Utilizing Concepts of Human Systems Engineering to Improve the Urine Specimen Collection Process

by

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ABSTRACT

Billions of dollars are spent annually on urine specimen collection and analysis as they are critical clinical components vital to human health. The mid-stream clean catch (MSCC) process is the gold standard of ambulatory urine specimen collection for clinical diagnosis of urinary tract infections (UTI). The MSCC process is over 60 years old and is plagued by ridiculously high specimen contamination rates. The MSCC has resisted numerous attempts aimed at improving it.

The purpose of this study was to determine if utilizing the concepts of Human Systems Engineering (HSE) could improve the urine specimen collection process. HSE concepts were not only targeted toward the problems, they were also used in the quest to develop effective solutions. Results obtained demonstrate that HSE concepts, when applied to urine specimen collection, can and do make a difference in terms of specimen quality and patient satisfaction. One low cost easily implemented targeted HSE-informed intervention effort resulted in a specimen contamination rate reduction of 16.6%.

A second targeted HSE-informed intervention involving the redesign of the specimen cup, its instruction set, and additional sign placement made it three times less likely for participants to provide a contaminated MSCC sample. The redesigned specimen cup automatically captures and isolates an initial void sample from an MSCC sample, both derived from one continuously provided patient specimen. Clinical utility comes in the form of improved MSCC specimen quality and a separated initial void available for analysis using Nucleic Acid Amplification Testing (NAAT) or other test protocols. Capturing and isolating both an initial void and an MSCC at the same time allows for a more complete diagnostic workup utilizing a higher quality MSCC without

requiring the patient to follow two different protocols to urinate into two different specimen cups.

The redesigned specimen cup also provides for automatic overflow prevention, incorporates a new ergonomic grip, and a saddle adapter that provides affordances for both women and men in terms of urine capture and the reduced likelihood of urinating on one's self.

DEDICATION

I did this for my family.

Thank you for your unwavering support.

ACKNOWLEDGMENTS

I would like to acknowledge the unwavering support of Nugget. Thank you for being there for my defense. So sorry you could not make it to graduation with me.

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INTRODUCTION

Proper assessment of the health of an individual often requires the performance of medical tests, some of which involve the collection and analysis of urine specimens. Medicare and private insurance companies in the United States spent approximately $8.5 billion on urine screenings and their related exams in 2014 (Schulte, Lucas, & Marco, 2017). When spending this quantity of money, it is advisable to ensure that one has the most accurate results possible, and accurate results require accurate inputs. In the case of suspected urinary tract infections (UTIs), the "gold standard" for urine specimen collection is the mid-stream clean-catch (MSCC) first introduced in 1958 (Boshell & Sanford, 1958). The purpose of the MSCC is to collect a self-obtained urine specimen that is uncontaminated by bacteria and epithelial cells not originating from the urinary tract. Contaminating bacteria and rogue epithelial cells from outside of the urinary tract can come from several sources including; hands, skin, urethra, genital area, underwear, and transfer surface contact.

Once obtained, the MSCC sample can be analyzed in a variety of ways such as; a dipstick analysis, a laboratory standard urinalysis, microscopic exam of the sample, and cultures. Contaminates that were introduced during the collection process will pass through to the analysis phase, where they then have the potential to cause a variety of errors. The MSCC technique has seen little to no modification or improvement since its inception despite studies outlining deficiencies, shortcomings, and failed attempts at improvement (Baerheim, Digranes, & Hunskaar, 1992; Frazee, Enriquez, Ng, &Alter, 2015; Maher, Brown, & Gatewood, 2017; Jacob et al., 2018).

Contaminants in a urine specimen can lead to false positives, misidentified bacteria, and false negatives in diagnosis. In the case of false positives, a patient without a urinary tract infection (UTI) may be prescribed antibiotics due to the inaccurate results. In the case of a misidentified bacterium, the actual bacterium strain may have weak or no sensitivity to the antibiotic prescribed. Both conditions can lead to over-prescription of antibiotics, unwanted side effects, as well as contributing to overall bacterial resistance to antibiotics (Holm, & Aabenhus, 2016; LaRocco et al., 2016). It is also possible to obtain a false negative due to contamination interfering with the analysis of the provided specimen. Research has demonstrated that 70% of all urine specimens provided by healthy women are contaminated (Frazee, Enriquez, Ng, & Alter, 2015). Further, their study identified that improper collection technique on the part of the patient contributed to the overall contamination rate of the samples collected.

Not only can contaminated cultures lead to misdiagnoses, but they also waste time and resources for both the physician and the patient (Jacob, et al., 2018).

In 2007, UTIs accounted for more than 8.6 million combined setting ambulatory care patient visits in the United States (Schappert, & Rechtsteiner, 2011). Combined setting visits include visits to one of the following; a primary care office, a surgical specialty office, a hospital outpatient department, or the emergency department. As stated before, in the case of a UTI visit, the standard diagnostic workup includes a urine collection via an MSCC. Frazee et al. (2012) demonstrated that 85% of all patients could not recall performing the MSCC process correctly. Applying this 85% potential error rate to the 8.6 million UTI visits per year (Schappert, & Rechtsteiner, 2011) results in the possibility

that 7.31 million MSCC urine specimens collected in the US each year are potentially performed incorrectly and contaminated.

The scope and duration of the failings associated with the urinalysis collection process and the potential implications for human health warranted a systematic investigation aimed to identify underlying issues and improve overall outcomes. A Human Systems Engineering approach was chosen as the means by which to guide both the investigation and improvement processes. Arizona State University defines Human Systems Engineering (HSE) as a methodology that utilizes the concepts of psychology and engineering to account for the limitations and capabilities of humans when designing technology for use by people in the real world (Human Systems Engineering Program, 2020). This paper will explore and detail the ways in which HSE concepts were applied to the improvement of the urinalysis specimen collection process as well as the design of an automated specimen collection device.

LITERATURE REVIEW

PICO

The PICO methodology (Hoffmann, Bennett, & Del Mar, 2017) was utilized to form an answerable clinical question for the purpose of serving as an investigative tool with which to begin conducting a literature search. The elements present in the PICO question were as follows:

- P – Problem / Population: In human urinalysis sampling, how does…
- I – Intervention: …modifying the diagnostic collection technique…

- C – Comparison: …compare to the standard collection technique…
- O – Outcome: …in terms of quality of the sample?

Databases and Repositories Searched

The following databases and repositories were electronically searched for items of relevance to the present study:

- PubMed
- CINAHL the Cumulative Index of Nursing and Allied Health Literature
- Cochrane Library
- National Guidelines Clearinghouse
- All resources accessible by the Arizona State University Library search tool

Search Terms

The following search terms were used in various combinations to uncover articles with possible relevance; *urinalysis, collection, technique, collection technique, contamination, Mid-Stream Clean Catch, MSCC, initial void.*

Search Results

Initial search results using a minimal number of the prior mentioned terms and logic resulted in returns greater than 1000 articles. Many articles that were returned included extraneous elements or constraints that were not judged to be relevant to the overall scope of this project. Examples include literature containing or referencing items such as; pregnancy, the efficacy of specific antibiotics relating to a single bacterium, drug testing, steroid usage, and unrelated clinical studies. The majority of the studies returned via initial search were quickly reviewed but ultimately judged to be unrelated had the

primary search terms returned in the body of the literature as opposed to the title or the abstract of the article itself. The order and quantity of the search terms mentioned in the section above and search logic were adjusted to obtain a manageable return of 71 articles across the multiple databases and repositories. The articles were then compiled for a detailed review. The review started with a reading of the abstracts, an examination of the date of publication, assessment of the level of evidence (Hoffmann, Bennett, & Del Mar, 2017), and the overall relevance to the present endeavor.

Discussion of Specific Relevant Literature

The most applicable portion of the identified literature relevant to the present study will be discussed and presented here. Literature found to be relevant but not specifically selected for examination in this section will be cited and discussed in other portions of this document.

In a synopsis of syntheses designed to determine the appropriate courses of action for improving patient outcomes through the use of the best practices for urine specimen collection, Dolan and Cornish (2013) focused a literature review on pathology, asymptomatic versus symptomatic urinary tract infections, and specimen collection techniques as means to develop and deploy methods to aid in the reduction rates of specimen contamination at a 350-bed hospital. The specific means recommended and deployed included; properly labeling the specimens with identifying data including the time and date of collection, utilizing a mid-stream collection technique, and keeping the specimens cold to prevent bacterial growth. The researchers reported that implementation of the recommendations resulted in an annual reduction of 250 contaminated samples, resulting in a direct savings of $32,250 in testing fees with an additional savings of

$3,000 per patient for a misdiagnosis generating a total potential savings of $750,000 per year. The most relevant findings were improvements shown when a mid-stream collection technique was utilized in conjunction with HSE relevant guidelines related to process improvements, specifically the importance of properly labeling specimens.

A randomized control trial was conducted at Rutgers University clinic in New Jersey involving 242 consecutive female patients (aged 17 – 50) presenting with symptoms of dysuria associated with a suspected UTI (Lefshitz, & Kramer, 2000). The goal of the study was to compare three different collection techniques by examining their effects on the urinalysis indices and urine culture results. Group One was simply instructed to urinate directly into a clean nonsterile collection container. Group Two was instructed to perform a mid-stream clean catch that included perineal cleansing and spreading of the labia, while Group Three was to follow the instructions given to Group Two with the further addition of the insertion of a vaginal tampon. Group One had a demonstrated contamination rate of 29%, Group Two had a 32% contamination rate, and Group Three had a 31% contamination rate. The results suggest that the tested methods of specimen collection in women presenting with symptoms of a UTI do not affect the rates of contamination. It is important to note that this study was designed to determine the rates of contamination present in women who are believed to have a possible UTI and it was used to inform the present study design.

A pseudo-randomized control trial utilizing 111 female nursing and medical laboratory technology students acting as their own controls was conducted by Baerheim, Digranes, & Hunskaar (1992) in order to investigate how the various steps of the clean-catch mid-stream sampling technique performed in combination or alone affected the

bacterial content of the urine samples collected. The study design consisted of eight consecutive early morning urine samples from each participant. Each participant was to follow a new written instruction set each day based on the group they were assigned to. The written instructions detailed which of the three parts of the mid-stream clean-catch process that was to be performed. The steps were defined as: (A) spread the labia majora and minora apart with one hand, (B) wash the perineum from front to back with five cotton swabs moistened in tap water, one at a time, (C) void a small portion of urine before collecting the middle portion, with the remainder being voided into the toilet. For half of the participants, the written instructions provided were presented in a specific order per the design of this study by Daerheim and Digranes (1992). The second half of the group was assigned the instructions in the reverse order. The results demonstrated that the best technique was following all of the steps in the mid-stream clean-catch process; however, even this process resulted in a contamination-free rate of 26.6%, meaning that 73.4% of the samples collected under the best of conditions were judged to be contaminated. Further, as all of the participants were enrolled in either nursing or medical laboratory technology, they were instructed to immediately prepare and inoculate their specimens for analysis which would represent a best-case scenario in the real-world in which a sample is collected under ideal conditions and immediately prepared for examination as opposed to questionable collection techniques and an unknown amount of delay in specimen preparation.

Morello et al. (2015) designed a diagnostic accuracy study (Hoffmann, Bennett, & Del Mar, 2017) as a piggyback study on a separate randomized control study. The diagnostic accuracy study designed by Morello et al. (2015) examined the effect of

suboptimal sampling and handling conditions on urinary metabolic profiles by analyzing the quality of within-subject repeated measures separated by time and collection location. Specifically, some samples were collected in a controlled hospital environment, and others were collected by the patient at home. The study's conclusion was that suboptimal sampling and handling of specimens resulted in increased bacterial contamination.

Maher, Brown, and Gatewood (2017) investigated the effect of posted written and visual instructions outlining the process to be followed for a patient to perform a proper MSCC. The goal of the study was to determine the effect of posting written and visual MSCC instructions for reference by the patient in the bathroom used to provide the sample on the rates of contamination. The experiment was conducted over a three-month period involving the collection and analysis of 754 samples and 193 urine cultures. Sample contamination rates for the treatment group, as determined by microscopy exam revealed 392 contaminated specimens (51.98%), while the treatment group of urine cultures revealed 77 contaminated results (39.8%) as defined by their culture standards. The contamination rate was compared to historical records from the previous year as a form of control. The historical control examined 827 samples and 251 urine cultures with a contamination of 430 samples (51.99%) and 125 (49.8%), respectively. The contamination rate for the urinalysis treatment group was 51.99% vs. 51.98% for the control with no significant difference. For urine culture, the treatment group contamination rate was 39.8% vs. 49.8% for the control with no significant difference. The results demonstrate that posting written and visual instructions had no significant effect on the rates of contamination. The authors speculate that this is either due to patient non-compliance with the MSCC process or poor efficacy of this technique. The

speculation by the authors is important to note in that it has particular relevance to the present study because it demonstrated that contamination issues revolved around patient non-compliance and/or an inefficient process. The present study was designed to address both of the identified factors.

The designers of the following study took a different approach. Jacob et al. (2018) created a mobile application designed to instruct the patient on the proper way to perform an MSCC. The experimenters recruited 257 participants who were medically ordered to perform a urinalysis and/or urine culture when presenting to an academic Emergency Department (ED). Participants in the treatment group viewed an instructional video and then provided their MSCC. The participants were pair-matched based on gender, urine specimen type, date of visit, and the ED work shift. A 38% contamination rate was observed over a total of 514 participants. Three were no significant differences in the rates of contamination between matched pairs overall, or when grouped by prior knowledge of the clean-catch process, gender, or type of urine specimen. The mobile instructional application was ineffective in reducing the rates of contamination in this study.

Research conducted in 2015 demonstrated that 70% of all urine specimens provided by healthy women are contaminated (Frazee, Enriquez, Ng, & Alter, 2015). Further, the study identified that improper collection technique on the part of the patient contributed to the overall contamination rate of the samples collected. This study supports the conclusion identified by Maher, Brown, and Gatewood (2017). A separate study conducted in an ED (Frazee, Frausto, Cisse, White, & Alter, 2012) utilizing patient self-reported measures, found that only 61% of patients received verbal instructions on how to

properly provide a urine sample, with only 15% reporting that they recall fully complying with the instructions provided. The results of this study, combined with the previous studies reviewed demonstrate that there are failures in terms of patient compliance, patient comprehension, and procedural execution. These issues can be addressed with HSE informed concepts and approaches.

Literature Review Informed Next Steps

After systematically reviewing the literature, both a need and a gap exist in the MSCC process as it is presently implemented. A process that was introduced in 1958 (Boshell & Sanford, 1958) simply should not have as many issues with quality and error rates, as demonstrated by the review of the literature. The studies reviewed showed that several techniques, without mention of or regard to the science of Human Systems Engineering, have already been tried and failed to significantly improve patient compliance and/or reduce contamination rates. Given the existence of these gaps and the apparent lack of human factors and ergonomics considerations, a Human Systems Engineering (HSE) approach to improving urine specimen collection is warranted. The research has helped determine that the HSE approach should concentrate on identifying and overcoming the human factors and ergonomic elements that have led to the perpetuation of such gross and persistent error and contamination rates. Specifically, a Human Systems Engineering approach will explore the gaps that exist between the existing processes and technology and the limitations of human performance. The utilization of an HSE lens will allow for a systematic examination of underlying causes of failure relating to patient cognition, limitations of memory, reasons for non-compliance, ergonomics, and device design. Further, application of HSE techniques will allow for the

development of improved processes, equipment, and procedures designed to maximize compliance and properly accommodate the human element. In the form of a concrete example, an HSE approach to eliminating error would be to automate a portion of the MSCC process. Automation would reduce the cognitive load on the patient as well as reducing the opportunities for the patient to introduce errors into the process.

The next section describes the prior art research that was performed as a methodological approach to uncovering existing ideas and products designed to automate the MSCC process.

PRIOR ART RESEARCH

Initially, a Google search was performed to identify any available products on the market designed to aid in the collection of an MSCC sample. Three products were identified and researched. Parameters for a patent search were developed based on the three products as well as other relevant criteria. Patents are a matter of public record and provide an excellent source of research material. In order to identify patents relevant to the automatic collection of urine samples of particular interest to isolating the MSCC process, a patent search was conducted utilizing the resources available at www.uspto.gov based on the relevant criteria. The patent search identified five recent patents which were explored in detail. The prior art cited in the five recent patents of interest was used to identify and examine over 300 additional patents of interest. The patents examined were not limited to devices designed to collect an MSCC, but also included devices designed to perform liquid assays and other types of testing far beyond urology.

Examination of the patents, as well as the currently available products, enabled the identification of significant gaps that can be addressed by taking a methodical Human Factors and Ergonomic approach to the design of a new specimen collection device. The majority of the gaps involved a lack of consideration for the person providing the sample, especially in the case of women. For example, most devices contained markings to indicate fluid levels and involved a collection technique that was clearly designed by a man for a man. In the case of fluid level markings, the only way for a woman to see the markings would be to stop filling the specimen cup, which means that they must pause urination, and physically move the cup into their visual range. If a woman determines that they have not provided the proper amount to sample based on visual inspection, she must replace the collection device and begin urinating again. In the case of the collection technique, it was obvious that the devices were designed with a relatively small opening. Such a small opening suggests that the patient providing the sample must have the ability to see the device and the urine stream at the same time as well as the ability to provide a steady and directable stream of urine to the collection vessel. The female anatomy is not conducive to either of these two inherent requirements in a collection device with a relatively small opening.

Prior Art Research Informed Next Steps

After systematically reviewing prior art in this area, it was determined that an opportunity existed to take an HSE informed approach to designing an automated specimen collection cup that would improve both sample quality and patient satisfaction at the same time. To that end, a concerted effort was undertaken to design such an automated specimen collection device.

The next section provides a description of the most applicable Human Systems Engineering concepts along with their basis for application towards improving the urine specimen collection process.

IDENTIFYING MISMATCHES BETWEEN THE PROCESS AND HUMAN CAPABILITIES

Capabilities

The statistics presented earlier, coupled with the literature review and the prior art search, present a compelling case for the use of a Human Systems Engineering (HSE) approach to evaluating the mechanisms and processes utilized in obtaining an MSCC collection. Human Systems Engineering as a discipline combines elements of psychology, sociology, engineering, ergonomics, and human factors to help ensure that technology meets the needs of people while aligning properly with the limitations of the human condition.

In viewing the overall problems through a human-factors lens, several contributing factors to the lack of success in improving the quality of urine specimen collection become visible. When a patient is asked to provide a urine sample, one must consider the barriers to performing a proper MSCC collection. The most obvious and overarching barrier is a mismatch between the process and human capabilities.

As noted, several techniques have been tried including; a training application for mobile devices (Jacob et al., 2018), the use of visual and written instructions (Maher et al., 2017, and providing verbal instructions to the patient (Frazee et al., 2012). Each of these techniques and interventions have failed to either properly identify or effectively address the problem of contaminated urine specimen samples.

When Maher et al. (2017) investigated the effect of posted written and visual instructions outlining the MSCC process, there is no evidence presented that they took an HSE approach. The study indicated that Maher et al. (2017) placed a singular sign, in the

bathroom to be used for the MSCC collection. Observational research and the results of the literature reviews indicated that for women, the average MSCC instruction set has 14 primary steps, with some additional sub-steps embedded. For men the average MSCC instruction set has 12 primary steps with some additional sub-steps embedded.

The 14 steps and embedded sub-steps are most often presented in a list of text with visual diagrams. The text elements of the list for women are as follows:

1. Wash hands with soap and dry completely.
2. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
3. Put the cap on the counter with the inside of the cap face up.
4. Open the provided towelette. Separate the folds of the urinary opening with fingers and clean utilizing the towelette.
5. Dispose of the towelette.
6. Continue to hold the folds open and begin urinating into the toilet.
7. Void approximately 15 ml of urine into the toilet and cease urinating.
8. Now collect urine utilizing the supplied specimen container.
9. Make sure not to overfill the container.
10. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
11. Place the filled urine specimen container on the counter or in a safe location.
12. Wipe yourself, stand up, and redress yourself.
13. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.

14. Turn the filled specimen container in or at the proper drop-off location.

The text elements of the list for men are as follows:

1. Wash hands with soap and dry completely.
2. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
3. Put the cap on the counter with the inside of the cap face up.
4. Open the provided towelette. Retract foreskin if present and clean the head of the penis including the urethral opening.
5. Dispose of the towelette.
6. Void approximately 15 ml of urine into the toilet and cease urinating.
7. Now collect urine utilizing the supplied specimen container. Make sure not to overfill the container.
8. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
9. Place the filled urine specimen container on the counter or in a safe location.
10. Redress yourself.
11. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.
12. Turn the filled specimen container in or at the proper drop-off location.

Memory, Attention, and Information Processing

Presenting a person with a list with 12 or 14 items while asking them to perform a task creates problems in both memory and attention, which affects the overall

information processing capabilities of an individual. Attention and memory, particularly working memory, compete for resources and often conflict while an individual is processing information (Baddeley, 2012; Lee, Wickens, Liu, and Boyle, 2017). Within the HSE discipline the terms Short Term Memory (STM) and Working Memory (WM) are sometimes used interchangeably. However, for the purposes of this paper a distinction will be drawn between STM and WM. STM can be considered a cognitive system that allows for the temporary storage of information over a brief period of time (Atkins & Shiffrin, 1968; Miller, 1956). WM involves the use of information stored in STM to not only recall the information but to provide the capabilities to exert attentional control over that information as well as allowing for greater understanding and evaluation of the information (Baddeley, 1986, 2000; Baddeley & Hitch, 1974). STM and WM also diverge when a task involves multitasking (Turner & Engle, 1989) or the ability to properly adhere to instructions (Engle, Carullo, & Collins, 1991) with WM outperforming STM in multitasking performance and adherence to instructions. After conducting many mental and physical walk-throughs of the traditional urine specimen collection process, it was determined that working memory was the most impactful cognitive mechanism involved in the proper performance of the procedure. Even if the participant could read through the 12-14 steps involved and commit them to STM, they would still have to execute executive control to correctly interpret the instructions and modify them for their specific situation in order to properly perform the process. Such interpretation and executive control removes the proper execution of this process from the realm of STM and places in squarely into the domain of WM. Further, if the participant is referring back to the sign while performing the collection process, a certain

amount of multitasking must be present which requires the execution of executive control over information stored in working memory (Baddeley, 1986, 2000; Baddeley & Hitch, 1974); thereby reinforcing the case for the recruitment of working memory.

In the broad sense, multitasking can be defined as situations in which an individual is performing more than one task at the same time. At a macro level, the concept of multitasking is simple to describe and examples such as exercising while listening to music are easy to provide. However, when drilling down into the actual mechanisms and exploring various examples in greater detail, multitasking becomes more nuanced, intricate, and variable. Grilling hotdogs and hamburgers outside while watching a football game on TV inside are two tasks that can be accomplished within the same frame, i.e., multitasking. In the first example of cooking while listening to music, the individual tasks that comprise the multitasking can be thought of as occurring concurrently whereas, in the example of watching grilling outdoors while watching a football game inside on the TV, the individual tasks comprising the multitasking event are actually occurring as separate sequential events. In the second example, one must be physically in two different places to accomplish the multitasking. Salvucci and Taatgen (2011) formalized a simple multitasking continuum model that used a line to visually depict the gradient that existed between tasks that could be performed concurrently, representing concurrent multitasking, and tasks that would have to be performed in a sequential manner, representing sequential multitasking. It is important to note that when multiple tasks require the use of the same resource, the hands for example, concurrent multitasking is no longer possible and sequential multitasking must be implemented. The shared resource that is only available to perform one task at a time creates a single

channel bottleneck that results in the serial processing of the tasks as described in the works of Broadbent (1958) and Welford (1967). Upon examining the steps present in the urine collection process, it becomes clear that the 12-14 individual steps have within them sequential multiple subtasks that must be performed in order to accomplish the specific overall task thereby constituting a multitasking event. For example, when the participant is instructed to open the towelette, they must redirect their cognitive and physical resources from the actual instruction set to the packet containing the towelette in order to determine how to open the packet and they must physically open it, then they must return their attention to referencing and/or performing the remainder of the instructions contained in the overall task of cleansing the ureteral opening. Further, as established previously, referring to the sign while performing the MSCC process requires multitasking which involves the recruitment of working memory (Turner & Engle, 1989).

The capacity of information that can be stored inworking memory varies by individual (Baddeley & Hitch, 1974), however, as established by Cowan (2001), the optimal quantity of instructions that can be chunked for memory is four plus or minus two. Both lists of instructions, shown on the previous page, present more than the optimal quantity of items for memory chunking, require multitasking, split attention, and call for executive judgement in regards to when to look at the sign for reference or to look at the task being performed. Certain tasks referred to in the paragraph below, such as the task of disposing of the used towelette, can be thought of as interrupting tasks that interfere with the performance of the ongoing task (Baily & Konstanz, 2006); thereby, making it difficult to resume proper performance of the ongoing task (Trafton & Monk, 2007; Wickens & Hollands, 2000). In the case of the urine specimen collection process,

the ongoing task was defined as reading and/or referring to the instructions overall for the proper performance of the collection process while the interrupting task(s) were the actual tasks to be performed with an emphasis on the portions actively involving urinating.

The initial task of hand washing for both men and women would normally involve looking away from the sign as one must locate the soap, operate the sink, and properly dry the hands, however, this step would not likely present a problem in performing the overall process properly provided that this task is completed and not overlooked or intentionally discarded, and the participant correctly locates the next instruction step on the sign and proceeds with the process. Steps two and three for both men and women *actively draw their attention away from the sign* in order to deal with the specimen cup and the proper placement of its cap. Tasks four, six, seven, and eight for women and tasks four, six, and seven for men involve making an executive judgement as to where to focus their attention both mentally and visually. These tasks specifically involve cleansing or actively urinating. These tasks are the most disruptive to the memory chunking process as they force the participant to choose where to focus their mental and visual resources. Task five, disposing of the towelette, is an interrupting task that requires both men and women to once again shift their focus from their previous task and/or the sign in order to locate the proper place to dispose of the used towelette. Additionally, since task five represents a disruption to the flow of activities, it presents the opportunity to disrupt the memory chunking recall process and interfere with the resumption of the ongoing process. The instructions on step nine for women and seven for men draw attention to the fact that it is possible to overflow the specimen cup and

possibly urinate on their hands. This introduces a potential fear and phobia that will be discussed in a later section. The remaining steps, ten through fourteen for women and nine to twelve for men, exhibit similar issues to steps two and three in that they require the participant to once again split their attention and actively seek out a place to put the specimen cup or to perform a task while not being able to refer to the sign. The relationship between executive judgement and visually referring to the sign requires the participant to either attempt to remember the instructions while maintaining their visual and mental focus on the physical performance of the task or shift their foci to refer to the posted sign in an effort to maintain the correct order of activities required to properly complete the process. Due to the number of steps in the process presented on the list and given the fact that the individual will have to attend to more than one thing at a time, it is a near certainty that the individual will have to refer back to the sign at some point in the process in order to determine the next step. Referring back to the sign will require that the participant find the proper place at which they are at in the process. This is often referred to as placeholding. Having to refer to the sign or shift focus at an inopportune time due to an interrupting task or event will present problems with the creation and recall of memory chunks and introduce the opportunity to improperly resume at the wrong place in the instruction set.

The new instruction sets were specifically written to provide for pause points within the limitations of memory chunking in which the patient could feel confident in pausing the process, setting a placeholder, and shifting their visual focus to refer to the instruction set without fear of urinating on themselves or missing an important step. The new instructions (See Figure 4) are divided into pre-process, in-process, and post-process

tasks in terms of the overall urinalysis collection process. Tasks one and two are pre-process and represent two instructions which are easily chunked into memory. Tasks three through six involve the actual collection of the urine and were chunked into a unit of four instructions so that the participant could easily recall the instructions while maintaining focus on the urine collection process. Tasks seven through nine are post process tasks chunked into an instruction block of three steps.

