BME Design-Fall 2023 - KATHERINE KAFKIS
Complete Notebook

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Table of Contents

Team contact Information

KAIYA MERRITT - Sep 08, 2023, 1:18 PM CDT

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Project description

KATHERINE KAFKIS - Sep 08, 2023, 1:01 PM CDT

Course Number: BME 200/300

Project Name: Vaginal self-swab device to minimize contact contamination

Short Name: Vaginal Self Swab

Project description/problem statement:

Design of a self contained vaginal self swab device for STD screening that avoid patient having to transfer the swab to transport media.

Self swab for sexually transmitted infection has been shown to increase early detection and treatment of STI in women. Universal screening for chlamydia is recommended in all young women, but screening targets are seldom met in practice.
The current self-swab technology in the US involves the patient using the collection system typically emplyoed by their provider, whcih requires collecting a specimen from the vagina and transferring to a closed tube containing liquid media (see references below). This method is rife with possibility for contamination due to improper transfer and to environmental contamination due to spill, splash, etc.
A single-unit dry swab technique could obviate these defects that occur when having patients self-collect a test designed for trained clinician use in a controlled environment.

About the client:

Ethics and Impact of the Project Research

KAIYA MERRITT - Dec 03, 2023, 9:24 PM CST

Title: How can HIV/STI testing services be more accessible and acceptable for gender and sexually diverse young people? A brief report exploring young people's perspectives in Queensland

Date: 11/28/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals:

To research the impact our project will have on different demographics. Identify needs beyond the need of the client when appropriate and is in context. Consider ethical considerations and address the impacts in global, economic, environmental, and societal context.

Content:

- Gender and sexual minority populations bear a disproportionate burden of STI's, and these inequalities are exacerbated within populations of young people.
    - Increasing HIV/STI testing among young people, particularly within gender and sexual minority groups, is an immediate challenge for health promotion practitioners.
- Literature highlights discriminatory and non-inclusive clinical settings where gender and sexually diverse young people do not feel safe or understoond due to gender expression, sexuality or ethnic background as key barriers to HIV/STI testing.
- This article explores HIV/STI testing with gender and sexually diverse young people in Queensland through a participatory workshop designed to understand current barriers to testing and capture ideas to increase accessibility and ac acceptability of HIV/STI testing for this group.
- Participants were aged 20- 25 years and selected their gender identities.
- Should be noted that this study received ethical clearance from the University of Queensland's Human Research Ethics Committee. The participants in the study out lined STI testing barriers related to travel and distance.
    - Proximity to other services, including general practices, pharmacies, mental health and homelessness services, were noted as important.
- The concept of a one-stop-shop was consistent across all groups with notes suggesting an ideal service would include treatment, prevention and access to health and well- being services such as counsellors and social workers.
- Cost barriers associated with consultations and prevention technologies were outlined as barriers, and facilitators included free contraceptives, female and male condoms, dental dams, family planning and hygiene products.
- Participants described the ideal clinical testing space as comfortable and safe.
    - Some suggesting worn couches and beanbags as well as representative flags and information posters.
- All groups noted discriminatory clinical settings as a barrier.
    - Some examples from the data included: forms with sexuality or gender categories that participants did not identify with, the use of binary language by staff, and not feeling safe due to gender expression, sexuality or ethnic background.
- Inclusive service would allow young people to engage in decision- making processes, have a culturally inclusive, comfortable and friendly atmosphere, and provide free sexual and reproductive health technologies.

Conclusions/action items:

This article provided really in-depth insight about people in gender and sexual minority groups that lack equal testing opportunities. While our product is solely intended for vaginal use, it's still important to acknowledge the barriers of inequalities across all gender groups. Our device is intended for clinical use and to be used in a clinical setting, so it's important to note that inclusive service will help break down some of the barriers.

E. Heard, E. Oost, L. McDaid, A. Mutch, J. Dean, and L. Fitzgerald, “How can HIV / STI testing services be more accessible and acceptable for gender and sexually diverse young people? A brief report exploring young people’s perspectives in Queensland,” *Health Promotion Journal of Australia*, Jun. 2019, doi: https://doi.org/10.1002/hpja.263.

Ethical Considerations of Project

Title: Ethical Considerations of Project

Date: 11/28/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- To better understand the ethical implications of our project

- Determining the impact of this project in global, economic, environmental, and social contexts

Content:

Global Context:

- This product has the potential to become commercially available, which could lead to an increase of screening rates globally as "home-based STI screening is a feasible, well-accepted, and often the preferred approach to test for STIs compared to testing at a traditional clinic venue. In almost all studies, higher testing rates were achieved with home- compared to clinic-based STI screening in both men and women. This suggests that improved STI screening rates might be achieved among young individuals, particularly those with less clinic access, by increasing the availability of home STI test kits." (Shih) This means that those who cannot go to clinics for in-person testing the option would now have the opportunity to test at home, increasing screening rates.

Economic Context:

- Taking into account the cost of the final device should be heavily considered. If the cost of the device was too high for the clinic purchasing it in bulk, the cost of the STI-screening would be inflated to adjust for it. If the device was meant to be commercialized for at-home use, an expensive price would deter vulnerable populations from self-screening. For reference, a study in Nairobi found that there was "a 60% decline in the attendance at an STD clinic when patients were charged about $1.75 for diagnosis and treatment, less than half a day pay for most city households." (Ayşen Bulut)

Social Context:

- Many cultures and religions view the act of inserting an object into the vagina as taboo and unacceptable. For example, in China, tampons are scarcely found, and many Chinese women have never even heard of a tampon. The absence of tampons in Chinese society is attributed to several factors, one of which being "Chinese girls may worry that tampons will break the hymen, a symbol of virginity and purity valued in a Confucian society" (Yang) and that "some people think of using tampons as shameful because they associate tampons with sexual activity, another taboo topic in China" (Yang). The tampon-esque design of the final product may eliminate certain religious groups and cultures from its use.

Conclusions/action items:

- Overall, the product has the potential to increase screening rates globally due to more accessible testing, but some cultural and religious groups would be excluded from using this product due to the mechanism of testing being a part of the product being inserted into the vagina.

- Ayşen Bulut, Cost benefit analysis of sexually transmitted diseases, *FEMS Immunology & Medical Microbiology*, Volume 24, Issue 4, July 1999, Pages 461–467, https://doi.org/10.1111/j.1574-695X.1999.tb01319.x

- Shih SL, Graseck AS, Secura GM, Peipert JF. Screening for sexually transmitted infections at home or in the clinic? Curr Opin Infect Dis. 2011 Feb;24(1):78-84. doi: 10.1097/QCO.0b013e32834204a8. PMID: 21124216; PMCID: PMC3125396.

-Yang Y, Ma X, Myrick JG. Social media exposure, interpersonal network, and tampon use intention: A multigroup comparison based on network structure. J Health Psychol. 2023 Mar;28(4):343-355. doi: 10.1177/13591053221120332. Epub 2022 Sep 1. PMID: 36047030; PMCID: PMC10026152.

Ethics and Barriers to STI Prevention/Testing 11-29-23

MORGAN KOPIDLANSKY - Dec 06, 2023, 5:32 PM CST

Title: "Sexually Transmitted Infections: Adopting a Sexual Health Paradigm"

Date: 11/29/23

Content by: Morgan Kopidlansky

Present:

Goals: Gain more understanding on the ethics regarding our project in greater context

Content:

- STIs pose a risk to public health that is worsened by stigma, misconceptions, differing values due to the sexual nature, discrimination, and socioeconomic barriers

- These barriers are much more prevalent in marginalized groups

-Stigma - leads to a lack of discussion and education

-People are less likely to seek out treatment or may not even be aware of available resources

-Religious beliefs can also play a role in whether or not individuals will opt to test

-Members of the LGBTQ are one such marginalized group that is heavily impacted especially by stigma

-Stigma is a product of the social environment and an increase of education would be help to limit it overall

-Disparities between race, age, gender identity, sexual orientation are largely in part due to racism/discrimination as well as socioeconomic disadvantage

- Lack of access to education/access to proper healthcare on top of the existing stigma heavily impact people within these marginalized groups

- putting policy in place at each level (local, state, federal) with protection/opportunity for all would be one step in the direction of fixing the injustice caused by these barriers

-treating sexual health as apart of overall health/healthcare (a human right) would open up a larger conversation and help to breakdown both the barriers of stigma/lack of knowledge but also those caused by lack of resources (as a result of discrimination)

Conclusions/action items:

Our project cannot address many of these barriers and ethical concerns, but they are very important to be aware of. Since our product would primarily be for in-clinic use, it is important to breakdown barriers at this point (easy instructions, low cost, inclusive and non-discriminatory service) and acknowledge that certain groups of people would still not benefit from our design. Overall, an increase in screening and testing of STIs is very possible even when just a few barriers can be/are limited.

National Academies of Sciences, Engineering, and Medicine;Health and Medicine Division;Board on Population Health and Public Health Practice;Committee on Prevention and Control of Sexually Transmitted Infections in the United States; Crowley JS, Geller AB, Vermund SH, editors. Sexually Transmitted Infections: Adopting a Sexual Health Paradigm. Washington (DC): National Academies Press (US); 2021 Mar 24.

1, Addressing STI Epidemics: Integrating Sexual Health, Intersectionality, and Social Determinants. Available from: https://www.ncbi.nlm.nih.gov/books/NBK573147/

Ethics and Impact of the Project - Medical Waste

MORGAN KOPIDLANSKY - Dec 12, 2023, 9:21 AM CST

Title: "Plastic panic in the pandemic: How single-use items meant to protect us will harm the planet"

Date: 12/9/23

Content by: Morgan Kopidlansky

Present:

Goals: Gain more understanding on the ethics regarding single-use plastic in the Medical field

Content:

- Single-use plastic in the medical field has seen a surge during the pandemic

-"a medical professional enters a patient's space about 50 to 80 times per day — and nearly every time, they have to wear a new set of personal protective equipment, or PPE ... When the visit is over, the equipment is thrown away."

- Plastics are polymers made from fossil fuels and take hundreds of years to decompose

- Medical waste is an issue all over the world (increasingly worse globally since the pandemic) and creates more waste that sits in landfills or enters the environment

-Doctors wear lots of protective gear that is replaced between patients (most of which is necessary for safety, but still plays a role in overall waste)

- Medical equipment is often frequently replaced especially during the pandemic (ex. stethoscopes)

- Once in the environment, plastics/microplastics cause harm

  - Incineration leads to release of toxic fumes

  - In landfills, chemicals can leak into groundwater

  - wildlife can be impacted (tangled/choking)

Conclusions/action items: Many forms of medical waste is unavoidable due to safety concerns, but there have been significant increases in overall plastic waste that could more easily be avoided. Our device has the potential to contribute even further to the more avoidable waste created. Re-using of certain portions of the device after proper sterilization may be possible to help limit waste produced. Looking into more environmentally friendly materials is also something that should be considered in the future (other plastics, carboard, etc). Reducing the overall size of our device will also be a step in a more environmentally conscious direction. Considering all of these things as well as the overall impact of single-use plastic is very important and should be kept in mind as this project continues.

Fishman, Zachary. "Plastic Panic in the Pandemic: How Single-Use Items Meant to Protect Us Will Harm the Planet." *Medill Reports Chicago*, 23 June 2020, news.medill.northwestern.edu/chicago/plastic-panic-during-the-pandemic-how-single-use-items-meant-to-protect-us-will-harmthe-planet/.

9/15/23 - Client Meeting 1

Title: First Client Meeting

Date: 9/15/23

Content by:

Present: All team members

Goals: Get to know the client and what they are asking of us

Content:

- meet with UW laboratory that actually tests the specimens - microbiology

1. Do you have a certain vision for this project or any guidelines you'd want us to follow?

- slider that retracts and then seals. Sliding down releases the swab. Sliding back up retracts it and seals the specimen in a media.

- similar to an IUD insertion device

- Is your goal only to limit contact contamination?
  - Main goal as of right now is to minimize contamination in the clinic and of the sample.
- Are you seeking to have a dry swab design that is easier to transport?
- Is making the design more accessible or possibly an at-home test one of your goals?
  - making universal testing more accessible: 6-8% universal testing
    - doubling that would be great
    - prevent infertility and prevent the spread of the disease
  - At-home testing has very low return rates, as for a general screen there is not really a motivator for patients to complete the test.
- End goal of over-the-counter testing?

2. Do you want a certain liquid contained in the self-swab device (can we use water for design purposes)?

Could you provide us with the media to be used? Standard cellular media. Could find online.

3. Will the self-swab we are designing hypothetically be used for screening any STI or is it for a specific STI?

- chlamydia, as this is the recommended STI for universal screening. In the clinic they tend to do it together with gonorrhea but only chlamydia screening is officially recommended so insurance may not cover gonorrhea screening.

4. Are there any swab materials that you recommend that are shown to not cause irritation?

- cannot be a cotton swab: contains fibers that interfere with the test

- proprietary swab. unisex specimen collection swab. noncotton fiber. proprietary fiber.

5. How often do you see cases of contact contamination?

- Must presume that contact contamination happens every time

- In order to place the swab into the sample tube, patients either have to stab the swab through a foil cover on the tube or peel the foil off with their hands. Either way, this process risks contamination of the swab and the environment.

6. Do you think that following the concept of a tampon design would be effective?

- Yes. Also look into IUD insertion device

7. How many of your patients do you think prefer the self-swab method over other methods of STI testing?

8. What is your budget for this project?

- $500

**Dr. Riquelme is out of the country on November 7-14.

Conclusions/action items:

The team will meet with the client to get these important questions answered. We will also continue to conduct our own independent research on the biology of STIs (where the bacteria grow within the vaginal canal) as well as research on current sealing methods that rely on the retraction of a component (retracting the swab should also seal the tube containing the sample).

After meeting with the client, our main takeaway is that her goal is for us to design a mechanical process for the sample collection that involves the use of a deployment slider or button that can be retracted after sampling into media, similar to designs we discussed earlier today in our advisor meeting. The main purpose of doing so is to make universal testing for chlamydia more accessible, in order to help prevent infertility and prevent the spread of disease. The best way of doing so may be to make this test possible to be completed at-home, but the main goal is to design a more streamlined process of sample collection.

10/6/23 - Client Meeting 2

JENNA SORENSON - Oct 06, 2023, 5:04 PM CDT

Title: Second Client Meeting

Date: 10/6/23

Content by: Jenna Sorenson

Present: All team members

Goals: Show the client our designs and ask if they are address contamination in the way she intended

Content:

- showed clients out three ideas

- she asked about how the device would open and close for #2

- single unit device is preferable

- for design #1, could be good to have a flange so that they cannot insert the device too deep and contaminate further

- likes the idea of a cap for 2 & 3

- likes the idea of the intuitive design that people know how to use

- want to make sure that the lab people can access the media liquid for testing

- #3 could be hard to manufacture

- #3 is patient friendly, #1 is lab friendly but lab friendly goes with safety

Conclusions/action items:

Pick up dacron swabs from her at Wingra clinic

11/1/23 - Client Meeting 3

KAIYA MERRITT - Nov 01, 2023, 4:57 PM CDT

Title: Third Client Meeting

Date: 11/1/23

Content by: Kaiya Merritt

Present: Kaiya, Katherine, Sara, Mia.

Goals: To show our client the final SolidWorks design and update her on the prototyping process.

Content:

- Shared our screen and showed her the SolidWorks of the design.
- Explained each piece of the swab to her.
- She said our measurements seem good.
- Told her the total for the print was $4.81 with the polypropylene material.
- We will email her a receipt of the total.
- Told her our two plans for leak testing: weighing the device vs. using dye.
- Mechanical testing of the device with hydraulic presses.
- She noted that she likes the aesthetics of our design.
- Updated her on Show-and-tell this Friday with getting advice and questions answered by students and faculty.
- Told her about WARF and that we are meeting with them on Friday.
- Exact Sciences in Madison could be interested - something she just pointed out when talking to her about WARF.
- Find our best biomaterial to print with eventually, okay to print with whatever plastic for show-and-tell.
- Cap needs to hold enough liquid to have swab completely submerged in liquid.
- Possible induction seal for sealing the media in the cap.
- Client will be back in town November 15th.

Conclusions/action items:

Keep updating the client with our progress reports and set up another meeting in a few weeks or so.

12/14/12 - Client Meeting 4

JENNA SORENSON - Dec 12, 2023, 9:01 PM CST

Title: Client Meeting 4

Date: 12/14/12

Content by:

Present: Jenna, Katherine, Mia, Kaiya, Morgan

Goals: Give her our final presentation and discuss budget

Content:

TBD

Conclusions/action items:

9/15/23 - Advisor Meeting #1

Title: Advisor Meeting #1

Date: 9/15/23

Content by: Mia LaRico

Present: Mia LaRico, Jenna Sorenson, Katherine Kafkis, Kaiya Merritt, Morgan Kopidlansky, Sara Morehouse

Goals:

- Update advisor on progress team has made since first class

- Ask advisor about frequency of notebook checks and method of grading

Content:

- Let advisor know that we have a meeting with our client today at 4:30pm and are hoping to gain clarification on what specifications the client has for us regarding the project design and budget.

- Does the client want this product to be something that can be done from home or does the client want it to be restricted to doctor's office use?

- Discussed competitive designs for current product with advisor

- Discussed current ideas for product design with advisor (ex: mechanism for deployment, sealing mechanisms, whether or not to use media, etc.)

- Discussed current limitations on screening procedures

- Using media involves the risk of media spilling

- Other methods involve refrigeration

- Discussed possibility of the product being approved for OTC use

- Advisor will be grading notebook based on ability to explain reasoning behind certain designs, why we chose to do what we did, etc.

- Discussed possibility of patenting project/product

Conclusions/action items:

- Work on PDS

- Meet with client

- Continue research into potential product design

9/22/23 - Advisor Meeting #2

MIA LARICO - Sep 22, 2023, 12:35 PM CDT

Title: 9/22/23 - Advisor Meeting #2

Date: 9/22/23

Content by: Mia LaRico

Present: Mia LaRico, Jenna Sorenson, Kaiya Merritt, Katherine Kafkis, Sara Morehouse, Morgan Kopidlansky

Goals:

- Update advisor on meeting with client

- Update advisor on progress made this week

Content:

- Told advisor about what we discussed with the client during our meeting last week

- Agreed that "preventing contamination" was misconstrued and is actually about preventing clinic room contamination and not about preventing contamination of the sample

Conclusions/action items:

- Conduct more research into how clinic rooms are actually contaminated during the self-swab process and brainstorm ways that we can redesign a self-swab device that would prevent that

- Ask client about her experience with clinic room contamination

10/1/23 - Advisor Meeting #3

JENNA SORENSON - Oct 01, 2023, 5:24 PM CDT

Title: 10/1/23 Advisor Meeting #3

Date: 10/1/23

Content by: Mia LaRico

Present: Mia LaRico, Pam Kreeger, Sara Morehouse, Kaiya Merritt, Jenna Sorenson

Goals:

-Go over design ideas and design matrix with Advisor

- Update advisor on where we are at in terms of the project

Content:

- Concern with design #1 about being user-friendly
    - Confusing that the orientation of the swab changes during the design
- Concern with design #3 about media pouches on side
    - May be a good method of telling patient where to stop inserting
- Will not need to make a CAD design for each design in the design matrix

Conclusions/action items:

- Continue work on preliminary presentation slides and presentation report
- Think about how we are going to fabricate design with ECB unusable for the moment
    - Probably will be more 3D printing-heavy

10-15-23 Advisor meeting #4

MORGAN KOPIDLANSKY - Oct 15, 2023, 1:19 PM CDT

Title: 10/15/23 Advisor Meeting #4

Date: 10/15/23

Content by: Morgan Kopidlansky

Present: Mia LaRico, Pam Kreeger, Sara Morehouse, Morgan Kopidlansky, Jenna Sorenson, Katherine Kafkis

Goals:

-Go over proposed final design and get feedback from our advisor

Content:

- flip over entire device before pushing through so swab stays in media - easier in terms of overall sealing

-include film to peel off before inserting swab (not rubber flaps - to avoid expelling anything during retraction)

-rubber blockade still important - backup of any leakage

-do not want to design to be overly complicated (we don't want too many parts - harder to fabricate)

-can include more ways to test (more than just survey) if we make more than one device : test if it leaks, simulate possible contamination (dye/simulate vagina - tube potentially)

-make a stop onto plunger and make plunger longer (in solidworks)

-make prototype (whichever is faster) to do initial surveying

- write up a testing plan to be looked over before implementing

Conclusions/action items:

Moving forward, we will plan on making an initial prototype (whichever can be made fastest) in order to start surveying and have something tangible for show and tell. We will also communicate with our client about how she wants to be billed (all at once or as we but things).

10/30/23 - Advisor Meeting #5

MORGAN KOPIDLANSKY - Oct 30, 2023, 12:28 PM CDT

Title: Advisor meeting #5

Date: 10-30-23

Content by: Morgan Kopidlansky

Present: Mia LaRico, Pam Kreeger, Morgan Kopidlansky, Jenna Sorenson, Katherine Kafkis

Goals: go over testing plans with our advisor

Content:

- 4 subplans - leaking, ease of use, clinical use, mechanical strength

-leaking testing plan - use colored dye and set device on filter paper - will be able to see any leakage, can be done for both leakage tests

-3-5 trials for leakage test

- include picture of prototype for survey rather than just a sketch

- survey will be classified as non human subjects - do not collect emails when surveying -must be anonymous!!

-for forwarding survey - Dr. P, SWE would also be an option, GWIS (only/mostly female), sororities as well

-consider population being tested- bias, note it

-ask client about clinical use testing plan - how to determine if you have scraped the side

-play around with dye, could use powder/spice that has color - may be easier to get a thin coating

-mechanical testing - for compressive/tensile strength - gripping

-could do mechanical testing of actual device

-go through plans, see what iterations we need to do/how to adjust

-survey questions should be very specific - people who do not write questions should take the survey

-come up with questions to ask other groups during show and tell - get more opinions/suggestions/feedback (mechanics, ask female students - mini survey)

Conclusions/action items:

A meeting with the TeamLab to clarify the SolidWorks design (one time snap) is happening on Tuesday. We will show our advisor the protoype in person after it has been 3d printed (later this week). We will prepare for show and tell this week and begin working towards testing our prototype after it has been printed.

12/1/23 - Advisor Meeting #6

MIA LARICO - Dec 01, 2023, 1:27 PM CST

Title: 12/1/23 Advisor Meeting #6

Date: 12/1/23

Content by: Mia LaRico

Present: Mia LaRico, Pam Kreeger, Katherine Kafkis, Kaiya Merrit, Sara Morehouse, Jenna Sorenson, Morgan Kopidlansky

Goals:

Update advisor about progress with testing and ask for advice.

Content:

- Product leaked when put right-side up. Plan on incorporating o-ring at base of plunger

- Clinical testing went well

- Could not figure out MTS machine

- Cannot ask for any health information on survey

- Patent denied by Wharf

- Poster board is usually 4x3 feet

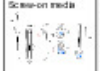
Conclusions/action items:

- Contact Dr. Willy for help with MTS machine

Design Matrix

JENNA SORENSON - Oct 01, 2023, 3:39 PM CDT

Self-Swab STI Test 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**	

(See larger images of the design ideas at the bottom of this document)

Criteria Descriptions:

Limiting contamination - This criteria refers to the ability of the overall design to limit the contamination of both the testing site and the swab used for specimen collection. A design that receives a 5/5 should ensure that the testing swab remains covered when not inside the vaginal canal and should also decrease the number of steps or transfers (transfer of the specimen into a media) required during testing.

Ease of Use - This criteria is a measure of how easily users can use a product. A design that receives a 5/5, in this case, would include easy to understand instructions in addition to being simple enough for patients to get viable samples on their own. The product should be user-friendly and serve to decrease barriers to testing through increased usability for all patients.

Ease of Fabrication - This criteria is a measure of the feasibility of the team having the skills and resources to fabricate the device. As one of the main goals for this device is to increase the

Download

Self_Swab_Design_Matrix.pdf (816 kB)

Proposed Final Design

JENNA SORENSON - Dec 12, 2023, 9:03 PM CST

Title: Proposed Final Design

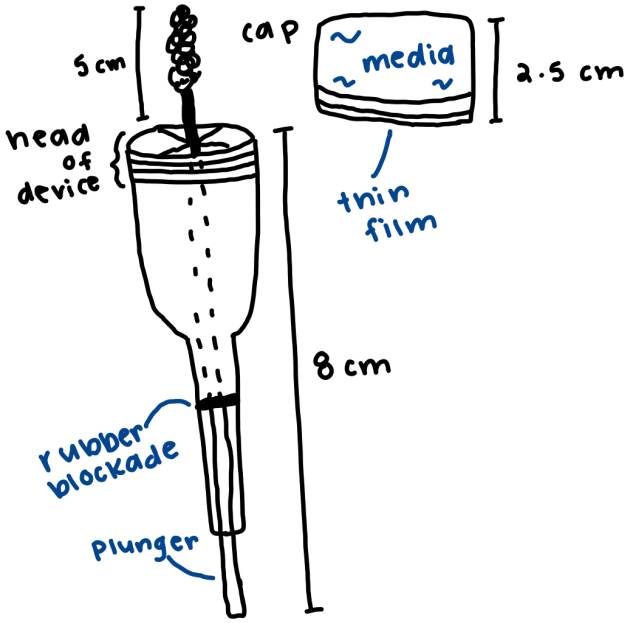
Date: 10/11/23

Content by: Jenna Sorenson

Present:

Goals: Demonstrate and explain the proposed final design

Content:



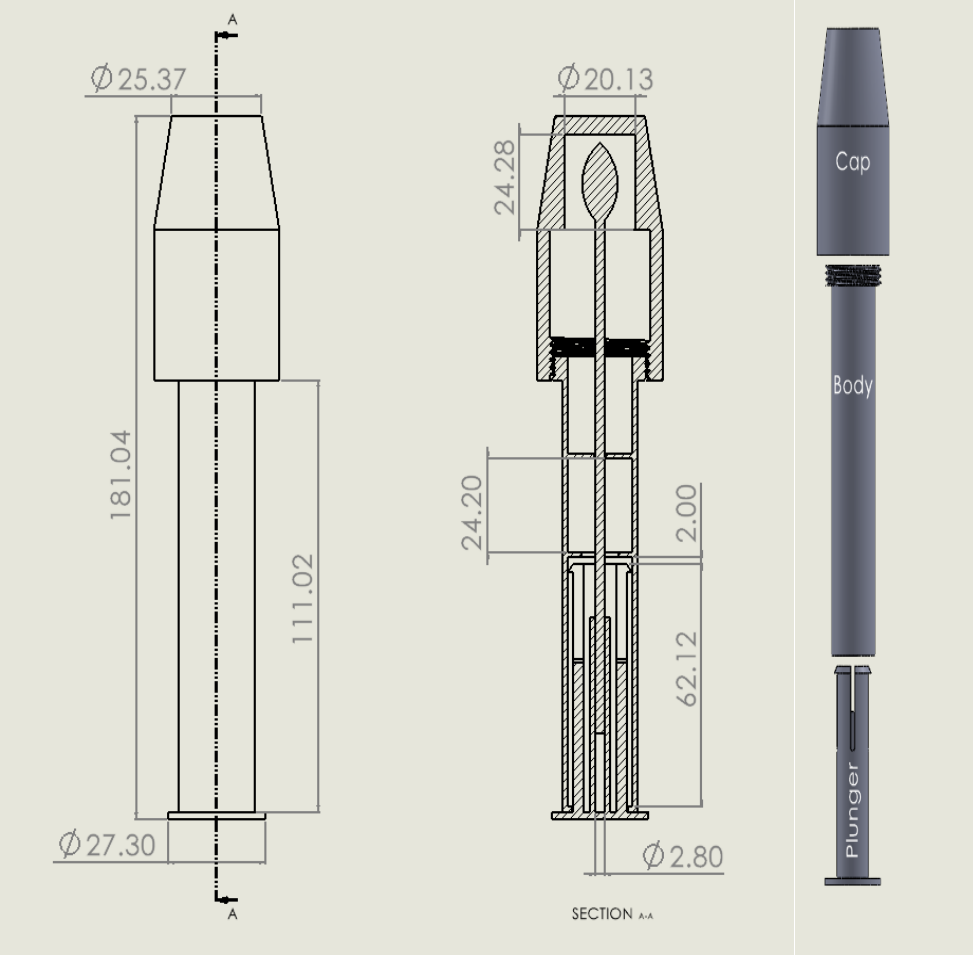
The proposed final design is inspired by the structure of a tampon, including a plunger stick that attaches to the swab. The patient rests the head of the device on the entrance to the vagina (without inserting the device inside the body) and pushes the plunger up to insert the swab into the vagina. After completing a circular swab motion five times, the patient pulls the plunger down and the swab is removed from the body. At this point, the top of the device and the swab are contaminated, but the swab is housed in the device, so it is safe from environmental contamination and will not taint any surfaces. To address the contamination of the top of the device, the user will screw on a media cap, as both the cap and the top of the device are threaded. At this point, the user will deploy the swab once more by pushing the plunger up and using the swab itself to break a thin layer of film on the bottom of the cap, releasing the media into the device. The liquid media helps to preserve the swab and promotes successful testing. Keeping the device in an upside-down orientation will limit the possibility of leaks and allow the swab to remain submerged in media, but a rubber stopper on the plunger will also prevent leaking should the device be jostled. In its final position, the swab will be resting in the media in the cap while the device is in an upside-down position, with the head of the device positioned downwards.

Conclusions/action items:

Start a SolidWorks drawing of this design

Final Design

JENNA SORENSON - Dec 12, 2023, 9:05 PM CST



Solidworks drawing process

JENNA SORENSON - Dec 12, 2023, 9:09 PM CST

Title: SolidWorks process

Date: 10/14-11/12

Content by: Jenna Sorenson

Present:

Goals: Explain the design process the team underwent in SolidWorks

Content:

- Got help from Jesse in the TeamLab on making the initial drawing (structure of cap, plunger, one-time snap)

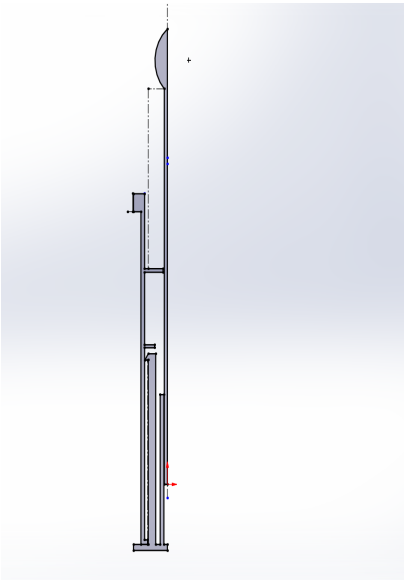
- Had to make the body longer to fit the whole swab

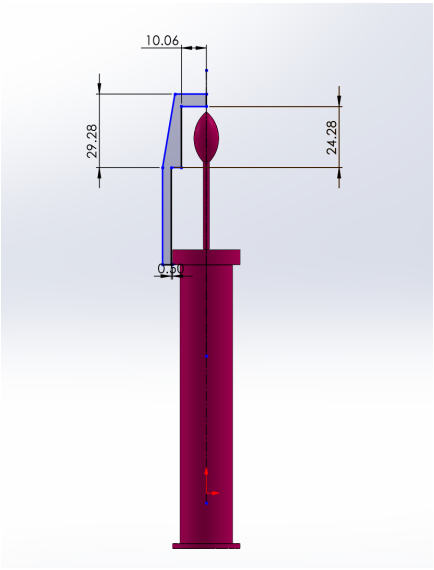
- Added a relief mechanism to the plunger

- Made the relief components thicker so they were less likely to snap off when the plunger was fitted into the body via the one-time snap system

- Made the cap overhang over the sides of the body to cover potentially contaminated areas

- made the cap taller so the plunger could be fully extended into it





Conclusions/action items:

- add a twist lock between plunger and body

- add O-rings to minimize leaking

BPAG purchasing guidelines meeting

MORGAN KOPIDLANSKY - Sep 29, 2023, 12:40 PM CDT

Title: BPAG meeting notes

Date: 9/29/2023

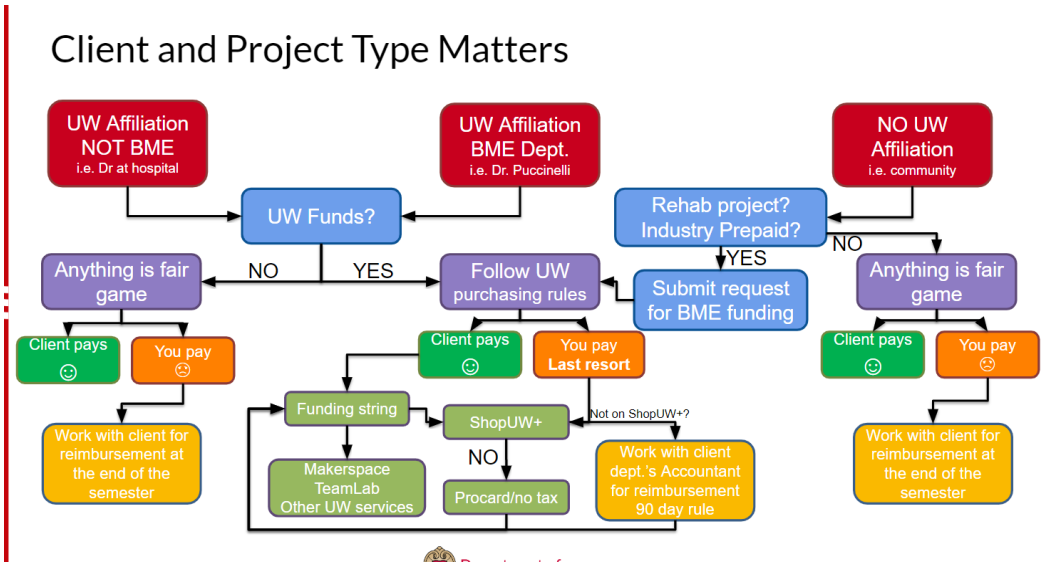
Content by: Morgan Kopidlansky

Present:

Goals: Learn about the purchasing guidelines

Content:

- Either get client to purchase for you OR
- We pay and then get reimbursed
- Get all expenses approved by client PRIOR to purchase
- Keep track of all purchases (detailed receipts kept in notebook)
- Our client is UW affiliated - UW funds?
    - If not then anything is fair game (work with client for reimbursement)
    - If yes, we pay as last resort-harder to get reimbursed
        - Funding string - shopuw+ or makerspace/teamlab/etc



- ShopUW+
    - Complete list of vendors
    - Client pays for materials with a funding string - we cannot order directly
    - If client is using UW funds, we must show vendors do not have product available to purchase elsewhere
- Makerspace
    - 3d printing
    - Expertise
    - Mini-mart
    - Payment types
        - Your client- fund number
            - Clients can set up account with funding string
            - We fill out team information excel sheet for your client – name team BMEDesign_team_catchphase
        - Us- credit card, debit, wiscard
- Teamlab (COE shop)
    - Machining, woodworking - subtractive manufacturing
    - Expertise
    - Stockroom (free with fee-any client)
    - Tool crib - hand tools, force gauges
- Reimbursement

        - Only BPAG will be reimbursed
        - E-reimbursement from UW clients- start before poster session -last resort
            - 90 days to be reimbursed from day of purchase
            - Detailed original receipt needed (not screenshot)
            - Requires valid project number, obtained from UW client
- BME design expenses for team
        - Labarchives notebook -$15 per team
        - Poster printing - about $50 per team
        - No teamlab fee
- Accounting
        - Keep table with ALL vital info needed to purchase again
        - Ensure table is legible-make sure links are clickable (make table for final design- only stuff we actually used for final design)
        - Keep in progress reports, team notebook,
- Contact Dr.P before completing transactions to avoid problems

Conclusions/action items:

This meeting gave me the information necessary to work with our client for purchasing and keeping track of those purchases.

Preliminary Materials and Cost estimates

SARA MOREHOUSE - Oct 11, 2023, 2:41 PM CDT

Title: Preliminary materials and cost estimates

Date: 10/11/23

Content by: Morgan Kopidlansky

Present: n/a

Goals: To describe the materials we will use and their predicted cost.

Content:

- Swab: The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab. The shaft of the swab is plastic. 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.
- Plunger: The plunger will be 3D printed using polypropylene. Polypropylene is a synthetic, autoclavable resin. It is biocompatible and often used in medical devices. This material is readily available for use in the Makerspace.
- Rubber Seal: The plunger will have a seal made from rubber that prevents leakage of media from the bottom of the device. This will be similar to the mechanism used in a syringe plunger.
- Cap: The cap will also be 3D printed using polypropylene due its biocompatibility and autoclavability. This material is readily available for use in the Makerspace. After which, the universal media will be sealed inside the cap with a thin, puncturable foil. Sealing the media within a thin foil keeps it from spilling or being contaminated, but also allows the media to be easily accessed when punctured by the swab. This foil will be made of aluminum foil.
- Body of device: The body of the device will also be 3D printed with polypropylene since it is biocompatible and autoclavable. This material is readily available for use in the Makerspace.

Material	Cost	Price Estimate	Expected Vendor	Part Number
Polypropylene	$0.13/gram	around $33	Makerspace	-
Transport Media	Free	-	Provided by client	-
Rubber Blockade	$1.87/per	$46.40 for pack of 25	Sigma-Aldrich	Z569941
Foil	$0.09/square foot	$4.48/pack	Amazon	B00279LYL6
Dacron Swab	Free	-	Provided by client	-

Conclusions/action items:

We will most likely use these materials however the cost may not be accurate as we do not know exactly how much we will need yet.

Final Materials and Cost

MORGAN KOPIDLANSKY - Dec 12, 2023, 9:31 AM CST

Title: Preliminary materials and cost estimates

Date: 12/12/23

Content by: Morgan Kopidlansky

Present: n/a

Goals: To describe the materials we will used and the total cost

Content:

Swab: The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab. The shaft of the swab is plastic. 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: Universal 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. Aptima Multitest Swab Transport Media (STM) was provided by the client and used solely for demonstration purposes. This media will ultimately be contained within the cap of the device.

Red Dye: Red dye was used as an indicator for testing. Its vibrance allowed the results of both the Leak Test and Clinical Use Test to be very clearly determined. A failing Leak test visibly had red dye seeping out of the device onto the paper while a passing Clinical Use test visibly had red dye staining the swab. The red dye was also low cost and easy to acquire.

Foil: Aluminum foil was used solely to mimic the sealing of both the body of the device and the cap. It was a non-expensive material that allowed for a more complete demonstration of how a medical-grade foil would be used once acquired. Sealing the swab within the body to maintain sterility before collecting a sample, and sealing media in the cap before being punctured were the two main criteria showcased with the foil.

Tube: The tube was used to mimic the vaginal canal in order to conduct Clinical Use Testing. It was 3D printed out of Polycarbonate (a misprinted cap), so it was readily available for use. The tube was also long enough and wide enough to properly insert the swab the necessary depth for an STI test, approximately 5 centimeters.

Initial prototypes: All parts of each initial prototype (body, plunger, and cap) were 3D printed out of Polycarbonate. It is an autoclavable, non-toxic, and biocompatible plastic. Polycarbonate was primarily selected for its availability at the UW Makerspace.

Final prototype: All parts of the final prototype (body, plunger, and cap) were printed out of pink Polylactic Acid (PLA). PLA is a biopolymer that is commonly used in medical applications. PLA is biocompatible and non-toxic, however it does not perform well at autoclave temperatures. It was chosen as the material for the final prototype due to its availability at the UW Makerspace as well as for aesthetic purposes.

Expense spreadsheet including the material, the cost per unit, the total cost, the vender, and the part number.

Material	Price per Unit	Total Cost	Place Purchased	Part Number
Polycarbonate	$3.74/device (on average)	$29.92	Makerspace	-

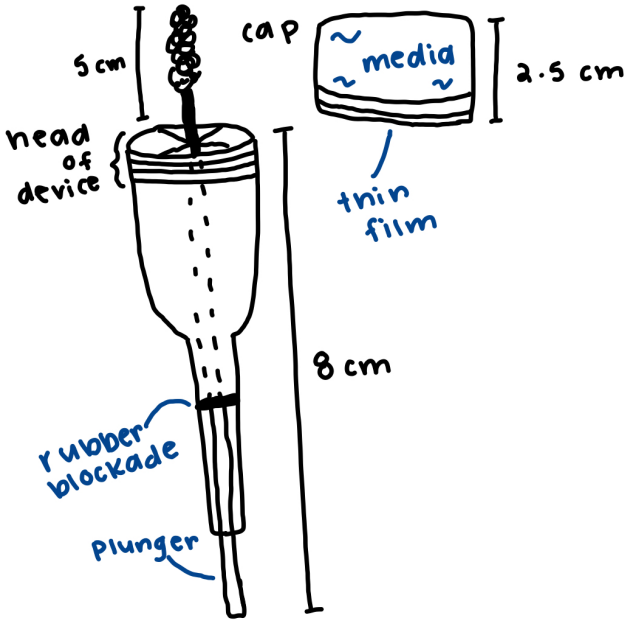
Polylactic Acid	$5.82/device (on average)	$23.28	Makerspace	-
Transport Media	-	-	Provided by client	-
Red Dye Testing Liquid	$2.50	$2.50	Makerspace Vending Machine	-
Foil	-	-	Already owned	-
Dacron Swab	-	-	Provided by client	-

Total expenses this semester: $55.70

Conclusions/action items: Our total expenses this semester were well under our budget of $500. Our expenses were comprised primarily of different iterations of prototypes.

