Vaginal Self-Swab to Minimize Contact Contamination

Katherine Kafkis (Leader), Jenna Sorenson (Leader), Sara Morehouse (Communicator), Mia LaRico (BWIG), Kaiya Merritt (BSAC), Morgan Kopidlansky (BPAG)

BME 200/300

Advisors: Dr. Pam Kreeger

Client: Dr. Jean Riquelme

Problem Statement

Current STI self-testing methods are contaminating the testing environment

- 99% of women find self-swabs easy to perform [1]
- 84% prefer self-swabs to gynecological exams [1]
- 67% of women received a false positive result due to contamination [2]

Contamination Methods

- Insertion into and swabbing of vaginal canal
  - Hands may be contaminated
- Transport to a media
  - May expel vaginal fluid
  - Spilling or splashing

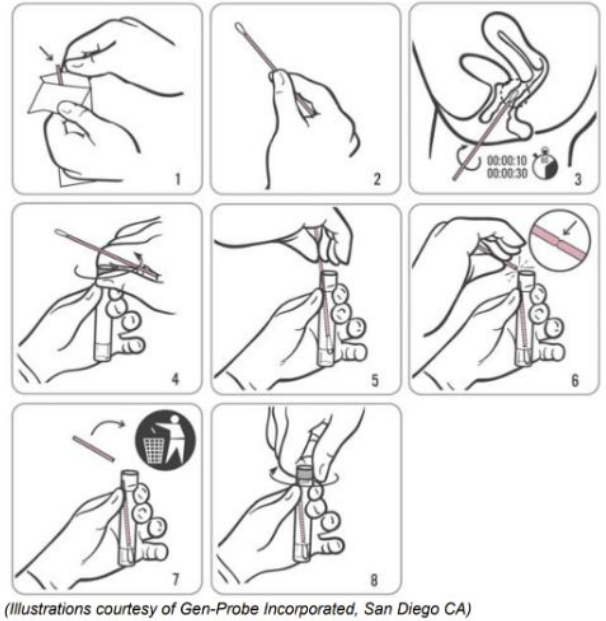


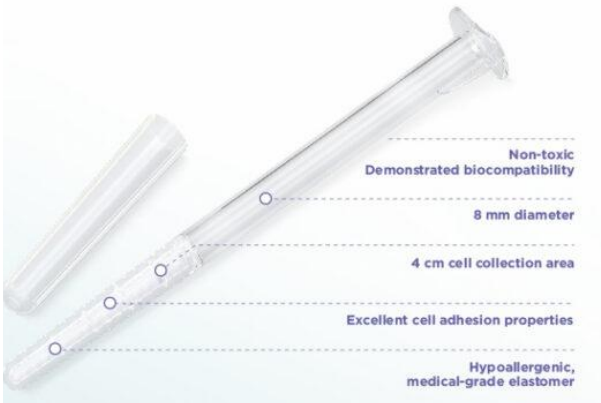
Fig.1 Current STI self-swabbing protocol [3].

Background Information

- STIs are under-tested especially in young women
  - 1 in 4 sexually active adolescent females in the US have an STI [4]
  - Barriers to testing include [4]
    - Socioeconomic
    - Location and transportation
    - Cost
    - Lack of awareness
    - Stigma
  - Many are asymptomatic (Chlamydia - universal testing)
- Long term complications if untreated [1]
  - Infertility
  - Pelvic floor disease

Background Information

- Current tests are Nucleic Acids Amplification test (typically PCR) [1]
- Existing designs do not address contamination of environment
  - Aptima test by Hologic [5]
  - Mía by Xytotest [6]
  - Viba-Brush [6]
- Swab and tube/storage are separate
- Contamination happens every time
- False positives are possible as a result
  - Patient RNA remained on testing room surfaces[2]
- Current designs overall less efficient
  - Require more thorough cleaning