Utilizing the figure of 8.6 million UTI infections per year in the US (Schappert, & Rechtsteiner, 2011) and dividing that by the population of the 328.8 million as provided by the US Census Bureau population clock (see https://www.census.gov/popclock/), averages out to performing an MSCC approximately once every 38 years. Repetition of tasks and specialized training can lead to improvements in performance. However, as established by Baerheim, Digranes, and Hunskaar (1992) even participants possessing specific knowledge of and training in the urinalysis collection process provided samples with a 73.4% contamination rate. This implies that even medically trained experts provide contaminated samples when performing an MSCC. Therefore, it is highly unlikely that an average patient who is untrained and unfamiliar with the process would be able to provide uncontaminated samples utilizing the traditional instructions. One conclusion that can be drawn from this is that training does not appear to be a significant factor capable of improving specimen quality.

Visual Areas of Interest, Divided Attention, and Inattentional Blindness

Faced with performing a 14 or 12 step process that is very likely new to the patient providing the sample, it seems reasonable to assume that they will rely on the sign to guide them through the steps of the MSCC process. Due to the limitations of working

memory, as discussed in the prior section, a patient would be expected to chunk a couple of instructions, perform them, and then refer back to the sign for the next chunk. Reading from a list and then performing a task such as an MSCC that involves multiple subtasks implies that there will be multiple visual areas of interest (AOIs). When access to information is spread across a spatially distributed environment, as in the case with two or more AOIs, the correlation between attention and eye movement can be considered to be valid (Wickens & McCarley, 2008). During the performance of an MSCC while referring to a wall-mounted sign containing instructions, visual attention, at least for males, must be split between two AOIs with visual switching occurring between them. During periods of urination, for men, the AOI of the greatest interest is assumed to be where they are directing their urine stream. The cost of looking away while urinating to refer to a sign may be assessed by the patient as an action that carries a high risk of urinating on the hand that is holding the specimen cup or elsewhere, such as their clothes. The desire to avoid the risk of urinating on one's hand or clothes may result in the overt decision, due to fear triggered by the potential for disgust (Oaten, Stevenson, & Case, 2009), not to switch AOIs back to the sign in order to retrieve the next set of steps to be completed in the process.

The MSCC task is a multi-tasking scenario which constitutes a form of a divided attention paradigm. In the absence of true automaticity, multi-tasking involves rapid task-switching in which attentional resources, relating both perception and information processing, are split based on top-down executive influences and bottom-up perceptual aspects. The desire to not urinate on oneself would constitute a form of executive influence whereas actually urinating on oneself would elicit a bottom-up stimuli of

disgust; both of these scenarios would influence the application of attentional resources on the part of the participant and would be expected to have an effect on the overall specimen collection process. Further, the ability to perform well on a divided attention task decreases when specific areas of interest are outside of the useful field of view and therefore require eye movement and/or head movement (Schons & Wickens, 1993; Wickens, 1993; Wickens, Dixon, & Seppelt, 2002). Once the eyes or head have moved from one area to another, delays and performance degradations resulting from acquisition, attentional engagement and disengagement, and reacquisition of the prior visual area of interest are incurred (Schons & Wickens, 1993; Wickens, 1993; Wickens & Carswell, 1995; Wickens, Dixon, & Seppelt, 2002). Men may not be able to keep both the specimen cup and the sign within their visual field at the same time while providing the specimen. Women may be able to see the instructional sign at all times while performing the task; however, due to anatomical factors, they cannot see the urine specimen cup. This creates slightly different attentional tasks than for men. Specifically, to make physical adjustments to the placement of the specimen cup and perform the mental calculation as to the quantity of urine voided and urine in the specimen cup, women must rely on dividing their attention between both the perceptual aspects of attention (bottom-up) and the mental aspects of attention (top-down) (Wickens & McCarley, 2008). In considering anatomical differences, it seems unlikely that a single sign can be placed in a location that is in an ideal visual AOI for both men and women to refer to while performing the MSCC process. Further, with regards to the instructional sign, it is possible that the patient may be so preoccupied with thoughts of potential illness or suffering from physical pain and discomfort that even if the sign is prominently

displayed in their visual field, they suffer a lapse of attention that results in them overlooking the sign entirely (Herslund and Jorgensen, 2003). This effect is known as inattentional blindness, often referred to as looked-but-failed-to-see (Carpenter, 2002; Mack & Rock, 1998).

Additional HSE concerns in regard to the sign in the Maher et al. (2017) study include; the ability of the content and formatting of the sign to capture attention (salience), its information content, the context in which it is presented and the patient's reaction to the context, its expected informational value, and the amount of effort required to access the AOI containing the sign in relation to other AOIs (Wickens & McCarley, 2008). Further, the typical MSCC instructional sign is one piece of laminated paper with instructions for both men and women presented in a top to bottom fashion with instructions separated by gender. The fact that information on the sign must be disregarded by gender represents clutter in the display that must be suppressed, thereby diminishing one's ability to properly focus attentional resources (Wickens & McCarley, 2008).

Additional HSE Concepts and Human Capabilities Mismatches

The Jacob et al. (2018) study involving viewing a video before performing the MSCC process seems to have overlooked several HSE concepts. The patient viewed the video before performance, thereby requiring the direction of attentional resources to holding the information in working memory, which is a limited resource. In reviewing the study, it does not appear that there was a sign posted in the restroom for reference after the patient had viewed the video. Multiple studies have demonstrated that a passive activity such as simply viewing a video once is unlikely to result in committing the

knowledge presented to long-term memory storage (Gale, Golledge, & Pellegrino, 1990; Pass, Renkl, & Sweller, 2003; Richland, Linn, & Bjork, 2007; Williams, Wickens, & Hutchinson, 1996). Further, it is not possible to determine to what extent the patient was actively engaged in attempting to mentally rehearse or attempted to learn the process from the video potentially signifying evidence of shallow processing of the information accompanied by a low level of learning effort investment (Craik & Lockhart, 1972; Leahy & Sweller, 2005). The possible lack of adherence to the HSE concepts stated above that are associated with internalizing video training into working memory makes it unlikely that the information contained in the video was available for recall for the purposes of process guidance to the patient while performing the MSCC. However, what is certain from the research conducted by Jacob et al. (2018) is that having the patient view the video prior to performing the process produced no significant benefits as demonstrated by the results of their experiment.

Research conducted by Frazee et al. (2012) instructed the staff of the ED to provide verbal instructions to the patients prior to their performance of an MSCC process. As referenced earlier, they found that only 61% of patients received verbal instructions on how to properly provide a urine sample, with only 15% reporting that they recall fully complying with the instructions provided. Not providing instructions on the part of the staff is a clear issue of failure to perform which may have arisen from a number of reasons including; a lack of training, simply forgetting to instruct the patient, apathy, embarrassment, or failing to recognize that the patient was to perform an MSCC collection. In the case of the patient, not remembering having fully complied with the instructions provided, it is quite possibly a simple failure of memory due to a lack of

salience of the task and/or interest in attempting to remember their performance during the process.

Separate from the studies discussed, there are a number of additional HSE concepts that must be considered. The next couple of paragraphs will explore these concepts in further detail.

The initial voided amount of 15ml has been the standard for the MSCC process since its introduction by Boshell and Sanford in 1958. In this situation, the concepts of Just Noticeable Difference (JND) as established by Weber's law should be considered (Fechner, 1860; Lee, Wickens, Liu, & Boyle, 2017). JND refers to the ability of an individual to notice the difference a small change in one dimension makes to the overall quantity and is directly related to Weber's law, which correlates perceived change to actual change in a stimulus. An HSE practitioner recognizes that voiding 15ml or urine into a toilet containing as much as 500ml of water cannot be reliably noticed by the visual change in volume apparent to the male patient, nor by the amount and length of sound generated by the female patient. Further, because we continue to use the English system of measure, 15ml is likely an unknown quantity for most patients.

Multiple Resource Theory (MRT) represents a formal attempt to quantify, qualify, and measure the human capability that is commonly referred to as attention while multitasking (Kahneman, 1973; Navon & Gopher, 1979; Wickens, 1980, 1984, 2002, 2005, 2008). MRT is particularly useful in predicting an individual's ability to successfully multitask by estimating the levels of interference that might arise between the separate tasks that encompass an attempt at multitasking. At its base, MRT is an HSE model that formalizes the fact that humans have a limited number of both physical and

mental resources available at their disposal to utilize when attempting to multitask. The availability of human resources can become strained and conflicted particularly while performing resource intensive concurrent tasks and/or while performing tasks in a high stress environment. Examples of these resources include; time, attention, visual field, mental processing, and physical capabilities representing both inputs and outputs of action and responses to stimuli (Broadbent, 1958; Craik, 1947; Welford, 1967; Wickens, 1991, 2002). Attentional resources can be occupied and engaged through the senses in a bottom-up mental processing fashion as demonstrated by the type of directed attention touching a hot surface would generate. As attention is a shared and finite resource, events presenting to the human senses are often screened, or filtered, by the subconscious mind. In the example of touching a hot surface, it is possible that the person is also wearing socks that are generating sensory input at the same time, however, the sensory inputs generated by the socks are not as relevant and therefore are screened out of the persons direct attentional space, while the act of touching the hot surface will result in the near immediate redirection of attentional resources. Attentional resources can also be assigned by executive direction based on how a person actively chooses to allocate them. Such executive direction of attentional resources (Baddeley, 1986) is often based on the expectancy of value received from the input being actively focused on. If one is watching a movie in a theater, visual and auditory senses are often focused at the screen as that is where the expected value of the overall experience is being generated. Inputs and events that proceed through the attentional "filter" are then available for information processing. The act of processing information also requires attention which is a limited resource at this mental level of processing. The limited nature of the attentional

resources that can be devoted to processing information is often described as the amount of "fuel" available for focusing the resources required to attend to the events passing through the filter (Wickens & McCarley, 2008).

Within the domain of HSE, the term Areas of Interest (AOIs), is used to describe and define areas within the visual field that contain sources of information or possess stimuli that may drive visual attention to a particular field of view. The SEEV model (Wickens, 2007, 2015; Wickens et al., 2007; Wickens, Goh, Helleberg, Horrey, & Talleur, 2003) provides a computational framework from which to derive predictions of visual scanning to, from, and between various AOIs. The overall SEEV model has been developed based on the concepts of various optimal models of scanning proposed by an array of notable researchers; see Moray (1986); Senders (1964); Carbonnell, Ward, & Senders, 1968; Sheridan (1970).

The initials of the SEEV model stand for the four primary factors that have been found to drive visual scanning; Salience, Effort, Expectancy, and Value. The concept of expectancy was introduced in the paragraph above in reference to where relevant information is anticipated to be received from. The SEEV model further incorporates the concept of the rate of change expected within the AOI into the notion of expectancy. The greater the expected rate of change, the more likely the AOI is to be attended to (Carbonnell, Ward, & Senders, 1968; Senders, 1964). In respect to the MSCC collection process, the AOI with the least expectancy to change is the sign as it is a fixed instruction set attached to a specific portion of the wall. The AOIs that would be expected to change, and therefore generate the greatest amount of expectancy, are the AOIs that involve utilizing the specimen cup to collect the sample and the AOIs that support the

manipulation of the specimen sample cup for the purposes of opening, closing, or putting it down.

Within the SEEV model, the term value establishes a relationship between the amount of time devoted to attending to a specific AOI based on the value of attending to or not attending to that specific AOI. AOIs involved in checking for vehicles before crossing the street would be expected to have a higher value and therefore be sampled more often, than looking at one's shoes determine if they really are a good color match for one's pants. The issue with value is that it is a multifaceted subjective measure. The amount of value placed on an AOI can be dependent experience, perspective, goals, and many other factors that affect one's ability to be fully informed and objective. In the case of the MSCC process, it is reasonable to assume that there is a knowledge gap in regards to the importance of properly performing the instructions between the medical professionals and the sample providers. This knowledge gap will result in a difference of value being assigned to the AOI of the sign. Handing a sample provider a specimen cup and asking them to provide a urine sample by following the instructions posted on the wall does not convey the importance of following the instructions nor does it likely cue them to expect a 12-14 step process to properly perform the sample collection. The relationship between the empty specimen cup and the need to fill it with urine may seem quite straight forward and therefore lower the value the specimen provider assigns to the AOI associated with the sign. The subjective nature of the assignment of value to the various AOIs was factored in when redesigning the sign.

Further illustrating the knowledge gap that separates how AOIs are attended to, expectancy and value are influenced by top-down mental models of how information is

acquired and are based on previous experience. A reasonable conclusion drawn during the process redesign was that the less experience one has with the MSCC process, the lower their expectancy and value assignments for important AOIs would be. These factors were taken into consideration when redesigning the process and signs. The new sign streamlined the process and provided for breakpoints in the instruction set which were hypothesized to more easily switch between AOIs during times of change when the expected value of the information contained in the various AOIs was most important to the next steps in the process.

Saliency and effort, the first two components of the SEEV model, are derived from a bottoms-up sensory perspective. Salience can be either a negative or positive influence on selection and maintenance of AOI's, whereas the amount of effort required to change focus from one AOI to another is considered to be a negative influence as effort increases (Wickens, 1993, 2007, 2015; Wickens & Carswell, 1995; Wickens, Dixon, & Seppelt, 2002; Wickens et al. 2007; Wickens, Goh, Helleberg, Horrey, & Talleur, 2003; Schons & Wickens, 1993). Effort was discussed in a prior section (see page 24), however, it is important to note effort, specifically within the SEEV model, refers to the physical effort required to change visual focus from one AOI to another. The greater the effort required, the less likely the participant is to change AOIs (Wickens, 1993; Wickens & McCarley, 2008). In the redesign work, signs were placed in multiple locations to encourage changing AOIs when appropriate by minimizing the amount of effort required by both men and women to do so.

Saliency has the traditional definition within the SEEV model of being an object possessing attributes that draw visual attention. Clear font, larger size, and high contrast

are examples of attributes that attract visual attention to instructions printed on a posted sign. Care was taken when redesigning the signs for the MSCC process to ensure that an appropriate level of salience was achieved in order to draw attention without being overtly distracting by visually infringing on other important AOIs. The standard 8.5 by 11 inch size was maintained for the redesigned process utilizing the original specimen cup, while the size was doubled to make room for the inclusion of an illustration demonstrating the proper use, by gender, of the redesigned specimen cup. For the purposes of salience, Ariel fonts were selected in the largest size that would fit all instructions on the appropriate sized pieces of paper. The redesigned instruction sets eliminated the separation by gender and provided for a gender-neutral set of instructions. This change allowed for larger fonts with greater spacing between the individual instructions, thereby increasing salience. In an additional effort to increase salience, the contrast of the signs was addressed by printing in dark black toner on white paper with a brightness score of 96.

Wickens' four-dimensional multiple resource model (4dMRM) (Wickens, 2008), which integrates concepts from his previous work on extending multiple resource theory (Wickens, 1984, 1991, 2002, 2005), provides an additional HSE resources from which to evaluate the potential reasons contributing to the lack of success with the current MSCC process. At its base, the 4dMRM is an attempt to identify and quantify the performance differences encountered during the attempted execution of time-sharing tasks. In general, the model is a method to examine the intersection between multiple resources at the point of multi-tasking. The model defines resources as finite and assignable across tasks and utilizes the term "multiple" to define the various task processing models ranging from

parallel to completely independent. The model makes a distinction between the pooled resources utilized for cognitive and perceptual activities and separately pooled resources utilized for the selection and execution of executive responses. The four-dimensional nature of the model is a direct reference to the separate categories named as being relevant to variable nature of performance on time-sharing tasks. Processing codes, processing stages, perceptual modalities, and visual channels comprise the four specifically named channels that represent the four-dimensional nature of the model.

It is important to note that for the purposes of this project, the 4dMRM was used as a conceptual design tool to help identify and catalog the various aspects of MRT that were involved in each instruction, task, sub-task, and instruction execution in the original MSCC process, the greater urinalysis process, and the redesign efforts. The 4dMRM provided a convenient framework with which to step through the various aspects of the overall processes and categorize them into the appropriate HSE classifications in order to allow for further study, refinement, and potential resolution. Prior to utilizing the 4dMRM to identify resource conflicts in a multitasking overload situation, one must first identify the resources involved, and how and when they are being utilized. The 4DMRM was most often used in initial identification of resources modality. For example, the 4dMRM model clearly illustrates the possibility within MRT that the auditory modality of perception can become resource constrained and by utilizing the 4dMRM model to step through the overall MSCC process, it became clear that both men and women may use auditory cues to determine how much urine is voided into the toilet as a way to estimate the 15ml amount prescribed by the instruction set. The use of the auditory channel was identified by running the process through the framework of the 4dMRM but

a conflict was not identified because nothing else within the process uses the auditory channel at the same time. Nevertheless, the 4dMRM proved useful as an identification tool in this case. Identifying the use of the auditory channel as a means to estimate the amount of urine voided led to discussions surrounding potential improvements to the process. In regard to modifying the instruction sets, methods were considered and examined to see if having a person count the number of seconds they urinated could be correlated to 15ml of urine output, however, they were determined to be as effective as staying with the 15ml instruction set. These results led to the conclusion that the most reliable way to ensure that 15ml was accurately voided was to automate the voiding process.

While primarily used as a design tool within the project, the 4dMRM framework was able to predict certain conflicts. The 4dMRM easily identified conflicts occuring within the perceptual modalities, particularly when a specific modality such as vision is a shared resource required to execute more than one task. The 4dMRM highlighted the fact that there was a visual-visual interference as a result of dispersed AOIs involved in switching focus between the sign and various other AOIs involved in task accomplishment. As noted earlier, multitasking exists on a continuum from concurrent to sequential operations (Salvucci and Taatgen, 2011) and when multiple tasks require the use of the same resource, the resulting bottleneck (Broadbent, 1958; Welford, 1967) prevents concurrent multitasking from occurring and causes a shift on the continuum of multitasking to sequential multitasking. While the 4dMRM was able to highlight such conflicts, they were rare and as a result, the project team still found the 4dMRM to be more useful as a conceptual modeling tool than a specific tool for the control of

multitasking overloads in the case of the urine specimen collection process redesign effort.

Specific applications and limitations of attention andresources were important to the redesign of the urinalysis process. In general, it is important for the patient to devote attentional resources to properly performing the procedure. HSE techniques such as shortening the length of the instructions provided to the participant providing the sample, adding additional signage for saliency, and incorporating automation have been utilized in a concerted effort to increase the sample provider's ability to focus their limited attentional resources on the process. Resource issues were addressed through automation and by providing additional signage in locations that allow for easier visual access while performing the process. The concepts introduced and explored in multiple resource theory were used to help model and design improvements to the redesigned process utilizing the current standardized specimen cup and for improvements to the automation specimen cup and its associated instruction set.

Examples of ergonomic and anatomical issues also exist within the current urine collection process and deserve mention. Two areas to highlight in particular are physical resource issues and issues with not being able to see a particular AOI due to interference.

Hands are an example of a shared physical resource that can create issues in multitask execution when more than one task requires the use of this shared resource. For example, one could not type on a keyboard while simultaneously opening a jar. For men, the point in the process in which they actually need to fill the specimen cup would seem to require three hands; one with which to hold up their pants, a second to hold the specimen cup, and a third to properly direct the urine stream into the specimen cup. No

solution was readily apparent when modifying the instruction set with the standard specimen cup. Both the original and modified instruction sets require men to either drop their pants further than normal when urinating standing up as a means to free up a hand or they can attempt to hold the specimen cup and their pants with the same hand. The automated specimen cup provides a solution in that is provides a much larger target area, therefore, freeing one hand by allowing for placement of the specimen cup in an area that does not require the use of a hand to aim.

For women, physical resource issues in the form of potential ergonomic strain and/or discomfort were identified. Women may experience difficulty when attempting to adapting from a normal position to urinate to one that allows for spreading of the legs far enough apart to accommodate a hand holding a urine specimen cup. Additionally, when seated and attempting to place the original specimen cup, womenmust hunch over and extend and rotate their shoulder, arm andhand far enough to place the urine specimen cup in a position to collect a specimen. No viable solution to these issues were found when attempting to modifying the original instruction set utilizing the original specimen cup. The new specimen cup with the modified instruction set does provide solutions for both of these issues.

Visual interference with the performance of the process occurs when a portion of the body blocks viewing of an area of interest. For men, visual areas of interest may be blocked by one's hands, clothing, or body. . Visual conflicts for women exist primarily because women sit on the toilet to urinate. It is anatomically difficult, if not impossible, for women to visually observe their urine stream without the aid of a mirror and/or a light, neither of which is part of the urine specimen collection process. Further, even if

some type of visual aid consisting of a mirror and light were provided for women, the fact that their hand is used to hold the urine specimen cup between their legs would prevent a clear view of the process.

Human error as it results from attentional error in general (Holnagel, 2007; Reason, 1990; Sharit, 2006; Wickens & McCarley, 2008) is another HSE component that must be considered when evaluating the mechanisms and processes involved in performing a urine specimen collection. It is entirely possible that the person providing the sample may have an attentional lapse (Endsley, 1995, 2006; Tenney & Pew, 2007; Wickens & McCarley, 2008) that results in an error being made in the process. Due to a lapse of attention, the person may be confident that they followed all of the steps of the MSCC properly, when in fact, they did not.

Stress, unfamiliarity with the process, absent-mindedness, underestimation of the importance of following the directions, lack of placeholding, and serial-position effects are all potential additional HSE related reasons for attentional errors resulting in the introduction of errors and/or the inability to recall mistakes during the collection process. The potential pain associated with a urinary tract infection, the fear of having and dealing with a potential UTI, and the anxiety associated with the overall medical experience as well as the process of providing a urine sample and the fear of urinating on one's self can all contribute to an overall feeling of stress. While all of the example stressors listed above are unique in nature, they fall under the general category of psychological stressors for the purposes of HSE. Psychological stressors have been shown to be detrimental to information processing (Driskell & Salas, 1991), degrade working memory (Hockey, 1997), and decrease accuracy by prompting the selection of speed over accuracy

(Hockey, 1986). Due to these factors, stress and its mitigation must be considered when attempting to improve the urine specimen collection process. The participants unfamiliarity with the urinalysis process will likely contribute to the overall possibility of making a mistake due to the novel nature of the process. The fact that the MSCC process is non-routine and is very likely outside of the normal experience for the person performing it contributes to the chances of making a mistake (Kirwan, 1994; McDowell, Ferner, & Ferner, 2009). Absent-mindedness is characterized by a lack of attention and/or a memory lapse resulting in the failure to properly complete a task. Absent-mindedness can be attributed to distractions, hyper-focusing on a separate thought or event, or a general lack of attention (Reason & Myceilska, 1982). Absent-mindedness on the part of the participant has an obvious potential to affect their performance on the prescribed urine collection process. A lack of knowledge as to the importance of properly following the directions can lead to the participant underestimating the consequences of improperly providing a sample. Specifically, the participant may underestimate the utility of properly following the directions and attribute a low expected value to proper adherence due to their inherent lack of understanding the associated risks of doing so (Schoemaker, 1980) which may drive noncompliance resulting in a poor sample collection. The patient is expected to follow written directions posted in the bathroom when providing the MSCC urine specimen sample. The nature of the collection process combined with the expectation of following posted written instructions can lead to issues with a lack of placeholding, serial-position effects, and recency effects. The MSCC process introduces the potential for two separate areas of interest, with one being the posted instructions and the other being the specimen cup. With two separate AOIs,

the participant may read the instruction set to a certain point establishing a mental placeholder, and then change their AOI in order to focus on the specimen cup. When the participant removes their focus from the specimen cup and focuses back on the sign, they must reacquire their placeholder and begin reading more instructions. The participant may have failed to set a placeholder or may have difficulty in reacquisition of their placeholder resulting in potential difficulties with resuming the process that may result in the introduction of errors. Serial positioning effects (Ebbinghaus, 1913) deal with the order in which items in a list are presented and the effects of such positioning on one's ability to recall the items. Items presented at the beginning of the list and at the end of the list are better recalled than those items presented in the middle of the list. The potential serial positioning effects have implications for how a participant would self-rate their adherence to the posted instructions. Attentional errors and the HSE reasons potentially driving them, as described and detailed in this paragraph, were considered when attempting to improve the process and developing measures to quantify the improvements.

Habit and the attentional resources required to overcome it must also be considered. Per the previous calculation, it is possible that a person will rarely be required to perform an MSCC. The MSCC represents a dramatic departure from one's natural urination routine. Imagine the force of habit (Lally, Van Jaarsveld, Potts, & Wardle, 2010) built up from urinating five times a day for 20+ years, representing approximately 36,500 urination events. This type of habitual action may lead to a form of automaticity (Wickens & McCarley, 2008) that triggers an action. How much executive control and attention is going to be required to break the force of habit and follow the MSCC

process? Or a better question is, how do we inform the patient of the value of following or the cost of non-compliance with the MSCC process? It is, without a doubt, far easier to simply disregard all of the instructions and processes required to perform an MSCC and simply urinate directly into the specimen cup. The MSCC process is 12-14 steps long, whereas simply urinating into the cup requires as little as 3 steps, therefore, there is a higher effort required on the part of the user to comply with the MSCC process. This *cost of compliance* (Wickens, Lee, et al., 2004; Wogalter & Laughery, 2006) can be defined in terms of the effort required to comply versus the expected value of such compliance(e.g., taking the time to read and understand the instructions, suppressing the urge to immediately start urinating in a normal fashion, and the potential mental and physical discomfort accompanying compliance with the procedure versus the assumed ratio between the perceived and actual value of compliance). It is likely that the choice to comply with the MSCC is a novel choice to the patient, and as such, they can be expected to make their decision based on the anticipated effort to comply and their estimate of the value of compliance. In the current process, the patient is unlikely to understand the value of compliance and is, therefore, most likely to significantly discount its importance (Wickens & McCarley, 2008).

Even when presented with all of the proper instructions and visual aids, a person may consciously choose to be non-compliant or unconsciously revert to their normal habit of urination without first voiding and therefore be noncompliant with the MSCC process. In all studies reviewed and in all investigations conducted, no evidence was found to indicate that instructions were provided to the patient on what to do if they fail to perform the MSCC properly. The instructions, both written and verbal, simply do not contain any

wording describing what the patient is to do if they realize that they did not properly execute the MSCC. There appears to be no system in place for the recognition of and recovery from error (Stanton, Salmon, Rafferty, Walker, Baber & Jenkins, 2013). The patient is not likely to be a medical expert and therefore is unlikely to understand or appreciate the importance of providing a proper MSCC sample. It is therefore assumed that the patient will simply provide the sample as is and hope for the best. From an HSE perspective, the inability to recover from errors represents a major shortcoming of the current process. Due to the one-way nature of the process, overcoming this obstacle through simple process modification would prove difficult. Automating the specimen collection process to prevent the introduction of errors to the greatest extent possible represents the preferred HSE pathway.

HSE INFORMED APPROACHES LEADING TO PRODUCT AND PROCESS CHANGES FOR ELIMINATING THE IDENTIFIED MISMATCHES

With the numerous mismatches between the MSCC process and the capabilities of humans identified, the next step was to utilize, and in some cases, reimagine HSE informed approaches that would lead to product and process changes designed to eliminating the identified mismatches and generate numerous measurable improvements to the overall urine specimen collection process. Included in the domain of HSE is the practice of user experience design (UXD), which is often shortened further to user experience (UX) (Roto, Law, Vermeeren, & Hoonhout, 2011). UX design concentrates on providing the user with the best possible experience by providing practitioners with toolsets to help design the interaction artifact for usability and usefulness (Hartson & Pyla, 2019). UX practices and toolsets were used as a basis for improving the user experience and in designing the improved specimen cup. These practices and toolsets were adopted, adapted, and modified for our use in our unique environment. If only someone had thought to document the process by which the Pyramids at Giza were built, much speculation, up to and including alien involvement, could be avoided. While not on par with such an accomplishment, this section will endeavor to detail how the elements of HSE and UX were adopted, adapted, and applied to the overall process of improving urine specimen collection and to the development of a redesigned medical device in the form of an automated urine specimen collection cup.

The overall effort to improve the urine specimen process described in this paper was self-funded by the author. Creative solutions were employed to minimize cost where

possible and will be detailed with the use of deidentification in areas that warrant such treatment.

The beginnings of the overall endeavor to improve the urine specimen collection process were similar in most respects to nearly all attempts at developing process and product improvements. The initial problem identification and research phase of the UX process was fairly typical because it could be performed with little capital outlay. The overall problem was identified, and generative research was undertaken to reduce or eliminate the problem. Efforts were made to understand the current process with particular interest in identifying steps or areas in which the current process either broke-down or contributed to generating contaminated urine samples.