10/11/23 - Proposed Final Design

JENNA SORENSON - Oct 11, 2023, 5:29 PM CDT



- User rests device on outside of body then uses plunger to push the swab up into the vaginal canal
- Insert swab approximately 5 cm inside the body and make circular motions for 30 seconds
- The pull plunger back down to reinsert swab into device
- screw media cap onto top of device
- push plunger up again so the swab breaks through the film and is resting in the media

10/23/23 - Meeting with TeamLab

JENNA SORENSON - Oct 23, 2023, 12:35 PM CDT

Title: Meeting with TeamLab

Date: 10/23/23

Content by: Jenna Sorenson

Present: Jenna, Katherine, Mia, Kaiya, Morgan

Goals: learn how we can fabricate our first prototype

Content:

- thought we'd want to fabricate with lathe and mill... they advise 3D printing since it is not that expensive ($5-10) & supports are easily made

- making a "one-snap" plunger so that the plunger cannot be removed or pushed too far into the device once it is inserted

- make a constriction around the top of the swab with some type of seal (O-ring?) to prevent leaking from the bottom

- threads will not seal so maybe need something else

- threads inside the device will minimize any potential discomfort to the user

- sketch half of device and then revolve it

- use swab in drawing for reference

Conclusions/action items:

switch gears to 3D printing

JENNA SORENSON - Oct 23, 2023, 12:36 PM CDT

Download

IMG_0434.HEIC (2.16 MB)

JENNA SORENSON - Oct 23, 2023, 12:36 PM CDT

Download

IMG_0435.heic (1.96 MB)

11/5/23 - Initial Prototype

KATHERINE KAFKIS - Nov 10, 2023, 12:12 PM CST

Title: Initial Prototype Fabrication Process

Date: 11/5/23

Content by: Katherine Kafkis

Present: N/A

Goals: To outline the ups and downs of the initial 3D printing process.

Content:

- An initial print using the Bambu printers with polypropylene (PP) was unsuccessful
  - Build plate that is meant for PC was used for a PP print leading to detachment
- A secondary print using the correct build plate on the Bambu printers was also unsuccessful
  - The cooling to heating ratio for the print was incorrect. Design was being cooled off too quickly and kept popping off the build plate
- A final print using polycarbonate on the Ultimaker was successful and took approximately 7 hours
  - The final print was grey (almost metallic) in color which will be changed to a light pink
- A secondary print will be completed with modifications based on the feedback received from show and tell
  - the threading on the outside of the design will be moved to the interior
  - the cap will be fabricated and 3D printed
  - additional overhang on our one-time snap mechanism will be added to prevent users form completely pulling the plunger out

Conclusions/action items:

Meet as a team to edit the SolidWorks design. Run a mechanical test on the modified SolidWorks design. Attempt to print the modified design in polypropylene, if this doesn't work, set up an individual meeting with the makerspace to discuss the issues with the 3D print. Make sure to print a few copies of the design so we can test them and break a few prototypes.

11/14/23 - Second Prototype

JENNA SORENSON - Nov 14, 2023, 6:45 PM CST

Title: Second Prototype Fabrication

Date: 11/14/23

Content by: Jenna Sorenson

Present: Jenna Sorenson, Katherine Kafkis & Morgan Kopidlansky

Goals: Change SolidWorks drawing & 3D print second prototype

Content:

Changed SolidWorks drawing to include:

- a slightly wider top rim

- a slightly skinner body

- a white colored body (not as intimidating as the metallic shade previously used)

- an overhang on the cap to cover potentially contaminated area

- more overlap in the one-time snap feature so the plunger is not as easily removed

3D printing summary:

- went a lot smoother than first time due to immediate changes in the software to allow printing with polypropylene (instead of PFA previously used)

- device took around 2.5 hours to print

- was able to print cap, plunger, and body in the same go

Conclusions/action items:

Need to conduct testing on second prototype

11/15/23 - Meeting with Jesse from DesignLab

KAIYA MERRITT - Nov 15, 2023, 3:19 PM CST

Title: Meeting with Jesse from DesignLab

Date: 11/15/23

Content by: Kaiya Merritt

Present: Kaiya, Katherine, Sara, Morgan

Goals: To discuss a sealing mechanism regarding the foil on our cap and implementing an O-ring.

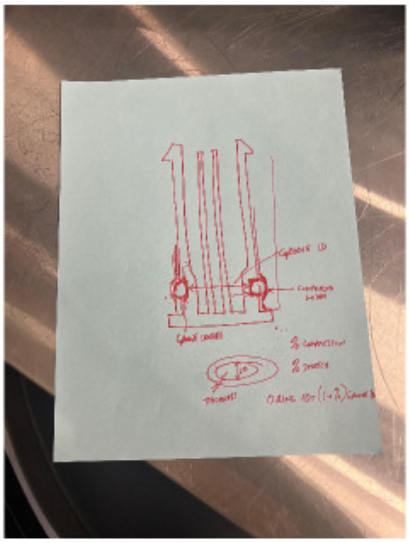
Content:

- Sketches in pdf below.
- Thinks we should glue whatever type of foil we use into the cap.
    - Thinks it's best for how much time we have/materials available.
- We could heat the foil and melt it over little triangle structures on the lip of the inside of the cap is another option.
- Drew a few designs/sketches of how we could alter our SolidWorks design for an O-ring to keep the design sealed.
- Suggested we go to Makerspace to see what O-rings they have available and then make all of our SolidWorks modifications around that.
    - If there are no options, we can order from McMaster Carr.
- Provides some constraints and measurements we should take into account for the O-ring as well.

Conclusions/action items:

Make modifications to our prototype, and then 3D print again. Hopefully start our testing after thanksgiving break. Email Jesse with any questions or concerns we have about our design.

KAIYA MERRITT - Nov 15, 2023, 3:19 PM CST



Download

Designs_from_meeting_with_Jesse.pdf (1.63 MB)

11/29/23 - Fabrication

SARA MOREHOUSE - Nov 29, 2023, 5:54 PM CST

Title: Fabrication on 11/29/23

Date: 11/29/23

Content by: Sara Morehouse

Present: Jenna Sorenson, Katherine Kafkis, Mia LaRico, Kaiya Merritt, Morgan Kopidlansky, Sara Morehouse

Goals: Our goals for today were to assemble multiple copies of our prototype, begin testing, and identify any last changes that needed to be made to the design in order to be ready for the final presentation.

Content:

Today we accomplished:

- Obtained and assembled 3 more copies of the prototype. Assembly revealed that the thickness of the leaves on the plunger are very thin and break easy, and multiple plungers broke in the process. See images attached for broken plunger.

- Tested out different sizes of O-rings on the base of the plunger to see if a compression fit seal could be used to prevent leaking. This proved to not be possible with the O-ring sizes available and with our current prototype as the O-ring just prevented the plunger from entering the tube all the way. We decided that the best way to prevent leaking on the bottom will be to create a twisting lock mechanism. If time permits, we will attempt to get this completed before next Friday, however, we are going to complete initial testing with the prototype as is.

- Updated the Solidworks design to increase the size of the hole that the swab fits in inside the plunger. We have been having issues with the swab not being able to fully push down into the hole in the plunger so we increased the hole diameter so the swab fits. We also updated the cap size as we realized the cap was not long enough for the entire swab to be inside the cap and have the plunger at the bottom be fully pushed inside. In the design, we added an additional ~4cm of length on the cap so that the swab can fit inside of it. We then began a new print of multiple copies of the plunger and cap with the updated dimensions.

- Updated survey questions and sent them to Dr. Puccinelli to be sent out to potential users.

- Created the final report and final poster as well as assigned sections for each team member to complete.

Conclusions/action items:

This was a productive meeting and helped us to identify what changes still need to be made and what we need to get done before the final presentation. Unfortunately, we were not able to start testing tonight but plan to complete it tomorrow night. The biggest accomplishments were updating the solidworks design with the necessary changes. Upcoming action items are just to complete testing tomorrow, analyze the results, and complete the final report and poster.

SARA MOREHOUSE - Nov 29, 2023, 5:57 PM CST

Download

IMG_2723.HEIC (2.6 MB) device with ~5.7cm of the swab sticking out

SARA MOREHOUSE - Nov 29, 2023, 5:57 PM CST

Download

IMG_2724.HEIC (3.14 MB) measurement of swab that sticks out of the device

SARA MOREHOUSE - Nov 29, 2023, 5:58 PM CST

Download

IMG_2725.HEIC (2.74 MB) measurement of swab that sticks out of the device when the plunger is fully retracted

SARA MOREHOUSE - Nov 29, 2023, 5:59 PM CST

Download

IMG_2726.HEIC (3.13 MB) Device with cap screwed on. Clearly, the cap is not long enough for the entire swab to be inside the device as the plunger is not able to be pushed in all the way.

SARA MOREHOUSE - Nov 29, 2023, 5:56 PM CST

Download

IMG_2727.HEIC (3.25 MB)

SARA MOREHOUSE - Nov 29, 2023, 5:59 PM CST

Download

IMG_2728.HEIC (2.02 MB) Measurement of the length of the plunger that sticks out when the cap is screwed on. This is approximately how much additional length needed to be added to the cap.

SARA MOREHOUSE - Nov 29, 2023, 6:00 PM CST

Download

IMG_2729.HEIC (2.39 MB) Broken leaf of the plunger. The thickness of this section is not sufficient.

12/4/23 - Final Prototype

KATHERINE KAFKIS - Dec 12, 2023, 2:05 AM CST

Title: **Final Prototype Printed out of pink PLA**

Date: 12/4/23

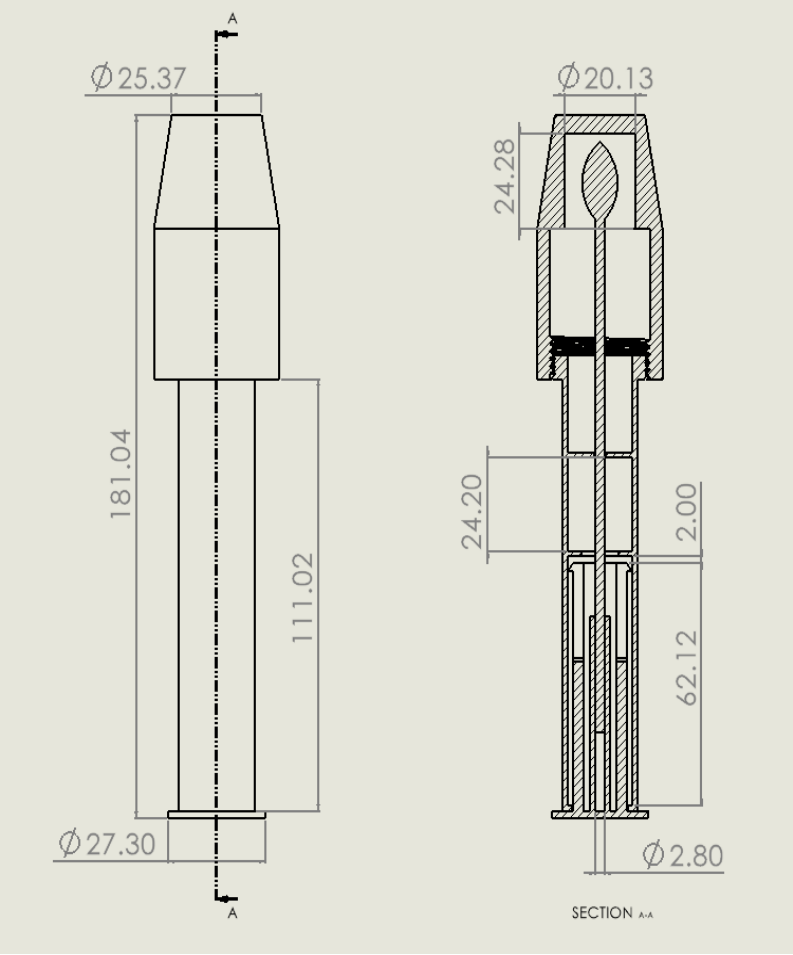
Content by: Team

Present: Team

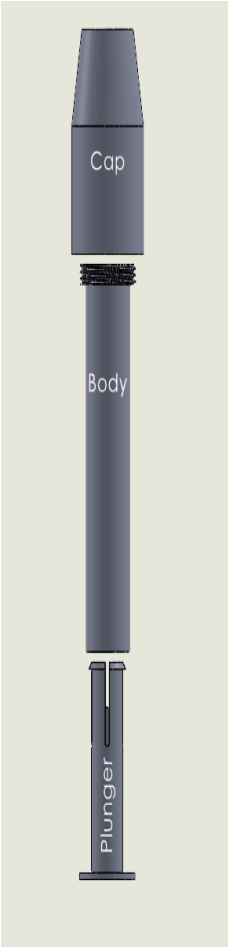
Goals: To alter the design and have a fully function prototype for show and tell

Content:

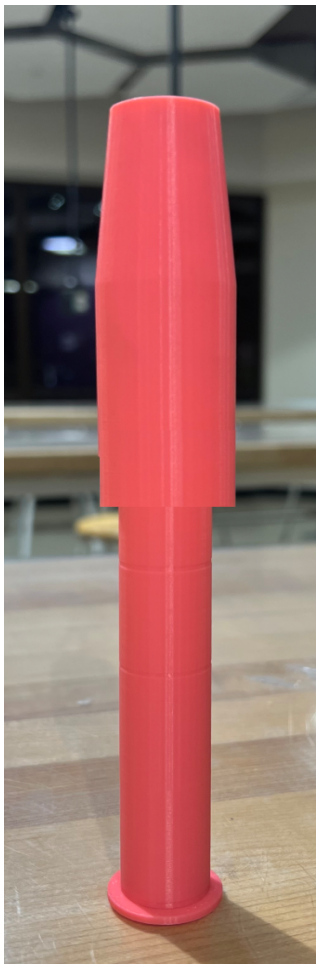
CAD Dimensioned Drawing:



CAD Drawing:



Final 3D print:



Conclusions/action items:

Make changes to the device based on feedback from the survey in the future. 3D-print out of polypropylene in the future as it is autoclavable. Investigate standard manufacturing practices such as thread sizes, fluid filling, injection moulding, sealing mechanisms, and more.

11/2/23 - Mechanical Strength Testing Protocol

Title: Mechanical Strength Testing Protocol

Date: 11/2/23

Content by: Katherine Kafkis

Present: N/A

Goals: To determine the ultimate tensile strength, ultimate tensile strength, and FOS of our device.

Content:

Materials:

- Individual SolidWorks parts of the body and plunger of the device.

Mechanical Strength Test**:** Plan for testing the ultimate compressive and tensile strength of the plunger and body of the device.

- ☐ Step 1: Generate a SolidWorks part of the body and plunger by saving the respective component as a separate SolidPart.
- ☐ Step 2: In the corresponding SolidPart file, navigate to Tools > Add-Ins.
  - ☐ Step 2a: If applicable, deselect SolidWorks Simulation.
  - ☐ Step 2b: Select SimulationXpress Analysis Wizard.
- ☐ Step 3: Perform a compression test.
  - ☐ Step 3a: Add a fixture to the part.
    - ☐ If testing the body, add a fixture to the surface of the rim without threading.
    - ☐ If testing the plunger, add a fixture to the solid bottom surface.
  - ☐ Step 3b. Apply a 10 N compressive load to the top of the part.
  - ☐ Step 3c: Apply the material, either polypropylene or a resin, to the part.
  - ☐ Step 3d: Run the simulation.
  - ☐ Step 3e: Select the Von Mises Stresses option to generate the stress distribution
  - ☐ Step 3f: Take a screenshot of the stress distribution and make note of the greatest stress.
- ☐ Step 4: Repeat step 3, increasing the force load by 10 fold until the device breaks or excessive deformation is observed. Ensure that a load of at least 700 Newtons is applied to the part as this is about the average weight of females ages 15 and older..
- ☐ Step 5: Perform a tensile test.
  - ☐ Step 5a: Add a fixture to the part.
    - ☐ If testing the body, add a fixture to the surface of the upper rim with threading.
    - ☐

If testing the plunger, add the same fixture as used in the compression test.

☐ Step 5b: Apply a tensile force of 25 N to the part.

☐ If testing the body, apply the load to the surface of the rim without threading.

☐ If testing the plunger, apply the load to the underside of the one-time snap mechanism.

☐ Step 5c: Apply the material, either polypropylene or resin, to the part.

☐ Step 5d: Run the simulation.

☐ Step 5e: Select the Von Mises Stresses option to generate the stress distribution

☐ Step 5f: Take a screenshot of the stress distribution and make note of the greatest stress.

☐ Step 5g: Increase the force by 25 N until the device breaks. Ensure that a load of 75 N is applied to the part as this is the average pulling strength of a seated woman.

Step 6: Use the data to determine the average greatest stress of the body and plunger of the device.

Conclusions/action items:

Run the mechanical tests on the solidworks part. Once the prototype is done 3D printing, use the UTS to run physical tests on the prototype and generate a stress-strain curve.

11-2-23 Clinical Use Testing Plan

MORGAN KOPIDLANSKY - Dec 09, 2023, 7:56 PM CST

Title: **Clinical Use Testing Plan**

Date: 11/2/23

Content by: Morgan Kopidlansky

Present: N/A

Goals: To make sure our prototype is capable of collecting viable samples for accurate testing

Content:

Materials:

- Prototype of self-swab device
- Tube (to mimic the vaginal canal)
- Red dye
- Marker
- Water (to mimic media)

Clinical Use Test: Plan for testing if the device performs as intended and could reasonably be used to take an intravaginal swab

- ☐ Step 1: Using a tube (approximately the size of an average vaginal canal - about 4 inches long and 2 inches wide), coat the interior edges with a thin film of food coloring. Be sure that it is not dripping and covers the interior evenly.
- ☐ Step 2: Mark the tube at 2 inches from the opening with a marker. This will indicate when the swab has reached the depth necessary for collecting samples.
- ☐ Step 3: After preparing the tube, the prototype self-swab device will be used to swab the interior of the tube as if it is a patient's vaginal canal.
  - ☐ Step 3a: Deploy swab into the tube using the plunger until the swab reaches the marked line. Be sure that the body of the device rests at the opening but does not enter the tube.
  - ☐ Step 3b: Rotate swab for 30 seconds allowing it to contact the walls of the tube.
  - ☐ Step 3c: Retract the swab from the tube back into the body of the device using the plunger.
  - ☐ Step 3d: Once fully retracted, twist the media cap on securely.
- ☐ Step 4: Use the plunger once more to push the swab up into the cap.This will break the film and allow the water (in place of cellular media) to come into contact with used swab.
- ☐ Step X: If food coloring bleeds into the water after the film is broken, test is considered passed

Conclusions/action items:

After our prototype is made, we will run this test (or something similar based on advice from our advisor) 3-5 times. After obtaining data, we will move forward as needed.

11/3/23 Ease of Use Testing

SARA MOREHOUSE - Nov 03, 2023, 11:49 AM CDT

Title: **Ease of Use Testing Protocol**

Date: 11/3/23

Content by: Sara Morehouse

Present: n/a

Goals: To lay out the protocol for ease of use testing.

Content:

Materials:

- Google survey with questions regarding ease of use
- Prototype of self-swab device (maybe picture of prototype if we have)

Ease of Use Test: Plan for testing if potential users find the device's design intuitive and easy to use (without actually performing the test)

Overall Goal: To get feedback from potential users and patients who would be likely to use the device if it were to be implemented for use in STI testing.

☐ Step 1: Create a Google Form survey to send out to potential users and patients. This survey will include a model of our design and instructions for how to use it. The respondents will be asked to rank different aspects of the design and will give their feedback on whether they think they could perform the test on their own.

☐ Step 2: Discuss this survey with Dr. Riquelme and give her access to the survey in order for her to share it with her patients.

☐ Step 3: Contact Dr. Puccinelli or a college dean to introduce the survey and ask if it can be sent out to all (or a subset of all) female students.

☐ Step 4: Share the survey with friends, classmates, family members who can give their feedback as well.

☐ Step 5: Gather data from this survey and analyze results to determine the qualities of the design that can be improved vs the qualities that are sufficient.

☐ Step 6: Use the data to improve the design in order for it to be as user-friendly as possible.

Notes: Clearly state that it is anonymous.

Reach out to SWE, GWIS, Dr. P.

Conclusions/action items:

This testing plan will be executed hopefully next week and will help us to get feedback from real potential users.

11/4/23 - Leaking Testing Protocol

Title: Leaking Testing Protocol for Our Device

Date: 1/4/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To determine if we observe and leaking from our device.

Content:

Materials:

- Prototype of self-swab device
- Water (to simulate liquid media) and Color Dye
- Filter paper
- Timer

Leaking test: Plan for testing if the media contained inside the device leaks at any point, mostly focusing on the top with cap and the bottom of the device with the syringe. Broken up into three parts for testing.

Part 1 - Testing for leakage while the device is stationary cap-side down.

- Step 1: Unscrew cap. Fill the prototype cap with colored dye-stained water. Screw cap back on device.
  Step 2: Push swab into the cap while the device is cap-side down.
  Step 3: Place filter paper on the table and set the device cap side down.
  Step 4: Let the device sit out for 5 minutes, remaining in the cap-side down position.
  Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.
  Step 6: Repeat process for 4 more trials.

Table for Part 1:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? *If yes, provide a detailed description.					

Part 2 - Testing for leakage while the device is stationary plunger side-down.

- Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.
  Step 2: Push swab into the cap while the device is cap-side down.
  Step 3: Place filter paper on the table and set the device plunger-side down.
  Step 4: Let the device sit out for 5 minutes, remaining in the plunger-side down position.
  Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.

Step 6: Repeat process for 4 more trials.

Table for Part 2:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? *If yes, provide a detailed description.					

Part 3 - Testing for leakage after the device has been shaken for a minute.

- Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.
  Step 2: Push swab into the cap while the device is cap-side down.
  Step 3: Place filter paper on the table.
  Step 4: Shake the device for one minute over the filter paper.
  Step 5: After 1 minute of shaking, place the device on the filter paper cap side down.
  Step 6: Let the device sit for 5 minutes, remaining in the cap-side down position on the filter paper.
  Step 7: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.
  Step 6: Repeat process for 4 more trials.

Table for Part 3:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? *If yes, provide a detailed description.					

Conclusions/action items:

We will run through this leaking testing protocol once we have a more final prototype 3D printed; sometime within the next few weeks.

11/29/23 - Ease of Use survey testing update

SARA MOREHOUSE - Nov 29, 2023, 6:05 PM CST

Title: **Ease of Use survey testing update**

Date: 11/29/23

Content by: Sara Morehouse

Present: n/a

Goals: To upload the survey and update about its progress

Content:

- Initial survey was created and sent to Dr. Puccinelli for review and to be sent out. However, we realized that in its current state the survey asked about medical history by asking if the respondent had ever performed a self-swab test, so changes needed to be made.

- Survey was updated and sent back to Dr. Puccinelli and Dr. Kreeger. Final format is as follows in the attached file.

Conclusions/action items:

Our goal is to have this survey be sent out within the next 24 hours and to gather some responses before the final presentation.

SARA MOREHOUSE - Nov 29, 2023, 6:06 PM CST

Download

survey.pdf (612 kB)

11/30/23 -- Leak Testing

KAIYA MERRITT - Nov 30, 2023, 5:27 PM CST

Title: Leak Testing

Date: 11/30/23

Content by:

Present: Jenna, Sara, Katherine, Kaiya, Morgan

Goals: Test if the media leaks from the top or the bottom of the device

Content:

Materials:

- Prototype of self-swab device
- Powerade
- Paper (for underneath)
- Timer

Leaking test: Plan for testing if the media contained inside the device leaks at any point, mostly focusing on the top with cap and the bottom of the device with the syringe. Broken up into three parts for testing.

Part 1 - Testing for leakage while the device is stationary cap-side down.

☐ Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.

☐ Step 2: Push swab into the cap while the device is cap-side down.

☐ Step 3: Place filter paper on the table and set the device cap side down.

☐ Step 4: Let the device sit out for 5 minutes, remaining in the cap-side down position.

☐ Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.

☐ Step 6: Repeat process for 4 more trials.

Table for Part 1:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? *If yes, provide a detailed description.	No Dye	No Dye	No Dye	No Dye	No Dye

Part 2 - Testing for leakage while the device is stationary plunger side-down.

- ☐ Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.
- ☐ Step 2: Push swab into the cap while the device is cap-side down.
- ☐ Step 3: Place filter paper on the table and set the device plunger-side down.
- ☐ Step 4: Let the device sit out for 5 minutes, remaining in the plunger-side down position.
- ☐ Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.
- ☐ Step 6: Repeat process for 4 more trials.

Table for Part 2:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? *If yes, provide a detailed description.	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out the bottom.	Yes. Nearly all the liquid came out the bottom.

Part 3 - Testing for leakage after the device has been shaken for a minute.

- ☐ Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.
- ☐ Step 2: Push swab into the cap while the device is cap-side down.
- ☐ Step 3: Place filter paper on the table.
- ☐ Step 4: Shake the device for one minute over the filter paper.
- ☐ Step 5: After 1 minute of shaking, place the device on the filter paper cap side down.
- ☐ Step 6: Let the device sit for 5 minutes, remaining in the cap-side down position on the filter paper.
- ☐ Step 7: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.
- ☐ Step 6: Repeat process for 4 more trials.

Table for Part 3:

Trial #	1	2	3	4	5

Colored dye visible - yes or no? *If yes, provide a detailed description.	N/A	N/A	N/A	N/A	N/A

** Because part 2 failed, we will not be continuing with part 3.

Conclusions/action items:

In conclusion, the cap did not show any leaking while the body showed a lot of leaking. In the future we hope to implement a twist and lock mechanism that will hopefully more efficiently secure the bottom of the device and will not let anything leak. Along with adding the twist and lock mechanism, we hope to be able to complete part 3 of the testing.

11/30/23 -- Ease of Use Testing

SARA MOREHOUSE - Dec 13, 2023, 4:11 PM CST

Title: Ease of use testing plan

Date: 11/30/23

Content by:

Present: Jenna, Katherine, Sara, Kaiya, Morgan

Goals: Evaluate if the instructions for use are comprehensible and ease to follow

Content:

Materials:

- Google survey with questions regarding ease of use
- Prototype of self-swab device (maybe picture of prototype if we have)

Ease of Use Test: Plan for testing if potential users find the device's design intuitive and easy to use (without actually performing the test)

Overall Goal: To get feedback from potential users and patients who would be likely to use the device if it were to be implemented for use in STI testing.

☐ Step 1: Create a Google Form survey to send out to potential users and patients. This survey will include a model of our design and instructions for how to use it. The respondents will be asked to rank different aspects of the design and will give their feedback on whether they think they could perform the test on their own.

☐ Step 2: Discuss this survey with Dr. Riquelme and give her access to the survey in order for her to share it with her patients.

☐ Step 3: Contact Dr. Puccinelli or a college dean to introduce the survey and ask if it can be sent out to all (or a subset of all) female students.

☐ Step 4: Share the survey with friends, classmates, family members who can give their feedback as well.

☐ Step 5: Gather data from this survey and analyze results to determine the qualities of the design that can be improved vs the qualities that are sufficient.

☐ Step 6: Use the data to improve the design in order for it to be as user-friendly as possible.

Conclusions/action items:

Once we get results, analyze them.

SARA MOREHOUSE - Dec 13, 2023, 4:20 PM CST

Title: Results from Ease of Use testing

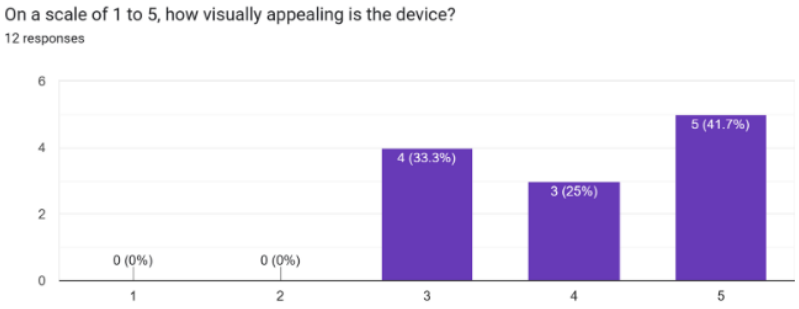
Date: 12/13/23

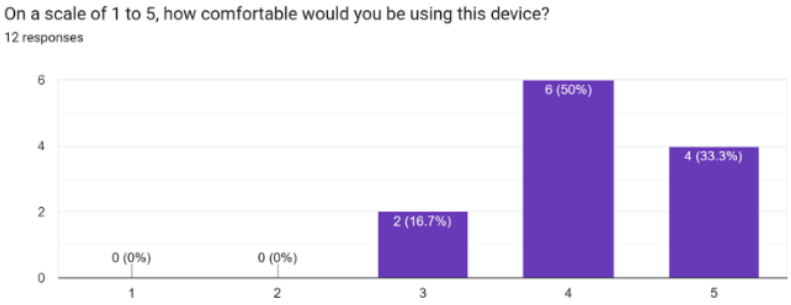
Content by: Sara Morehouse

Goals: To review and present the results for the survey.

Content:

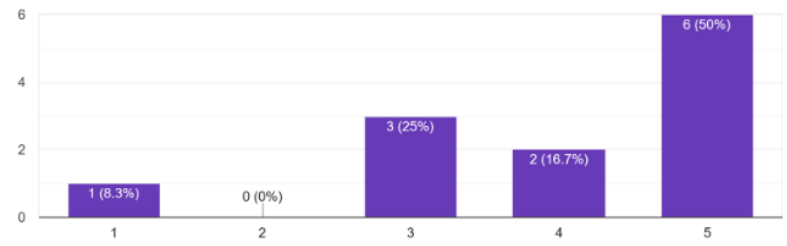
Results:





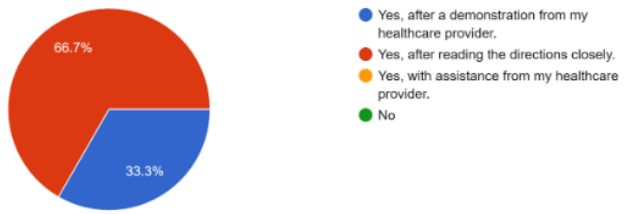
On a scale of 1 to 5, how clear are the directions?

12 responses



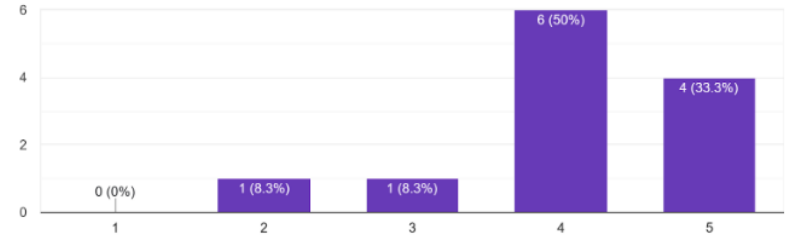
Would you be able to use this device to perform a self-swab?

12 responses



On a scale of 1 to 5, how clean do you think this new self-swab process would be in terms of contamination of the testing environment? (transfer...ids to hands, counter, other surfaces in the room)

12 responses



No

2 responses

The ridges on the top of the device makes me a bit uncomfortable

1 response

not really the threads could be uncomfortable if someone put it in too far. Also, I'd be slightly worried about aim since it does not go inside.

1 response

N/a

1 response

Even though it is just a model, the color white for the device is a little unappealing to me

Not that I can think of!

1 response

Harsh materials may appear intimidating

1 response

Not really

1 response

No, seems pretty straightforward

1 response

Even though the treaded portion of the tube wouldn't be inserted into the vagina, I would be a little concerned about if the edge of the treads would be sharp or feel uncomfortable if it touches the opening of the vagina.

1 response

I think it would be helpful to flare the edge of the tube out so it would contain more fluids from escaping and discourage insertion of the tube into the vagina. I also think that in addition to including written instructions, a visual guide of how to use the device would be helpful for patients using the device.

1 response

Adding grips to the tube, like a tampon might make the swab insertion process easier/more comfortable

1 response

n/a

1 response

When the instructions say to "push the plunger into the device" or "pull the out of the device" it may be more helpful to use directional language like "push the plunger upward into the device" and "pull the plunger downward away from the vagina"

1 response

Conclusions: Overall, respondents (n=12) rated the aesthetics, usability, and cleanliness of the device fairly high. ⅔ of respondents rated the device as either very visually appealing or moderately visually appealing. ⅚ of respondents stated they would be moderately or very comfortable with using this device. All respondents felt able to perform the self-swab with the device after either reading the instructions or seeing a demonstration, and ⅔ thought the directions were either moderately or very clear to understand. ⅚ of respondents felt that the new device would be moderately or very clean and prevent contamination of the testing environment. Regarding the open-ended questions, some of the most common responses about aspects of the design that were unappealing included the threading on the outside of the tube and the white color of the initial prototype. Other feedback included flaring the top edge of the tube out to prevent accidental insertion into the vagina, adding grips to the bottom of the tube, altering the directions to include more specific language, and extending the cap.

11/30/23 -- Clinical Use Testing

Title: Clinical Use Testing Plan

Date: 11/30/23

Content by:

Present: Jenna, Katherine, Sara, Kaiya, Morgan

Goals: Evaluate if the device can be used efficiently in a clinical setting

Content:

Materials:

- Prototype of self-swab device
- Tube (to mimic the vaginal canal)
- Red dye
- Marker

Clinical Use Test: Plan for testing if the device performs as intended and could reasonably be used to take an intravaginal swab

☐ Step 1: Using a tube (approximately the size of an average vaginal canal - about 4 inches long and 2 inches wide), coat the interior edges with a thin film of food coloring. Be sure that it is not dripping and covers the interior evenly.

☐ Step 2: Mark the tube at 2 inches from the opening with a marker. This will indicate when the swab has reached the depth necessary for collecting samples.

☐ Step 3: After preparing the tube, the prototype self-swab device will be used to swab the interior of the tube as if it is a patient's vaginal canal.

- ☐ Step 3a: Deploy swab into the tube using the plunger until the swab reaches the marked line. Be sure that the body of the device rests at the opening but does not enter the tube.
- ☐ Step 3b: Rotate swab for 30 seconds allowing it to contact the walls of the tube.
- ☐ Step 3c: Retract the swab from the tube back into the body of the device using the plunger.

☐ Step 5: If food coloring stains the swab, test is considered passed

Trial #	1	2	3	4	5
Colored dye visible on swab - yes or no? *If yes, provide a detailed description.	yes, swab is clearly stained red	yes, swab is clearly stained red	yes, swab is clearly stained red	yes, swab is clearly stained red	yes, swab is clearly stained red

Conclusions/action items: The test passed every trial. The swab being stained red indicates that our device is able to be deployed far enough into the vagina to collect viable samples for STI testing.

11/30/23 -- Mechanical Strength Results

KATHERINE KAFKIS - Dec 12, 2023, 2:01 AM CST

Title: Mechanical Strength Results - Body

Date: 11/30/23

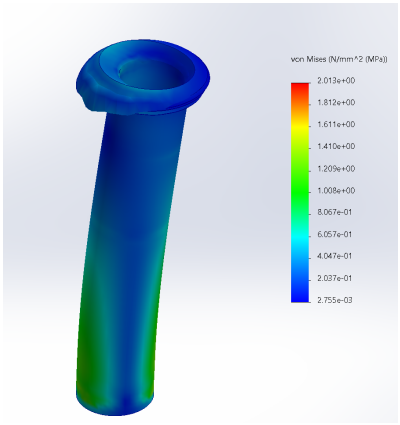
Content by:

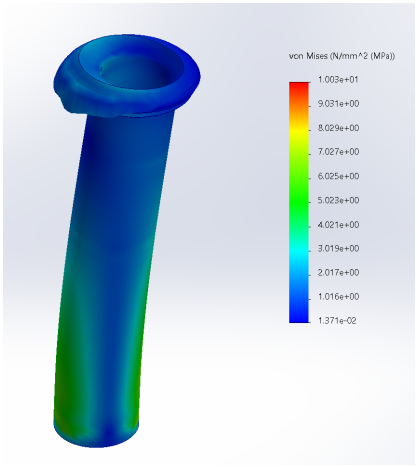
Present: Mia and Katherine

Goals: Evaluate the mechanical properties of the body of the device

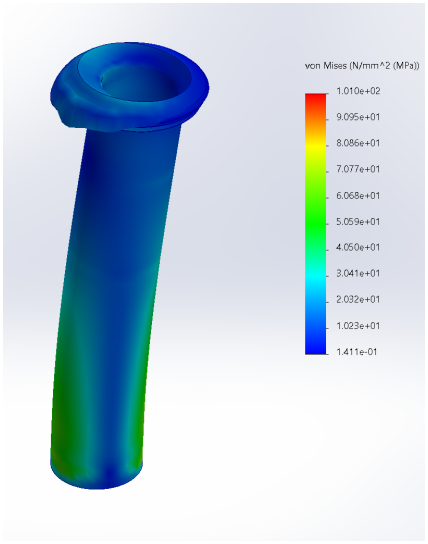
Content: Mechanical Strength Results:

Body - Compression:

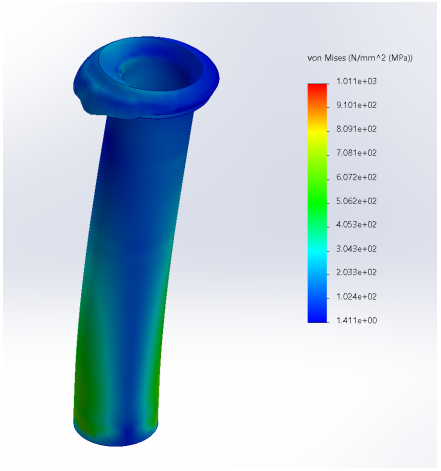
- 10 N
  - 

- 20 N
  - 

- 100N

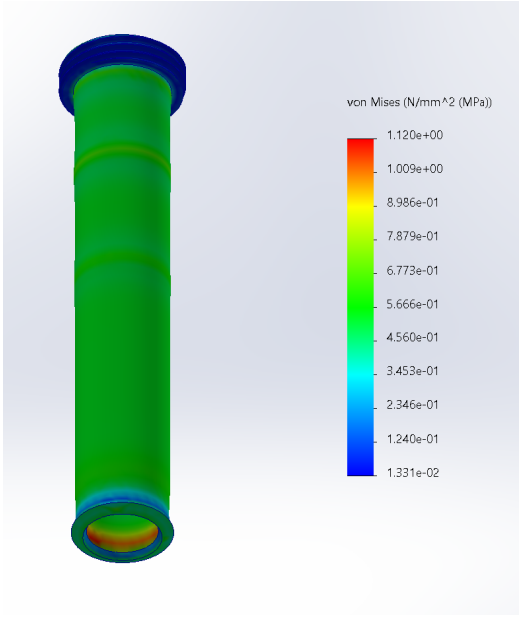


- 10,000N

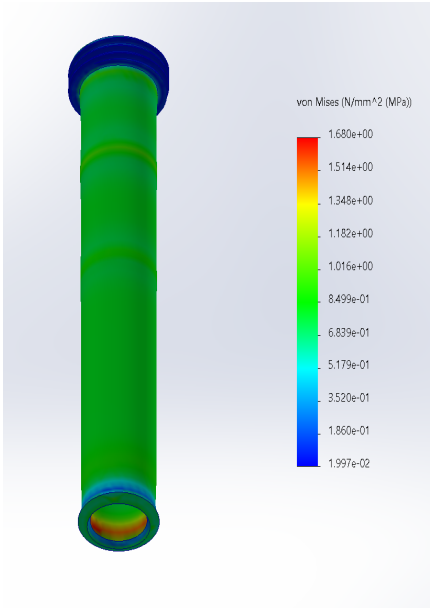


Body - Tension

- 25 N



- 75 N



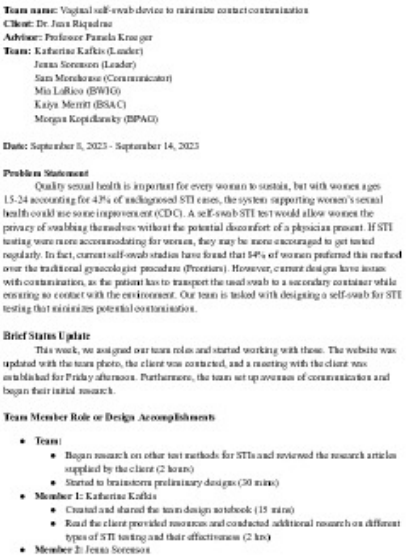
-

Conclusions/action items:

The body of the device is not expected to break under the load of the average female (700 N) or when being pulled with the pulling strength of the average female (75 N).

