

# YOU, ME & HPV

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I wish to acknowledge the women who participated in this design project, in the survey, as part of the interviews, and user testing. Your responses, feedback and experiences have shaped this project in its entirety and the design intervention resulting from the research.

I believe that users are always at the heart of good, meaningful design and therefore, your participation has been the most important driver behind this project. For which I am extremely grateful.

A thank you is in order for my parents and siblings, who have provided support and encouragement in abundance and as many cups of tea as my heart desired.

A final thank you to my friends, who kept me motivated, and inspired throughout this past year, reading chapters, testing iterations and facilitating much needed distractions.

You will never know how much it has meant to me, but thank you nonetheless.

# STRATEGIC FOCUS STATEMENT

How do young women understand and experience, Cervical Screening and HPV vaccination, and how do we include their opinions and attitudes in a design solution?



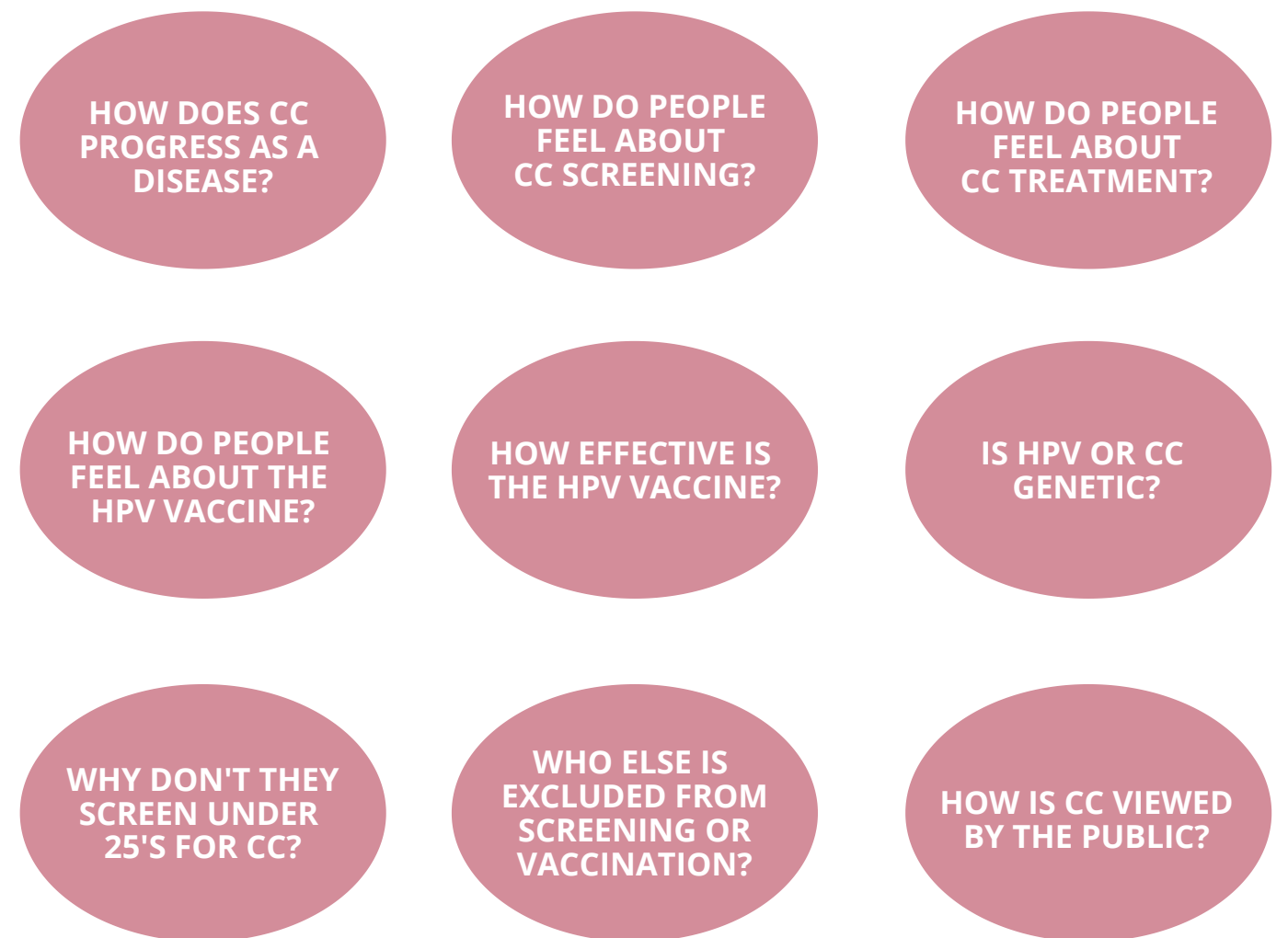
# KNOWNNS & UNKNOWNS

Before beginning the bulk of the research, the author documented what they knew about CC and HPV as well as outlining what they didn't know. This allowed the author to identify what areas needed to be supplemented with research.

## Knownns



## Unknownns



# ABBREVIATIONS

BMC – Business Model Canvas  
CC - Cervical Cancer  
CE – Circular Economy  
CIN - Cervical Intraepithelial Neoplasia  
ED - Environmental Design  
GSPR - General Safety and Performance Requirements  
HPV - Human Papilloma Virus  
HIV - Human Immunodeficient Virus  
HSE - Health Service Executive (Irish)  
IP – Intellectual Property  
MDR - Medical Device Regulation  
mHealth – Mobile Health  
NHS - National Health Service (United Kingdom)  
PRRC – Person Responsible for Regulatory Compliance  
PS – Polystyrene  
PCR - Polymerase Chain Reaction  
PMS – Post Market Surveillance  
qPCR - Qualitative PCR  
QMS – Quality Management System  
QoL - Quality of Life  
RMS – Risk Management System  
SEO- Search engine optimisation  
STI - Sexually Transmitted Disease  
SNP - silver nanoparticle  
UK- United Kingdom  
USA - United States of America

# RESEARCH

BACKGROUND RESEARCH

MARKET RESEARCH

STAKEHOLDER LIST

RESEARCH QUESTION

REVIEWING THE LITERATURE

RESEARCH METHODS

ETHICS

FINDINGS

NEEDS STATEMENTS

NEEDS FILTERING

DESIGN GUIDE

# BACKGROUND RESEARCH

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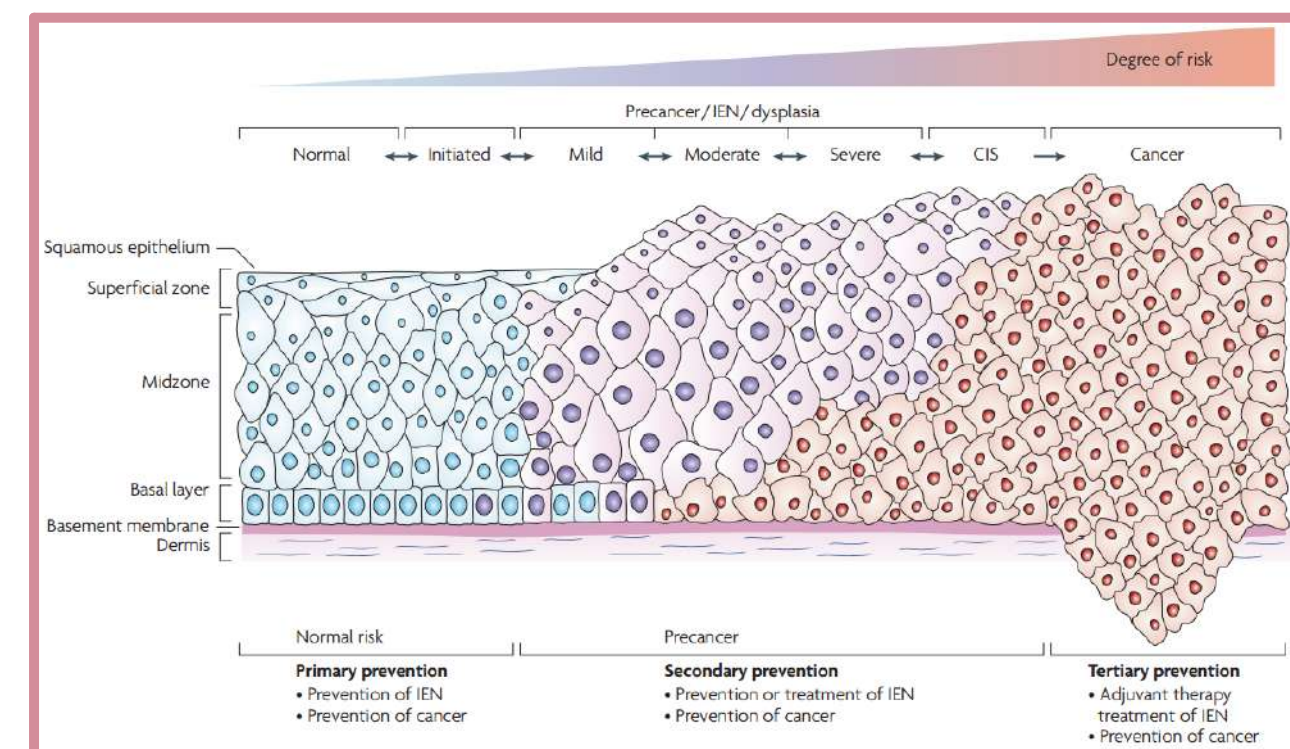
INTRODUCTION TO CERVICAL CANCER & HPV  
HISTORY OF CERVICAL CANCER  
VACCINATION  
SCREENING  
TREATMENT



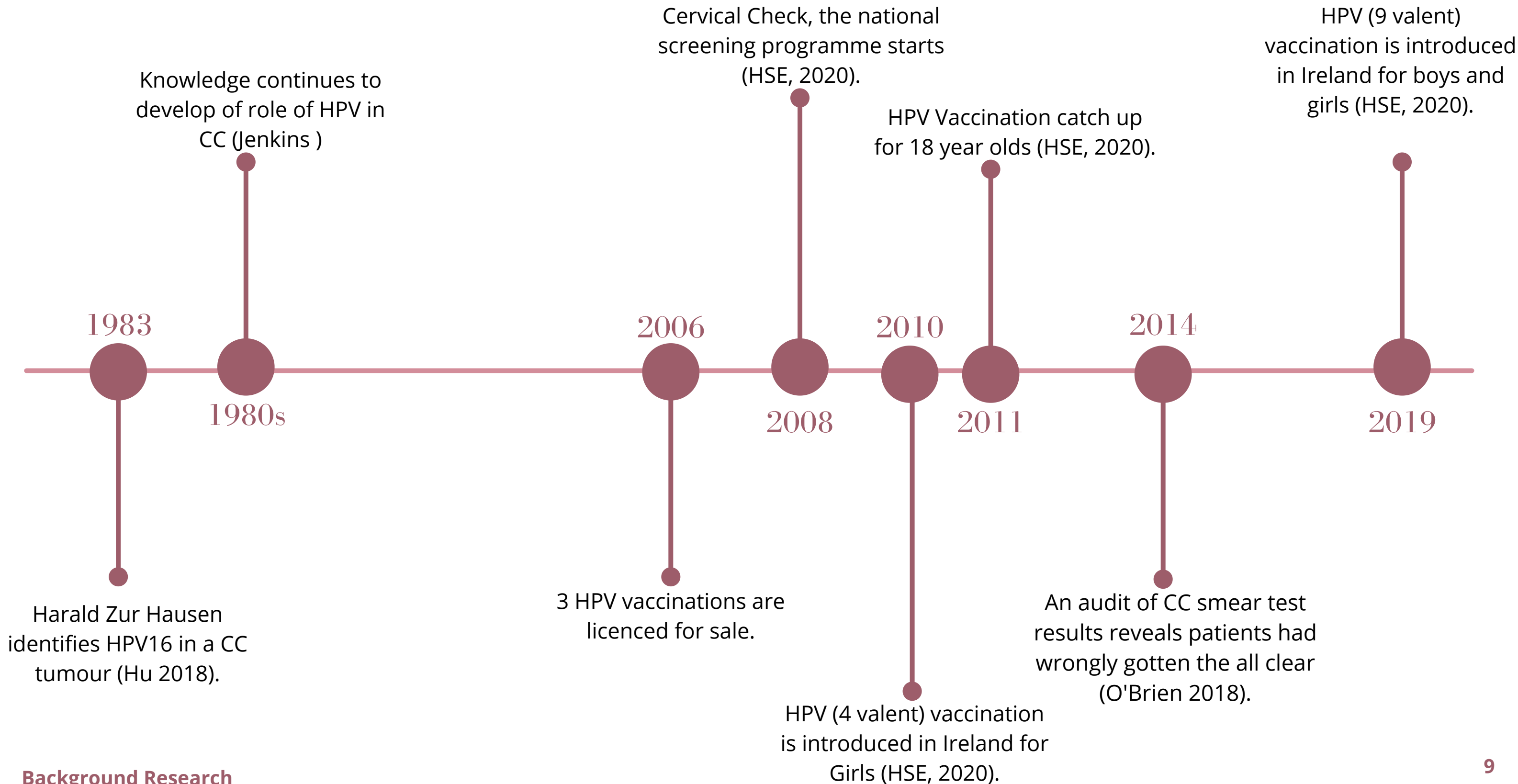
# CERVICAL CANCER & HPV

Cervical cancer (CC) is one of the most prevalent cancers in the world (Chrysostomou et al. 2018), with the second highest prevalence and mortality in women aged 15 – 44 in Europe (Nunes et al. 2020).

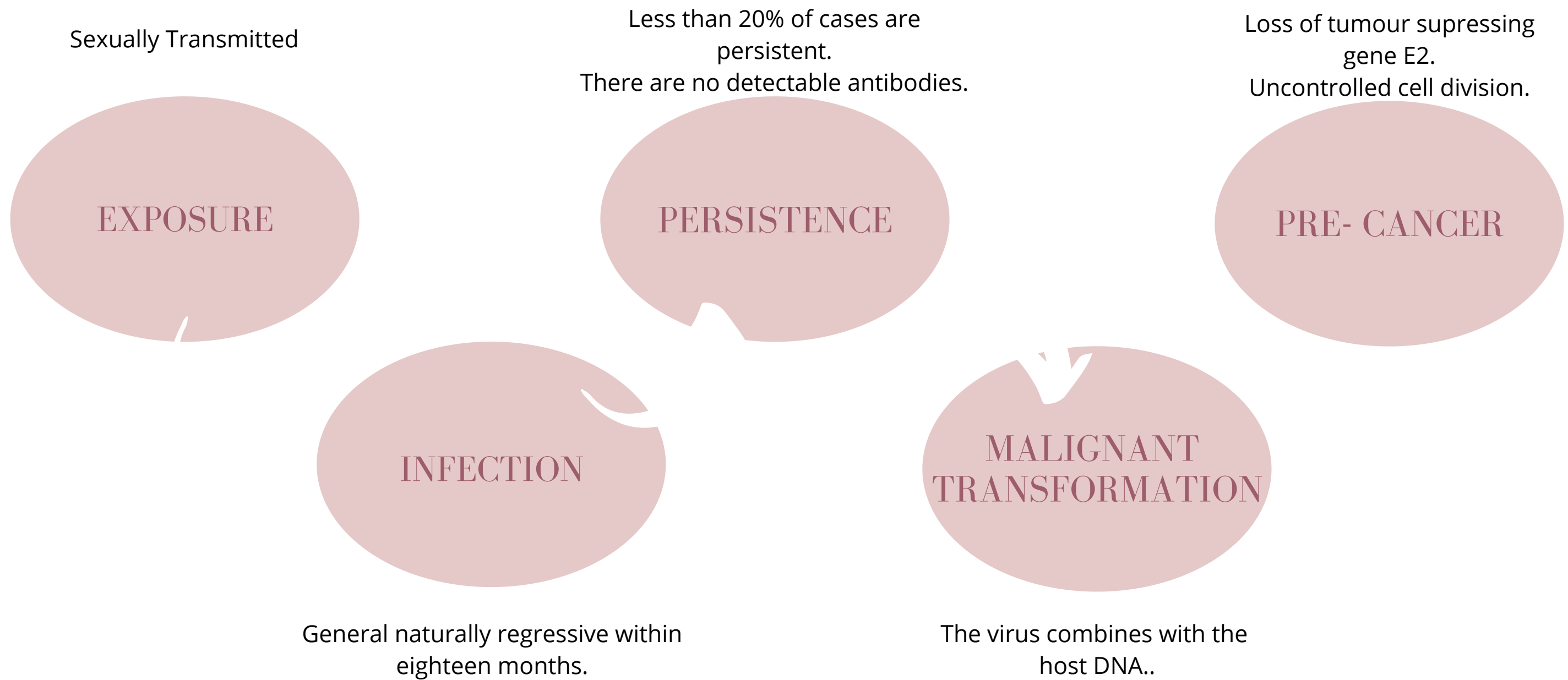
The human papillomavirus (HPV) is present in almost all cases of cervical cancer (Walboomers et al. 1999). Additional risks of the development of HPV include; multiple sexual partners, early age sexual activity and long term use of oral contraceptives (Asiaf et al. 2014). A majority of HPV viruses however, are no longer detectable after 12- 24 months (Brianti et al. 2017). HPV is the main risk factor for detecting a cervical intraepithelial neoplasia (CIN). These can range from CIN1 to CIN3 and cancer (Mirabello et al. 2018). The progression of CIN1 – CIN3 differs greatly, CIN1 is low grade and less likely to become undetectable or revert to normal on its own (Insinga et al. 2009). Whereas, CIN2 and CIN3 are high grade. CIN2 is less likely to progress to cancer, and is inclined to regress within 4-6 years (Rositch et al. 2012). CIN3 is precancerous and when left untreated may become an invasive cancer, however when treated effectively it is unlikely to become invasive (Gravitt et al. 2013).



# HISTORY OF CERVICAL CANCER & HPV



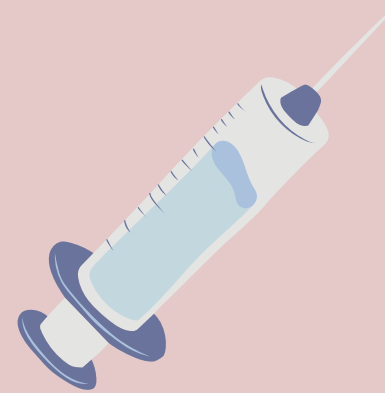
# DEVELOPMENT OF HPV



# PREVENTION OF DEATH

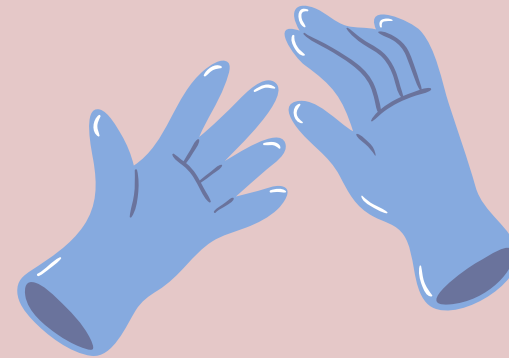
## PRIMARY PREVENTION

Vaccination against the HPV virus



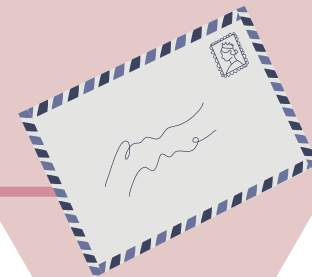
## SECONDARY PROTECTION

Screening for pre-cancerous changes in the cervix.



## EARLY DETECTION

Prompt assessment and referral for women who have symptoms



# VACCINATION

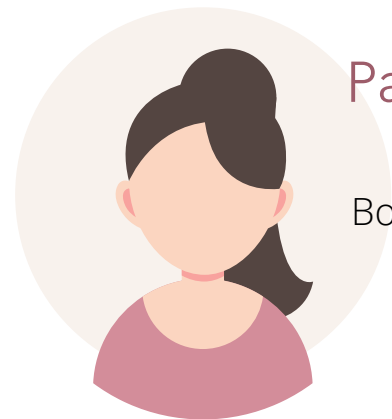


The HPV vaccine prevents development of cervical lesions (Asiaf et al. 2014). The vaccination protects against two strains of HPV, which are associated with most cervical cancer cases, HPV16 and HPV18 (Tyler et al. 2014). As a result of the vaccination uptake, cases of genital warts and HPV have significantly decreased (Drolet et al. 2019).

The vaccine is offered to young girls, (since 2010) and boys (since 2019) in school. Therefore, women who are currently between 15 - 25, have almost all been vaccinated besides those who turn 25 this year and who did not receive their vaccination for various reasons. It is important to note that over the coming years, in light of the increasing population of vaccinated women, these women will have a decreased risk of CC (Castanon et al. 2018).

There is little to no education in school about HPV or the HPV vaccine before immunization. With many young women frustrated at their lack of understanding of the vaccine and indeed the virus itself (Robbins et al. 2010). This lack of education can be attributed to high fear and anxiety related to the vaccination (Burns and Davies 2015). Knowledge and understanding about HPV promotes a positive attitude towards vaccination.

# VACCINATION PROCEDURE



## Patients

Boys and Girls in Secondary school, ages 12 - 13.



## Providers

Public Health Nurses - Injection  
Public Health Nurses - Monitoring post injection  
Supervising Doctor  
GP  
Admin Staff  
Teachers  
Parents

## Vaccination Flow - School



## Vaccination Flow - GP



## Vaccination Flow - Through Health Office (If home schooled)



# SCREENING



The goal of cervical screening is to prevent invasive cervical carcinoma by detecting and treating its precursors CIN2 & CIN3 (Ronco et al. 2014).

## HPV vs Cytology

HPV based screening provides greater protection for prevention of cervical cancer (Ronco et al. 2014) although, HPV screening is less specific than cytology (Arbyn et al. 2012). A reduced mortality rate can be seen in women where HPV based screening was used compared with cytology, because of this many health systems are moving to HPV based screening (Wentzensen and Arbyn 2017).

## Healthcare Approaches around the World

European guidelines recommend HPV based screening for cervical cancer, rather than conventional or liquid based cytology screenings. HPV screening offers the possibility of self-screening and could increase time between screenings of negative women (Maver and Poljak 2019).

The Australian cervical screening campaign used to recommend cytology screening every 2 years for women between 18 and 69 who are sexually active (Lew et al. 2017), however they have moved to using primary testing for HPV which brings their age back up to 25 (Smith et al. 2016).

In Denmark screening is recommended for women from the age of 23. Women aged 23 to 59 are screened via cytology while women aged 60-64 are recommended for HPV based screening (Thomsen et al. 2020).

# SCREENING PROCEDURE



## Patients

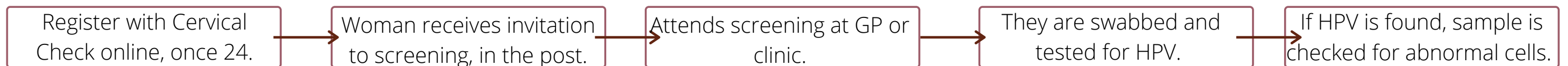
Women between 25 - 65 (HSE, 2020)  
Women between 20 - 65 who are HIV positive



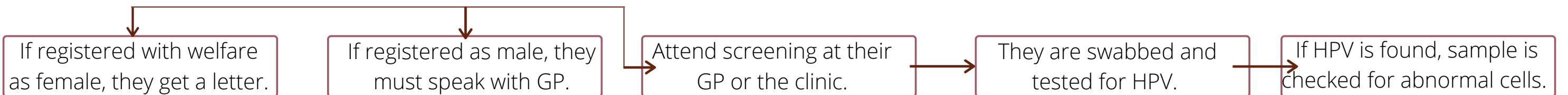
## Providers

GP  
Gynaecologist  
Nurse

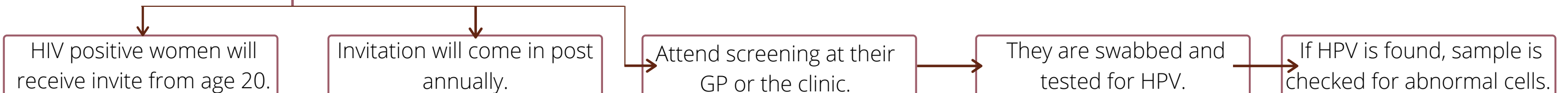
### Regular Women between 25 - 65 (Every 3 - 5 years)



### Transmasculine person between 25 - 65



### Woman who is HIV positive





# TREATMENT



## Colposcopy

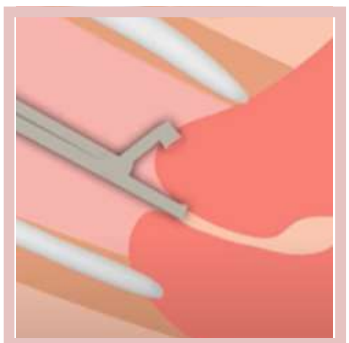
Patients are referred for a colposcopy as a result of an abnormal smear test. The smear test is done to detect early changes in the cervix (pictured). The abnormal result means that there were signs of changes, these changes can be; inflammation, infection, atypical cells (when the cells look different but it's not certain if there is an abnormality) and presence of the HPV virus. When this is treated it almost always prevents cancer.



A speculum (pictured) is inserted into the vagina, to keep it open during the examination. A microscope with a light, (colposcope) is used to examine the cervix. The doctor uses, a vinegar like solution, and an iodine like solution which dye the cells of the cervix to help see the changes of the cervix.



A smear is taken, and so is a punch biopsy. A punch biopsy (pictured) is a little pinch of tissue which is sent off to the lab. Following the punch biopsy, the area bleeds and silver nitrate is applied to stop bleeding.



If the abnormal cells are obvious, they may be removed during the procedure, this can be done under local anaesthetic and involves a large loop excision of the transformation zone (pictured). It burns away the abnormal cells and then the coagulator clots the blood.



Sometimes abnormalities will disappear on their own and there is no further treatment needed (Appanna 2016).

# TREATMENT



## Hysterectomy

A hysterectomy refers to the removal of the uterus or womb. Patients are referred for a hysterectomy, if the cancer in their cervix has reached an advanced stage. It is usually only considered after other less invasive treatments have been used. Generally in CC cases, a total hysterectomy is required, which removes the womb and the neck of the cervix.

It can be done in three different ways:

### 1. Laparoscopic hysterectomy

Also known as keyhole surgery, it is the preferred method for the removal of reproductive organs and surrounding tissue.

A small tube with a telescope and a camera is inserted through a small hole in the stomach.

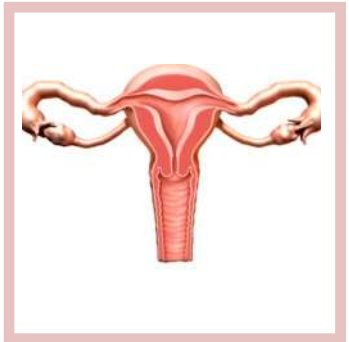
Equipment is inserted through the vagina or other small incisions in order to remove the womb and parts of the cervix. The patient is under general anaesthetic for this.

### 2. Vaginal hysterectomy

This time the incision is made at the top of the vagina and equipment is inserted through the vagina to detach the womb from the surrounding ligaments. This procedure can be done under general anaesthetic, local anaesthetic or spinal anaesthetic. This method is less invasive than an abdominal hysterectomy and recovery time is quicker.

### 3. Abdominal hysterectomy

For abdominal hysterectomies, a large incision is made on the abdomen. This procedure is usually done when the womb is enlarged as a result of fibroids and would not be possible to remove through the vagina.



(NHS Wales 2019)

(NHS 2019)

# WHAT IS THE CC PATHWAY IN IRELAND?

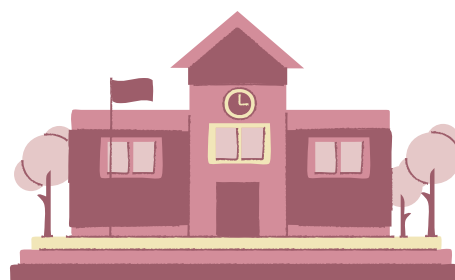
An overview of the CC pathway.

## National Immunisation Programme

12 - 13  
year olds



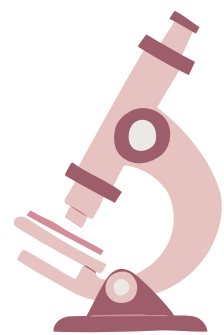
HPV  
Vaccination



Vaccination generally takes place in Secondary School for free. If a parent decides to wait they must pay for the vaccination. Children who are home schooled can be vaccinated for free by the public health nurse.

## National Cervical Screening Programme

25 - 65  
year olds

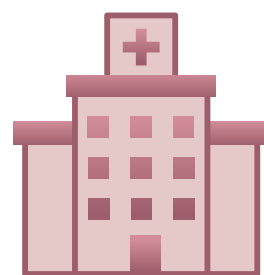


HPV  
Screening

Repeat every  
5 years

Normal  
Cells

Abnormal  
Cells

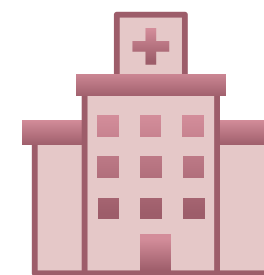


Screening can be done for free, in designated GP's or Clinics.



Precancerous  
Treatment

Colposcopy



Treatment generally takes place in hospitals, and usually as an outpatient.

# MARKET RESEARCH

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MARKET SIZE  
MARKET TRENDS AND DRIVERS  
KEY PLAYERS  
SWOT ANALYSIS  
PESTLE ANALYSIS

# MARKET SIZE

Examine the market sizes for CC and HPV vaccination in the global market.

## The Global Market

CC is the 4th most prevalent cancer in women worldwide. In 2018, about 570,000 women were diagnosed with the disease, and an estimated 311,000 women died from CC (WHO 2020). The global market size for the treatment of CC was estimated at USD 6.2 billion in 2018 and is expected to expand (GrandviewResearch 2018). The growth is likely to be due to an increase in technological and medical advancements in terms of diagnostic equipment and procedures (Persistence Market research 2020).

Asia-Pacific is the fastest growing market for cervical cancer diagnostic tests, this growth is due to the increasing prevalence of cervical cancer in developing countries. Growth of the Asia-Pacific market can also be linked to improvements of the economy and an emphasis on preventative healthcare (Grandview research 2018).

There are currently two vaccinations against HPV, Gardasil and Cervarix. There have been over 270 million doses of the vaccine distributed since with no major issues apart from anaphylaxis in 1.7 cases per 1 million doses. Therefore the vaccine is classified as extremely safe (WHO 2017).



# MARKET SIZE

Examine the market sizes for CC and HPV vaccination in the Irish market.

## The Irish Market

CC is the 9th most common cancer in Ireland, and annually around 300 women are diagnosed with CC. It accounts for about 90 deaths (HSE 2019). CC most commonly affects women between 25 - 65, and which in 2016 included 1,290,774 Irish women (CSO Ireland 2016). The Irish population is also increasing (Worldometer 2021). Therefore it is likely that the CC market size in Ireland will continue to increase. Factors including the increase in obesity in Ireland (Bel-Serrat 2017) are also likely to contribute to the increase in the market size, and therefore contribute to the growth of the CC screening market in the future

The cost of CC is high, and while data is lacking of the cost of CC to the HSE, a look at the NHS, the UK's health service can be used as a helpful comparison. The cost incurred by CC in the UK is 21.1m annually (Salter 2014).

The HPV vaccination programme has vaccinated over 240,000 girls since its commencement. The vaccination used against HPV in Ireland is Gardasil 9 (HSE 2020b). Uptake of the vaccination originally had a high rate of 86.9% in 2014-2015 however, dropped to 50% in 2016-2017 as a result of parental concerns regarding the safety of the vaccine (Corcoran 2018).



# MARKET SIZE

Examine the market sizes for CC and HPV vaccination in the US, to determine the scale of the issue at hand.

## The US Market

Annually, it is estimated that about 14,480 women will be diagnosed with CC in the US. About 4,290 women die as a result of the disease each year (Cancer.net 2021).

North America is the largest market for CC diagnostics and therapeutics. This can be attributed to the high awareness about disease prevention among women in the region, as well as to the many initiatives launched to prevent cervical cancer, which have increased the reach of insurance coverage for cervical screening tests, especially for low-income women.

Vaccination uptake in the US is low, at about 43%. A target of 80% uptake is required to reach herd immunity of HPV (Yoo, et al. 2020)



# MARKET TRENDS

Examining current and future market trends in CC treatment landscape as well as the market for the HPV vaccination.



