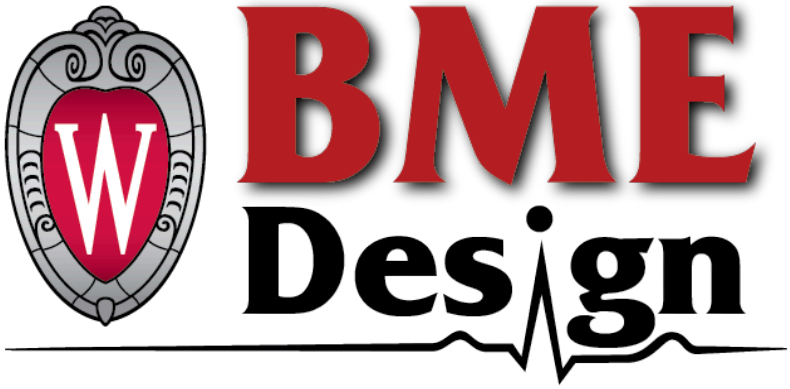

Vaginal Self-Swab Device to Minimize Contact Contamination

Preliminary Report

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Abstract

Sexually transmitted infections (STIs) are under-tested in many sexually active people. As a result, common infections such as chlamydia and gonorrhea are highly prevalent, with four million cases of chlamydia occuring in 2018 [1]. In order to encourage routine, universal testing of STIs, the screening process must be less intimidating and more attainable. The primary way to accomplish this is through self-swab testing, which allows women to complete an intravaginal swab in the privacy of a clinic room, rather than experience the discomfort of being vaginally swabbed by a physician [2]. However, self-swab testing introduces the potential for contamination of the environment the test is administered in. Self-swab tests involve a swab that must be inserted into the body, then removed and transported to an external vial of transport media. In this process, contamination can occur via the swab coming in contact with surfaces or the media vial spilling [2]. The goal of this project is to create a device that limits the potential contamination of the testing environment and of the swab. The team has developed a novel self-swab STI testing device that allows women the privacy of swabbing themselves while reducing contamination of the testing environment. However, the current design has issues with media leaking from the device after use, as well as with the aesthetics of the design. The team is tasked with modifying the original design to address the issues currently being faced while still seeking to limit contamination of the device and testing environment as well as account for patient comfort.

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Introduction

Chlamydia is the most frequently diagnosed bacterial sexually transmitted infection in the United States, affecting an estimated 1 in 20 young women from ages 14-24, with 43% of those women accounting for undiagnosed cases [1]. Many cases go undiagnosed due to the commonly asymptomatic nature of the infection; between 50-70% of people diagnosed with chlamydia presented asymptomatically [1]. Sexually active women are recommended to be tested annually for chlamydia, but barriers to testing such as lack of transportation, concerns about confidentiality, cost, and violation of privacy limit the frequency of routine testing [2][3]. Although these barriers decrease the likelihood of testing, one way that has been found to increase the likelihood of testing is a self-swab method. In fact, in recent studies, it was found that 84% of women prefer the self-swab method to traditional gynecological procedures, and 94% would be more willing to routinely test for STIs if self-swabbing was available [1]. Self-swabbing allows patients to play a more autonomous role in their health and helps them to feel more comfortable with a somewhat invasive process. However, one limitation of patient-collected STI samples is the potential for contamination of the testing environment and the swab itself during the collection process. The collection process involves the patient inserting a swab into the vaginal canal, which gives plenty of opportunity for potentially infected vaginal fluid to transfer from the patient's hand to other surfaces of the examination room while transferring the swab from vagina to the media container. Furthermore, contamination of the swab, which could happen if the swab simply touches the patient's leg or a table, could lead to false-positives, as other patients' samples may have contaminated the environment previously[4]; if false-positives are not caught, patients may be treated for STIs that they do not have.

Manufacturers of STI self-swabbing kits exist both in the United States and internationally, but all commonly used methods involve at least a 2-component system. The kit used in the UW-Health System clinics is the Aptima Combo 2 Assay by Hologic®, which employs the use of a proprietary Dacron swab for sample collection, and a small media-filled tube for sample preservation [5]. Competing design Mía by XytoTest® utilizes the same design and sample collection method [6]. During the transfer of the sample to the media tube, there is a high probability of contact contamination as the patient must first collect their sample, then hold the swab as they attempt to transfer it into the transport media. The swab could fall out of their hands, the media container could spill, or the patient could transfer vaginal fluid onto nearby surfaces as they undergo the process of handling both the sample and media at the same time, causing contact contamination. Therefore, the aim is to create a one-component device that limits contact of the patient's hands with their vaginal fluid as much as possible.

Background

Chlamydia results from infection with the *Chlamydia trachomatis* (CT) bacterium – a species of the *chlamydophila* genus [1] [7]. This bacteria is an anaerobic, gram-negative, obligate intracellular parasite that only naturally manifests in humans [8]. CT bacteria can be subclassified into 18 serologically variant strains (serovars), with serovars D-K leading to genital or neonatal infections [7]. The CT bacteria can spread during vaginal, anal, or oral sex with an infected person, and can be transferred to a newborn baby from an infected mother during childbirth [1]. CT bacteria have a unique infectious life cycle with an elementary body (EB) that is metabolically inactive and a reticulate body (RB) that is metabolically active [7]. When first coming into contact with CT bacteria, host cells take up the EB form which then differentiates into RB [7]. RB can then replicate to form additional EB and further spread the infection [7]. Chlamydia is typically asymptomatic, with only 30% of women developing symptoms [1]. Some of these symptoms include endocervical bleeding or discharge, urethritis (frequent urination), and pelvic inflammatory disease (abdominal or pelvic pain) [1]. In women, the CT bacteria initially infects the cervix but may spread to the urethra or upper reproductive tract [1]. If the bacteria spreads to the uterus and fallopian tubes, pelvic inflammatory disease can develop (PID) [1]. PID can lead to additional health complications such as chronic pelvic pain, tubal factor infertility, ectopic pregnancy, and Fitz-Hugh-Curtis Syndrome [1].

