

INVESTIGATING EMERGENCY MEDICAL SERVICE (EMS) PROVIDERS' BEHAVIORS
WITH PACKAGING IN A PREHOSPITAL CONTEXT

By

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ABSTRACT

INVESTIGATING EMERGENCY MEDICAL SERVICE (EMS) PROVIDERS' BEHAVIORS WITH PACKAGING IN A PREHOSPITAL CONTEXT

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Little is known about how packages perform in emergency contexts and the behaviors that Emergency Medical Service (EMS) responders use to deal with any shortcomings in package designs in these environments. Our years of work with healthcare providers in varied care settings yields anecdotal evidence that emergency personnel interact differently with healthcare packaging than providers in perioperative environments (e.g. one-handed use and use of teeth/tools for opening). It is not unreasonable to purport that these behaviors have the potential to play a role in patient outcomes. As such, investigation into difficulties with packaging, the designs, and conditions that induce them, is warranted.

The overarching goal of this work is to *develop packages optimized for prehospital settings and austere use contexts*. In support of this overarching goal, a total of four data collections was conducted.

A survey was distributed to 12,000 paramedics. Of the 1,912 responses (16% response rate), 1,702 were usable for analysis. Survey results reinforced anecdotal observations that EMS providers have difficulty with packaging, namely, identifying, opening, and using. Over 20% of respondents included in the analysis reported that they had experienced difficulties identifying (21.1 %) or opening (20.0%) medications and identifying (17.1 %) or opening (23.5%) medical supplies within the past year. This was reported to negatively impact patient care for between 1.2% (identifying a medication) and 3.0% (opening supplies) of total responses. The results suggested difficulties associated with packaging use (identify, open, and use) induced coping

strategies and negative patient outcomes and supports our anecdotal observation that paramedics use coping strategies (e.g. one hand use and use of teeth/tools, etc.) to deal with shortcomings of package design.

We created a collective case study for the purpose of designing the final study, a formative usability study employing simulation scenarios for two patients. Findings suggested patient demographics (namely infants and obese patients); condition (those requiring care on multiple systems) and behavior (e.g. belligerent, intoxicated, non-responsive patients) formed “worst case” scenarios. Sudden stops, bumps and potholes were all reported as further impacting difficulties. These findings coupled with a thorough review of ISO 2631 and the literature regarding whole body vibration and human ability informed decisions regarding the creation of a vibration profile intended to present realistic, but extreme, conditions likely to induce difficulties.

Simulation scripts were drafted and conducted in our ambulance simulator that incorporated motion with paramedics. Video collected from varied angles was analyzed post-hoc to conduct a formative usability analysis. Usability metrics included in analysis were informed by ISO 9241-11; namely, 1) *efficiency* (time task analysis), 2) *error* (identification of designs that induced unintended behaviors, and 3) *satisfaction* informed by ISO 9241-11 (2018 International Organization for Standardization [ISO], 2018).

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This dissertation is dedicated to my family who always supports or pushes me to succeed in my life and my career. Thank you for all your love and belief in me. I also want to dedicate this to my grandfather. I am sorry it is too late, but I believe you have been watching me and taking care of me from where you are. I hope you rest in peace.

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Chapter 1. Introduction

Background and Hypothesis

Based on anecdotal evidence and observations we have made over years of research with healthcare providers, we believe that the designers of sterile barrier systems (SBS) tend to focus on creating designs that work well in perioperative¹ contexts, potentially sub-optimizing their performance in other healthcare contexts (e.g. prehospital). An SBS is defined by ISO 11607-2:2019 as, the “minimum package that prevents ingress of microorganisms and allows aseptic presentation of product *at the point of use*” [emphasis added] (2019 International Organization for Standardization [ISO], 2019). When designers do not appropriately consider the use context, the design is sub-optimized because it is not created with the environment’s purpose, or challenges, in mind. Consider, for instance prehospital contexts; administration of medical care is provided to patients in urgent need to abate morbidity and mortality resulting from sudden, frequently unexpected, occurrences (The National Highway Traffic Safety Administration [NHTSA], 2007). If our hypothesis holds (that package designers tend to consider the perioperative context when designing healthcare packaging), we would expect behavioral differences, or unexpected behaviors, as people work with the products of healthcare in prehospital contexts. Work proposed herein objectively, and formally, explores this idea by

¹ The perioperative is comprised of three phases; *preoperative*, *intraoperative* and *postoperative*. *Preoperative* period is initiated with announcement of the need for surgery to patients. Patients can physically and psychologically prepare for the surgery during this period. This will end when patients are transferred to Operation Room (Goodman & Spry, 2013). *Intraoperative* begins when the patient is transferred to the opening room bed and ends with transfer to the post anesthesia care unit (PACU) or another area where *postoperative* is initiated. During this period, monitoring, anesthetizing, prepping, and draping is administered to patients and the procedure is conducted (Goodman & Spry, 2013). *Postoperative* ends with the resolution of surgical sequelae (Goodman & Spry, 2013).

employing a mixed methods approach in a series of evaluations which culminate in a formalized assessment of package usability (2018 International Organization for Standardization [ISO], 2018) assessed as part of two healthcare simulation scenarios .

Chapter 2. Literature Review

The concept of ‘affordances’ underpins the aim(s) of this work, but affordance theory is not likely familiar to many people working in packaging. As such, in this chapter, the concept of affordance behavior is introduced, along with relevant terminology caged in examples related to the proposed research. Among these, the object of interaction (packaged products of healthcare) and the actor (Emergency Medical Service (EMS) personnel) are introduced with other relevant concepts from the literature.

Figure 1 provides an overview of the literature review of this research. Affordances (actionable possibilities) are offered by the object (packaged product) within an explicit setting (e.g pre-hospital) unfolding as a context* (specific conditions) to the actor (an EMS provider). These actionable possibilities (affordances) might be clearly communicated or hidden (or weak). As such, it is important to design sterile barrier systems (SBS) that clearly communicate the intended behaviors or actions, the appropriate affordances (e.g. sterile opening and presentation of a medical device), to EMS personnel and also enable these behaviors in a context/setting that can be quite demanding.

* Context: A series of situations where events occur within a setting.

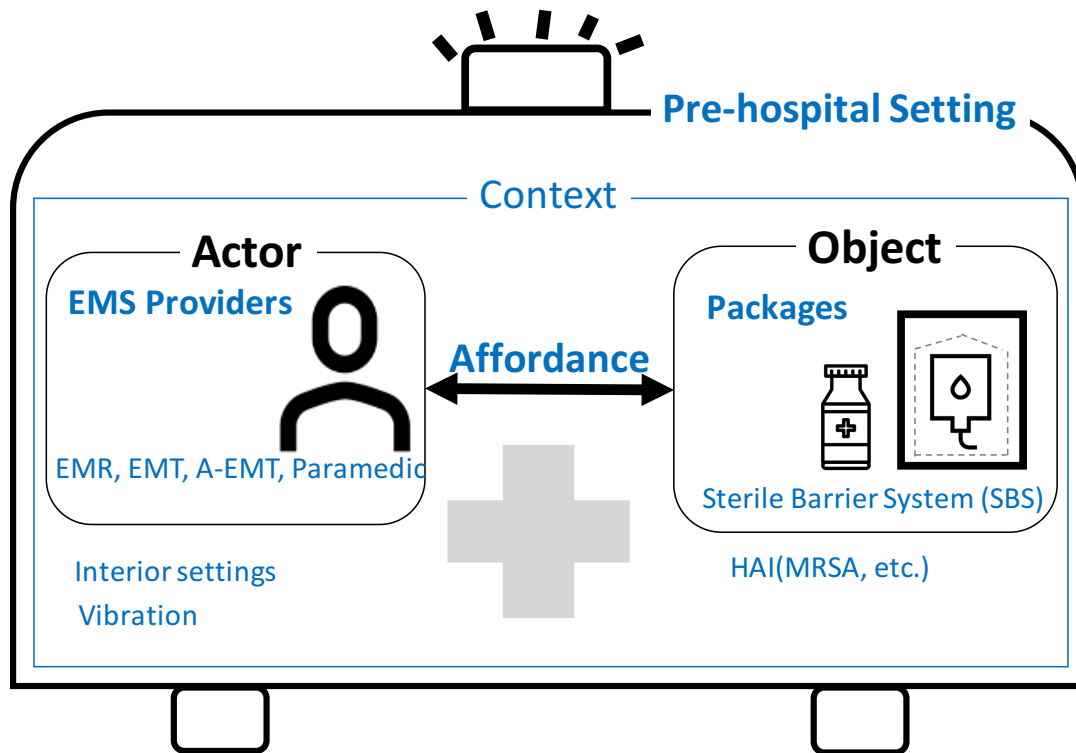


Figure 1. Overview of the research construct

2.1 Affordances

The concept of affordance theory was originally created by James Gibson (1979). Donald A. Norman (2013) extended it further to include the concept of ‘perceived affordances’. These two authors are major contributors to the theory, and we heavily leverage their concepts to frame our work. Additionally, the work of Galvao and Sato (2005) and Javier de la Fuente, Stephanie Gustafson, Colleen Twomey, and Laura Bix (2015a) is utilized to guide the development of new designs, which consider the harsh realities imposed by prehospital contexts.

2.1.1 Definition of affordance

Gibson (1979) asserts that, “the affordances of the environment are what it *offers* the animal, what it *provides* or *furnishes*, either for good or ill”, implying dual consideration is required, “the complementarity of the animal and the environment.” (Gibson, 1977) Norman adapted Gibson’s concept to a more industrialized frame of reference, defining affordances as, the “relationship between the properties of an object and the capabilities of the agent [actor in Gibson’s archetype] that determine just how the object could possibly be used” (Norman, 2013). Affordances represent the possible actions that a human can take with objects, also described as ‘– ability’. For example, SBS packages require ‘open- ability’ and sterile ‘transferability,’ (the package should be opened by users in ways that enable sterile removal and transfer of the contents within), and ‘grip-ability’ (the package has to offer the user the ability to grip), etc. Under Norman’s frame, the existence of an affordance, a behavioral possibility, is “dependent upon qualities of the object and the abilities of agent that is interacting [with it]” (Norman, 2013).

We would also assert that the relationship, and its outcomes, are impacted by the setting/ context surrounding the interaction as well. If EMS personnel cannot grip a package (either

because of inadequacy of form or limits imposed by the surrounding context such as blood from the scene), the package does not afford ‘grip-ability’, it does not induce the intended affordance, the ability to grip firmly.

In light of this, affordances are not just a property, but a relationship. Norman (2013), further emphasized the importance of the relationship construct when he coined the term ‘perceived affordances,’ suggesting for an affordance to be effective an actor must *perceive* it as an available possibility (Norman, 2013). In other words, the actor (in our case an EMS provider) must *perceive* that the package can be gripped and opened in a fashion that allows the sterile transfer of its contents under a specific setting with particular circumstances (context) to accomplish the work that needs to be done (see Figure 2).

The concept of the perceived affordance led to the idea of ‘signifiers. ‘Signifiers’ are design cues within the object that signal the intended action to be performed, yielding the desired function(s) from all possible action(s) that can occur (affordances) (Norman, 2013).



Figure 2. Affordance (Norman, 2013) and an example (in navy font under the boxes)

According to Gibson, affordances exist although they might not be perceived. The efficacy of the signifier, or design cue’s, ability to communicate the appropriate affordance behavior has been termed as its “signal strength,” by Winder (2006). Javier de la Fuente et al. (2015a) summarized the work of others into a list comprised of six kinds of affordance signifiers (See Table 1). Utilizing design cues that send strong signals results in actors easily and quickly perceiving the intended affordances and is indicative of optimized designs. “Strong, true”

signifiers, those that lead to intended affordances, influence users' behaviors in ways the designer intends. Those which negatively impact users' behavior, for example-leading them to affordances that are not intended (false affordances or negative affordances), should be improved.

Table 1. Definitions of Affordances described in Javier de la Fuente et al. (2015a)

Type of Affordance	Descriptions	Authors
Weak affordances	"..vague cues about how to operate an object, forcing users to focus on the task and use purposeful, effortful processing."	Winder (2006)
Strong affordances	"..evident that minimal cognitive resources are needed to intuit the proper actions of use."	
False affordances	"..inefficient and mislead the user, resulting in inappropriate actions."	
True affordances	"..provide clues that, if followed, will enable the successful completion of the intended task"	
Hidden affordance	"An affordance that does not convey its existence through perception."	Hsiao, Hsu, and Lee (2012)
Negative affordance	"..the potential unintended action"	(Maier & Fadel, 2009)

2.1.2 Constraining Affordances

Other authors added and evolved affordance theory with the additional concept of "constraints." The idea of constraints further enhances the practicality of the theory as a tool for the design and optimization of objects (Lidwell, Holden, and Butler (2010)). Constraints limit possible affordance behaviors using one of two broad paradigms: physical and psychological (Norman (2013); Lidwell et al. (2010)). Constraints induce users to limit their possible action with the object (e.g. packages), providing fewer potential actions/pathways to accomplish the desired task(s), resulting in less confusion about using a new object. This is an attractive strategy for packaged products that are likely to be unfamiliar, such as novel introductions to the market.

2.1.2.1 Physical constraints

By redirecting physical motion in specific ways, physical constraints limit the range of possible actions available with objects using physical properties such as size, shape, weight and configuration, etc. to do so (Lidwell et al., 2010). For example, the only portion of a Chevron pouch, commonly used for medical supplies, which allows the user to readily separate the layers of material is at the top (See Figure 3). The intention of the designer is that the actor (i.e. a healthcare provider) will grip the pouch at the top-center portion and peel the sealed layers apart using a single, fluid motion that is parallel to the length of the design. The sealed areas on all other sides of the pouch do not afford the user/actor with the ability to separate the two layers, signifying to the actor that they should start at the top. That said, the large, triangular areas which afford actors (healthcare providers) with a more powerful grip due to the increased available area enables a “false affordance” because it does not encourage the healthcare provider to peel open the package as it was intended (i.e. path of motion parallel to the pouches length- Right side of Figure 3). The signifier of the design cue (the small amount of material directly above the chevron) affords the actor a weak grip; this, in combination with the false affordance signaled by the large area directly to the side of the intended grip area (i.e. Left side of Figure 3) is likely to result in a weak signal strength for the appropriate affordance behavior (i.e. a pull path parallel to the pouches length).

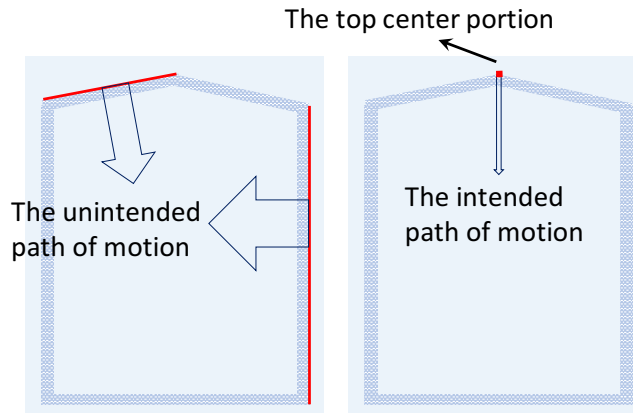


Figure 3. Chevron pouch labeled with unintended paths of motion (left) and intended peel path beginning from the top center portion (right)

Trays commonly used in the medical device industry (See Figure 4) often have a small tab, or tabs, that afford the separation of the lid stock from the tray, enabling the actor the ability to start the opening process. The sides and the corners that do not include the tabs represent the principles of physical constraint; these areas would be difficult for users to physically separate in order to begin the opening process.

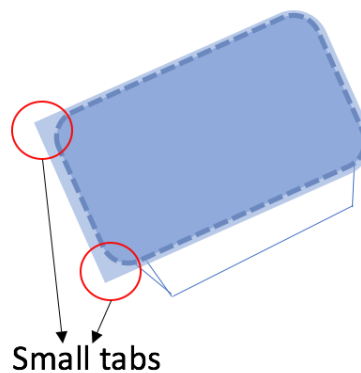


Figure 4. Tray package

Another example of the idea of physical constraints is a candy package that has two parts to take candy(s). The affordance, “pour-ability,” is constrained on the side of the package which

has a small opening, limiting the amount that can be easily and quickly removed from the container (Figure 5).



Figure 5. Two openings which enable candy(s) removal.

2.1.2.2 Psychological constraints

Another way to guide actors to intended behaviors when interacting with packaging is through the use of psychological constraints. Psychological constraints influence the actor's behaviors by utilizing conventions related to the actor's thoughts and perceptions, limiting the set of possible actions. Psychological constraints are sub-classified into semantic constraints, cultural constraints and logical constraints.

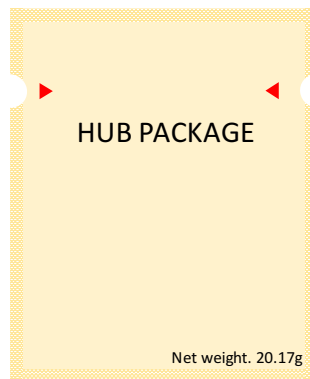


Figure 6. An example of physical and semantic constraint: a tear notch (a physical constraint) with an arrow mark (a semantic constraint) on a pillow package.

Semantic constraints (eg. symbols) encourage intended actions and limit unintended possible actions by conveying meaning. This type of constraint relies upon “knowledge of the situation and of the world”(Norman, 2013). An arrow marked next to a tear notch on package is an example of a semantic constraint (See Figure 6). When the actor perceives this feature on the

package, based on their previous knowledge and the designer's intention, they are likely to grip the top and side in an attempt to enable tearing to propagate from the notch.

Cultural constraints are conventions commonly accepted in a group, such as traditions and practices (Lidwell et al., 2010). A closure on prescription medication that should be rotated counterclockwise to open and clockwise to close is an example of a constraint formed from cultural convention.

Logical constraints, or "reasoned mapping," limits the range of possible actions (Lidwell et al., 2010) through the use of a logical analogy. A pill box organizer represents an example of logical mapping. When consumers see this product, they may map a weekly planner to the organizer, which has an arrangement composed of seven columns. Additionally, semantic symbols can be added to further enhance actions with the container. One such example would be the use of the sun and moon to help indicate 'for morning' and 'for night'. Together, these are intended to signify a map for days of the weeks and times of the day to help manage a medical regimen for seven days scheduled at varied times (see figure 7).

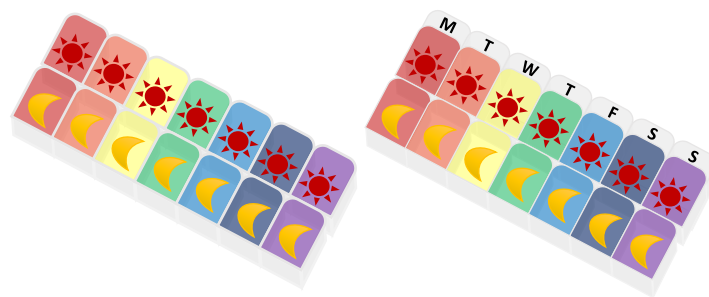


Figure 7. An example of 'logical constraint' coupled with semantic symbols: A pill box organizer.

2.2. Establishing the prehospital setting/context

EMS providers give initial care at disaster scenes, and are generally the first ones to respond to such scenes (Hanfling, Altevogt, Viswanathan, & Gostin, 2012). They are required to provide immediate evaluation and needed medical resources (Hanfling et al., 2012). As such, the nature of prehospital setting is typically urgent and unpredictable. Our study investigates one context of the prehospital setting, namely, the ambulance, in order to objectively explore how the relationship between the setting (prehospital), context (particulars of a scenario within an ambulance), actor (EMS personnel) and objects (packaged products) influence affordance behaviors related to packaging. The following sections are intended to form the basis of information for the creation of the simulation context (Aim 3) and inform those unfamiliar with nuances related to this extreme caregiving environment.

2.2.1 Specifications Related to the Ambulance

Ambulances are specified according to different standards, including:

- KKK-A-1822F (Federal Specification for the Start-of Life Ambulance),
- the National Fire Protection Association (NFPA) 1917, 2016 and
- the Commission on Accreditation of Ambulance Service (CAAS) Ground Vehicle Standard (GVS -2015).

Although KKK-A-1822 F was the first ambulance standard, further need for safety requirements were compulsory because existing requirements lacked sufficient detail; as such, new standards by the NFPA and CAAS were developed (Busch, 2015). Herein, we employed KKK-A-1822, the seminal standard, to inform the design of a box structure which was mounted to a vibration table; simulations were conducted within this box structure in an attempt to induce unintended affordance behaviors (namely, use of teeth and trauma shears).

2.2.1.1 Compartment of the ambulance.

KKK-A-1822F, identifies four different ambulance types; type I, type II, type III, and type IV. Types I and III are comprised of a square patient compartment equipped for Advanced Life Support (ALS). The difference between them is mainly the shape of the chassis; Type I uses a truck-like chassis while type III is outfitted with a cut-a-way van chassis. Type II is mounted on a van type chassis equipped with Basic Life Support features. Type IV is a mini ambulance that is intended to have the ability to access scenes where a conventional ambulance cannot reach. Type IV ambulances are built with a modified Yamaha golf cart chassis.

There are two levels of vehicle service types, Advanced Life Support (ALS) and Basic Life Support (BLS). Basic Life Support (BLS) involves “transportation by ground ambulance vehicle and the provision of medically necessary supplies and services, including BLS ambulance services as defined by the State” (The Centers for Medicare and Medicaid Services, 2011).

Table 2. Interventions in two different level of ambulance service (Woodall, McCarthy, Johnston, Tippet, & Bonham, 2007)

Basic Life Support (BLS)	Advanced Life Support (ALS)	
	ASL 1	ASL 2
Defibrillation	Endotracheal intubation (ETI), intravenous cannulation and cardioactive drugs	Manual defibrillation/cardioversion, Endotracheal intubation, Central venous line, Cardiac pacing, Chest decompression, Surgical airway, or g. Intraosseous line

Ambulances classified as having Advanced Life Support (ALS) service are categorized into ALS levels 1 and 2. ALS 1 involves “transportation by ground ambulance vehicle and the provision of medically necessary supplies and services including the provision of an ALS assessment or at least one ALS intervention (The Centers for Medicare and Medicaid Services, 2011).” The ALS and BLS interventions are shown in the Table 2.

ALS2 can also provide services available from the ALS1 teams, but with added capabilities. ALS2 teams have the ability to administer “at least three separate administrations of one or more medications by intravenous push/bolus or by continuous infusion (excluding crystalloid fluids)” or at least one of the following ALS2 procedures:

1. Manual defibrillation/cardioversion;
2. Endotracheal intubation;
3. Central venous line;
4. Cardiac pacing
5. Chest decompression;
6. Surgical airway; or Intraosseous line. (The Centers for Medicare and Medicaid Services,2011)

2.2.1.2 Lighting and Sound in the Ambulance

Ambulance Manufacturers Division (AMD) standards attempt to provide guidance related to sound and light in ambulance environments in order to provide a convenient working environment for EMS personnel; according to the standards, at the least, lighting and sound should not distract or negatively influence EMS providers as they perform their duties. The standards, AMD 006- “Patient compartment Sound Levels” and AMD 016- “Patient Compartment Lighting Levels” specify maximum or minimum levels regarding expectations for sound and minimum levels for lighting.

In accordance with these specifications, a minimum of 15-foot candles intensity is present at the centerline of the clear floor within the patient compartment; additionally, a minimum of 90% of the primary cot’s surface should be measured to have at least 35-foot

candles of illumination, and the sound in the patient compartment should not surpass 80 dB at any time.

2.2.2 Vibrational Inputs Experienced by Ambulances

A limited amount of work is available regarding vibration in the ambulance and how it impacts the abilities of EMS providers. When working on an ambulance, the exposure of EMS providers to shocks and vibrations that occur during transport are inevitable (Klegraefe, 2010). This section is intended to enhance understanding of definitions of shock and vibration, review the current state of knowledge regarding the possible impact of shock and vibration transmitted to the human body (Whole-Body Vibration (WBV)) and provide information regarding the (limited) state of understanding of this topic specific to ambulances.

2.2.2.1 Shocks and vibrations

Vibration is “a term that describes oscillation in a mechanical system (Harris & Piersol, 2002)”. Vibration is explained by frequency(s) and amplitude. The frequency is “cycles per unit time” and amplitude is the maximum value in the cycle, known as the magnitude (Harris & Piersol, 2002). Magnitude is reported as either peak amplitude or the root mean square of a signal (rms, ms^{-2}), (Savage, Billing, Furnell, Netto, & Aisbett, 2016) with *rms* preferably used (A. M. Nakashima, 2005). Additionally, vibration can be measured in three directions, the x-axis (fore-to-aft axis), y-axis (right-to-left axis) and z-axis (vertical axis) (See Figure 8) (Harris & Piersol, 2002).

Shock is “a somewhat loosely defined aspect of vibration wherein the excitation is non-periodic ” (Harris & Piersol, 2002). In our context, EMS personnel would experience vibration racing down the highway toward the hospital, where a shock input would occur when driving over a curb, bump or pothole. As such, the following studies, and data we have gathered using an

ambulance on under varied conditions of road and speed informed the profile which drove the motion of a vibration table. While in motion, two healthcare simulation scenarios were conducted with paramedics for the purpose of reviewing their affordance behaviors while interacting with a variety of healthcare packages.

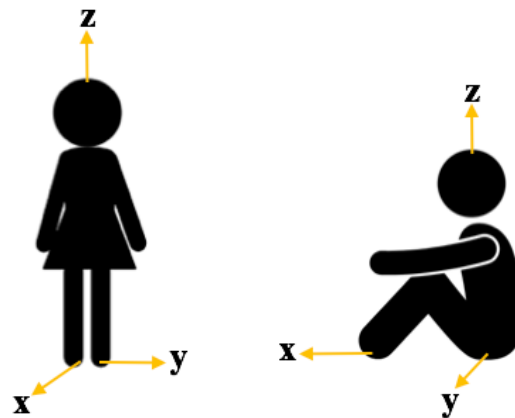


Figure 8. Vibration direction when standing (left) and sitting (right)

2.2.2.2 Whole-Body Vibration (WBV) and human performance

The effects of these inputs on the human body are termed as Whole-Body Vibration (WBV) defined as, “the vibration transmitted to a person’s entire body via his/her contact with a vibration source, usually through sitting or standing on a vibration surface” (Smith & Leggat, 2005). Measures common within the dynamics field (e.g. frequency, magnitude, direction, and duration) are correlated with factors such as discomfort and danger (Klegraefe, 2010; A. Nakashima & Cheung, 2006). Exposure levels are dependent on the type and the speed of the vehicle, environmental conditions (e.g. road) and body posture (A. M. Nakashima, 2005). A considerable amount of study has investigated the effect of WBV (e.g. physiological response, physical response (e.g. Low back pain) and muscle activity, etc.). Representative findings are summarized in Table 3; research has been conducted relating to the effect of WBV on standing

balance (Graaf & Van Weperen, 1997), visual perception (M. J. Griffin, 2012; Richard Wayne Shoenberger, 1972), discomfort (M. Griffin & Whitham, 1978) and hand-transmitted vibration (M. J. Griffin, 2012).

Table 3. Previous studies regarding WBV effects on human body

Type of vibration	Range of frequency	Acceleration magnitude and duration	Posture	Vibration axis	Effect(s)	Literature
N/S	N/S	$>0.93\text{m/s}^2$	Stand	N/S	“Leading to balance loss in a stationary, standing adult”	Graaf and Van Weperen (1997)
Sinusoidal	10 Hz*	N/S	N/S	Z axis	“No evidence of vibration effects on central cognitive process. Performance changes appeared entirely due to the visual disruption caused by vibration, seen as a shift in the intercept of the derived session line but with no change to the slope”	Richard Wayne Shoenberger (1972)

Table 3. (cont'd)

Sinusoidal	5 Hz	1.2 m/s^2 rms	N/S	Z axis	Decrement of performance (Writing task)	Gray, Wilkinson, Maslen, and Rowlands (1976)
Sinusoidal	4Hz	5 seconds of 1.0 m/s^2 rms	N/S	Z axis	Produce discomfort	M. Griffin and Whitham (1978)
Random vertical	2-6 Hz	N/S	Seat	X and Z axes	“large displacement of the hand”	M. J. Griffin (2012)
	4-8 Hz	N/S	Seat	Y axis	“largest displacement of the hand”	
N/S	Around 10 Hz	N/S	N/S	Z axis	“Vision no longer accurately adjust for the displacement of the image on the retina”	M. J. Griffin (2012)
N/S	Around 20 Hz	N/S	N/S	Z axis	“effect resonances within the human eye muscles and can cause even more distortion of visual perception”	M. J. Griffin (2012)

Frequencies ranging from 0.5 Hz -100 Hz are common among the reviewed studies characterizing WBV (M. J. Griffin, 2012; ISO, 1997). The vertical axis (z-axis) is usually considered as the worst vibration direction (Paddan & Griffin, 2002) and ranges between 4 and 8 Hz in the vertical direction have been suggested by Smith and Leggat (2005), with 5 Hz, vertically, creating maximum transmission to the body (Paddan & Griffin, 2002). Thus, it's been postulated that the impactful vibration, when it comes to human performance, occur in the vertical axis at 5 Hz (A. M. Nakashima, 2005).

The magnitude of interest with WBV range from about 0.01 to 10 ms^{-2} (peak) (M. J. Griffin, 2012). The magnitude at 10 ms^{-2} is considered as a hazard while 0.01 ms^{-2} is assumed to be dangerous depending on the frequency, direction and duration of the vibration (M. J. Griffin, 2012). Vibrations over the road and in rail vehicles generate a range from 0.2 ms^{-2} to 1.0 ms^{-2}

during a smooth ride, and exceed 1.0 ms^{-2} for rough rides (M. J. Griffin, 2012). Griffin stated that humans are more likely to encounter events with high magnitudes (e.g. pot-holes) and feel discomfort when the duration of riding in the vehicle is longer, compared to when the duration is shorter (M. J. Griffin, 2012).

Most of studies reviewed evaluate effects on humans using ISO 2631 -1 (Mechanical vibration and shock-Evaluation of human exposure to whole-body vibration; Part 1: General Requirements, 1997) . This standard utilizes 6 different levels of amplitude with regard to ‘uncomfortableness’. Researchers use these levels of “uncomfortableness” to explore things like seating posture and z-axis movement. Findings suggest:

- Less than 0.315 m/s^2 : Not uncomfortable
- $0.315\text{-}0.63 \text{ m/s}^2$: A little uncomfortable
- $0.5\text{-}1 \text{ m/s}^2$: Fairly uncomfortable
- $0.8\text{-}1.6 \text{ m/s}^2$: Uncomfortable
- $1.25\text{-}2.5 \text{ m/s}^2$: Very uncomfortable
- Greater than 2.5 m/s^2 : Extremely uncomfortable (Mechanical vibration and shock-Evaluation of human exposure to whole-body vibration; Part 1: General Requirements, 1997)

This suggests that human performance in a mobile vehicle is adversely impacted at magnitude levels that are greater than 2 m/s^2 .

McLeod and Griffin (1986) tested the influence of vibration on more specific motor abilities (also in the vertical direction) when they investigated WBV and a writing task under vibration. They report that vertical vibration frequencies between 4 and 6 Hz are the most

impactful to writing and vibration magnitudes of 1.0 m/s^2 rms and higher make it ‘very difficult’ to write.

McLeod and Griffin (1989) articulated that frequencies of vibration around 10 Hz impede the ability to observe a moving object; that is, humans cannot track the shift of the object on their retina, whereas visual perception is not influenced by vibrations below 2 Hz as the eyes are able to chase moving objects. Furthermore, resonance within the eyes’ muscles occurs when the frequency of vibrations are approximately 20Hz, causing more distortion of the vision (McLeod & Griffin, 1989). In contrast to McLeod and Griffin (1989), Nakashima and Chuen (2006) suggested that vertical vibration around 5 Hz have maximum impact on tracking performance (eg. tracking a moving object) (A. Nakashima & Cheung, 2006). They assert that the greater magnitude is, the more tracking error exists. However, little is known about the other axes of movement, though Nakashima and Chenung (2006) suggest that there are effects of horizontal vibration on vision, with frequencies below 3 Hz negatively influencing tracking (A. Nakashima & Cheung, 2006).

We are not aware of available data which characterizes the relationship between the inputs experienced by ambulances (shocks and vibration) and EMS providers’ ability to perform tasks, although limited work investigates its impacts on the workers themselves (e.g. Muscle reflex, heart response, hand-eye coordination, etc.) (Klegraefe, 2010; Mani, Milosavljevic, & Sullivan, 2010; McLeod & Griffin, 1989; Richard W Shoenberger, 1972) and how patients on a cot (Ahlin & Granlund, 2002; Bouchut, Van Lancker, Chritin, & Gueugniaud, 2011; Prehn et al., 2015; WADDELL, 1975) react to motion within the ambulance.

Physical capabilities are important to the job performance of EMS personnel, as well as those working in the military (Bos, Mol, Visser, & Frings-Dresen, 2004; Rayson, Pynn,

Rothwell, & Nevill, 2000) and vibrations have been noted to adversely influence EMS providers' ability to administer patient care (Klegraeffe, 2010). As little is known about how the effect of vibration negatively impacts EMS providers' job performance, this unique work setting should be investigated; products should be designed with both setting (prehospital) and context (ambulance with specific scenario) in mind.

As such, the previously reviewed studies have been used to make decisions regarding pilot data collected by the research team to create an input signal for the table where EMS simulations were conducted to test the impact of setting and context on the affordance behaviors elicited by EMS personnel as they interacted with multiple healthcare products.

2.3 The Actor: Practice, scope, and responsibilities EMS providers

One of the main components comprising the affordance concept is the actor. The actor, or the human, an EMS provider, has the potential to perceive affordance possibilities and interacts with object(s) (packages) within the context to accomplish the desired behaviors. As such, having an understanding of EMS provider's duties is important to work presented herein. This section attempts to provide that understanding.

There are four licensure levels of EMS providers available through the National Highway Traffic Safety Administration (NHTSA); practical licensure levels and titles are incredibly varied over regional and local municipalities. As such, we utilize the NHTSA frame of reference to structure our discussion of licensure level.

2.3.1 Emergency Medical Responder (EMR) (The National Highway Traffic Safety Administration [NHTSA], 2007)

Emergency Medical Responders are people with the necessary knowledge and skills to administer basic lifesaving interventions with minimal equipment while waiting for additional EMS response. Additionally, they serve to assist EMS providers with higher levels of licensing at the scene and during transport.

2.3.2 Emergency Medical Technician (EMT) (The National Highway Traffic Safety Administration [NHTSA], 2007)

The primary responsibility of Emergency Medical Technicians (EMTs), is to administer basic emergency medical care and provide transportation for critical patients needing emergency medical service. They perform basic interventions with equipment contained within the

ambulance. This level is the minimum licensure level to transport patients in an ambulance. As such, EMTs serve as a connection from the scene to the emergency health care system.

2.3.3 Advanced Emergency Medical Technician (A-EMT) (The National Highway Traffic Safety Administration [NHTSA], 2007)

The primary responsibility of Advanced Emergency Medical Technicians (A-EMTs) is to administer basic, and limited advanced, emergency medical care and to provide transportation for patients in need of emergency medical services. Like EMTs, they are capable of providing limited acute care, but can provide pharmacological interventions and support health with advanced equipment within the ambulance, serving as a connection from the scene to the emergency health care system. This level is the minimum licensure level to administer limited advanced patient care at the scene or during transportation.

2.2.4 Paramedics (The National Highway Traffic Safety Administration [NHTSA], 2007)

The primary responsibility of paramedics is to administer advanced emergency medical care and to provide transportation for critical patients in need of emergency medical services. Paramedics have more advanced knowledge and skills essential to administering basic and advanced patient care (e.g. performing invasive and pharmacological interventions) with both basic and advanced equipment placed in the ambulance, and, of course, serve as a connection from the scene to the emergency health care system. Table 4 represents differences between each licensure level to clarify responsibility.

Table 4. Difference of scope of practice between the level of EMS providers. (The National Highway Traffic Safety Administration [NHTSA], 2007)

Difference of scope of practice between the level of EMS profession	Between EMT and EMT	Between EMT and AEMT	Between AEMT and Paramedic
	“The knowledge and skills necessary to provide medical transportation of emergency patients.”	“The ability to perform limited advanced skills and provide pharmacological interventions to emergency patients.”	“The ability to perform a broader range of advanced skills. These skills carry a greater risk for the patient if improperly or inappropriately performed, are more difficult to attain and maintain competency in, and require significant background knowledge in basic and applied sciences.”

Paramedics are capable of administering care in the most extreme of prehospital settings and cases, and, therefore, have access to the widest range of products. As such, they were chosen as the target population for this research.

2.4 Objects within the pre-hospital setting (Healthcare Packaging)

While the primary function of packaging is to contain products (Marotta, 1998); it performs other tasks as well, serving to protect and identify products, enable processing, enhance ease of product use and facilitate integrity of package contents throughout distribution and handling. Different functions take on different levels of relevance and importance based on the products being packaged and the context of use. ‘Sterility’ or ‘preventing ingress of microorganisms’ is emphasized for many medical device packages; sterile medical devices must have sterility maintained from sterilizer until use (Bruch & Reich, 1998). This is accomplished through the use of a “sterile barrier system (SBS).”

Many factors, including material selection, device profile and characteristics, sterilization technique, risks associated with SBS failure, etc., guide decisions made when designing an SBS. Designs that facilitate sterilization and maintain package integrity (the ability to hold out microbes during shipping, distribution, storage and handling), are paramount for the SBS. One aspect of package integrity relates to package seals. Seal integrity is the “characteristics of the seal, which ensures that it prevents the ingress of microorganisms under specified conditions” (“ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems ", 2006). “Seals must be free of channels and must withstand the rigors of sterilization and transit (J de la Fuente & Bix, 2009)”.

Although the definition of an SBS encompasses prevention of the ingress of microbes from processing through distribution and use, it also specifically spells out the need to facilitate aseptic transfer. Despite this fact, most of the purposeful work used to validate the efficacy of the SBS centers squarely on ensuring integrity throughout processing and distribution, neglecting to put the same thoughtful science to how designs perform in the hands of providers.

As mentioned, packaging designed for healthcare environments has very different demands, emphasizing and requiring different features than those designed for sale in retail that are used in home environments. One of the main concerns regarding SBS is that Healthcare-Associated Infections (HAIs) are a problematic. HAIs are infections that patients acquire while being provided patient care within a healthcare setting (CDC, 2016). These infections pose both human and economic burdens to our society (Glance, Stone, Mukamel, and Dick (2011); Allegranzi, Nejad, and Pittet (2017)).

Allegranzi et al. (2017) suggest healthcare provider's hands to be the most common vector for transmitting microorganisms that cause HAIs. Although the most obvious route of transfer of these organisms would occur directly from the provider to the patient (direct contact transfer), it is also possible that a provider's hands (or objects that they have touched- like the outside of the package) can contact medical devices that are used on the patient, creating the potential for indirect transfers of the microbes (transfer through a contaminated, intermediate object or person) (Siegel, Rhinehart, Jackson, & Chiarello, 2007).

One possible solution to this is to employ a user-centered design approach, undergirded with affordance theory, to create package designs which strongly signal appropriate/intended affordance behaviors to actors, enabling clean transfer of the device. Decisions made regarding the design, and the design cues, must also account for the setting and the context in which the device must be used.

Chapter 3. Study Aims and an overview of data collection

3.1 Study Aims

The overarching goal of this study was to *develop packages optimized for the prehospital settings and severe contexts using simulation scenarios informed by pilot work conducted by the research team*. Four proximal aims were built in support of this overarching goal. They are:

- *Aim 1*-Verify the presence of difficulties with packaging in prehospital contexts, the coping strategies employed to overcome difficulties, and begin to characterize the prevalence of each.
- *Aim 2*- Identify factors (both package design and context) that induce unintended behaviors/coping strategies (e.g. use of teeth and scissors) in prehospital settings.
- *Aim 3*-Create simulation scenarios (contexts) that induce the unintended behaviors/coping strategies studied previously.
- *Aim 4*- Develop an understanding of affordance behaviors EMS personnel use to deal with packaging (i.e. coping strategies) during tasks (opening, identifying) and characterize design cues and contextual factors that induce them.

3.2 An overview of data collection

A total of 4 data collections were taken. In support of Specific *Aim 1*, a survey was conducted to verify anecdotal observation that EMS providers have difficulty identifying, opening and using products from packaging under their urgent context. After verification of

anecdotal observation through the online based survey, a case study was developed utilizing a series of semi-structured interviews for the purpose of garnering insights into the contextual factors that negatively impact their ability to interact with packaging (*Aim 2*). Vibration data were collected using two type III ambulances with varied road conditions for use in the simulations conducted under Specific Aim 3. Based on all insights gathered under Specific Aims 1-2, the ambulance simulator and simulation scenarios were crafted with the intention of being realistic but severe enough to induce the unintended affordances reported under Specific Aims 1-2. All details of methods for each are elucidated in the following chapters. Figure 9 provides an overview of the body of work.

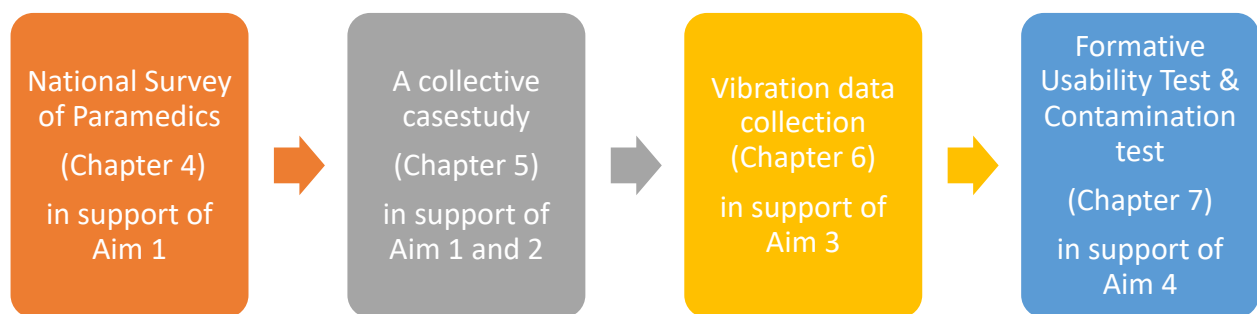


Figure 9. An overview flow chart of the proposed method

Chapter 4. Online-based Survey

An online survey was conducted under IRB approval (IRB#x16-1412e) in support of Specific Aim 1. The main goal of this survey was to garner insight into the behaviors of EMS (Emergency Medical Service) professionals when identifying, opening, and using packaging and to begin to characterize the prevalence of problems with packaging in the prehospital context.

4.1 Method

4.1.1 Implementation and Participants

The survey was created in close collaboration with the National Registry of Emergency Medical Technician (NREMT). An early draft, created jointly, was trialed by the NREMT as a “Cognitive Walk-Through”. The purpose of this pretest was to ensure survey items to be functioning as intended. NREMT and MSU personnel convened to discuss pretest results and arrive at consensus changes to the survey. These changes were intended to enhance understanding amongst respondents (e.g. “medical device” was changed to “medical supply” to enhance respondent understanding).

The online survey was distributed through NREMT to a random selection of 12,000 EMS professionals registered in their database which included an email address (See Appendix B). Survey participation was voluntary, and respondents could quit or skip any portion of the survey. Participants who completed a survey by December 1st of 2016, were put into a random drawing, with 10 of the participants provided a \$100 Amazon gift card.

To participate in this survey, respondents had to;

- Be between 18 and 85
- Be employed (currently or formerly) as paramedic
- Have provided medical treatment in pre-hospital setting within a year

The survey began with demographic questions, as the respondent proceeded into the content of the survey, a cascading system of questions (described below) was employed.

4.1.2 Survey Formatting

Two large categories of products were investigated, medications and medical devices (termed “medical supplies,” a term more common to EMS providers). Within each category, questions were organized to probe three broad tasks: •identifying, •opening, and • administering (or using). Where initial responses warranted it, within each task, questions probed the reasons for difficulty EMS personnel encountered, coping strategies they employed and experiences that resulted, including any negative impacts/outcomes related to patient care. The details of each question are shown in Table 5. Other questions characterizing the demographics and work history of the participants are available in Appendix C.

Table 5. Questions in the survey

Type of product	Task Behaviors	Questions
Medication	Identify Medications	• In the past 12 months, have you had difficulty identifying a medication? • In the past 12 months, which of the following has made it difficult for you to identify a medication? • In the past 12 months, which of the following have you used to cope when medications were difficult to identify? • In the past 12 months, has an issue with identifying a medication negatively impacted your patient care?
	Open Medications	• In the past 12 months, have you had difficulty opening a medication? • In the past 12 months, which of the following has made it difficult for you to open a medication? • In the past 12 months, which of the following have you used to cope when medications were difficult to open? • In the past 12 months, has an issue with opening a medication negatively impacted your patient care?

Table 5. (cont'd)

	Administer Medications	• In the past 12 months, have you had difficulty administering a medication? • In the past 12 months, which of the following has made it difficult for you to administer a medication? • In the past 12 months, has an issue with administering a medication negatively impacted your patient care?
Medical supply	Identify Medical Supplies	• In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)? • In the past 12 months, which of the following has made it difficult for you to identify medical supplies? • In the past 12 months, which of the following have you used to cope when medical supplies were difficult to identify? • In the past 12 months, has an issue with identifying medical supplies negatively impacted your patient care?
	Open Medical Supplies	• In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)? • In the past 12 months, which of the following has made it difficult for you to open medical supplies? • In the past 12 months, which of the following have you used to cope when medical supplies were difficult to open? • In the past 12 months, has an issue with opening medical supplies negatively impacted your patient care?
	Use Medical Supplies	• In the past 12 months, have you had difficulty using a medical supply? • In the past 12 months, which of the following has made it difficult for you to use a medical supply? • In the past 12 months, has an issue with using a medical supply negatively impacted your patient care?

Table 6 provides a scaffold of the types of responses that were received within each section of the survey as it was organized. A cascading system of questions was employed; when the participant answered ‘yes’ with regard to a specific difficulty, a probing question would be presented; when ‘no’ was coded, they were forwarded on. (e.g., if a participant indicated, yes, that they had experienced difficulty in identifying a medication within the past 12 months, then a series of possible reasons would present (as well as the opportunity for open-ended write in), these intended to develop details regarding the obstacles encountered. This same approach was

taken regarding the reasons for the difficulty and the coping strategies (affordance behaviors) that EMS personnel employed when dealing with the difficulty.

Table 6. Questions under each broad task behavior

		Identifying	Opening	Administering
Medication	Reasons	• Lack of transparency of package made it difficult to tell what product was • Crowded label made it difficult to read • Small text on label made it difficult to read • Different supplies had similar packaging • Confusing names • Dark conditions made it difficult to read labels • Other	• Too small of an area to grip • Materials meant to separate stuck together • Product required too much force to open • Product required two hands to open • Unfamiliar with product packaging • Packaging directions for opening were not clear • Other	• Medication characteristics made it difficult to remove • Product stuck to package • Complicated packaging features • Vehicle (e.g., ambulance) movement and vibration • Other
	Coping Strategies (Affordance behaviors)	• Flashlight • Touch/feel • Changed the location of product within container, bag or ambulance • Other	• Knives • Scissors • Teeth • Pen • Partner assistance • Other	N/A

Table 6. (cont'd)

		Identifying	Opening	Using
Medical Supplies	Reasons	• Lack of transparency of package made it difficult to tell what product was • Crowded label made it difficult to read • Confusing names • Dark conditions made it difficult to read labels • Other	• Too small of an area to grip • Materials meant to separate stuck together • Product opened with too much force • Product required two hands to open • Unfamiliar with product packaging • Packaging directions for opening were not clear • Other	• Product characteristics made it difficult to remove • Product stuck to package • Multiple layers of packaging • Multiple, loose items • Other
	Coping Strategies (Affordance Behaviors)	• Flashlight • Touch/feel • Changed the location of product within container, bag or ambulance • Other	• Knives • Scissors • Teeth • Pen • Partner assistance • Other	N/A

4.1.3 Analysis method

Analysis of the survey responses was completed using SPSS (IBM, Version 22). Results were grouped by the task behavior (identifying, opening and administering) and subdivided into the two product categories of interest (Medications and Medical Supplies). There was a total of 1,912 respondents to this survey. 1,719 respondents reported that they had provided patient care in the prehospital setting in the past 12 months. After removing respondents who had not administered care within the past 12 months, and those who partially completed the survey, there were a total 1,702 respondents used for the analysis. Responses to the open-ended questions, ‘other’ for reasons for the difficulty in task behaviors and coping strategies related to difficulties are tabulated in Appendix D.

An ‘odds ratio’ approach was employed to conduct pairwise comparisons related to reasons for difficulties encountered and coping strategies (affordance behaviors) employed to overcome the reasons for the difficulties. An odds ratio represents the relative chance of an event happening under two different conditions.

$$\frac{\textit{The odds that an outcome will occur given a particular exposure}}{\textit{The odds of the outcome occurring in the absence of that exposure}}$$

(Szumilas, 2010)

If the 95% of confidence interval estimates do not include 1, this indicates that the likelihood of the probability of the occurrence of one event relative to the other is significantly different.

Using this concept, the data was analyzed regarding;

- Reasons for the difficulty
- Coping strategies (affordance behaviors) for each difficulty

The analysis of ‘Reasons for the difficulty’, intended to probe the design cues likely to induce difficulty when performing task behaviors (identifying, opening, administering). The statistical analysis of reported ‘coping strategies (affordance behaviors) for each difficulty’, was intended to explore the affordance behaviors that were likely to result when a particular difficulty was evident.

4.2 Results

4.2.1 Demographic

80.26% (1,350) of total respondents included for analysis (1,702) were male and 19.7% (332 of total respondents) were female (with 20 electing not to provide a response- See Figure 10). Self-reported educational frequencies are available in Figure 11.

More than a quarter of the respondent population 28.3% (481) had more than 21 years working experience (See Figure 12). A majority, 55.3% (938), performed their EMS work only for one organization while 44.7% (759) of them (1,702) responded that they work for two or more organizations as an EMS professional (See Figure 13). Most reported the main focus of their work to be patient care; specifically, 74.8% (1,272) of respondents reported that the best description of their primary role is a 'Patient Care Provider' (See figure 14). "Fire Department" was reported as the primary EMS Agency/Organization by 38.6% (656) respondents (See Figure 15) with the most respondents reporting 'Primarily 911 response with or without transport capability -Immediate response to an incident location, regardless of method of notification (for example, 911, direct dial, walk-in, flagging down)' was reported by a majority 72.2% (1,228) (See Figure 16). 13.82% (235) of total respondents analyzed (1,702) have been employed or volunteered at their main EMS job for 'more than 21 years' (See Figure 17). A majority were employed in this work 'Full time' (1,472 respondents; 86.9% of respondents included in the analysis; See Figure 18). 502 respondents (29.5 % of total respondents) responded to calls in a typical week at their main EMS job (See Figure 19). 21.7 % (369 of total respondents included for analysis) and 21.9% (273 of total respondents included for analysis) work in 'Small Town (2500-24999 people)' and 'Medium Town (25000-74999 people)', respectively (See Figure 20).