## Market trends

Increased adoption of HPV home testing kits is likely to be the next trend for the market (BusinessWire 2020). There has been reported success of the use of self testing home kits (Harper *et al.* 2002; Boggan *et al.* 2015 ).

Technological advancement and affordable health related devices is fuelling research behind patient generated health data (PGHD). This has contributed to an increase in PGHD, and there is a continued increase in the acceptance of PGHD. There is opportunity for the CC treatment and prevention market to enter the area of PGHD, and use the data collected to improve care for patients (Lai *et al.* 2017).



# MARKET TRENDS

Examining market drivers for growth of the CC prevention and treatment market.



## Market Drivers

There has been an increase in awareness among the general population regarding the care, prevention, and treatment of cervical cancer. There has been a rise in certain risky behaviours, including multiple sexual partners and smoking. A number of genetic factors, and weak immune systems are linked to the growth of the cervical cancer diagnostics and therapeutics market (Research and Markets 2020). Increase in R&D expenditure in oncology is also likely to provide growth for the market (GrandviewResearch 2018).

Increased awareness of CC as a result of the Cervical Check Screening scandal could be seen as a driver for the uptake of screening, however, the lack of trust caused by the scandal may also reduce screening uptake in the country. Another factor of the growth of the market can be linked to the rising population in Ireland. There has also been an increase in disease prevalence.

Another driver of the market results from the patent expiration of the HPV vaccinations, which will be within the next 10 years. This patent expiration will allow for new entrants, offering the vaccination at a cheaper price. Currently there are expected new entrants from India and China over the next few years (UNICEF 2018).

Ageing population is another contributing factor to the expansion of the CC prevention and treatment market (GlobeNewswire 2020).

# MARKET TRENDS

Exploring restraints preventing the growth of the CC screening and prevention market.



## Market Restraints

A restraint to the continued growth of market leaders, is the impending patent expiration of the drug used in vaccination. Although this can and has encouraged the development of new drugs (UNICEF 2018), the new drugs are likely to saturate the market. This saturation will hinder any further growth.

There is also a high cost associated with the treatment of CC, limiting access to treatment, retraining the growth of the market.

The stigmatised nature of the disease, can also hinder the growth of the market, as patients are less likely to attend their follow up clinics due to their embarrassment and or anxiety relating to the disease (Milner and McNally 2020).

# KEY PLAYERS

## Global Market

Some of the current global market leaders of innovations in the area of CC prevention and treatment include:

Abbott Laboratories

Bristol-Myers Squibb Company

GlaxoSmithKline PLC

Merck & Co. Inc.

Pfizer Inc.

Qiagen NV Advaxis Inc

Becton, Dickinson and Company F. Hoffmann-La Roche Ltd

Merck & Co Inc are likely to remain strong competitors due to their important role in Gardasil and its continued success as a HPV vaccination.

## Irish Market

In Ireland the vaccination used in the national immunisation programme is Gardasil (HSE 2020). The Gardasil vaccine is provided by Merck & Co, so they are current market leaders in the Irish market in terms of vaccination.

Key players for any Irish healthcare innovation would include the governing bodies for healthcare. These include, the HSE, the Department for health, the HPRA and Irish insurance companies. These bodies are of huge importance for the funding, approval and support of any new healthcare design intervention in Ireland.

# RECENT INNOVATIONS

## Screening Innovations

### *Policy Innovation*

Australia is a leader in cervical cancer prevention and treatment. They have an impressive protocol for evaluation of the infrastructure currently in place. In Australia they have developed a road map, for a 'pathway' to a cancer free future, where they focus on five of the cancers which effect their population. Pathways – Cervix is their cervical cancer control, framework from prevention through to treatment and survivorship. It works on the basis of using research to action change by involving stakeholders and policy-makers. It's success and flexibility means it is applicable in other countries and also with various groups and demographics (Velentis 2019).

### *Innovation for Inclusion*

There has been an increase in the documented success of using mobile health (mHealth) to increase screening rates among refugees in Australia. A study showed that using text messages to promote screening was hugely successful (Anaman 2017).

There is a large amount of research which suggests that innovation is required to increase screening uptake in vulnerable segments of the population. It is suggested that self-testing for HPV is highly successful for the inclusion of these underserved populations (Vahabi and Lofters 2018).

## Vaccination Innovations

### *Vaccine dosage innovation*

Recent research has indicated the possibility for decreasing the HPV vaccination dosage from two doses given at an interval of at least six months to a single dose vaccine. Trials are currently underway in countries and some data suggests that it would be successful among young healthy girls (Whitworth et al. 2020).

### *Innovation for vaccine delivery*

The success of school vaccination has been previously noted, although it does have limitations including its high cost. It also can fail to account for girls who are not regular attendees of school. In places such as Tanzania and Sengal they have implemented a blended approach to service delivery combining school programmes with facility based vaccination. This is key for reaching those excluded girls who are not consistently attending school (Kumar 2021).

In Zambia they use online registration tracking to follow uptake, dropout and coverage of the vaccination, particularly for girls who are not in school (Kumar 2021).

# SWOT ANALYSIS

This analysis considers the internal strengths and weaknesses as well as external opportunities and threats of using design intervention within the Cervical Cancer healthcare setting.

## Strengths

Proven success for reducing cases of genital warts (HPV infection) among young people.  
Vaccination programme accesses a large number of children quickly.  
Screening is highly effective.

## Opportunities

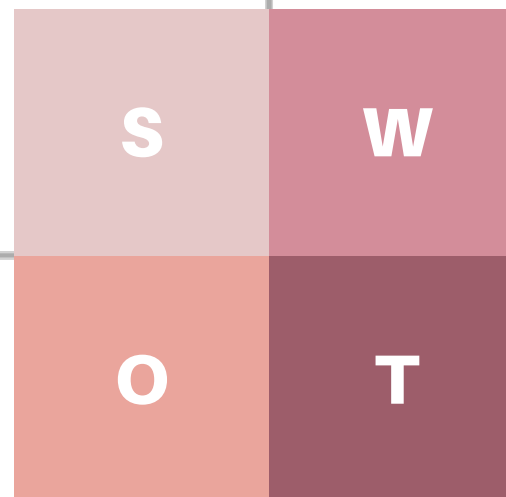
Support for improvements to be made to existing screening system.  
Growing market.  
Increased awareness.  
Increased funding in technology for prevention and treatment.  
Proven success of design intervention in stigmatised conditions.

## Weaknesses

Uptake of vaccination is below requirement for herd immunity.  
Lack of trust in immunisations and screening capabilities.

## Threats

Potential for another scandal which would disrupt the market again.  
Large Competitors with funding and customer relationships.  
Strict government and European regulations on medical devices.



# PESTLE ANALYSIS

This analysis considers the various way Political, Economic, Social, Technological, Legal and Environmental impacts influence the CC screening market.

**P**

## Political

The HPV vaccine is of pharmaceutical concern, and politics shape every aspect of pharmaceutical life and therefore are deeply intertwined (Casper and Carpenter, 2008).

Decline in number of students who took the vaccine from 80% in 2014 to 50% in 2016, due to misinformation spread by parents (Corcoran *et al* 2018).

Irish cervical cancer scandals which negatively impacted the trust of Irish women in the screening process. The system for cervical screening in Ireland was “doomed to fail at some point” and had problems that were “redolent of a whole system failure” (Dyer 2020).

**E**

## Economic

In Belgium with Cervical Cancer, has an annual cost per patient of €9,716. The total annual cost of Cervical Cancer is €6.5 million (from a healthcare payer perspective (Annemans, *et al* 2008).

The pandemic has served as a catalyst for a culture of supporting local businesses. Consumers are increasingly being urged to buy Irish and spend their money with Irish businesses in order to support the Irish economy, this looks favourably at the possibility of an Irish made cervical cancer medical device (O'Brein 2020).

**S**

## Social

283,960 women between 15-24 in the 2016 census. Positive net migration and natural increase has resulted in a 1.1% increase in population in 2020.

Social impact of cancer, on patients friends and families, however recognizing a patient as 'cured' of cancer greatly improves patient quality of life(QoL) (Tralongo, 2019)

In Brazil cervical cancer prevention campaigns increased the number of women getting smear tests, but also reinforced the idea women's sexuality is dangerous and needs to be controlled (Casper and Carpenter, 2009).

**T**

## Technological

Eve Medical Inc - allows at home testing with a tampon shaped product to obtain own vaginal sample, and mail it to a lab.Approved in the EU.

Biop Medical - a device which emits light, and the light is reflected by the cervical tissue identifying cancerous or pre cancerous lesions, for immediate results (Frost and Sullivan 2018).

The HPV vaccine stronger immunological response in girls aged ten to fifteen (Casper and Carpenter, 2009).

**L**

## Legal

The CervicalCheck Tribunal Act 2019  
The legislation provides for the establishment of a tribunal for women affected by CervicalCheck to have their cases heard without having to go to court.

The Equal Status Acts 2000-2018 prohibit discrimination. - discrimination based on age by not including under 25's.

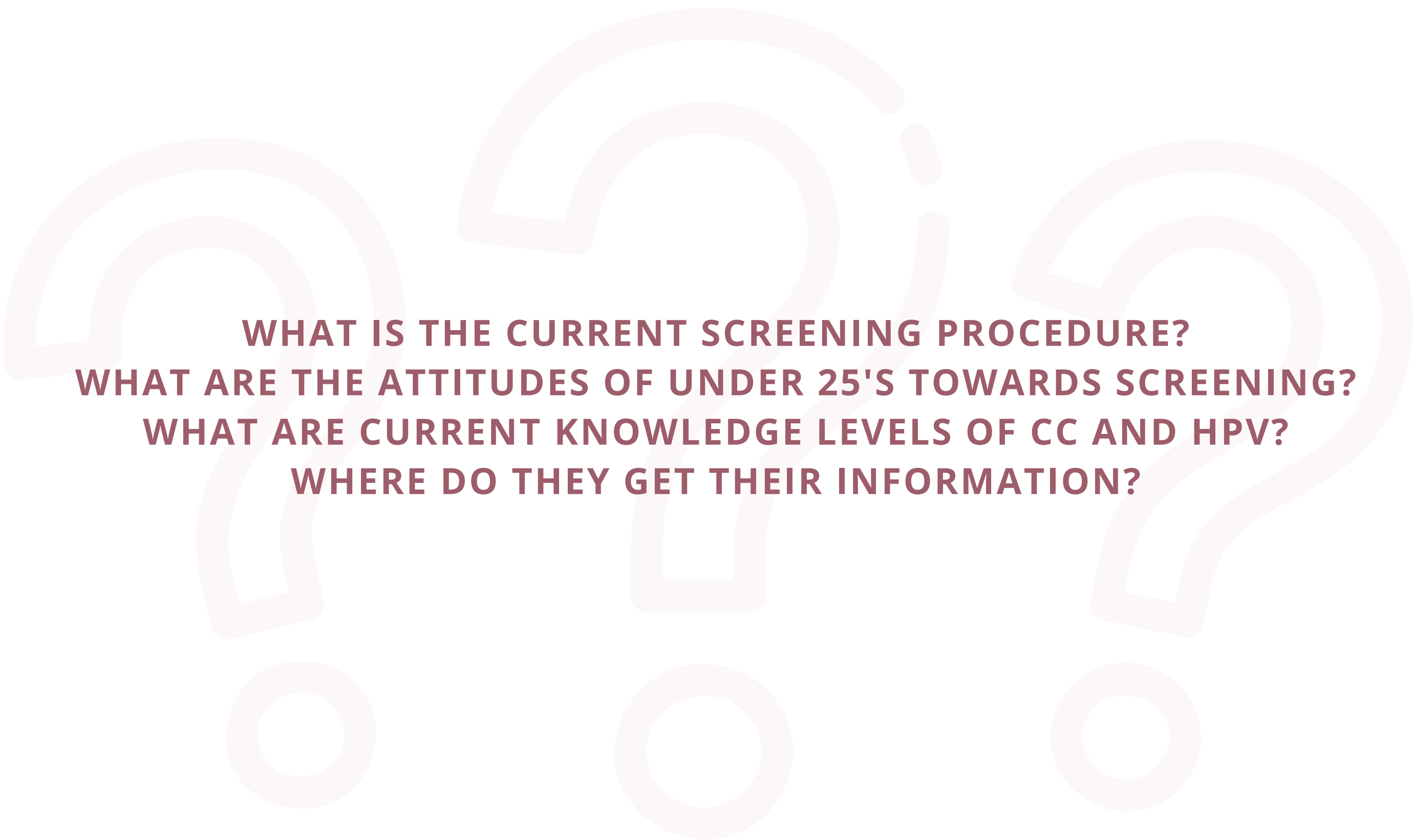
**E**

## Environmental

Extreme weather events such as storms and flooding can destroy or damage health-care infrastructure, reducing health-care quality and availability. Leading to the disruption of the complex and integrated health-care delivery systems required for cancer diagnosis, treatment, and care (Hiatt and Beyeler, 2020).

# RESEARCH QUESTIONS

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**WHAT IS THE CURRENT SCREENING PROCEDURE?  
WHAT ARE THE ATTITUDES OF UNDER 25'S TOWARDS SCREENING?  
WHAT ARE CURRENT KNOWLEDGE LEVELS OF CC AND HPV?  
WHERE DO THEY GET THEIR INFORMATION?**



# REVIEWING THE LITERATURE

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TOPICS RESEARCHED

INTRODUCTION

EDUCATION FUELING ATTITUDES

YOU ME & THE HPV VACCINE

SELF-TESTING: HEALTHCARE IN THE HANDS OF THE USER

DESIGN INTERVENTION IN HEALTHCARE

# TOPICS RESEARCHED

This is a sample of the main topics which were researched.

Information was acquired from a number of online resources including: PubMed, Google Scholar

**CERVICAL CANCER**

**HPV**

**SCREENING**

**SELF - SCREENING**

**HPV & VACCINE  
KNOWLEDGE**

**SCREENING  
KNOWLEDGE**

**DESIGN  
INTERVENTION**

**HPV & VACCINE  
ATTITUDES**

**SCREENING  
ATTITUDES**

# INTRODUCTION

This section of the process book, will explore existing literature relating to attitudes and knowledge levels of CC and HPV. This literature review, exists to examine the current climate for CC and HPV and also to identify gaps which the designer can then aim to bridge through her own primary research.

The literature review was conducted by selecting studies from databases including: CINAHL, Google scholar, PubMed and MEDLINE. A number of the search terms included HPV, women under 25, education and HPV and cervical cancer, cervical cancer screening, and HPV vaccine. These studies were systematically reviewed by examining the study population, stated methods, and main findings related to cervical cancer and HPV knowledge.

This review will begin by exploring research surrounding current practices. From there the author explores lack of education as it promotes negative attitudes towards cervical screening in both women and healthcare professionals. Then the issue of vaccination, education and attitudes is addressed. A quick look at the success of self testing for cervical screening, followed by design interventions in healthcare to gain an understanding of design for health.

# CURRENT PRACTICES

Currently in Ireland, CC screening is transitioning to HPV based screening from cytology screening, this transition began in March of 2020 (Kelly et al. 2020). The national screening programme in Ireland is, Cervical Check (Flannelly et al. 2018). The move to HPV based screening is cost effective compared to cytology based screening and will involve 5 year intervals between screenings (Murphy et al. 2017). It is a public health programme which involves women from the age of 24 registering their details online. Once registered they will be invited to a screening, when their screening is due. This invitation will be repeated every five years. Women can check when their next test is online and they can also withdraw from the register if they wish. The screening can be done by a GP or a registered cervical check clinic (HSE 2019).

In Ireland, women under 25 do not qualify for free cervical screening. In recent years there have been a number of issues with the Irish national screening programme. Including, misdiagnosis and loss of life due to these misdiagnoses (Dyer 2018). There is an abundance of research which suggests screening under 25's does not reduce the rates of cervical cancer, and there is a high chance of detecting abnormalities within the cervix of this age group (McAllum et al. 2011; Landy et al. 2014). Research also acknowledges no significant difference in the Health Related Quality of Life (HRQoL) of women under 25 with CIN2 (Taghavi et al. 2017). A majority of studies do not carry out a long term follow up. However, one study found long lasting negative effects on mental health following referral for a colposcopy. It was not the treatment which affected the patients however, it was the abnormal result. This study does not focus solely on under 25s (Hellsten et al. 2009). The studies which assess under 25s usually do not take into account anxiety, or other feelings of the young women (Landy et al. 2014).

# CC & HPV EDUCATION FUELING ATTITUDES

## **Women: Lack of knowledge and negative emotions.**

Many studies report a lack of knowledge with regard to CC and HPV, with a particular focus on college students, these students are often between 18-22 (Mofolo et al. 2018; Alafifi et al. 2019; Altamimi 2020). It can be assumed that for the low knowledge levels of the educated students, non-educated women may have even lower levels of knowledge. It is appreciated that this lack of knowledge can be attributed to fear, anxiety and stigma associated with CC (Patel et al. 2018). Research supports that increased knowledge will reduce negative emotions associated with the illness (Brown et al. 2007; Staples et al. 2018). At a school level, educational intervention has yielded impressive results in terms of increasing knowledge of CC and HPV (Staples et al. 2018). A similar study in Sweden reported heightened knowledge post intervention, however also noted that attitudes are less likely to be adjusted by educational programmes alone (Gottvall et al. 2010).

In support of this another study, reported that negative emotions still remained after CC education (Kim et al. 2019b). It is worthwhile noting these negative emotions and feelings can potentially hinder both screening uptake and empowerment of women with the disease (Barreto et al. 2016). There is a lack of evidence supporting ways by which knowledge, and attitudes can be changed with relation to HPV and CC. However, attitude manipulation through education has been achieved in other areas including; climate change (da Rocha et al. 2020; Nousheen et al. 2020; Sevim 2020), anemia (Singh et al. 2019) and even other female stigmatised topics like menopause (Koyuncu et al. 2018; Gebretatyos et al. 2020). The positive affect of targeted education on attitudes of health related topics (Árnason et al. 2018), may imply that targeted education can improve attitudes towards CC and HPV.

The Similar behaviour has been noted in health professionals, with knowledge levels of the health professionals determining screening and vaccination uptake among their clientele. The impact of knowledge on female emotions towards screening is accurately portrayed in studies of women in Australia, as they changed from cytology based screening, to HPV based screening which would involve a longer wait time between screening. This time extension is seen to be problematic for women, along with the change in age range, perceived to be leaving women under 25 at risk. This was concluded in the study to be as a result of minimal knowledge about HPV and its slow progression (Dodd et al. 2019b). Where patients have been seen to be dependent on their health professionals for information with regard to the changes, they are less concerned and less likely to engage in over-treatment from testing outside the age bracket (Dodd et al. 2019a). This over treatment comes from disregarding the guidelines, testing too frequently or testing too young (Tatar 2020). The dependency on providers may not prove as efficient as women think. Due to mixed levels of knowledge in terms of CC and HPV.

### **Health Professionals: Knowledge and Attitudes.**

In Ireland, research suggests that male General Practitioners (GPs) have less knowledge than their female counterparts on the topic of HPV and CC (McSherry et al. 2012). This is not unusual however, it has been since reflected in Ethiopia (Getahun et al. 2019) and Saudi Arabia (Almazrou et al. 2020). In Saudi Arabia, almost half of the physicians involved, were unaware that CC could be fatal. In some cases, knowledge of CC was high, but attitudes and practice were poor (Esike et al. 2018). It may not be just males who lack the knowledge, female student nurses in a study in the US were noted to have low knowledge and awareness (Dönmez et al. 2019). Although previously, it has been noted that medical students possessed good knowledge of CC (Maharajan et al. 2015). In Norway a study records Public Health Nurses (PHNs) and GPs as having higher self-reported knowledge, than actual knowledge (Nilsen et al. 2017). Another study in Saudi surfaces the fact that female physicians also lack the relevant information with only 25% of them being screened themselves. This survey is difficult to generalise as it only took place in one health centre and involved women of various background specialities (Heena et al. 2019).

The low number of physicians participating in screenings, can be seen again in a study of educators and health professionals, as they had lower rates than other professionals (Xenaki et al. 2020). Similarly in India, female student Nurses, Physiotherapists and Pharmacists also reported low screening or vaccination uptake (Priya and Kumar 2020). Many nurses, who don't receive the vaccination, regard lack of knowledge as the leading factor (Koç and Çinarli 2015).

This same study remarked that although high levels of knowledge were seen regardless of profession, the health practitioners did not hold excellent levels of knowledge, as might be expected.

Could the lack of knowledge of male practitioners be a result of their attitudes towards CC? The opinion of male health professionals in Ireland, suggest that CC is a women's issue, and therefore the role of a female nurse or practitioner. This study took place in 2012, and may it important to keep in mind that attitudes may have changed (McSherry et al. 2012).

It would be interesting to know whether this is still the case. Healthcare professionals have been seen to hold a bias toward CC (Liang et al. 2019), this may be due to the availability of screening and vaccination as prevention methods. The existence of the preventative measures create grounds for a blaming culture, where clinicians may presume the patient contributes to the illness. It can also be linked to the sexually transmitted nature of the disease (Miller 2017) This is mirrored by nurses, however often nurses attempt to suppress this bias (Kim et al. 2019a). This bias adds to the stigma around cervical cancer, and can negatively affect screening rates (Milner and McNally 2020).

# VACCINATION; EDUCATION & ATTITUDES

In Ireland, the majority of women between 15 and 24 have received a HPV vaccination.

The HPV vaccine prevents development of cervical lesions (Asiaf et al. 2014) and has been seen to reduce cases of genital warts and HPV infections (Drolet et al. 2019). The vaccination successfully protects against two of the strains of HPV, HPV16 and HPV18, which can be linked with 70% of cervical cancer case (Tyler et al. 2014) Currently, it is found that protection against the virus can last up to at least 10 years (Kjaer et al. 2018) The vaccine is offered to young girls and boys in school. School is a suitable medium for delivering the immunization as a large population of children can be vaccinated over a short period of time (Paul and Fabio 2014). It also provides the vaccination to disadvantaged groups, many of whom are less likely to participate in regular screening (Marshall et al. 2013). School vaccination is cause for concern in terms of women who do not attend school, they can of course be vaccinated in health centre facilities (LaMontagne et al. 2011). However, this vaccination uptake is inconsistent (Gallagher et al. 2017).

Despite the success schools have as a medium for providing the vaccination to the general population, there is little to no education in school about HPV or the HPV vaccine before immunization (Flood et al. 2020). This lack of education can be attributed to high fear and anxiety related to the vaccination (Burns and Davies 2015). With many young women frustrated at their lack of understanding of the vaccine and indeed the virus itself (Robbins et al. 2010a). Knowledge and understanding about HPV promotes a positive attitude towards vaccination. Educational intervention has documented success for improving knowledge of HPV and CC (Staples et al. 2018). With the success of educational intervention, it is surprising that there is no standardised education on the topic (Flood et al. 2020).



Awareness of the HPV vaccination has improved in recent years despite, lack of standardised education. Young adolescents are still becoming more knowledgeable on the topic, with varying sources of information, some females admitting their knowledge comes from health providers while males stating their knowledge is as a result of the internet (Barnard et al. 2017). This study took place in the US, it would be worthwhile understanding if it is replicated in Ireland. Despite females saying their knowledge came mostly from their health care professionals, another study captured that it is not doctors who influence them in receiving the vaccine. It is often parental influence, or cost. They also express concern for the vaccination of their partners (LaJoie et al. 2018). This study took place in a college in the US, therefore there is data lacking as to whether or not this would be replicated in a less educated or even culturally different population. The influence of cost is less relevant in Ireland as the vaccination is free for children in school or those being homeschooled. The vaccination is only charged for when the child does not get it as part of the schools vaccination programme (HSE 2020). In terms of parental influence, it has been noted that where parents are highly educated, children are most likely to be vaccinated. It was also found that parents in the US share more concern for associated side effects than parents in the UK and Australia (Nickel et al. 2017).

# SELF TESTING; HEALTHCARE IN THE HANDS OF THE USER

There are many diseases which involve self-testing as a method of screening, including skin cancer (Wernli et al. 2016; Koh et al. 2019; Robinson et al. 2020), diabetes (Devarajoo, 2017), and HIV (Krause et al. 2013). The opportunity for self-testing vitally increases population coverage.

## *Self-Testing for Cervical Cancer*

Knowledge of the connection between HPV infection and CC allows for self-screening for HPV, to understand the potential risk for CC. A study shows that deregulated micro-Ribonucleic acid (miRNA) expression associated with CIN3 and cervical cancer development can be detected by sRNA-Seq in HPV-positive self-samples. The analysis of miRNA expression presents promising triage strategy for detecting CIN3 and cervical cancer, which can be used in self-samples (Snoek et al. 2019).

Research supports self-sampling, as an efficient alternative to clinician sampling for detecting high risk HPV. It has been reported that women view obtaining their own samples, positively (Harper et al. 2002). However, more recent research shares that women have low confidence in their ability to self-sample, and they have low trust in the ability for the test to identify women who are at risk for CC (Malone et al. 2020).

A majority of research addresses under screened and underrepresented populations, finding that vaginal samples effectively improve screening rates in these populations (Boggan et al. 2015). This research is supported by observing more completed self-samples than screening rates among medically underserved, Hispanic, Haitian and non-Hispanic Black women (Kobetz et al. 2018).

There is a clear opportunity for expanding self-screening, for women who don't participate in traditional cytological screening (Nelson et al. 2017). It has also been noted that transmasculine people have lower rates than cisgendered women. This is thought to be related to the power dynamic between doctor and patient, along with low self-confidence of the transmasculine patient (Bernstein 2019). Self-screening has been seen to improve cervical screening rates in this underserved population. This study, took place in Boston, and had a diverse sample which can be presumed a generalized representation (Reisner et al. 2017). Although HPV self-screening, is generally examined with relation to underserved populations, it can be hypothesised that it would have the same efficiency in the general population. It's success in under-represented populations allows it in theory, to work efficiently for under 25's.

# DESIGN INTERVENTION IN HEALTHCARE

*Design for the purpose of this study, refers to an intervention which came about from the use of design thinking, and followed a design process of research-ideation-testing.*

Universally, design is having a positive impact in health care (von Frankenberg Berger et al. 2020). Including technological advances (Alloghani et al. 2018; Orji and Moffatt 2018), the transition of patients to users, and user centered design (Luna et al. 2017; Runaas et al. 2017). Despite the many design interventions within healthcare, it has been argued that healthcare continues to redesign the queuing system in Blockbusters (video rental store), rather than creating Netflix (Daigre 2019). Insinuating that there have been many attempts at incremental innovation as opposed to radical innovations. A radical innovation, similar to Netflix and movies, would require reimagining what it currently means to be treated in healthcare. It is difficult to quantify the impact design has on healthcare due to the lack of description in recording methods or results for design projects (Bazzano et al. 2017). It important to note design is often implemented, rather than reported on and published. Therefore, it may be most suitable to examine case studies in which design interventions have been used in healthcare. Particularly as methods of design thinking, often prove valuable for redesigning healthcare systems (Chanpuypetch and Kritchanchai 2020). The author will explore a number of examples where design intervenes with healthcare, with regard to: *Environmental Design and reducing stigma through design.*

NETFLIX

## ***Environmental Design***

Environmental Design (ED) speaks to how our surroundings are designed, our buildings, workplaces, parks and even healthcare facilities. Good design pleases us, and poor design displeases us (Friedmann et al. 1978). ED has been commended for its ability to improve both provider and patient experiences within healthcare settings, through acoustics (Astron Health 2020) as an example. For example, in Mercy Health – West Hospital, USA, modular furniture and adjustable furnishings along with a mix of centralized and decentralized work spaces, was able to increase collaboration and enhance patient experience (Knoll 2015). However, generally ED research is used to recommend adjustments for facilities, to improve patient or provider experience. In recent years it has been used to suggest improvements for patients visual and auditory privacy (Bjorngaard 2010). Along with implying that the ED of a healthcare facility can affect occurrence of violence against staff (MohammadiGorji et al. 2020). ED positively impacts patient health outcomes (Laursen et al. 2014), and more recently has even been seen to decrease suffering and increase QoL for patients who are in end of life care (Zadeh et al. 2018). With this in mind, there are studies which make suggestions based on ED and are then followed up.

For instance, a neurological rehabilitation unit was examined with the intention to identify reasons behind healthcare professionals' errors, naming lighting, ergonomics and layout design in particular (Chaudhury et al. 2009). A follow up study reassessed the same neurological rehabilitation unit and found many of the suggestions had been improved upon (McCunn and Gifford 2013). So, research and design work well together to create and improve healthcare facilities which stimulate wellbeing (Ulrich 2001).

## ***Design Intervention against Stigma***

In stigmatised conditions, design has often intervened to make part of the process easier for patient or provider. It can often act to destigmatize the condition, topic or illness. For example, nonprofit organisations like the Case for Her (The Case For Her 2021), work to reduce stigma around female healthcare. Over the past two years, they have sponsored design briefs for the popular New Blood Awards for student designers, to shed light on topics like menstruation, and female pleasure allowing young designers to tackle these issues through design (Ljungberg 2020). These awards saw the creation of ClitarHero, a touch screen game, for matching specific pleasure techniques to music (Higgins 2020) through UX design. Along with a marketing campaign, 'Am (i) Normal?' with visual design to normalise vulvas (Donagh 2020).

It's not just women's health which is stigmatised. Males mental health is heavily stigmatiaed (Chatmon 2020), so is male physical health, and the stigma can be seen as a barrier to males accessing health and wellbeing services (McCreary et al. 2020). Design has intervened in the form of community-based promotion, where programmes are designed to promote trust and normalise the involvement of men in the services (Robertson et al. 2016; Oliffe et al. 2020).

Of course the stigmatisation of diseases is non gender specific, it exists when something is deemed undesirable, and subsequently individuals are devalued in accordance (Goffman 2009). Design has an important role in assisting with the removal of stigma and creation of a new norm. Displayed in the stigmatised Human Immunodeficient Virus (HIV) (Turan et al. 2017), design has intervened to create a self-screening kit for HIV, where participants can collect their own sample from the comfort of their home. It has proved highly effective for collecting samples, and improving screening uptake (Ngure et al. 2017). As mention, it even proves successful for self-sampling for CC screening (Nelson et al. 2017; Kobetz et al. 2018). In bowel cancer, a prototype was developed for collection of faeces at home, with a view to normalize bowel cancer screening. The approach adopted a particular view to change the language; switching the narrative from bowel cancer to bowel health. This served to improve patient experience and limit stigma associated with this specific type of cancer (Helix Center 2018). This change of language is crucial to the way which a disease is viewed. Changing language surrounding a disease can be of huge importance and lead to successes in treatment of the disease.

For example, changing language from praising weight loss for patients who are obese, to praising the behaviors which lead to the weight loss can lead to more consistent weight loss, and positive behaviour changes (Daundasekara et al. 2019). This idea is represented differently more recently as the global COVID-19 being described as 'a perfect storm'. This negatively impacts the idea of the virus as out of the control of humans, like a storm. However, there are many ways in which people can help slow the transmission of the virus. To say it is unpredictable like a type of weather damages the reputation of the Public Health prevention efforts and allows it's control to be mere chance (Brandt and Botelho 2020).

The success of design intervention in healthcare, and the positive outcomes of designing for stigmatised conditions are promising. It could be hypothesised that a design intervention would be applicable in CC screening or prevention as it is another stigmatised condition (Ongtengco et al. 2020). Perhaps mindfulness of language and narrative behind interventions would be of particular interest, in reducing stigma surrounding the disease (Wearn and Shepherd 2020).

# CONCLUSION

There is an abundance of literature which implies a lack of knowledge surrounding HPV and CC. This literature acknowledges that the lack of knowledge is often attributed to fear, anxiety and other negative emotions. It is also widely accepted that knowledge of HPV and CC can be greatly increased however it is much more difficult to address attitudes towards the disease.

Design as a method of intervention is hugely successful in healthcare, however usually in the form of incremental design. The success of design, and the opportunity to improve education, attitudes and uptake of screening and vaccination for CC and HPV, highlight a fantastic gap. This gap is what I intend to examine with further primary research, and as a result close the gap with the means of design.

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***Improving Knowledge of HPV and CC.***

***Improving Attitudes towards HPV and CC.***

***Increasing uptake of screening for CC***

***Increasing uptake of vaccination for HPV***

# THE RESEARCH GAPS

***Improving Knowledge of HPV and CC.***

***Improving Attitudes towards HPV and CC.***

***Increasing uptake of screening for CC***

***Increasing uptake of vaccination for HPV***

These research gaps, can be seen throughout services and within the attitudes of people. Their existence inspires the designers research to explore these gaps, and create a design intervention to bridge the gaps.

