress - handling multiple pumps at a time
stress - in a situation where you can't anticpate what is going to happen next
stress - nurse scared when makes a mistake
stress - patient's family has too high expectations of your standard of care
stress - unsure what will happen to patient
stress - unusual medication order
switch - between primary - piggyback
syringe pump
taught to investigate if pump alarms (organization)
trained- all departments not trained
transfer patient from nursing home into hospital
transfer patient to OR
transferring patient for a procedure
unexpected medical situation
unfamiliar with pumps in different ward NICU (organization)
unsure of proper dose (organization)
using one channel on a triple channel pump is frustrating
walking around - patient
ward closed on weekends (organization)
workers in next shift find errors of previous shift (organization)
working in a hospital in another country
working in cardiac and respiratory
working in hospital wards (on on of the floors, not ER)
working in labor and delivery (ward)
working in oncology
working in orthopedics
working with admitting doc
working with aides
working with anesthesiologist
working with efficient nurses
working with nursing supervisor
working with pump representative
working with recovery nurse

working with senior nurse

Group 1 and Group 2

3 channel can be used even if one channel not working
Critcal work
alarm - distinctive
alarm constantly
alarm is obnoxious (too loud)
alerts are a distraction
anesthesiologist
babies - pump functioning critical for them
certain drug mistakes can kill patients (stress)
certain drugs are weight based
certain medications can't go in too fast - adverse patient reaction
certain medications need to go in fast (like a bolus)
conflict between pharmacy dose and what is needed in ward
critical patient
difficulty finding desired medication in iv pump medication list
dispensing critical drip
distracton - hiding broken/failed pump in another room / stairwell
do not have time for equipment issues (frustration)
floor nurses have to keep checking IV so it doesn't run out
forget a step
full census (lots of patients)
giving multiple infusions
in nighttime you don't want the screen bright because it keeps patients up
in nighttime you want to be quiet so you don't disrupt patient
infiltration
medication not infusing at all (surprise)
mistakes happen when you are busy & trying to do things quickly
nurse - worried
nurses (busy)
nurses (frustrated)
nurses (in a hurry)
nurses (stress)
nurses (tired)
nurses clean pumps
nurses know about mistakes of other nurses (organization)
nurses provide double checks
occlusion
older nurses have problems seeing
patient attempts to reprogram pump
patients transferred from ER to wards
pca pumps
piggyback medication
pump failure
pump failure during patient transfer
pumps sent to central sterile to get cleaned
pumps set to biomed to get fixed
safety paramount
same IV pump brand (Baxter) used in all hospital wards
screeching noise-annoying
stress - everything is happening all at once
stress - patients stress increases nurses stress
time constraints
training is insufficient (organization)
transfer patient to radiology
transferring patient in elevator
transferring patient to another facility
transferring patient to different ward
unable to figure out problem
unable to fix problem (satisfaction)
understaffed / shortstaffed
unsure who programs pharmacy information into pumps
vital signs machine
what you thought was happening is not happening
working in ER ward
working in NICU (ward)
working in OB ward
working in PCU
working in different wards
working in the ICU

working in the OR (ward)
working night shift
working with doctor

E.5 Spatial Themes by Group

Group 1 only

IV pump used in home health care (chemo)
ambulance
outpatient
radiology
work place -trauma room
working in an ambulance
working in birthing center
working in critical care
working in medical services - pediatrics
working in the cath-lab

Group 2 only

Recovery room
clean pumps are in supply room
distance from nurses station
nurses stay in room with patient to monitor first 15 min of transfusion
patient walking
pharmacy (busy)
walking around - patient
working in a hospital in another country
working in cardiac and respiratory
working in hospital wards (on on of the floors, not ER)
working in labor and delivery (ward)
working in oncology
working in orthopedics

Group 1 and Group 2

transfer patient to radiology
transferring patient in elevator
transferring patient to another facility
transferring patient to different ward
working in ER ward
working in NICU (ward)
working in OB ward
working in PCU
working in different wards
working in the ICU
working in the OR (ward)