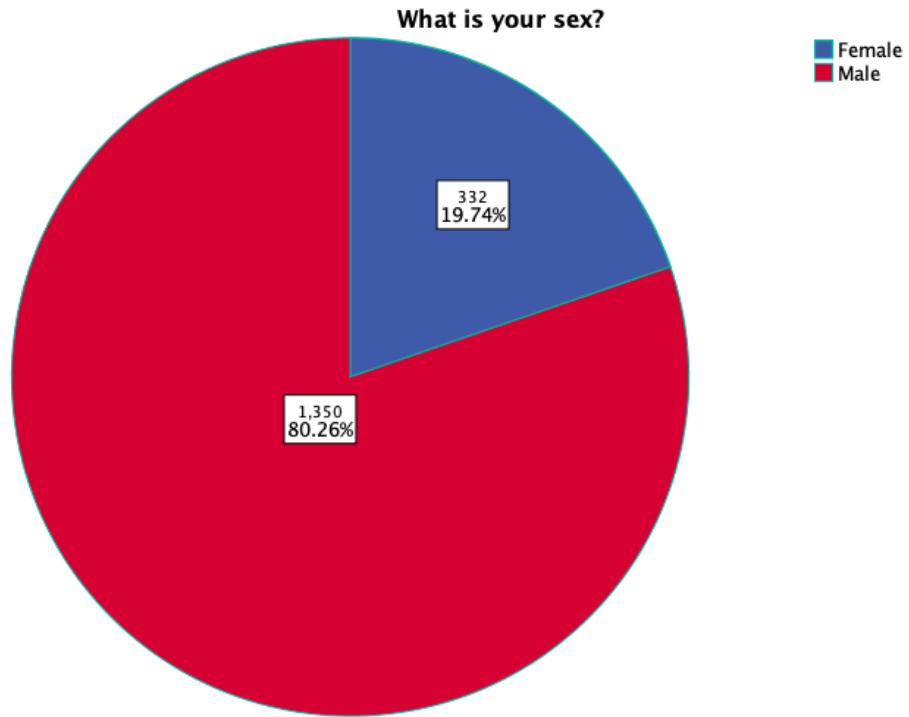


Figure 10. Sex rate of respondents

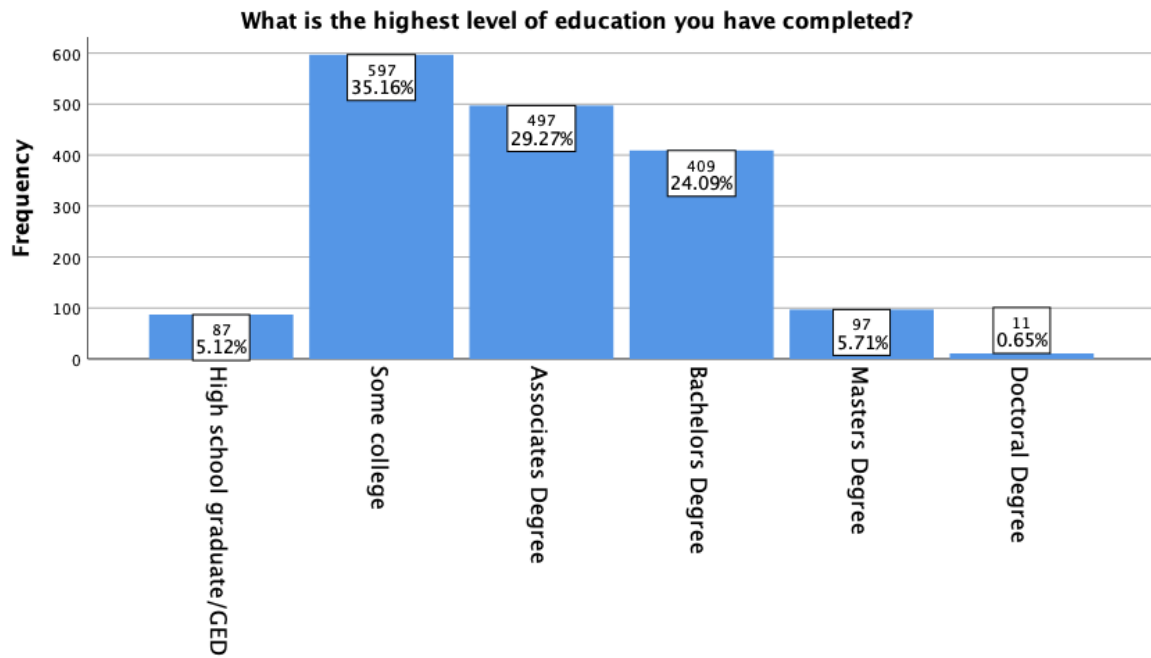


Figure 11. Educational Level

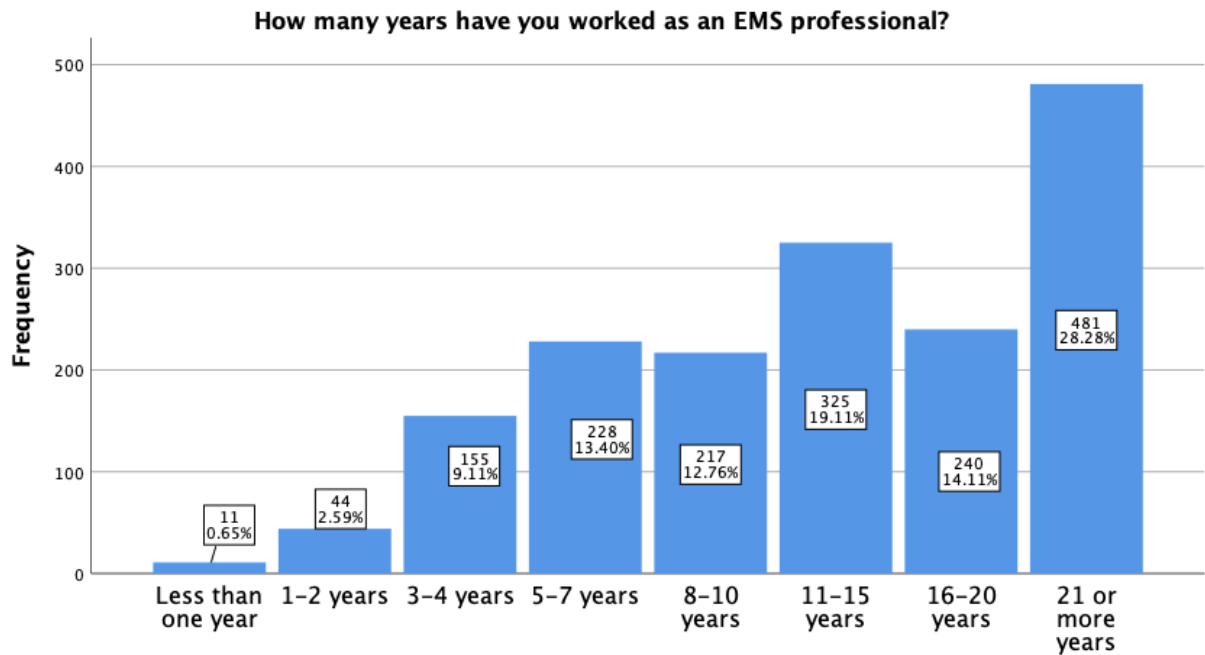


Figure 12. Years working as an EMS professional

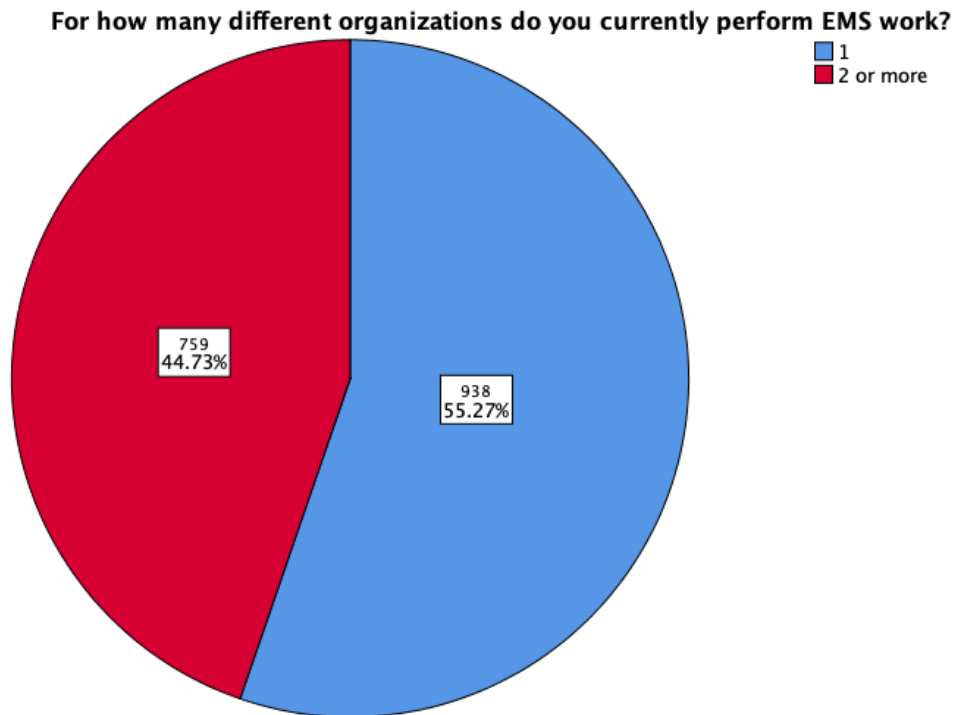


Figure 13. The number of organizations they currently perform EMS work

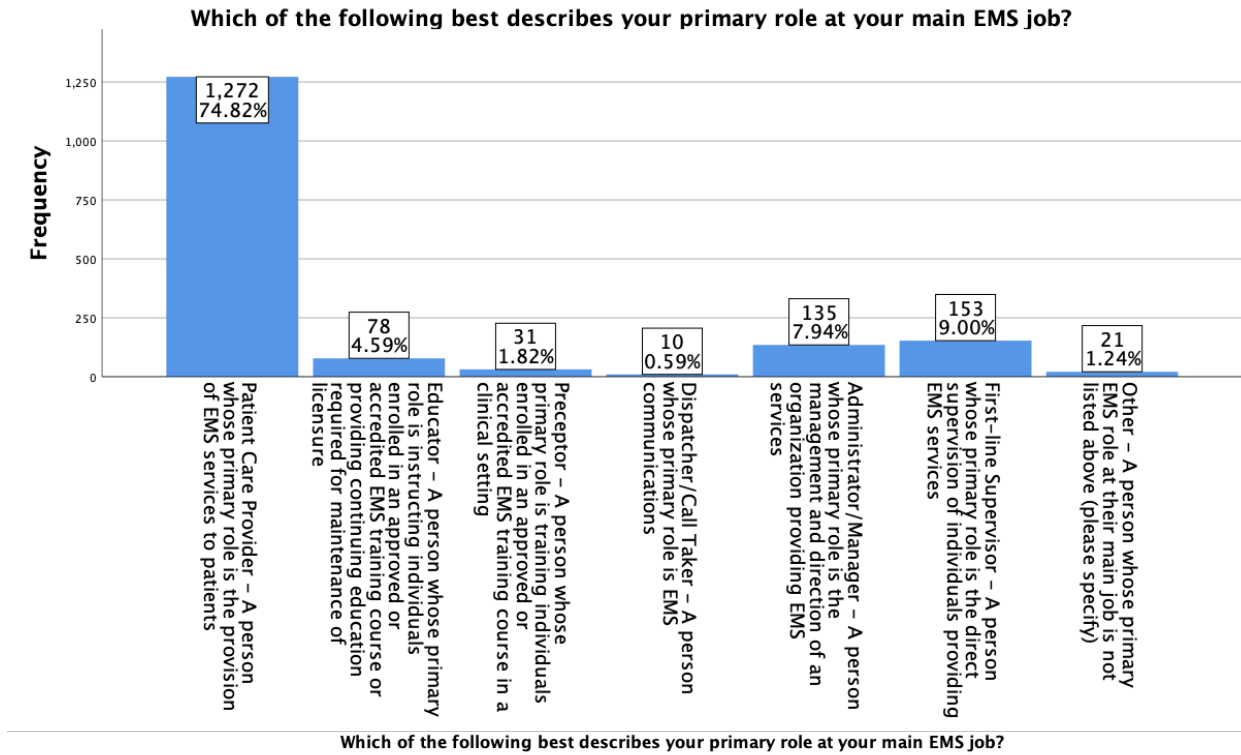


Figure 14. Primary role/activities within EMS

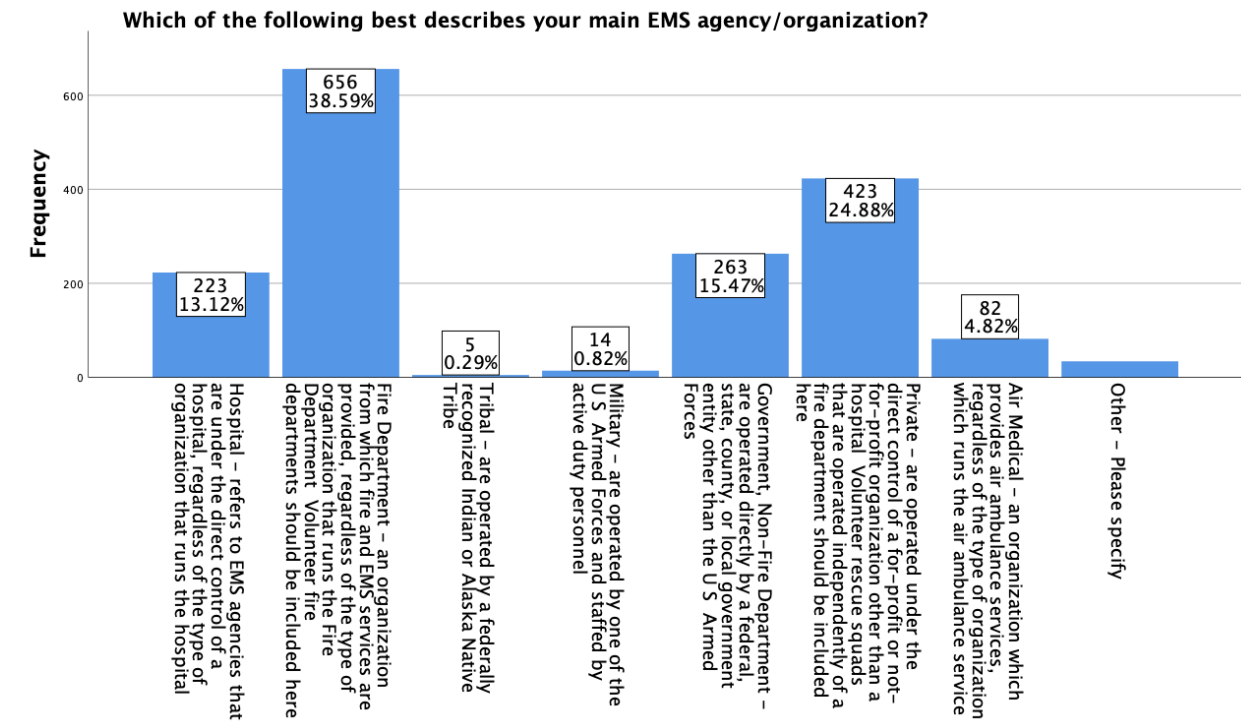


Figure 15. Main EMS agency/organization

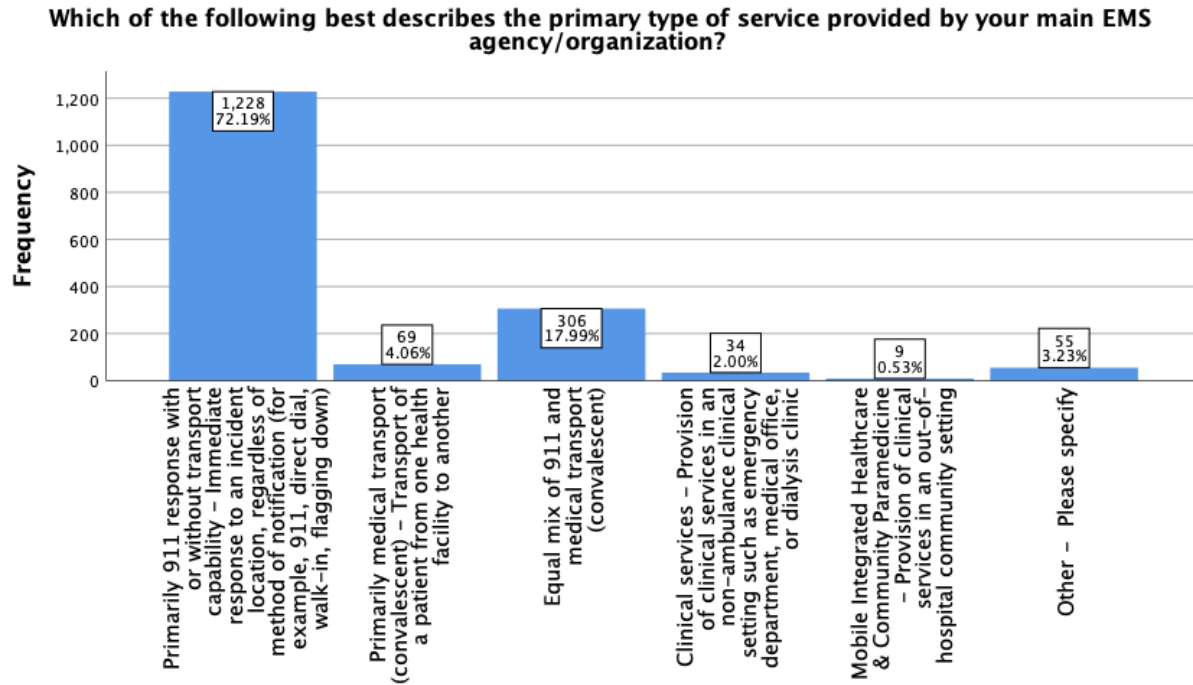


Figure 16. Service type of main EMS job

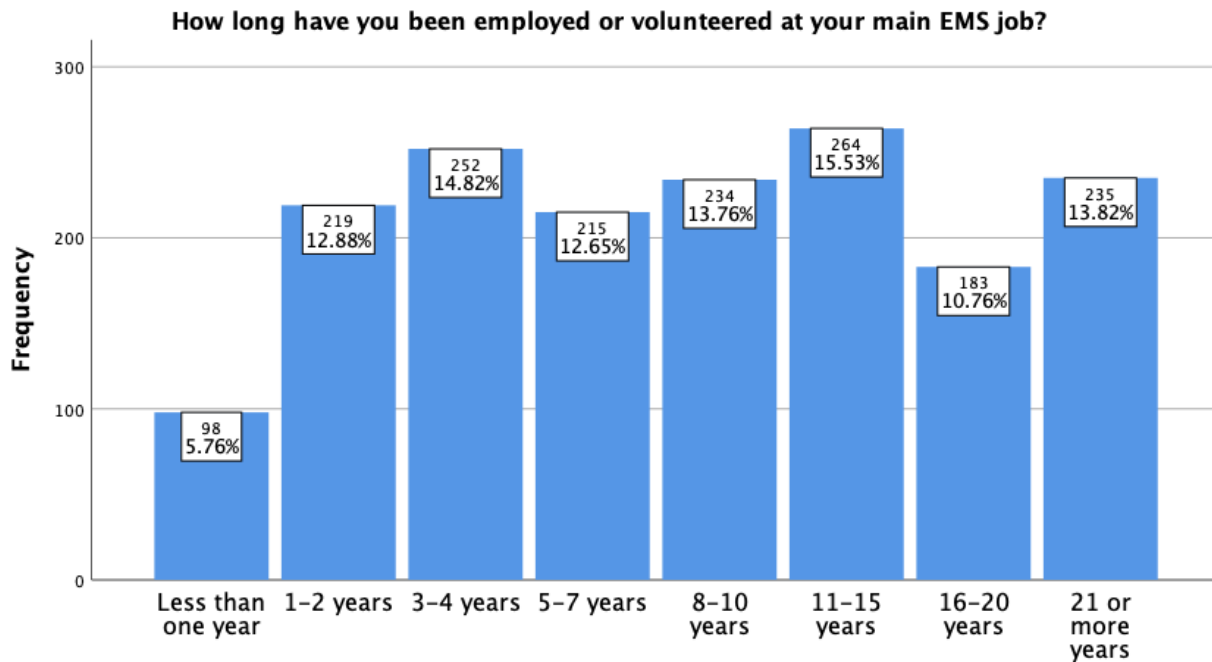


Figure 17. The time that they have been employed or volunteered at their EMS job

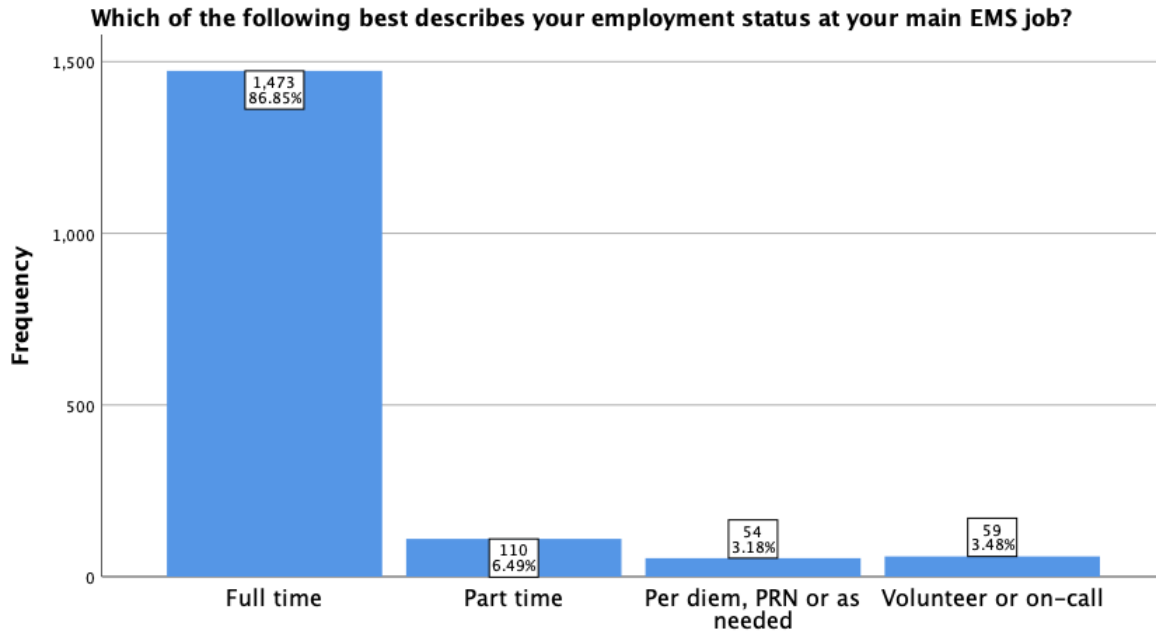


Figure 18. Employment status

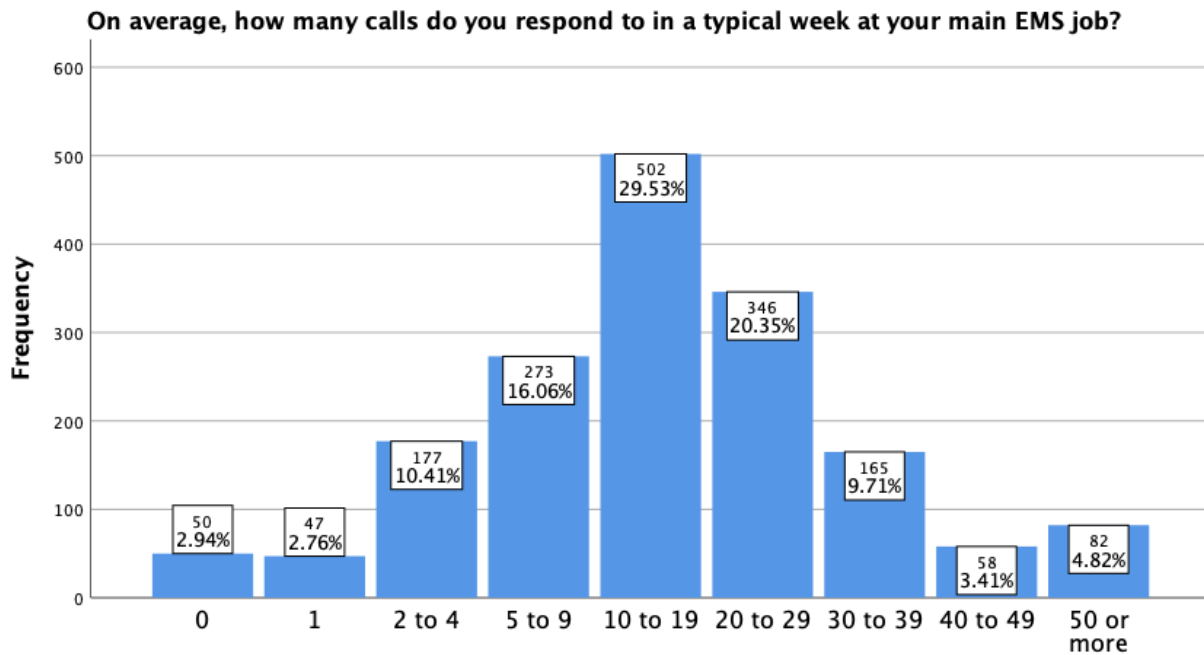


Figure 19. Average calls that answered in a typical week

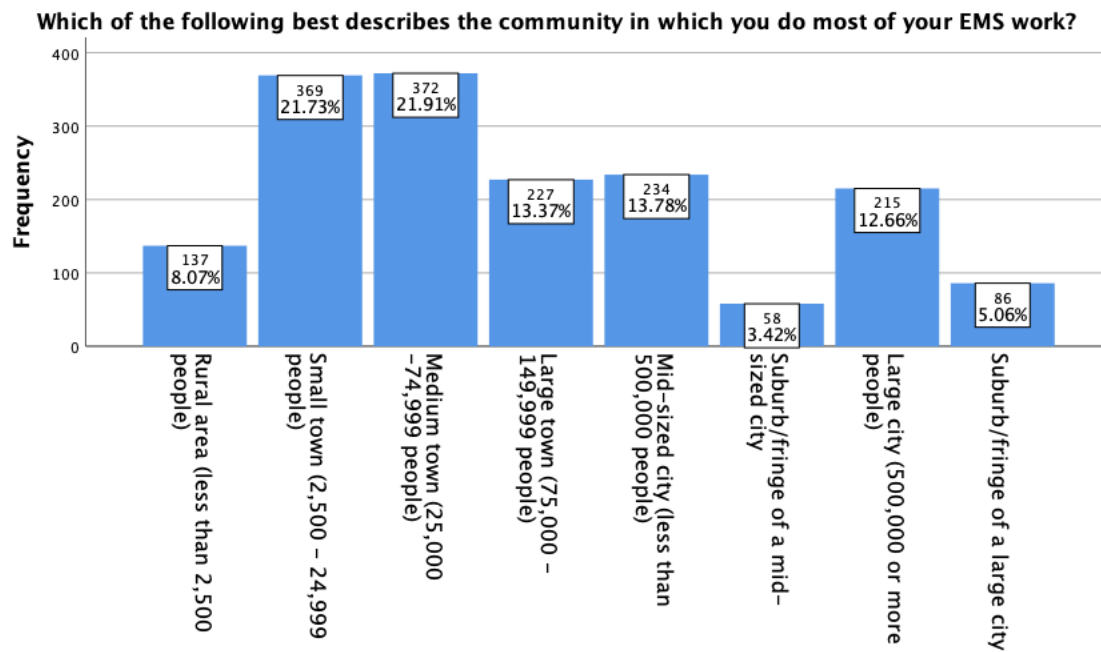


Figure 20. Communities where respondents work

4.2.2 Responses Related to Interactions with Medication

4.2.2.1 Identify (Medication)

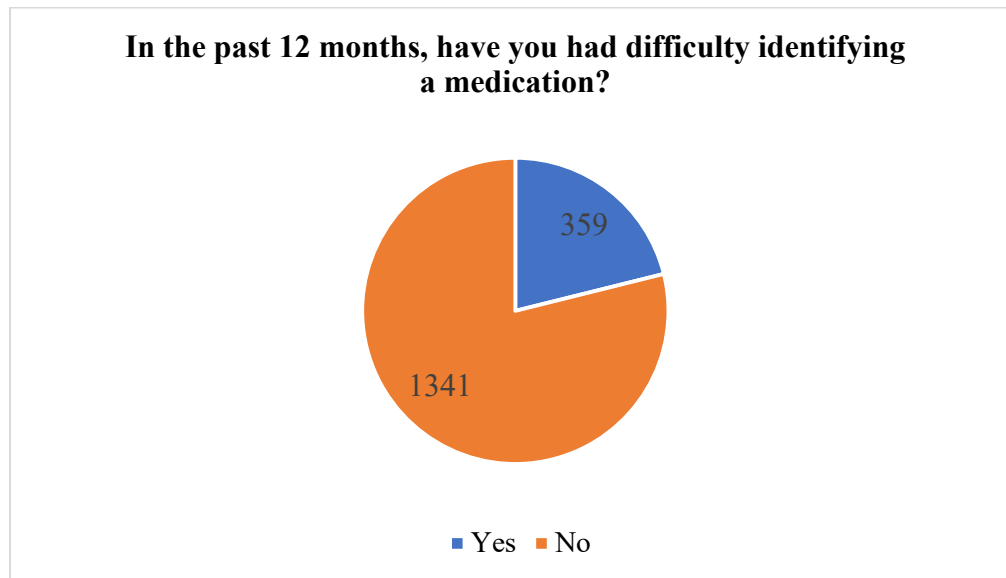


Figure 21. Responses to difficulty identifying a medication within the past 12 months

Table 7. Frequencies and proportion of responses to difficulty identifying a medication within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	359	21.1%	1,702
No	1,341	78.79%	1,702
No Entry	2	0.01%	1,702

Of the 1,702 respondents included for analysis, 359 answered that they had difficulty identifying a medication within the past 12 months (21%; See Figure 21 and Table 7); of these, 20 respondents (5.6%) claimed that these issues had negatively impacted patient care (see Figure 22). The most common reason indicated among those reporting the issue was, ‘*Different supplies had similar packaging*’ (68.5%, 246/359; See Figure 21 and Table 8). The most common coping strategy reported was ‘Changed the location of product within container, bag or ambulance’ (45.9%, 174/359; see Figure 23).

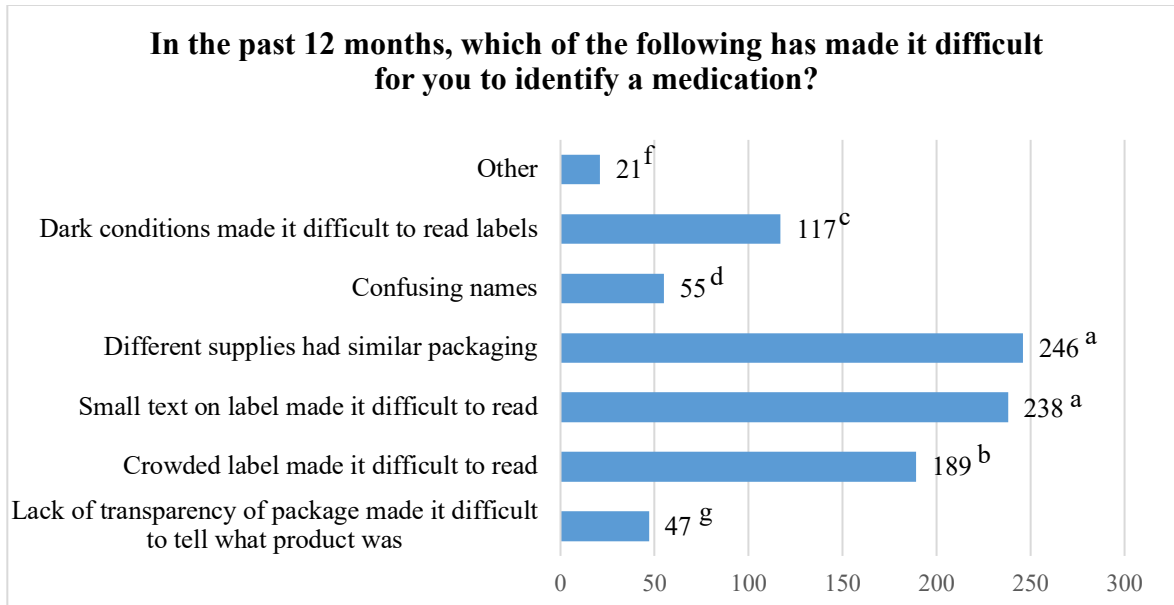


Figure 22. Reasons for the difficulty in identifying a medication within the past 12 months (a single respondent can respond to multiple) *Different alphabet indicates significant difference at $\alpha=0.05$.

Table 8. Frequencies and proportion of responses on reasons for the difficulty in identifying a medication within the past 12 months (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Lack of transparency of package made it difficult to tell what product was	47	13.1% (359)	2.8% (1,702)
Crowded label made it difficult to read	189	52.6% (359)	11.1% (1,702)
Small text on label made it difficult to read	238	66.3% (359)	14.0% (1,702)
Different supplies had similar packaging	246	68.5% (359)	14.5% (1,702)
Confusing names	55	15.3% (359)	3.2% (1,702)
Dark conditions made it difficult to read labels	117	32.6% (359)	6.9% (1,702)
Other	21	5.8% (359)	1.2% (1,702)

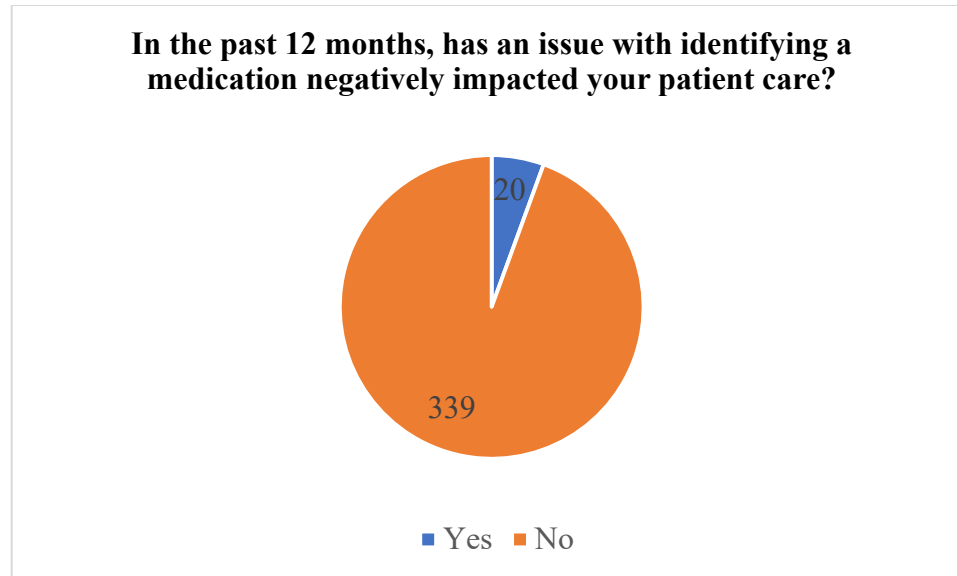


Figure 23. Difficulties with identification and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Table 9. Difficulties with identification and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	20	5.6% (359)	1.2% (1,702)
No	339	94.4% (359)	98.8% (1,702)

In order to explore which reasons were most likely to be reported, we conducted pairwise comparisons of the likelihood of the reasons being reported. 95% confidence interval estimates for odds ratios were used for pairwise comparison (see Table 10). If the interval does not include 1, it indicates statistical difference for the rates of reporting for the two reasons being compared associated with the task of identifying a medication. The bolded text in the table represent evidence of statistically significant difference at $\alpha=0.05$ when compared.

Table 10. 95% Confidence Interval Estimates for odds ratios of reasons for the task identifying a medication

95% Confidence interval Estimates	Lower	Upper
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Crowded label made it difficult to read'	5.097	10.686
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Small text on label made it difficult to read Different medications'	8.958	19.031
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Different supplies had similar packaging'	9.893	21.112
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Dark conditions made it difficult to read labels'	.789	1.828
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Other'	2.200	4.683
Odds ratio 'Crowded label made it difficult to read' vs 'Small text on label made it difficult to read'	1.445	2.654
Odds ratio 'Crowded label made it difficult to read' vs 'Different supplies had similar packaging'	.114	.232
Odds ratio 'Crowded label made it difficult to read' vs 'Dark conditions made it difficult to read labels'	.321	.589
Odds ratio 'Crowded label made it difficult to read' vs 'Other'	.034	.091

Table 10 (Cont'd)

Odds ratio 'Small text on label made it difficult to read' vs 'Different supplies had similar packaging'	.064	.132
Odds ratio 'Small text on label made it difficult to read' vs 'Dark conditions made it difficult to read labels'	.180	.335
Odds ratio 'Small text on label made it difficult to read' vs 'Other'	.019	.052
Odds ratio 'Different supplies had similar packaging' vs 'Dark conditions made it difficult to read labels'	.162	.304
Odds ratio 'Different supplies had similar packaging' vs 'Other'	.017	.047
Odds ratio 'Dark conditions made it difficult to read labels' vs 'Other'	.203	.581
*Texts in bold indicate a significant different difference between options * $\alpha=0.05$		

In order to better understanding the pairwise analysis presented in table 10, and, ultimately the most salient reasons why EMS personnel have difficulty identifying medications, Table 11 presents a synopsis of the results when analyzed according to $\alpha=0.05$.

The most frequently reported reasons (design cues) associated with difficulty identifying medications were: ‘Different medications have similar packaging’ and ‘Small text on label made it difficult to read’. No evidence of statistical significance was present when these reasons were compared, however, each of these yielded significantly higher rates of report than any other reasons provided, such as ‘Crowded label made it difficult to read’, ‘Dark conditions made it difficult to read labels’, ‘Confusing names’, ‘Lack of transparency of package made it difficult to tell what product was’ and ‘Others’.

Table 11. Pairwise comparison for reasons for the difficulty with identification

Different medications have similar packaging ^a Small text on label made it difficult to read ^a Crowded label made it difficult to read ^b Dark conditions made it difficult to read labels ^c Confusing names ^d Lack of transparency of package made it difficult to tell what product was ^d Other ^f Dark conditions made it difficult to read labels ^g
*Different alphabet indicates significant difference. *The highest rate is on the top row *$\alpha=0.05$

The most frequently reported coping strategies associated with difficulty identifying medications were: ‘Flashlight (n=211, 58.8% of the participants included in analysis)’ and ‘Changed the location of product within container, bag or ambulance (n=174, 48.5% of the participants included in analysis.’

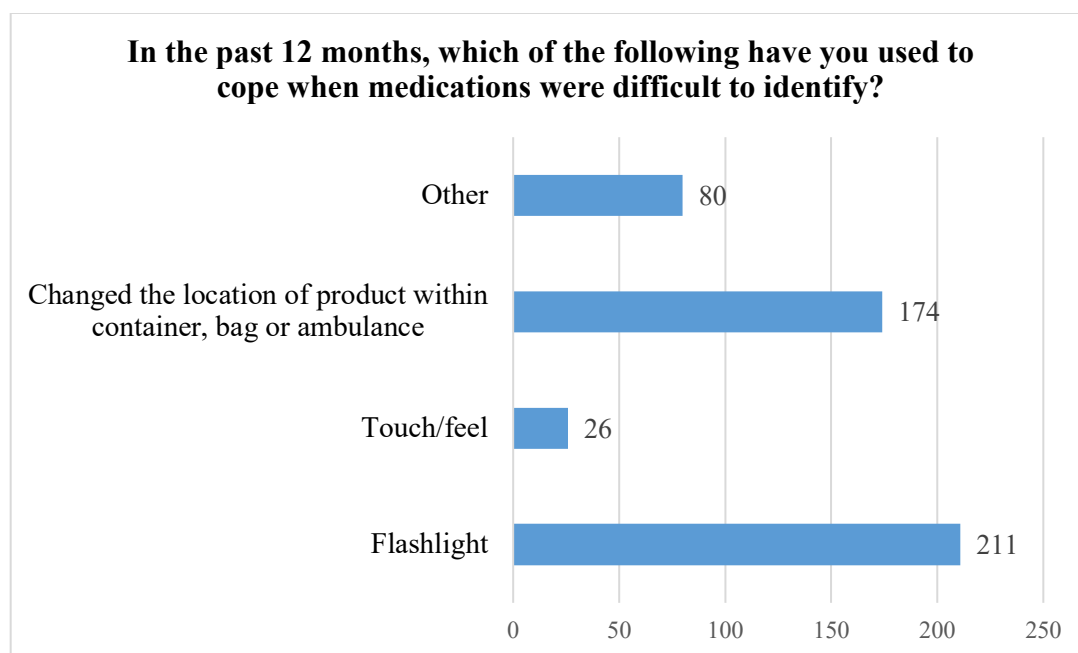


Figure 24. Coping strategies (affordance behaviors) to the difficulties identifying a medication within the past 12 months (a single respondent can respond to multiple)

Table 12. Coping strategies (affordance behaviors) to the difficulties identifying a medication within the past 12 months (a single respondent can respond to multiple)

Coping strategies (Affordance behaviors)	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Flashlight	211	58.8% (359)	12.4% (1,702)
Touch/feel	26	7.2% (359)	1.5% (1,702)
Changed the location of product within container, bag or ambulance	174	48.5% (359)	10.2% (1,702)
Other	80	22.3% (359)	4.7% (1,702)

Table 13 presents 95% Confidence Interval Estimates for odds ratios comparing the likelihood of rates of reporting for coping strategies (affordance behaviors) associated with the difficulty of identifying a medication. If the interval does not include 1, it suggests a significant difference ($\alpha=0.05$) between two coping strategies for each difficulty (bolded texts in the table).

Table 13. 95% Confidence Interval Estimates for odds ratio of coping strategies for each difficulty identifying a medication

95% Confidence Interval Estimates	Lack of transparency of package made it difficult to tell what product was		Crowded label made it difficult to read		Small text on label made it difficult to read	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Flashlight' vs 'Touch/feel'	0.005	.	.	.	0.037	0.269
Odds ratio 'Flashlight' vs 'Changed the location of product within container, bag or ambulance'	0.121	.	.	.	0.183	0.962
Odds ratio 'Flashlight' vs 'Other'	0.031	.	.	.	0.061	0.383
Odds ratio 'Touch/feel' vs 'Changed the location of product within container, bag or ambulance'	0.019	0.262	1.438	10.457	1.574	11.386
Odds ratio 'Touch/feel' vs 'Other'	0.114	0.696	0.258-	2.706	0.533	4.477
Odds ratio 'Changed the location of product within container, bag or ambulance' vs 'Other'	1.438	8.746	0.077	0.608	0.147	0.904
95% Confidence Interval Estimates	Different medications have similar packaging		Confusing names		Dark conditions made it difficult to read labels	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Flashlight' vs 'Touch/feel'	0.044	0.32	0.029	0.235	0.01	0.103
Odds ratio 'Flashlight' vs 'Changed the location of product within container, bag or ambulance'	0.221	1.142	0.307	1.605	0.042	0.369
Odds ratio 'Flashlight' vs 'Other'	0.063	0.408	0.052	0.343	0.013	0.127
Odds ratio 'Touch/feel' vs 'Changed the location of product within container, bag or ambulance'	1.574	11.386	3.015	23.741	1.565	9.523
Odds ratio 'Touch/feel' vs 'Other'	0.458	3.997	0.526	4.977	0.487	3.307
Odds ratio 'Changed the location of product within container, bag or ambulance' vs 'Other'	0.126	0.809	0.076	0.483	0.138	0.784

Table 13. (cont'd)

95% Confidence Interval Estimates	Other	
	Lower	Upper
Odds ratio 'Flashlight' vs 'Touch/feel'	0.038	1.171
Odds ratio 'Flashlight' vs 'Changed the location of product within container, bag or ambulance'	0.522	6.331
Odds ratio 'Flashlight' vs 'Other'	0.428	5.251
Odds ratio 'Touch/feel' vs 'Changed the location of product within container, bag or ambulance'	1.593	46.807
Odds ratio 'Touch/feel' vs 'Other'	1.309	38.771
Odds ratio 'Changed the location of product within container, bag or ambulance' vs 'Other'	0.244	2.785

*Texts in bold indicate the significant difference between the options at $\alpha=0.05$

In order to enhance understanding of Table 13, Table 14 provides pairwise comparisons. For most of difficulties such as 'Lack of transparency of package made it difficult to tell what product was', 'Crowded label made it difficult to read', 'Small text on label made it difficult to read', and 'Dark conditions made it difficult to read labels', evidence showing a statistical significant difference was presented when 'Flashlight' and 'Changed the location of product within container, bag or ambulance' were compared.

Table 14. Pairwise comparison for coping strategies by difficulty

Lack of transparency of package made it difficult to tell what product was
Flashlight^a
Changed the location of product within container, bag or ambulance^b
Other^c
Touch/feel^d
Crowded label made it difficult to read
Flashlight^a
Changed the location of product within container, bag or ambulance^a
Touch/feel^b
Other^b

Table 14. (cont'd)

Small text on label made it difficult to read
Flashlight^a
Changed the location of product within container, bag or ambulance^b
Other^c
Touch/feel^d
Different medications have similar packaging
Flashlight^a
Changed the location of product within container, bag or ambulance^a
Other^b
Touch/feel^b
Confusing names
Flashlight^a
Changed the location of product within container, bag or ambulance^a
Other^b
Touch/feel^b
Dark conditions made it difficult to read labels
Flashlight^a
Changed the location of product within container, bag or ambulance^b
Other^c
Touch/feel^c
Other
Changed the location of product within container, bag or ambulance^a
Other^a
Flashlight^{ab}
Touch/feel^b

*Different alphabet indicates significant difference.

*The highest rate is on the top row

* $\alpha=0.05$

‘Flashlight’ use was repeatedly reported as a coping strategy to deal with most of difficulties associated with identifying a product. In ‘Other’ options, EMS provided most frequently reported ‘glasses use’ as their coping strategy (See Appendix D).

4.2.2.2 Opening (Medication)

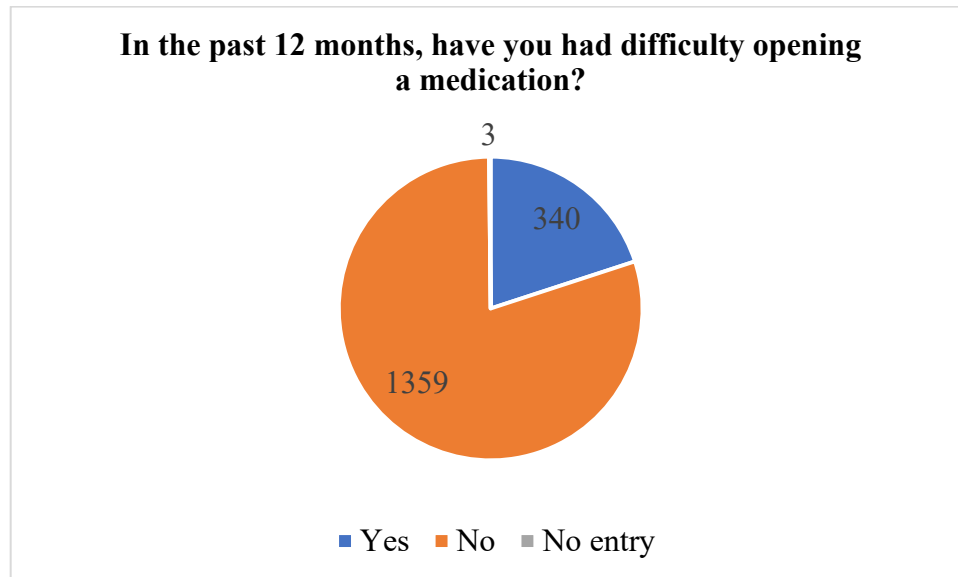


Figure 25. Responses related to a difficulty opening a medication within the past 12 months

Table 15. Frequencies and proportion of responses related to a difficulty opening a medication within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	340	20.00%	1,702
No	1359	79.90%	1,702
No Entry	3	0.17%	1,702

Of the 1,702 respondents included in the analysis, 340 respondents answered that they had had difficulty opening a medication within the past 12 months (21%; Figure 25 and Table 15). ‘*Product required two hands to open*’ was the reason for the difficulty most frequently reported among those reporting opening difficulties (50.6%, 172/340; Figure 26 and Table 16). Of the 340 respondents reporting difficulty in opening medication, 2.6% (9 respondents out of 340 respondents) claimed that the issue had negatively affected patient care within the past 12 months (See Table 17). Additionally, the coping strategy (affordance behaviors) most commonly reported by respondents dealing with difficulty opening a medication was the use of ‘*scissors*’ (55.6%) (See Figure 27 and Table 20).

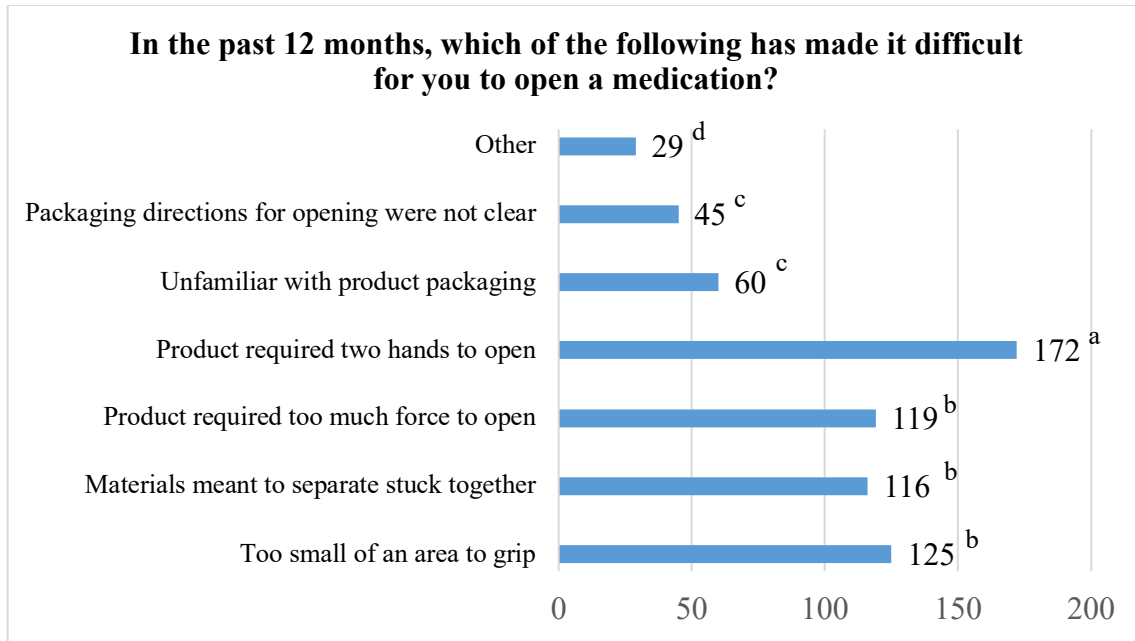


Figure 26. Reasons for the difficulty in opening a medication within the past 12 months (a single respondent can respond to multiple) *Different alphabet indicates significant difference at $\alpha=0.05$

Table 16. Frequencies and proportion of reasons for the difficulty in opening a medication within the past 12 months (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Too small of an area to grip	125	36.8% (340)	7.3% (1,702)
Materials meant to separate stuck together	116	34.1% (340)	6.8% (1,702)
Product required too much force to open	119	35.0% (340)	7.0% (1,702)
Product required two hands to open	172	50.6% (340)	10.1% (1,702)
Unfamiliar with product packaging	60	17.6% (340)	3.5% (1,702)
Packaging directions for opening were not clear	45	13.2% (340)	2.6% (1,702)
Other	29	8.5% (340)	1.7% (1,702)

Table 17. Difficulties with opening and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	32	9.4% (340)	1.9% (1,702)
No	308	90.60% (340)	18.1% (1,702)

In order to investigate specific difficulties associated with package opening, and the coping methods that participants reported using to deal with specific difficulties, pairwise comparisons were conducted. 95% confidence interval estimates for odds ratios were used for pairwise comparisons (see Table 18). If the interval does not include 1, it indicates a significant difference exists regarding the rates of reporting for the difficulties being compared. The bolded texts indicate evidence of a significant difference was found.

Table 18. 95% Confidence Interval Estimates for odds ratio of reasons for difficulty opening a medication

95% Confidence Interval Estimates	Lower	Upper
Odds ratio 'Too small of an area to grip' vs 'Materials meant to separate stuck together'	0.65	1.22
Odds ratio 'Too small of an area to grip' vs 'Product opened with too much force'	0.677	1.267
Odds ratio 'Too small of an area to grip' vs 'Product required two hands to open'	1.296	2.392
Odds ratio 'Too small of an area to grip' vs 'Unfamiliar with product packaging'	0.258	0.526
Odds ratio 'Too small of an area to grip' vs 'Packaging directions for opening were not clear'	0.179	0.385
Odds ratio 'Too small of an area to grip' vs 'Other'	0.103	0.249
Odds ratio 'Materials meant to separate stuck together' vs 'Product opened with too much force'	0.758	1.426
Odds ratio 'Materials meant to separate stuck together' vs 'Product required two hands to open'	1.452	2.693
Odds ratio 'Materials meant to separate stuck together' vs 'Unfamiliar with product packaging'	0.289	0.592
Odds ratio 'Materials meant to separate stuck together' vs 'Packaging directions for opening were not clear'	0.2	0.433
Odds ratio 'Materials meant to separate stuck together' vs 'Other'	0.116	0.28
Odds ratio 'Product opened with too much force' vs 'Product required two hands to open'	1.397	2.587
Odds ratio 'Product opened with too much force' vs 'Unfamiliar with product packaging'	0.278	0.569
Odds ratio 'Product opened with too much force' vs 'Packaging directions for opening were not clear'	0.193	0.416
Odds ratio 'Product opened with too much force' vs 'Other'	0.111	0.269
Odds ratio 'Product required two hands to open' vs 'Unfamiliar with product packaging'	0.147	0.297
Odds ratio 'Product required two hands to open' vs 'Packaging directions for opening were not clear'	0.102	0.218
Odds ratio 'Product required two hands to open' vs 'Other'	0.059	0.141
Odds ratio 'Unfamiliar with product packaging' vs 'Packaging directions for opening were not clear'	0.468	1.083
Odds ratio 'Unfamiliar with product packaging' vs 'Other'	0.271	0.697
Odds ratio 'Packaging directions for opening were not clear' vs 'Other'	0.373	1.001
*Texts in bold indicate a significant different difference between options		
* $\alpha=0.05$		

In order to better understand, pairwise comparisons of all the reasons leading to difficulty with opening are tabulated in Table 19. 'Product required two hands to open' was the reason

provided most frequently as indicative of designs that were difficult to open and was found to be significantly different from all other reasons provided. ‘Too small of an area to grip’, ‘Product opened with too much force’ and ‘Materials meant to separate stuck together’ yielded no evidence of a significant effect when compared with one another but were suggested to be significantly different from the reasons which were least frequently reported. Namely, ‘Unfamiliar with product packaging’ and ‘Packaging directions for opening were not clear’ Analysis did not yield evidence of significant difference when the reasons within this group were compared.

Table 19. Pairwise comparison for reasons for difficulty opening a medication

Product required two hands to open ^a Too small of an area to grip ^b Product required too much force ^b Materials meant to separate stuck together ^b Unfamiliar with product packaging ^c Packaging directions for opening were not clear ^c Other ^d
*Different alphabet indicates significant difference. *The highest rate is on the top row * $\alpha=0.05$

Researchers also investigated the coping strategies that EMS personnel reported to cope with the aforementioned reasons that resulted in difficulty with opening. For the purpose of analysis, ‘Knives’, ‘Scissors’ and ‘Pens’ were grouped together as a ‘Sharp Tools’ (See Table 20 and Figure 29). Table 21 depicts 95% Confidence Interval Estimates associated with odds ratios related to the rates of report for coping strategies (affordance behaviors) for each difficulty listed as a barrier to package opening for medications. Bolded text in the table represents evidence of significant difference at $\alpha=0.05$.

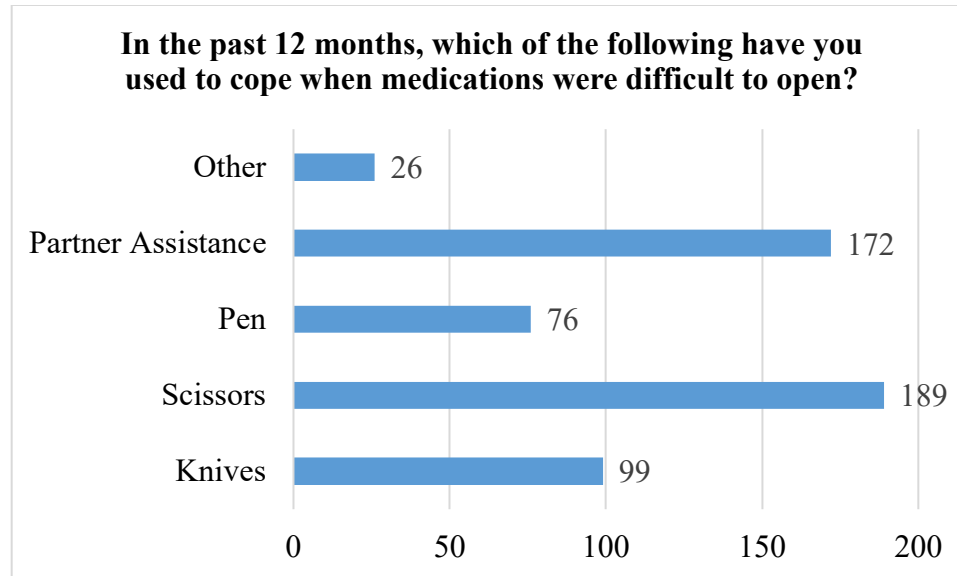


Figure 27. Coping strategies (affordance behaviors) employed to deal with difficulties associated with opening a medication within the past 12 months (a single respondent can respond with multiple answers)

Table 20. Frequencies and proportion of Coping strategies (affordance behaviors) employed to deal with difficulties associated with opening a medication within the past 12 months (a single respondent can respond with multiple answers)

Coping strategies (Affordance behaviors)	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Knives	99	29.11% (340)	5.8% (1,702)
Scissors	189	55.6% (340)	11.1% (1,702)
Pen	76	22.4% (340)	4.5% (1,702)
Partner Assistance	172	50.6% (340)	10.1% (1,702)
Other	26	7.60%	1.5% (1,702)

Table 21. 95% Confidence Interval Estimates for odds ratio of coping strategies for each difficulty opening a medication

95% Confidence interval Estimates	Too small of an area to grip		Materials meant to separate stuck together		Product opened with too much force	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.044	0.32	0.044	0.305	0.082	0.475

Table 21. (cont'd)

Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	0.088	0.636	0.064	0.43	0.2	1.118
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0	.	0.001	0.037	0.004	0.08
Odds ratio 'Teeth' vs 'Partner assistance'	0.876	4.521	0.623	3.26	1.042	5.52
Odds ratio 'Teeth' vs 'Other'	0	.	0.005	0.304	0.018	0.401
Odds ratio 'Partner assistance' vs 'Other'	0	.	0.003	0.212	0.008	0.166
95% Confidence interval Estimates	Product required two hands to open		Unfamiliar with product packaging		Packaging directions for opening were not clear	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.093	0.551	0.1	0.566	0.071	0.468
Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	0.185	1.098	0.336	1.978	0.192	1.303
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0.001	0.054	0.001	0.067	0.004	0.071
Odds ratio 'Teeth' vs 'Partner assistance'	0.876	4.521	1.469	8.039	1.162	6.447
Odds ratio 'Teeth' vs 'Other'	0.004	0.231	0.004	0.277	0.026	0.363
Odds ratio 'Partner assistance' vs 'Other'	0.002	0.116	0.001	0.081	0.009	0.134

Table 21. (cont'd)

95% Confidence interval Estimates	Other	
	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.128	1.077
Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	0.268	2.135
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0.128	1.077
Odds ratio 'Teeth' vs 'Partner assistance'	0.708	5.857
Odds ratio 'Teeth' vs 'Other'	0.339	2.953
Odds ratio 'Partner assistance' vs 'Other'	0.171	1.413

*Texts in bold indicate the significant difference between the options.

* $\alpha=0.05$

Table 22 depicts the pairwise comparisons of the coping strategies employed by reasons for difficulty when opening medications over the last 12 months. As indicated, 'Sharp Tools' were reported at a significantly higher rate than other coping strategies when the associated difficulties were 'Too small of an area to grip' and 'Materials meant to separate stuck together'; however, for the other difficulties, 'Partner Assistance' indicated no evidence of statistical significance when comparisons were made with 'Sharp tools'.

Table 22. Pairwise comparison for coping strategy for each difficulty opening a medication

Too small of an area to grip
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^b
Teeth^b
Other^b
Materials meant to separate stuck together
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^b
Teeth^b
Other^c
Product opened with too much force
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^a
Teeth^b
Other^c
Product required two hands to open
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^{ab}
Teeth^b
Other^c
Unfamiliar with product packaging
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^a
Teeth^b
Other^c
Table 22 (Cont'd)
Packaging directions for opening were not clear
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^a
Teeth^b
Other^c
Other
Sharp Tools (Knives, Scissors, Pens)^a
Partner assistance^a
Teeth^a
Other^a

*Different alphabet indicates significant difference.

*The highest rate is on the top row

* $\alpha=0.05$

‘Sharp tools’ was repeatedly reported as a coping strategy used to deal with most of difficulties followed by ‘Partner Assistance’. In ‘Other’ options, EMS personnel mostly claimed ‘Brute force’ as their coping strategy (See Appendix D).

4.2.2.3 Administering(using) Medications

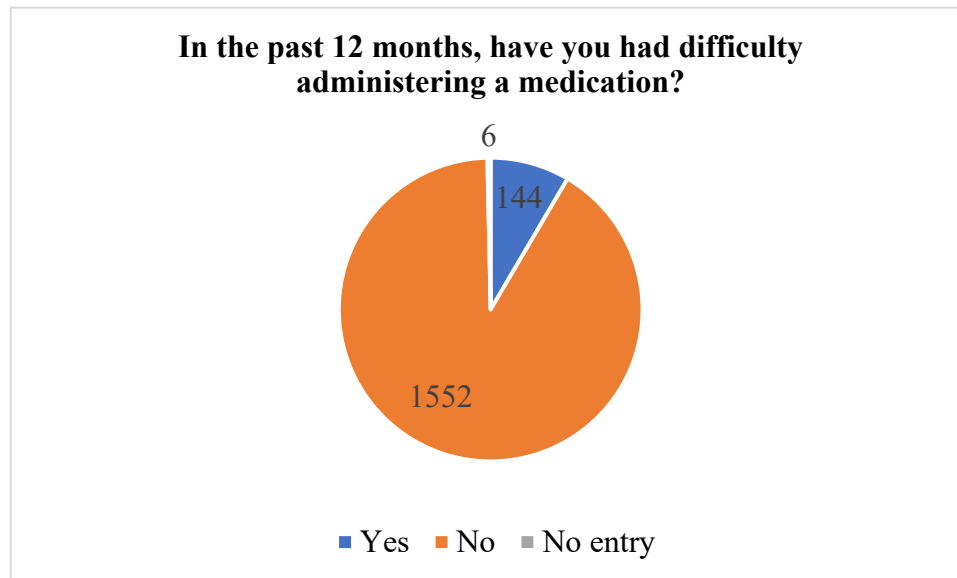


Figure 28. Responses to difficulty administering a medication within the past 12 months

Table 23. Frequencies and proportions of responses to difficulty administering a medication within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	144	8.50%	1,702
No	1552	91.20%	1,702
No entry	6	0.30%	1,702

Of the 1,702 responses included in the analysis, 144 respondents answered that they had difficulty administering a medication within the past 12 months (8.5% of those who answered this question; Figure 28 and Table 23). ‘*Vehicle (e.g., ambulance) movement and vibration*’ was the reason most frequently reported to induce difficulties related to administration

of a medication (34.0%, 49/144 who reported difficulty, or 2.9% of the 1,702 total respondents included in the analysis; Figure 29 and Table 24). 13.2% (19/144 respondents indicating difficulty), 1.1% of the total population analyzed (19/1,702) claimed that issues with administering a medication had negatively affected patient care within the past 12 months (See Table 25).

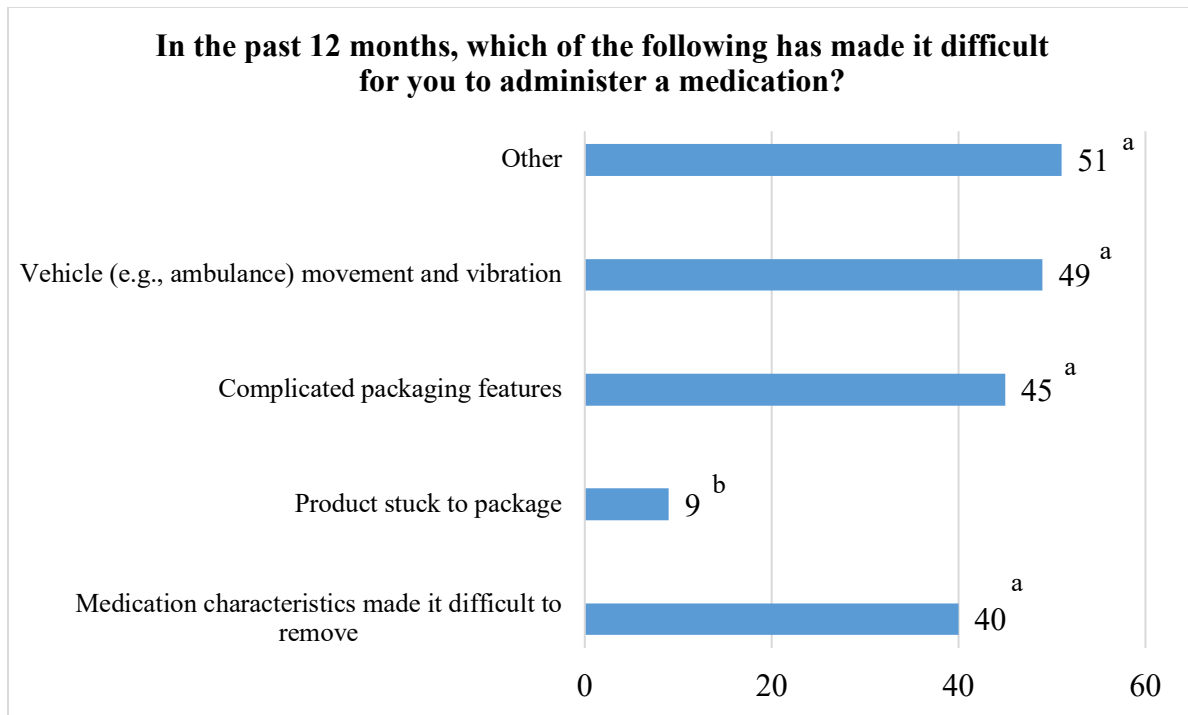


Figure 29. Reasons for this difficulty with administration of a medication (a single respondent can respond to multiple) *Different alphabet indicates significant difference at $\alpha=0.05$

Table 24. Frequencies and proportions of reasons for difficulty with administration of a medication (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Medication characteristics made it difficult to remove	40	27.8% (144)	2.4% (1,702)
Product stuck to package	9	6.3% (144)	0.5% (1,702)
Complicated packaging features	45	31.3% (144)	2.6% (1,702)
Vehicle (e.g., ambulance) movement and vibration	49	34.0% (144)	2.9% (1,702)
Other	51	35.4% (144)	3.0% (1,702)

Table 25. Difficulties with administration and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	19	13.2% (144)	1.1% (1,702)
No	125	86.8% (144)	7.3% (1,702)

Table 26 shows 95% Confidence Interval Estimates for odds ratios related to difficulties administering a medication in order to explore which reasons resulted in a significantly greater likelihood of being reported. If the interval does not include 1, it implies that it has significant difference when compared. Bolded text in the table indicate the significance at $\alpha=0.05$.

Table 26. 95% Confidence Interval Estimates for odds ratio of difficulties administering a medication

95% Confidence Interval Estimates	Lower	Upper
Odds ratio 'Medication characteristics made it difficult to remove' vs 'Product stuck to package'	0.08	0.373
Odds ratio 'Medication characteristics made it difficult to remove' vs 'Complicated packaging features'	0.712	1.962
Odds ratio 'Medication characteristics made it difficult to remove' vs 'Vehicle (e.g., ambulance) movement and vibration'	0.812	2.215
Odds ratio 'Medication characteristics made it difficult to remove' vs 'Other'	0.865	2.35
Odds ratio 'Product stuck to package' vs 'Complicated packaging features'	3.185	14.597
Odds ratio 'Product stuck to package' vs 'Vehicle (e.g., ambulance) movement and vibration'	3.627	16.506
Odds ratio 'Product stuck to package' vs 'Other'	3.861	17.523
Odds ratio 'Complicated packaging features' vs 'Vehicle (e.g., ambulance) movement and vibration'	0.693	1.858
Odds ratio 'Complicated packaging features' vs 'Other'	0.739	1.971
Odds ratio 'Vehicle (e.g., ambulance) movement and vibration' vs 'Other'	0.654	1.727
*Texts in bold indicate a significant different difference between options * $\alpha=0.05$		

To enhance understanding of Table 26, Table 27 provides a synthesis of pairwise comparisons. 'Other,' 'Vehicle (e.g., ambulance) movement and vibration', 'Complicated packaging features' and 'Medication characteristics made it difficult to remove' were all provided as reasons for reported difficulties associated with the administration of medication, though analysis yielded no evidence of difference in rates of reporting. However, when comparing the reason 'Product stuck to package' it was reported at a significantly lower rate for all the comparisons. In 'Other' option, different types of package features (eg. Carpuject, lure-lock on syringe, etc.) were reported (See Appendix D).

Table 27. Pairwise comparison for difficulties administering a medication

Other ^a
Vehicle (e.g., ambulance) movement and vibration ^a
Complicated packaging features ^a
Medication characteristics made it difficult to remove ^a
Product stuck to package ^b
*Different alphabet indicates significant difference. *The highest rate is on the top row * $\alpha=0.05$

4.2.3 Responses Related to Interactions with Medical device

4.2.3.1 Identify (Medical Device)

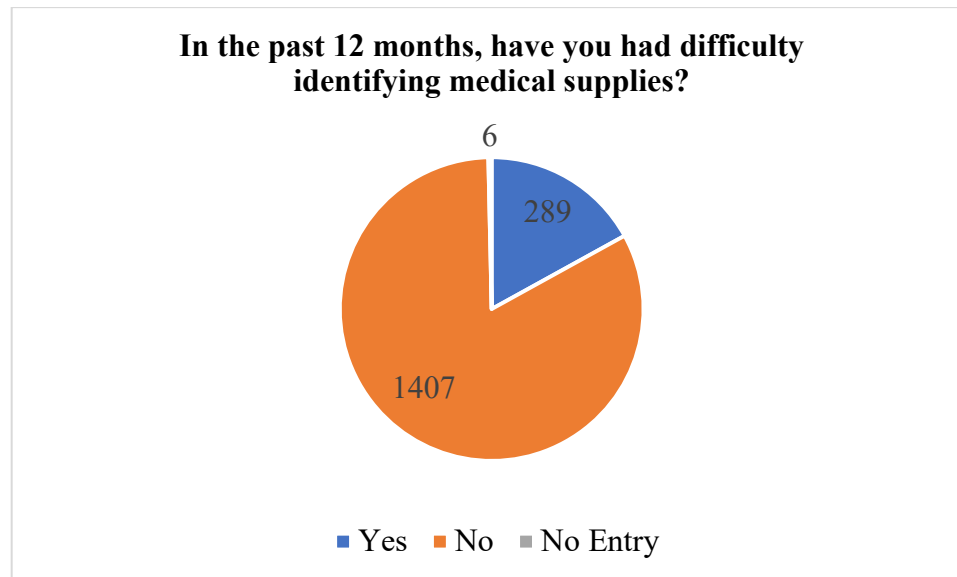


Figure 30. Responses to difficulty identifying medical supplies within the past 12 months

Table 28. Frequencies and proportions of Responses to difficulty identifying medical supplies within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	289	16.90%	1,702
No	1407	82.70%	1,702
No Entry	6	0.35%	1,702

Of the 1,702 respondents included in the analysis, 289 respondents indicated that they had difficulty identifying medical supplies within the last 12 months (16.9%; Figure 30 and Table 28). The most commonly reported reason for this difficulty was ‘Crowded label made it difficult to read’ (65.4%, 189/289 people indicating this issue within the last 12 months; Figure 31 and Table 29); 11.0% % of the analysis population (1,702). Of the 289 respondents indicating that they had difficulty identifying a medical supply within the past 12 months, 10.7% (31 respondents), 1.8 % of the analyzed population, claimed that the issue had negatively affected patient care within the past 12 months (See Table 30). Additionally, as with the analysis related to identification of medical supplies, the use of a flashlight was the most popular coping mechanism, with 54% (156/289) of those reporting the difficulty suggesting this was how they coped (See Figure 32 and Table 33).

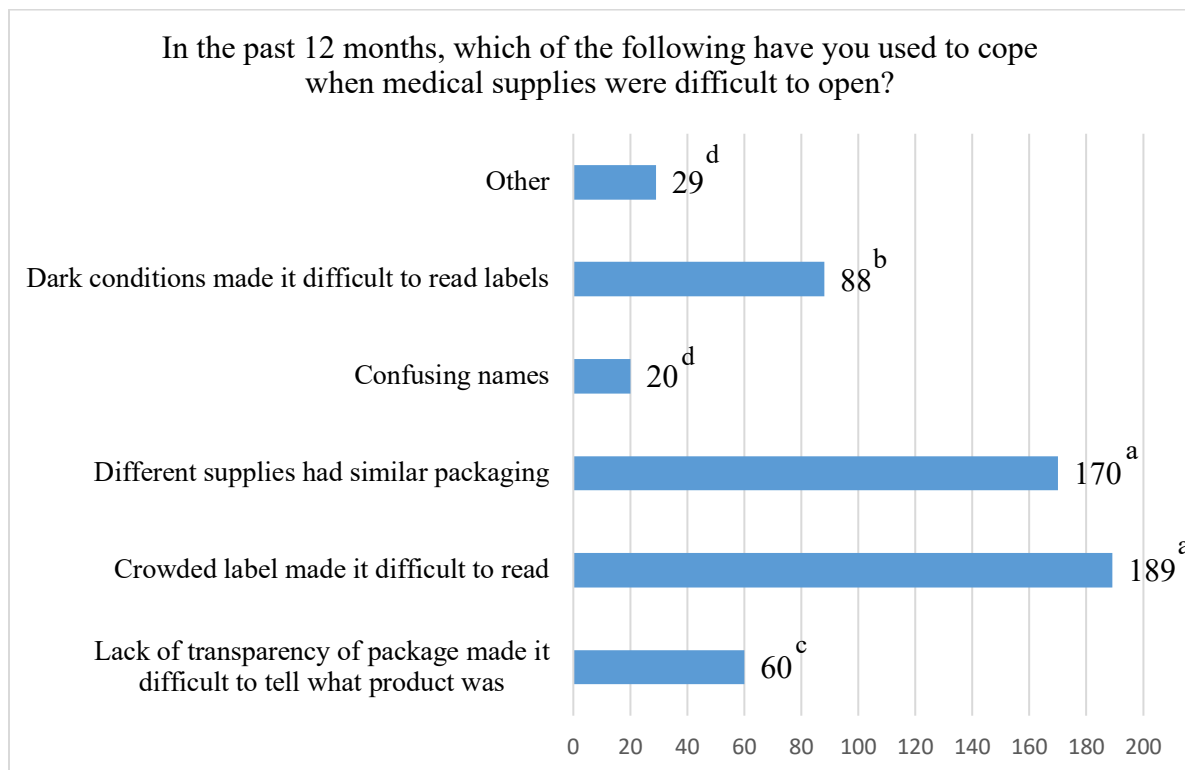


Figure 31. Reasons for the difficulty in identifying medical supplies within the past 12 months (a single respondent can respond to multiple) *Different alphabet indicates significant difference at $\alpha=0.05$

Table 29. Frequencies and proportions of reasons for the difficulty in identifying medical supplies within the past 12 months (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Lack of transparency of package made it difficult to tell what product was	60	20.8% (289)	3.5% (1,702)
Crowded label made it difficult to read	189	65.4% (289)	11.10% (1,702)
Different supplies had similar packaging	170	58.8% (289)	10% (1,702)
Confusing names	20	6.9% (289)	1.2% (1,702)
Dark conditions made it difficult to read labels	88	30.4% (289)	5.2% (1,702)
Other	29	10% (289)	1.7% (1702)

Table 30. Difficulties with identification and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	31	10.7% (289)	1.8% (1,702)
No	258	89.3% (289)	15.2% (1,702)

Table 17 depicts 95% Confidence Interval Estimates of odds ratios related to the rate of reported difficulties associated with identifying medical supplies. Most of the comparisons yield evidence of statistical significance at $\alpha=0.05$. (Odds ratio ‘Crowded label made it difficult to read’ vs ‘Different supplies had similar packaging’ and Odds ratio ‘Confusing names’ vs ‘Other’).

Table 31. 95% Confidence Interval Estimates for odds ratios of difficulties identifying medical supplies

95% Confidence Interval Estimates	Lower	Upper
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Crowded label made it difficult to read'	4.965	10.48
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Different supplies had similar packaging'	3.772	7.881
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Confusing names'	0.166	0.485
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Dark conditions made it difficult to read labels'	1.144	2.441
Odds ratio 'Lack of transparency of package made it difficult to tell what product was' vs 'Other'	0.264	0.686
Odds ratio 'Crowded label made it difficult to read' vs 'Different supplies had similar packaging'	0.54	1.059
Odds ratio 'Crowded label made it difficult to read' vs 'Confusing names'	0.024	0.066
Odds ratio 'Crowded label made it difficult to read' vs 'Dark conditions made it difficult to read labels'	0.163	0.328
Odds ratio 'Crowded label made it difficult to read' vs 'Other'	0.037	0.093
Odds ratio 'Different supplies had similar packaging' vs 'Confusing names'	0.031	0.087
Odds ratio 'Different supplies had similar packaging' vs 'Dark conditions made it difficult to read labels'	0.217	0.432
Odds ratio 'Different supplies had similar packaging' vs 'Other'	0.05	0.122
Odds ratio 'Confusing names' vs 'Dark conditions made it difficult to read labels'	3.505	9.893
Odds ratio 'Confusing names' vs 'Other'	0.828	2.719
Odds ratio 'Dark conditions made it difficult to read labels' vs 'Other'	0.161	0.403
*Texts in bold indicate a significant different difference between options * $\alpha=0.05$		

Pairwise comparisons are shown in Table 32 based on 95% Confidence Interval Estimates. There was no evidence of statistical significance when reporting rates for 'Crowded label made it difficult to read' and 'Different supplies had similar packaging' were compared.

However, rates do vary significantly when the difficulties ‘Dark conditions made it difficult to read labels’, ‘Lack of transparency of package made it difficult to tell what product was’, ‘Other’ and ‘Confusing names’, were compared; though a comparison of other and confusing names yielded no evidence of difference at $\alpha=0.05$.

Table 32. Pairwise comparison for reasons for difficulty identifying medical supplies

Crowded label made it difficult to read ^a Different supplies had similar packaging ^a Dark conditions made it difficult to read labels ^b Lack of transparency of package made it difficult to tell what product was ^c Other ^d Confusing names ^d
*Different alphabet indicates significant difference. *The highest rate is on the top row *$\alpha=0.05$

Table 34 shows 95% Confidence Interval Estimates for odds ratios comparing the reporting rates for the coping strategies employed when difficulty identifying medical supplies was encountered by EMS personnel within the last year. Bolded text in the table indicates evidence of statistical significance at $\alpha=0.05$.