When testing for the CT bacteria using a swabbing technique, it is important that a non-toxic material is used. Any toxic materials can lead to bacteria death when using cell culture techniques or interference with non-culture methods like Nucleic Acid Amplification Tests (NAATs) [9]. As a result, any materials that have not been provided by a manufacturer should be tested for toxicity in cell culture and interference with non-culture testing methods [9]. The swab shaft can be made of plastic or wire, and the tip should be made of dacron or rayon as they are absorptive materials that will not inhibit the bacteria isolation during laboratory testing [10] [11]. All swab samples should be stored in a chlamydia transport media that do not contain antibiotics [10]. Samples that are inoculated within 24 hours of collection should be stored at 4℃ while samples that are to be inoculated more than 24 hours after collection should be stored at -70℃ [10]. A material that can withstand this wide range of temperatures must be used to store the sample and the media.

The client, Dr. Jean Riquelme, is a family medicine specialist based in Madison with over 31 years of experience. Dr. Riquelme graduated from the Medical College of Wisconsin in 1993 and completed her residency in family medicine at Aurora Healthcare (Milwaukee). Dr. Riquelme has requested a vaginal self-swab device that limits contact contamination of the testing room for use in Chlamydia screening. Given that the device is to be used as a self-swab, it must be user friendly and should ultimately promote universal testing. The device must allow for both swabbing and storage in a media in order to mitigate the contamination of the testing room [2]. This will be accomplished by employing a design that has a contained deployment, retraction, and sealing mechanism. The swab that is within the device must be deployed at least 5 cm into the vaginal canal to allow for adequate collection of CT bacteria [12]. All components of

the device must be biocompatible as they will enter the vaginal canal and potentially come into contact with CT bacteria [9]. For a more detailed description of the design specifications, see Appendix A.

Preliminary Designs

Design 1: Modified Plunger

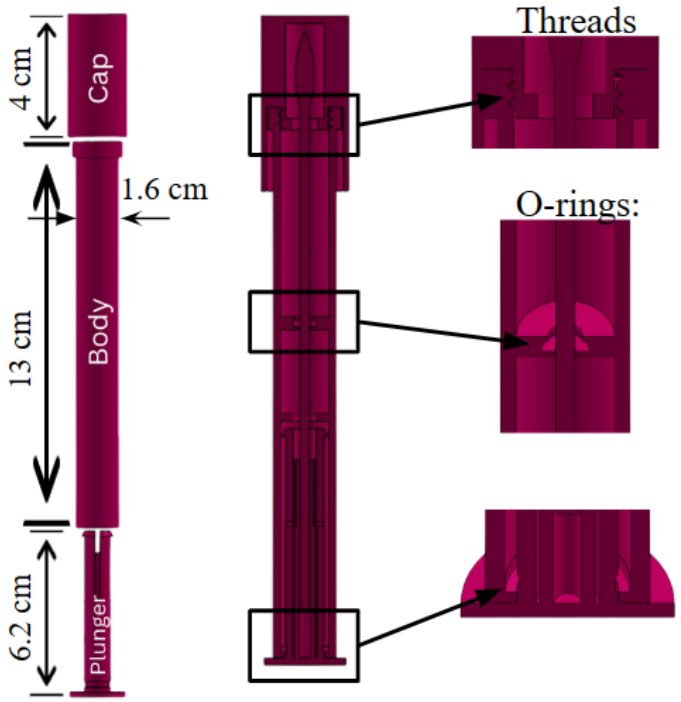

Fig. 1: Modified plunger design with the cap, body, and plunger shown. A section view of the entire design with the threadings for the cap attachment on the interior of the body and two o-ring insertion sites indicated.

The first design idea, as seen in Figure 1, is a modification of the prototype completed last semester. This design idea was chosen to be modified due to its similarity to a tampon, a device that approximately 50% of menstruating women regularly use [13]. This modified plunger design consists of three components - a plunger, body, and cap (Fig. 1). The plunger of the design acts as the deployment and retraction mechanism necessary to insert the swab at least 5 cm into the vagina and to remove the swab after specimen collection. The body of the design acts to limit contamination of the testing environment by keeping the swab covered before and after use and providing an external casing that could be safely set down on a surface. The cap of the design is to store 2.9 mL of transport media via an induction-sealed thin film. As seen in Figure 1, there is a rim within the cap that is available for the attachment of this thin film.

When using this design, a patient would rest the top of the body against the vaginal opening, plunge the swab into the vaginal canal, grip and rotate the body to collect a sample, and then once again use the plunger to remove the swab from the vagina. The patient would then screw the cap onto the body of the device, flip the device upside down, and use the plunger one last time to puncture the thin film and soak the swab with media. To prevent leakage of media from the device, two locations for O-rings have been integrated into the body of the device. One advantage of this design is its ability to limit contamination of the testing room as the only portion of the design that will enter a potentially infected vaginal canal is to be contained by the body. Additionally, this design's use of a plunger makes it similar to a tampon, which may make the testing process a bit more comfortable when compared to conventional testing methods. While the design is suspected to reduce contamination, media may leak out of the device if the O-rings do not provide an adequate seal. If this leakage occurs, then the testing environment will inherently become contaminated. Additionally, the design will require extensive instructions to ensure that patients do not insert the body of the device into the vaginal canal and that they properly attach the cap after use.