Building upon the abundance of previous literature and research, the designers research will take the form of interviews and surveys. The aim will be to identify participants attitudes towards these areas, and understanding the education levels of women, as well as how they understand the HPV vaccine and HPV itself.

In the following sections the designer will identify the stakeholders, and conduct their own research to explore the aforementioned gaps to aid the creation of a design intervention.



# STAKEHOLDERS

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INITIAL STAKEHOLDER IDENTIFICATION  
CYCLE OF CARE ANALYSIS  
FLOW OF MONEY ANALYSIS

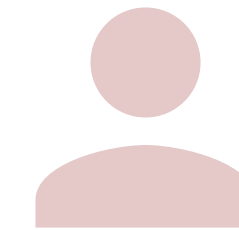
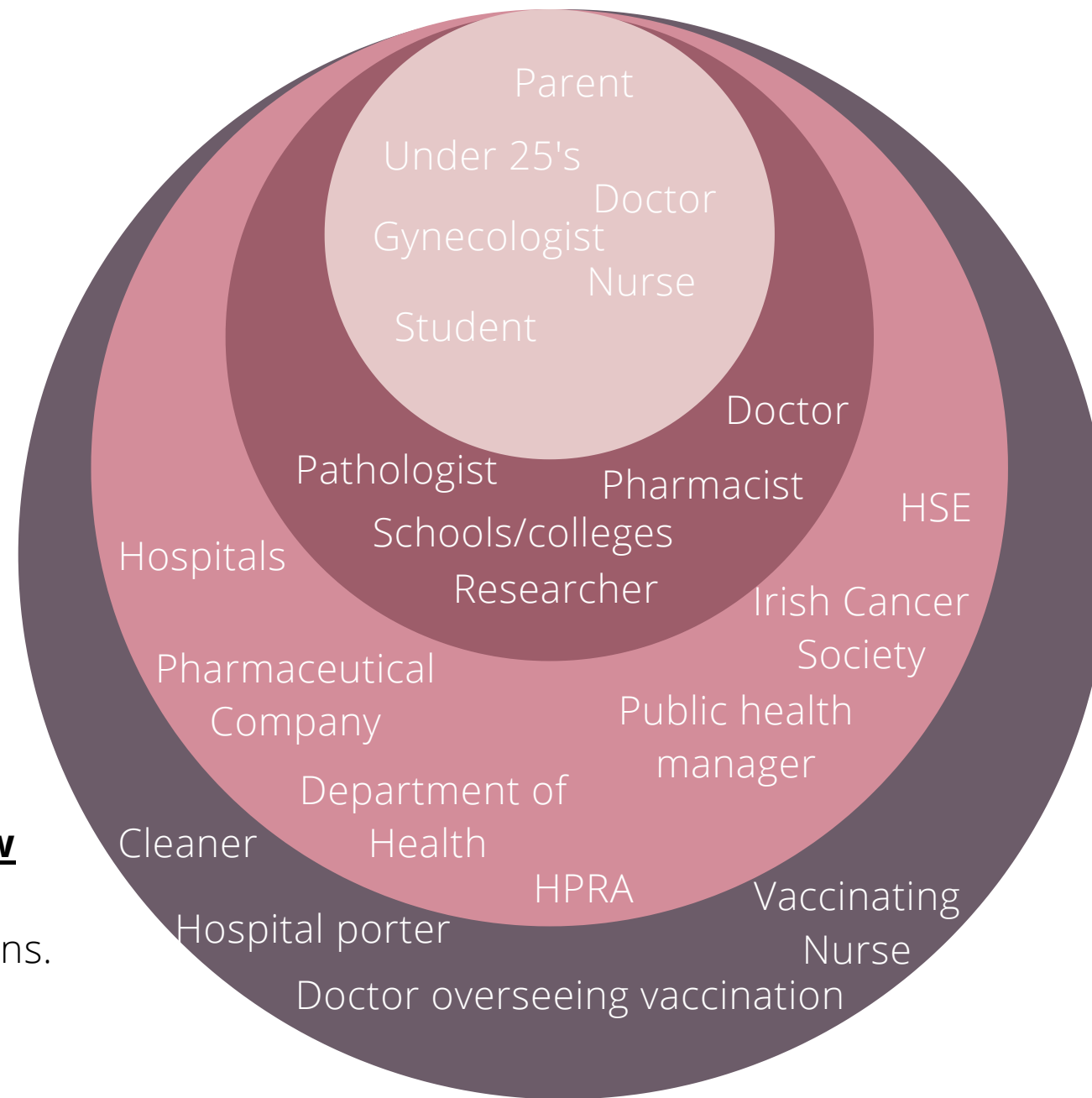
# STAKEHOLDERS

There are two ways by which the author will identify stakeholders in the field of CC prevention and treatment. With regard to Cycle of Care - Patient prevention, diagnosis and treatment as well as Flow of money - following the transactions. This identification can be used to triangulate results with the primary and secondary data collection at a later stage (Yock 2015). Firstly, the author quickly from intuition, mapped the stakeholders by interest and influence.



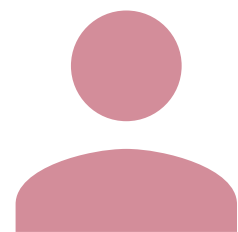
**High Interest/  
Low Influence**

Keep them informed.



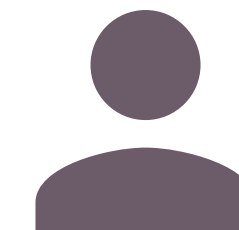
**High Interest / High Influence**

These are the most important. They are to be fully engaged and kept satisfied.



**High Influence / Low Interest.**

They control regulations. They need to be kept satisfied & informed.



**Low Interest/Low Influence**

Monitor them but no need for regular contact.

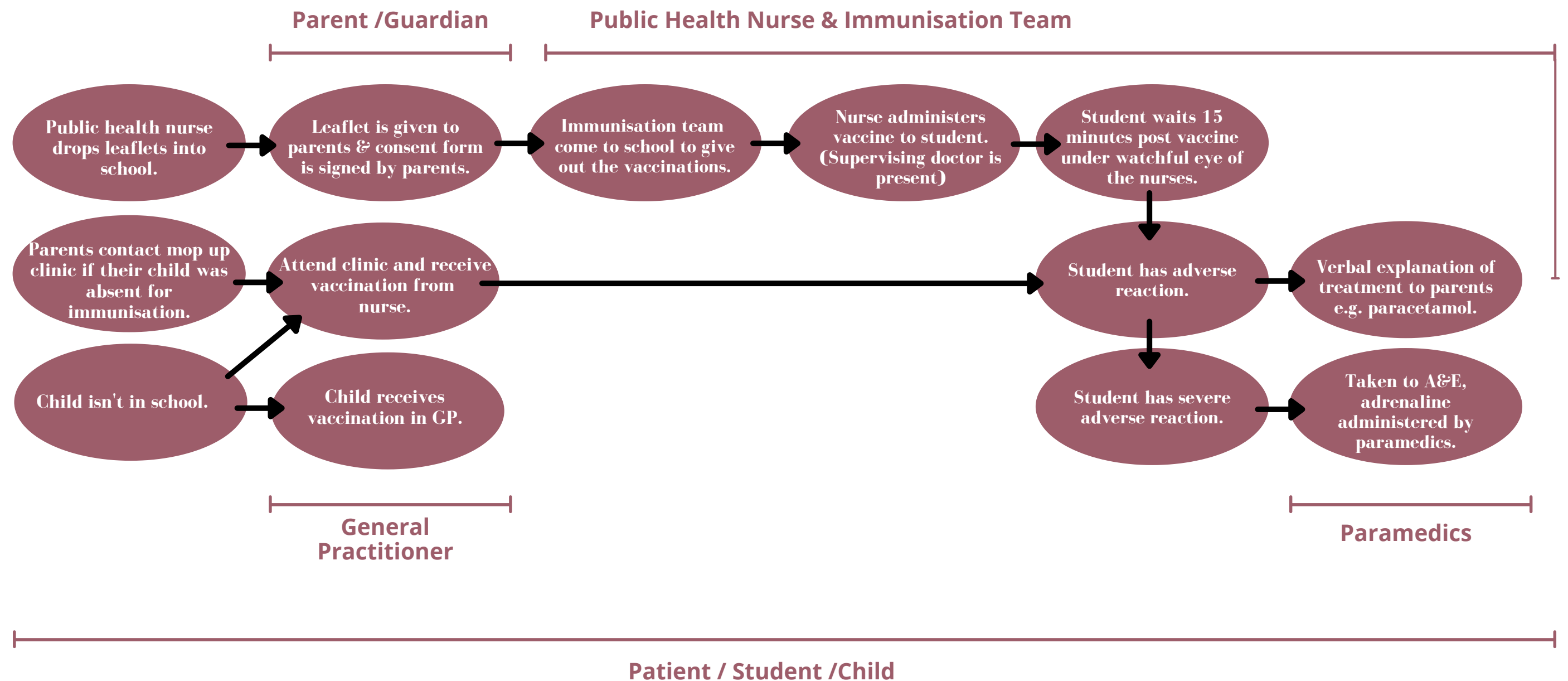
# CYCLE OF CARE

Mapping the way by which patients interact with the systems. There are two systems which are in play here:

1. The immunisation Programme for the HPV vaccination.
2. The Cervical Check Programme for the screening process of cervical cancer.

The cycle of care continues after the cervical screening, however this falls outside the strategic focus for this project.

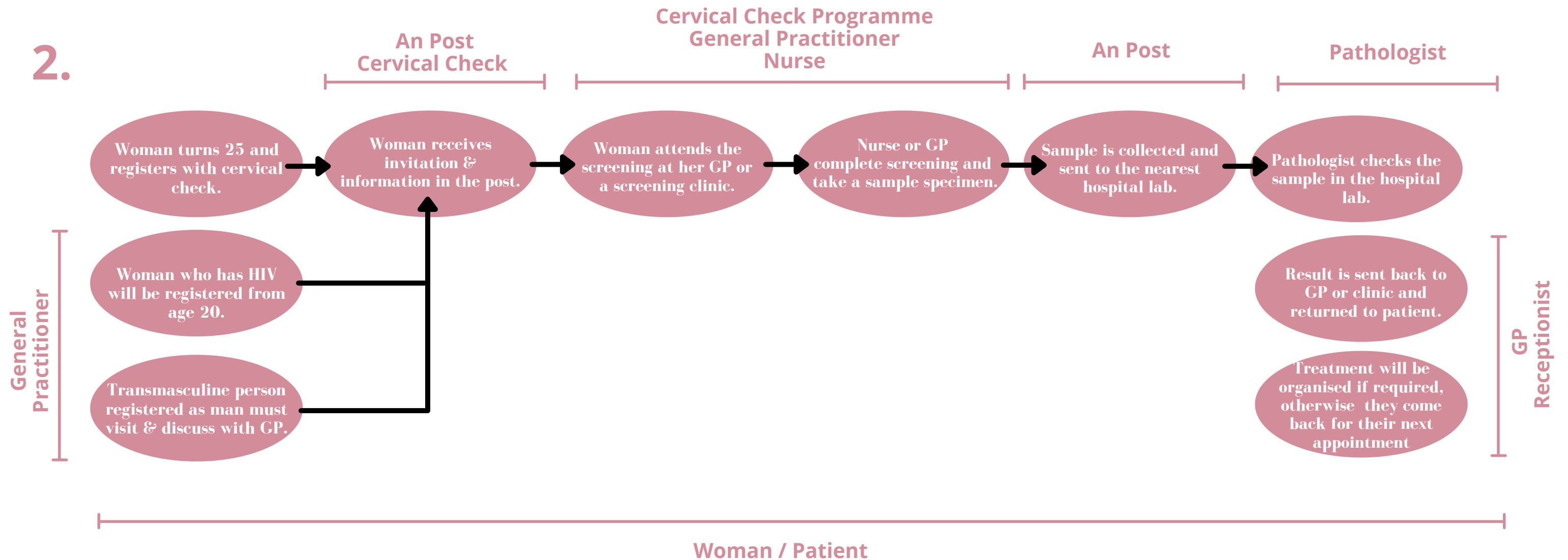
1.



# CYCLE OF CARE

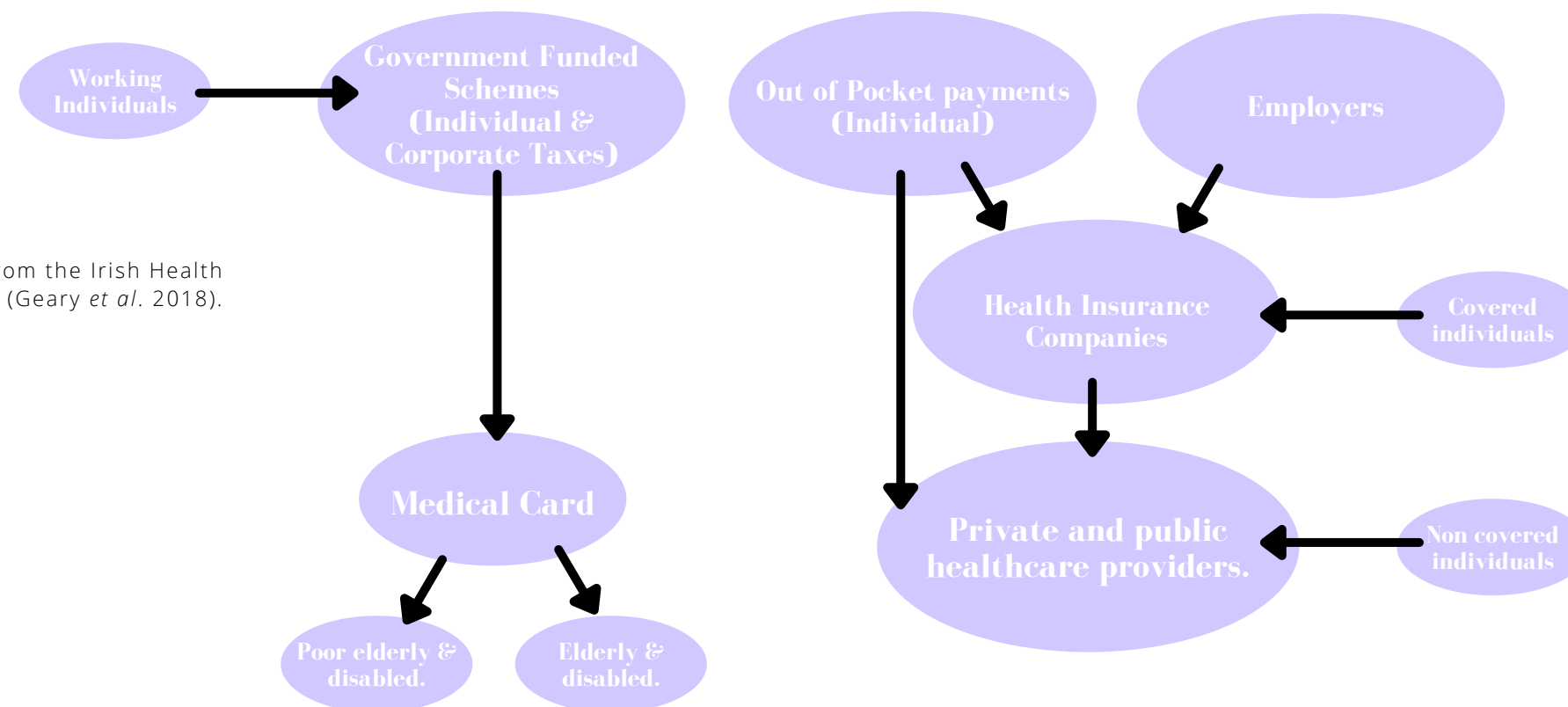
2. The Cervical Check Programme for the screening process of cervical cancer.

The cycle of care continues after the cervical screening, however this falls outside the strategic focus for this project.



# FLOW OF MONEY

Flow of money analysis considers the stakeholders who are funding the cycle of care. Including who pays for the treatments and services involved (Yock *et al.* 2015). In Ireland the public healthcare system is managed by a third-party payer system, in that the patients do not pay for their treatments. Although private treatments, and trips to the GP without a valid medical card are paid for by the patient. This analysis addresses the flow of money in the Irish public healthcare system.



This diagram has been adapted from the Irish Health Insurance Authority report 2018 (Geary *et al.* 2018).

## **Funding**

Funding for the Irish healthcare system, comes mainly from government sources with additional contributions from out of pocket payments and private health insurance.

72% is government funded.

13% Household out-of-pocket.

12% Voluntary Health Insurance

3% Other Voluntary care payments including non-profit institutes and employer-provided healthcare.

Essentially, working individuals pay taxes. These taxes fund schemes such as medical cards, these medical cards often entitle the holder to free healthcare, the entitlement to the card is based off: income, disability and age. If you are not entitled to a card, you pay healthcare insurance or pay your fees directly to the healthcare provider. Some employers pay for their employees healthcare. The cervical check and HPV vaccination programme are both government funded.

# ETHICS

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RECRUITMENT  
DATA PROTECTION

# RECRUITMENT

Details of the ethics approval can be found in both Appendix 1 and the Design History File/3.Validation.

## ***Participant Access***

Due to COVID-19 restrictions, all sampling methods will take place remotely. The sampling method will involve surveys via Microsoft Forms and interviews via Microsoft Teams. This sample will be that of a purposive sample, research suggests that purposive style is efficient for sampling specific groups online (Gentles et al. 2015). Recruitment will be via posts on the researcher's social media accounts, via Twitter, Facebook, and Instagram. Social media is seen to be efficient for recruitment of hard to reach populations (Topolovec-Vranic and Natarajan 2016). Issues may arise with regard to participants answering questions quickly and randomly as they are self-administered, but data collected which is not beneficial[M1] will be excluded from the analysis (Necka et al. 2016).

Social media provides an effective method of recruitment based on a wide variety of variables and will be time and cost efficient (Boas et al. 2020). For the interviews, women will be recruited online from social groups which cater to gynaecology and women's health. There will be 25[M2] women recruited. Previous design research through my MSc module ' Design Research' has provided me with continued access to Gynaecologists at Cork Obstetrics & Gynaecology associates. Therefore, I will recruit participants from this clinic, and no HSE staff will be used. Five of these healthcare professionals will be recruited for interviews . They will be recruited via a phone call, where they will be provided the relevant information and asked if they would like to partake in the research. They have expressed their interest in helping with future projects in the past.

**Inclusion criteria:** female, between 18-24, able to consent

**OR**

Able to consent, current or past experience working in women's health or cervical cancer screening (this includes male gynaecologists).

**Exclusion:** Male, out of age range or unable to consent

**OR**

no experience in women's health/cervical cancer screening.

# DATA PROTECTION

Data collected will be treated with confidentiality and participants treated with anonymity. The research will be GDPR compliant. At the beginning of the research, participants can freely enter the research, after being informed of what is involved with taking part, e.g., information collected regarding opinions and attitudes towards Cervical Cancer.

Once fully briefed they can ask further questions or give their consent. Information about the storage and anonymity of the data will be given. The participant will also be informed that they can withdraw from the study, for any reason, at any time. Participants' data will be processed with the sole intention of achieving the research objective.

All data will be anonymized as it is collected. In a written academic paper at the end of the year, if data is to be used, identities of participants' will be anonymized by pseudonyms. The storage of the data will be stored on a password protected university computer, in a locked room.

The full ethics approval request form is available in Appendix 1 as well as the designhistoryfile/3.Validation/EthicsReport.



# RESEARCH METHODS

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SECONDARY RESEARCH  
PRIMARY RESEARCH  
METHODOLOGY

# SECONDARY METHODS



## Reddit Forums

Exploring subreddits on reddit, to examine women's experiences of screening, their opinions and knowledge surrounding HPV and CC & opinions on the HPV vaccination.

Reddit is frequently used(Record et al.2018; Du et al. 2020) as an inexpensive and reliable method of data collection(Jamnik and Lane 2017). Also notably recorded as useful for acquiring health opinions, which is lacking in scientific research(Foufi et al. 2019). It is also beneficial as it does not require ethics approval, as the information is already existing on the internet



## Scientific Papers

An examination of existing literature to gain an understanding of CC and HPV. To understand what the came before, and what methods and findings previous researchers and designers used and uncovered. This helps to create a picture of what exists and what is missing and helps direct the rest of this project.

Papers which were used came from Journals including: PubMed, the BMJ, the Lancet, the American Journal of Lifestyle Medicine, International Journal of Sustainability in Higher Education and the Journal of American College Health.

# PRIMARY METHODS



## Survey

The intention of the survey was to find understand attitudes towards and knowledge levels of Irish women between 18 - 24, with regard to Cervical Cancer, and the role HPV plays in cervical cancer.

Questions to understand their current knowledge of both Cervical Cancer and HPV, along with understanding their attitudes towards the cancer, it's screening and it's vaccination process. In an attempt to understand their feelings, in order to make an informed design intervention.



## Interviews

The purpose of the interviews was to understand the health care professionals opinion on the screening process, how they approach it and if they feel women have the correct information. To understand what the screening process is and to identify if it could be replicated.

It is important to also acquire opinions and attitudes of women who have been screened, to understand how they relate to the process and if there is anything which needs to be improved upon.

# METHODOLOGY

The research in this study was designed to identify gaps in the knowledge of Irish women under 25 surrounding CC and HPV. The aim was to uncover potential needs to create a design intervention that would increase knowledge levels and improve attitudes among this cohort of Irish women. The author used an inductive process, whereby the data were collected and analysed to identify patterns which may be indicative of relationships between variables. This allowed the designer to establish meanings in order to categorise the data. All data collection was completed remotely due to COVID-19 restrictions. A mixed methods approach was used by combining quantitative and qualitative methods, this allowed for a generalisation from the sample to a population, for a more rich, contextual understanding of the knowledge and attitudes towards HPV (Gray 2014). The research was gathered to understand people's experience of the social reality. A form of phenomenological research was applied, in preference of ethnographic research. This was to understand people's experiences of cervical screening and the HPV vaccine rather than examine the relationship between culture and behaviours around screening and vaccination (Tesch 1994).

Firstly, data was used from existing sources and compiled to identify current research. Secondly, primary research was carried out by the author, through conducting surveys and interviews.

Reddit forums were also examined to find relevant information about knowledge levels and attitudes towards CC and HPV (Record et al. 2018) as an inexpensive and reliable method of data collection (Jamnik and Lane 2017). Reddit has proven successful in the exploration of urinary incontinence (Du et al. 2020), which may be considered stigmatized. Reddit is also notably recorded as a useful tool for acquiring health opinions from members of the general public, which is arguably often lacking in scientific research (Foufi et al. 2019).

# TYPE OF RESEARCH

The author carried out both primary and secondary research. The primary research was carried out in the form of a mixed methods approach. This included a combination of both quantitative and qualitative research. This mixed methods approach has proven useful for capturing overlapping but also different elements of the topic (Gray, 2014).

## **Primary Research**

Primary research took the form of a questionnaire and semi-structured interviews. The use of questionnaires was chosen due to several advantages they provide including the fact they are low cost with regard to both time and money.

Questionnaires also provide data quickly and make sampling a large cohort of people easy. Additionally, data collected using closed questions can be analysed relatively quickly. The survey contained both open and closed questions. Closed questions provided data which was easy to analyse, however lacked rich insight. The open questions allowed the opportunity for elaboration and often, rich insight, but they were more difficult to analyse.

A mixture of both questions allowed for a deeper understanding of answers. The interviews were semi structured, this allowed the author to probe for attitudes and opinions based on original answers, which was not possible throughout the questionnaires. These interviews were completed by a separate sample of participants, who were gathered following their completion of the original questionnaire. They sought to explore the themes from the survey with an emphasis on the 'why', to indicate why the participant felt this type of way. The interviews took place over Microsoft teams due to COVID-19 government restrictions. The visual element of the interviews, and the fact they were usually taking place in the participants house allowed for a development of trust and efficient inter-personal communication (Gray 2014).

## **Secondary Research**

Secondary research was carried by examining existing research and producing a literature review. This was done with the intent of establishing an up-to-date understanding of the current knowledge of and attitudes towards CC and HPV. It allowed the author to identify issues and themes which are currently studied and to highlight gaps in current knowledge. It was also beneficial to explore how design intervention has been successfully used previously in healthcare settings, to guide the author in her own exploration of design as an intervention in CC and HPV.

# PARTICIPANTS

## ***Recruitment***

The sample can be described as a convenience sample as well as a snowball sample. This is due to the authors approach to recruiting easily accessible subjects via social media. Social media was used as an efficient way to recruit hard to reach populations (Topolovec-Vranic and Natarajan 2016). Once the initial subjects were recruited, they in turn shared the questionnaire and were given the opportunity to volunteer for interview participation. It also offers an effective method of recruitment based on a wide variety of variables and is time and cost efficient (Boas et al. 2020).

## ***Participants***

Participants for the questionnaires were individuals aged between 18-24 with a cervix and the ability to provide informed consent. They were living in Ireland and had not yet undergone cervical screening.

Participants for the semi-structured interviews were also women between 18 – 24 as well as health professionals with a speciality in gynaecology.

# DATA COLLECTION - WOMEN

## ***Online Survey***

An online survey was administered via social media. Including posts on Twitter and Instagram. Social media is seen to be efficient for recruitment of hard-to-reach populations (Topolovec-Vranic and Natarajan 2016). Social media also provides a time and cost-efficient method of recruitment (Boas et al. 2020) The purpose of the survey was to obtain general knowledge and opinions of a population of Irish women in relation to CC and HPV. The questions were a mix of qualitative and quantitative, including questions regarding trust in the Irish Cervical Cancer Screening programme using a Likert scale. There were open ended questions asking, 'what is cervical cancer'. These questions were used to identify where exactly the information is lacking, if there is a repeated misinformed answer, and where the source of this misinformation is. These participants were eligible for participation if they were 18-25 years old and had a cervix. There were responses from 103 participants, however 8 were unable to complete the survey due to their age. 93 participants completed the survey. There was no interaction with the researcher during the survey and there was no incentive for participation. Exclusion of an incentive allows the outcomes of the survey to be objective.

## ***Interviews***

The author used a mixture of purposive, convenience and snowball sampling to select individuals who were between the ages of 18 and 25 with a cervix. The participants were purposefully selected as they fit the age criteria. The sampling progressed into a snowball sample as the participants shared the opportunity to partake in an interview with their friends. Participants were recruited via social media platforms including, Twitter and Instagram. This aspect of using social media made the sample some what of a convenience sample.

The semi-structured interview took place via Microsoft teams and lasted between 15-35 minutes. These interviews took place in English and were audio recorded.

# DATA COLLECTION - HEALTH CARE PROVIDER

## ***Interviews***

The author used purposive sampling to select individuals who were between the ages of 18 and 65, with experience in gynaecology. Practitioners were recruited via a phone call. These practitioners had been worked with in the past and had previously expressed interest in helping with future projects.

As written consent is required for participation and due to COVID-19 restrictions, informed consent had to be obtained online. The semi-structured interview took place via Microsoft teams and lasted between 30-45 minutes. These interviews took place in English and were audio recorded. These interviews were subsequently transcribed verbatim, and then the recordings were destroyed.



# DATA ANALYSIS

## ***Online Survey***

The survey was closed to new responses after 5 days of being open. Microsoft forms generates basic statistics, so this information was used. The raw data were then compiled into an excel file, and the designer read through the data. They were looked over twice before themes were identified, from repeated ideas and topics. In another file, each question and its answers were addressed, common answers were noted along with any anomalies. The author then drew observations from these themes. The observations were analysed to identify the problem or opportunity from the observation, along with the design need which this presented.

## ***Interviews***

The interviews were transcribed verbatim with the aid of Otter, a transcription tool. These transcripts were read over, and themes began to form. The designer created a code book to identify various themes within the transcriptions. There were two rounds of coding, before the final codes were identified. The author proceeded to draw observations from the themes and the interview quotes. These observations were analysed, and problems or opportunities were identified for each observation. Then the design need was established.

## ***Needs Filtering***

The needs identified from the interviews, and the surveys were joined with observations pulled from the secondary research. These needs were categorised by colour in an excel file. Once categorisation was complete, the needs were filtered. First the initial 325 needs were examined and repeated needs were removed. From there 200 needs were assessed in terms of the impact addressing the need would have on the individual, the provider and the treatment landscape. After rating the needs from 1 – 5, low scoring needs were eliminated. A further 88 needs were rated by the authors personal preference to addressing the need. 42 needs were then assessed by a public health care professional to identify the public health preference and these 12 needs underwent a market analysis. This left 4 needs which were then examined in terms of the impact addressing them would have on the triple bottom line (e.g People, Profit, Planet). These needs were used to inform a design guide, for the design of a solution.

# FINDINGS

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# CODING THE FINDINGS

With the data collected, the designer created a codebook, to identifying certain themes as they arose in the transcripts and surveys. A copy of the codebooks and their iterations can be seen in Appendix 2. The codebooks exist in their entirety in the Design history file/0.Feasability/Interviews. This coding process took place in two stages. The designer read through the results and jotted down themes. Then these themes were highlighted in various colours and read over. New themes were created, and given colour codes. These were then shared with an expert who suggested the addition of a number of other codes. This took place for both the interview transcripts and the surveys.

The coding of the interviews saw the creation of the following codes and their subsequent colours which can be seen below:

**Agency**

**Distrust in Healthcare**

**Attitudes**

**Gender**

**Education**

**Knowledge / Information Acquisition**

- *Friends* - *Google /Online* - *Family*

**Ability to Self-Test**

Coding of the surveys resulted in similar codes and a selection of codes which were unique to the survey results. These codes and their subsequent colours can be seen below.

**Mixing up vaccine and HPV**

**Information sources**

- *Google* - *Parents* - *School* - *Gossip* - *Didn't care*

**Negative Emotions**

**Sexualisation**

**Catholicism**

**Stigma**

**Negative Prejudice**

**Fear**

**Causality**

# THEMES

A number of themes which were uncovered throughout the primary research.

## **Knowledge Acquisition**

Where do they get the information from?  
What do they think of this information?

## **Education**

How is something addressed in formal education?  
Did the participant enjoy or find the education beneficial?

## **Agency**

The degree to which someone is making their own decisions, or the feeling of need for them to make these decisions.

## **Attitudes**

Displayed attitudes towards any topic discussed.

## **Equitable Access**

The need to give everyone access to something, and taking into consideration the individuals limitations to access.

## **Dignity**

Issues that impact the ability for someone to be respected and valued.

## **Gender**

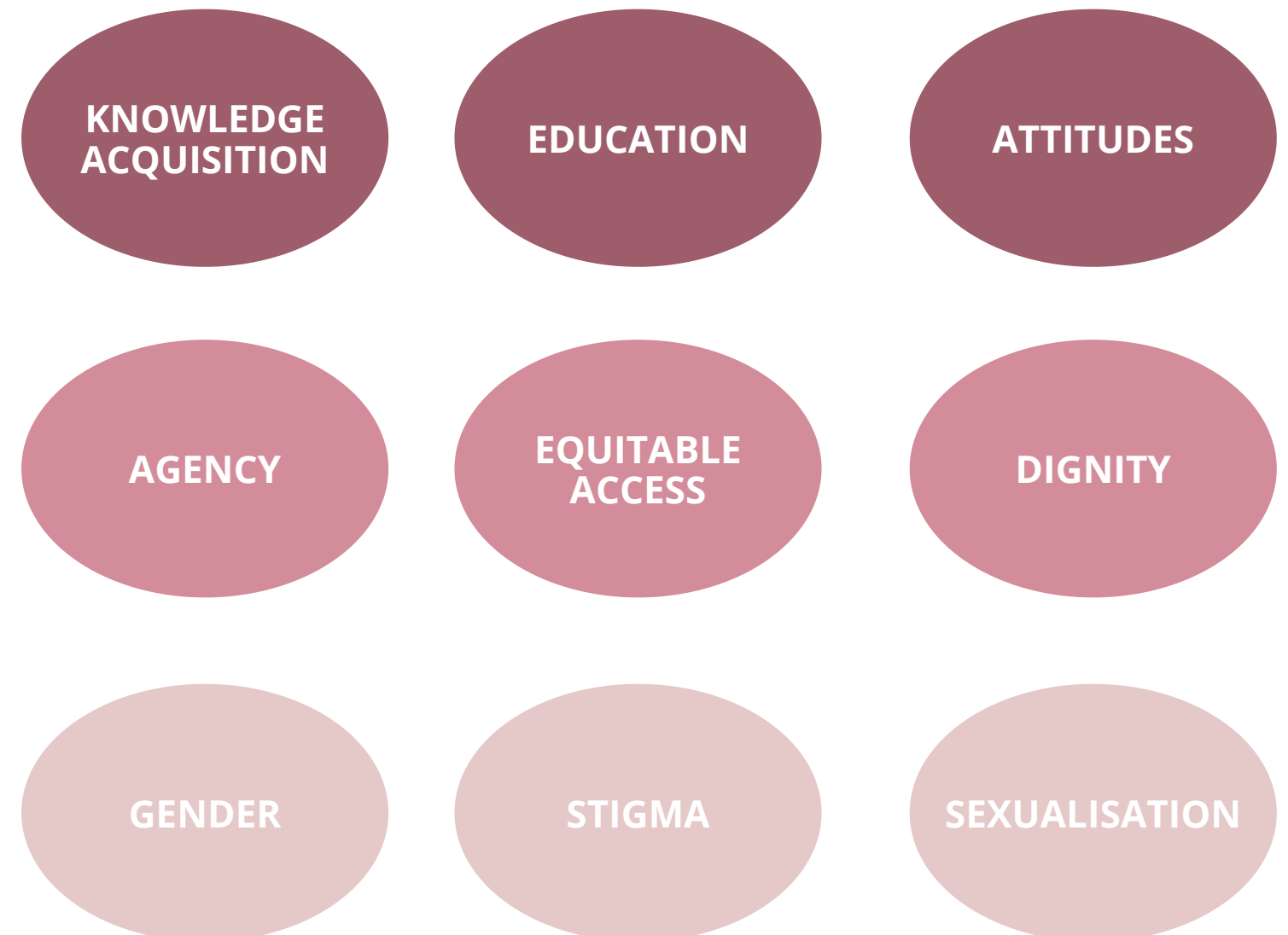
The issue of bias, knowledge and patient comfort that are rooted in gender.