The generative research focused on understanding the overall urine specimen collection process, the types of analyses performed, the manner in which the urine sample was collected as well as how the sample was processed for analysis by medically trained personnel, and the actions and experiences of the specimen providers. The initial generative and the ongoing continual research was conducted through the use of literature reviews, patent searches, investigational research into the analysis of urine specimens, contextual inquiries, interviews, task analysis, and walk-throughs consisting of self-generated mental imagery of the processes and procedures as understood and applied. The literature reviews and patent searches are described in detail in the previous section; however, it is worth noting that they served as valuable tools in providing overall knowledge and insight allowing the team to reach a level of understanding necessary to conduct productive contextual inquiries and interviews.

"Know the user" (Hansen, 1972) is a common refrain in the HSE domain and is often applied in a general nature when working in the discipline without questioning the original context and implications of the quote. Hansen (1972) was clearly focused on utilizing engineering principles to create user profiles of the end user as an aid in the design of digital computer systems. While Hansen's (1972) focus on the end user was deliberate, one of the key areas of general insight gained while conducting the literature review was that user experience was viewed from the end user's perspective in a literal sense without apparent consideration. The inherent implications of joining the term "end" with "user" constrained the membership of the populations studied. These assumed constraints had an impact on the overall examination of the UX experience and appear to have been carried over into various aspects of previous research and product design. In order to assume the user's perspective, one must first define who the user is. In the literature reviewed, the user was always defined as the person providing the urine sample. The primary defining factors in the user groups studied were that they were ambulatory and able to urinate into a specimen cup without assistance. By performing further research into the existing HSE literature regarding contextual design and contextual inquiry, it was discovered that a potentially unintended narrowing of the population to be included in the generalized research efforts had occurred. Contextual inquiry grew out of the contextual design work performed and published by Beyer and Holtzblatt (1998, 1999). In their original work, Beyer and Holtzblatt (1998, 1999) make it clear that the focus for both contextual design and contextual inquiry is on discovering exactly who the customers are and understanding their requirements. However, possibly due to the Information Technology (IT) domain that they were working in and drawing

upon to illustrate their methodologies, they also introduce the term user into their writings thereby conflating the terms user and customer. This inadvertent narrowing of Beyer and Holtzblatt's original works can be seen in later writings by Privitera (2015) and Lee et al. (2017) in their respective texts that both cite the original work of Beyer and Holtzblatt, and in both cases, specifically define contextual inquiry as a focused study of the user. It is particularly important to note that explicit purpose of the work by Privitera (2015) is to demonstrate the application of contextual inquiry to the design of medical devices. In returning to Beyer and Holtzblatt's (1998, 1999) original intended population of users, now understood to be customers, the population of interest could be expanded beyond the individual providing the sample to include anyone interacting with the processes, specimens, analysis, and/or the results. This population now included, but was not limited to; medical professionals, medical technicians, laboratory technicians, and medical administration. Expanding the user group allowed for a more thorough investigation and thoughtful solutions.

Contextual Inquiry Process

Contextual inquiries were conducted with several relevant subject matter experts (SMEs). Each contextual inquiry (CI) was slightly different, with some being conducted at the SME's work location while others consisted of phone and/or email conversations. However, each CI was designed and executed in a bi-directional manner that allowed for questions and answers that facilitated the transfer of information and knowledge held by the SME to the interviewer ("Usability Body of Knowledge", 2010).

Multiple CIs were conducted with SME 1 from July 2017- May 2020. SME 1 provided a broad range of initial knowledge and acted as a continual resource for

feedback throughout the design and development process. Two CIs were conducted with SME 2, the first in October of 2019 and a second occurring in May of 2020. SME 2 provided general information regarding urinalysis, specific information concerning female anatomy as it related to UTIs and performing an MSCC, and feedback on design and development efforts. One CI was conducted with SME 3 on July 17, 2019. A patient was also present during the CI conducted with SME 3. Having a patient and the SME present during the CI proved to be a valuable learning experience for all parties involved. In particular, having the patient and SME 3 present highlighted the extent of the knowledge gap that existed between the user (the patient) who was expected to perform an MSCC and the customer (SME 3) who would rely on the results of the urinalysis to diagnose and treat the patient. A modified email-based CI was conducted during March of 2020 with SME 4. SME 4 provided the clinical laboratory perspective necessary to understand what happens to the urine sample once it is delivered to a laboratory for processing, testing, and reporting of results. During June of 2019, a modified email and phone-based CI was conducted with SME 5. SME 5 provided valuable information in regard to how a patient would be instructed to provide various types of urine specimens including an initial-void and an MSCC. The CI with SME 5 provided valuable insight into the potential for implicit bias and gender bias in both the overall urine specimen collection process as it has existed and in the ongoing attempts to improve the process. Specifically, the PI recognized several failures to scrutinize medical concepts that are taken for granted (Hamberg, 2008) based on the gender of the patient, the gender of the person providing the instructions to the patient, and the inherent HSE gender affordances built into the processes and products as designed and utilized.

Financial Considerations Driving the UX Development Process

Research indicated that per 21 CFR 864.3250, urine specimen containers are FDA Class 1 exempt devices, sharing the same FDA classification as tongue depressors and adhesive bandages. The initial thought was to use financial capital to acquire the necessary human capital in terms of resources and knowledge to bring the desired medical device into existence. The PI, David Wallace, would act as a project manager and bring an HSE informed design methodology approach to leading a hired team of medical product designers. The inherent assumptions were that the development of an FDA Class 1 exempt medical device would be relatively easy for a properly positioned company to assist in the development of and that this effort would not represent a large capital expense on the part of the PI. To this end, a trusted colleague set up an introduction to the Chief Executive Officer (CEO) of a local medical design consultancy company. Emails and phone calls were exchanged between the PI and the CEO to establish an understanding of the scope of the project and generalities of the device being considered for development short of disclosing specific intellectual property (IP) that would have required the signing a non-disclosure agreement (NDA). The CEO clearly understood that the device under consideration was an FDA Class 1 exempt urine specimen cup representing the lowest level of complexity and risk as viewed by the FDA. The CEO provided an estimated cost of $200,000 - $300,000 to get the device to the computer-aided drafting (CAD) prototype stage. This estimate did not include the cost of manufacturing prototypes or performing testing, but simply brought the design process to the place where a potential prototype could theoretically be constructed. Further market exploration revealed that the estimate was on the low-end of the spectrum for similar

Class 1 medical device development undertakings. This validated estimated cost effectively ended the ability of the PI to take the self-funded approach of hiring outside resources to assist in product development. The potential to obtain research grants and funding from various organizations such as the National Institute of Health (NIH) had been previously explored and evaluated. Given the early-stage nature of the project and the dollar amount involved, coupled with the desire to complete the project within a short-time period, none of the grant or funding options were judged to be viable. Further, while the PI had some ability and willingness to self-fund, $200,000 - $300,000 was not a possibility particularly given the expected outcome of an electronic CAD prototype. Another path had to be found that delivered more while simultaneously costing less in terms of capital expense.

The CEO of the medical of the medical design consultancy company delivered the estimated cost and project scope during a phone meeting on the afternoon of Friday, February 15, 2019. At this point in time, Arizona State University had been ranked #1 in innovation by U.S. News and World Report for four years in a row and would later go on to claim the title for a fifth straight year (Toshner, 2019). A title bestowed upon a university by a magazine, even when the criteria by which it was judged is clearly defined, is in most ways an abstraction to the students of the university itself.

The immediate challenge became finding the means and methods to turn the abstract title into representational action. That evening an email was sent to the Executive Director of an innovation lab at ASU called “The Luminosity Lab”. The email was essentially an elevator pitch that described the current project, the estimate provided by the CEO of the medical design consultancy firm, detailed the problems associated with

contaminated urine specimens, quantified the potential number of patients affected in the US annually, estimated the size of the urinalysis market in the US, and ended with an ask for assistance in identifying resources available to help complete the project. The Director of the lab responded to the email with a request for a face-to-face meeting on Thursday, February 21, 2019. At the meeting, the project was personally pitched to the Director and it so happened that The Luminosity Lab was actively looking for new projects that could have a large and positive societal impact. The pitch convinced the Director that improving the urine specimen collection process as a way to improve patient diagnosis and outcomes would have a positive medical impact at a potentially large scale. The Director asked that a formal presentation be prepared and presented to the members of his lab the following day. On Friday, February 22, 2019 at approximately 12:30 pm the formal presentation describing the urine specimen collection improvement project was made to the members of The Luminosity Lab. The project received overwhelming interest and was adopted as an official development effort within the lab.

Adapting the Traditional UX Approach.

There are four generally accepted lifecycle activities that are performed iteratively as part of the overall UX design life cycle; understanding the needs of the users, designing potential solutions, performing some type of prototyping of the potential design solutions, and solution evaluation (Hartson & Pyla, 2019). These four activities are normally depicted as a two-dimensional wheel that rotates clockwise starting with the step of understanding user needs (see Figure 1).

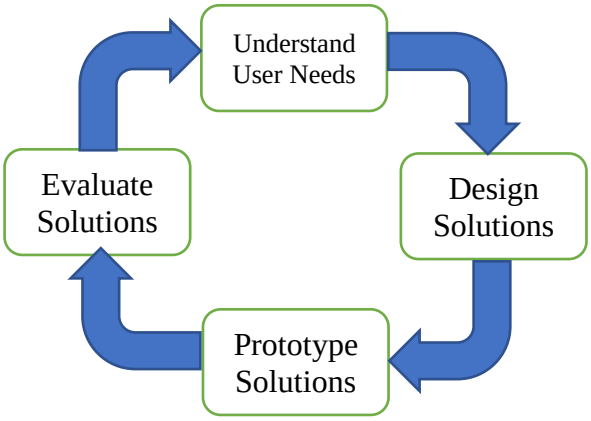


Figure 1. The iterative UX design process consisting of the four traditional steps.

The initial generative research performed in support of understanding the needs of the users in the urine specimen collection process provided enough insight and information to warrant moving further along the UX development cycle. For this project to move forward, more resources in both terms of human and financial capital would have to be expended.

As mentioned earlier, the development effort to improve the urine specimen collection process was a self-funded project with a focus on improving the overall specimen collection process including the development of the automated specimen cup. As discussed in the financial considerations section above, after looking into the cost of hiring an outside 3rd party contractor to perform the necessary development work this approach was deemed far too costly to pursue. Instead, an ASU centric development process utilizing ASU resources with the PI serving as the project manager was undertaken.

ASU's Luminosity Lab during the time period of this project consisted of a collection of approximately 50 students employed as student researchers who are managed and assisted by a small staff of full-time ASU employees. The charter of the lab was to bring together interdisciplinary groups of students to work on innovations that can have a positive impact on society. The lab did not have a formal methodology for innovation and instead adopts a collaborative and open environment in which all members of the lab are invited to participate directly in or contribute to the various projects undertaken by the lab and/or to develop their own proposed projects by generating interest and recruiting assistance from the greater Luminosity Lab group at large ("Luminosity – where creative genius works", n.d.).

For formally adopted projects, a core group is defined to work directly on the project. This core group is charged with moving the project forward through their efforts while recruiting resources, ideas, and feedback from the larger group. In response to the COVID-19 pandemic, on March 16th, 2020 Arizona State University transitioned to a remote model for academic instruction and research activities (Lieberman, Ravikumar, & Myskow, 2020). From late February of 2019 until the closing of in-person academic and research activities in March of 2020, the core project team had access to the physical facilities of the Luminosity Lab. The primary office and meeting space for the Luminosity Lab was situated on the first floor of the Fulton Center located on ASU's main campus in Tempe, Arizona. All members of the Luminosity Lab had access to and were encouraged to utilize the Fulton space to facilitate interaction with other members of the Lab. "All hands" meetings were often scheduled twice a week in the Fulton space

to provide the opportunity for every member of the Lab to attend at least one of the meetings.

The core project group could engage the larger group through presentations and by providing updates at the weekly "all-hands" meetings. However, weekly updates and presentations were not a requirement of the smaller core groups and the resources of the larger group could be engaged at any time using the electronic communications platform application known as SLACK (Searchable Log of All Communication and Knowledge). Following the COVID-19 suspension of in-person activities on ASU's campuses, the "all hands" meetings and the group engagement components of face-to-face activities facilitated by the shared Fulton space were transitioned into the online environment using SLACK and the video conferencing software ZOOM. This transition to a fully online environment from one that provided for a mix of in-person and online interactions provided for more asynchronous involvement opportunities both within the core group and with the larger Luminosity Lab group.

The fully online environment when coupled with asynchronous communications means made it easier to interact with other members of the groups in shorter time frames. One of the primary driving factors for this were the asynchronous communication abilities allowed members to contribute when they were individually available as opposed to attempting to find an opportunity when all members were available to meet as a collective group. The second primary driving factor to improved interaction was that the online environment seemed to alleviate awkwardness of reaching out in a face-to-face manner to recruit new potential contributors to work on a urinalysis device. Even at the college level, there is some apprehension surrounding potential or actual embarrassment

when talking about the process of collecting and analyzing urine samples. Providing a link to the current project as well as an electronic invitation to participate often seemed to be easier than presenting to a group of people in person.

The lab utilized an informal and fluid innovation process, however, for projects that were officially adopted, an Agile management framework was implemented as an administrative tool. The Agile management framework is an outgrowth of the Agile software development methodology based on the *Manifesto for Agile Software Development* (Beck et al, 2001). In 2004, Jim Highsmith, one of the original authors of the *Manifesto for Agile Software Development* (Beck et al, 2001) published *Agile Project Management: Creating Innovative Products* (Highsmith, 2004) in which he expanded the concepts and processes of Agile software development into the realm of project management. Within an Agile management framework, iterations of the product are designed and delivered within fixed time frames that are normally two weeks in length. The manner in which the Agile management framework was utilized within the Luminosity Lab did not mesh well with the traditional UX design methodology particularly with regards to the innovative work that needed to occur in order to bring about change to the urinalysis process and develop the automated specimen collection cup. The dynamic nature of the innovative process does not lend itself to the well-defined short-term iterations that are integral to the Agile management framework. Fixed deadlines and management framework do not in and of themselves create innovation. Innovation on the urinalysis process and the automated specimen cup did not proceed in a linear fashion and this created friction at the beginning of the project. As a result, a unique UX development process was proposed and adopted for the benefit of the project.

In 1988, Don Norman coined the term "User Experience" in his book *The Psychology of Everyday Things* (Norman, 1988). At the time, Don was attempting to draw a distinction between what was a systems focused design to one that put the user at the center of the design effort. In an interview in 2007 conducted by Peter Merholz, Don remarked that the term "User Experience" had become so widespread in use that it had begun to take on a more general meaning than his original definition (Merholz, 2007). What started as an effort to highlight the user as the center of the design effort has now grown into an entire field of study (Roto, Law, Vermeeren, & Hoonhout, 2011). When viewed as an entire field of study, UX has many design models and methodologies. The most immediate challenge with this project in terms of UX development was in resolving the issues surrounding the Lab's management framework and the uncertainty of the innovation process. The solution to this challenge was to implement a new UX design process based on the elements and concepts present in one of the most basic and standard UX design process models. No empirical study was undertaken to compare the new process to existing processes nor are any claims made to its performance against other models as that was not the intent of the effort. The model developed is presented in the following section.

The 6 Degree of Freedom (6DoF) UX Ball

Transitioning the urine specimen collection process improvement effort and the product development of the automated specimen collection device into the Luminosity Lab environment allowed for adaptation and improvisation. It allowed for the space to be creative and for the possibility to explore new methodologies to bring innovation to life including reimagining the standard UX development process to better align it for our

purposes to the management framework employed by the Luminosity Lab. Figure 1 is a basic model that demonstrates the overall iterative UX design process as a wheel with four primary process steps that are progressed through in a circular fashion with one being step being started after the completion of the previous step. As a model, the user has the choice to deviate from its literal depiction, however, the user must be aware of this freedom in order to take advantage of it. Figure 2 depicts this process in a literal sense as an actual wheel on a track. This depiction is used to illustrate the fact that travel along the traditional UX design wheel implies only one direction of rotation and one direction of travel. This represented an implied lack of freedom that did not exist in the actual UX design process created and utilized for the purpose of interacting with the Luminosity Lab core team in redesigning the urinalysis collection process.

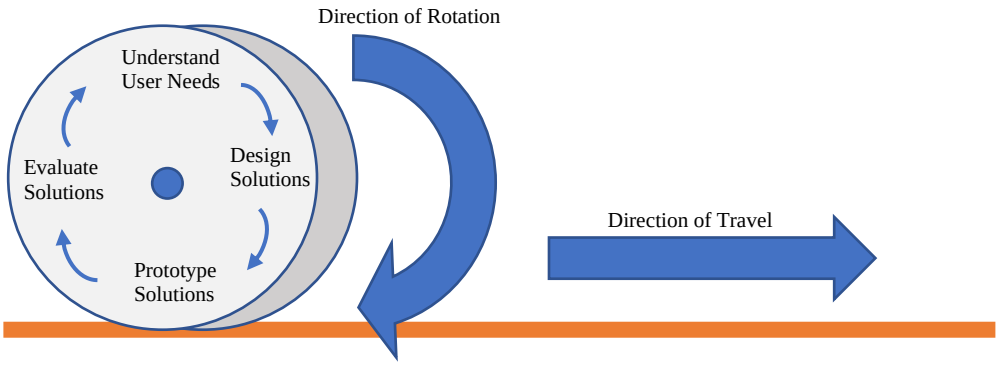


Figure 2. Depiction of the UX design wheel as a train wheel on a track demonstrating the lack of freedom in the direction and degrees of travel.

Other UX lifecycle models could have been utilized for the purposes of this project, however, the overall goal was to introduce the lab personnel to basic concepts and quickly direct their attention to the development process while the PI managed the overall

responsibility for maintaining proper UX controls. To this end, the PI decided to start with a basic UX lifecycle model and expand upon it. This may not be the best approach for every project; however, it was the one that was deemed to be most efficient and flexible for this project. The model created by the PI was deemed the 6 Degree of Freedom (6Dof) UX Ball. Within the limited scope of this project, it provided a model with which the PI could demonstrate to the personnel of the Luminosity Lab how to think beyond the implied confines of the basic UX Wheel model.

The team did not always advance in a forward direction nor did it always progress from one discrete task such designing solutions to prototyping solutions. Setbacks and outright failures led to dead ends that resulted in design rollbacks. For example, the development of a locking mechanism to seal the overflow tube initially progressed well (i.e. forward travel) and went through multiple iterations (i.e. forward rotation) until it had to be completely redesigned (i.e. backward travel) due to incompatibility with a separate but equally important feature. Tasks were not discrete and separate due to the collaborative nature of the development environment. Often, new understandings of user needs were acquired not as a result of the evaluation of a specific solution (i.e. forward rotation) but rather through interaction with the larger group. The use of modeling software allowed us to rotate counterclockwise or even directly transition between any of the three solution stages; design, prototype, or evaluation.

The actual UX design process utilized is better represented by a ball that can travel through and along six separate degrees of freedom (6DoF); Figure 3 depicts this 6DoF UX Ball. The 6DoF UX Ball can travel along all axes of movement and rotate about

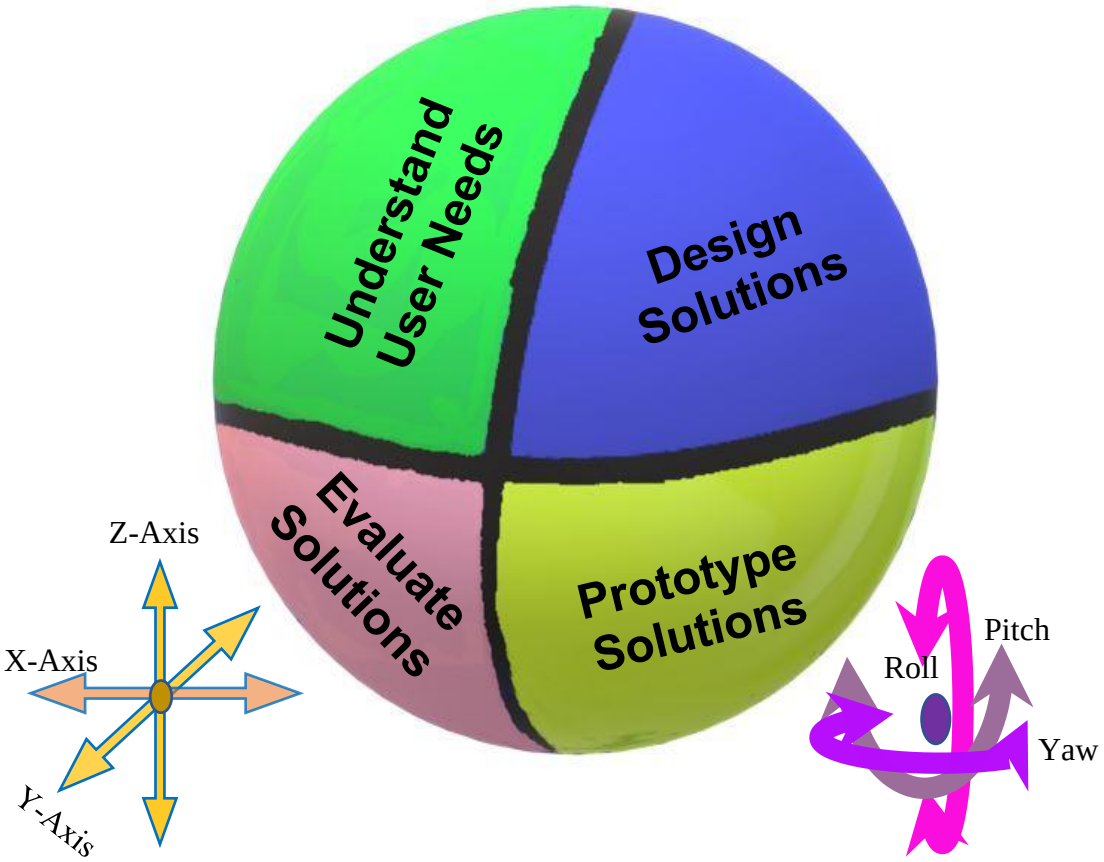


Figure 3. The 6DoF UX Ball is a newly proposed UX Development model. UX development activities are able to move and rotate along all 6 Degrees of Freedom.

each axis illustrating the actual nature of development in an innovative setting. Innovation is a dynamic process that cannot be constrained to a UX Wheel model that visually implies travel and rotation in one direction. If innovation is the goal of the UX design process, then the models used to represent the process must evolve to reflect the

true nature of innovation. The 6DoF UX Ball model is what was utilized to direct the innovation that occurred in support of the overall urinalysis improvement effort.

Initial generative research was performed in support of getting the overall UX design effort started, however, research and the acquisition of new knowledge did not stop at any point in the process nor did is always arrive as the result of a concerted and timed effort. If the design group were utilizing the UX Wheel model in a literal sense, new information regarding the needs of users would be expected to arrive after the performance of evaluating the latest design. However, new information arrived at multiple points along the design process and originated from multiple sources. The new information was not discarded because it did not arrive during the proper phase or from the expected source indicated by the traditional UX development model. One unexpected source of information arrived when a new literature search uncovered an article by Blake and Doherty (2006) that demonstrated a clinical use for the initial void of urine. Prior to the discovery of this article, all development efforts had focused on simply improving the MSCC sample by isolating and/or discarding the initial void of urine. At that point in time, several iterations of the re-designed specimen cup had already been designed, 3D printed, and bench tested. This new knowledge could have been ignored by the team and design could have continued to proceed to the point where a fully functional automated MSCC specimen cup could be produced that met the initial design goals. Essentially this new knowledge could have been considered out of scope for the current effort and noted for possible future development. However, the freedom of thought afforded by the innovative environment and the non-restrictive nature of the 6DoF UX Ball allowed for further exploration of this newly acquired knowledge.

A research effort was initiated to explore the usefulness of the initial void including gaining a better understanding of nucleic acid amplification testing (NAAT). This effort included technical research as well as reinitiating contact with SME 1, SME 4, and SME 5. Exploring the usefulness of the initial void led to the decision to redesign the Clean Catch Collection Cup (C4) device to capture and allow access to the initial void for the purposes of laboratory testing including NAAT analysis. Capturing and providing access for testing to both the MSCC and the initial void samples allows for the performance of a more complete panel of assessments from a single patient provided sample. This allows for the patient to provide a single sample that is then automatically divided so that it can be analyzed for UTIs as well as sexually transmitted infections (STIs). This redesign provided more clinical utility to both the patient and the provider.

The 6DoF UX Ball design process allowed the team to acquire and incorporate new information that resulted in the dynamic adjustment of the goals of the overall project thereby better addressing the needs of the users. The ability to move in all directions and make changes with global impact are not readily apparent features when utilizing a traditional UX design process, however, they are intentionally inherent in the 6DoF UX Ball design process. As a result of the changes in scope and goals of the product development efforts, the name of the redesigned urine specimen collection device was formally changed from C4 to Automated Simplified Urine Specimen Collection and Separation Container (ASU_SC_SC) to reflect the expanded scope and usefulness of the device.

Generating Feedback

The ability to generate quality feedback is one of the essential keys to ensuring the success of a UX based design project. Without proper feedback, a project is at risk of being steered in the direction of the developers desires and/or the assumed needs and wants of the envisioned customer. During the course of the urine specimen improvement project, feedback was generated using multiple techniques, methods, and means in structured, semi-structured, and informal manners; highlights of which will be described in the following paragraphs.

When the project was officially sanctioned by the Luminosity Lab, the staff of the lab and the PI worked together to identify, recruit, and assign members of the core project group. Members of the core project group consisted of the PI, a student researcher who held a bachelor's degree in Healthcare Innovation and was working on a master's in Digital Marketing, and a Design Supervisor for the Luminosity Lab. Once the core group was established, it was the responsibility of the PI to transfer the knowledge gained from the investigational research process to the other members of the group. This knowledge transfer process was not a one-way transmission of information, rather, it generated feedback from the core members that identified areas requiring more research and highlighted instances where either the PI or the SME had made assumptions that affected the information available from the original CIs. The feedback from the core group was used to inform additional research and guide additional SME engagement.

The opportunity for the core group to present current updates at the "all hands" meetings to the greater Lab population coupled with the access provided to groups and individuals either through the in-person Fulton lab space or online through SLACK

enabled the solicitation of feedback in the form of formalized and ad-hoc engagement across a multitude of modalities. The utilization of the 6DoF UX Ball model coupled with the opportunities presented by the multitude of means for soliciting and receiving facilitated experimentation and cross pollination in the innovation process (Kelly & Littman, 2005). Diversity and inclusion in the makeup of the core team and members of the Lab directly benefited the UX development effort by providing unique perspectives, observations, and inputs that uncovered unique and nuanced issues that helped highlight areas for improvement and innovation. The role of diversity and inclusion will be highlighted in areas where it can be directly attributed to a specific aspect of the UX development process and will be specifically addressed in a later section of this paper.

Redesigning the Process

The current MSCC technique is clearly not working as intended terms of design, implementation, and outcomes in its present form. Outside of the development of a completely new urinalysis device and its associated processes, utilizing the currently available standard urine collection cup coupled with an HSE informed process redesign would be the most immediate and cost-effective way to address some of the limitations in the MSCC process. The following sections will detail the efforts undertaken to redesign the process, and it should be noted that certain elements of the redesign can be implemented in isolation or built upon utilizing additional HSE approaches that will be detailed later in this paper.

