Vaginal Self-Swab Device to Minimize Contact Contamination

Client: Dr. Jean Riquelme
Advisor: Prof. Randolph Ashton
Date: 09/25/2024

Team:

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PROBLEM STATEMENT

Bacterial Vaginosis (urinary tract infections), yeast infections, and sexually transmitted infections (STIs) can be detrimental to the well-being of an individual and cause a variety of health concerns if left untreated. The vaginal self-swab device is to be utilized by patients to easily collect cervicovaginal mucus samples from the vaginal canal to diagnose vaginal infections and STIs. This device design aims to provide a convenient, accessible method of breaking the swab into the transfer tube while minimizing cross-contamination of the self-collected sample. Cross-contamination, with the surface and environment, typically occurs while transferring the sample to the culture media, which can alter the results. In order to overcome this, the device should allow the testing swab to break into the culture media solution directly, and to prevent media leakage.

BRIEF STATUS UPDATE

- The team collaborated on improved design ideas to include in the design matrix.
- The team chose the best design and discussed the justifications as to why it was the best.

SUMMARY OF WEEKLY TEAM MEMBER DESIGN ACCOMPLISHMENTS

- Team:
    - Met as a team to discuss the design matrix logistics (09/25), and to share design ideas in order to complete the design matrix (09/26).
    - Began material considerations and order form.
    - Begin PDS revisions based on the provided feedback.
- Jackie Behring:
    - Continued to research
    - Updated Lab Archives
    - Completed assigned tasks of design matrix
    - Updated past semester design with improved additions

- Tatiana Predko:
    - Collected additional research on competing designs and recorded in LabArchives.
    - Facilitated a team meeting over Zoom.
    - Completed assigned portions of the Design Matrix.
    - Came up with a design concept to be potentially utilized in the Design Matrix.
- Mariah Smeeding:
    - Completed my proposal design idea to be potentially used
    - Finished my portion of the design matrix
    - Communicated with my team my busy schedule and worked with them to ensure I contributed fairly to the design.
    - Submitted progress report 3 and design matrix to our website.
- Ava Fevold:
    - Continued to research and update Lab Archives with findings
    - Created a design for a design matrix
    - Filled in assigned parts of the design matrix
    - Facilitated 9/26 Zoom meeting

PROJECT DIFFICULTIES

- Finding meeting times where everyone is available has been a challenge.

UPCOMING TEAM AND INDIVIDUAL GOALS

- Team:
    - Take and upload a team picture to the website.
    - Complete the Design Matrix by 09/26/2024.
    - Meet as a team prior to Preliminary Design presentations to complete assigned parts and to rehearse the presentation.
- Jackie Behring:
    - Begin the Preliminary Design Presentation
    - Begin modeling the chosen design in SolidWorks
    - Continue researching and keep lab archives updated
- Tatiana Predko:
    - Email the client and advisor with updates on the project, and confirm the next meeting time.
    - Complete assigned portions of the Preliminary Design presentation and rehearse.
    - Record additional research and design process in LabArchives.
- Mariah Smeeding:
    - Continue researching possible contaminants to the self sampling process.
    - Compare and contrast similarities (or understand differences) to the nasal mucosa (very well known site for self sampling due to covid 19) and the vaginal mucosa
    - Add further research to lab archives
    - Complete my portion of the preliminary presentation and rehearse.
- Ava Fevold:

- Work on the Preliminary Design Presentation
- Continue to research and update LabArchives
- Rehearse Preliminary Design Presentation with group

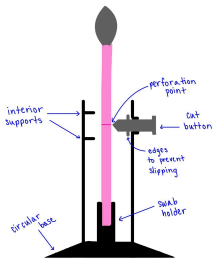
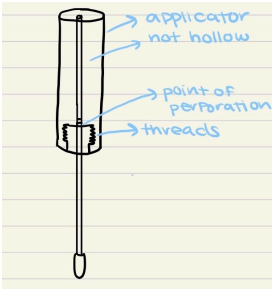
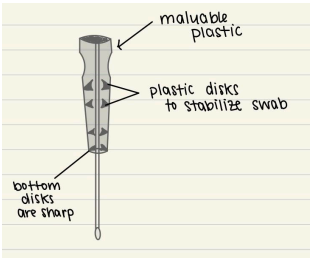
PROJECT TIMELINE

Task	Sep.			Oct.					Nov.				Dec.		
	12	19	26	3	10	17	24	31	7	14	21	28	5	11	12
Deliverables															
Progress Report	X	X	X												
PDS Draft		X													
Design Matrix			X												
Preliminary Oral Presentation															
Preliminary Lab Notebook															
Preliminary Report															
Preliminary Evaluations															
Show and Tell															
Final Poster Presentation															
Final Lab Notebook															
Final Report															
Final Evaluations															
Meetings															
Team															
Advisor															
Client															

EXPENSES

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
TOTAL:								$0.00

DESIGN MATRIX

Design Criteria (weight)	Design 1: Altered Bend Design 		Design 2: Tilt - and - Break 		Design 3: The Tunnel 	
Limiting Contamination (30)	4	24	4	24	4	24
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (5)	4	4	5	5	2	2
Cost (5)	5	5	5	5	5	5
Total Score (100)		81		92		74

Determination of Criteria and Weights:

- *Limiting Contamination (30):* Leaking contamination refers to the ability to inhibit the spread of microorganisms from biological fluids or the testing environment. This criterion was discussed in the *Accuracy and Reliability* section of the PDS, and was assigned a weight of 30/100 due to its significance of being an accurate measurement. The device must demonstrate a consistent snapping mechanism while transporting the swab into the culture media. This requires the minimization of contamination caused by the patient's own bacterium, such as their hands, or from the environmental bacterium, such as a countertop.
- *Leakage Prevention (25):* Leakage prevention refers to the degree to which spilling of contained culture media is prevented. This criterion was assigned a weight of 25/100 because it is of paramount importance that the culture media does not leak. Leakage of the contained culture media can lead to inaccurate testing results, due to partial loss of the sample or external contamination. Additionally, skin contact with the culture media should be avoided, as it could lead to injury of the patient.
- *Ease of Use (15):* This section focused on the simplicity of the process using the device. Relevant information was covered in the *Life in Service* and *Shelf Life* sections of the PDS. This criterion was given a weight of 15/100 because it is important that a patient would be able to understand and correctly use the device. A simple testing process is essential since the self-swab would be done without a doctor or physician's guidance.
- *Ease of Fabrication (10):* This criterion assesses the ease of fabricating the insertion and stand mechanism, including the production and assembly of its components. Ease of fabrication was given a 10/100 because it's crucial that the design is feasible within the given time frame, both for prototyping and potential commercial manufacturing. A higher score in this category reflects a design that aligns with our fabrication skills and can be more readily scaled for commercial production.
- *Patient Comfort (10):* Patient comfort refers to the comfort level of the patient while using the product, notably to which degree discomfort and pain are avoided. This criterion was assigned a weight of 10/100, as it is not an essential component of device functionality, but it is vital in the marketability and convenience of the product. Due to its convenience, patients are more likely to self-swab than to obtain a physician-collected sample [1].
- *Safety (5):* Safety refers to risks (specifically to the user) associated with the product. This category ensures that the shaft portion of the swab can only be inserted 5 cm to prevent mechanical-induced tissue injury to the user [2]. Every material to be used is known to be biocompatible with the human body to reduce the risk of hypersensitivity [3].
- *Cost (5):* The cost portion of the matrix is used to determine whether the cost of the materials are justifiable and within the client's budget. Points off in this category indicate costs exceeding the budget.

Justification of Assigned Scores:

- *Limiting Contamination (30):* The "Altered Bend" design scored a ⅘ because although the base was extended to provide more stability, the device still has the potential of being knocked over, which could lead to contamination if the swab comes into contact with an external surface. The "Tunnel" design scored a ⅘ in limiting contamination because the mechanism is made out of malleable plastic, meaning it could tip easier without the added weight. Similarly to the other two design concepts, the "Tilt-and-Break" design received a score of ⅘. This is because although the design consists of a solid "handle" (as compared to the hollow "handles" of the other two designs) making it less prone to tipping over, there is still the possibility of the device being knocked over and becoming contaminated after unintentionally coming into contact with a surface.

- *Leakage Prevention (25):* The "Altered Bend" design scored a ⅘ in the leaking prevention category because of its inability to screw onto the device containing the transportation medium. The patient could accidentally knock over the tube containing the medium, leading to the potential spilling of viable bacterium through the crevices of the device. Similarly to the "Altered Bend" design, there is a possibility for tipping with the "Tunnel" design, so it is ranked a ⅘. Since there is no solid divide between the swab-holder and the tube, the culture media could spread throughout the hollow holder and escape the container. The "Tilt-and-Break" design scored full points in this category, because the "handle" component of the device is solid, and has no hollow voids for fluid to seep into if the device is not upright. Additionally, this design utilizes threads to allow for a secure, "screw-on" tightening of the two components.
- *Ease of Use (15):* The "Altered Bend" design was given a score of ⅘ for ease of use because the button mechanism could malfunction, leading to inconclusive results. The "Tunnel" design was ranked the lowest, with a ⅗, because of the need to apply substantial, and variable (due to the user), pressure in order to break the swab. Finally, the "Tilt-and-Break" design scored full points in this category. This is because the device solely consists of a simple "screwing-on" mechanism, making it simple to use.
- *Ease of Fabrication (10):* When it comes to the ease of fabrication, the "Altered Bend" design was assigned a score of ⅗ because, in previous semesters, the button had issues with rotating, providing an inaccurate breaking of the swab (either too long or too short). Fabricating a "button" mechanism and assembling it in a non-rotational manner would be difficult. Ranked ⅖, the "Tunnel" design would be difficult to fabricate due to the incorporation of sharp inserts within the holder used to stabilize the swab. Lastly, the "Tilt-and-Break" design was given a score of ⅘; this device would be relatively easy to fabricate due to its simplistic design, but it may be difficult to create a "handle" into which the swab can be sufficiently pressure-fit. Additionally, the "Tilt-and-Break" design

utilizes threads, which is an added component of difficulty with regard to the ease of fabrication.

- *Patient Comfort (15):* Each of the designs scored full points for patient comfort because all of the designs have a similar mechanism in terms of specimen collection by the patient. During the process, the patient must insert the swab 5 cm into the vaginal canal, which provides little-to-no discomfort to the patient if done correctly [2].
- *Safety (5):* The "Altered Bend" design received a score of ⅘ for safety because the button could potentially malfunction and pinch the user if not pressed correctly. The "Tunnel" design ranked the lowest, with a ⅖, due to the sharp insert at the bottom of the holder. This can be dangerous to the user during the swabbing process, as well as while breaking the swab. The simplistic design of the "Tilt-and-Break" mechanism leaves little room for the user to injure themselves, which is why this design received a full score in this category.
- *Cost (5):* Each of the designs received full points within the cost category because all of the proposed design ideas require a minimal amount of material for fabrication, leading to affordability. All of the costs required to manufacture either device are anticipated to be within the $250 budget of the client.