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A novel collection cup for tuberculosis sputum in South Africa: engineering design and user testing considerations

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Abstract

Low-cost, targeted engineering interventions can revolutionise health care, particularly in low-income environments. We outline a process for user testing of novel sputum collection cup models for PCR-based based tuberculosis assays in Cape Town, South Africa. Providing a sputum sample is difficult for many patients, and the quality of the sample affects downstream test performance. Observational data was collected from six representative sites including outpatient clinics, hospitals, and processing laboratories, and interviews were performed with individuals involved with sputum collection (n=10), processing (n=10), and transportation (n=3). Participants compared "rocket" and "squeeze" prototypes to the current cup by answering standardised questions and ranking the usability and perceived safety of the models. Sputum collectors found the current model significantly easier to use (p-value: 0.0091) and safer (p-value: 0.0044) than the "squeeze" model. Sputum processors found the "squeeze" model more difficult to use than both the current jar (p-value: 0.0091) and the "rocket" model (p-value: 0.0012). They additionally perceived the "squeeze" model to be less safe than the "rocket" prototype (p-value: 0.0007). These results were incorporated into a remodelled sputum collection cup that contains a stable, upright base, maximum and minimum markers, and a tight seal to meet the needs of primary users.

Keywords: engineering, design, user testing, healthcare, tuberculosis

Introduction

Design can have dramatic effect on workflow, particularly when multiple parties interact with a single device. Those intimately involved in the research and development of a product are inherently flawed in their ability to determine whether it is usable to an average consumer (Barnum, 2010). Therefore, user testing is an essential element in every product development project. Barnum delineates user testing into formative and summative. Formative testing is iterative and is used to inform further development of a product, such as we do in this study. Summative testing, performed once a device is deemed ready for market, requires a larger sample size and more funding to gain feedback on the final product.

User testing is best done in the setting where the product will be used. Advantages include the ability to observe the local environment, the opportunity to learn about the surrounding culture, and the ease of scheduling interviews (Barnum, 2010; Dray and Siegel, 2004). Disadvantages include the cost and time of travel as well as the logistical difficulty of planning testing from a different location. Here we describe the use of formative testing as it is applied to a novel sputum collection cup for tuberculosis (TB) nucleic acid testing (NAT).

The global burden of TB is high, causing over 10.4 million infections and 1.4 million deaths in 2016. Ninety-five percent of these deaths were in low- and middle-income countries (World Health Organization, 2017). In South Africa, TB is the leading cause of death for those aged 15 to 64 (Statistics South Africa, 2014). Rapid and reliable diagnosis of TB is essential to reduce transmission, morbidity, and mortality. Culture is the gold standard for diagnosis, but it is lengthy (14-21 days) and requires extensive laboratory infrastructure (Pfyffer and Whittwer, 2012). NATs are considerably faster, producing results within a few hours. The CDC has recommended that NAT be performed on at least one sputum sample from patients on whom a diagnosis of TB is considered (CDC, 2009).

Inadequate sputum collection is a significant problem with current NAT models. The Cepheid Gene Xpert MTB/RIF NAT is the current market leader, responsible for over 16 million TB tests in 122 countries between 2011 and 2016 (Albert et al., 2016). According to Marokena et al. (2016), 8.27% of the 2.65 million sputum samples collected by the National Health Laboratory Services (NHLS) of South Africa for Xpert MTB/RIF analysis in 2015 were rejected. 74.5% of rejections were due to insufficient

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specimen volume, either as a result of initial suboptimal collection or leakage during transport and processing. Rejection of samples leads to missed opportunities for diagnosis and treatment.

Our lab in collaboration with Quidel Corporation is developing the XtracTB Screening assay with the goal of achieving a similar sensitivity as culture in less than one hour. The XtracTB Screening assay combines a streamlined detergent and proteolysis sputum thinning method with sequence specific capture to prepare specimens for qPCR without dilution (Reed, et al. 2016; Reed et al., 2017). For ease of use and to reduce cost, the assay was designed so that one tablet of solid reagent can process 1-5ml of sputum. At least 1ml is needed for the assay to reliably match the sensitivity of culture (10 CFU/ml of M. tuberculosis), and 5ml represents the upper volume that one tablet can reliably process (Fisher, 2017). In order to ensure that the proper volume of sputum is provided by the patient, a novel sputum collection cup was designed to: a) provide volume cues so that the patient can easily understand the amount of sputum to produce and b) make volume estimation easier by using a tapered cup design.

Two versions of the cup corresponding to different sputum processing methods and manufacturing approaches (blow vs. injection moulding) were developed and tested (Figure 1B and 1C) (Fisher, 2017). Previous research from this lab demonstrated that patients using the two sputum collection cup designs with volume markings provided very similar quantities of sputum, with only 2% of patients producing too much sputum (>5 mL) and 0% of patients producing too little (<1 mL). In cups without volume markings (Figure 1A), 19% produced too little and 12% produced too much (Fisher, 2017). These cups appear promising in solving the problem of acquiring the correct volume of sputum, but research is lacking into whether these cups are compatible with the clinical testing workflow.