The identified and targeted HSE areas for improvement in the process included the following:

- Memory

- Attention
- Information Processing
- Visual Areas of Interest
- Divided Attention
- Inattentional Blindness
- Affordances for Sitting or Standing Positions

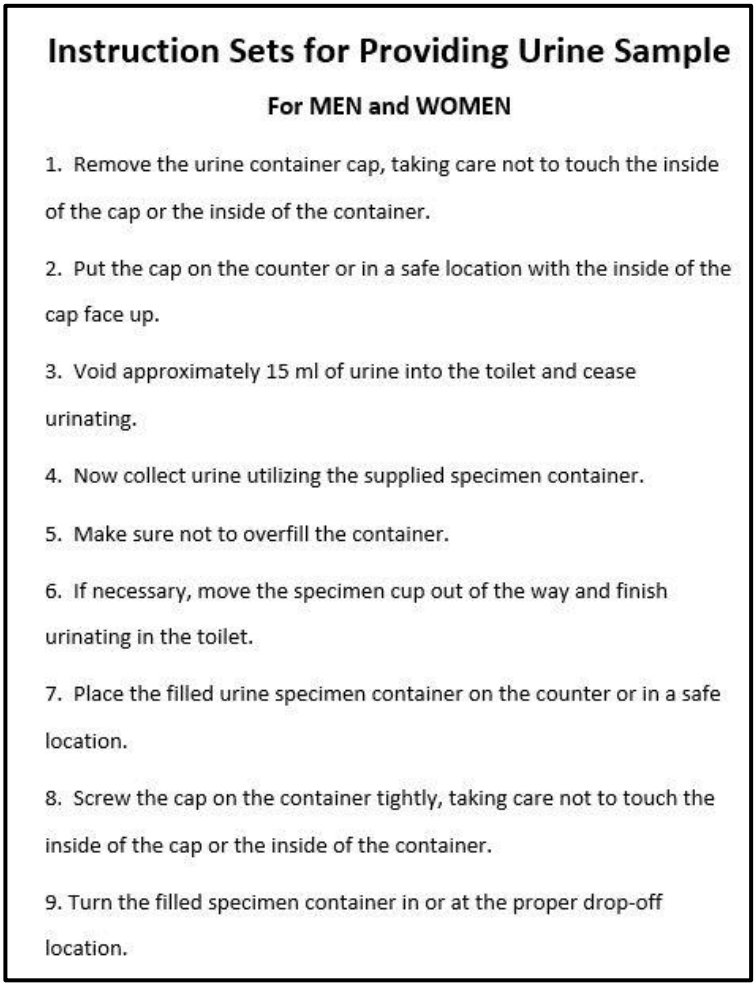
Start With the Sign

The concepts of HSE have made it apparent that the sign detailing the MSCC process should be redesigned. Starting with the sign makes sense both economically and in terms of efficiency of deployment. As medical administrators are one of the identified users, it makes sense that they would welcome a solution that could be implemented quickly at a low cost.

Shortening the Amount of Instructions

The number of items in the list is too large to be held in working memory leading to the possibility of a cascade of failures stemming from this single design feature. Cowan (2001) established the optimal quantity of instructions for chunking into working memory is four plus or minus two. The goal with the new sign, in terms of length, was to bring the amount of instructions between procedural break-points in the process down to what could be reasonably held in the working memory of the patient.

The new shortened version of the instruction is demonstrated in Figure 4.



Instruction Sets for Providing Urine Sample

For MEN and WOMEN

1. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
2. Put the cap on the counter or in a safe location with the inside of the cap face up.
3. Void approximately 15 ml of urine into the toilet and cease urinating.
4. Now collect urine utilizing the supplied specimen container.
5. Make sure not to overfill the container.
6. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
7. Place the filled urine specimen container on the counter or in a safe location.
8. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.
9. Turn the filled specimen container in or at the proper drop-off location.

Figure 4. The new shortened version of the MSCC instruction set.

The number of instructions has been reduced to 9 from the previous 12 to 14. It was deemed important to ensure that all tasks involving urinating into the specimen cup came at or before the sixth instruction with the most important instructions appearing between the third and sixth positions. In this way, if the patient does need to refer to the sign, it can be done at points in the process that are less critical, more favorable to HSE considerations, and less likely to introduce error and/or contamination. Specifically, the first two instructions are pre-procedural to the actual urination process and can be read

and eliminated from working memory as soon as they are performed. The instructions in the third through sixth position are favorable to memory chunking (Cowan, 2001) as they are relatively short, are directly related, and apply to a continual process that proceeds in a sequential manner (Wickens, Hollands, Banbury, & Parasuraman, 2013). Instructions seven through nine are post-procedural to the actual urination process thereby providing the specimen provider an opportunity during a less stressful and demanding point in the procedure to divert attentional and visual resources to the sign in order to complete the MSCC process.

The instructions to use a moist towelette to cleans the opening around the urethra were removed because multiple studies have shown it to be ineffective (Baerheim & Digranes, & Hunskaar, 1992; Blake & Doherty, 2006; Frazee, Enriquez, Ng, & Alter, 2015; Lefshitz, & Kramer, 2000). From an anatomical and logical perspective, eliminating this step would also seem to make sense. The MSCC process and follow on uranalysis testing is interested in identifying and eliminating non-renal epithelial cell. The urethral lining is one of the primary sources of non-renal epithelial cells and is therefore a prime candidate for introducing cellular contamination. This is one of the primary reasons an initial void is so important to the overall MSCC process. The average length of the female urethra is 4.0 cm (Gray, Standring, Ellis, & Berkovitz, 2005), and the average male urethra is 22.3 cm (Kohler, Yadven, Manvar, Liu, & Monga, 2008) in length. Cleaning the rim of a long tube does not make the interior of the tube clean.

Examination of the original instruction set revealed that with some rewording, it would be possible to rework the instruction set so that it could be used by both men and women. This eliminated the need for separate sections. Eliminating the separate sections

allowed for the removal of visual clutter, an increase in font size, and increases in spacing and contrast. These changes allow for improved salience, readability, placeholding, and an overall reduction on the demands of working memory (Cowen, 2001; Gray, 2000; Lee, Wickens, Liu, & Boyle, 2017; Loftus, Dark, & Williams, 1979).

Increasing Placement to Accommodate Multiple AOIs

While conducting a mental walk-through exercise to understand user experience, it became apparent that men and women have different visual AOIs while performing the MSCC. In terms of sign placement, there is normally a single sign placed in a location, often taped to a wall to the side of the toilet, in an attempt to allow it to be seen by both men and women performing the MSCC (see Figure 5).

Figure 5. MSCC typical sign placement. Single sign placed so that men can see it to their right while standing and women can see it to their left while sitting.

During the mental walk-through, it became apparent that the typical sign placement was a compromise for both men and women in an effort to find and utilize a shared AOI. This paradigm needed to be broken. Signs are essentially free, and there appeared to be little reason why more signs could not be hung in the other AOIs identified during the mental walk-through.

Figure 6. New locations for MSCC sign placement. The original location allows for reference by both standing and sitting while also attracting attention when walking into the restroom. Additional signs added to accommodate easy access AOIs from sitting and standing positions

The new sign placement utilizes the traditional location as it can still be referenced from either a sitting or standing AOI; however, it does represent a significant amount of head movement if utilized. The original location also attracts visual interest on the part

of the patient when walking into the restroom, thereby cueing them that there are posted instructions to follow. The additional sign location for sitting is in an easy to access AOI for those that chose to sit to provide their MSCC sample. The additional sign location for standing is in an easy to access AOI for those who stand to provide their sample. Depending on the specific configuration of the restroom used for the process, sign placement, size, and quantity can be adjusted to accommodate multiple AOIs.

Reducing the number of steps posted, redesigning the sign, and placing the sign in multiple AOIs addressed many of the HSE identified gaps. In terms of memory and cognitive load, reducing the instruction would be expected to help. Attention was aided by placing more signs, which increases the likelihood of being noticed. Attention, divided attention, and information processing were aided, and the capacity for inattentional blindness was possibly reduced, by allowing for easier access to information while performing the MSCC through the increased use of signage in AOIs that are readily accessible while performing the process. Affordances were made for accommodating access to information from both the sitting and standing positions.

The low cost of these HSE informed redesigns, along with the speed at which they could be implemented, made them worthy of experimental testing. Two of the hypotheses for this study directly related to these changes and were experimentally tested.

Expanding Beyond the MSCC

To this point, the singular focus has been on the Mid-Stream Clean-Catch (MSCC) urine sample collection process. In support of obtaining the best possible MSCC sample, various HSE informed approaches to modifying the process and procedures have been

examined and will be tested. However, if a patient were to present to a provider with a complaint of dysuria, an MSCC would be just one part of the overall examination and testing process. This argument makes a good case for expanding the use of HSE informed practices beyond just the MSCC in an effort to improve patient outcomes where possible.

The Role of Automation

In addition to the HSE techniques examined thus far, there is also the potential role of automation to consider. Human Systems Engineering seeks to improve human interactions with systems by enhancing safety, performance, and satisfaction. Automating a portion of the MSCC by redesigning the specimen cup to perform a number of the steps is a logical HES approach for improvement because it can establish a level of human involvement that will lead to the best possible performance (Lee, et al., 2017).

Refocusing On the Larger Picture

Procedural fixes, even when implemented with the concepts and techniques of HSE have limitations; instructions have a limit on simplification, signs may or may not be seen, and the best procedure can simply be disregarded by the person expected to perform it. Automation was considered as a means to support the gains made by procedural fixes while attempting to overcome the limitations posed by procedural fixes alone.

Initial efforts and research focused on how best to isolate or discard the contaminated initial void from the MSCC. The initial void is exactly what its name implies and performing an initial void is included in both the original and HSE improved instruction set. The initial void is the 15 – 30 ml of urine the specimen provider is instructed to void

into the toilet prior to providing the uncontaminated MSCC sample. The initial void is discarded in the MSCC process because it is considered to be contaminated by bacteria and skin cells from the urethra, the urethral opening, and the skin surrounding the urethral opening picked up when the initial urine stream passes through these areas.

The MSCC sample is provided to a laboratory and examined for the presence of bacteria. If bacteria are found and/or the specimen meets certain guidelines, the specimen is "reflexed" for additional testing. The process of testing bacteria and their antibiotic sensitivities is known as a culture and sensitivity (C&S) test. Bacteria cultures are grown from any bacteria, including contaminating bacteria, present in the provided MSCC sample. The bacteria culture growths are then exposed to various antibiotics to determine the expected level of antibiotic performance against the specific bacterial strain(s). The patient is then prescribed an appropriate antibiotic based on the results of the C&S test.

The article by Blake & Doherty (2006) not only lent support to eliminating the cleansing of the urethral opening by using a disinfecting towelette but brought two important additional facts to light. The first is the fact that not all patients presenting with symptoms such as painful urination, also known as dysuria, have a urinary tract infection (UTI) that can be identified through the use of an MSCC process with gonococcal and chlamydial urethritis being provided as two examples other common sources of dysuria. The second important fact brought forward is that both chlamydia and gonorrhea can be identified by performing nucleic acid amplification tests (NAAT) on the first void.

In their article, Blake and Doherty (2006) described the process by which a patient would be expected to provide both a first-void and an MSCC sample at the same time while following the recommended procedures for both voids. The process was described as having the patient void the initial sample into one specimen cup, cease urinating, open the provided towelette and cleanse the area surrounding the urethral opening, and finally resume urinating into a second specimen collection cup for the collection of the MSCC sample. In order to verify that this was still the process, communication was initiated with SME 5, (SME 5, personal communication, 2019). SME 5 verified and expanded on the description of the process provided by Blake and Doherty (2006) to include the addition of utilizing a Sharpie marker to draw a line on the first specimen cup to indicate the level at which the patient should stop their first void and switch to the second sample container. The Sharpie mark was then utilized by the technicians to discriminate the first void from the MSCC as the first void is in the specimen container with the Sharpie line.

Adding a first-void collection onto an MSCC collection increases the number of instructions the patient must follow and introduces more opportunities for error and contamination. Only the instructions for the MSCC are present in written and posted form in the bathroom. The patient must remember the verbal instructions provided for the collection of the first-void and must create a mental model of the combined process. The patient must now deal with two separate specimen cups and switch them at the appropriate times. Opening, closing, and switching the specimen cups introduces more opportunities for contamination based on contact with the sterile insides of the cups. Further, having two specimen cups introduces additional opportunities for stray urine, increases ergonomic and resource conflicts. In performing a mental walk-through of the

overall process, it becomes obvious that women are again at a disadvantage. The process described involved using a Sharpie to mark a line on a specimen cup. Attempting to view the line presents obvious obstacles to women and some men. Adding steps and specimen cups further exacerbates the HSE problems identified with the simpler MSCC process.

The Automated Specimen Cup

Often, when the term automation is used today, electronic and computing advancements come to mind. The automated specimen cup was designed with the use of advanced software, computing hardware, and cutting-edge 3D printing. However, the actual automated portions of the cup are all mechanical and physical. Within the world of HSE, automation is defined in more broadly as creating a bridge between humans and technology through the use of the human-centric automation practices (Billings, 1996) that are relevant to the desired goal. The primary automation goals in the specimen cup effort were to assist the patient in providing a contamination free specimen with minimal effort while providing maximum comfort and increased clinical utility.

The initial goals of the automated specimen cup were to assist in the improvement of the MSCC process that could not fully be addressed by redesigning the process and procedures. Automating a portion of the instruction set reduces the length of the list of tasks the patient must follow, thereby reducing the cognitive load, relaxing memory requirements, eliminating opportunities for error, and reducing the chances for contamination.

The very first designs relied heavily on the HSE informed concepts of rapid prototyping (Wright, 2005) and proof of concept testing. Figure 7 is a photo of the actual components of the initial rapid prototype; a rubber ball from a tethered paddle game and

two disposable sports drink containers. Figure 8 is a photo of the proof of concept testing performed on the initial rapid prototype using food coloring and water.

Figure 7. Components of the initial rapid prototype.

Figure 8. Proof of concept testing with the initial rapid prototype.

The initial rapid prototype and the proof of concept testing coupled with a basic understanding of the needs of the users provided enough detail to begin the ideation and brainstorming processes necessary to begin advancing through the UX design lifecycle activities (Hartson & Pyla, 2019). As described previously in this paper, a diverse group, including product development specialists, mechanical engineers, healthcare innovation specialists, and human systems engineers was assembled with the aid of ASU's Luminosity Lab to help work through the UX design lifecycle in a loose agile development environment aided by the creation and utilization of the 6DoF UX Ball methodology. Figure 9 is a photo of the results of an actual ideation and brainstorming session. Figure 10 is a rendering of one of the original concepts of the automated specimen cup.

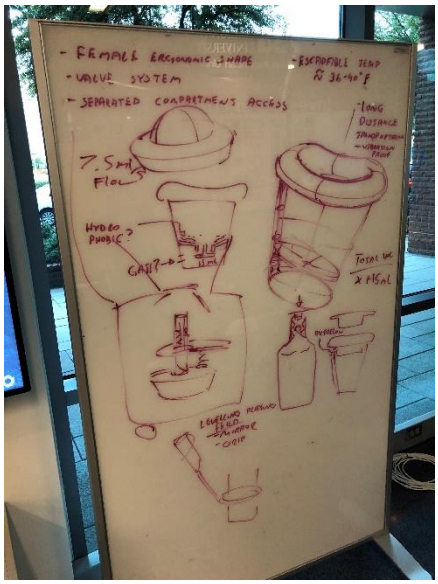


Figure 9. Results of an ideation and brainstorming session.

Figure 10. Rendering of one of the original concepts for the device.

Diversity and Inclusivity Lead to Innovation

Diversity and inclusivity have been shown to be key contributors to innovation (Hong & Page, 2004; Woolley, Chabris, Pentland, Hashmi, & Malone, 2010). Diversity and inclusivity were key contributing components in all aspects of the UX lifecycle of this project. Diversity may be approached as a recruitment activity that can create the potential for innovation, whereas inclusivity requires directed effort to create an environment in which all members of a group are empowered to contribute innovative capital. Specifically, from an HSE informed perspective, it was obvious that the MSCC process itself and any prior innovations intended to produce a better process, or an improved specimen collection device, were heavily skewed male, despite the fact that women are 238% more likely to be diagnosed with a UTI than men (Griebling, 2004). In a "know the user" (Hansen, 1972) type approach to diversity, it is clear that previous

studies and attempted design innovation recruited female users as study participants but failed generate meaningful improvements. This is likely due to the presence of diversity, but not inclusion. It was important to gain a female perspective on the design of any proposed new specimen collection device and such perspectives were actively sought out and engaged. If one looks closely at Figure 9, the beginnings of a more female-friendly device interface can be seen. Prior to the introduction of the idea of a more female-friendly device interface, the development had primarily concentrated on cognitive and sensory affordance. The automation of the device began movement into areas of functional affordances; however, it was the diversity in thinking that lead to the realization to include the HSE tenants of physical affordances, accessibility in design, and universal design with its principles of equitable use, flexibility in use and intuitive design (Hartson & Pyla, 2019). The female-friendly device interface brought forward the realization that whether intentional or not, the standard urine specimen cup had the affordance incorrect. The standard urine specimen cup favors men in many ways, and this goes against the principles of universal design. An ideal specimen cup would have the affordances favor women as it would provide more equity and flexibility in use. To this end, the opening of the device evolved from the simple circular interface found on a standard urine specimen cup that is not advantageous to women, to a much larger and inclusive saddle design that provided for universal affordance. The saddle design is useful for capturing urine flow that is not aimed well and provides a physical barrier to urinating on one's hands. Both of these issues could not be addressed with the changes implemented to the process and procedures; it takes a redesigned urinalysis cup to fully address these issues. The saddle design also helps ensures that all the urine is captured

and available for use in the specimen analysis process. In terms of flexibility and equitable use, men are not impacted by having a larger target to hit and can simply adapt to using the larger opening whereas, women now have a device that allows for a much larger target to act as physical accommodation for their lack of visible and physical aiming abilities in relationship to their urine stream. The new specimen cup saddle (see Figure 12) provides an area of 13.11 inches square, making it 391% larger than the standard specimen cup (see Figure 11).

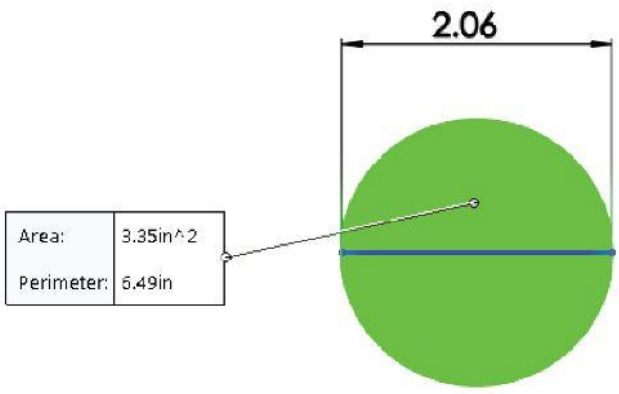


Figure 11. Dimensions of a standard urinalysis cup. The target area is only 3.35 inches square.

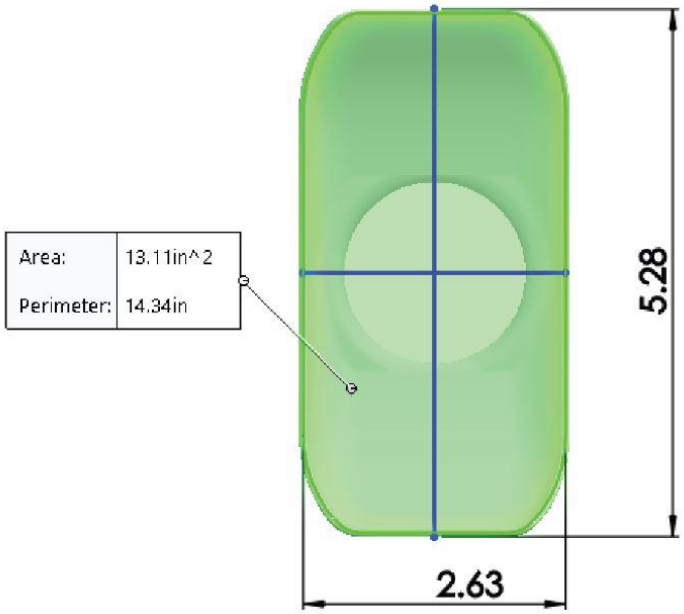


Figure 12. Dimensions of new urinalysis cup saddle. The target area is 13.11 inches square representing an increase of 391% over the standard specimen cup.

Diversity also allowed us to identify and address a second ergonomic issue concerning the way the specimen cup is gripped and held by women. A traditional specimen cup can require a woman to rotate her hand and wrist into a maximum position of range of motion that may result in the further need to rotate her forearm, elbow, and shoulder in order to place the cup properly for collection. A unique pinched body design (see Figure 16) coupled with a new way to grip the collection device (see Figures 13, 14, and 15) was shown to be effective in addressing this ergonomic issue and was incorporated into the new specimen cup.

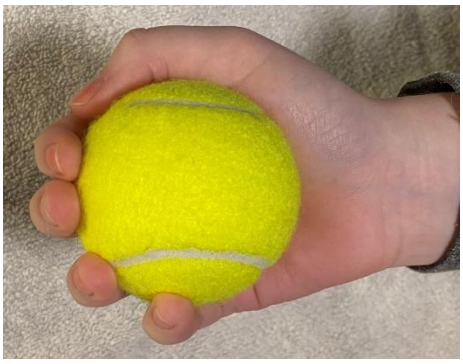


Figure 13. Demonstrating an underhanded grip.

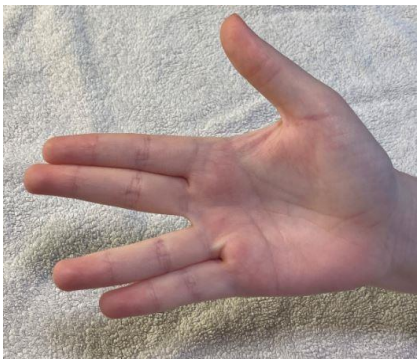


Figure 14. Underhanded grip with fingers spread.

Figure 15. Holding the new specimen cup with the new grip.

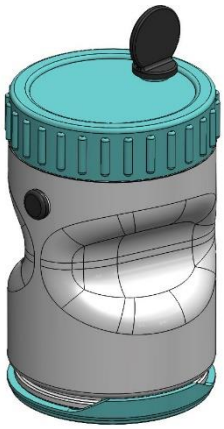


Figure 16. Rendering of pinched body design without saddle.

The Ultimate Goal and Designing to Close Gaps

As the methodological advancement of the product development cycle continued, more successes were achieved, and an end goal began to coalesce. The end goal was defined as the creation of a product and process capable of collecting and isolating two

high-quality samples from a patient during the course of a single urine void in order to provide specimens to run a full end-to-end battery of diagnostic tests with the instructions to the patient simply being, “please urinate as much as you can into the specimen container and do not worry about it overflowing. When you are finished, please hand the specimen container to the collection technician”.

The ability to isolate two separate samples had existed since the construction of the original rapid prototype. What did not exist in the original rapid prototype was an ability to access the initial void sample. Designing a method to access the initial void allowed for the expansion of the user base beyond just the patient. It was not the patient who needed to access the initial void sample; it was the medical and laboratory technicians. This design task called for the HSE process of data collection through the use of contextual inquiry (“Usability Body of Knowledge”, 2010) modified to work over email. SME 4 (SME 4, personal communication, 2020) was identified as a subject matter expert in urological diagnostic methodology. Questions, answers, and information were exchanged over email, allowing the design team to assemble enough knowledge to understand the process of extracting urine samples from specimen containers. The knowledge conveyed enabled the design of two extraction ports, one on the body and one on the lid, of the new specimen cup. The extraction ports were designed to allow for easy access while preventing accidental exposure or spillage of the sample resulting in improved safety for those charged with handling and processing the specimen.

Included in the ultimate goal was the ability to not overfill the specimen cup. This is important in terms of both cognitive and physical affordances. Designing a cup that is impossible to overfill provides functionality that allows the instruction set and the actions

on the part of the patient to be reduced by eliminating the step that stated one must ensure not to overfill the cup and the associated movement that would be required to remove the specimen cup. Further, doing so provides functional, physical affordances, and emotional reassurance to those who are unable to see the level of urine in the specimen cup as the only way to ensure that one does not overfill the standard urine cup is to look at the level of urine in it. Producing a specimen cup incapable of overflowing at the top helps ensure that one does not urinate on their hand, does not splash urine while attempting to move the cup out of the urine stream, and further prevents spillage of urine while moving the cup to a stable location in which to put the cap on. This automatic functionality was provided by the inclusion of an overflow tube that directs excess urine out the bottom of the cup and directly into the toilet. The implementation of the overflow tube was an excellent feature from a patient standpoint; however, it represented a potential liability in the form of means of urine spillage after the specimen cup was filled. It is common in product design to solve one problem only to introduce additional downstream problems. To address this downstream problem, a physical mechanism was designed to seal off the overflow tube after the patient provided the specimen as a means to ensure the safe and secure transport of the specimen.

The following storyboard (see Figures 17, 18, and 19) demonstrates the fluid flow and device operation.

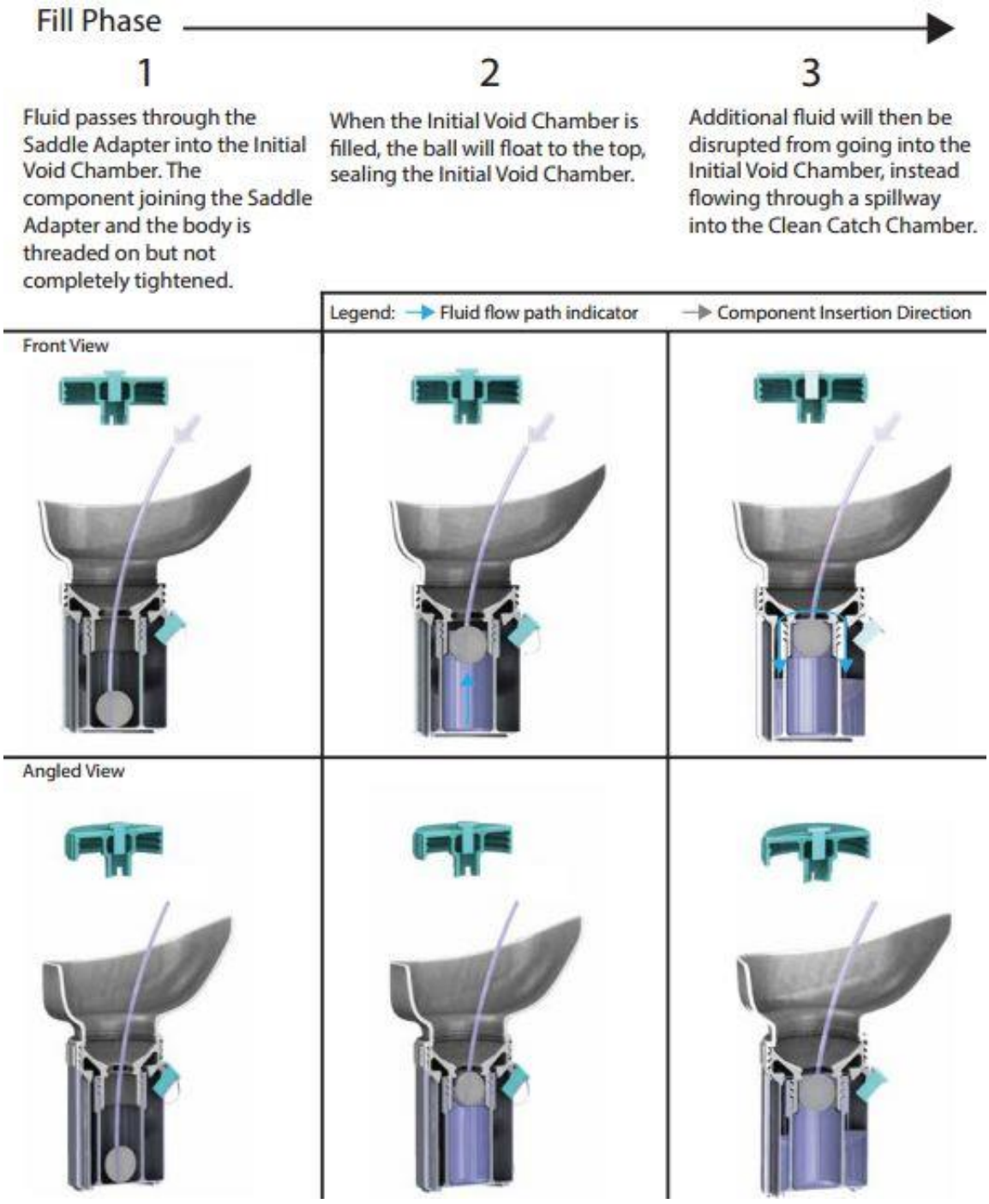


Figure 17. Storyboard rendering demonstrating the fluid flow and device operation during the fill phase.