E.7 Social Themes by Group

Group 1 only

3 channel pumps are used even when single channel not available
CNAs (certified nurse assistant)
CNAs (certified nursing assistant) locate replacement for defective IV pump
IV pumps more available on floor wards
Techs locate replacement for defective IV pump
adult pump not used for babies
availability more in OB
doctors change pump settings without telling anyone
doctors unfamiliar with pump
dreaded paperwork for errors mistakes (organization)
guard takes broken screeching pumps to central sterile
lack of standards to handle malfunctioning equipment (organization)
mag infusions are different on different floors - wards (organization)
not all pumps have colleague guardian installed
not having enough equipment affects co-workers relationships
number of patients varies by hospital (organization)
number of patients varies by unit (organization)
nurses not aware of all iv pump features (eg, colleague guardian)
nurses unaware of special neo natal pumps in hospital
pace of hospital varies (organization)
pace of unit varies (organization)
patient's family attempts to reprogram pump
patients watch nurses program pump to learn how to use it
pharmacy provides double checks
preference- medication over saline, in using pump
responsibility: nurse responsible for life of every patient your take care of
setup - periodic checks
standard to always put young & old patiens on pumps (organization
standardized tubing (organization)
taking one patient off pump so another can have it
taking over a patient who already has an IV pump running
taking patient to CT scan
transfering patient BACK to ER
transferring patient with EMS
transportation patient outside hospital
trusting other nurse set up IV correctly when you take over for them
unsure about how to clean pumps (organization)
unsure how other wards dispense drugs (organization)
unsure of standards for dispensing critical drugs (organization)
unsure who is able to program pumps (organization)

Group 2 only

OR calls ward to say battery died
add fluid to the bag-nurse
battery - frequent checking
call nursing supervisor to get correct pump
call pharmacy to check drug compatibility
calling doctor to get order
calling doctor to interpret results of test (eg, PPT)
calling equipment people when pump dies
calling pharmacy to place order
calling surgery
confidentiality of incidents
contact anesthesiologist about drug
critical drugs are always put on colleague guardian (safety)
critical drugs need to be checked by two licensed staff
doctor trusts pump warning over nurse warning
doctor will think that more infused than really did if previous shift forgot to clear
doublechecking with doctor that the order is what they want
drug standards are changing
errors are nurse errors (organization)
incident report (colleague)
incident report (self)
lab calls with critical value
lab results say medication needs to be changed
making use when run out of proper bags - supplies (organization)

multiple nurses work on one patient
newer nurses practice more than more experienced nurses
next shift check IV settings of previous shift
non-punitive approach to incidents
nurse and doctor disagree on medication order
nurses catch mistakes of other nurses (eg, bag not infusing)
nurses create workarounds when pump doesnt act as expected
nurses feel not necessary to learn all features (organization)
nurses figure out pump features on their own
nurses go with patients when transfered to other wards because other staff isn't trained on iv pumps (eg, radiologists)
nurses learn from each other
nurses need to be accountable for actions
nurses need to know when pharmacy info is updated into pumps (organization)
nurses stay in room with patient to monitor first 15 min of transfusion
nurses train other nurses on IV pump
patient kept on pump (KVO) when not getting medicine (organization)
patients transferred from OR (surgery) to wards
patients who don't complain are forgotten about during high patient loads
people understand incident rules (organization)
pharmacy does the drug calculations
pharmacy mixed up bin and medication
poster -guide to the pump
previous shift sometimes forgets to clear
reaction to incidents - troubleshoot problem (organization)
recovery nurse tells ward about patient
relationship- good with co-workers]
rescue and transport people unfamiiiar with pump (organization)
responsibility: check concentration in bag and concentration in pump (organization)
responsibility: nurse responsibility to check settings against medication order
responsibility: nurse takes on additional responsibility to make life easier for patient
responsibility: pharmacy update pump information
reveal mistake to patient (organization)
scan medication prior to dispensing it (organization)
shift change
standard procedure - always put certain medications on IV pump (organization)
taught to investigate if pump alarms (organization)
trained- all departments not trained
transfer patient from nursing home into hospital
transfer patient to OR
transferring patient for a procedure
unfamiliar with pumps in different ward NICU (organization)
ward closed on weekends (organization)
workers in next shift find errors of previous shift (organization)
working with admitting doc
working with aides
working with anesthesiologist
working with efficient nurses
working with nursing supervisor
working with pump representative
working with recovery nurse
working with senior nurse