South Africa has implemented the Xpert MTB/RIF test as the initial diagnostic assay for TB, replacing smear microscopy. In performing the Xpert test, a sputum specimen of at least 1 ml is diluted and homogenised by the provided sample reagent (SR) at a specific ratio of 2:1 to 3:1. Thus, the user must be able to accurately estimate the volume of sputum into which they are adding the buffer (Lawn & Nicol, 2011). From a biosafety standpoint, the volume in a container should be easily estimated and the buffer directly added to the sample. However, the current sputum collection cups have a wide base that makes for unreliable estimations of small volumes (Figure 1A). Our hypothesis was that a redesigned sputum cup that makes volume estimation easier could reduce the number of rejected specimens of the Xpert MTB/RIF assay.

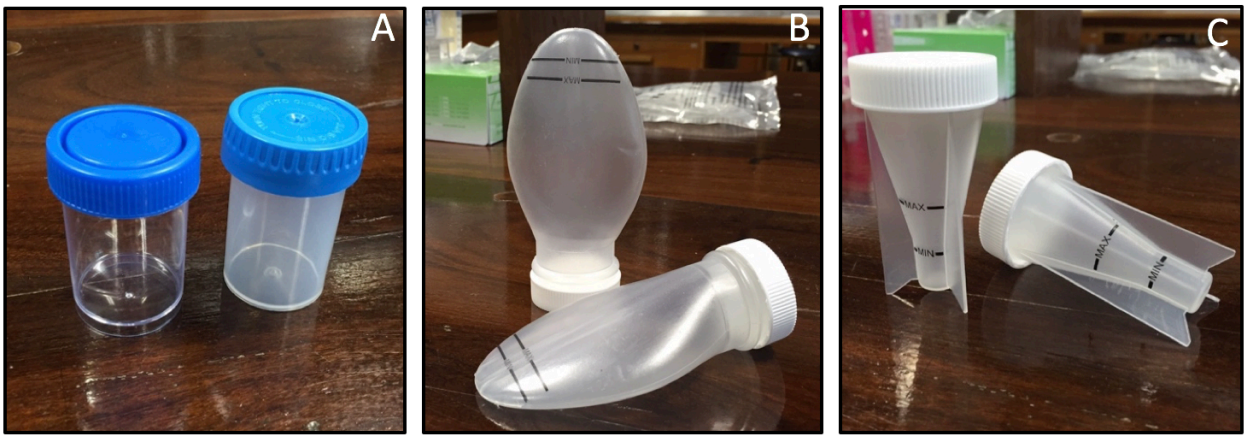

Figure 1. Sputum collection cup models. Current model (A), "squeeze" model (B), and "rocket" model (C).

Here we outline a prudent approach to user testing for engineering design in international healthcare settings focused on the testing of two novel sputum collection cup designs for use with Xpert MTB/RIF assays in Cape Town, South Africa. This strategy employs observational data collection and focus group interviews to better understand the perspectives, needs, and workflow of all users while minimizing designer biases (Krueger & Casey, 2002; Mack, et al., 2005).

Methods

Observational Data

Observational sites in Cape Town, South Africa were selected to represent a wide range of user interactions with the current sputum collection cup. These sites are listed below:

1. Scottsdene Clinic, a community clinic where sputum is collected and transported to a central laboratory for analysis.
2. Wallacedene Clinic, a community clinic where sputum is collected and transported to a central laboratory for analysis.
3. Brooklyn Chest Clinic, a residential treatment hospital for TB patients with drug-resistant disease or high risks of drug non-adherence or adverse events.
4. TASK Applied Science Clinic at Brooklyn Chest Clinic, a facility running clinical trials on drug-resistant TB.
5. Tygerberg Hospital, a major tertiary hospital providing care for many patients with TB.
6. Dr Grant Theron's laboratory at Stellenbosch University Medical School, a laboratory performing a range of biomedical TB research.
7. The National Health Laboratory Service (NHLS), Green Point, an Xpert MTB/RIF processing centre.

At each site, detailed notes were recorded throughout the day, including the time and date, site, and participants' roles. Information including the physical space, human traffic, and interpersonal dynamics were noted, with special attention paid to user workflow and interactions with the sputum cup. Maps were drawn when possible and pictures were taken when it was appropriate to do so. Within one week, this data was transcribed and organized digitally.

Interviews

Entry criteria for focused interviews included professionals in and around Cape Town, South Africa who expressed verbal, informed consent to participate, had obtained 18 years of age, and were: 1) health workers who assist in gathering sputum samples from patients into a collection cup, 2) drivers who transport patient sputum for a healthcare organization, or 3) laboratory users involved in the processing of patient sputum for the Xpert MTB/RIF assay (Table 1). In each case, participants were read a consent document, and their willingness to participate, job title, and current date were recorded.