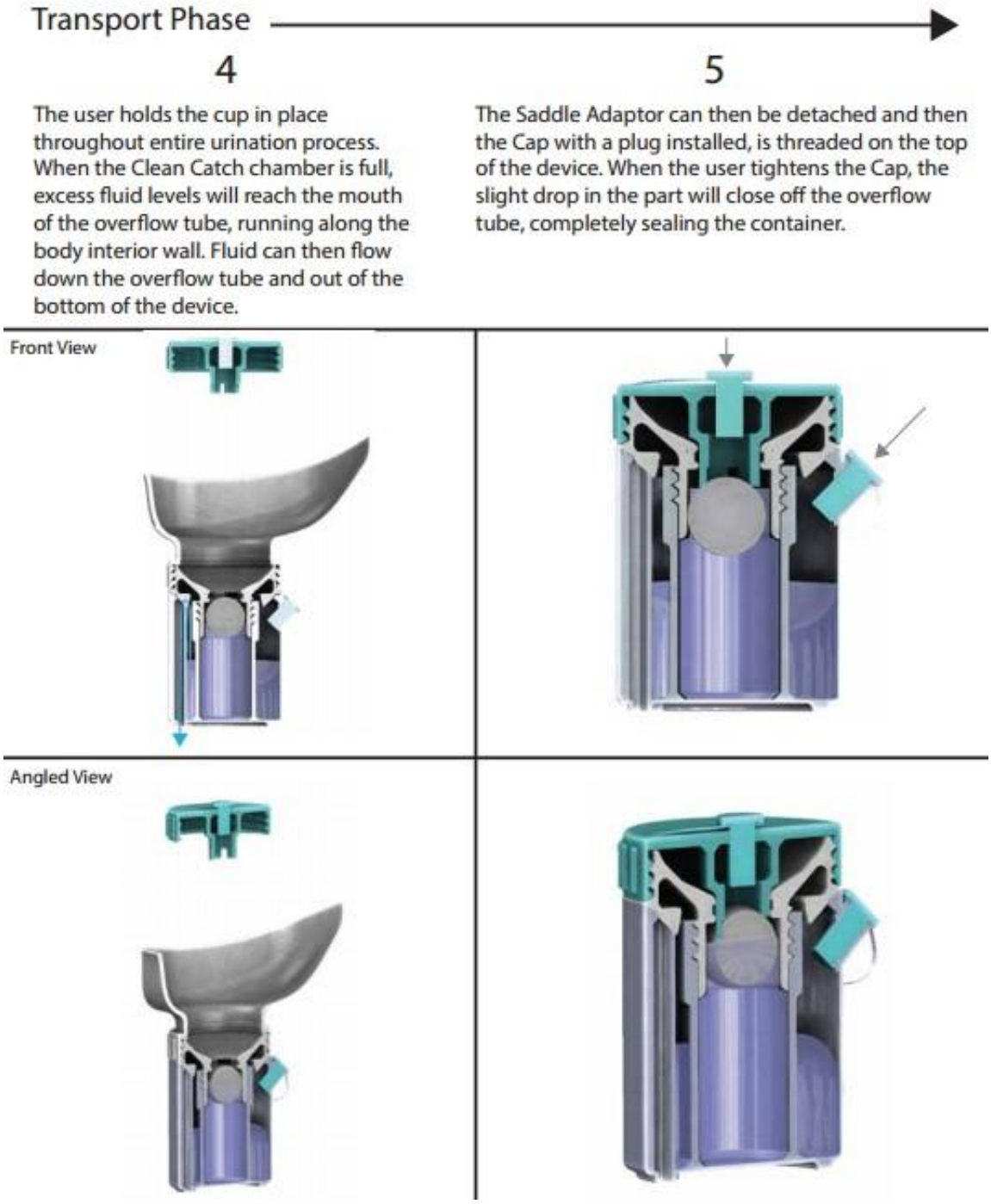


Figure 18. Storyboard rendering demonstrating the fluid flow and device operation during the final fill and transport phases.

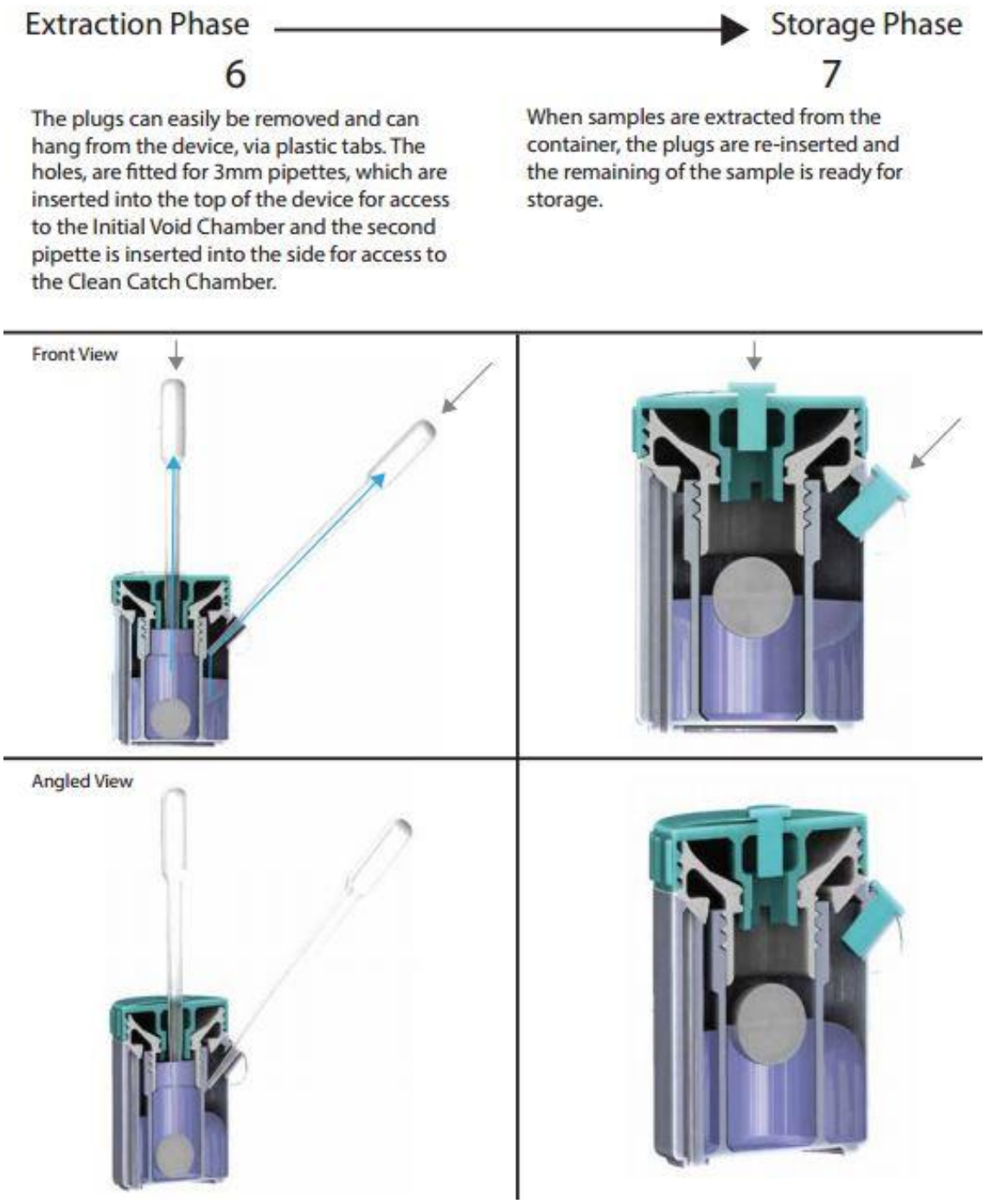


Figure 19. Storyboard rendering demonstrating the fluid flow and device operation during the extraction and storage phases.

The following photos demonstrate the actual functionality of a prototype device. Figure 20 demonstrates the extraction of the two separate samples with the blue representing the MSCC portion and the red representing the first void. Please note that if they had mixed, one or both of the samples would be green in color.

Figure 20. Photograph of the prototype device during the extraction phase. The blue sample is the MSCC portion and the red sample is the initial void sample. Note if they had mixed, one or both samples would be green.

Figure 21 is a photo demonstrating the functionality of the overflow tube by showing that the blue fluid, representative of an excess of MSCC sample, has collected on the paper plate below the prototype device.

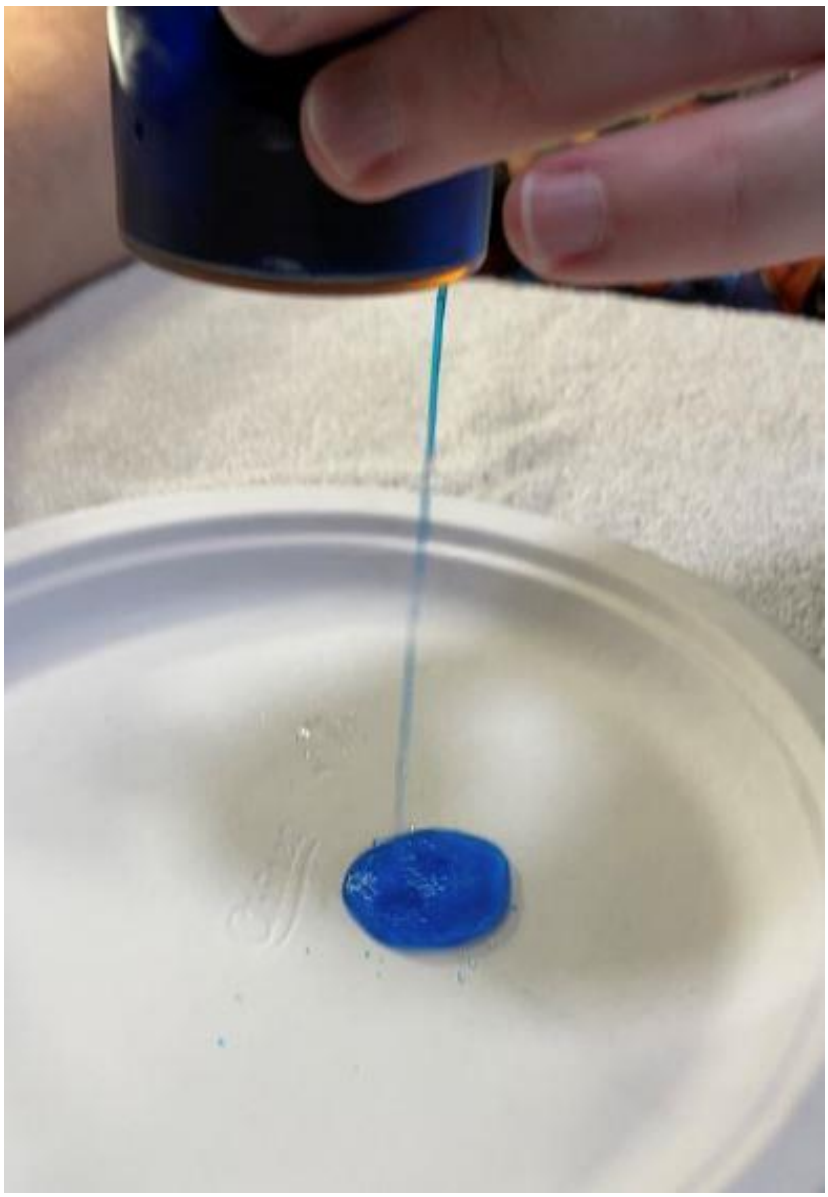


Figure 21. Photograph demonstrating the functionality of the overflow tube. Note the blue liquid represents excess urine from the MSCC specimen.

Figure 22 is a photo demonstrating the extraction of the samples from the prototype specimen collection device and their placement into separate containers. The blue fluid is the MSCC specimen, the red is the initial void specimen and the green fluid in the center container represents what would have happened if the two samples had mixed at any point.

Figure 22. Photograph demonstrating extraction of the separate samples and what the color would have been if they the specimens had mixed.

New Sign Needed

After the technical issues were solved and sorted with the automated specimen collection cup, the focus returned to the instruction set and signage. The new specimen cup has different capabilities and functionalities than the traditional specimen cup. Additionally, it is to be held differently.

The new specimen cup is designed to be essentially error-proof to the point that the instruction set could be simplified to three sentences. The new specimen cup is designed

to be gender-neutral with the proper affordances. The three sentences appearing on the signs accompanying the new specimen cup are as follows:

1. Begin urinating directly into the supplied specimen container.

2. Urinate into the container until you are finished – it is impossible to overfill the container so do not worry about doing so.

3. Turn the filled specimen container in or at the proper drop-off location.

The method of holding the new specimen cup was recognized to be new and unique. In order to communicate this to the users, a new graphic was designed to be posted with the written and visual directions on the actual operation and use of the new device. It is possible, particularly for males, to hold the device is a different manner, however the device is designed and operates best when held utilizing the new grip. Figure 23 is the visual storyboard demonstrating how to hold the new cup.

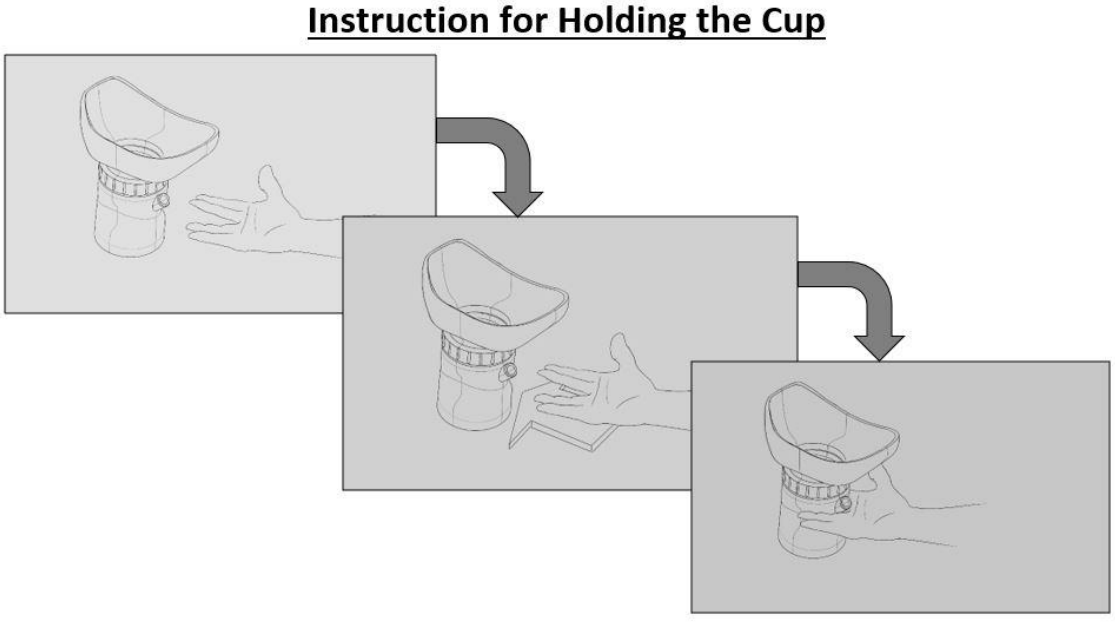


Figure 23. Image of the visual aid demonstrating how to hold the new specimen cup properly.

In addition to the visual aid storyboard depicting the new method of holding the cup, the overall instructions to be posted on the wall include the three sentences outlined above as well as a separate visual aid storyboard depicting how to place the cup for specimen collection. The visual aid storyboard depicting placement of the cup is separated by gender and offers women two suggested methods for collection; a sitting and a squatting method. Figure 24 is the visual aid depicting cup placement.

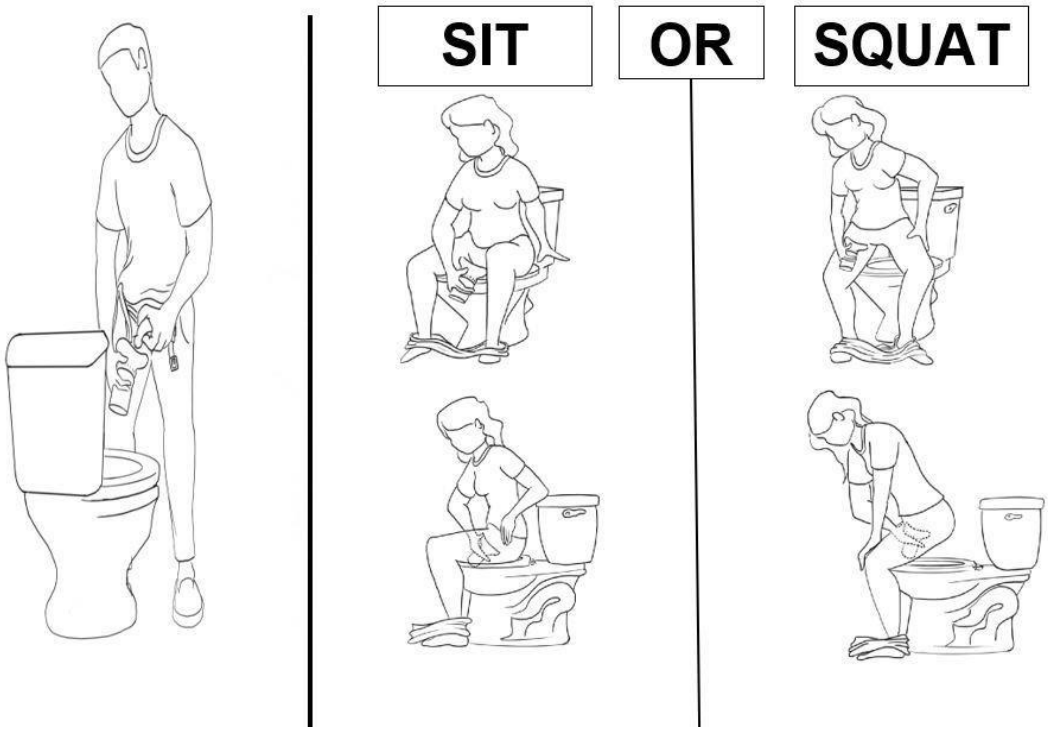


Figure 24. Image of the visual aid demonstrating how to place the cup properly for collection.

Summary of Design Process and Practices

The design process for the new specimen cup was led by strong HSE guidelines such as consultations with experts, “know the user” feedback loops, inclusivity, and rapid prototyping. The fluid nature of this project lead to the development of the 6DoF Ball model of design, which differs from the traditional UX design wheel model by allowing for the designers to innovate along all directions of travel and to move freely between stages. This model was then implemented to evaluate the existing procedure protocols for a midstream clean catch urinalysis sample. After realizing the shortcomings of this approach, lack of patient compliance namely, it was determined that a new HSE informed collection device would need to be created as a means to properly address the numerous shortcomings that existed with the current process, collection device, and procedures. To this end, the Automated Simplified Urine Specimen Collection and Separation Container was developed. Through this process, HSE concepts continued to guide the way. The most illuminating aspect was the power of inclusion, which revealed flaws not only in the male dominated paradigm surrounding development of urinalysis samples, but also showed critical flaws in the ergonomics of existing urinalysis devices. By following these guidelines, and accepting the fluid nature inherent to the 6DoF model, a more equitable design was able to be developed that not only followed HSE guidelines to greatly simply the urinalysis sample process, but also allowed for the inclusion of elements that enhanced urinalysis diagnostic capabilities beyond existing designs.

HYPOTHESES

The purpose of this study is to determine if, through the utilization of the concepts of Human Systems Engineering, improvements in the urine specimen collection process can be achieved in terms of improved specimen quality and patient satisfaction. The empirically testable hypotheses for this study are as follows:

H1)

After performing an HSE informed redesign of the process, procedure, and increased placement of modified signs in visual areas of interest (AOI) detailing the process for conducting an MSCC, specimen quality will improve over the baseline established by the first sample collected utilizing the standard MSCC process, procedures, and single sign placement.

H2)

Utilizing the newly designed specimen cup combined with its redesigned process, procedure, and increased placement of signs in visual AOIs detailing the redesigned process for conducting an MSCC with the new specimen cup, specimen quality will improve over the baseline established by the first sample collected utilizing the standard MSCC process, procedures, and single sign placement.

The following logical hypotheses are investigated using data and statistical analysis:

H3)

Specimen quality is the redesigned cup is expected to be dichotomous as the specimens are isolated with the intent of capturing, separating, and making available for sampling both an initial void specimen and a mid-stream clean-catch

specimen. Specifically, the initial void specimens are expected to have a higher contamination rate than the mid-stream clean catch specimens.

H4)

The specimen quality of the isolated initial voided samples is expected to have a higher contamination rate than that of the baseline mid-stream clean catch samples. The automated specimen cup automatically separates the initial void from the MSCC, whereas in methods of sample collection utilizing the standard urinalysis cup, it is incumbent upon the specimen provider to void the initial 15ml of urine into the toilet. If the person providing the specimen does in fact properly into the toilet and provided that the void accomplishes the expected task of cleansing the urethra and surrounding areas, the isolated initial void in the automated specimen cup should have a higher rate of contamination than the MSCC sample collected in the standard cup.

H5)

Users will have a preference for one of the two HSE informed modified processes and procedures over the original MSCC process and procedure.

METHODOLOGY

Institutional Review Board Approval

Arizona State University's Institutional Review Board (IRB) approved the protocol for this study. The ASU IRB ID for this study is: STUDY00011985.

Participants

Fifteen participants (10 Female and 5 Male) were recruited electronically through the use of the word of mouth-snowball method. The study protocol specifically excludes participants that are not fluent in English or are a member of a protected group (e.g., under 18). The participants were consented electronically prior to any data collection activities. All participants completed the study in its entirety. Participants were electronically paid $25.00 for their participation in the study.

Design

The study used a repeated measures protocol with the participants acting as their own controls. The study design notation is as follows:

O1 X1 O2 X2 O3

O1) Observation 1 consisted of a urinalysis from which to establish a baseline and a follow-on questionnaire. Each participant was provided with a standard specimen cup (see "Materials" section) and verbally instructed to follow the instructions posted in the restroom. The posted sign contained the traditional process and methods for providing an MSCC (see "Materials" section) and was placed in a commonly used location for MSCC sign placement (see Figure 25). The bathroom was equipped with a sink and supplies for handwashing. A table was placed in the restroom (see Figure 25) with a box of moist towelettes (see "Materials" section) for use in the cleansing steps of the MSCC

instruction set. Additionally, the table could serve as a safe location in which to place the urine specimen cup as needed.

Figure 25. Photograph of actual rest restroom showing; the sink and supplies for handwashing, placement of the traditional MSCC sign, and the table holding the moist towelettes for use in cleansing.

After supplying the urine sample, the participant electronically completed a follow-up survey prior to providing their next urine sample.

X1) Treatment 1 consisted of maintaining a standard specimen cup but with HSE informed modifications to the MSCC process and sign placement.

O2) Observation 2 consisted of a urinalysis and a follow-on questionnaire. Each participant was provided with a standard specimen cup (see "Materials" section) and verbally instructed to follow the instructions posted in the restroom. The posted signs contained the modified process and methods for providing a MSCC (see "Materials" section). The signs were placed in three locations (see Figure 26) that were determined to be visual areas of interest (AOI) commonly used location for MSCC sign placement. The bathroom was equipped with a sink. A table was placed in the restroom (see Figure 26) to provide a safe location to place the urinalysis cup. Handwashing supplies and the moist towelettes were moved to a counter with a sink just outside of the restroom entrance.

Figure 26. Photograph of actual rest restroom showing; the placement of the three modified MSCC signs, and a table.

After supplying the urine sample, the participant electronically completed a follow-up survey prior to providing their next urine sample.

X2) Treatment 2 consisted of supplying the participant with the redesigned specimen cup, HSE informed modifications to the MSCC process specific to the new specimen cup, and sign placement in the same identified visual AOIs utilized for Treatment 1 and Observation 2.

O3) Observation 3 consisted of a urinalysis and a follow-on questionnaire. Each participant was provided with the redesigned specimen cup (see "Materials" section) and verbally instructed to follow the instructions posted in the restroom. The posted signs contained the modified process and methods specific to the redesigned specimen cup for providing a MSCC (see "Materials" section). The signs were placed in three locations (see Figure 27) that were determined to be visual areas of interest (AOI) commonly used location for MSCC sign placement. The bathroom was equipped with a sink. A table was placed in the restroom (see Figure 27 to provide a safe location to place the urinalysis cup. Handwashing supplies and the moist towelettes were moved to a counter with a sink just outside of the restroom entrance.

Figure 27. Photograph of actual rest restroom showing; the placement of the three modified MSCC signs unique to the redesigned specimen cup, and a table.

After supplying the urine sample, the participant electronically completed a follow-up survey prior to providing their next urine sample.

Material

The standard urine specimen collection cups (see Figure 28) were provided by LabCorp.

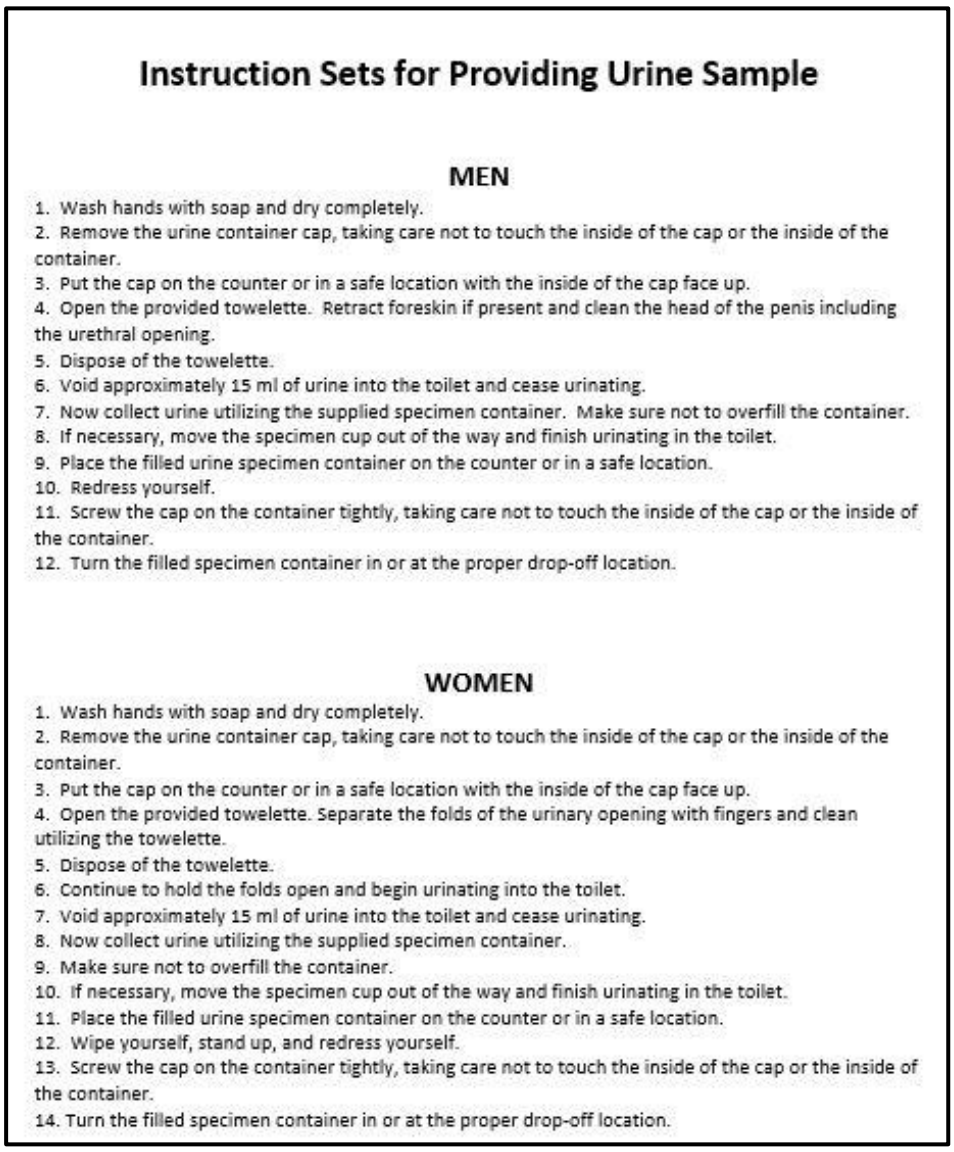
Figure 28. Standard urine specimen collection cup.

The moist towelettes (see Figures 29 and 30) for cleaning the opening of the urethra were provided by LabCorp.