## **Stigma**

The impact of negative opinions about a person based on differences or illness.

## **Sexualisation**

Making something sexual in nature, often making the topic uncomfortable to discuss.



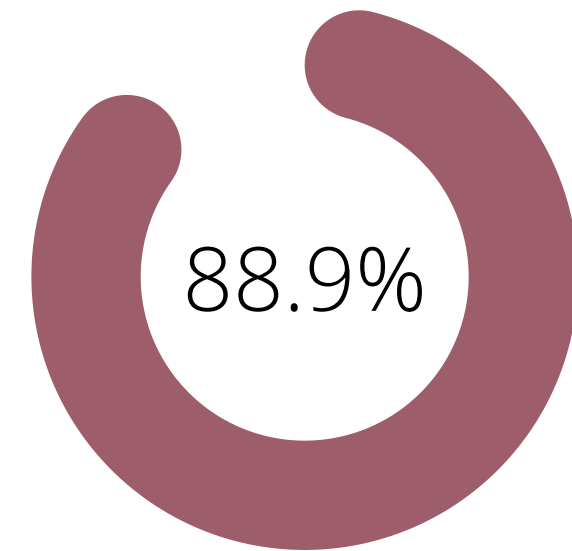
# SURVEY RESULTS

## **Response Rates**

Of the 162 participants, 2 (1%) did not give their informed consent for continued participation in the survey.

Of the remaining 160 participants, 18 (11.25%) fell outside the required age bracket so they were excluded.

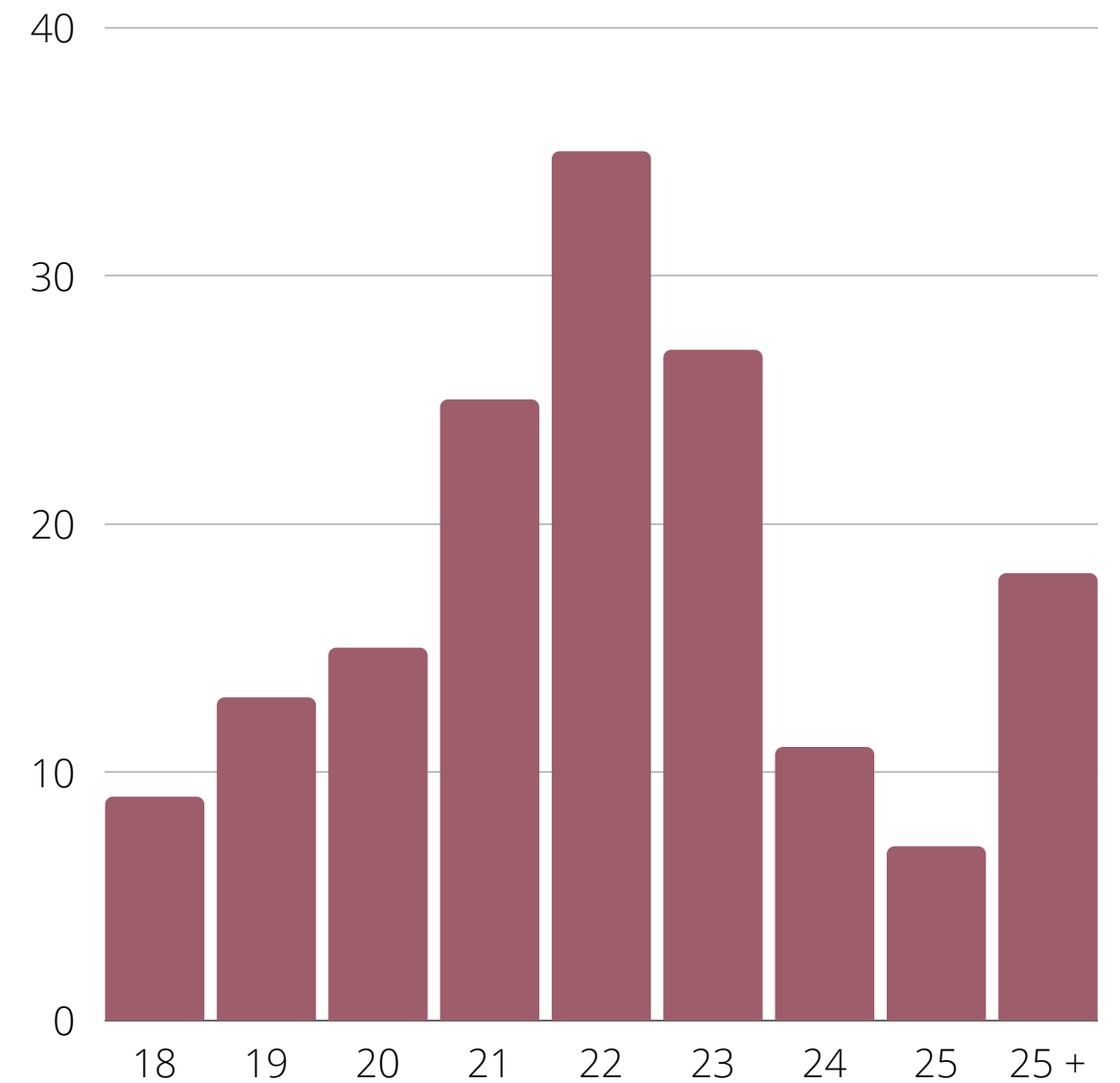
In total 144 questionnaires were completed, yielding a response rate of 88.89%.



## **Demographic Details of the Sample**

Of the 162 participants who responded, the largest portion of the sample were 22 years of age making up 21.88% of the sample. While the lowest response rate was from 18 year olds responsible for 5.63% of the sample. A summary of the demographic information is available in the bar chart to the right.

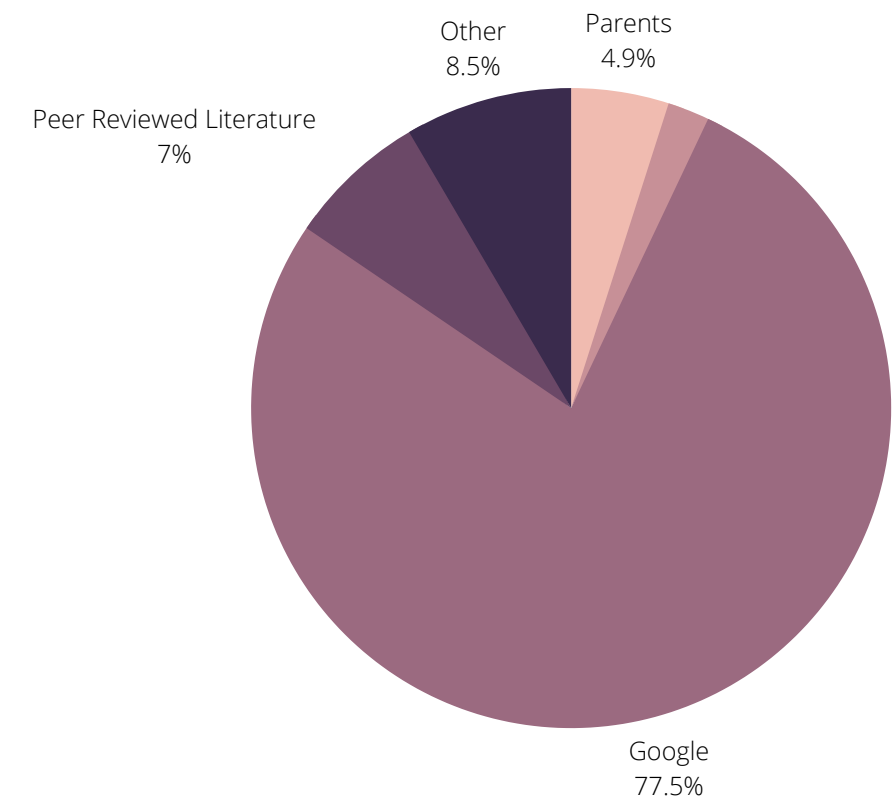
The survey results are available in the Design History File/0.Feasability/Surveys.



# QUANTITATIVE FINDINGS

## **Knowledge Levels**

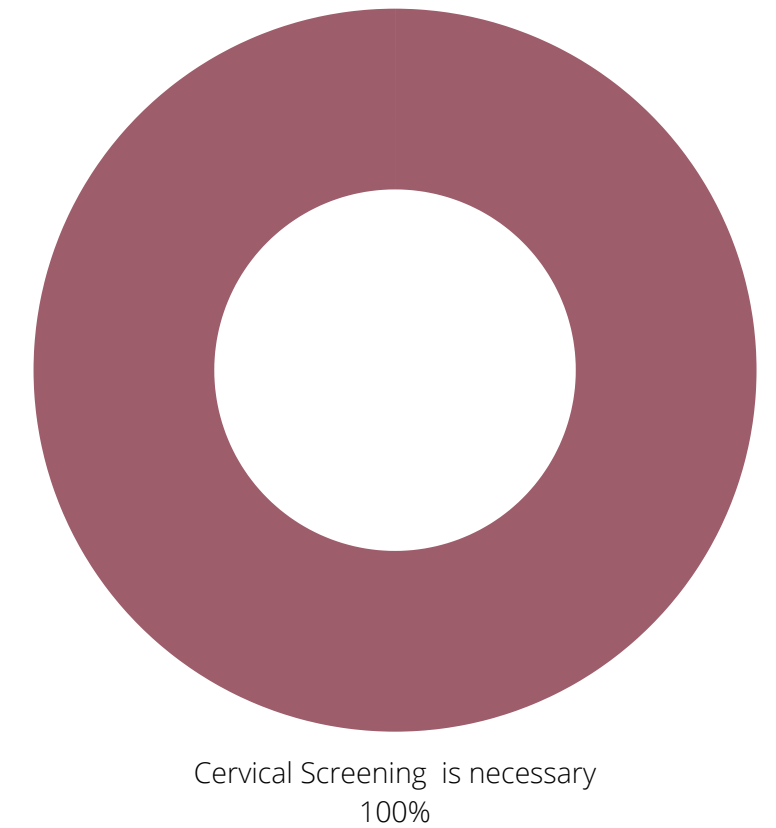
Of the participants which responded to the survey, 144 (80%) said they had heard of HPV before. 88 (62%) said they did not learn about HPV in school compared to the 31 (22%) who did. When asked whether they thought there was enough available information on HVP, 79 (56%) of the participants thought there was not sufficient information available. The place where these participants would go to find this information was 110 (77%) google, 10 (7%) peer-reviewed literature, 7 (5%) parents and 3 (2%) friends. 101 (73%) of the participants rated themselves as having a low knowledge of CC. 113 (82%) rated their knowledge of HPV as low but in comparison 88 (64%) rated their knowledge of the HPV vaccination as low. So, despite having low knowledge levels relating to HPV, knowledge levels are rated higher regarding the HPV vaccination.



# QUANTITATIVE FINDINGS

## ***Attitudes toward prevention and treatment***

Of the participants 110 (77%) had been vaccinated and those who were noted they had because it was free 48 (44%) and because their parents had told them to 37 (34%). Attitude towards cervical screening was that 139 (100%) thought it was necessary, and 126 (91%) felt that under 25's should be offered cervical screenings. Confidence in the cervical screening however, gathered that 15 (11%) of participants rated their confidence as high. On the other hand, confidence in the vaccination programme was higher with 72 (52.4%) participants recording their confidence as high.



# QUALITATIVE FINDINGS

Before delving into the findings from the qualitative research it is beneficial to know who took part in this research. As well as the questions they were asked. A sample of the questions asked can be seen below, and the reminder of the questions can be seen in Appendix 1 or in the Design History File/1.Feasability/Interviews.

- Do you frequently google symptoms online?
- Have you ever had a cervical smear? (Talk me through it) (How did you feel)
- Would you go for a cervical smear?
- Did you receive the HPV vaccine? (Did you get any information beforehand) (Where did you get)
- What do you know about cervical cancer & HPV?
- What are your concerns for cervical screenings?
- How would you feel about using your own cervical screening kit?

For the healthcare professionals the a sample of the questions can be seen below:

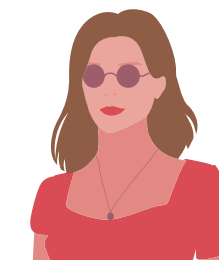
- Talk me through the cervical screening procedure
- What is the screening process looking for?
- Are there any other ways to identify abnormal cells?
- Are the screenings accurate?
- What can be done to improve accuracy/what makes them so accurate?

A selection of the interview participants are represented graphically below.



**Participant 1.**

Under 25.  
Highest Education: Leaving Cert.  
Occupation: Waitress



**Participant 2.**

Over 25.  
Highest Education: Leaving Cert.  
Occupation: Clerical Officer



**Participant 5.**

Under 25.  
Highest Education: Bachelors Degree.  
Occupation: Public Servant



**Participant 7.**

Under 25.  
Highest Education: Masters Degree  
Occupation: Student



**Participant 10.**

Under 25.  
Highest Education: Bachelors Degree.  
Occupation: Teacher



# QUALITATIVE FINDINGS

## **Information Acquisition**

The process by which information is acquired has been identified to stem from a number of sources, but in line with the data collected within the survey the main source of information is the internet, closely followed by family members, in particular mothers. Issues identified with the validity of the information, and although almost all participants searched online for their information, they were cautious of the source of this information noting “it’s just google so I’m not going to believe everything I see”. Participants raised issues surrounding the amount of information, and how a large portion of the data was negative, or suggestive of the “worst case scenario”.

## **Education**

Participants largely felt that school had ill prepared them for their vaccination and that they felt let down by the school system. Many noted they felt their school didn’t provide them with any sexual health information because the school was catholic. A participant noted the school organised a talk out of school hours for HPV information, while another mentioned them receiving vaccination information after receiving the vaccination itself. In terms of general health information participants also felt the school had missed the opportunity to educate them on health, particularly women’s health.

“**My mam tells me to cop on**”

Participant 01 U/25

“**It's just google so I'm not going to believe everything I see**”

Participant 01 U/25

“**Implications of that (googling symprotms) are mentally worse**”

Participant 08 U/25

“**No Jesus no, we didn't in school, there was no information about anything**”

Participant 07 U/25

# QUALITATIVE FINDINGS

## **Agency**

Several participants brought up the issue of consent and noted that because the vaccination is given to children, they require written consent from the parents. It was communicated that often there was a lack of information provided to the children regarding health decisions, but a sample of participants wondered if it was an issue that the kids were not aware. A few participants noted that if they had gotten the vaccination now, they would investigate the vaccination, to understand what they are putting into their body. However, at the time it wasn't a major concern for them. It was also mentioned that the students are young when they get the vaccination, so they typically don't care, and they rely on their parents to care.

## **Gender**

A participant mentioned their increased comfort in the presence of female practitioners. That female practitioners were gentler in nature. They also mentioned that they would be more comfortable with female practitioners, and that they weren't aware males could carry out the screening.

**“I suppose we were only young so it wasn't me giving the consent.”**

Participant 10 U/25

**“I didn't question it at the time.”**

Participant 12 U/25

**“I don't think I even contested it.”**

Participant 05 U/25

**“Men don't know what the limits are..”**

Participant 02 O/25

**“I always found it more uncomfortable when it was a man.”**

Participant 02 O/25

# QUALITATIVE FINDINGS

## ***Stigma***

The issue of stigma was raised on numerous occasions. It was mentioned as an issue of women's health. That women's health wasn't taken seriously and that it was stigmatised. The stigmatisation of STIs was also noted, that people don't like talking to their doctors about STI. It was also suggested that the education of both sexual and women's health was stigmatised. One of the reasons given for this stigmatisation was based on the catholic nature of many of the Irish schools. The issue of the location of the cervix was given as a reason for stigmatisation, given that the cervix is reached through the vagina and that the vagina is a 'private part' makes it a taboo topic. A participant also blamed the state for the stigmatisation of sex and sexual health. On several occasions, it was mentioned that the boys in school had slagged the girls over the vaccination which caused them increased anxiety.

## ***Sexualisation***

To the surprise of the author the issue of sexualisation arose. A participant noted that breast cancer is a commonly spoken of disease due to the value society places on breasts. Along with the idea that "if someone loses a breast, they're not a woman anymore".

## ***Equitable Access***

The issue of access also presented itself during the research, and how participants thought perhaps members of the Travelling community, people in direct provision centres and children being home-schooled may miss out on the HPV vaccination and valuable information about this vaccine. One participant pointed out that anyone who attended catholic schools may have missed out sufficient education about the HPV vaccination and sexual health. There was mention of the need to give these marginalised groups equal access to this education. But the author notes that perhaps equal access is not sufficient, that they need equitable access in order to wholly benefit from the education.

# OBSERVATION - PROBLEM - NEED

Observations were pulled from research, opportunities/problems were identified and needs were highlighted. This is a sample of the Observations which came from the literature review. The remainder of the observations is linked in Appendix 3 and in its entirety in the Design History File/0.Feasability/DataSynthesis.

Observation	Problem / Opportunity	Need
Lack of understanding of HPV and the HPV vaccine makes women frustrated.	Opportunity to improve understanding of the HPV vaccination.	For consistent education about HPV in school.
Where parents are highly educated, their children are more likely to be vaccinated.	Opportunity to improve parents education of HPV and CC to allow them to educate their kids.	For engaging education about HPV and CC for parents.
Transmasculine people have lower screening rates than cisgendered women.	Transmasculine people are missing out on screening . Cases of CC in transmasculine people may be missed.	A way to improve the experience of transmasculine people during female health checks. A way to increase uptake CC of screening in transmasculine people.
Male GPs have higher self perceived knowledge of HPV than actual knowledge of HPV.	GPs think they know more about HPV than they do so there is potential for misinformation.	A way to improve knowledge levels of male practitioners around HPV.
Nurses who haven't received the vaccination say it is due to lack of knowledge around the topic.	Health professionals can't provide correct information to patients / members of the public.	A way to improve knowledge levels of health practitioners around the HPV vaccine.
Male practitioners in Ireland describe the smear test as a females issue.	Opportunity to provide education for male practitioners about HPV and CC.	A way to improve knowledge levels of male practitioners around HPV & CC.
Male practitioners in Ireland believe the smear test is the role of a female practitioner.	Male practitioners don't actively upskill with relation to CC and screening Opportunity to provide education for male practitioners about HPV & CC.	A way to improve knowledge levels of male practitioners around HPV and CC. A way to remove gender roles from women's health check ups.
There is a bias towards CC due to the sexually transmitted nature of HPV.	People are embarrassed about having CC or HPV due to the sexually transmitted nature of HPV.	A way to reduce stigma around CC & HPV.
Most HPV infections naturally regress	Opportunity to raise awareness that most HPV infections are nothing to worry about	A way to determine if HPV infection is a cause for concern or not.
Patients perceive HPV infection as CC.	HPV infection may cause concern but might not be something to worry about Unnecessary cause for concern	A way to determine if the HPV infection is of a strand which causes CC (HPV16) A way to increase knowledge of the slow progression of HPV.
European guidelines suggest HPV as the primary method for CC screening.	Lack of knowledge of HPV causing unwarranted anxiety Opportunity to raise awareness of role of HPV in CC	A way to increase awareness of the role of HPV infection in CC.
Screening under 25's is unlikely to reduce cervical cancer rates.	Opportunity for self testing for HPV Opportunity to raise awareness of why under 25's are not screened	A way to increase awareness of reasoning behind not screening women under 25.
Screening women under 25 may lead to over treatment.	Women under 25 can still get HPV & CC and they'd be missed. Over treatment of CC can lead to infertility Opportunity to raise awareness of likelihood of under 25's getting CC.	A way to screen women under 25 who may be at risk. For treatment of CC which does not cause infertility. A way to increase awareness of issues which may arise if women are over treated.

- Education
- Information Acquisition
- Agency
- Anxiety
- Stigma
- Information Interpretation
- Equitable Access
- Gender
- Inclusion / Under 25's

# OBSERVATION - PROBLEM - NEED

This page adds to the previous pages findings, with some additional observation-problem-needs.

Observation	Problem / Opportunity	Need
Girl got the vaccine because everyone else was getting it, and her sister had recently gotten it.	Lack of information passed from family to child, leaving child uninformed.	For children to be informed about the vaccination.
Students are young when they get the vaccination, they don't give it much thought.	Child is too young when receiving vaccination, they don't care.	For raised awareness about f the vaccine & importance of knowing what is going into your body.
Students are too young to care about the vaccine.	Child is too young when receiving vaccination, they don't care.	For engaging education about HPV vaccination for the students in school
Students are throwing the information pamphlet into the bin.	Vaccination information is not engaging enough to make it home to the parents.	For engaging education about HPV vaccination for the students in school
Students are leaving school during the vaccination talk.	Vaccination information is not engaging enough for students to want to listen.	For engaging education about HPV vaccination for the students in school
Belief that the travelling community would miss out on information about the HPV vaccine.	Opportunity to target the travelling community for HPV vaccinations and education.	A way to insure everyone has access to the vaccination and HPV information.
Belief that people in direct provision centres would miss out on the HPV vaccine.	Opportunity to target people in direct provision centres for HPV vaccinations.	A way to insure everyone has access to the vaccination and HPV information.
Cervical cancer is a taboo topic	There is a stigma associated with CC because it can come from an STI & affects a 'private area'	A way to reduce stigma around CC.
Breast cancer has a good advertising campaign.	Opportunity to use breast cancer techniques to improve CC advertising.	A way to increase awareness of the success of CC treatment.
Breast cancer affects breasts, which are valued because they're sexualised.	Opportunity to de-sexualise breasts	A way to increase awareness of the success of CC treatment.
	Opportunity to remove sexualisation from women's health.	A way to increase awareness of the success of CC treatment.
There is an idea that women who loose a breast, are no longer a woman.	Opportunity to de-sexualise breasts	A way to reduce sexualisation of women's health.
	Opportunity to remove sexualisation from women's health.	A way to reduce sexualisation of women's health.
Lung cancer is spoken about because it's not taboo and doesn't affect a private organ.	Opportunity to remove stigma around CC	A way to reduce stigma around CC.
Irelands connection with the church makes talking about sexual health difficult	Opportunity to separate state education and church	A way to separate the church from education systems.
	Sexual health is not addressed in school education in catholic schools.	A way to include sexual health education in catholic schools.
Google just shows you the worst possible case scenario (when you google symptoms)	Over consumption of negative health information online causes unnecessary anxiety.	A way to mitigate the negative and over-dramatic results when looking up symptoms. A way to show the most likely causes of symptoms rather than worst case.



# NEEDS STATEMENTS

From the 325 needs, a quick filtering process ruled out the repeated needs, and afterwards the remaining 200 needs were categorised. Below is a sample of the remaining needs statements and their subsequent category. The rest of the need statements are linked in Appendix 3, and can be found in the design history file/0.Feasibility/DataSynthesis.

For standardised education of HPV for young students in schools.

A way to explain patients screening results without causing concern.

For raised awareness of the meaning of 'abnormal results'

A method to prevent the sexualisation of women in a healthcare setting.

A way to increase uptake of cervical screening in transmasculine people..

A way to remove stigma around sexual health among young students in school.

For increased awareness of the HPV and HPV infection among the general population.

For parents to be provided correct information to inform their kids about the vaccine.

For engaging education about HPV vaccination for students in school

For easily accessible, unbiased and engaging information about the vaccination for kids.

For ease of access to correct health information.

For the option to have the vaccination at a later date, when they can make their own decisions.

For kids to be open with their parents about health decisions.

For kids to be informed about health decisions which impact them

A way to spark conversation about sexual health and HPV with boys at home.

A way to reduce stigma of female sexual health education.

A way to promote the importance of sexual health education in catholic schools.

A way to increase awareness of the sexually transmitted nature of HPV.

A way to reduce fear of HPV infection through education.

A way to insure equal/ equitable access to the free vaccine.

A way to support students wellbeing before and after the vaccination.

A way to support the patients wellbeing post diagnosis (of cc).

- Education
- Information Acquisition
- Agency
- Sexualisation
- Stigma
- Emotional Support
- Equitable Access
- Gender
- Communication

# NEEDS CATEOGRISATION

The needs are initially organised by thematic analysis.



# DATA SYNTHESIS

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NEEDS FILTERING



# NEEDS FILTERING

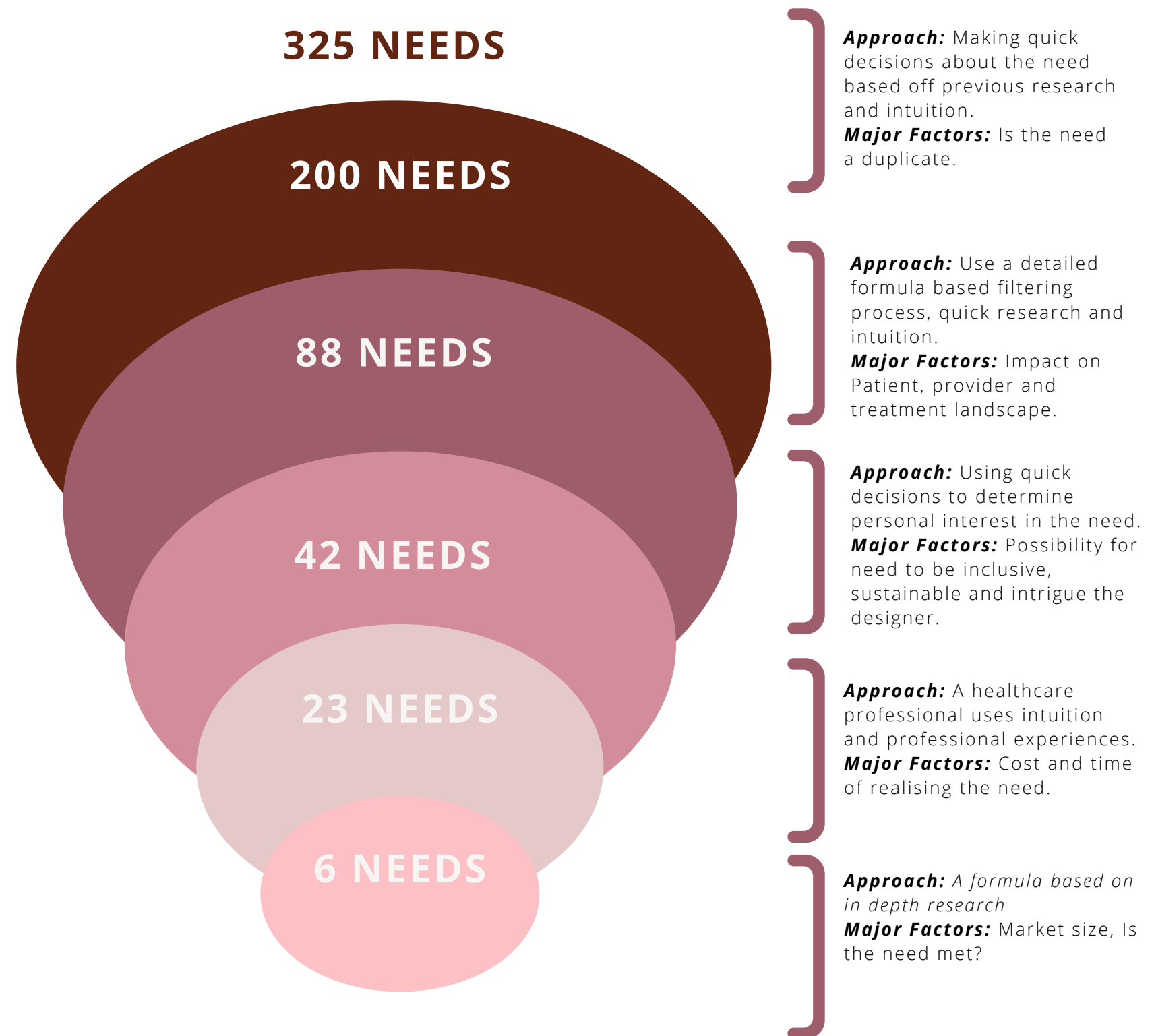
After the replicated needs were filtered and the remaining needs were categorised. These needs then began the filtering process. Needs filtering is subjective, however the process insures the needs are aligned with the designers interests and strengths. It is also essential for the consideration of the commercial viability of the needs (Yock et al. 2015). The approach relates to how the filtering was interpreted and the major factors are the key considerations for filtering.

The needs statements were filtered based on the impact addressing the need would have on the individual, the provider and the treatment landscape.

These needs were then filtered further based on criteria including personal interest, and the direction which the designer wants to go with a solution.

Finally the market was assessed again, and this time needs were filtered based on the market acceptability of a solution.

This needs filtering process can be found in the design history file/0.Feasability/DataSynthesis and is linked Appendix 3.



**Approach:** Making quick decisions about the need based off previous research and intuition.  
**Major Factors:** Is the need a duplicate.

**Approach:** Use a detailed formula based filtering process, quick research and intuition.  
**Major Factors:** Impact on Patient, provider and treatment landscape.

**Approach:** Using quick decisions to determine personal interest in the need.  
**Major Factors:** Possibility for need to be inclusive, sustainable and intrigue the designer.

**Approach:** A healthcare professional uses intuition and professional experiences.  
**Major Factors:** Cost and time of realising the need.

**Approach:** A formula based on in depth research  
**Major Factors:** Market size, Is the need met?

# NEEDS FILTERING

Firstly, the needs were rated for the impact they have on the individual in this context. The Impact is assessed and then based on the criteria the need is given a score between 1 - 5.

1.	Addressing the need has no impact on the individual.
2.	Addressing the need is convenient for individual but has no major impact on their physiological or psychological needs.
3.	Addressing the need has impact on either physiological or psychological needs of individual.
4.	Addressing the need has major impact on physiological or psychological need and helps ease / complete role.
5.	Addressing the need will greatly impact both psychological and physiological needs of individual and save time or makes role easier.

# NEEDS FILTERING

Secondly, the needs were rated for the impact they have on the provider in this context. The Impact is assessed and then based on the criteria below the need is given a score between 1 - 5.

1.	Addressing the need has no impact on the provider.
2.	Addressing the need is convenient for provider but has no major impact on their physiological or psychological needs.
3.	Addressing the need has major impact on physiological or psychological need and saves time or money.
4.	Addressing the need has impact on either physiological or psychological needs of provider as well saves time or money.
5.	Addressing the need will greatly impact both psychological and physiological needs of provider and save time and money.

# NEEDS FILTERING

Lastly, under this category needs were rated for the impact they have on the treatment landscape in this context. The Impact is assessed and then based on the criteria below the need is given a score between 1 - 5.

1.	Solutions to address the need that are generally well accepted by the target user population and address the need well.
2.	Solutions exist to address the need but have minor deficiencies that must be overcome.
3.	Solutions exist to address the need but have serious deficiencies that must be overcome, or they exist just not in Irish health system.
4.	No existing solution available to address the need but numerous inventors/companies have tried to address the need and failed many workarounds..
5.	There are no existing solution available to address the need and the field is not littered with inventors/companies who have tried to address the need and failed.