Table 1: Interview participants

Sputum Collection	**Sputum Transportation**	**Sputum Processing**
Physiotherapist 1	Driver 1	Lab Manager
Physiotherapist 2	Driver 2	Masters Student 1
Physiotherapy Student	Driver 3	Masters Student 2
Research Nurse 1		Pathologist
Research Nurse 2		Post-Doctoral Research Fellow
Research Nurse 3		Research Assistant 1
Research Nurse 4		Research Assistant 2
Research Nurse 5		Research Assistant 3
Sister 1		Technical Officer
Sister 2		Technician

Sputum Collection Interviews

Two separate interview guides were created to tailor questions to specific roles. Those involved in sputum collection were first asked six questions covering their role, workflow, and opinions of the current sputum collection cup. They then rated the ease of the sputum collection process as well as the usability, comfort, and safety of the current cups on a scale of 1 to 10. They were asked for their ideal design of a sputum cup. Next, a prototype was introduced in random order, and participants were asked the following questions:

1. What is your general feedback on this cup?
2. What changes do you anticipate in your sputum collection process workflow due to the differing design of this cup?
3. What do you like about this cup?
4. What do you dislike about this cup, and what would you change?
5. More specifically, what do you think about the maximum and minimum markings?
6. What do you think about the general shape of the cup?

Anticipated usability, comfort, and safety were then rated on a scale of 1 to 10. This process was repeated for the second cup. Later, the user was asked to identify the preferred prototype and to compare it to the current cup. The sputum collection process and the usability, comfort, and safety of the current design were again assessed on a scale of 1 to 10. Finally, the participant was asked for their ideal design and any concluding remarks. The total interview time was less than 15 minutes.

Sputum Transportantion and Processing Interviews

Participants involved in sputum transportation and processing were first asked to describe every interaction they have with the current sputum collection cup. Four more questions were asked regarding what they liked, disliked, and wished to change about the design.

The first prototype was introduced in alternating order between interviews, and participants were asked the following questions:

1. How would this type of collection cup impact your workflow?
2. What would you like about using this type of collection cup?
3. What problems would arise from using this cup?
4. How could you make this device easier for you to use?
5. Do you have any other opinions about this prototype?

Participants were also asked to consider a potential rubber seal on the lid through which reagents could be added. These questions were repeated for the second prototype. Next, the participants compared the current cup to each of the prototypes. Finally, they ranked the cups on usability and safety on a scale of 1 to 10. The total interview time was less than 15 minutes.

Data Organisation

Interview notes were taken by hand directly on interview guides. Later, they were expanded into full sentences and transcribed into a digital word processor. Qualitative answers were separated into three digital documents for sputum collection, transportation, and processing roles. Each response was placed directly under the respective question and was identified by the participant's job title and number (see table 1). This system allowed for organised comparison of qualitative data.

Data Analysis

Quantitative data was compiled and analysed in Microsoft Excel. Paired, two-tailed t-tests were performed to assess for significance with an alpha value of 0.05. Box-and-whisker plots were created via the Excel "Box and Whisker Plot Template" from Vertex42 and were verified manually.

Results

Sputum Collection

Ten healthcare workers involved in the sputum collection process participated in interviews (see Table 1), henceforth referred to as "collectors", and four collection sites were observed. In all cases, the patients were handed the sputum cup and asked to collect their sputum in a designated area. At Brooklyn Chest Clinic, this was an enclosed room with an opening through which to pass the cup. At Scottsdene Clinic, this was a three-walled structure attached to the main building. Six collectors instructed the patients to rinse their mouths before the collection, and four collectors advised breathing exercises or treatments to loosen sputum. All ten participants instructed the patient to close the sputum cups before providing them to clinic staff. Labels were added to the cups. In one case, the collector attached labels before the collection step to minimize sputum interaction.

Sputum collectors had difficulty identifying what they liked about the current design; a general theme is that the cups "do what they need to" and nurses "accept it as it is." Five healthcare workers expressed concern over exposure, with one commenting that some jars leak and another stating the cups can be messy when returned. Three participants thought the lid was difficult to attach, particularly for patients, and two wished for a sliding or snapping cap. One participant requested a design that fit better around the mouth.

All ten participants approved of the minimum and maximum markings on the "squeeze" model. Five stated it was more comfortable to hold, while four stated is would be more difficult to handle, especially for patients with disabilities. Five participants were concerned that the model cannot stand upright, and four thought the material was too fragile. Two participants imagined the groove inside the opening would prohibit pouring out sputum, two felt the design was too wide for proper pouring, and one worried that the pliable plastic material would prevent sputum from sliding out properly.

Eight of the ten participants felt their collection procedure would be the same or better with the "rocket" model. Five felt the lid screwed on better than the current cups, and five thought the material was more durable. Four workers were concerned about the prototypes' stability. Two disliked the cloudiness of the material because they must describe the sputum's colour. One noted that there was nowhere to affix a label.

Between the two prototypes, eight of ten collectors would prefer to use the "rocket" model, one preferred the "squeeze" model, and one was indecisive. Given all the options, seven of ten prefer the current cups, and three prefer the "rocket" model.

All ten sputum collectors ranked the ease of use of the current jar, the "squeeze" prototype, and the "rocket" prototype on a scale of 1 to 10, with 1 being most difficult to use and 10 being easiest (see Figure 2). The current model was thought to be easier to use than the "squeeze" model (p-value: 0.0091). There was no difference in perceived ease of use between the "rocket" model and the current design (p-value: 0.24) or between the "rocket" model and the "squeeze" model (p-value: 0.26). Participants also ranked how comfortable the design was to hold, with 1 being most uncomfortable and 10 being most comfortable. There was no difference in comfort between the "rocket" model and the current jar (p-value: 0.33), the "squeeze" model and the current jar (p-value: 0.63), or the "rocket" and "squeeze" designs (p-value: 0.34).