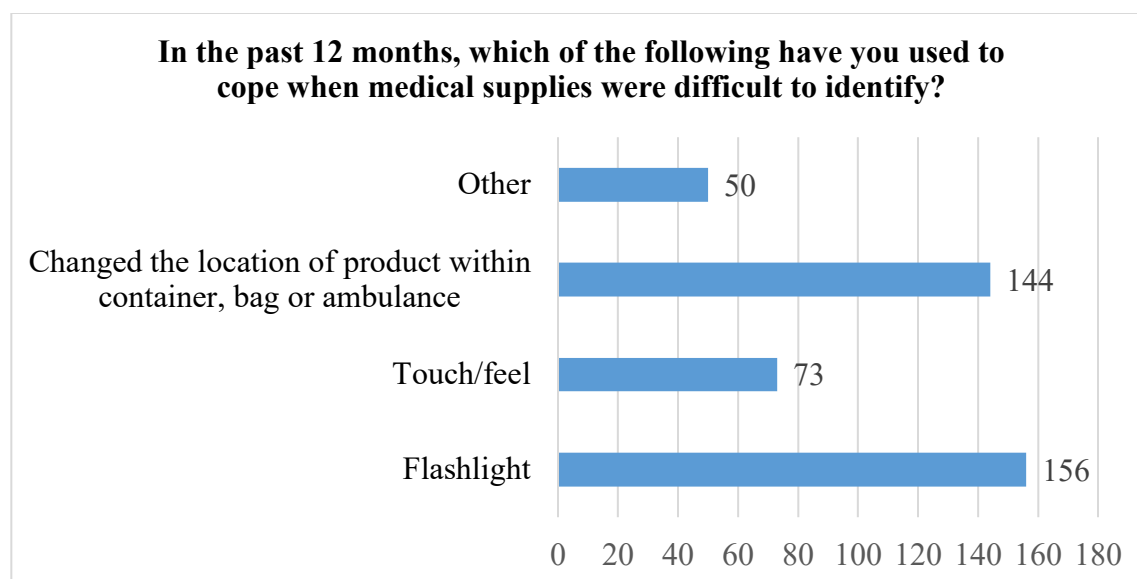


Figure 32. Coping strategies (affordance behaviors) reported to deal with difficulties associated with identifying medical supplies within the past 12 months (a single respondent can respond to with multiple strategies)

Table 33. Frequencies and proportions of coping strategies (affordance behaviors) reported to deal with difficulties associated with identifying medical supplies within the past 12 months (a single respondent can respond to with multiple strategies)

Coping strategies (Affordance behaviors)	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Flashlight	156	54% (289)	9.2% (1,702)
Touch/feel	73	25.3% (289)	4.3% (1,702)
Changed the location of product within container, bag or ambulance	144	49.8% (289)	8.5% (1,702)
Other	50	17.3% (289)	2.9% (1,702)

Table 34. 95% Confidence Interval Estimates for odds ratio of coping strategies for each difficulty identifying medical supplies

95% Confidence Interval Estimates	Lack of transparency of package made it difficult to tell what product was		Crowded label made it difficult to read		Different supplies had similar packaging	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Flashlight' vs 'Touch/feel'	0.044	0.32	0.044	0.305	0.082	0.475
Odds ratio 'Flashlight' vs 'Changed the location of product within container, bag or ambulance'	0.088	0.636	0.064	0.43	0.2	1.118
Odds ratio 'Flashlight' vs 'Other'	0	.	0.001	0.037	0.004	0.08
Odds ratio 'Touch/feel' vs 'Changed the location of product within container, bag or ambulance'	0.876	4.521	0.623	3.26	1.042	5.52
Odds ratio 'Touch/feel' vs 'Other'	0	.	0.005	0.304	0.018	0.401
Odds ratio 'Changed the location of product within container, bag or ambulance' vs 'Other'	0	.	0.003	0.212	0.008	0.166

Table 34. (cont'd)

95% Confidence Interval Estimates	Confusing names		Dark conditions made it difficult to read labels		Other	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Flashlight' vs 'Touch/feel'	0.093	0.551	0.1	0.566	0.071	0.468
Odds ratio 'Flashlight' vs 'Changed the location of product within container, bag or ambulance'	0.185	1.098	0.336	1.978	0.192	1.303
Odds ratio 'Flashlight' vs 'Other'	0.001	0.054	0.001	0.067	0.004	0.071
Odds ratio 'Touch/feel' vs 'Changed the location of product within container, bag or ambulance'	0.876	4.521	1.469	8.039	1.162	6.447
Odds ratio 'Touch/feel' vs 'Other'	0.004	0.231	0.004	0.277	0.026	0.363
Odds ratio 'Changed the location of product within container, bag or ambulance' vs 'Other'	0.002	0.116	0.001	0.081	0.009	0.134

*Texts in bold indicate the significant difference between the options at $\alpha=0.05$

Table 35 summarizes the findings of Table 34 with pairwise comparisons of coping strategies for reported difficulties associated with identifying medical supplies. The coping strategy 'Flashlight' use did not yield evidence of a significant difference when response rates were compared with 'Changed the location of product within container, bag or ambulance' (reported the first highest and the second highest of difficulties in the descriptive analysis) for difficulties such as 'Lack of transparency of package made it difficult to tell what product was', 'Crowded label made it difficult to read' and 'Confusing names' whereas

difficulties such as ‘Different supplies had similar packaging’ and ‘Other’ difficulties did indicate significant difference when ‘Flashlight’ and ‘Changed the location of product within container, bag or ambulance’ were compared.

Table 35. Pairwise comparison of reported coping strategies by difficulties associated with identifying medical supplies

Lack of transparency of package made it difficult to tell what product was
Flashlight ^a
Changed the location of product within container, bag or ambulance ^a
Touch/feel ^b
Other ^c
Crowded label made it difficult to read
Flashlight ^a
Changed the location of product within container, bag or ambulance ^a
Touch/feel ^b
Other ^b
Different supplies had similar packaging
Flashlight ^a
Changed the location of product within container, bag or ambulance ^b
Touch/feel ^b
Other ^b
Confusing names
Changed the location of product within container, bag or ambulance ^a
Flashlight ^a
Touch/feel ^b
Other ^b
Dark conditions made it difficult to read labels
Flashlight ^a
Changed the location of product within container, bag or ambulance ^a
Touch/feel ^a
Other ^b
Other
Flashlight ^a
Changed the location of product within container, bag or ambulance ^b
Touch/feel ^b
Other ^c

*Different alphabet indicates significant difference.

*The highest rate is on the top row

* $\alpha=0.05$

4.2.3.2 Opening (Medical Device)

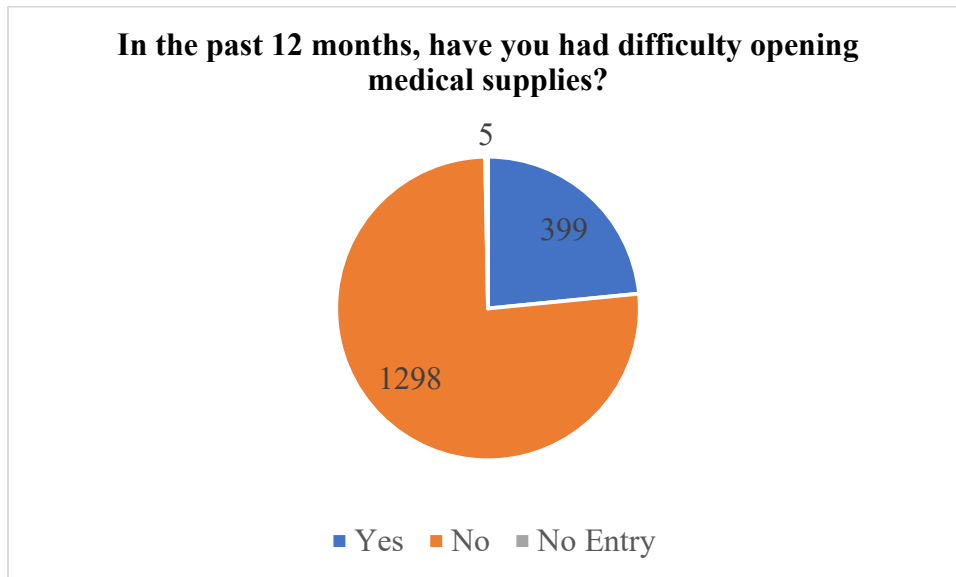


Figure 33. Responses to difficulty opening medical supplies within the past 12 months

Table 36. Frequencies and proportions of responses to difficulty opening medical supplies within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	399	23.50%	1702
No	1298	76.30%	1702
No Entry	5	0.20%	1702

Of the 1,702 respondents included in the analysis, 399 reported that they had had difficulty opening medical supplies within the past 12 months (23.5% of the 1,702; Figure 33 and Table 36). ‘*Too small of an area to grip*’ was the most common reason reported among those who indicated difficulty opening medical supplies within the past 12 months (63.2%, 252/399, or 14.8 % of the total population of respondents analyzed; Figure 34 and Table 37). Of the 399 respondents indicating difficulty, 12.8% (51 respondents, or 3.0% of the population analyzed, 1,702) claimed that difficulties associated with opening medical supplies had negatively affected patient care within the last 12 months (Table 38). Additionally, 76.9% (307) of respondents who

answered that they had a difficulty opening reported using ‘*Scissors*’ to cope with the difficulties that they encountered when opening medical supplies within the past 12 months (See Figure 35 and Table 41).

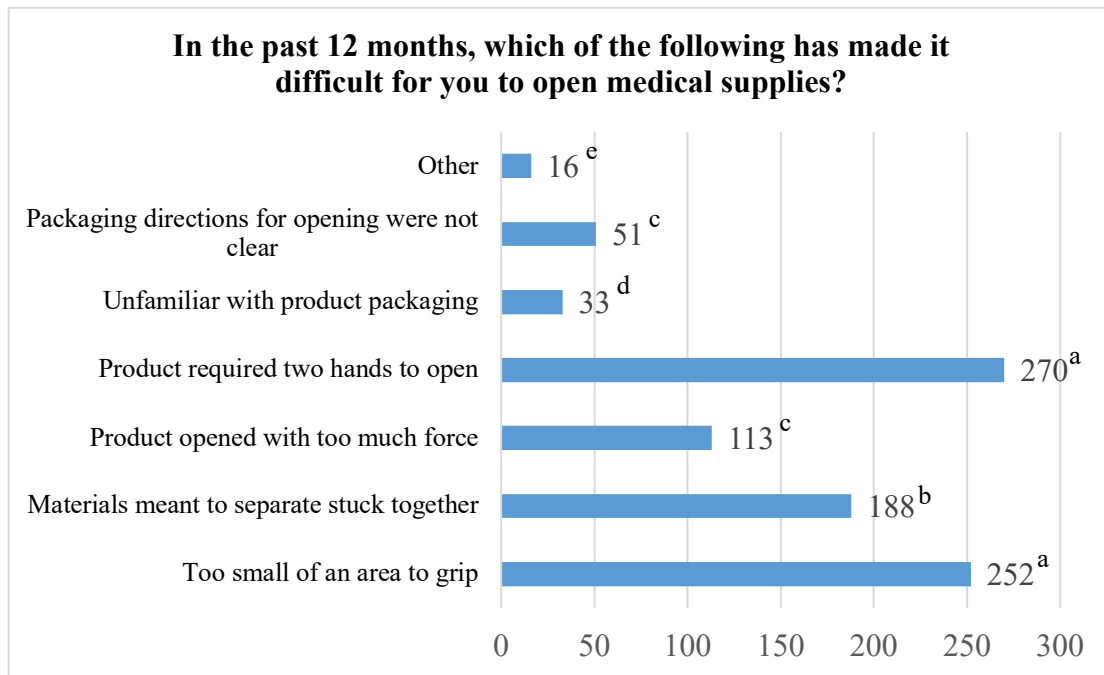


Figure 34. Reasons for this difficulty opening medical supplies within the past 12 months (a single respondent can respond to multiple)

Table 37. Frequencies and proportions of reason for difficulty opening medical supplies within the past 12 months (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Too small of an area to grip	252	63.2% (399)	14.8% (1,702)
Materials meant to separate stuck together	188	47.1% (399)	11.0% (1,702)
Product opened with too much force	113	28.3% (399)	6.6% (1,702)
Product required two hands to open	270	67.7% (399)	15.9% (1,702)
Unfamiliar with product packaging	33	8.3% (399)	1.9% (1,702)
Packaging directions for opening were not clear	51	12.8% (399)	3.0% (1,702)
Other	16	4.0% (399)	0.9% (1,702)

Table 38. Difficulties with opening and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	51	12.8% (399)	3.0% (1,702)
No	348	87.20% (399)	20.4% (1,702)

Table 39 shows 95% Confidence Interval Estimates for odds ratios associated with the likelihood of reporting specific difficulties related to opening medical supplies. Most of 95% Confidence Interval Estimates do not fall into 1 except for the pairwise comparison between odds ratio of ‘Too small of an area to grip’ vs ‘Unfamiliar with product packaging’.

Table 39. 95% Confidence Interval Estimates for odds ratio of difficulties opening medical supplies

95% Confidence Interval Estimates	Lower	Upper
Odds ratio 'Too small of an area to grip' vs 'Materials meant to separate stuck together'	0.392	0.69
Odds ratio 'Too small of an area to grip' vs 'Product opened with too much force'	0.171	0.31
Odds ratio 'Too small of an area to grip' vs 'Product required two hands to open'	0.912	1.635
Odds ratio 'Too small of an area to grip' vs 'Unfamiliar with product packaging'	0.035	0.079
Odds ratio 'Too small of an area to grip' vs 'Packaging directions for opening were not clear'	0.06	0.122
Odds ratio 'Too small of an area to grip' vs 'Other'	0.014	0.042
Odds ratio 'Materials meant to separate stuck together' vs 'Product opened with too much force'	0.331	0.595
Odds ratio 'Materials meant to separate stuck together' vs 'Product required two hands to open'	1.762	3.131
Odds ratio 'Materials meant to separate stuck together' vs 'Unfamiliar with product packaging'	0.067	0.152
Odds ratio 'Materials meant to separate stuck together' vs 'Packaging directions for opening were not clear'	0.115	0.234
Odds ratio 'Materials meant to separate stuck together' vs 'Other'	0.027	0.08
Odds ratio 'Product opened with too much force' vs 'Product required two hands to open'	3.915	7.168
Odds ratio 'Product opened with too much force' vs 'Unfamiliar with product packaging'	0.15	0.346
Odds ratio 'Product opened with too much force' vs 'Packaging directions for opening were not clear'	0.257	0.535
Odds ratio 'Product opened with too much force' vs 'Other'	0.061	0.182
Odds ratio 'Product required two hands to open' vs 'Unfamiliar with product packaging'	0.028	0.065
Odds ratio 'Product required two hands to open' vs 'Packaging directions for opening were not clear'	0.049	0.1
Odds ratio 'Product required two hands to open' vs 'Other'	0.012	0.034
Odds ratio 'Unfamiliar with product packaging' vs 'Packaging directions for opening were not clear'	1.024	2.579
Odds ratio 'Unfamiliar with product packaging' vs 'Other'	0.251	0.856
Odds ratio 'Packaging directions for opening were not clear' vs 'Other'	0.16	0.509
*Texts in bold indicate a significant different difference between options * $\alpha=0.05$		

There was no evidence of a significant difference in reporting rates from respondents when the difficulties ‘Product required two hands to open’ and ‘Too small of an area to grip’, (the first and second highest response rates (relatively speaking)), were compared. Similarly, comparisons of reporting rates generated by the reasons, ‘Product opened with too much force’ and ‘Packaging directions for opening were not clear’, yielded no evidence of a statistically significant difference.

Table 40. Pairwise comparison for difficulties opening medical supplies

Product required two hands to open ^a Too small of an area to grip ^a Materials meant to separate stuck together ^b Product opened with too much force ^c Packaging directions for opening were not clear ^c Unfamiliar with product packaging ^d Other ^e
*Different alphabet indicates significant difference. *The highest rate is on the top row *$\alpha=0.05$

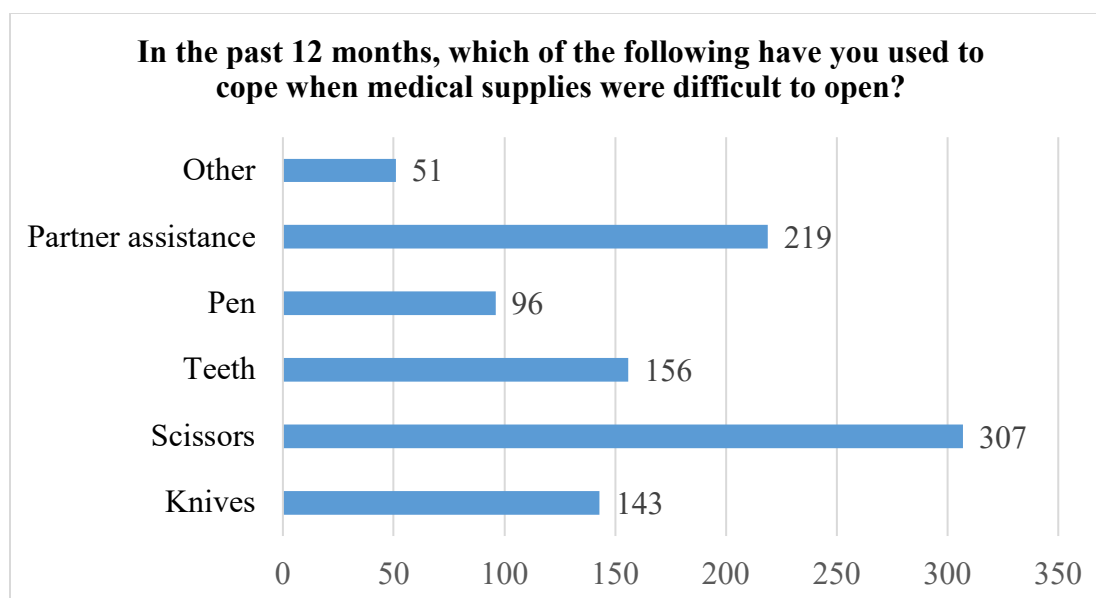


Figure 35. Coping strategies (affordance behaviors) to difficulties opening medical supplies within the past 12 months (a single respondent can respond to multiple)

95% Confidence Interval Estimates for odds ratios of reporting frequency by coping strategy relating to the difficulties associated with opening medical supplies are represented in Table 42. As with responses regarding opening medical supplies, coping strategies such as ‘Knives’, ‘Scissors’ and ‘Pen’ were combined into the category ‘Sharp Tools’. Bolded text in the table indicates evidence of statistically significant differences between frequency of reports by coping strategies (affordance behaviors).

Table 41. Frequencies and proportions of coping strategies (affordance behaviors) to difficulties opening medical supplies within the past 12 months (a single respondent can respond to multiple)

Coping strategies (Affordance behaviors)	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Knives	143	35.8% (399)	8.4% (1,702)
Scissors	307	76.9% (399)	18.0% (1,702)
Teeth	156	39.1% (399)	9.2% (1,702)
Pen	96	24.1% (399)	5.6% (1,702)
Partner assistance	219	54.9% (399)	12.9% (1,702)
Other	51	3.5% (399)	2.9% (1,702)

Table 42. 95% Confidence Interval Estimates for odds ratio of coping strategies for each difficulty opening medical supplies

95% Confidence Interval Estimates	Too small of an area to grip		Materials meant to separate stuck together		Product opened with too much force	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.035	0.312	0.021	0.223	0.012	0.254
Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	0.054	0.479	0.025	0.265	0.012	0.254
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0.001	0.029	0	0.019	0	.
Odds ratio 'Teeth' vs 'Partner assistance'	0.68	3.462	0.526	2.681	0.443	2.255
Odds ratio 'Teeth' vs 'Other'	0.011	0.233	0.004	0.231	0	.
Odds ratio 'Partner assistance' vs 'Other'	0.007	0.152	0.003	0.194	0	.

Table 42. (cont'd)

95% Confidence Interval Estimates	Product required two hands to open		Unfamiliar with product packaging		Packaging directions for opening were not clear	
	Lower	Upper	Lower	Upper	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.081	0.496	0.068	0.639	0.027	0.241
Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	0.147	0.904	0.211	2.283	0.07	0.632
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0.002	0.058	0.001	0.061	0.001	0.029
Odds ratio 'Teeth' vs 'Partner assistance'	0.805	4.129	1.163	9.477	1.131	5.98
Odds ratio 'Teeth' vs 'Other'	0.013	0.277	0.004	0.272	0.014	0.303
Odds ratio 'Partner assistance' vs 'Other'	0.007	0.152	0.001	0.085	0.005	0.117

Table 42. (cont'd)

95% Confidence Interval Estimates	Other	
	Lower	Upper
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Teeth'	0.047	1.135
Odds ratio Sharp Tools 'Sharp Tools (Knives, Scissors, Pen)' vs 'Partner assistance'	1.185	41.359
Odds ratio 'Sharp Tools (Knives, Scissors, Pen)' vs 'Other'	0.007	0.632
Odds ratio 'Teeth' vs 'Partner assistance'	4.351	211.49
Odds ratio 'Teeth' vs 'Other'	0.027	3.127
Odds ratio 'Partner assistance' vs 'Other'	0.001	0.117

*Texts in bold indicate the significant difference between the options at $\alpha=0.05$

Pairwise comparisons were conducted to assess significant differences among coping strategies (affordance behaviors) by reported difficulty (See Table 43). No evidence of significant difference in reporting rates associated with the coping strategies 'Sharp Tools' and 'Partner Assistance' were evident for the reasons 'Product opened with too much force', 'Product required two hands to open', 'Unfamiliar with product packaging', 'Packaging directions for opening were not clear' and 'Other' whereas for the reason 'Too small of an area to grip', 'Sharpened Tools' yielded a significantly different rate of report compared to 'Partner Assistance'.

Table 43. Pairwise comparisons for coping strategy for each difficulty opening medical supplies

Too small of an area to grip
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^b
Teeth ^b
Other ^b
Materials meant to separate stuck together
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^b
Teeth ^b
Other ^c
Product opened with too much force
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^a
Teeth ^b
Other ^c
Product required two hands to open
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^{ab}
Teeth ^b
Other ^c
Unfamiliar with product packaging
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^a
Teeth ^b
Other ^c
Packaging directions for opening were not clear
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^a
Teeth ^b
Other ^c
Other
Sharp Tools (Knives, Scissors, Pen) ^a
Partner assistance ^a
Teeth ^a
Other ^a

*Different alphabet indicates significant difference.

*The highest rate is on the top row

* $\alpha=0.05$

4.2.3.3 Use (Medical Device)

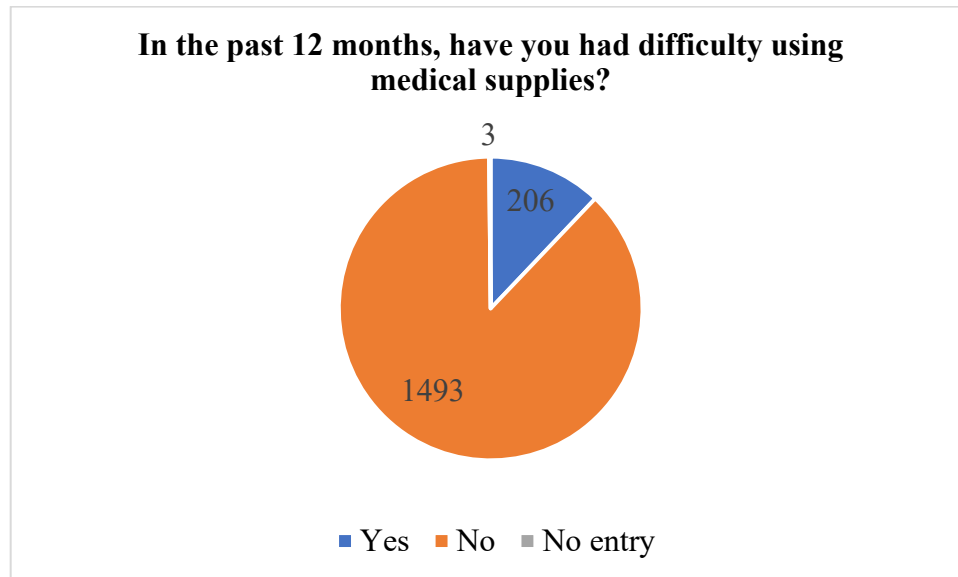


Figure 36. Responses to difficulties using medical supplies within the past 12 months

Table 44. Frequencies and proportions of responses regarding difficulties using medical supplies within the past 12 months

Response	Frequency	Percent	Respondents after screening
Yes	206	12.10%	1,702
No	1,493	87.70%	1,702
No entry	3	0.20%	1,702

Of the 1,702 respondents included in the analysis, 206 respondents answered that they had difficulty using medical supplies within the last 12 months (12.1% of 1,702; Figure 36 and Table 44). ‘Multiple, loose items’ was the most common difficulty reported (35.4%, 73/206, 4.3% of the population analyzed; Figure 37 and Table 45). 16% of the 206 reporting difficulties using medical supplies within the past 12 months (33 respondents), or 1.9% of the total population, claimed that these issues had negatively affected patient care within the past 12 months (See Figure 46).

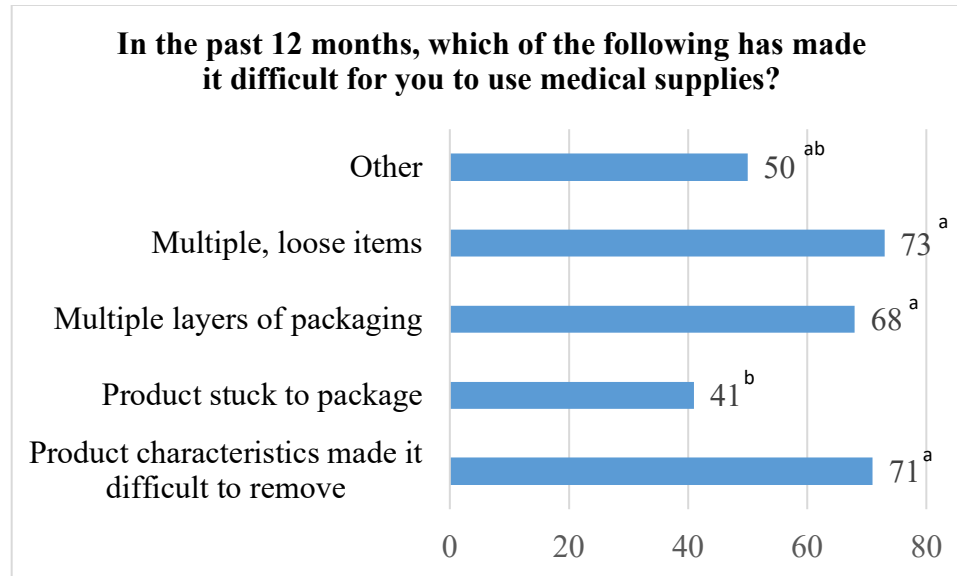


Figure 37. Reasons for this difficulty with use of medical supplies within the past 12 months (a single respondent can respond to multiple)

Table 45. Frequencies of proportions of reasons for this difficulty with use of medical supplies within the past 12 months (a single respondent can respond to multiple)

Reported reasons for the difficulty	Frequency of individuals reporting difficulty	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Product characteristics made it difficult to remove	71	34.5% (206)	4.2% (1,702)
Product stuck to package	41	19.9% (206)	2.4% (1,702)
Multiple layers of packaging	68	33.0% (206)	4.0% (1,702)
Multiple, loose items	73	35.4% (206)	4.3% (1,702)
Other	50	24.3% (206)	2.9% (1,702)

Table 46. Difficulties with use and the frequency and proportion of respondents indicating negative impact on patient care (within the subset indicating difficulty and within the population of respondent data analyzed)

Response	Frequency	Percent (out of respondents indicating difficulty)	Percent (out of total respondents after screening)
Yes	33	16.0% (206)	1.9% (1,702)
No	173	84.0% (206)	10.2% (1,702)

There was no evidence of a significant difference in reporting rates from respondents when the difficulties ‘Multiple, loose items’, ‘Product characteristics made it difficult to remove’ and ‘Multiple layers of packaging’, reported as the first, second and third highest frequency, respectively, were compared. Similarly, comparisons of reporting rates generated by the reasons, ‘Other’ and ‘Product stuck to package’, yielded evidence of a statistically significant difference.

Table 47. 95% Confidence Interval Estimates for odds ratio of difficulties using medical supplies

95% Confidence Interval Estimates	Lower	Upper
Odds ratio ‘Product characteristics made it difficult to remove’ vs ‘Product stuck to package’	0.271	0.814
Odds ratio ‘Product characteristics made it difficult to remove’ vs ‘Multiple layers of packaging’	0.609	1.641
Odds ratio ‘Product characteristics made it difficult to remove’ vs ‘Multiple, loose items’	0.86	2.265
Odds ratio ‘Product characteristics made it difficult to remove’ vs ‘Other’	0.459	1.272
Odds ratio ‘Product stuck to package’ vs ‘Multiple layers of packaging’	1.229	3.694
Odds ratio ‘Product stuck to package’ vs ‘Multiple, loose items’	1.732	5.104
Odds ratio ‘Product stuck to package’ vs ‘Other’	0.926	2.859
Odds ratio ‘Multiple layers of packaging’ vs ‘Multiple, loose items’	0.86	2.265
Odds ratio ‘Multiple layers of packaging’ vs ‘Other’	0.459	1.272
Odds ratio ‘Multiple, loose items’ vs ‘Other’	0.332	0.901
*Texts in bold indicate the significant difference between the options. * $\alpha=0.05$		

Pairwise comparisons for rates of reporting of varied reasons that resulted in difficulties using medical supplies were conducted and shown in Table 47 (enhanced comprehensibility version -see Table 48). There is no evidence of a significant difference when rates of report

related to the difficulties ‘Multiple, loose items’, ‘Product characteristics made it difficult to remove’, ‘Multiple layers of packaging’, and ‘Other’ were compared at $\alpha=0.05$. Also, respondent rates for the following reasons ‘Product stuck to package’ did not yield evidence of significant difference from those reasons grouped as ‘Others’.

Table 48. Pairwise comparison for difficulties using medical supplies

Multiple, loose items^a Product characteristics made it difficult to remove^a Multiple layers of packaging^a Other^{ab} Product stuck to package^b
*Different alphabet indicates significant difference. *The highest rate is on the top row *$\alpha=0.05$

4.3 Discussion and conclusions

The objective of this pilot study was to garner insight into EMS providers' behavior regarding the identification, opening and use of medications/medical supplies in order to inform the design cues that are likely to induce problematic affordance behaviors during simulations.

The results suggested that difficulties associated with packaging have the potential to result in negative patient outcomes (1.2%-3.0% of participants included in analysis depending on the task and product type (i.e. medication or medical device- See Figure 38), which indicating that purposeful design cues for medication/medical supplies are an important area to focus for the future research.

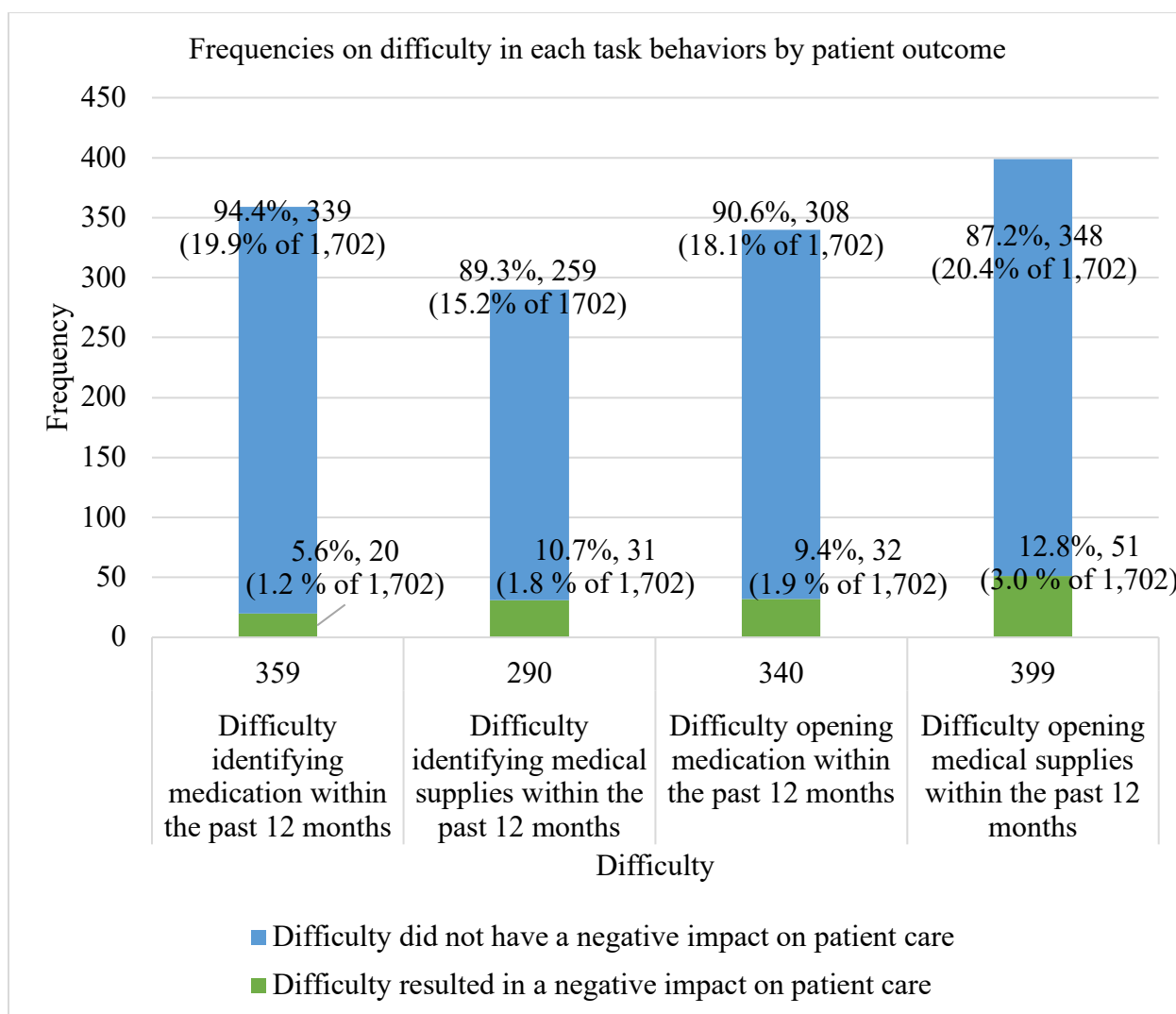


Figure 38. Frequencies on difficulty in each task behaviors by patient outcome

Difficulties result in different coping strategies (affordance behaviors) and suggest that the design cues for both medications and medical supplies can be improved. Further, we offer insights into significant reasons for the difficulties, ‘Product required two hands to open’ and ‘too small of an area to grip’. These insights will serve to inform our simulation design in the next steps of our research.

Chapter 5. A collective case study of ambulance setting/context and EMS providers experience with packaging

5.1 Methodological framework

A series of semi-structured interviews were conducted focusing on factors intended to inform the design of the simulator, the scenarios, and products that result in difficulty (Specific Aim 2). Insights garnered from this work were used to inform decisions regarding the creation of the simulated context (collection of vibration data-Specific Aim 3) and the final phase of research (the formative usability test- Specific Aim 4). Choices were made with the intention of creating a context likely to induce the unintended affordance behaviors reported in our previous work (Survey-Specific Aim 1). Of specific interest for the guided interviews was the configuration of seating, the physical working spaces, storage areas, type of vibration/motion, and patient conditions likely to induce difficulty. Specific to workspaces, researchers also wanted to better understand, “supply or jump bags”. Namely, to identify what types of items and medical supplies were typically carried in the bag, how they were physically configured within and where the bag was normally stored.

Study objectives for the guided interviews were intended:

- a. To gather insights into EMS settings and specific contexts (physical spaces and storage areas, patient conditions, road and motion conditions) which induce difficulties in performing intended tasks with packaging.
- b. To gather insights into good package design and poor package designs within these settings.

Five semi-structured interviews were conducted in accordance with procedures approved under IRB# x17-1041eD using a standard moderator guide informed by learnings from the preceding study and with objectives (a and b) in mind (See Appendix G).

5.1.1 Recruitment

Participants were recruited through the Tri-County Emergency Medical Control Authority and Lansing Community College by distributing an email with a recruitment advertisement (See Appendix E) to paramedics employed in Clinton, Eaton and Ingham Counties (Michigan, USA). To be eligible, participants had to: be employed currently as a paramedic, have administered patient care within the last year, be willing to be videotaped, be willing to bring their supply bag or a digital representation (i.e. video or photo) of the same. Interviews took no longer than 2 and a half hours, and participants were provided with \$60.

5.1.2 Moderator guide (Appendix G)

To enhance the consistency of discussion and ensure that all points were covered with all participants, the research team created a moderator guide (see Appendix G). In addition to guiding the researcher by providing a scaffold of questions, this document also included a series of questions/activities which participants completed (e.g., characterizing the physical space within the ambulance and marking common seating and storage). The guide was comprised of several sections, each with a different purpose in support of the creation of a realistic simulator and healthcare simulations which were likely to induce the unintended behaviors that were noted in the survey and reported to impact patient care (Specific Aim 1).

The *Education* section of the moderator guide was intended to reduce misunderstandings related to terms commonly used throughout the discussion. Following the education section, a

warm-up section allowed the participants to introduce themselves to the research team (and to others that were present) and catalyzed them to think about difficulties that they had encountered with package designs. Once the moderator introduced herself to the group or a participant, participants were asked to introduce themselves based on the demographic sheet (Appendix H) that they had completed.

The next section of the moderator guide had the objective of “*Characterizing the working environment.*” This section intended to garner insight into aspects of the setting/context likely to induce challenges, with particular emphasis on seating, the physical working spaces, and storage areas. Questions were informed using anecdotal observations coupled with survey results.

To further inform the creation of the physical setting for the proposed simulation, we asked specific questions related to the medical supply/jump bag, a bag that generally holds medical supplies and is frequently assigned to a specific ambulance. During this section of the discussion, questions focused on the types of medical supplies that were usually kept within the bag (the language related to the same: “Supply bag,” “jump bag,” “mini-ambulance,” “medical bag”, “orange bag” and “trauma bag” were some of the terms that emerged to describe the bag that carries supplies to the scene) or stored within the ambulance. In an attempt to inventory common items in the bag and the drug box, a second supply area where drugs are stored, participants were asked to bring the bag they used in the course of employment or take a photo/video of it and its contents. Participants itemized products common to the bag during one of the activities conducted. Participants were debriefed after the activity using probes related to the itemization.

Based on results from the online survey (Chapter 4- Specific Aim 1), scissor use (trauma shears in their language) was indicated as a common strategy for opening medical supplies (18%

of 1,702 respondents). As such, during the interview, among the items of particular interest to us were the trauma shears. Specifically, if trauma shears were reported in a participant's list, they were asked to share an experience involving the same.

We also probed for information specific to 'Vibration and Motion'. Survey results (Chapter 4- Specific Aim 1) suggested the factors of motion, and by association, vibration, potentially influenced affordance behaviors on the ambulance. Specifically, 49 respondents (34 % of 144 respondents who responded that they have had difficulty administering medication within the past 12 months) reported vibration and motion to be a reason for difficulty administering medication within prehospital settings within the past 12 months of service. This is consistent with the literature focused on Whole Body Vibration (WBV), which indicates that vibration has the potential to physically impact the human body (Ruiz-Ruiz, Mesa, Gutiérrez, & Castillo, 2002), as well as the ability to perform tasks as intended. As such, responses to this section informed the creation of the profile of the vibration profile which ultimately controlled the motion of the table during the usability testing.

5.1.3 Procedures

An IRB approved recruitment advertisement (See Appendix E) was distributed over three counties in the Lansing area via Tri-County Emergency Medical Control Authority, and Lansing Community College advertised the opportunity to Fire Departments in the Lansing area. Interested participants contacted a member of the research team to schedule interview sessions. When participants were available within the same time frame, they were scheduled for the same session while others were individually scheduled. Upon initial contact, the researcher went over the inclusionary criteria previously described to ensure the caller was eligible to participate. A

reminder phone call was placed to participants 24 hours prior to their interview, at which time they were reminded of the need to take photos/videos of the medical bag and its contents (or to bring it to the interview site). Researchers also addressed questions regarding the study, location, driving directions, etc. Three interviews were held in the conference room at Tri-County Emergency Medical Control Authority located in Lansing, Michigan and two were taken at Lansing-Area Fire Stations.

Gopro Heros 3 (San Mateo, CA) were mounted on a table where participants were seated to videotape the interview and a Boocosa Voice Recorder VR001(Guang Dong, China) was used to clearly and completely record audio responses.

Discussion was framed with the moderator guide (Appendix G) and led by a single researcher for all interviews; a second member of the research team assisted with set up, equipment, note-taking and ensured that the guide was followed thoroughly and consistently.

Once a participant arrived, eligibility was confirmed, and the consent process was undertaken (See Appendix F). After informed, written consent was obtained, the participant was asked to fill out a demographic sheet (See Appendix H). The sheet included age, gender, primary role within the prehospital context, years working in these contexts and experience related to packaging. Additionally, a guide containing packaging terminology which would be used throughout the course of the interview was provided (See Appendix I). This was intended to help participants and the research team to develop a common understanding related to terminology; misunderstandings regarding terminology were discussed and clarified.

5.2 Analysis method

Cross-case analysis (Glesne, 2015) was conducted to find patterns across the five cases. Specifically, recorded audio files of each interview were manually and individually transcribed in their entirety using Microsoft Word (2016 version; Redmond, WA) and Quick Time Player 7 (Cupertino, CA) by a single member of the research team who served the moderator role during the interviews. Transcripts of the five interview events were broken into thought units; thought units focused on varying aspects of setting/context were organized into emergent themes and sub themes. Each transcript was reviewed to identify the patterns related to each question (See Appendix G for questions). NVivo 12 (Doncaster, Australia) was used for analysis to construct the major themes and sub-themes and gather participants' responses into them.

5.3 Findings

5.3.1 Participants

A total of 8 participants partook in the five semi-structured interviews conducted. Two participants took part as individuals in the interview while other 6 participants were grouped into 3 groups comprised of 2 individuals per session. All participants were male, and the average age was 46 (standard deviation ± 8.25). Average years of their EMS work experience was 18.63 years (standard deviation ± 7.50) and all participants were employed as paramedics with full time status. The communities in which they do most of their EMS works were reported; small town (n=1), medium towns (n=2), large towns/cities (n=4), and suburb/fringe of a large city (n=1). Average time spent on a run was reported as 45 minutes (standard deviation ± 30 minutes).

5.3.2 Ambulance Settings

5.3.2.1 Jump bag and drug box (See inventory list obtained from participants in Appendix K)

A jump bag (or a trauma bag) is regularly used within the pre-hospital setting. EMS personnel carry the bag to the scene to administer patient care. As such, the majority of needed medical devices and tools are stored in the bag. In order to accurately depict the physical context and products required for our simulations and understand the conditions that likely induce difficulties, it was necessary to explore how paramedics store devices and tools within the bag. Figure 39 shows the inside of a jump bag provided by participant 3. The jump bag has different compartments to store different types of tools and medical devices while medications, generally stored within a locked “drug box” or cabinet, are not housed within the bag. Medications, and storage of the same, are strictly regulated by the Medical Control Authority (See the drug box

inventory form in Appendix L). Exemplar comments from participants that informed our understanding of the storage conditions for medications follow:

P1: “You have to use a drug box so this place that we're in, the Tri County, regulates what's in that drug box and so that's what we use.”

P2: “The drug box is very regulated.”

P3: “Tri-county (Medical Control Authority) doesn't authorize us to carry any drugs –medication[s] outside of their box.”

P7: “That[medication] comes in what we refer to as a drug box so that's a controlled --it's a controlled item.”



Figure 39. Participant Provided photos of typical Jump Bag Storage provided by participant 3

Figure 39. (cont'd)



Figure 39 depicts the jump bag of a single participant; participants consistently indicated that product placement (and the products included) within the jump bag varies from department to department, Agency to Agency. The idea of varied storage environments also emerged as

participants discussed storage areas. “I know a lot of departments don't have this similar setup and the same bag.” (P2).

Also discussed was the concept of jump bag “density,” (i.e. did each paramedic have a jump bag? Did a given ambulance have a jump bag?). Varied comments were made in this regard. Generally, participants indicated that the number of available bags was “based on how many ambulances we have.” (P1). That said, there was also an indication that bags were not consistently stocked, that is, that not all available bags contained all items required for ALS (Advanced Life Support). A response from participant 2 lends insight into this, “we have one station-- we have ... five bags but only one of them is going to have all the stuff that we're talking about --the advanced equipment in it” (P2).

The location of the jump bag (both within the station and within the ambulance) was another point for discussion during the interviews. Participants consistently indicated that the jump bag “stays in the ambulance” (P1) while not on a run, but the specific location that they put the jump bag within the ambulance was indicated to be variable. Some participants expressed that they kept their bags in a familiar location, making it ready to ‘grab and go’ (e.g. near the door or on the cot) at the back of the ambulance, so they “can open up the door and grab it” (P2). With kindred purpose, other participants suggested “Sometimes it will be on the cot”(P1) because, again, “[we] take that cot with us into the house normally so just that's already on the cot then we're just grabbing a cot and go on.”(P1). Although these statements suggest a lack of standardized practice regarding the jump bag, a limited number of participants suggested that certain stations standardize the precise location of bag placement between runs. “I know some departments [fire stations] have a specific spot like inside of a cabinet but we don’t” (P2) and “in

a designated cabinet” (P3). This is not surprising because “it is shared within the departments [fire stations] each one assigned to an ambulance” (P3).

- Trauma shears

As mentioned previously, we were interested in exploring information related to the storage and use of trauma shears as we had anecdotally observed their use as a tool to open packaging and confirmed this as a technique with our survey data (Chapter 4 Specific Aim 1). During the course of the guided interviews, we explored how often they were cleaned or replaced, as well as instances where they were used to open packages.

Participants indicated trauma shears to be “common supplies” (P1) within the pre-hospital setting as “they are cheap and disposable” (P2). Participants generally believed that they should be quickly accessible. Representative of this sentiment is a statement from participant 2, “if you need trauma shears, you need them pretty quick”(P2), they are stored in “multiple different locations” (P2), which, like the jump bag, can differ by agency or department or EMS provider’s preference. While some indicated “there's a lot of people that will carry another set of trauma shears on them on their person or so” (P1), others didn’t find this to be common practice, “I don’t think anybody in our department carries them” (P2). General consensus among our participants was that the main use of trauma shears was to cut away patient clothing at the scene of injury (e.g. car accident); “[it’s] usually on car accidents when we use trauma shears and we have to cut people's clothes off in order to access [the patient’s injury].” (P2)

Consistent with our findings of the storage of supplies, when probed for information about the cleaning and sterilization of trauma shears, the overall theme was that inconsistent approaches existed across agencies and departments. A single participant indicated trauma shears were not ever cleaned; instead, in his experience, they were replaced with a new set. “They're

[trauma shears] disposable so after a run we can throw them away and we can go to our EMS supply and grab another one.” (P1). Another participant echoed this sentiment, “I have never cleaned [trauma shears] before (P2)”. Other participants indicated that their departments clean the shears when contamination is obvious with naked eyes; “if we get around any kind of bodily fluids, clean them up.” (P3). Yet others indicated cleaning to be more prevalent, “every time that they’re [trauma shears]’ used, they [his department] wipe down and if they’re [trauma shear] ever visibly contaminated they [his department] dispose that [trauma shear] and they [his department] get a new set.” (P4).

Participants indicated that trauma shears were not commonly used to open packaging (after indicating that their primary use was to cut clothing in order to expose injuries for work) “Most of the packages we use we can open with our hands.”(P5), but did suggest that sometimes the shears are used to assist with opening packaging, though this occurred infrequently.

P3: “maybe on a rare occasion over the years I may have had to, you know, maybe once open up the bag that holds the I.V. solution.” (P3)

P7: “once with the really poor corner peel packaging.” (P7).

5.3.2.2 Seatbelt Use and Spaces within the ambulance

Three major seating areas generally exist within the ambulance (see Figure 40 A (Captain’s seat) B (Bench Seat) and C (CPR Seat)), and seatbelts are readily available for paramedics to use, regardless of where they sit. We hypothesized that seatbelt use could potentially limit paramedics’ movement, restricting their ability to administer patient care. As such, prompts related to seatbelt use and potential impacts of the same were built into our moderator guide (See Appendix H).

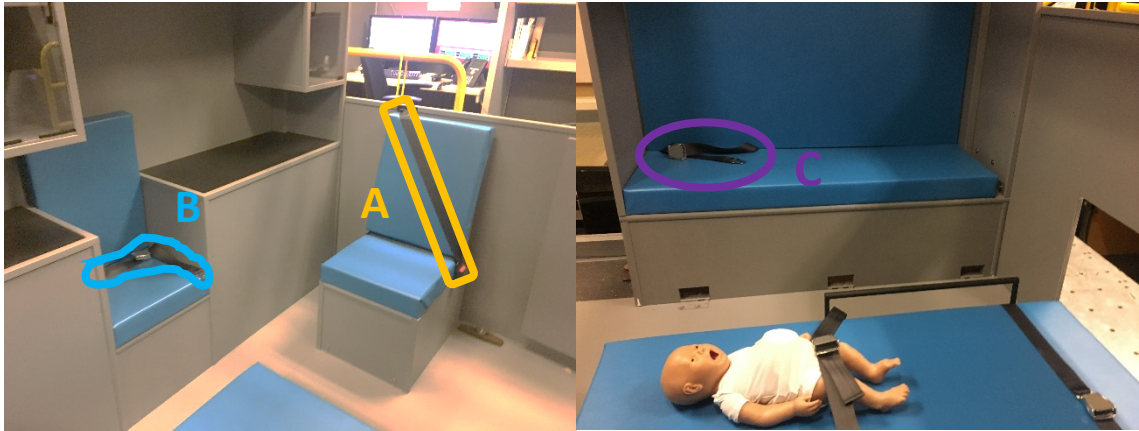


Figure 40. Seatbelt's setup in the prehospital simulator

All 8 participants reported that they rarely wore a seatbelt, and the prevailing sentiment regarding the reason for not engaging it was that it impaired their ability to render patient care. Representative statements included “cannot reach patients (P6)” and “can’t work for a patient” (P5). “We have to move around and a seatbelt would be very-- would be too restrictive of us to be able to do proper patient care” (P5).

P8: “If we’re [paramedics] doing C.P.R. or something more critical where we’re going to grab the person to go into a lot of work on the way there, someone that’s, you know, unresponsive, we need more stuff done-- I.Vs and the airways but we want to get them to the hospital quicker. Nobody’s wearing the seatbelt because it’s very flowing over there [ambulance]. A lot of things happening. We are like standing in a room moving down the road.”

Despite the consistent theme that seatbelts restricted them, half of them did report that there are times when they wore them.

P1: “You could say the less serious the call the more inclined I would be to wear the seat belt.”

P3: “If we’re going on the highway, I usually try to make sure I put a seatbelt on.”

P4: “If there is [are] poor weather conditions or I have a partner driving [and] I don’t particularly trust their ability behind the wheel, I would put a seatbelt on.”

P8: “Sometimes--- nature of the call, nature of the condition of the patient. If they're sitting in upright and responsive in a normal nice, easy transport, I will wear my seatbelt on that bench seat.”

We also probed information relating to the workspaces within the ambulance with the idea that small spaces had the possibility of restricting paramedics’ movement. The participants confirmed the idea that space was limited within the ambulance, especially on the left side (where the CPR seat is located—See Figure 41) after the cot is locked into place, indicating that they needed to either kneel, or to cope in some other way, to stabilize themselves while administering care at the right side of the patient. The following are representative statements that are typical of what was said across the group.

P6: “Many times the cot is shifted far to the patient's right to allow the caregiver to sit on the bench and have a little bit more room. I mean, many times we have to do procedures on the right side of the body and usually have about this much room [with a hand gesture indicating ‘very little’]. It's really tough, actually you end up probably kneeling on the cot with your right knee and maybe your left foot can make it on the floor.”

P7: “Some of our cots are so close that you can't even slide your boot in between the cot and the side there [left side of the ambulance] so the only way you have to have your knee or something on the cot. It’s tight, so often it probably looks awkward but I am often straddling my patient”



Figure 41. A CPR seat (left) and a bench seat (right) within an ambulance (in the red circle)

5.3.3 Context

As described in the introduction, context refers to a series of situations where events occur within a setting (in our case, prehospital, specifically on the ambulance). Physical locations of paramedics are dependent upon the specific context, including the vibration and motion occurring. Other factors that make up the specifics of the context include patient condition and behavior, lighting and sound which differ based upon situations as well as the configuration of the storage areas and the designs of the packages within.

5.3.3.1 Physical locations of paramedics

When probed about their physical location within the ambulance, participants' responses tended toward two themes: how critical the patient's condition was, and their own preference regarding seating. There was a tendency to indicate a preference for sitting in the captain's seat (See Figure 41) when administering airway care (or intubation) or when "making the radio call"

(P3) to hospitals because “the head of the patient is at the captain’s seat”(P3) and the radio is nearby. Respondents indicated that they sit on the CPR seat (See Figure 41) during scenarios where they need to check the heart monitor, and on the bench seat (See Figure 41) when intravenous care or primary care was required. Participant 2 provides a statement representative of the majority interviewed, “if we’re working on an IV, we’ll probably stay right here [(indicating the bench seat – see Figure 41)] this is pretty much the primary care position for the patient” (P2).



Figure 42. A captain seat within the ambulance (in the red circle)

5.3.3.2 Vibration and motion

Vibration and motions were probed in order to inform the next phase of experiment (Specific Aim 4- a formative, usability test utilizing healthcare simulations incorporating motion); findings from the semi-structured interviews were used to guide the creation of the vibration profile that ultimately would be used to drive the motion of the table. Specifically, patterns of the participants’ responses regarding the types of vibration that makes their job

difficult were identified (e.g. ‘a sudden stop or start’ and ‘bumpy road/dirt road’). The general consensus was that horizontal accelerations and decelerations, in the forms of starts and stops and turns, were the type of motion that most impacted their ability to perform their job.

P3: “Sometimes a driver will have to put the brakes on quick.”

P4: “Sudden starts and stops are far more detrimental to patient care.”

P6: “Yeah, stopping is always bad.”

P7: “Acceleration, deceleration but turn-- along with that speed is a factor.”

P8: “A sudden stop--- Decelerations and acceleration.”

One participant clarified some of the challenges in further detail, “Turn[s] along with the speed is a factor” (P7) that poses a challenge for them but “usually lane changes are not that big of a deal.” (P7).

Some participants noted that noises induced by the road and ambulance resulted in difficulty hearing patient sounds (e.g. respiration or heart sounds) or even the patients, themselves. This impairment was reported to work bidirectionally; “... if you're dealing with elderly patients and they can barely hear. On a bumpy road they're not going to hear anything, and neither am I [paramedic]” (P1). Road hazards were reported to pose challenges, particularly in combination with other factors, such as patients with time sensitive conditions and vehicle construction; bumpy roads, maybe high speeds, a loud ambulance, bad suspension. Anything that's going to create additional movement [rattle or vibrate within the vehicle or create more action]” (P2). This is likely because a significant amount of the vibration transmits to them in the back of ambulance; “Potholes in the winter and dirt roads-- those are probably the two big ones that you get a lot of vibration in the back” (P3).

Bumps and potholes were reported as problematic when it comes to performing their job. A general assessment that emerged from comments regarding bumps was that paramedics “can’t

adjust” (P4), that they could “do hardly anything” (P7). Some paramedics report that “patients come clean up off the cot.” (P7). It was consistently reported that this poses a challenge to start an IV and secure airway “... starting an I.V.s-- while you're going down the road. That can be one of your high-risk [activities]” (P3). Also, “potholes definitely present a challenge” (P4).

We were somewhat surprised that railroad tracks did not induce indications of problematic conditions among the paramedics that we talked with. “The railroad tracks seem to be better than the actual road” (P6) because “a lot of potholes and bumps and the fills-- filling they have done—so—it’s generally bumpier [than railroad track] and then I would say rail road track is expecting something larger and it’s nothing” railroad tracks also offer the benefit of the ability to anticipate, either through familiarity with the route, through the window or being provided with a warning from the driver (the details of coping strategies on railroad tracks will be articulated further in next section).

Seasonal road conditions were noted as a factor with the potential to impact performance as well. “Highways are not that bad unless it's the wintertime or shortly after the winter. When it’s really -- the bumps are increased” (P1). This supports the idea that road conditions (presumably bumps and potholes) create difficulty for paramedics administering patient care. Also, statements provided from participant 4 support the seasonality of this difficulty “Road conditions in regard to weather certainly do [pose a challenge]” (P4).

5.3.3.3 Coping strategies regarding vibration and motion

We asked participants about ways that they coped with motion and vibration to better understand how we needed to structure the simulation environment and scenarios for the same. Overhead bars were mentioned during this portion of the interview. “We [paramedics] have an

overhead bar we [paramedics] can hold onto” (P5). Use of overhead bars was reported as a mechanism to deal with difficult road conditions, particularly for sudden stops “if they [drivers] hit the brake you may have to grab for that bar” (P6). They also reported using the bar to steady themselves during repositioning while the vehicle was in motion; “if it's going to be bouncing or you're making a turn and if you do have to move, when you're in the back [of the ambulance] with the patient. If you do have to move around, usually there's a grab, hold bar [overhead bar] someplace you can hold onto” (P3).

As previously mentioned during the discussion of railroad exposure, paramedics reported situational awareness as a coping strategy employed to deal with the motion of the vehicle. Specifically, knowing where they are and anticipating how the road will be. They do this by keeping tabs “through the driver's window so they [paramedics] can see where they're going...” (P3). Furthermore, familiarity with their community assists them in anticipating how the road will be, so that they can brace against bad road conditions; “familiarity with the area to anticipate when there's going to be a large bump and we [paramedics] may have ... to brace ourselves better.” (P5). Situational awareness combined with experience enable paramedics to anticipate motion prior to events on the road. “Once you decelerate then you know you're going to accelerate” (P7).

This ability to anticipate suggests that paramedics are adapted to the many of the contexts they encounter within their communities. That said, their comments suggest that there is no singular strategy for dealing with motion. They also discussed strategies for balancing while in route; “move and sway with the motion of the ambulance” (P4) and “develop the sea legs” (P3). Multiple strategies for mitigating the negative effect of motion appeared to be employed in our

analysis. This is possibly because, as participant 7 explained, “there's never hardly anything on the sides that you can hang on to.” (P7).

Balancing in sync with the motion of the ambulance is not the only biomechanical technique they reported, kneeling was a frequently reported posture to cope with problematic vibration and motion. “Kneeling is all the best you can do-- for me personally -- Kneeling.” (P8) but they also acknowledged that the physical space would sometimes limit the ability to cope with the motion of the ambulance using this technique “if there's a space to kneel--because that's pretty stable platform to work off of.” (P7). Also, when kneeling, they can “hang onto the cot [handle] because many times for transport you know right on a semi power position --so that cot is a great handle” (P7)

Participants also suggested communicating with the driver as a way to mitigate the effects of motion on performance. “Communicate with the driver to either slow down or let them [drivers] know that they [paramedics] are going to start an I.V.” (P3) Of course, that communication can take place in both directions. The drivers “yell back to me and notify me if I am ready to go to a railroad track so I can prepare for it” (P4). Other strategies discussed were delaying procedures. Representative of this are the following quotes from two participants. We “just wait until the situation is improved” (P2). “I can wait until after we cross the tracks.” (P4).

5.3.3.3 Ambient sound and light within the setting

During the course of our interviews, we also probed how sound and light impacted paramedics’ ability to perform tasks. Incident scenes (e.g. patient’s home) were reported as problematic when it comes to lighting while the lighting system within the ambulance was generally indicated to be acceptable. Participants suggested that light levels within the

ambulance did not interfere with their ability to work, though they recognized that this could also be impacted by the paramedic's own limitations. As participant 3 stated, "They [ambulances] are pretty good about making sure there's plenty of lighting" (P3) however, "as we get older, in my case, I definitely got to keep the reading glasses available. And just adjusting [sic] to lighting stuff like that --that may be a little bit of a challenge with the opening packages stuff like that but especially at night too." (P3).

Though communication (both with the patient and driver partner) was already indicated as critically important to delivering care and coping with obstacles that are present in these settings, sound within the ambulance was indicated to be problematic. "Listening to the lung sounds [of the patient] is probably the most difficult" (P2) due to the fact that "we're [paramedics] sitting on the top of the muffler." (P2). "It is hard--it does get pretty loud in there so you sit behind them [patients]—They [patients] really can't hear you very well." (P3), or paramedics have difficulty communicating with the patients "if it's a respiratory patient --have to listen to lung sounds multiple times especially if you [are] treat[ing] them." (P2)

5.3.3.4 Patient condition

A portion of the moderator guide probed patient conditions that presented challenges. Because our goal was to develop realistic scenarios likely to induce unintended behaviors related to packaged products, the bulk of the discussion focused on worst case scenarios.

Patient age was explored regarding clinical procedures that pose challenges in this context. Infant patients were typically viewed as "a challenge" (P7) due to "little, tiny veins and so we're using really small needles." (P7). Another reason for difficulty working with infants was that "their whole airways are different than an adult. It's not actually harder to intubate them, but it's

different and you just feel like-- I mean you have to be much gentler.” (P7) Participant responses gave the impression that infant patient cases also induced psychological effects when administering patient care “Anxiety level is a lot higher with-- the smaller, they are anxiety level is usually a lot higher especially for [those in] bad shape if they are crying and looking at you moving around ” (P7). This may be because “they're kids and -you know-- it's more emotional.” (P2). One of the participants explained this in detail.

P4: I think that the majority of providers would tell you that working with a child is more difficult than working with an adult purely, by the fact that with the frequency with which we see them, and surprisingly and maybe it's because I'm not a parent --but surprisingly to me how many people don't call an ambulance for a truly sick children and instead they just pick them up, throw them in the car, take them to hospital. So-- if we --when we do see kids they tend to either be not sick at all and the parents are just overreacting or they're very, very sick so I think that just the infrequency with which we contact -- have that population-- contact with that patient population.. I think most people would tell you that it's more difficult.”

In stark contrast, a single participant argued, “babies are actually a lot easier to manage because they are smaller and we [paramedics] have a special mobilization of device that make them a little bit easier to manage.” (P5).

Obese patients were also identified to be a challenging patient type within the ambulance context. As with the discussion regarding infants, locating the veins of these patients was suggested to be a challenge. “Probably worse than anything. Because they can be very difficult to find main zone on and you know just locating landmarks everything.” (P7)

We also probed the relationship of patient scenarios and sense of urgency in order to identify those which increase immediacy for care that could be incorporated into simulation scripts. “The two biggest for that would be trauma and stroke--stroke is the number one thing where speed/ time is of the essence. Trauma is the close second and cardiac is the third.” (P4). Participants explained this saying,

“There is nothing that we [paramedics] can do for a stroke in pre-hospital besides get them to the hospital quickly. Trauma. There's an emerging research that says the things that we do in the ambulance if we waste time doing them actually have potential for worse patient outcomes. So it's better for us just to go faster and then with cardiac we do have some medications and things that we can give that actually help improve patient outcomes so that's slightly less time sensitive but it is also still very time sensitive because ultimately the intervention is going to be with the cardiologist.” (P4).

We also probed how the conditions that patients presented with cause stress or difficulty in the ambulance context. Participants who presented with multiple conditions were noted to be difficult because it can be challenging to decide the appropriate care plan. “I wasn't sure exactly what path I was chasing.” (P2) Participant 2 described a case to illustrate the challenges of those with multiple conditions “There was a lady that her S.P.O. was down to sixty she was on opiates, she was having seizures, and she was a diabetic” (P2). Another theme that emerged during this line of questioning was patients that presented with severe trauma; “The more serious the patient is, the more life threatening the more difficult. It is period” (P1).

But it was not just their characteristics (age, BMI) or their health status (multiple conditions) that amped the stress regarding their cases, but also patient behavior. Paramedics consistently mentioned unmanageable patients as contributing to the difficulties in prehospital contexts. Descriptions from participants included phrases such as, “Combative patients” (P5), “Unruly patients” (P1) and “Drunk patient” (P4) to describe their most difficult scenarios. Combative patients are challenging because “it's hard to manage them and to secure them properly so that they can't injure themselves or us”, and also unruly patients “move around a lot.” (P5).

5.3.4 Packaging Design

Another section of the interview explored packaging designs, specifically the design cues (signifiers), that tend to lead to difficulties associated with identifying, opening, and using needed products.

5.3.4.1 Good Package Design

The following section groups the themes related to paramedic's considerations for well-designed packaging; that said, it is important to remember that user preference does not always align with enhanced usability, or functionality of the system (2018 International Organization for Standardization [ISO], 2018; Perez, 2018) or better patient outcomes. Where applicable, reporting includes specific products referenced during the course of discussion.

- Identification

When it comes to identifying products within the ambulance, participants mentioned “color-coded” (P2) schemes could be used to differentiate products in the trauma bag (see Figure 39). Generally speaking, participants indicated that they found it hard to identify critical information (e.g. sizes and expiration dates (P2 and P7), and brand (P7)) without removing substantial amounts of product from the bag for closer examination. To find them quickly and easily, they suggested using color-coding schemes. Consider, for instance, IV catheters. As one participant put it, “IV catheters which are color-coded, they are just perfect” (P2). Another participant described this in more details that

“I like the fact that our packaging thing. All of our catheters, they're all color coded and it's easier to see colors than numbers. So, I know that if I can find a pink catheter, that's a twenty and that is what I'm looking for. I know the green is the eighteen and I know the blue is the twenty or twenty-two. So, I like the color

coding because you can just really quick look at the back of the box and pick one out and you know what it is” (P7).