Figure 29. Box of moist towelettes provided by LabCorp.

Figure 30. Image of an individual package containing one moist towelette.

The traditional mid-stream clean-catch (MSCC) instruction set (see Figure 31) was created from an amalgamation of research into the existing process and sign designs in common ambulatory healthcare settings. This instruction set is commonly printed on a standard 8.5 inch by 11inch piece of printer paper.



Instruction Sets for Providing Urine Sample

MEN

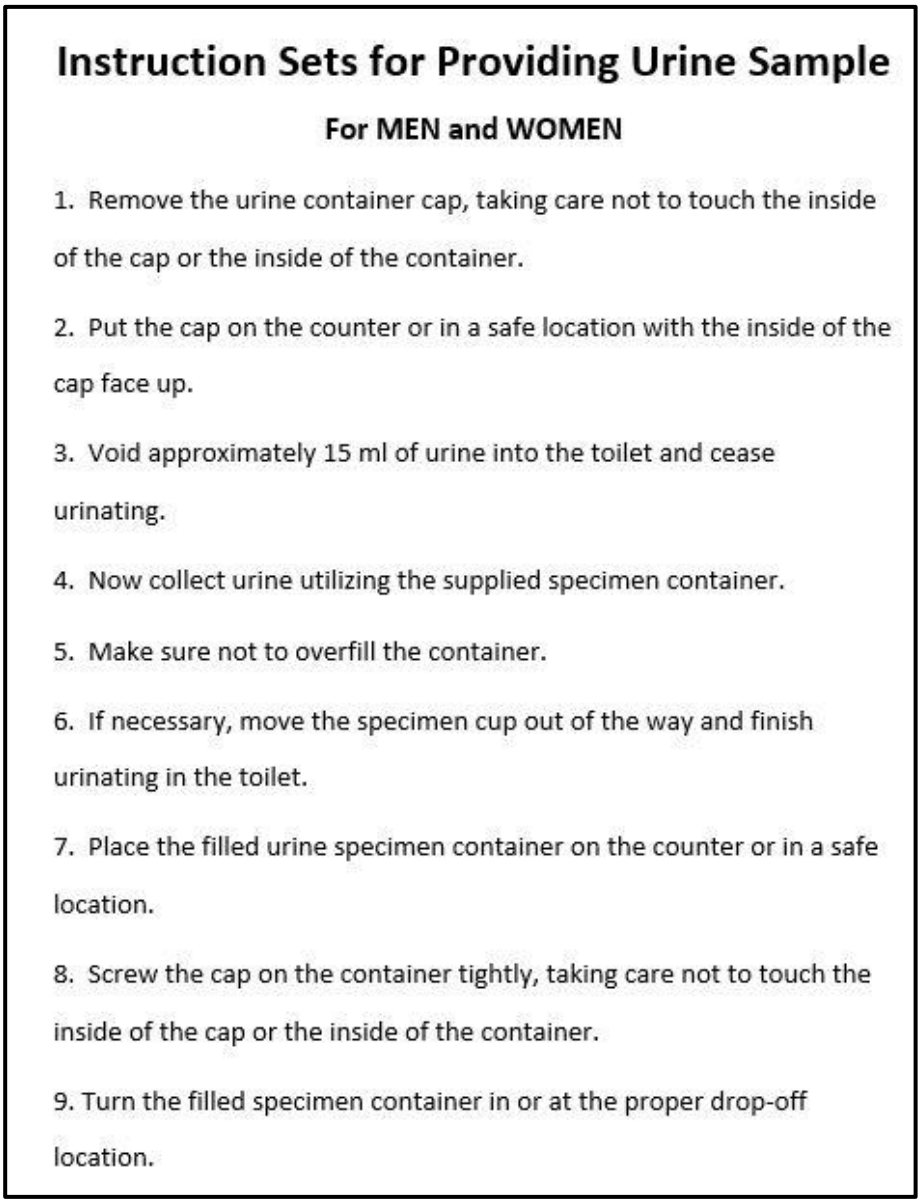
1. Wash hands with soap and dry completely.
2. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
3. Put the cap on the counter or in a safe location with the inside of the cap face up.
4. Open the provided towelette. Retract foreskin if present and clean the head of the penis including the urethral opening.
5. Dispose of the towelette.
6. Void approximately 15 ml of urine into the toilet and cease urinating.
7. Now collect urine utilizing the supplied specimen container. Make sure not to overfill the container.
8. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
9. Place the filled urine specimen container on the counter or in a safe location.
10. Redress yourself.
11. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.
12. Turn the filled specimen container in or at the proper drop-off location.

WOMEN

1. Wash hands with soap and dry completely.
2. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
3. Put the cap on the counter or in a safe location with the inside of the cap face up.
4. Open the provided towelette. Separate the folds of the urinary opening with fingers and clean utilizing the towelette.
5. Dispose of the towelette.
6. Continue to hold the folds open and begin urinating into the toilet.
7. Void approximately 15 ml of urine into the toilet and cease urinating.
8. Now collect urine utilizing the supplied specimen container.
9. Make sure not to overfill the container.
10. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
11. Place the filled urine specimen container on the counter or in a safe location.
12. Wipe yourself, stand up, and redress yourself.
13. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.
14. Turn the filled specimen container in or at the proper drop-off location.

Figure 31. Common depiction of the standard MSCC instruction set. Note it is separated by gender.

The modified MSCC instruction set (see Figure 32) was created by utilizing an HSE informed methodology. The from eliminates several steps and combines the instructions such that they are gender-neutral. This allows for a larger font size and increased spacing between instructions while maintaining the ability to print on a standard 8.5 inch by 11inch piece of printer paper.



Instruction Sets for Providing Urine Sample

For MEN and WOMEN

1. Remove the urine container cap, taking care not to touch the inside of the cap or the inside of the container.
2. Put the cap on the counter or in a safe location with the inside of the cap face up.
3. Void approximately 15 ml of urine into the toilet and cease urinating.
4. Now collect urine utilizing the supplied specimen container.
5. Make sure not to overfill the container.
6. If necessary, move the specimen cup out of the way and finish urinating in the toilet.
7. Place the filled urine specimen container on the counter or in a safe location.
8. Screw the cap on the container tightly, taking care not to touch the inside of the cap or the inside of the container.
9. Turn the filled specimen container in or at the proper drop-off location.

Figure 32. The modified MSCC instruction set.

The prototype urine specimen cups (see Figure 33) were 3D printed on a Formlabs 3 SLA printer utilizing Formlabs Surgical Guide resin. They were cleaned in an isopropyl alcohol bath and sanitized for three hours in an ozone sterilization system.

Figure 33. Image of the redesigned urine specimen collection cup.

The modified MSCC instruction set (see Figure 34) accompanying the redesigned urinalysis specimen cup were specifically developed for use with the prototype specimen cup. The prototype specimen is designed to automatically collect the initially voided urine as well as an isolated MSCC sample, therefore, the instruction set necessary to explain the process to the specimen provider is greatly reduced. HSE concepts were

utilized when designing the graphics, wording, and size of the modified MSCC instruction set. It is designed to be printed in a landscape format across two standard 8.5 inch by 11inch sheets of printer paper.

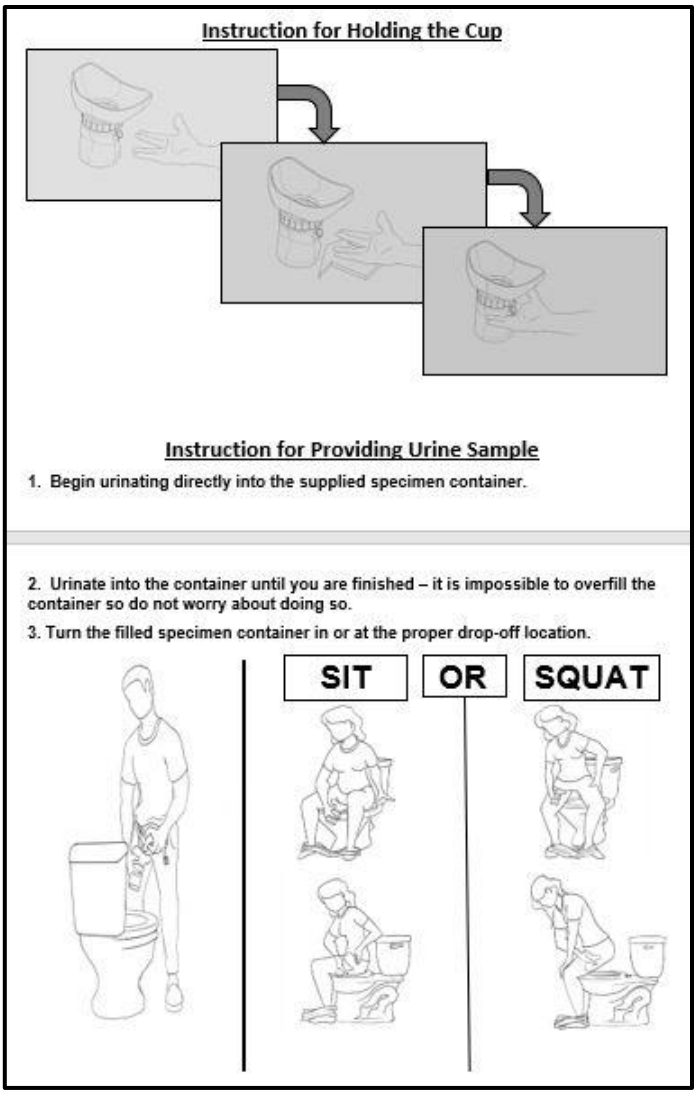


Figure 34. Image of the modified MSCC instruction set accompanying the redesigned urinalysis specimen cup.

Procedure

Participants were instructed to provide specimens on three consecutive days starting on a Tuesday. The specimens were collected at a 3rd party urine sample collection facility in Tempe, AZ. Each participant was verbally instructed to follow the instructions posted in the restroom for providing the sample. Each participant provided three urine specimens with the design of the prototype cup splitting the final urine specimen into two separate specimens; an initial-void and an MSCC. This resulted in a total of 4 specimens per participant. Once collected, the specimens were processed and cold stored for quick transport to a nearby LabCorp location in Phoenix, AZ. LabCorp test number 003772 "Urinalysis, Complete with Microscopic Examination" was performed on the specimens.

Participants were instructed to complete the electronic post-survey prior to providing their next specimen. The content of the surveys is presented in the Appendix for review. Each post-survey was unique; however, some of the questions were reused across all surveys. Once the participant had completed their final survey, they were electronically transmitted $25.00.

DATA ANALYSIS AND RESULTS

Data Analysis

The empirical hypotheses relating to urine specimen quality were analyzed using McNemar's test for repeated measures. All McNemar's tests were performed using SPSS version 25. McNemar's test was deemed the appropriate statistical test because of the following criteria; each participant acted as their own control, participants could be in only one state at a time, and there were only two possible outcomes; contaminated or uncontaminated. The independent variable was the type of HSE informed intervention utilized; either the modified signage and procedure used with the standard specimen cup or the modified signage and procedure used with the prototype specimen cup. The dichotomous dependent variables were the outcomes of the laboratory testing, obtained with observation two (O2) and observation three (O3) as measured against the results obtained with the initial control (O1). The logical hypotheses related to the expected outcomes from the sample separation were analyzed using data obtained from the urinalysis results as well as data obtained from the three post surveys.

Outcome Measures

The primary outcome was the quantity of abnormal results indicative of contamination from bacteria and/or non-renal epithelial cells, as indicated on the lab reports received from LabCorp utilizing LabCorp test number 003772. Abnormal results were defined as any test that indicated: epithelial cells (non-renal) > 10/hpf and/or bacteria > none seen.

Results

Samples and Participants. A total of fifteen (10 Female and 5 Male) participants were enrolled and acted as their own controls. Participants provided one sample per day for three consecutive days creating a total of 45 samples. The prototype urinalysis cup automatically separated the final fifteen samples into two separate specimens; one initial void specimen and one MSCC specimen. This made the specimen total for a third day 30. A total of 60 specimens were sent to LabCorp for analysis. LabCorp was unable to process three of the samples collected with the modified MSCC redesign with the standard cup. Table 1 demonstrates the breakdown of the samples and specimen totals by process and specimen title.

Table 1

Sample and Specimen Quantity Detail

	Traditional MSCC Process w/ Standard Cup	Modified MSCC Redesign w/ Standard Cup	Modified MSCC Redesign w/ New Specimen Cup		Total
Samples provided	15	15	15		45
Specimen Title	Baseline	New Process / Standard Cup	Initial Void Sample from Prototype Cup	MSCC Sample from Prototype Cup	
Specimens sent for analysis	15	15	15	15	60
Specimens successfully analyzed by LabCorp	15	12	15	15	57
		Total specimens available for study			57

Baseline

A total of fifteen samples were collected utilizing the standard MSCC process and the standard urinalysis cup. These specimens were sent to LabCorp for analysis. All fifteen of the baseline samples were successfully analyzed by LabCorp, and the appropriate reports were generated. The overall baseline contamination rate was found to be 60% (9 of 15), which is in line with previous findings detailed earlier in this paper.

H1) Specimen Quality Will Improve Through the Use of the HSE Informed Redesign and Improvements While Utilizing the Standard Specimen Cup

Fifteen samples were collected utilizing the HSE informed redesign and the standard specimen cup. Three of the fifteen samples from the HSE informed redesign were not processed by LabCorp within the allowable timeframe for urine specimens, thereby reducing the number of samples in this group to twelve. This reduced the number of matched pairs from the anticipated fifteen to twelve.

The results demonstrated that the actual number of contaminated specimens in the matched pairs was reduced from seven to five utilizing the redesigned process. The baseline contamination rate in the matched pairs was 58.3% (7 of 12), and the MSCC redesigned process with the original specimen cup had a contamination rate of 41.7% (5 of 12), a reduction of 16.6%. This represents a substantial reduction in the overall contamination rate and highlights the potential for a beneficial intervention that can be implemented at little to no cost. The contamination rate was reduced by 16.6% simply by making changes to the instruction, which strongly suggests that changes to the instructions can make improvements in the results, but the statistical analysis stopped short of demonstrating a significant result. Tables 2 and 3 demonstrate that the paired

nature of the participants acting as their own controls, as per the protocol for a McNemar's statistical analysis, combined with the loss of statistical power due to the reduced number of samples available for analysis resulted in the retention of the null hypothesis which was that changing the signage would not have a significant effect on the outcome.

Table 2

Crosstabs for Baseline vs. HSE Redesign w/ Standard Urinalysis Cups

	HSE Redesign w/ Standard Urine Specimen Cups	
Baseline	Uncontaminated	Contaminated
Uncontaminated	4	1
Contaminated	3	4

Note: The overall contamination rate decreased however, it did not decrease in matched pairs as demonstrated in the crosstab data.

Table 3

Test Statistics[a] for Baseline vs. HSE Redesign w/ Standard Urine Specimen Cups

N	12
Exact Sig. (2-tailed)	.625[b]

Note: a. McNemar's Test; b. Binomial distribution used.

H2) Specimen Quality Will Improve Utilizing the New Specimen Cup Combined With an HSE Informed Process and Procedure Redesign

Fifteen samples were collected utilizing the new specimen cup combined with the HSE informed redesigns. All fifteen samples were successfully processed by LabCorp, and the appropriate reports were generated. This provided for a total of 15 matched pairs.

The number of contaminated samples was reduced from nine at baseline to three post-intervention. The baseline contamination rate in the matched pairs was 60% (9 of 15), with a 20% (3 of 15) contamination rate for the new specimen cup and procedures. Participants were three times less likely to provide a contaminated sample with the new specimen cup and process when compared to the current MSCC gold standard.

Tables 4 and 5, demonstrate that this intervention made a statistically significant difference in the portion of contaminated specimens pre- and post-intervention, $p = 0.031$.

Table 4

Crosstabs for Baseline vs. HSE Redesign w/ Redesigned Urinalysis Cups

	HSE Redesign w/ Redesigned Urine Specimen Cups	
Baseline	Uncontaminated	Contaminated
Uncontaminated	6	0
Contaminated	6	3

Note: The overall contamination rate decreased in the matched pairs as required for statistical validity per McNemar's test.

Table 5

Test Statistics[a] for Baseline vs. HSE Redesign w/ Redesigned Urine Specimen Cups

N	15
Exact Sig. (2-tailed)	.031[b]

Note: a. NcNemar's Test; b. Binomial distribution used.

This result rejects the null hypothesis that the distribution of values across Baseline and the HSE Redesign w/ New Urinalysis Specimen Cups is equally likely. It demonstrates that the intervention consisting of an HSE redesigned urine specimen cup coupled with HSE informed process, and signage changes provided statistically significant improvements over the standard baseline MSCC process and specimen cup in use today.

The following logical hypotheses are investigated using data and statistical analysis:

H3) The Initial Void Specimens Are Expected to Have a Higher Contamination Rate Than the Mid-Stream Clean-Catch Specimens.

The initial void specimens isolated by the new specimen cup had a contamination rate of 46.6% (7 of 15). The isolated MSCC specimens had a contamination rate of 20% (3 of 15). This demonstrates a contamination variance of 233% between the two isolated chambers in the exact expected direction with the initial void capturing and isolating a significant amount of contamination. In the standard MSCC procedure, the patient is asked to void approximately 15ml of urine directly into the toilet to cleanse the urethra and surrounding areas of contaminates before providing the MSCC sample for capture

and analysis. The redesigned cup automatically captures and isolates the initial 15ml of urine rather than having the patient simply pass this portion of the urine stream into the toilet. The redesigned specimen cup makes the initial void available for analysis via NAAT testing while automatically providing a proper MSCC sample. The fact that the redesigned specimen cup demonstrated greater contamination in the initial void than in the MSCC sample portion establishes the fact that the redesigned specimen cup works as intended. Additionally, the results demonstrate that there is contamination present in the initial 15ml of urine and voiding this amount does in fact help cleanse the urethra and surrounding area.

Interestingly, the three contaminated samples identified in the MSCC specimens were correspondingly contaminated across all participant matched samples. Stated another way, the same three participants provided samples judged to be contaminated across all of their individual specimens analyzed.

H4) The Specimen Quality of the Isolated Initial Voided Samples is Expected to Have a Higher Contamination Rate Than That of the Baseline Mid-Stream Clean-Catch Samples.

Stated more plainly, the initial isolated void obtained by urinating directly into the redesigned cup should be more contaminated than the MSCC portion of the sample obtained during the baseline collection. The isolated initial void contamination rate was 46.6% (7 of 15) and the baseline mid-stream clean catch sample contamination rate was 60% (9 of 15). These results demonstrate the reverse of the hypothesis. If the participants properly followed the instructions and did not introduce contamination into the standard specimen cup via contact with bodily surfaces or through other means, this

hypothesis should have been proven correct. This result is not statistically significant but presents an interesting area for further study into possible methods of contamination introduction utilizing the standard MSCC process while lending further support for the importance and benefits of automating the process.

H5) Users Will Prefer One of the Two Modified Processes and Procedures Over the Original MSCC Process and Procedure.

The participants were asked to indicate their preference based on their experience providing the three samples (see Figure 35). Overall, 86.7% preferred the HSE informed redesigned process, procedure, and new specimen cup. This is important because this combination is the one that also demonstrated a significant difference in specimen quality.

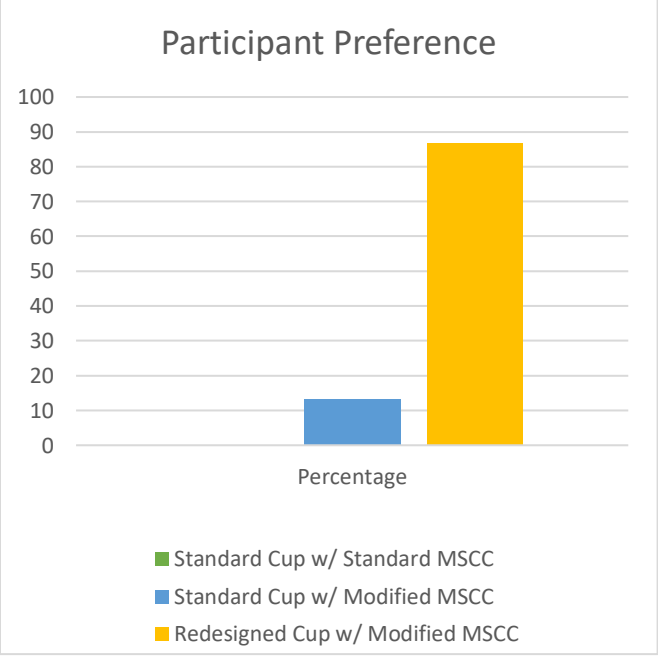


Figure 35. Graph of participant preference by percentage.

CONCLUSIONS, DISCUSSION, AND FUTURE DIRECTION

Conclusions

This study was undertaken in order to determine if the utilization of the concepts of Human Systems Engineering would result in improvements in the urine specimen collection process measured in terms of improved specimen quality and patient satisfaction. As evidenced by the results, HSE practices contributed greatly to reducing the rates of contaminated specimens, as demonstrated by the results of H2, while improving patient satisfaction with the processes, procedures, and products utilized in the urine specimen collection process as per the results of H5 (see Figure 35).

The results obtained while testing H1 demonstrated that it is possible to improve patient satisfaction and improve specimen quality with HSE informed improvements. Results from the testing of H1 supported the results of previous studies showing that cleansing of the ureteral opening and the surrounding area has no effect on the overall quality of the MSCC sample. This finding supports the reduction in the number of instructions provided to and the quantity of steps performed by the patient. Redesigning the signage utilizing HSE guidelines to increase saliency, exclude the steps related to cleansing with a moist towelette, and placing additional signage in areas of visual interest resulted in improved patient satisfaction and an overall reduction in the quantity of contaminated MSCC specimens.

Results obtained in the testing of H2 of this study demonstrate that the redesigned specimen cup coupled with its redesigned instruction set and additional sign placement clearly provides for statistically significant improvements over the standard baseline MSCC process and specimen cup in use today ($p = 0.031$). The redesigned specimen cup

and process provides clinical utility to patients, providers, and payors in the form of improved MSCC specimen quality and a separated initial void, both captured at the same time from the same specimen, while improving patient satisfaction as demonstrated by the results of H5 (see Figure 35), and providing for a more complete diagnostic workup. Implementation of the findings of H2 would increase the economic and diagnostic values of a urinalysis collection.

Discussion

HSE concepts were used throughout the entire effort to improve the urine specimen collection process. Not only were the concepts applied to the study and understanding of the problem of specimen contamination itself, but they were also applied to the overall efforts aimed at designing, developing, and testing proposed solutions. The same fundamentals that enabled identification also directed resolution. Toolsets and foundational concepts were mixed together to frame the problems and generate results.

Specific HSE concepts have been discussed throughout the paper to this point, however, I would like to highlight a few that were of particular importance. The areas I would like to briefly highlight are; the creation and utilization of the 6DoF UX innovation model, the role of attention, the limitations of resources, and the importance of diversity and inclusion.

The 6DoF UX innovation model (see Figure 3) allowed for a free-flowing design and development process that proved to be very conducive to encouraging, stimulating, and harnessing the power of innovation for the purposes of improving user experience. The 6DoF UX model provided the necessary flexibility to assimilate and apply new

knowledge gained at any point during the UX life cycle. The UX cycle was allowed to proceed in a non-linear fashion which greatly sped up the innovation process.

Attention is a basic tenet of HSE and is a component or the basis for many models of human behavior and understanding. Considerations for attention on the part of the specimen provider drove many of the redesign efforts. On the surface, the process of urinating into a specimen collection cup seems quite easy, however, upon close examination, it becomes obvious that properly providing an MSCC is a multifaceted process that involved many aspects of attention that provide opportunities for the introduction of error on the part of the specimen provider. Detailed study of the attentional aspects required to properly perform the specimen collection process lent significant support for the effort to ultimately design and develop an automated specimen collection cup. Results obtained when comparing the automated specimen cup to the standard and modified collection processes demonstrated significantly reduced levels of contamination in the MSCC sample.

The limitations of both mental and physical resources we carefully examined in the course of this study and utilized to inform the redesign efforts. Physical and mental resources have finite limitations and can interfere within a modality and/or across modalities. Mental resources available for assignment to monitoring and/or performing tasks are limited by filter and fuel (Wickens & McCarley, 2008). Physicals resources are limited by capabilities, availability, and interference. To the extent possible, the redesign efforts sought to either eliminate or minimize the physical and mental resource demands and conflicts experienced by the user. The redesigned process that utilized the standard specimen cup was able to eliminate some of the mental resource demands placed on the

user, however, due to the fact that the standard specimen cup was utilized, none of the physical and many of the mental resource demands could not be addressed. For example, the size of the opening on the standard specimen cup did not increase and therefore did not provide any affordances for improved accuracy and cleanliness in the specimen collection process. The automated specimen cup greatly reduced the number of instructions the user was expected to follow (see Figure 34), allowed for a targeted surface area that was 391% larger (see Figure 12), provided for a better ergonomic design (see Figure 15), and helped prevent the user from urinating on themselves.

Diversity and inclusion were essential to the success of the overall endeavor. Diversity and inclusion allowed for unique perspectives and insight into issues of universal design, equitable use, ergonomic and anatomical factors, usability, goals, and user experience. Diversity involved the recruitment and solicited feedback from multiple groups, whereas, inclusion involved the active decision and continued effort to involve multiple groups in the design and development process. The role of inclusion provided to be more important to this project than simple diversity. Several specific examples of the role of inclusion can be seen in the redesigned ergonomics and collection process associated with the automated specimen cup. One of the female designers, who had equal authority over design decisions based on the equality established by the established inclusion standards, specifically pointed out that where the male demonstrators were placing the standard specimen cup was not actually where women would have to place it in order to collect a specimen. This designer pointed out the ergonomic difficulties that were not obvious and were being overlooked by other male designers. This contribution specifically led to the pinched design of the redesigned specimen cup (see Figure 15) and

the “sit” or “squat” process options and instructions on the signage associated with the automated cup (see Figure 34). The same female designer also pointed out the shortcoming with the size and shape of the opening in standard specimen cup. Her male colleagues who could see the opening during their mental walkthrough of how they would perform the process failed to realize that a woman would not have the same visual advantage. The female designer applied a female panty liner to the top of the standard specimen cup as a rapid prototyping tool to demonstrate the benefits of elongating and modifying the standard opening. Further, the designer made the very valid argument that a larger target benefited everyone regardless of gender. This led directly to the design of the saddle adapter (see Figures 15 & 16). Without the unique perspectives provided by diversity and inclusion, the 60+ years of inaccurate affordances could not have been identified and addressed. Simply stated, without diversity and a concentrated effort at inclusion, these results would not have been obtained.

Limiting Factors

This study was conducted under the COVID-19 in-person experimental protocols enacted by Arizona State University. The protocols prevented the use of Arizona State Facilities for the use of specimen collection and analysis. As a result, the PI had to contract with a third-party urine specimen collection provider that specialized in the collection of urine for drug testing purposes. The third-party provider was not familiar with experimental protocols and the PI had to provide detailed instructions for the third-party provider to follow. Further, these protocols prevented the PI from being onsite, at the third-party contracted specimen collection facility, during the administration of the experiment. The third-party provider had only one bathroom for the purposes of

specimen collection and continued to conduct their standard drug screening urinalyses while this experiment was being conducted. It was deemed unfeasible by the third-party provider to alternate the order of the experimental treatments due to the complexity of doing so as well as the possible disruption to their standard business. Given the two possibilities of not collecting specimens at all and waiting for the COVID-19 restrictions to be lifted or proceeding with identified limitations, the PI chose to proceed with the data collection. Due to the limitations imposed by the COVID-19 restrictions and the possible effects on the results, this experiment should be viewed as a preliminary pilot / proof of concept study. The study protocol remains open at ASU and follow-up studies implementing less restrictive protocols eliminating the possibility for order effects are planned.

The inability to randomize the presentation of treatments leads to possible order effects that must be considered and discussed. The fact that the pre-test conducted as part of O1 was similar to the intervention (X1) which was administered in a serial fashion, as opposed to a randomized presentation, to all participants leads to questions regarding the possible introduction of order effects. These order effects have potential impacts to both the X1 and X2 interventions as the specimen cup design used in O1 was retained for X1 and O2 while it was changed for X2 and O3. Due to the potential limitations of the order effects on the test results, only H1 and H2 were analyzed and reported for statistical significance using McNemar's test.