Progress Reports

JENNA SORENSON - Sep 14, 2023, 4:21 PM CDT



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Riquelme
Advisor: Professor Pamela Kreuger
Team: Katherine Kaftis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: September 8, 2023 - September 14, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, we assigned our team roles and started working with those. The website was updated with the team photo, the client was contacted, and a meeting with the client was established for Friday afternoon. Furthermore, the team set up avenues of communication and began their initial research.

Team Member Role or Design Accomplishments

- **Team:**
  - Began research on other test methods for STIs and reviewed the research articles supplied by the client (2 hours)
  - Started to brainstorm preliminary designs (30 mins)
- **Member 1:** Katherine Kaftis
  - Created and shared the team design notebook (15 mins)
  - Read the client provided resources and conducted additional research on different types of STI testing and their effectiveness (2 hrs)
- **Member 2:** Jenna Sorenson

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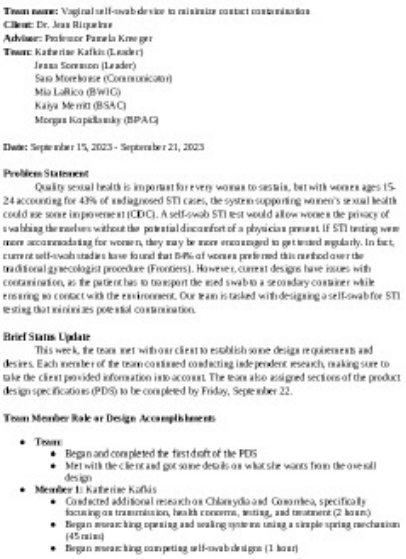
Vaginal_self-swab_-_Progress_Report_1.pdf (97.6 kB)

JENNA SORENSON - Oct 11, 2023, 5:24 PM CDT



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Riquelme
Advisor: Professor Pamela Kreuger
Team: Katherine Kaftis (Leader)
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Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: September 15, 2023 - September 21, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team met with our client to establish some design requirements and desires. Each member of the team continued conducting independent research, making sure to take the client provided information into account. The team also assigned sections of the product design specifications (PDS) to be completed by Friday, September 22.

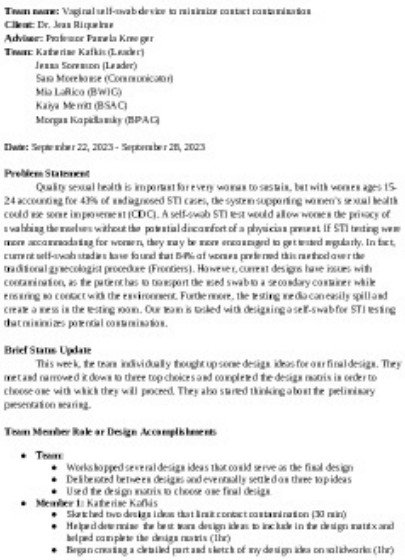
Team Member Role or Design Accomplishments

- **Team:**
  - Began and completed the first draft of the PDS
  - Met with the client and got some details on what she wants from the overall design
- **Member 1:** Katherine Kaftis
  - Conducted additional research on Chlamydia and Gonorrhea, specifically focusing on transmission, health concerns, testing, and treatment (2 hours)
  - Began researching opening and sealing systems using a simple spring mechanism (45 mins)
  - Began researching competing self-swab designs (1 hour)

Download

Vaginal_self-swab_-_Progress_Report_2.docx (11.9 kB)

JENNA SORENSON - Oct 11, 2023, 5:25 PM CDT



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: September 22, 2023 - September 28, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team individually thought up some design ideas for our final design. They met and narrowed it down to three top choices and completed the design matrix in order to choose one with which they will proceed. They also started thinking about the preliminary presentation nearing.

Team Member Role or Design Accomplishments

- **Team:**
  - Workshopped several design ideas that could serve as the final design
  - Deliberated between designs and eventually settled on three top ideas
  - Used the design matrix to choose one final design
- **Member 1:** Katherine Kafkis
  - Sketched two design ideas that limit contact contamination (30 min)
  - Helped determine the best team design ideas to include in the design matrix and helped complete the design matrix (1hr)
  - Began creating a detailed part and sketch of my design idea on solidworks (1hr)

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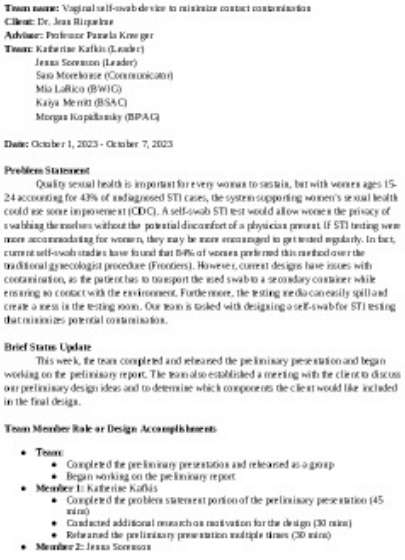
Vaginal_self-swab_-_Progress_Report_3.docx (470 kB)

JENNA SORENSON - Oct 11, 2023, 5:25 PM CDT



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: October 1, 2023 - October 7, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team completed and rehearsed the preliminary presentation and began working on the preliminary report. The team also established a meeting with the client to discuss our preliminary design ideas and to determine which components the client would like included in the final design.

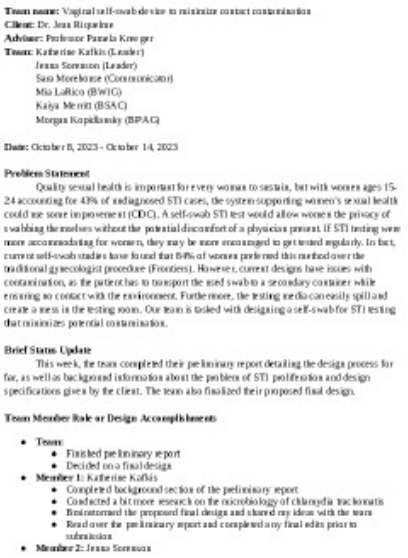
Team Member Role or Design Accomplishments

- **Team:**
  - Completed the preliminary presentation and rehearsed as a group
  - Began working on the preliminary report
- **Member 1:** Katherine Kafkis
  - Completed the problem statement portion of the preliminary presentation (45 mins)
  - Conducted additional research on motivation for the design (30 mins)
  - Rehearsed the preliminary presentation multiple times (30 mins)
- **Member 2:** Jenna Sorenson

Download

Vaginal_self-swab_-_Progress_Report_4.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:11 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidansky (BPAG)

Date: October 8, 2023 - October 14, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team completed their preliminary report detailing the design process for for, as well as background information about the problem of STI proliferation and design specifications given by the client. The team also finalized their proposed final design.

Team Member Role or Design Accomplishments

- **Team:**
  - Finished preliminary report
  - Decided on a final design
- **Member 1:** Katherine Kafkis
  - Completed background section of the preliminary report
  - Conducted a bit more research on the microbiology of chlamydia trachomatis
  - Brainstormed the proposed final design and shared my ideas with the team
  - Read over the preliminary report and completed any final edits prior to submission
- **Member 2:** Jenna Sorenson

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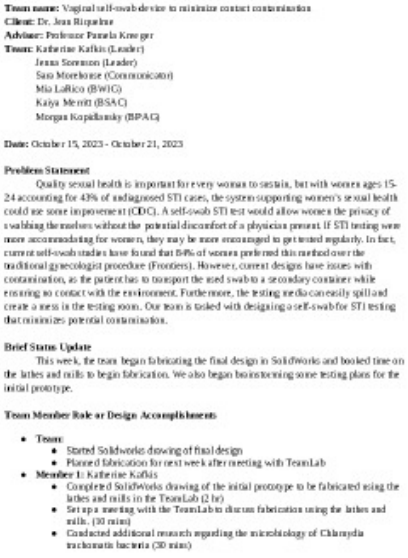
Vaginal_self-swab_-_Progress_Report_5_1_.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:11 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidansky (BPAG)

Date: October 15, 2023 - October 21, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team began fabricating the final design in SolidWorks and booked time on the lathes and mills to begin fabrication. We also began brainstorming some testing plans for the initial prototype.

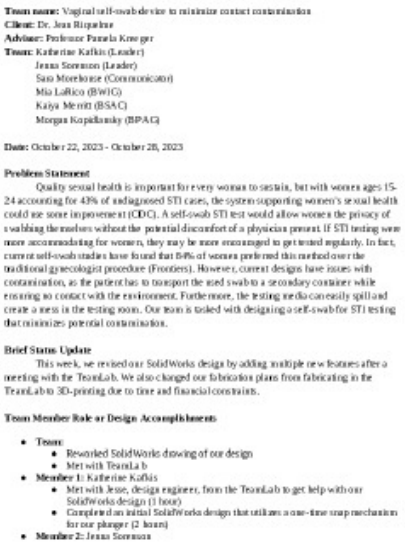
Team Member Role or Design Accomplishments

- **Team:**
  - Started Solidworks drawing of final design
  - Planned fabrication for next week after meeting with TeamLab
- **Member 1:** Katherine Kafkis
  - Completed SolidWorks drawing of the initial prototype to be fabricated using the lathes and mills in the TeamLab (2 hr)
  - Set up a meeting with the TeamLab to discuss fabrication using the lathes and mills. (30 mins)
  - Conducted additional research regarding the microbiology of Chlamydia trachomatis bacteria (30 mins)

Download

Vaginal_self-swab_-_Progress_Report_6.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:12 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: October 22, 2023 - October 28, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, we revised our SolidWorks design by adding multiple new features after a meeting with the TeamLab. We also changed our fabrication plans from fabricating in the TeamLab to 3D-printing due to time and financial constraints.

Team Member Role or Design Accomplishments

- **Team:**
  - Reworked SolidWorks drawing of our design
  - Met with TeamLab
- **Member 1:** Katherine Kafkis
  - Met with Jesse, design engineer, from the TeamLab to get help with our SolidWorks design (1 hour)
  - Completed an initial SolidWorks design that utilizes a one-time snap mechanism for our plunger (2 hours)
- **Member 2:** Jenna Sorenson

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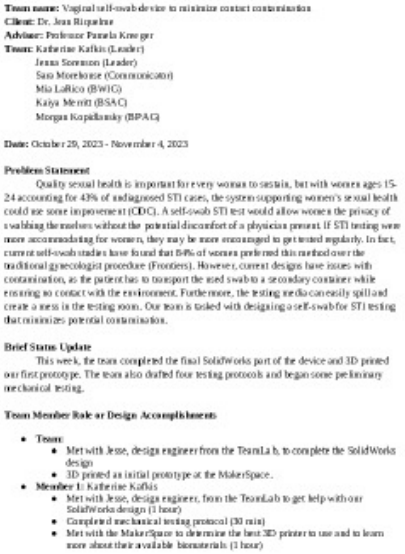
Vaginal_self-swab_-_Progress_Report_7.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:12 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripalmo
Advisor: Professor Pamela Kreeger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: October 29, 2023 - November 4, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team completed the final SolidWorks part of the device and 3D printed our first prototype. The team also drafted four testing protocols and began some preliminary mechanical testing.

Team Member Role or Design Accomplishments

- **Team:**
  - Met with Jesse, design engineer from the TeamLab, to complete the SolidWorks design
  - 3D printed an initial prototype at the MakerSpace.
- **Member 1:** Katherine Kafkis
  - Met with Jesse, design engineer, from the TeamLab to get help with our SolidWorks design (1 hour)
  - Completed mechanical testing protocol (30 min)
  - Met with the MakerSpace to determine the best 3D printer to use and to learn more about their available biomaterials. (1 hour)

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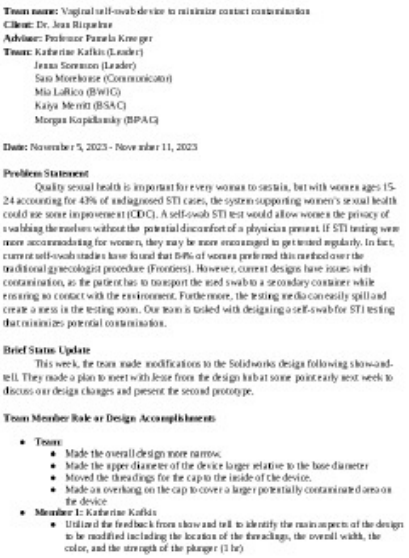
Vaginal_self-swab_-_Progress_Report_8_1_.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:12 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripsalme
Advisor: Professor Pamela Krueger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: November 5, 2023 - November 11, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team made modifications to the Solidworks design following show-and-tell. They made a plan to meet with Jesse from the design hub at some point early next week to discuss our design changes and present the second prototype.

Team Member Role or Design Accomplishments

- **Team:**
  - Made the overall design more narrow.
  - Made the upper diameter of the device larger relative to the base diameter
  - Moved the threadings for the cap to the inside of the device.
  - Made an overhang on the cap to cover a larger potentially contaminated area on the device
- **Member 1:** Katherine Kafkis
  - Utilized the feedback from show and tell to identify the main aspects of the design to be modified including the location of the threadings, the overall width, the color, and the strength of the plunger (1 hr)

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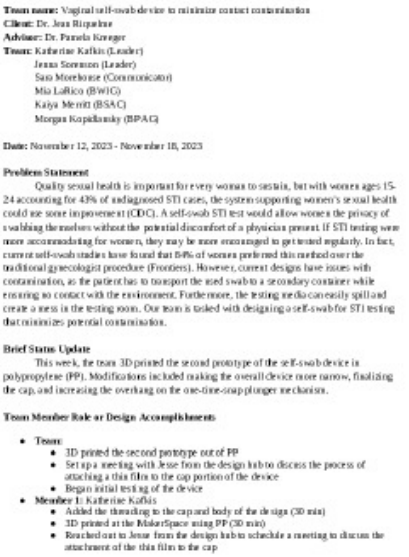
Vaginal_self-swab_-_Progress_Report_9.docx (471 kB)

JENNA SORENSON - Dec 12, 2023, 9:12 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripsalme
Advisor: Dr. Pamela Krueger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: November 12, 2023 - November 18, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team 3D printed the second prototype of the self-swab device in polypropylene (PP). Modifications included making the overall device more narrow, finalizing the cap, and increasing the overhang on the one-time-snap plunger mechanism.

Team Member Role or Design Accomplishments

- **Team:**
  - 3D printed the second prototype out of PP
  - Set up a meeting with Jesse from the design hub to discuss the process of attaching a thin film to the cap portion of the device
  - Began initial testing of the device
- **Member 1:** Katherine Kafkis
  - Added the threading to the cap and body of the design (30 min)
  - 3D printed at the MakerSpace using PP (30 min)
  - Reached out to Jesse from the design hub to schedule a meeting to discuss the attachment of the thin film to the cap

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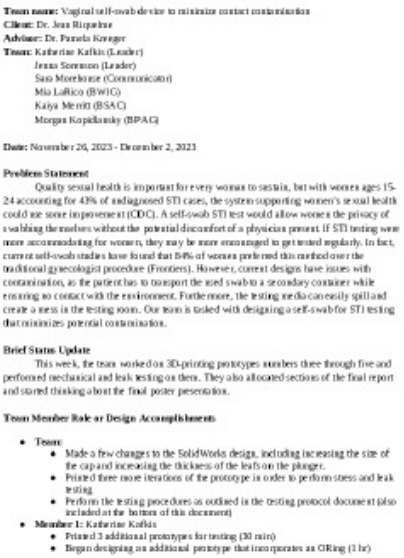
Vaginal_self-swab_-_Progress_Report_10.docx (470 kB)

JENNA SORENSON - Dec 12, 2023, 9:13 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripaolne
Advisor: Dr. Pamela Krueger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: November 26, 2023 - December 2, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team worked on 3D-printing prototypes numbers three through five and performed mechanical and leak testing on them. They also allocated sections of the final report and started thinking about the final poster presentation.

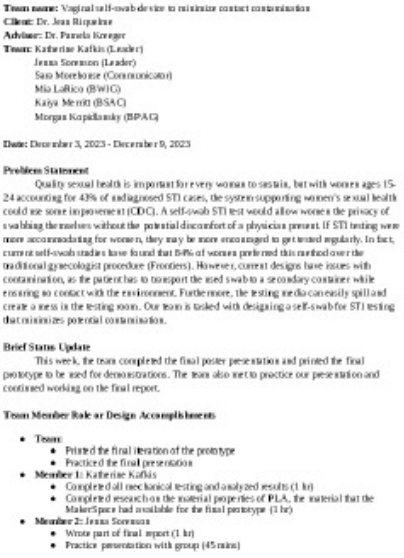
Team Member Role or Design Accomplishments

- **Team:**
  - Made a few changes to the SolidWorks design, including increasing the size of the cap and increasing the thickness of the leafs on the plunger.
  - Printed three more iterations of the prototype in order to perform stress and leak testing
  - Perform the testing procedures as outlined in the testing protocol document (also included at the bottom of this document)
- **Member 1:** Katherine Kafkis
  - Printed 3 additional prototypes for testing (30 min)
  - Began designing an additional prototype that incorporates an OlRing (1 hr)

Download

Vaginal_self-swab_-_Progress_Report_11.docx (475 kB)

JENNA SORENSON - Dec 12, 2023, 9:13 PM CST



Team name: Vaginal self-swab device to minimize contact contamination
Client: Dr. Jean Ripaolne
Advisor: Dr. Pamela Krueger
Team: Katherine Kafkis (Leader)
Jenna Sorenson (Leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: December 3, 2023 - December 9, 2023

Problem Statement
Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). A self-swab STI test would allow women the privacy of swabbing themselves without the potential discomfort of a physician present. If STI testing were more accommodating for women, they may be more encouraged to get tested regularly. In fact, current self-swab studies have found that 84% of women preferred this method over the traditional gynecologist procedure (Frontiers). However, current designs have issues with contamination, as the patient has to transport the used swab to a secondary container while ensuring no contact with the environment. Furthermore, the testing media can easily spill and create a mess in the testing room. Our team is tasked with designing a self-swab for STI testing that minimizes potential contamination.

Brief Status Update
This week, the team completed the final poster presentation and printed the final prototype to be used for demonstrations. The team also met to practice our presentation and continued working on the final report.

Team Member Role or Design Accomplishments

- **Team:**
  - Printed the final iteration of the prototype
  - Practiced the final presentation
- **Member 1:** Katherine Kafkis
  - Completed all mechanical testing and analyzed results (1 hr)
  - Completed research on the material properties of PLA, the material that the MakerSpace had available for the final prototype (1 hr)
- **Member 2:** Jenna Sorenson
  - Wrote part of final report (1 hr)
  - Practice presentation with group (45 mins)

Download

Vaginal_self-swab_-_Progress_Report_12.docx (475 kB)

Preliminary Report

JENNA SORENSON - Oct 11, 2023, 5:26 PM CDT

Vaginal Self-Swab Device to Minimize Contact Contamination

Preliminary Report

Client: Dr. Jean Riquelme
Advisor: Professor Pamela Kreeger
Class Section: 306

Jenna Sorenson (Co-leader)
Katherine Kafkis (Co-leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: October 11, 2023

Download

Preliminary_Report.docx (1.1 MB)

Poster

JENNA SORENSON - Dec 12, 2023, 9:10 PM CST

Download

Poster.pdf (1.96 MB)

WARF Meeting - 11/3/23

KAIYA MERRITT - Nov 03, 2023, 2:58 PM CDT

Title: First WARF Meeting

Date: 11/3/23

Content by: Kaiya Merritt

Present: Katherine, Jenna, Sara, Kaiya

Goals: First Meeting with WARF to discuss our product.

Content:

- Hear back the 17th from their meeting on whether it is patentable and if they will follow through.
- A lot of sub criteria to meet.
- Typically accept 40-50% of disclosures submitted.
- Next meeting would have an attorney.
- 20% would be split between us as a team. 15% would go to the department, and the rest goes back to WARF.
- Gave him a run-down of our product and our design.
- Asked about any certification necessary.
- He asked about insurance coverage in clinical testing.
- He asked about a statistic of women who preferred to self-test.

Conclusions/action items:

Wait to hear back in a few weeks and can email him with any questions or concerns that we have.

9/11/23 - Vaginal Swab Device Study

JENNA SORENSON - Sep 11, 2023, 12:29 PM CDT

Title: A pilot clinical validation study for a self-collected vaginal swab device for the detection of *chlamydia trachomatis* in women

Date: 9/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the effectiveness of current self swab devices

Content:

Current testing = Polymerase Chain Reaction test on First Catch Urine Samples

- these samples can be inconvenient to store and transport due to refrigeration and spillage

- study focuses on self swab that uses Nucleic Acid Amplification Tests, is dry-stored, & does not need to be refridgerated; detect the presence of an organism by recognizing certain series of nucleic acids

- less than half of at-risk youth seek out preventative STD testing

- chlamydia can be asymptomatic in up to 75% of women

Other past methods = culture plates; had prolonged periods of incubation, refrigeration, liquids buffers and required lots of resources to have viable pathogens

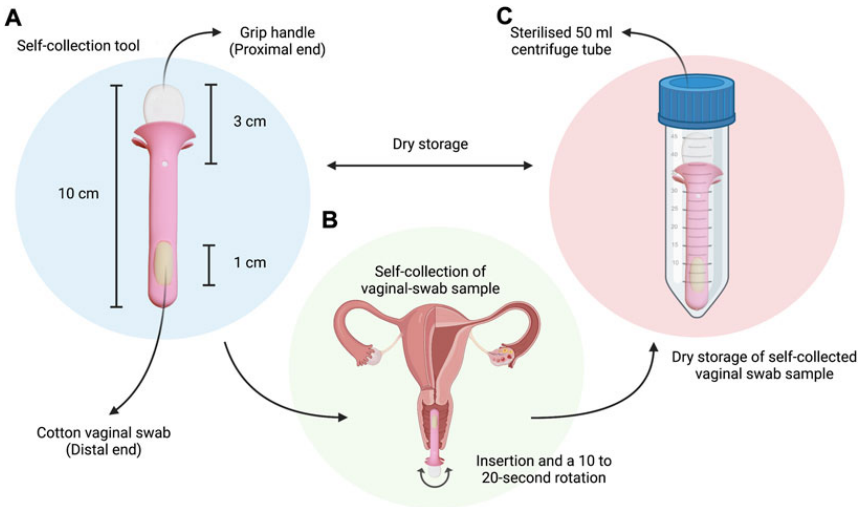
- detection through NAATs has shown to be more reliable that cervical or urine samples; no difference between self-collected and physician-collected samples

- 99% of women said self-swab was easy to perform; 84% preferred it over gyno exams

- NAATs also have similar issues with refrigeration and transportation

- Swab in study is 10 cm long

Study swab procedure:



- There was evidence to suggest that the vaginal self-swab collection device could be an alternative testing method

- The study found that NAATs are still the recommended testing method

Conclusions/action items:

Maybe need to consider transportation and refrigeration constraints in our design?

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.

9/11/23 - Self-obtained vaginal swabs

JENNA SORENSON - Sep 11, 2023, 12:43 PM CDT

Title: Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing

Date: 9/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about studies done on self-swab STD testing

Content:

Current standard for NG (Neisseria Gonorrhea)/Chlamydia trachomatis (CT) testing = NAAT with provider-perfomed endocervical swab

- uncomfortable, needs exam room, uses a clinician's time

Self-swabs were found to have a sensitivity of 95% (where 90% or higher was considered noninferior to the provider-performed swab)

93% of patients thought self swabbing was acceptable, but 28% of patients worried they did not do it correctly

26% of patients refused self-swab due to reasons such as uncomfortable performing, worried might do incorrectly, or prefer physician

Due to the low end of the 95% confidence interval (88%) being less than 90% sensitivity, technically the study did not prove noninferiority to the physician swabs -- but the results of the self-swab are still promising.

Conclusions/action items:

The self-swab has a high sensitivity and therefore, is shown to be a promising alternative in future STD testing.

Bond, Christopher, et al. “Hot off the Press: Self-obtained Vaginal Swabs for Sexually Transmitted Infection Testing.” *Wiley Online Library*, Academic Emergency Medicine, 4 Sept. 2021, onlinelibrary.wiley.com/doi/10.1111/acem.14387.

9/14/23 - Materials Safe for Vagina

JENNA SORENSON - Sep 21, 2023, 6:07 PM CDT

Title: An Approved List of Things That Can Go Into Your Vagina

Date: 9/14/23

Content by: Jenna Sorenosn

Present:

Goals: Learn more about what materials are safe to use for our device

Content:

- Fingers are okay to enter the area during swabbing as long as nails are maintained and hands are clean

- To assure cleanliness while swabbing, user could wear gloves

- Some water-based products are incompatible with the pH of the vagina

- make sure bacteria could not be harbored in potential pores in the swab or applicator

- Silicone, titanium, aluminum blends, glass, properly sealed ceramic, and wood are all safe materials

- Don't want any sharp edges

Conclusions/action items:

There are a lot of materials we could use in our design.

Fournier, Anabelle Bernard. “An Approved List of Things That Can Go In The Vagina.” *SheKnows*, 19 Apr. 2023, www.sheknows.com/health-and-wellness/.

9/15/23 - NAATs

JENNA SORENSON - Sep 21, 2023, 6:23 PM CDT

Title: Nucleic Acid Amplification Testing

Date: 9/15/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about how NAAT testing works

Content:

- can be used in the detection of COVID-19

- identifies the RNA sequences that are characteristic of the genetic material of the virus

- first works to amplify (or copy) the virus's genetic code if present in a patient

- amplification allows NAATs to identify even the smallest of sequences making these tests highly sensitive

use many different methods to amplify the nucleic acids:

1. reverse transcription polymerase chain reaction

2. isothermal amplification

- nicking endonuclease amplification reaction

- transcription mediated amplification

- loop-mediated isothermal amplification

- helicase-dependent amplification

- clustered regularly interspaced short palindromic repeats

- strand displacement amplification

Conclusions/action items:

I think our best chance at doing something nonobvious is mechanical unless I can figure out how to do these reactions

“Nucleic Acid Amplification Tests (NAATs).” *Nucleic Acid Amplification Tests (NAATs)*, Centers for Disease Control and Prevention, 12 May 2023, www.cdc.gov/coronavirus/2019-ncov/lab/naats.html#:~:text=The%20NAAT%20procedure%20works%20by,sensitive%20for%20diagnosing%20COVID%2D19.

9/21/23 - Polymerase Chain Reaction

JENNA SORENSON - Sep 21, 2023, 6:33 PM CDT

Title: Polymerase Chain Reaction (PCR) Fact Sheet

Date: 9/21/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the actual process that occurs during NAAT

Content:

1. heat the sample until the DNA denatures

2. enzyme called "Taq polymerase" synthesizes two new strands of DNA

this process proceeds 30-40 times and can lead to >1 billion exact copies of the original DNA segment

- can be completed in just a few hours

-done by a machine called a thermocycler

Conclusions/action items:

Maybe I could do this?? But not sure I have access to these (probably expensive) materials

“Polymerase Chain Reaction (PCR) Fact Sheet.” *Genome.Gov*, National Human Genome Research Institute, 17 Aug. 2020, www.genome.gov/about-genomics/fact-sheets/Polymerase-Chain-Reaction-Fact-Sheet#:~:text=To%20amplify%20a%20segment%20of,the%20original%20strands%20as%20templates.

10/1/23 - Assessment of self swabs

JENNA SORENSON - Oct 01, 2023, 3:38 PM CDT

Title: Assessment of self taken swabs versus clinician taken swab cultures for diagnosing gonorrhea in women

Date: 10/1/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the effectiveness of self-swabs

Content:

- vaginal swabs are shown to be much better at detecting an STI than first-catch urine samples

- in women with at least one symptom, vulvovaginal swabs detected 100% of all gonorrhea cases

- in women with no symptoms, they only detected 96.9% of cases

* possible explanation for this that gonorrhea infects both the urethra and endocervix and if the infection is confined to the urethra, the woman is more likely to asymptomatic

* endocervical swabs are less likely to detect urethra confined infections

- women can collect a vulvovaginal swab as well as a clinician

Conclusions/action items:

Self-swab vulvovaginal samples are a completely viable route to follow

Stewart, Catherine M W, et al. “Assessment of Self Taken Swabs versus Clinician Taken Swab Cultures for Diagnosing Gonorrhoea in Women: Single Centre, Diagnostic Accuracy Study.” *The BMJ*, British Medical Journal Publishing Group, 12 Dec. 2012, www.bmj.com/content/345/bmj.e8107.

10/11/23 - STI Screening Recommendations

JENNA SORENSON - Oct 11, 2023, 1:16 PM CDT

Title: Screening Recommendations and Considerations Referenced in Treatment Guidelines and Original Sources

Date: 10/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about who should be regularly screening

Content:

Chlamydia:

- sexually active women under 25

- sexually active women over 25 if at increased risk

- retest 3 months after treatment

Gonorrhea:

- sexually active women under 25

- sexually active women over 25 if at increased risk

- retest 3 months after treatment

increased risk = new sex partner, more than one sex partner, a sex partner w concurrent partners, or a sex partner that has an STI

Syphilis:

- screen asymptomatic adults at increased risk

increased risk = history or incarceration, transactional sex work, geography, race/ethnicity

Conclusions/action items:

The target for this device would probably be sexually-active women under 25 since that is who is recommended to always partake in universal testing.

[X] “Gonococcal infections among adolescents and adults - STI treatment guidelines,” Centers for Disease Control and Prevention, https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm.

10/11/23 - Universal STI Testing

JENNA SORENSON - Oct 11, 2023, 1:30 PM CDT

Title: Opt-Out Screening with a Universal Approach

Date: 10/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about what universal testing entails

Content:

- Adolescents or young females are notified that testing will be performed unless they decline it (regardless of reported sexual activity)

- many patients have concerns about privacy or don't want to admit sexual activity; this approach solves that problem

- 1 in 2 new STI are caught by people ages 15-25

- more than 84% of chlamydia and gonorrhea cases are asymptomatic

- 5.6 million new cases of chlamydia and gonorrhea every year just in the United States

- 30% of untreated chlamydia infections progress to pelvic inflammatory disease

- 45% of tubal factor infertility cases were caused by chlamydia infections

benefits of universal testing:

- detecting care opportunities than may have been missed otherwise

- decreasing the prevalence of STIs and infertility

- reducing the total cost of healthcare

- only 44-55% of sexually active women ages 16-24 are screened annually for chlamydia

- cases of chlamydia and gonorrhea still found in people that report abstinent

Conclusions/action items:

Universal testing includes simply testing all women of a certain age annually as part of procedure that they have the freedom to decline

[X] “Universal STI Screening,” Hologic Women’s Health, https://hologicwomenshealth.com/universalscreening/.

10/11/23 - Advances in STI Testing at Home

JENNA SORENSON - Oct 11, 2023, 6:08 PM CDT

Title: Advances of STI Testing at Home and in Non-Clinical Settings Close to Home

Date: 10/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the sphere of home testing

Content:

- There are new internet-based STI tests and remote laboratories

- There is a need for new ways to screen for STIs

Strategy 1: Home specimen self-collection models with send-off to testing laboratory

- Telehealth approach where doctor on the phone sends the kit, the patient takes the sample, and then sends it off

- High test result agreement between self-collected and physician-collected mucosal swab specimens with NAATs

- For both dry and wet, speciman is stable for up to three weeks for gonorrhea & chlamydia NAATs

- Currently no STI home seld-collected speciman systems that are cleared by the FDA

- Current kits sold online have posed issues with oversight and quality

Strategy 2: Point-of-care testing at home or close to someone's house

- Competitor = "Sexual Health Test" by Visby Medical

* 30 min PCR test performed on a disposable, single-use, hand-held device

* only cleared for self-collected vaginal swabs in a healthcare setting

- Competitor = "binx health io CT/NG Assay"

* 30 min NAAT

* also collects urine from males along w vaginal samples

- Competitor = "Xpert CT/NG" by Cepheid

* 90 min NAAT

* needs an instrument

Strategy 3: Home self-testing

- test feature 1: need for confirmatory testing

* could home tests like those used for COVID-19 be useful for STI testing?

- test feature 2: suitability for screening asymptomatic persons

* some early COVID tests were only for symptomatic people, but lots of STI are asymptomatic

- test feature 3: suitability for teenagers

* some COVID tests cannot be used in teenagers under 15

- test feature 4: prescription requirements

* some COVID tests require a pre-test prescription, possibly with insurance reimbursments

- test feature 5: pricing

Conclusions/action items:

There is a lot to consider when it comes to home testing for common STIs.

[X] E. N. Kersh, “Advances in STI Testing at Home and in Non-Clinical Settings Close to the Home,” HHS Public Access, https://stacks.cdc.gov/view/cdc/119356/cdc_119356_DS1.pdf (accessed Oct. 11, 2023).

10/19/23 - Vaginal swab instructions

JENNA SORENSON - Oct 19, 2023, 4:40 PM CDT

Title: Vaginal Swab Instructions

Date: 10/18/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about how self-swabs are performed clinically

Content:

Test contents:

- Sample tube (filled with preservative media)

- Separate swab in peel-away packet

- Foil lid

- '95KPA' bag

Before:

- Wash hands

Steps:

1 - remove cap from sample tube

2 - remove swab from packet

3 - insert swab 3-4 cm into vagina and turn gently against vaginal walls for 30 seconds

4 - remove carefully, careful not to snap the swab

5 - insert the swab into the sample tube and snap off top half

6 - screw the lid back on tightly, taking care not to pierce foil lid

7 - add a barcoded sticker lengthwise on the sample tube

8 - place samples in a plastic bag and seal tightly

Conclusions/action items:

Interesting that they use a cap and a bag -- could be good to do as well

[X] “Vaginal swab instructions,” Oxfordshire Sexual Health Service, https://www.sexualhealthoxfordshire.nhs.uk/sti/kits/vaginal-swab/ (accessed Oct. 19, 2023).

12/10/23 - Chlamydia and gonorrhoea contamination of clinic surfaces

JENNA SORENSON - Dec 10, 2023, 10:42 AM CST

Title: Chlamydia and gonorrhoea contamination of clinic surfaces

Date: 12/10/23

Content by: Jenna Sorenson

Present: Jenna Sorenson

Goals: Find statistics on how often testing rooms are contaminated after a self-swab

Content:

- method: they swabbed surfaces from a city center testing facility

- goal: determine the extent of surface contamination of gonorrhea and chlamydia and evaluate potential contamination of containers used in the collection of a sample

- out of 154 surfaces swabbed, 20 had contamination of either chlamydia, gonorrhea or both

- 46 of the caps from containers did not test positive for the presence of chlamydia or gonorrhea

- risk of infection of staff is low

- contamination could lead to false-positives

Conclusions/action items:

Surface contamination is very possible

https://pubmed.ncbi.nlm.nih.gov/22535909/

9/11/23 - Self-Collected Vaginal Swabs

Title: Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia

Date: 9/11/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about existing designs

Content:

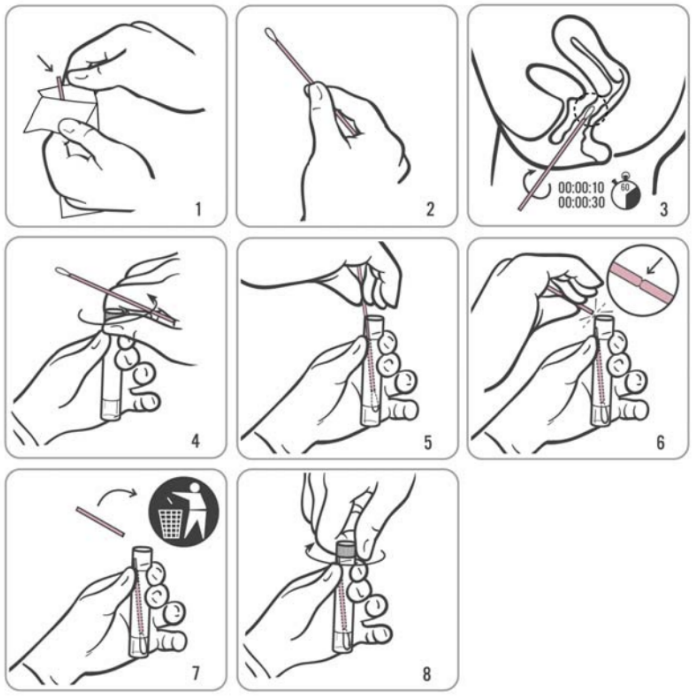
- Women that do need a pelvic exam maybe be tested for gonorrhea and chlamydia with self-swabs

- If soft tip of swab is set-down, dropped, or touched, it is considered contaminated

- Insert tip of swab into vagina about 2 inches and circle about for 10-30 seconds

- Withdraw swab without touching skin

Current procedure:



Conclusions/action items:

We need to make sure that the patient is able to rotate the swab around inside of the vagina.

"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.

9/14/23 - Is self-swabbing good?

JENNA SORENSON - Sep 14, 2023, 4:58 PM CDT

Title: Is self-swabbing for STIs a good idea?

Date: 9/14/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the feasibility of self-swabbing

Content:

- Even in women that are asymptomatic, chlamydia and gonorrhea can have significant negative effects on reproduction

- Annual screening for both diseases is recommended for women

- For both chlamydia and gonorrhea, self-collected vulvovaginal swabs were much more sensitive than endocervical swabs

- Sensitivity was 97% in both women with symptoms and without

- NAAT is expensive and does not allow for antibiotic sensitivity (gonorrhea is becoming for antibiotic sensitive)

- Self-collected NAAT samples will save time and make the patient feel more comfortable

Conclusions/action items:

Self-performed vulvovaginal swabs are the test method of choice when it comes to testing for chlamydia or gonorrhea, regardless if the patient displays symptoms or not.

Page C, Mounsey A, Rowland K. PURLs: Is self-swabbing for STIs a good idea? J Fam Pract. 2013 Nov;62(11):651-3. PMID: 24288710; PMCID: PMC3948498.

9/19/23 - Shelf life of current products

Title: Does the STI kit expire? How long do I have to use it?

Date: 9/19/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about the shelf life of existing products

Content:

- At-home swab kits should be used within 30 days of receiving it
    - this ensures that the preservation liquid (which keeps sample stable) remains effective
- Used swabs should not be stored for more than 14 days

Conclusions/action items:

These durations will be good to include in PDS

“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-Hc

“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%20b

9/21/23 - Five At-Home STI tests

Title: The Best At-Home STD Test Kits in 2023

Date: 9/21/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about competing designs

Content:

1. Let's Get Checked

- results in 2-5 days

- uses hospital labs

- covers 13 STDs

2. My LabBox

- results in 2-5 days

- covers 14 STDs

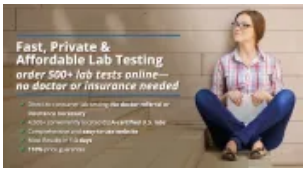
3. STDcheck.com

- detects 10 STDs

- results in 1-2 days

- testing at a lab

4. Healthlabs.com



- order online, test in a clinic

- covers 11 STDs

- results in 1-3 days

5. check my body health

- only detects chlamydia, gonorrhea, and trich

- tests at home

- results in 1-2 days

Conclusions/action items:

Not much on the market for an at-home test that does not need to be sent to lab

"The Best At-Home STD Test Kits in 2023." *At Home STD Test*, STDWatch.com, Sept. 2023, www.stdwatch.com/us/home-kit?campid=2030801688&agid=70177923965&itemid=&targetid=kwd-39247334258&locint=&locphy=9018948&type=e&network=g&d=c&gclid=Cj0KCQjw06-oBhC6ARIsAGuzdw36c4z6R7cGEqcVv_YLdqRq-PqNImCgodNLKKzZ-393U-d3NHH1unYaAj4jEALw_wcB&creative=392426668700&kw=at+home+sti+testing&position=&devicemodel=.

9/21/23 - Everlywell at-home test

Title: Discreetly test for six common sexually transmitted infections

Date: 9/21/23

Content by: Jenna Sorenson

Present:

Goals: Learn more about our main competitor

Content:

- tests for 6 STIs: chlamydia, gonorrhea, hepatitis C, human immunodeficiency virus (HPV), Syphilis and Trichomoniasis

- if something abnormal is detected, able to contact their independent network of physicians

- discrete packaging

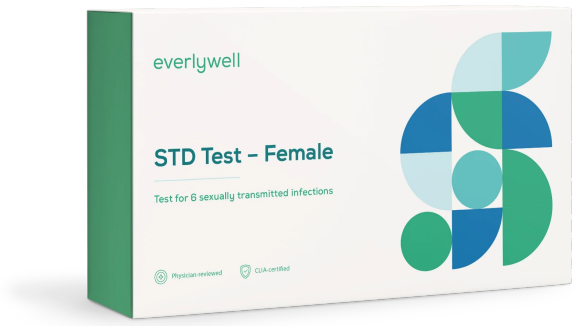
- medications available

- finger prick & vaginal swab sample collection

- they also offer a subscription service

- tested in a lab

- mail back in your sample and get results in days



Conclusions/action items:

Assuming the blood test is for at least syphilis detection and maybe others?