Group 1 and Group 2

3 channel can be used even if one channel not working
anesthesiologist
conflict between pharmacy dose and what is needed in ward
nurses know about mistakes of other nurses (organization)
nurses provide double checks
patient attempts to reprogram pump
patients transferred from ER to wards
pumps sent to central sterile to get cleaned
pumps set to biomed to get fixed
same IV pump brand (Baxter) used in all hospital wards
training is insufficient (organization)
transfer patient to radiology
transferring patient to another facility
transferring patient to different ward
understaffed / shortstaffed
unsure who programs pharmacy information into pumps
working in different wards
working with doctor

E.8 Technological Themes by Group

Group 1 only

blood pressure cuffs
charting computers
crash cart
defibrillators
monitor strip used to monitor baby in OB ward
monitoring computers
transferring patient - iv pump is switched out to their facility's IV pump]
ventillators

Group 2 only

bladder scanner
blood pressure flow sheet (technological)]
cardiac monitors
cell phone interaction with pump - may lead to failure
medication bin
new tubing system at hospital
nurses aren't taught all of the features (organization)
older versions of infusion pumps
pca pumps have different alarms
syringe pump

Group 1 and Group 2

pca pumps
vital signs machine

E.9 Hygienic Themes by Group

Group 1 only

unsure about how to clean pumps (organization)
unsure how often the pumps are cleaned (organization)

Group 2 only

central sterile - stores clean pumps]
clean pumps are in supply room
necessary sterile equipment available]

Group 1 and Group 2

nurses clean pumps
pumps sent to central sterile to get cleaned

E.10 Physical Themes by Group

Group 1 only

IV backlighting / visibility depends on lighting in room
noisy work environment makes it hard to find beeping iv pump]

Group 2 only

stress - exposure to a lot of hospital sounds

E.11 Activity Themes by Group

Group 1 only

ER ward - burning down!
ER ward is busy
You think an IV pump is working but it's not (surprise)
accidental bumps can disrupt IV settings
check patient every hour or so
condition of patients changing
demands of doctors
different patient scenarios in different wards
doctors change pump settings without telling anyone
double checks provide comfort
errors create additional tasks for nurses
feedback- incorrect< occlusion>
fiddling with defective pump trying to make work
fluids gone faster than expected (surprise)
frustration - alerts when there isn't anything wrong
frustration - doctor
frustration - having to do same thing twice
frustration - patient
guardian - stress
hectic situation
hospital is chaotic
hurry - depends on patients condition
insecurity
locating equipment
long medicinne list
making do when a pump is not available (organization)
medication infusing at wrong rate (surprise)
multiple pumps needed for multiple medications
noise-beeping-pump, really annoying
normal pace in ER is patients seen quickly & efficiently
number of patients varies by hospital (organization)
number of patients varies by unit (organization)
nurse - impatient
nurses (unsettled by what's going on)
nurses feel guilty when make a mistake
pace of hospital varies (organization)
pace of unit varies (organization)
patient adverse reaction (surprise)
patient frightened
patients rely on nurses
pump keeps pumping when out of vein and medication goes to floor (surprise)
shift change-wrong dosage
stress - family stress increases nurse stress
stress - fear of overdosing patient
stress - patient's family is anxious
stress - running in & out of patient's room
stress - working a code (somebody who is almost dead)
stress caused by not knowing what's going on
stress during initial set-up period
stress when working on children
stress when working on patient type not usually working with
stressed when working with babies
stressed when working with labor patients
stressed when working with preterm moms
taking one patient off pump so another can have it
thinking you are doing the right thing but you aren't (surprise)
too busy to double check things
unexpected problem
wandering around trying to find beeping pump
working on your own
workload - doing multiple things at once
workload - see many different patients quickly