# NEEDS FILTERING - RESULTS

The scores from each of the filter categories were added up, and needs with an overall score below 11 were eliminated. The breakdown of the filtering process, and which needs were eliminated can be found linked in Appendix 3, and in the design history file/01.Feasibilit/DataSynthesis. .

**200 Need Statements**



**88 Need Statements**

# NEEDS FILTERING

The needs which remain after the initial filtering process are then assessed in terms of personal interest of the author. It is important to the designer that she addresses a need which will have a positive social and environmental impact.

## ***Universal Design***

Is it possible that answering this need would result in something easy to use, needing low physical effort, & flexible, etc,. ?

## ***Inclusive Design***

Does addressing this need mean the inclusion of a group of people who are currently excluded?

## ***Project Direction***

The designer has an interest in developing a product, in order to improve their product design skills. However, they are open to service design as they have not had experience in service design. A combination of a product service would be most intriguing.

## ***Social Design***

Does this need require a social impact to solve? Will solving it make a difference for it's users in a positive way?

## ***Sustainability***

Will this need allow for a sustainable solution? Will it add extra waste to the environment, or can it potentially be sustainable?

## ***Circular Economy***

Is there opportunity to potentially include circular economy into the answering of this need?

# NEEDS FILTERING

The scoring for this round of filtering is similar to the last round and this time needs which score below 3 will be eliminated.

1.	Addressing the need is not inline with designers personal interests.
2.	Addressing the need answers to one of designers personal interests.
3.	Addressing the need answers to one or more of designers personal interests.
4.	Addressing the need answers to more than one of designers interests and designer is interested in a solution.
5.	Addressing the need answers to all of designers interests and the designer is invested in rectifying the need.

# NEEDS FILTERING 2 - RESULTS

The scores from the personal filtering round were noted and needs scoring below 4 were eliminated. The breakdown of the filtering process, and which needs were eliminated can be accessed through a link in Appendix 3 and in its entirety in the Design History File/0.Feasability/DataSynthesis.

**88 Need Statements**



**42 Need Statements**



# NEEDS FILTERING

The needs which were remaining after the personal filtering process were then assessed in terms of a public health preference. An ex-public health manager assessed, and rated the needs. The criteria by which they eliminated needs is outlined below.

## ***Cost of Running the Programme (need) vs Cost of treatment of advanced disease***

Is the cost of the need of huge expense?

Where does this need sit with regard to the treating advanced CC?

Is one much more expensive than the other?

## ***Cost of Saving vs Programme (need) cost***

If the need is addressed, is there subsequent savings, in terms of treatment, labour and death?

How much is being saved by the programme and how much does the programme cost? If the programme costs more than the savings, what is the point?

## ***Psychosocial Impact***

What is the impact of addressing the need on social support, social status and the work force. What cost is not addressing the need having, if someone is being treated, their social status may negatively be affected, they're out of work they are drawing social welfare. Some of these issues are immeasurable, but they were estimated by the healthcare professional.

## ***Political Issue***

The issue of CC is very much a political issue, especially at the moment. Much more women are affected by breast cancer than CC.

What is the political impact of addressing the need?

# NEEDS FILTERING 3 - RESULTS

The scores from the public health preference filtering round were noted and needs scoring below 4 were eliminated.

**42 Need Statements**



**23 Need Statements**

# NEEDS FILTERING

The needs which were remaining after the public health preference filtering round were then assessed in terms of market analysis. The needs are explored by the size of the market. This round of filtering has 4 sub categories, this allows the author to explore the market specific to the need and whether or not it is worth exploring the need further.

## ***Market Size***

Number of people affected / patients.

Total USD value of the market.

Market segment growth.

## ***Market Dynamics***

Number of competitors in the segment.

Maturity of the products and services on offer.

Investor interest in the segment.

## ***Market Needs***

Is the need being met by existing product or service?

What are the unmet needs and market gaps?

## ***Willingness to Pay***

Likelihood of adoption of new solutions.

Willingness of stakeholders to pay for the product/service.

# NEEDS FILTERING

This round of need filtering involved eliminating needs which scored below 4. If the market is not there, there should be no point in exploring the need further.

1.	This market is non existent / Over saturated market / Established competitors & market leaders.
2.	The market is small and has no buyer interest / over saturated market.
3.	The market is of a sufficient size but has no buyer interest.
4.	The market is large, there are few competitors and potential buyer interest.
5.	The market is large, few competitors and stakeholders are highly likely to purchase a solution.

# NEEDS FILTERING 4 - RESULTS

The scores from the public health preference filtering round were noted and needs scoring below 4 were eliminated. A number of the resulting needs have been combined, this will allow for a deep dive into specific areas the needs fall under.

**23 Need Statements**



**6 Need Statements**

# NEEDS FILTERING - RESULTS

After 4 rounds of filtering, the remaining 6 needs will be explored as part of a deep dive. These 6 needs are themes which are made up of a number of similar needs. These needs can be seen below.

- A way to remove stigma around women's sexual health.
- A way to include women's health and sexual health education in school.
- For treatment of CC which does not cause infertility.
- A way to do self cervical screening that mitigates opportunity for mistakes.
- A way to identify family members of CC patients to get them screened & vaccinated.
- A way to ensure everyone has access to the HPV vaccination
- A way to ensure everyone has access to the vaccination and HPV information.
- A way to insure patient the screening is not painful.
- A way to reduce side affects associated with CC screening.
- A way to increase CC screening uptake.
- A way to reduce the pain of cervical screening.

- Need to address sexual health stigma
- Need to insure treatment doesn't cause infertility.
- Need for self screening which is user friendly
- Need to triage relatives of CC patients.
- A need for equitable access to vaccination & information
- A need to improve cervical screening uptake and procedure.

# DESIGN GUIDE

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DESIGN CONSIDERATIONS  
REGULATORY CONSIDERATIONS  
ERGONOMIC CONSIDERATIONS  
AESTHETIC CONSIDERATIONS  
ENVIRONMENTAL CONSIDERATIONS  
ETHICAL CONSIDERATIONS  
PERSONAL CONSIDERATIONS  
MUST HAVES & NICE TO HAVES

# DESIGN GUIDE

Considerations to keep in mind when designing the solution. The design considerations vary for each need, the designer will discuss a number of these considerations.

The considerations will be examined under the following headings:

***Regulatory***

***Ergonomic and Usability***

***Aesthetic***

***Environmental***

***Ethical***

***Personal***

Once these areas have been examined, the designer formulates a list of must haves, which the solutions will require and then a list of nice to haves for the solutions.

Each need will be examined separately due to their various directions and requirements.



# REGULATORY CONSIDERATIONS

## ***Irish Regulatory Requirements***

The Health Products Regulatory Association (HPRA) is responsible for the regulation of medical devices on the Irish market and is designated as Competent Authority (CA) for medical devices in Ireland (HPRA 2020). The solution must therefore comply with the relevant regulations. The solution would also have to be audited by the HPRA.

## ***European Regulatory Requirements***

Products sold within the European are required to have a CE conformity mark. This CE mark must be present on Medical Devices, and be awarded by a notified body. It is therefore essential that the solution conforms to European regulations and can be awarded a CE mark.

## ***Trademark and Patent Laws***

The Intellectual Property Office Ireland, is the government body responsible for Intellectual Property. The solution must not infringe on any existing patents. The name/logo of the solution would be trademarks, but would not necessarily need to be registered as such (Trade marks Act 1996).

# ERGONOMIC/USABILITY CONSIDERATIONS

## ***Risk Factors***

Solution should avoid requiring repetitive, forceful, or prolonged exertions of the hands. These considerations will help avoid repetitive strain injuries. Solution should not be sharp, painful or cause injury to cervix or vagina.

## ***Anthropometrics***

Anthropometrics considers human measurements and proportions. This is essential for considering various sizes of vaginas, hands and people who may use this solution.

## ***Control of Error***

There is a need to consider possibility of use errors, and how best they can be avoided. If error does how can it be reversed, can this be designed into the solution?

## ***Usability***

The solution must be usable; unusable products are considered design failures. Addressing this need must be done in a way that is intuitive, safe & free of possibly life-threatening errors.

# AESTHETIC CONSIDERATIONS

## ***Commercial Aesthetic***

If the solution is to be a commercial, consumer based solution the aesthetic could reflect colour blocking. It should be bright and fun in contrast to the taboo of cervical smears and cervical cancer. Similar to how feminine hygiene products are addressing the taboo of period products with bold feminine packaging.

## ***Functional Aesthetics***

The designer should consider the functionality of the solution. The end goal for the design should be to create a positive user experience. The solution should favour intuitive use.

# ENVIRONMENTAL CONSIDERATIONS

## ***Circular Design***

The solution needs to insure raw materials are ethically and sustainably sourced. Materials should be chosen with their environmental impact in mind. The supply chain should be clean and ethical and the end of life case needs to be factored in at the design stage. There is a need to slow, narrow and close loops (Wuyts, et al 2020).

Moving from linear lifecycle to a circular lifecycle, and that environmental impact is considered at every stage of this cycle.

## ***Environmental Trends***

Environmental trends are celebrating recycled plastic as raw material, companies including Adidas are on this trend (Walstack 2020). It is important to take into consideration that consumers favour products that are sustainable and environmentally conscious (Grebitus, et al 2020). In the medical setting it is slowly moving towards this area, particularly if the medical device is for consumers.

# ETHICAL CONSIDERATIONS

A number of the key considerations to keep in mind in order to create an ethical design.

## ***User Involvement***

The design should be constantly considering the end user. Therefore, the designers must be mindful when dealing with the users, how they manage their expectations, and how they involve them in designing and testing. Ensuring nothing is dangerous, and that the users have all of the relevant information they need.

## ***Sustainability***

The designer must be conscious of the impact their design will have on the environment, resources, and climate. The design must be created responsibly and should encourage sustainable behaviour of the end users.

## ***Society***

The solution must be mindful of its effects on relationships, mental health, and democracy. It's good to consider the global economy, communities, politics, and health.

## ***Accessibility***

Answering the need must lead to a design which is accessible. It should benefit everyone, covering a range of needs and capabilities. The solution should focus on Who benefits from this solution? Who is (un)intentionally left out? Who falls outside the "target customer segment"?

## ***Privacy***

The need should be addressed with the aid of the abundance of consumer data available to shape the solution best of the end users. However, the solution must protect the data and use the data responsibly with it. During the design, the designer should decide if the information is necessary and be mindful of how the data is being collected.

# PERSONAL CONSIDERATIONS

No matter what needs are chosen to address, the most important requirements for the solution, are under these headings; Social Design, Sustainability, Circular Economy, Universal & Inclusive Design.

As a designer my main focus is on two of the P's in the triple bottom line, namely, People & Planet.

## ***Social Design***

The design must make a positive social impact.



## ***Sustainability***

Solution must be sustainable. The solution must consider material choices, raw materials, processes and end of life.



## ***Circular Economy***

Answering the need must add to circular economy, a closed loop, designing for the end of life, as well as it's use.



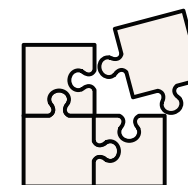
## ***Universal Design***

This need must be answered by something easy to use, needing low physical effort, & flexible, etc,. ?



## ***Inclusive Design***

By addressing this need there should be inclusion of a group who are currently excluded, and there should not be further exclusion.



# MUST HAVES & NICE TO HAVES

An examination of the design requirements for the remaining needs is useful as it helps aid the designer during the following stages of the design process. This is done by determining what the solution must have in order to be successful and well designed. Along with establishing what would be nice for the solution to have.

## ***Need to address sexual health stigma***

### Must haves

- The solution MUST be accessible to a multitude of women.
- The solution MUST improve users attitudes towards sexual health.
- The solution MUST empower women.
- The solution MUST consider the end users and be age appropriate.
- The solution MUST focus on changing attitudes as well as educating users.
- The solution MUST be inclusive.

### Nice to haves

- It would be nice for the solution to create a positive conversation online about sexual health.
- It would be nice for the solution to be applicable in different cultures.
- It would be nice for the solution to be accessible to women in less developed countries.
- It would be nice for the solution to have the ability to be tailored for specific minorities.
- It would be nice for the solution to have an online presence around empowering sexuality.
- It would be nice for the solution to address female pleasure as part of sexual health.

# MUST HAVES & NICE TO HAVES

The next need which will be examined in terms of requirements which would be nice to have and requirements which are essential is:

## ***Need to insure treatment doesn't cause infertility.***

### Must have

The solution MUST fit into a multitude of different sized vaginas.

The solution MUST not damage the cervix.

The solution MUST be accessible to a range of women in various socioeconomic backgrounds.

The solution MUST not be painful for the patient.

The solution MUST be inclusive of minority groups, including transmasculine people.

### Nice to have

It would be nice for the solution to improve fertility post procedure..

It would be nice for the solution to be painless.

It would be nice for the solution to prevent over treatment.

It would be nice for the solution to be free for the women.

It would be nice for the solution to be a quick procedure.



# MUST HAVES & NICE TO HAVES

An examination of the design requirements for the remaining needs is useful as it helps aid the designer during the following stages of the design process. This is done by determining what the solution must have in order to be successful and well designed. Along with establishing what would be nice for the solution to have.

## ***Need for self screening which is user friendly***

### Must haves

The solution MUST be accessible to a multitude of socio-economic backgrounds.

The solution MUST fit a wide variety of vaginas.

The solution MUST be simple to operate.

The solution MUST be able to take samples from the vagina.

The solution MUST include legible and informative instructions.

The solution MUST require low physical effort to use.

The solution MUST consider varying literacy levels for instructions.

The solution MUST have limited opportunity for error.

### Nice to haves

It would be nice for the solution to be able to obtain samples from males.

It would be nice for the solution to offer immediate results.

It would be nice for the solution to include an interactive feedback system to insure correct use.

It would be nice for the solution to empower women.

It would be nice for the solution to be usable in less developed countries. (e.g limited electricity)

It would be nice for the solution use colour blocking packaging to encourage uptake.

It would be nice for the solution have a social media presence based on female empowerment.

It would be nice for the solution to address the stigmatisation of HPV and CC.

# MUST HAVES & NICE TO HAVES

The next need which will be examined in terms of requirements which would be nice to have and requirements which are essential is:

## ***Need to triage relatives of CC patients.***

### Must haves

- The solution MUST be reliable.
- The solution MUST not cause unnecessary concern for the identified relatives.
- The solution MUST consider the emotional impact of potentially being high risk on the woman.
- The solution MUST be mindful of women's data protection.

### Nice to haves

- It would be nice for the solution to encompass user journey from identification to prevention.
- It would be nice for the solution to offer support to the user.
- It would be nice for the solution link high risk women with survivors.
- It would be nice for the solution allow for home self testing.

# MUST HAVES & NICE TO HAVES

The next need which will be examined in terms of requirements which would be nice to have and requirements which are essential is:

## ***A need for equitable access to vaccination & information***

### Must haves

The solution MUST be accessible to a multitude of people.

The solution MUST consider various levels of literacy.

The solution MUST present the most up-to-date information.

The solution MUST include the most relevant information.

The solution MUST be gender neutral.

The solution MUST include approved health information.

The solution MUST be concise.

### Nice to haves

It would be nice for the solution to link with women in other countries to empower them.

It would be nice for the solution to be colourful and engaging.

It would be nice for the solution to be free.

It would be nice for the solution to have different versions for different people, for equity.

It would be nice for the solution to encourage a positive narrative about the vaccine online.

It would be nice for the solution to encourage a peer support system for health.

It would be nice for the solution to encourage a conversation about access to health.

# MUST HAVES & NICE TO HAVES

The last need which will be examined in terms of requirements which would be nice to have and requirements which are essential is:

## ***A need to improve cervical screening uptake and procedure.***

### Must haves

The solution MUST be accessible to a multitude of women.

The solution MUST consider reasons behind poor uptake.

The solution MUST consider various sized vaginas.

The solution MUST be accessible to a multitude of socio-economic backgrounds.

The solution MUST consider various pain thresholds.

The solution MUST consider emotional impact of screening.

### Nice to haves

It would be nice for the solution to encourage support groups around screenings.

It would be nice for the solution to empower women.

It would be nice for the solution to be painless.

It would be nice for the solution to provide emotional support for women.

It would be nice for the solution to allow for self screening options.

It would be nice for the solution to improve experience of screening.

# IDEATION

**BRAINSTORMING**  
**PROJECT SCOPE REVIEW**  
**USER FRIENDLY SELF SCREENING**  
**EQUITABLE ACCESS**  
**INCREASING SCREENING UPTAKE**  
**FILTERING IDEAS**

# IDEATION

The research chapter provided insights and needs which will be drawn upon to create design interventions. The guiding light for the remainder of this process will be the design guide which was formulated with nice to haves and must haves in the previous chapter. A recap of this will provide the basis needed to create new design interventions which speak to the insights found throughout the research.

## ***Design Guide***

To recap on the design guide contents it is useful to note the guide was broken into various categories:

*Regulatory*

*Ergonomic and Usability*

*Aesthetic*

*Environmental*

*Ethical*

*Personal*

These contained considerations which had to be kept in mind as the ideas were being generated. Although it was not essential for every idea to satisfy all aspects at first, for ideas to be considered for the concept development phase they must be considerate of the aforementioned guidelines.

It is important to note that the research has not come to a halt as the end of the research chapter may suggest. This chapter will explore ideas, and it will draw upon the primary research already collected as well as explore new research. Aiming to understand factors for potential success or failure of a number suggested ideas. It will draw upon scientific research into HPV detection, and psychological reasoning behind vaccination hesitancy. There are a variation of blue sky ideas, radical and incremental innovations throughout the brainstorming phase. These ideas narrow as ideation becomes more focused to ideas which have potential of actualisation.

# DESIGN GUIDE

## ***Need to address sexual health stigma***

The solution MUST be accessible to a multitude of women.

The solution MUST improve users attitudes towards sexual health.

The solution MUST empower women.

The solution MUST consider the end users and be age appropriate.

The solution MUST focus on changing attitudes as well as educating users.

The solution MUST be inclusive.

## ***Need to improve screening uptake and procedure***

The solution MUST be accessible to a multitude of women.

The solution MUST consider reasons behind poor uptake.

The solution MUST consider various sized vaginas.

The solution MUST be accessible to a multitude of socio-economic backgrounds.

The solution MUST consider various pain thresholds.

The solution MUST consider emotional impact of screening.

## ***Need for user friendly self sceening***

The solution MUST be accessible to a multitude of socio-economic backgrounds.

The solution MUST fit a wide variety of vaginas.

The solution MUST be simple to operate.

The solution MUST be able to take samples from the vagina.

The solution MUST include legible and informative instructions.

The solution MUST require low physical effort to use.

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The solution MUST have limited oportunity for error.

## ***Need to triage patients***

The solution MUST be reliable.

The solution MUST not cause unncessessary concern for the identified relatives.

The solution MUST consider the emotional impact of potentially being high risk on the woman.

The solution MUST be mindful of womens data protection.

## ***Need to insure screening does not cause infertility***

The solution MUST fit into a multitude of different sized vaginas.

The solution MUST not damage the cervix.

The solution MUST be accessible to a range of women in various socioeconomic backgrounds.

The solution MUST not be painful for the patient.

The solution MUST be inclusive of minority groups, including transmasculine people.

## ***Need for equitable access to vaccine and information***

The solution MUST be accessible to a multitude of people.

The solution MUST consider various levels of literacy.

The solution MUST present the most up-to-date information.

The solution MUST include the most relevant information.

The solution MUST be gender neutral.

The solution MUST include approved health information.

The solution MUST be concise.

# BRAINSTORMING

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# BRAINSTORMING

Following on from the analysis of the findings and the design guide, the author now explores the final need statements to begin the creative ideation process. These needs will be used in a brainstorming session where ideas are generated without an emphasis on the reality of the solutions. A number of brainstorming aids will be drawn upon, including the SCAMPER tool, some methods of Lateral Thinking.

The following number of pages will explore the 6 needs statements through a number of the techniques, before narrowing the focus to 3 needs to explore through further ideation.

1. **Need for self-screening which is user friendly**
2. ***Need to address sexual health stigma***
3. ***Need to ensure CC treatment doesn't cause infertility.***
4. ***A need for equitable access to vaccination & information***
5. ***Need to triage relatives of CC patients.***
6. ***A need to improve cervical screening uptake and procedure.***

Key ideas will be highlighted, if they are thought to have potential for further exploration.

# USER FRIENDLY SELF SCREENING

a cream to identify HPV infection.

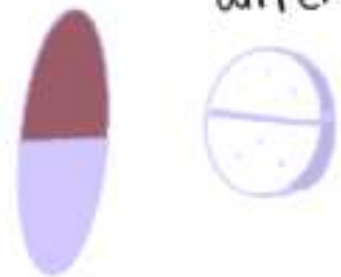


HPV turns cream bright pink.

Underwear that prevent HPV infection



a tablet you take that turns your urine different colour with HPV infection



Pants that prevent HPV infection

Underwear that identifies HPV infection



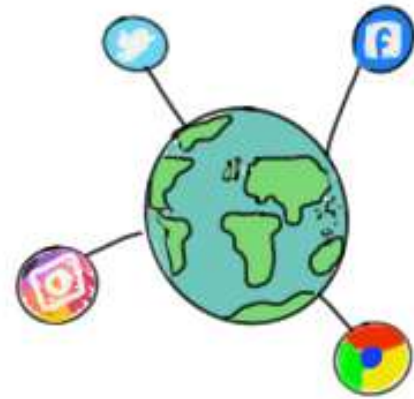
changes colour with presence of HPV

# USER FRIENDLY SELF SCREENING



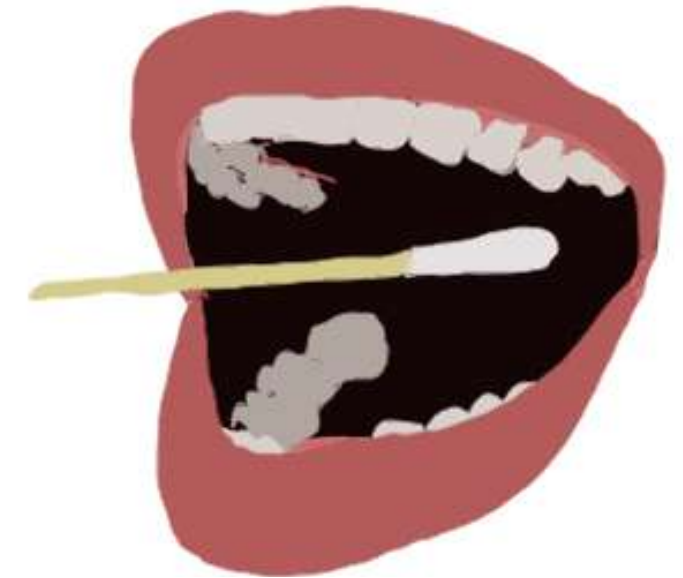
Available  
in pharmacies.

Online  
community of  
users.



Scan person  
to determine if  
they have HPV  
infection.

Take sample from  
elsewhere? mouth?



Drone postage of samples  
to labs.

Hand out  
tests like  
condoms.



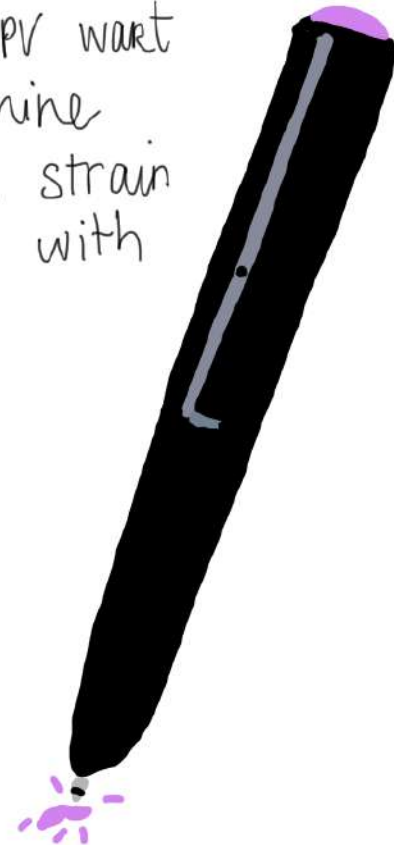
monitor HPV levels



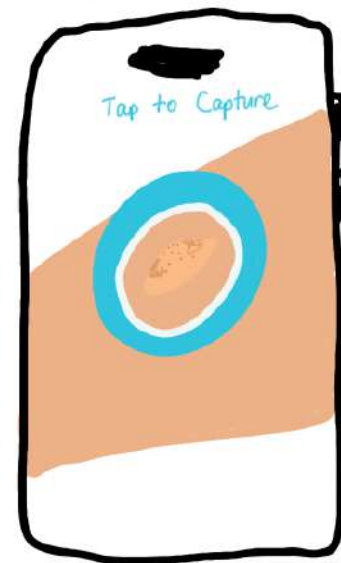
Determine if the  
HPV infection is a  
Cancerous strain  
of HPV.

# USER FRIENDLY SELF SCREENING

hold a pen over the HPV wart and determine if it its a strain associated with HPV

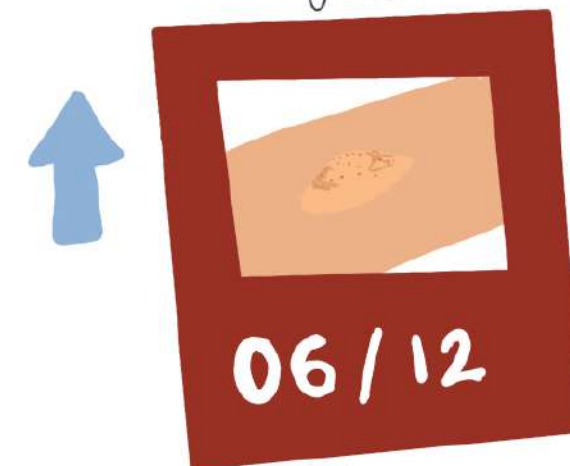


Take a picture of the raised skin via an app.  
Get a preliminary result.

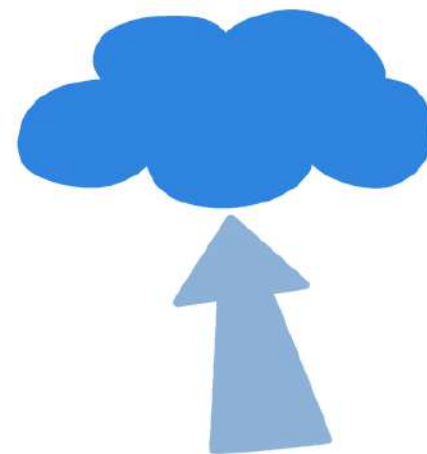


A condom that changes colour with HPV infection.

Upload the picture and check in the future for any changes



Upload a picture to the cloud for a specialist to check.



# SCAMPER

Scamper is an effective brainstorming method where the user is forced to explore the acronym and how the problem can be expressed in different ways.

## S ubstitute

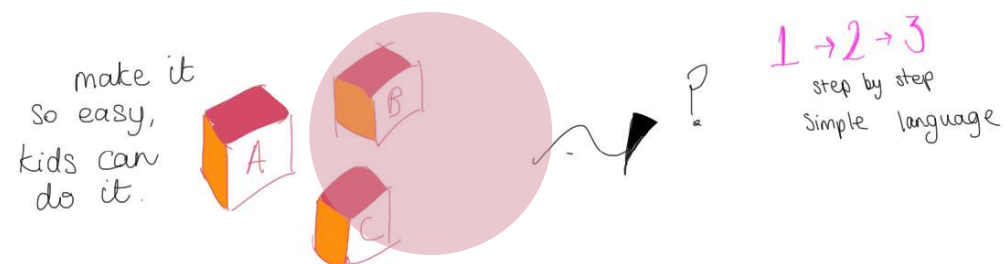
## C ombine



## A dapt



## M odify



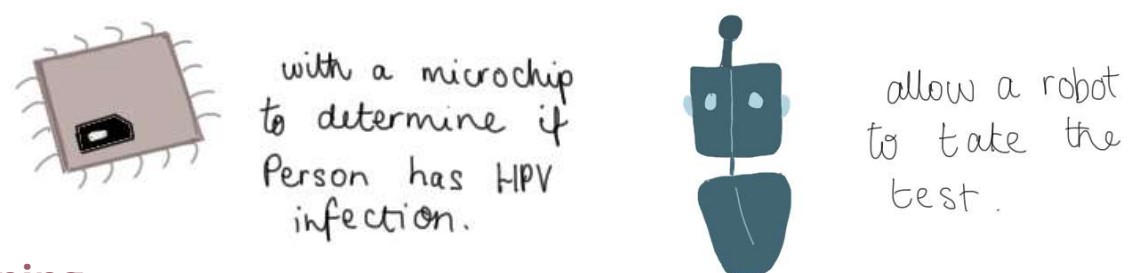
## P ut to another use



## E liminate



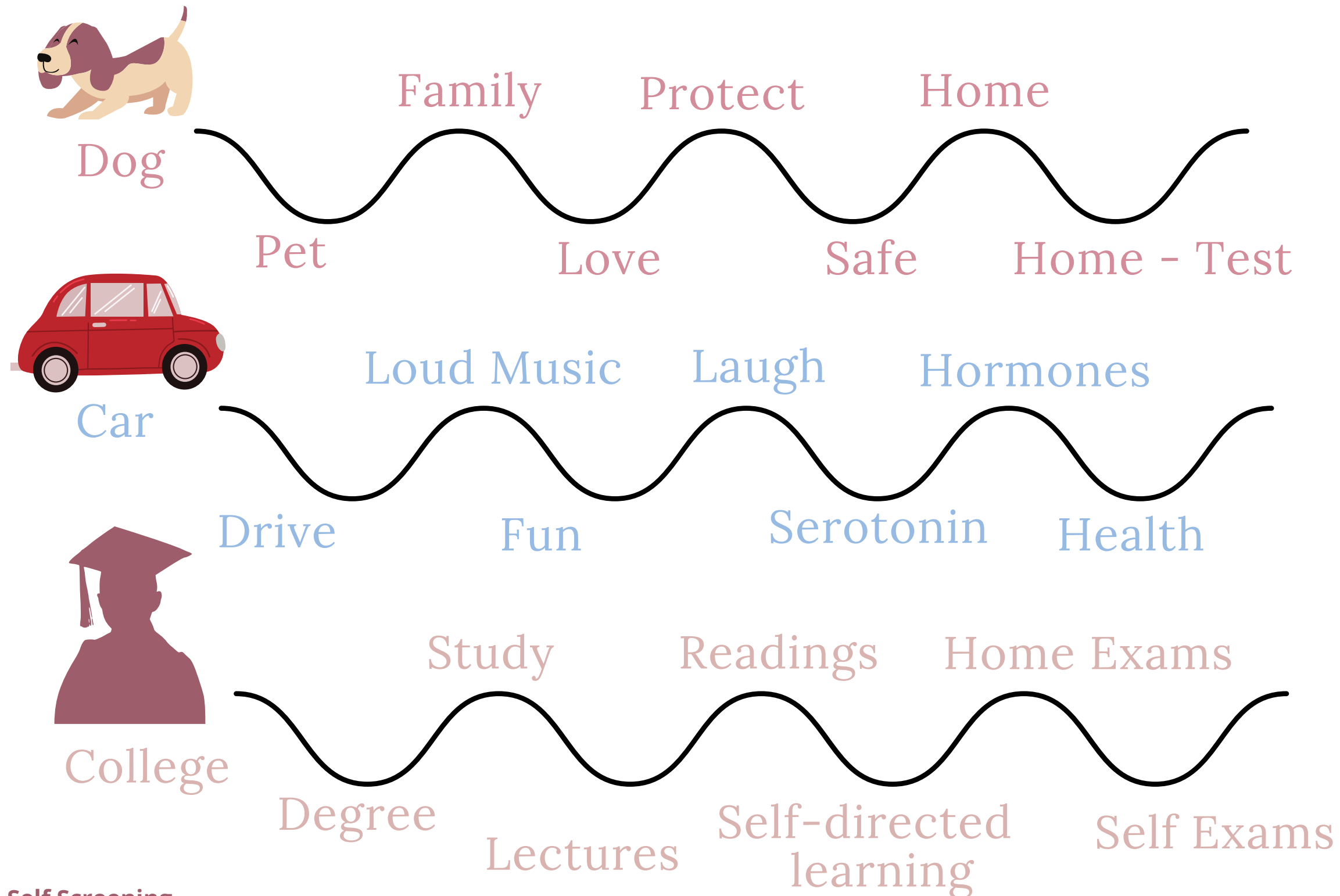
## R eplace



# LATERAL THINKING

Random Input Technique.

A random word is chosen and the author explores its connection with self screening. This technique is useful for exploring random connections to get ideas flowing.



Self Screening

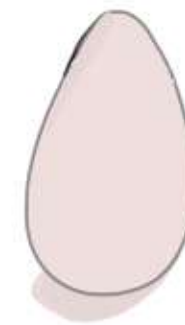
# TREATMENT WHICH DOESN'T CAUSE INFERTILITY



Give patients babies before treatment

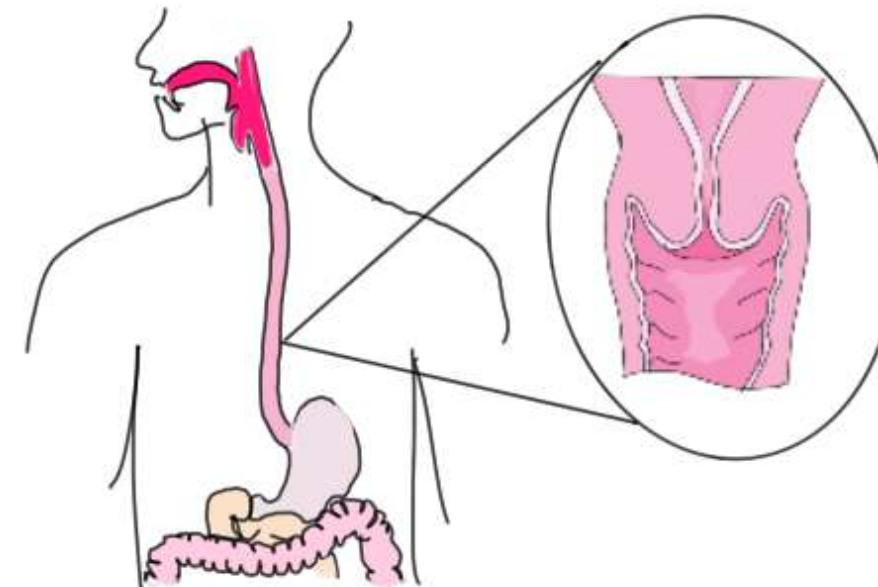


Deliver babies post treatment.



Option to freeze eggs during treatment.

Automatically adopt baby before treatment.

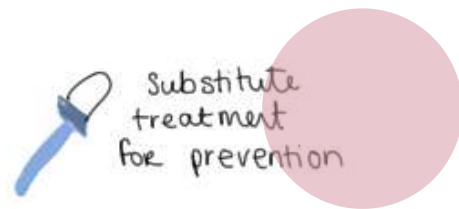


move the cervix from the reproductive system to the digestive system

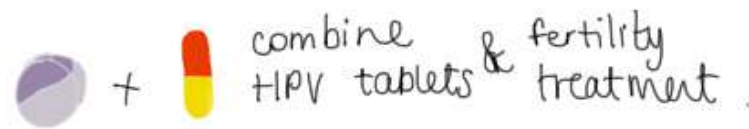
# SCAMPER

Scamper is an effective brainstorming method where the user is forced to explore the acronym and how the problem can be expressed in different ways.

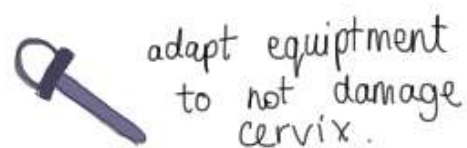
**S**ubstitute



**C**ombine



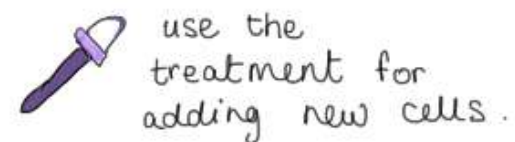
**A**dapt



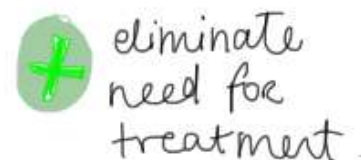
**M**odify



**P**ut to another use



**E**liminate



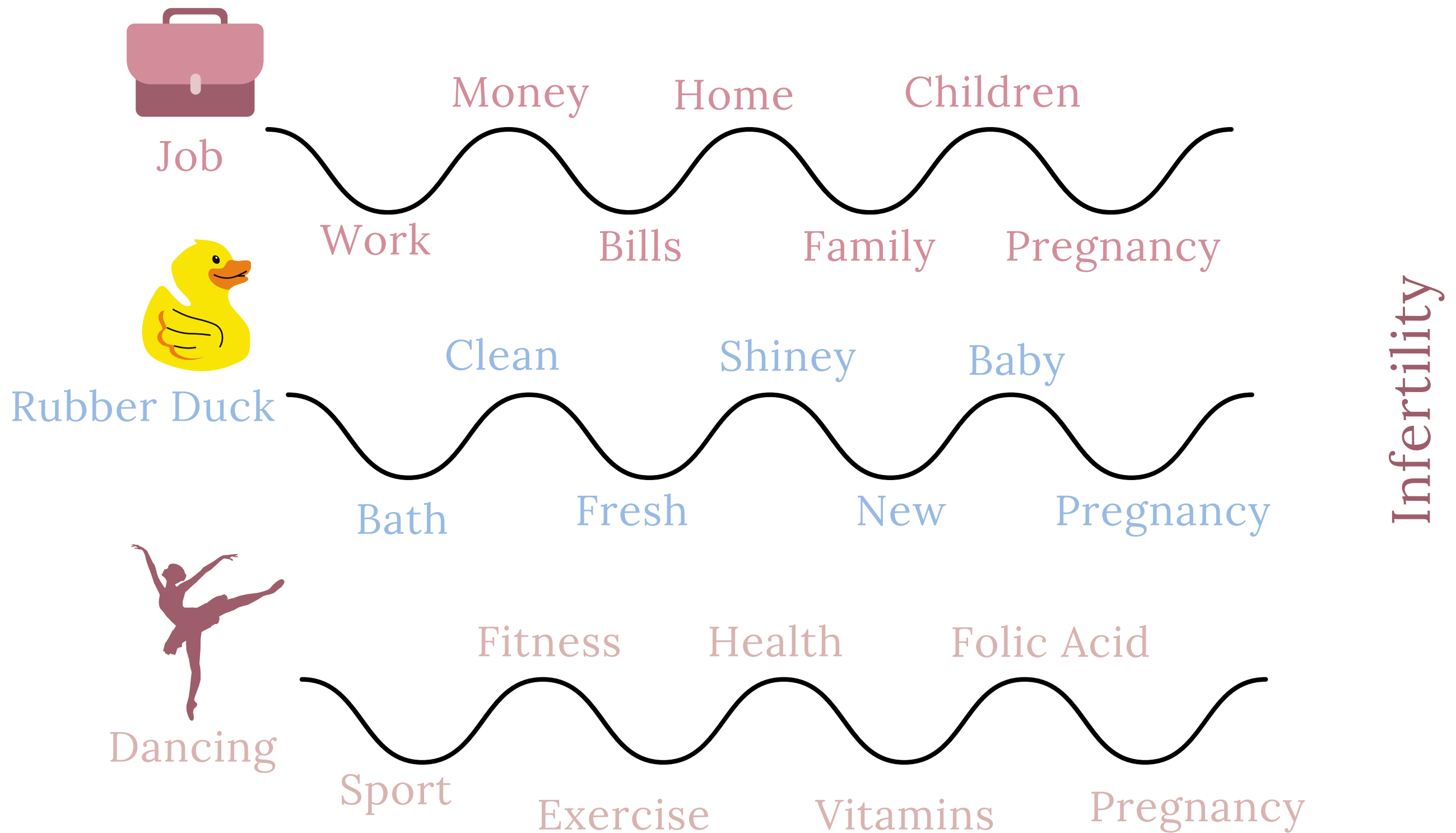
**R**eplace





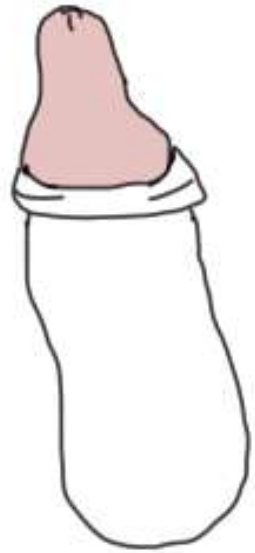
# LATERAL THINKING

Using the random input technique to get ideas flowing for the the need for a treatment that does not cause infertility.



Infertility

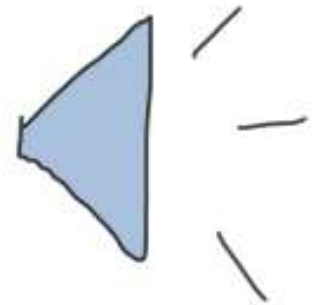
# ADDRESSING SEXUAL HEALTH STIGMA



ween people  
off their  
own pre conceptions  
& prejudgements



Ensure people have the  
Conversation.



follow the  
mental health  
model - speak up  
& speak out.



Separate church  
& state


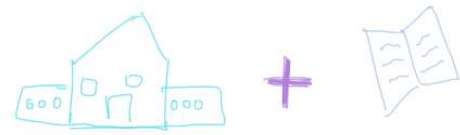
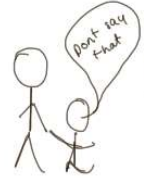




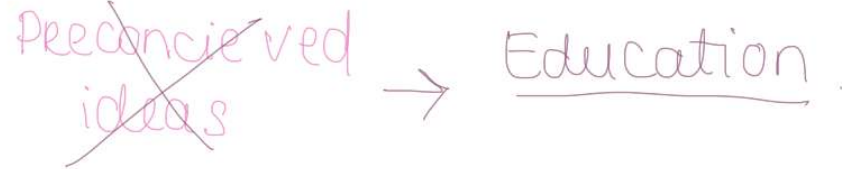


Inclusive education.

- all genders
- all sexual orientation.

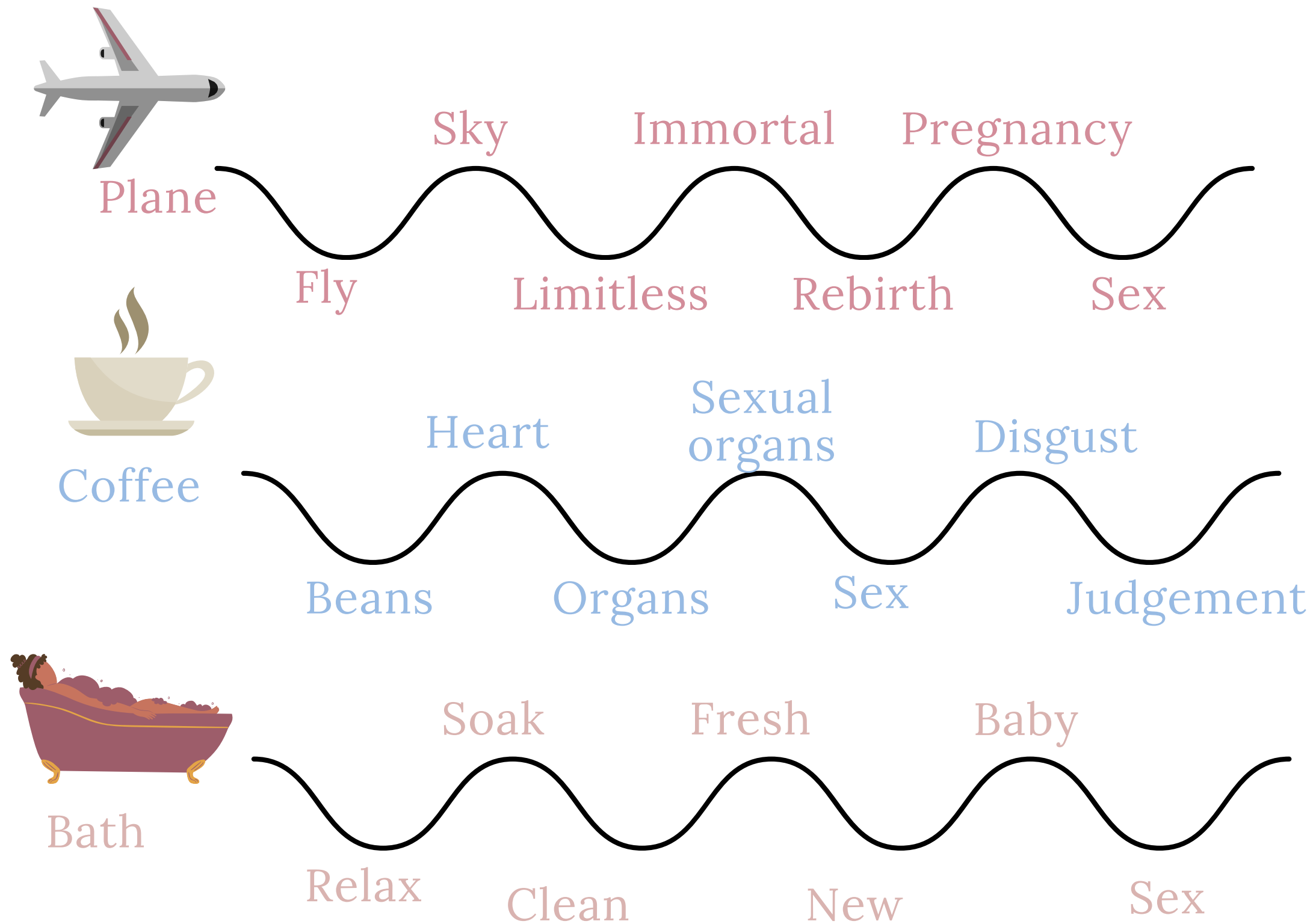
# SCAMPER

Using SCAMPER to determine ways to prevent and remove the stigma surrounding sexual health.

- S**ubstitute  Negative comments with nice comments
- C**ombine  School sex-ed with de-stigmatisation.
- A**dapt  Adapt marketing to target kids.
- M**odify  modify rules to not allow stigma.
- P**ut to another use  make stigma cool.
- E**liminate  eliminate stigma.  eliminate people who stigmatise
- R**eplace  ~~Preconcieved ideas~~ → Education.

# LATERAL THINKING

Using the random input technique to address sexual health stigma.

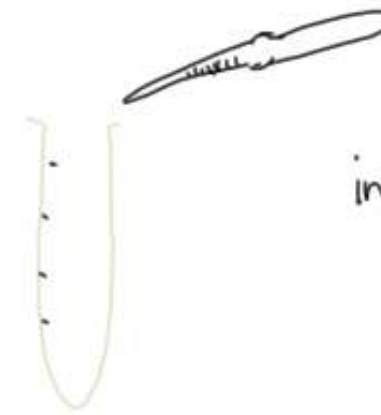


Sexual Health Stigma

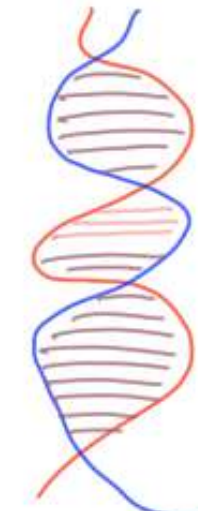
# TRIAGE FAMILY MEMBERS OF PATIENTS



Family tree  
DNA tests identify  
HPV infection.



encourage in-vitro  
in cases of familial CC.



Change DNA to  
be less susceptible  
to HPV infection.



Family Tickets to testing.

parties for testing  
or encourage  
family testing at  
parties.



make it  
an exciting preventative  
event.

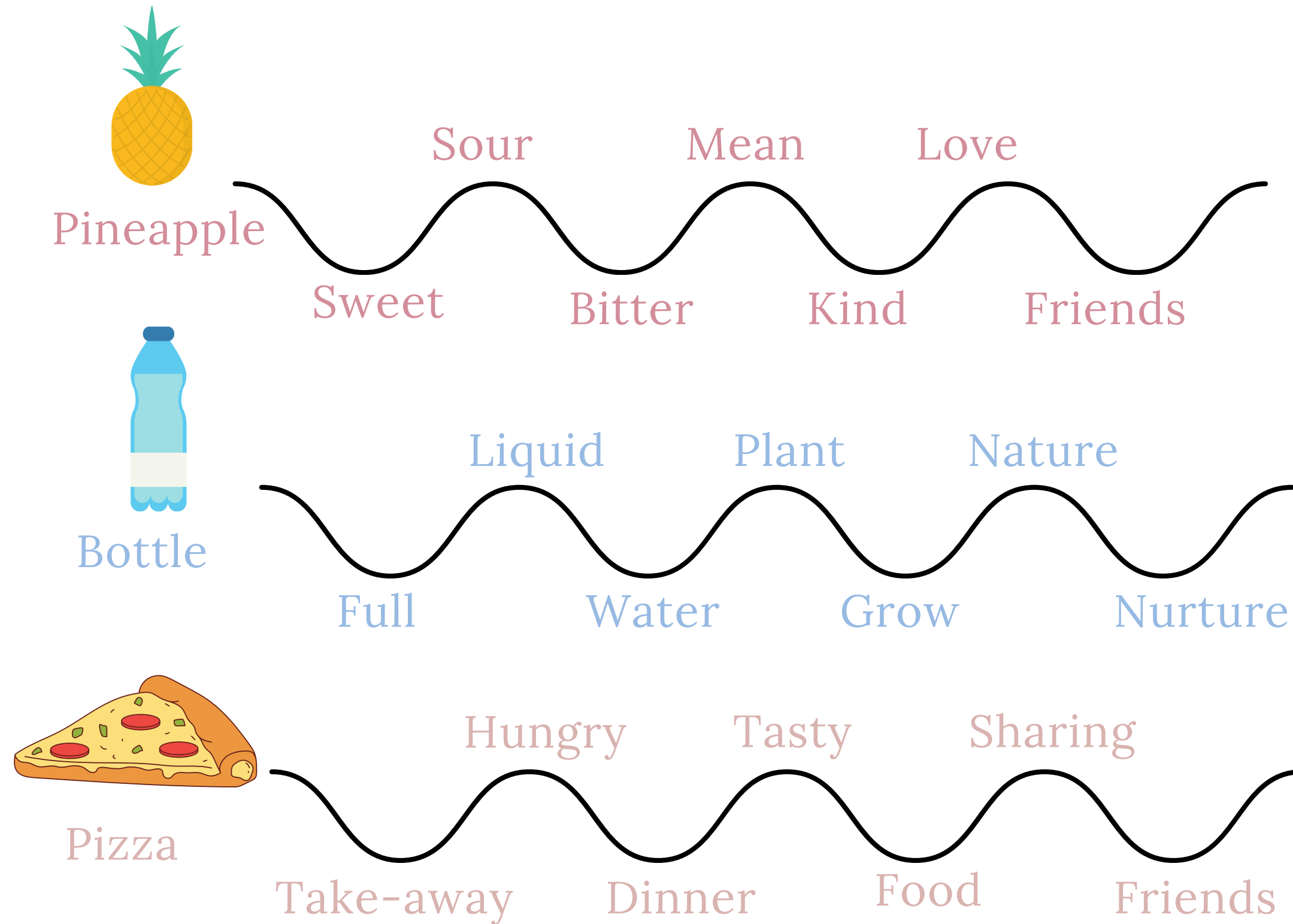
# SCAMPER

Exploring SCAMPER to identify new ways to look at the issue of Triage.

- S**ubstitute  Substitute family members with HPV to stop familial contraction.
- C**ombine  DNA tests with HPV tests.
- A**dapt  Adapt HIV family testing for HPV.
- M**odify  A&E triage system.   modify HIV drugs to work for HPV.
- P**ut to another use  match HPV prone people that don't want kids.
- E**liminate  Eliminate possibility of inheriting HPV.
- R**eplace  replace HPV shame with HPV pride.

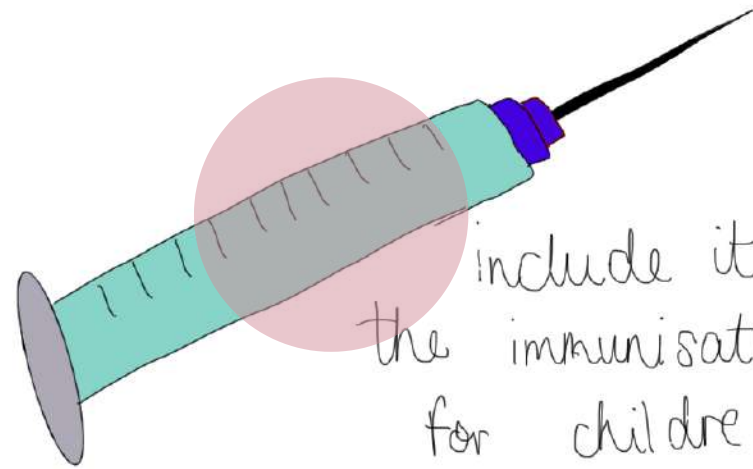
# LATERAL THINKING

Again, using the random input technique to get from random words to family to get the creativity going.



Family

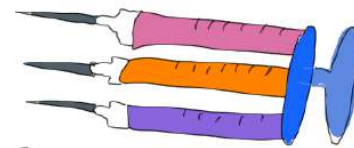
# EQUITABLE ACCESS TO THE VACCINATION



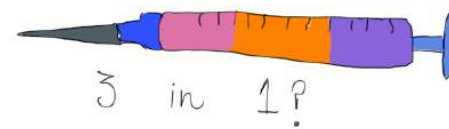
include it in the immunisation programme for children.

Public health nurse delivers injections to everyone in their area.

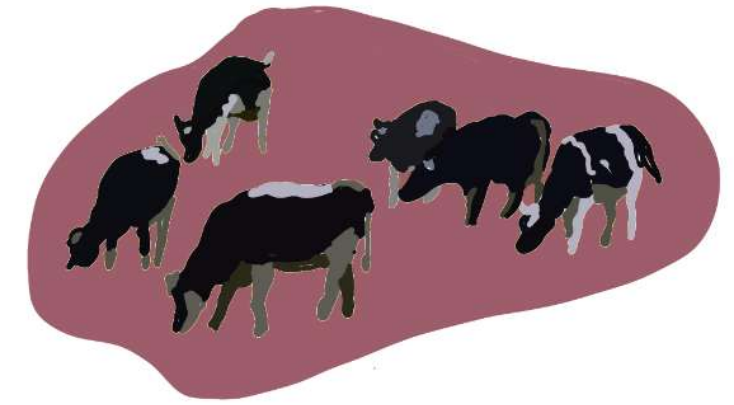
a multishot?



3 all attached?



3 in 1?



Rely on herd immunity.



like an epipen can they inject themselves?

→ or parents?



does it have to go into arm?

↓  
Any muscle works.



# SCAMPER


Using the SCAMPER acronym to explore ways to insure equitable access to the HPV vaccination, and HPV information.

**S**ubstitute  Substitute a traditional compulsory subject with health so everyone does it. 

**C**ombine  Public health nurse visits with vaccine. 

**A**dapt  Adapt the law to insure inclusion in health care.

**M**odify  modify curriculum to cover sexual health in health / PE.

**P**ut to another use  make community nurse responsible for educating kids & parents. Public health nurse gives out vaccines at home.

**E**liminate  Eliminate hierarchy for schools.

**R**eplace  Replace current sex education with compulsory education specialised to age/school area / background.

# LATERAL THINKING

Random Input Technique.

A random word is chosen and the author explores its connection with self screening. This technique is useful for exploring random connections to get ideas flowing.

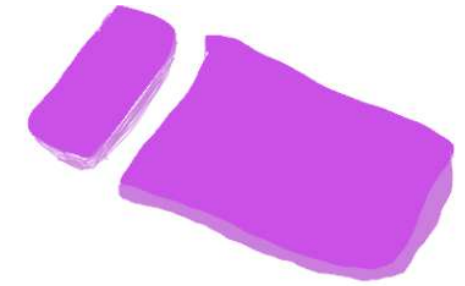


Equitable Access

# IMPROVE SCREENING UPTAKE

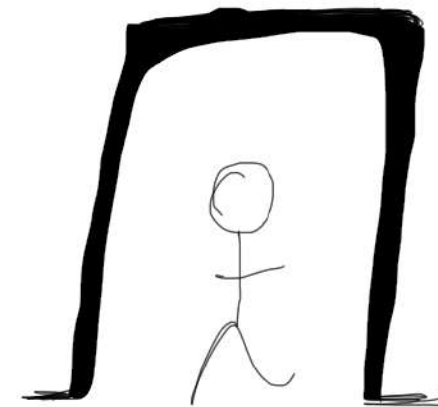


At home testing.



make testing more comfortable.

monetary initiatives to encourage people.



walk-through screening test.



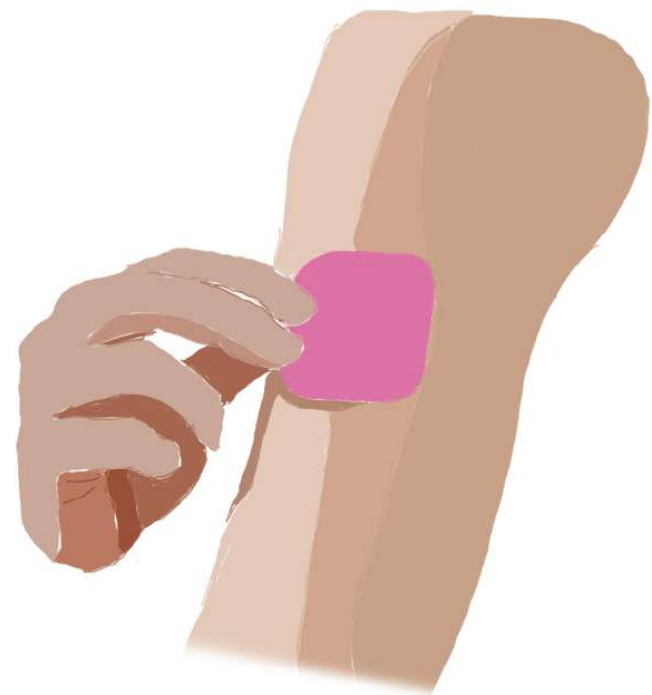
stamp system  
'8th one free' or  
a prize after the  
8th screening.

phone alert  
when it's time  
to test.



badge to show  
you've been  
tested

# IMPROVE SCREENING UPTAKE



wear a patch that releases antibodies to fight HPV infection




A blood test to determine infection

gloves that change colour in presence of HPV.

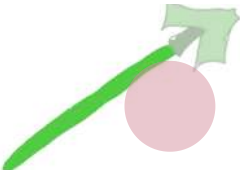


# SCAMPER

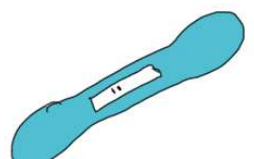
Using SCAMPER to improve CC screening uptake.



**S**ubstitute  Substitute current procedure for something less invasive.

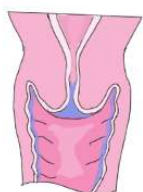
**C**ombine  Combine breast & cervical checks. 2 in 1.

**A**dapt  Adapt the Brush to be less painful.

**M**odify  Modify the speculum to be less uncomfortable.

**P**ut to another use  Use Cervical screening to test fertility.

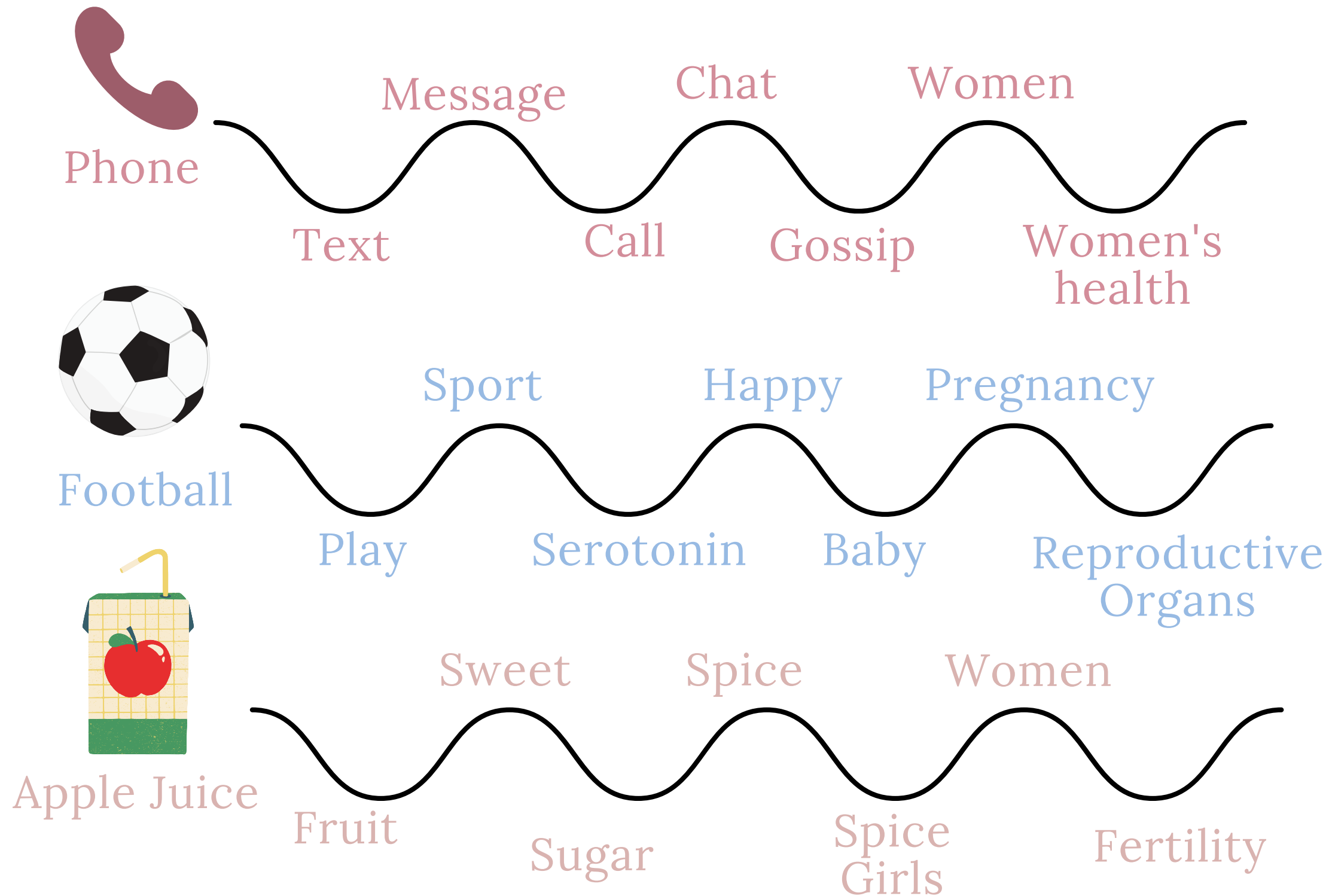
**E**liminate  Eliminate the cervix.  Eliminate Cervical Check. (a major cause for distrust).

**R**eplace  Replace Squamous cells with biocompatible plastics to prevent infection.

# LATERAL THINKING

Random Input Technique.

Mapping the association between random words, and CC screening.



CC Screening

# PROJECT SCOPE REVIEW

After the initial brainstorming the author reassessed the scope of the project and her area of interest. Due to the timeframe given for this project and the number of ideas generated the designer decided to merge two of the needs, and get rid of two of the needs.

Leaving the following 3 needs for exploration through sketches, task flows and prototyping.

1. **Need for self screening which is user friendly**
2. ***A need for equitable access to vaccination & information.***
3. ***A need to improve cervical screening uptake and procedure so that the procedure does not cause infertility.***

The author has already highlighted a number of ideas which have potential to be design interventions, or indeed to hold value for inspiration of design interventions. These will be revisited, explored further and new ideas and scenarios will be identified.

It is important to note that although some needs have been eliminated to focus brainstorming, they are not forgotten and they may be brought back to support other ideas in the future.

# USER FRIENDLY SELF SCREENING

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# USER FRIENDLY SELF SCREENING

Using backcasting, a method of visualising the ideal situation and figuring out what needs to be in place, or happen for this scenario to exist. By imagining a world where women test themselves annually for HPV infections at home, what does it look like and how do we get there?



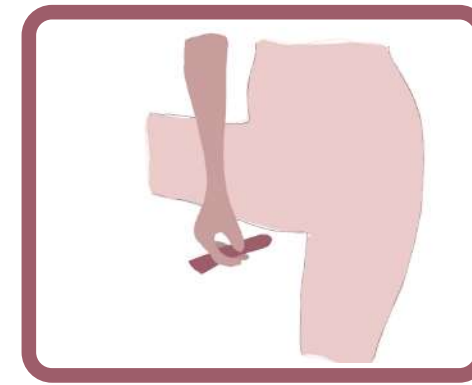
The user can go online and sign up to a subscription of HPV tests, they'll be sent out annually.



The testing kit is sent out via the postal service and delivered to the user at home.



The user will unbox the test, and encounter some bright graphics and tasteful packaging.



The user can use the device much like a tampon, inserting it into the vagina for a HPV reading.

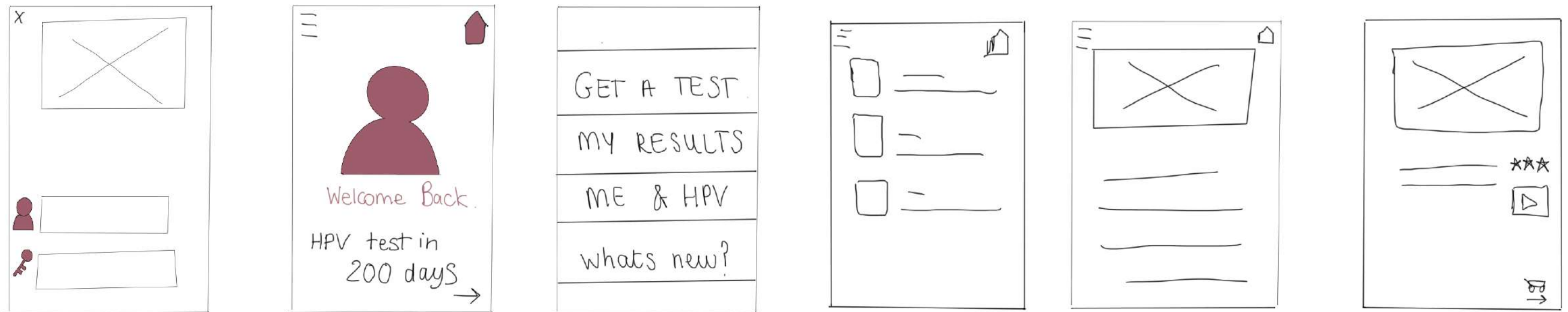


The device displays result instantly, determining if the user has a HPV infection.

This story board, depicts an ideal scenario where the user can order a product online to take their test at home, similar to a tampon, and get immediate results. The author must explore each aspect of this board to determine how it could happen and various ways each stage could be achieved.

# USER FRIENDLY SELF SCREENING

Exploration of an online platform giving information to users about HPV, HPV testing and ordering HPV home kits. Exploring this platform through some wireframes.

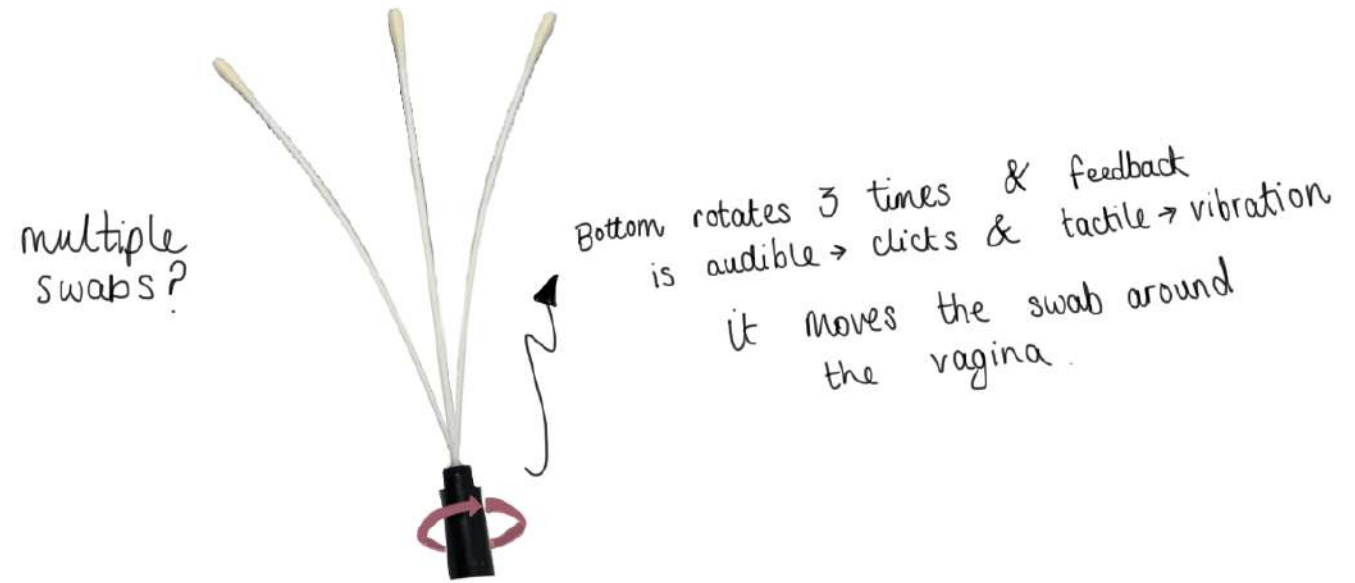


User would create an account with their details. The account would let them view their past tests, their results, learn about HPV and organise tests.

They could order a test online, look at various products and pick which one they want. They would get a rating of ease of use and they could add it to their cart and purchase it.

# USER FRIENDLY SELF SCREENING

The self screening kit needs to be easy to use, and remove the possibility of error, including injury to the user.



like a really long cotton swab.

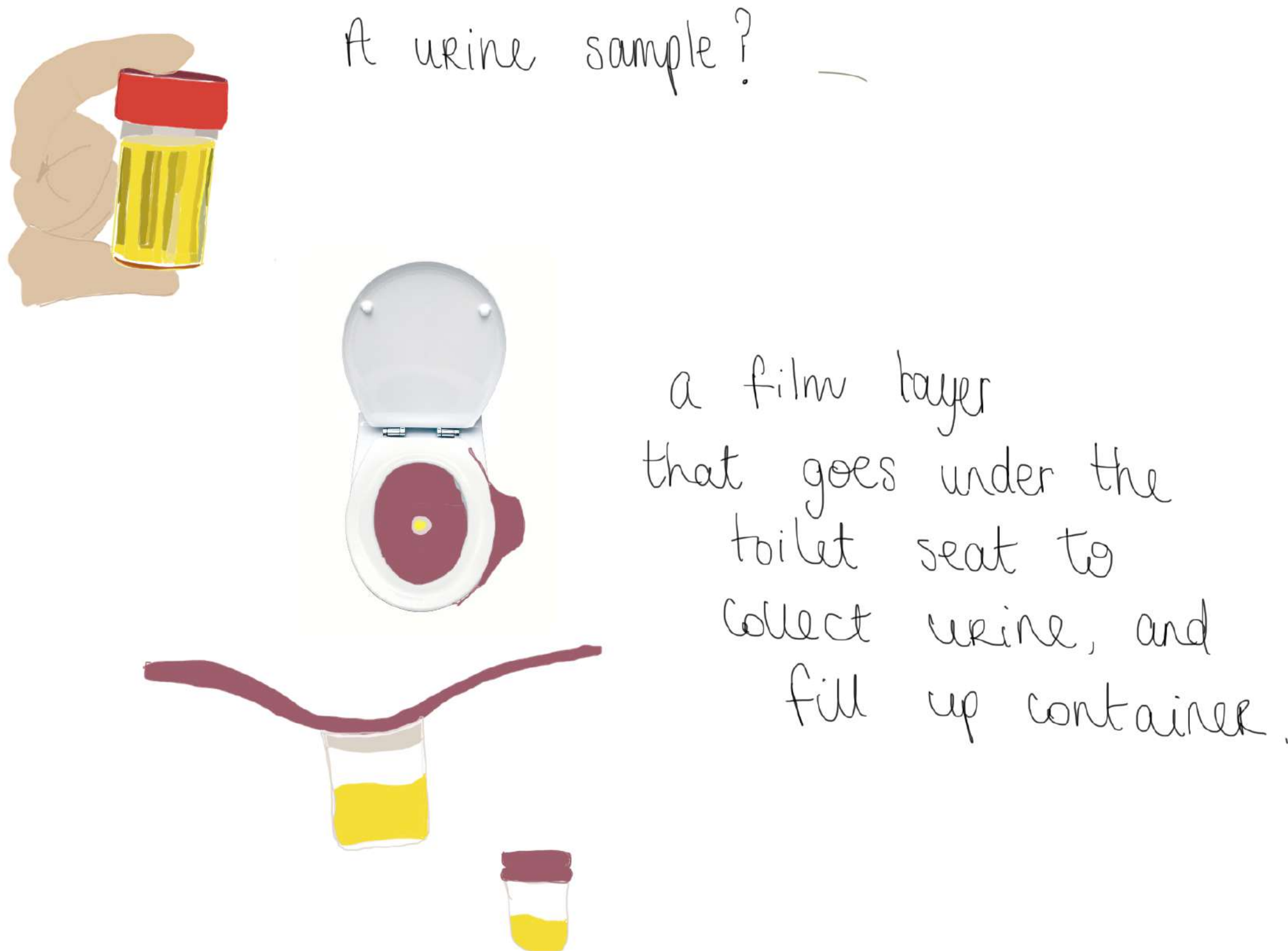


like what is used currently for vaginal swabs.



# USER FRIENDLY SELF SCREENING

The self screening kit needs to be easy to use, and remove the possibility of error, including injury to the user.



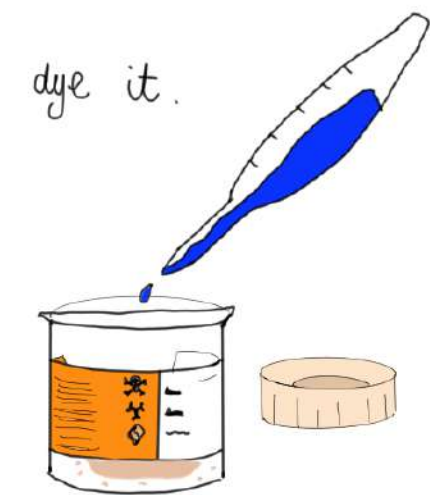
# USER FRIENDLY SELF SCREENING

The self screening kit needs to be easy to use, and remove the possibility of error, including injury to the user.



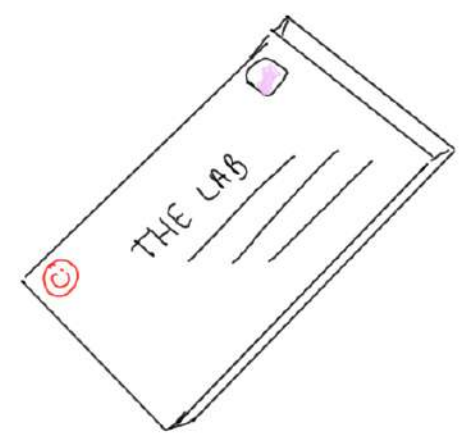
Use a grater type device to grate the skin around warts.

Collect it in a tub.



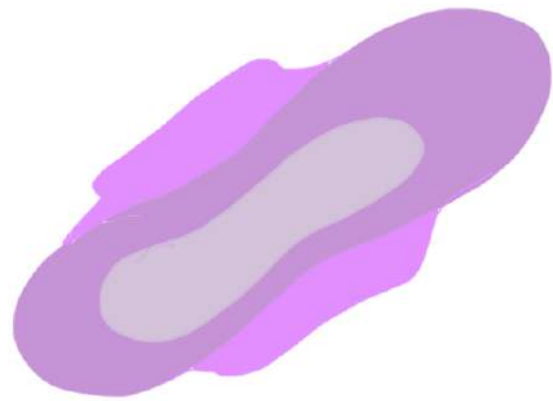
dye it.

Send it to a lab.



# USER FRIENDLY SELF SCREENING

The self screening kit needs to be easy to use, and remove the possibility of error, including injury to the user.



Can the pad catch cells?



The pad changes colour in presence of HPV.

Test pH levels?



The tampon pulls cells from the vaginal walls.



Put the tampon into a container & send it off for testing.

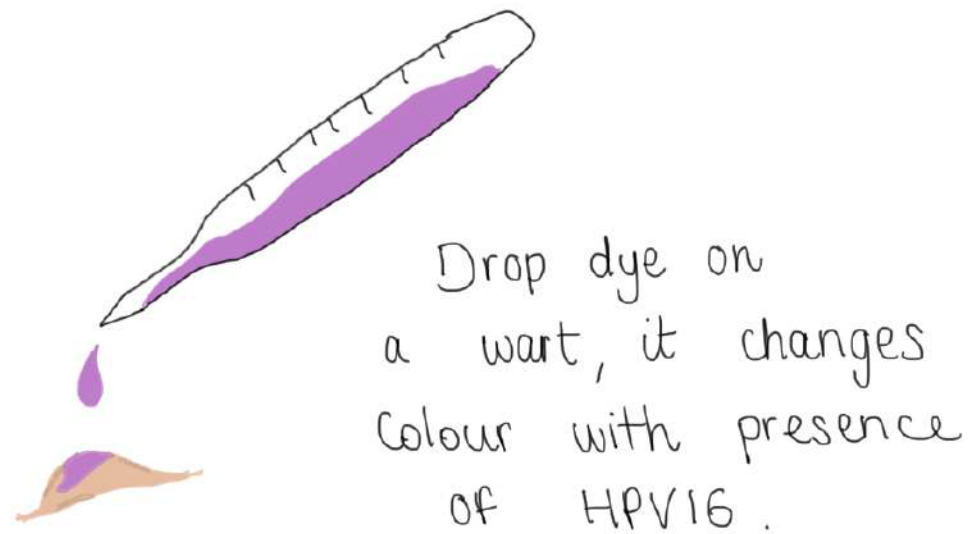
Can the menstrual blood detect HPV virus?



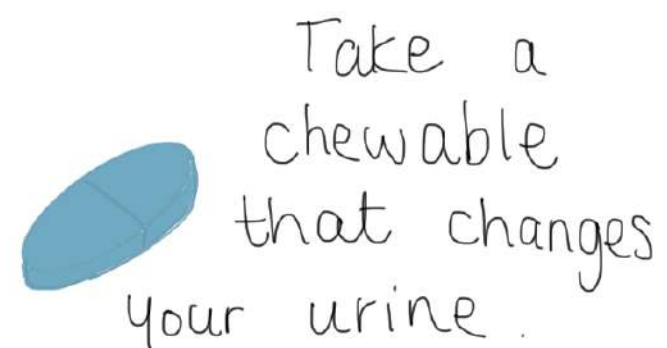
Pour the blood into a container & send it to the lab.

# USER FRIENDLY SELF SCREENING

The self screening kit needs to be easy to use, and remove the possibility of error, including injury to the user.



Drink a powder that changes the colour of your urine in the presence of HPV infection.



# TASK FLOW OF SELF SCREENING

Having a look at problems that might occur during self screening by creating a task flow for a user interacting with the product and highlighting their potential errors.





# USER FRIENDLY SELF SCREENING

Potential errors identified in this task flow include:

1. User being confused by the instructions.
2. User is Unable to insert the device.
3. User inserts the device with too much force.
4. User doesn't insert the device far enough.
5. The user injures themselves.
6. The user gets an inaccurate result.

The author now explores methods by which these errors can be eliminated.

## 1. Instructions



Step by step instructions on an app.



Audio - descriptive instructions for insertion & reading results.

# USER FRIENDLY SELF SCREENING

## 2. Insertion Issues

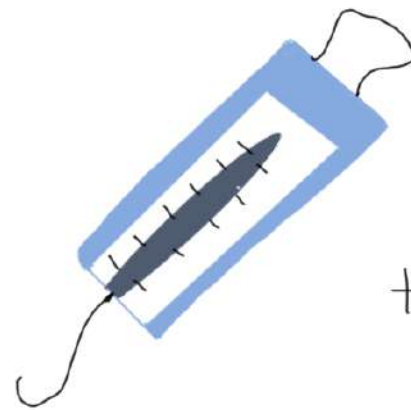


accompanied by  
a tampon applicator  
type device.

## 3. Too Much Force



a weighted handle  
to make it more  
difficult to force  
it in



measure the  
force used by  
the user & notify  
them or prevent too  
much force.

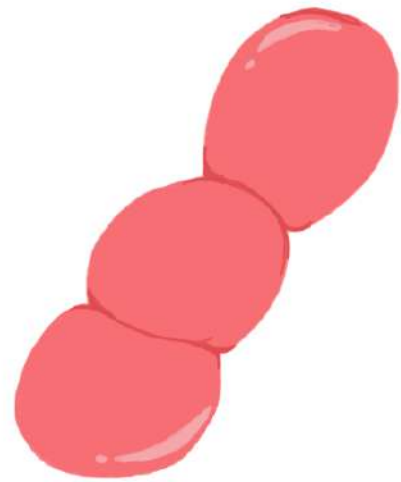
## 4. Not inserted far enough



a pre determined  
distance for the device  
to be inserted in.

# USER FRIENDLY SELF SCREENING

## 5. Causes Injury



rounded edges  
to avoid injury.

## 6. Inaccurate Results



Double check results  
by sending them to the lab.

# SELF SCREENING BARRIERS

The idea of self screening for HPV is not without its issues, it has been reported that some women need reassurance from their practitioners that the test is effective.

The inability to determine whether the test has been completed correctly and the fear that the user could not carry out the testing have been seen as barriers to self screening (Mira *et al.* 2016). This issue was also identified through primary research, finding women didn't trust themselves to carry out the procedure.

One study, focusing on women in Ethiopia cite spousal permission as a main barrier to self screening (Brandt *et al.* 2019). Although this was not mirrored in primary research it is an important cultural difference worth exploring if a design intervention should be applicable in other countries. Perhaps educational interventions in places where this is of concern, could focus on males, educating the men to empower the women. As well as this, there could be an emphasis on testing both male and females so it is no longer a female issue, and may become less stigmatised.

# TRUST THE SCREENING

Research highlighted that some women would need re-assurance from their doctor before carrying out the procedure, and other women doubt their own ability. How can these issues be resolved?

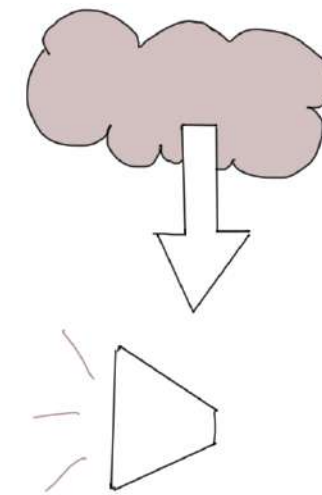
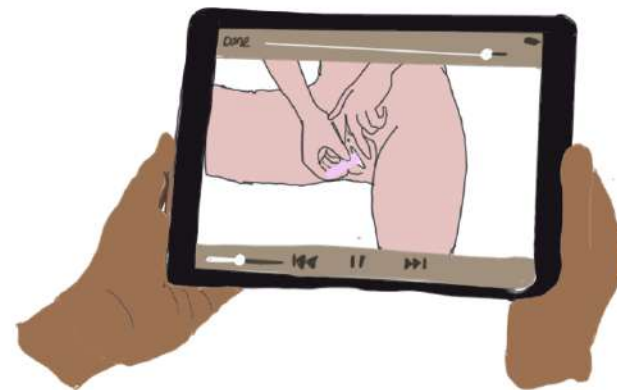


Ring an on-call doctor.

Ring your own GP.



Watch a step-by-step video explanation



Download audio descriptive guide.

Online customer rating for ease of use.



# HOW IS HPV DETECTED?

Identifying how HPV is detected, will provide rigor to the ideation concepts developed, whether they will be able to support the current methods of HPV detection.

HPV infection is most commonly detected through productive infection for example warts where the virus particles can be detected by electron microscopy and immune detection of the virus capsid protein (Villa 2006).

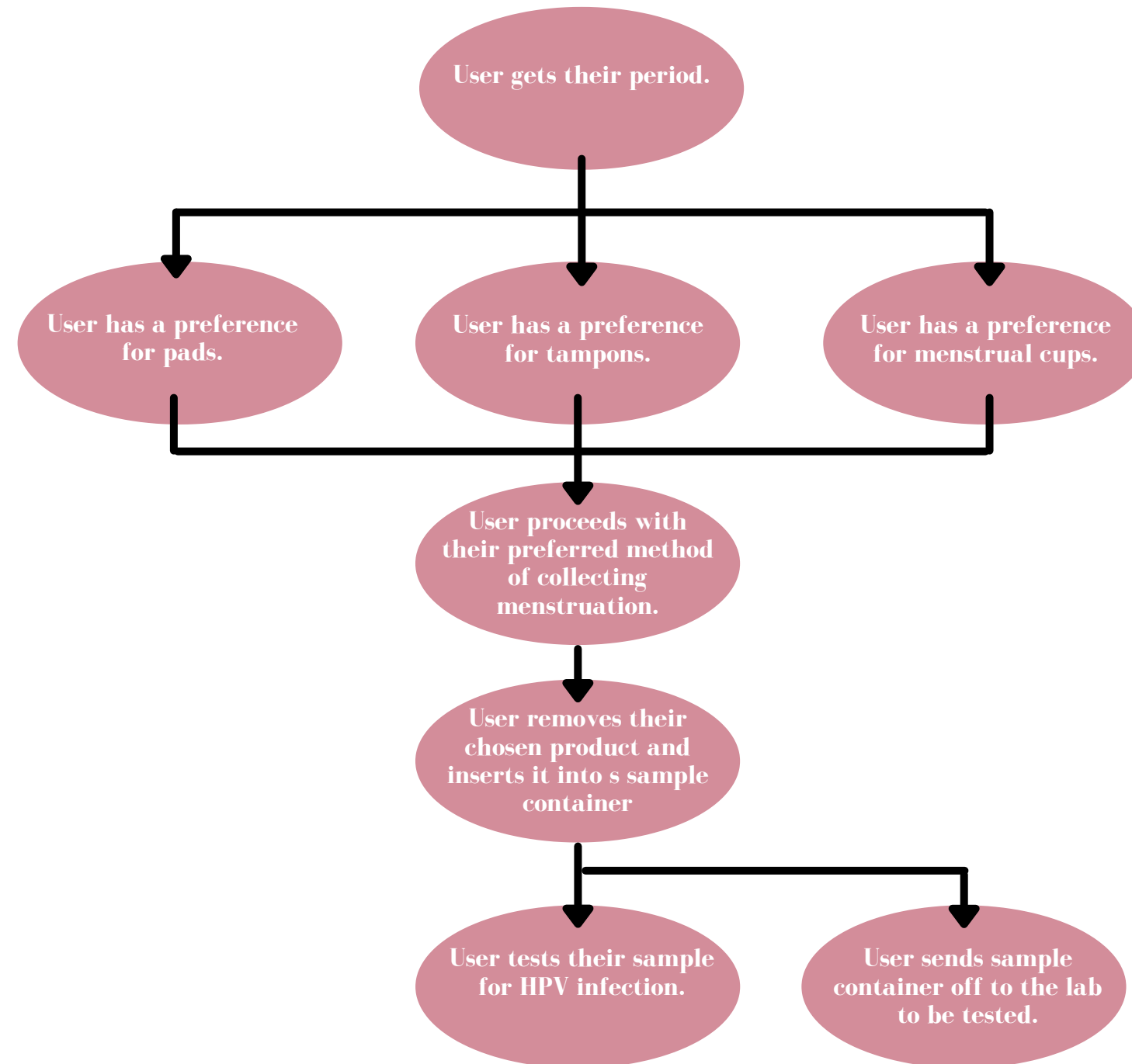
HPV infection is difficult to detect because these capsid proteins are only present in productive infection. In early infection these proteins are expressed in small quantities so they are difficult to identify. As well as this there are few antibodies produced which are specific to HPV (Villa 2006).

There is no one biomarker which can predict the progressions of lesions into CC (Arbreu 2012). However recently it has been found that genotyping is suitable for determining risk of CC. As previously identified HPV16 plays a significant role in the risk of CIN3 (Bonde 2020).

A number of studies have identified menstrual blood to be a suitable bio-marker for HPV infection (Wong et al. 2010; Lee et al. 2016; Wong et al. 2018). This is promising as menstrual blood may be obtained in a non-invasive manner.

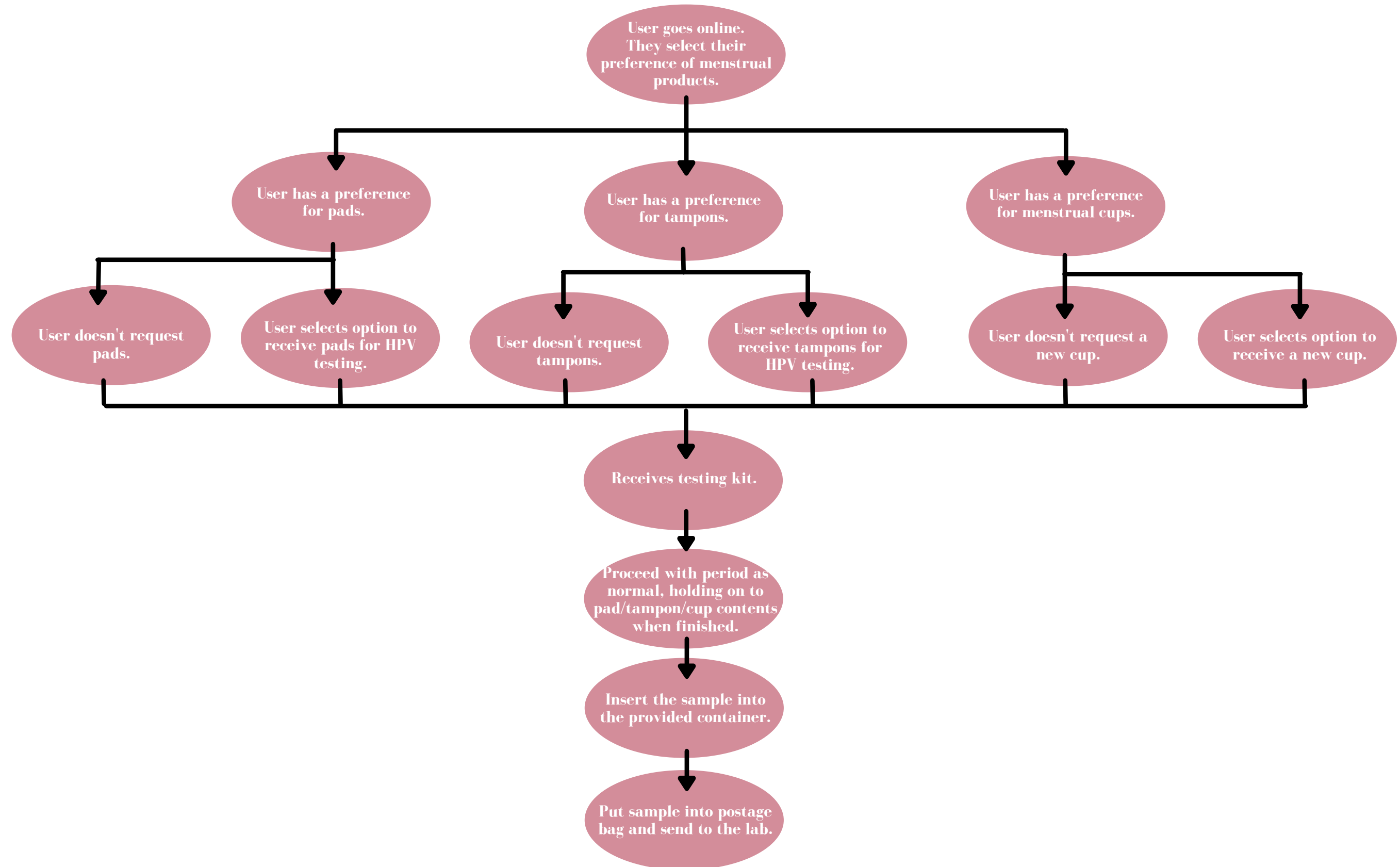
# MENSTRUAL BLOOD & HPV

As research suggests menstrual blood to be an efficient method of monitoring HPV infection. How would it be obtained, and tested in a user-friendly way? Using a task flow to identify the process and where design intervention can be used.



# MENSTRUAL BLOOD & HPV

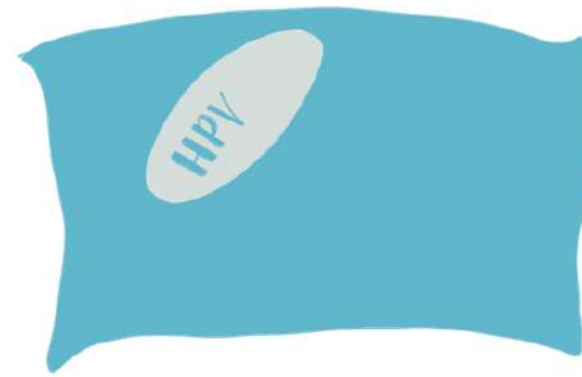
Exploring how a user might experience an online sign up and purchasing of a menstrual blood HPV testing kit.



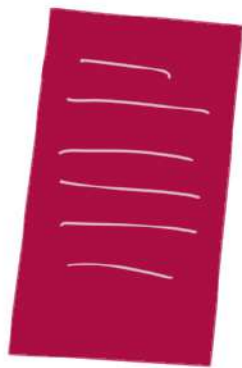


# MENSTRUAL BLOOD & HPV

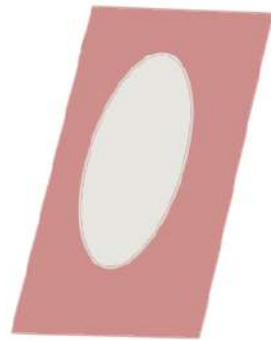
If a user opts to register online for menstrual blood HPV testing, what would it look like?



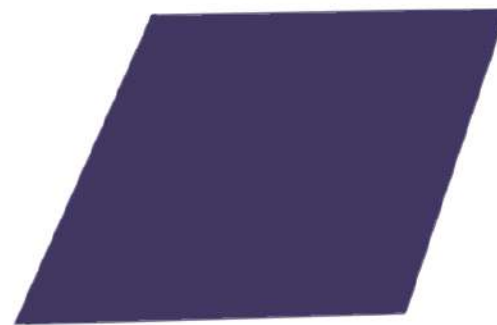
HPV testing kits given out in period packs.



information leaflet.



Re-usable pads /



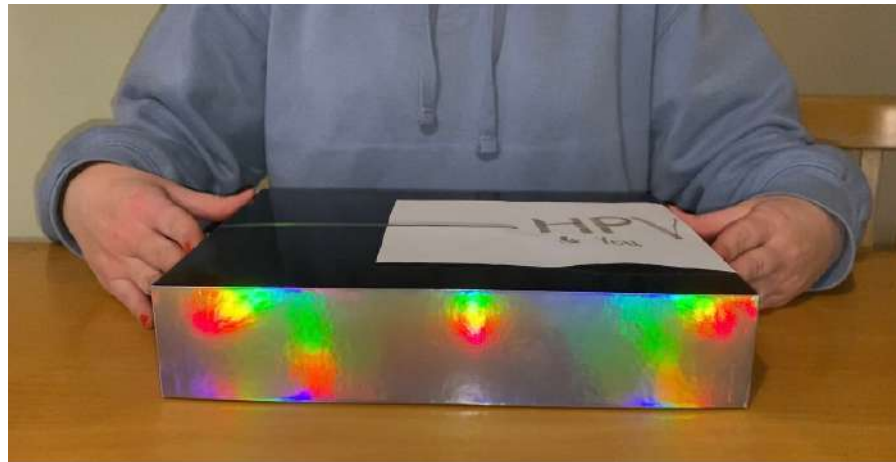
Re-usable sanitary underwear



A menstrual cup.

# PERIOD PACK & HPV KIT UNBOXING

What would the unboxing of this pack look like? What is contained inside? These packs could be given out in schools, workplaces and college campuses.



User receives their Period Pack & HPV kit from their job.



They open the pack and remove its familiar contents, pads tampons and a menstrual cup.



The user located the HPV kit. They didn't know what the box was for at first but presumed it was the HPV test.



They unboxed the HPV test which was packaged separately so it did not open or get damaged during transit.