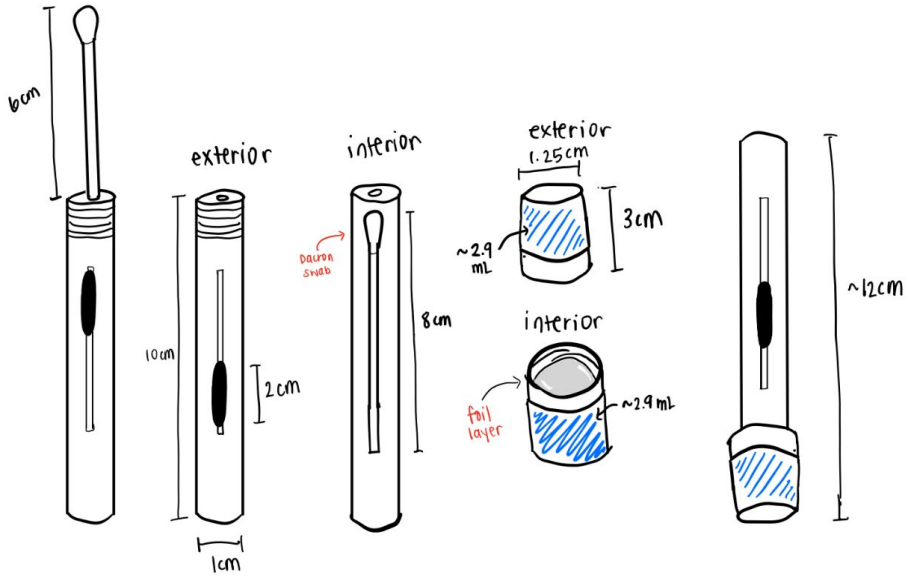
Product Design Specifications

Goal: Create a vaginal self-swab device that reduces contamination of the environment and the sample while prioritizing patient comfort in order to increase universal testing.

- Deployment, retraction, and sealing mechanisms (slider or plunger)
  - Similar to tampon or IUD insertion device
- Head of swab must insert 5 cm into the vagina [3]
- Transport media [1]
- Biocompatible and non-toxic materials
  - Non-cotton fiber (Dacron) [7]
  - Universal transport media
  - Autoclavable body of device (i.e. polypropylene, resin)
- User-friendly
- Overall device length under ~17 cm
- Able to manufacture with 3D-printing
- Budget: $500

https://www.ael.com/media/fwff0m3z/aptima-multitest-swab-transport-media-stm.png

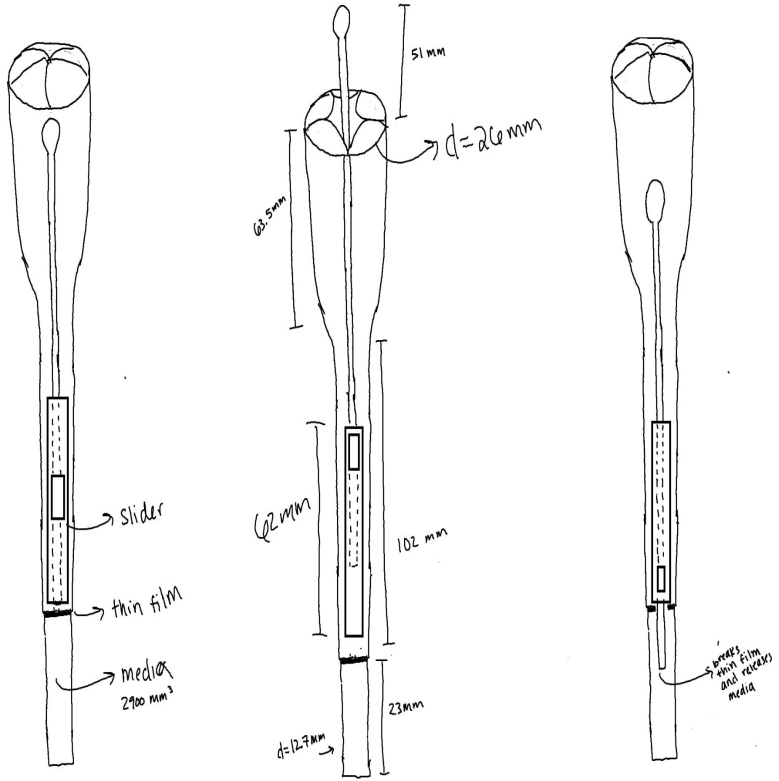
Design Idea 1



“Screw-On Media with Slider”

- Slider allows for deployment & retraction of swab
- Pierce container’s foil with swab
- Unscrewable media container limits spillage
- Potential contamination when unscrewing

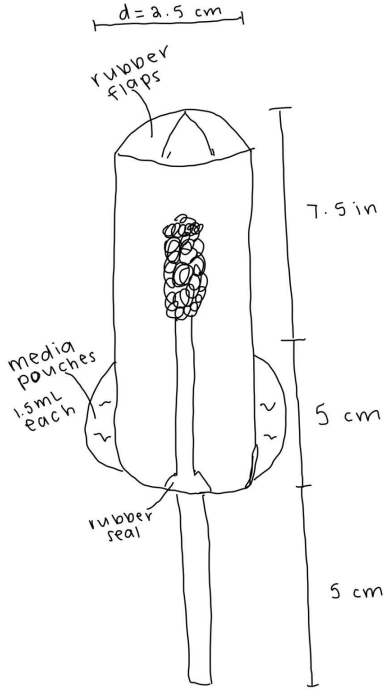
Design Idea 2



“Slider Swab”

- Imitates tampon with slider to deploy/retract swab
- Media at bottom of device
- Film protecting media may be easily broken
- Potential spillage in opening of device

Design Idea 3



“Plunger Swab”

- Insert device in body until media pouches
- Plunger stick pushes & pulls swab in & out
- Squeeze pouches to release media into device
- Risk of leakage in two points

Jenna Sorenson

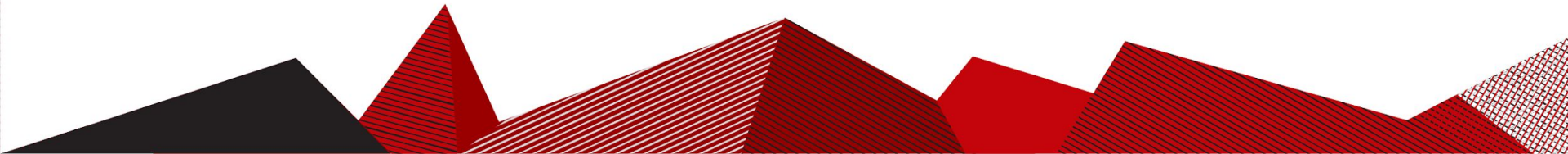
Design Matrix

Criteria	**Weight**	**Design 1:** Screw-on media		**Design 2:** Slider		**Design 3:** Plunger	
Limiting contamination	30	3/5	18	4/5	24	5/5	30
Ease of use	20	3/5	12	4/5	16	5/5	20
Ease of fabrication	15	4/5	12	3/5	9	3/5	9
Patient Comfort	15	4/5	12	4/5	12	5/5	15
Safety	15	5/5	15	3/5	9	3/5	9
Cost	5	3/5	3	4/5	4	4/5	4
Total	**100**	**72**		**74**		**87**	

Jenna Sorenson

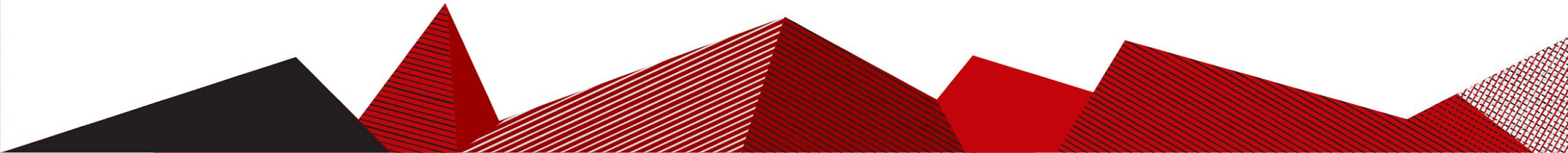
Future Work

- Finalize our final design and its specifications
- Acquire necessary materials
- Begin the fabrication process for our design
- Test the design - media containment
- Analyze our results to evaluate the final prototype



Thank you!

Special thanks to Dr. Jean Riquelme and Dr. Pamela Kreeger for their guidance and input!



References

[1]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.

[2]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.

[3]“Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia.” Accessed: May 05, 2020. [Online]. Available: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf

[4]R. J. Steiner, S. L. Michael, J. E. Hall, L. C. Barrios, and L. Robin, “Youth Violence and Connectedness in Adolescence: What Are the Implications for Later Sexually Transmitted Infections?,” *Journal of Adolescent Health*, vol. 54, no. 3, pp. 312-318.e1, Mar. 2014, doi: https://doi.org/10.1016/j.jadohealth.2013.09.008.

[5]“Aptima® Multitest Swab | Hologic,” *www.hologic.com*. https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab (accessed Sep. 12, 2023).

[6]M. J. Gibert, C. Sánchez-Contador, and G. Artigues, “Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear,” *Scientific Reports*, vol. 13, no. 1, p. 2809, Feb. 2023, doi: https://doi.org/10.1038/s41598-023-29255-y.

[7]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.