Participants also preferred packaging with “large text” (P7) because “it’s easier to identify, for example, in low light conditions” (P4).

- Opening

When discussing preferences related to opening features, participants tended to mention chevron pouches. Specifically, they regarded the chevron as having an easy-to-find opening because “it doesn’t matter which corner I grab” (P4) indicating that they “don’t have to find a corner” (P4) (on chevron pouches). They explicitly mentioned the packaging for endotracheal tubes (frequently packaged in Tyvek with a poly side that has opening features at either end- See Figure 43) as preferable for opening. “This is fast as if you kind of grab the packaging and open it.” (P7) This flexibility in approach to opening (either end) was particularly helpful due to the time-sensitive nature of their work setting (P4 and P5). Recommendations for improvement included tabs that are a “little longer” (P4) indicating “bigger fingers make the smaller tabs more difficult.” (P2). They also specifically mentioned zip lock baggies as a preferred option for packaging because “you peel them open. That’s it.” (P1).



Figure 43. An example photo of Endotracheal tube

- Using

When discussions focused on packaging dispensing and product use, ‘ready-to-go’ types of packaging emerged from discussion. “Anything that is-- that you can open and [is] ready to use, I think, it is hands down with the best option--- just for speed” (P1). He continued stating that, “I envision a perfect world would be you open at once-- it's already done for you and now you're ready to start an IV” (P1). Later in the interview participant 1 reiterated this notion, “there's just more steps involved [establishing an IV] and if you can look [to] decrease those steps and [get] the timing shorter then you're just more efficient-- use of your time.” (P1)

Examples that participants provided with regard to ‘Ready-to-go’ types of products were ‘filter needles’, ‘pre-filled syringes’ and ‘carpuject style² (See Figure 44)’. All of these represent products which, by design, reduce step(s) so that they can be administered quickly. Participants generally explained the benefit as gaining time. “So, I don't have to get a syringe and then find a needle.” (P7) “Ones that are pre-loaded in a syringe so just got [to] take the cap off and then you could administer.” (P3) Also, these are preferred because “the general size needle works, you know, probably seventy-five percent of time.” (P7).

P8: “the prefilled syringes [are] easy [and] fast as I don't have to draw the medication out of vial, you know to, administer it.”

P4: “carpuject style that would be a far faster route for administration.”

P7: “Filter needle -- I don't even know if there are any cases that you don't need filter needles”

² A drug syringe holder that have a reusable channel to hold a drug syringe

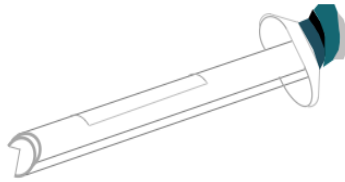


Figure 44. An exemplary image of carpuject -Syringe holder

5.3.4.2 Poor Package Design

Thoughts expressed by paramedic participants did not just center on what worked well, but also problems that they had encountered with packaging and how they solved them (coping strategies). As with the previous section, responses were categorized into tasks (identifying, opening, and using).

- Identification

Emergent patterns when discussing problems related to difficulties with the task of identifying products primarily focused on similar packaging. Products that were intended for infants and pediatric patients and those for adults were discussed as being easily confused. Paramedics illustrated this point by referencing specific products; “small OPA [oropharyngeal airway], NPA [nasopharyngeal airway] and ET [endotracheal] [products]-- those packages are roughly the same size as the adult packaging.” (P4). Similarity of package was an ongoing theme among the problems “the things that are most frequently opened unintentionally are four by fours and five by nines just due to the similarity of the packaging” (P4).

Given the literature regarding medical errors and confusion resulting from similar packaging and labeling for drug products (Berman, 2004), we were not surprised to hear the paramedics discuss labeling as a concern related to problems with identification. Small fonts are problematic, especially because “medications are in tiny, little vials” (P7) so that “the font [size] is like four or three and eight” (P7). Paramedics also discussed their own frailties as playing a

role in this difficulty; “as we [paramedics] get older, I need reading glasses” (P3). They also mentioned conditions within the setting as playing a role in these difficulties, namely lighting conditions. “using my glasses and I'm trying to find the light just to see what that says.” (P7). One potential design strategy previously discussed is larger font because “it's easier to identify, for example, in low light conditions” (P4). Consistent with the findings of others studying usability in medical device packaging for perioperative setting (J. Cai, 2012) which found “non-critical information gets in the way making it harder to find the wanted information” (J. Cai, 2012), paramedics suggested that extraneous information on the packaging interfered with their ability to find critical information.

Indicative of the finding that packaging does not consider the context related to the ambulance, specifically that designers don't give credence to the areas where products are stored within the ambulance, participants suggested that labeling is not explicitly designed for the storage areas (i.e. jump bag). Specifically mentioned were E.T. tubes. “We [paramedics] have our E.T. tubes and we have them in a bag--. we only can see the top of the packaging.” (P7). As such, they reported frequently coping with this shortcoming by writing on the top of the packaging, the exposed area when the items were stored in the jump bag. They indicated that they wrote “The actual size of it on each of them so that you're not having to pull it out and try to figure out where does it say how big this thing is.” (P7). A single participant expressed “the position of the labeling is important.” (P7) “E.T. tubes are in one orientation and it doesn't help to have any label down the package if it was all up at the top that would be great.” (P7).

Not being able to easily identify the opening features associated with packaging in order to determine where and how a package should be opened emerged as a theme as well. One

product mentioned specifically in this regard was syringe packaging. “They're all parallel there's no obvious corner or something like that--- sometimes that is hard.” (P7).

Explicit pieces of information that were indicated as resulting in difficulty were ‘size, expiration date (P2 and P7), and the brand (P7); this is very kindred to the findings of Cai (J. Cai, 2012), whose focus group participants (perioperative personnel focused on medical device labeling) found four pieces of critical information (product name, expiration dating, sterility status and latex status) to be difficult to identify for a variety of reasons. Participant 2 provided some indication of what made these pieces of information difficult to locate and read. “The [information about product size and expiration date are the] same size as the rest of the text” he also indicated “the sizes [are] on different spots and it's often small.” (P2).

- Opening

One of the sections probed participants’ experiences and opinions related to different packaging and the process of opening the same. Paramedics reported that when aspirin is packaged in a blister pack, it can be difficult to access and dispense because of the need to individually “push it through and then you [paramedics] catch it with your other hand.” (P2). Four pills require four distinct openings. Corner-peel packages were noted to be problematic because “the size of the full tab is too small” (P8) and “there was no peel thing where it's supposed to be” (P1).

Not only were opening features indicated as being difficult to locate, they were also reported to be (at times) challenging to use.

- Notch

Notches, were reported to be problematic; “the notch doesn't really work.” (P7). Related to our previous topics, some participants reported that when they had difficulty with notches, they would utilize their trauma shears. “That's where the trauma shear coming handy-- right for IV bags” (P7).

- IV tubing

One particular item that was discussed when probing difficulties with package opening were IV tubes. IV tubing, which contains a long perforation along the length of the package, was also mentioned as problematic “the back edge is intended to be opened from the top of a tear open, [however, it] seldom tears easily there. Actually, it's easier to rip it from the side.” (P4). Other difficulties that paramedics conveyed regarding the IV tubing emphasized the capped end of the tubing; specifically, that the IV tubing often falls on the ground after the other end of it is connected to the IV solution. One participant specifically called out the removal methods for the cap to be less than ideal, “but you'd be amazed at the number of people who open that with their mouth.” (P4).

- Using

As mentioned in the section covering well-designed packaging, products with fewer steps are preferred by paramedics. During the course of discussing use, procedures which required multiple steps were a consistent theme resulting in consternation. Consider, for instance, airway care. Participant 1 explained how multiple steps and products sometimes encumbered care. “Airway stuff, especially intubation. There's five or six different things that we have to unpackage and fit together before we can do a thing [intubation].” (P1). Others suggested that parenteral drugs imposed similar obstacles. When administering medication via syringe, an

ampule needs to be broken first and then needle applied to the syringe in order to draw medication from the ampoule into the syringe.

Other ideas that came up during the discussion of the relationship of packaging to use and administration of products was that the placement of items inside the package can pose a challenge. IV tubing was, again, provided as an example of this; “once you're in the package, you have to find the two ends of it [IV tubing] and then you have to get them so they're not entangled like a garden hose and all knotted up.” (P6).



Figure 45. Tridil package and its seal.

Medication packaged in tridil³ seals were presented as causing difficulty with drug administration; “Some of vials that we use are difficult because we have to break them or we have to draw a medication with the tridil seal (See Figure 45).” (P6). Paramedics also attributed difficulties associated with this packaging to be caused by the time required to fully complete the necessary steps for proper administration of the medication. “[tridil seals] isn't necessarily bad but seizures frequently are time sensitive.” (P5).

There was also discussion about how, contextual factors (many of which have already been discussed) conspired to impair their ability to open packages. “That [wet or bloody hands] would make it [opening package] difficult --slippery” (P2). Sometimes when it is rainy outside, , gloves become wet, so “opening those [tiny medication] packages can be difficult.” (P2).

³ Nitroglycerin Injection’ that use for reducing a chest pain.

Concerns regarding the sterility of the product were also discussed in light of the sometimes-urgent need for care. In fact, one participant suggested this as one of the hardest challenges that they faced.

P1: “Being sterile is what is probably the most difficult because equipment wants us to be sterile as possibly because that equipment is sterile which is why it's mainly--sealed anyways. So, when he is talking about airway, trying to maintain that sterility is probably the most difficult thing. And then when you add multiple things that you have to open and you're trying to keep things sterile, that's why I would keep going back to in a perfect world, if you had one opened, and the equipment that you are going to use is all right there, that's easier and more efficient .”

Pressures mount when the call is serious, participants made statements like, “you add in like a serious call” (P1) this is “more stressful” (P1) “it just seems like little things like that [opening a prefilled syringe package], you know, can sometimes be more difficult ” (P1).

5.4 Discussion and conclusions

A series of semi-structured interviews provided insights into paramedics' thoughts and experiences regarding how: context (e.g. physical areas, ambient factors (lighting and noise), patient conditions and behaviors, vibrational inputs, and packaging designs influence providers' ability to identify, open, and use products). Generally, their setting is limited but flowing, meaning that there are multiple tasks to be completed (e.g. inform the hospital, administer patient care). Where necessary, they adapt to the particulars of the context using coping strategies, in order to deliver patient care as quickly and effectively as possible. As such, they prefer having packages that reduce steps (such as prefilled syringes and IV start kits) to the packaged products that require multiple steps.

Insights garnered which informed the creation of the simulation and simulator for the formative, usability study (Specific Aim 4) included the following.

1. The ambulance simulator was created to be dimensionally accurate, reflecting the three seating areas available to conduct work and the space limitations discussed. Seatbelts should be available but not mandated. Grip bars, a cot with handle for gripping and dimensioned storage cabinets should be available.
2. Simulations should have noise levels that potentially create difficulty regarding two way communication (road sounds and rattling of the ambulance).
3. The ambulance simulator should be driven by a vibration profile that incorporates bumpy road/dirt roads, and potholes and vibrations/motions that are typical in quick stops/starts.
4. Each patient simulation scenarios should contain multiple indications with implication for varied systems within the body (per a simulation), and comprise urgent care.

5. Patient demographics should include those that induce the most stress and difficulty (either infants or obesity).
6. Worst-case scenario (multiple symptoms, severe trauma- to the right side- where space is limited, which requires changes of position in seating and incorporates packaging with features that were indicated as problematic), utilizing scenarios that require problematic products for primary care (IVs) and airway care (ET tube).

Chapter 6. Collection of Vibration Data

As mentioned previously, our survey data (Chapter 4 Specific Aim 1) suggested that motion in the ambulance contributed to the difficulty administering medication packaging experienced by EMS personnel. This was also reinforced by the results of the guided interviews (Specific Aim 2). As such, shock and vibration profiles on varied road surfaces were collected with two ambulances. Collected vibration data was reviewed in light of the existing literature and ISO standard regarding Whole Body Vibration (WBV) and human performance (see literature review) in an attempt to identify conditions/portions of the collected spectra that were likely to be problematic with regard to the tasks (identifying, opening, and using) associated with package design. The refined profile was then used to drive the motion vibration table while paramedics performed healthcare simulations (Specific Aim 3) for the purpose of evaluating the performance of packaging designs.

6.1 Ambulance

In order to begin to build a profile that could be used to simulate the movement of the ambulance using a vibration table, vibration data was collected using two ambulances outfitted with a Cut-way van chassis ambulance body, type III: one owned by Lansing Community College (LCC Lansing, MI; Figure 46) and a second owned by Delaware County Ohio (Figure 47). Each was capable of delivering the ALS services that were proposed as necessary for use in the healthcare simulations. The LCC ambulance was used to collect data throughout the mid-Michigan area on publicly available roadways adhering to all legalities regarding the operation of the vehicle.



Figure 46. Type III ambulance owned by Lansing Community College



Figure 47. Type III ambulance owned by Delaware County in Ohio

As with the mid-Michigan ambulance, the second ambulance (Delaware County, OH) collected vibration data in and around the Greater Columbus Area, but additionally, was driven over varied road surfaces comprising a closed test track operated by the Transportation Research Center (TRC; East Liberty, OH). The addition of the test track allowed for the collection of extreme road (and driving) conditions (See Figure 48 and Figure 49 for Google earth road mapping).

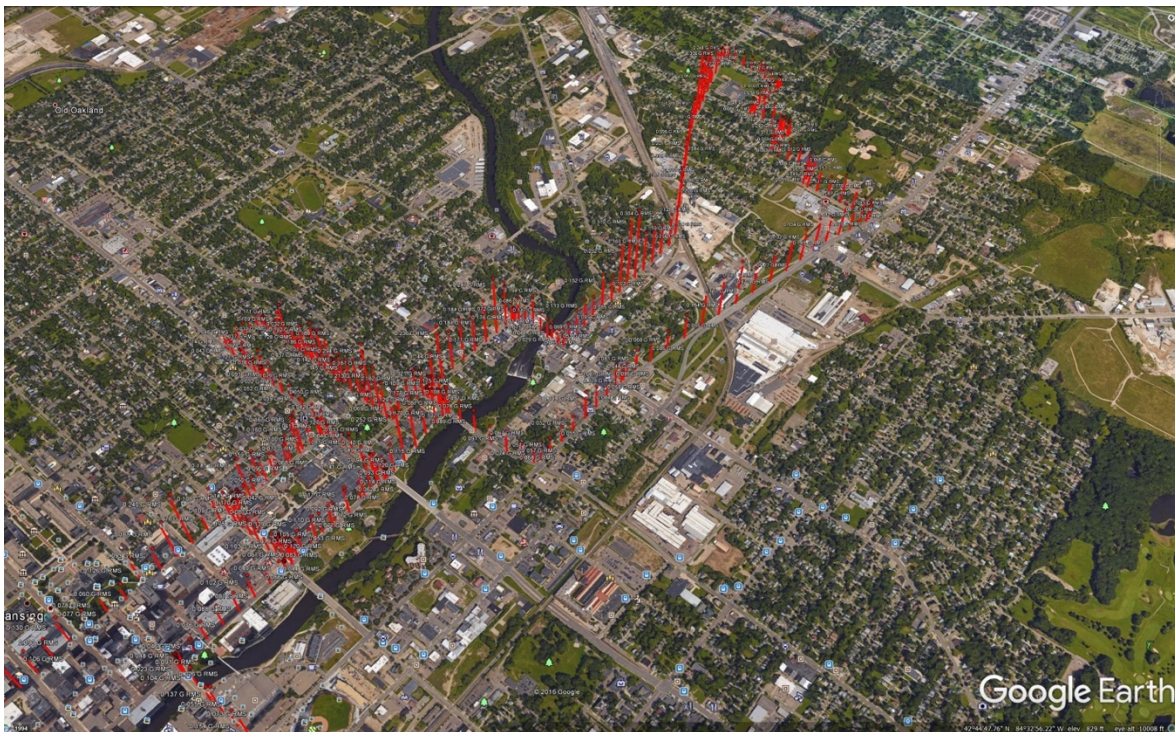
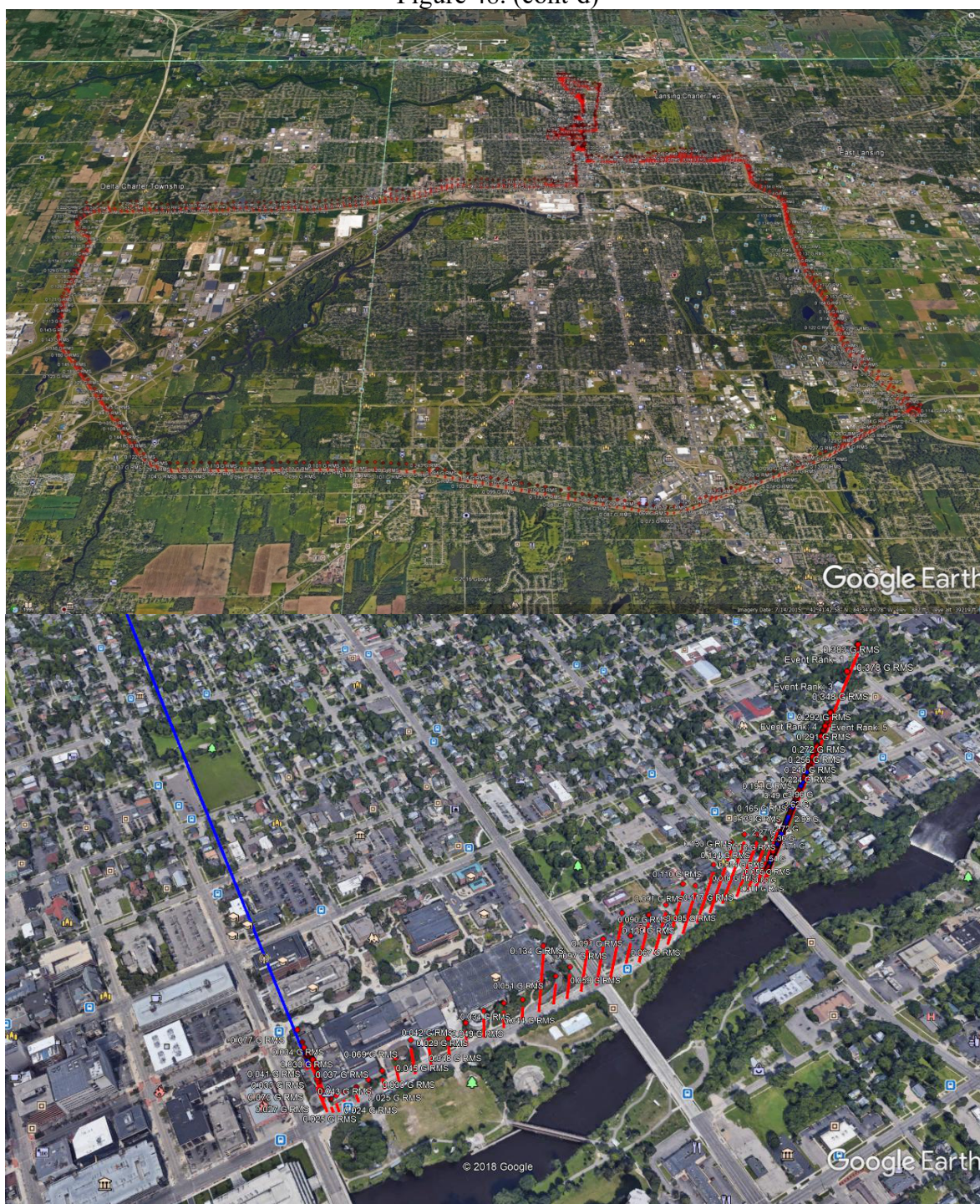
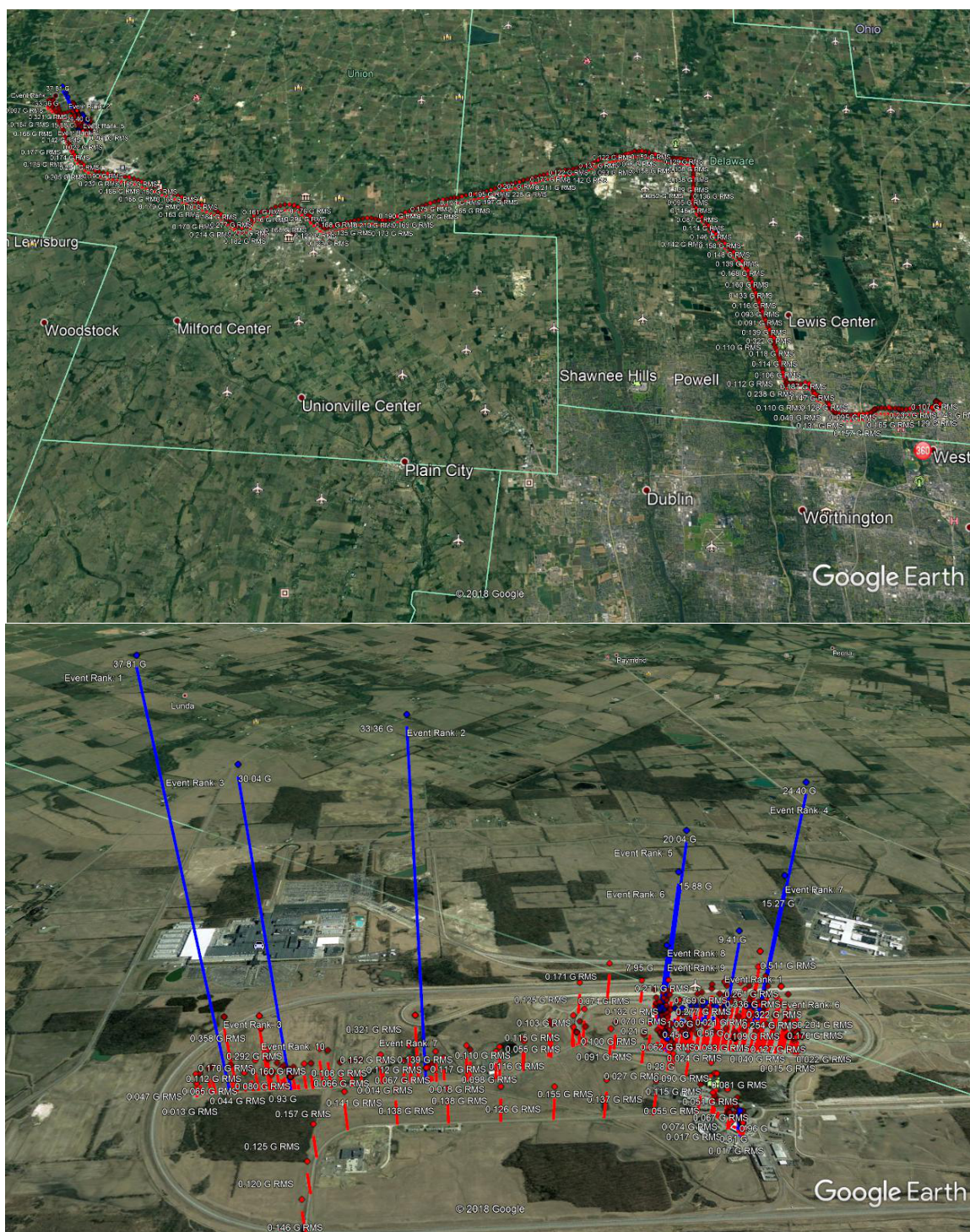


Figure 48. 'Google earth' map running through the mid-Michigan area

Figure 48. (cont'd)





6.2 Accelerometer

An acceleration data recorder, a Saver 9X30 (Lansmont; Monterey, CA), with 9 dynamic channels (an internal tri-axial accelerometer plus 6 external accelerometer inputs), was mounted to the floor of the ambulances to collect shock and vibration data transmitted into each vehicle (See Figure 50 for precise positioning).



Figure 50. Location of tri-axial accelerometers and Saver on the floor of an ambulance.

6.3 Gopros

A series of four Gopro Hero 3s (San Mateo, CA) (See Figure 51) were mounted inside and outside the ambulances to record movement in addition to a Hitcar GPS (Guang Dong, China) to provide a record of GPS tracking information for all ambulance routes (See Figure 50). The locations of the Gopros inside of the ambulance were placed with the intention of capturing the entire space within the ambulance box and some of the road conditions as well.

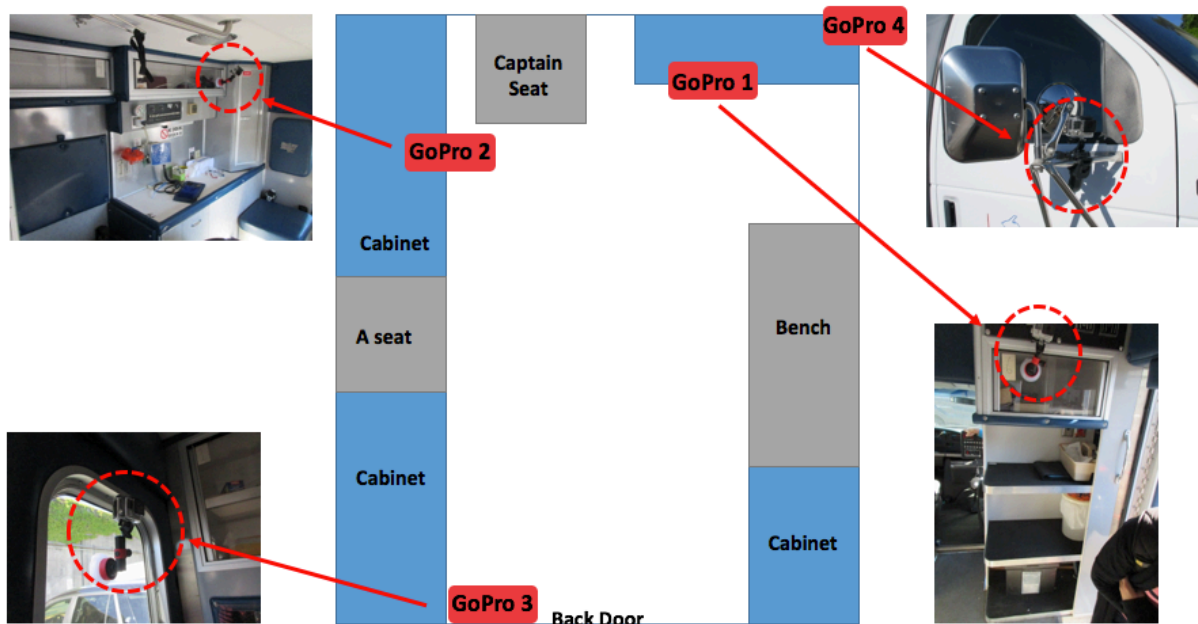


Figure 51. Locations of GoPros mounted inside and outside of ambulances

6.4 Vibration profiles

Vibration data collection, taken from the TRC Test Track (described in Table 49) and local roads (Ohio and Michigan, see Figure 48 and Figure 49) using the aforementioned configuration within the ambulance, were compared with the literature to identify portions of vibration spectra that were most likely to impact human performance (see section 2.2.2 for details) . This was synthesized with available “worst case” simulation data provided by Adient for vehicles experiencing extreme road conditions into a simulated spectrum which was used to run a vibration table capable of movement with six degrees of freedom (Adient Technologies; Plymouth, MI).

Table 49. Road types and descriptions with pictures

Road type		Description
1	7.5-Mile Test Track	Total 7.507 mi to 7.539 mi, depending on lanes, asphalt lanes with different slopes (10° with 80 mph, 19° with 110 80 mph). The maximum speed is up to 140mph

Table 49. (cont'd)		
2	Bus & Truck Durability Course	Comprised of staggered bumps, sine waves, chuckholes, chatter bumps significantly and a high crown intersection. (See note for details)
3	Cobblestone Durability Course	1,320-foot (402.3 km) long roadway with a cobble protrusion.
4	Paved and Gravel Hilly Road Courses	8 miles (12.8 km) long roadway including a 1,000-foot (304.8 m), 10 percent asphalt slope, various stone slopes, a 23 percent asphalt slope, a 1.5-mile (2.4 km) gravel road, two level cross-country courses and an off-road course.
5	Profile Roads – VDA	Various types of realistic road condition such as Tire Slap, Unsprung Mass Vibration, Long Curb, Water Drain, Speed Bumps, Road Joint, Undulation Road, Positive and Negative Shocks, Stability Road, Belgian Block Roads, Chip and Seal Roads, Concrete Choppy Road, Concrete Downhill Wavy, Concrete European Union Road and a High-speed Railroad Crossing.
6	Vehicle Dynamics Area	Asphalt pad for any kind of vehicle dynamic test

6.5 Vibration Table

A man-rated vibration table with six degrees of freedom (6DOF), capable of replicating real-world vibration conditions via six actuators attached to the table (3 vertical, 2 fore-aft and 1 lateral hydraulic cylinder) was utilized to replicate vehicle motion. 6DOF refers to being able to move in the linear x-y-z axes and have rotational movement around these axes, all simultaneously. The table stroke is +/-250mm, and it can replicate vibration in the range of 2-50Hz. Time on a 6DOF vibration table with a large enough footprint to accommodate the simulated ambulance box was contracted from Adient Technologies (Plymouth, MI) - See Figure 52.



Figure 52. Six degrees of freedom (6DOF) vibration table at Adient Technologies (Plymouth, MI)

6.6 A criterion of data assortment

Data was sorted and selected by a criterion based on ISO 2631-1 (1997 International Organization for Standardization [ISO], 1997) – See details in literature review (section 2.2.2). According to this standard, human performance is adversely impacted when the vibration amplitude is at least 2.0 m/s^2 . To find the data that were equal or more than 2.0 m/s^2 , SaverXware software (Lansmont; Monterey, CA) was used to provide a Power Spectral Density (PSD) analysis of the distribution of vibration energy across the frequency spectrum of interest. The collected data was initially in an unprocessed, or “raw”, format identified by an SXd file extension. SaverXware processes the SXd file into a series of data points spaced across time, and then converts this information to PSD plots, saving the resulting file with an SXe extension (See Figure 53).

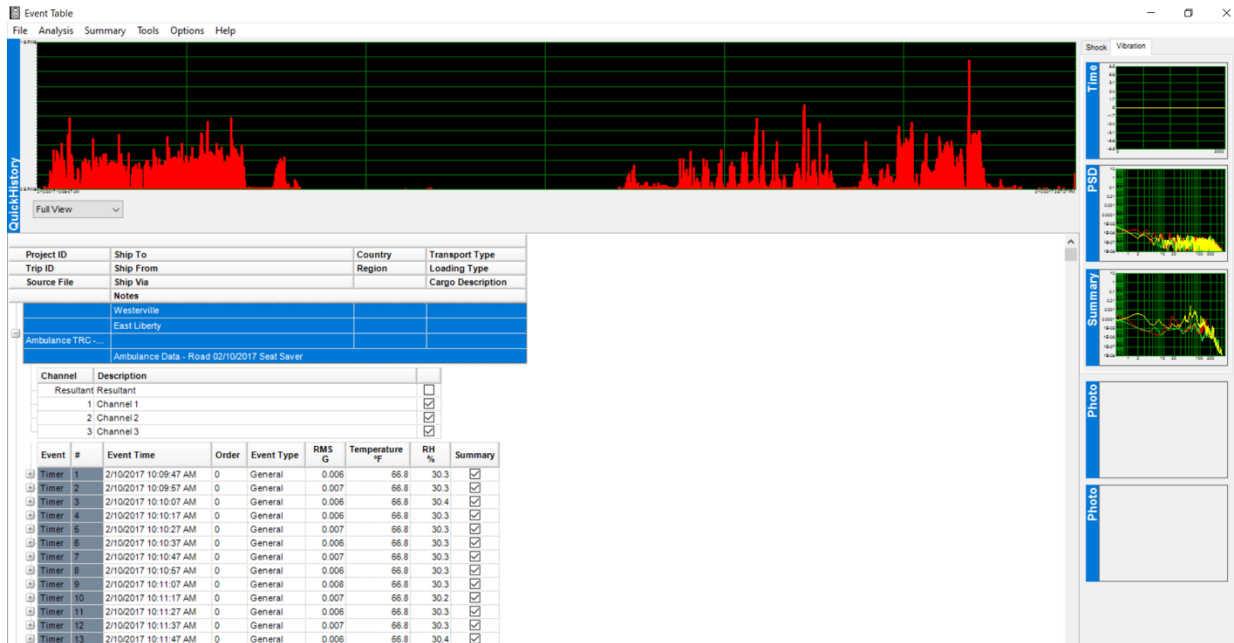


Figure 53. A snapshot of SaverXware when data is successfully processed and opened

To obtain data meeting criterion that was above the identified threshold where difficulty was noted (2.0 m/s²), units were first converted into Grms (the units used by the SaverXware).

$$2.0 * \frac{m}{s^2} / 9.8 = 0.2 \text{ Grms}$$

Then, data events were selected by SaverXware. To do this, after selecting one of the events from the data opened on SaverXware, the criterion of data, 0.2 Grms can be set from 'Summary Selector' from the 'Summary' menu under the menu bar (See Figure 54). As a result, seven data files were processed, resulting in a total of 1,373 events (a totla 151 minutes and 43 seconds of data -See Table 50).

Summary Selection X

Event Master

LCC_Ambulance_06062017.SXd / Ship To: Westerville
LCC_Ambulance_3X_06062017.SXd / Ship To: Westerville
LCC_Ambulance_3X_06062017.SXd / Ship To: Westerville

☒ Signal Triggered Events
☒ Timer Triggered Events

Select v

Level Event Time Impact Type Event Type Speed

Greater than or Equal to Add

Value

☒ Acceleration 0.00 G
☐ Delta V
☐ Grms
☐ Drop Height
☐ Temperature
☐ RH

Clear Criteria Run

Select All DeSelect All Close

Figure 54. Summary Selection menu

Table 50. Outcomes from data processed with criteria.

	File name	Starting Time	Ending Time	Event s > 0.20 Grms	Time interval (s)	Total time of interest (s)
Lansing 1st	MSU Ambulance Data 08-08-16.Sxe	8/8/2016 10:15	8/8/2016 11:08	34 events	4 seconds	136
TRC/Delaware	Ambulance TRC - 6DOF_02102017.SXd	2/10/2017 10:08	2/10/2017 14:48	73 events	10 seconds	730
	Ambulance TRC - 9X Rear_02102017.SXd	2/10/2017 10:10	2/10/2017 15:34	28 events	10 seconds	280
	Ambulance TRC - Chair_02102017.SXd	2/10/2017 10:09	2/10/2017 15:57	91 events	10 seconds	910
	Ambulance TRC_02102017.SXe	2/10/2017 10:08	2/10/2017 14:48	587 events	10 seconds	5870

Table 50. (cont'd)

Lansing 2nd	LCC_Ambulance_06062017.SX d	6/6/2017 9:57	6/6/2017 11:36	280 Events	2 seconds	580
	LCC_Ambulance_06062017.SX e	6/6/2017 9:57	6/6/2017 11:36	280 Events	2 seconds	580

Additional data was analyzed for potential selection with the intention of replicating sudden stops and starts, along with bumpy roads. Recall that these types of events were identified in the guided interviews (Specific Aim 2) as causing difficulty when administering patient care. This data was subjected to the same assortment process that was used for previous data, see Table 51.

Table 51. The semi- final data set extracted from the collected data

Location where data collected	Road type	Speed (mile/h)	File Name	Duration (seconds)	Notes
Delaware in Ohio	Highway	Avg. 64	Ohio - Highway 1.txt	20	1
	Highway	Avg. 67	Ohio - Highway 2.txt	30	1, 3
	Highway	Avg. 65	Ohio - Highway 3.txt	30	1, 3
	Highway	Avg. 68	Ohio - Highway 4.txt	28	1,2
TRC		0->11->7	TRC - Shock 1.txt	24	1,4
	VDA flat	Avg.6	TRC - Shock 2.txt	24	1,4
		0->23-	TRC - Shock 3.txt	24	1,4
		Avg.45	TRC - Shock 4.txt	28	1, 2, 6
		Avg.45	TRC - Shock 5.txt	24	1, 4, 6
		Avg.25	TRC - Shock 6.txt	24	1, 4, 6
	Turtle back	Avg.23	TRC - Shock 7.txt	30	1, 5, 6
1st Lansing	Highway	35	LCC 1 - Highway 1.txt	32	
3rd Lansing	1st quick stop		LCC 3 - 1st Quick Stop.txt	25	
	2nd quick stop		LCC 3 - 2nd Quick Stop.txt	15	
	Swirling		LCC 3 - Swirling.txt	22	
	Quick turns		LCC 3 - Quick Turns.txt	36	

Table 51. (cont'd)

Note 1. A Tukey windowing function with $\alpha = 0.05$ was used to combine shorter event segments into a base event file.
 Note 2. A base file was replicated twice to create this file.
 Note 3. A base file was replicated three times to create this file.
 Note 4. A base file was replicated four times to create this file.
 Note 5. A base file was replicated five times to create this file.
 Note 6. Filtered out by below 50 HZ

6.7 Window function

To avoid discontinuities when combining selected noncontiguous sections of vibration data from different road segments into a single contiguous control file for the vibration table, it was necessary to use a “window function” to ramp the ends of the individual data sections to zero amplitude. This allowed for smooth transition from one segment of road data to the next without inducing any unwanted table movement. Programming software ⁴created by Dr. Ricky Speck was used to conduct window functioning, resulting in data meeting required criterion (2.0 m/s² and higher and frequency range between 2-50 hz).

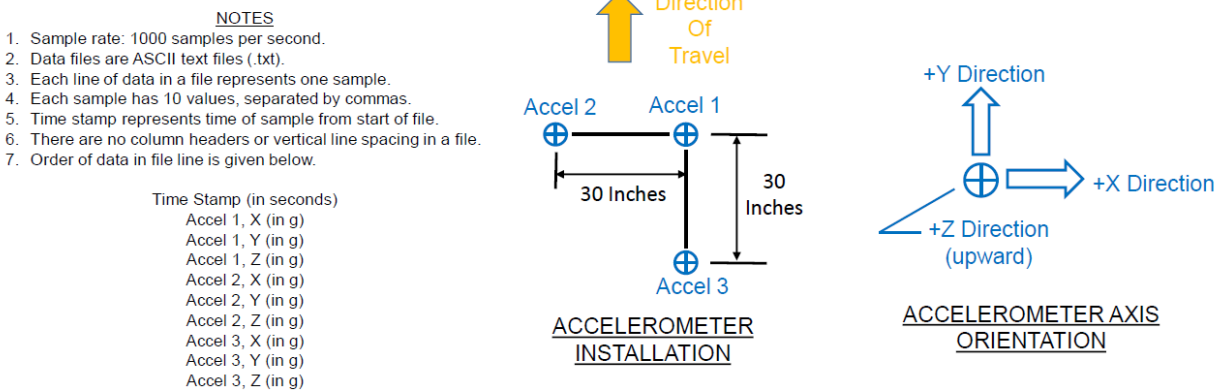


Figure 55. Test layout information regarding collection of vibration data (created by Dr. Ricky Speck) provided to Adient.

⁴ Copyrighted by Dr. Ricky Speck.

Accelerometers in a standard “L” shaped pattern were placed at predetermined distances from each other, as shown in Figure 55, to allow collection of 6DOF data for ambulance movement. The measurement of the distance from each accelerometer was collected as suggested and the direction of movement of the vehicle (ambulance) was recorded. Key parameters were sampling rate, data file formatting, and accelerometer positioning; these were provided to Adient to allow them to do an iterative adjustment process to ensure proper conversion for their table so that it accurately replicated the movement.

Table 52. The rated scale on data files and comments

Data files	Scale (1to 5)	Comments
TRC - Shock 1.txt	2	
TRC - Shock 2.txt	5	
TRC - Shock 3.txt	1	
TRC - Shock 4.txt	2	
TRC - Shock 5.txt	5	The worst vibration
TRC - Shock 6.txt	1	
TRC - Shock 7.txt	1	
LCC 1 - Highway 1.txt	3.5	
LCC 3 - 1st Quick Stop.txt	4	Did not simulate ‘quick stop/quick start’
LCC 3 - 2nd Quick Stop.txt	2	Had a lateral movement
LCC 3 - Quick Turns.txt	4	
LCC 3 - Swirling.txt	5	
Ohio - Highway 1.txt	2	
Ohio - Highway 2.txt	4.5	
Ohio - Highway 3.txt	5	Severe on the bench seat location
Ohio - Highway 4.txt	3	

Once the iteration process was complete and the vibration table able to replicate the road vibration accurately, each road segment replication was rated for severity in terms of a scale of 1 (less severe) to 5 (most severe), see Table 52. Only road segments with vibration rated 4 or higher were included in the final data set. To ensure that the data set include components meeting a “worst case” scenario of measured vibration, additional road vibration data provided by Adient were added to the final data set, resulting in the data set test configuration shown in Table 53.

Table 53. The final data that used for formative usability test

Data files
TRC - Shock 2.txt
TRC - Shock 5.txt
LCC 3 - 1st Quick Stop.txt
LCC 3 - Quick Turns.txt
LCC 3 - Swirling.txt
Ohio - Highway 2.txt
Ohio - Highway 3.txt
Adient data 1
Adient data 2

Chapter 7. A Formative Usability Test and Contamination Test

Utilizing findings from the literature review, the survey (Specific Aim 1)⁵, the collective case study (Specific Aim 2)⁶, and the review of the literature regarding whole body vibration⁷, both an adult simulation scenario and an infant simulation scenario were crafted to be used in the formative evaluation (Specific Aim 3). This testing was conducted in accordance with methods approved under IRB STUDY00000824.

Formative evaluation is defined as the

“Process of assessing, at one or more stages during the device development process, a user interface or user interactions with the user interface to identify the interface’s strengths and weaknesses and to identify potential use errors that would or could result in harm to the patient or user.” (Center for Devices and Radiological Health [CDRH], 2016) .

The vibration profile and patient simulation scripts were crafted with the intention of simulating realistic, but worst-case, scenarios in an attempt to replicate the unintended, problematic affordance behaviors indicated by the survey data (Specific Aim 1).

Using a ‘task analysis scheme’ (See details in next analysis section), the following was performed;

- Identify tasks (identifying and opening medications and medical supplies and use products) and the subtasks associated with each task
- Measure the time duration for each subtask, and task –(Efficiency measures)
- Evaluate the user satisfaction-(Satisfaction measures)

⁵ Reported difficulties with packaging; designs and scenarios that catalyzed them– Chapter 5

⁶ Information about the environmental context surrounding difficulties. Location of available supplies, available supplies storage and scenarios resulting in difficulties. – Chapter 7

⁷ Whole body vibration and the impact of vibration on human capability – Chapter 6

- Capture affordance behaviors (i.e. the interaction between users and products- both intended and unintended)
- Document the presence of use error (unintended behavior) and appropriate use (intended behavior) -Error measures (Effectiveness)

7.1 Materials

7.1.1 The ambulance simulator

7.1.1.1 Interior components and layout of the ambulance simulator

Descriptions from the literature related to Type III Advanced Life Support ambulances (ASL) guided the design and dimensions of our simulator. A Type III design was leveraged because simulation scenarios (See Appendix R) required advanced levels of care; additionally, the Type III is more compact than the Type I ambulance, a factor that has the potential to impact affordance behaviors (limited space for storage, movement, etc.). Based on findings from the case study, specific interior components were targeted as important for our simulator (See Table 54.).

Table 54. Required interior components for the simulator

Interior Components	Details	Reference	Other design considerations
Seating	A captain's seat, a bench seat, and a CPR seat	Outcomes of the guided interviews	Fixed to the simulator
Storage/cabinets	Four cabinets (or storage areas) to store extra endotracheal intubation tubes, intravenous tubes, IV start kits and other supplies	Outcomes of the guided interviews	Fixed to the simulator
Cot	A platform which represents a "stretcher", "cot," or "gurney" to hold the simulated patients which includes handles which paramedics indicated that they sometimes grip to steady themselves.	Outcomes of the guided interviews	Includes bar handles which enable participants to signal to the research team that they are ready to begin by locking the cot into place.
Overhead bars	At least one pair of overhead bars. The purpose of the bars is to allow paramedics to steady themselves when required to stand or adjust position while the table is in motion	Outcomes of the guided interviews	Surface scan-able (and cleanable) for analyte under the UV light

Table 54. (cont'd)

An Intravenous (IV) hanger	Need for hanging an IV solution.	Outcomes of the guided interviews	Fixed to the simulator
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Although the size of the compartment “shall be not less than 325 cubic feet” according to KKK-A-1822F (U.S. General Services Administration [USGSA], 2007), the size of the vibration table at Adient Technologies (10’ x 8’) constrained the creation of the simulator; the maximum size that could be accommodated was 10’ x 8’ X 6.8’ feet high (544 cubic feet). Based on Table 54, the necessary components of the simulator are depicted in Figure 56 with basic dimensions for the simulator and key components identified from the guided interviews.

Figure 57 represents the picture of the final ambulance simulator.

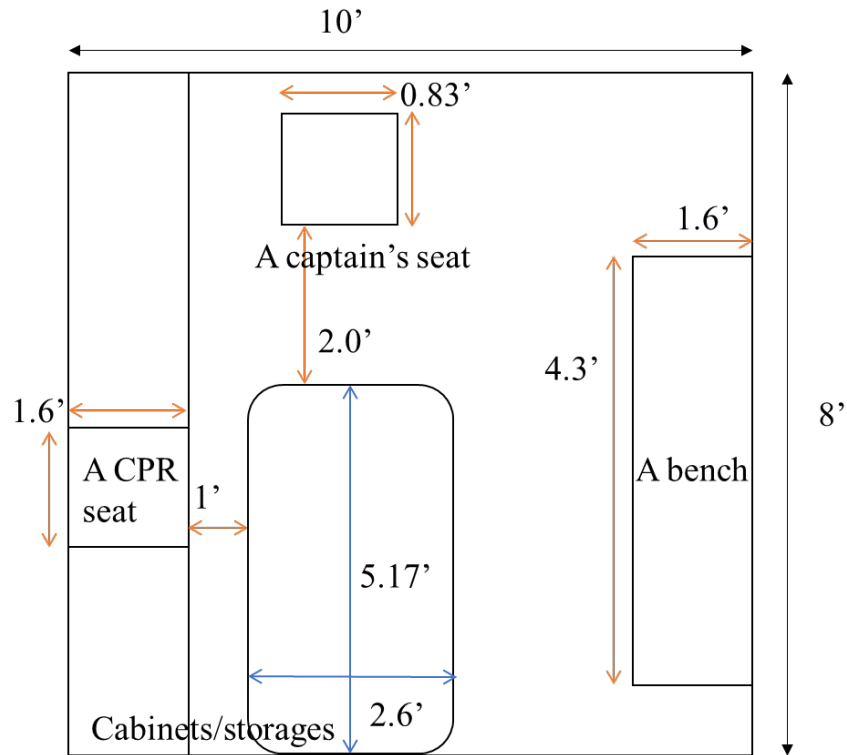


Figure 56. A layout with approximate dimensions of the simulator



Figure 57. The ambulance simulator mounted on the vibration table at Adient

Figure 57. (cont'd)



7.1.2. Vibration table and imposed safety measures

As discussed, in the previous chapter, we leveraged a vibration table capable of motion in 6 degrees of freedom to conduct formative usability testing which incorporated motion. Participant safety was enhanced through the presence of a series of manually-activated, mechanical E-stops which safely shut down the table (See Figure 59). These were located in multiple locations throughout the room (at the sides, at the control center, and one placed near the captain's seat within the simulator). Additional safety measures included accelerometers attached to the table capable of monitoring vibration throughout the test. Accelerometers are monitored and table software imposed limits so that if more than 2Gs of acceleration was recorded, the table would automatically shut down. Additionally, pressure sensors were located on the shaker table, monitoring the load on the table. These features were used in conjunction with a controller system which limits the flow of hydraulic oil to the servo-valves on the

cylinders – meaning that the cylinders can only apply so much acceleration to the table because the flow of oil is restricted. Collectively, these safety features comprise the ‘Human Rate Mode,’ and are applied anytime a person is present on the table for a vehicle simulation. A visible display on the control panel designates this mode (See Figure 58).

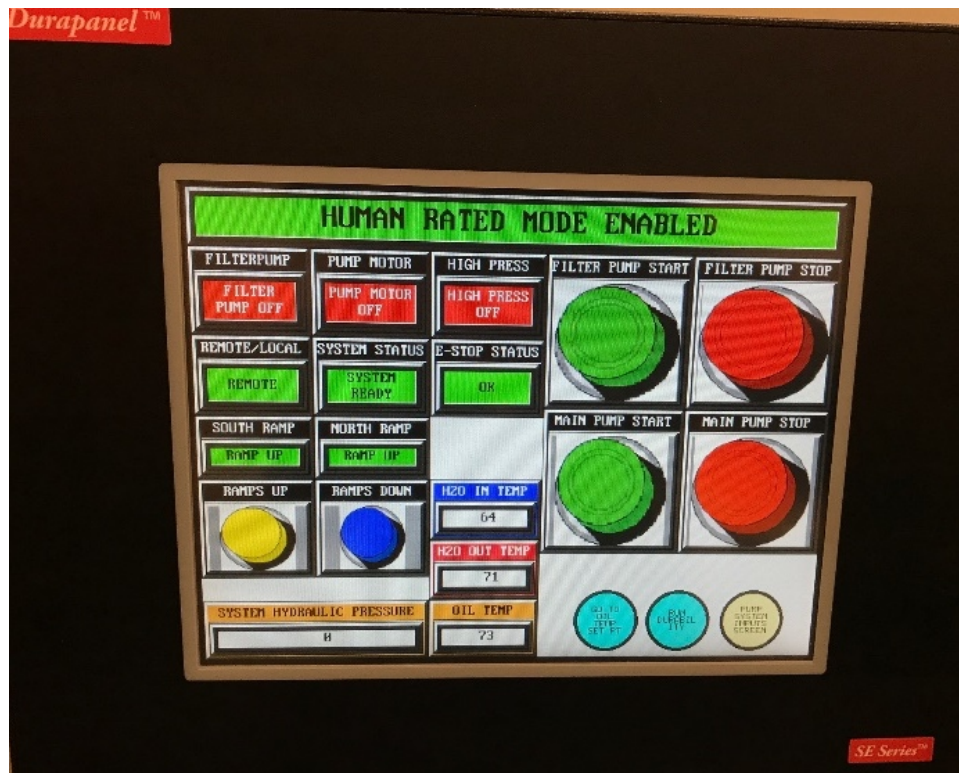


Figure 58. The screen of Human rated mode system



Figure 59. Mechanical E-stop nearby captain's seat

7.1.3 Medical devices

Products included in the simulations (and subsequently analyzed during formative usability testing) were ‘4 by 4 pads’, ‘gauze packaged in a transparent flexible plastic film (shortened to gauze (film))’ and ‘gauze packaged with form-fill seal type (shortened to ‘gauze (FFS))’, ‘IV tubing’, ‘IV solution’, ‘IV start kit’, ‘IV catheter’, ‘IV catheter with an extension’, and ‘ET tube’ (See Table 55 for manufacturer details). Products were chosen as they were necessary to care for the patients during the simulations that were built based upon the findings from the guided interviews (Specific Aim 2- Chapter 5); specifically, products intended to start IVs (IV start kit, IV tubing, IV solution, and IV catheter) and to intubate both patients (ET Tube; size 7 for adult simulation scenario and size 2.5 for infant simulation scenario). Additionally, ‘4 by 4 pads’ and ‘gauze’ were available to care for the simulated patient’s injured right arm during the adult simulation scenario. Two types of gauze (film and FFS) and IV catheters were supplied/stored in the jump bag for use at participants’ convenience and preference. (These products were introduced to them at the introductory phase of the experiment – See Figure 69).

Intended behaviors (for opening) were defined and are reported in Table 55. The opening features of the packaging associated with each product carry their own unique signifier(s) (where the opening action is intended to take place (Javier de la Fuente, Stephanie Gustafson, Colleen Twomey, & Laura Bix, 2015b)). For instance, a notch on the packaging of the IV solution signifies the initiation point for the appropriate action of ‘tearing’ to open; “arrow marks” signify the appropriate area to grip for several of the lidded trays that were utilized in the study. As such, behaviors characteristic of intended and unintended affordances was defined by the package itself where possible; for those that did not have these overt signifiers, we relied on experience and conventional practice to define intended affordance behaviors.

Table 55. Medical devices included in analysis, its opening features and intended openings

Product (s)	Picture(s) of products and packaging Type (J. Cai, 2012)-	Opening features of packages (within the red line) and intended opening path (Blue arrow)	Description of intended opening
Gauze (film) (LINE2design; Mentone, CA)	 Flexible pouch	 Either the top or the bottom of package.	Grip either the top or the bottom package and tear open.
Gauze (FFS) (LINE2design; Mentone, CA)	 Lidded flexible trays	 Form-fill seal type; Grip space is located on the top of the package.	Grip at the top where materials can be separated (see red box in the opening feature column)

Table 55. (cont'd)

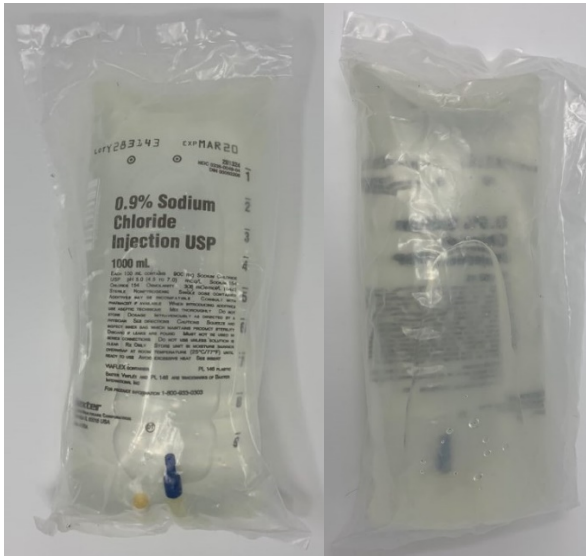
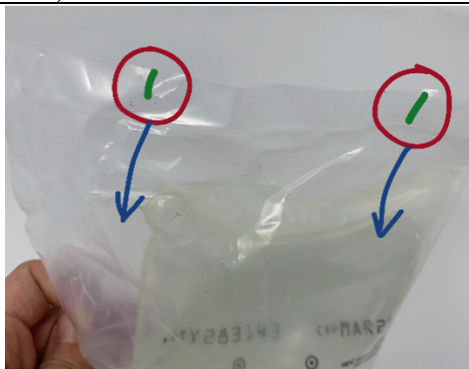
IV solution (Baxter-0.9% Sodium chloride injection usp 1000ml; Deerfield, IL)	 Flexible pouch	 A notch (green colored line) on the top	Open from the top beginning with the notch
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Table 55. (cont'd)

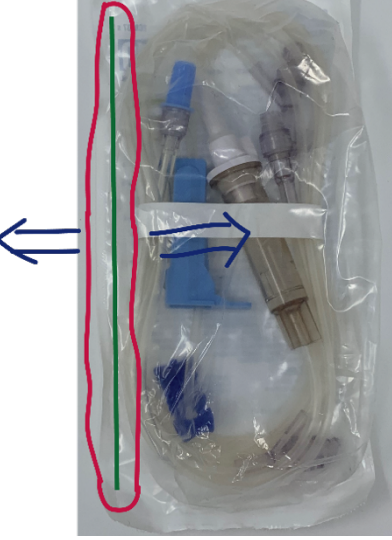
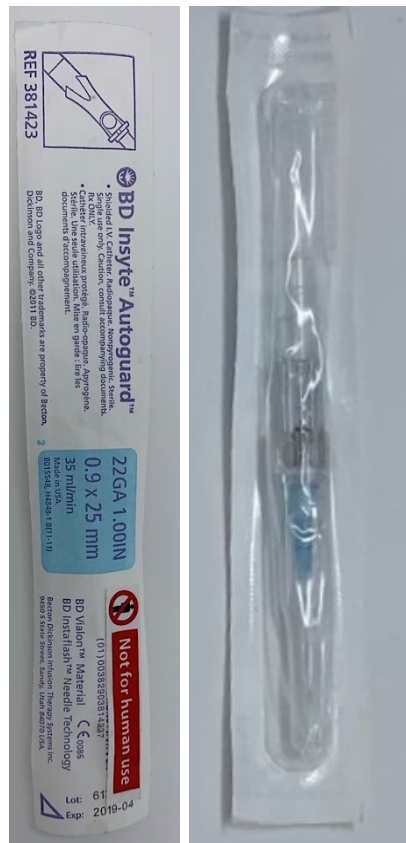
IV tubing (Baxter- Continu-Flo solution set; Deerfield, IL)	 Flexible trays	 Perforated line (green colored line) on the side of IV tubing	Create a breach utilizing the perforated line to open
--	--	--	--

Table 55. (cont'd)

IV Catheter
(BD-22GA 1 in
(0.9*25mm,
Instyte
Autoguard);
Sandy, Utah)



Lidded flexible trays



Form-fill seal type; Grip space is located on the top of the package.

Grip at the top where materials can be separated (see red box in the picture of the left column)

Table 55. (cont'd)

IV Catheter with an extension (BD-22GA 1 in Cathether (0.9*25mm, Nexiva) ; Sandy, Utah)	 The image shows the packaging and a lidded rigid tray for the BD Nexiva 22GA 1.00IN 0.9 x 25mm IV Catheter. The packaging is white with blue and red text. It includes the BD Nexiva logo, the product name, and various specifications. A red arrow points to the bottom left corner of the lid, which has a blue triangle and the text "Not for human use". The lidded rigid tray is blue and contains the catheter and its extension. Lidded rigid tray	 The image shows the packaging for the BD Nexiva 22GA 1.00IN 0.9 x 25mm IV Catheter. The packaging is white with blue and red text. It includes the BD Nexiva logo, the product name, and various specifications. A red arrow points to the bottom left corner of the lid, which has a blue triangle and the text "Not for human use". The packaging also features a corner peel instruction: "Corner peel- Open from the bottom left to enable separation of materials where signifier is located". The arrow marks located at the bottom left of the lid.	Corner peel- Open from the bottom left to enable separation of materials where signifier is located
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Table 55. (cont'd)

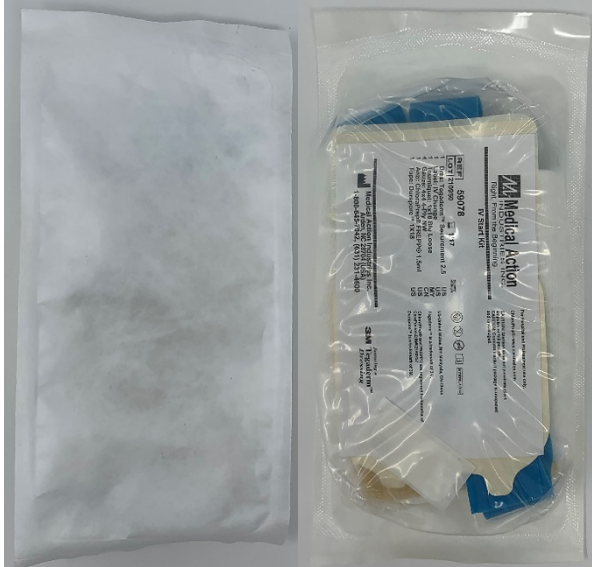
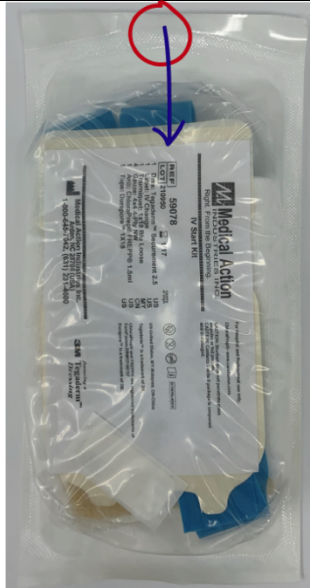
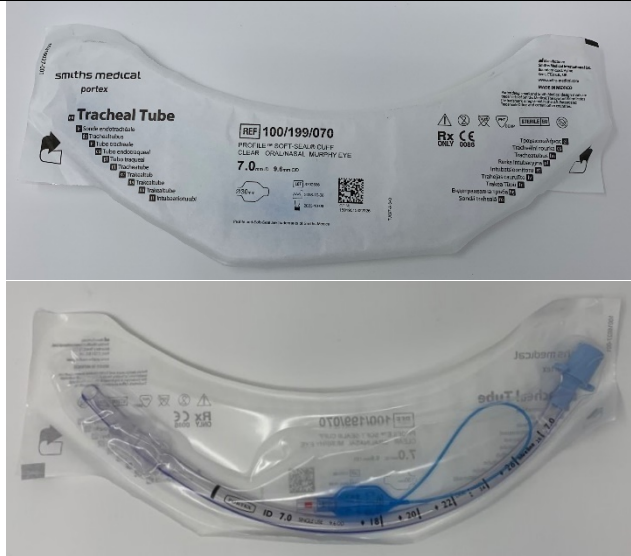
IV start kit (Medical Action Industries; Arden, NC)	 Lidded flexible trays	 Chevron type.	Open from the top center
4 by 4 pad (Baxter- (Sterile) Non-woven gauze sponges (4*4 in); Deerfield, IL)	 Unknow web pouch		Grip at the top where materials can be separated

Table 55. (cont'd)

Endotracheal intubation tube (size 7) (Smith medical; Minneapolis, MN)	 Lidded flexible trays	 The arrow marks located at the bottom left of the lid.	Open from where the arrow indicator is located.
Endotracheal intubation tube (size 2.5) (Dynarex; Orangeburg, NY)	 Lidded flexible trays	 The arrow marks located at the bottom right of the lid or open from bottom left	Open from where the arrow mark indicator is located.

7.1.3.1 Medical devices stored in a jump bag.

A jump bag is a so-called “mini-ambulance” utilized by EMS professionals. These bags contain many necessary items, including medical supplies, and tools (e.g. trauma shears), etc. (Refer Appendix K for the details). That said, medications are carried in a separate “medication box” which is regulated by the Medical Control Authority (See details of its inventories in Appendix I). The jump bag is typically brought to a scene in support of delivering patient care and is frequently assigned to a specific ambulance. The organization of the bag and the items contained within are dependent on the requirements of the specific Agency (e.g. one Agency requires IVs be kept in storage while another agency which might require all IV items be kept in the jump bag). For our work, the items of interest contained within the jump bag for use (or consideration for use) during the simulation are shown in Figure 60. These items were informed by findings collected in support of Specific Aim 2- Chapter 5 (guided interviews) and were intended to enable the care of patients during simulation scenarios. Items were stored with a specific configuration that was consistent from participant to participant; ET tubes in the back compartment, while gauze (film and FFS), 4 by 4 pads and IV solution were placed within the main compartment and the IV start kit, IV tubing and IV catheter (with/without extension) were stored in the front of the compartment.



Figure 60. The layout of the compartments of the jump bag and medical device setup in the jump bag

The jump bag (LINE2design; Mentone, CA), itself, was purchased via the EMSstore.com and also included the following items;

- 20 *Waterproof Adhesive Bandages
- 2 *Emergency Mylar Blankets
- 1 *Triangular Bandage
- 2 *CPR Clear Masks
- 1 *EMT Shears-Black 7.5"
- 1 *Disposable Diagnostic Penlight
- 1 *Dressing Forceps 4"
- 2 *Elastic Bandages
- 4 *Clear Rolls of Tape 1"
- 6 *Conforming Stretch Gauze 2"

- 6 *Conforming Stretch Gauze 3"
- 6 *Conforming Stretch Gauze 4"
- 2 *Instant Cold Packs
- 2 *Instant Hot Packs
- 20 *Cleaning Hand Wipes
- 10 *Triple Antibiotic Ointments
- 3 *Pair Disposable Gloves
- 1 *Flex-All Splint
- 1 *CPR Rescue Mask
- 2 *Sterile Multi Trauma Dressing
- 1 *Burn Sheet
- 1 *Sprague Stethoscope,
- 1 *Adult Blood Pressure Cuff
- 1 *Adult BVM Resuscitator Mask
- 2 *NRB O2 Masks
- 1 *Berman Oral Airway Kit
- 1 *Pair Safety Glasses
- 1 *Tactical Tourniquet,
- 1 *L2d Shove Knife w/cover
- 1 *Lifesaver Hammer
- 1 *Burn Spray, 2 oz.
- 2 *Quick-Stopper Gauze Bandage
- 1 *Sting Relief Spray, 2 oz.

- 10 *Ammonia Inhalants
- 10 *4 x 4 Gauze Pads

These were also present during the course of the usability testing.

7.1.3.2 Medical devices stored in cabinets

Extra medical devices were stored in the cabinets, based on findings from the guided interviews (Specific Aim 2) which suggested that some agencies keep the extra devices and tools in cabinets within the ambulance.

Extra IV tubing (n=15-20) was placed on the upper shelf of the cabinet 1 (See Figure 61) while additional IV start kits (n=30- 40) were located in the bottom shelf of the cabinet 1. Cabinet 2 contained a simulated medication box and extra IV solutions (n=15-20). In cabinet 3, extra boxes of gloves and Clorox Wipes were stocked. As such, if participants prepared for the next simulation scenario (as instructed), or they preferred to obtain medical devices from the cabinet, these supplies were available for their use.