Can't find what type of testing they use

"At-Home Std Test for Women: Check for 6 Common Stds." *Everlywell*, 2023, www.everlywell.com/products/std-test-female/?utm_source=google&utm_mec
8287&g_adgroupid=&g_adid=&g_adtype=none&g_campaign=PMax%3A%2BSexual%2BHealth%2BCategory&g_campaignid=20269955715&g_keyw
oBhC6ARIsAGuzdw2qVThPrsn2NE8LwiLkeM68eFNAgEFRgkF2Udve6NoP9_39XvsnnQkaAsbXEALw_wcB.

9/24/23 - Design 1

JENNA SORENSON - Sep 24, 2023, 6:02 PM CDT

Title: Design 1

Date: 9/24/23

Content by: Jenna Sorenson

Present:

Goals: Come up with ideas for designs

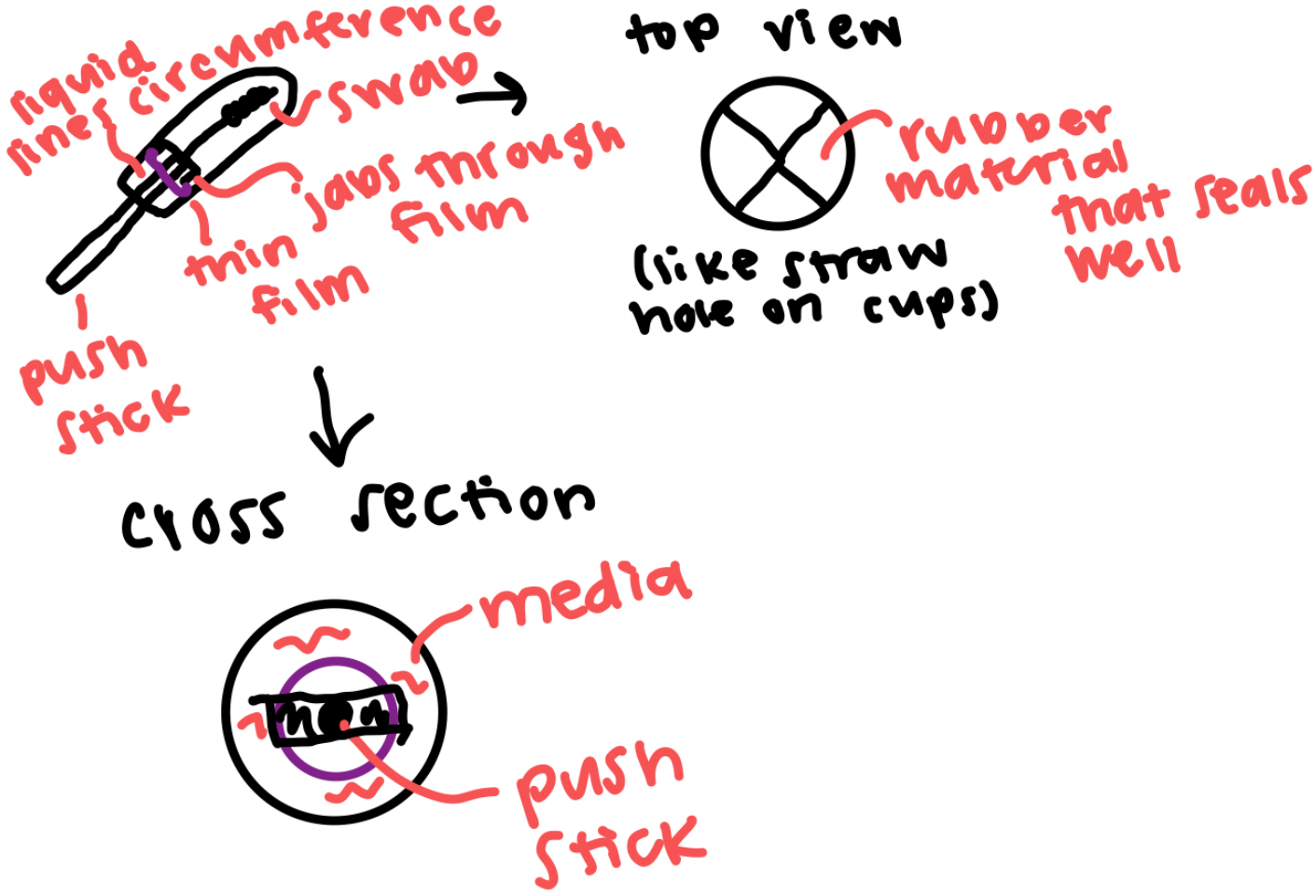
Content:

This one is similar to a tampon

media is contained around the circumference of the device with a push stick coming through the middle

deploy the swab by pushing up on the push stick

pull down on push stick and juts on swab platform break through the film



Conclusions/action items:

Don't love this idea -- would be hard to construct

9/24/23 - Design 2

JENNA SORENSON - Sep 24, 2023, 6:14 PM CDT

Title: Design 2

Date: 9/24/23

Content by: Jenna Sorenson

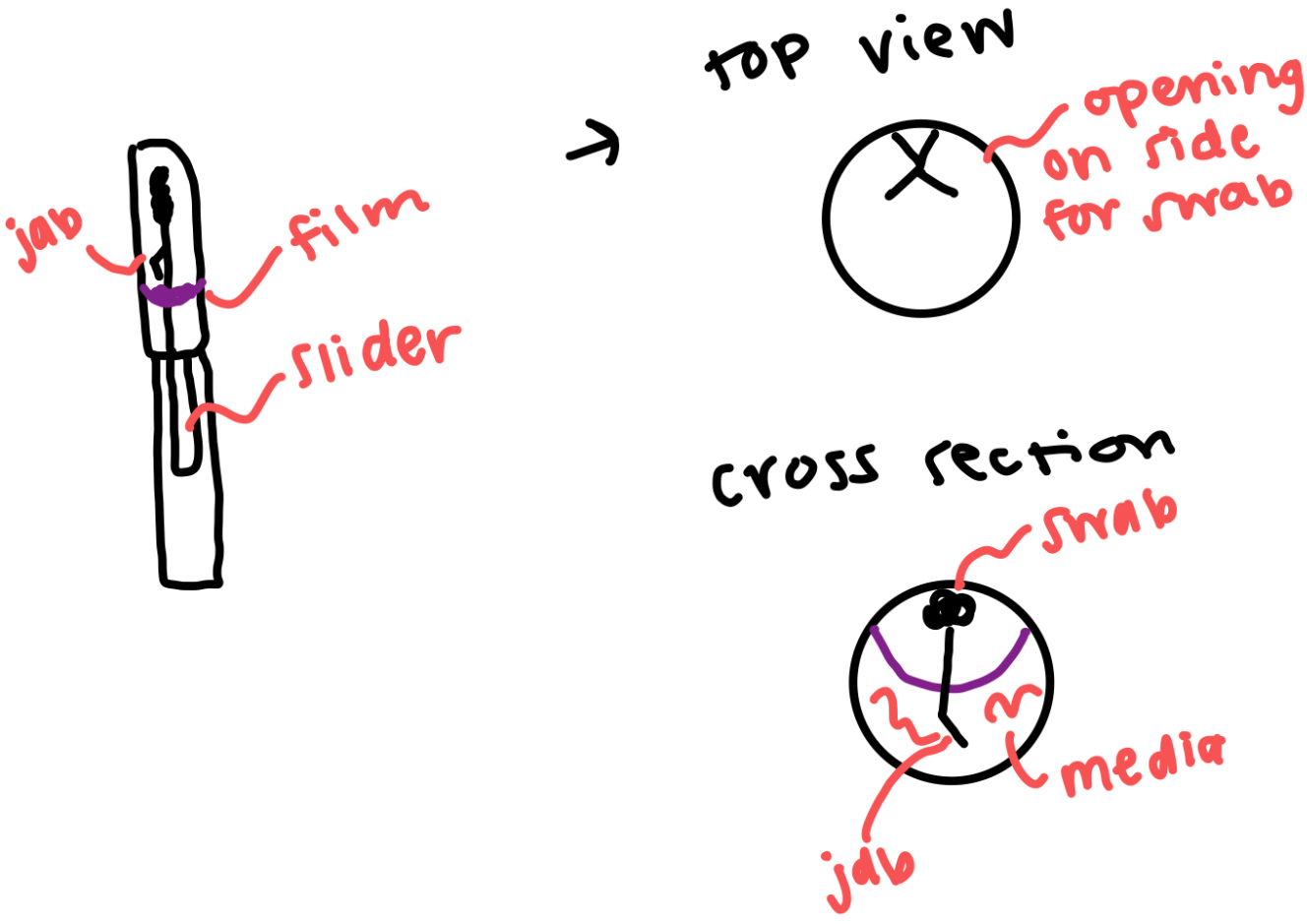
Present:

Goals: Improve upon design one by coming up with an idea with a simplier fabrication process

Content:

this is similar to design 1 but the opening is towards the side of the top and the swab is off center in the device

this allows the fluid to be just on the other side of the device and may be easier to fabricate



Conclusions/action items:

Also don't like this idea very much... it is hard to think of way to have the media contained and then only released when the swab is contracted

9/24/23 - Design 3

JENNA SORENSON - Sep 24, 2023, 6:22 PM CDT

Title: Design Three

Date: 9/24/23

Content by: Jenna Sorenson

Present:

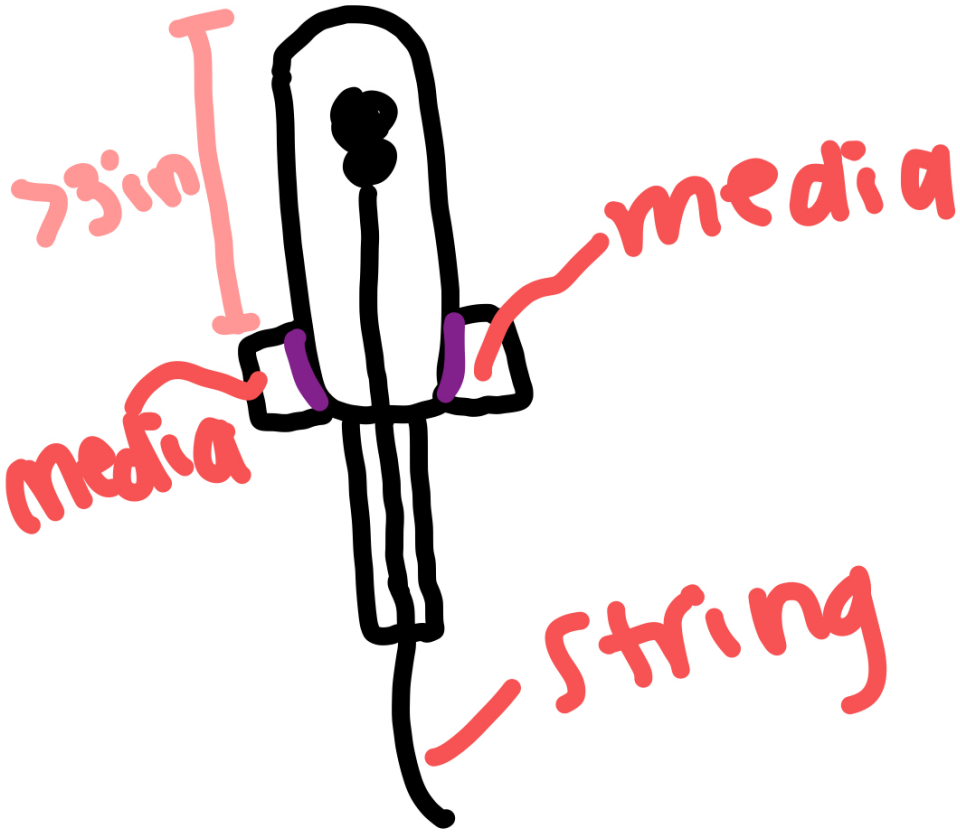
Goals: Come up with something feasible

Content:

Same top as design 1

After using this like a tampon you squeeze the side pouches of media and it breaks through the film and enters into the swab area

top of device from the media pouches must be over 3 inches to allow for proper and comfortable insertion

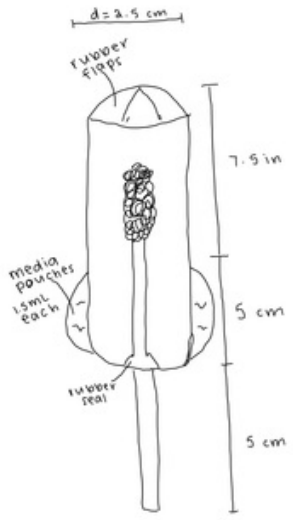


Conclusions/action items:

I like this one more!! Seems the most viable

10/11/23 - Improved Design 3 Drawing

JENNA SORENSON - Oct 11, 2023, 5:35 PM CDT



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design3updated.jpg (154 kB)

Trainings

JENNA SORENSON - Oct 11, 2023, 5:36 PM CDT

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

This certifies that Jenna Sorenson has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety 102: Bloodborne Pathogens for Laboratory and Research	Biosafety 102: Bloodborne Pathogens Safety in Research Quiz 2023	10/9/2023	
Biosafety Required Training	Biosafety Required Training Quiz 2023	1/29/2023	1/29/2028
Chemical Safety: Compressed Gas Cylinders	Survey	10/4/2023	
Chemical Safety: Cryogen Safety Training	Part 1 Final Quiz	10/8/2023	10/8/2028
Chemical Safety: Cryogen Safety Training	Part 2 Final Quiz	10/8/2023	10/8/2028
Chemical Safety: Fume Hood Safety Training	Fume Hood Final Quiz	10/8/2023	10/8/2028
Chemical Safety: Hazard Communication - Identifying Chemical Hazards	Final Quiz	10/9/2023	10/9/2028
Chemical Safety: The OSHA Lab Standard	Final Quiz	1/8/2023	
Disposing of Hazardous Chemicals	Final Quiz	10/8/2023	10/8/2028

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11/10/23 - Tong Lecture

JENNA SORENSON - Nov 10, 2023, 12:30 PM CST

Title: One Engineer's Journey: Where Preparation Meets Opportunity

Date: 11/10/23

Content by: Jenna Sorenson

Present:

Goals: Learn about the story of one engineer

Content:

- went to Pit and super bored freshman year in biology

- her want to help people transitioned into studying biomedical engineering

- made microspheres during research at UW-Madison

lessons:

1. find your people

2. do things that scare you

3. laugh until you cry, cry until you laugh *someone is counting on you

YOU will do this too!

Conclusions/action items:

Everyone's journey is different

9/14/2023 - Validation Study of Self-Collected Vaginal Swab Device

Title: A Pilot Clinical Validation Study of a Self-Collected Vaginal Swab Device for the Detection of Chlamydia Trachomatis in Women

Citation: 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.

Search Terms: Client provided

Date: 9/14/23

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand the differences between vaginal self-swabs vs clinician swabs as well as the other methods of testing.

Content:

- In 2011 - Chlamydia Trachomatis made up the largest number of cases ever reported to the CDC for any condition with 1.4 million cases
- Neisseria Gonorrhoea (N. Gonorrhoea) averaged 104 cases per 100,000 population
    - highest rates in adolescents 15-24 years old
- Both Chlamydia and Gonorrhoea are associated with female infertility including tubal factor infertility, and pelvic inflammatory disease (PID)
- adolescents are known to be less than compliance when it comes to screening
    - only less than half of at-risk youth took preventative STD screening measures
    - fear and lack of knowledge
    - absence of symptoms leading young women to not get tested
- Chlamydia is asymptomatic in up to 70-75% of women
- Nucleic Acid Amplification Tests (NAATs) detect the presence of a particular organism through a detection specific nucleic acid sequences in a sample
    - superior to other methods such as culture plates which require long periods of incubation and resources. Culture plates rely on viable pathogens
    - NAATs do not rely on viable pathogens
- In chlamydia asymptomatic women, detection via NAAT is most accurate through self-collected vaginal swabs when compared to cervical and urine samples
    - no difference in self-collected and clinical-collected vaginal swabs
- compared performance of 3 NAATs using self-collected vaginal swabs
    - Chlamydia and gonorrhea had polymerase chain reaction (PCR) sensitivities of 100% with specificities of 99.3 and 98.8%
- 90.4% collection rate of self-collected vaginal swabs (Doshi)
- 99% of participants in Wiensenfeld's study reported that self-collected swabs were easy to perform and 84% reported preference over gynecological exams
- most self-collected vaginal swabs rely on immediate refrigeration on site or storage into a buffer or NAAT transport fluid by participants themselves
    - complicates collection procedure due to risk of spillage, refrigeration requirements, and transport from clinic or home to lab

- According to the CDC - the use of FDA-cleared NAATs such as the Abbot RealTIme CT/NG requires stringent specimen transport and storage conditions - specimens from asymptomatic women need to be stored between 2 and 30 Celsius and used within 14 days. Specimens from symptomatic women have to be thaw-frozen and stored at the same temperature range
    - Challenge in remote areas where refrigeration may not be available
- fast catch urine samples are acceptable but might detect up to 10% fewer infections compared to vaginal swab samples
- no commercially available NAAT vaginal swab test kits approved by the FDA
    - self-swab that employs NAAT (does not require fluid or refrigeration)
- Study: potential clinical feasibility of a self-collected vaginal swab device that utilizes PCR NAAT technology and the advantages of dry storage in the absence of a buffer for qualitative detection of C.trahcomatis
    - results tested against PCR of doctor collected vaginal swab samples
    - also tested against IgM and IgG chlamydia antibodies from blood samples
    - tested against chlamydia PCR from fast catch urine (FCU) samples
- Materials and Methods:
    - Self-collection tool:
        - 10 cm length rod with a diameter of 1 cm
        - small grip handle of about 3 cm on the proximal end
        - cotton swab of approximately 1 cm length on distal end for collection fo vaginal discharge samples
    - Clinician-collected vaginal swab samples:
        - pelvic examinations using a wet, sterile cotton swab of 10 cm in length
        - cotton swabs were then stored in a sterile specimen jar for storage and transport
    - Self-collection
        - insert swab at least approximately 2.5 cm into the vagina
        - 10-20 s rotation
        - storage of sample in sterile 50 ml centrifuge tube for transport
    - Sample processing
        - both self-collected and doctor-collected vaginal swab samples were transported to the lab followed by processing
        - Nucleic Acid Amplification Tests (NAATs) do not depend on viable pathogens
    - Self-collected and doctor-collected swab samples were introduced to 10 ml of sterilized PBS in original specimen tube
        - samples incubate in PBS for 10 min followed by 1 min of mixing using vortex machine
        - 2 ml of samples were collected for chlamydia testing using an in vitro Polymerase Chain Reaction (PCR) assay
            - Abbott REALTIME CT/NG
        - remaining samples were stored for future use under -20 celsius
- Results
    - self-collected vaginal swabs testing for chlamydia have the highest sensitivity (100%) and specificity 100%
        - specificity: accurately identify people who do not have the disease (negative)
        - sensitivity: capacity to detect the disease (positives)
    - FCU PCR was found to have a sensitivity of 75% (false negative rate - type 2 error rate of 25%) and specificity of 100%
    - Blood IgM antibody was found to have a sensitivity of 25%and a specificity of 100%
    - blood IgG antibody was found to have a sensitivity of 100% and a specificity of 69.23% (false positive rate - type 1 error rate - 30.77%)
- NAAT self-swab stored in a dry tube and have no risk of spillage

Conclusions/action items:

Ask the client if her main goal is to simply limit contact contamination with the testing mechanism she is currently using (swab to media), or if she is looking to employ the NAAT method with PCR testing. Also, conduct further research on nucleic acid amplification tests and PCR.

9/15/23 - Self-obtained vaginal swabs for sexually transmitted infection testing

Title: Hot off the press: Self-Obtained Vaginal Swabs for sexually transmitted infection testing

Date: 9/15/23

Content by: Katherine Kafkis

Search Terms: Client provided

Citation: C. Bond, J. Morgenstern, and W. K. Milne, “Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing,” Academic Emergency Medicine, vol. 28, no. 12, pp. 1448–1451, Sep. 2021, doi: https://doi.org/10.1111/acem.14387.

Present: N/A

Goals: To better understand the differences, if any, between clinician vaginal-swabs and patient self-swabs.

Content:

- Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) are the two most common sexually transmitted infections (STIs) in the United States.
- Emergency departments (EDs) are increasingly diagnosing NG/CT cases compared to STI clinics.

Issues with Current Diagnosis:

- The current criterion standard for NG/CT diagnosis is nucleic acid amplification testing (NAAT), which typically involves provider-performed endocervical sampling.
- Provider-performed sampling can be uncomfortable for patients and has logistical limitations, including the need for exam rooms, available providers, and often a female chaperone.
- The need for universal pelvic examination in the ED to perform STI testing is under scrutiny.

Vaginal Self-Swab Sampling:

- Vaginal sample collection with self-obtained swabs has been researched primarily in non-ED settings, showing comparable sensitivity for NG/CT diagnosis and high patient acceptability.
- However, most of these studies focused on asymptomatic screening rather than acute care environments.

Article Summary:

- This study is a prospective observational cohort study conducted in a single ED.
- It involved female patients aged 18 or older who required NG/CT testing.
- The treatment arm allowed patients to obtain vaginal swabs for NG/CT themselves, while the control arm had provider-performed endocervical swabs.
- The primary outcome aimed to establish the noninferiority of self-obtained swabs for NG/CT diagnosis (with a threshold of 90% sensitivity).
- Self-obtained swabs were found to be highly sensitive in diagnosing NG/CT, and patients generally found this method acceptable.

Quality Assessment:

- The study was generally of good quality but had some limitations, such as being a single-center study, potential selection bias, and narrowly missing the enrollment goal due to the COVID-19 pandemic.
- The study used a rapid turnaround NAAT swab, which might not be available in all EDs.

Key Results:

- Among 515 patients, self-swabs showed a sensitivity of 95% for detecting NG/CT compared to provider-performed swabs.
- Secondary outcomes indicated an excellent kappa of 93% and self-swab sensitivities of 97% for NG and 94% for CT.
- A majority (93%) of patients found self-sample collection acceptable, but some (28%) were concerned about performing swabs incorrectly.
- A portion of patients (26%) refused self-swabs primarily due to discomfort or concerns about self-swab performance rather than the consent process.

Conclusions/action items:

Self-swabs appear to be an excellent method for STI testing in women. Furthermore, many patients find the self-swab environment more comfortable, however, worries about incorrect swabbing continue to be an issue. It is important that our self-swab method includes detailed instructions on use and remains a fairly simple design to mitigate some of the patient concerns with incorrectly performing the test. A design that follows the idea of a tampon (using a plunger to deploy the swab) would likely be the most comfortable mechanism for women.

9/18/23 - Is self-swabbing for STIs a good idea?

Title: Is self-swabbing for STIs a good idea?

Date:9/18/23

Content by: Katherine Kafkis

Search Terms: NIH, self-swab testing for STIs

Citation:C. Page, A. Mounsey, and K. Rowland, “PURLs: Is self-swabbing for STIs a good idea?,” *The Journal of Family Practice*, vol. 62, no. 11, pp. 651–653, Nov. 2013, Accessed: Sep. 19, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948498/

Present: N/A

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Importance of Chlamydia and Gonorrhea:

- Chlamydia and gonorrhea are persistent public health concerns, with millions of reported cases annually in the United States.
- These infections can have serious consequences on reproductive health, even in individuals who do not experience symptoms.

Annual Testing Recommendations:

- The CDC and the US Preventive Services Task Force recommend annual chlamydia screening for sexually active women under 25 and older women with risk factors like multiple sex partners or residing in high-burden communities.
- Annual gonorrhea screening is also recommended for sexually active women with risk factors.

Testing Methods:

- Nucleic acid amplification tests (NAAT) are the most sensitive tests for detecting chlamydia and gonorrhea.
- A key question has been whether self-collected vulvovaginal swabs are as effective as clinician-collected urethral or endocervical swabs for gonorrhea detection.

Study Details:

- The study involved 3,973 women aged 16 to 59 who visited a sexual health center in the UK.
- Women self-collected vulvovaginal swabs for NAAT before a speculum exam, while clinician-collected endocervical swabs and urethral swabs were obtained for both NAAT and culture.
- The findings were as follows:
    - Chlamydia: Self-collected vulvovaginal swabs were significantly more sensitive than endocervical swabs (97% vs. 88%).
    - Gonorrhea: Self-collected swabs and clinician-collected swabs analyzed by NAAT had equally high sensitivity (99% vs. 96%).
    - Self-collected samples analyzed by NAAT were significantly more sensitive than clinician-collected samples cultured for gonorrhea (99% vs. 81%).

Conclusion and Implications:

- The study suggests that self-collected vulvovaginal swabs are the preferred method for chlamydia and gonorrhea testing in women, whether they have symptoms or not.
- This approach can improve sensitivity, patient comfort, and diagnostic efficiency.
- Implementing this change in clinical practice may require adjustments to office visit protocols and patient instruction in self-collection techniques.
- Practical considerations, such as the availability and cost of NAAT, should be taken into account.

Conclusions/action items:

Chlamydia and gonorrhea continue to be seen as public health concerns, with recommendations for annual testing in at-risk women. There is high sensitivity in nucleic acid amplification tests (NAAT), and a high effectiveness of self-collected vulvovaginal swabs for both chlamydia and gonorrhea testing, regardless of symptoms. Action items include considering annual screening, prioritizing NAAT, encouraging self-collection, preparing for potential office protocol changes, and addressing practical considerations for implementing these testing methods. Additional research on NAAT testing should be conducted and a meeting with the UW microbiology lab should be established.

9/19/23 - CDC Detailed Fact Sheet - Chlamydia

KATHERINE KAFKIS - Oct 10, 2023, 8:32 PM CDT

Title: CDC detailed fact sheet on Chlamydia.

Date: 9/19/23

Content by: Katherine Kafkis

Search Terms: CDC - STI fact sheets

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

Present: N/A

Goals: To better understand how chlamydia is transmitted, what the signs and symptoms are, and how we can better prevent the spread of chlamydia via testing.

Content:

- Chlamydia is a common sexually transmitted disease (STD) caused by infection with Chlamydia trachomatis.
- It can lead to various infections, including cervicitis (inflammation of the cervix), urethritis (inflammation of the urethra), and proctitis (inflammation of the rectum).
- Chlamydia spreads through vaginal, anal, or oral sex with someone with the infection. Semen does not have to be present to get or spread the infection.

Effects of Chlamydia in Women:

- In women, Chlamydia infections can result in serious consequences, including pelvic inflammatory disease (PID), tubal factor infertility (damage to the fallopian tubes), ectopic pregnancy (a pregnancy outside the uterus), and chronic pelvic pain.
- Lymphogranuloma venereum (LGV) is another STD caused by C. trachomatis and has been associated with recent proctitis outbreaks among men who have sex with men (MSM).

Prevalence of Chlamydia:

- In 2018, the CDC estimated that there were approximately four million chlamydial infections in the United States.
- Chlamydia is the most frequently reported bacterial STD in the U.S.
- It is challenging to account for many cases because most infected individuals have no symptoms and do not seek testing.
- Chlamydia is particularly common among young people, with two-thirds of new infections occurring among individuals aged 15-24 years.

Risk Factors for Chlamydia:

-
- Sexually active individuals can contract chlamydia through vaginal, anal, or oral sex with an infected partner.
- It is highly prevalent among young people due to behavioral, biological, and cultural factors.
- Some individuals may not consistently use condoms, have multiple sexual partners, or engage in serial monogamy.
- Teenage girls and young women may be at increased risk due to cervical ectopy (presence of endocervical cells on the ectocervix), which may increase susceptibility to chlamydial infection.

- Barriers to accessing STD prevention services, such as transportation, cost, and stigma, can contribute to its prevalence.

Symptoms of Chlamydia:

-
- Chlamydia is often referred to as a "silent" infection because most infected individuals do not experience symptoms.
- Studies suggest that only a minority of infected individuals develop symptoms, with the proportion varying by setting and study methodology.
- Symptoms in women may include cervicitis (endocervical discharge and bleeding), urethritis (pyuria, dysuria, urinary frequency), and pelvic inflammatory disease (abdominal or pelvic pain).
- Men with symptoms typically have urethritis with discharge and dysuria, and some may develop epididymitis.
- Chlamydia can also infect the rectum, throat (via oral sex), and cause conjunctivitis through contact with infected genital secretions.

Health Problems Resulting from Chlamydia:

-
- Untreated chlamydia can lead to serious health problems, including pelvic inflammatory disease, chronic pelvic pain, tubal factor infertility, ectopic pregnancy, and Fitz-Hugh-Curtis Syndrome (perihepatitis).
- Chlamydia in pregnant individuals can result in pre-term delivery, conjunctivitis, and pneumonia in newborns.
- Untreated chlamydia may increase the risk of acquiring or transmitting HIV.

Diagnosis of Chlamydia:

-
- Chlamydia is diagnosed using nucleic acid amplification tests (NAATs), cell culture, and other tests.
- NAATs are highly sensitive and can be performed on vaginal swabs (clinician- or patient-collected) or urine specimens.
- For rectal or pharyngeal infections, testing should be performed at the anatomic exposure site.
- Culture is less common for diagnosis due to limited availability and lower sensitivity compared to NAATs.

Treatment for Chlamydia:

-
- Chlamydia can be easily cured with antibiotics.
    - Antibiotic treatment is effective for both individuals with or without HIV.
- Patients should complete their prescribed treatment course, avoid sexual activity during treatment, and not share medication.
- Repeat infection is common, and retesting is recommended about three months after treatment.
- Partners of infected individuals should also be notified and seek treatment to prevent re-infection.

Prevention of Chlamydia:

-
- Consistent and correct use of condoms during sexual activity can reduce the risk of chlamydia transmission.
    - Abstaining from vaginal, anal, and oral sex is the only surefire way to avoid chlamydia.
- In long-term, monogamous relationships, both partners should be tested for chlamydia.
- Routine screening for chlamydia is recommended for sexually active women under 25 and for older women with risk factors.
- Screening is also recommended for sexually active men in certain clinical settings.

- Individuals with HIV should be tested for chlamydia during their initial care visit and periodically thereafter.

Conclusions/action items:

Conduct additional research on where the Chlamydia bacterium grows within the vaginal canal to get a better understanding of how deep the vaginal self-swab must enter. Also, conduct similar notes on gonorrhea as both STIs are commonly tested for together.

9/19/23 - CDC Detailed Fact Sheet - Gonorrhea

Title: CDC Detailed Fact Sheet - Gonorrhea

Date: 9/19/23

Content by: Katherine Kafkis

Search Terms: CDC, Gonorrhea Facts

Citation: CDC, “Detailed STD Facts - Gonorrhea,” *Centers for Disease Control and Prevention*, Apr. 12, 2022. https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm

Present: N/A

Goals: To better understand how gonorrhea is transmitted, how it manifests in women (and men), and how it is typically tested for and treated.

Content:

- Gonorrhea is a sexually transmitted disease (STD) caused by infection with the Neisseria gonorrhoeae bacterium.
- It primarily infects the mucous membranes of the reproductive tract in both men and women, as well as the mouth, throat, eyes, and rectum.

Prevalence of Gonorrhea:

- Gonorrhea is a very common infectious disease, with approximately 1.6 million new gonococcal infections estimated in the United States in 2018.
- Over half of these infections occur among young people aged 15-24.
- Gonorrhea is the second most commonly reported bacterial STD in the United States, but many cases remain asymptomatic and undiagnosed.

Transmission and Risk Factors:

- Gonorrhea is primarily transmitted through sexual contact with an infected partner, including penis, vagina, mouth, or anus contact.
- Ejaculation is not required for transmission.
- Perinatal transmission from mother to baby during childbirth is also possible.
- Anyone who has had gonorrhea and received treatment can be reinfected through sexual contact with an infected partner.

Signs and Symptoms:

- Many men with gonorrhea are asymptomatic, but when symptoms are present, they may include dysuria (painful urination) or urethral discharge.
- Most women with gonorrhea are also asymptomatic, and even when symptoms are present, they are often mild and nonspecific, such as dysuria, increased vaginal discharge, or vaginal bleeding between periods.
- Rectal infection may cause symptoms like anal itching, soreness, bleeding, or painful bowel movements, but it can also be asymptomatic.
- Pharyngeal infection (throat) is usually asymptomatic but may cause a sore throat.

Complications of Gonorrhea:

- Untreated gonorrhea can lead to serious and permanent health problems in both women and men.
- In women, it can cause pelvic inflammatory disease (PID), which may lead to infertility, ectopic pregnancy, and chronic pelvic pain.
- In men, it may lead to epididymitis, which can result in infertility.
- If left untreated, gonorrhea can spread to the blood, causing disseminated gonococcal infection (DGI), which can be life-threatening.

Gonorrhea and HIV:

- Untreated gonorrhea can increase the risk of acquiring or transmitting HIV, the virus that causes AIDS.

Effects on Pregnant Women and Babies:

- Pregnant women with gonorrhea can transmit the infection to their babies during childbirth, potentially causing complications like blindness, joint infection, or life-threatening blood infection.
- Prompt treatment during pregnancy can reduce these risks.

Who Should Be Tested for Gonorrhea?

- Anyone with genital symptoms, such as discharge, burning during urination, sores, or rash, should seek immediate medical attention.
- Individuals with recent sexual contact with a partner diagnosed with an STD should also be evaluated.
- CDC recommends yearly gonorrhea screening for sexually active women under 25 and older women with risk factors, as well as for men in certain clinical settings.

Diagnosis of Gonorrhea:

- Gonorrhea can be diagnosed using nucleic acid amplification testing (NAAT), which can analyze urine, urethral (in men), or endocervical or vaginal (in women) specimens.
- Culture tests can also be used with swab specimens.
- Rectal and oral diagnostic tests for gonorrhea have been validated for clinical use.

Treatment for Gonorrhea:

- CDC recommends a single 500 mg intramuscular dose of ceftriaxone for the treatment of gonorrhea, given the increasing concern about antimicrobial resistance.
- Alternative regimens are available when ceftriaxone cannot be used.
- Patients should complete their prescribed treatment, even if symptoms resolve, and follow-up is necessary in some cases.

Conclusions/action items:

Begin researching the current competing self-swab designs. Specifically look for swabs that are used to test for Chlamydia and Gonorrhea and if there are any that currently limit contact contamination.

9/28/23- Detection of Chlamydia trachomatis andNeisseria gonorrhoeae by Enzyme Immunoassay, Culture, and Three Nucleic Acid Amplification Tests

Title: Detection of *Chlamydia trachomatis* and*Neisseria gonorrhoeae* by Enzyme Immunoassay, Culture, and Three Nucleic Acid Amplification Tests

Date: 9/28/23

Citation: E. Van Dyck, M. Ieven, S. Pattyn, L. Van Damme, and M. Laga, “Detection of Chlamydia trachomatis and Neisseria gonorrhoeae by Enzyme Immunoassay, Culture, and Three Nucleic Acid Amplification Tests,” *Journal of Clinical Microbiology*, vol. 39, no. 5, pp. 1751–1756, May 2001, doi: https://doi.org/10.1128/jcm.39.5.1751-1756.2001.

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand how the lab processing of STI samples works.

Content:

- The study aimed to evaluate and compare three commercially available nucleic acid amplification tests (NAATs) for the detection of Neisseria gonorrhoeae and Chlamydia trachomatis.

  - Specifically, Roche PCR and Becton Dickinson strand displacement amplification (SDA) were compared, and Abbott ligase chain reaction (LCR) was performed on a subset of samples.

- The study used endocervical swab specimens from commercial sex workers.

- The goal was to assess the performance of these tests against traditional methods such as culture and enzyme immunoassay (EIA) for N. gonorrhoeae and C. trachomatis detection.

- In this study, NAATs (PCR, SDA, and LCR) outperformed traditional methods like culture and EIA for the detection of these infections.

- The study highlights that NAATs are sensitive and specific, with SDA showing 100% specificity for both N. gonorrhoeae and C. trachomatis in endocervical specimens.

Sensitivity and Specificity Calculation:

- For N. gonorrhoeae, a positive result was defined as a positive result by culture or by two NAATs.

- For C. trachomatis, a positive result was defined as a positive result by two tests.

Specificity and Sensitivity Results:

- For the subsample of 396 specimens:

  - Sensitivities for N. gonorrhoeae detection were as follows: culture (69.8%), PCR (95.2%), SDA (88.9%), and LCR (88.9%).

  - Specificities for N. gonorrhoeae detection were 100%, 99.4%, 100%, and 99.1%, respectively.

- Sensitivities for C. trachomatis detection were as follows: EIA (42.0%), PCR (98.0%), SDA (94.0%), and LCR (90.0%).

- Specificities for C. trachomatis detection were 100%, 98.0%, 100%, and 98.6%, respectively.

METHODS:

- Endocervical specimens were collected each month using Dacron swabs for the detection of N. gonorrhoeae and C. trachomatis.

- Three swabs were collected: one for N. gonorrhoeae culture, one for C. trachomatis EIA antigen detection, and one dry swab stored at 4°C and later shipped on dry ice for PCR testing.

Sample Preparation and Processing:

- Dry swabs collected between May 1999 and December 1999 were used for comparing different NAATs to detect N. gonorrhoeae and C. trachomatis.

- Specimens were thawed and mixed with diluted phosphate-buffered saline.

- Four aliquots of 250 µl of the sample suspension were prepared for immediate testing or stored at -20°C.

- For each amplification assay (PCR, SDA, LCR), a 250-µl sample was centrifuged, and the pellet was used for DNA extraction following specific procedures for each assay.

Analysis of Results:

- Specimens tested by PCR, SDA, and LCR were considered true positive for N. gonorrhoeae if they were positive by culture or by two NAATs and true positive for C. trachomatis if they were positive by any two tests (EIA, PCR, SDA, or LCR).

- Specimens tested by PCR and SDA were considered true positive for N. gonorrhoeae if they were positive by culture or by both amplification assays and true positive for C. trachomatis if they were positive by any two tests (EIA, PCR, or SDA).

- For N. gonorrhoeae culture-negative, PCR-SDA-discordant samples and for C. trachomatis EIA-, PCR-, or SDA-only-positive samples, N. gonorrhoeae LCR or C. trachomatis LCR tests were performed, and LCR-positive samples were considered true positive in discrepant analysis.

RESULTS

N. gonorrhoeae:

- All 733 specimens were tested by culture.

- For the first 396 specimens, 63 were N. gonorrhoeae-positive, and 5 specimens were positive in one test only.

- Sensitivities of culture, PCR, SDA, and LCR were compared, with PCR and SDA being significantly more sensitive than culture.

- For the 337 samples tested by culture, PCR, and SDA, 55 specimens were N. gonorrhoeae culture-positive or positive by both PCR and SDA.

C. trachomatis:

- All specimens were tested by ELISA.

- For the first 396 specimens, 50 were C. trachomatis positive, with some samples positive in one test only.

- Sensitivities and specificities of ELISA, PCR, SDA, and LCR were compared, with NAATs being significantly more sensitive than ELISA.

- Samples positive by one test only were further tested by LCR.

Combined Results:

- The performance characteristics of N. gonorrhoeae culture, PCR, and SDA for all 733 specimens were estimated.

- PCR and SDA had significantly higher sensitivity than culture.

- For C. trachomatis, the performance of PCR and SDA was evaluated before and after resolution of discrepant results by LCR, with PCR being slightly less sensitive after LCR analysis.

- N. gonorrhoeae culture had lower sensitivity (65%) compared to NAATs.

- C. trachomatis culture (not performed in this study) is reported to have low sensitivity (50-85%).

- Specificities of PCR and SDA were more than 99% for N. gonorrhoeae, while SDA had 100% specificity for C. trachomatis.

- PCR and SDA showed higher sensitivity and similar specificities compared to culture and ELISA, making them suitable for screening genital gonorrhea and chlamydial infections in female endocervical specimens.

Conclusions/action items:

Overall, the study suggests that PCR and SDA are reliable methods for diagnosing N. gonorrhoeae and C. trachomatis infections in female patients, with higher sensitivity than traditional culture and ELISA techniques.

9/28/23 - Environmental Contamination

Title: Environmental Contamination by *Chlamydia trachomatis* RNA Can Cause False-Positive Test Results in Clinical Samples

Date: 9/28/23

Search Terms: Google Scholar, Environmental contamination STI testing

Citation: 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.

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand the risks and likelihood of environmental contamination and if it can lead to false positives.

Content:

- The study investigates unexpected positive test results for Chlamydia trachomatis (CT) at a women's health clinic in Sweden.

- It suggests that the positive results were due to RNA contamination in the clinic. Such contamination had been theorized before but had not been demonstrated in practice.

Background:

- Commercial nucleic acid amplification tests (NAATs) are commonly used for diagnosing sexually transmitted infections (STIs).

- These tests are highly sensitive and specific but can sometimes yield false-positive results.

- The study describes an unusual event in which a cluster of positive CT results prompted further investigation.

Methods:

- On a single day (day 0) in 2018, a women's health clinic in Gothenburg, Sweden, tested 15 patients for CT, Neisseria gonorrhoeae (NG), and in most cases, Mycoplasma genitalium (MG).