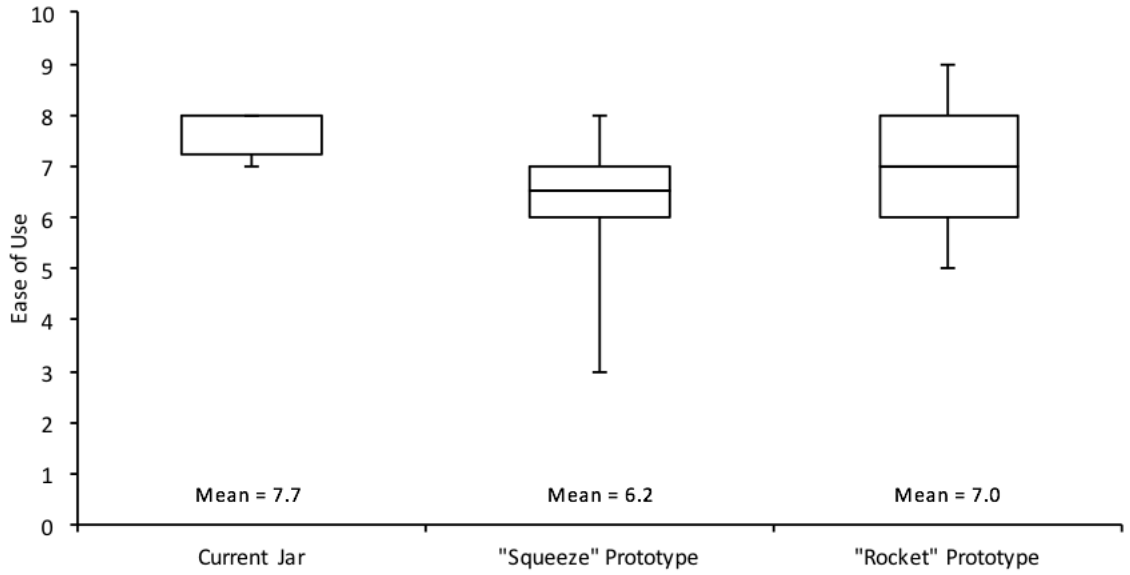

Figure 2. Box and whisker plot of perceived ease of use vs. collection cup model as ranked by collection staff, with 10 being easiest.

The ten sputum collectors also ranked the perceived safety of the three jars on a scale of 1 to 10, with 1 being least safe and 10 being safest (see Figure 3). Users felt significantly safer with the current jar than with the "squeeze" model (p-value: 0.0044). There was no significant difference found between the current jar and the "rocket" model (p-value: 0.074) or between the "rocket" and the "squeeze" designs (p-value: 0.40).

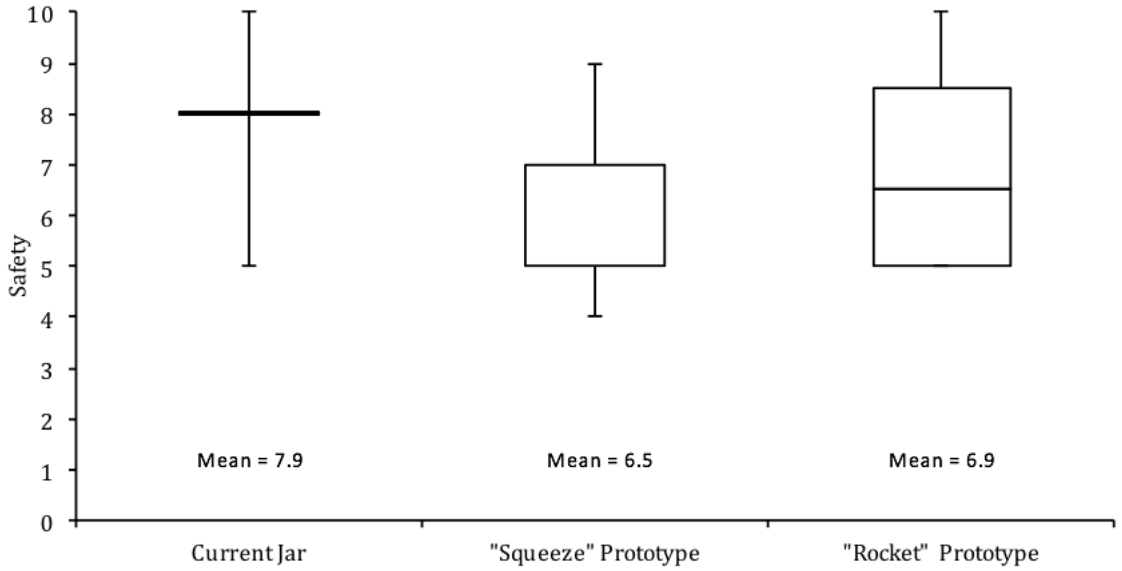

Figure 3. Box and whisker plot of perceived safety vs. collection cup model as ranked by collection staff, with 10 being safest.