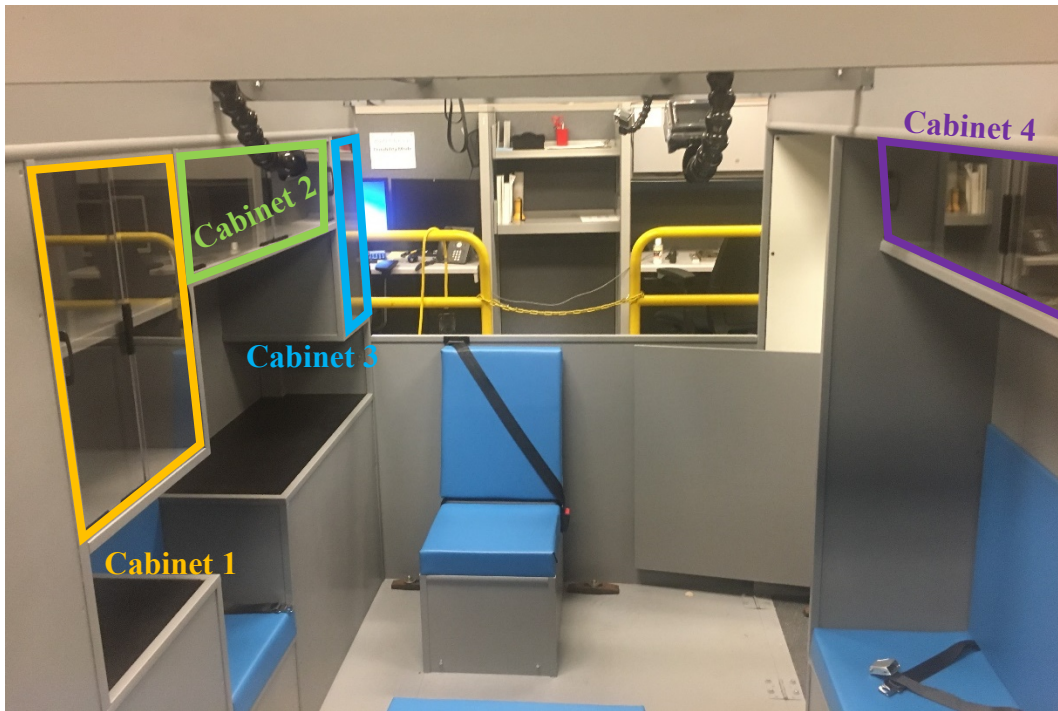


Figure 61. Location of cabinets within the simulator



Figure 62. Safety Label "Not for human use" attached to the products

As depicted in Figure 62, a safety label was applied to all products to identify them as not for human use. The template of the label design was obtained from the website of healthcare simulation safety⁸, resized to 6.0 cm * 1.4 cm (2.36 inch * 0.55 inch) for the IV tubing, IV solution, and ET tubes (see Figure 55), and was resized (6 cm * 1cm (2.36 inch *0.39 inch) for small products (IV catheter, IV catheter with an extension)) using Adobe Illustrator (San Jose, CA). Seven labels per sheet were printed onto a label paper incorporating 3” by 2” templates (Matt paper - Stock number 074971; Primera; Plymouth, MN) by Primera LX 900(Plymouth, MN – See Figure 63).



Figure 63. Primera LX 900 Label printer

7.1.4 Medication -- Combination product (prefilled syringe)

Three percent of survey respondent (51/1,702) indicated that difficulty opening medical supplies within the past 12 months of service had negatively impacted patient care. As such, we concentrated our formative, usability assessment on the design of packaging for medical devices.

⁸ healthcaresimulationssafety.org/labels/

However, to enable more realistic care simulations, medications were also available. Simulated, prefilled syringes, representing ‘nitroglycerin’ for emergency cardiovascular care, with a safety label ‘not for human use’ provided by Lansing Community College (See Figure 64) were placed in a 6–quart, plastic container (Sterilite; Townsend, MA) which simulated a drug box placed in Cabinet 2 (See Figure 61)



Figure 64. Simulated medications provided by Lansing Community College

7.1.5 Other items for the simulation

7.1.5.1 Gopros (San Mateo, CA)

A series of four Gopros HERO 3s were mounted to the simulator to capture interactions between participants and packaged products, and one head-mounted Gopro was affixed to each participant’s head using a head strap camera mount (Amazon; Seattle, WA). Captured videos were reviewed post-hoc to conduct the task analysis. Features of the cameras that were important to the work included;

Built in Wi-Fi enabling connection to a mobile app, ‘Gopro’, which allowed researchers to simultaneously view what was being captured via mobile phone. The Wi-Fi feature also allowed cameras to be started remotely from the app. This is important as the Gopro HERO 3 does not have a screen to display what they capture.

1080 HD / 30 fps (frame per second): the high resolution provided a nice clarity for reviewing details required (e.g. grip technique).

7.1.5.2 CLUE Spray (Brevis corporation, Salt Lake City, Utah)



Figure 65. CLUE Spray invisible fluorescent aerosol spray powder.

To investigate the transfer of microbes through possible routes of indirect contact with nonsterile surfaces within the ambulance, a simulated contaminant, CLUE spray,(Figure 65) was used. This simulated contaminant (Brevis corporation, Salt Lake City, Utah) is invisible to the eye under normal conditions of lighting and visible (glows green) when exposed to an Ultraviolet A (UVA) light (Figure 66) and readily transfers to other surfaces.



Figure 66. Clue Spray glowing green under the UV light

Because of these properties, it is frequently used in infection control programs to teach concepts like germ transfer and hand hygiene. Of all different forms of the simulated contaminant, CLUE Spray was chosen over the lotion to mitigate the likelihood that frictional interfaces occurring between the package and paramedic would be affected during the opening process, and the powder-version of the product could not be applied to certain materials (e.g. metal grip bars and cloth seatbelts).

Our review of the literature indicates that MRSA has been found on cot handles, overhead bars, seatbelts, and workspace decks within the ambulance (Brown, Minnon, Schneider, & Vaughn, 2010; Rago et al., 2012). As such, we applied consistent quantities of CLUE Spray (approximately 13 cm * 20 cm of area – see Figure 67) to each of these surfaces (See section 7.1.5.2) prior to each paramedic's arrival for testing. This simulant was sprayed from a distance of approximate 15 cm and applied until the researcher checked the space with the

UV light to demonstrate that the areas of interest were all covered by the simulant. Covered area will be illustrated in later section (7.2.3 indirect transfer and contamination test)

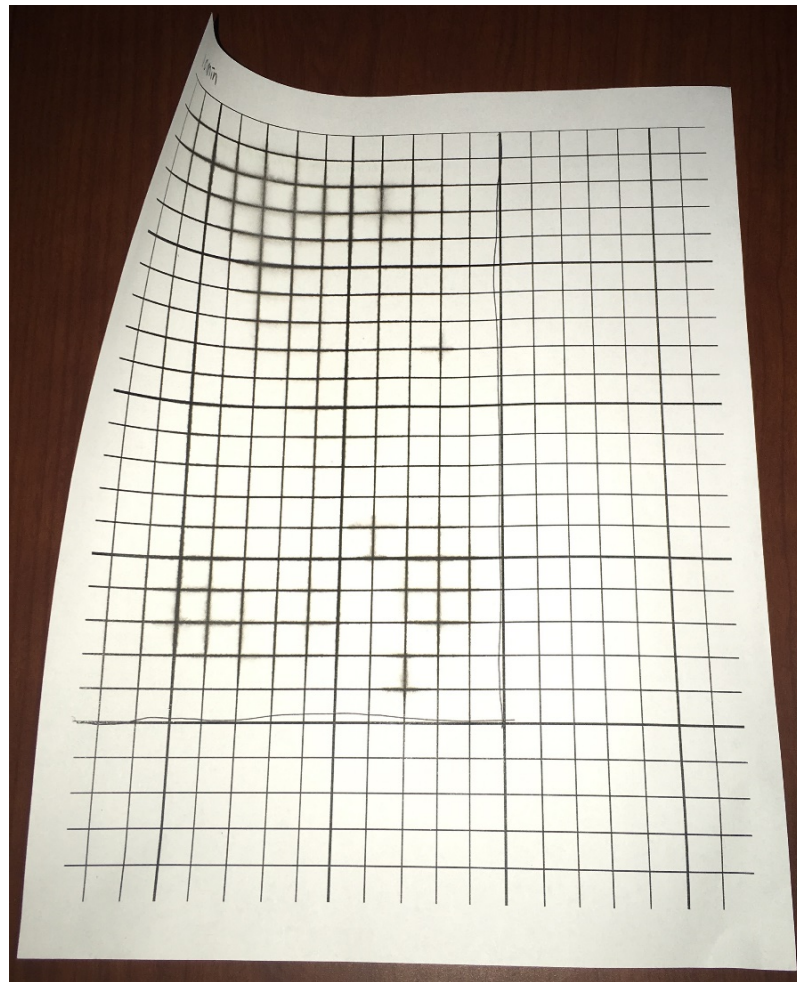


Figure 67. Spray scatter check grid applied one press of CLUE Spray (One cell indicates 1 cm by 1 cm)

7.1.5.3 Simulation scenarios (See Appendix R)

Simulation scenarios, informed by both the survey (Specific Aim 1-Chapter 4) results and the findings from the case study (Specific Aim 2- Chapter 5), were crafted to represent realistic “worst-case scenarios” likely to induce unintended affordance behaviors related to opening medical supplies. Based on the findings from the case study (see Chapter 5) and the anecdotal observations, patient type was offered as influencing difficulty (obese individuals and infant

scenarios). Interview respondents also reported that when administering care to multiple systems for a single patient (e.g. administering an IV to the circulatory system and enabling the airways of the pulmonary system), they frequently have to change their position (e.g. from the bench seat for general care delivery to the captain's seat to work on the airway; See Figure 41 and Figure 42 for the typical varied seating arrangements within the ambulance).

Simulation scenarios were crafted with these ideas in mind and, refined in consultation with members of the research team from Lansing Community College and the Learning Assessment Center at MSU as well as other healthcare professionals involved in the research study. The two simulation scenarios utilized for each of the participants in support of the formative usability study (Specific Aim 3) are briefly described in Table 56 and Table 57.

Table 56. 1st Scenario: Adult Patient Scenario (Laerdal; Stavanger, Norway)

Adult Patient Scenario
Scenarios The patient is the victim of a mass casualty event, a stage collapse at a concert due to high winds from an impending storm. Emergency services (both prehospital and at the emergency room) in the area are overwhelmed. As a result, advanced levels of patient care are needed in route. Because you and your partner were in the area of the collapse, you are on scene with only two EMS providers (yourself and a driver). A 65-year-old male has fallen in the chaos, resulting in a significant injury on his right arm. He is having difficulty speaking, is showing signs of shock and has indicated that he is having chest pains.

Table 56. (cont'd)

Simulation Activity		
Stages	Roles	Details
Stage 1	Moulage	The victim has a significant injury on his right arm.
	Settings	- BP (Blood Pressure):148/90 - HR (Heart Rate):128 - R (Respiration): 32 EKG(Electrocardiogram) - ST (Sinus Tachycardia) with occasional PVCs (Premature ventricular contractions) - SPO₂ (peripheral capillary oxygen saturation): 92%
	Manikin/simulator vocals	heavy breathing, moaning, pain in right arm and chest
	Participant expectations	Initial assessment & interventions (monitor, O ₂)
	History if inquired	No family or friends to provide information; no significant history of HBP (High Blood Pressure), cardiac hx (cardiovascular history) or diabetes. History of high cholesterol and takes “some pill” for that and some Vitamin D
Stage 2- EMS vehicle begins to move as transport begins	Settings	- BP 80/40 - HR 50 - R 16 - EKG: SB (Sinus Bradycardia) with PVCs - SPO₂: 80%
	Manikin	Increased pain in chest then transition to occ. moaning, decreasing LOC (Level of consciousness)
	Participant expectations	Note monitor, request EKG, initiate IV, increase O ₂ , may ask for EKG
	Operator	If EKG is requested, provide. May verbalize, “His abdomen appears very distended”, call report to hospital (ETA 10 min.)

Table 56. (cont'd)

Stage 3	Moulage	Victim becomes nonresponsive
	Settings	• No BP • No R • No HR • EKG: PEA (Pulseless electrical activity)
	Participant expectations	Bag/Valve/Mask then Intubation, emergency cardiovascular medications
	Operator	“ETA 4 minutes”
Stage 4-termination of simulation	Operator	- Indicate end when a victim has an IV and has been intubated - State, “We have arrived at the hospital where transition of care has taken place

Table 57. 2nd scenario: Infant Patient (GAUMARD SCIENTIFIC COM; Miami, FL) Scenario

An Infant Patient Scenario		
Scenarios Patients are victims of a car accident. Emergency services (both prehospital and at the emergency room) in the area are overwhelmed because of a mass tragedy happening nearby. As a result, advanced levels of patient care are needed in route. You are on scene with only two EMS providers (yourself and a driver). Because of the car crash, her parents passed away at the scene, so she is not accompanied by a guardian.		
Simulation Activity		
Stages	Roles	Details
Stage 1	Moulage	Cyanotic around mouth, weak cry
	Settings	- HR: 170 - BP: 80/40 - R: 32 - EKG: SVT (Supraventricular Tachycardia)
	Operator	May need to state the baby has weak cry if no audio
	Participant expectations	Warm infant, stimulate infant, place in supine sniffing position, initial assessment, suction, Oxygen

Table 57. (cont'd)

Stage 2- EMS vehicle begins to move as transport begins	Settings	- HR 80 - BP: 70/50 - R: 12 - EKG: SR (Sinus Rhythm) with PVCs
	Operator	“This isn’t looking good. The roads are horrible...ETA is about 5-7 minutes.”
	Participant expectations	Oxygen mask, Intraosseous IV, meds
	Settings	- HR: none - BP: none - R: none - EKG: VF (Ventricular Fibrillation)
	Participant expectations	CPR (Cardiopulmonary Resuscitation), intubation, meds
Stage 4- termination of simulation	Operator	- Indicate end when a victim has IV and has been intubated - State, “We have arrived at the hospital where the transition of care has taken place. You will now debrief with the research team after which time we will do the second simulation.”

7.2 Methods

7.2.1 Preparations before test

7.2.1.1 Recruitment

A total of nine paramedics were recruited from in and around the mid-Michigan area in accordance with methods approved under IRB STUDY00000824, leveraging the contacts of our partners at Lansing Community College (LCC) and the Learning and Assessment Center (LAC) MSU. Further, the IRB approved recruitment (See Appendix O) email was provided to fire stations, medical control authorities, and agencies within the Plymouth area by visiting them (with presentations made to interested stations upon request).

Researchers scheduled with participants over the phone, or via email, and a reminder call was made 1 to 2 hours prior to their scheduled appointment. During both the initial contact and the reminder call, researchers went through the inclusion/screening criteria and offered to email directions to the test location (Adient Technologies; Plymouth, MI).

Inclusion criteria were as follows:

- Aged 18 or older
- A paramedic or student with practical care experience on the ambulance who has delivered care within the past 12 months
- NOT currently pregnant
- Have NO history of back, neck, shoulder, arm, wrist or hand injuries or ailments.
- Not be under medical treatment for cumulative trauma resulting from repetitive motion.
- Not have taken any drug or medication 24 hours prior to the experiment with the potential to cause drowsiness or impair ability to participate in this experiment.
- Have no known history of skin condition (e.g. eczema, latex allergy, etc.)

- Have transportation to the test site (Adient Technologies; Plymouth, MI)
- Be willing to be videotaped during two care scenarios taking place in our ambulance simulator

7.2.1.2 Preparation Process Before Test

Because our recruitment strategy concentrated on paramedics in close proximity to the research location (Plymouth EMS) and a population traveling from a distance (mid-Michigan), two consent forms and incentive schemes were used. One which indicated that participants would receive the incentive (\$100) and mileage to and from Lansing or further (\$96), and another targeting local paramedic participants (only the \$100 incentive indicated). During the phone screening, researchers collected prospective participants' phone numbers and email addresses as well as information about the area from which they would be traveling. This not only allowed researchers the ability to remind participants about the travel time and the location of the experiment but also ensured that they received the appropriate compensation.

Additionally, researchers contacted participants 1 to 2 hours prior to the starting time of the experiment to remind them of the event and potentially clarify any difficulties that they were anticipating/having with navigation. Upon arrival at Adient, participants were registered to building's guest list, after which point researchers escorted them to the room containing the vibration table. Recruitment location (Plymouth or Mid-Michigan) was reaffirmed in order to pull the forms referencing the appropriate compensation.

7.2.2.3 Preparation of the Simulator

GoPro cameras and simulated contaminant were prepared in advance of participant arrival. Participants were outfitted with a single camera strapped to their head in an attempt to

capture user views of package handling. Gopros were also mounted as shown in Figure 68 and Table 58.

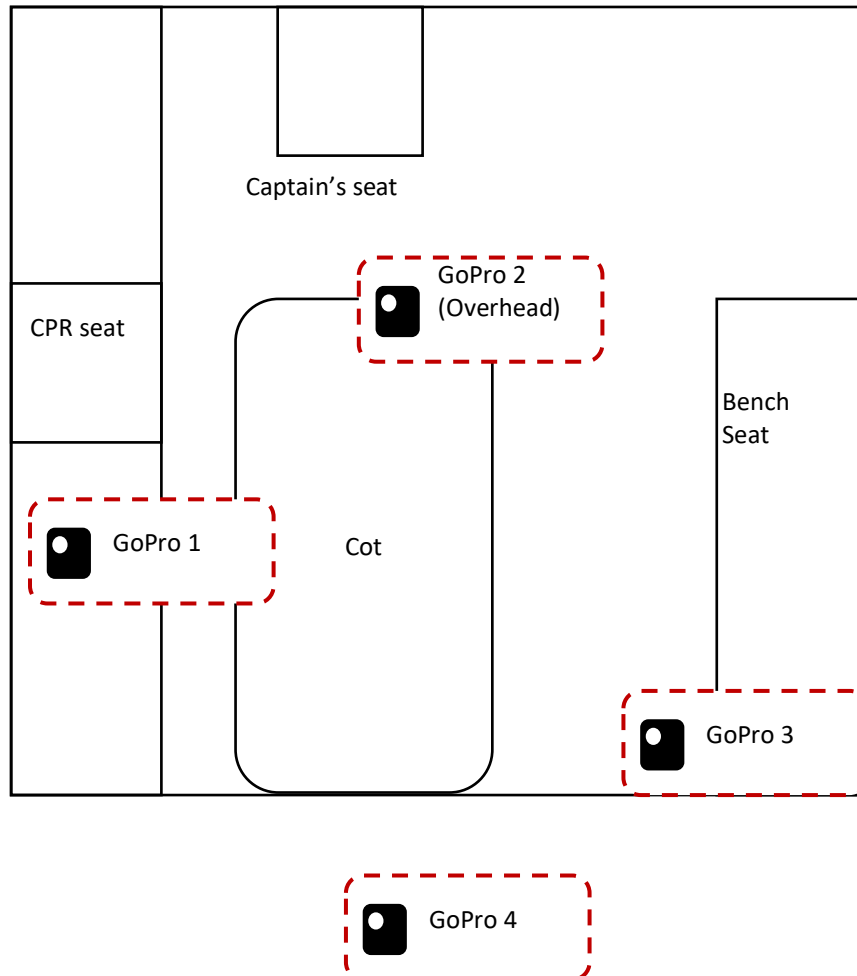


Figure 68. GoPro locations in the simulator

Table 58. Details of set-up location of GoPros

Details of locations	Captured area from Gopros
 A photograph showing the interior of a medical training module. A mannequin lies on a blue gurney. A red square highlights a GoPro camera mounted on a shelf above the gurney. A white label with a GoPro icon and the text 'GoPro 1' is placed over the red square.	 A photograph showing the area captured by GoPro 1. The mannequin is lying on the gurney, and a person in a black shirt is attending to them. An orange and black medical bag is visible on a shelf in the background.
 A photograph showing the interior of the same medical training module from a different angle. A red square highlights a GoPro camera mounted on a shelf. A white label with a GoPro icon and the text 'GoPro 2' is placed over the red square.	 A photograph showing the area captured by GoPro 2. The mannequin is lying on the gurney, and a person in a black shirt is attending to them. The camera angle is from above, showing the mannequin's head and torso.

Table 58. (cont'd)

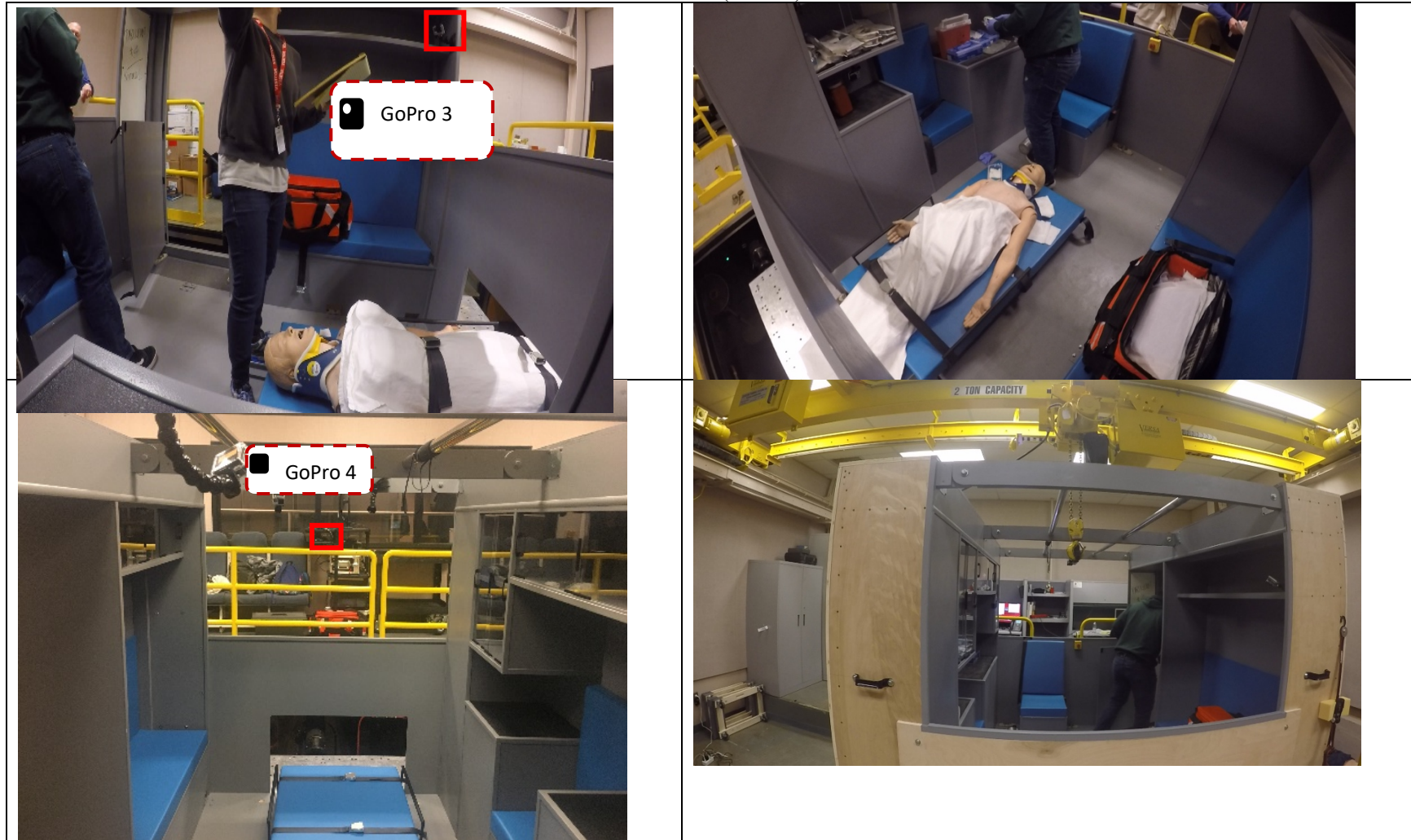
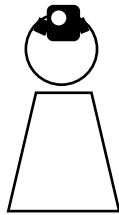


Table 58. (cont'd)



Because battery span was a significant concern to the research team, camera batteries had to be fully changed and recharged between each participant. Thirty-two GB and sixty-four GB micro SD card (Milpitas, CA) were used to contain and store recordings.

Lastly, simulated contaminant (CLUE Spray) was applied to surfaces noted by previous studies (Brown et al., 2010; Rago et al., 2012) within the ambulance (See details of this area and spraying method in the previous section 7.1.5.2). Even application to the seat belt, workspace deck, overhead bars and cot handles were verified using UV light prior to the beginning of the formative usability testing.

7.2.2 Formative usability testing

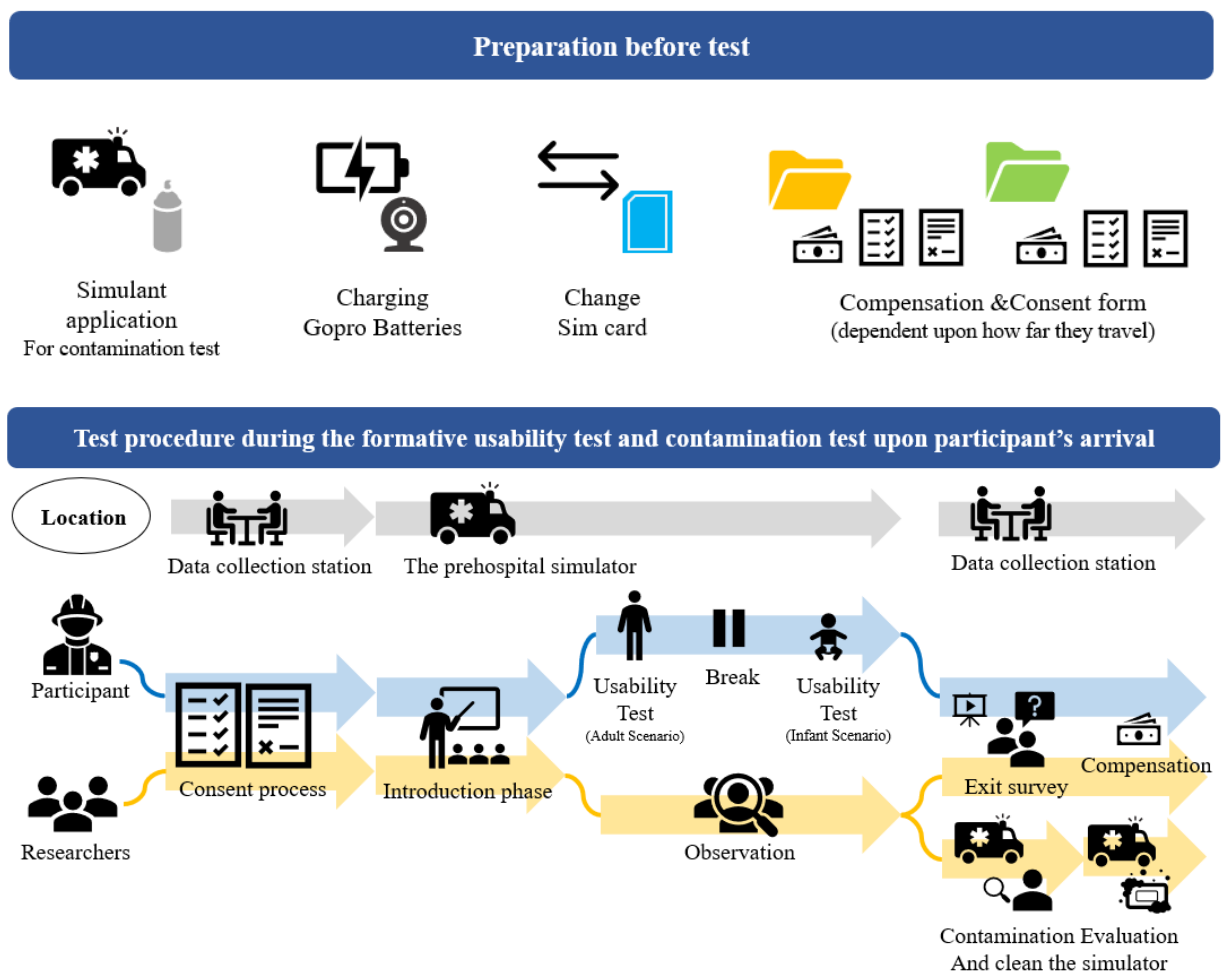


Figure 69. Test procedures/preparation before/during the formative usability test

Figure 69 provides a summary schematic of the methodological flow of the formative usability test. Specific details regarding each phase of the experiment are addressed in the following sections.

7.2.2.1 Welcoming, Consent Process and Collection of Demographic Data

Upon arrival at Adient, research participants were asked to sit at a ‘data collection station’ (See Figure 70) where researchers introduced research team members, their roles and provided a brief description of the experiment; additionally an informed, written consent process (See Appendix P and Appendix Q) was conducted.

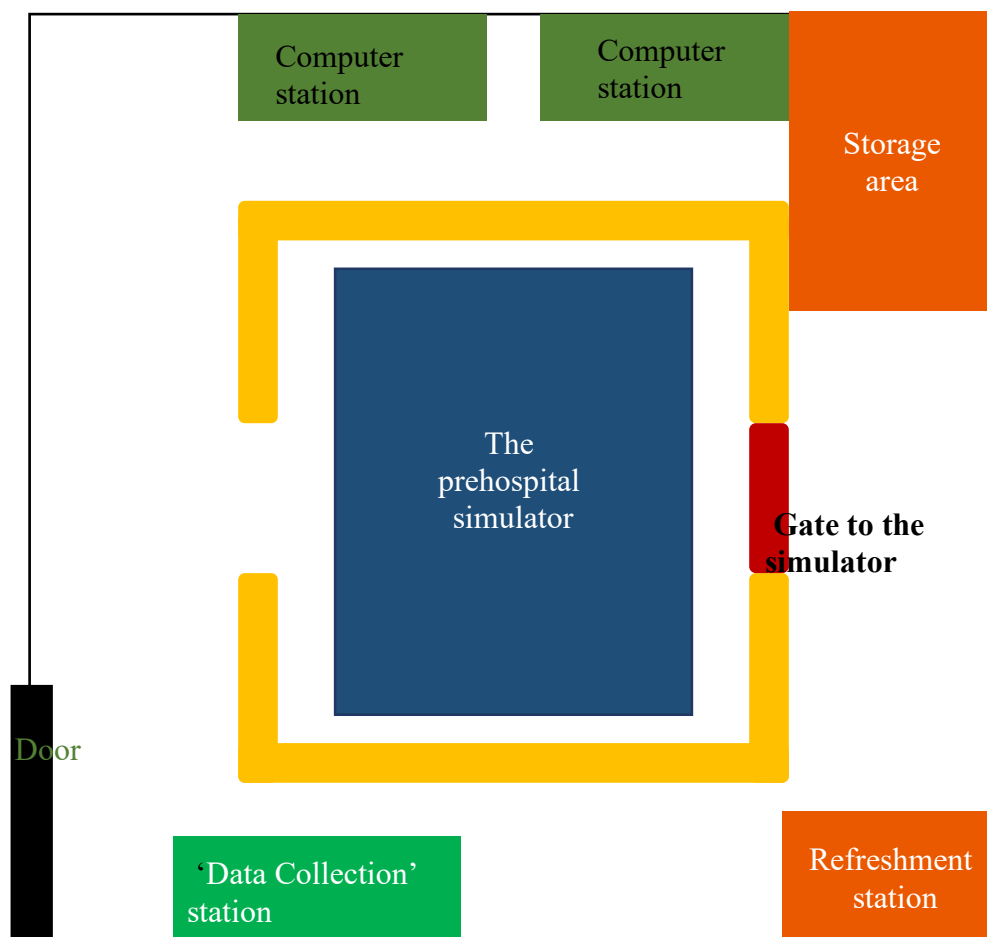


Figure 70. The layout of the research area

During the consent process, inclusionary criteria was reiterated to each participant, and they were told that they could stop the simulation(s) at any time by lifting a hand over their head and saying "stop" or by pushing the mechanical E-stop placed near the captain's seat. It was explained that they would still receive the incentive if they chose to discontinue participation. After this point, the participant was given time to review and sign the consent form. There were two levels of consent on our form: one that indicated willingness to have video recorded data shown for the purposes of education and research presentations; another that consents to the overall study. In the event that a participant indicated that the recordings may be used, the participant number was written on the whiteboard within the ambulance buck. Otherwise, the participant number with the statement 'disagree' was written on the board. In this way, we had the consent for presentation of videos for educational purposes embedded within the video permanently without compromising the identity of the participant.

Following consent, demographic information and information about each participants' work history was collected using a data collection form created for this purpose (See Appendix S).

7.2.2.2 Introduction Phase

To introduce participants to the simulator, which differed from their working environment, procedures included an "Introduction phase." It is not uncommon for paramedics to work in differing ambulances over varied agencies and medical control authorities. During the introduction phase, researchers introduced paramedics to the simulator and showed them where products (e.g. medical devices, medication, Clorox wipes, gloves, etc.- See section 7.1.3 and 7.1.4 for details) were stored both within the simulator (i.e. cabinets) and the jump bag.

After this, in order for them to feel comfortable with the vibration/motion of the simulator, participants were asked to sit on any of seats in the simulator while a brief test pattern was run. After this “trial run”, GoPros were started and the simulations commenced.

7.2.2.3 Formative Usability Testing (Specific Aim 3)

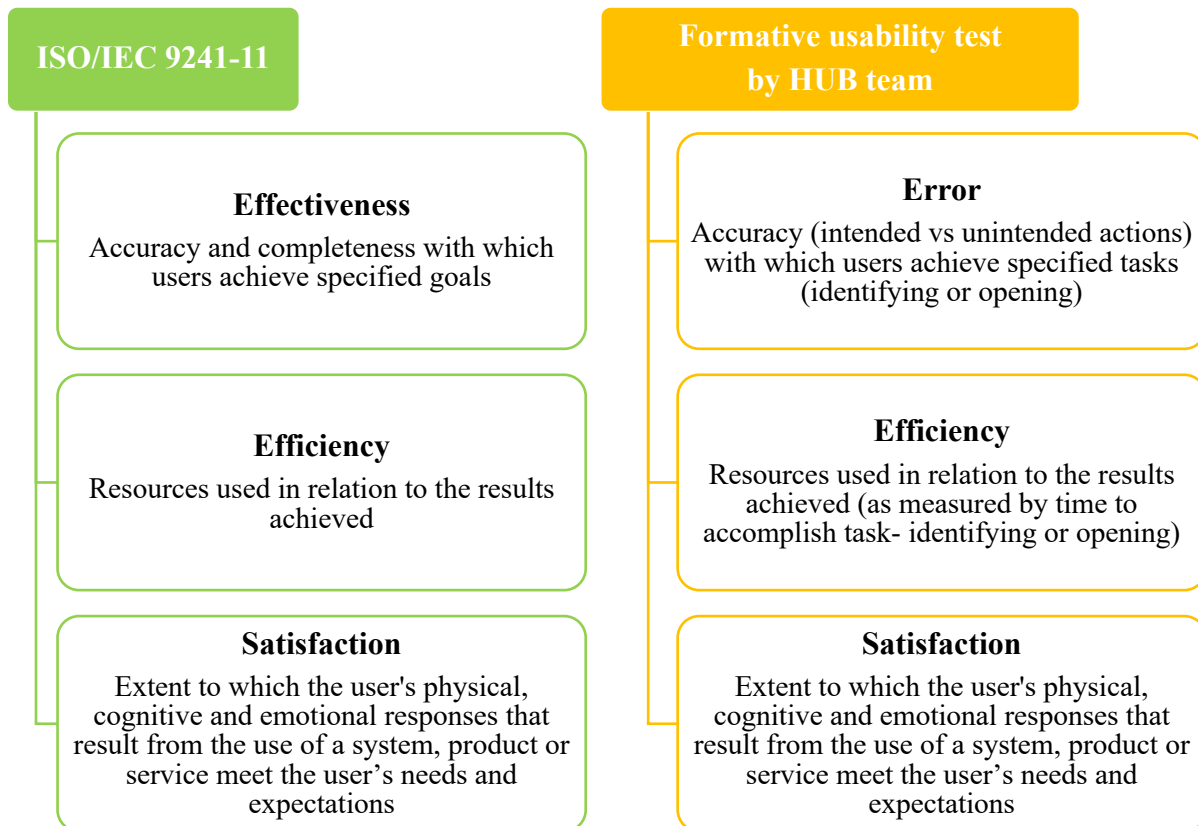


Figure 71. Original definitions from ISO 9241-11 with our modified versions for packaging

A single paramedic at a time was tested to assess packaging usability using two simulation scenarios (see Table 56 and Table 57); scenarios were crafted to be realistic but severe enough to induce unintended affordance behavior with packaging. Usability was assessed using the following measures, informed by a definition of usability metrics described in ISO 9241-119(2018 International Organization for Standardization [ISO], 2018)- See Figure 71 for

⁹ Limited open source can find at: <https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-2:v1:en>

descriptions of definitions. Definitions/measures of ISO 9241-11 were modified to be suitable for our purpose, the evaluation of packaging usability.

The formative usability test began with instructions provided by a research team member playing the driver and the patient roles (See Appendix R for script). The team member, a working paramedic hired for this purpose, began by indicating that participants would signal readiness to start the simulation by moving the cot forward to lock it in place. Further, he reminded participants about each of the safety measures previously discussed. Following this, participants were asked to prepare for the next run (See details in Table 56). The team member introduced the scenario, including the patient condition and background.

As soon as the cot was moved into place, the adult simulation scenario commenced. Guided by the simulation script (Refer to section 7.1.5.3 for details), our team member responded to questions and the actions of the participants as the scenario unfolded. When finished, participants were given 10 minutes to prepare for the next run and 10 minutes to rest as the research team set up the second (infant) simulation scenario. When ready for the second simulation scenario, our paramedic reminded participants about safety information as well as how to signal that they were ready to start the simulation, and the second scenario's background was introduced (See details in Table 57)

7.2.2.4 Exit interview with post-hoc review of recordings

After completing the two simulation scenarios, exit interviews (See Appendix T) were conducted with paramedics to gather insights regarding usability. Usability was assessed as a collective assessment of three components informed by our adapted version of the components from the ISO standard. Namely, efficiency, satisfaction and error.

After completing the two scenarios, participants were asked to take a seat at the ‘data collection station’. The micro SD card of Head mounted Gopro was removed from the camera and inserted into a computer (Dell Inspiron 7773, Round Rock, TX) to review the video together with the participant. A single member of the research team led all of the pos-hoc video reviews.

To characterize Satisfaction, one of the components of usability, during video review (See Table 55), the researcher replayed the frames associated with each of the tasks (identification, opening, dispensing) for each product of interest. During the course of the review, the participant was asked, ‘Overall, how satisfied were you with your ability to (identify, open, use) this product. For example, the researcher would pause the video when the participant used the IV start kit and relay this question.

In addition to the questions related to satisfaction, questions regarding the context (e.g. package design, personal experience, physical space, patient condition) were also probed in an attempt to explore their impact on interactions to investigate the influence of context on unintended behaviors (‘error’ measures). An example of the type of probe employed for this purpose was:

- “What are the package/product designs (design cues) that posed a challenge for you as you were working with this product?”

When unintended affordance behaviors (use errors) were exhibited, the researcher might ask something like.

- “I see that you are using (e.g. glasses, one hand, the trauma shears, your teeth, etc.) in order to successfully (e.g. identify/open/use) the product at this point in

the video. What is happening here (the context/setting) that encouraged you to do this?’

- “Did other elements, such as personal experiences/characteristics or other things happening in the scene, pose a challenge for you as you were working with this product?”

The data collection sheet used to explore satisfaction measures as well as unintended affordance behaviors (error) can be found in Appendix V.

7.2.3 Indirect transfer and Contamination test

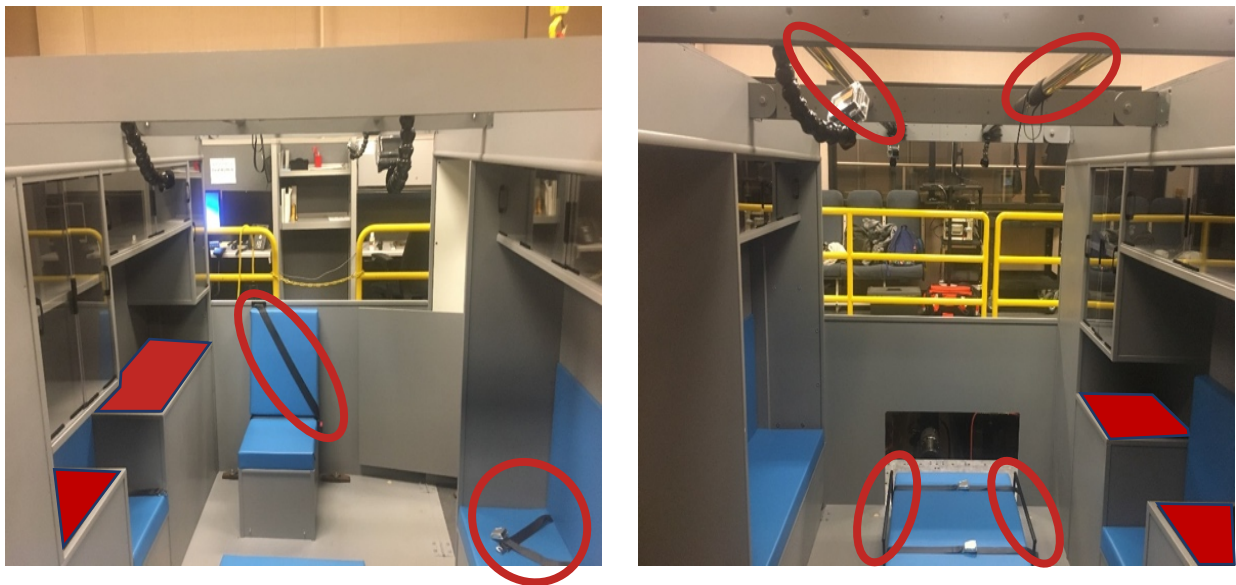


Figure 72. Areas of interest that applied CLUE Spray

The research team was also interested in the practice of cleaning between runs in the ambulance (specifically related to the areas where CLUE Spray had been applied, namely ‘seatbelts, cot handles, overhead grab bars, and the workspace deck’- see Figure 72). A single container of Clorox Wipes (Oakland, CA) was placed into storage cabinet 3 (See Figure 61) so

that they could be used if the participants chose to clean upon being instructed to “prepare for the next run as you normally would” between runs or before the testing started. The supplies were introduced when researchers familiarized each participant with the simulator, during the introduction phase of the study. Cleaning was noted in binary fashion (yes or no) for each participant and verified with recorded video files afterwards.

CLUE Spray was used to evaluate transfer of the simulated contaminant to surfaces other than where it had been originally applied. Locations of original application included ‘seatbelts, cot handles, overhead grab bars, and the workspace deck’. Participants were not aware of the areas sprayed with the CLUE Spray. After two simulation scenarios were completed by participants, the inside of the ambulance simulator, the simulated patients, and products/packages of interest to the study were investigated under the UV light. If the presence of simulated contaminant was noted, the presence(s) was captured by a Canon Power Shot camera (Tokyo, Japan) and recorded. Between participants, the surface where the evidence of contamination was found and where the CLUE spray had been originally applied were thoroughly cleaned with Clorox wipes by the research team.

7.2.4 Analysis methods

To assess the measures related to efficiency and error, video files recorded from the head-mounted Gopro, were reviewed (See identified patterns in Figure 73). Post-hoc review enabled researchers to break each task into a series of subtasks, which, once aggregated, became the series of actions that formed a given, critical task (identifying, opening, using). Consider, for instance, the task of opening. Opening the product came after the participant had accomplished the first task, successfully identifying the product; opening was comprised of the sub tasks of

identifying the area to open, applying some type of mechanical approach to gather the materials (e.g. tip pinch, lateral pinch, chuck pinch) and physically exerting force to separate the substrates or breach a single material. A single member of the research team identified the start and stop times for each of the subtasks and tasks of interest using post-hoc review of the videos.

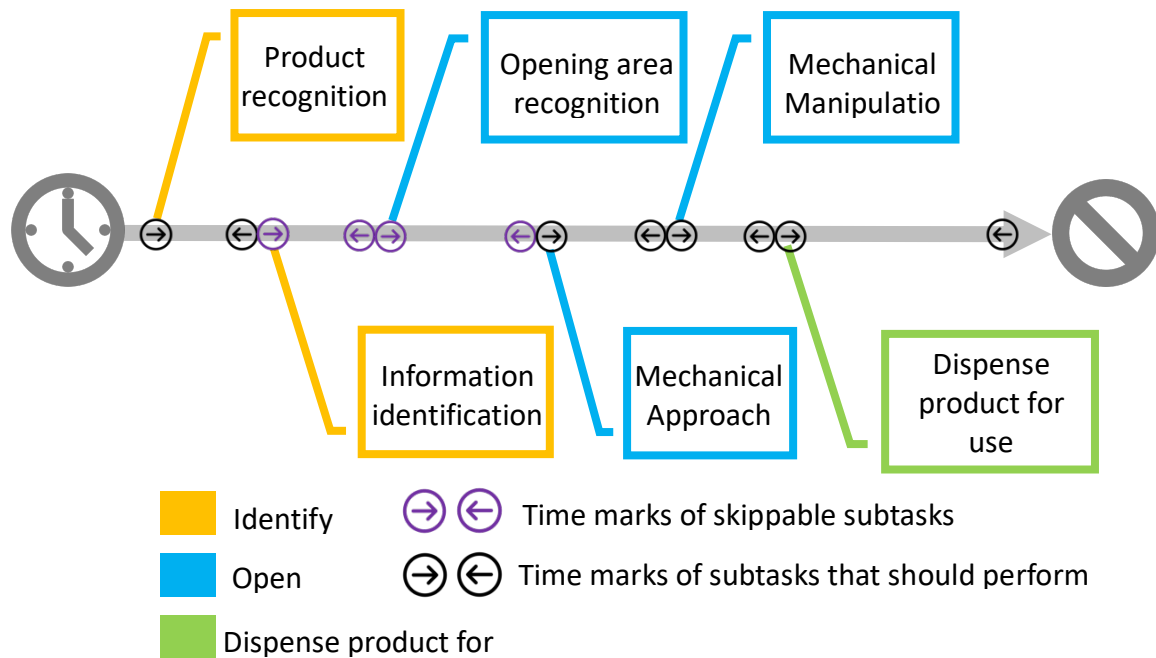


Figure 73. Patterns of packaging use by participants

Based on these identified patterns, tasks and subtasks were defined (See Table 59 for details).

Table 59. Definitions of tasks and subtasks of packaging use on healthcare products

Task Order #	Tasks	Subtasks	Description(s)
1	Identify	Recognize the appropriate/needed product from where it is stored (Shortened to 'Product recognition')	Recognize the shape or size of the appropriate/needed product from the cabinet or the jump bag by casting a glance to the product

Table 59. (cont'd)

1		Identify the critical information (expiration date and size - findings resulted from collective case study) of the product (Shortened to 'Information identification')	A course of behavior identifying product information including orienting package along with its text orientation or flipping the package to find the correct information, etc.)
2	Open	Recognize an opening area (Shortened to 'Opening area recognition')	Searching for a space to grip or use their teeth to enable opening
2		Mechanical approach in holding the package (Shortened to 'Mechanical approach')	Use either their hands or teeth to hold package, including repositioning.
2		Mechanical manipulation to successfully separate components of the package (Shorten to 'Mechanical manipulation')	A course of mechanical separation of components to open package.
3	Dispense Product for use	Take product out of package	Product removal

Recorded videos were reviewed again to mark time for subtasks (in support of efficiency measures). Post-hoc review of videos also included analysis of the affordances that participants exhibited with the packages of interest and whether these behaviors were consistent with those intended by the designer (see Table 55 for review of study packages and intended affordances), or whether they were unintended affordances (in support of error measures).

Efficiency of overall task was measured based on the sum of the subtasks defined in See Table 59. The time was marked at several key events based on identified subtasks. As no empirical technique which directly track attention was employed (e.g. eye tracking), educated assumptions were made regarding their subtask behaviors within the frame of the recorded videos. Subtasks (e.g. information identification, opening area recognition) were, at times, not characterized because some participants immediately opened the package after recognizing products (e.g. participants forewent the 'information identification' subtask as a label is not

present for some products such as gauze (film), or they were familiar with the product. The subtask ‘opening area recognition’ could happen quite quickly if the products were familiar enough to them. The start time and end time were marked at the key events by Adobe Premiere Pro CC 2018 (San Jose, CA) in time units of 60 fps (default setup). Later, units were converted into seconds.

Table 60. Measurement method on each of subtasks

<i>Tasks</i>	<i>Subtasks</i>	Measure method by digitally recorded video files for each subtask	
Identify	Product recognition	Starting point	The frame containing an opened jump bag as well as the product that the participant was about to use
		End point	The frame prior to the frame containing first touch of the package
	Information identification	Starting point	The frame containing first touch of the product as well as product’s information on the package
		End point	The frame out of focus on the product information
Open	Opening area recognition	Starting point	The frame after starting to show the out focus of the product information
		End point	The frame prior to the frame containing first touch of the package near its opening feature
	Mechanical approach	Starting point	The frame containing first touch of the package near its opening feature
		End point	The frame before the frame containing the participant’s arms moving outward
	Mechanical manipulation	Starting point	The frame containing the participant’s arms moving outward

Table 60. (cont'd)

		End point	The frame containing one of participant's hands is off from the package
Use	Take product out of package	Starting point	The frame containing first touch of the product
		End point	The frame prior to the frame that the product is just fully removed.

The second component of usability, Satisfaction was collected using Likert scale measurements (from 'very unsatisfied' to 'very satisfied' with package design) as we debriefed the experience during the video review at the end of their session. The frequencies of each scale were recorded as they related to each of the three tasks.

The third component of ISO's usability frame, effectiveness, was modified to Error for our purposes, and also assessed. Error was evaluated to identify design cues and contextual nuances that induce unintended behaviors (e.g. identify false affordances inspired by packages, the design cues that they employ and the context that inspires the same – See Section 2.1.1 for details). This was evaluated in binary fashion (as the designer intended yes/no) during the video review process with the participant. These were subsequently synthesized into recommendations for changes to design cues. Behaviors representing 'negative affordances' and 'false affordances', unintended behaviors with the potential to result in any harm (negative affordance) or other unintended behaviors (false affordance), were considered as requiring change. Behaviors resulting in 'weak affordances,' those that vaguely convey design cues to users and 'hidden affordances', that users never noticed, were also considered to be in need of change. Design cues that result in intended behaviors were considered 'true affordances'; those that inspired this consistently and efficiently would be indicative of 'strong affordances' in other words, effective.

7.3 Results and Discussions

A total of nine participants partook in two simulations intended to assess the usability of packaging for products commonly used on the ambulance. Eight participants were male and 1 was female. The average age of all participants was 38.13 years old (standard deviation $\pm$ 10.19). Five participants reported more than 11 years of experience while the remainder reported less than 10 years. Three participants worked for 2 or more organizations and six for a single agency. Seven participants' primary role at their main EMS job was 'Patient Care Provider' while 1 participant's role was 'Administrator/Manager' and 1 participant reported multiple roles; 'Patient Care Provider', 'Educator', 'Preceptor', 'Administrator/Manager' and 'First-line supervisor'. When asked to provide their best description of their main EMS agency/organization, participants reported: 'Hospital (n=1)', 'Fire Department (n=2)', 'Government, Non-Fire Department (n=2)', 'Private (n=4)' and 'Student (n=1)'; a single participant reported working for both 'Hospital' and 'Private'. The primary type of service provided by their main EMS agency/organization was 'Primarily 911 responsibilities with or without transport capability (n=6)', 'Equal mix of 911 and medical transport (n= 2)' and 'student (n=1)'. The years of employment or volunteer service within EMS was 'Less than 8 year (n=2)', and 'more than 8 years (n=7)'. Their employment status was 'Full time (n=6)', 'Part time (n=2)' and 'student (n=1)'. The average number of calls that they respond to in a typical week at their main EMS job was 'Less than 20 calls (n=4)' and 'more than 20 calls (n=5)'. The community size in which they do most of their EMS work was 'Rural area and small town (less than 25,000 people in the community, n= 3)', 'Medium town and Large town (25,000 – 149,999 people in their community, n=4)', 'Large city (500,000 or more people, n=1)' and 'Other (not employed as of the test date, n=1)'. Level of education was also reported; 'High school graduate/GED (n= 1)',

‘Some college (n=5)’, ‘Associate’s degree (n=2)’ and ‘Bachelor’s Degree (n=1)’. All participants reported their race/ethnicity as ‘white’.

7.3.1 Task analysis for the usability test

The frequency of use of IV tubing, and IV solution (during the simulation process) were fairly consistent across participants while frequency of usage for other products within the simulator were varied (See Table 61).

Table 61. The frequency of the use of products for each scenario

Products	The frequency of use for adult patient care	The frequency of use for infant patient care	The total number of uses
4 by 4 Pad ¹	N=9 (8 Participants with Participant 4 using twice)	Not applicable	N=9
Gauze (flexible film)	N= 6	Not applicable	N=6
Gauze (FFS)	N= 2	Not applicable	N=2
IV tubing	N=8	N=9	N=17
IV solution	N=9	N=9	N=18
IV start kit	N=9	N=8	N=17
IV Catheter	N=5	Not applicable	N=5
IV catheter with an extension	N=4	Not applicable	N=4
ET tube (Size 7) ²	N=8	N=9	N=17

Note 1: One participant used the ‘Trauma Dressing’ to treat the simulated wound, but this was not included in the analysis

Note 2: One participant used the ET tube, which package was already removed, to deliver airway care

7.3.1.1 Effectiveness measures

Interactions with the packaged products were analyzed using the definitions we created relating to the tasks/subtasks (See Table 59). As described in the Methods section, the time marks of different subtasks relating to products included in the analysis were used to descriptively compare use with other products. We firstly describe the task, and then subtasks of each task.

Identification of product based on packaging

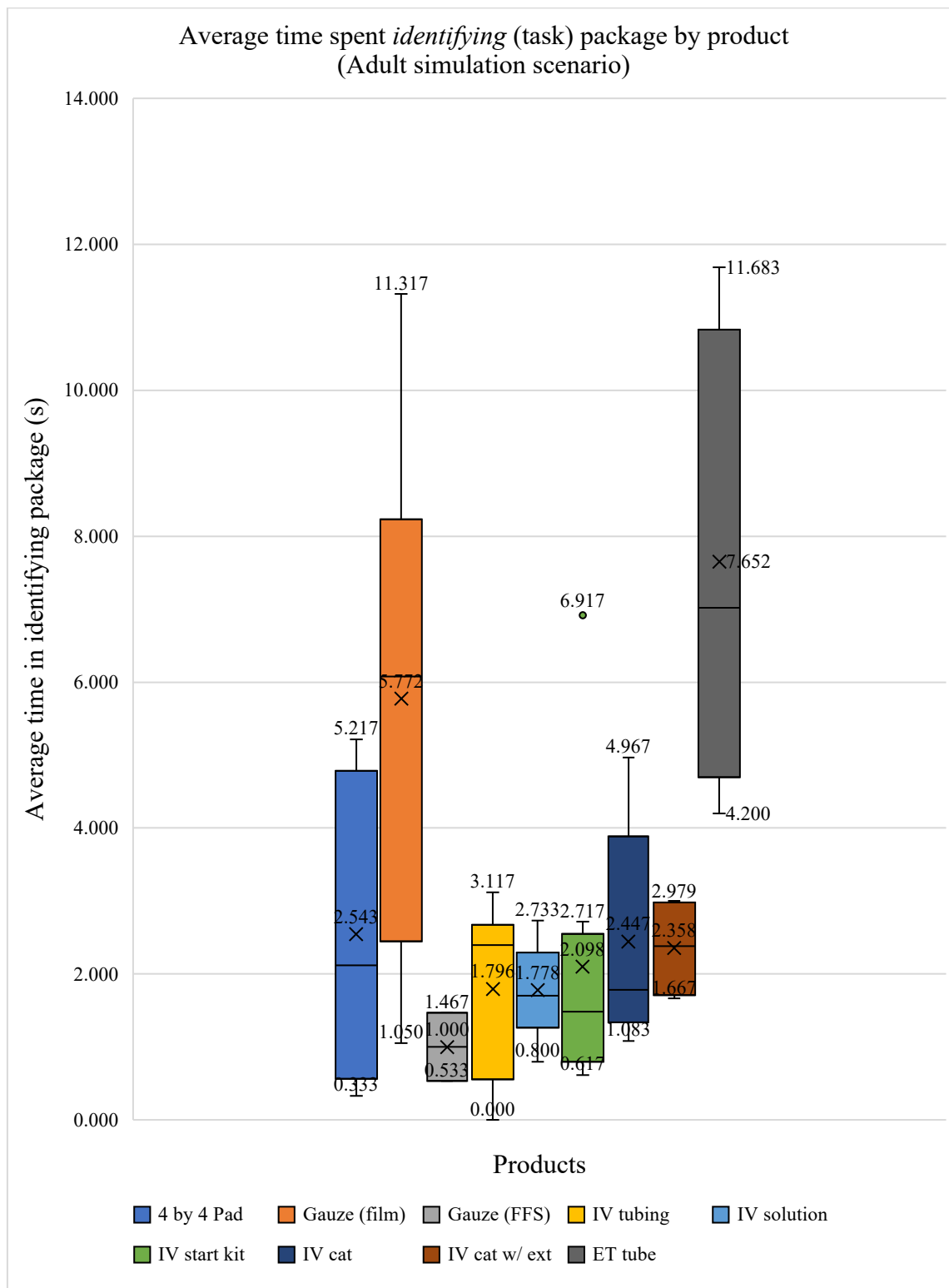


Figure 74. Average time spent identifying (task) package by product (Adult simulation scenario)

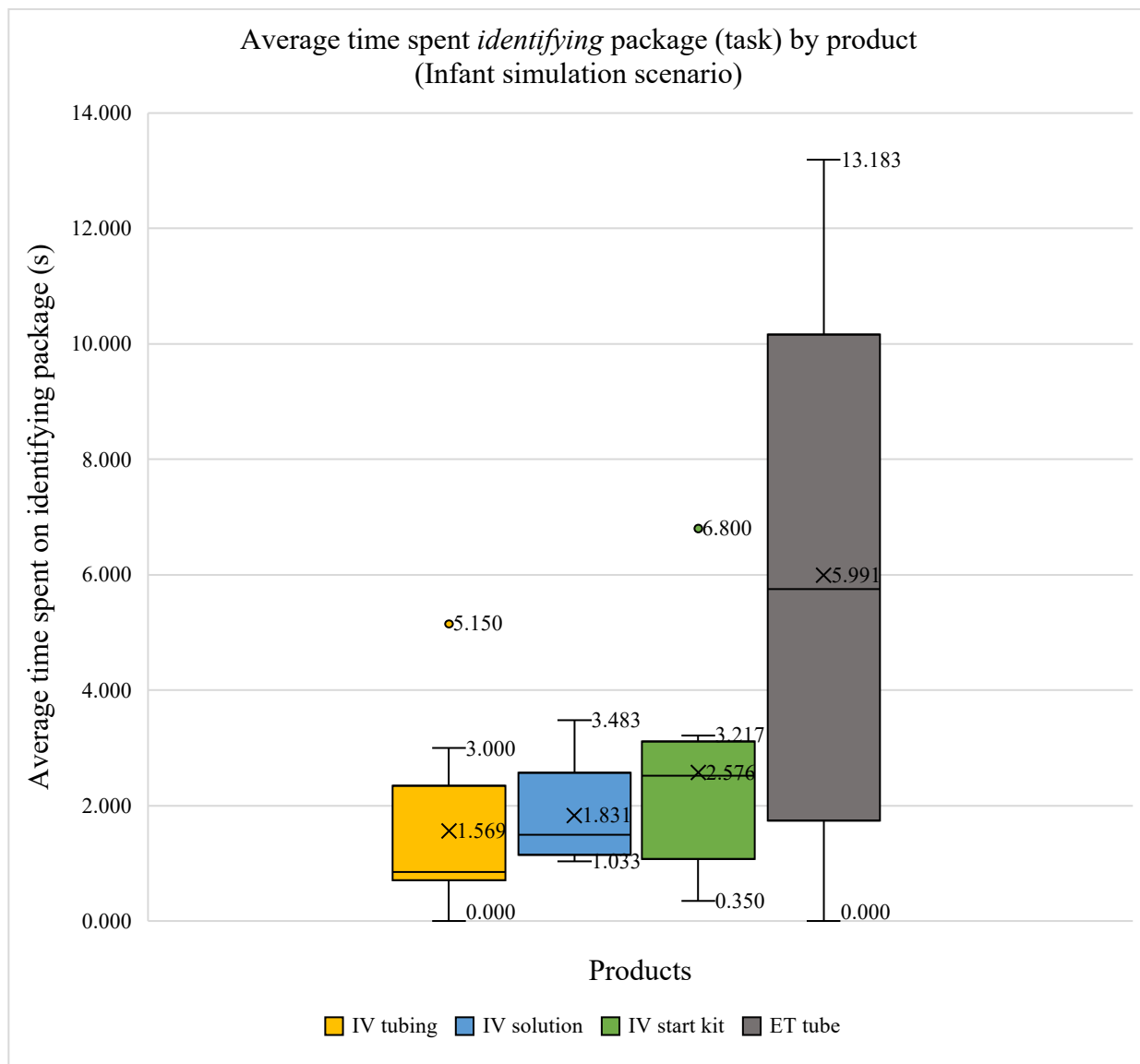


Figure 75. Average time spent identifying (task) package by product (Infant simulation scenario)

This task “identification” (See Figure 74 and 75) was subcategorized into the subtasks ‘product recognition’ and ‘information identification’. The ‘identification’ is a serial behavior of identifying the general product based on its shape and size (product recognition) and then using the information on the packaging and labeling to further illuminate details (information identification). However, information identification is not always necessary, and is seemingly dependent upon product type (are explicit details regarding size, type, etc. needed) and

participants' familiarity with the product (will be articulated in detail in the following section).

The time marks associated with the overall task 'identification' started from the first frame containing an appropriate product and the opened jump bag and ended at the first frame that the product information is out of focus. Product tendencies related to the task, "identification" were consistent across both simulation scenarios; time participants spent identifying ET tubes were the longest, followed by IV start kit. Details are articulated in the discussion related to the subtasks (product recognition and information identification) .