Design 2: Snap On

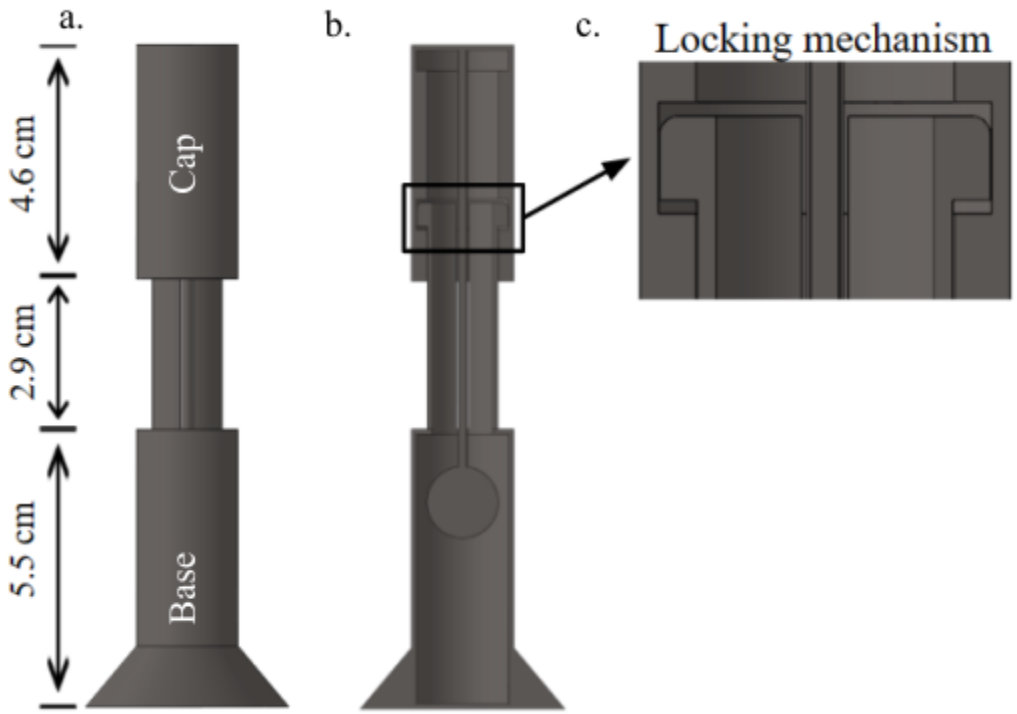

Fig. 2: The Snap On design with the cap and the base. The section view shows the locking mechanism used to attach the cap to the base.

The second proposed design consists of two separable components, the cap and the base. A 5 cm swab is attached to the cap, while the media is contained at the bottom of the base. As seen in Figure 2, the cap can vertically actuate in line with the base. The base has four thin vertical tabs with locking mechanisms which serve to hold the cap in a predetermined position. There are two positions the cap can be placed in, the up position and the down position. The tabs are designed so that a horizontal force causes the locking mechanism to disengage, allowing the cap to slide up and down. An additional feature of this proposed design is the wide base. The wide base will allow the device to stand on its own, decreasing the likelihood of the patient laying it on its side causing contamination. Moreover, this design will not require the patient to hold any additional objects in their hands while they perform the swab, further reducing the likelihood of contamination.

To use the device, the patient would enter the testing room with the device in the up position. The patient would then push on the tabs, pulling the cap from the base. After completing the swab, the patient would push the cap into the base until the down position is reached. The head of the swab would be submerged in media and the patient could leave the room without needing to touch the device again.

Design 3: Pull-Back

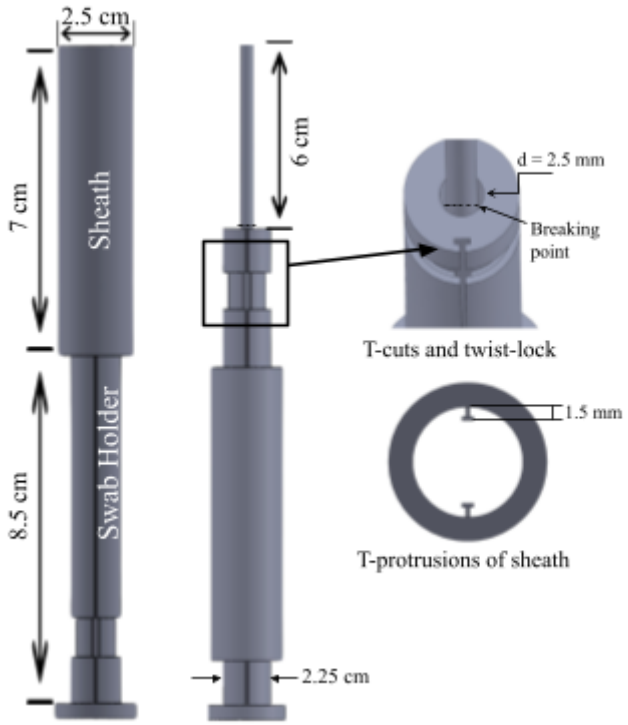

Fig. 3: Pull-Back Design. From left to right: Patient received orientation with sheath locked into place. Pulled back to the second locking position, leaving 6 cm of the swab available for specimen collection. T-cuts and T-protrusion views for illustration of sliding mechanism.

The third design idea consists of two components - a sliding sheath (outer cylinder) and a swab holder (inner cylinder). As seen in Figure 3, the swab holder contains two T-shaped cuts along the outer surface of its cylinder while the sheath has two T-shaped protrusions on its interior surface. These two parts - the cuts and protrusions - align to create a sliding track that is 1.5 mm in depth. The swab holder also has two secondary cuts that merge with the sliding track. These cuts allow the sheath to be twisted and locked into place at a particular location. Together, the swab holder and the sheath act to limit contamination of the testing environment as they provide complete coverage of the swab before and after use and should not be coming into contact with the vaginal canal.

When using this design, a patient would receive the device in the orientation shown in the leftmost view of Figure 3. In this orientation, the swab is completely covered and the sheath is locked in place. The patient would then twist the sheath 90 degrees counterclockwise to align the protrusions of the sheath with the cuts of the holder and pull the sheath down to the second locking position located 6 cm below the first. Once at the second locking position, the patient would rotate the sheath 90 degrees clockwise, locking it at this location and leaving 6 cm of the swab available for specimen collection (Fig. 3). The patient would then use the device to insert the swab into the vaginal canal, collect the specimen, and remove the swab. After removing the swab from the vaginal canal, the patient would have to transfer the swab into the Aptima Transport Media tube by snapping it at the breaking point (Fig. 3). Some advantages of this design include its ability to limit contact contamination and its relative ease of use. The sliding sheath acts as a barrier that allows the device to be set down without the risk of spreading contaminated fluids. Additionally, this design poses less risk of improper use as it is a relatively intuitive design that simply requires twisting and sliding. However, there is a risk of contamination via the spilling or splashing of media during the transport of the swab into the secondary media container. Furthermore, the fabrication of this design may pose a challenge as its multiple fine parts must perfectly align for the design to function as intended.