- Six patients tested positive for CT, while MG and NG results were negative.

- The clinic suspected a testing anomaly because positive STI test results had been rare previously.

- The study used the Aptima Combo 2 Assay for CT and NG and the Aptima Mycoplasma genitalium Assay for MG.

- Repeat testing of positive patient samples and environmental sampling was conducted to investigate the issue.

- The environmental investigation included swabs from a keyboard and ultrasound equipment in the examination room (room 1).

Results:

- Four of the six patients initially testing positive for CT were later found to have false-positive results.

- Retesting of these patients on day 5 showed that 4 were negative, and 2 were still positive.

- An environmental investigation revealed that the keyboard sample was positive for both CT and MG, while the ultrasound equipment was negative.

- On day 9, the ultrasound equipment was retested and showed positive results for both CT and MG. However, these results were not confirmed by DNA PCR.

- Environmental samples from six other examination rooms were negative for CT, NG, and MG.

Discussion:

- The investigation concluded that patient samples were likely contaminated at the clinic, leading to false-positive CT results.

- Previous studies had suggested the possibility of CT and NG being detected in environmental samples, which could lead to contamination of patient samples.

- The exact mechanism of contamination was not determined, but it was speculated that sampling practices allowed cross-contamination of CT RNA.

- False-positive results are a concern with highly sensitive nucleic acid amplification tests, and they can be caused by contamination, especially with high-copy-number RNA genes.

- In this case, contamination persisted for at least 9 days in environmental samples.

- The study emphasizes the importance of infection control practices and highlights the need for surveillance of sensitive nucleic acid tests in both clinical and laboratory settings.

- Clinicians and laboratories should be aware of the risk of sample contamination and the potential for false-positive results, especially when a cluster of positive results is observed.

- The study also suggests that lower test sensitivity might be preferable to prevent false positivity due to contamination.

Conclusions/action items:

It is clear that environmental contamination can and has led to false positive results. The information from this article should be used in our presentation as part of our motivation for limiting this contact contamination.

10/4/23 - Women find it easy and prefer to collect their own vaginal swabs to diagnose Chlamydia trachomatis or Neisseria gonorrhoeae

KATHERINE KAFKIS - Oct 11, 2023, 10:26 AM CDT

Title: Women find it easy and prefer to collect their own vaginal swabs to diagnose Chlamydia trachomatis or Neisseria gonorrhoeae infections

Date: 10/4/23

Citation: M. A. Chernesky *et al.*, “Women Find It Easy and Prefer to Collect Their Own Vaginal Swabs to Diagnose Chlamydia trachomatis or Neisseria gonorrhoeae Infections,” *Sexually Transmitted Diseases*, vol. 32, no. 12, pp. 729–733, Dec. 2005, doi: https://doi.org/10.1097/01.olq.0000190057.61633.8d.

Content by: Katherine Kafkis

Present: N/A

Goals: To find some statistics that can be used as part of our motivation for developing an STI self-swab that limits contact contamination.

Content:

- 90.4% of women found it very easy to self-collect a vaginal swab
- 76% preferred a vaginal swab over a pelvic examination, 60% over a urine collection, and 94% indicated that they would be tested more often if a vaginal swab was available

Conclusions/action items:

Include these statistics in our preliminary presentation and report as they are useful motivating factors.

10/6/23 - Laboratory Diagnostic of Chlamydia

Title: **The laboratory diagnosis of Chlamydia trachomatis infections.**

Date: 10/6/23

Content by: Katherine Kafkis

Citation: 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/

Present: N/A

Goals: To better understand the microbiology of CT bacteria and how it is tested for in the lab.

Content:

Labile Nature of Chlamydiae:

- Chlamydiae are fragile bacteria and require special handling to maintain viability.

- Cold storage and minimizing the time between specimen collection and laboratory processing are crucial to preserve the integrity of Chlamydiae specimens.

Swab Types:

- A variety of swab types can be used for specimen collection.

- However, the materials in swabs may introduce toxicity concerns.

- It is advisable to test swab types for toxicity in cell cultures or interference in nonculture assays when proprietary swabs are not provided by the manufacturer.

- As a general rule, swabs with wooden shafts should not be used.

Suitable Swab Tips:

- Cotton, Dacron, and calcium alginate swabs are commonly used for chlamydia specimen collection.

- Note that toxicity issues have been observed with specific lots of each of these swab types.

Cytobrush:

- The cytobrush is an alternative to swabs for collecting endocervical specimens.

- It has been associated with higher recovery rates of chlamydiae and higher rates of antigen detection by direct fluorescent antibody (DFA) in some investigators' experiences.

Training and Specimen Collection:

- Regardless of whether a cytobrush or swab is used, clinicians and health care providers should receive training to collect adequate specimens for chlamydia detection.

Recommendations for Specimen Type:

- Table 1 summarizes recommendations for matching specimen types to diagnostic methods, which helps guide healthcare professionals in choosing the appropriate collection method.

Transport Media for Culture:

- For successful culture of chlamydiae, swabs, scrapings, and small tissue samples should be forwarded to the laboratory in a special chlamydial transport medium, such as 2SP.

- 2SP contains 0.2 M sucrose-phosphate transport medium, 10 µg of gentamicin/mL, 25 µg of vancomycin/mL, and 25 U of nystatin/mL.

- Avoid the use of broad-spectrum antibiotics like tetracyclines, macrolides, or penicillin in the transport media, as they have activity against chlamydiae.

Storage of Chlamydial Specimens:

- Chlamydial specimens should be refrigerated upon receipt in the laboratory.

- If specimens cannot be processed within 24 hours after collection, they should be frozen at -70°C to maintain specimen integrity.

Legal Abuse Cases:

- Currently, culture is the only assay that provides acceptable results for detecting C. trachomatis in legal abuse cases.

- Simultaneously collecting specimens for nucleic acid amplification (NAA) tests can enhance an investigation by providing additional diagnostic information.

Conclusions/action items:

The effective handling of Chlamydiae specimens involves careful selection of swab types, avoiding toxic materials, using appropriate transport media, and timely processing. Talk with the client about cotton swabs as she had previously said that they cannot be used.

10/8/23 - Chlamydia, Microbiology

Title: **Chlamydia Microbiology**

Date: 10/8/23

Content by: Katherine Kafkis

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

Present: N/A

Goals: To gain a detailed understanding of the cell biology of Chlamydia and the different strains of the Chlamydia trachomatis bacteria.

Content:

- Chlamydia trachomatis belongs to the Chlamydophila genus.
- These bacteria are gram-negative, anaerobic, and obligate intracellular pathogens, replicating within eukaryotic cells.
- C. trachomatis differentiates into 18 serovars based on monoclonal antibody-based typing assays, each associated with specific medical conditions.

Serovars and Medical Conditions:

- Serovars A, B, Ba, and C:
  - Associated with trachoma, an ocular disease endemic in Africa and Asia.
  - Characterized by chronic conjunctivitis and potential to cause blindness.
- *Serovars D-K:
  - Linked to genital tract infections and neonatal infections.
- Serovars L1-L3:
  - Associated with lymphogranuloma venereum (LGV), which correlates with genital ulcer disease in tropical countries.

Epidemiology:

- Urogenital chlamydia infections are the most commonly reported bacterial infections in the United States.
- They are also the most common cause of sexually transmitted infections (STIs) globally.
- In the U.S., women have a higher overall rate of urogenital infection than men.
- Higher prevalence is observed in women aged 15-24, while men aged 20-24 have a higher incidence.

Pathophysiology:

- Chlamydia is unique among bacteria due to its infectious cycle with two developmental forms: the elementary body (EB) and the reticulate body (RB).
- The EB is metabolically inactive and is taken up by host cells.
- Inside the host cell, the EB differentiates into the metabolically active RB.
- The RB uses host energy sources and amino acids to replicate and form new EBs, which can infect additional cells.
- In women, C. trachomatis primarily targets the squamocolumnar epithelial cells of the endocervix and upper genital tract.

- In men and women, it can affect the conjunctiva, urethra, and rectum.
- Transmission occurs through direct contact with infected tissue, including vaginal, anal, or oral sex.
- It can also be transmitted from an infected mother to her newborn during childbirth.

Conclusions/action items:

Chlamydia trachomatis is a significant public health concern, with distinct serovars associated with various medical conditions. Its unique infectious cycle, high prevalence, and the potential for serious complications, such as blindness and infertility, make it an important focus in the field of infectious diseases and sexual health. All the information from this paper should be included in the background section of the report.

10/9/23 - Recommendations for the Laboratory based detection of Chlamydia and Gonnorhea

Title: Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Date: 10/9/23

Content by: Katherine Kafkis

Citation: "Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014," 2019.

Present: N/A

Goals: To better understand what types of materials can be included in our design and how they may interact with the Chlamydia trachomatis bacteria. Additionally, to gain an understanding on the laboratory techniques used so that we can take those factors into account when designing our device.

Content:

Specimen Collection Swabs:

- Swabs for C. trachomatis culture should have a plastic or wire shaft.
- The swab tips should be made of rayon, dacron, or cytobrush materials, as other materials may inhibit isolation.

Specimen Collection Procedure:

- Specimen collection for C. trachomatis culture is an invasive process, typically requiring the insertion of a swab.
- For males, the swab is inserted 2-3 cm into the urethra.
- For females, the swab is inserted 1-2 cm into the endocervical canal (client recommended 2.5 cm)
- After insertion, the swab is rotated two or three times to collect sufficient columnar or cuboidal epithelial cells.

Transport and Storage of Culture Samples:

- Culture samples must be stored in appropriate transport media, such as sucrose phosphate glutamate buffer or M4 media.
- These samples should be transported at a temperature of ≤4°C to the laboratory within 24 hours of collection to maximize the recovery of viable organisms.
- If transport is delayed for more than 24 hours, the transport media containing the specimen should be stored at -70°C to preserve the integrity of the specimen.

Inoculation of Specimens:

- Once the specimen has reached the laboratory, it is inoculated by centrifugation onto a confluent monolayer of host cells.
- Common host cell lines used for C. trachomatis culture include McCoy, HeLa 229, or Buffalo green monkey kidney cells.
    - These host cells support the growth of C. trachomatis.

Cycloheximide Addition:

- After inoculation, 2µg/ml of cycloheximide is added to the growth medium.

- Cycloheximide suppresses protein synthesis by the host eukaryotic cell, promoting the growth of C. trachomatis within the host cell.

Harvesting Infected Cells:

- Inoculated cells are allowed to grow for 48-72 hours.
- During this time, infected cells develop characteristic intracytoplasmic inclusions that contain a substantial number of C. trachomatis elementary and reticulate bodies.
    - These inclusions are indicative of a successful culture.

Conclusions/action items:

Proper specimen collection, transport, and culture techniques are essential for the accurate diagnosis and research of C. trachomatis. Swabs should be made of Dacron tips with plastic shafts and we should be able to find these available online, however, the client has provided us with some Dacron proprietary swabs. I plan on looking into commercially available transport media and ordering it as soon as possible so that it is available during fabrication and testing.

10/9/23 - Chlamydia trachomatis: The Persistent Pathogen

KATHERINE KAFKIS - Oct 11, 2023, 11:17 AM CDT

Title: **Chlamydia trachomatis: the Persistent Pathogen**

Date: 10/9/23

Content by: Katherine Kafkis

Citation: 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.

Present: N/A

Goals: To gather additional research on the cell biology of the chlamydia trachomatis bacteria and the ways that it evades destruction by the immune system.

Content:

- Chlamydia trachomatis is a Gram-negative, obligate intracellular bacterium with humans as its exclusive natural host.
- It encompasses different serovars, causing a range of health issues, including preventable blindness, sexually transmitted infections, and lymphatic system infections.
- One of its distinctive features is the ability to establish chronic infections, often without symptoms, which can lead to severe consequences, especially in the female genital tract.

Chlamydia trachomatis Life Cycle:

- The chlamydial life cycle is characterized by two distinct phases: elementary body (EB) and reticulate body (RB).
- EB, the infectious extracellular form, initiates infection by binding to epithelial cell surface receptors.
- Following internalization, EBs transform into RBs within intracytoplasmic inclusions, where they replicate using host cell resources.
- When RB-filled inclusions reach a critical volume and nutrient depletion occurs, RBs convert back into EBs.
- EBs are released through host cell lysis or extrusion of the cytoplasmic inclusion.
- Released EBs can then initiate another round of infection by attaching to adjacent epithelial cells.

Pathogenic Consequences and Persistence:

- Many infected women remain asymptomatic, allowing the bacterium to evade the immune system and migrate to the upper genital tract.
    - Without treatment, up to 50% of infected women may remain so for more than a year.
    - Prolonged exposure to C. trachomatis, or its released antigens, can lead to fallopian tube scarring and disruption, causing tubal factor infertility, ectopic pregnancy, and other complications.
    - Upper genital tract infections in women can result in conditions like pelvic inflammatory disease, endometritis, and perihepatitis.

The Role of the Immune Response:

- C. trachomatis has evolved mechanisms to avoid destruction by autophagy and the host immune system.

- The bacterium can persist within host epithelial cells, entering a nonreplicative but viable state under unfavorable conditions.
- During persistence, the bacterium stops producing major structural and membrane components but upregulates the synthesis of its 60-kDa heat shock protein (hsp60).
- The immune response to hsp60, combined with repeated cycles of productive infection and persistence, may promote damage to fallopian tube epithelial cells, scar formation, and tubal occlusion.

Conclusions/action items:

Chlamydia trachomatis represents a unique and challenging pathogen, with the ability to persist, evade the immune system, and cause severe health complications. I should conduct external research on the differences between EB and RB so that I can write about it in a way that makes sense to the reader.

10/10/23 - Screening Tests to Detect (CDC)

KATHERINE KAFKIS - Oct 11, 2023, 11:27 AM CDT

Title: Screening Tests To Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections

Date: 10/10/23

Content by: Katherine Kafkis

Citation: "Screening Tests To Detect," www.cdc.gov. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5115a1.htm

Present: N/A

Goals: To better understand the requirements for cell culture of Chlamydia trachomatis bacteria and what materials should be used/avoided in our design.

Content:

- Proper specimen collection and handling are critical for the culture of Chlamydia trachomatis (C. trachomatis), ensuring accurate results and successful isolation.
- Various swab materials and techniques are employed, but quality control measures are essential to ensure optimal performance.

Choice of Swabs:

- Swabs with plastic or wire shafts are suitable for obtaining specimens for cell culture.
- Swab tips can be made of cotton, rayon, or Dacron but should not be made of calcium alginate.
    - talk to the client about this as I have found literature that says calcium alginate can be used and that cotton cannot be used
    - maybe stick to just rayon or dacron as both have been said to be fine
- Swabs with wooden shafts should be avoided due to the potential toxicity of wood to C. trachomatis and tissue culture cells.

Quality Control:

- As part of routine quality control, samples from each lot of swabs used for collecting C. trachomatis specimens should be screened.
- The screening aims to detect possible inhibition of C. trachomatis growth and toxicity to tissue culture cells.

Endocervical Brush:

- The substitution of an endocervical brush for a swab may increase the sensitivity of culture for endocervical specimens from nonpregnant women.
- However, using an endocervical brush can induce bleeding, which does not interfere with C. trachomatis isolation.
- Patients should be advised regarding the potential for spotting.

Combined Specimens:

- For culture isolation of C. trachomatis from women, collecting specimens from both the urethra and endocervix can increase sensitivity by 23%
- Placing the two specimens in the same transport container is acceptable.

Storage and Inoculation:

- When the elapsed time between specimen collection and inoculation is <24 hours, specimens should be stored at 4ºC and inoculated in cell culture as quickly as possible.
- If specimens cannot be inoculated within 24 hours, they should be stored at -70ºC.
- Specimens for culture should never be stored at -20ºC or in frost-free freezers, as this may compromise the viability of the organisms.

Conclusions/action items:

Definitely talk to the client about discrepancies in the literature regarding safe materials for the swab tip. Look to see if the FDA has an approved material for the tip. Conduct research on plastics that can withstand -70 to 4 degrees Celsius and are also autoclavable. I have a feeling this material will not exist in which case we should focus on a material that can withstand 4 degrees Celsius and autoclave temperatures and recommend that if the lab is going to wait more than 24 hours then they should transfer the specimen into another material for freezing at -70.

10/26/23 - One-time-snap Mechanisms

KATHERINE KAFKIS - Dec 13, 2023, 5:35 PM CST

Title: **One-time snap designs in plastics**

Date: 10/26/23

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand how the one-time snap mechanism used in the plunger should be designed

Citation: “Snap-Fit Design Manual.” Available: https://productdesignonline.com/wp-content/uploads/2019/08/Snap-Fit-Design-Manual.pdf

Content:

Overhang should not be completely straight but angled as below. Jesse from the design hub suggested that our angle be downward in order to keep the plunger in the body.

The relief mechanism should be tapered. Ours will likely be circular cut-outs around the plunger.

Conclusions/action items:

Work on designing the one-time snap mechanism in SolidWorks. Once it is completed, send it over to Jesse from the design hub to get feedback.

11/22/23 - Mechanical Considerations

KATHERINE KAFKIS - Dec 12, 2023, 2:14 AM CST

Title: **Mechanical Considerations of our Device**

Date: 11/22/23

Content by: Katherine Kafkis

Present: N/A

Goals: To gauge some thresholds for values to be used in the tension and compression tests on our device.

Content:

- average weight of females ages 15 and older (50th percentile) is around 700 Newtons [1]
    - this load should be used in the compression testing of both the body and plunger of the device
- average pulling strength of a seated women is about 75 N [2]
    - most of our patients will be seated or squated when using the device
    - this load should be used in the tensile testing of both the body and plunger of the device
    - it should be applied to the flanges of the plunger to mimic pulling down on the plunger with 75 N of force
    - it should be applied to the bottom rim of the body to mimic pulling down on the body with 75 N of force

Conclusions/action items:

Ensure that loads of at least 700 N and 75 N are applied during mechanical testing. Also, make sure to talk about this during show and tell as justification for our testing parameters.

References:

[1] B. C. Moyer and A. M. Branum, “Anthropometric Reference Data for Children and Adults: United States, 2015–2018,” Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/index.htm (accessed Nov. 20, 2023).

[2] B. Das and Y. Wang, Isometric pull-push strengths in workspace: 1. Strength Profiles, https://www.tandfonline.com/doi/abs/10.1080/10803548.2004.11076594 (accessed Nov. 20, 2023).

12/2/23 - Sterilization Methods - PP vs PLA

KATHERINE KAFKIS - Dec 13, 2023, 5:29 PM CST

Title: **Sterilization of PP vs PLA**

Date: 12/2/23

Content by: Katherine Kafkis

Present: N/A

Goals: **To investigate the sterilization methods of PP vs PLA to create a more re-usable design.**

Citation: Plastics sterilization compatibility. Industrial Specialties Mfg. https://www.industrialspec.com/resources/plastics-sterilization-compatibility

Content:

PLA:

- Autoclave - poor
- Dry heat - fair
- Ethylene Oxide - good
- Gamma Irradiation - good
- Electron beam - good

PP:

- Autoclave - good
- Dry Heat - fair
- Ethylene Oxide - good
- Gamma Irradiation - fair
- Electron beam - fair

Conclusions/action items:

Polypropylene appears to be the material that better aligns with the sterilization method detailed in our PDS. Although PP was not available at the MakerSpace for 3D printing, it should be investigated in future iterations of the device that utilize injection molding rather than 3D printing.

9/14/2023 - Self Collected Vaginal Swabs for STI Testing

KATHERINE KAFKIS - Sep 19, 2023, 5:53 PM CDT

Title: Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia

Date: 9/14/23

Content by: Katherine Kafkis

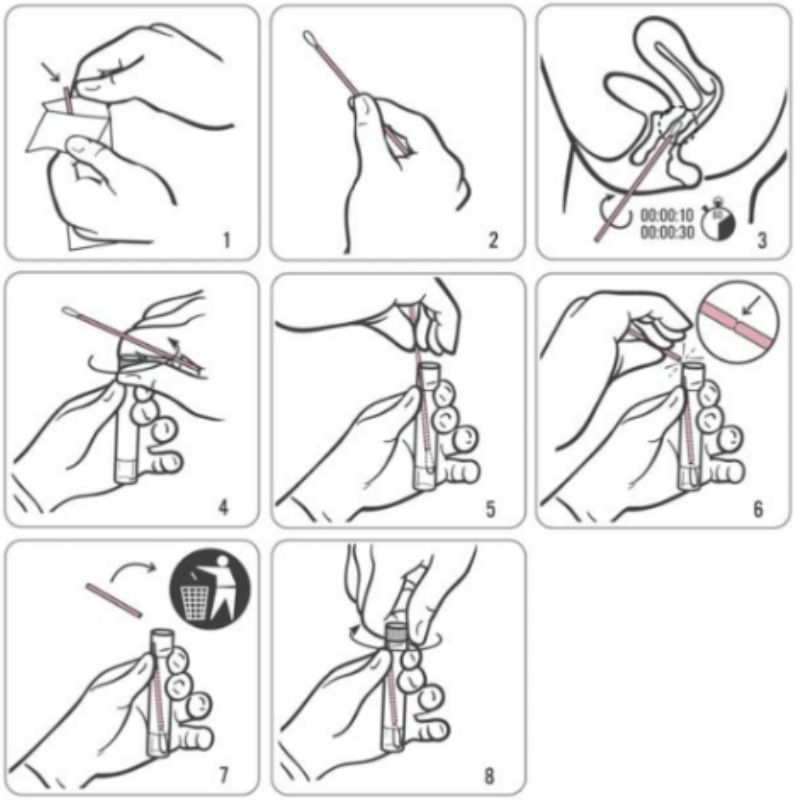
Citation: “Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia.” Available: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf

Present: N/A

Goals: To better understand the current self-swab method and its limitations.

Content:

- women who do not need a pelvic exam as part of their evaluation can be screened for chlamydia and gonorrhea via self-swab
- current method:
    - remove the cotton swab from its packaging
    - place swab into vaginal canal (2 inches deep)
    - swab in circular motion for 30 seconds
    - remove swab and place the tip into the media
    - break off excess handle portion
    - seal the container containing the media and sample



(Illustrations courtesy of Gen-Probe Incorporated, San Diego CA)

- it is important that the tip of the swab is not touched or placed on any external surface but remains in the packaging until it is used
- if any media is spilled or if the tip of the swab touches anything other than the vaginal canal, a new kit must be used

Conclusions/action items:

The current method has a fairly high risk of contact contamination. If a patient uses the swab without reading the instructions, they may touch the tip with their fingers or lay it down on the counter before placing it into the vaginal canal or the media. As a result, the team should look into a design that contains the swab and the media all in one container to mitigate some of the contamination risks. The team should also all look into the media type that is used as well as the type of swab. Further research on where chlamydia or gonorrhea grow in the vaginal canal should be conducted as well.

9/28/23 - Evaluation of rapid diagnostic tests

Title: Evaluation of Rapid Diagnostic Tests: Chlamydia and Gonnorhea

Search Terms: Google Scholar, STI self swab tests

Citation: A. Herring, R. Ballard, D. Mabey, and R. W. Peeling, “Evaluation of rapid diagnostic tests: chlamydia and gonorrhoea,” *Nature Reviews Microbiology*, vol. 4, no. S12, pp. S41–S48, Dec. 2006, doi: https://doi.org/10.1038/nrmicro1562.

Date: 9/28/23

Content by: Katherine Kafkis

Present: N/A

Goals: To learn more about the other types of self-swab tests available.

Content:

- Early diagnosis and treatment are crucial for controlling sexually transmitted infections (STIs).

- This approach prevents complications in affected individuals and interrupts disease transmission.

- Asymptomatic infections are common and require screening or partner notification for detection.

- The WHO reports high rates of genital Chlamydia trachomatis and Neisseria gonorrhoeae infections, especially in areas with limited access to laboratory services.

- Rapid point-of-care diagnostic tests (RDTs) are valuable, allowing immediate diagnosis and treatment, particularly in settings where returning to clinics for results is challenging.

- RDTs are also beneficial for outreach programs targeting high-risk, marginalized individuals.

Syndromic Management

- For symptomatic patients without access to laboratory services, the WHO recommends syndromic case management.

- Syndromic management treats all probable causes of a specific clinical syndrome.

- WHO provides guidelines and flowcharts for syndromic management of various STI syndromes.

- National control programs can adapt these flowcharts to local disease patterns and antimicrobial susceptibilities.

- Syndromic management's advantage is simplicity and cost-effectiveness.

- However, it may lead to unnecessary treatment, especially for syndromes like vaginal discharge.

Types of Diagnostic Tests

A. Traditional Laboratory Tests

- Microscopy of Gram-stained urethral or cervical smears allows direct visualization of N. gonorrhoeae.

- Microscopy is more sensitive in symptomatic cases, particularly in men.

- Cytological staining methods are not suitable for C. trachomatis but direct immunofluorescence staining can be used.

B. Antigen-Detection Tests

- Commercially available tests use monoclonal or polyclonal antibodies to capture chlamydial or gonococcal antigens.

- These tests come in laboratory-based immunoassay formats and immunochromatographic strips for rapid visual results.

- Their performance characteristics and utility in disease control programs require further evaluation.

The Need for Field Evaluation of RDTs

- Traditional laboratory testing requires well-equipped facilities, trained personnel, and refrigeration.

- Samples often need to be transported to centralized facilities, delaying results.

- Rapid diagnosis is essential for timely treatment and disease control.

- Field evaluation of RDTs is crucial to assess their performance in resource-limited settings.

General Issues in Study Design

1. Reference Standards

- Bacterial culture remains the reference standard for gonococcal infection.

- Nucleic acid amplified tests (NAATs) can be used when bacterial culture is not feasible.

- Some NAATs may have compromised specificity due to cross-reactivity with other Neisseria species.

2. Local Epidemiology and Study Population

- Local disease prevalence and population subgroups must be considered when selecting the appropriate test.

- Study populations should be well-defined based on the study's objectives.

- Syndromic management specificity can be improved by including specific patient groups.

- Screening programs may target individuals at risk, regardless of symptoms.

- Standardized data collection and treatment protocols should be followed.

- Early diagnosis and treatment are vital for STI control.

- Syndromic management and RDTs play crucial roles, especially in resource-limited settings.

- Field evaluations are needed to assess the performance of RDTs.

- Accurate testing and targeted treatment are essential for reducing unnecessary treatment and controlling STIs effectively.

Factors Affecting Test Performance

1. Specimen Sampling and Preparation

- Gonorrhoea and chlamydial infections present different symptoms in men and women.

- Men typically present with urethral discharge, while women often have localized, asymptomatic infections in the endocervix.

- Specimen collection should use sterile dacron, rayon, or cotton swabs (note that some cotton swabs and calcium alginate swabs can be toxic to N. gonorrhoeae).

- Avoid the use of antiseptics, analgesics, and lubricants during specimen collection, as these substances can inhibit laboratory tests.

- Collect two or three vaginal swabs and two or three cervical swabs to allow for multiple tests, including RDTs, NAATs, bacterial culture, and additional testing if needed.

- Vaginal swabs should be collected before cervical swabs to prevent contamination.

- Clear instructions for specimen collection, labeling, and transport should be provided, and self-taken vulvo-vaginal swabs can be considered as an alternative.

2. Transport and Storage of Specimens

- Specimens for N. gonorrhoeae culturing should ideally be inoculated immediately onto growth medium with a CO2-enriched atmosphere.

- Transport media that maintain N. gonorrhoeae viability for up to 48 hours can be used when immediate incubation is not possible.

- Minimize the time between sample collection and plating onto culture medium.

- Transport media should be stored at 20°C ± 5°C.

- Specimens for C. trachomatis detection by NAAT should follow the product's package insert instructions, using appropriate swabs or transport media.

- Store samples at 4°C if they cannot be processed immediately, and freeze at -20°C or -70°C if processing is delayed beyond 7 days.

3. Transport and Storage of RDTs

- High temperatures during transport and storage can negatively impact RDT performance.

- Maintain RDT storage between 2°C and 30°C, in accordance with manufacturer recommendations.

- Expiry dates are set based on these conditions, and exceeding recommended storage temperatures can reduce shelf life and sensitivity.

- Monitor RDT transportation from manufacturers and within countries closely.

- Provide shipping details to consignees and notify air carriers of temperature storage requirements.

- Ensure prompt ground transportation without prolonged exposure to high temperatures.

- Storage at centralized field facilities should adhere to manufacturer specifications, typically below 30°C.

- Monitor and maintain proper storage conditions, especially in remote areas where RDTs are most useful.

- Develop quality-assurance procedures for RDTs exposed to temperatures above 30°C.

4. Training of Staff

- Adequate training and supervision of end-users of RDTs should be integrated into existing health worker training and quality-assurance programs.

- Staff should be proficient in performing both the reference test and the RDTs.

- Laboratories should participate in external quality-assurance schemes and Proficiency Panel testing.

5. Recent Treatment

- Recent antibiotic use can affect test results but should not necessarily exclude individuals from testing.

- Document any recent antibiotic use within the past 2-3 weeks.

6. Laboratory Facilities and Testing Sites

- Reference laboratories should have clear Standard Operating Procedures (SOPs) for RDTs.

- Ensure adherence to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) or Good Clinical Laboratory Practice (GCLP) guidelines.

- GCLP guidelines are specifically designed for clinical trials and diagnostics.

7. Co-morbidities

- Chlamydial and gonococcal infections are associated with increased HIV risk.

- Testing for HIV and other STIs should be offered alongside C. trachomatis or N. gonorrhoeae testing.

Conducting the Evaluation

1. Obtaining Informed Consent

- Follow the guidelines for informed consent as discussed in the generic guidelines for diagnostic test evaluations.

2. Biosafety Guidelines

- Adhere to general biosafety guidelines for clinic and laboratory staff.

3. Use of Test Kits

- Follow the general guidelines on the use of test kits.

4. Testing

- Perform all tests according to the manufacturer's recommendations and document any deviations.

- Implement blinding to ensure independent interpretation of test results.

- Consider having at least two individuals read RDT results independently.

- Assess the stability of results 1 hour after the recommended reading time for busy clinics.

VI. Quality Assurance

- Check RDT sensitivity at a central laboratory upon receipt and periodically throughout the test's shelf life.

- Send a portion of positive reference standard tests and 10% of negative specimens to an external laboratory for validation.

Recording and Analysis of Results, and Archiving of Specimens

- Maintain separate records for the two readings of RDT results to ensure independent interpretation.

- Record results of RDTs and reference tests for each specimen in a spreadsheet.

- Data from patients, clinic tests, RDTs, and reference tests should be entered into a standardized spreadsheet for analysis.

- Double-entry data to reduce errors and perform data backups regularly.

- Retain collected information until the study concludes, data analysis is completed, and final publication is achieved.

- Dispose of unused samples, unless informed consent for future studies has been obtained.

Analysis of Results

- Calculate sensitivity, specificity, positive and negative predictive values, and 95% confidence intervals for each RDT compared to the reference test.

Conclusions/action items:

This paper did not have much information on the different types of swabs which makes me believe that there is pretty much just a standard self-swab kit. This paper did have very good information on the temperature that the samples must be stored at as well as the media which should be included in our PDS as well as on the instruction sheet of our design.

9/27/23 - Initial Design Sketch no media

KATHERINE KAFKIS - Sep 28, 2023, 7:58 PM CDT

Title: Self-swab device that would be deployed into a media.

Date: 9/27/23

Content by: Katherine Kafkis

Present: N/A

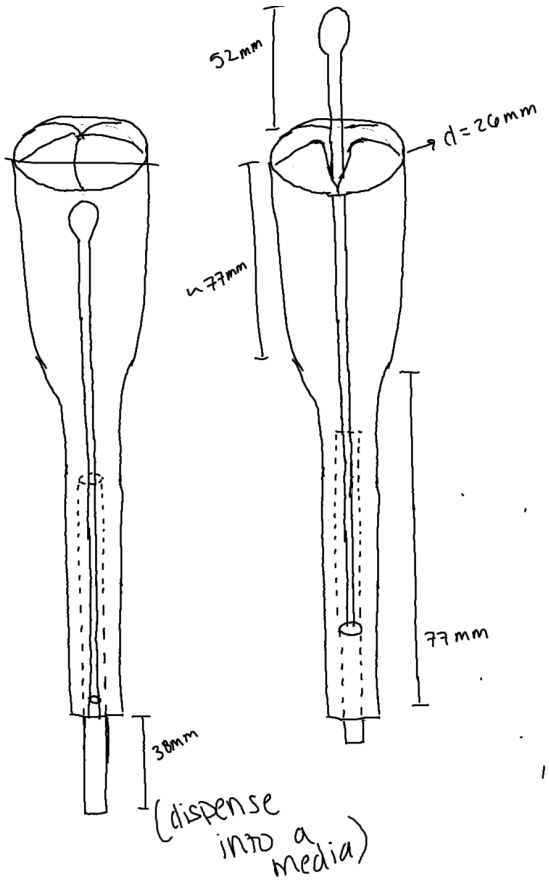
Goals: To draw an initial design idea for our device.

Content:

- the device should limit contact contamination as only the swab will enter the vaginal canal and will then be immediately retracted back into the device

- after retracting it into the device, the patient can then deploy the sample into the media container without every needing to hold the actual swab in their hand.

- since the swab is contained in the external device, there should be no vaginal fluids on the external device and transport into a media can be done without ever touching the swab to the media container



Conclusions/action items:

Although this design should help to limit contamination of the environment, transport into a media is still required. Keep brainstorming a mechanism where there is no need for transport.

9/27/23 - Initial Design Sketch With Media

KATHERINE KAFKIS - Sep 28, 2023, 8:00 PM CDT

Title: Self-swab device that contains the transport media.

Date: 9/28/23

Content by: Katherine Kafkis

Present: N/A

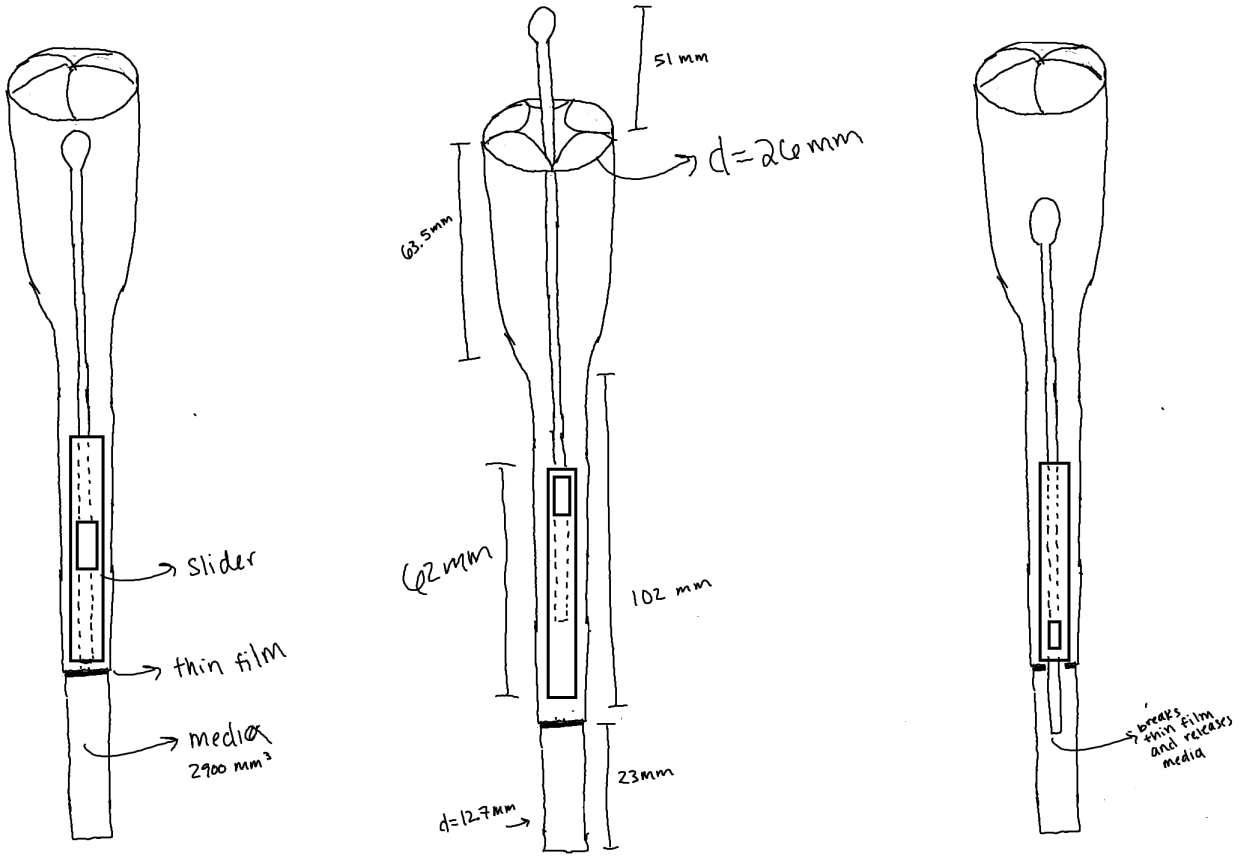
Goals: To draw an initial design idea for our device that includes the transport media.

Content:

- the device should limit contact contamination as only the swab will enter the vaginal canal and will then be immediately retracted back into the device

- after retracting it into the device, the patient can then break a thin film and release the media

  - since the swab is contained in the external device, there should be no vaginal fluids on the external device and no need for transport into a media



Conclusions/action items:

Share this design idea with the team as I think it could be feasible. My only concern with this design is the risk of breaking the thin film before swabbing. If the patient were to pull the slider back by accident, then they would break the film and release the media. Look into a mechanism that would only allow for the slider to be pulled back after being moved forward.

11/10/23 - Tong Lecture

KATHERINE KAFKIS - Nov 10, 2023, 12:33 PM CST

Title: **Tong Lecture**

Date: 11/10/23

Content by: Katherine Kafkis

Present: BME

Goals:

Content:

- find your people
- do things that scare you
  - if they are too comfortable, they are too easy
- need to have big-picture thinking
  - must take risks to fulfill dreams
- laugh and cry
- someone is counting on you
- the journey leads to a story
- loved her queen!

Conclusions/action items:

I need to take some more risks and prioritize my research in order to achieve what I want in the future.

9/11/23 - Connecting COVID-19 Self-swabs to Other Infection Implications

KAIYA MERRITT - Sep 17, 2023, 10:51 PM CDT

Title: Evolution of Specimen Self-Collection in the COVID-19 Era: Implications for Population Health Management of Infectious Disease

Date: 9/11/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To gain more knowledge and information regarding the concept of our design project.

Content:

- In 2012, the Food and Drug Administration (FDA) approved the first self-collected and self-performed test for an infectious disease. The approved test was developed by OraSure Technologies and detected HIV antibodies from saliva.

- For females, self-collection of vaginal swabs for STI testing has been reported to be valid and acceptable for a number of STIs.

- Patients may like the self-swab idea because it provides easy, timely access to testing and the avoidance of a potentially embarrassing visit to a clinic or personal physician.

- Self-collected vaginal swabs have been reported to yield greater sensitivity than first-catch urine for chlamydia and gonorrhea.

Conclusions/action items:

This article gave a little history on the rise of self-swabs and gave some new insight about the self-swab appeal.

Cockerill FR;Wohlgemuth JG;Radcliff J;Sabol CE;Kapoor H;Dlott JS;Marlowe EM;Clarke NJ; (2021). *Evolution of specimen self-collection in the covid-19 ERA: Implications for Population Health Management of Infectious Disease*. Population health management. https://pubmed.ncbi.nlm.nih.gov/33544647/

9/11/23 - Notes on "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

KAIYA MERRITT - Sep 18, 2023, 3:13 PM CDT

Title: A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women

Date: 9/11/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To read and review this article sent by the client to better understand what we need to do for our project.

Content:

- Chlamydia made up the largest number of cases ever reported to the CDC for any condition at 1.4 million infections worldwide.
- The highest rates of which were in adolescents aged 15–24 years old.
- Despite benefits associated with it, adolescents are known to be less than compliant when it comes to screening.
    - Is this because it feels invasive to them? How can we make it feel less invasive?
- In chlamydia asymptomatic women for example, detection via NAAT has been shown to be most accurate through self-collected vaginal swabs when compared to cervical and urine samples.
- 99% of participants in Wiesenfeld's study also reported that self-collected vaginal swabs were easy to perform.
    - So, people in this study did not think it was challenging, but I'm curious how many of the thought it was challenging to not self-contaminate or to contaminate the environment around them.
- Moreover, there are not commercially available NAAT vaginal swab test kits approved by the Food and Drug Administration (FDA).
- There is opportunity in this space to engineer a device for the self-collection of vaginal swabs for use in the screening of C. trachomatis.
- Must incorporate the advantages of NAATs, with the addition of ease of storage and transport for patients through the absence of transport buffer or fluid, and refrigeration requirements.
- This study looks at a self-swab with NAAT technology and a dry storage.