Transportation Staff

Interviews were obtained from three professional drivers with experience transporting sputum samples (see Table 1). In each case, sputum was received from nurses in small, closed plastic bags. The lids of the cups were screwed down and further sealed with Parafilm (Bemis NA) to prevent leaking. Driver 3 turned the cup upside down in the bag to ensure the seal was intact; if it was not, he returned it to the nurses. One participant placed the bags in a biohazard container with a screw-top lid, and the others stored the samples in a Styrofoam container. These containers were placed in the back of a transportation van. Driver 1 placed the containers in a crate and carried the whole crate to laboratories if there are more than 3 or 4 containers. Driver 2 used a box for the same purpose. Driver 2 and Driver 3 worked with non-disposable gloves.

To Driver 1, the current design is simple and straightforward. Driver 2 felt that the jars are unsafe, because the material is too opaque to properly visualize the sputum. He also worried about exposure when the jars leak into the bag. Driver 1 and Driver 2 wished for a more secure lid.

Drivers were largely neutral on the "squeeze" model. According to Driver 2, there is enough room in the containers for a bigger model. Driver 3 worried about the size and extra weight, because he sometimes puts ice in the containers. Driver 1 and Driver 2

were very concerned about the cups cracking at the seams, noting that the design would undergo stress in transport.

Driver 1 liked the small size of the "rocket" model and said it had a "striking" design. Driver 2 recommended a holder to make it easier to grip, but stated this would not affect transport. Driver 3 worried that kids would play with the "rocket" model when it is sent home. He was also concerned that the sharp fins would puncture skin and lead to infection.

Overall, Driver 1 and Driver 2 would prefer to use the "rocket" prototype. Driver 3 preferred the current design, then the "rocket" model, and then the "squeeze" model.

All drivers ranked the difficulty of use of the current jar, the "squeeze" model, and the "rocket" model on a scale of 1 to 10, with 1 being easiest to use and 10 being most difficult (see Table 2). There was no significant difference in perceived difficulty of use between the current jar and the "squeeze" model, between the current jar and the "rocket" model, or between the "squeeze" and the "rocket" models. Drivers also ranked the perceived safety of the current jar, the "squeeze" model, and the "rocket" model on a scale of 1 to 10, with 1 being least safe and 10 being safest. There was no significant difference in perceived safety between the current jar and the "squeeze" model, between the current jar and the "rocket" model, or between the "squeeze" and the "rocket" models.

Table 2: Data from transportation staff (n=3)

Difficulty of Use	**Average**	**Safety**	**Average**
Current jar	4.00	Current jar	7.00
"Squeeze" model	4.67	"Squeeze" model	6.00
"Rocket" model	3.33	"Rocket" model	4.67
Comparisons (difficulty of use)	**p-value**	**Comparisons (safety)**	**p-value**
Current jar vs. "squeeze" model	0.81	Current jar vs. "squeeze" model	0.58
Current jarl vs. "rocket" model	0.80	Current jar vs. "rocket" model	0.57
"Squeeze" model vs. "rocket" model	0.27	"Squeeze" model vs. "rocket" model	0.58

Sputum Processing

Interviews were performed with 10 laboratory users of the current sputum collection jars (see Table 1), and six processing sites were observed. Each user received the sputum in small, sealable plastic bags from transportation staff. The jars were typically sealed with Parafilm, though Masters Student 2 noted this is only the case when there is a copious amount of sample. Processing occurred in laboratory hoods, either on site (at TASK and Scottsdene clinics) or at a remote laboratory such as Tygerberg Hospital. At NHLS Green Point, the samples were placed into 6x5 metal holders for batch mixing, followed by a GeneXpert Infinity machine for batch processing (see Figure 4).

Figure 4. NHLS Green Point batch processing. Mixer (left) and GeneXpert Infinity machine (right).

When asked what they liked about the current design, half the participants praised the dimensions of the jars, with three appreciating the small size and one complimenting the wide opening. Both staff at NHLS Green Point liked that the jars were designed to fit into their mixers. When asked what problems exist with the current design, seven were concerned with leaking. Another potential problem is working with the cups in the BSL3 lab; there, the user typically wore double gloves and often opened jars with one hand, requiring a cup that is small enough to handle and lid that is easy to manipulate. Additionally, both the Technical Officer and the Technician were worried about cracking if the cup falls. Suggestions for improvement included a tighter seal (seven), a lid without a screw mechanism (two), pre-placed fluid inside the jar to make extraction easier (three), and markings for volume (one).

Nine out of ten participants felt that the "squeeze" model would negatively impact their workflow. Both NHLS staff were concerned with the jar fitting into their mixing trays. Nine participants were concerned that the cup could not stand independently. Research Assistant 2, for example, lined up the label on the cup with the paper report in the hood, which would not be possible if the cup could not stand. Research Assistant 3 often lined up 10 at time in the hood, and was concerned about space if the jars were on their side. Three participants were concerned that cracks would develop at the edges. Research Assistant 2 was worried that the protruding lip would catch sputum as she attempted to pour. Laboratory users frequently estimate volume in these containers, and for this reason, three stated that lines for every ml would be desirable. The Technical Officer noted this would be particularly important for the squeeze model, as the non-uniform width makes volume estimation challenging. Four participants stated that the minimum and maximum lines were an improvement over the current models.

