Early-Detection Cervical Cancer Testing Team

Preliminary Product Design Specifications

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Problem Statement:

Cervical cancer is one of the most common cancers in women and also is one of the most treatable cancers when diagnosed early [1]. Current cervical cancer screenings include Pap smears and HPV (human papillomavirus) tests. Testing methods such as the Pap smear must be collected by a medical professional, as it requires cells to be collected from the surface of the cervix and vagina [3]. While these tests are somewhat successful at detecting cervical cancer [2], they are not easily accessible for people in developing countries and can be an uncomfortable experience. The development of a discrete self-collected urine sample test would increase early cervical cancer detection by providing a cost-effect and culturally sensitive screening option. This device would allow cervical cancer screenings to be easily accessible worldwide, which in turn would prevent many cervical cancer-related deaths.

Client Requirements:

- Small and lightweight so that the device can easily be held
- Each device will cost between $3.00 to $5.00 US dollars
- Must be non-invasive and discrete
- Created from non-toxic materials that are not biodegradable
- Accessible to women ages 13 to 60 in developing countries
- Must be able to detect cervical cancer without the use of medical professionals

1. Physical and Operational Characteristics:

a. Performance Requirements

- This device should be a comfortable and safe alternative for detecting HPV markers.
- It should test for the presence of certain HPV strains and/or cervical cancer biomarkers and notify the user of the results without the use of medical lab facilities.
- The material should be biocompatible and non toxic to the user and should not cause any infection or inflammation.
- The design should be easy to hold and made of a rigid material that is not biodegradable.
- The design should be easily stored and distributed for home usage.

b. Safety:

- This device will remain in individual packaging to maintain a sterile environment prior to use.

- It should be biocompatible with no toxic materials and not cause any infections or inflammation.

c. Accuracy and Reliability:

- This device should be able to detect HPV markers from a sample collected at home. It should produce at least 70% accurate results.

d. Life in Service:

- The device should be disposed of after each use.

e. Shelf Life:

- This device should be stored in sealed, sterile packaging prior to use. The device will operate in temperatures ranging from 50^{o}F-110^{o}F. It will have a shelf life of approximately 1 year, while remaining in a sealed package.

f. Operating Environment:

- The device is designed to be used by women in developing countries in a non-medical environment.
- The device will provide clear instructions to conduct the test in any setting with no other equipment necessary.

g. Ergonomics:

- The device will be small and lightweight so that it may easily be held.

h. Size:

- The device needs to be as small as possible without compromising the usability of the device and should be no larger than 10” long and 5” wide.

i. Weight:

- The device should be lightweight to increase usability and to prevent unnecessary stress on the user and should weigh no more than 0.5 pounds.

k. Materials:

- Materials used for the sample collection method should be biocompatible
- No materials used should be biodegradable
- Materials should be lightweight and comfortable for the user if contact with skin is necessary
- The surface in which the sample is tested on should be capable of containing the sample for the duration of the test.

l. Aesthetics, Appearance, and Finish:

- This device should be compact so that it can be easily be held in the users hand
- Results should be easy to read and use no words so that users who speak any language can read the results universally
- Test should be discrete in appearance to avoid taboos around women’s health

2. Product Characteristics

a. Quantity:

- One functional sample collection prototype

b. Target Product Cost:

- The device should cost between $3-$5 per test to manufacture.

3. Miscellaneous

a. Standards and Specifications:

- Does not require a doctor or other healthcare professionals
- Discrete packaging
- Clear indicator of positive or negative results

b. Patient-Related Concerns:

- This product is designed for women in rural areas who do not have access to doctors or healthcare. The test must be easy to use and available for women in cultures where women's health topics are not discussed. It is important that the product will provide a clear answer if the patient has HPV markers or not, this way the patient can make an informed decision toward next steps and receive medical care.

c. Competition:

- Currently there is no non-invasive method for testing for cervical cancer. The main way for testing is a Pap Smear, which is a very invasive method, requires a doctor, and can be very expensive. A Pap Smear, is where a provider inserts a speculum to visualize the cervix and uses a wooden or plastic scraper and/or cervical brush to collect cell samples[3]. This method helps screen for abnormal cells that have the ability to turn into cervical cancer.
- Another method used in more rural parts of Africa and India is Visual Inspection with Acetic Acid(VIA). The procedure is similar to a Pap Smear except a 5% solution of acetic acid is swabbed onto the cervix and left there for 60 seconds. After the time has passed, a precancerous lesion will turn white with clear and dense margins, this is considered a positive result[4]. After a positive result the patient would be referred for further treatment.

References

[1] “Cervical cancer,” *World Health Organization*. [Online]. Available: https://www.who.int/health-topics/cervical-cancer#tab=tab_1. [Accessed: 23-Sep-2021].

[2] E. Nkwabong, I. Laure Bessi Badjan, and Z. Sando, “Pap smear accuracy for the diagnosis of cervical precancerous lesions,” *Tropical Doctor*, vol. 49, no. 1, pp. 34–39, 2018.

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