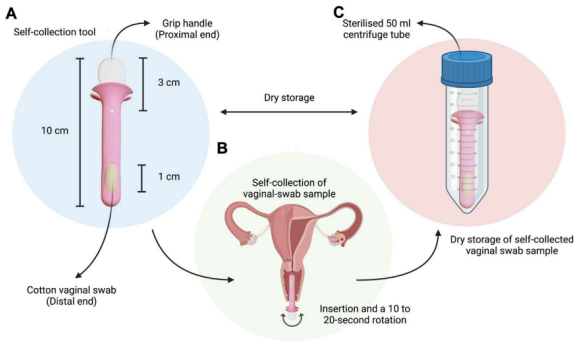


FIGURE 1
Simple schematic highlighting: **(A)** The vaginal swab self-collection tool given to study participants, with a total designated length of approximately 10 cm, a 3 cm handle on the proximal end for comfortable grip, and a 1-cm cotton vaginal swab embedded on the distal end; **(B)** The self-collection procedure instructed to study participants during visit to the outpatient clinic (insertion and; **(C)** The dry storage of samples in a sterilised 50 ml centrifuge tube for transport to the lab for further processing and analysis. Created with BioRender.com (https://app.biorender.com/).

- Self-swabs had highest sensitivity and specificity (than other forms) compared to gold standard.

Conclusions/action items:

Self-swabs are a very promising technology. Our device needs to limit contamination. Next article should be looking at NAAT testing to better understand how a "dry" sample would work. Maybe ask client and talk to her about refrigeration and if a media will be involved?

Source:

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.

9/15/23 - Viability PCR & NAAT Tests

KAIYA MERRITT - Sep 17, 2023, 10:41 PM CDT

Title: Viability-PCR Shows That NAAT Detects a High Proportion of DNA from Non-Viable Chlamydia trachomatis

Date: 9/15/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To have a better understanding of PCR and NAAT Testing

Content:

- One of the main disadvantages of NAAT assays is that the available DNA is amplified without discriminating between DNA originating from viable and non-viable CT.
- Cell culture is the gold standard as it approaches a specificity of 100% for the assessment of viability.
- For the V-PCR DNA samples were extracted and stored at -20 degrees Celsius.
- DNA amplification of non-viable CT potentially results in an overestimation of quantitative test positivity by currently used NAATs.
- Traditionally, cell culture is the gold standard as it approaches a specificity of 100% for the assessment of viability. However, cell culture methods are labor-intensive, technically demanding, expensive, and lack sensitivity for the detection of CT infections.
- One promising strategy relies on the use of DNA intercalating dyes also called viability-PCR (V-PCR).
- In this study, technical validation of the V-PCR method was conducted by the assessment of predefined viability ratios of CT cultures.
- Results showed that as expected, for all pre-mixed ratios the values without PMA treatment were similar.
- To demonstrate clinical applicability, this study used the V-PCR method on self-collected vaginal swab samples from 50 CT positive women before treatment with antibiotics.

Conclusions/action items:

In conclusion V-PCR has the ability to discriminate viable from non-viable bacteria without the need of labor-intensive cell culture methods. NAAT testing is just as effective and useful as cell culturing to determine if an STI is present.

Source:

Janssen, Kevin J. H., et al. “Viability-PCR Shows That NAAT Detects a High Proportion of DNA from Non-Viable Chlamydia Trachomatis.” *PLOS ONE*, vol. 11, no. 11, 3 Nov. 2016, p. e0165920, https://doi.org/10.1371/journal.pone.0165920. Accessed 11 Nov. 2020.

9/18/23 - IUD Applicator Notes

Title: Insertion and Removal of Intrauterine Devices

Date: 9/18/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To better understand how an IUD applicator works as the mechanism may be able to be applied to our design.

Content:

- Copper (ParaGard) IUD and inserter

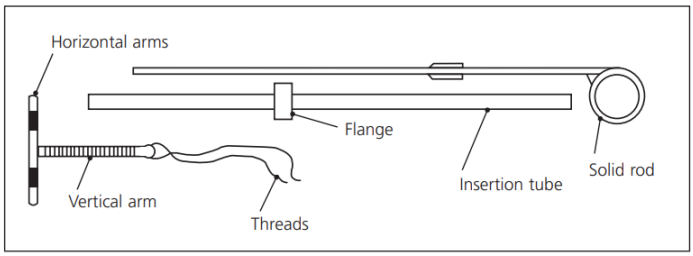
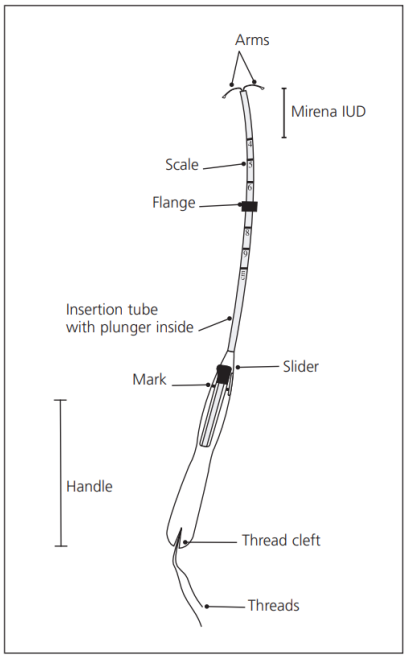


Figure 1. Copper-releasing intrauterine device (ParaGard) and inserter.

Reprinted with permission from FEI Women's Health.

- Another image of an IUD and it's inserter.
- The slider mechanism is what I'm taking note of as it expulses the IUD but then it contracts back in.



- **Figure 2.** Hormone-releasing intrauterine device (Mirena) and inserter.
- Steps on IUD insertion:
  - The physician should stabilize the cervix during the insertion of the IUD with a tenaculum.
  - A sterile uterine sound should be used to determine the depth of the uterine cavity.
  - An IUD should not be inserted if the depth of the uterus is less than 6 cm.
  - The physician should use sterile gloves to remove the IUD from the sterile package.
  - The white inserter rod should then be placed into the insertion tube at the end opposite the arms of the IUD and approximated against the ball at the base of the IUD.
  - The physician should then insert the IUD into the uterus until the flange is against the cervix.

    - The clear inserter tube should be pulled back on the insertion rod approximately 2 cm so that the arms can spread to the “T” position.
    - The tube should be advanced slowly to ensure a correct positioning of the and the physician should remove the insertion rod by holding the insertion tube in place.
- The physician releases the IUD by pulling the slider all the way down while holding the inserter firmly in position. The threads will be released automatically, and the inserter should be removed from the uterus.

Conclusions/action items:

In conclusion, the client's initial thought about somehow connecting our design to an IUD inserter could prove to be promising. The slider tactic could be promising to release the swab in the vagina and then retract it back into the device. The images included above showing where the slider is located on the mechanism will be useful. However, something to note is that the size of our design with need to be much smaller than the IUD inserter as the swab does not need to reach the cervix.

Source:

Johnson, Brett Andrew. “Insertion and Removal of Intrauterine Devices.” *American Family Physician*, vol. 71, no. 1, 1 Jan. 2005, pp. 95–102, www.aafp.org/pubs/afp/issues/2005/0101/p95.html.

9/18/23 - Potential Implications and Limitations of Our Design

KAIYA MERRITT - Sep 18, 2023, 2:59 PM CDT

Title: Love My Body: Pilot Study to Understand Reproductive Health Vulnerabilities in Adolescent Girls

Date: 9/18/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: The goal from this article is to learn about limitations, ethics, and stigmas around STI testing.

Content:

- People aged 15 to 24 years comprise half of all new sexually transmitted infections (STIs) in the United States, despite the fact that this age group accounts for just 27% of the sexually active population.
- CDC recently reported 25% of sexually active adolescent girls currently have an STI.
- There is a lack of STI testing among adolescents and young adults aged 15 to 25 years, with 42% of sexually active adolescents reporting not testing because they said they claimed to not be at risk for an STI.
- Sexual health knowledge is lacking among adolescents. One study found that 65% of 14 to 21-year-olds were aware of hepatitis, 57% were aware of human papillomavirus, and only 6.5% were aware of trichomoniasis.
- When asked about the relationship between alcohol and condomless sex, most said that these were *strongly connected* because drinking too much lowers inhibition and impairs decision making.
    - Other reasons for condomless sex including male pressure for condomless sex, lack of female sexual empowerment, the societal stigma of female sexuality, and a lack of concern or knowledge of STIs.
- The lack of concern about STIs was often attributed to the belief that young women simply did not realize how common these infections were.
- Some expressed ignorance because they had never had an STI, and their friends had not either.
- The study emerged two strong themes, one that young women are largely ignorant of STIs and their health effects, and second young women are relatively unconcerned about STIs, but rather, extremely concerned about pregnancy.

Conclusions/action items:

In conclusion, this article mainly highlights how there is a severe lack of STI knowledge in young adults. Many people won't go get tested because they feel they aren't at risk and because they have no symptoms. As a society STI's clearly are not being talked about enough and maybe if people had the proper knowledge, they would do the routine testing. I feel like a personal takeaway from reading this article that our product we design should have an aesthetic appeal that at least tries to make testing seem less scary for women.

Source:

Tzilos Wernette, Golfo, et al. “Love My Body: Pilot Study to Understand Reproductive Health Vulnerabilities in Adolescent Girls.” *Journal of Medical Internet Research*, vol. 22, no. 3, 30 Mar. 2020, p. e16336, https://doi.org/10.2196/16336. Accessed 15 Mar. 2022.

9/25/23 - Possible Environmental Contamination

Title: Environmental Contamination by Chlamydia trachomatis RNA Can Cause False-Positive Test Results in Clinical Samples

Date: 9/25/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To try and further understand why our client is concerned about environmental contamination of self-swab devices.

Content:

- This study is an investigation of unexpected positive test results for Chlamydia Trachomatis at a women's health clinic in Sweden that revealed samples were contaminated by RNA in the clinic.
- **I want to personally disclaim that this study's sample size is very small.
- Current commercial NAATs dominate the STI diagnostics, but they have high sensitivity and specificity that often neglects the risk of false positives.
- The clinic test 6 women and the clinic suspected a testing anomaly because of the sporadic positive STI testing.
    - All 6 patients were found positive for Chlamydia.
- All analyses were performed using the Aptima Combo 2 Assay swab device.
    - The Aptima test is highly sensitive and identifies ribosomal RNA.
    - Specific target rRNA is captured and amplified by a transcription-mediated amplification.
- The target DNA was detected by using an in-house polymerase chain reaction.
- 4 of the 6 patients initially tested were reevaluated and understood to be false positive after further inquiry.
- All six patients were retested on day 5
    - 4 of them were found negative
    - 2 were found positive
    - The retested positive patient samples were further confirmed by DNA PCR.
    - On day 5, with the suspicion of false-positive results, an environmental investigation was initiated.
    - Environmental sampled from the keyboard and ultrasound equipment were collected from the room.
    - The keyboard sample was found positive for Chlamydia.
- The investigation revealed that the patient samples most likely were contaminated at the clinic.
- The primary clinical laboratory has routine to minimize contamination by implementing daily cleaning of surfaces with hypochlorite followed by surface disinfection.
- Overall discussion that clinicians should be aware of the possibility of false positive results and if the predominance of positive results is found localized to specific examination rooms.
- Although the likelihood of false positives due to cross-contamination during sample collection is very low, false positives are not negligible.
- False positives in some countries could be a severe issue as Chlamydia in some countries is included in communicable disease laws, and false positives may result in improper legal notification and harm.

Conclusions/action items:

There are a few critiques I have with study first off, however, I feel it does initiate some powerful insight. In this investigation it was concluded that the keyboard was possibly contaminated with Chlamydia and therefore is what caused some false positives in patients. Routine sanitation should be a must, as well as patient handwashing. We should include a step in our instructions for our self-swab device. I can also maybe see why environmental contamination is an issue with the aspect of false positives. If a negative patient touches fluid on the counter of a positive patient and then it ends up on the swab, their results will be incorrect. Our device will have to minimize this kind of contamination.

Source:

Toepfe, Michael, et al. “Environmental Contamination by Chlamydia Trachomatis RNA Can Cause False-Positive Test Results in Clinical Samples.” *Sexually Transmitted Diseases*, vol. Publish Ahead of Print, 21 Oct. 2020, https://doi.org/10.1097/olq.0000000000001323. Accessed 19 May 2021.

10/12/23 - Availability of Testing Services for Self-swabs Review

KAIYA MERRITT - Oct 12, 2023, 10:02 PM CDT

Title: Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis

Date: 10/12/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To learn more about the appeal to self-swabbing and learn more about the availability of self-testing services.

Content:

- Self-collection of samples for diagnostic testing offers the advantages of patient autonomy, confidentiality and convenience.
- Self-collected samples for sexually transmitted infections are as accurate as clinician collected methods.
    - Research in high-income countries, where organized lab facilities and healthcare are available, shows that self-collected STI samples are as diagnostically accurate as clinician-collected samples.
- Self-swabs are feasible and acceptable in a variety of populations.
- While STI diagnostic tests are available and used in many high-income countries, diagnostic tests in low-income and middle-income country settings are largely unavailable.
- Globally, social stigma and a lack of effective policies also affect STI testing uptake and treatment-seeking behavior.
- Low STI testing coverage and high transmission rates are common among at-risk vulnerable adolescents.
- Self-collection approaches also have the potential to address some common barriers to clinician-dependent diagnosis, such as concerns around autonomy, inconvenience, stigma and lack of privacy.
- Despite a limited evidence base and considerable heterogeneity in meta-analyses, the existing literature suggests that using self-collection of samples for STI testing increases uptake of STI testing services.

Conclusions/action items:

I think one important thing to definitely takeaway from this article is to keep in mind the fact that low-income countries, diagnostic self-swabs are largely unavailable. I think this article is beneficial because it reinforces the goal/idea of our design to be low cost. Ideally, if this were a mass distributed product, we would want it to be available to everyone, especially middle and lower income countries.

Y. Ogale, P. T. Yeh, C. E. Kennedy, I. Toskin, and M. Narasimhan, “Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis,” *BMJ Global Health*, vol. 4, no. 2, p. e001349, Apr. 2019, doi: https://doi.org/10.1136/bmjgh-2018-001349.

10/17/23 - Article in Regards to Testing

KAIYA MERRITT - Oct 17, 2023, 6:10 PM CDT

Title: Acceptability of Sexually Transmitted Infection Testing Using Self-collected Vaginal Swabs Among College Women

Date: 10/17/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To better understand other female attitudes around self-swab testing, so we know what types of questions to ask in case we decide to survey UW females.

Content:

- Rates of STI testing among college students are low, ranging from 23% to 32% in previous studies.
- Testing uptake may be low due to barriers such as shame, stigma, fear, denial, perceived negative social consequences, inaccurate beliefs about STIs, privacy concerns, cost, and inconveniences.
- University health centers are opportune sites at which to offer STI testing services.
    - A survey on the availability of STI testing services at US colleges found that 60% of colleges have a student health center, and, of these, 66% provide STI testing.
- Clinician-obtained specimens may be perceived as invasive.
- The goals of this study were to assess the acceptability of STI testing using Self-collected vaginal swabs among college women and preferences for STI testing using self-swabs versus urine samples.
- Participants completed monthly surveys throughout their first year of college and were invited to receive STI testing free of charge at the end of the academic year.
- Questions the surveys asked:
    - The women provided their age, race, and ethnicity.
    - They were asked if they participated in STI testing offered through the study. Women who indicated that they participated were asked why.
    - Testers were asked to rate the ease of understanding the instructions for self-collecting their vaginal swab and the ease of self-collecting your vaginal swab, on a Likert scale from 1 to 4.
    - Testers were asked if they would test themselves more often for STIs if self-collected vaginal swabs were available.
    - All women, regardless of testing participation, were asked which STI testing method they would prefer.
- Across all participants, self-swab was the most preferred method of STI testing (38%), 28% preferred urine samples, 3% preferred a pelvic examination by a medical provider, 17% had no preference, and 14% were not sure.
- The high rate of willingness to repeat the test in the future indicate that this testing method was acceptable to the majority of college women in our sample. Thus, the availability of SCVS may help health care providers increase rates of chlamydia screening.
- Women reported positive feedback about STI testing using self-swab.
- The women noted that they felt comfortable, relaxed, and in control while collecting their specimens.
- Reported anxiety and embarrassment were low, despite undergoing STI testing, which has the potential for unsettling results, and using a new testing method for the first time.

Conclusions/action items:

Overall, I think this article aligns nicely with what we've seen in previous research that women prefer self-swab testing above anything else. However, my point in reading this article was to see a few sample questions and gain some ideas for when we test our device. I liked how they asked the women in the study to rate the ease of the instructions and the swab. I think for our survey we could have them rate how understandable the instructions are, and maybe ask if they would think the device would be easy to use just from aesthetics.

R. L. Fielder, K. B. Carey, and M. P. Carey, “Acceptability of Sexually Transmitted Infection Testing Using Self-collected Vaginal Swabs Among College Women,” *Journal of American College Health*, vol. 61, no. 1, pp. 46–53, Jan. 2013, doi: https://doi.org/10.1080/07448481.2012.750610.

10/29/23 - Notes on Testing for Leakage

KAIYA MERRITT - Oct 29, 2023, 4:56 PM CDT

Title: Notes on Two Articles to Help Formulate Testing Plans

Date: 10/29/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To find beneficial ways to formulate a testing plan for our device regarding leaking.

Content:

Notes on article regarding using dye to detect leakage.

M. Saruwatari *et al.*, "Assessment of a novel biliary-specific near-infrared fluorescent dye (BL-760) for intraoperative detection of bile ducts and biliary leaks during hepatectomy in a preclinical swine model," *Lasers in Surgery and Medicine*, vol. 55, no. 5, pp. 480–489, Apr. 2023, doi: https://doi.org/10.1002/lsm.23661.

- Postoperative bile leakage is a common complication of hepatobiliary surgery and frequently requires procedural intervention.
- Use of intra and extrahepatic fluorescence detection was used and the bile ducts to the liver parenchyma was quantitatively measured.
- Currently, intraoperative cholangiography, which uses intraductal contrast dye and fluoroscopic X- rays, detects bile leaks.
- Methylene blue enables easy detection of biliary leaks due to visible contrast between dye leaking from ducts and background parenchyma.
    - If we use water and dye to test for leaks, we definitely will need to use a bright and vivid color.
- The experimenters used an FDA approved fluorescence imaging system and this camera is favorable because it can capture both wavelength and conventional red-green-blue images.

Notes on article with water leakage

S. A. Sadr-Al-Sadati and M. Jalili Ghazizadeh, "The experimental and numerical study of water leakage from High-Density Polyethylene pipes at elevated temperatures," *Polymer Testing*, vol. 74, pp. 274–280, Apr. 2019, doi: https://doi.org/10.1016/j.polymertesting.2019.01.014.

- Increasing pressure on the pipes significantly increased the rates of leakage over-time.
    - Good to note this and think about the environment the device will be stored in.
- The leak opening deformation in plastic pipes under pressure depends on several factors such as the diameter, thickness and material of pipes and also the form of leak openings and loading history.
- The main focus of this experiment proved the importance of water losses through distribution pipelines, it is necessary to improve the awareness of pressure-leakage relationship.

Conclusions/action items:

Neither of these articles were outstandingly helpful in regard to leak testing ideas, however they were insightful. I do not foresee pressure being a big factor will need to worry about at this point with our prototype because it will be exposed to very similar pressures. I liked the dye idea as well; however, it might be hard to precisely measure the amount of dye (if any) that has leaked through because we lack access to the necessary system. I am thinking maybe we could do something with weighing the mass of the device and seeing if any water mass was lost after a certain amount of time.

9/11/23 - Aptima vaginal swab specimen collection kit

Title: Aptima vaginal swab specimen collection kit

Date: 9/11/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To find competing vaginal self-swab designs.

Content:

- There is currently a self-swab STD screening kit called Aptima made by Hologic.

- It can detect up to 7 infections and diseases.

- The kit is stored at room temperature.

- It uses nucleic acid amplification testing technology (NAAT).

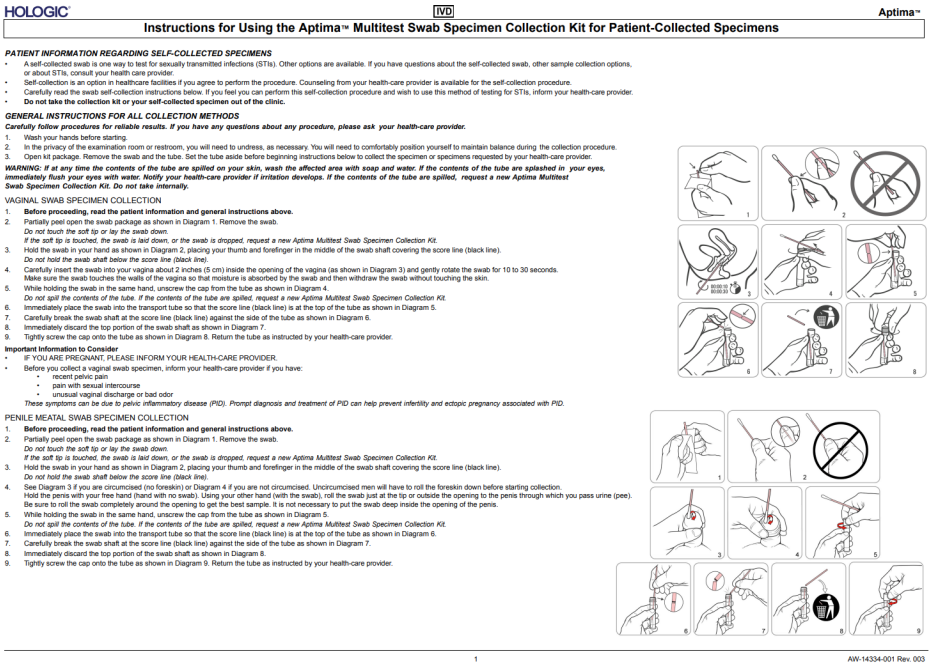
- Self-swabbed or used by healthcare provider.

- The swab is FDA approved and also known as Aptima Combo 2 Assay

- How the Aptima swab works/steps to take when using the swab itself:

  - Partially peel open the swab package and remove the swab.
  - Do not touch the soft tip or lay the swab down.
  - Hold the swab in hand and be careful not to touch the swab. If the swab is touched a new kit will need to be used.
  - Insert the swab into the vagina about 2 inches (5 cm) inside the opening of the vagina and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
  - While holding the swab, unscrew the cap from the tube and do not spill the contents of the tube. If the contents of the tube are spilled, a new Aptima kit is necessary.
  - Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube.
  - Carefully break the swab shaft at the score line (black line) against the side of the tube.
  - Immediately discard the top portion of the swab shaft into the trash

- Tightly screw the cap onto the tube and give/return the tube as instructed by the health-care provider.



HOLOGIC® IVD Aptima™

Instructions for Using the Aptima™ Multitest Swab Specimen Collection Kit for Patient-Collected Specimens

PATIENT INFORMATION REGARDING SELF-COLLECTED SPECIMENS

- A self-collected swab is one way to test for sexually transmitted infections (STIs). Other options are available. If you have questions about the self-collected swab, other sample collection options, or about STIs, consult your health care provider.
- Self-collection is an option in healthcare facilities if you agree to perform the procedure. Counseling from your health-care provider is available for the self-collection procedure.
- Carefully read the swab self-collection instructions below. If you feel you can perform this self-collection procedure and wish to use this method of testing for STIs, inform your health-care provider.
- **Do not take the collection kit or your self-collected specimen out of the clinic.**

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

Carefully follow procedures for reliable results. If you have any questions about any procedure, please ask your health-care provider.

1. Wash your hands before starting.
2. In the privacy of the examination room or restroom, you will need to undress, as necessary. You will need to comfortably position yourself to maintain balance during the collection procedure.
3. Open kit package. Remove the swab and the tube. Set the tube aside before beginning instructions below to collect the specimen or specimens requested by your health-care provider.

WARNING: If at any time the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your health-care provider if irritation develops. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit. Do not take internally.

VAGINAL SWAB SPECIMEN COLLECTION

1. **Before proceeding, read the patient information and general instructions above.**
2. Partially peel open the swab package as shown in Diagram 1. Remove the swab.
   Do not touch the soft tip or lay the swab down.
   If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.
3. Hold the swab in your hand as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line (black line).
   Do not hold the swab shaft below the score line (black line).
4. Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina (as shown in Diagram 3) and gently rotate the swab for 10 to 30 seconds.
   Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4.
   Do not spill the contents of the tube. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.
6. Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube as shown in Diagram 5.
7. Carefully break the swab shaft at the score line (black line) against the side of the tube as shown in Diagram 6.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 7.
9. Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

Important Information to Consider

- IF YOU ARE PREGNANT, PLEASE INFORM YOUR HEALTH-CARE PROVIDER.
- Before you collect a vaginal swab specimen, inform your health-care provider if you have:
  - recent pelvic pain
  - pain with sexual intercourse
  - unusual vaginal discharge or bad odor

These symptoms can be due to pelvic inflammatory disease (PID). Prompt diagnosis and treatment of PID can help prevent infertility and ectopic pregnancy associated with PID.

PENILE MEATAL SWAB SPECIMEN COLLECTION

1. **Before proceeding, read the patient information and general instructions above.**
2. Partially peel open the swab package as shown in Diagram 1. Remove the swab.
   Do not touch the soft tip or lay the swab down.
   If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.
3. Hold the swab in your hand as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line (black line).
   Do not hold the swab shaft below the score line (black line).
4. See Diagram 3 if you are circumcised (no foreskin) or Diagram 4 if you are not circumcised. Uncircumcised men will have to roll the foreskin down before starting collection.
   Hold the penis with your free hand (hand with no swab). Using your other hand (with the swab), roll the swab just at the tip or outside the opening to the penis through which you pass urine (pee).
   Be sure to roll the swab completely around the opening to get the best sample. It is not necessary to put the swab deep inside the opening of the penis.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 5.
   Do not spill the contents of the tube. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.
6. Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube as shown in Diagram 6.
7. Carefully break the swab shaft at the score line (black line) against the side of the tube as shown in Diagram 7.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 8.
9. Tightly screw the cap onto the tube as shown in Diagram 9. Return the tube as instructed by your health-care provider.

1 AW-14334-001 Rev. 003

The image above is the instructions on how to use the Aptima Multitest Swab Specimen Collection Kit.

Sources:

Instructions for Using the Aptima™ Multitest Swab Specimen Collection Kit for Patient-Collected Specimens Aptima ™ PATIENT INFORMATION REGARDING SELF-COLLECTED SPECIMENS.

Aptima® Multitest Swab | Hologic. (n.d.). Www.hologic.com. Retrieved September 12, 2023, from https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

Conclusions/action items:

In conclusion, there is a lot of room for human error when using an Aptima self-swab kit. The user has to be very cautious at all times or else they risk contamination. Creating a test that elimantes contamination would be optimal. Not over the counter, given in a lab setting and the patient either collect it in clinic or does it at home and has to mail back in to clinic.

9/25/23 - Preliminary Design Ideas #1 & 2

KAIYA MERRITT - Sep 27, 2023, 10:02 PM CDT

Title: Design Ideas Before Design Matrix

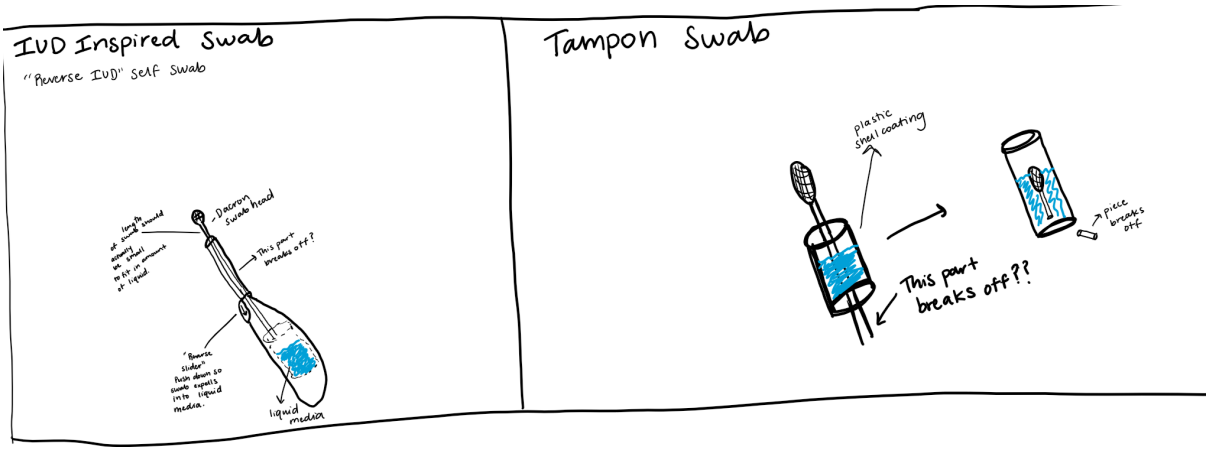
Date: 9/25/23

Content by: Kaiya Merritt

Present: Kaiya Merritt

Goals: To come up with a few design ideas before meeting with the group to decide on 3 designs for the Design Matrix.

Content:



- These are the two designs I came up with using two different mechanisms.
- The IUD inspired swab would have a reverse slider mechanism that would allow the swab to fall into the liquid which would be compartmentalized inside the device.
    - The "top" piece could then break off keeping the size of the container to a minimum.
    - Having the media inside the base of the device would allow for it to no come in contact with the vagina.
- The Tampon Swab design idea would have a similar plastic outer shell that would encapsulate the media and the bottom part of the swab would break off.
    - The bottom would have to be sealed with some sort of foil ensure the liquid does not leak out.

Conclusions/action items:

They both need more work and I have some questions about how to optimize them, but I will go over that with the group when we meet up. I think the IUD Inspired swab is more feasible, however getting the reverse mechanism might be tricky as I was looking at having the swab release into the media.

9/13/23 - Notes on Provided Article "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia"

MIA LARICO - Sep 15, 2023, 12:07 PM CDT

Title: Notes on Provided Article "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia"

Date: 9/13/23

Content by: Mia LaRico

Present: Mia LaRico

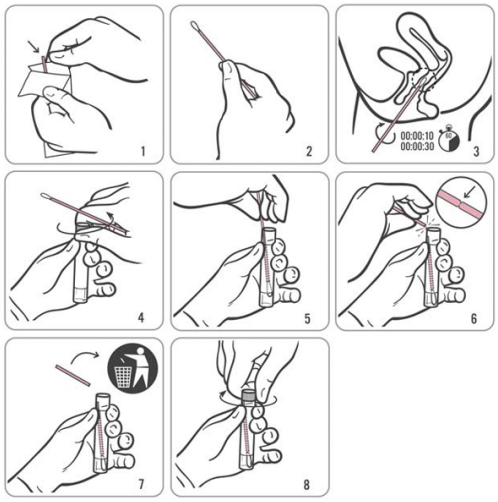
Goals: Review PDF given by client and take note of information relevant to potential product design and impact.

Content:

- Need to insert sample into a tube of liquid while maintaining sterility. Tube could easily spill or become contaminated.

- Current self-collected vaginal swabs rely on the collector being able to maintain a sterile-ish environment while attempting to collect the sample.

- Need to break off portion of the swab after insertion into tube, which greatly increases risk of spillage.



(Illustrations courtesy of Gen-Probe Incorporated, San Diego CA)

Conclusions/action items:

- Much of the current self-collected vaginal swabs process is tedious and has many opportunities for error. Risk of contamination is high.

NC Sexually Transmitted Diseases Public Health Public Health Program. (2011). *Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia*.

9/13/23 - Notes on "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

MIA LARICO - Sep 19, 2023, 8:52 PM CDT

Title: Notes on "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

Date: 9/13/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Conduct personal research

Content:

- The self-collected vaginal swab device has been a great alternative for women to avoid more privacy-violating procedures to screen for STDs. It is also better for storage as it doesn't require refrigeration, and is easier to transport as there is no urine so there is no reason to worry about potential spillage.

- Chlamydia is one of the most common preventable/treatable STDs spread in the world. Among women, the disease can present as asymptomatic and certain barriers such as comfortability, privacy, and lack of access to screening methods prevent women from being tested routinely.

- Nucleic Acid Amplification Tests (NAATs) have been discovered to be a better solution for screening as compared to urine tests and culture plates.

- Urine tests have the possibility of spilling during transport, and are held to certain refrigeration requirements.

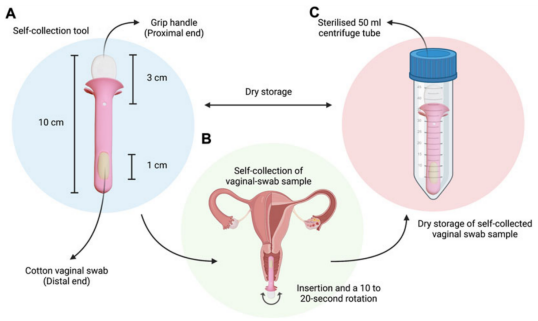
- Culture plates need to be incubated, may require extra resources such as liquid buffer and refrigeration, and are collected by the physician, which can be an invasion of privacy for many women.

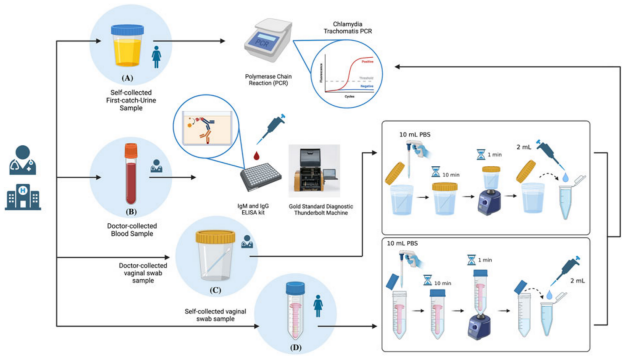
- NAAts can be stored dry, are self-collected by the patient, which gives the patient privacy, and doesn't need to be refrigerated.

- Blood antibodies are also an option for STD screening, but are not as accurate as NAATs.

- An important goal of increasing NAAT usage is to encourage women to get more routine STD tests.

- Research found that there was no difference in accuracy between NAATs and physician-collected samples.





Conclusions/action items:

- NAATs are our best option for the method of self-swab test

- With research finding that there was no difference in the accuracy of NAATs and physician-collected samples, the pros of self-swab seem to outweigh those of other methods of STI testing.

Muljadi M, Cheng C-M, Yang C-Y, Chang T-C and Shen C-J (2022) A pilot clinical validation study of a self-collected vaginal swab device for the detection of *chlamydia trachomatis* in women. *Front. Bioeng. Biotechnol.* 10:1008761. doi: 10.3389/fbioe.2022.1008761

9/13/23 - Notes on "Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing"

MIA LARICO - Sep 19, 2023, 8:54 PM CDT

Title: Notes on "Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing"

Date: 9/13/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Conduct personal research

Content:

- Provider-collected samples are not only invasions of the patient's privacy but require exam rooms, a provider, and occasionally a female chaperone.

- Since NAATs are self-collected, they require no exam room, no provider, and usually do not require a chaperone.

- According to the study, 26% of the 500+ patients involved in the study did not prefer the self-swab as they were either worried they would perform the swab incorrectly, or preferred a provider to screen them instead.

Conclusions/action items:

- Patients usually prefer to self-swab rather than have a physician collect a sample, so our self-swab device has potential to be used widely and can perhaps get people to be tested more routinely as they will be more comfortable with the test.

Bond, C., Morgenstern, J., & Milne, W. K. (2021). Hot off the Press: Self Obtained Vaginal Swabs for STI Testing. *Academic Emergency Medicine*, *28*(12), 1448–1451. https://doi.org/10.1111/acem.14387

9/15/23 - Notes on "Nucleic Acid Amplification Tests (NAATs)"

MIA LARICO - Sep 19, 2023, 8:55 PM CDT

Title: Notes on "Nucleic Acid Amplification Tests (NAATs)"

Date: 9/15/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Understand how NAATs work and what they are currently used for

Content:

- Is a commonly used test for COVID-19

- Makes many, many copies of the DNA given in a sample, then the NAAT identifies certain sequences within the DNA provided in a test sample, if they are present, allowing the test to show either a positive or negative result.

- NAATs are not restricted to one method for amplification. For example, there exists NAATs that utilize PCR, CRISPR, other types of isothermal amplification such as:

    - Transcription mediated amplification (TMA)

    - Loop-mediated isothermal amplification (LAMP)

    - Nicking endonuclease amplification reaction (NEAR)

    - Helicase-dependent amplification (HDA)

    - Strand displacement amplification (SDA)

- Possibility of making NAATs a rapid test. Then STI screening could potentially be available commercially, and encourage testing.

Conclusions/action items:

- We will most likely go with a PCR-type NAAT test as they are very commonplace and are already proven to be successful distributing commercially through the COVID-19 pandemic.

Centers for Disease Control and Prevention. (n.d.). *Nucleic acid amplification tests (NAATs)*. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html

9/15/23 - Notes on "Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) – Nucleic Acid Amplification Testing (NAAT)"

MIA LARICO - Sep 19, 2023, 8:58 PM CDT

Title: Notes on "Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) – Nucleic Acid Amplification Testing (NAAT)"

Date: 9/15/23

Content by: Mia LaRico

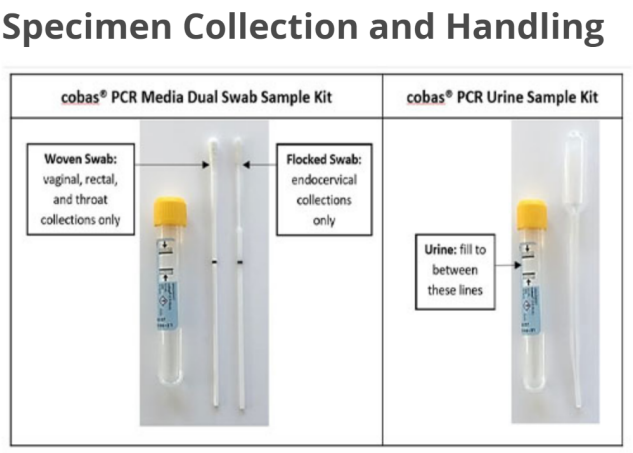
Present: Mia LaRico

Goals:

- Understand how NAATs are already being used in current medical practice

Content:

- In Canada, "(NAAT) is the recommended method for initial screening or testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) infections."



- Uses transport media

- Roche cobas PCR Media Dual Swab Sample Kit contains two kinds of swabs: Woven and Flocked. Woven swabs are used for vaginal swab collection

- In Canada, "CT and NG culture is the preferred and recommended method for medico-legal investigations" but NAAT can also be accepted

- Samples are kept at 2-30°C to be shipped to a laboratory

- Turnaround time is around 3 business days for results

- Is possible to order these kits, but most likely only hospitals/clinics can purchase through company (can't buy individual kits, must buy at least a box of 100)

Conclusions/action items:

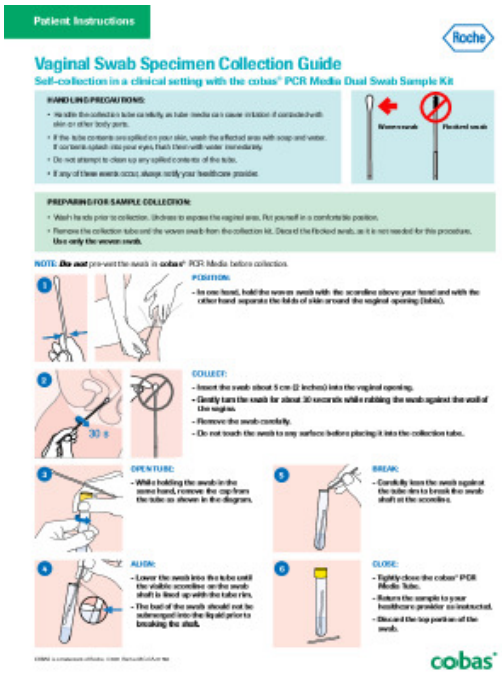
-NAATs have already been proven to be effective and a reliable way of testing by the Public Health Department of Canada.

- Currently, these units are not available to be purchased individually -- only in bulk. Find out why this is and if there are laws in place that restrict the sale of individual self-swab NAATs or if that is simply the most cost-effective way for the company to test samples and make money.

"Chlamydia Trachomatis/Neisseria Gonorrhoeae (CT/NG) – Nucleic Acid Amplification Testing (NAAT)." *Public Health Ontario*, www.publichealthontario.ca/en/Laboratory-Services/Test-Information-Index/Chlamydia-trachomatis-NAAT-Swabs. Accessed 15 Sept. 2023.

9/15/23 - Instructions for Vaginal Self-Swab

MIA LARICO - Sep 15, 2023, 2:01 PM CDT



Download

Self-collection_Vaginal_sample_2021.pdf (383 kB)

Title: Instructions for Vaginal Self-Swab

Date: 9/15/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Understand process of vaginal self-swab

Content:

See attached document

Conclusions/action items:

- The collection process is fairly straightforward, yet leaves much room for contamination/spillage.