Six out of ten laboratory users stated that the "rocket" model would have a positive effect on their workflow. Seven praised the minimum/maximum lines, and five mentioned that the rubber seal safety mechanism on the lid would be beneficial. Participants liked the smaller size (four), the ease of pouring (one), and the smooth lid mechanism (three). Both staff at NHLS Green Point stated it would have a negative impact on workflow, as it does not fit in their mixing trays and there is no flat surface for labels. Five participants stated it was less stable than the current jar. The Postdoctoral Research Fellow was particularly worried about stability in the metal hood. One suggestion was to include the "rocket" design inside the current jar (two). Five participants suggested adding more granulated volume markings.

Three users compared the "rocket" cup and "squeeze" cup to the current jars; all three ranked the "rocket" first, followed by the current cup, and then the "squeeze" model. Seven users directly compared prototypes, with all preferring the "rocket" model over the "squeeze" model.

All ten laboratory users ranked the difficulty of use of the current jar, the "squeeze" prototype, and the "rocket" prototype on a scale of 1 to 10, with 1 being easiest to use and 10 being most difficult (see Figure 5). The current jar was significantly easier to use than the "squeeze" model (p-value: 0.0091), while no significant difference existed between the current jar and the "rocket" model (p-value: 0.43). The "squeeze" model was also regarded as significantly more difficult to use than the "rocket" model (p-value: 0.0012).

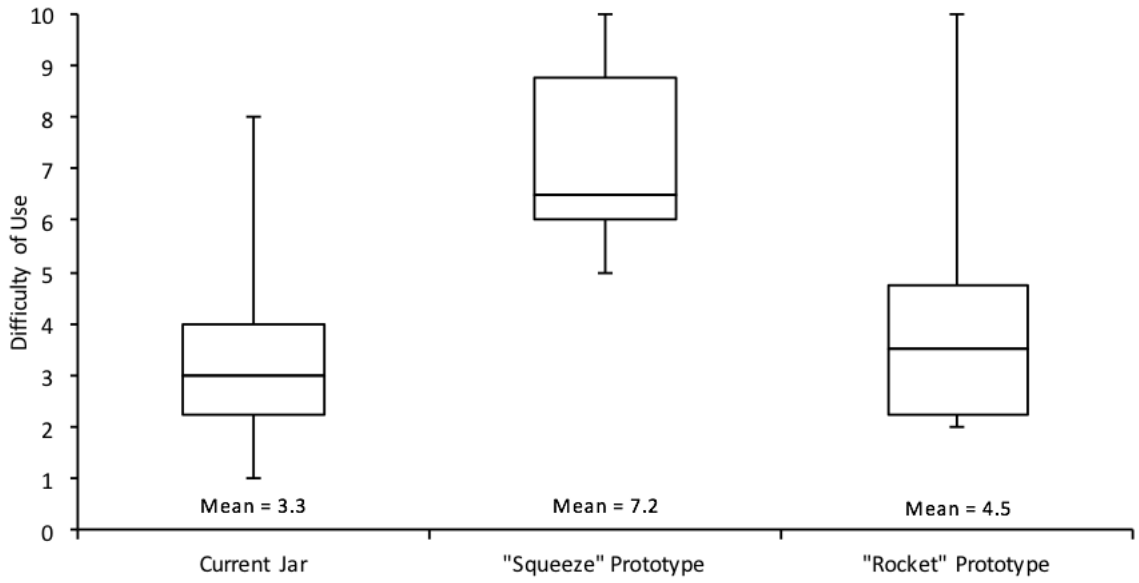

Figure 5. Box and whisker plot of perceived difficulty of use vs. collection cup model as ranked by laboratory users, with 10 being most difficult.

Laboratory users also ranked perceived safety of the current sputum collection jar, the "squeeze" model, and the "rocket" model, with 1 being least safe and 10 being safest (see Figure 6). There was no significant difference in perceived safety between the current jar and the "rocket" prototype (p-value: 0.21) or between the current jar and the "squeeze" prototype (p-value: 0.20). However, the "squeeze" model was viewed as significantly less safe than the "rocket" prototype (p-value: 0.0007).