Group 2 only

IV pump too sensitive to air
all information lost during battery failure
alter treatment based on patient's response
baby in distress

calling pharmacy to place order
cannot leave the patient
damage - patient ripped pump of the stretcher pole
different patient tolerances for air in tube young & old
different rate tolerances for older & younger patients
difficlult for patients to move when hooked to pump
difficult moving IV pump from one pole to another
dispensing non-routine medications
doctor - impatient
doctor will think that more infused than really did if previous shift forgot to clear
drip stops when battery dies - frustrating
experience - helps in learning the operation fast
fast paced work environment
frustration - patient eating causes IV occlusions (bending of arm)
hard to carry pumps around (too heavy)
hard to swtich pumps from bed to bed (too heavy)
humans are error prone
ideal workload is 4 patients to one nurse
in surgery fluids are given quickly (bolus)
lab calls with critical value
learning one technology helps with other technologies
locate pump at central sterile
managing multiple critical patients
manually fix pump during failure
many things going wrong
medication wont' scan (surprise)
mistakes happen when you are in a hurry
monitoring
need to act quickly
need to be careful with toxicity
need to draw blood if you don't have blood in stock
nurse (experienced)
nurse - headache
nurse - nervous
nurses (cautious)
nurses (not always paying attention)
nurses can program pump faster than pump can respond
nurses go to other wards to find pumps
nurses in ER monitoring IVS for short period of time (few hours)
nurses need to troubleshoot
nurses on floor monitoring IVs for long time - 12 hours
one-to-one patient ratio in chemo
patient crashing
patient lost a lot of blood during surgery
perfect timing needed
pretending to be calm when really frustrated
ratio - better nurse to patient ratio expected
remove pump from patient's room during pump failure
restart an IV because it is beeping too much
select between primary or secondary
shift work
shifting beds - so pumps are unplugged
some work is tedious
stress - difficulty monitoring symptoms of unresponsive patient
stress - doing chemo is scary
stress - everything seems to go wrong when you are busy
stress - exposure to a lot of hospital sounds
stress - handling multiple pumps at a time
stress - in a situation where you can't anticpate what is going to happen next
stress - nurse scared when makes a mistake
stress - patient's family has too high expectations of your standard of care
stress - unsure what will happen to patient
stress - unusual medication order
switch - between primary - piggyback
unexpected medical situation
unsure of proper dose (organization)
using one channel on a triple channel pump is frustrating

Group 1 and Group 2

Critcal work
alarm - distinctive
alarm constantly
alarm is obnoxious (too loud)
alerts are a distraction
babies - pump functioning critical for them
certain drug mistakes can kill patients (stress)
certain drugs are weight based
certain medications can't go in too fast - adverse patient reaction
certain medications need to go in fast (like a bolus)
conflict between pharmacy dose and what is needed in ward
critical patient
difficulty finding desired medication in iv pump medication list
dispensing critical drip
distracton - hiding broken/failed pump in another room / stairwell
do not have time for equipment issues (frustration)
floor nurses have to keep checking IV so it doesn't run out
forget a step
full census (lots of patients)
giving multiple infusions
in nighttime you don't want the screen bright because it keeps patients up
in nighttime you want to be quiet so you don't disrupt patient
infiltration
medication not infusing at all (surprise)
mistakes happen when you are busy & trying to do things quickly
nurse - worried
nurses (busy)
nurses (frustrated)
nurses (in a hurry)
nurses (stress)
nurses (tired)
nurses clean pumps
occlusion
older nurses have problems seeing
patient attempts to reprogram pump
piggyback medication
pump failure
pump failure during patient transfer
safety paramount
screeching noise-annoying
stress - everything is happening all at once
stress - patients stress increases nurses stress
time constraints
unable to figure out problem
unable to fix problem (satisfaction)
understaffed / shortstaffed
what you thought was happening is not happening
working night shift