"Vaginal Swab Specimen Collection Guide - Rochecanada.Com." *Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG)*, 2021, www.rochecanada.com/content/dam/rochexx/roche-ca/products/docs/education/Self-collection_Vaginal%20sample%202021.pdf.

9/20/23 - Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear

Title: 9/20/23 - Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear

Date: 9/20/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Investigate the potential of a tampon-like STI test swab deployment device

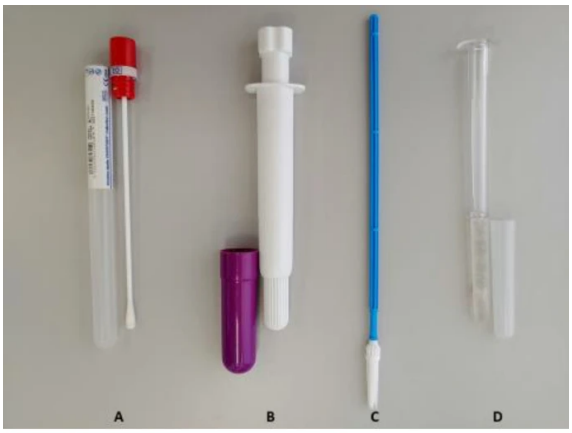
Content:

- This study conducted research into which method of swab women preferred more and they tested swab, lavage, brush, and tampon and women mostly preferred things that were most similar to a cotton swab

- Although this study was about conducting HPV tests, the self-swabbing method is very similar to CT testing.

- The materials the swab was made of was mainly nylon, cotton, and dacron.

- An option for the women in the study was to use the lune HPV sterile test cannula from Canda Health Solutions, Mallorca. However, when attempting to google the device, absolutely zero results came up, which confused me.



A. Sterile viscose swab with a polystyrene stem into a sterile polypropylene tube.

B. lune HPV sterile test cannula.

C. Viba-Brush®.

D. Mía by XytoTest®

Conclusions/action items:

- Conduct more research into tampon-like devices for STI exams

- Try to figure out why the lune HPV sterile test cannula from Canda Health Solutions, Mallorca did not get commercialized

Gibert, M.J., Sánchez-Contador, C. & Artigues, G. Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear. *Sci Rep* **13**, 2809 (2023). https://doi.org/10.1038/s41598-023-29255-y

9/22/23 - Surface Contamination by CT & NG

MIA LARICO - Sep 22, 2023, 12:54 PM CDT

Title: 9/22/23 - Surface Contamination by CT & NG

Date: 9/22/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Conduct research into how surface contamination occurs in clinic rooms during CT self-swab

Content:

- 154 sites in one sexual health clinic were tested

- Tested caps of containers of the self-swab test, as well

- 13% tested positive for CT contamination, NG contamination, or both

- Patient toilets were more likely to be contaminated than examination rooms

- 46 caps tested negative, but they did not give how many were tested

- According to a different study, contamination "is common particularly in areas where urine samples are being taken."

Conclusions/action items:

- Although risk of contamination is small, it is still important to try and prevent it as much as possible as contamination could lead to false positives for CT self-swabs.

Lewis, Natasha, G. D. Dube, Christine Carter, Rachel Pitt, Sarah Alexander, Catherine Ison, J. W. Harding, Louise Brown, John Denis Fryer, James Hodson, and Jonathan Ross. 2012. “Chlamydia and Gonorrhoea Contamination of Clinic Surfaces: Table 1.” *Sexually Transmitted Infections* 88(6):418–21. doi: 10.1136/sextrans-2012-050543.

Ross J. D. (2015). Nucleic acid contamination in sexual health clinics. *Current opinion in infectious diseases*, *28*(1), 80–82. https://doi.org/10.1097/QCO.0000000000000126

10/8/23 - "Chlamydia – CDC Detailed Fact Sheet"

MIA LARICO - Oct 08, 2023, 4:31 AM CDT

Title: 10/8/23 - "Chlamydia – CDC Detailed Fact Sheet"

Date: 10/8/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Gain more insight on Chlamydia

Content:

- Two-thirds of new chlamydial infections occur among youth aged 15-24 years.

- 1 in 20 sexually active young women aged 14-24 years has chlamydia

- High chlamydia prevalence among young people also may reflect barriers to accessing STD prevention services. These barriers can include lack of transportation, cost, and perceived stigma.

- Most people with the infection have no symptoms or abnormal physical exam findings.

- If a woman does not receive treatment, chlamydia can spread into the uterus or fallopian tubes, causing PID.

- CDC recommends yearly chlamydia screening of all sexually active women younger than 25

- To diagnose genital chlamydia in women using a NAAT, vaginal swabs are the optimal specimen

Conclusions/action items:

Since many young women go undiagnosed with Chlamydia due to certain barriers, self-collected STI tests may be able to increase routine testing.

Control and Prevention, C. for D. (2023). Retrieved from https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm

10/8/23 - "Annual STI Testing Among Sexually Active Adolescents"

MIA LARICO - Oct 08, 2023, 4:27 AM CDT

Title: 10/8/23 - "Annual STI Testing Among Sexually Active Adolescents"

Date: 10/8/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Get more information to put in introduction section of preliminary report

Content:

- Women are more likely to get STI tested than men

- It is estimated that young people aged 15 to 24 years acquire half of all new sexually transmitted infections (STI) annually and that 1 in 4 sexually active adolescent females in the United States has an STI

- There are multiple barriers to testing adolescents for STIs, either as part of routine screening or symptom-based testing. Adolescents and young adults have historically had lower use of health care, in part because of confidentiality concerns, limited awareness of the need for screening, and logistical barriers (eg, transportation and cost)

Conclusions/action items:

A commercially available self-collected STI test would benefit high-school students and push them to get routinely tested.

Liddon, N. (2022). Annual STI Testing Among Sexually Active Adolescents. Retrieved from https://publications.aap.org/pediatrics/article/149/5/e2021051893/186749/Annual-STI-Testing-Among-Sexually-Active?autologincheck=redirected

11/28/23 - Cost Benefit Analysis of Sexually Transmitted Diseases

MIA LARICO - Dec 08, 2023, 12:31 AM CST

Title: 11/28/23 - Cost Benefit Analysis of Sexually Transmitted Diseases

Date: 11/28/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Better understand the costs of STDs

Content:

- Besides adverse health effects, women afflicted with STIs are also affected by social stigma

- "In some situations, charges may deter patients from seeking care. One study in Nairobi reported a 60% decline in the attendance at an STD clinic when patients were charged about $1.75 for diagnosis and treatment"

- Most of the direct costs and indirect costs are incurred by women since they experience the vast majority of the complications of STDs

- The risk of acquiring an STD correlates closely with the socioeconomic status and countries or areas with the highest rates of STDs may have the least ability to deal effectively with their management

Conclusions/action items:

- Ayşen Bulut, Cost benefit analysis of sexually transmitted diseases, *FEMS Immunology & Medical Microbiology*, Volume 24, Issue 4, July 1999, Pages 461–467, https://doi.org/10.1111/j.1574-695X.1999.tb01319.x

11/28/23 - Screening for Sexually Transmitted Infections at Home or in the Clinic?

MIA LARICO - Dec 08, 2023, 12:32 AM CST

MIA LARICO - Dec 08, 2023, 1:00 AM CST

Title: 11/28/23 - Screening for Sexually Transmitted Infections at Home or in the Clinic?

Date: 11/28/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Understand effect of in-home testing vs clinic testing

Content:

- In recent studies, the testing rate with home-based screening was up to 11 times greater than the testing rate with clinic-based screening

- Self-collection and testing of urine or vaginal specimens at home was considered to be easy, acceptable, and often preferred over testing at a clinic

- A study from the United States concluded that home-based screening is cost saving

- Making low-cost home test kits available may encourage at-risk young individuals with less access to clinic care, who may not otherwise be screened, to self-test for sexually transmitted infections

- Of 122 women who completed a survey regarding testing satisfaction, all women reported use of the vaginal selfswab to be easy, and 70% felt self-collection of vaginal samples was extremely easy. The majority of hometesters (83%) also preferred home STI testing in the future, whereas only 49% of clinic-testers preferred to be tested at a clinic.

- In almost all studies, higher testing rates were achieved with home-based compared with clinic-based STI screening in both men and women

Conclusions/action items:

- The potential for at-home STI-testing is extremely high

Shih SL, Graseck AS, Secura GM, Peipert JF. Screening for sexually transmitted infections at home or in the clinic? Curr Opin Infect Dis. 2011 Feb;24(1):78-84. doi: 10.1097/QCO.0b013e32834204a8. PMID: 21124216; PMCID: PMC3125396.

11/28/23 - Social media exposure, interpersonal network, and tampon use intention: A multigroup comparison based on network structure

MIA LARICO - Dec 08, 2023, 1:07 AM CST

Title: 11/28/23 - Social media exposure, interpersonal network, and tampon use intention: A multigroup comparison based on network structure

Date: 11/28/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- To better understand the implications of attempting to commercialize this product's usage in STI-testing globally.

Content:

- Research revealed that amongst Chinese women, one-third of them had never heard of tampons and approximately 40% did not know how to use one

- Culture plays a crucial role in the absence of tampon usage amongst Chinese women. Specifically, some people think of using tampons as shameful because they associate tampons with sexual activity, another taboo topic in China

- Chinese girls may worry that tampons will break the hymen, a symbol of virginity and purity valued in a Confucian society

Conclusions/action items:

- Although the goal of this product is partially to promote universal testing of STIs, there are certain countries/regions that may not be as receptive to the design of the product due to certain cultural/religious reasons.

Yang Y, Ma X, Myrick JG. Social media exposure, interpersonal network, and tampon use intention: A multigroup comparison based on network structure. J Health Psychol. 2023 Mar;28(4):343-355. doi: 10.1177/13591053221120332. Epub 2022 Sep 1. PMID: 36047030; PMCID: PMC10026152.

9/20/23 - Swab with Detachable head - PCR Testing for CT & NG

Title: 9/20/23 - Swab with Detachable head - PCR Testing for CT & NG

Date: 9/20/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Understand more about the competing PCR Test for CT & NG

- Compare to our potential design using self-swab NAATs

Content:

- PCR test is one of the most common tests for STIs

- This product is from India and is from a company called LifeCell

- Works by amplifying the given sample of DNA, then tries to identify a specific section of a gene or the lack of presence of a specific section of gene

- Requires temperature regulation at every step, because DNA requires certain temperatures, to denature, anneal, and synthesize.

- Uses a thermocycler

- Has high accuracy & sensitivity as it can take even a small sample of tissue that has CT or NG and amplify it enough to produce a detectable sample

- Can test using a urine sample or a vaginal swab.

- Test for females (vaginal swab) costs ~$32 and can buy to ship to your home -- then have it picked up for testing after swab is collected

    - At-home test kit includes:

        1. Cervical brush

            a. Their cervicle brush allows the head to detach after collection with the help of a remover tube

            b. Their brush uses bristles and not a swab

        2. Collection cup

        3. Biohazard bag

        4. Collection manual

        5. Return envelope

        6. Hologram sticker

7. Declaration form

- Use an app to allow you to notify LifeCell that your sample is ready to be collected

Conclusions/action items:

This detachable head design is similar to what we were thinking of for our own design and would be useful to analyze to see how their product functions. In addition, the way they have been able to commercialize their product for at-home use would be useful for us to study.

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.

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

9/20/23 - Aptima Combo 2 Assay

Title: 9/20/23 - Aptima Combo 2 Assay

Date: 9/20/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- To better understand how Aptima's self-swab product works

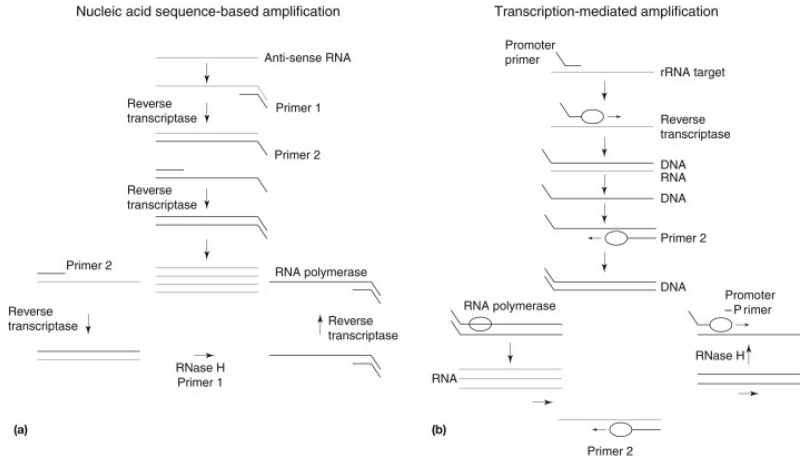
Content:

- Aptima test is a nucleic acid probe test that differentiates rRNA from CT and can be collected by patient vaginally, but there are other methods available with this test, as well (ex: physician-collected sample)

- This vaginal specimens collection kit is not for at-home use, only in-clinic

- "Chlamydiae are nonmotile, gram-negative, obligate intracellular bacteria."

- Aptima claims that first-generation NAATs are limited in performance and claim that their second-generation NAAT utilizes target capture, Transcription Mediation Amplification (TMA) and Dual Kinetic Assay (DKA)



- The solutions the samples are stored in prevent degradation of the sample during storage

- Sample can be stored at room temperature for up to 60 days and can be frozen for up to 12 months

- Aptima produces Aptima Multitest Swab which has a tube with a penetrable cap.

- Directions of use are as expected-- where the patients inserts the swab, rotates, places sample into uncapped container, and then recaps container.

Conclusions/action items:

- The process of swabbing is similar to pamphlet given by client. It is the standard way of testing where a cap to a tube needs to be unscrewed to insert the sample and then screwed back on.

- Aptima's website states that they have a tube with a penetrable cap, but in their directions for use they never mention it. They only mention the removable cap. Perhaps this design is still in development.

Schweitzer, B., & Kingsmore, S. F. (2001). Combining nucleic acid amplification and detection. *Current Opinion in Biotechnology*, *12*(1), 21–27. https://doi.org/10.1016/s0958-1669(00)00172-5

Aptima Combo 2® Assay. (n.d.). *Aptima Combo 2*®. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.hologic.com/sites/default/files/package-insert/502487-IFU-PI_001_01.pdf

Anon. n.d. “Aptima® Multitest Swab | Hologic.” Retrieved (https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab).

Aptima® Multitest Swab Specimen Collection Kit. (n.d.). *HOLOGIC*®. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.hologic.com/sites/default/files/2018-01/AW-15641-REG_002_01_0.pdf

9/26/23 - Design Idea #1 - Mia

MIA LARICO - Oct 11, 2023, 11:17 AM CDT

Title: 9/26/23 - Design Idea #1 - Mia

Date: 9/26/23

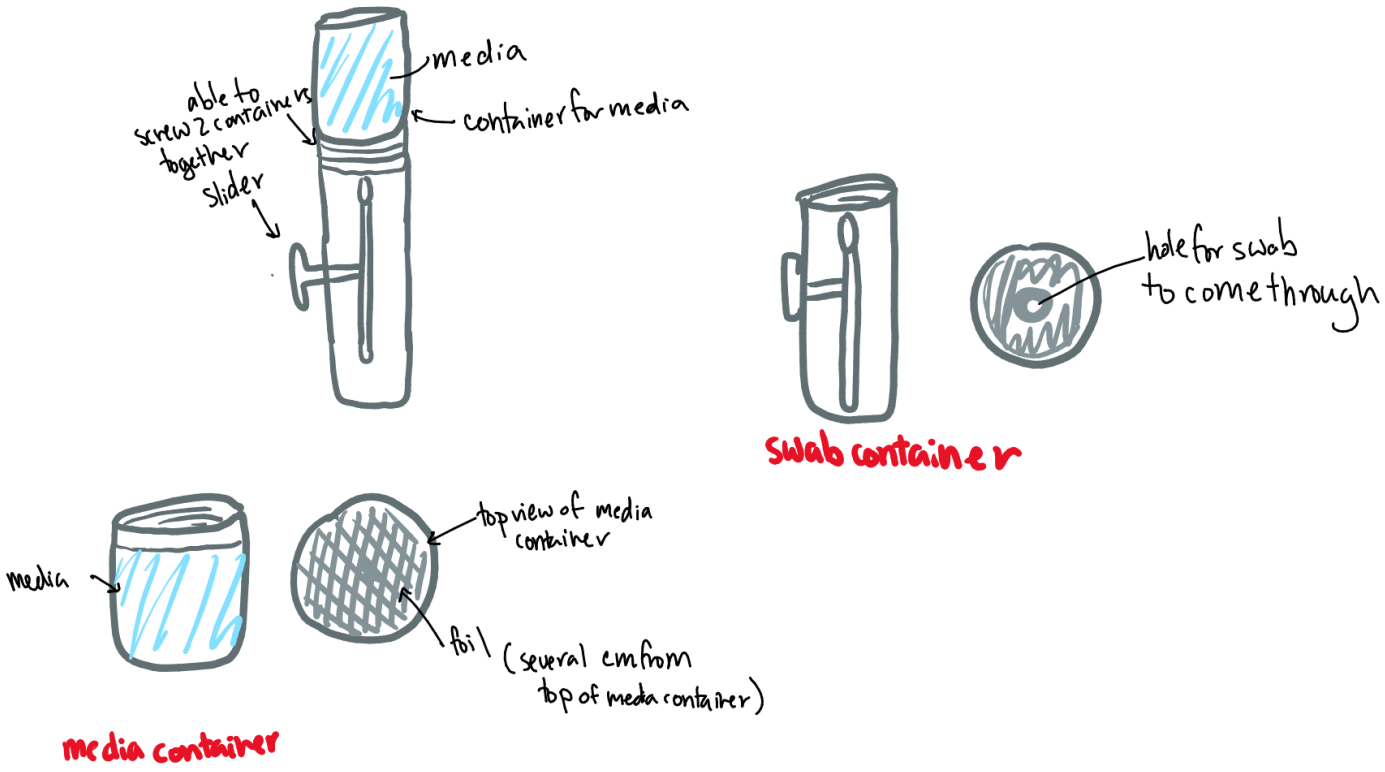
Content by: Mia LaRico

Present: Mia LaRico

Goals: To draw up an initial design idea to critique with our design matrix

Content:

- This device would allow the patient to unscrew the two containers to take their self-swab sample-- which is deployed through use of a slider mechanism. Then, the patient would be able to retract the swab back into the container after self-swabbing, screw the media and swab container back together, then push the slider up further in order to pierce the foil containing the media to mix the sample and the media together.



Conclusions/action items:

- Ideally, there will be a mechanism in place between where the swab and the media containers meet that can break off the portion of the swab and leave it in the media, then allow the media container to be sealed without the client physically screwing a cap on it so that the container that holds the swab can be discarded with only the media container left to be sent to the lab

11/10/23 - Tong Distinguised Lecture

MIA LARICO - Dec 07, 2023, 1:15 PM CST

Title: 11/10/23 Tong Distinguished Lecture

Date: 11/10/23

Content by: Mia LaRico

Present: Mia LaRico

Goals:

- Understand the viewpoint of the distinguished lecturer

Content:

- Your path in life is not always defined, be prepared for unexpected twists

- Your life is what you make of it

- Failures do not define you

Conclusions/action items:

Do not think that just because I have my path in life planned that it will actually go the way I expect it to. Be prepared to adjust for unexpected events.

9-13-23 Notes on "Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing"

MORGAN KOPIDLANSKY - Sep 17, 2023, 9:31 AM CDT

Title: Notes on Hot off the press: Self-obtained vaginal swabs for sexually transmitted infection testing

Date: 9/13/2023

Content by: Morgan Kopidlansky

Goals: Learn more about self swabbing and current data/study information available

Content:

- Gonorrhea and chlamydia are some of the most common STDs and more are being reported of in emergency departments
- Self swabbing offers benefits to both patient and care provider (less use of rooms and more availability for healthcare providers elsewhere, more comfortable for many patients to do on own)
- Many studies showing comparable sensitivity for self swabbing vs. healthcare provider performed were done in non-emergency departments
- An observational cohort done in an emergency department showed self swabs to be sensitive in diagnosis
- Many patients liked the self swab however some were worried about doing it incorrectly
- Study was a good indication for continued (and further developed) use of self swabbing but confidence intervals allowed a range that included levels lower than the desired (at least) 90% sensitivity

https://onlinelibrary.wiley.com/doi/full/10.1111/acem.14387

Bond, Christopher, et al. “Hot off the Press: Self-obtained Vaginal Swabs for Sexually Transmitted Infection Testing.” *Wiley Online Library*, Academic Emergency Medicine, 4 Sept. 2021, onlinelibrary.wiley.com/doi/10.1111/acem.14387.

Conclusions/action items:

Self swabbing is a promising clinical procedure. Through more studies and improved design/instruction, the process can be improved to become a more accurate diagnosis tool.

Decreased accuracy could be in part due to inaccurate self swabbing. How can this device be made for easier use by patients? What are other sources of error in this test thta can be improved upon (timing, placement, materials, etc)?

9-13-23 Notes on "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

MORGAN KOPIDLANSKY - Sep 17, 2023, 9:30 AM CDT

Title: A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women

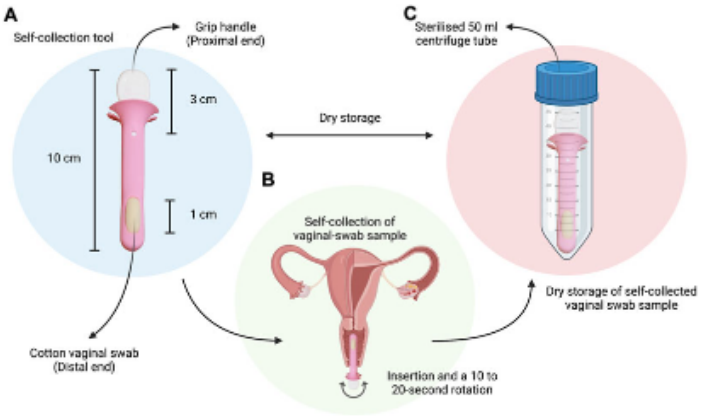
Date: 9/13/2023

Content by: Morgan Kopidlansky

Goals: Learn more about a study done on self swabbing for STD diagnosis

Content:

- Chlamydia is one of the most common STDs can lead to negative long term impacts for women
- Women are often under tested (ex. privacy concerns or asymptomatic) and tests themselves hold many complications (transport, spilling, refrigeration)
- Self swab devices hold many potential benefits (less barrier to young women, dry-stored, non refrigerated), would encourage screening and help prevent the spread
- Routine screening is very important in catching Chlamydia and gonorrhea due the common asymptomatic nature
- NAATs are better than culture plates (and other traditional methods) in part because they greatly simplify the process/steps needed and require less materials (and have comparable specificity)
- Self swabbing is described as a highly valuable and overall reliable form of screening (and increased screening) for young women
    - Accuracy as well as acceptance
- Self swabs require immediate refrigeration or buffer storage or transport fluid done by patients themselves (risks/complications arise)
    - Not widely available to rural areas or places with limited public infrastructure
    - Different specific procedure for either asymptomatic vs symptomatic
    - No commercially available self swab kits
- Self swabs designs should incorporate: advantages of NAATs, easy storage/transport with no buffer/fluid/refrigeration requirements
- This study looks at a self swab with NAAT technology and a dry storage
- Markers IgM and IgG trachomatis antibodies and PCR from first urine catch (currently utilized tests to compare)
- Tool: 10cm rod, 1 cm diameter, cotton swab for collection of vaginal discharge
    - Insertion of at least 2.5 cm in vagina
    - 10-20 second rotation
    - Storage in sterile 50 ml Abbott RealTime CT/NG testing kit
    - Transported to lab (no refrigeration) and same process done on self swab vs. provider taken samples/tests



- Self swabs had highest sensitivity and specificity (than other forms) compared to gold standard

https://www.frontiersin.org/articles/10.3389/fbioe.2022.1008761/full

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.

Conclusions/action items:

Self swabbing is a very promising form of diagnosis and prevention of STDs in women. The design in this article does have barriers, but the lack of buffer/refrigeration greatly elevates the potential. Creating a design with similar improvements from complications of provider-given test is definitely things to think about/incorporate (lack of buffer, no refrigeration - less room for error/potential contamination).

9-18-23 Notes on "Nucleic Acid Amplification Tests"

MORGAN KOPIDLANSKY - Sep 18, 2023, 7:07 PM CDT

Title: Nucleic Acid Amplification Tests

Date: 9/18/2023

Content by: Morgan Kopidlansky

Goals: Learn about the biological aspects of NAAT and how they actually work

Content:

- viral diagnostic test for SARS-CoV-2 (but we also know that it is used in vaginal self swabbing)
- detect genetic material (nucleic acids)
- steps include:
    - amplifying (making copies of) virus genetic material, if present
    - by amplifying, NAATs can then detect (small amounts) of whatever genetic material is present (for SARS-CoV-2 it is RNA)
- Different methods for amplification/detection include:
    - Reverse transcription polymerase chain reaction (RT-PCR)
    - Isothermal amplification
        - Nicking endonuclease amplification reaction (NEAR)
        - transcription mediated amplification (TMA)
        - loop-mediated isothermal amplification (LAMP)
        - helicase-dependent amplification (HDA)
          clustered regularly interspaced short palindromic repeats (CRISPR)
        - strand displacement amplification (SDA)
- Some are rapid and sensitivity varies by test

https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html

"Nucleic Acid Amplification Tests (NAATs)." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, www.cdc.gov/coronavirus/2019-ncov/lab/naats.html. Accessed 18 Sept. 2023.

Conclusions/action items:

There are many ways/methods to use NAAT technology. It is important to have a general understanding of the biology/what is occurring within the samples taken using self swabs. The commonly used PCR is just one example of an NAAT.

9-21-23 Notes on "Annual STI Testing Among Sexually Active Adolescents"

MORGAN KOPIDLANSKY - Sep 21, 2023, 1:45 PM CDT

Title: Annual STI Testing Among Sexually Active Adolescents

Date: 9/21/2023

Content by: Morgan Kopidlansky

Goals: Develop a greater understanding of patient related concerns and gain background on specific client goals

Content:

- Low prevalence of STD testing in groups with barriers (especially young adults)
- 1 in 4 sexually active young women have an STI
- Regular screening is very important due to complications of pelvic floor disease and infertility with untreated STIs
- Other barriers to regular testing include stigma, confidentiality concerns (of adolescents), less awareness overall, transportation and cost

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

Conclusions/action items:

This articles highlights one of the clients goals: increase universal STI testing. The continuously under-tested group of adolescents only leads to further spread and medical complications. This product would be a step in the right direction making testing more comfortable and less invasive especially for young women. This article also highlights barriers that will still exist for certain patient demographics even with a new testing method.

9-27-23 Notes on " Environmental Contamination by Chlamydia trachomatis RNA Can Cause False-Positive Test Results in Clinical Samples"

MORGAN KOPIDLANSKY - Sep 27, 2023, 9:45 PM CDT

Title: Environmental Contamination by Chlamydia trachomatis RNA Can Cause False-Positive Test Results in Clinical Samples

Date: 9/27/2023

Content by: Morgan Kopidlansky

Present:

Goals: Learn more about the client's goal of reducing contamination of the testing environment

Content:

- Tests in Sweden clinic were contaminated with RNA (false positives)
- NAAT testing is very dominant and have high sensitivity/specificity
- Devices used was Aptima Combo 2 Assay (CT, NG) - (a familiar and previously researched brand)
- This test identifies ribosomal RNA and through investigation the environment was found to be contaminated
    - the computer keyboard in the clinic tested positive for CT and MG
    - after 9 days, the ultrasound equipment was also positive for CT and MG
    - Samples remaining on these surfaces and others allowed for false positives of patients samples
- Environmental contamination and false positives in this way had only been discussed theoretically before this
    - Our client told us to assume environmental contamination happens every time
- This study provides evidence to support the clients goals of limiting environmental contamination
- Routine cleaning of supplies and testing rooms must be more thorough to prevent this (and hopefully our final design as well)

https://journals.lww.com/stdjournal/fulltext/2021/07000/environmental_contamination_by_chlamydia.12.aspx

Toepfe, Michael, et al. “Environmental Contamination by Chlamydia Trachomatis RNA Can Cause False-Positive Test Results in Clinical Samples.” *Sexually Transmitted Diseases*, vol. Publish Ahead of Print, 21 Oct. 2020, https://doi.org/10.1097/olq.0000000000001323.

Conclusions/action items:

This is one of the only sources regarding environmental contamination during STI testing. This investigation brings to light the importance of limiting contamination (cleaning surfaces and spaces, and hopefully a more streamlined device with less room for contamination). It would be impossible to tell how many times false positives have occurred from contamination, but this instance was only found through specific investigation. This source demonstrates the importance of one of our clients goals and what we are working for. In conjunction with cleaner surfaces, our design (and instructions that are clear about hand washing) should reduce environmental contamination at clinics.

10-19-23 Notes on "Writing Survey Questions"

MORGAN KOPIDLANSKY - Oct 19, 2023, 10:28 AM CDT

Title: Writing Survey Questions

Date: 10/19/2023

Content by: Morgan Kopidlansky

Present:

Goals: Learn how to best write survey questions and what to consider when doing so

Content:

-it is important that questions accurately reflect the true opinions/beliefs of the group we are surveying (female UW students)

-things to consider include...

- question order (earlier questions impact how people answer subsequent questions)
- length of survey
- open ended vs close ended questions (and whether you can pick multiple options)
- question wording (very important)

-people may also answer in a way that they feel is 'socially desirable'

-in our case, length probably will not come up as an issue

-wording our questions well is probably the most important aspect from the list (should be clear and specific, ask only ONE question at a time, etc)

https://www.pewresearch.org/our-methods/u-s-surveys/writing-survey-questions/

“Writing Survey Questions.” *Pew Research Center*, Pew Research Center, 26 May 2021, www.pewresearch.org/our-methods/u-s-surveys/writing-survey-questions/.

Conclusions/action items: I don't think that we will run into many issues with our survey because I think it can (and will be more effective) with a few simple questions (and it doesn't ask anything controversial). Being aware of the best ways to write survey questions is still very important because we do want a true reflection of how the female students actually feel. We do not want to have questions that influence anyone's answer, and we do not want to use strong wording. Making sure our survey is (and feels) completely anonymous should also help. Overall, our survey should not be too difficult to write well as long as we keep these things in mind.

9-13-23 Notes on "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia"

MORGAN KOPIDLANSKY - Sep 17, 2023, 9:27 AM CDT

Title: Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia

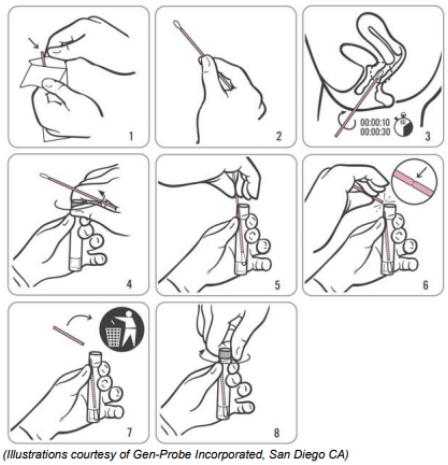
Date: 9/13/2023

Content by: Morgan Kopidlansky

Goals: Learn about a current process/procedure for self swabbing

Content:

- self-collected swabs for women who do not need pelvic exam (still done in clinic)
- Process includes:
  - Inserting swab into vagina about 2 inches
  - Rotating for 10-30 seconds (making sure it reaches the walls to absorb moisture)
  - Quickly placing tip into rube of liquid and breaking in half so the tube can be screwed shut
- Many possible sources of error (instructions continually mention not spilling/not letting swab touch anything else)
  - Not inserting far enough
  - Not reaching the walls to get enough moisture
  - Spilling (could happen at multiple stages)
  - Allowing swab to brush against any other surface
  - Timing (not long enough rotation, not putting into tube quick enough)



(Illustrations courtesy of Gen-Probe Incorporated, San Diego CA)

Source: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pd

"Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia." *NCDHHA,* Gen-Probe Incorporated, Apr.

2011. epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf

Conclusions/action items:

There are many areas that can be improved upon in future designs.

How can we make the design more user friendly? Potentially use a different liquid?

9-17-23 Notes on "Aptima® Multitest Swab Specimen Collection Kit"

MORGAN KOPIDLANSKY - Sep 18, 2023, 12:54 PM CDT

Title: Aptima® Multitest Swab Specimen Collection Kit

Date: 9-17-23

Content by: Morgan Kopidlansky

Present:

Goals: learn more about existing designs

Content:

- made by Hologic

- Step 1: prepare (wash hands)

  - remove swab (do not allow it to touch anything/do not hold above score line)

  step 2 - insert 2 inches and rotate for 10-30 seconds touching vaginal walls. Withdraw without touching skin

  step- immediately place into tube (no capping/uncapping necessary)

This design has essentially the same procedure as the example given to us by the client. It does remove the need to uncap/cap which takes away one source of cross contamination of the swab itself. Despite this innovation, this design does not address the main concern of the client (contamination of the environment).

It seems the most common route of self swabbing is very overall very similar and fails to limit contamination to environment (moving swab from vagina to tube).

Unclear as to whether or not this test is meant more for in clinic or at home.

It can detect up to 7 infections.

https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

Hologic (n.d.). *Aptima® Multitest Swab Specimen Collection Kit*. Retrieved September 17, 2023, from https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

Conclusions/action items:

Contamination of the environment is very prevalent and happens every time when a swab must be manually placed within a tube. Creating a design that streamlines this process and combines the media/tube aspect to the swab itself would greatly reduce any contamination (to environment and swab itself). Our client has highlighted contamination of the environment as a main concern, something that competing designs (researched thus far) do not address. Our client also pointed out that the main infection to be tested for is Chlamydia (universal screening - unsure if funding will allow inclusion of others).

9-21-23 Notes on "Notification of Extended Expiry Dating for the Aptima Multitest Swab Specimen"

MORGAN KOPIDLANSKY - Sep 21, 2023, 1:03 PM CDT

Title: Notification of Extended Expiry Dating for the Aptima Multitest Swab Specimen

Date: 9/21/2023

Content by: Morgan Kopidlansky

Goals: Learn more about shelf life/life in service for the PDS

Content:

- Always refer to expiration date and specifics of exact product
- Generally 12-18 months of shelf life for similar STI testing products

"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. Accessed 21 September 2023.

https://www.albertahealthservices.ca/assets/wf/lab/if-lab-hp-bulletin-notification-of-extended-expiry-dating-for-the-aptima-multitest-swab-specimen-collection-kits.pdf#:~:text=The%20Aptima%20Multitest%20Swab%20Specimen%20Collection%20Kits%20%28PRD-03546%29.by%20the%20manufacturer%20%28from%2012%20to%2018%20months%29.

Conclusions/action items:

The specifics of the expiration date/longevity of shelf life for our product will depend on the exact materials/media used. Looking at similar products sets up good guidelines to follow/be aware of when designing our own product.

9-21-23 Notes on "APTIMA Specimen Transfer Kit package insert"

MORGAN KOPIDLANSKY - Sep 21, 2023, 1:04 PM CD

Title: APTIMA Specimen Transfer Kit package insert

Date: 9/21/2023

Content by: Morgan Kopidlansky

Goals: Learn more about shelf life/life in service for the PDS

Content:

- Storage between 2 – 8 °C (36 – 46 °F) is standard for similar tests
- This allows the media to be keep in proper condition before being used
- Proper storage conditions will give product maximum shelf life

"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. Accessed 21 September 2023.

https://www.hologic.com/sites/default/files/package-insert/AW-11586-001_002_01.pdf#:~:text=Store%20specimen%20transfer%20tubes%20prior%20to%20use%20at,reagents%20beyond%20expiration%20date%20indicated%20on%20the%20via

Conclusions/action items:

Looking at similar products gives good guidelines to follow and be aware of. The temperatures given in this article are pretty standard for most cellular me

9-21-23 Notes on "APTIMA STI Panel, NAAT, Swab, Urine"

Title: APTIMA STI Panel, NAAT, Swab, Urine

Date: 9/21/2023

Content by: Morgan Kopidlansky

Goals: Learn more about shelf life/life in service for the PDS

Content:

- Samples can be kept at room temperature in lab for a maximum of 14 days
- Samples can also be refrigerated as well

“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%2

Conclusions/action items:

Knowing about the expected storage time/conditions of used swabs before testing is done is vital information. This allows a framework to be in place (once/if product is in use) to be sure r

9-27-23 Notes on “Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear”

MORGAN KOPIDLANSKY - Sep 27,

Title: Notes on “Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear”

Date: 9/27/2023

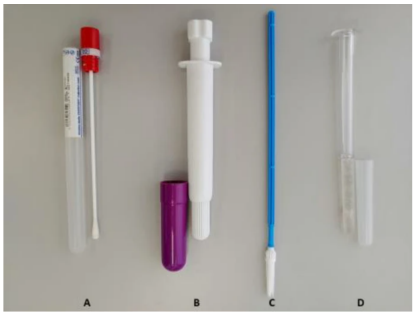
Content by: Morgan Kopidlansky

Present:

Goals: Learn more about commonly used self swabbing tools to potentially incorporate aspects into our design

Content:

- This was a study done to test for HPV through differing methods
- The correctness of results for each method as well as which ones were preferred for self swabbing by women in the study
- Different methods of testing used were
    - viscose swab (most similar to cotton swab) - without medium
    - Iune HPV test cannula - without medium
    - Viba-Brush® - with medium
    - Mía by Xytotest® - with medium



- The second one is very tampon-like, a well known tool that could translate into our design
- Women preferred the viscose swab (most commonly used type of swab, thin and small)
- All devices worked well in terms of the gold standard accuracy (collecting specimen to test for other infections uses similar devices - comparable device components to take into c

https://www.nature.com/articles/s41598-023-29255-y

Gibert, M.J., Sánchez-Contador, C. & Artigues, G. Validity and acceptance of self vs conventional

sampling for the analysis of human papillomavirus and Pap smear. Sci Rep 13, 2809 (2023).

https://doi.org/10.1038/s41598-023-29255-y

Conclusions/action items:

The accuracy results, while important, were not my main focus as I read this. Getting more acquainted with what works and different devices will make our own design proce tampon deployment method seems viable and would be very familiar. A combination of some sort of tampon-like device with a swab could be promising if it can be containec procedure (and contained entirely immediately after use) and would serve to limit contamination of the testing environment.

9-18-23 Notes on "Mirena® Insertion and Removal"

MORGAN KOPIDLANSKY - Sep 18, 2023, 7:05 PM CDT

Title: Mirena® Insertion and Removal

Date: 9/18/2023

Content by: Morgan Kopidlansky

Goals: Learn about a potential mechanism to use shown to us by client

Content:

-During our first client meeting, she showed us an iud inserter and brought our attention to the slider

-For out design purposes, the mechanism does not need to be as robust or powerful, but the idea of inserting and retracting is important

-A slider like this one could be incorporated to insert a swab and then pull it back into some sort of sealable container area to limit cross contamination

-Our client is mailing us one for reference

Mirena inserter

https://www.mirenahcp.com/insertion-and-removal

"Mirena® (Levonorgestrel-Releasing Intrauterine System) 52 Mg IUD." *HCP*, www.mirenahcp.com/insertion-and-removal. Accessed 18 Sept. 2023.

Conclusions/action items:

A mechanism similar to the iud inserter is important to consider when designing our product. A feature that allows insertion and retraction and keeps the swab contained at all times besides when inside the vagina is the best way to limit contamination of the environment. Once we have the inserter from our client, we can more readily see how the slider fully works/the mechanics.

Design Idea #1

MORGAN KOPIDLANSKY - Sep 28, 2023, 11:50 AM CDT

Title: Design Idea #1

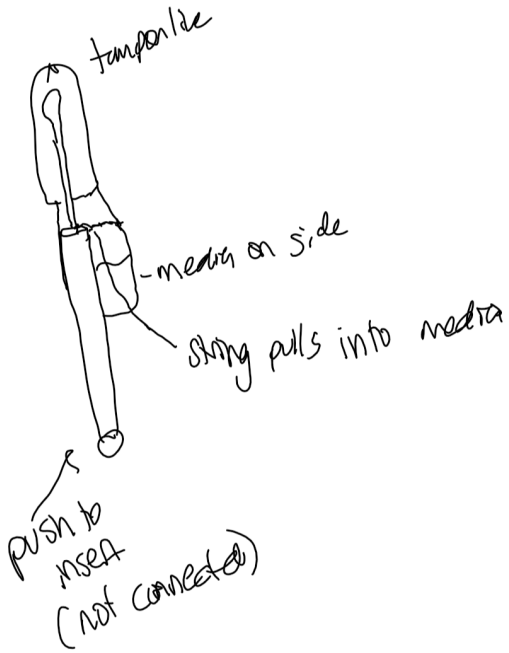
Date: 9/27/2023

Content by: Morgan Kopidlansky

Present:

Goals: Start formulating possible ideas for a final design

Content:



- This idea was based on a the design of a tampon

-Has an odd shape, may be unnatural to use in practice

-Unsure of how to get swab in media after retracting back into device

-Unsure of how the mechanism itself would fully seal

Conclusions/action items:

This design has many issues and would not work in practice, but it has helped me to get more ideas flowing about better ways of limiting contamination and having a more 'usable' device.