The order effect could also cause transfer of training between O1 and X1 / O2 which should be considered in relation to the objective and subjective results obtained through X1 / O2 and X2 / O3. In terms of the objective results when viewed as the outcomes of a

laboratory test to determine the level of contamination in the specimens, the results are binary and dichotomous. The question of order effect and transfer of training applies to any possible changes, either in technique or preference, made on the part of the specimen provider as a result of previous exposure to a similar process that may have introduced an uncontrolled variable into the process. A participant may remember the instructions from O1 and carry them forward to X1 / O2 and/or X2 / O3 in a positive or negative way thereby introducing variability that might have had an effect on the test results. These same types of effects may also be transferred to the subjective results reported by the participants. The additional serial exposure to the original specimen cup, possibly resulting in a transfer of training, may possibly lead to a preference for or an aversion to the traditional specimen cup over the highly dissimilar newly redesigned specimen cup (Barnett & Ceci, 2002).

The nuances, differences, similarities, and interdependencies of short term memory (STM), working memory (WM), long term memory (LTM), and the influence of novelty vs. familiarity must be considered when discussing the possible occurrences and potential effects of order and transfer of training on the results obtained. As stated earlier in this paper, a MSCC is a process that is rarely performed by a patient and doing so, may result in a novelty effect which could make it more memorable. The order effect introduces the possibility of familiarity with the process and procedures of providing a urinalysis sample. ~~Poppenk & Moscovitch (2010) demonstrated that familiarity is more advantageous to memory than novelty. This finding supports the conclusion that novelty did not influence the preference of the new specimen cup and its related processes but could have led to some form of familiarity between O1 and X1 / O2.~~ This limitation can

be addressed in future studies by having a larger sample size and through randomization of the treatment order. STM serves as a cognitive memory buffer and the contents of STM may or may not be passed on to WM for additional retention and possible commitment to LTM. The open question in regards to the patient performing the specimen collection and reading the instructions is how they passively or actively process the procedure and information provided. It is possible that they simply follow a linear methodology where the process and instructions are placed in STM for use and then discarded post procedure (Atkinson & Shiffrin, 1968; Norris, D. 2017). If the patient performing the procedure needs to temporarily memorize the information, possibly through the use of chunking (Cowan, 2001), for the purposes of storage, comprehension, or mental manipulation WM will be engaged (Baddeley, 2000). However, WM has a time limit of less than one minute (Lee, Wickens, Liu, & Boyle, 2017, pp. 179) for which its contents will either be discarded or begin the processes necessary to be committed to LTM. The collection of patient specimens we separated by at least 24 hours, so either the patient committed the process to LTM or it was discarded from WM. While it is possible that LTM had some effect on this study independently or in conjunction with order effects and the transfer of training, the potential for occurrence and the extent of involvement cannot be determined from the information available. Further studies could be designed and conducted to better illuminate the possible effects of these variables.

The overall sample size of the study was an additional limiting factor. The clinical portion of this study involving the testing of human participants was undertaken during July of 2020 in the Phoenix metropolitan area amid the COVID-19 pandemic. A conscious decision was made to structure the study design to keep the sample size small

but as effective as possible by using participants as their own controls and performing the statistical analysis using McNemar's test. The results of this study that could be compared to the results of larger studies were found to be consistent in findings with studies involving larger populations.

Survey Results of Interest Not Discussed Elsewhere

During the course of this study, the participants completed a total of three surveys, with one being electronically administered after each specimen collection.

On each of the surveys, the participants were asked how much 15ml was with the correct answer being ½ fl. Oz. which always appeared as the first choice. The second choice was always 1.0 fl. Oz., followed by 2.5 fl. Oz., with 15 fl. Oz. as the final answer. This was considered important because the standard MSCC instructions state to void 15ml of urine before beginning collection. At any point in the study, the participants could have looked up the correct answer and began answering correctly. However, as Figure 36 depicts, the results were consistent with nearly half (46.7%; 7 of 15) repeatedly answering incorrectly.

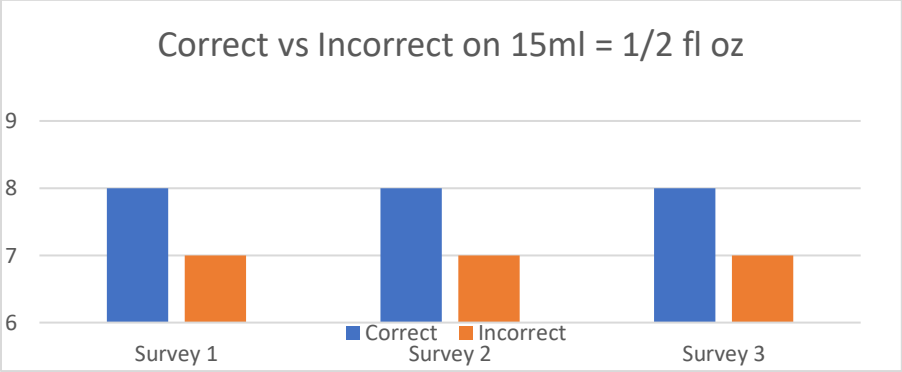


Figure 36. Correct vs incorrect answer to 15ml = ½ fl oz by survey. The amount of correct and incorrect answers remained constant across all three surveys.

Each survey also asked participants if they began urinating directly into the cup. Only the instruction set accompanying the specimen sample utilizing the new prototype cup called for the participant to start urinating directly into the cup. As Figure 37 indicates, several participants report doing the exact opposite of what the instructions indicated. Either the participant did not follow the instructions or did not understand the question.

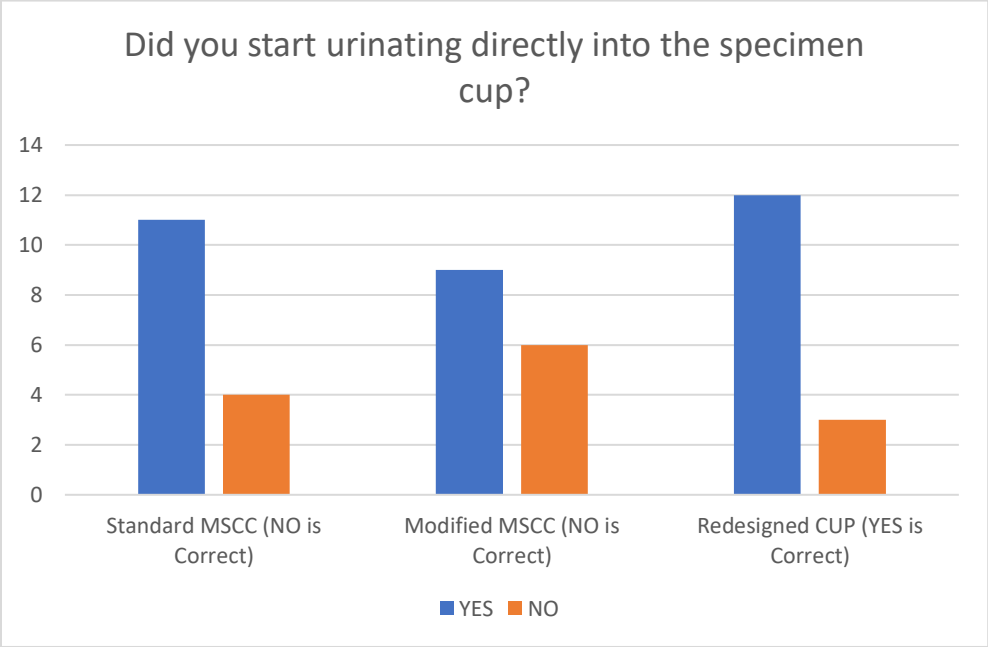


Figure 37. Answers to the question, "Did you start urinating directly into the specimen cup". "NO" is the correct answers for the Standard MSCC and the Modified MSCC. "YES" is only correct for the Modified CUP.

If we assume that the participants were non-compliant with the instructions, then 73.3% were non-compliant with the standard MSCC process, 60.0% were non-compliant with the modified MSCC, with non-compliance reduced to 20.0% with the redesigned specimen cup. Stated in the converse, 26.7% were compliant with the standard MSCC process, 40.0% were compliant with the modified MSCC, and 80% were compliant with

the instructions accompanying the redesigned specimen cup. Figure 38 depicts the compliance rate.

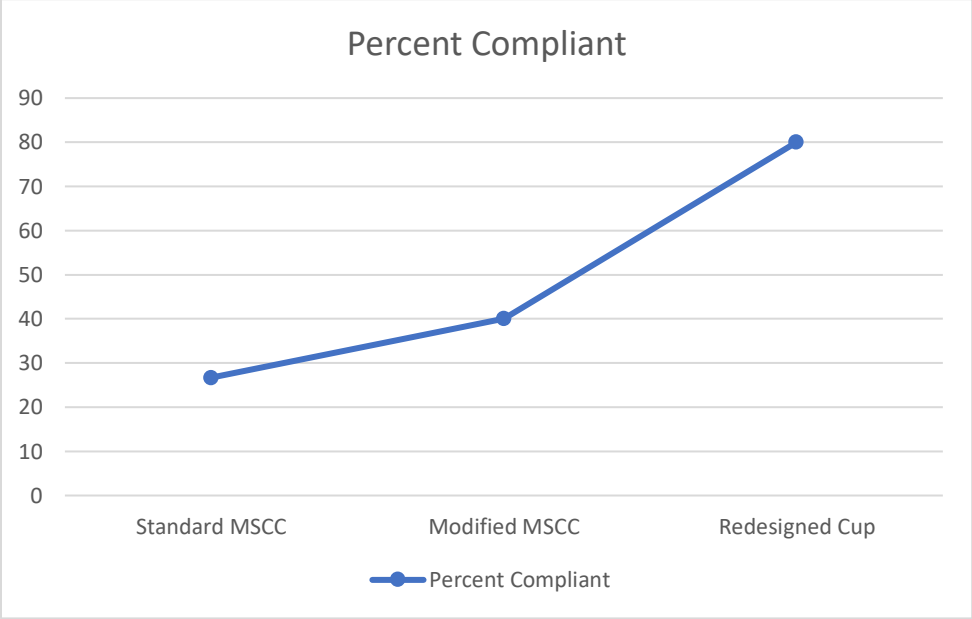


Figure 38. Percent compliant with posted instructions based on answers to questionnaires.

Of interest to intentional blindness and visual areas of interest, the participants were asked after each specimen collection how well they could see the sign(s) while performing the process. The survey question was, "Were you able to see the sign(s) containing the instructions while providing your sample?"

1 represents "Yes - saw the sign(s) the whole time."

5 represents "No - never saw the sign(s)."

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

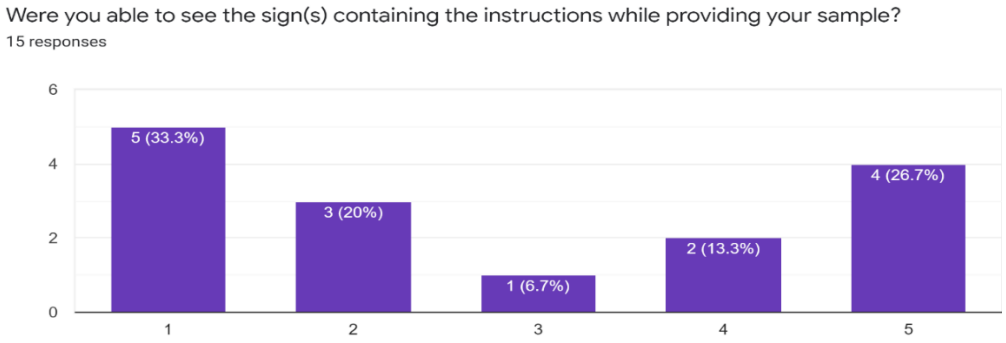


Figure 39. Rated difficulty of seeing the posted sign for the standard 1 sign placement MSCC process. "1" represents the response "Yes - saw the sign(s) the whole time" and "5" represents the response "No – never saw the sign(s)".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

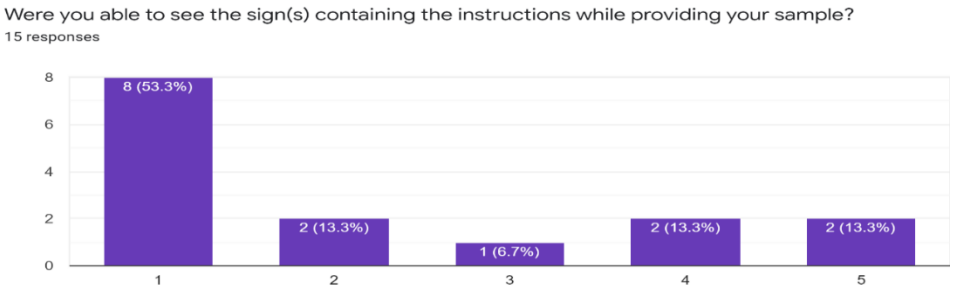


Figure 40. Rated difficulty of seeing the posted sign(s) for the modified process, modified signage, and standard urinalysis cup. "1" represents the response "Yes - saw the sign(s) the whole time" and "5" represents the response "No – never saw the sign(s)".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs.

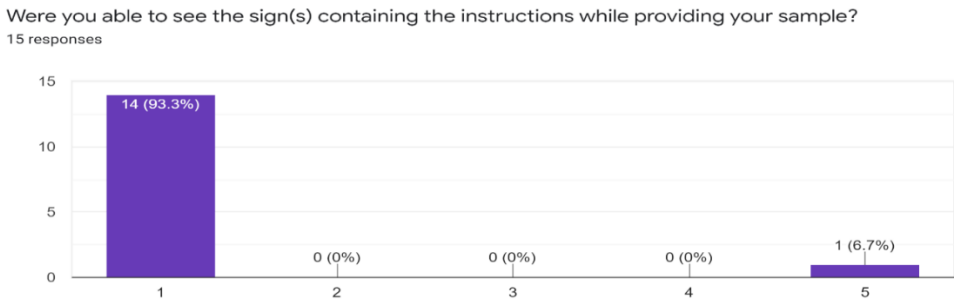


Figure 41. Rated difficulty of seeing the posted sign(s) for the redesigned specimen cup and the redesigned signs that accompany it. "1" represents the response "Yes - saw the sign(s) the whole time" and "5" represents the response "No – never saw the sign(s)".

Relevant to the participant's understanding of the instructions provided, they were asked following each specimen collection if they were confused by the instructions. The survey question was, "Did you find the instructions confusing?".

1 represents "No - Not at All."

5 represents "Yes – Very Confusing."

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

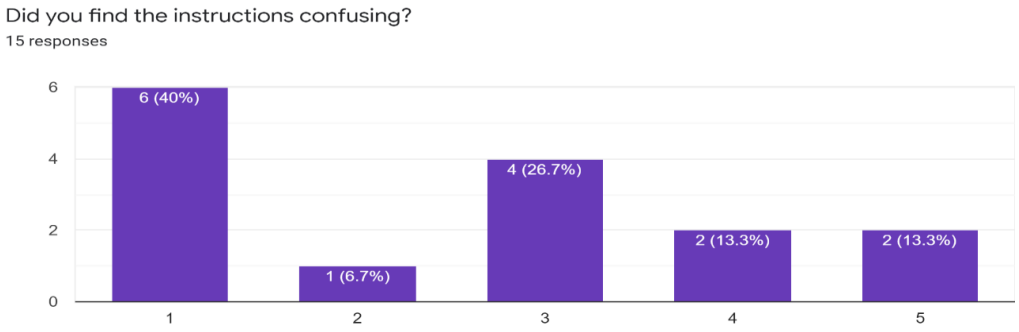


Figure 42. Rated difficulty of confusing instructions with the posted sign(s) for the standard MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "No – Not at All" and "5" represents the response "Yes – Very Confusing".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

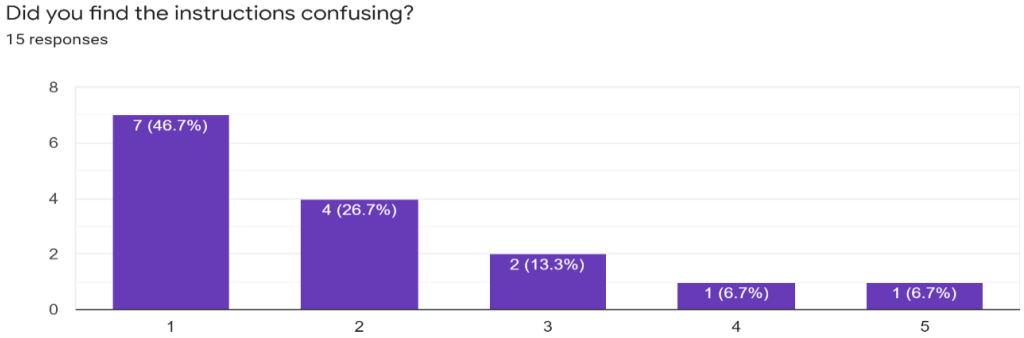


Figure 43. Rated difficulty of confusing instructions with the posted sign(s) for the modified process, modified signage while utilizing the standard specimen cup. "1" represents the response "No – Not at All" and "5" represents the response "Yes – Very Confusing".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs with the instructions that matched the new specimen cup process.

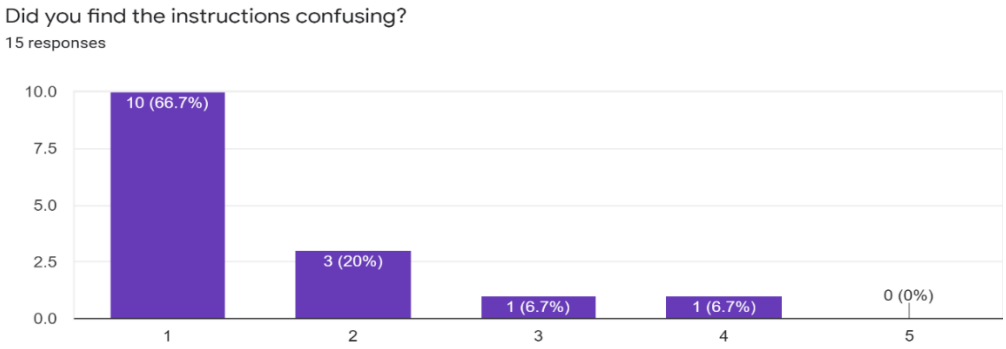


Figure 44. Rated difficulty of confusing instructions with the posted sign(s) for the redesigned specimen cup and the redesigned signs that accompany it. "1" represents the response "No – Not at All" and "5" represents the response "Yes – Very Confusing".

Participants were asked to self-report their confidence in properly following the instructions provided on the survey that followed each specimen collection. The survey question was, "Do you feel that you properly followed all of the printed instructions on the sign(s) when providing your sample?".

1 represents "Very sure."

5 represents "Unsure."

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

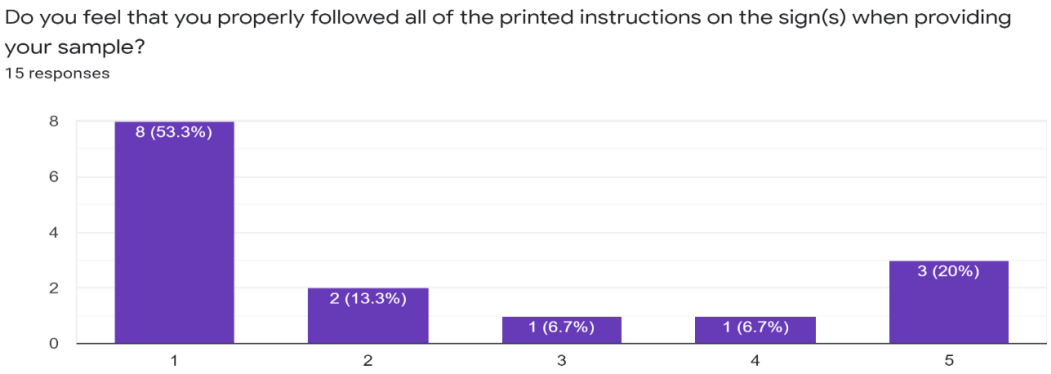


Figure 45. Self-reported confidence in following the instructions posted on the sign(s) for the standard MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "Very Sure" and "5" represents the response "Unsure".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

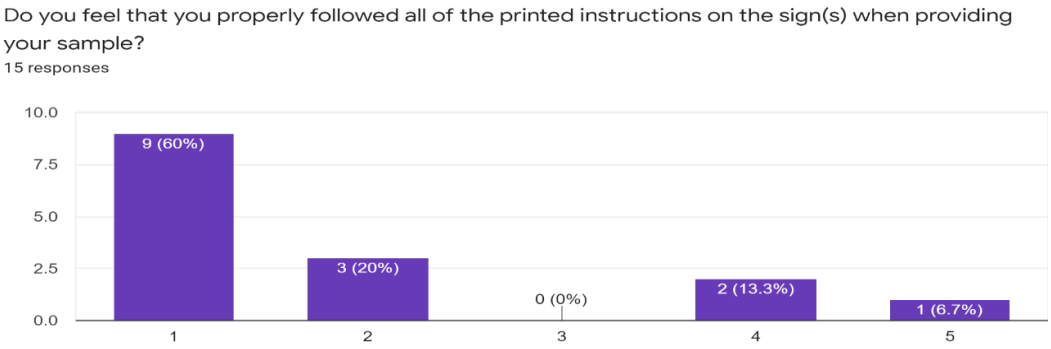


Figure 46. Self-reported confidence in following the instructions posted on the sign(s) for the modified process, modified signage while utilizing the standard specimen cup. "1" represents the response "Very Sure" and "5" represents the response "Unsure".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs with the instructions that matched the new specimen cup process.

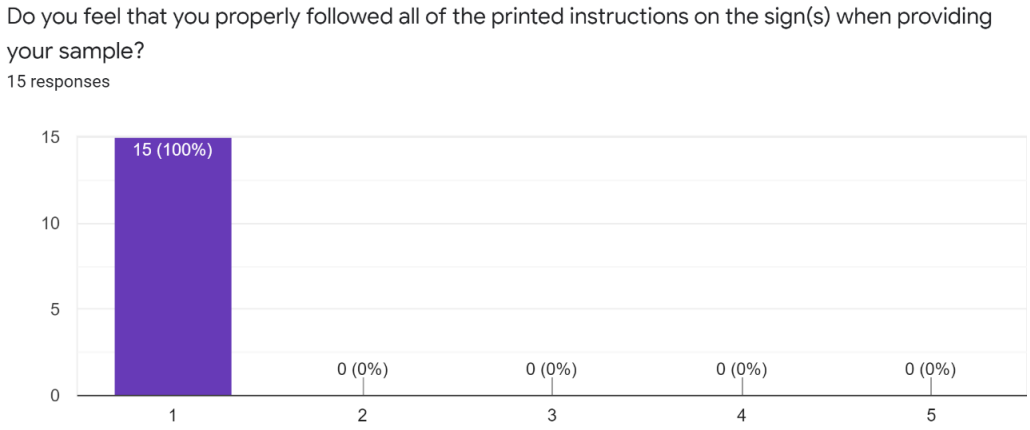


Figure 47. Self-reported confidence in following the instructions posted on the sign(s) for the redesigned specimen cup and the redesigned signs that accompany it. "1" represents the response "Very Sure" and "5" represents the response "Unsure".

One question on the survey was targeted toward the ergonomics of holding both types of specimen cups. The survey question was, "Was it easy to hold the specimen cup while providing the sample?" and was asked on post-survey questionnaire following each specimen collection.

1 represents "Very easy."

5 represents "Very difficult."

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

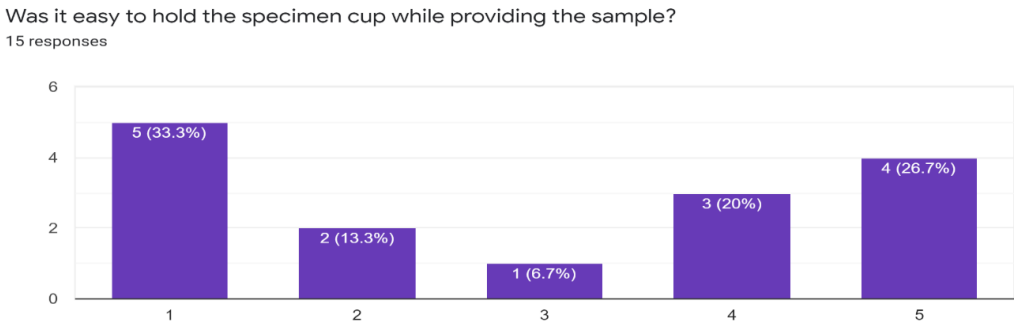


Figure 48. Self-reported ease of holding the specimen cup with the standard MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "Very Easy" and "5" represents the response "Very Difficult".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

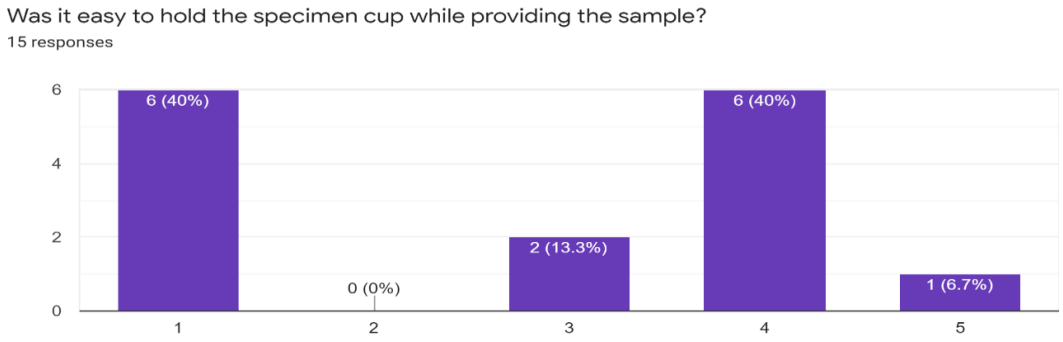


Figure 49. Self-reported ease of holding the specimen cup with the modified process, modified signage while utilizing the standard specimen cup. "1" represents the response "Very Easy" and "5" represents the response "Very Difficult".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs with the instructions that matched the new specimen cup process.

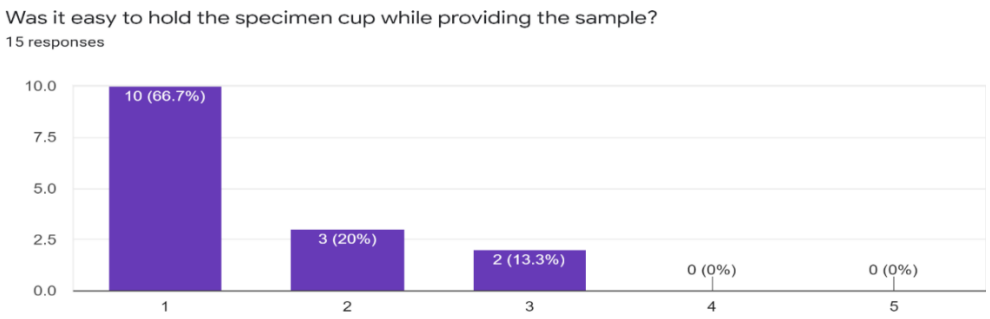


Figure 50. Self-reported ease of holding the specimen cup with the redesigned specimen cup and the redesigned signs that accompany it. "1" represents the response "Very Easy" and "5" represents the response "Very Difficult".

An additional survey question was aimed at determining if the modifications had an effect on the participants ability to position the specimen cup for proper collection. The survey question was, "Did you find it easy to position the cup in order to collect the urine stream?".

1 represents "Very easy."

5 represents "Very difficult."