Preliminary Design Evaluations

Design Matrix

Table 1: The Design Matrix evaluating potential solutions for the Self-Swab Device.

Criteria	**Weight**	**1. Modified Plunger** 		**2. Snap On** 		**3. Pull Back** 	
Limiting contamination	30	5/5	30	3/5	18	4/5	24
Leakage Prevention	25	3/5	15	5/5	25	2/5	10
Ease of use	15	3/5	9	5/5	15	4/5	12
Ease of fabrication	10	3/5	6	5/5	10	2/5	4
Patient Comfort	10	5/5	10	4/5	8	4/5	8
Safety	5	5/5	5	5/5	5	5/5	5
Cost	5	5/5	5	5/5	5	5/5	5
Total	**100**	80		**86**		68	

The design matrix criteria were chosen in accordance with the main client requirements and design requirements. The first category, limiting contamination, refers to the ability of the device to prevent the spread of biological fluids and infectious species in the testing environment. The leakage prevention category was added to evaluate the ability of this design iteration to keep all media contained within the device via a sealing mechanism, which was the

main objective of the project for this semester and thus was given a high scoring weight. The ease of use category describes the overall simplicity of the device and the process for using it to collect a sample. The ease of fabrication category describes the feasibility of device fabrication by the team via 3D printing, machining, or a combination, and evaluates the complexity of the machining required to fabricate specific design components. The patient comfort category evaluates how comfortable a patient would be with using the device and considers any intimidation they may experience. Safety takes into account the potential biological and physical threats that are associated with device use, and cost refers to the price of manufacturing a singular unit.

For limiting contamination, designs 1 and 3 both scored the highest as they prevent any exposure of the swab with the environment; instead, they keep the head of the swab enclosed until it is inserted into the vaginal canal and then it is enclosed again after removal. By doing so, both devices limit the possibility of the swab contacting surfaces in the testing room and spreading infected vaginal fluids. However, in terms of leakage prevention, design 2 scored the highest because there is no plunger or slider that media could leak through. By eliminating this design element, the Snap On design is able to prevent the situation in which the device is upside-down and media is freely falling within the device and out any orifices, thereby reducing the risk of leakage. Additionally, eliminating the plunger or slider mechanism creates a more simplistic design that is easier to use, as it requires less moving parts, and easier to fabricate, as it does not require complex machining or threading. Therefore, design 2 scored the highest in these categories. When considering patient comfort, design 1 scored the highest due to its similarity to the tampon, a device that most female patients are familiar and comfortable with. In terms of safety, all three designs scored equally as they all require the insertion of the swab into the vaginal canal but do not require insertion of any other materials that could potentially have adverse effects. Lastly, all three designs scored equally on cost as they are all extremely inexpensive to 3D print at around $1-3 per print.

Based on the criteria and evaluations presented, the Snap On design stands out as the most well-rounded design that meets all required criteria.

Proposed Final Design

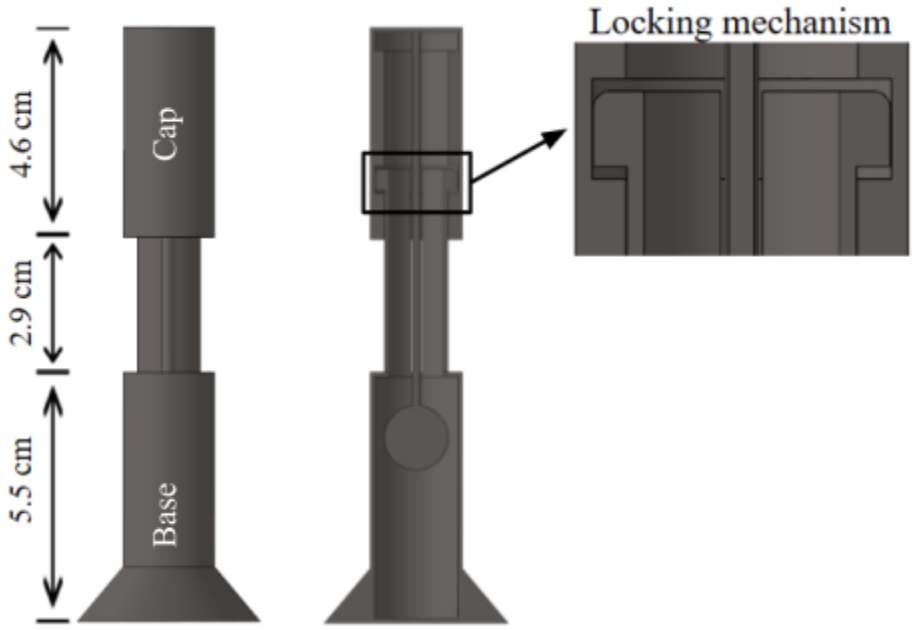

Fig. 4: The Snap On was chosen as the proposed final design. The cap, base and locking mechanism of this design are all visible.

The Snap On design was chosen as the proposed final design due to its high scores in leakage prevention, ease of use, and ease of fabrication. The intuitive design and functionality will mitigate leakage since the patient is never required to move or lift the media-filled base. Additionally, this design does not require the patient to hold any extra objects while they perform the swab, resulting in a high ease of use score. Relative to the other designs, the Snap On will have the most straightforward fabrication process. There are no threads that will need to be 3D printed and there are a lower number of parts requiring intricate details. However, testing and rapid prototyping will be required to hone the tabs and locking mechanism that are attached to the base.

The biggest area of concern for this design is the potential for contamination. The Snap On is the only design in which the swab is exposed after insertion into the vaginal canal. This gives the potential for the patient to lay the swab on a surface, contaminating the room. This risk will be mitigated by clear instructions which detail exactly how the test is to be performed. Further precautions will be taken by creating a cap with a sturdy top so that if the patient puts it on the table, the swab does not contact the surface.

Fabrication/Development Process

a. Materials

Swab: The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab [14]. The shaft of the swab is plastic [15]. Dacron swabs are most commonly used for STI testing due to their non-toxic and hydrophilic nature. They are both safe for patients as well as most compatible with biological samples.