Design Idea #2

MORGAN KOPIDLANSKY - Sep 28, 2023, 11:59 AM CDT

Title: Design Idea #2

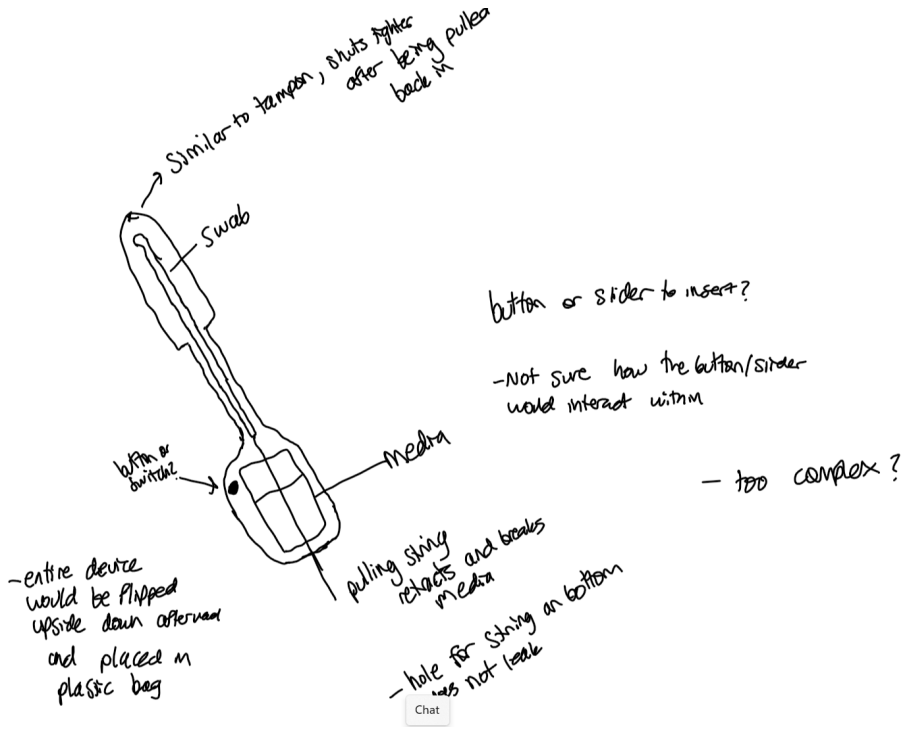
Date: 9/27/2023

Content by: Morgan Kopidlansky

Present:

Goals: start formulating possible ideas for a final design (improve upon previous ideas)

Content:



- Similar tampon insertion

-Entire device would need to immediately be placed in a bag after use

-Shape still not great for patient use

-Unsure of how a slider mechanism would work for deployment

-Many issues with sealing and leakage here

-I like the idea of flipping the entire device over for media to reach swab (sealing concerns come up)

Conclusions/action items:

This design is more complex than the last and still has many issues. Trying to wrap my head around getting the swab in the media feasibly and contained within the device.

Design Idea #3

MORGAN KOPIDLANSKY - Sep 28, 2023, 12:03 PM CDT

Title: Design idea #3

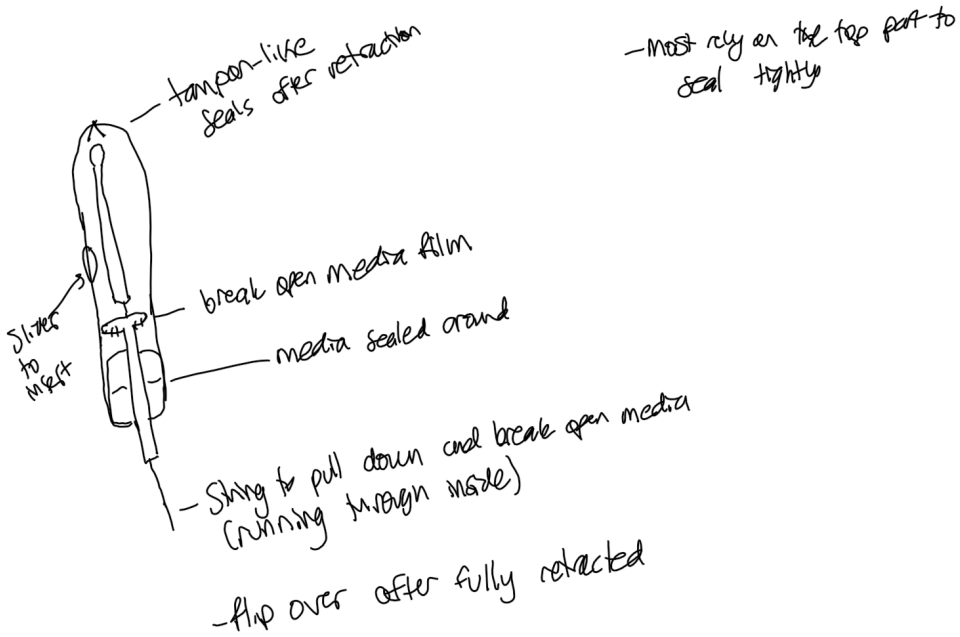
Date: 9/27/2023

Content by: Morgan Kopidlansky

Present:

Goals: continue improving upon past designs

Content:



-Very similar to my last one but shape is better

-Still the issue of sealing the top after retraction since this would still require being flipped over after media is opened

-media container is around the piece containing the string so leakage would not happen at the bottom

-Pulling the string would allow the media seal to be broken

Conclusions/action items:

This design is definitely my best one yet, however, there are still issues. Leakage from the top is a concern and feasibility of creation is another (it sems like too many parts).

10-10-23 Notes on "The influence of a swab type on the results of point-of-care tests"

MORGAN KOPIDLANSKY - Oct 10, 2023, 9:43 AM CDT

Title: "The influence of a swab type on the results of point-of-care tests"

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: Learn more specifics about the Dacron swab we will use in our design (for preliminary report)

Content:

- Dacron swabs are non-toxic and non-cotton

-the tips are synthetic fiber-wrapped

-being non-cotton and synthetic allows the swab tip to be hydrophilic which is best for collecting biological samples (and preserving them)

-Dacron swabs are already the main swab type used in STI specimen collection

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

https://amb-express.springeropen.com/articles/10.1186/s13568-020-00978-9#citeas

Conclusion/Action Items:

Dacron swabs are not only the preferred swab for what our product will be used for but also the most accessible for us. Our client already has some set aside for us to use. They are both patient safe and better for sample longevity.

10-10-23 Notes on "Thermo Scientific Swab, Dacron, sterile, plastic shaft, 6"L x 1/10" dia"

MORGAN KOPIDLANSKY - Oct 10, 2023, 9:57 AM CDT

Title: "Thermo Scientific Swab, Dacron, sterile, plastic shaft, 6"L x 1/10" dia"

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: Learn about the shaft of the Dacron swab (for preliminary report)

Content:

-This is a website selling Dacron and other swabs for medical use

-shaft can be wood or plastic (we will only be using swabs with a plastic shaft)

-shaft is made of a plastic that is safe and biocompatible for patients

“Thermo Scientific Swab, Dacron, sterile, plastic shaft, 6"L x 1/10" dia.” *Cole*, 10 Oct. 2023. www.coleparmer.com/i/thermo-scientific-swab-dacron-sterile-plastic-shaft-6-l-x-1-10-dia/1400110.

https://www.coleparmer.com/i/thermo-scientific-swab-dacron-sterile-plastic-shaft-6-l-x-1-10-dia/1400110

Conclusion/Action Items: I wanted to get a better understanding of the overall swab since it already exists, and we will not have to fabricate our own. Other sources did not focus on the shaft of the swab but primarily the tip. The shaft is made of a patient-safe plastic that is already used for collecting biological samples.

10-10-23 Notes on "TRANSPORT MEDIUM"

MORGAN KOPIDLANSKY - Oct 10, 2023, 10:18 AM CDT

Title: Transport Medium

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: Learn about universal transport media

Content:

-Vircell Transport Medium is one such brand of universal transport media

-universal transport media keeps microbiological samples (many kinds including those testing for STIs) viable for longer by:

-not letting them dry up

- limiting bacterial growth of potentially contaminated samples (though our design also aims to limit this in the first place)

- allowing them to be kept at room temperature

-universal transport media is also safe and is already commonly used for many different specimen sample collections

TRANSPORT MEDIUM - Vircell. en.vircell.com/products/transport-medium.

https://en.vircell.com/products/transport-medium/

Conclusion/Action Items: Universal transport media is an important component of our device. During the time in between sampling and lab testing, the samples need to remain viable. There are no concerns with using transport media as it is already widely used in the same type of sample collection.

10-10-23 Notes on "Application of Plastics in Medical Devices and Equipment"

MORGAN KOPIDLANSKY - Oct 10, 2023, 10:44 AM CDT

Title: "Application of Plastics in Medical Devices and Equipment"

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: Learn more about polypropylene and why we can use it

Content:

-Polypropylene is an autoclavable and synthetic resin

-it is also biocompatible and has been used in medical applications

Czuba, Len. “Application of Plastics in Medical Devices and Equipment.” *Handbook of Polymer Applications in Medicine and Medical Devices* (2014): 9–19. doi:10.1016/B978-0-323-22805-3.00002-5

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151894/

Conclusion/Action Items: Being sure of the safety of polypropylene was the main point of this research. Being biocompatible and already being used in medical environments is of utmost importance for our design. Since polypropylene is readily available for 3d printing in the makerspace, it is the best option for us to proceed with for our design.

10-10-23 Notes on "NovaPure® Syringe Plungers"

MORGAN KOPIDLANSKY - Oct 10, 2023, 10:58 AM CDT

Title: "NovaPure® Syringe Plungers"

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: Look at an existing design element to incorporate something similar

Content:

-our design will require a similar syringe plunger to avoid leakage

- ours will need a hole to allow the swab and connected plunger to run through - snugly to avoid leakage

“Novapure Elastomeric 1ml 3ml Plungers.” Ensuring Safe and Consistent Drug Delivery with NovaPure® Plungers, www.westpharma.com/products/prefillable-systems/syringe-components/novapure-elastomeric-1ml-3ml-plungers.

https://www.westpharma.com/products/prefillable-systems/syringe-components/novapure-elastomeric-1ml-3ml-plungers

Conclusion/Action Items: Getting a better idea of each individual component of our design is very important to get a general understanding of how it will work/be put together before we start the actual fabrication. Based on our final proposed design, this is an extra safety against leakage as the device will be/should be kept flipped upside down after media cap has been punctured.

10-10-23 Notes on "Pierceable Foil Lidding Offers High Barrier for Diagnostic Accuracy"

MORGAN KOPIDLANSKY - Oct 10, 2023, 1:13 PM CDT

Title: "Pierceable Foil Lidding Offers High Barrier for Diagnostic Accuracy"

Date: 10-10-23

Content by: Morgan Kopidlansky

Goals: learn more about a potential thin foil for the cap

Content:

- looking into the best/easiest way to contain the media but also make it easily accessible when needed

-made from aluminum

-this example is designed to seal but also be pierced (exactly what we need)

-puncture itself does not require much force - easier for the patient to use

-this kind of aluminum is heat sealable to polypropylene (whatever material we move forward with would also require this trait)

Sookne, Keren. “Pierceable Foil Lidding Offers High Barrier for Diagnostic Accuracy.” *Healthcare Packaging*, 12 Oct. 2021, www.healthcarepackaging.com/machinery-materials/package-design/article/21747608/pierceable-foil-lidding-offers-high-barrier-for-diagnostic-accuracy.

https://www.healthcarepackaging.com/machinery-materials/package-design/article/21747608/pierceable-foil-lidding-offers-high-barrier-for-diagnostic-accuracy

Conclusion/Action Items: Looking into potential film/foil mechanisms is an integral part of the functioning of our product. Something like this would work very well as it is designed for our purposes and is able to be sealed onto polypropylene (the material we are 3D printing with). Some sort of aluminum foil also seems the most accessible and practical for us to acquire and use.

12-9-23 Notes on "Polycarbonate (PC) Labware"

MORGAN KOPIDLANSKY - Dec 09, 2023, 7:08 PM CST

MORGAN KOPIDLANSKY - Dec 09, 2023, 7:29 PM CST

Title: "Polycarbonate (PC) Labware"

Date: 12-9-23

Content by: Morgan Kopidlansky

Goals: learn more about the properties of polycarbonate

Content:

- Polycarbonate is autoclavable and rigid

-it is also non-toxic

-PC is the "toughest of all thermoplastics"

Conclusion/Action Items: Since polycarbonate was the most readily available material for 3D printing in the makerspace, it was used for all iterations of initial prototyping (not the final). It still has the most important qualifications for this device (nontoxic/autoclavable), so it worked for our purposes of getting prototype iterations more quickly despite more rigid/stiff than desired.

https://www.thermofisher.com/us/en/home/life-science/lab-plasticware-supplies/plastic-material-selection/polycarbonate-pc-labware.html

Polycarbonate (PC) Labware. Thermo Fisher Scientific - US. (n.d.). https://www.thermofisher.com/us/en/home/life-science/lab-plasticware-supplies/plastic-material-selection/polycarbonate-pc-labware.html

12-9-23 Notes on Polylactic Acid

MORGAN KOPIDLANSKY - Dec 10, 2023, 5:23 PM CST

Title: Notes on Polylactic Acid

Date: 12-9-23

Content by: Morgan Kopidlansky

Goals: learn more about the properties of polylactic acid

Content:

- PLA is commonly used in medical devices in a wide variety of applications [1]

-it is biocompatible nontoxic [1]

-it is biodegradable both within and on the surface (by hydrolysis) [1]

-PLA is not autoclavable [2]

Conclusion/Action Items: Polylactic acid was not our first choice of material for the final prototype this semester, however, it still satisfies the most important traits our device needs (biocompatible and nontoxic). It was also able to be printed in pink for better aesthetics despite not being autoclavable. PLA also has some degree of biodegradability which is an added benefit of using this material for out final prototype.

[1] Silva, da Dana et al. “Biocompatibility, biodegradation and excretion of polylactic acid (PLA) in medical implants and theranostic systems.” *Chemical engineering journal (Lausanne, Switzerland : 1996)* vol. 340 (2018): 9-14. doi:10.1016/j.cej.2018.01.010

[2] Ism. (n.d.). *Plastics sterilization compatibility*. Industrial Specialties Mfg. https://www.industrialspec.com/resources/plastics-sterilization-compatibility

9/12/23 Notes from "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia"

SARA MOREHOUSE - Sep 12, 2023, 6:12 PM CDT

Title: "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia"

Date: 9/12/23

Content by: Sara Morehouse

Present: n/a

Goals: To learn what the commonly used procedure for vaginal self-swabs is.

Citation: “Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia.” Available: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf

Content:

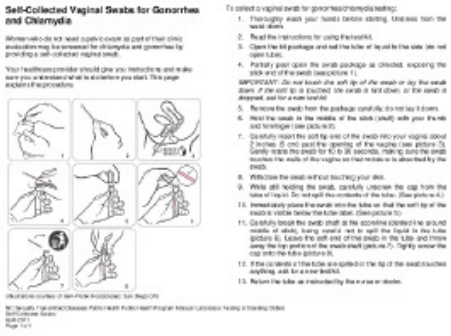
- Procedure involves patient using a single-use swab similar to a q-tip to swab their vagina about 2in past the opening, the withdrawing it and placing it into a tube of liquid. The patient then breaks the swab stick off and screws the cap on.
- This process has many stages of possible contamination, including:
    - While opening the swab package
    - While inserting the swab
    - While withdrawing the swab
    - While simultaneously holding the swab and unscrewing the tube cap
    - While placing the swab into the tube
    - While breaking the swab stick
    - While screwing on the tube cap
- Additionally this process could fail to be effective if the patient does not swab thoroughly in the correct spot for sufficient time.

Conclusions/action items:

This current process has many areas of possible error and contamination. Clearly there is a need for a more streamlined process.

Questions to research further: What is the swab made of? How efficient is it at absorbing vaginal fluid? What is the liquid in the tube? Why does the tube have to be submerged in liquid immediately? Are there studies/stats on contamination rates of this test?

SARA MOREHOUSE - Sep 12, 2023, 6:05 PM CDT


Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia

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selfcollectedswabs_instructions.pdf (69.6 kB)

9/17/23 Relevant Standards

SARA MOREHOUSE - Sep 19, 2023, 6:06 PM CDT

Title: Research on standards that may be relevant to this project

Date: 9/17/23

Content by: Sara Morehouse

Present: n/a

Goals: To identify and examine standards that are relevant when designing a medical device such as a vaginal swab.

Content:

Possible standards:

- ISO 6717: In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

- ISO 17822: In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Laboratory quality practice guide

- ISO 20658: Requirements for the collection and transport of samples for medical laboratory examinations

-CFR - Code of Federal Regulations Title 21 (fda.gov) According to the FDA, the transport culture medium that we will be using in our device will maintain the viability of the pathogen contained in the patient specimens while in transit to the laboratory. This is classified as a Class I (general controls) medical device.

-CFR - Code of Federal Regulations Title 21 (fda.gov) Microbiological specimen collection and transport device. Our sample collection device will be classified as a Class I (general controls) medical device. The device is identified as:

- `A microbiological specimen collection and transport device is a specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.`

Conclusions/action items:

Have to find the best way to access the content of these standards or at least see a preview of them. Once I can do this, then I can take better notes on what is required of our device so we can include this information in the PDS.

Update: I requested access to the standards through the university so once I get access I can read and note what requirements we have. However, I can use the information from the CFR to begin working on the PDS.

9/18/23 Notes on "A systematic review on materials, design, and manufacturing of swabs"

SARA MOREHOUSE - Sep 19, 2023, 12:04 AM CDT

Title: Notes on "A systematic review on materials, design, and manufacturing of swabs"

Date: 9/18.23

Content by: Sara Morehouse

Present: n/a

Goals: To learn about what types of materials are used for medical swabs and to help identify requirements for the material choices in order to help draft the PDS.

Citation:

[1] 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.

Content:

- used for collection of bacteria and other pathogens
- tip materials include rayon, polyester, nylon, polyurethane, etc
- 3 major designs
    - wound swabs = pure long fibers being wound up to the shaft
    - flocked swabs = fibers attached perpendicularly at the end of a swab stem
    - pad swabs = inspired by foams, sponge-like porous materials
- swabs are produced today with automated manufacturing
    - most recently, additive manufacturing aka rapid prototyping aka 3D printing
    - major shift to this method due to its efficiency and ability to avoid health risks
- As swabs are stored/transported, do NOT want materials that degrade or lose/shed samples during any phase of the process thru experimentation.
- differences in chemical properties of fibers influences in the efficiency of sample recovery.
- Common materials:
    - cotton:
        - not an option as specified by client because it sheds fibers
    - Rayon
        - very absorptive
        - made from cellulose
        - no abrasion of fibers
        - excellent chemical resistance and compatibility
        - mediocre specimen release
        - cost efficient
        - has to be wound externally
        - doesn't leave behind fibers
    - Polyester
        - pretty absorptive, quick dry
        - excellent chemical resistance and compatibility
        - no abrasion of fibers
        - good efficiency in specimen release
        - cost efficient
        - synthetic, from petroleum
        - can be manufactured with machines

    - Nylon
        - pretty absorptive, quick dry
        - swab material is left on substrate of rough surfaces
        - very efficient specimen release
        - excellent chemical resistance and compatibility
        - fibers have split ends for improved surface area, surface tension, microchannels for increased absorption/extraction
        - expensive
        - most commercially produced synthetic fiber
        - recovery efficiency up to 48.4%
    - Polyurethane
        - very absorptive, quick dry
        - excellent chemical resistance and compatibility
        - no abrasion
        - natural sponge
        - foam is typically attached externally
        - efficient specimen release
        - expensive
        - tips have gotten detached from stem = safety issue
- With flocked swabs, the absorbent material is attached via 'flocking', where fibers are placed perpendicularly to the adhesive-coated surface of the tip in an electrostatic field.
    - possible materials: rayon, polyester, nylon, polyamide, carbon fiber, alginate, cotton, silk
    - Easily 3D printed
    - most commonly used for testing of SARS-2 virus
- Stem part of the swab can be manufactured using stereolithography apparatus printers (3D print) using an autoclavable biocompatible resin.

Conclusions/action items:

This article gave a really helpful review of materials commonly used for the tip of medical swabs. It also confirmed that 3D printing should work for fabrication of our product. Looking forward, I want to research more about vaginal swabs specifically to see what materials are used as well as research nylon and rayon more.

9/19/23 Notes on "Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials"

Title: Notes on "Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials"

Date: 9/19/2023

Content by: Sara Morehouse

Present: n/a

Goals: To further understand the requirements for the material of the head of the swab.

Citation:

[1] 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.

Content:

- effectiveness of tests depends on the collection of the specimen, its protection during transport, and recovery from nutrient medium.
- Diagnostic sensitivity of a clinical test depends on the number of cells colelcted and released by the swab
- There is a need for correct sampling to provide a reliable and accurate diagnosis
- 2 main types of swab materials:
  - foamed polymer materials with an open porous structure
  - fiber materials with capillary effect and good absorption/retention/release of moisture, microbes, antigens, and nucleic acids
    - 1st generation was spun fibers like viscose, Dacron, cotton
    - 2nd generation uses flocking techniques to apply polymer fibers to the swab shaft at an angle of 90 degrees
    - why use flocked? spun fibers have much less recovery of organisms so they are less effective
- Ideal swab:
  - should collect many cells
  - ensure their release into medium
  - construction of the swab head should increases the number of diagnostic samples recovered (in order to accurately diagnose a patient, effective collection of clinical samples is required)
- Can apply a biopolymer coating such as alginate or protein to improve collection
- In this study they measured absorption of various nylon swabs and flocked swabs by measuring liquid uptake by weighing.
  - Method: preweigh swabs then place in liquid medium for 15s. Fibers cut from swab, weighed, placed in Eppendorf tube. add 0.5mL distilled water, then shake and let sit for 2 mins. Centrifuge at 10000 rpm for 5 mins, then remove residue by blotting. (3x). Then weigh fibers
  - Also tested bacterial cells in a simulated sample collection.
  - Results revealed that the flocked swab was the most effective swab overall due to its high water- and protein-absorbing capacity and high level of retrieval of bacteria

Conclusions/action items:

This article was useful in two ways: 1) It seems that a flocked design for the swab is most effective at absorbing and recovering the specimen. 2) This article also uses a great method for testing the effectiveness of the swab using a simulated sample collection, which may be something that we do to test our design later on.

SARA MOREHOUSE - Sep 19, 2023, 9:26 PM CDT

DOI: 10.1007/s10527-021-10124-z

Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials

B. N. Kashupov[1]* and A. N. Tikhin[2]

The COVID-19 pandemic has induced a sharp rise in demand for consumables for laboratory diagnosis and, in particular, for swabs for sampling biomaterials. Test quality depends strongly on swab quality. The aim of this work was to run experimental studies to evaluate the physical and operational properties of fiber-type medical swabs. This study compared swabs from leading manufacturers traditionally regarded as the quality standard on the Russian market in the premium sector: Copan Diagnostics (Italy), Puritan Medical Products (PMP) (USA), and PharmMedPolis (PMMP) (Russia). The following properties were studied: absorption, zeta potential, and surface morphology (by scanning electron microscopy). The techniques for biomaterial collection and release were also considered. Experiments using Streptococcus pneumoniae cultures as an example showed that the Copan Diagnostic swab had a recovery rate (RR) of 76.3%, compared with 80.13% for the Puritan Medical Products swab, 97.49% for the PMP swab, and 93.72% for the HydraFlock® swab. The HydraFlock® swab was found to be especially effective due to its high ability to absorb water and protein and its high bacterial recovery rate. The second best results were for the PharmMedPolis® swab, followed by the Copan swab and the nylon swab from Puritan Medical Products.

Introduction

The effectiveness of detecting viruses, cells, and proteins depends strongly on the effectiveness of collection of biomaterial, its protection during transportation, and its recovery from nutrient medium. Despite the fact that aspirates, body fluids, and tissue samples are the most effective for primary isolation, samples are often collected using swabs during patient care and testing [1]. This has become particularly relevant during the global COVID-19 pandemic caused by SARS-CoV-2. The pandemic has produced a sharp rise in demand for consumables used for laboratory diagnosis, among which are swabs for collecting biomaterials. The quality of these swabs largely determines the test reliability. As the diagnostic sensitivity of a clinical test depends on the number of cells collected and released by the swab, there is a constant need for correct sampling to provide reliable and accurate diagnosis.

Swabs from different manufacturers covering a wide price range are now available on the market. Such a wide diversity demands comparative evaluation. Currently available swabs are made of different materials and have different physical properties affecting the efficiency of biomaterial collection and preservation. Two main types of swab materials can be identified: foamed polymer materials with an open porous structure and fiber materials with pronounced capillary effect and good absorption, retention, and release of moisture, microbes, antigens, and nucleic acids. In turn, fiber-type swabs can be subdivided into first-generation swabs with the working part made of spun fibers (viscose, Dacron, cotton) and swabs of the second generation, where flocking technologies are used to apply perpendicular fibers to the working part, which is at an angle of 90° to the surface of the swab shaft. It is believed that only a small proportion of the organisms collected on traditional spun fiber swabs can be recovered. Rose et al. [2] showed that spun-type swabs extract

[1] Kazan (Volga region) Federal University, Kazan, Russia. E-mail: ...

[2] Research Institute for Healthcare Organization and Medical Management, Moscow Healthcare Department, Moscow, Russia.

* To whom correspondence should be addressed.

289

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comparison_of_the_physical_properties_and_effectiveness_of_medical_swabs....pdf (1.38 MB)

10/11/23 Notes on "The influence of a swab type on the results of point-of-care tests"

SARA MOREHOUSE - Oct 11, 2023, 2:56 PM CDT

Title: **The influence of a swab type on the results of point-of-care tests**

Date: 10/11/23

Content by: Sara Morehouse

Present: n/a

Goals: To learn more about how material choices/design of the swab can affect the results.

Content:

- measured the absorption capacity and efficiency of release of nucleic acids and proteins of 4 types of swabs
- Large differences in absorbed volume
- The efficiency of DNA and protein release was not correlated to the absorbed volume of a sample - but was correlated to the properties of the swabs
- Swabs studied were flocked nylon swab, rayon swab, dacron swab, and a polyurethane foam swab.
- Flocked nylon absorbed the most, followed by dacron.
- The largest amount of DNA was obtained from the flocked nylon swab
- The most proteins were recovered from dacron and rayon swabs

Conclusions/action items:

It seems depending on the type of test, different swab types may be preferred. For ours, as we are obtaining nucleic acids, a dacron or flocked nylon swab should work well. As the current swab used is dacron, we will go with this for now to simplify the fabrication process as we have it available already. However, in the future, we could consider trying a flocked nylon swab instead to see if results become more accurate.

9/12/23 Notes on "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

SARA MOREHOUSE - Sep 13, 2023, 1:41 PM CDT

Title: "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women"

Date: 9/12/2023

Content by: Sara Morehouse

Present: n/a

Goals: To understand the process of self-collection better and to learn about how effective it is.

Source: 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.

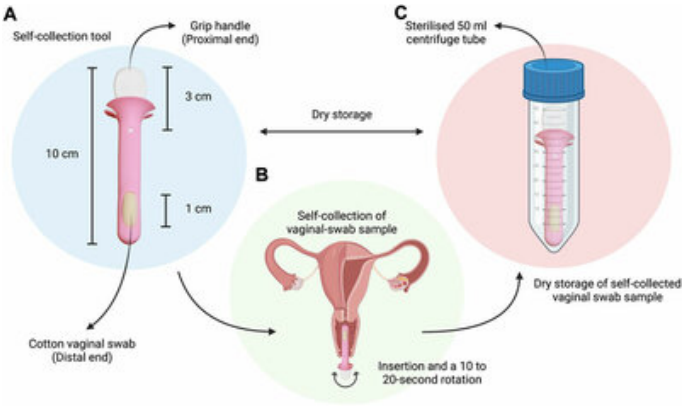
Content:

- Chlamydia is both extremely prevalent and preventable
    - in 2011, there was 1.4 million infections worldwide.
- Gonorrhea is another highly preventable STD
- in 2019, >376 million cases of chlamydia, gonorrhea, trichomoniasis, and syphilis
- Can lead to pelvic inflammatory disease, ectopic pregnancies, tubal factor infertility if undetected or untreated.
- Challenges to detected = asymptomatic infections, non-compliance to STD screening
- Patient concerns for testing = violation of privacy, fear of discomfort
- Clinical tests to diagnose include PCR testing of first-catch urine (FCU) samples
    - challenges: inconvenient to store/transport, spillage, refrigeration requirements, can't really be accomplished in remote areas where refrigeration/transport aren't possible
- Benefits of an improved self-collection device include breaking down barriers of STD testing, encouraging screening with an easier method
- Nucleic Acid Amplificiation Tests (NAATs)
    - detect specific nucleic acid sequences in a sample to detect a specific organism
    - do not rely on viable pathogens to perform
    - however, most self-collected swabs must be refrigerated on site/stored in buffer or NAAT transport fluid
    - ex: specimens from asymptomatic patients must be stored between 2-30 degrees C, used within 14 days. Speciments from symptomatic patients must be frozen and stored
- In this study they compared a self-collected vaginal swab device using PCR NAAT with dry storage in the absence of uffer to PCR doctor-collected samples
- The tool used was a 10cm length rod, 1cm diameter, with grip handle of 3cm in length from the root, and a cotton swab of 1cm length on the distal end for sample collection
- instructions for self collection: insert at least 2.5cm into the vagina. 10-20s rotation, store sample in sterile 50mL centrifuge tube.
    - did not need to be refrigerated
- samples were then introduced to 10mL of sterile PBS into the original tube. incubated in PBS for 10 mins, then 1 min of vortexing. 2mL of this was collected for PCR testing.
- Results found that the self collected swabs yielded identical results to the doctor-collected swabs.
- this suggests a high potential for the self-collection device to become an alternative diagnostic tool

Conclusions/action items:

This data suggests that self-collected swabs can be very accurate. After seeing the design used in this study for the swab, I am interested in seeing what other designs for swabs have been tested.

SARA MOREHOUSE - Sep 13, 2023, 1:42 PM CDT



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swab_image.jpg (47.6 kB) Depiction of the swab used for self-collection in this study.

SARA MOREHOUSE - Sep 13, 2023, 1:43 PM CDT

frontiers | Frontiers in Bioengineering and Biotechnology

A pilot clinical validation study of a self-collected vaginal swab device for the detection of *chlamydia trachomatis* in women

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fbioe-10-1008761.pdf (1.51 MB)

9/17/23 Visby Medical Sexual Health Vaginal Specimen Collection Kit

SARA MOREHOUSE - Sep 17, 2023, 5:41 PM CDT

Title: Notes on Competing Design: Visby Medical Sexual Health Vaginal Specimen Collection Kit

Date: 9/17/23

Content by: Sara Morehouse

Present: n/a

Goals: To investigate the Visby Medical STI test and to evaluate if it is a viable option for our client's needs/identify where it falls short.

Links:

Sexual Health Test — POC rapid PCR device | Visby Medical

Visby-Medical-Sexual-Health-Point-of-Care-Instructions-for-Use.pdf (visbymedical.com)

Visby-Medical-Sexual-Health-Vaginal-Specimen-Collection-Instructions-for-Use.pdf (visbymedical.com)

Content:

- 97% Accurate rapid PCR test for chlamydia, gonorrhea, and trichomoniasis.
- not for at-home use
- Allows for self-collection of samples by patients and fast results within 30 minutes
- The pack consists of an individually packed sterile swab, a tube containing 3.2mL of collection media, and self-collection instructions.
- The patient solely collects the specimen, and then it is passed off to the physician or lab for testing with the Visby device.
- The device must be plugged into the wall. The user then gently mixes the patient sample and uses a pipet to transfer the sample to the device port. The sample is then enclosed and the test starts. The test takes approximately 28 minutes to complete and then results can be read.

Conclusions/action items:

While this test seems to be a great product and makes in-clinic testing for STIs much easier and efficient, it does not address our client's needs for a sample collector that minimizes contamination. This design still utilizes the same simple swab and tube of media that the patient has to handle simultaneously while collecting the sample. It is clear that while advances are being made in the field of rapid testing and eventually home STI testing, there is still a need to minimize contamination.

Notes on "Evaluating Medical Devices Remotely: Current Methods and Potential Innovations"

SARA MOREHOUSE - Oct 26, 2023, 12:06 AM CDT

Title: **"Evaluating Medical Devices Remotely: Current Methods and Potential Innovations"**

Date: 10/25/23

Content by: Sara Morehouse

Present: n/a

Goals: To learn about how surveying is used in testing and find information that may be applicable for when we are surveying potential users about our device.

Citation: A. C. McLaughlin et al., “Evaluating Medical Devices Remotely: Current Methods and Potential Innovations,” Human Factors: The Journal of the Human Factors and Ergonomics Society, vol. 62, no. 7, pp. 1041–1060, Sep. 2020, doi: https://doi.org/10.1177/0018720820953644.

Content:

- FDA mandates human factors evaluation of medical devices
- This data can be collected remotely
- Remote testing can apply to all classes of medical devices but is most difficult for Class III devices
- Remote testing allows for collection of data from larger and more diverse populations quickly at a low cost
- Remote testing relies on surveys
- Can evaluate 3D objects by displaying a 3D prototype on a flat screen, or by using VR/AR to show the user the prototype.
- Survey a wide range of users including those with limited/low language proficiency as this will help to increase accessibility of the final product

Conclusions/action items:

This article was not super helpful in terms of coming up with questions to ask on our survey but it was useful to affirm that the idea of remote testing is valid and used by those in research and industry. I also like the idea of specifically targeting users with low language proficiency because this will help us reach more patients in the end with our product and help to increase universal testing even more.

One way valve mechanism

Title: One-way valve mechanism for swab collection in media

Date: 9/25/23

Content by: Sara Morehouse

Present: n/a

Goals: To come up with a way for the head of the swab to be pulled into the transport media without allowing the media to come near the vagina or to exit the tube.

Content:

Ideas:

- Similar to a heart valve? could do a tri-leaflet valve where there is 3 sections strung between struts and when you pull down on the swab it enters the media and the valve closes up so the media does not come back up (challenges: not sure how to make this)

- Could do a ball check valve (one-way valve), made with 3 segments of tube where the central segment fits inside the outer segments and there is a ball inside the middle segment that blocks one side, but a nail or rod inside that prevents the other side from being blocked (pros: cheap and easy to make, cons: this works for fluid flow but how would it let the swab inside?) (Link to video for how to make one: How to Make the Easiest Check Valve at Home (One Way Valve) - YouTube)

- could do a tilting disk valve, either with a single disk or with a bileaflet design. this would allow the swab to enter and prevent the media from coming back up. could be made with simple hinges on either side but may not be entirely splash-proof. However it would need a spring to close it.

- could use the foil method that the current Aptima media tubes have where pulling or pushing the swab through breaks the foil. Would have to remove the device from the vagina before pulling the swab into the tube.

- Could model after a dual-plate check valve that has two leaflets that are joined in the middle with a torsional spring and open outwardly. as pressure increased the leaflets open but when pressure decreases the spring works to close the valve and does not allow reverse flow. (source: Types of Check Valves | Different Check valves | Types of NRV Valves (instrumentationtools.com)). Could do something similar to this using a torsional spring but with only one disk/leaf.

- tampon valve has 4 leaflets. swab could start in the chamber above the valve and after swabbing the patient could pull a string and pull the swab and rod through the valve into the media. there could also be the foil layer here to further protect the patient from media spillage or splashing.

After playing around with one of the swabs from the client, I learned that what she initially told us, that the swab is stabbed through the tube cap, was incorrect. While attempting to do this, I realized there was two layers of foil with foam in between and a very narrow opening that did not allow the swab to pass through. Then I double checked the instructions and realized that they just said to unscrew the cap and screw it back on after breaking off the swab handle.

I also drilled a hold in the bottom of one of the media tubes to see if there was a way to pull the swab through it while still containing the media inside. Simply drilling a hole the same size as the swab rod and inserting it inside then filling it

up with water did not allow for water/"media" to stay contained inside the tube without leaking out the hole. Some other mechanism must be used to pull the swab head into the media tube. (see image attached).

Conclusions/action items:

From looking into valves, I think the best idea I have is to just do a foil layer with the tampon-like valve above it so it is relatively simple to build.

From playing with the swab materials, I have realized that my initial idea for having a pull-through rod won't really work as the media will leak out. If there is a way to still have this and to make sure the media is sealed inside still, that would be ideal. However, until I discuss this with the rest of the team, I don't have any idea how to make that happen, so my design will have some kind of push or slider mechanism that will slide the swab head inside the tube instead.

SARA MOREHOUSE - Sep 25, 2023, 9:00 PM CDT

Download

IMG_2216.HEIC (1.79 MB) I drilled a 7/64" hole in the bottom of the tube and inserted the swab inside. The tube cap did not allow the swab head to pass through without damaging the head which would interfere with sample collection. Also, the hole in the bottom leaked when filled with water.

SARA MOREHOUSE - Sep 25, 2023, 9:00 PM CDT

Download

IMG_2217.HEIC (1.78 MB) I drilled a 7/64" hole in the bottom of the tube and inserted the swab inside. The tube cap did not allow the swab head to pass through without damaging the head which would interfere with sample collection. Also, the hole in the bottom leaked when filled with water.

SARA MOREHOUSE - Sep 25, 2023, 9:01 PM CDT

Download

IMG_2218.HEIC (1.74 MB) I drilled a 7/64" hole in the bottom of the tube and inserted the swab inside. The tube cap did not allow the swab head to pass through without damaging the head which would interfere with sample collection. Also, the hole in the bottom leaked when filled with water.

SARA MOREHOUSE - Sep 25, 2023, 9:01 PM CDT

Download

IMG_2219.HEIC (1.67 MB) I drilled a 7/64" hole in the bottom of the tube and inserted the swab inside. The tube cap did not allow the swab head to pass through without damaging the head which would interfere with sample collection. Also, the hole in the bottom leaked when filled with water.

SARA MOREHOUSE - Sep 25, 2023, 9:01 PM CDT

Download

IMG_2220.HEIC (1.68 MB) I drilled a 7/64" hole in the bottom of the tube and inserted the swab inside. The tube cap did not allow the swab head to pass through without damaging the head which would interfere with sample collection. Also, the hole in the bottom leaked when filled with water.

Initial design idea

SARA MOREHOUSE - Sep 29, 2023, 12:54 PM CDT

Title: Initial Design idea

Date: 9/25/23

Content by: Sara Morehouse

Present: n/a

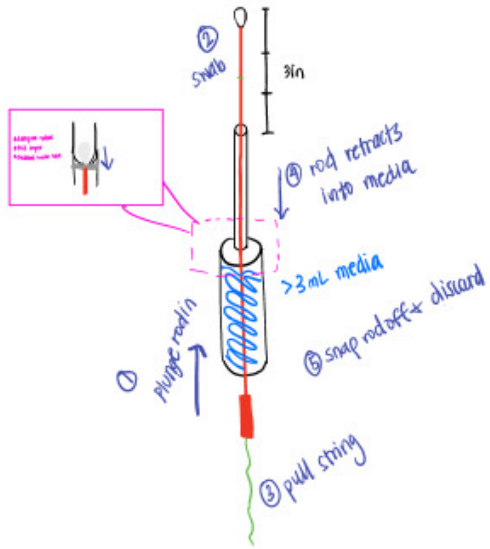
Goals: to draw and describe an initial design idea

Content:

drawing in PDF

Conclusions/action items: This design has elements that we may want to use for the final design but is not one that we will include in the matrix.

SARA MOREHOUSE - Sep 26, 2023, 8:04 PM CDT



Download

Design_idea.pdf (218 kB)

Screw-on design idea

SARA MOREHOUSE - Sep 29, 2023, 12:56 PM CDT

Title: Screw-on Design Idea

Date: 9/28/23

Content by: Sara Morehouse, Mia LaRico

Present: n/a

Goals: To sketch a clearer drawing with dimensions of Mia's screw-on design idea.

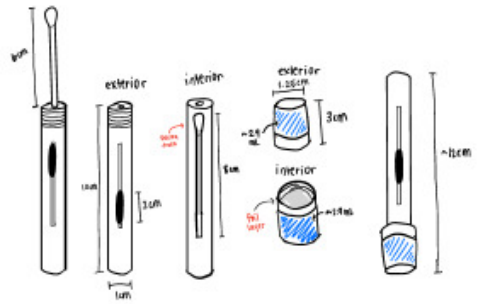
Content:

drawing in pdf.

Conclusions/action items:

This design is a really great way to make the sample collection process cleaner while also prioritizing the patient's safety by keeping the media separate.

SARA MOREHOUSE - Sep 29, 2023, 12:57 PM CDT



Download

Copy_of_Screw_on_design_idea.pdf (246 kB)

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

SARA MOREHOUSE - Sep 19, 2023, 8:16 PM CDT

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: