Vaginal Self-Swab Device to Minimize Contact Contamination

Client: Dr. Jean Riquelme
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Team:

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PROBLEM STATEMENT

Many cases of bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs) can be asymptomatic and go undiagnosed. This can be detrimental to the well-being of an individual and cause a variety of health concerns if left untreated. It is crucial for individuals to have access to accurate and reliable screening to ensure healthy bodily function. The vaginal self-swab device offers women a noninvasive and less intimidating way for a greater population of women to get tested. By collecting and analyzing mucus samples from the vaginal canal, infections and STIs can be detected. The vaginal self-swab created by Hologic, the Aptima Multitest Swab Specimen Collection Kit, has the intention of increasing effective screening accessibility; however it fails to ensure a low-enough risk of contamination which jeopardizes its accuracy. This is due to excessive external contact to the swab, inaccurate breakage of the swab shaft, and the potential for transport media spillage. The goal of the project is to create a device that minimizes cross-contamination ensuring accurate test results. The proposed final design, The Tilt-and-Break, adds a third component that would secure onto Hologic's Self Swab. By doing so, external contact to the swab is eliminated, accurate breakage is ensured, and stability is given to reduce risk of spilling.

BRIEF STATUS UPDATE

- The team is testing the swab-breaking accuracy and cross-contamination aspects of the device, and working on the final deliverables.

SUMMARY OF WEEKLY TEAM MEMBER DESIGN ACCOMPLISHMENTS

- Team:
    - Met as a team on 11/25 to complete the swab-breaking accuracy portion of the testing protocol, as well as to begin the cross-contamination testing.
    - Met as a team on 11/26 to complete the cross-contamination portion of the testing protocol.

    - Met as a team on 12/04 to complete the revised cross-contamination protocol, complete data analysis of the agar plate data, and to complete/print the final poster.
    - Met as a team on 12/05 to rehearse the final poster presentations.
- Jackie Behring:
    - Met with team to complete testing protocols
    - Ordered another set of agar plates because first order had bad agar
    - Researched and added additional information to lab archives
    - 3D printed final prototype using clear resin
        - Total: $4.96
        - Quantity: 20.67 mL of material
    - Completed assigned sections of Final Report and Poster
    - Met as a team to complete and practice poster presentation
    - Printed and picked up final poster
- Tatiana Predko:
    - Wrote the swab-breaking accuracy testing protocol; included in LabArchives under “Team Activities”>”Testing and Results”>”Protocols”.
    - Met with the team on 11/25 in the ECB to complete the swab-breaking accuracy protocol and begin the cross-contamination testing; Met with the team again on 11/26 to complete the cross-contamination testing portion of the protocol.
    - Researched additional information on agar plate usage and included in LabArchives.
    - Wrote a revised version of the cross-contamination protocol; included in LabArchives under “Team Activities”>”Testing and Results”>”Protocols”.
    - Arranged a team meeting for additional cross-contamination testing and final poster rehearsal.
    - Completed the assigned portions of the final report and final poster.
    - Met with the team to complete and rehearse the final deliverables.
    - Emailed the client with project updates.
- Mariah Smeeding:
    - Met with team on 11/25 in ECB to complete Hologic Aptima swab breakage testing and discuss cross contamination testing.
    - Met with Team on 11/26 in ECB to finish breakage testing with the Tilt-and-Break device.
    - Completed Statistical analysis of the swab breakage data and bacterial colony data in R studio to determine if our data proved statistical significance with a one sided Welch Two Sample t-test for the swab breakage and a two sided Welch Two Sample t-test.
    - Created graphs in R studio for each test.
    - Began my assigned portion of the final report and made edits based off of previous comments.
    - Met with team on 12/4 to review Final Poster and prepare it for printing
    - Met with team on 12/5 to practice presenting final presentation
- Ava Fevold:

- Researched agar plate testing and recorded notes in lab notebook
- Met with the team on 11/25 in the ECB to complete the swab-breaking accuracy protocol and begin the cross-contamination testing
- Met with team on 12/4 to check on contamination testing and count colonies
- Met with team on 12/5 to practice presenting final presentation
- Created and finalized the final poster
- Began working on my assigned portion of the final report

PROJECT DIFFICULTIES

- No bacterial proliferation on the agar plates following the given protocol.

UPCOMING TEAM AND INDIVIDUAL GOALS

- Team:
  - Print the final poster.
  - Practice the final presentation.
  - Begin patenting process.
- Jackie Behring:
  - Present poster!
  - Complete and upload all final deliverables
  - Begin patenting process.
- Tatiana Predko:
  - Meet with the team to complete the rest of the testing protocol.
  - Present during final poster sessions.
  - Begin the patenting process.
- Mariah Smeeding:
  - Present poster presentation on 12/5
  - Meet with team to finalize the report
  - Complete the testing and discussion section of the report.
  - Review and edit the report to ensure it is free of errors.
  - Contribute to conclusion based off of my assigned section.
  - Upload final deliverables to the website.
  - Understand what the IDA and FDA regulations are required for legal purposes.
  - Begin patenting process.
- Ava Fevold:
  - Practice the final presentation
  - Attend poster presentation and give presentation with team
  - Finish the final report
  - Meet with the team to begin the patenting process

PROJECT TIMELINE

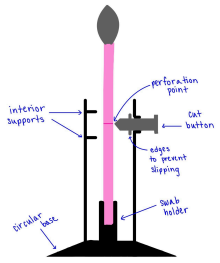
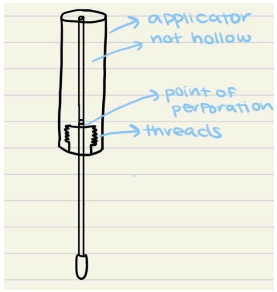
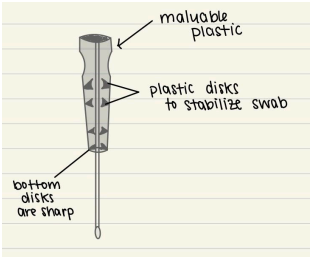
Task	Sep.	Oct.	Nov.	Dec.

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

EXPENSES

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
base	3D printed base (PC)	UW Makerspace	N/A	10/29/2024	1	0.33	0.33	Makerspace
base	3D printed (PLA)	UW Makerspace	N/A	10/31/2024	1	0.33	0.33	Makerspace
tilt-and-break	PC	UW Makerspace	N/A	10/29/2024	1	0.45	0.45	Makerspace
tilt-and-break	PLA	UW Makerspace	N/A	10/31-11/25	4	0.45	1.80	Makerspace
agar plates	testing agar plates	Amazon	N/A	11/20	3	22.10	66.30	Amazon Agar Plates
TOTAL:								$74.17

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	5	10	5	10	5	10

(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.