Transport media: A universal transport media will be used such as Vircell Transport Medium. Transport media increases the viability of the obtained specimen by keeping it in a non-dry environment and allowing the sample to be kept at room temperature [16].

Device body: The device prototype will be 3D-printed out of polylactic acid (PLA). PLA is a thermoplastic derived from an organic source such as sugar cane or starch. It is biodegradable and has similar characteristics to petroleum-based thermoplastics such as polypropylene or polyethylene [17].

Thin film/foil: The device prototype will include a thin foil lining to contain the media and prevent contamination of the swab. Aluminum foil will be used as the lining material to mimic a medical grade film for fabrication and testing purposes.

See Appendix A for further descriptions of pricing and sourcing of material components.

b. Methods

The proposed final design was first designed in SolidWorks. The design included the required length and thickness specifications that were established last semester. Once the drawing of the final design was completed, the top and the base were exported as two separate stereolithography (STL) files to be 3D printed.

The 3D printing process will be done at the UW-Madison MakerSpace using the Bambu Lab printers. Both STL files will be uploaded to the MakerSpace computers and then the printing process will be carried out by the MakerSpace staff. Once the design is done printing, the supports will be removed from both pieces. Both pieces will then be sanded to give the design a smoother finish.

Testing

Ease of Use and Comfort Survey:

A survey will be conducted to determine opinions on the current design and if people would be comfortable using it. The survey will be given to current BME students and will be done anonymously.

Leak Testing:

A similar leak testing protocol to last semester will be followed. The cap will be filled with water stained red using food coloring to mimic the media stored inside the cap. During testing, the swab will be pushed into the cap and then the device will be tested for leakage in three different positions, the cap right side up, upside down, and being shaken. The test is considered successful if there is no red colored liquid visible on the filter paper.

Anatomical Testing:

The design is required to have the swab extend at least 5 cm into the vaginal cavity. Using the medical model provided from the client, testing will be conducted to ensure that the swab is able to deploy to the required length. The medical model provides a transparent side view of the vagina, which will allow for an accurate measurement of how deep the swab extends.

Bacterial Testing:

To make sure the design can accurately diagnose either chlamydia or gonorrhea, testing will be conducted to see if the swab - being stored in the cap - can still adequately pick up bacteria and transfer it into the media. CT bacteria will be cultured in a Biosafety Level 2 laboratory and sampled using the proposed final design. The media of the design will be tested using Nucleic Acid Amplification testing to determine if the usage of the device results in an accurate test. Additionally, this test will serve as an indicator for contamination as the environment in which the sample is collected - a BioSafety cabinet - will be tested for bacteria. If excessive amounts of bacteria are found on the surfaces of the BioSafety cabinet then contamination has occurred.

Discussion

Based on the Design Matrix, the Snap On Design would be the best design to go forward with, but it must be redesigned due to the new requirement of being compatible with a Hologic Panther machine. After redesigning the Snap On, fabrication and testing will be conducted. The primary goal of this project is to provide greater accessibility and safety for STI testing. By making STI tests more accessible, more people will be able to get tested and protect their health. Adequate healthcare is a universal right, so the device needs to maintain a low budget in order to still be easily accessible.

Conclusion

Contamination of STI self-swab testing environments with chlamydia or gonorrhea is prevalent, with one study finding 13% of testing rooms to have at least one of these bacteria on their surfaces [18]. Although the threat of transmitting infection to other patients is low, this contamination of surfaces has led to false positives, with another study finding that 67% of women who tested in the clinic received a false positive due to surface contamination [4]. As a result, there is a need for extensive cleaning of the testing room between every patient, which requires both time and resources.

The goal of this project is to limit the contamination of the testing environment during vaginal self-swab STI tests. To do this, a design that provides coverage of the swab and containment of the transport media has been proposed. The proposed final design, the Snap On, utilizes an external casing (cap) that holds the swab. This casing should limit the risk of potentially infected vaginal fluids getting onto the hands of the patients and thus spreading to surfaces of the testing room. Additionally, the media containing base mitigates the risk of leaking, spilling, or splashing of the media as it does not need to be picked up or moved after specimen collection and does not require the breaking of the swab. While the proposed final design provides an intuitive design that should help reduce contamination of the testing room, it will need to be modified to further address contamination concerns and to ensure compatibility with Hologic's Panther System testing assay. The current design of the cap may not provide adequate thickness to keep the swab elevated from surfaces if it were to be laid on its side. As a result, the cap of the Snap On design will be adjusted to ensure that the swab cannot come into contact with the surfaces of the testing room. Additionally, the Snap On design must be made compatible with the Panther testing assay. This testing assay is currently employed by most laboratories and requires the use of the Aptima Transport media tubes to conduct the Nucleic Acid Amplification test [2]. As a result, the proposed final design will need to be modified to make the overall testing process - from specimen collection to laboratory diagnostics - smooth, rapid, and free of contamination.

Redesigning of the Snap On design will first be conducted to ensure that it allows for the transfer of the swab from its cap into the Aptima Transport Media tube. This transfer typically requires the swab to be snapped at its breaking point so components of the Pull Back design may be integrated into the Snap On design. Additionally, the snapping of the swab does introduce the risk of contamination through expelled vaginal fluids. To combat this risk, an investigation into a method of cleaving and ejecting the swab from its casing or mechanisms that can contain this contamination will be conducted. Upon completion of these design tasks, prototypes will be fabricated via 3D printing at the UW-Madison Makerspace. These prototypes will be tested for their ease of use, their anatomical compatibility, and their ability to limit contamination. Additionally, the prototypes will be tested in the laboratory to ensure that the diagnostic experts can efficiently test specimens collected by the device and that adequate amounts of bacteria are being collected.

References

[1] CDC, “Detailed STD Facts - Chlamydia,” Centers for Disease Control and Prevention, Apr. 12, 2022. https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm

[2] M. Muljadi, C.-M. Cheng, C.-Y. Yang, T.-C. Chang, and C.-J. Shen, “A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women,” Frontiers in Bioengineering and Biotechnology, vol. 10, Oct. 2022, doi: https://doi.org/10.3389/fbioe.2022.1008761.