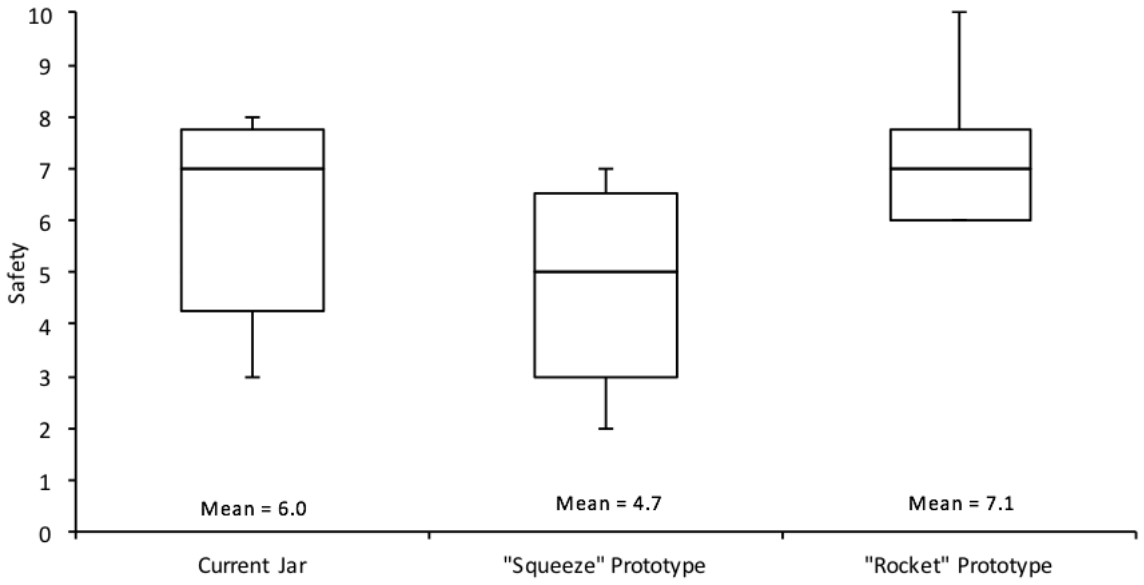

Figure 6. Box and whisker plot of perceived safety of use vs. collection cup model as ranked by laboratory users, with 10 being safest.

Laboratory users also ranked perceived safety of the current sputum collection jar, the "squeeze" model, and the "rocket" model, with 1 being least safe and 10 being safest (see Figure 6). There was no significant difference in perceived safety between the current jar and the "rocket" prototype (p-value: 0.21) or between the current jar and the "squeeze" prototype (p-value: 0.20). However, the "squeeze" model was viewed as significantly less safe than the "rocket" prototype (p-value: 0.0007).

Discussion

Engineering design requires conscientious and targeted user testing in order to produce a product that meets the needs of the consumer. This is particularly important in unfamiliar healthcare settings, where many users may interact with the same design in unanticipated ways. This paper presents a systematic approach to user testing that relies upon observation and targeted interviews to redesign a sputum collection cup for tuberculosis samples. With the current cup design, it is difficult for patients and providers to estimate the minimum volume necessary for Xpert MTB/RIF. When volume is easily estimated, patients are more likely to provide an adequate sample and buffer can be directly added into a sample, decreasing safety concerns (Fisher, 2017).

Despite the fact that the collection cup design affects their work, the nurses and sisters who instruct patients on how to collect sputum each day noted that they had never considered changing the cup's features. However, when provided the two cup prototypes, the majority of participants liked the minimum and maximum volume markings. The sputum collectors thought it would assist the patients in producing the correct amount of sputum, and the sputum processors felt it would better assist them in adding reagents in the correct ratio and suggested volume lines for every ml.

The lid mechanism of the "rocket" model was also well-received, with most participants who commented on it finding it more secure than that of the current model. This is an important feature, as the majority of those interviewed across all sputum roles mentioned the lid as a design flaw of the cup currently in use. The sputum processors praised the tapering shape of the "rocket" model, as it would make it easier to pipette, pour, and measure small volumes of sputum. The greatest strengths of the current cups are their ease of use and the participant's familiarity with the design.

A cup's stability was a concern for the sputum collectors and processors. Many were worried that the "rocket" model would tip or slide in hoods given its three points of ground contact. Most noted that the "squeeze" model cannot stand independently. Users thought they would place the cup on its lid, which may predispose it to leak. Additionally, participants were concerned that the "squeeze" model could crack at its seams. The screw top of this model has a slight lip that many felt could make pouring more difficult. Some participants felt the "rocket" model was uncomfortable to hold due to its fins. Finally, sputum collectors and processors noted there was no place to affix a label on the "rocket" model.

Many concerns expressed by the users were unanticipated by the designers, underscoring the value of asking open-ended questions to people in a wide variety of roles. For example, it was not foreseen that manufacturing the cup from an opaque material would impact the workflow of research nurses, who must record the colour of collected sputum. Additionally, the amount of equipment built for processing the existing cup design was underestimated. At NHLS Green Point, large mixing trays were designed to fit the current sputum cups and would not necessarily fit new cup models. Redesigning equipment is an expensive and inconvenient process; therefore, this barrier must be addressed in future designs.

The results of this study led to a redesigned sputum collection cup incorporating the best qualities of the existing model and the "rocket" prototype (Figure 7). The new design maintains the funnel shape of the "rocket" prototype, which allows for easier aspiration of contents and improved volume determination based on height. Markers for maximum volume, minimum volume, and patient information are included on the outer surface as these were almost universally preferred by those interviewed. The circular

base provides improved stability over the "rocket" model, and the absence of fins makes it more comfortable to hold. It also incorporates the same screw-top mechanism that was praised in interviews. Finally, the widened base better integrates with existing processing equipment, such as the mixing trays at NHLS Green Point.