Recognizing a wanted/appropriate product, 'Product recognition'-subtask of identification

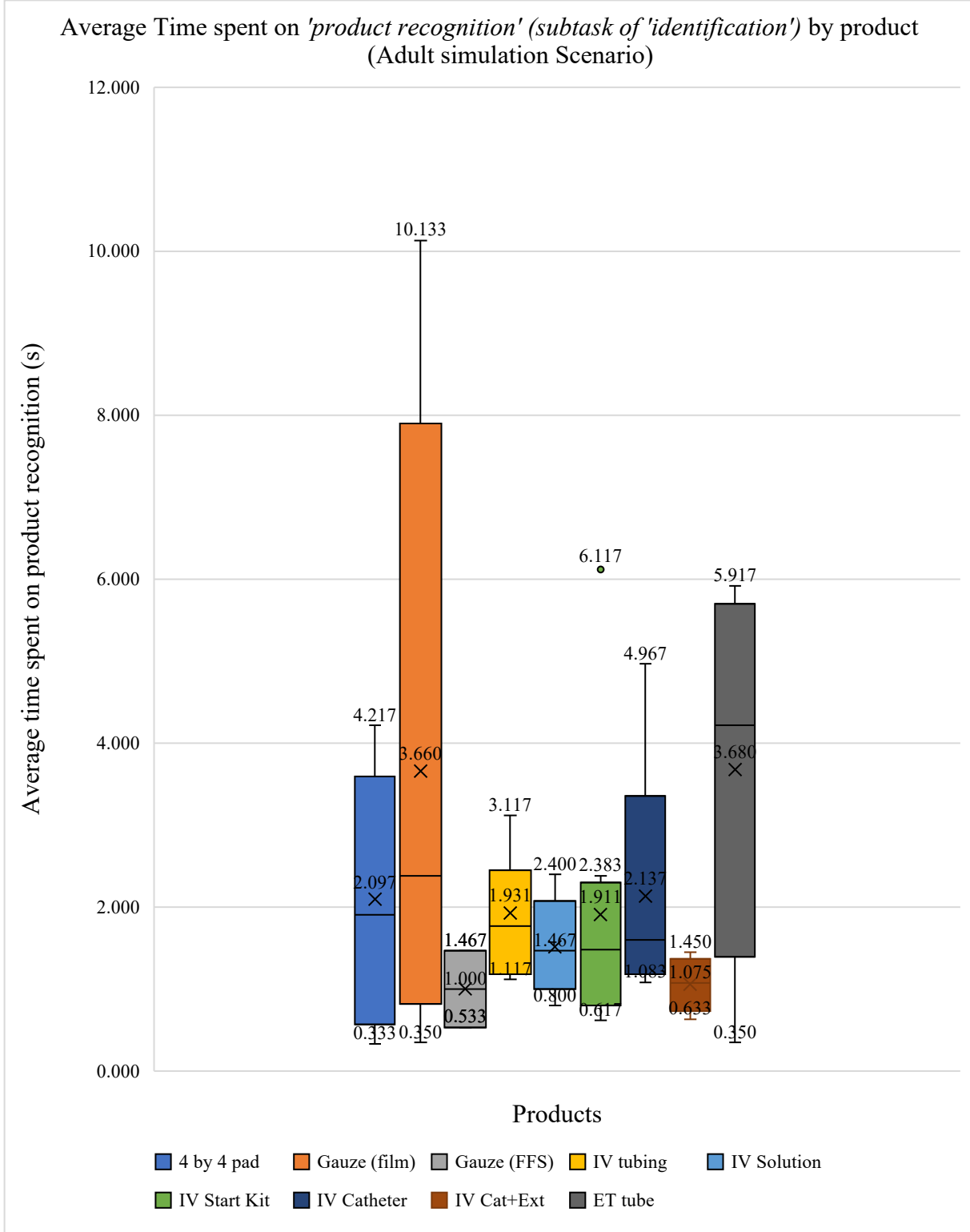


Figure 76. Average time spent on 'product recognition' (subtask) by product (Adult simulation scenario)

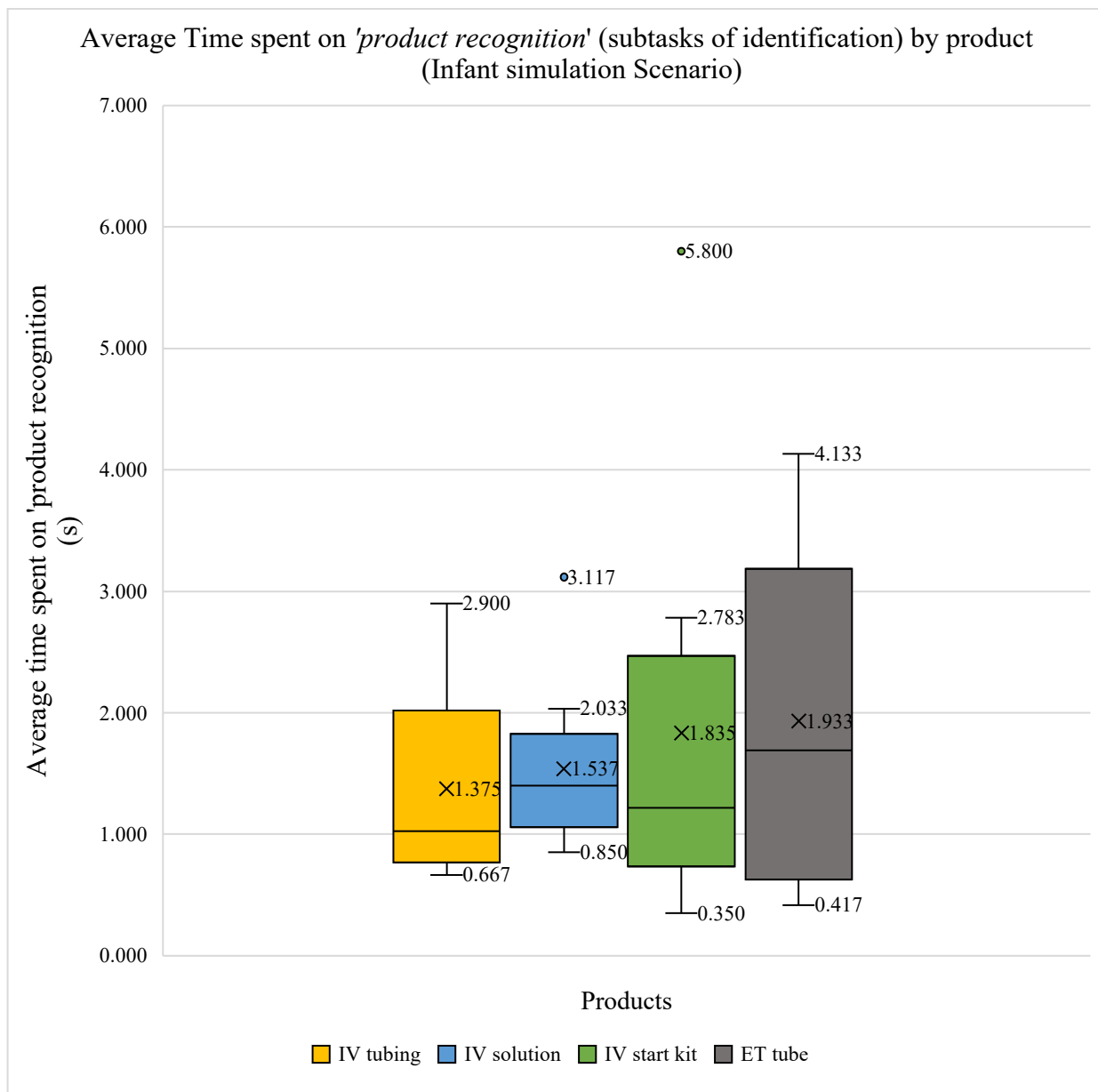


Figure 77. Average time spent on 'product recognition' (subtask of identification) packaging by product (Infant simulation scenario)

The subtask 'product recognition,' a subtask of 'identification' is the behavior involving recognizing the product generally from its location, size and/or shape. As such, "product recognition," was measured from the first frame the head mounted camera contained both the opened jump bag and the product being measured and lasted until a single frame before participants first touched the package. The time participants spent on the subtask of 'product

recognition’ represented the initial subtask which supported the task of identification. If a participant had prior use/familiarity with the packaged product, or the package was transparent, enabling them to view the product directly, or if they remembered (from the introductory phase of the research) where the needed product was stored, this process occurred very quickly.

Both Figures 76 and Figure 77 depict the average times participants spent on the subtask “recognizing the product” for each of the two simulation scenarios. Endotracheal tubes (ET) averaged the longest time across participants; this may be due to the fact that the transparent product was packaged in unknown poly plastic with a Tyvek lid stock and was stored in the back compartment of the jump bag (See jump bag section in the method); additionally, this product was present within the bag in different sizes (size 2.5 and 7).

By contrast, the gauze (film) was recognized more quickly by participants. The gauze (within the film) had a transparent package, which previous research suggests is preferred by healthcare providers because of ease of identification (J. Cai, 2012); findings gathered during Specific Aim 2 also support this idea. This design cue, combined with the fact that these were stored in the main compartment of the jump bag, along with the relative nonspecific nature of the product (the varied size of gauze isn’t as crucial as varied sizes of more explicit products) may have conspired to the reduced subtask (product identification) time.

Identifying information of product based on packaging 'product identification' – subtasks of identification

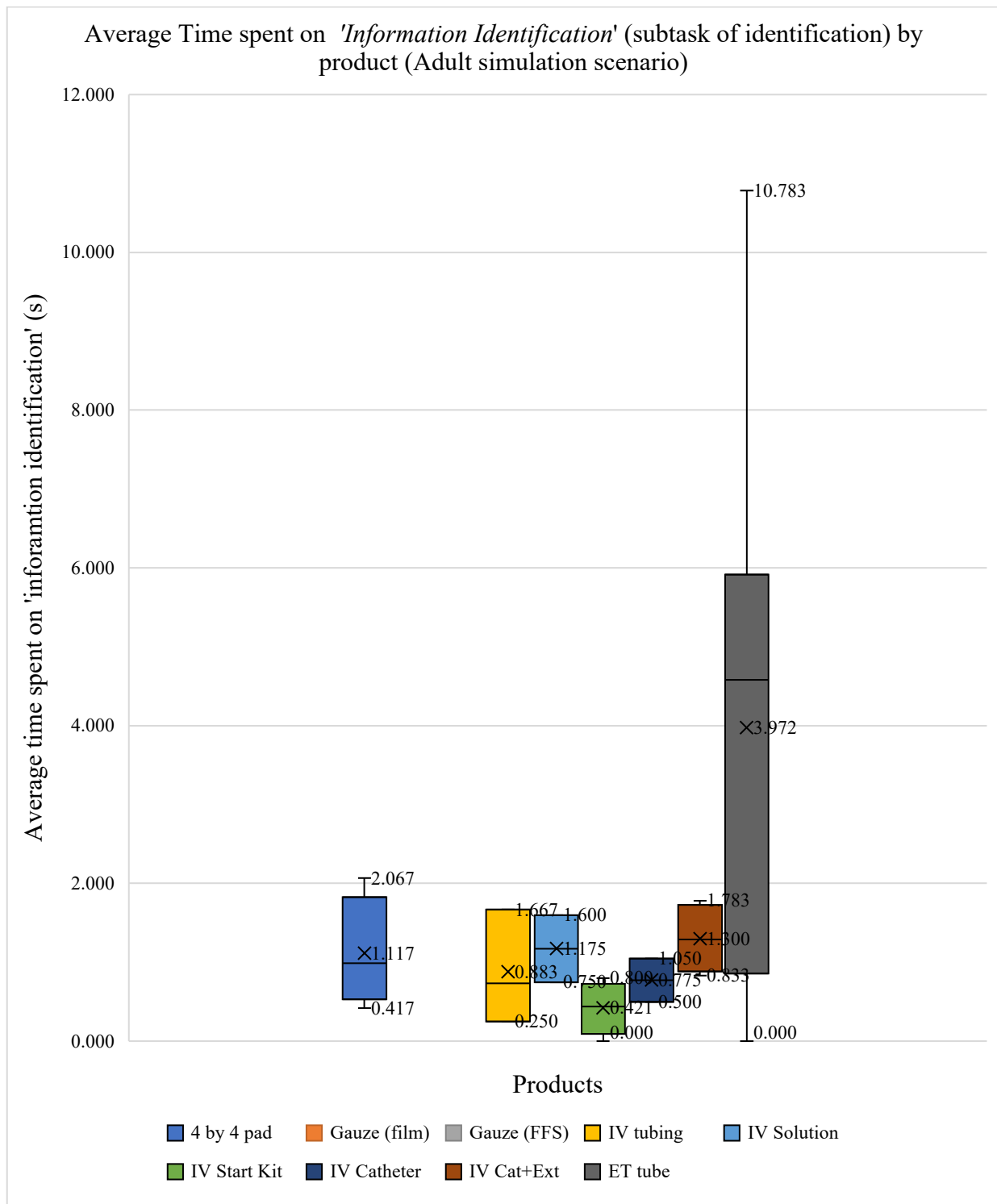


Figure 78. Average time spent on 'information identification' (subtask of identification) packaging by product (adult simulation scenario)

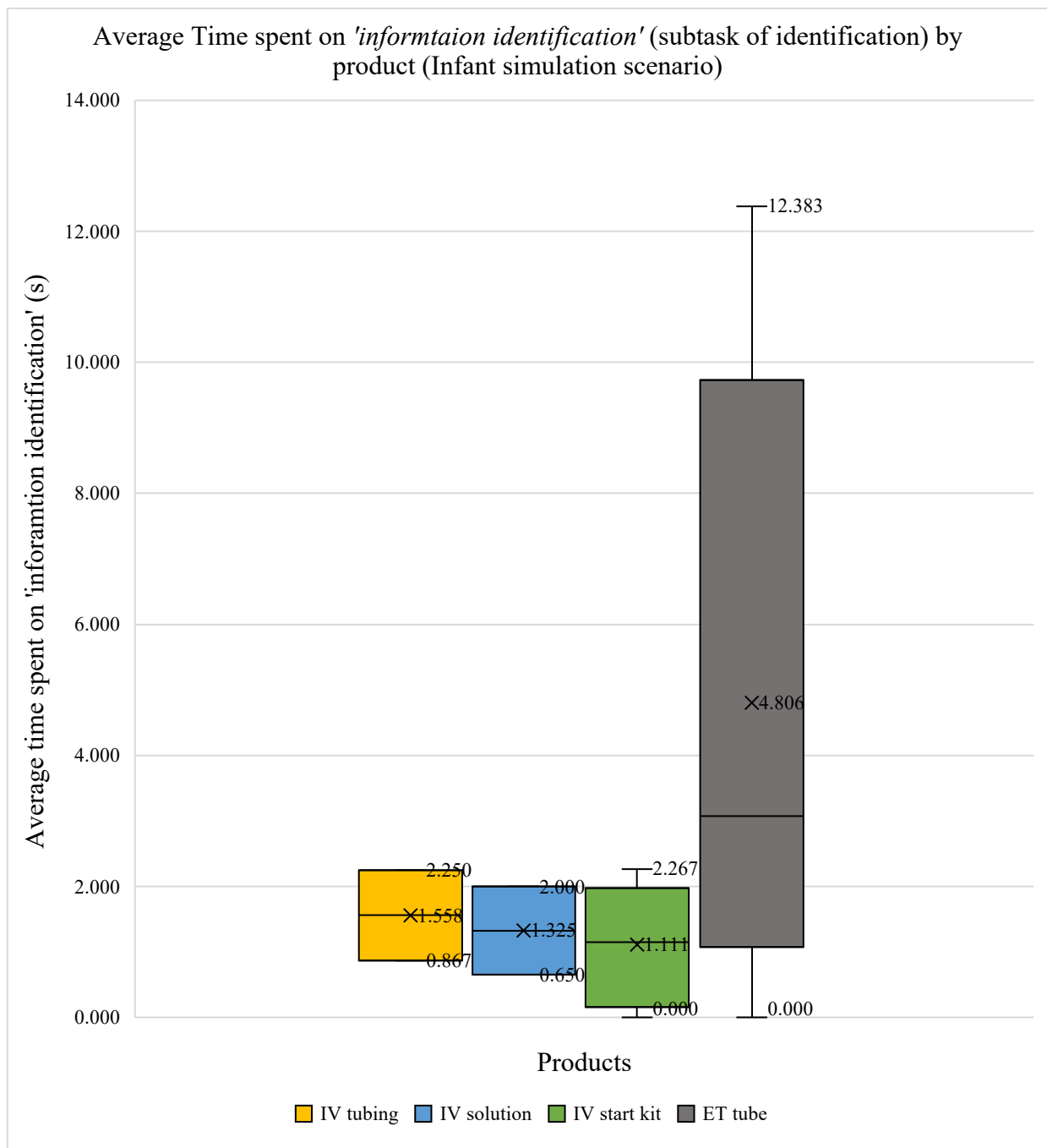


Figure 79. Average time spent on 'information identification' (subtask) packaging by product (infant simulation scenario)

'Information identification' is the one of subtasks of identification where participant's refined the identification of the product using critical information (e.g. sizing information, expiration date, and brand); that is, information that is more detailed than what was required or

investigated during the first subtask (product identification). This process may be skipped dependent upon: participants' familiarity with the product; how the product is packaged (i.e. transparent plastic film); the presence of only one product of this type; certainty of location, lack of the need for more explicit information (or lack of the presence of more explicit information), etc. For instance, our participants did not engage in this subtask when they interacted with gauze in either of the two package types (film and FFs); the packages did not contain detailed information and the product use likely does not demand it. The subtask time was defined as the frame after the participant had finished the first subtask, "identified the product", (i.e. the first frame that they touched the product), the "end point" was the first frame where the information appearing on the package was out of focus. The subtask "information identification" related to how labelling or other packaging signifiers enabled participants to quickly identify critical, specific information related to the product.

When averaged across participants (See Figure 78 and Figure 79), the product where participants recorded the longest amount of time in this subtask, 'information identification' was the ET tube. This parallels the findings from the semi-structured interviews (Specific Aim 2) that identification of ET tubes tends to be problematic for participants; specifically, they previously indicated (Specific Aim 2) that they have to pull all ET tubes out of the jump bag to identify the correct size. In our scenarios, there were two different sizes of ET tubes stored in one compartment. Participants needed to compare the two sizes in order to ensure they selected and used the correct size. Even in the second simulation scenario, where they were likely more familiar with the setting of the jump bag, they took extra time to identify product sizes using label information.

Opening package (Task)

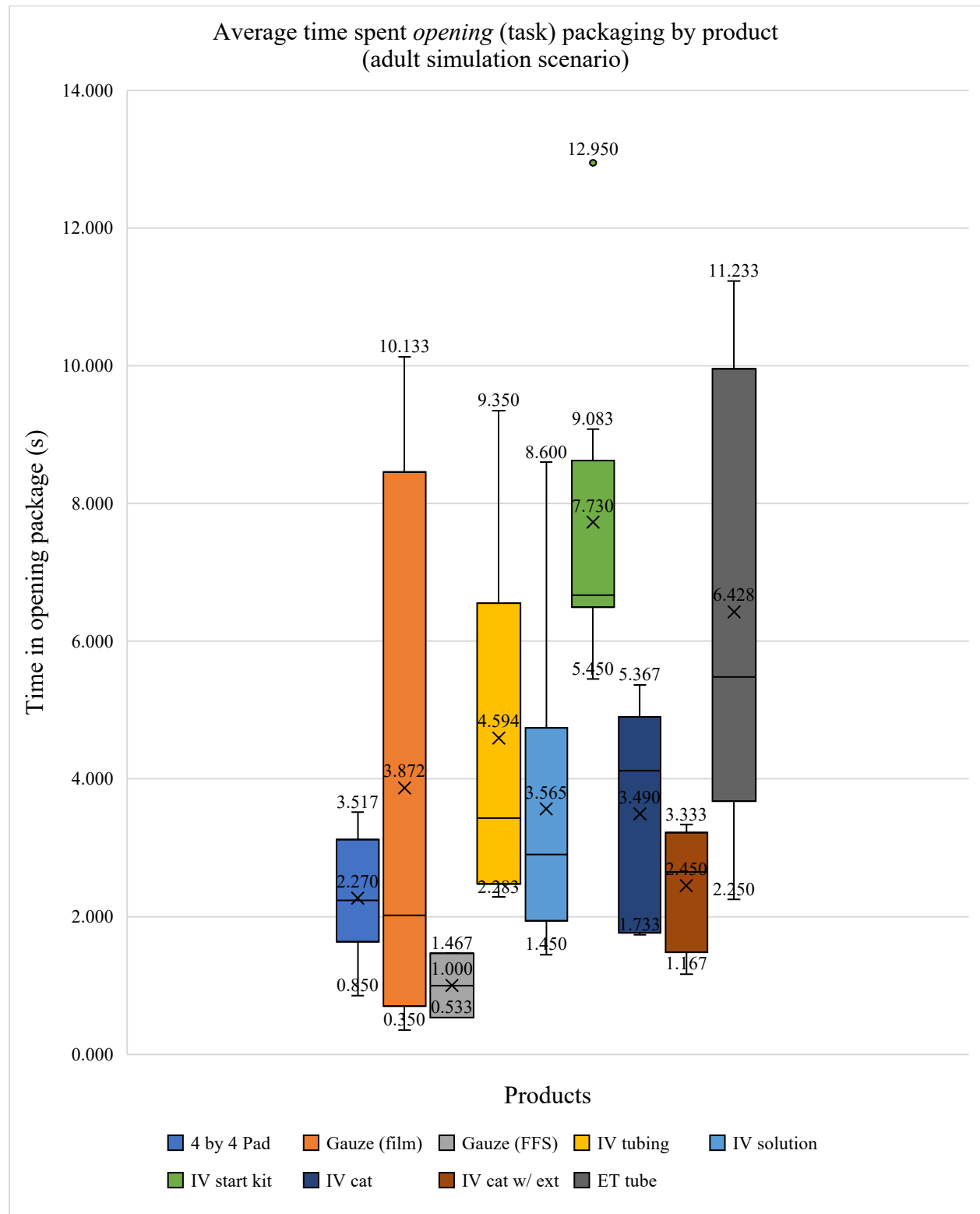


Figure 80. Average time spent opening (task) packaging by product (adult simulation scenario)

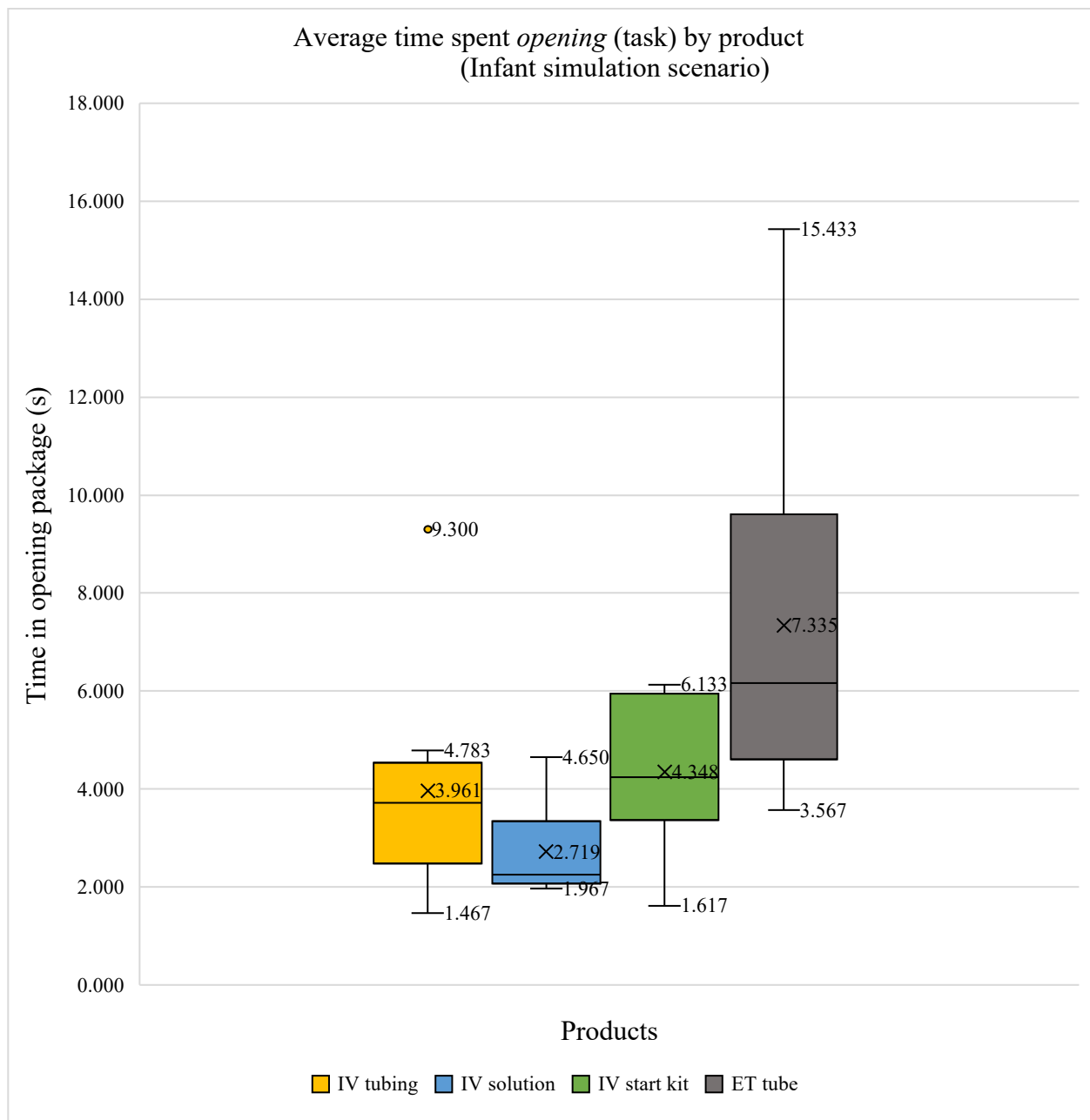


Figure 81. Average time spent opening (task) packaging by product (infant simulation scenario)

Average time spent on the task, opening, was explored and is presented in Figure 80 and Figure 81. The task start time was marked by the frame immediately following the end point of the task of identifying (sub task- identification of information); you'll recall that this was specifically the first frame that product information was out of focus. The end time marking the opening task ended at a frame containing one of participant's hands is off from the package. The

task, opening, was comprised of three specific subtasks (search for identification of opening area, mechanical approach, and mechanical manipulation).

Identification of opening feature on package 'Opening area recognition' - subtasks of opening

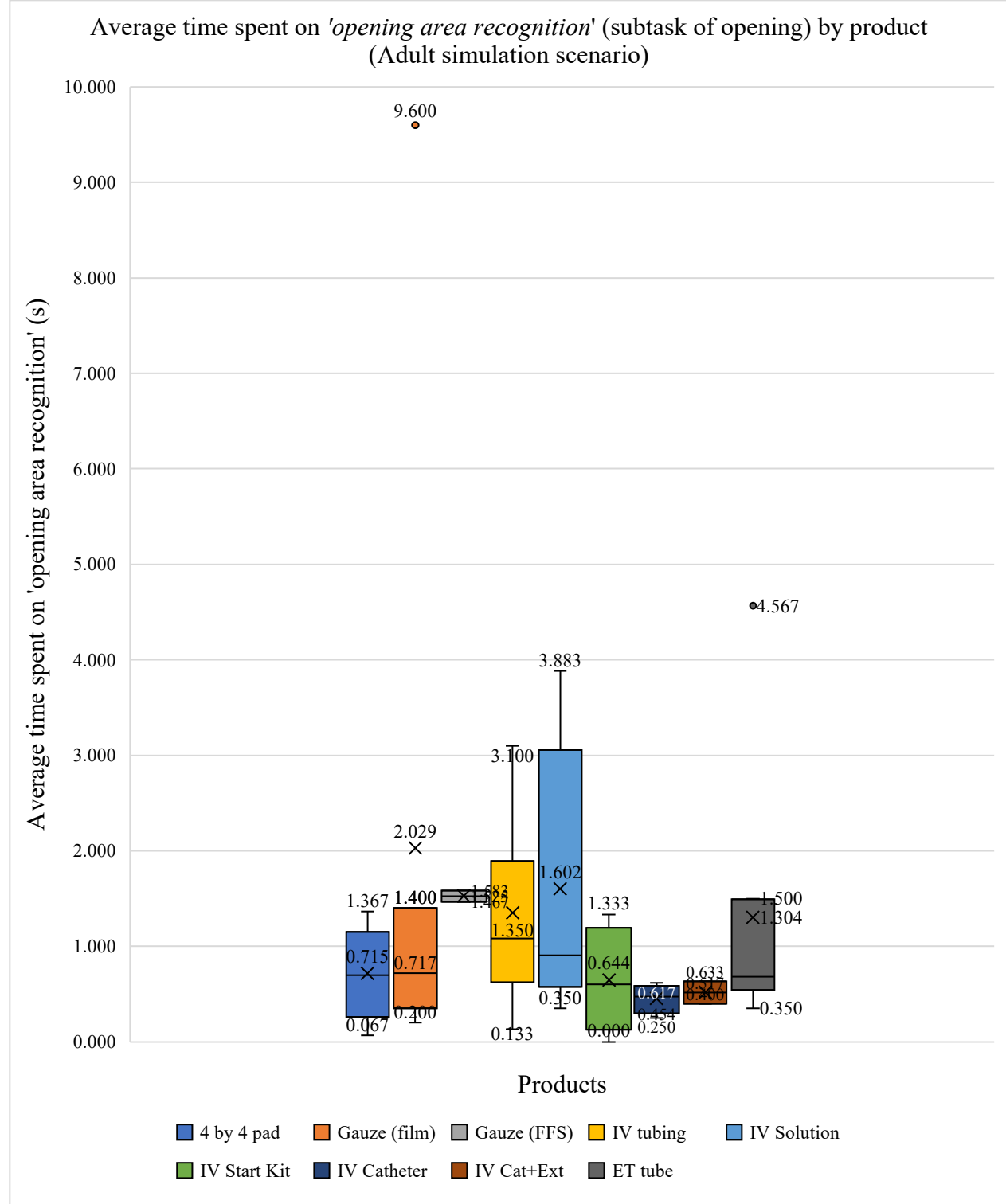


Figure 82. Average time spent on 'opening area recognition' by product (adult simulation scenario)

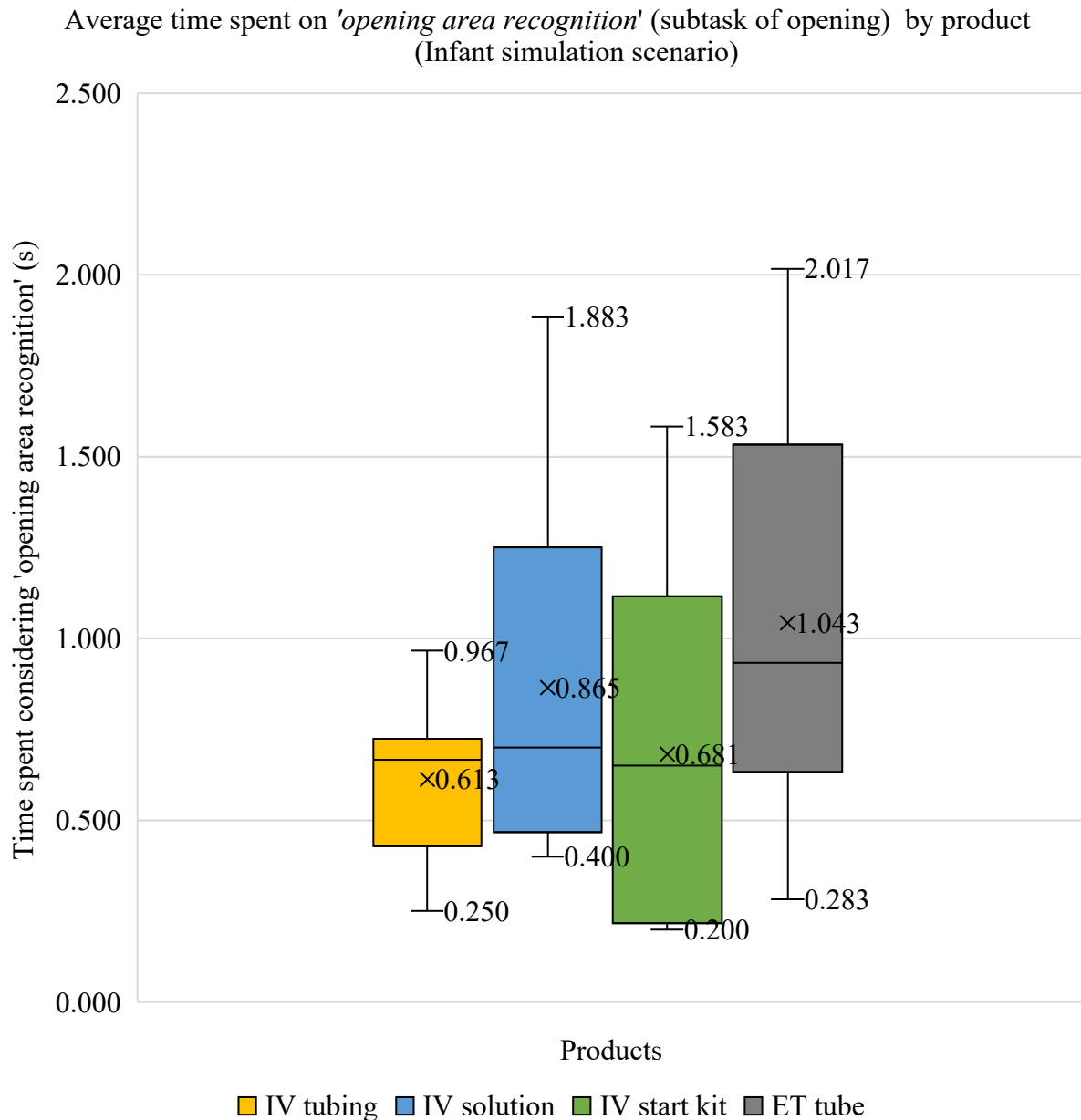


Figure 83. Average time spent on 'Opening area recognition' by product (Infant simulation scenario)

Recognizing the opening area was the first of the subtasks of 'opening,' specifically where participants looked for the opening feature (either with visual signifier or without visual signifier depending on the product) on the package to grip. As with other subtasks, this sometimes occurred quite rapidly, particularly when participants were quite familiar with the

products and their packages. Time participants spent in ‘recognizing the opening area’ was marked from the first frame after starting to show the out-focus product information and ended when the participant first touched the package near its opening feature (See Figure 82 and 83). This provides a form of evaluation regarding how effective the design features intended to serve as signifiers of opening are; under Norman’s construct, a measure of how the opening feature communicates its purpose (American National Standard & Advancing Safety in Medical Technology, 2013). Within the affordance frame, if the participant takes a comparatively long time to recognize the opening feature, it could be considered a ‘weak affordance’ while quickly (and correctly) identifying where to start would be considered as a ‘strong affordance’.

The results regarding ET tubes support that the mark does not have a dramatic effect with regard to efficiency (time to first notice the opening feature). Even during the second simulation scenario (infant simulation), where participants were presumably more familiar with the ET tube product (repeated in the second simulation) and where it was stored, this product generated the highest average time regarding the subtask “recognition of opening area.” Although the arrow mark did not enhance efficiency in searching for the opening feature, all participants who used the ‘IV catheter with an extension’ and ‘ET tube (size 2.5 and size 7)’ noticed the design signifiers (arrow mark) available (refer Table 55 for the pictures of these products’ opening feature) and opened the package near the arrow mark. This provides preliminary suggestion that these signifiers are a helpful indicator in identifying opening location.

Holding package in preparation for opening 'Mechanical approach' -subtasks of opening

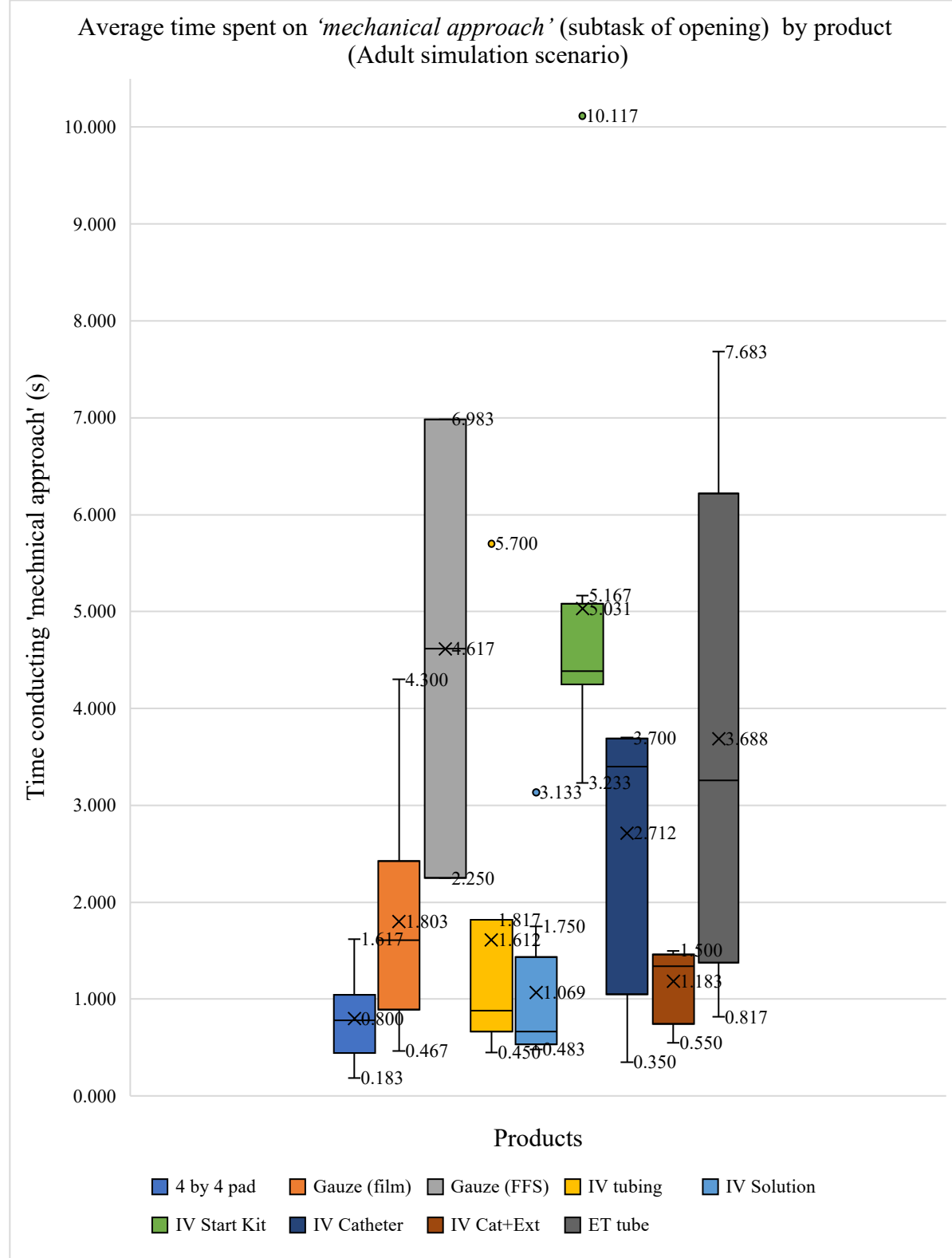


Figure 84. Average time spent on 'mechanical approach' by product (Adult simulation scenario)

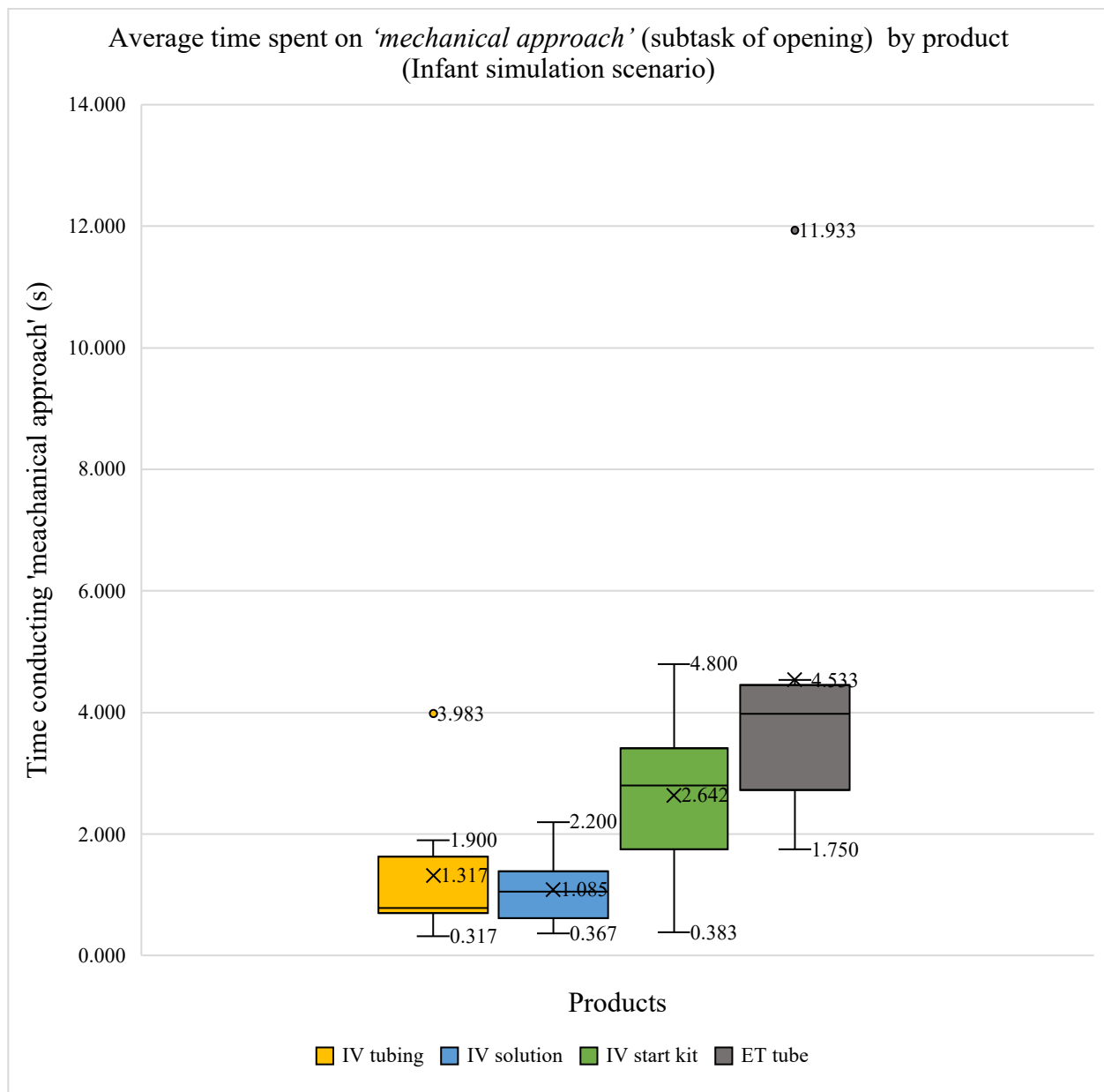


Figure 85. Average time spent on 'mechanical approach' by product (Infant simulation scenario)

Another of the subtasks which supported the task, package opening, was 'mechanical approach'; participants tended to hold the package for a moment prior to repositioning themselves to exert a force required to separate an interface or breach the material, to open the package. Generally, they would begin by repositioning their hands on the package and switching their opening approach (e.g. from hands to teeth). The second sub task termed mechanical

approach, began from the frame containing participant's first touch of the package near its opening feature (the endpoint for subtask-recognition of opening area) and ended when the participant began to shift their arms away from their body to begin the opening process. Time spent in the subtask 'mechanical approach' may provide an indication of how efficiently participants can interact with the packages' opening feature. For instance, the product with the longest time in the subtask in the adult patient scenario "mechanical approach" was the IV start kit; closer observation of the task suggested that participants had difficulty separating the interface of the packaging for this product (Figure 84 and 85).

Mechanical manipulation- subtasks of opening

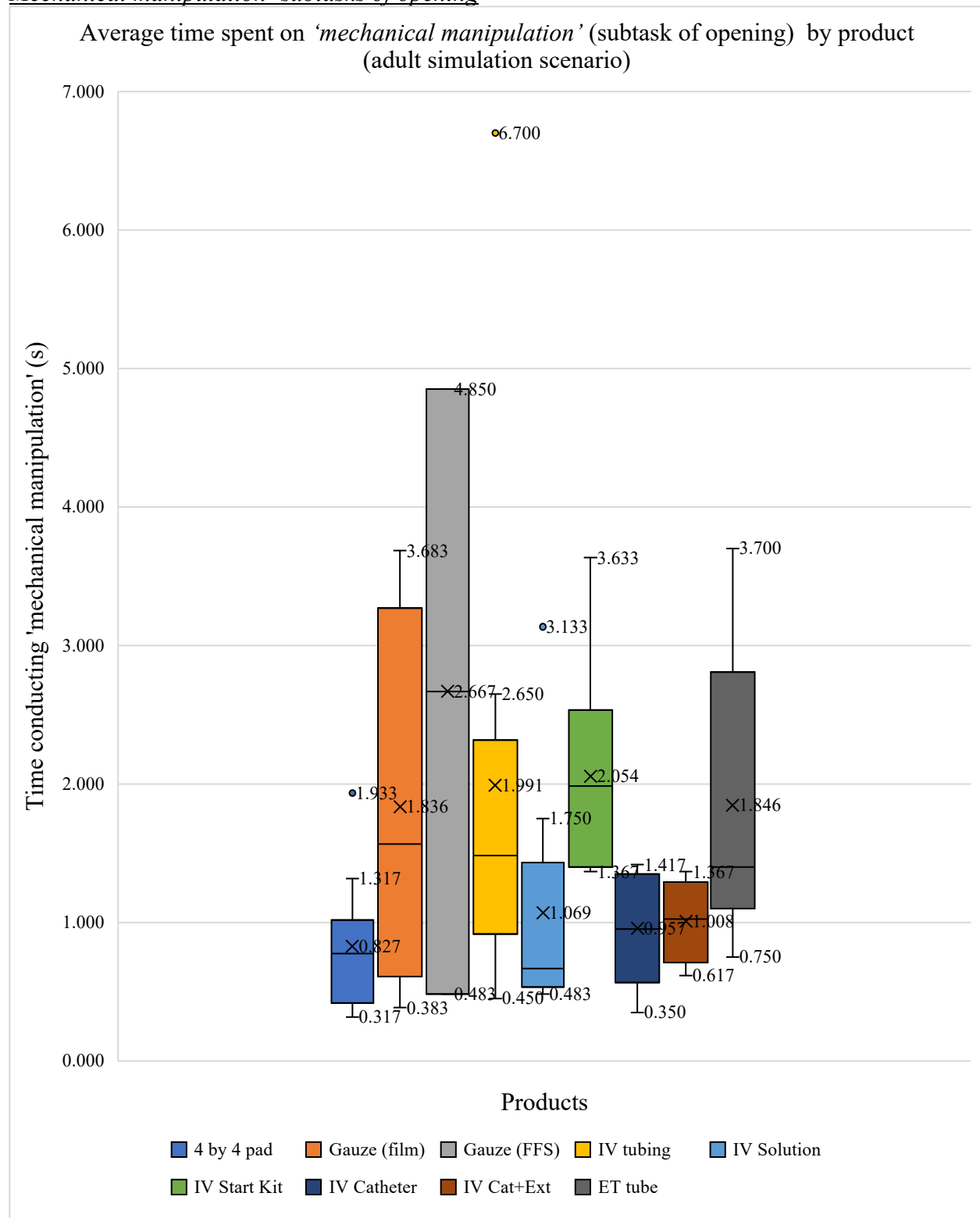


Figure 86. Average time spent on 'mechanical manipulation' by product (adult simulation scenario)

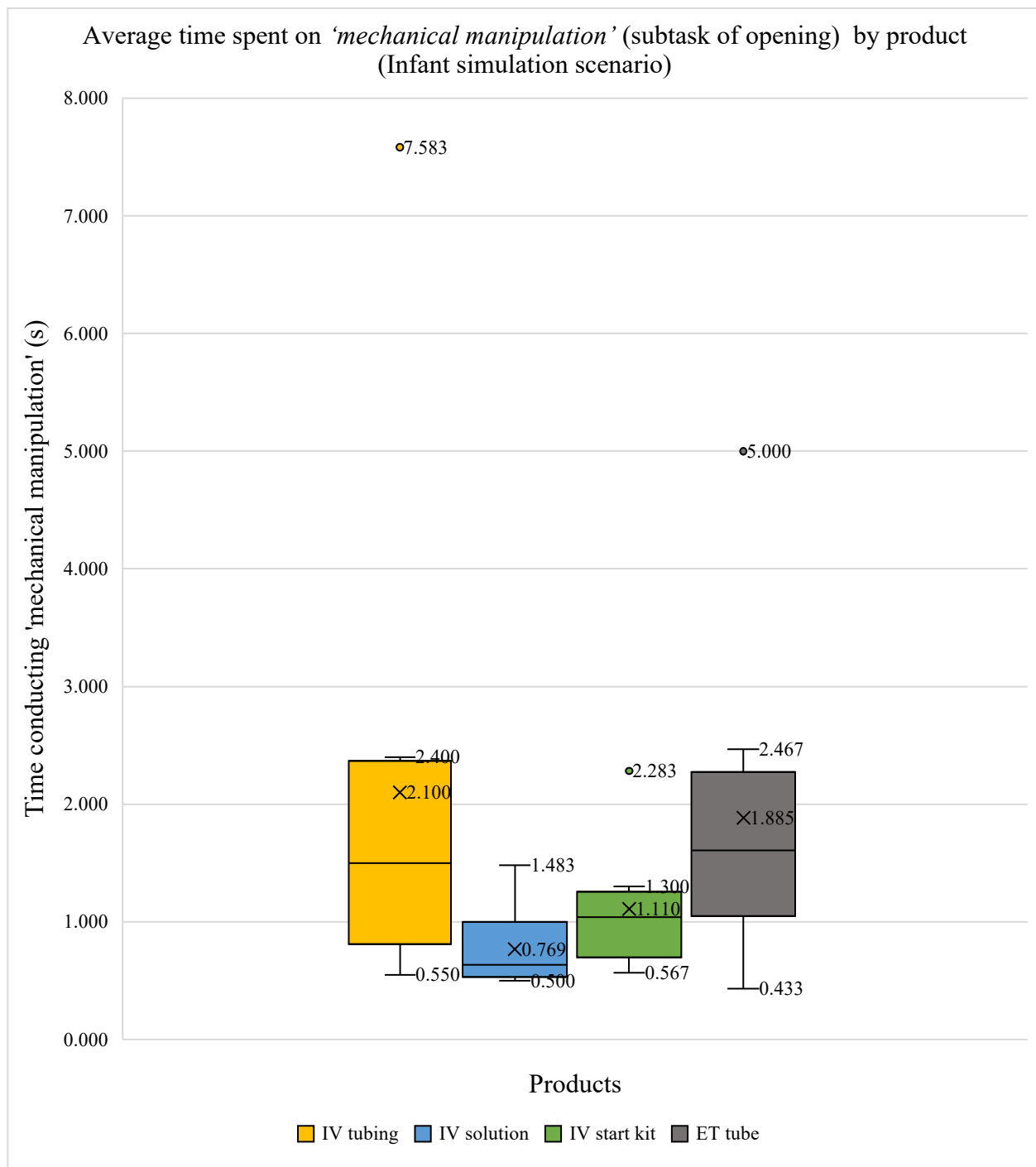


Figure 87. Average time spent on 'mechanical manipulation' by product (Infant simulation scenario)

The final subtask which supports the task “opening” was “mechanical manipulation” of the package where participants exert force to mechanically separate components of packages or breach a single material to expose the product to the surroundings. (See Figure 86 and 87). This

subtask was marked with the starting marked from the frame that the participants arms moving outward (the end point of the subtask ‘mechanical approach’). The end point of the ‘mechanical manipulation’ subtask was the frame immediately prior to their first touch of product. The implication of the time comprising ‘mechanical manipulation’ is related to packaging/seal structure but also dependent upon how participants mechanically manipulated the packages. For the products with a package type that was intended to be separated at a seal interface (e.g. IV start kit, ET tube, IV catheter, IV catheter with an extension, Gauze (FFS)) the ‘mechanical manipulation’ provides some indication of the forces required for separation.

When participants interacted with IV tubing (8 out of 9 for adult simulation scenario and 7 out of 9 for infant simulation scenario), most mechanically manipulated package by piercing the package from either the top and the side of them and/or pulling it apart, which required more force to completely open (meaning that an opened space is enough for participants to use product), rather than using the perforated line on the side of package (intended opening). The reason why it required more force for mechanical manipulation was that the package material has high elongation so that it might be easy to pierce the package, but it would be difficulty to provide enough space to use product by pulling them apart. This resulted in outliers of IV tubing data because they were pulling apart the highly elongated package. Also, this may be the one of reasons for difficulty opening medical devices reported in Chapter 4 (Aim 1) that ‘product required too much force to open (28.3% (n=113) of participants included in analysis (n=1,702) responded that they had had difficulty associated opening medical device in the past year of service)’.

Dispensing product (Task)

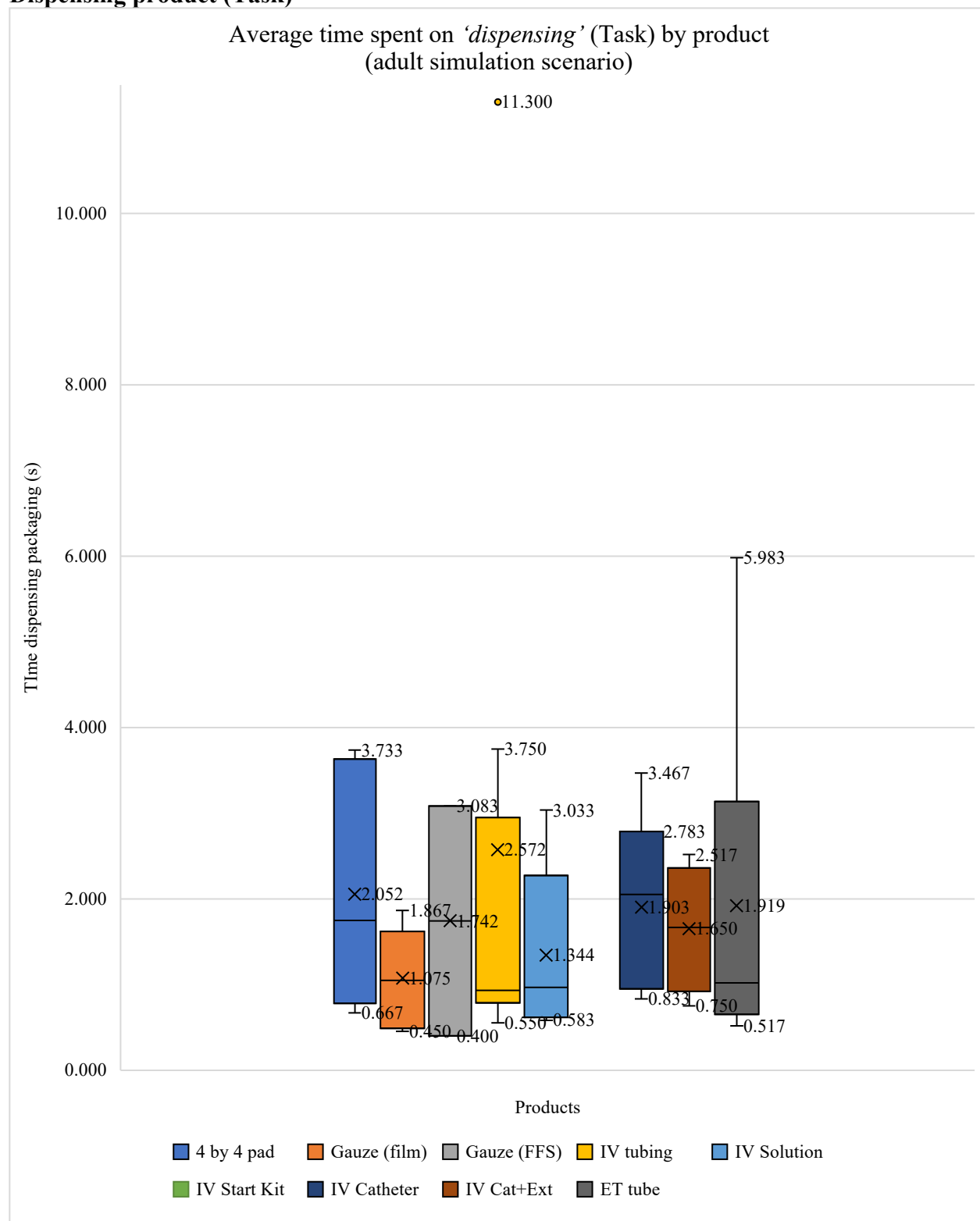


Figure 88. Average time spent on 'dispensing' (task) by product (adult simulation scenario)

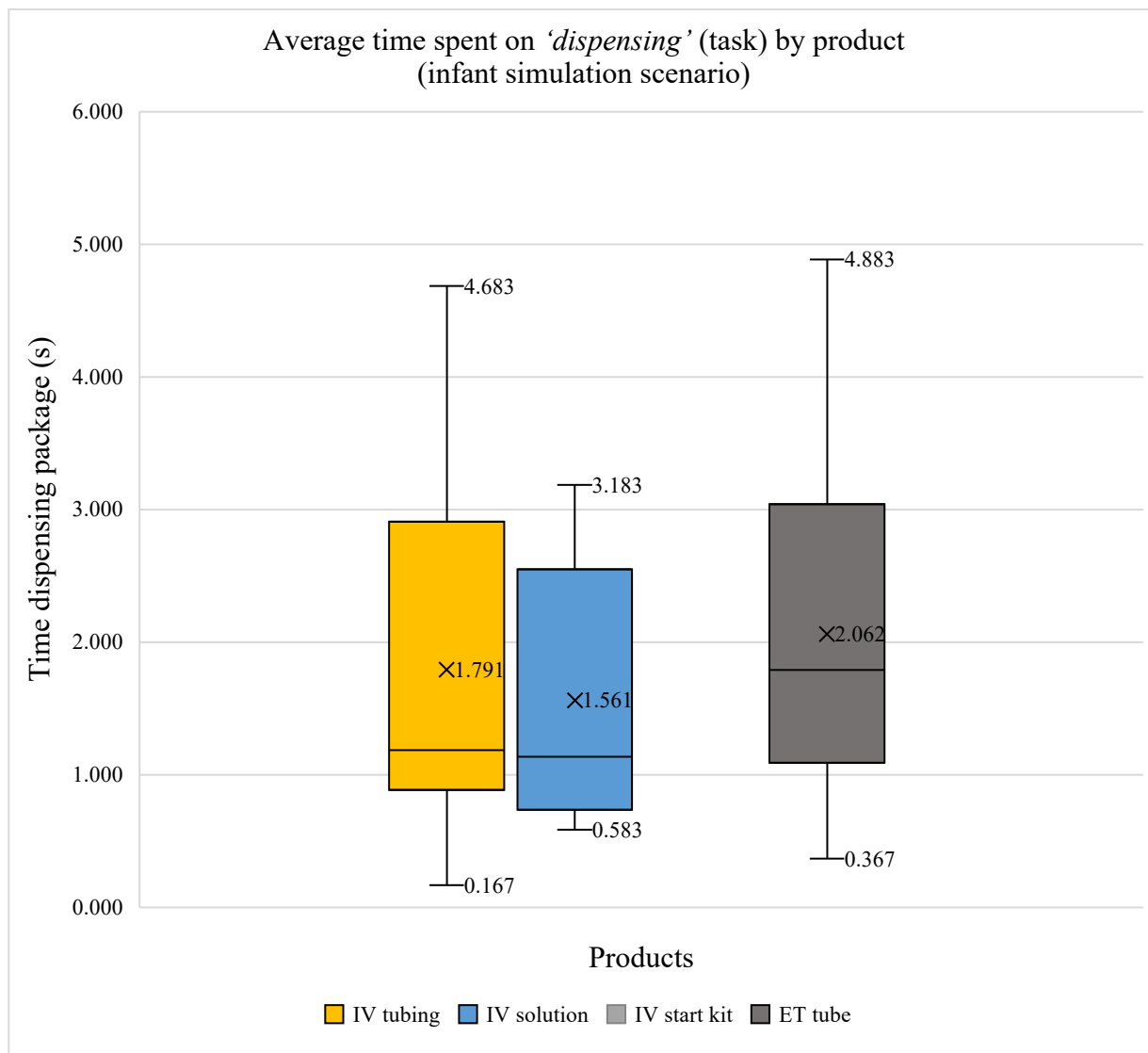


Figure 89. Average time spent on 'dispensing' (task) by product (infant simulation scenario)

The initiation of time for the task "dispensing" began when the participant first touched on the product until the product was completely out of the package. The time dispensing the product from its package suggests that how efficiently participants was able to remove a product (See Figure 88 and 89). Data collected during the adult simulation scenario (see Figure 88) suggested the average of dispensing time is typically less than 2.000 seconds, with one

exception, the IV tubing. Most participants did not open the IV tubing as intended ¹⁰ so that the material of package did not give them proper access to the product. As such, although further investigation is needed, this may imply that serialized behavior can impact the following steps of use of a product. Also, the data of the infant scenario supported this findings that one participants exhibited an unintended behavior ¹¹when opening the ET tube and this unintended behavior resulted in the longest time dispensing ET tube because when the participant pierced the package (unintended behavior), the space to dispense the product was not adequate so he manipulated the space again to enable efficient removal.

The average time dispensing the multiple products contained within the IV start kit was not recorded because its use was inherently different from the other products tested. Specifically, participants generally placed the kit next to them when administering patient care and then utilized the products item by item, so this would be the longest dispensing time if recorded.

¹⁰ Intended opening of IV tubing: Mechanically manipulate package using a perforated line located on the side of the ET tube package.

Observed unintended behavior on IV tubing: pierce the package or/and pull it apart once their gripping position is settled.

¹¹ Pierced the package

7.3.1.2 Satisfaction measures

Likert-Scales

Satisfaction measures were recorded using a Likert-scale (1-5; very unsatisfied to very satisfied with product) and were, again, analyzed during the post-hoc video review with participants. Table 62 shows the frequency and proportion of participants that responded for each of the tested products.

Colored columns indicate at least one response to the Likert-scale (Dark green- very satisfied, light green- satisfied, bright yellow-okay , light orange-unsatisfied and red- very unsatisfied).

Only 8 participants used the 4 by 4 pad. Of all products, the 4 by 4 pads were the only product that all participants were “very satisfied” with for all tasks (identifying, opening, and dispensing) for both the adult and infant scenarios. Participants were generally satisfied with IV solution, which only had reports of “satisfied” or “very satisfied” associated with all tasks.

Table 62. Satisfaction measures collected for each product during the adult scenario

	Tasks	Total N	Very satisfied N (%)	Satisfied N (%)	Okay N (%)	Unsatisfied N (%)	Very unsatisfied N (%)	Total (%)
4 by 4 pad	Identification	8	8 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	8	8 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Use	8	8 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
Gauze (Plastic flexible film)	Identification	6	6(100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	6	3 (50%)	1(17%)	1(17%)	0 (0%)	1 (17%)	100%
	Use	6	4 (67%)	33%	0 (0%)	0 (0%)	0 (0%)	100%
Gauze (FFS)	Identification	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	2	1 (50%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	100%
	Use	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%

Table 62. (cont'd)

IV solution	Identification	9	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	9	8 (89%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)	100%
	Use	9	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
IV Catheter	Identification	5	3 (60%)	2 (40%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	5	2 (40%)	1 (20%)	1 (20%)	1 (20%)	0 (0%)	100%
	Use	5	4 (80%)	1 (20%)	0 (0%)	0 (0%)	0 (0%)	100%
IV Catheter w/ extension	Identification	4	2 (50%)	0 (0%)	1 (25%)	0 (0%)	1 (25%)	100%
	Open	4	2 (50%)	1 (25%)	1 (25%)	0 (0%)	0 (0%)	100%
	Use	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
IV start kit	Identification	9	6 (67%)	1 (11%)	1 (11%)	1 (11%)	0 (0%)	100%
	Open	9	5 (56%)	2 (22%)	1 (11%)	1 (11%)	0 (0%)	100%
	Use	9	7 (78%)	2 (22%)	0 (0%)	0 (0%)	0 (0%)	100%
IV tubing	Identification	9	7 (78%)	2 (22%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	9	5 (56%)	1 (11%)	2 (22%)	0 (0%)	1 (11%)	100%
	Use	9	7 (78%)	0 (0%)	2 (22%)	0 (0%)	0 (0%)	100%
ET tube	Identification	8	4 (50%)	0 (0%)	3 (37%)	1 (13%)	0 (0%)	100%
	Open	8	3 (38%)	3 (38%)	2 (24%)	0 (0%)	0 (0%)	100%
	Use	8	5 (63%)	2 (25%)	1 (12%)	0 (0%)	0 (0%)	100%

*Fonts were bolded when 'ok' 'unsatisfied' or 'very unsatisfied' were reported.

Table 63 shows the results of the Likert reports for all products used during the infant scenario. A total of four products were descriptively analyzed. As before, satisfaction measures were grounded in tasks of concern (identifying opening and using). Of the four products, the IV solution was the only one that participants reported they were “mostly satisfied” with regarding the task of identifying. ‘Very unsatisfied’ scale was again reported to opening IV tubing.

Colored columns indicate at least one response to the Likert-scale (Dark green- very satisfied, light green- satisfied, bright yellow- okay, light orange-unsatisfied and red- very unsatisfied).

Table 63. Satisfaction measures collected for each product during infant scenarios

Products	Tasks	Total (N)	Very satisfied (%)	Satisfied (%)	Okay (%)	Unsatisfie d (%)	Very unsatisfied (%)	Total (%)
IV solution	Identification	9	8 (89%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)	100%
	Open	9	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
	Use	9	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100%
IV start kit	Identification	7	5 (71%)	0 (0%)	0 (0%)	2 (29%)	0 (0%)	100%
	Open	7	4 (57%)	1 (14%)	2 (29%)	0 (0%)	0 (0%)	100%
	Use	7	6 (86%)	0 (0%)	0 (0%)	1 (14%)	0 (0%)	100%
IV tubing	Identification	9	8 (89%)	0 (0%)	1 (11%)	0 (0%)	0 (0%)	100%
	Open	9	4 (44%)	1 (11%)	2 (22%)	0 (0%)	2 (22%)	100%
	Use	9	8 (89%)	0 (0%)	0 (0%)	1 (11%)	0 (0%)	100%
ET tube	Identification	9	5 (56%)	1 (11%)	2 (22%)	1 (11%)	0 (0%)	100%
	Open	9	4 (44%)	2 (22%)	3 (33%)	0 (0%)	0 (0%)	100%
	Use	9	7 (78%)	1 (11%)	1 (11%)	0 (0%)	0 (0%)	100%

7.3.1.3 Error (affordance) measures

Based on definitions adapted from ISO (related to effectiveness), behaviors that were not intended, unintended behaviors, were considered to be “errors” in use. Paramedics’ interactions with packages of products were captured within the electrically recorded video frames (See Appendix V for all of their interactions). Although all subtasks were captured (See Appendix V), in this section, only the subtasks related to, ‘opening’ were assessed for error (with no direct measure of participant attention (i.e. eye tracking) this was impossible for identification.