[3] N. Liddon, S. Pampati, R. Dunville, G. Kilmer, and R. J. Steiner, “Annual STI Testing Among Sexually Active Adolescents,” Pediatrics, vol. 149, no. 5, Apr. 2022, doi: https://doi.org/10.1542/peds.2021-051893.

[4] M. Toepfe, B. Hermann, M. Sansone, C. Lilja, and P. Nolskog, “Environmental contamination by Chlamydia trachomatis RNA can cause false-positive test results in clinical samples,” Sexually Transmitted Diseases, vol. Publish Ahead of Print, Oct. 2020, doi: https://doi.org/10.1097/olq.0000000000001323.

[5] “Aptima ® Multitest Swab Specimen Collection Kit Patient collection procedure guide.” Accessed: Oct. 11, 2023. [Online]. Available: https://www.hologic.com/sites/default/files/Aptima%20Patient%20Vaginal%20Collection_0.pdf

[6] P. in your hands, “Mía by XytoTest® | HPV Test,” Mel-Mont Medical. https://www.mel-montmedical.com/products/mia/ (accessed Oct. 11, 2023).

[7] M. Mohseni, S. Sung, and V. Takov, “Chlamydia,” National Library of Medicine, 2019. https://www.ncbi.nlm.nih.gov/books/NBK537286/

[8] S. S. Witkin, E. Minis, A. Athanasiou, J. Leizer, and I. M. Linhares, “Chlamydia trachomatis: the Persistent Pathogen,” Clinical and Vaccine Immunology, vol. 24, no. 10, Aug. 2017, doi: https://doi.org/10.1128/cvi.00203-17.

[9] M. A. Chernesky, “The laboratory diagnosis of Chlamydia trachomatis infections,” The Canadian Journal of Infectious Diseases & Medical Microbiology, vol. 16, no. 1, pp. 39–44, 2005, Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2095010/

[10] “Screening Tests To Detect,” www.cdc.gov. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5115a1.htm

[11] “Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014,” 2019. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm

[12] “Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia.” NCDHHS, Gen-Probe Incorporated, Apr. 2011, epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf.

[13] 677 H. A. Boston and Ma 02115, “Menstrual hygiene products: pads and tampons are the go-to choice,” Apple Women’s Health Study, May 18, 2023.

https://www.hsph.harvard.edu/applewomenshealthstudy/updates/menstrualhygieneproducts/

[14] Zasada, A.A., Zacharczuk, K., Woźnica, K. et al., “The influence of a swab type on the results of point-of-care tests,” AMB Expr 10, 46 (2020). https://doi.org/10.1186/s13568-020-00978-9

[15] “Thermo Scientific Swab, Dacron, sterile, plastic shaft, 6"L x 1/10" dia.” Cole, www.coleparmer.com/i/thermo-scientific-swab-dacron-sterile-plastic-shaft-6-l-x-1-10-dia/1400110.

[16] “TRANSPORT MEDIUM - Vircell,” en.vircell.com.

[17] TWI, “What is PLA? (Everything You Need To Know),” www.twi-global.com, 2023. https://www.twi-global.com/technical-knowledge/faqs/what-is-pla

[18] N. Lewis, G. Dube, and C. Carter, “Chlamydia and gonorrhoea contamination of clinic surfaces,” Sexually transmitted infections, https://pubmed.ncbi.nlm.nih.gov/22535909/&sa=D&source=docs&ust=1702230217102438&usg=AOvVaw3phlk8IhBYmDTXeF0tAAF- (accessed Dec. 10, 2023).

Appendix

Appendix A: Expense Spreadsheet

Table 2: The expense spreadsheet for the design project

Material	Cost	Price Estimate	Expected Vendor	Part Number
PLA	$0.05/gram	n/a	Makerspace	-
Transport Media	Free	-	Provided by client	-
O-ring	$11.07	$11.07	Grainger	(exact part TBD but Item 1BYC1 used for calculations)
(film/foil)				
Dacron Swab	Free	-	Provided by client	-

Appendix B: Product Design Specifications

Function:

This device should be a vaginal self- swab used for STI testing in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. A swab such as this would allow women to comfortably test and screen for these common STIs in a clinical setting. Current self-swab studies have found that 84% of women prefer this self-swab method of testing to getting swabbed by a clinician [1]. However, the current methods provide many avenues for contamination of the swab and of the environment. If the swab touches any exterior surfaces, such as the leg or table, it is considered contaminated and results can be faulty [2]. Furthermore, liquid in the testing kit can easily spill and contaminate the testing space in a clinic [1]. A design in which the swab is deployed into the vagina and then contracted back into the device to cause the release of transport media within the device would decrease the probability of contamination.

Client Requirements:

- The swab head will be contained in an external tube that is safe to enter the vagina.
- The swab head will be deployed from the external tube into the vagina and retracted back into the tube.
- The tube will seal upon retraction.
- The device must allow for the transfer of the swab to the Hologic® transport media tube
- The device must ultimately make universal STI testing more accessible and limit contamination of the testing room.
- A budget of 500 dollars will be observed.

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements:

i. The external tube must comfortably rest against the vaginal opening.

ii. The external tube must have a mechanism for deployment, retraction, and sealing of the test specimen.

1. Deployment and retraction will be accomplished via a slider mechanism or plunger mechanism.

2. The swab head will be sealed off by a screw-on cap that contains transport media or by an external tube containing media. The media will be contained in the cap by a puncturable, induction-sealed, thin film.

3. The bottom of the device must seal via a mechanism that prevents any leakage, such as threading with an o-ring seal or a compression seal, in order to preserve the sample within the media and prevent contamination of contact surfaces.

iii. The head of the swab must be deployed 5 centimeters into the vaginal canal [2].

iv. The swab must remain connected to the external tube and allow patients to self-swab for up to 30 seconds [2].

b. Safety:

    i. All components of the device including the swab head, shaft, and any external casing must be biocompatible and bioinert to prevent any irritation or immune response.

    ii. The swab shaft must not dislodge from the deployment and retraction mechanism throughout the duration of use to mitigate contamination concerns and patient discomfort.

    iii. The transport media used must be nontoxic and biocompatible in case of device malfunction or splashing that could cause it to come in contact with skin or internal vaginal tissue.

    iv. The device must pass a toxicological risk assessment as defined by ISO-10993-17 to ensure that the device will not have any harmful chemical or biochemical interactions with the vaginal or bodily components that it comes in contact with [3].

c. Accuracy and Reliability:

    i. The swab device must be reliable at detecting Chlamydia and Gonorrhea STIs for every test. To quantify this, our swab device must have high statistical sensitivity.

    ii. To ensure accuracy, the swab must be able to be inserted 5 cm into the vagina and be rotated for 10-20 seconds each time to collect the sample [1].

    iii. The tip of the self-swab device should be approximately 1 cm length for optimal collection of vaginal discharge samples [1].

d. Life in Service:

    i. Fully assembled STI tests should have a shelf life ranging from 12-18 months. The exact standard cellular media used will further dictate the precise storage longevity of the test as a whole [4].

    ii. Tests should not be stored in direct sunlight and should be kept between 2 – 8 °C (36 – 46 °F) for maximum shelf life before use [5].

    iii. After samples have been collected, the test will be in service until the lab has gathered cells from the swab. Swabs can be stored at room temperature in the lab for a maximum of 14 days [6].

    iv. Each test will only be used once.

e. Shelf Life:

    i. The STI test should be used within 30 days of arrival [7].

    ii. Swabs should be transported and/or tested within 14 days after the test is administered [6].

f. Operating Environment:

    i. The STI swab must be user-friendly and able to withstand room temperature (20-22°C) for several hours before and after use.

    ii. Tests are to be conducted in the testing room of a clinic and kept in clinic-provided storage until lab processing.

    iii. The swab should have no risk of outside contamination or environmental contamination when in use.

iv. The device must be able to insert into the vagina and withstand the acidic environment of the vagina (pH of 3.8-4.5) [8].

g. Ergonomics:

i. The swab should be easily and comfortably hand-held and self-insertable.

ii. The swab should be able to be comfortably inserted five centimeters inside the vagina [2].

iii. All materials used in the swab and applicator should be compatible with the intravaginal environment.

iv. Even though the media will always be contained within the device, it will still be biocompatible.

h. Size:

i. The device will not exceed 17 cm in length. This provides the patient with enough length to comfortably swab the vaginal canal.

1. The average depth of an unaroused vaginal canal is 9 cm [9].

i. Weight:

i. The device will not exceed 7 grams to ensure the device is not cumbersome in the hands of patients. This includes the weight of the external tube, the swab, and the cell culture media within the device.

j. Materials:

i. The head of the swab must be made of a non-cotton fiber that will not shed in the process of sample collection or analysis. The material must have chemical resistance and biocompatibility to withstand both the physiological environment of the vagina as well as the chemical processing involved with experimentation [10]. The swab head material must be highly absorbent for water and proteins to collect many specimens and must allow for their release and collection in a medium for testing [11]. Per CDC recommendation, suggested materials include rayon, dacron, or cytobrush [12].

1. Dacron swabs have been provided by the client and will be used in all future prototype iterations. These swabs are inert materials and can be purchased with a wooden or plastic shaft [13].

ii. An appropriate transport media must be used to store the sample following insertion into the vaginal canal. Commonly used, commercially-available media includes M4 media or Vircell Transport Medium [14]. Use of a transport media will allow for improved microorganism viability when testing is performed [15].

1. Discussion with members of the specimen processing lab should be conducted to determine the preferred transport media.

iii. The body of the sample collector should be manufactured from an autoclavable, single-use plastic. The material must not irritate the vaginal

canal or induce an immune response. Possible materials include polyethylene or polypropylene, similar to the composition of a plastic tampon applicator.

1. Investigation into compostable biopolymers should be conducted to minimize the contribution to single-use medical waste. Viable biopolymers to be used include blends of Polylactic Acid (PLA) with Polybutylene Succinate (PBS) or Polybutylene Adipate Terephthalate (PBAT) [16].

k. Aesthetics, Appearance, and Finish:

i. The finished product will be similarly shaped to a standard tampon applicator or IUD insertion device.

ii. The exterior finish of the product will be smooth and sleek to prevent damage to tissue during insertion into the vagina.

1. The external tube is not meant for insertion, but if insertion does happen the tube should biocompatible, inert to the body, and of appropriate size to not harm the patient.

iii. The product will be long enough to allow swab insertion of at least 5 cm into the vagina for sample collection purposes [2].

iv. The device will be made of a colored material that appeals to patients.

2. Production Characteristics

a. Quantity:

i. Multiple self-swab device prototypes will be developed for testing and quality assessments.

ii. The design should be replicable for the potential to be mass-produced for clinical-use settings.

1. Investigation into mass-production methods of single-use medical devices should be conducted, and the number of units expected to be produced determined. Potential methods of large-scale production include injection molding.

2. Production of the design has the potential to be used globally in clinics, impacting millions.

b. Target Product Cost:

i. The end cost of the design process should not exceed the client's budget request of $500.

1. 3D printing of the device costs an average of $5 with additional costs to be expected from the dacron swab and the cell culture media. Dacron swabs are available for purchase from most medical manufacturing companies. The expected price of the Dacron swab is $0.57 per swab [13].

3. Miscellaneous

a. Standards and Specifications:

i. As defined by the FDA in the Code of Federal Regulations, Title 21, Sec. 866.2900, the vaginal sample collector is classified as a microbiological specimen collection and transport device and a Class I (general controls) medical device [17]. The media contained within the device is a transport culture medium and Class I (general controls) device as specified in Sec. 866.2390 [18]. This classification means that the device is exempt from premarket notification 510(k), but is still subject to registration and listing, labeling, and good manufacturing practices.

ii. The device is subject to requirements for the collection and transport of samples for medical laboratory examinations as outlined by ISO 20658 [19].

b. Customer:

i. The customer would like to limit cross contamination of the environment with a product that is able to seal the swab, so it is no longer necessary to transfer from the vagina to the tube.

ii. The customer would like to make universal testing of Chlamydia more accessible (ideally doubling the existing 6%-8%) in order to prevent both infertility and the spread of the infection. The customer would also like to reach younger women, who are typically under-tested [20].

c. Patient-Related Concerns:

    i. This product will make patients more comfortable with regular STI screening by providing a safe, reliable, and user-friendly option.

    ii. Barriers to universal testing will still exist (socioeconomic, location, age, etc) [20].

        1. The device should aim to be relatively inexpensive to dismantle the socioeconomic barrier to STI testing

    iii. Proficient self-swabbing is important in collecting vaginal samples to be tested.

        1. The patient must be provided with clear instructions that include a visual component to model the actions the patient will perform.

d. Competition:

    i. There exist similar products to a self-swab for *Chlamydia Trachomatis*, none of which address the client's concern for contamination as they all require the screwing/unscrewing of sample containers [21].

        1. The current standard test used by the client is the Aptima Multitest Swab Specimen Collection Kit. This test consists of a Dacron swab and a media tube with a screw-on cap. After collecting a sample with the swab, the patient unscrews the cap of the tube, inserts the head of the swab, breaks off the end of the swab shaft, and screws the cap of the tube back on [5].

ii. A design for a swab with a detachable head exists, yet the collection process still involves a separate entity, the collection tube, being unscrewed to place the head into. [22]

References

[1] Muljadi, Michael, et al. "A Pilot Clinical Validation Study of a Self-Collected Vaginal Swab Device for the Detection of Chlamydia Trachomatis in Women." *Frontiers in Bioengineering and Biotechnology*, Frontiers, 20 Sept. 2022, www.frontiersin.org/articles/10.3389/fbioe.2022.1008761/full.

[2] "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia." *NCDHHS*, Gen-Probe Incorporated, Apr. 2011, epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf.

[3] ISO - International Organization for Standardization, "ISO 10993-17:2023," ISO, 2023. https://www.iso.org/standard/75323.html.

[4] "Laboratory Bulletin." Notification of Extended Expiry Dating for the Aptima Multitest Swab Specimen Co, www.albertahealthservices.ca/assets/wf/lab/if-lab-hp-bulletin-notification-and-collection-of-muscle-biopsy-specimens.pdf.

[5] "Aptima Specimen Transfer Kit Package Insert - Hologic." APTIMA Specimen Transfer Kit Package Insert, stage.hologic.com/sites/default/files/package-insert/AW-11586-001_002_01.pdf.

[6] "Laboratory Test Catalog Powered by Mayo Clinic Laboratories." Laboratory Test Catalog, Spectrum Health, 2023, spectrumhealth.testcatalog.org/show/LAB1230566#:~:text=or%20SH%20MRN)-,Laboratory%20Retention%3A%20Swab%20specimens%20will%20be%20stored%20at%20room,for%2014%20days%20from%20collection.&text=Male%20Urethral%20Specimens-,Collection%20Instructions%3A,hour%20prior%20to%20sample%20collection.

[7] "Does the STI Kit Expire? How Long Do I Have to Use It?" *Help Center*, Legacy, 2 Jan. 2023, help.givelegacy.com/s/article/Does-the-STI-Test-Kit-expire-How-long-do-I-have-to-use-it.

[8] W. E. Contributors, "What Is Vaginal pH Balance?," *WebMD*, Apr. 25, 2021. https://www.webmd.com/women/what-is-vaginal-ph-balance

[9] Cleveland Clinic, "Vagina: Anatomy, Function, Conditions & What's Normal," *Cleveland Clinic*, Mar. 08, 2022. https://my.clevelandclinic.org/health/body/22469-vagina

[10] V. Vashist, N. Banthia, S. Kumar, and P. Agrawal, "A systematic review on materials, design, and manufacturing of swabs," *Annals of 3D Printed Medicine*, vol. 9, p. 100092, Feb. 2023, doi: https://doi.org/10.1016/j.stlm.2022.100092.

[11] R. N. Kashapov and A. N. Tsibin, "Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials," *Biomedical Engineering*, vol. 55, no. 4, pp. 289–293, Nov. 2021, doi: https://doi.org/10.1007/s10527-021-10120-z.

[12] "Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014," 2019. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm

[13] “Cole-Parmer US - Fluid Handling and Analysis Supplies from Cole-Parmer,” *www.coleparmer.com*. https://www.coleparmer.com/

[14] S. L. Jones et al., “Performance evaluation of two microbial transport media designed for preservation and transport of Chlamydiae, Mycoplasma and Ureaplasma,” *Journal of Medical Microbiology*, vol. 64, no. 4, pp. 382–389, Apr. 2015, doi: https://doi.org/10.1099/jmm.0.000044.

[15] “TRANSPORT MEDIUM - Vircell,” en.vircell.com. https://en.vircell.com/products/transport-medium/ (accessed Sep. 21, 2023).

[16] G. Cappiello, C. Aversa, and M. Barletta, “Design of compostable materials for the manufacturing of flexible tampon applicators,” Procedia CIRP, vol. 110, pp. 342–347, 2022, doi: https://doi.org/10.1016/j.procir.2022.06.061.

[17] Microbiological specimen collection and transport device, 21 C.F.R. § 866.2900 (2023).

[18] Transport culture medium, 21 C.F.R. § 866.2390 (2023).

[19] ISO - International Organization for Standardization, “ISO 20658:2023,” ISO, 2023. https://www.iso.org/obp/ui/en/#!iso:std:80035:en.

[20] Liddon, Nicole, et al. “Annual STI Testing among Sexually Active Adolescents.” American Academy of Pediatrics, American Academy of Pediatrics, 11 Apr. 2022, publications.aap.org/pediatrics/article/149/5/e2021051893/186749/Annual-STI-Testing-Among-Sexually-Active

[21] Pandya, N., & Pandya, N. (2023). Benefits Of PCR Testing For Chlamydia And Gonorrhoea. Lifecell International Pvt Ltd. https://www.lifecell.in/blog/health-check/benefits-of-pcr-testing-for-chlamydia-and-gonorrhoea#:~:text=In%20A%20Nutshell,of%20infections%20in%20your%20sample.

[22] LifeCell International Private Limited. (2022, December 13). Vaginal swab self sample collection & dispatch -Explainer video [Video]. YouTube. https://www.youtube.com/watch?v=gMpfNOQtZfg.