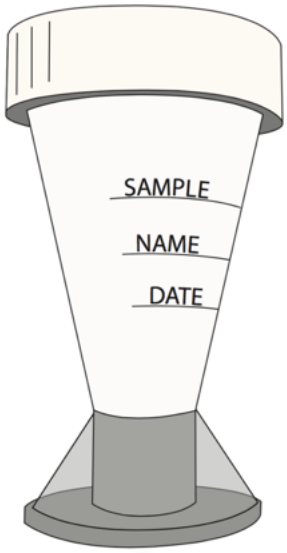

Figure 7. Initial mockup of redesigned sputum collection cup

A limitation of this study was that we did not solicit comments about the sputum cup from patients. The scope of this study was restricted to determining the impact of the sputum cup design on healthcare professionals and the sample transport system. In Fisher's study (Fisher, 2017), it was demonstrated that the same volume of sputum was collected in both cup designs, but data about the user experience was not collected. When the newly redesigned collection cup (Figure 7) is tested for performance, the inclusion of an assessment of patient experience will improve the design and overall success of the product.

Conclusion

This study demonstrates that small changes in sputum cup design potentially have broad and unintended consequences for sputum processing workflow. The user testing strategy outlined here relies on observation and focused user interviews to elucidate needs and obstacles that may otherwise be hidden. Through this approach, designers can create a user-friendly product, even in unfamiliar environments.

Future studies should continue to gain user feedback on the sputum collection cup prototypes. Analysis should also be done after the implementation of any new device to seek further areas for improvement. Understanding the impact of new devices on those using them will continue to provide benefit to patients.

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Ethics Approval

Ethics approval was granted by Northwestern University Institutional Review Board Office, reference number STU00202885, and by Stellenbosch University Health Ethics Committee 1, reference number N14/10/136.

References

Albert, H., Nathavitharana, R.R., Isaacs, C., Pai, M., Denkinger, C., Boehme, C.C. 2016. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better? *European Respiratory Journal,* 48, p 516-425. DOI: 10.1183/13993003.00543-2016

Barnum, C.M. 2010. Usability Testing Essentials: ready, set... test!. 1st ed. Burlington, MA: Morgan Kaufmann Publishers, pp.9-23, 319-354.

Centers for Disease Control and Prevention (CDC). 2009. Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis. *MMWR: Morbidity and Mortality Weekly Report,*58(1), p.7.

Fisher, M., Dolby, T., Surtie, S., Omar, G., Hapeela, N., Basu, D., DeWalt, A., Kelso, D., Nicol, M. and McFall, S. 2017. Improved method for collection of sputum for tuberculosis testing to ensure adequate sample volumes for molecular diagnostic testing. *Journal of Microbiological Methods,* 135, pp.35-40. DOI: 10.1016/j.mimet.2017.01.011

Krueger, R. 2002. Designing and Conducting Focus Group Interviews. St. Paul: University of Minnesota.

Lawn, S.D. and Nicol, M.P. 2011. Xpert® MTB/RIF assay: development, evaluation and implementation of a new rapid molecular diagnostic for tuberculosis and rifampicin resistance. *Future Microbiology,* 6(9), 1067–1082. DOI: http://doi.org/10.2217/fmb.11.84

Mack, N., Woodsong, C., MacQueen, K., Guest, G. and Namey, E. 2005. *Qualitative Research Methods.* 1st ed. Research Triangle Park, N.C.: Family Health International.

Marokane P., Ndlovu S., Mahlatsi O., Ntsimane S., Silva P., and Berrie L. 2016. *Analysis of Xpert MTB/RIF rejection rates using laboratory data 2011-2015, South Africa.* African Society for Laboratory Medicine Conference; Cape Town, South Africa.

Pfyffer, G.E. and Wittwer, F. 2012. Incubation time of mycobacterial cultures: how long is long enough to issue a final negative report to the clinician? *Journal of Clinical Microbiology,* 50(12), pp.4188-4189. DOI: 10.1128/JCM.02283-12

Reed, J.L., Basu, D., Butzler, M.A. and McFall, S.M. 2017. XtracTB Assay, a Mycobacterium tuberculosis molecular screening test with sensitivity approaching culture. *Scientific Reports,* 7(1), p.3653. DOI: 10.1038/s41598-017-03930-3

Reed, J.L., Walker, Z.J., Basu, D., Allen, V., Nicol, M.P., Kelso, D.M., McFall, S.M. 2016. Highly sensitive sequence specific qPCR detection of Mycobacterium tuberculosis complex in respiratory specimens. *Tuberculosis* 101. P 114-124. DOI: 10.1016/j.tube.2016.09.002

Statistics South Africa. 2014. *Mortality and causes of death in South Africa, 2011: Findings from death notification.* Available: http://beta2.statssa.gov.za/publications/P03093/P030932011.pdf

Steingart, K.R., Sohn, H., Schiller, I., Kloda, L.A., Boehme, C.C., Pai, M. and Dendukuri, N. 2013. Xpert® MTB/RIF assay for pulmonary tuberculosis and rifampicin resistance in adults. *Cochrane Database Syst Rev,* 1(1). DOI: 10.1002/14651858.CD009593.pub3.

WHO. 2017. *Global tuberculosis report.* Available: http://www.who.int/tb/publications/global_report/en/.