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

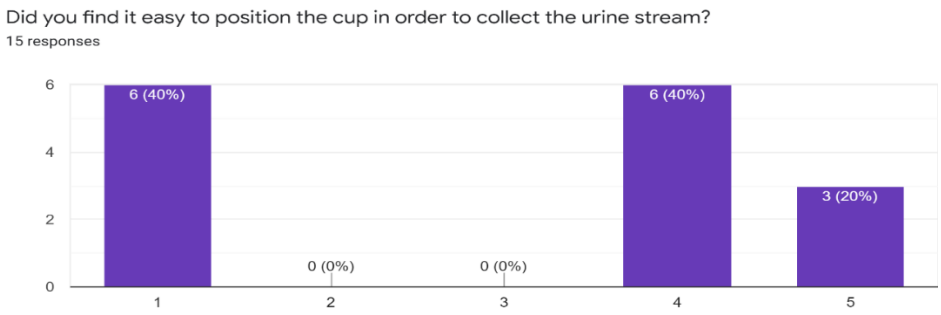


Figure 51. Self-reported ease of positioning the specimen cup for proper collection with the standard MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "Very Easy" and "5" represents the response "Very Difficult".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

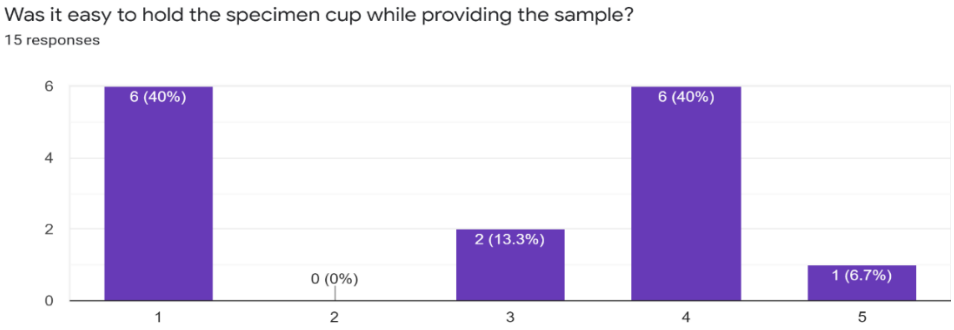


Figure 52. Self-reported ease of positioning the specimen cup for proper collection with the modified process, modified signage while utilizing the standard specimen cup. "1" represents the response "Very Easy" and "5" represents the response "Very Difficult".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs with the instructions that matched the new specimen cup process.

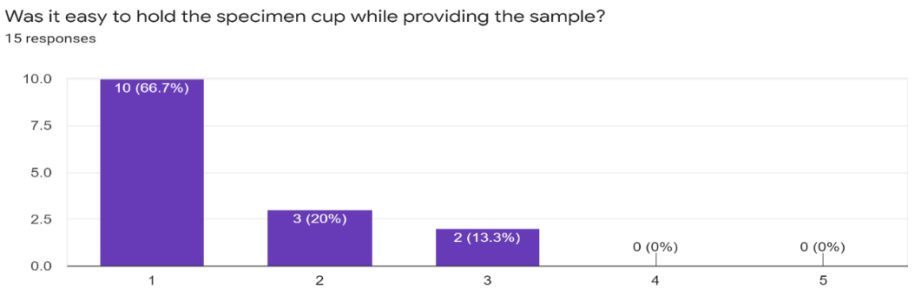


Figure 53. Self-reported ease of positioning the specimen cup for proper collection with the redesigned specimen cup and the redesigned signs that accompany it. “1” represents the response “Very Easy” and “5” represents the response “Very Difficult”.

One of the survey questions was designed to gauge user satisfaction with the both the instruction sets and the specimen cups. The survey question was, “Please rate your overall experience in relation to the instruction set and specimen cup provided” and was asked on each post-survey that followed a specimen collection.

1 represents “Very satisfied.”

5 represents “Extremely dissatisfied.”

For Sample 1: The control using only 1 sign placement and the standard specimen cup.

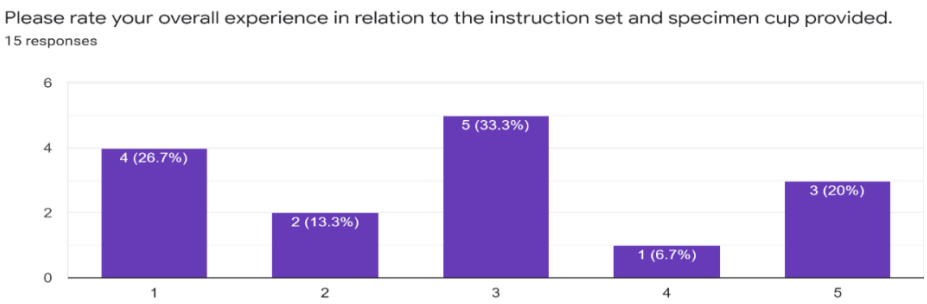


Figure 54. Self-reported overall satisfaction with the instructions and the specimen cup with the standard MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "Very satisfied" and "5" represents the response "Extremely dissatisfied".

For Sample 2: Utilizing 3 sign placements with a modified process, modified signage, and standard urinalysis cup.

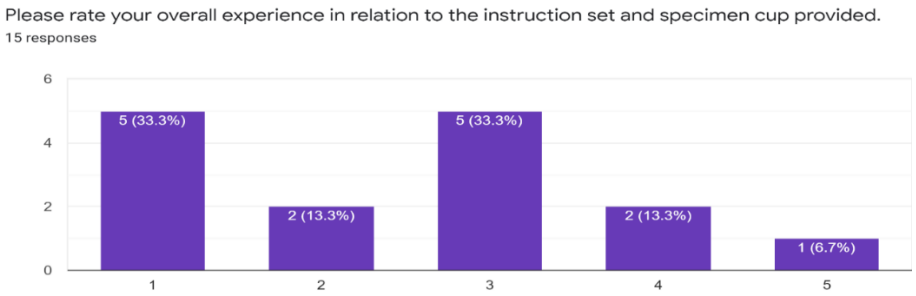


Figure 55. Self-reported overall satisfaction with the instructions and the specimen cup with the modified MSCC instruction sign placement utilizing the standard specimen cup. "1" represents the response "Very satisfied" and "5" represents the response "Extremely dissatisfied".

For Sample 3: Utilizing 3 sign placements with the redesigned specimen cup and the redesigned signs with the instructions that matched the new specimen cup process.

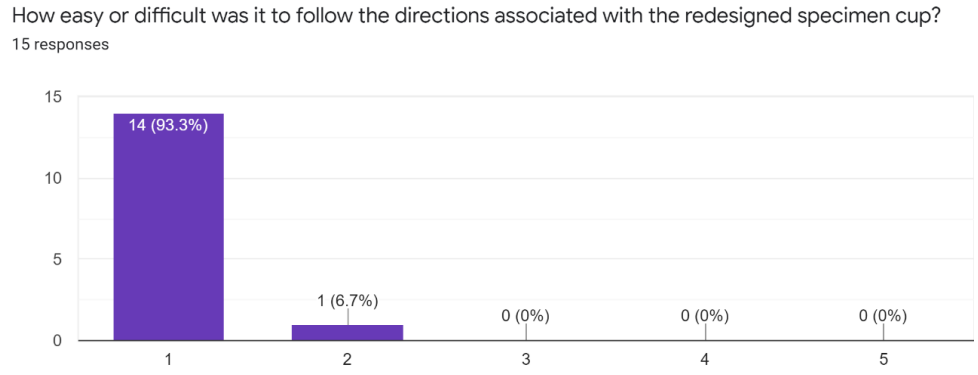


Figure 56. Self-reported overall satisfaction with the instructions and the specimen cup with the redesigned specimen cup and the redesigned signs that accompany it. "1" represents the response "Very satisfied" and "5" represents the response "Extremely dissatisfied".

On the final survey, the participants were asked to choose which of the processes they felt most confident in adhering to the posted directions. The survey question was, "Of the three samples you provided, which one do you have the most confidence in your ability to follow the directions correctly?" This question was a stand-alone only asked on the final survey after the participants had gone through all three collection processes. The results of the survey demonstrate that 0% of the respondents had the most confidence properly following the directions utilizing the original specimen cup with the standard MSCC instruction set, 13.3% had the most confidence in performing properly with the modified instruction set and the standard specimen cup, while 86.7% had the most confidence in the fact that they followed the posted directions using the modified specimen cup with the accompanying modified instructions and multiple sign locations.

Response 1 was, “Sample 1 (original cup, original instructions, common sign location).”

Response 2 was, “Sample 2 (original cup, modified instructions, multiple sign locations).”

Response 3 was, “Sample 3 (redesigned cup, modified instructions, multiple sign locations).”

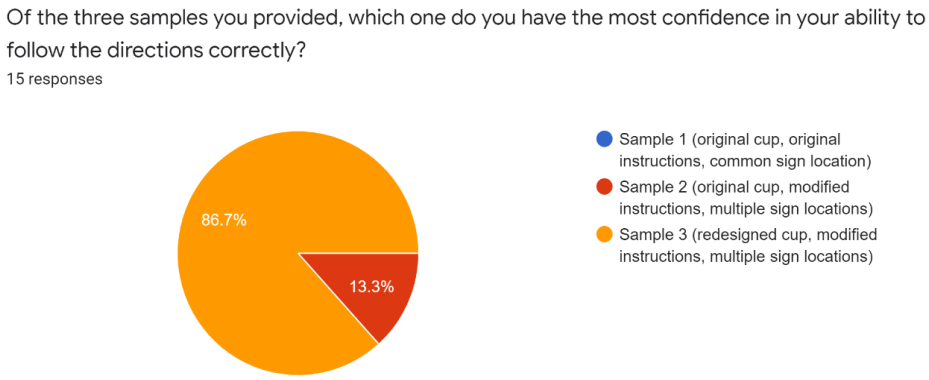


Figure 57. Self-reported confidence in the participant’s ability to follow the directions correctly. 0% or respondents chose the original cup, original instructions, and common sign location. 13.3% of respondents chose the original cup with the modified instructions and multiple sign locations. 86.7% of respondents chose the redesigned cup with its modified instruction set and multiple sign locations.

Participant Submitted Feedback

Survey number three provided for the inclusion of participant submitted free-form feedback. All feedback included below had been de-identified to protect the privacy of the participants.

> The ease of not having to void a bit of urine before using the specimen cup was convenient. When you have an infection it can be difficult to void first, the specimen cup would resolve the issue of having to void a bit first (Deidentified Study Participant A).

This comment specifically mentions the difficulty in executing a first void when having a UTI. This comment is further supported by information collected during the CI with SME 3 supporting intentional non-compliance with the first void process of the standard MSCC due to the pain associated with inflammation of the bladder known as cystitis. The redesigned urine specimen cup was specifically designed to address issues related to non-compliance with the initial void.

"I liked the designs and the easy grip of the newly designed specimen cup. It was easier to use and overall better experience" (Deidentified Study Participant B). This feedback is encouraging as the new grip and the instruction set for its use were identified as a potential issue due to its novelty.

"Very easy to use and did not have to worry about overfilling or a mess caused by removing the first 2 cups" (Deidentified Study Participant C). This comment helps confirm that the overflow tube was needed and worked as anticipated. Additionally, it

confirms that urine can splatter when attempting to move a standard urinalysis specimen cup out of the urine stream.

"The cup was easy to use and I liked not having to start and stop peeing. The top part kept urine off my hands" (Deidentified Study Participant D). This comment supports the sentiments expressed by Deidentified Study Participant C. Further, this comment indicates that the saddle attachment was successful in preventing this participant from urinating on their hand. The fact that this participant specifically mentions that the new device "kept urine off my hands" reinforces the need to address the fear of disgust associated with urinating on one's self.

"Although the 3rd cup was larger in size it was very easy to use and provide the sample. It was also great that the cup is designed to not overflow so when providing the sample I did not need to remove the cup" (Deidentified Participant E). The size of the redesigned specimen cup was cited as a potential area of concern, and it is reassuring to know that this participant specifically mentioned that it was not an issue for them. The comments by this participant about the cup's capability to not overflow further reinforce comments made by Deidentified Participants C and D.

"In the directions the image showed the small hole unplugged. When I removed the plug, as the image showed, urine was overflowing" (Deidentified Participant F). This is an interesting comment and will be addressed in future designs and prints of the image. Removing the plug is not part of the written instructions, and after reviewing the image, it is not clear how the user came to the decision to remove the plug. With that said, the goal is to make the design of the new specimen cup as error-proof as

possible. Potential changes will be examined and tested to help address the possibility of reoccurrence of this error in the future.

Future Direction

Significant amounts of time and financial resources have been invested in this quest to determine if the utilization of HSE concepts could improve the urine collection process. This study represents the proverbial line in the sand, demarcating the point at which the overall research question was put to the test. The test results clearly demonstrate the benefits of applying HSE concepts to this domain and will serve as a launchpad for future development, inquiry, testing, and refinement. The results and findings of this study will serve as a launchpad for future development and refinement of the HSE informed concepts, processes, and products presented here.

The article by Blake and Doherty (2006) that clearly identified a clinical use for the initial void expanded the focus of this present study beyond just the original goal of improving upon 1958's MSCC process into providing improvements across the entire urine specimen collection process. In a similar manner, further interaction with the patient who provided the initial inspiration for this overall endeavor, it was discovered that it is possible to pass a "radiation seed" through the urethra. Radiation seeds are implanted in a patient as the primary component of brachytherapy to treat prostate cancer. The seeds are supposed to be permanently implanted in the prostate; however, it is now known to the medical community (SME 3, personal communications, 2019) that over time, the prostate can shrink to the point that the radiation seeds become dislodged. Dislodged seeds can enter the bladder and block the upper urethral opening causing an inability to urinate due to a physical blockage while at other times, they do not cause a

blockage and can be passed during the normal process of urination. The fact that a radiation seed can be passed in the urine stream has inspired the future potential addition of a mesh screen to the automated specimen cup. The screen could be utilized to catch any foreign objects (such as kidney stones or radiation seeds) passed in the urine stream and allow for their collection and analysis.

HSE informed research and development will continue in this domain uncovering new challenges and rising to overcome them. The nature of continuous improvement is perpetual, and its fuel is scientific curiosity.

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APPENDIX A

ASU IRB APPROVAL LETTER

ASU IRB APPROVAL LETTER

APPROVAL: EXPEDITED REVIEW

Robert Gutzwiller
IAFSE-PS: Human Systems Engineering (HSE)

Robert.Gutzwiller@asu.edu

Dear Robert Gutzwiller:

On 6/25/2020 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Evaluation of Human Systems Engineering Approaches to Improving Urine Specimen Collection
Investigator:	Robert Gutzwiller
IRB ID:	STUDY00011985
Category of review:	Expedited Categories 3, and 7(a)(b)
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Consent Form v6 updated 24 June 2020.pdf, Category: Consent Form; • Example Quality Sample Report uploaded 02-06-2020.pdf, Category: Other; • Fluid Flow Storyboard updated 23-01-2020.pdf, Category: Technical materials/diagrams; • Instruction Sets for Participants in HSE Study for Urine Specimen Collection.pdf, Category: Recruitment Materials; • Post Survey #1 v2.1 Updated 18 June, 2020 - Google Forms.pdf, Category: Recruitment Materials; • Post Survey #2 v2.0 Updated 18 June, 2020 - Google Forms.pdf, Category: Recruitment Materials; • Post Survey #3 v2.0 Updated 18 June, 2020 - Google Forms.pdf, Category: Recruitment Materials; • Recruitment Script v4.0 Wallace Urine for Word of Mouth-Snowball and email electronic 18-06-2020.pdf, Category: Recruitment Materials; • v2.0 Fastest Labs Signed Letter - 19 June 2020.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc);

• v6 HSE study for Urine Specimen Collection Filled out IRB Form-Bioscience-Protocol_updated 04302020_final updated 24 June 2020.docx, Category: IRB Protocol;

The IRB approved the protocol from 6/25/2020 to 6/24/2022 inclusive. Three weeks before 6/24/2022 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 6/24/2022 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

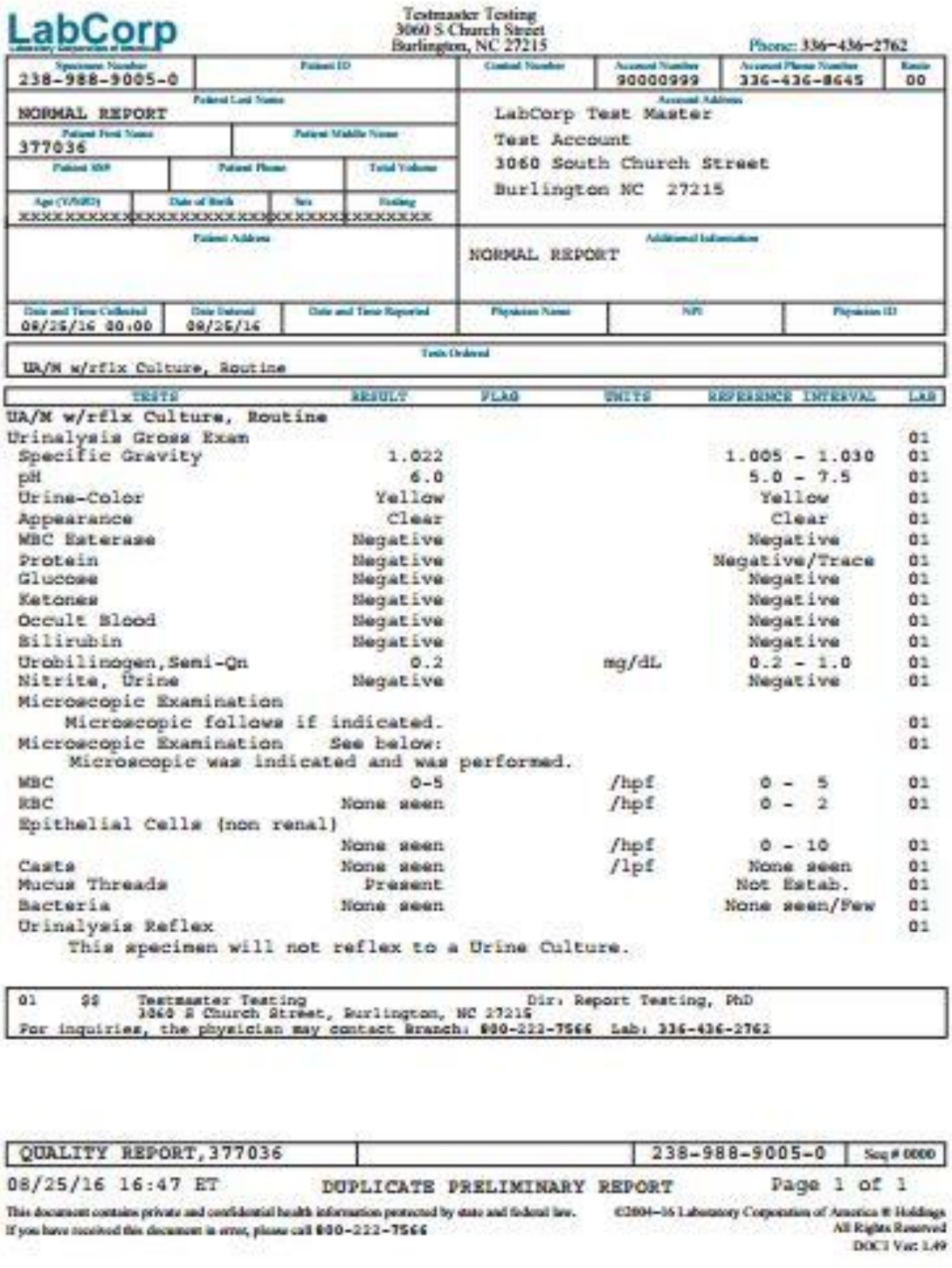
IRB Administrator

cc: David Wallace
Robert Gutzwiller
David Wallace

APPENDIX B

LABCORP TEST 003772 SAMPLE REPORT FOR NORMAL RESULT

LABCORP TEST 003772 SAMPLE REPORT FOR NORMAL RESULT



LabCorp

Testmaster Testing
3060 S Church Street
Burlington, NC 27215
Phone: 336-436-2762

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Route
238-988-9005-0			90000999	336-436-8645	00

Patient Last Name: NORMAL REPORT
Patient First Name: 377036
Patient Middle Name:
Patient SS#:
Patient Phone:
Total Volume:
Age (Y/M/D): XXXXXXXXXX
Date of Birth: XXXXXXXXXXXXXX
Sex: XXXXXX
Fasting: XXXXXXXX

Account Address:
LabCorp Test Master
Test Account
3060 South Church Street
Burlington NC 27215

Patient Address:

Additional Information:
NORMAL REPORT

Date and Time Collected	Date Entered	Date and Time Reported	Physician Name	NPI	Physician ID
08/25/16 00:00	08/25/16				

Tests Ordered:
UA/M w/rflx Culture, Routine

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
UA/M w/rflx Culture, Routine					
Urinalysis Gross Exam					01
Specific Gravity	1.022			1.005 - 1.030	01
pH	6.0			5.0 - 7.5	01
Urine-Color	Yellow			Yellow	01
Appearance	Clear			Clear	01
WBC Esterase	Negative			Negative	01
Protein	Negative			Negative/Trace	01
Glucose	Negative			Negative	01
Ketones	Negative			Negative	01
Occult Blood	Negative			Negative	01
Bilirubin	Negative			Negative	01
Urobilinogen,Semi-Qn	0.2		mg/dL	0.2 - 1.0	01
Nitrite, Urine	Negative			Negative	01
Microscopic Examination					
Microscopic follows if indicated.					01
Microscopic Examination See below:					01
Microscopic was indicated and was performed.					
WBC	0-5		/hpf	0 - 5	01
RBC	None seen		/hpf	0 - 2	01
Epithelial Cells (non renal)					
	None seen		/hpf	0 - 10	01
Casts	None seen		/lpf	None seen	01
Mucus Threads	Present			Not Estab.	01
Bacteria	None seen			None seen/Few	01
Urinalysis Reflex					01
This specimen will not reflex to a Urine Culture.					

01 99 Testmaster Testing Dir: Report Testing, PhD
3060 S Church Street, Burlington, NC 27215
For inquiries, the physician may contact Branch: 800-222-7566 Lab: 336-436-2762

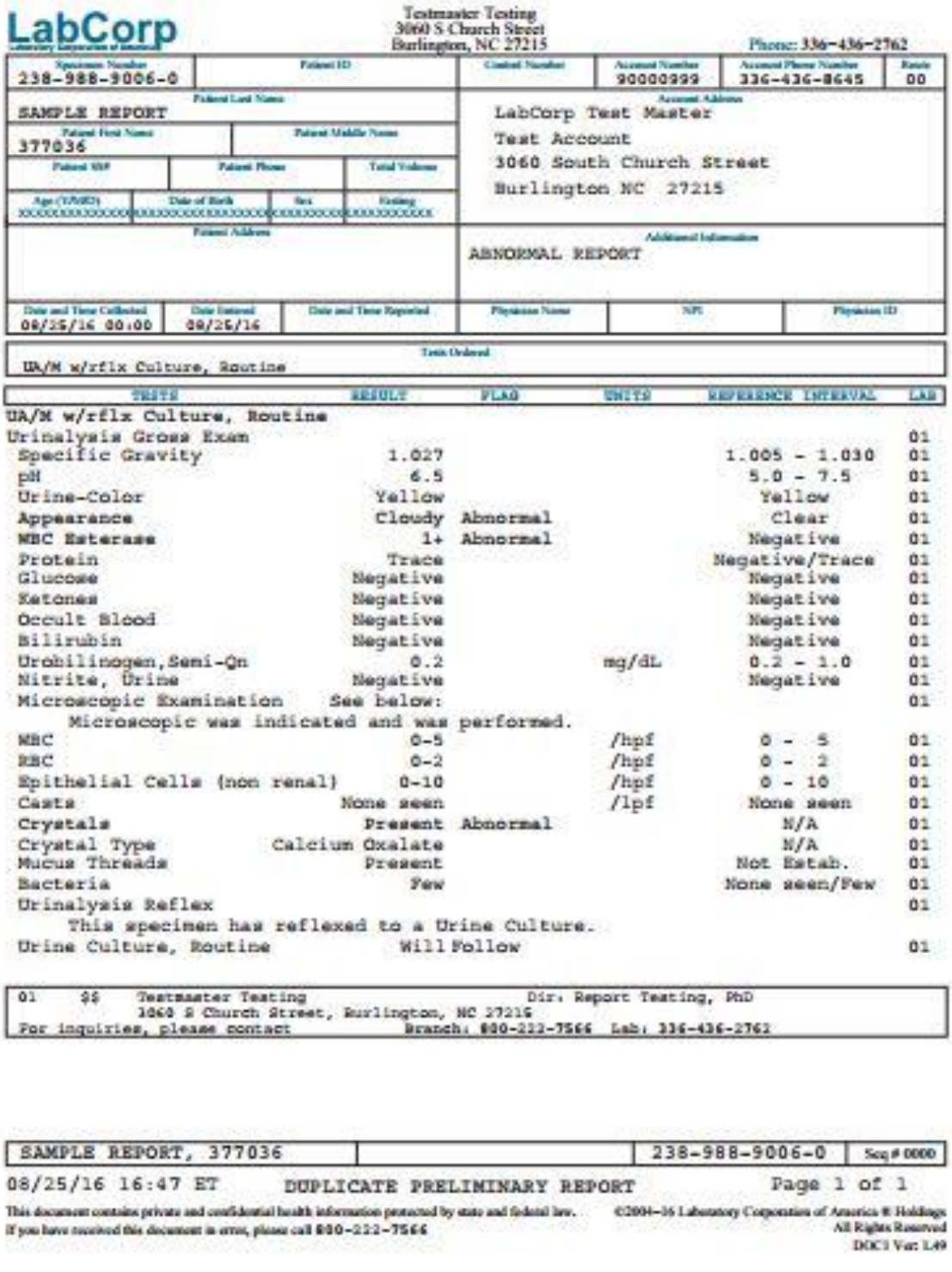
QUALITY REPORT,377036		238-988-9005-0	Seq # 0000

08/25/16 16:47 ET DUPLICATE PRELIMINARY REPORT Page 1 of 1

APPENDIX C

LABCORP TEST 003772 SAMPLE REPORT FOR ABNORMAL RESULT

LABCORP TEST 003772 SAMPLE REPORT FOR ABNORMAL RESULT



LabCorp

Testmaster Testing
3060 S Church Street
Burlington, NC 27215
Phone: 336-436-2762

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Route
238-988-9006-0			90000999	336-436-8645	00

Patient Last Name: SAMPLE REPORT
Patient First Name: 377036
Patient Middle Name:
Patient SS#:
Patient Phone:
Total Volume:
Age (YMD):
Date of Birth:
Sex:
Fasting:
Patient Address:

Account Address:
LabCorp Test Master
Test Account
3060 South Church Street
Burlington NC 27215

Additional Information: ABNORMAL REPORT

Date and Time Collected	Date Entered	Date and Time Reported	Physician Name	NPI	Physician ID
08/25/16 00:00	08/25/16				

Tests Ordered: UA/M w/rflx Culture, Routine

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
UA/M w/rflx Culture, Routine					
Urinalysis Gross Exam					01
Specific Gravity	1.027			1.005 - 1.030	01
pH	6.5			5.0 - 7.5	01
Urine-Color	Yellow			Yellow	01
Appearance	Cloudy	Abnormal		Clear	01
WBC Esterase	1+	Abnormal		Negative	01
Protein	Trace			Negative/Trace	01
Glucose	Negative			Negative	01
Ketones	Negative			Negative	01
Occult Blood	Negative			Negative	01
Bilirubin	Negative			Negative	01
Urobilinogen,Semi-Qn	0.2		mg/dL	0.2 - 1.0	01
Nitrite, Urine	Negative			Negative	01
Microscopic Examination	See below:				01
Microscopic was indicated and was performed.					
WBC	0-5		/hpf	0 - 5	01
RBC	0-2		/hpf	0 - 2	01
Epithelial Cells (non renal)	0-10		/hpf	0 - 10	01
Casts	None seen		/lpf	None seen	01
Crystals	Present	Abnormal		N/A	01
Crystal Type	Calcium Oxalate			N/A	01
Mucus Threads	Present			Not Estab.	01
Bacteria	Few			None seen/Few	01
Urinalysis Reflex					01
This specimen has reflexed to a Urine Culture.					
Urine Culture, Routine	Will Follow				01

01 $$ Testmaster Testing Dir. Report Testing, PhD
3060 S Church Street, Burlington, NC 27216
For inquiries, please contact Branch: 800-222-7566 Lab: 336-436-2762

SAMPLE REPORT, 377036		238-988-9006-0	Seq# 0000

08/25/16 16:47 ET DUPLICATE PRELIMINARY REPORT Page 1 of 1