Table 64. Affordance behaviors by products (Adult simulation scenario) – Green cells indicate intended behavior and red colored cells indicate unintended behaviors

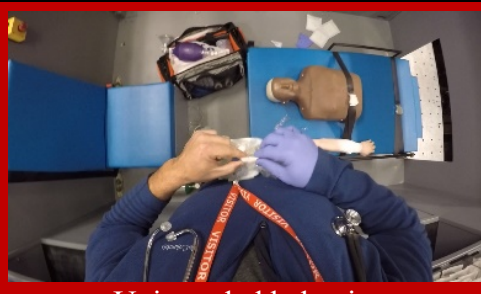
# of Participant	4 by 4 pad	Gauze	IV tubing
1	 Unintended behavior	 Unintended behavior	 Unintended behavior
2	N/A	N/A	 Unintended behavior
3	 Unintended behavior	 Intended behavior	 Unintended behavior

Table 64. (cont'd)

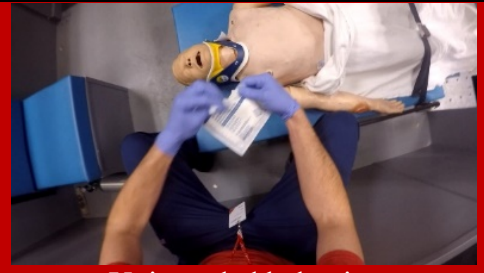
4	 Unintended behavior	 Intended behavior	 Unintended behavior
5	 Unintended behavior	 Intended behavior	 Unintended behavior
6	 Unintended behavior	 Intended behavior	 Unintended behavior

Table 64. (cont'd)

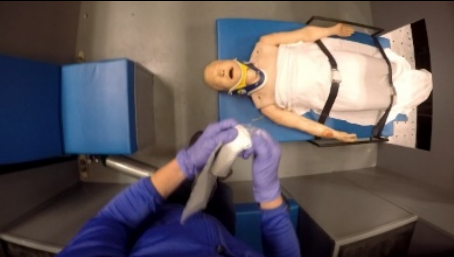
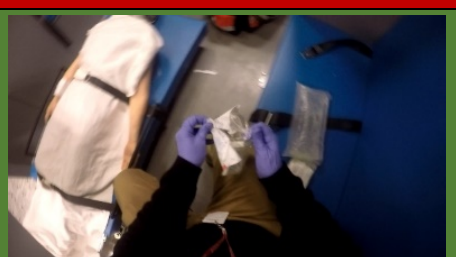
7	 Unintended behavior	 Intended behavior	 Unintended behavior
8	 Unintended behavior	 Unintended behavior	 Unintended behavior
9	 Unintended behavior	 Intended behavior	 Intended behavior

Table 64. (cont'd)

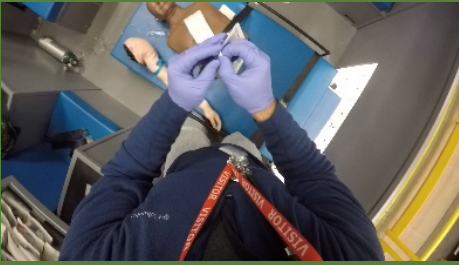
# of Participant	IV solution	IV catheter	IV start kit
1	 Intended behavior	 Intended behavior	 Unintended behavior
2	 Intended behavior	 Intended behavior	 Unintended behavior
3	 Intended behavior	 Intended behavior	 Unintended behavior

Table 64. (cont'd)

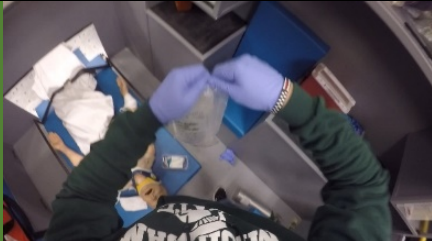
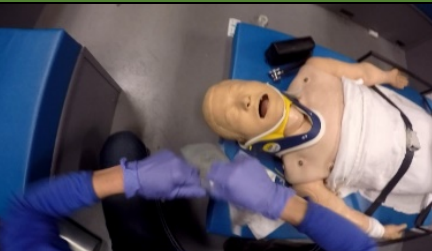
4	 Intended behavior	 Intended behavior	 Unintended behavior
5	 Intended behavior	 Intended behavior	 Unintended behavior
6	 Intended behavior	 Intended behavior	 Unintended behavior
7	 Intended behavior	 Intended behavior	 Unintended behavior

Table 64. (cont'd)

8	 Intended behavior	 Intended behavior	 Unintended behavior
9	 Intended behavior	 Intended behavior	 Unintended behavior

Table 64. (cont'd)

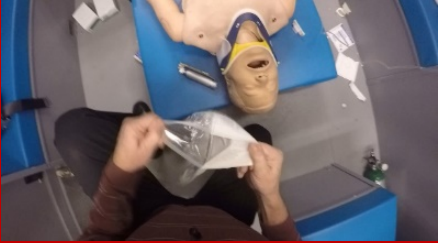
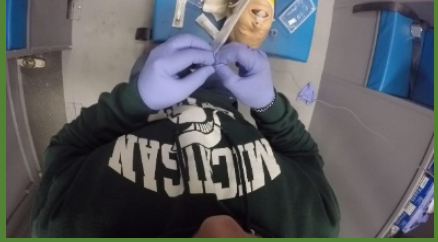
# of Participant	ET tube
1	 Intended behavior
2	N/A
3	 Intended behavior
4	 Intended behavior

Table 64. (cont'd)

5	 Intended behavior
6	 Intended behavior
7	 Intended behavior
8	 Intended behavior

Table 64. (cont'd)

9	 Intended behavior
---	---

Table 65. Affordance behaviors by products (Infant simulation scenario) – Green cells indicate intended behavior and red colored cells indicate unintended behaviors

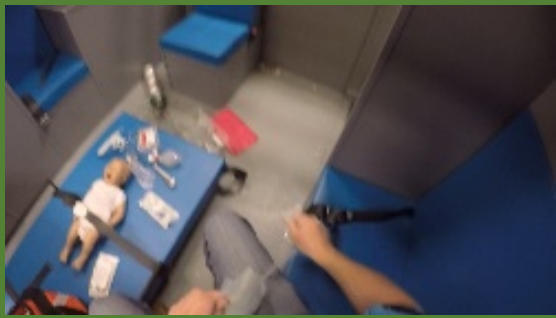
# of Participant	IV tubing	IV solution
1	 Unintended behavior	 Intended behavior
2	 Unintended behavior	 Intended behavior
3	 Intended behavior	 Intended behavior

Table 65. (cont'd)

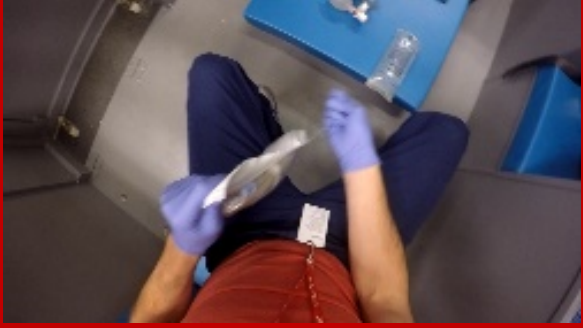
4	 Unintended behavior	 Intended behavior
5	 Unintended behavior	 Intended behavior
6	 Unintended behavior	 Intended behavior

Table 65. (cont'd)

7	 Unintended behavior	 Intended behavior
8	 Unintended behavior	 Intended behavior
9	 Intended behavior	 Intended behavior

Table 65. (cont'd)

# of Participant	IV start kit	ET tube
1	 Unintended behavior	 Intended behavior
2	 Unintended behavior	 Intended behavior
3	 Unintended behavior	 Intended behavior

Table 65. (cont'd)

4	 Unintended behavior	 Intended behavior
5	N/A	 Intended behavior
6	 Unintended behavior	 Unintended behavior

Table 65. (cont'd)

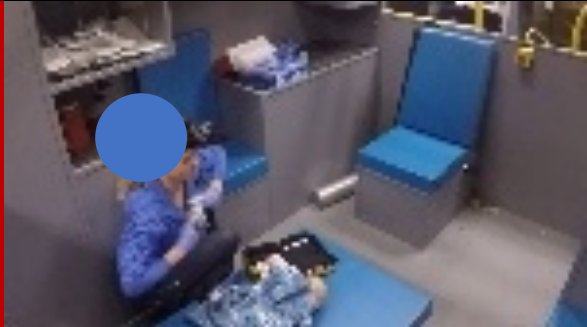
7	 Unintended behavior	 Intended behavior
8	 Unintended behavior	 Intended behavior
9	 Unintended behavior	 Intended behavior

Table 64 and Table 65 shows a single, captured frame depicting unintended behaviors by product. *All* participants that utilized the ‘4 by 4 pads’, exhibited unintended behaviors during the task, opening, by tearing open the pouch. Specifically, they opened the product from the middle (either top or side) using a tearing motion as opposed to separating the two layers of package and opening it from the top as intended. Also, the IV start kit, packaged in a chevron pouch, elicited unintended behaviors. Specifically, 9 out of 9 participants gripped one of the large corners of IV start kit (unintended behavior on chevron type) to open. For the gauze (film), 1 out of 6 participants used their ‘teeth’ to open while the participant performed other tasks using their other hand (e.g. held ‘4 by 4 pad’ onto the simulated patient’s injury on its right arm). This same unintended behavior, use of teeth, was observed when a single participant used the gauze (FFS). Unintended behaviors also occurred when opening the IV tubing 8 out of 9 (in adult simulation scenario) and 7 out of 9 (in infant simulation scenario) participants utilized ‘brute force’ to pierce the package to open the ‘IV tubing,’ as opposed to opening along the vertical perforation intended to assist with opening. This was accomplished by either pulling the material itself apart or piercing the package.

Unintended behaviors were **not** observed on opening actions associated with the IV solution; all of participants used the notch on package to open. Also, all participants utilizing the ‘IV catheter with an extension (4 out of 4) opened them as intended; they opened the package beginning at the arrow mark signifier. We could construe from this observation that participants selectively use their coping strategies dependent upon the package type and the explicit circumstances surrounding the product (context). For instance, even though both the opening feature of the IV solution and the IV tubing did not clearly communicate (hidden affordance), participants (either through prior familiarity or attentive behaviors) identified the opening feature

(notch) on the IV solution while only a few of participants used the perforated line to open IV Tubing.

Table 66 and Table 67 present the frequency and proportion of unintended behaviors and intended behaviors in adult simulation scenario and infant simulation scenario, respectively. The tendency of observed intended behaviors for products are similar across the two simulation scenarios. Intended behaviors were not present for the ‘IV solution (9 out of 9)’ for either simulation scenario. Also, most of participants opened the ‘ET tubes (8 out of 8 participants in the adult simulation scenario) as intended during the adult simulation, while 1 out 9 participants exhibited unintended affordance behaviors during the infant simulation scenario.

Table 66. Unintended behaviors recorded (Adult simulation scenario)

	Total (N)	Intended behavior N (%)	Unintended behavior N (%)
4 by 4 pad	8	0 (0%)	8 (100%)
Gauze (film)	6	5 (83%)	1 (17%)
Gauze (FFS)	2	1 (50%)	1 (50%)
IV solution	9	9 (100%)	0 (0%)
IV Catheter	5	5 (100%)	0 (0%)
IV Cat w/ extension	4	4 (100%)	0 (0%)
IV start kit	9	0 (0%)	9 (100%)
IV tubing	9	1 (11%)	8 (89%)
ET tube	8	8 (100%)	0 (0%)

Table 67. Unintended behaviors recorded (Infant simulation scenario)

	Total (N)	Intended behavior N (%)	Unintended behavior N (%)
IV solution	9	9 (100%)	0 (0%)
IV start kit	8	0 (0%)	8 (100%)
IV tubing	9	2 (22%)	7 (78%)
ET tube	9	8 (89 %)	1 (11%)

7.4 Overall discussion of usability measures with exit survey commentary

Comments were collected utilizing an exit survey during the course of the post-hoc video review for the purpose of probing how context and experiences shape the way that participants interact with the packaging. This section will be articulated as emerging themes in the comments with the three-usability metrics (efficiency, satisfaction and error) by products.

- 4 by 4 pads

A common theme that emerged when discussing satisfaction and identification of the 4 by 4 gauze pads was ‘familiarity (P1, P9)’. The participants consistently indicated that they were satisfied with the product because they can quickly and easily identify them. Participant 7 provided insight into why participants might have consistently indicated satisfaction identifying the product, specifically, that ‘Almost all [4 by 4 pads] packages looks like this’ (allowing them to easily identify it).

However, efficiency measurements did not support the idea that participants quickly identify this product. The average time of identification of the 4 by 4 pads was about two times higher

than the other products (e.g. IV Catheter and Gauze (FFS)- see Table 74 and 75 for its efficiency). When discussing satisfaction regarding opening, participants preferred the way they opened (- an unintended behavior where they tore or ripped the package from its middle) as it was perceived to be ‘faster and easier’ (P6). Interestingly, one participant expressed that he would not change his way to open even if there is an indicator [to open package] because it is faster (P5). Finding a tab and pulling it apart is difficult (P5). Also, a comment was made that removing the pad out of package is ‘not a challenge’ (P1) because he can grip the package with his two hands (not a finger) to tear it.

- Gauze Packages (Plastic flexible film) and Gauze (Form fill seal)

When discussing the process of identifying the plastic gauze (plastic flexible film), participants stated a tendency to look for white paper and clear back, indicating text was not how they identified this product (P1) as the package is clear (P6). This preference for transparency parallels previous research with participants in perioperative settings who indicated that transparent packaging enabled them to forego reading, saving critical time (J. Cai, 2012). Although the preference for transparent packaging is a popular sentiment among healthcare providers, a single responder from our online survey (Specific Aim 1) reported (in the free response field) that transparency can be “problematic when identifying medications” as ‘Print on transparent containers [and] no contrasting background makes them blend in’. Another participant in the formative usability test (Specific Aim 3) indicated that it is “hard to recognize what product is in there because both package and the tube are transparent (P9)” in reference to ET tubes.

Not surprisingly, satisfaction can be tied to other metrics we are assessing regarding usability, namely the error of a package design. Specifically, participant 1 opened the gauze package with his teeth (an unintended affordance behavior), describing the experience as, ‘... not an easy package to use (P1) as there is no pull tab’ and he had to ‘readjusted on my [his] teeth to tear a tiny piece of it first (P1)’.

This same, unintended behavior (use of teeth) was employed when a different participant opened the gauze (FFS). He reported ‘okay’ as the satisfaction level associated with opening of this product. When asked about any challenge that he had specifically for this product, the participant argued this type of package is not familiar and suggested a ‘twist open’ package as it is easier than peeling (P8).

- IV solution

Overall, participants were satisfied with their experience with opening IV solution packages although the time that they spent recognizing the opening feature was the longest or the second longest. This product was identified primarily by its size relative to other items critical to care (P1); identification is further supported by the fact that they can see the product because its package is clear and clean (P1). This also means that identifying the notch is more difficult than the participant’s current package design (P3) but once the notch is found, it is easy to tear open (P2, P4). Additionally, at least one participant recommended, a bigger hanger tab (P2)

- IV Catheter

While some participants expressed their satisfaction with their experience with the opening feature related to IV catheters: ‘it has a good pull tab’ (P6) and ‘better than other brands

[that he uses]' (P2), other participants were not satisfied with the opening feature, stating that 'the tab is hard to find' (P3) and 'getting the tab is a bit tricky' (P5). Although the average time finding an opening feature (opening area recognition) is the shortest and no unintended behaviors were observed for this product, reported satisfaction levels with regard to opening were varied (from very satisfied to unsatisfied). This is an important insight which supports the notion that users' assessment of satisfaction is not necessarily indicative of usability (2018 International Organization for Standardization [ISO], 2018); that is, just because they like it does not necessarily mean that the package is optimized for performance. This is consistent with findings from Perez who found perioperative personnel reported a high preference for a sterile barrier system as easy to use (in terms of aseptic presentation) that actually resulted in one of the highest rates of contact with non-sterile surfaces of the four treatments she tested (Perez et al., 2018).

- IV Catheter with an extension (lidded rigid tray)

Participants stated that this product and package was not familiar with them; 'Never seen a needle like this before' (P7) and 'usually used for the hospital setting' (P1). One participant expressed that this unfamiliarity made the scenario critical (P1) although no reasons were reported. This sentiment transferred into satisfaction metrics. One participant reported being very unsatisfied with his/hers experience with regard to identification of the product. Despite the fact that many indicated that they were unsatisfied with their ability to identify this product, it was not apparent in their efficiency measures relative to the other products (See Table 74 and 75). This reinforces the notion that satisfaction does not directly correlate to the other two factors of usability which are intended to measure how quickly and accurately a design can be used (efficiency and error).

- IV Start Kit

Unintended behaviors were observed across all participants using the IV start kits, which participants gripped from the corner of the chevron seal as opposed to the top center (intended behavior). This parallels to Trier's work that participants in his focus group indicated ease of opening and identification of the corner of chevron type package (Trier, 2016). Although the corner of package has more space to grip than the top center (see Table 55), efficiency related to mechanical approach was comparatively low (the longest time in adult simulation scenario and second longest in infant simulation scenario). Participant comments provide some insight into the low efficiency level; 'tabs are small (P2)'. Many recommended design changes to assist, a bigger tab is suggested (P2, P3, and P9) and the use of signifiers; arrow [mark] for what corner they are supposed to opening (P2) or 'pull here' text on the tab (P9).

- IV tubing

The size and the shape of the IV tubing was reported to help them to identify this product (P1). In terms of opening, their experiences were varied; 'The material is easy to grip and pierce (P1)' while another participant expressed that 'Terrible unlike the [IV] solution, Very cumbersome, does not work very well – not perforated and managed plastic to get it open (P2)' – participant did not notice the existence of the perforated line.

- ET tubes

When identifying the size of the product on the label, the participants pointed out that the font size of ET tube product is not big enough to quickly identify (P2 and P3) another foregoes the font, looking for the particular shape (curved) to identify the product (P1). Others noted, it is

hard to recognize the product by seeing through the package because both package and the tube are transparent (P9). These statements are consistent with the result of the efficiency metrics which indicate the average time that participants spend identifying this product is the longest among those we tested. In contrast to the low efficiency, participants appear generally satisfied with this design; only one participant reported ‘unsatisfied’ across all simulation scenario.

7.4.1 Cleaning and Contamination test

Evidence of transmission of the CLUE spray was found near the simulated patient’s mouth on the adult simulator (for 5 out of 9 participants) and on the infant simulator (for 2 out of 9) and near the simulated wound of the adult patient (for 2 out of 9). Finally, 5 medical devices used appeared to have simulated contaminant on them (See Table 68). Not a single participant cleaned the inside of ambulance after each run despite being asked to “prepare for the next run as you normally would” before the first scenario began and between the first and second scenario.

Table 68. The evidence on transmission of the simulant on medical device and the patient simulator

# of participant	Adult simulation scenario	
	Medical device	Body
1	N/A	

Table 68. (cont'd)

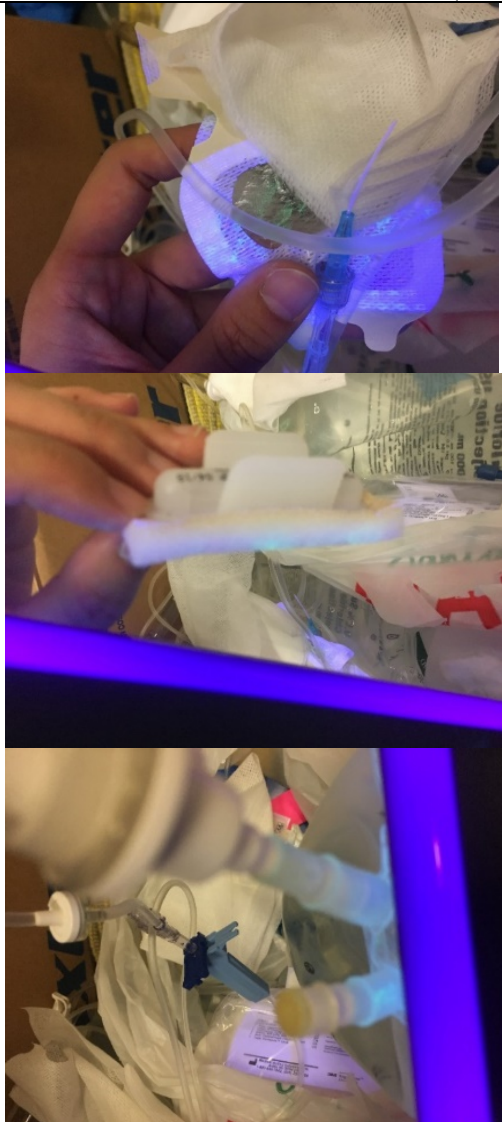
2		N/A
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Table 68. (cont'd)

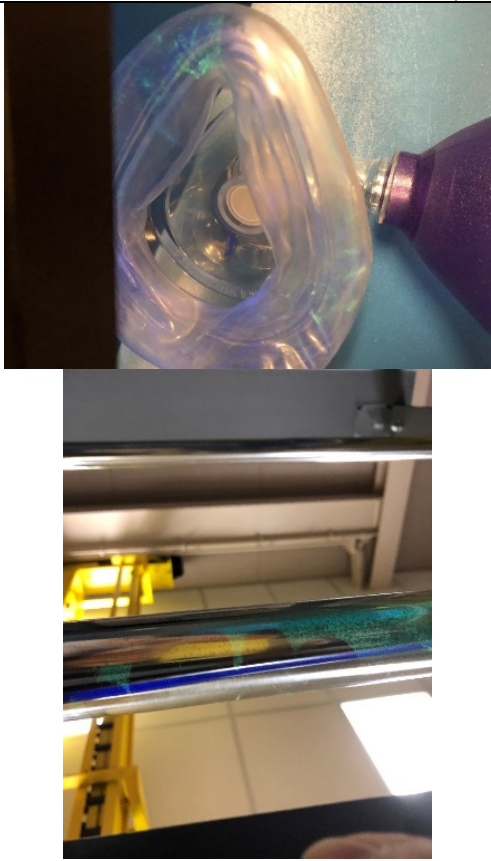
3		
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Table 68. (cont'd)

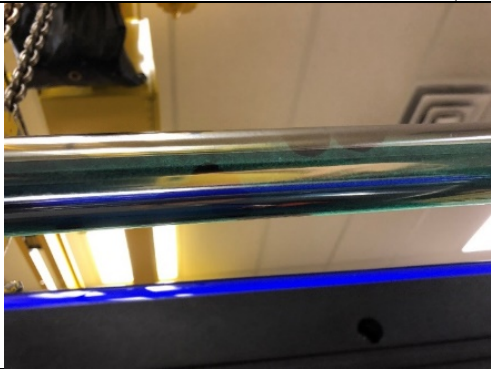
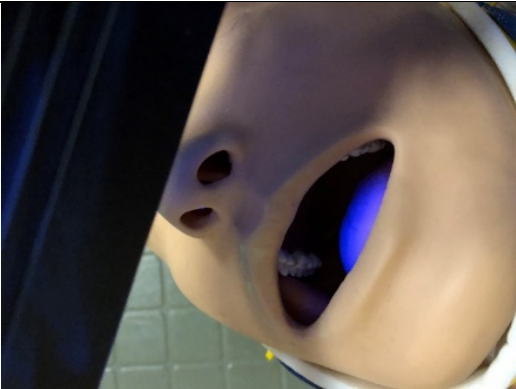
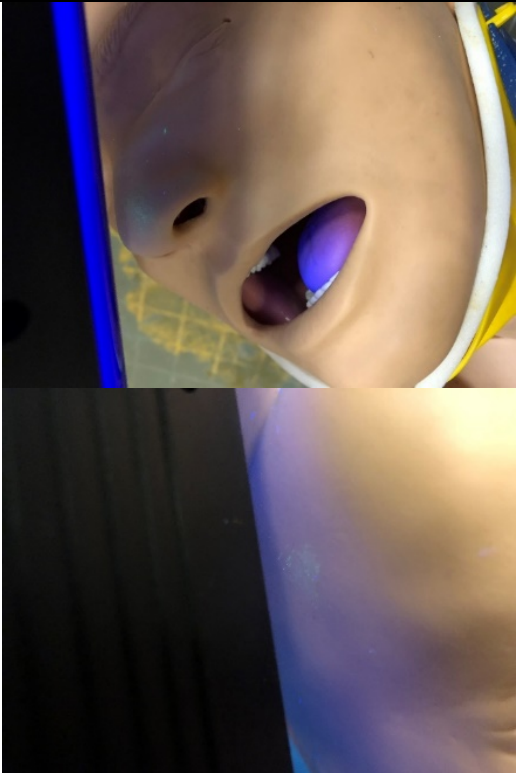
4		N/A
5	N/A	N/A
6	N/A	
7	N/A	N/A
8	N/A	

Table 68. (cont'd)

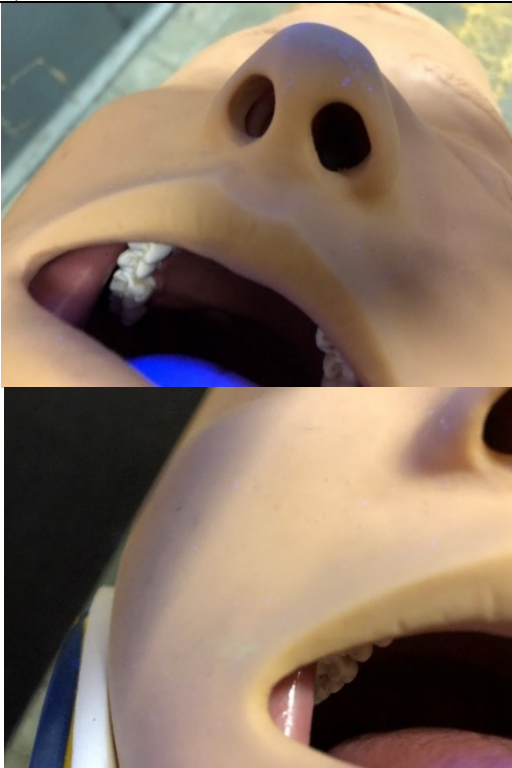
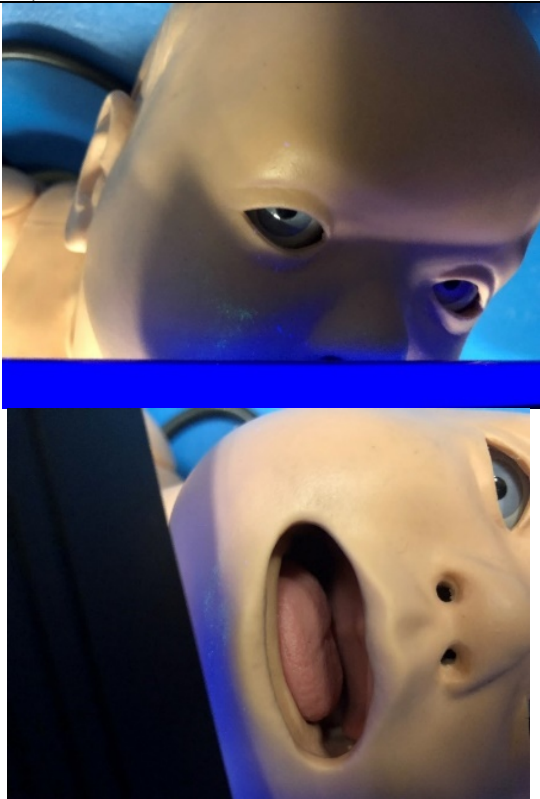
9		
# of participant	Infant simulation scenario	
	Medical device	Body
1	N/A	
2	N/A	N/A
3	N/A	N/A
4	N/A	N/A
5	N/A	N/A

Table 68. (cont'd)

6		
7	N/A	N/A
8	N/A	N/A
9	N/A	N/A

Chapter 8. Overall conclusions, future studies and limitations

8.1 Overall conclusions

Prehospital contexts (specifically the ambulance) are flowing and urgent. EMS providers need to simultaneously take care of multiple tasks within their limited and moving setting, which are significantly different from the perioperative setting. Despite obvious contextual differences in these settings, package designs seem to primarily consider the perioperative setting. According to Cai (2012), commonly reported difficulties for perioperative personnel include: hard to open packages, cluttered label contents, difficult identification of opening features, unyielding material during opening, and difficulty in separating package interfaces. Not surprisingly, our participants, paramedics who perform care in more austere context reported experiencing kindred difficulties in the prehospital setting.

That said, there were differences as well. Specifically, participants repeatedly reported the availability of a single hand to open packaging. This finding is not present in any of the prior work reported with perioperative personnel, likely due to the controlled setting and standards and guidelines that form practice for appropriate aseptic technique (Association of perioperative Registered Nurses [AORN], 2006; Association of Surgical Technologist [AST], 2008)

The finding that designers should design for one handed use when considering healthcare products represents a significant contribution. From a Universal Design perspective (The Center for Universal Design [The center for Universal Design], 1997), this hits the Principal number one, “Equitable use.” That is, the design should be as accessible to a one-handed user as it is to someone with two hands.

Another finding specific to the population of EMS providers relates to the gender imbalance of this population. A majority of EMS providers (specifically paramedics and

Emergency Medical Technicians) are male (75% nationally certified EMS professionals in the United States (The National Registry Data Dashboard, 2017). Package designs were consistently reported to have too small of an area to grip to open packages (one of the reported difficulties was ‘Too small of an area to grip’ in the online based survey). Men are documented to have larger hands than women (American National Standard & Advancing Safety in Medical Technology, 2013); this potentially explains the situations related to difficulty in gripping due to “too small of a grip area” based on the results from the survey. Additionally, small grip areas will only enable the weakest of the three pinch grips ¹². **Packaging designers should account for demographic factors during the design phase and enable the strongest possible grip for all users.**

The IV start kit was demonstrative of some of the difficulties reported by our test participants. When they positioned their hands on the gripping area, separating the two layers was not easy for them, largely due to the small gripping space on the top of the package. Despite a preference for IV start kits in the guided interview, the efficiency is very low on mechanical approach (subtasks of opening)- the longest time they spent separating (mechanical approach) the layers of IV start kit in the adult simulation scenario and the second longest time performing the same in the infant simulation scenario. A similar theme emerged from the 4 by 4 pads. Although users reported being “highly satisfied” with this product regarding opening (8 out of 8 participants in adult simulation scenario), unintended behaviors ¹³were observed across all participants (100 %, 8 out of 8 participants). **This indicates, in brief, the preference and reported**

¹² 1) Pulp Pinch Pull (PPP) grip, Lateral Pinch Pull (LPP) grip and Chunk Pinch Pull (CPP) grip (Yoxall et al., 2007)

¹³ Unintended behaviors on the 4 by 4 pad product: participants (8 out of 8) opened it from the side of packaging by tear opening (while the intended behaviors were to separate the layers of package and then pull open.)

satisfaction of the user does not necessarily mean that the packaging is more usable/functions optimally for its intended use. Asking users their preference and satisfaction does not equate to usable, optimized designs. As the healthcare packaging industry struggles to objectively address multiple standards and regulations (American National Standard & Advancing Safety in Medical Technology, 2013; Center for Devices and Radiological Health [CDRH], 2016; International Organization for Standardization [ISO] 2014; ISO, 2006; U.S Food and Drug Administration [US FDA], 2019; Union, 2017) that require objective assessment of packaging usability in realistic contexts of care, this is an incredibly relevant and timely finding. **Usability testing should objectively evaluate packaging performance based on features rather than developing packaging features from Voice of Customers.**

Furthermore, the method proposed herein, represents one means to conduct testing as grounded in usability-related ISO standards (2004 International Organization for Standardization [ISO], 2004; 2018 International Organization for Standardization [ISO], 2018) adapted from documents which focus on the design of complex products and software. **Study ramification also suggest that is important that usability testing consider the specific contexts where packages will be, as work presented herein clearly indicates that setting and context impacts user behavior (and potentially, outcomes). Designing according to Universal design principals would suggest that designing for the more austere settings of use will likely result in designs that perform well in a broader range of setting.**

8.2 Future study

Although the results of the online based survey provided insight into difficulties identifying, opening, and using packaged products within the pre-hospital setting with reports of negative patient outcomes, they failed to indicate the frequency of the occurrences related to specific failures and the severity of the negative outcome related to specific failures (risk). We recommend, a ‘Risk Assessment’ utilizing the existing ISO standards (2007 International Organization for Standardization [ISO], 2007) regarding risk evaluation. Further investigation is needed to define ‘Probability of Occurrence of Harm’ and ‘Severity of Harm’ relating to the problematic outcomes associated with healthcare packaging (in prehospital settings and others).

Also, recommended are studies focused on explicit design cues, such as color-coding. Participants commonly suggested design improvements during the semi-structured interviews and formative, usability test; ‘color coding systems for labeling’, especially for critical information, was a common recommendation. This approach, however, is of limited assistance if not standardized across commercial brands and can even lead to error if not carefully designed. Other limitations include a lack of comprehensible color options and failure to understand the system (J. Cai, 2012). It has also been suggested that simple heuristics, such as color, can lead to error due to the fact that people fail to read the explicit details when these types of design cues are present. As such, even though users commonly indicate a prefer for color-coding, readers are cautioned to remember that results provided herein, and the result from the previous study (Perez, 2018) and ISO standard (2018 International Organization for Standardization [ISO], 2018)suggest that preference does not always leverage usability. As such, we recommend an objective evaluation of the performance of color coding with the goal of objectively testing a system for the purpose of international standardization.

Not only the investigation on standardized color-coding system is recommended with regard to design cues, but also, further investigation on affordance of design cues dependent upon its presence and the location within the same package is suggested. In this study, as the results of efficiency on the task, identification, was made with the best assumption, the results of usability suggested that participants spent comparatively less amount of time on finding an opening area of IV catheter with an extension even though the product is not familiar with them (e.g. lidded rigid tray is usually for the hospital setting). To objectively test this, empirical tools (e.g. eye tracking or change detection) are suggested to use. For more details of the method, refer Lee, et al (Lee, Ladoni, Richardson, Sundar, & Bix, 2019), Becker, et al (Becker, Bello, Sundar, Peltier, & Bix, 2015), Seo (Seo, 2014), Sundar et al (Sundar, Becker, Bello, & Bix, 2012).

Lastly, the familiarity with products needs to be further investigated related to the satisfaction. All participants reported their satisfaction level as ‘very satisfied’ and also reported their familiarity when they identified 4 by 4 pad.

Also, the further investigation on the correlation between the familiarity and the level satisfaction is suggested. Although the usability study was not designed for this purpose so that there was not enough evidence, 4 by 4 pad was rated as very satisfied in terms of their satisfaction level associated with identification of the package and also participants stated that this product generally look similar across all brands, indicating familiarity. Another comment related to ‘familiarity’ was made on the ET tube. 50% of participants (4 out of 8 participants in adults scenario) and 56% of participants in infant scenario (5 out of 9 participants) highly rated their satisfaction. This is probably because the interview regarding the identification (task) was not subcategorize as other usability metrics did, so that the other 50% or 46% of participants did not report their satisfaction as high as others.

8.3 Limitations

In order to simulate severe vibration data, in addition to the data that was collected via the ambulances, the research team incorporated “worst case” vehicle vibration data commonly employed for simulating over the road conditions for ride assessment provided by our automotive partner, Adient. Even with this, we were still not able to simulate ‘quick stops/starts,’ reported as problematic by paramedics participating in the guided interview section of the study.

The CLUE Spray was absorbed by the material on the surface of workspace deck and seatbelts within the ambulance simulator, so the indirect transfer was not appropriately captured. Improvements are needed to purposefully test the indirect transfer by either replacing the material of use in the simulator or change the type of the simulant (e.g. lotion type). Additionally, correlation with regard to how this material behaves relative to microorganisms would be useful. The failure to rotate or randomize the simulation scenarios (adult vs infant) resulted in a confound of the CLUE spray dose with simulation scenario. As such, readers are strongly cautioned regarding these results, which indicated a higher prevalence of transfer during the adult scenario, as confounded and likely impacted by the study design itself.

Lastly, although the method of the formative, usability test was created in attempt to simulate realistic contexts, the test was not purposefully designed to investigate differences between signifiers; because we were designing in an attempt to create an ecologically valid context, package signifiers were either present, or absent, depending on reality. As such, the results may not convey more meaningful insights as much as it could be.

APPENDICES

Appendix A. Email invitation to participants for the survey

Initial E-mail

Subject: National EMS Study

Dear {First Name},

The National Registry of EMTs (NREMT) is conducting a survey regarding EMS professionals' experience with medical supplies and medications in the prehospital setting. The results of this survey will help us understand how packages can be better designed for prehospital environments. Even if you are not currently practicing in the prehospital setting, your participation in this study is important.

You have been selected to provide your expert opinions as an EMS professional. This will only take 5-10 minutes of your time. Your participation in this research project is entirely voluntary. The NREMT does not mandate or require participation in this project, and there are no penalties associated with not participating or discontinuing participation at any time. Further, there are no foreseeable risks in participation.

Your privacy is important to us, and your responses will be kept absolutely confidential. Only data summarizing groups of participants will be reported. If you have any questions, or want to obtain more information about this very important project, please contact the NREMT Research Department at 614-888-4484 or via email at research@nremt.org. If you have concerns or questions about your rights as a participant, you can contact the Chair of AIR's Institutional Review Board at 1-800-634-0797 or via email at IRBChair@air.org.

The time you spend answering this questionnaire can have a real impact on our profession.

Those individuals whose surveys are received by December 1, 2016 will be entered into a drawing to win one of ten \$100 Amazon gift cards, as a token of appreciation for your participating in this important research project.

If you would like to participate, please [click here](#).

Once again thank you for your help!

Respectfully,

The NREMT Research Team

Appendix B. Recruitment flyer for the survey

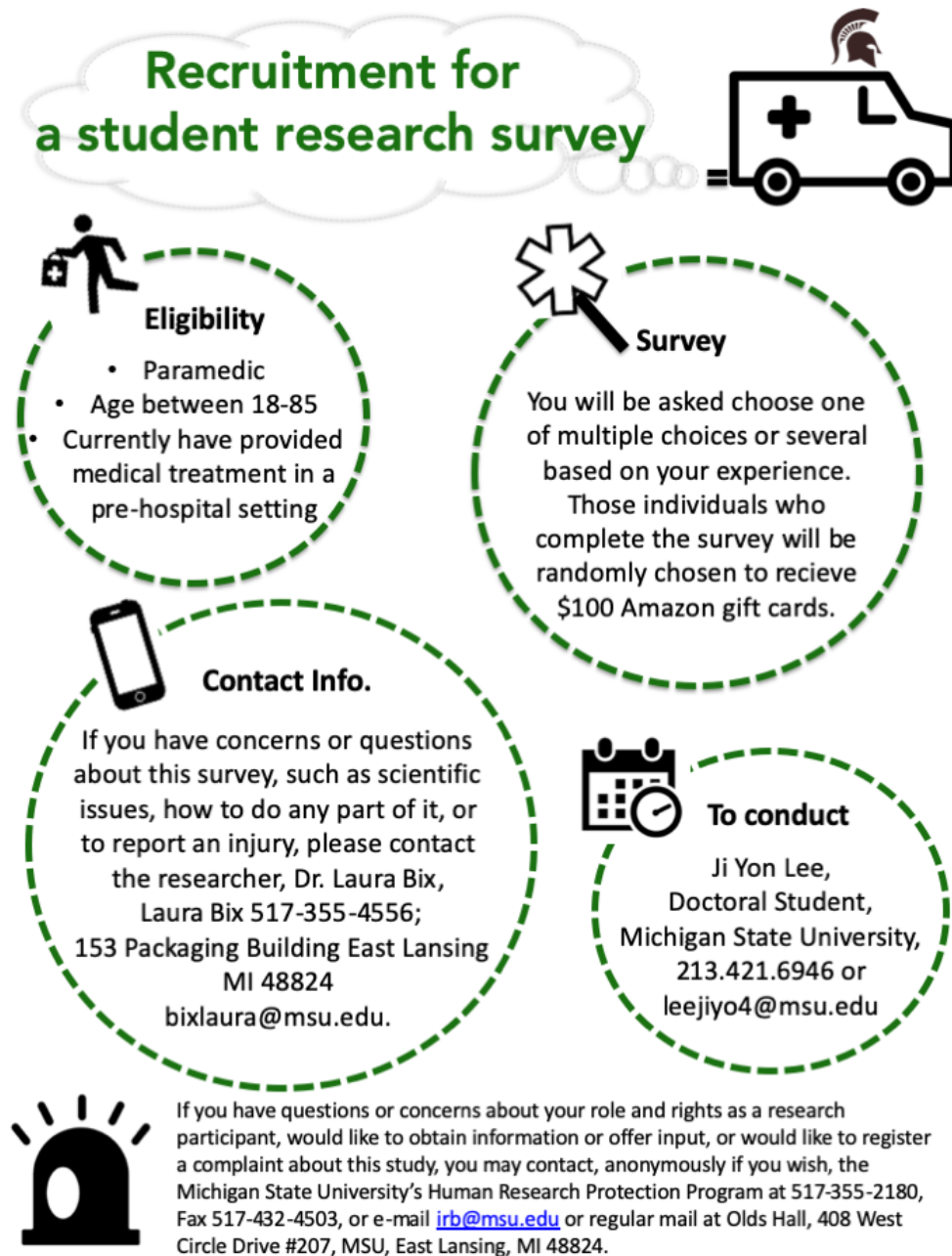


Figure 90. Recruitment flyer for the survey

Appendix C. Survey Codebook

Survey Legend: Packaging

Vcust1 - Invite Custom Field 1: NREMT assigned ID number

Vrid - Response ID: consecutive numbering of responses

Vdatesub - Date Submitted: mm/dd/yyyy hh:mm:ss am/pm (based on Eastern time zone)

Vstatus - Status: complete (n = 1,877) or partial (n = 35)

How many years have you worked as an EMS professional?

SPSS Variables: q1

Option Title	Reporting Value
I have never worked as an EMS professional	1
Less than one year	2
1-2 years	3
3-4 years	4
5-7 years	5
8-10 years	6
11-15 years	7
16-20 years	8
21 or more years	9

For how many different organizations do you currently perform EMS work?

SPSS Variables: q2

Display When: Question "How many years have you worked as an EMS professional?" is one of the following answers ("Less than one year", "1-2 years", "3-4 years", "5-7 years", "8-10 years", "11-15 years", "16-20 years", "21 or more years")

Option Title	Reporting Value
0	0
1	1
2 or more	2

Which of the following best describes your primary role at your main EMS job?

SPSS Variables: q3, q3a (free text for other)

Option Title	Reporting Value
Patient Care Provider - A person whose primary role is the provision of EMS services to patients.	1
Educator - A person whose primary role is instructing individuals enrolled in an approved or accredited EMS training course or providing continuing education required for maintenance of licensure.	2
Preceptor - A person whose primary role is training individuals enrolled in an approved or accredited EMS training course in a clinical setting.	3

Dispatcher/Call Taker - A person whose primary role is EMS communications.	4
Administrator/Manager - A person whose primary role is the management and direction of an organization providing EMS services.	5
First-line Supervisor - A person whose primary role is the direct supervision of individuals providing EMS services.	6
Other - A person whose primary EMS role at their main job is not listed above (please specify).	7

Which of the following best describes your main EMS agency/organization?

SPSS Variables: q4, q4a (free text for other)

Option Title	Reporting Value
Hospital - refers to EMS agencies that are under the direct control of a hospital, regardless of the type of organization that runs the hospital.	1
Fire Department - an organization from which fire and EMS services are provided, regardless of the type of organization that runs the Fire Department. Volunteer fire departments should be included here.	2
Tribal - are operated by a federally recognized Indian or Alaska Native Tribe.	3
Military - are operated by one of the U.S. Armed Forces and staffed by active duty personnel.	4
Government, Non-Fire Department - are operated directly by a federal, state, county, or local government entity other than the U.S. Armed Forces.	5
Private - are operated under the direct control of a for-profit or not-for-profit organization other than a hospital. Volunteer rescue squads that are operated independently of a fire department should be included here.	6
Air Medical - an organization which provides air ambulance services, regardless of the type of organization which runs the air ambulance service.	7
Other - Please specify	8

Which of the following best describes the primary type of service provided by your main EMS agency/organization? If more than one type of service is provided, pick the service with the greatest number of calls in the past 12 months.

SPSS Variables: q5, q5a (free text for other)

Option Title	Reporting Value
Primarily 911 response with or without transport capability - Immediate response to an incident location, regardless of method of notification (for example, 911, direct dial, walk-in, flagging down).	1

Primarily medical transport (convalescent) - Transport of a patient from one health facility to another.	2
Equal mix of 911 and medical transport (convalescent)	3
Clinical services - Provision of clinical services in a non-ambulance clinical setting such as emergency department, medical office, or dialysis clinic.	4
Mobile Integrated Healthcare & Community Paramedicine - Provision of clinical services in an out-of-hospital community setting.	5
Other - Please specify	6

In the past 12 months, have you provided any patient care in the prehospital setting?

SPSS Variables: q6

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty identifying a medication while providing care in the prehospital setting?

SPSS Variables: q7

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to identify a medication?

Display When: Question "In the past 12 months, have you had difficulty identifying a medication while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Lack of transparency of package made it difficult to tell what product was	0/1	q8a
Crowded label made it difficult to read		q8b
Small text on label made it difficult to read		q8c
Different medications have similar packaging		q8d
Confusing names		q8e
Dark conditions made it difficult to read labels		q8f
Other - Please describe		q8g q8g1(free text for other)

In the past 12 months, which of the following have you used to cope when medications were difficult to identify?

Display When: Question "In the past 12 months, have you had difficulty identifying a medication while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Flashlight	0/1	q9a
Touch/feel		q9b
Changed the location of product within container, bag or ambulance		q9c
Other - Please describe		q9d q9d1 (free text for other)

In the past 12 months, has an issue with identifying a medication negatively impacted your patient care?

SPSS Variables: q10

Display When: Question "In the past 12 months, have you had difficulty identifying a medication while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty opening a medication?

SPSS Variables: q11

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to open a medication?

Display When: Question "In the past 12 months, have you had difficulty opening a medication?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Too small of an area to grip	0/1	q12a
Materials meant to separate stuck together		q12b
Product required too much force to open		q12c
Product required two hands to open		q12d

Unfamiliar with product packaging	q12e
Packaging directions for opening were not clear	q12f
Other - Please describe	q12g q12g1 (free text for other)

In the past 12 months, which of the following have you used to cope when medications were difficult to open?

Display When: Question "In the past 12 months, have you had difficulty opening a medication?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Knives	0/1	q13a
Scissors		q13b
Teeth		q13c
Pen		q13d
Partner assistance		q13e
Other - Please describe	q13f	q13f1 (free text for other)

In the past 12 months, has an issue with opening a medication negatively impacted your patient care?

SPSS Variables: q14

Display When: Question "In the past 12 months, have you had difficulty opening a medication?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty administering a medication?

SPSS Variables: q15

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to administer a medication?

Display When: Question "In the past 12 months, have you had difficulty administering a medication?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Medication characteristics made it difficult to remove	0/1	q16a
Product stuck to package		q16b
Complicated packaging features		q16c

Vehicle (e.g., ambulance) movement and vibration	q16d	
Other - Please describe	q16e	q16e1 (free text for other)

In the past 12 months, has an issue with administering a medication negatively impacted your patient care?

SPSS Variables: q17

Display When: Question "In the past 12 months, have you had difficulty administering a medication?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty identifying a medical supply (e.g., syringe, endotracheal tube, IV administration set) while providing care in the prehospital setting?

SPSS Variables: q18

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to identify medical supplies?

Display When: Question "In the past 12 months, have you had difficulty identifying a medical supply (e.g., syringe, endotracheal tube, IV administration set) while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Lack of transparency of package made it difficult to tell what product was	0/1	q19a
Crowded label made it difficult to read		q19b
Different supplies had similar packaging		a19c
Confusing names		q19d
Dark conditions made it difficult to read labels		q19e
Other - Please describe	q19f	q19f1 (free text for other)

In the past 12 months, which of the following have you used to cope when medical supplies were difficult to identify?

Display When: Question "In the past 12 months, have you had difficulty identifying a medical supply (e.g., syringe, endotracheal tube, IV administration set) while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Flashlight	0/1	q20a
Touch/feel		q20b
Changed the location of product within container, bag or ambulance		q20c
Other - Please describe		q20d q20d1 (free text for other)

In the past 12 months, has an issue with identifying medical supplies negatively impacted your patient care?

SPSS Variables: q21

Display When: Question "In the past 12 months, have you had difficulty identifying a medical supply (e.g., syringe, endotracheal tube, IV administration set) while providing care in the prehospital setting?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)?

SPSS Variables: q22

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to open medical supplies?

Display When: Question "In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Too small of an area to grip	0/1	q23a
Materials meant to separate stuck together		q23b
Product opened with too much force		q23c
Product required two hands to open		q23d
Unfamiliar with product packaging		q23e
Packaging directions for opening were not clear		q23f
Other - Please describe		q23g q23g1 (free text for other)

In the past 12 months, which of the following have you used to cope when medical supplies were difficult to open?

Display When: Question "In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Knives	0/1	q24a
Scissors		q24b
Teeth		q24c
Pen		q24d
Partner assistance		q24e
Other - Please describe	q24f	q24f1 (free text for other)

In the past 12 months, has an issue with opening medical supplies negatively impacted your patient care?

SPSS Variables: q25

Display When: Question "In the past 12 months, have you had difficulty opening medical supplies (e.g., a syringe, endotracheal tube, or IV administration set)?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, have you had difficulty using a medical supply?

SPSS Variables: q26

Option Title	Reporting Value
Yes	1
No	0

In the past 12 months, which of the following has made it difficult for you to use a medical supply?

Display When: Question "In the past 12 months, have you had difficulty using a medical supply?" is one of the following answers ("Yes")

Option Title	Reporting Value	Var Name
Product characteristics made it difficult to remove	0/1	q27a
Product stuck to package		q27b
Multiple layers of packaging		q27c
Multiple, loose items		q27d
Other - Please describe	q27e	q27e1 (free text for other)

In the past 12 months, has an issue with using a medical supply negatively impacted your patient care?

SPSS Variables: q28

Display When: Question "In the past 12 months, have you had difficult using a medical supply?" is one of the following answers ("Yes")

Option Title	Reporting Value
Yes	1
No	0

How long have you been employed or volunteered at your main EMS job?

SPSS Variables: q29

Option Title	Reporting Value
Less than one year	1
1-2 years	2
3-4 years	3
5-7 years	4
8-10 years	5
11-15 years	6
16-20 years	7
21 or more years	8

Which of the following best describes your employment status at your main EMS job?

SPSS Variables: q30

Option Title	Reporting Value
Full time	1
Part time	2
Per diem, PRN or as needed	3
Volunteer or on-call	4

On average, how many calls do you respond to in a typical week at your main EMS job?

SPSS Variables: q31

Option Title	Reporting Value
0	1
1	2
2 to 4	3
5 to 9	4
10 to 19	5
20 to 29	6
30 to 39	7
40 to 49	8

Which of the following best describes the community in which you do most of your EMS work?

SPSS Variables: q32

Option Title	Reporting Value
Rural area (less than 2,500 people)	1
Small town (2,500 - 24,999 people)	2
Medium town (25,000 - 74,999 people)	3
Large town (75,000 - 149,999 people)	4
Mid-sized city (less than 500,000 people)	5
Suburb/fringe of a mid-sized city	6
Large city (500,000 or more people)	7
Suburb/fringe of a large city	8

In what year were you born?

SPSS Variables: q33

Type: TEXTBOX

What is the highest level of education you have completed?

SPSS Variables: q34

Option Title	Reporting Value
Didn't complete high school	1
High school graduate/GED	2
Some college	3
Associate's Degree	4
Bachelor's Degree	5
Master's Degree	6
Doctoral Degree	7

What is your sex?

SPSS Variables: q35

Option Title	Reporting Value
Male	1
Female	0

Are you Hispanic or Latino?

SPSS Variables: q36

Option Title	Reporting Value
Yes	1
No	0

Which of the following best describes you? You may choose more than one.

Option Title	Reporting Value	Var Name
American Indian or Alaskan Native	0/1	q37a
Asian		q37b
Black or African American		q37c
Native Hawaiian or other Pacific Islander		q37d
White		q37e
Refuse		q37f

Appendix D. Responses for ‘others’ option in the survey

1. Identifying Medication

Table 69. Responses for ‘others’ option in the survey – Reasons for difficulty identifying medication

	Reasons for difficulty identifying medication
1	small bottles all similar
2	Similar packing if different medications
3	Same packaging, different medications look the same
4	Same color as other med .poor labeling
5	Print on transparent containers. No contrasting background makes them blend in.
6	No standardized packaging. Every medication should have a standard color for the medication label and cap.
7	My system removes drug from box to place in bag
8	Meds placed in daily pill box, no names or labels avail.
9	Medications available in multiple packaging types, colors, etc for the same medication.
10	Many medication use the same color of tops (gray, lite gray, or white) so it makes grabbing the wrong medication easy.
11	Lack of proper labeling for albuterol and ipratropium. Hard to see which is which
12	Labels wearing away because of frequency of them being checked.
13	label not high-lighted on container
14	information blends with color of packaging
15	Inconsistency between manufactures of the same medication, for example, cap and label color of vials changing per manufacturer.
16	Expiration dates too small, hard to find.
17	Different medications with the same top
18	Colorblind
19	Changed from D50 to D10, which looks similar to dopamine packaging
20	change in how the medication was packaged
21	All with small writing some now from a different supplier with different labels and concentrations

Table 70. Responses for ‘others’ option in the survey – Coping strategies for difficulty identifying medication

	Coping strategies for difficulty identifying medication
1	visual inspection
2	Used glasses
3	used cell phone as a magnifying glass
4	Used a marker to highlight raised but clear marking, reading glasses for small rint
5	Use of Reading Glasses to Magnify

Table 70. (cont'd)

6	use of marker pen to label
7	took off my eyeglasses
8	Took extra time to make sure it was correct
9	Take extra time to properly identify the needed medication
10	Take extra time to examine vial/read label.
11	Study and review of medications
12	stronger reading glasses
13	stronger glasses
14	Stopping to read extra carefully
15	Smartphone apps, internet
16	Self markings
17	removed from bag to read
18	Relabeling & color coding
19	Reconfirming the medication with other methods such as reading the external packaging or discarding the medication and obtaining a new dose.
20	Rechecked medication and had partner confirm
21	Reading magnifying glasses
22	reading glasses, labeling the medication box
23	reading glasses with magnification
24	reading glasses with increased strength
25	Reading Glasses
26	Reading Glasses
27	readers
28	Read labels to identify
29	Re-read labels
30	Placed in baggies with larger label.
31	nonprescription magnifying glasses
32	No change
33	More brightly lit area
34	Make sure to triple check prior to administration
35	Magnifying glass
36	Magnifying glass
37	magnifying glass
38	magnifying glass
39	Mac check
40	Lorazepam and fentanyl refilled syringes are nearly identical. The viscosity of the solution can show the difference in low light situations
41	Looked it up on the internet
42	Looked at field guide and/or asked partner
43	Learn to deal with it
44	labeling or specifying use of meds on package
45	Know layout of equipment - keep standardized equipment inventory and layout across entire fleet. All bags are the same. When a change in packaging occurs from a manufacturer or shortage, all officers, providers, etc are sent email w/ pictures, sometimes

Table 70. (cont'd)

46	Incorporated Operative IQ labeling
47	I have a small Fresnel magnifying lens.
48	hold up to light
49	Had another person read the label
50	Glasses, move to lighted area
51	Glasses with magnifiers
52	glasses due to small print
53	Glasses
54	Glasses
55	Glasses
56	glasses
57	Feverishly searching every drug/location
58	eye glasses
59	extra time to verify med
60	Extra time taken to read and verify
61	Exchanged medication with supervisor
62	Double check label
63	Double checking specially to check the concentration of the drug
64	data searches
65	Daily review of the drug box contents to ensure familiarity
66	Compared to similar med
67	Color of lid
68	Color Markers
69	Color code labels.
70	Circle the name of the medication on the vial
71	CE and training
72	Careful Verification
73	Better lighting location confer with partner
74	Ask my emt
75	Ask another medic
76	Always read the label multiple times on similarly packaged
77	2 person confirmation
78	'Helper' eye glasses

2. Opening Medication

Table 71. Responses for 'others' option in the survey – Reasons for difficulty opening medication

	Reasons for difficulty opening medication
1	Tridil seal is the worst.
2	tops came off controlled drugs when not needed
3	Thick plastic not tearing as designed... IV solutions etc...
4	Solumedrol packaging, the plunger will get stuck in between the saline and powder form. A long needle is then required to push the plunger through the gap and allow the medication to properly mix.
5	Solu-Medrol. Went to reconstitute by pressing on orange cap, the liquid squirted out the top, instead of pushing the middle stopper down
6	Same Med that utilizes different packaging depending on manufacturer
7	safety seal added by employer impossible to open without scissors
8	pull tab regularly breaks on tridil
9	Press out tabs hard to open and crumbled the tablet
10	Plunger to solu Medrol broke loose made drawing medication difficult without bending a syringe
11	Packaging required scissors or knife to open
12	One medication Versed not only has a pop off top but also was and is wrapped in a label which is difficult to remove.
13	no directions for opening and an unfamiliar package
14	Narcotic safety seal not easy to get off with gloves on
15	Medications 'shrink wrapped' together by the ambulance company.
16	Iv zofran preloads are a pain to use.
17	Glass vials
18	glass broke while opening spilling meds
19	Glass ampules- always a pain to open. With a high chance of cutting yourself.
20	Glass ampoule is very difficult to deal with inane emergency
21	Extra tamper-resistant packaging on controlled meds (applied by our service) make efficient opening difficult
22	Epi glass ampules which require you to break the glass top
23	different pharm companies had different bristoljects
24	Could only be opened from one end
25	Cardizem bag with dry medication requires assembly
26	Breaking old style ampules remains archaic. Sharp shards and spilled medicine is always possible
27	Box wears down, someone tapes it back together, you have to cut through the layers to access medicine.
28	attempting to use a vial access needle on a medication
29	Accidentally depressing a carpuject when not wanting to.

Table 72. Responses for ‘others’ option in the survey – Coping Strategies for difficulty opening medication

	Coping strategies for difficulty opening medication
1	Wasted medication and started again
2	Wasted defected product and used another vial off the shelf
3	used at actual hypodermic needle access vial
4	Two hands, gauze, and a knee.
5	Two hands, focusing
6	Twisting until seal breaks
7	Towel
8	Teeth? Used scissors
9	Syringe to draw
10	SMACKED IT WITH A LARYNGOSCOPE BLADE
11	Read directions
12	Padding for use with glass ampules
13	none
14	Non gloved hand
15	More force to break vial
16	Long needle to reach into vial of solumedrol and finish pushing the plunger which got stuck between chambers.
17	In some cases
18	Glass ampules require too many steps and are inferior in every way.
19	Extreme force
20	Container was small, lid was small. Was able to open on my own.
21	Calling supervisor for help
22	Brute force
23	Brute force
24	Bending of syringe needle
25	4x4's to open ampule

3. Administering medication

Table 73. Responses for ‘others’ option in the survey – Reasons for difficulty administering medication

	Reasons for difficulty administering medication
1	wrong route
2	wouldn't flow via IO
3	When using sodium bicarbonate in a brista jet the glass vial shattered and med was unable to be properly administered
4	We have to draw up from multiple vials to get correct dose.
5	Viscosity of Med (Ativan)
6	Venting of glass container.
7	Valium in carpject form rarely works as designed
8	Unable to obtain IV access
9	tuberculin syringe the medication was drawn up in not compatible with luer lock on drip set
10	trying to get narcan out of a prefill amp that has a fixed needle to work with a MAD
11	The time it takes to draw up cardiac meds or times sensaitve medications
12	Small dose made it difficult to draw up given concentration on hand.
13	Pushing the plunger to push the med. and it does not move.
14	prefilled syringes for every medication would help
15	poor seat on carpujets to IV tubing with Fentanyl mainly
16	Poor administration device quality
17	Patient movement and combativness.
18	no lure lock on syringe
19	no IV access, diff patient
20	No carpject to administer medication
21	MAD defects
22	Luer lock on bristo-jet kept falling off needle
23	Lack of administration materials needed
24	IV infusion with no pump, difficult to titrate
25	Incompatible IV dripset tubing made for needle injection port but the medication supplied was in a needleless preparation.
26	inaccessibility of injection sites in our small work space
27	Hole in nipple of IV bag where it joins to bag, NOT from administration set spike
28	hard to read
29	Geodon is difficult to reconstitute.
30	Gauge of access needle was too small
31	Failure of Carpject
32	Drawing up Dextrose 50% when supplies are diminished is a pain.
33	Drawing up amiodarone from 150ml vial
34	dosage printing too small - or unclear; and air in the vial.
35	Difficult to push through IO
36	Difficulty with carpo-jet
37	Difficulty obtaining patent IV/IO.

Table 73. (cont'd)

38	Difficult mixing instructions on infusions
39	Dextrose 50% preload takes too much effort to administer IV.
40	D10 via IO
41	could not gain IV access
42	Component of pre-filled syringe broke, unable to use
43	Carpulejects
44	Bent needle
45	back of ampule displaced spilling med
46	Atropine injector would not work. I could not push it.
47	atomizer fluid loss
48	Ativan is thick. And glass ampules are a pain to draw from.
49	Ampules
50	Adenosine needs to be pushed rapidly followed by a rapid saline flush because of its short half-life. It is a tricky medication to administer by yourself.
51	'Safety' devices that are difficult to operate, don't lock as they should

4. Identifying Medical supplies

Table 74. Responses for ‘others’ option in the survey – Reasons for difficulty identifying medical supplies

	Reasons for difficulty identifying medical supplies
1	Too small of font - or unclear markings
2	Too much writing and too many different number sizing. Also the font sometimes can be too small and light color. Just one big number with its size that stands out would be helpful. The rest could be printed separately on another piece of paper with packag
3	The monochromatic color scheme make it difficult to quickly determine the sizes/types
4	Text size too small
5	Some Iv tubing is not marked with its drip
6	Small, generic print
7	Small writing
8	Small Text
9	Small tabs for opening packages.
10	Small print on adult vs pedi oxygen devices. I prefer the brand that uses blue paper for pedi labels
11	Small print for a lot of ett tubes shoved in a bag. I always write the size big with a sharpie. We need big sizes visible from both ends on both sides.
12	small ET tube sizes on pkg
13	Sizes specifically need to be more prominently displayed.
14	similar packaging
15	Product description insert (Pedi vs Adult NRB for example) may get folded to where you can't read it.
16	Printing too small and no contrast with the background
17	packageing labels too crowded and sizes should be larger and bold
18	Messy
19	Many types of packaging for different brands/variations of same supply
20	limited space to keep multiple medical supplies
21	Label twisted inside packaging but label also blocked the equipment inside makonhou
22	King airways should be marked better to distinguish sizes
23	It is difficult to find size of endotracheal tubes own package. I usually use a marker to write it on the edge of the package.
24	Embossed labeling. Labeling on product but not package.
25	Defective supplies
26	confusing size markings
27	Clear id of sizes or types needed
28	Change of supplies without notification to the providers

Table 75. Responses for ‘others’ option in the survey – Coping Strategies for difficulty identifying medical supplies

	Coping Strategies for difficulty identifying medical devices
1	Wrote size big on package with permanent marker
2	Wrote on the outside of the package
3	Wrote on package with Sharpie during rig check
4	Written ET tube size on packaging in bold permanent marker, also expiration dates
5	Write on the device in large characters with a sharpie what the size of the tube, syringe, or dripset was. This is common practice where I work because of difficulty reading packaging.
6	write on packaging
7	Write on package wit marker.
8	verify quantities, dates, sizes before and after every where the item is used
9	used marker to identify
10	Used a sharpie to write on packaging. Example ET tube sizes on packaging
11	Use of standardized equipment and layout across entire fleet
12	training
13	Took extra time to make sure it was correct/ opened packages until I found the correct one
14	taking more time to differentiate the correct product
15	Taking extra time to search label
16	Take more time, using two hands to see through packaging
17	study and familiarization
18	stronger glasses
19	Spent more time reading the packaging.
20	spend extra time verifying what supplies I'm using
21	Slow down
22	Reviewed different equipment that was accidentally given out by the hospital that provided it.
23	Retread the label a number of times
24	Replaced drip set with one I knew
25	rely on co-workers
26	relabeled
27	Relabeled with sharpie to make it easier to identify
28	Read packaging carefully
29	Putting tape on the package and writing in big black marker what I need to know. (Usually pedi VS adult - ill label the pedi stuff)
30	Pre-marking packages
31	Opened products to determine which size it was when a label wastwis
32	Open wrong package
33	Open Pedi N/C, just open adult afterwards
34	On some medical supplies, I highlight or circle the size before shift.
35	None of these
36	Moved to lighted area

Table 75. (cont'd)

37	marking with markers
38	Made sure to read the label before opening the package. Have not changed anything.
39	Inservice training on where to get information by company after several staff complained
40	If I couldn't read the expiration date I would dispose of item and replace it with a item that had a printed dare
41	Hand Wrighting on Package
42	had to take time to find info, not easy to identify.
43	extra time
44	Circled the size of ETT located on the package
45	Circle the pertinent info with marker
46	Ask partner to identify as well.
47	another set of eyes
48	Additional time reading label.

5. Opening Medical supplies

Table 76. Responses for ‘others’ option in the survey – Reasons for difficulty opening medical supplies

	Reasons for difficulty opening medical supplies
1	Product required 2 hands and was difficult to grasp w/ gloves
2	Tubing always tangles when opening IV tubing.
3	Gloves made it hard to grip and small areas to open packages made it hard
4	Multiple small items in a hard to open package that makes everything fly everywhere when you open it.
5	IV tube packaging was difficult to open with one hand and many time takes trauma sheers to open
6	IV tubing no longer with perforated edges
7	Similar packages with different designs for opening
8	IV cath and saline lock flaps too close together, unable to grip with gloves on
9	Too much air in the packaging
10	IV catheters are flimsy and not user friendly in the prehospital setting
11	Tangled IV drip set tubing
12	The iv tubing packing at times can be rather annoying to open when wearing gloves. Most of the time I end up taking my gloves off to try and not delay the process and then reapply some new gloves.
13	slick surface of package
14	Package had multiple individually packaged parts
15	Gloves
16	issue with IV catheters shredding or needle itself being bent/unusable

Table 77. Responses for ‘others’ option in the survey – Coping strategies for difficulty opening medical supplies

	Coping Strategies for difficulty opening medical devices
1	forcing the spike into the iv bag and causing it to puncture the bag
2	nothing, just kept at it until I got it.
3	I pre cut a small slit in all the packages to make it easy.
4	Extra, unnecessary time used
5	Trauma sheers are a go to but if there's more providers on scene then usually they help out.
6	Brute force
7	Pull harder
8	Just used my hands. Simply took a bit more time to open
9	worked it out
10	more effort than it should
11	brute force
12	Brut force tearing product open

Table 77. (cont'd)

13	stop other work, and use 2 hands to open
----	--

6. Using Medical supplies

Table 78. Responses for 'others' option in the survey – Reasons for difficulty opening medical supplies

	Reasons for difficulty using medical supplies
1	Needle bent
2	Difficulty administration with carpo-jet
3	Koban wrap fused to itself
4	Defective
5	Defective king airway/et balloons; lost time.
6	Uncooperative pt
7	Not enough room left on packaging to separate the layers
8	iv extensions were not compatable with the iv line.
9	Setting up a nebulizer to CPAP.
10	machine failed
11	product sticks to self
12	Loose connections on iv lock/extension sets
13	Malfunction of IV tubing, Luer lock would not stay attached
14	IV tubing kinked while trying to unravel to use
15	CPAP Mask application is difficult due to prongs and head band placement in a severe respiratory distress!
16	Again, "safety" devices tend to be more difficult to use than standard medical devices
17	IO would not flush, you could aspirate bone marrow.
18	Catheter sticking to protective covering and pulling off of needle (IV)
19	Said product did not work as well as agency was trained to use the product (airway device) therefore it did cause somewhat of a negative outcome due to not being able to adequately secure airway.
20	Operator error/poor vascular access/difficult airway.
21	Poor safety syringe design
22	Identical items operate differently
23	Unclear directions unable to read because they are packed in product packages
24	unconventional design
25	No instructions in packaging for device adapter
26	King Vision screen faulty marriage to blade
27	Cheap cap circuit mask assembly came apart in the bag, other times small plastic tabs have broken off
28	Incorrect syringes in ET tube set up
29	Tubing doesn't stay tight allowing Pt to bleed out of 10 drip sets and IV catheters don't release from hub causing pain and multiple IV sticks for pts
30	stylette too big to slide out of et tube without dislodging et tube
31	Manufacturers forgetting that products are used in environments that can be very slick with bodily or other fluids on nitrile gloves.

Table 78. (cont'd)

32	IO needle wouldn't unscrew from catheter hub
33	Ballon separated from tube, would not inflate.
34	Poor success with King airways despite retaining
35	Quality of product was poor. These were made by Medstorm. They were replaced at my department with better equipment.
36	Bbraun Iv needless port is difficult to connect a syringe
37	No perf lip to open IO stabilizer
38	Certain meds such as Narcan packaged in low dose vials which involve having to draw up from multiple vials.Pre packaged syringes are faster and easier .This may be an availability issue.
39	new equipment without training.
40	Hard to prime 60gtt pump burette for ped
41	ETT packaged without a BVM adapter
42	Zofran in prefilled syringe with plunger, hard to put together
43	Packaging can be difficult to open if the indicated corner to open is way to small or hard to grip with gloves.
44	drawing up product from on vial to move it by needle to the administration appliance
45	Faulty equipment
46	*answered in the wrong section* MAD defects
47	An IO needle was stuck together and would not unscrew after I drilled it into the patients leg
48	ETT tube holder moved significantly after securing and tightening straps and taping tube to holder
49	Electrodes fell apart, IV Cath with an imperfection in cath
50	shredded iv caths, damaged needles

Appendix E. Recruitment advertisement for the case study

Recruitment for a focus group for a student research





Focus group

You will be asked to complete a survey and participate in a focus group regarding your working environment and use of packaging based on your experiences. All discussion will be videotaped. It will not take more than 2 hours and half. You will receive \$60 as a compensation for participation



Eligibility

- Be employed as a paramedic
- Age between 18-85
- Have provided medical treatment in a pre-hospital setting within the last year
- Be willing to be videotaped discussing a topic regarding your job environment and packaging
- Be willing to bring and share the contents of a supply bag which is filled with inventories for a run or willing to take a picture/video of each inventory in the bag.



Contact Info.

If you have concerns or questions about this focus group, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher,
Dr. Laura Bix,
517-355-4556;
114 Packaging Building East Lansing
bixlaura@msu.edu.



To schedule

Jiyon Lee,
Doctoral Student,
Michigan State University,
213-421-6946 or
leejiyo4@msu.edu



If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail jrb@msu.edu or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI 48824.

Figure 91. Recruitment Advertisement for the case study

Appendix F. Consent form for the case study

Research Participant Information and Consent Form

Principal Investigator:

Dr. Laura Bix, School of Packaging, Michigan State University 517-355-4556

Secondary investigator:

Jiyon Lee, Doctoral Student, Michigan State University, 213-421-6946

Participation is voluntary, you may choose not to participate at all, or you may refuse to participate in certain procedures or answer certain questions or discontinue your participation at any time without consequence (e.g. you will still receive the participant incentive). This study will take no longer than 2.5 hours of your time.

To participate in this research you MUST:

- be employed as a paramedic
- be 18-85 years of age
- have provided medical treatment in a pre-hospital setting within a year
- be willing to be videotaped discussing a topic regarding your job environment and packaging
- Be willing to bring and share the contents of your personal supply bag

What you will do:

You will be asked to complete a survey and participate in a focus group regarding your working environment and use of packaging based on your experiences. We will ask you to share the contents of your bag and discuss work related situations that have created difficulties with products and product packaging. All discussion will be videotaped. It will not take more than 2 hours and half.

Benefit

Although there is no direct benefit to you for participating in this research, it is our hope that the data gathered can be used to understand the working environment that healthcare professionals face and the interface between them and packaging in order to create better packaging designs.

Risk

Risks affiliate with participation in this study are limited. We are going to ask you about difficulties that you have had with products and packaging in the context of your working environment. The only risk is that you share something that you wish you had not regarding patient care or product design. You may choose to not participate in any aspect of the research that makes you uncomfortable.

Privacy & confidentiality

The whole focus group process will be recorded using video cameras. Video will be used by the research team to analyzed the data and recall specific details of the focus group. For those that consent (below), video clips may be used for educational purposes

Appendix G. Moderator Guide for the case study

Moderator Guide

Text with Yellow Highlights indicates supporting handout/poster is being produced.

Text in Red will not be read by test personnel, but signifying an action that they will take or something that they should keep in mind during this section of the focus group.

Goals

- 1) To garner insight into EMS professionals' behavior and the context of their working environment
- 2) To gain a better understanding of potential difficulties they encounter when opening and using medicines and medical supplies
- 3) To use these insights to develop a simulation that accurately replicates the challenges in ways that induce affordances that are reported in the NREMT survey

Target participants

- 1) Advanced Emergency Medical Technicians or Paramedics who have provided patient care within the last year.

Collecting demographic handout

Introduction

Hello everyone. My name is Jiyeon Lee majoring in Packaging at Michigan State University. I appreciate your time and willingness to help me with my research. A focus group is a target group, in my case EMS providers, gathered to discuss a specific topic. The purpose of my focus group is to garner insight into EMS providers' actions with packaging in the prehospital setting.

I am your moderator today, and XX, will help this focus group smoothly proceed. My job here is to help keep the discussion going and to make sure everyone gets a chance to talk. As I am a packaging student, and not an expert in the EMS field, all of your answers will be valuable to me; please feel free to share anything that you wish. I am here to learn. I may call on you if we haven't heard your point of view or cut discussion short if we are going too long. As an international student, my first language is not English, so, if you want to ask a question or have me repeat something, please feel free to do so.

We want everyone to feel comfortable sharing their opinions, and want to hear from everyone.

As a result, there are some rules for focus groups

1. There are no right or wrong answers.
2. Feel free to agree or disagree with other's opinions. We expect people to have different opinions.
3. But, please try not to interrupt each other.
4. I might skip over you if you have talked a lot or I might call on you if you haven't talked much. Our goal is to hear everyone's thoughts.

We have Gopros around the room to videotape this focus group. If you agreed to allow your image to be shown, we may use it for classroom and educational purposes. If you did not, clips that include you will not be included in these presentations. The mat in front of you serves as a permanent marker in the video signifying this.

Do you have any questions? If not, I would like to start.

I. Education

Moderator will pass out handout (Packaging terminology).

Because my field (packaging) is quite different from yours, I have a handout of terms that you can reference during the discussion so that we can all be on the same page, and minimize misunderstanding. If you could use these terms as we get into discussions, that would be helpful.

Has everyone finished filling in the answers for the initial section of the demographic sheet that you have? Ok, if so, I would like to take a few minutes to introduce the topic that we are talking about today by having everyone report their answers from the sheet. Please introduce yourself, tell the group how many years that you have worked in EMS, what your primary role is and, if you had an example of difficulty that better package design could improve, please share it with the group

II. Characterizing the Working Environment

I am new to thinking about the prehospital context that you guys face everyday, and I would very much like to better understand the types of things that challenge you so that we can consider the things that you face as we design packaging for this environment. Because my field designs many of the products that you use on a regular basis, I am really interested in knowing about *the products that you use and where you store them*. Specifically: medication, medical supplies and any tools that you require for your work.

1. Seating

- a. Please refer back to the sheet that you filled out when you first came in. Flip to the next page. This page has a seating location common to many boxes, the back of the ambulance. Please mark on the drawing where you usually sit in the

box when patients are seriously injured and where (and how) your team stores it medications and medical supplies.

- b. Do you usually sit in the same place within the box when patients are seriously injured?
- c. How often do you wear a seat belt when riding in the box?
(For this question, I will give you two circumstances that you might face. If none of these are corresponding to your case, feel free to tell me more about your circumstance)
 - When a patients is severly injured
 - When they are severely injusred?
- d. How do you steady yourself in the ambulance?

PROBES

- *Under what circumstances might you use the bar*
- *Standing to grab medications or medical supplies on a severe road condtion?*
- *Standing to administer patient care on a severe road condtion?*

2. Working space and storage

- a. Does space ever pose a challenge for you?
 - a. *in storing, identifying, opening, or administering medication or medical supplies? (PROMT Limited space, type 2 or type 3, layout in ambulance, etc.)*
- b. Are medications and medical devices consistently stored so that they can be quickly located, or are they in variable locations/orientations?

3. Bag

We would like to know what medication, medical supplies and tools are essential for your work that you keep in your peronal bag. Please take a few moments to fill out the information regarding the contents of the bag that you brought and the other supplies that are stored in the box on page 4 and 5 of the sheet.

Has everyone had a chance to fill in the answers? OK, I would like to take a minute to fill in some tables regarding the responses that everyone recorded.

	Medications	Medical Supplies	Tools	Other	
Bag					

Box					
-----	--	--	--	--	--

Thank you for waiting for me. I would like to ask further based on this answers.

- a. Do you bring your personal bag on runs? Or Is it shared with other EMS professions?
- b. Where do you keep your bag when you are not on a run?
- c. Where do you store it when you are on a run?
 - i. Does where you store it change depending on where you sit in the box?
 - ii. Do you usually store it in the same place within the box?
- d. I would like to spend some time to hear about your experiences with trauma shears (or XXXXX *based on the result*).
 - i. I would like everyone to give me one or two things that you do with the different *tools* that you listed

PROBES

*Clothing removal,
opening packaging with it*

- ii. How frequently are they cleaned? Disinfected? Or Sterilized?
- iii. How frequently are they replaced?

4. Vibration and Motion

- a. What conditions make your job difficult?

PROBES

- *Long runs?*
- *Bad road conditions : Cobblestone, Railroad, Chuppy road, A big bump, Gravel road,*
- *Driving*
 - i. *Curves*
 - ii. *Lane Changes*
 - iii. *Quick starts and stops*
 - iv. *Traffic*
- *Vibration and motion*
- *Temperature or weather*

- b. Is motion more of a problem when seated or standing?
- c. How do you cope with the motion?
 - i. PROMPTS Bar, Widen Stance, Seat belt, Steady self with hand

5. Clinical procedure

We would like to know about how clinical procedure proceede and what kind of clinical procedure impacts more on your duty when it comes to opening packages.

- a. What age of patient make you difficult to work on?

PROBES

- Infant/adolescent/adult/senior
- Femal/Male
- Native speaker/international

b. What type of patient condition has caused difficulties for you?

PROBES

Need I/ Bleeding/ Drunken

c. How does the clinical procedure look like with the difficult situation you face?
Could you describe in details?

6. Problematic and good designs

a. Problematic design

- i. What features of package design has caused difficulties for you?
- ii. Under what circumstances do these problems occur?
- iii. What coping strategy did you use to solve difficulties?

a. Good design

- i. Do any instances come to mind where you can think of packaging features that extremely helpful, specifically, to pre-hospital setting?

Appendix H. Demographic/Data Collection Sheet for the case study

Focus Group- Prehospital Personnel

Prehospital Context and its impact on care

Please take a few minutes to fill out this basic information about yourself and your experiences working in Emergency Medical Services. We will reference this document once the focus group starts.

Demographic information

Sex

☐ Transgendered

☐ Male

☐ Female

Age

How many years have you worked in EMS?

What is your primary role within EMS (Check all that apply)?

☐ Paramedics

☐ Others (_____)

☐ Full time

☐ Part time

☐ Per diem

☐ Volunteer

☐ On Call

What is your primary role within EMS (Check all that apply)?

☐ Paramedics

☐ AEMT

☐ Full time

☐ Part time

☐ Per diem

☐ Volunteer

☐ On Call

Characterizing care delivery

Which of the following best describes the community in which you do most of your EMS work?

Primary County for delivering care _____

_____ Rural area (less than 2,500 people)

_____ Small town (2,500 - 24,999 people)

_____ Medium town (25,000 - 74,999 people)
people)

_____ Large town (75,000 - 149,000

_____ Mid-sized city (150,000 - 499,999 people)

_____ Suburb/fringe of a mid-sized city

_____ Large city (500,000 or more people)

_____ Suburb/fringe of a large city

What is the average time that you spend on a run?

How often do you encounter difficulties that could be eliminated/improved with better package design?

Never ☐ ☐ ☐ ☐ ☐ ☐ ☐ Daily

Share a situation where you had difficulty with packaging. Did the situation impact patient care?



Please wait here for the focus group to start. The moderator will let you know when to continue filling out the sheet from here.

Characterizing the working environment

Please mark the location where you usually sit in the box when patients are seriously injured with an “A.” Please mark the location of your supply bag with a “B”. Mark the location of medications with a “C” medical supplies with a “D.” If this layout in the compartment does not look like yours, please draw the layout you use and mark where you usually sit when patients are seriously injured on the diagram on the right hand side.

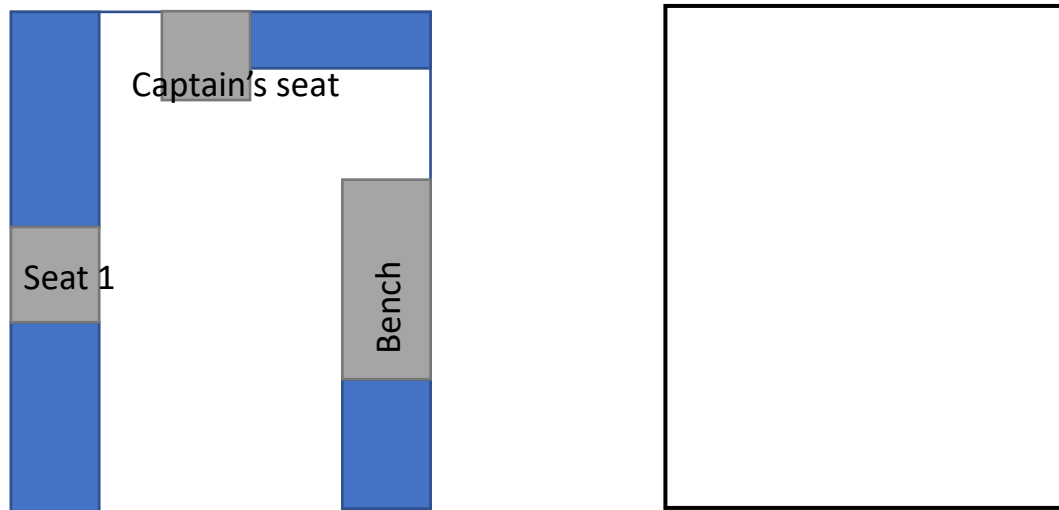


Figure 92. Seating position within the ambulance

Is storage space a critical concern within the ambulance?

☐ Yes

☐ No



Please wait here for the focus group to start. The moderator will let you know when to continue filling out the sheet from here.

Please take out your bag and inventory the supplies that are present. Think about what you typically carry in your personal bag. List the items that are present in your bag and those that would usually be present if they are not.

Medications ☐

Medical Supplies

☐

Tools ☐

Other ☐

Think about what typically carry in the box. List the items that you can rely on to be present in the box during a run. List where these items would be stored.

Medications ☐

Medical Supplies

☐

Tools ☒

Other ☐

Appendix I. Packaging Term Guide

Packaging term Guide

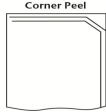
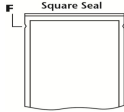
Medication and seal

Table 79. Definitions and examples of medication package and its seal

Types	Glass	
Examples		
Description	All medication made up of glass.	
Example of Medication	Solu-Medrol, Adenosine, Amiodarone, Dextrose, Ativan	
Types	Plastic	
Examples		
Description	All medication made up of plastic.	
Example of Medication	Dextrose, Ativan, Carpujects	
	Seal	
Examples	 Narcotic safety seal	 Tridil seal
	Seal is usually using to seal tight on package for any safety reasons.	
Example of seal	Narcotic safety seal, Seal on Tridil.	

Medical supplies

Table 80. Definitions and examples of medical supplies package

Types		Flexible pouches			
Examples	 Chevron	 Corner peel	 Tear open	 Header Bag	
Description ¹⁴	Plastic films or papers are used to fabricate this pouch as well as transparent flexible plastics				
Example of Device	High-volume and lightweight devices including: Gloves, catheters, tubing, dressing and others				
Types		Lidded rigid trays			
Examples	 Surgical Kits				
Description	Trays are rigid structures (many times compartments specifically made for a given product) with lidding material generally fabricated from paper and Tyvek®.			Trays and lids are rigid and frequently hinged. Locking mechanisms may be welded or frictionally fit together	
Example of Device	Heavier or multiple-components products: procedural kits				
Types		Lidded flexible trays			
Examples					
Description	Appearance of a tray with a flexible bottom generally lidded with paper and Tyvek®				
Example of Device	Lightweight and self- supporting : IV start kit				

¹⁴ Cai, Jingzhe. (2012). *Perceptions of medical device packaging used by operating room personnel*. MICHIGAN STATE UNIVERSITY.

Appendix J. Types of Medical Device Packages

Flexible and rigid constructions represent two broad types of packaging employed for use with medical devices (Barcan & Miller, 1998). Flexible constructions are generally constructed using plastic films or paper in order to fabricate a pouch style of package (Jingzhe Cai, 2012). Pouches for medical devices are normally comprised by four types; Chevron, Corner peel, Tear open and Header Bag (See figures in Table 79).

Table 81. Medical device packages: Types, descriptions and examples

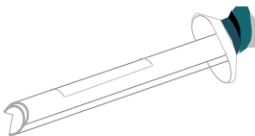
Flexible pouches				
Types				
				
Description	Chevron	Corner peel	Tear open	Header Bag
	Plastic films or papers are used to fabricate this pouch as well as transparent flexible plastics(Jingzhe Cai, 2012)			
Example of Device	High-volume and lightweight devices including: Gloves, catheters, tubing, dressing and others			
Lidded rigid trays				
Types				
				
Description	Trays are rigid structures (many times compartments specifically made for a given product) with lidding material generally fabricated from paper and Tyvek®.(Jingzhe Cai, 2012)			
Example of Device	Heavier or multiple-components products: procedural kits			

Table 84. (cont'd)

Types	Lidded flexible trays
	
Description	Appearance of a tray with a flexible bottom generally lidded with paper and Tyvek®(Jingzhe Cai, 2012)
Example of Device	Lightweight and self- supporting: IV start kit

Table 80 shows packages using for medication. Those medication packages are divided into parental and not-parental that are mostly made of glass and plastic (Dean, Evans, & Hall, 2005). However, herein, that classification does not fit into this study, so medication packages are categorized into either glass and plastic.

Table 82. Medication: Types, examples and descriptions

Types	Glass
	
Description	All medication made up of glass.
Example of Medication	Solu-Medrol, Adenosine, Amiodarone, Dextrose, Ativan
Types	Plastic
	
Description	All medication made up of plastic.
Example of Medication	Dextrose, Ativan, Carpujects, etc.

Appendix K. Responses regarding items stored in the jump bag

Table 83. Responses regarding items stored in the jump bag

Participant #	Jump bag			
	Medication	Medical supplies	Tools	Others
1	Normal saline Oral Glucose	4 X4, 5X9, Kling, ACE wrap, EZ IO supplies Trauma Dressing, SAM splint Band Aids, Cravat, Occlusive Dressing, Gloves, BVM, IV Catheters Alcohol Preps, ET tubes OPAs, NPAs Stylet, Smart Cap King Airways	Scissors, Laryngoscope, Blades Pen, Light, Laryngoscope, Handles Breslow Tape, Adult BP Cuff Glucometer, Stethoscope EZ IO, Sharp Shuttle	-
2	No meds except - Oral Glucose	- IV - Jump Kit will have oral glucose - Trauma supplies (bandaging equipment) Tape - Airway supplies (basic + intermediate) - protection equipment (Gloves, Glasses)	- Trauma Sheers - Vital Sign tools * Blood pressure cuff *Stethoscope - Blood glucose monitor	- Gown for protection - Pen - Pen Light - Nose Clips
3	-Glucose - Normal Saline	- BVM, Sharps shuttle - IV catheters, Needles - Varies size syringes, Trauma supplies - Varies size ET tubes, Gloves, Glasses - Stylet, Iv supplies	- Bp cuff, trauma scissors - Stethoscope, pen light - Glucometer - Pulse Oximetry reader - Laryngoscope blades+ handles	-

Table 83. (cont'd)

4	-IV solutions - Tubes of oral glucose	- BP cuff, stethoscope - Airway/ Intubation supplies - Glucometer (Blood sugar) - Tape Bandaging	- Scissors (Trauma Sheers) - Pen+ Paper	- Gloves + PPE goggles - Gown- biohazard sleeves
5	- Oral glucose - O2 - Activated charcoal	- Syringe (1 ml, 3 ml, 10 ml), TB, IV catheter (14,16,18,22,24) - 2 X2 gauge, 4X4 gauge, 5X9 Gauge - 3" cling, 6"Cling - ET tube (3.0, 4.0, 5.0,5.5, 6.0, 6.5, 7.0, 8.0) - Oral airway, Nasal airway - Bag valve, Yellow sheets - Suction tubing - Trauma Dressing - Nasal O2 tubing - Endtodal CO2 tubing - ET tube clamps, Tourniquets, Alcohol prep, Tape	- Sharp shuttle, Intubation equipment, Handle & Blade - Suction machine, Breslow tape - Arm splints, BP cuff - Trauma scissors, Sterile wipe - Glucose meter, O2 Bottle - IO gun & Needle - Scarph, megilei forceps	-
6	- Oxygen - Oral glucose - (All other meds kept in 'Drug Box' Activated charcoal)	- Dressings/Bandages/Tape/BVMs (Adult, Ped, Infant) - OB kit/ OP sites/ O2 tubing, canula, masks - OPA/ NPA/ KY / Decompression needles - ET tubes, Alcohol/Iodine swipes/ Biohazard bags - King airways/ Emesis bags/ IV fluid/ Lock - IV catheter/start kits, Yellow sheets (for messy PTs), Interosseous saline - Syringes/needles, Glucometer straps/lancets	- Breslow tape, Megill forceps - Laryngoscope/Blades , Pen light - IO (Ez- IO) - Trauma sheer - Bandage sheer - BP cuffs (adult, Ped, Infant) - Stethoscope - Glucometer - Sharp shuttles	-

Table 83. (cont'd)

7	- Oxygen with regulator 1-25	- Gauzes, Bandaging, Oropharyngeal and nasal airways - Bag valve masks, Oxygen delivery items - IO, nasal cannulas, non-rebreather masks, Lube portable suction device - Blood pressure cuffs of assorted sizes, Stethoscope, Burn sheets - OB kit	- Ring cutter, trauma or bandage shears	-
8	- Oxygen	- O2 Mask, 5X9 bandages, OB kit - Tubing, Bite sticks, Trauma Dressing - BP cuff, Oral airways - Stethoscope, nasal airways, Sterile water - 4X 4 bandages/ Gauzes, Burn sheets	- Ring cutter, Trauma Scissors	EMS gloves Safety glasses

Appendix L. Responses regarding items stored in ambulance

Table 84. Responses regarding items stored in ambulance

Participant #	Ambulance			
	Medication	Medical supplies	Tools	Others
1	Tylenol, Epinephrine, Fentanyl Aspirin, Atropine, Morphine Albuterol, Calcium Chloride, Narcan Atrovent, Mag Sulfate, Dopamine Nitro, Adenosine, Solumedrol Dextrose, veiseal, Ketamine Glycogen, Valium	Duplicates of Bag supplies Sterile Water, Blue pads Thermometer probe cove's Ice packs Hot Packs	Duplicates of Bag Tools (-) Laryngoscope blades & handles	Splints, Pillows Traction Splint, Blankets Backboard, Rip Belt C-collar, Smith Cot Stair Chair, Flashlights
2	Drug Box 36 total meds in drug box - Oral Glucose	- IV catheters - IV tubing - Vital sing (B/D cuff, Stethoscope) - ECG patches - Tape	- Blood Glucose monitor - Oxygen tank - ECG monitor - Oxygen supplies (Nasal cannula, BVM, Non- rebreather) - Linen, Cot	- Radio, Back board, Splinting supplies - Computer
3	- Normal Saline - Oxygen, Narcon, Benadryl - Nitro, Albuterol, Solumedrol - Aspirin, Epinephrine	- IV supplies - Nasal canula,	- ECG monitor, Blood glucose monitor, stethoscope - ECG patches, Pulse oximeter	- Sheets - Pillows - Blankets

Table 84. (cont'd)

4	- Orange drug box - IV soludal (extra)	- Bandage oxygen supply (Extra) - Extra- gloves, PPE	- Suction unit - Heart monitor	
5	- Activated charcoal - Duodote - WMD kit	- ECG patch - Towels/Sheets/ Pillows/ Blade - Gloves/ Masks/ Tyvek suits - Hot/Cold patch	- Heart monitor/ Sharp Shuttles - Bed board & Straps / Steer Stool - Splints/ Trash cans - Seager splint/ Radios, Telephones - Cot/ maps - Stair chair/ Computers - Thermometer/ Ring cather	- Stuffed animals - Raffled veets
6	-	-	-	-

Table 84. (cont'd)

7	- Narcan (Naloxone)	C- Collar, Immobilization pads, Cong spine board with straps, - Traction splint, KED immobilization board, Lows splints	- Automatic external Defibrillator - Safety glasses - Nitrile gloves	- Password protection equipment for eye, splash, protection
8		Narcan	- Long board for splinter - C-collar, Back board, Back board straps - Traction splint - KED board	- AED

Appendix M. Drug box inventory form by Tri-County Medical Control Authority

Table 85. Drug Box inventory form at Tri-County Medical Control Authority

Tri-County Medical Control Authority Systems Protocol DRUG BOX INVENTORY FORM		
Date: November 25, 2015		Page 1 of 1
QUANTITY	DRUG	STRENGTH
4	ACETAMINOPHEN	160mg/5ml dose cup/with syringes
1	ADENOSINE	6 mg vial
2	ADENOSINE	12mg vial
5	ALBUTEROL	2.5 mg/3 ml Neb
3	AMIODARONE	150 mg / 3ml vial
8 tablets	CHEWABLE "BABY" ASPIRIN	81 mg/tablet in blister packaging
3	ATROPINE SULFATE	1mg/10ml syringe
1	CALCIUM CHLORIDE	1 gm/10 ml syringe
2	DEXTROSE 50%	25 gm/50 ml syringe
2	DIAZEPAM (Valium)	10mg / 2ml syringe
2	DIPHENHYDRAMINE (BENADRYL)	50 mg/1 ml syringe
1	DOPAMINE	400 mg/10 ml syringe/vial
1	EPINEPHRINE (ADRENALINE)	1:1,000 (1 mg/ml) 30 ml vial
6	EPINEPHRINE (ADRENALINE)	1:10,000-1 mg/10 ml (syringe)
5	FENTANYL (FENTANYL CITRATE)	100mcg/2ml syringe/vial
1	GLUCAGON	1mg vial with 1 ml diluting solution
2	IPRATROPIUM	500mcg Neb
2	KETAMINE	500mg/10ml vials
3	LIDOCAINE (XYLOCAINE)	100 mg/5 ml syringe
1	LIDOCAINE HYDROCHLORIDE	0.4%/D5W /500 ml bag
2	MAGNESIUM SULFATE	1 gm/2ml vials
3	MIDAZOLAM (VERSED)	5 mg/1ml Vial
5	MORPHINE SULFATE	4 mg/1 ml syringe
3	NALOXONE (NARCAN)	2 mg/2 ml syringe
25	NITROGLYCERIN	0.4 mg tablet
2	SODIUM BICARBONATE	50 mEq/50 ml syringe
2	SOLU-MEDROL	125mg/2ml vial
2	ZOFRAN	4mg/2ml vial
2	MISTY-NEB (INCLUDES ONE EA. 5' CORRUGATED TUBING MOUTHPIECE, TEE, NEBULIZER & O2 TUBING)	
1	NEBULIZER MASK	
2	T.B. SYRINGE 1ML	
2	3 ML SYRINGE	
2	10 ML SYRINGE	
1	20 ML SYRINGE	
2	CARPUJECT HOLDERS	
1	0.9 % Sodium Chloride	250 ml
2	BAXTER MINI DRIP 60 drops/ml	
1	0.9% Sodium Chloride	100 ml
4	VIAL ACCESS CANNULAS	
3	NEEDLE 21 GA X 1.5	
2	FILTER NEEDLE, 21 ga.	
4	BLUNT PLASTIC CANNULAS	
1	3-WAY STOPCOCK	
1	RED PLASTIC LOCK	1 GREEN PLASTIC LOCK

MCA Name: Tri County Emergency MCA
MCA Approval Date: May 13, 2015
MDCH Approved: December 3, 2015
MCA Implementation Date: December 2, 2015

Section 6-10

Appendix N. Road profiles at Transportation Research Center (TRC)

Table 86. Road profiles at Transportation Research Center (TRC)

	Road type	Description	Pictures
1	7.5-Mile Test Track	Total 7.507 mi to 7.539 mi, depending on lanes, asphalt lanes with different slopes (10° with 80 mph, 19° with 110 80 mph). The maximum speed is up to 140mph	

Table 89. (cont'd)

2	Bus & Truck Durability Course	Comprised of staggered bumps, sine waves, chuckholes, chatter bumps significantly and a high crown intersection. (See note for details)	Washboards  Deep Chuckhole  Staggered bumps 	Random Chuckhole  Sine waves  Turtle back 
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Table 89. (cont'd)

3	Cobblestone Durability Course	1,320-foot (402.3 km) long roadway with a cobble protrusion.		
4	Paved and Gravel Hilly Road Courses	8 miles (12.8 km) long roadway including a 1,000-foot (304.8 m), 10 percent asphalt slope, various stone slopes, a 23 percent asphalt slope, a 1.5-mile (2.4 km) gravel road, two level cross-country courses and an off-road course.		
5	Profile Roads – VDA	Various types of realistic road condition such as Tire Slap, Unsprung Mass Vibration, Long Curb, Water Drain, Speed Bumps, Road Joint, Undulation Road, Positive and Negative Shocks, Stability Road, Belgian Block Roads, Chip and Seal Roads, Concrete Choppy Road, Concrete Downhill Wavy, Concrete European Union Road and a High-speed Railroad Crossing.	Water Drain 	Potholes 

Table 89. (cont'd)

6	Vehicle Dynamics Area	Asphalt pad for any kind of vehicle dynamic test		
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Appendix O. Recruitment flyer for formative usability test

EMS Personnel Needed for Simulated Care Scenarios

(MSU research)



About the research

You will be given **two patient scenarios** that you need to respond in an ambulance simulator on a vibration table. Simulated care will be given to manikins while the table is in motion, and all your responses will be videotaped. We will ask you to talk about the decisions that you made and obstacles to providing care for the purpose of improving products within prehospital environment. This whole test will not take more than 2 hours. You will receive **\$100 as a compensation** for participation. If you are coming from Lansing, we will provide mileage

Eligibility

- Be 18 or older
- Be an EMS provider or students with practical care experience on the ambulance who has delivered care within the past 12 months
- Not be pregnant
- Have no history of back, neck, shoulder, arm, wrist or hand injuries or ailments that would be aggravated by riding our table which simulates the motion of an ambulance
- Have not received medical treatment for cumulative trauma resulting from repetitive motion.
- Not have taken any drug or medication 24 hours prior to the experiment that may cause drowsiness or impair your ability to participate in this experiment.
- Have no known history of skin condition (e.g. eczema, latex allergy, etc.)
- Have transportation to the test site (Adient Technologies; Plymouth, MI)

To schedule

Jiyon Lee leejiyo4@msu.edu (Ph.d student)	Michelle Clarkson clarks64@msu.edu (Undergraduate Researcher) 517-304-9111
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Figure 93. Recruitment flyer for formative usability test

Appendix P. Consent Form for formative usability test for those of whom travel from Lansing area or further

Research Participant Information and Consent Form

Principal Investigator:

Dr. Laura Bix, School of Packaging, Michigan State University 517-355-4556

Secondary investigator:

Jiyon Lee, Doctoral Student, Michigan State University, 213-421-6946

Participation is voluntary, you may choose not to participate at all, or you may refuse to participate in certain procedures or answer certain questions or discontinue your participation at any time without consequence (e.g. you will still receive the participant incentive). This study will take no longer than 2 hours of your time.

To participate in this research, you MUST:

- Be 18 or older
- Be a Paramedic or a student who are in paramedic program with practical care experience on the ambulance who has delivered care within the past 12 months
- Not be pregnant
- Have no history of back, neck, shoulder, arm, wrist or hand injuries or ailments that would be aggravated by riding our table which simulates the motion of an ambulance
- Have not received medical treatment for cumulative trauma resulting from repetitive motion.
- Not have taken any drug or medication 24 hours prior to the experiment that may cause drowsiness or impair your ability to participate in this experiment.
- Have no known history of skin condition (e.g. eczema, latex allergy, etc.)
- Have transportation to the test site (Adient Technologies; Plymouth, MI)

What you will do:

We will collect some demographic information and information about your work history. You will be asked to familiarize with the pre-hospital simulator which is comprised of an ambulance look-like structure on a vibration table. After this session, you will be asked to participate in two simulations where you will provide care to an adult patient and an infant patient (both manikins) given two different health scenarios. While delivering care to the “patients,” you will be riding a vibration table that’s motion emulates that of a real ambulance; your care delivery will be videotaped, and we will review the video with you after the simulations to ask about the decisions you made and obstacles you faced as you delivered care. The research will not take more than 2 hours of your time. You will receive \$100 as a compensation for participation. If you have traveled from the mid-Michigan area to participate in the research, we will also provide you an additional compensation for the mileage to travel to the study site.

Benefit & Risk

Although there is no direct benefit to you for participating in this research, it is our hope that the data gathered can be used to better understand the obstacles that EMS personnel face as they try to deliver care in an attempt to inform those that design products for these environments.

Risks are not greater than those that you face in the course of your everyday job delivering care to patients in a vehicle in motion. These include: starting IVs, becoming nauseated by the motion of the table etc. Additionally, there is a potential to mis-step as you enter or exit the table, or possibly being embarrassed as a result of being filmed and having to review and reflect on the decisions of care that you made during the course of the simulation.

Privacy & confidentiality

All information will be tied to a subject number; you will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information collected during this entire study will be protected on a password protected computer or in a locked file cabinet on the campus of Michigan State University for a minimum of three years after the close of the project. Data will only be shared in deidentified formats, or video clips for educational purposes and conferences (if permission is granted). If you do not consent to have clips of your videos shown for conferences/educational purposes, only the appointed researchers and the Institutional Review Board will have access to the research data.

Within these restrictions, results of the study will be made available to you at your request.

Your rights to participate

As part of this research study, all subjects are required to be videotaped. However, you have an option of allowing your video tape for public viewing in presentations of the study results or not. If you agree that your video tape may be used for public viewing, we will provide a green blanket on the manikin, if not, the manikin will have a pink blanket. Video recordings not used for presentations will be destroyed upon completion of the data analysis.

I voluntarily agree to allow the researchers to use the videotapes of the experiment for educational and presentation(s) purposes. ☐ Yes ☐ No Initials _____

Costs and Compensation

There is no cost for being in this study. You will be given a \$100 as compensation for participation. If you have traveled from the mid-Michigan area, you will receive the mileage bonus as well.

The right to get help if injured

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for this research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Dr. Laura Bix, MSU, 517-355-4556, or Jiyon Lee 213-421-6946 with any questions or to report an injury.

Contact Information

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Dr. Laura Bix, 517-355-4556; 114 Packaging Building East Lansing, MI 48824. bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

Documentation of Informed Consent

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

You will be given a copy of this form to keep.

Appendix Q. Consent Form for formative usability test for those of whom travel from near Plymouth area

Research Participant Information and Consent Form

Principal Investigator:

Dr. Laura Bix, School of Packaging, Michigan State University 517-355-4556

Secondary investigator:

Jiyon Lee, Doctoral Student, Michigan State University, 213-421-6946

Participation is voluntary, you may choose not to participate at all, or you may refuse to participate in certain procedures or answer certain questions or discontinue your participation at any time without consequence (e.g. you will still receive the participant incentive). This study will take no longer than 2 hours of your time.

To participate in this research, you MUST:

- Be 18 or older
- Be a Paramedic or a student who are in paramedic program with practical care experience on the ambulance who has delivered care within the past 12 months
- Not be pregnant
- Have no history of back, neck, shoulder, arm, wrist or hand injuries or ailments that would be aggravated by riding our table which simulates the motion of an ambulance
- Have not received medical treatment for cumulative trauma resulting from repetitive motion.
- Not have taken any drug or medication 24 hours prior to the experiment that may cause drowsiness or impair your ability to participate in this experiment.
- Have no known history of skin condition (e.g. eczema, latex allergy, etc.)
- Have transportation to the test site (Adient Technologies; Plymouth, MI)

What you will do:

We will collect some demographic information and information about your work history. You will be asked to familiarize with the pre-hospital simulator which is comprised of an ambulance look-like structure on a vibration table. After this session, you will be asked to participate in two simulations where you will provide care to an adult patient and an infant patient (both manikins) given two different health scenarios. While delivering care to the “patients,” you will be riding a vibration table that’s motion emulates that of a real ambulance; your care delivery will be videotaped, and we will review the video with you after the simulations to ask about the decisions you made and obstacles you faced as you delivered care. The research will not take more than 2 hours of your time. You will receive \$100 as a compensation for participation.

Benefit & Risk

Although there is no direct benefit to you for participating in this research, it is our hope that the data gathered can be used to better understand the obstacles that EMS personnel face as they try to deliver care in an attempt to inform those that design products for these environments.

Risks are not greater than those that you face in the course of your everyday job delivering care to patients in a vehicle in motion. These include: starting IVs, becoming nauseated by the motion of the table etc. Additionally, there is a potential to mis-step as you enter or exit the table, or possibly being embarrassed as a result of being filmed and having to review and reflect on the decisions of care that you made during the course of the simulation.

Privacy & confidentiality

All information will be tied to a subject number; you will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information collected during this entire study will be protected on a password protected computer or in a locked file cabinet on the campus of Michigan State University for a minimum of three years after the close of the project. Data will only be shared in deidentified formats, or video clips for educational purposes and conferences (if permission is granted). If you do not consent to have clips of your videos shown for conferences/educational purposes, only the appointed researchers and the Institutional Review Board will have access to the research data.

Within these restrictions, results of the study will be made available to you at your request.

Your rights to participate

As part of this research study, all subjects are required to be videotaped. However, you have an option of allowing your video tape for public viewing in presentations of the study results or not. If you agree that your video tape may be used for public viewing, we will provide a green blanket on the manikin, if not, the manikin will have a pink blanket. Video recordings not used for presentations will be destroyed upon completion of the data analysis.

I voluntarily agree to allow the researchers to use the videotapes of the experiment for educational and presentation(s) purposes. ☐ Yes ☐ No Initials _____

Costs and Compensation

There is no cost for being in this study. You will be given a \$100 as compensation for participation. If you have traveled from the mid-Michigan area, you will receive the mileage bonus as well.

The right to get help if injured

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for this research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Dr. Laura Bix, MSU, 517-355-4556, or Jiyon Lee 213-421-6946 with any questions or to report an injury.

Contact Information

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Dr. Laura Bix, 517-355-4556; 114 Packaging Building East Lansing, MI 48824. bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

Documentation of Informed Consent

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

You will be given a copy of this form to keep.

Appendix R. Simulation scenario for formative usability test

I. Initial Preparation and Information

- Apply CLUE SPRAY to gurney handles, the overhead bar, the seat belt and work space deck by applying the aerosol using templates that enable a known surface area of application.
- Check if all medical devices, medications and tools needed for the test are in the jump bag, and cabinets or storages (store extra medical devices and medications).
- Run trial pattern with vibration table to make sure if the vibration table properly operates.
- Set the storage section to store/hide simulated patients.
- Set the sign-in desk to welcome participants and perform post-hoc analysis.
- Check cameras for adequate power and storage
- Check file folders for required forms

Participants will be oriented to the simulator during the 'Introductory phase' (see Methods 2.2). Participants will be instructed that sliding the simulated gurney forward and locking it into place signals that they are ready to begin a scenario. This will be done a total of three times: for the first, a brief pattern (also used at the beginning of the day to confirm proper set up and operation) of vibration will be run for the purpose of familiarizing participant with the simulator); the other two times will signal the start of two simulation scenarios. During the first (introductory phase) a member of the research team will familiarize them with the simulator for the purpose of informing them of the location of medical supplies, medications, cleaning supplies and tools.

- GoPros will be restarted and synchronized before each simulation.
- Within the simulated ambulance, researcher will mark the participant's number on an erasable surface so that the data is imbedded within video records to ease subsequent analysis which is linked to the same.

II. Simulation Scripts

Case #1: Adult Fall (Blunt Heart Injury & arm injury)

Introduction

- Instruct participants as to how to slide gurney forward and lock into place
- Orient to auditory prompts-when gurney is locked at the start of the scenario
- Orient participant to simulator and equipment
- Suspend disbelief: "We can agree that the simulator is not real. This being said, you may treat it as if it were. Any questions? Let's get started"

Phase 1: Brief Participants

- As mentioned before, if at any point in the scenario you would like to stop the simulation, please signal this to us by raising your arm above your head and saying, “stop.”
- This simulation will last approximately 10 minutes and I will indicate verbally to you when it is finished.
- Provide the following case information to the participant:

“You are nearing the end of a 24-hour shift and are called to an accident scene at the county fairgrounds where an entertainment stage collapsed due to high winds and impending storm. There are multiple victims with injuries of varying severity. There are only four units with EMS personnel on the scene so far and the nearest hospital is ten minutes away.

Other triage personnel has assigned your first priority victim as a 65-year-old male who fell off the stage and experience trampling from others fleeing the scene. You have placed the victim on a gurney and transferred to rig. I am an EMT driving and will answer questions during the simulation. When you are ready to begin, please slide the gurney forward to lock it in.”

Phase 2: Simulation Activity

1. Stage 1

- Settings/moulage: Victim has a significant injury on his right arm.
BP 148/90 HR 128 R 32 EKG: ST with occ. PVCs SPO2: 92%
- Manikin/simulator vocals: heavy breathing, moaning, pain in rt. arm, abd & chest
- Participant expectations: initial assessment & interventions (monitor, O2)
- History if inquired: No family or friends to provide information; no significant history of HBP, cardiac hx or diabetes. Hx high cholesterol and takes “some pill” for that and some Vitamin D

2. Stage 2-EMS vehicle begins to move as transport begins

- Settings: BP 80/40 HR 150 R 16 EKG: SB with PVCs SPO2: 80%
- Manikin: Increased pain in chest then transition to occ. moaning, decreasing LOC
- Participant expectations: Note monitor, request EKG, initiate IV, increase O2, , may ask for EKG

- Operator: If EKG is requested, provide. May verbalize, “His abdomen appears very distended”, call report to hospital (ETA 10 min.)
1. Stage 3-Intensity of situation increases
 - Victim becomes nonresponsive
 - Settings: No BP, No R, No HR EKG: PEA
 - Participant expectations: Bag/Valve/Mask then Intubation, emergency cardiovascular medications
 - Operator: “ETA 4 minutes”
 2. Stage 4-termination of simulation
 - Indicate end when victim has IV and has been intubated
 - State, “We have arrived at the hospital where transition of care has taken place.

Case #2: Newborn Resuscitation

Introduction

- Remind participants as to how to slide gurney forward and lock into place
- Remind to auditory prompts-when gurney is locked at the start of the scenario
- Orient participant to simulator and equipment
- Suspend disbelief: “Again, we can agree that the simulator is not real. This being said, you may treat it as if it were. Any questions? Let’s get started”

Phase 1: Brief Participants

- As mentioned before, if at any point in the scenario you would like to stop the simulation, please signal this to us by raising your arm above your head and saying, “stop.”
- This simulation will last approximately 10 minutes and I will indicate verbally to you when it is finished.
- Provide the following case information to the participant:

“It has been snowing heavily for 8 hours with a foot of accumulation. You and your partner have been dispatched, in addition to a second rig, to the home of a mother who has just given

as her husband is stranded at the airport and nearest relatives and friends could not arrive in time to transport her to the hospital. The neighbor next door will stay with the mother as she is transported in the second rig. ETA to hospital is 10 minutes under normal conditions. I am the EMT driving and will answer questions during the simulation. When you are ready to begin, please slide the gurney forward to lock it in."

6 months old infant vomiting and loose stool for 2 days lethargic.

Phase 2: Simulation Activity

1. Stage 1

Settings/moulage: cyanotic around mouth, weak cry

HR: 170 BP: 80/40 R: 32 EKG: SVT

Operator: may need to state the baby has weak cry if no audio

Participant expectations: Warm infant, stimulate infant, place in supine sniffing position, initial assessment, suction, Oxygen

2. Stage 2

Settings: HR 80 BP: 70/50 R: 12 EKG: SR with PVCs

Operator: "This isn't looking good. The roads are horrible...ETA is about 5-7 minutes."

Participant expectations: Oxygen mask, Intraosseous IV, meds

3. Stage 3

Settings: HR: none BP: none R: none EKG: SBR

Participant expectations: cpr, intubation, meds

4. Stage 4-termination of simulation

a. Indicate end when victim has IV and has been intubated

b. State, "We have arrived at the hospital where transition of care has taken place. You will now debrief with the research team after which time we will do the second simulation."

Phase 3: Debrief

Thank you for helping us with the study. You may have figured out by now, being from the School of Packaging, we are primarily focused on how package design influences your ability to perform your job effectively. We will be reviewing the videos collected to look for common problems that emerged from

d)

the various package designs that you worked with. The intent of the work is to try to create designs that are easier to identify, open and assist with product use.

I'd very much appreciate it if you could pass out flyers to any EMS friends that you have that would qualify to participate, but if you do, please just tell them that the study is about understanding how the extreme contexts of care presented by prehospital environments potentially interfere with people's ability to use products, and that we are trying to improve designs of healthcare products so that they work better in these environments.

Appendix S. Demographic Collection Sheet for formative usability test

Demographic information

Subject # _____

1. What is your Sex

☐ Transgendered

☐ Male

☐ Female

2. In what year were you born? _____

3. How many years have you worked as an EMS professional?

☐ I have never worked as an EMS professional

☐ 8-10 years

☐ Less than one year

☐ 11-15 years

☐ 1-2 years

☐ 16-20 years

☐ 3-4 years

☐ 21 or more years

☐ 5-7 years

4. For how many different organizations do you currently perform EMS work?

☐ 0

☐ 1

☐ 2 or more

5. Which of the following best describes your primary role at your main EMS job?

☐ Patient Care Provider - A person whose primary role is the provision of EMS services to patients.

☐ Educator - A person whose primary role is instructing individuals enrolled in an approved or accredited EMS training course or providing continuing education required for maintenance of licensure.

☐ Preceptor - A person whose primary role is training individuals enrolled in an approved or accredited EMS training course in a clinical setting.

☐ Dispatcher/Call Taker - A person whose primary role is EMS communications.

☐ Administrator/Manager - A person whose primary role is the management and direction of an organization providing EMS services.

☐ First-line Supervisor - A person whose primary role is the direct supervision of individuals providing EMS services.

☐ Other - A person whose primary EMS role at their main job is not listed above (please specify).

6. Which of the following best describes your main EMS agency/organization?

☐ Hospital - refers to EMS agencies that are under the direct control of a hospital, regardless of the type of organization that runs the hospital.

☐ Fire Department - an organization from which fire and EMS services are provided, regardless of the type of organization that runs the Fire Department. Volunteer fire departments should be included here.

- ☐ Tribal - are operated by a federally recognized Indian or Alaska Native Tribe.
 - ☐ Military - are operated by one of the U.S. Armed Forces and staffed by active duty personnel.
 - ☐ Government, Non-Fire Department - are operated directly by a federal, state, county, or local government entity other than the U.S. Armed Forces.
 - ☐ Private - are operated under the direct control of a for-profit or not-for-profit organization other than a hospital. Volunteer rescue squads that are operated independently of a fire department should be included here.
 - ☐ Air Medical - an organization which provides air ambulance services, regardless of the type of organization which runs the air ambulance service.
 - ☐ Other - Please specify
-

1. Which of the following best describes the primary type of service provided by your main EMS agency/organization? If more than one type of service is provided, pick the service with the greatest number of calls in the past 12 months.

- ☐ Primarily 911 response with or without transport capability – Immediate response to an incident location, regardless of method of notification (for example, 911, direct dial, walk-in, flagging down).
 - ☐ Primarily medical transport (convalescent) - Transport of a patient from one health facility to another.
 - ☐ Equal mix of 911 and medical transport (convalescent)
 - ☐ Clinical services - Provision of clinical services in a non-ambulance clinical setting such as emergency department, medical office, or dialysis clinic.
 - ☐ Mobile Integrated Healthcare & Community Paramedicine - Provision of clinical services in an out-of-hospital community setting.
 - ☐ Other - Please specify
-

2. How long have you been employed or volunteered at your main EMS job?

- | | |
|---|---|
| ☐ Less than one year | ☐ 8-10 years |
| ☐ 1-2 years | ☐ 11-15 years |
| ☐ 3-4 years | ☐ 16-20 years |
| ☐ 5-7 years | ☐ 21 or more years |

3. Which of the following best describes your employment status at your main EMS job?

- | | |
|------------------------------------|---|
| ☐ Full time | ☐ Per diem, PRN or as needed |
| ☐ Part time | ☐ Volunteer or on-call |

1. On average, how many calls do you respond to in a typical week at your main EMS job?

- | | |
|-----------------------------------|-------------------------------------|
| ☐ 0 | ☐ 20 to 29 |
| ☐ 1 | ☐ 30 to 39 |
| ☐ 2 to 4 | ☐ 40 to 49 |
| ☐ 5 to 9 | ☐ 50 or more |
| ☐ 10 to 19 | |

2. Which of the following best describes the community in which you do most of your EMS work?

- ☐ Rural area (less than 2,500 people)
- ☐ Small town (2,500 - 24,999 people)
- ☐ Medium town (25,000 - 74,999 people)
- ☐ Large town (75,000 - 149,999 people)
- ☐ Mid-sized city (less than 500,000 people)
- ☐ Suburb/fringe of a mid-sized city
- ☐ Large city (500,000 or more people)
- ☐ Suburb/fringe of a large city

3. What is the highest level of education you have completed?

- | | |
|--|--|
| ☐ Didn't complete high school | ☐ Bachelor's Degree |
| ☐ High school graduate/GED | ☐ Master's Degree |
| ☐ Some college | ☐ Doctoral Degree |
| ☐ Associate's Degree | |

4. Which of the following best describes you? You may choose more than one.

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Refuse

Appendix T. Exit survey sheet for formative usability test

Participant #	Type of scenario (Adult/Infant)	Product:	(# / _)			
Type of Action	Likert-scale					Comments
	Overall, how satisfied were you with your ability to (identify, open, use) this package?					
	Unintended affordance					
Identify	1 Very Satisfied	2 Somewhat Satisfied	3 Okay	4 Somewhat unsatisfied	5 Very unsatisfied	What we observe
	Was unintended behavior noted?				Yes No	Brief description of unintended behavior
	“What are the package/product designs (design cues) posed a challenge for you as you were working with this product?”					
Open	1 Very Satisfied	2 Somewhat Easy	3 Okay	4 Somewhat unsatisfied	5 Very unsatisfied	What we observe
	Was unintended behavior noted?				Yes No	Brief description of unintended behavior
	“What are the package/product designs (design cues) posed a challenge for you as you were working with this product?”					
Use	1 Very Satisfied	2 Somewhat Easy	3 Okay	4 Somewhat unsatisfied	5 Very unsatisfied	What we observe
	Was unintended behavior noted?				Yes No	Brief description of unintended behavior
	“What are the package/product designs (design cues) posed a challenge for you as you were working with this product?”					
Found unintended behavior because of context?					Yes No	What we observe
“I see that you are using (e.g. glasses, one hand, the trauma shears, your teeth, etc.) in order to successfully (e.g identify/open/use) the product at this point in the video. What is happening here (the context/setting) forced you to do this?”						Brief description of unintended behavior
Unintended behavior due to personal experience?					Yes No	What we observe
“Do other elements of what is happening such as personal experiences or issues posed a challenge for you as you were working with this product?”						Brief description of unintended behavior

Appendix U. Clean and contamination evaluation sheet for formative usability test

Cleaning/Contamination Evaluation

Participant # _____

Parts to check		Presence of CLUE SPRAY	Other
Type of parts	Sub-types	Binary fashion coding	
Cleaning evaluation			
Interior components of the simulator	Seat belt	Yes / No	
	Cot handles	Right: (Yes/No)	
		Left: (Yes/No)	
	Bars	Yes / No	
	Work space deck	Yes / No	
Contamination evaluation			
Patients	Around the wound	Yes / No	
	Mouth	Yes / No	
Paramedics	Gloves	Yes / No	
Packages		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
Products		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	
		Yes / No	

Appendix V. Participants' interactions with package by products and subtasks

■ Adult simulation Scenario

Participant 1

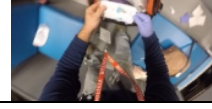
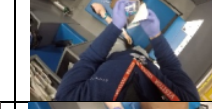
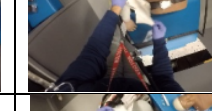
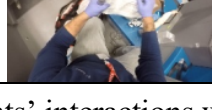
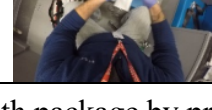
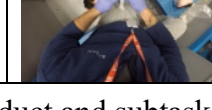
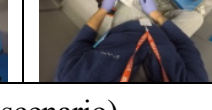
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing		N/A				
IV solution		N/A				
IV catheter (with an extension)						
IV start kit		N/A				
ET tube						

Figure 94. Participants' interactions with package by product and subtasks (Adult simulation scenario)

Figure 94. (cont'd)

Participant 2

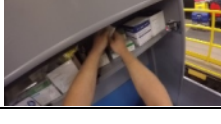
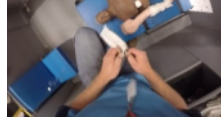
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
Trauma Dressing						
IV tubing		N/A				
IV solution						
IV catheter			N/A			
IV start kit						
ET tube	Did not use					

Figure 94. (cont'd)

Participant 3

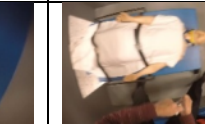
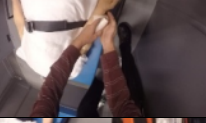
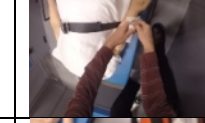
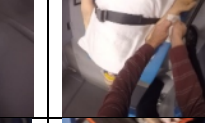
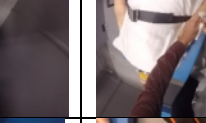
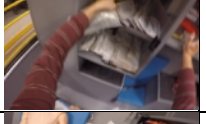
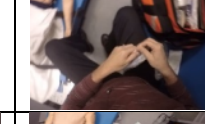
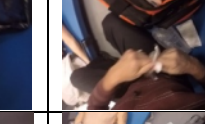
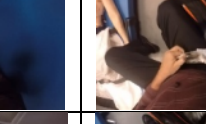
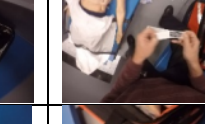
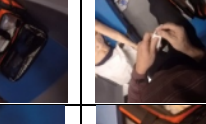
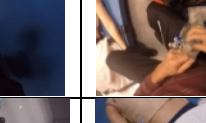
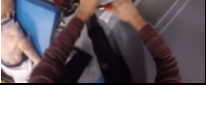
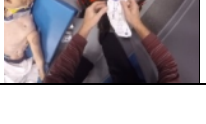
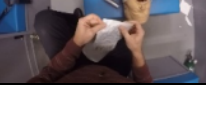
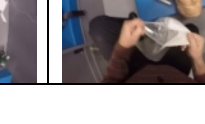
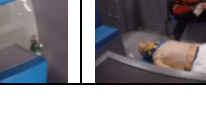
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing						
IV catheter						
IV solution						
IV start kit						
ET tube						

Figure 94. (cont'd)

Participant 4

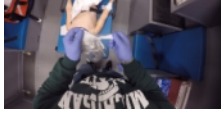
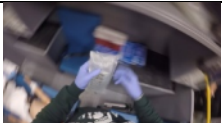
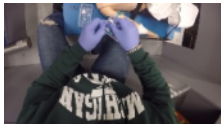
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing		N/A				
IV solution						
IV catheter(with an extension)						
IV start kit						
ET tube						

Figure 94. (cont'd)

Participant 5

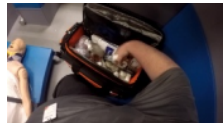
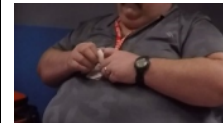
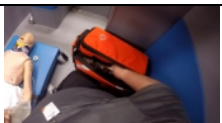
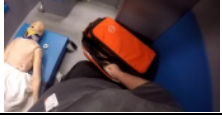
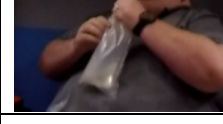
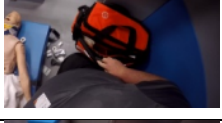
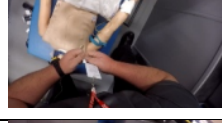
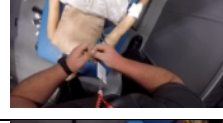
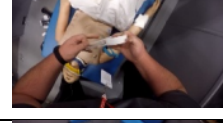
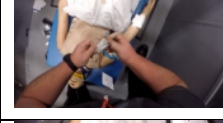
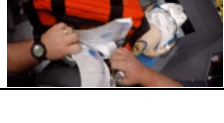
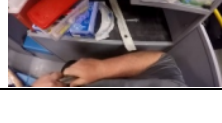
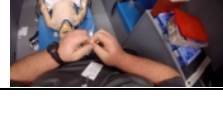
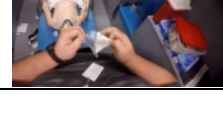
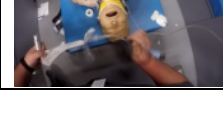
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing						
IV solution		N/A				
IV catheter(with an extension)		N/A				
IV start kit						
ET tube						

Figure 94. (cont'd)

Participant 6

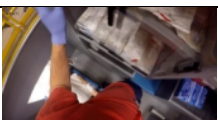
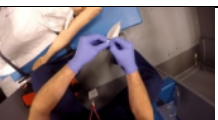
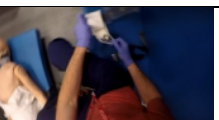
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4 by 4 pad						
Gauze (plastic flexible film)		N/A				
IV tubing						
IV solution		N/A				
IV catheter(with an extension)		N/A				
IV start kit		N/A				
ET tube						

Figure 94. (cont'd)

Participant 7

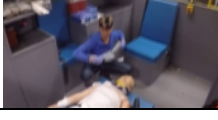
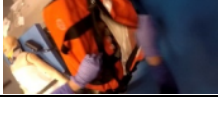
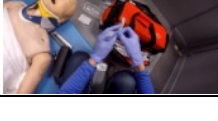
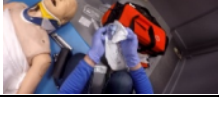
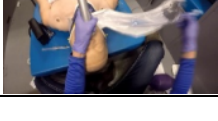
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4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing		N/A				
IV solution		N/A				
IV catheter(with an extension)						
IV start kit		N/A				
ET tube						

Figure 94. (cont'd)

Participant 8

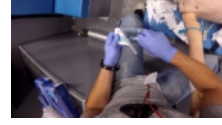
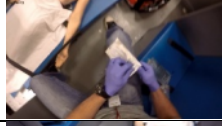
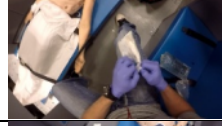
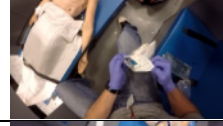
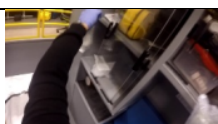
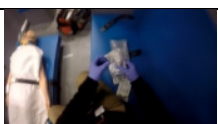
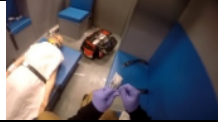
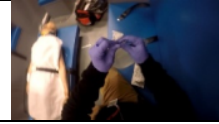
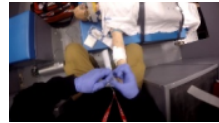
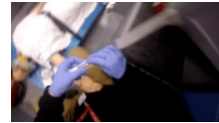
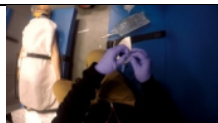
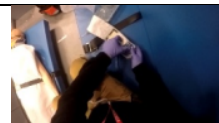
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad						
Gauze (plastic flexible film)						
IV tubing						
IV solution		N/A				
IV catheter(with an extension)						
IV start kit						
ET tube						

Figure 94. (cont'd)

Participant 9

	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
4 by 4 pad		N/A				
Gauze (plastic flexible film)						
IV tubing						
IV solution		N/A				
IV catheter(with an extension)						
IV start kit						
ET tube						

- Infant simulation Scenario

Participant 1

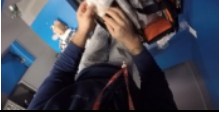
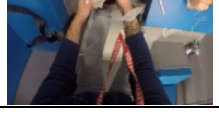
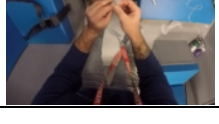
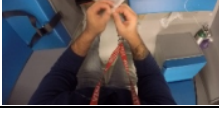
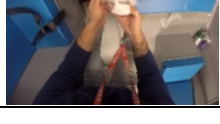
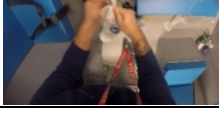
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing		N/A				
IV solution		N/A				
IV start kit						
ET tube		N/A				

Figure 95. Participants' interactions with package by product and subtasks (Infant simulation scenario)

Figure 95. (cont'd)

Participant 2

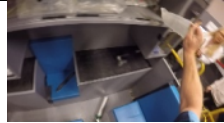
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution		N/A	N/A			
IV start kit						
ET tube						

Figure 95. (cont'd)

Participant 3

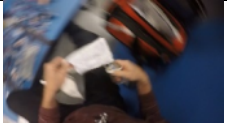
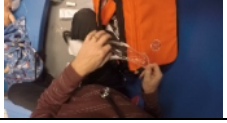
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing		N/A				
IV solution		N/A				
IV start kit		N/A				
ET tube						

Figure 95. (cont'd)

Participant 4

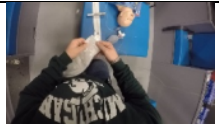
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution						
IV start kit						
ET tube						

Figure 95. (cont'd)

Participant 5

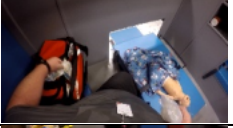
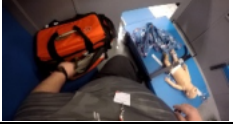
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution						
IV start kit			Did not use			
ET tube						

Figure 95. (cont'd)

Participant 6

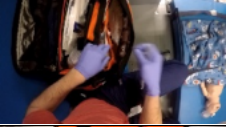
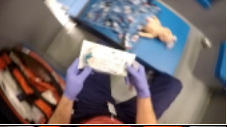
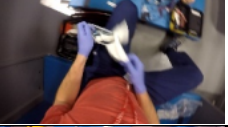
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution						
IV start kit						
ET tube						

Figure 95. (cont'd)

Participant 8

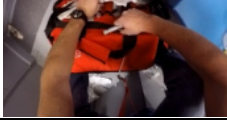
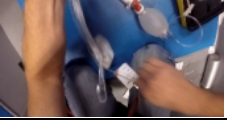
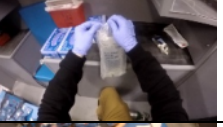
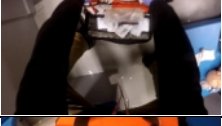
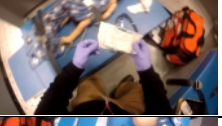
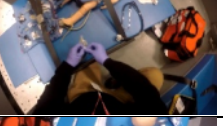
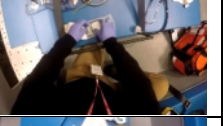
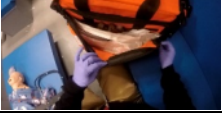
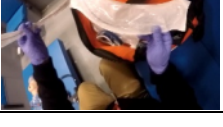
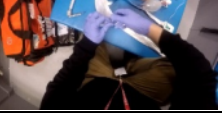
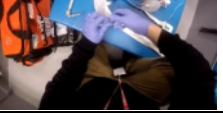
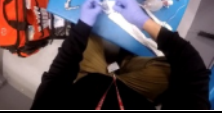
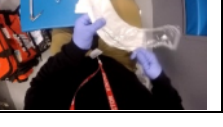
	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution						
IV start kit						
ET tube						

Figure 95. (cont'd)

Participant 9

	Product identification	Product interaction	Grip identification	Grip interaction	Open	Use
IV tubing						
IV solution						
IV start kit						
ET tube						

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