## **User Feedback**

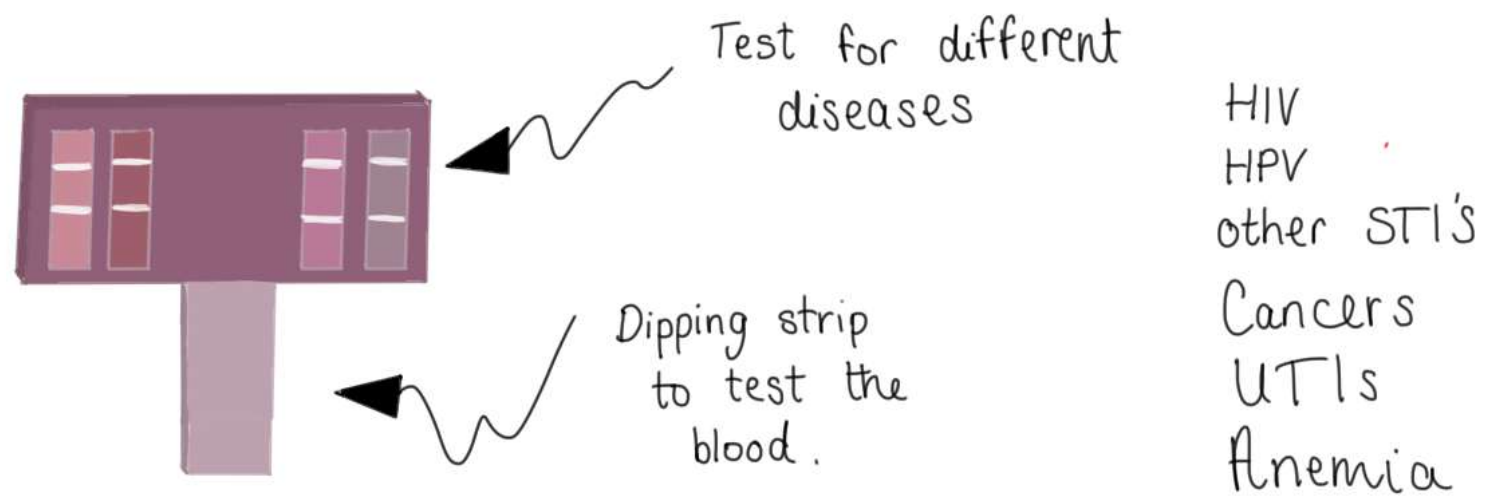
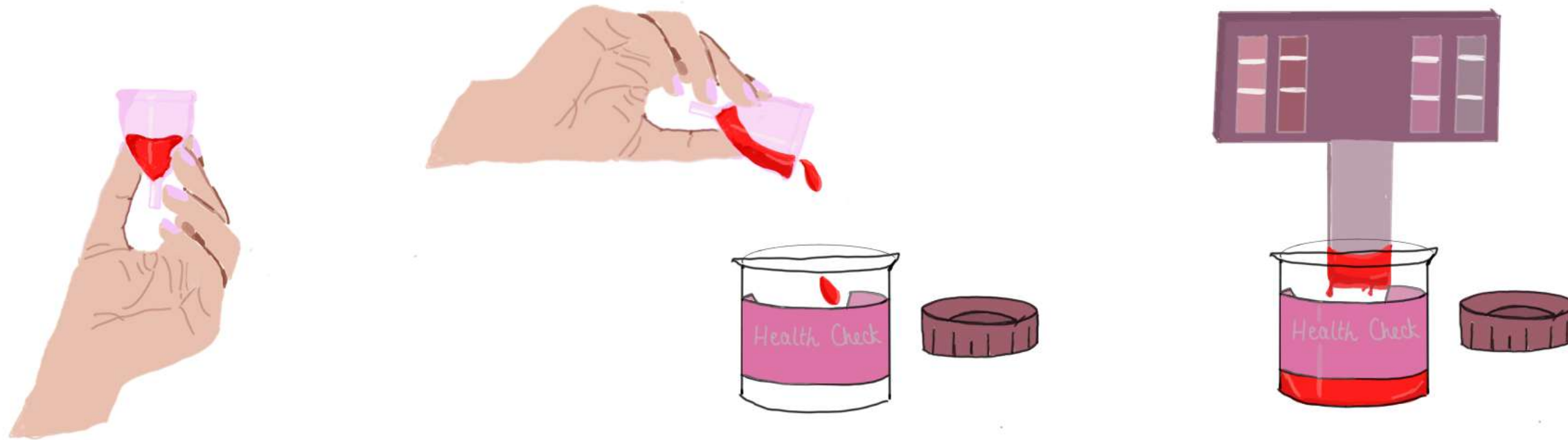
The user noted they loved the box, perhaps a more subtle logo or subtle branding rather than the HPV on the front in big letters would make it easier to receive in the workplace. They also noted it was quite a large box. Containing a lot, perhaps one type of period product rather than a selection.

## **Findings**

The box was easy to move through, and user understood the concept very easily. As noted by the user the next iteration should be smaller in size and have different branding. As well as that perhaps an shift of emphasis to period health including period 'treats' like chocolate instead of including tampons, pads and menstrual cups, allowing choice of pack contents.

# MENSTRUAL BLOOD & HPV

Can users use their menstrual blood to test for HPV and identify other diseases?



# MENSTRUAL BLOOD & HPV

What does the process of the HPV screening look like?



User orders the kit online.



The kit comes in the post.



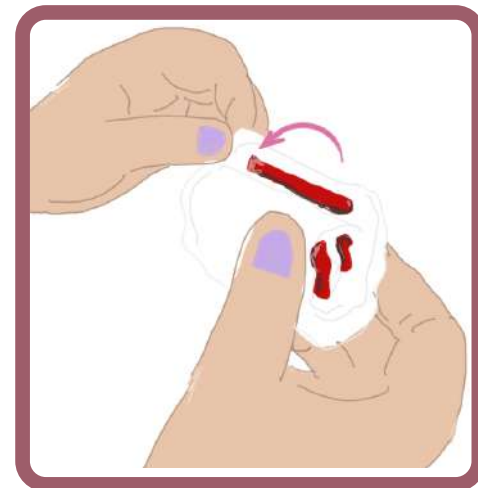
They open the box & read instructions.



They apply the pad to their underwear.



User wears the pad during the day.



User removes the pad at the end of the day.



They place the pad in the prepaid envelope.



They get a text with their test results.

# MENSTRUAL BLOOD & HPV

Using a low fidelity prototype with a user to identify potential problems with this concept.



User has removed their tampon and inserts it into the container provided.



User writes their details on the slip.



The slip is placed inside a plastic vile to avoid contamination.



They secure the lid and their tampon is ready to be sent to the lab for analysis.

## **User Feedback**

The user noted that the idea of inserting the blood covered tampon to be a bit disgusting, what if they didn't have it in the bathroom or if their period was heavy. They found the concept easy to work through.

## **Findings**

The information should be better designed into the process, rather than being written on a slip and inserted, perhaps it has an external sticker, the container has a code specific to the user to avoid mix ups.

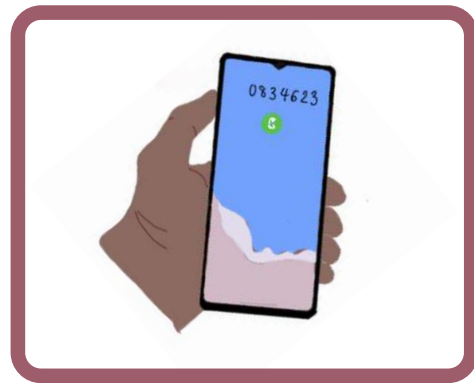
It was difficult to read the users hand writing, which could lead to confusion within a lab setting. So the next iteration should consider using another way to identify the sample.

# EQUITABLE ACCESS

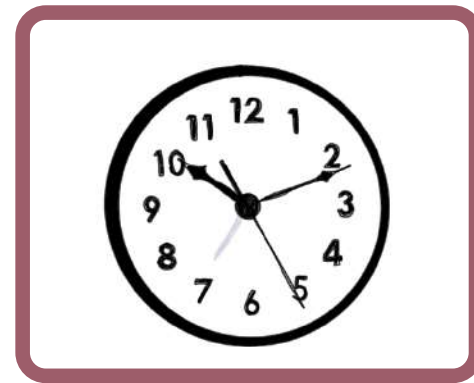
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# EQUITABLE ACCESS TO VACCINATION

As with before using backcasting, identifying the ideal scenario and how to get there. The ideal scenario is every child has access to the vaccination and they have information about the vaccine which they can comprehend.



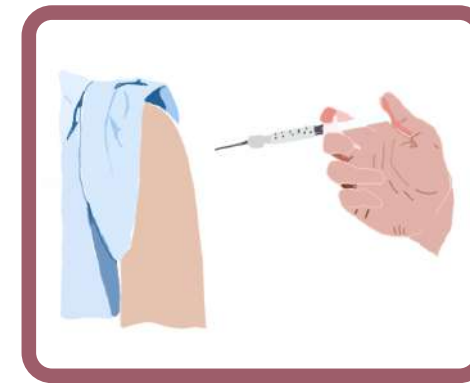
The immunisation team contacts parents of children in the travelling community and in direct provision.



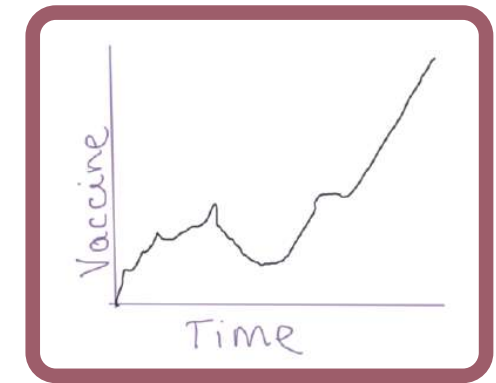
They organise a time to meet and vaccinate the child. They are offered information prior to the vaccination.



The public health nurse or member of the immunisation team attends the place of residence of the child.



They vaccinate the child and provide them with relevant information to their level of literacy in their language.

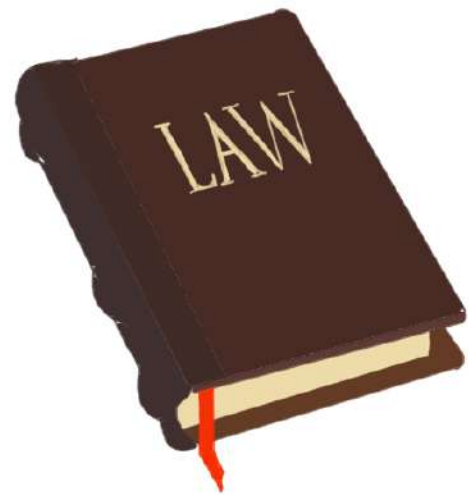


The uptake of vaccinations increase and previously excluded groups are now receiving vaccinations.

This story board, depicts an ideal scenario where the child is provided with a vaccination regardless of their educational status. The current system, as we are aware caters for students in school and provides a 'mop up' clinic to reach children who may have been absent at the time of the vaccination.

# EQUITABLE ACCESS TO VACCINATION

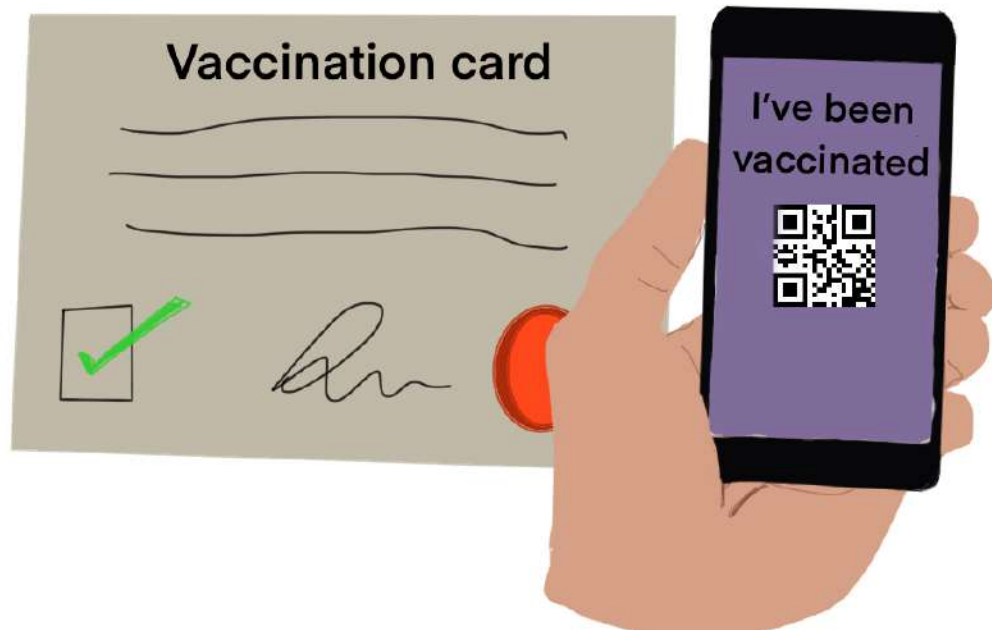
For equitable access, it is likely to be a top down approach, in that governing bodies must make changes which will in turn be accepted by the people. (get a reference)



make it illegal  
to miss your  
vaccination.



new legislation  
allowing non citizens  
& refugees qualify  
for healthcare  
& the HPV  
vaccine.



A mandatory  
vaccination card  
& QR code  
required for travel.

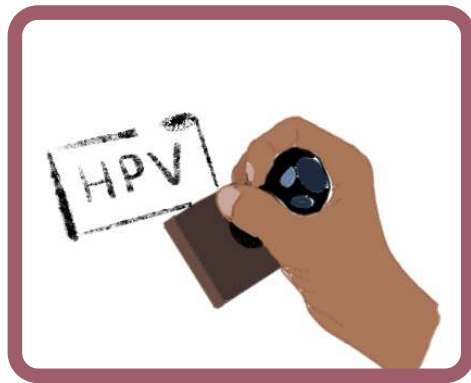


a van  
drives around  
telling people  
to sign up.



# VACCINATION PASSPORT

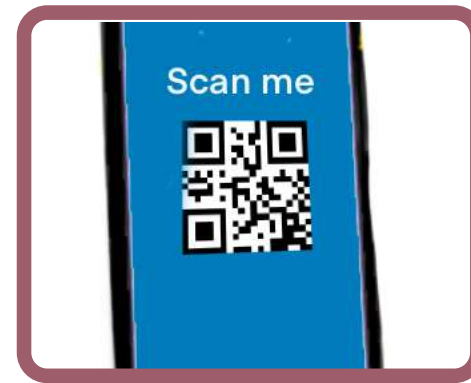
Storyboarding the use of a vaccination passport, required for travel.



Upon receiving the HPV vaccination, the nurse stamps the vaccination passport.



The vaccination passport can be accessed online.



The app provides the user with a QR code which can be scanned to show proof of vaccination.



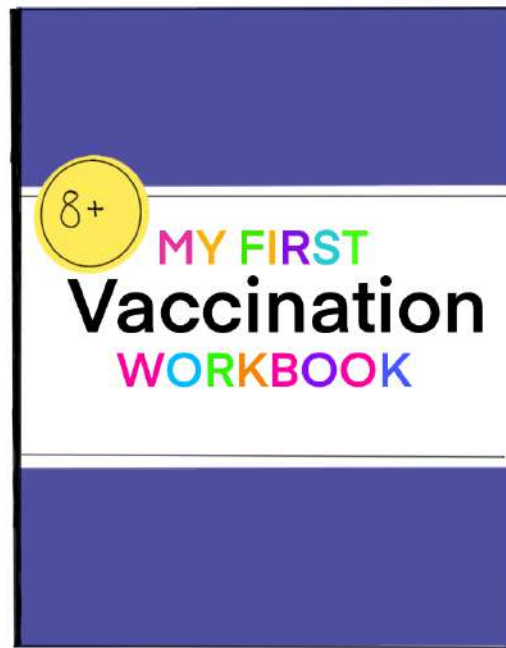
Another phone can scan the QR code and get a notification to open up the vaccination records.



The other person can view the records of vaccination.

# EQUITABLE ACCESS TO INFORMATION

Vorstors (2017) makes reference to a number of ways to increase access to information about the HPV vaccination, including; an FAQ guide, a hotline, and through the media. They note that media also plays a key role in the acceptance of the vaccine, and that it is important for journalists to be briefed so they do not spread fake news. It's also noted that relatable language, colour and trendy design should be used to convey the importance of the vaccine to these girls.



a workbook to learn about vaccination & HPV.



An informative podcast.



an audiobook version available for lower literacy levels / preference.



a vaccination storybook.

# EQUITABLE ACCESS TO INFORMATION

Storyboarding a scenario where children are given workbooks in school, and they go through them with their parents at home. A task flow should follow this storyboard, as the storyboard depicts a perfect scenario and it is important to explore other ways this could unfold.



Workbook is handed out in school.



Child brings the workbook home.



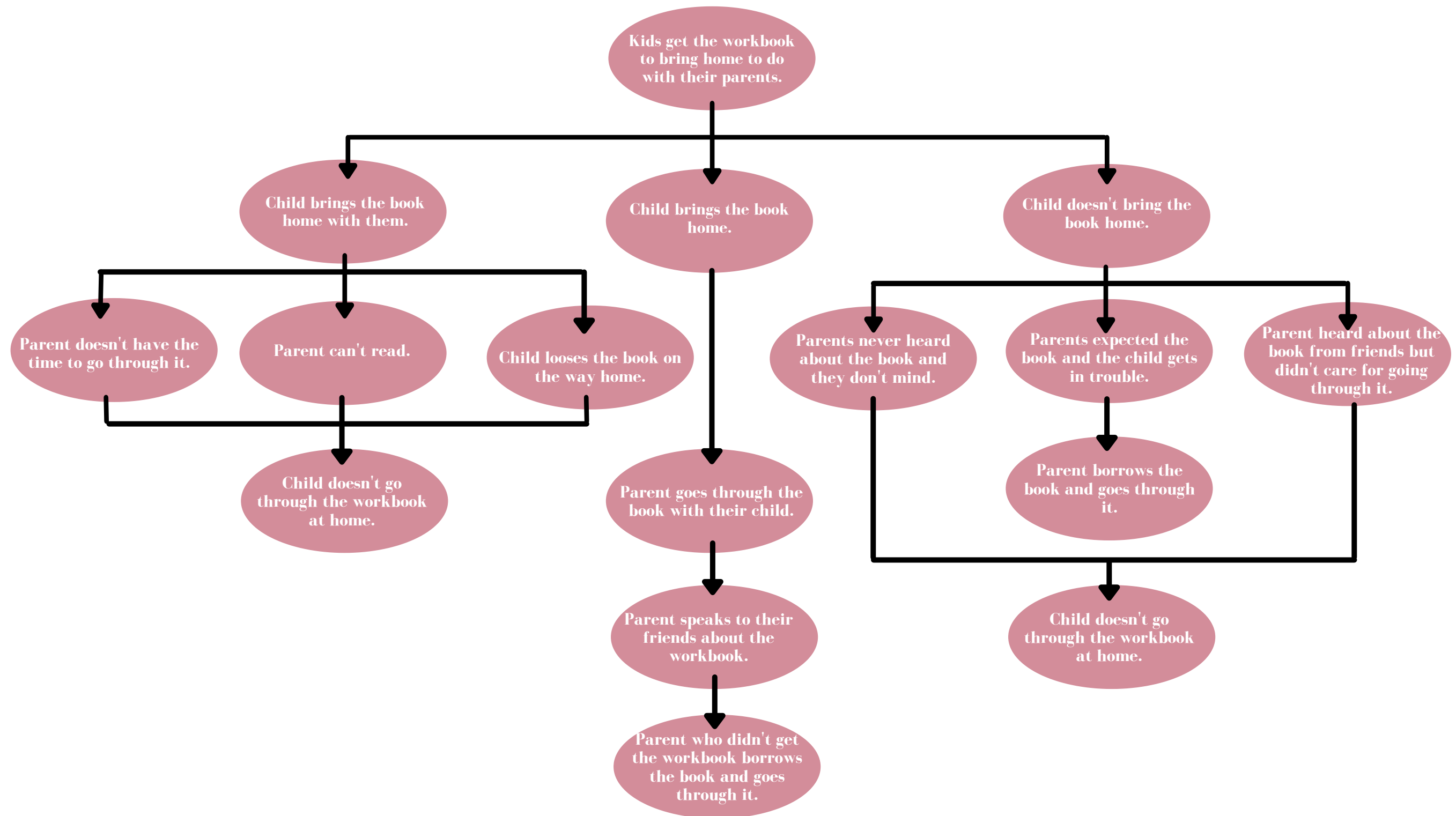
The parent and the child go through the workbook together.



The child is familiar with vaccinations & their importance. They understand the vaccine when they get it themselves.

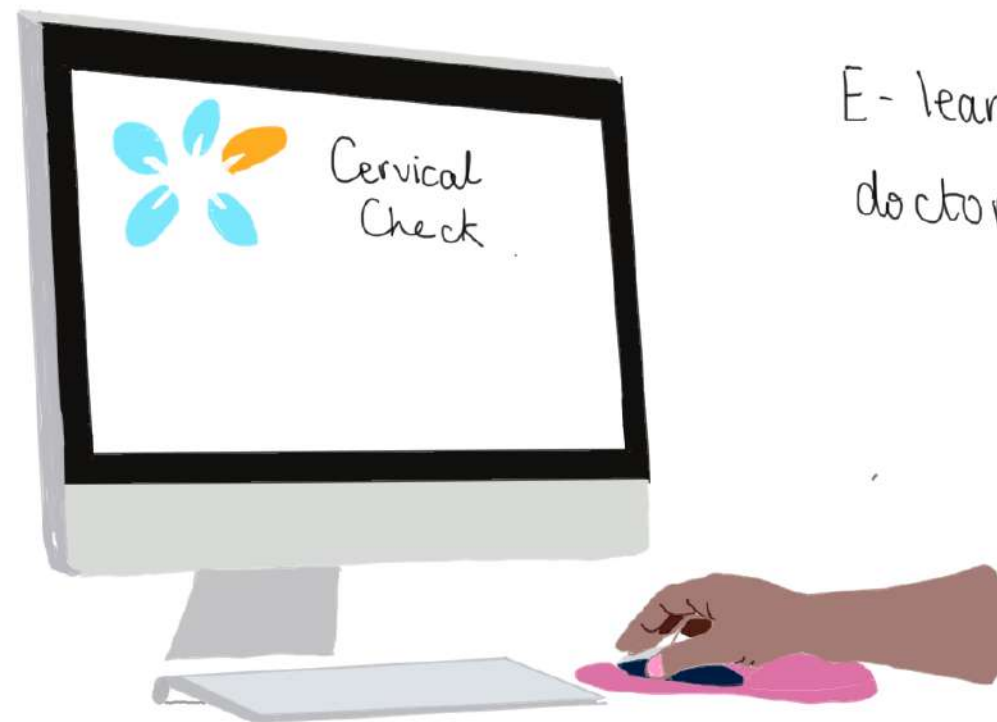
# EQUITABLE ACCESS TO INFORMATION

Using a task flow to explore various ways a workbook would fit into peoples lives.



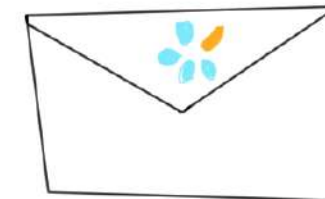
# EQUITABLE ACCESS TO INFORMATION

GP's and healthcare workers are the most trusted source of medical information (Bouder 2015). How can they be kept in the loop about vaccination information and ensure they provide correct, unbiased, relevant information to those who need it?



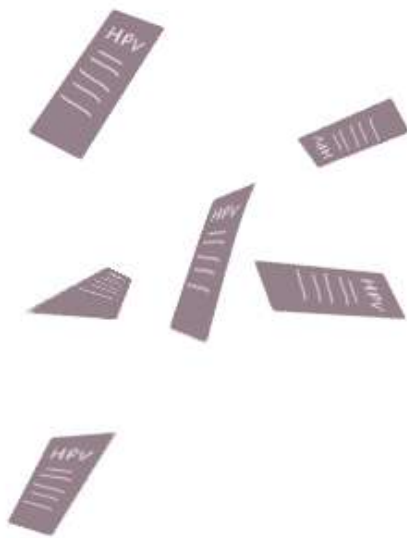
E-learning for doctors.

Weekly/monthly email update.



# EQUITABLE ACCESS TO INFORMATION

If the target group have no access to the internet or phones how can they get the information? Can the HPV information be dropped from a helicopter? This technique derived from helicopter money an economic term for dropping money to boost an economy (Buiter 2003). When used by the Syrian government, before the army would attack cities, it is used to warn civilians and get them to leave their homes. They use pictures due to low literacy levels in the country (HASHTAG SYRIA 2020).



Drop information leaflets on the city / town.

↳ what about people who can't read?



The Syrian government drop these types of leaflets on cities



Shoot information out of a confetti cannon.

# VACCINATION HESITANCY

In order to identify ways to improve accessibility to vaccination and increase vaccination uptake it is worthwhile looking at reasoning behind this poor access and low uptake. In 2019 the WHO announced vaccine hesitancy (VH) as one of its major challenges for the year (WHO 2019).

It has been suggested that the lack of information around vaccination is not the only reasoning behind hesitancy. It has been seen that VH is also rooted in trust issues and the complicated relationship between the Irish state, Irish women and healthcare. There is a view, that the option to take part (or not partake) in immunisation can give agency back to those who have been victim to gender and power roles within healthcare (Grodzicka 2021).

Not partaking in vaccination programmes, can be seen as an anti-social act and legislation in a number of states in the US including Michigan condemns this behaviour.

Anti-vaxxers as they have been called in the past, are present across all social and economic groups, and it can be suggested that an approach to reaching them would need to be universal and applicable despite class (Grodzicka 2021). Vargha argues that in order to address vaccination the idea of *them vs us* must be addressed, noting that a deficiency in knowledge is not the cause of the hesitancy and conspiracy (2018). *Them vs Us* refers to the conspiracy theorists and their friends and families VS. the doctors, scientists and governments .

Conspiracy theorists provide a threat to democracy (Holmes *et al* 2019)

Studies show when provided information about the presence of risk associated with vaccination, peoples perception about the risks are reduced. Compared with the negation of the existence of these risks causing increased risk perception (Betsch and Sachse 2013).

So as argued by Grodzicka a design intervention for VH must move beyond the focus of knowledge, to the trust issues and power dynamic issues the hesitancy is rooted in (2021).

# INCREASING GOVERNMENTAL TRUST

Research suggests that if people perceive their government to have knowledge of a potential hazard, or an issue they are more likely to trust them (Murphy 2018).



Get the Taoiseach  
to do conferences  
to share his  
knowledge on  
HPV & HPV vaccine



# MANDATING VACCINATION

Is it possible to support a mandatory HPV vaccination?

A move towards mandatory vaccination, supports a vision of a significant public health benefit (Doan and Kirkpatrick 2013).

Before the FDA approval of Merck's Gardasil HPV vaccine, the company had been campaigning for mandatory vaccination (Wilson 2007). Their lobbying for legislation was successful in some states, leading to the creation of a number of different types of legislation. These legislative changes ranged from providing knowledge to parents and children prior to vaccination (Koulova *et al.* 2008), to requiring vaccination prior to school entry. Lobbying by a vaccination manufacturer, although typically correct by principle was thought to be too aggressive in the case of Merck and Gardasil (Mello *et al.* 2021)

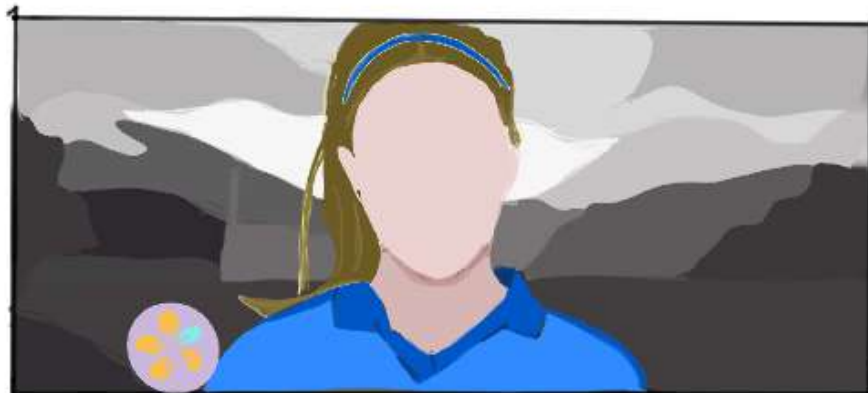
Graham argues that mandatory vaccination subtracts from the autonomy of the girls being vaccinated. A majority of those concerned with the bioethics in this area find mandatory vaccination problematic as patient autonomy is of the utmost importance (Colgrove 2010).

When examined from other ethical areas, including justice ethics, communitarian ethics or utilitarian ethics. The concerns are: the girls lose their autonomy, the individual choice for the girl is lost and it's result is not the greatest good for the most people, respectively (Colgrove 2010).

Mandatory vaccination has been seen to increase uptake over time (Odone 2021). It is difficult to argue that the benefits of mandatory vaccination for a disease which is not contagious in the same way that Measles, Mumps and Rubella would threaten society. HPV although potentially serious, can be sexually transmitted and therefore in theory, prevented by the use of condoms. Also the recommended age at which girls get the vaccination makes it more difficult to ensure they are all vaccinated in comparison to the control for the strongly recommended child immunisations. The author is of the opinion a more holistic approach to mandating the vaccination would be more successful.

# MANDATORY VACCINATION IN SPORT

Rather than making the vaccination mandatory, perhaps it could be filtered down through organisations. For instance, playing sport at a high level would require the vaccine, and players who want to participate at this level would get the vaccine. As well as this there is potential, for young players to see their role models have been vaccinated and be inclined to want to be vaccinated themselves. It is known that sporting role models are efficient for promoting gender equity and empowerment (Meier 2015) and could be thought to work well for empowering young women to get the vaccination.



a campaign where your favourite athletes promote vaccination.



Sponsor athletes with Cervical check gear.

# VACCINATION MANDATION

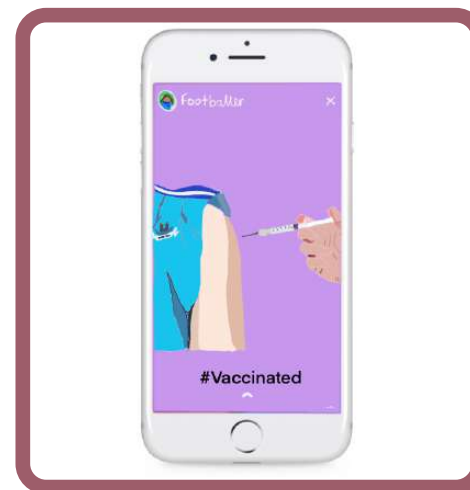
Using storyboarding to communicate the vision of sporting role models inspiring vaccination for participation.



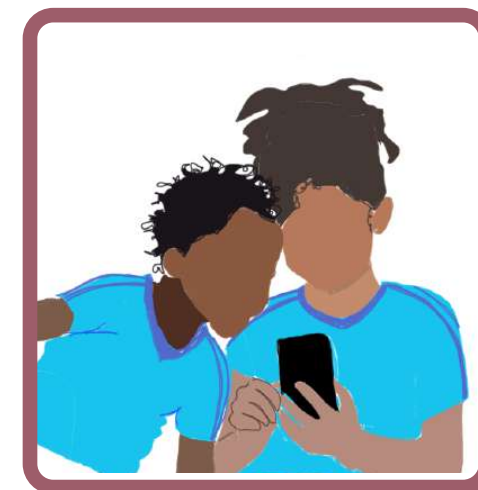
Vaccination is made mandatory for high performance athletes.



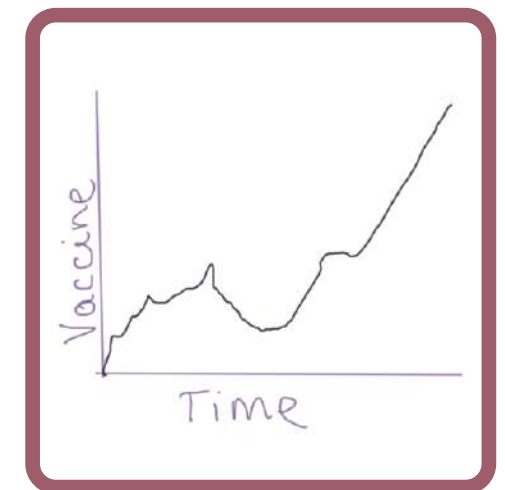
High performance athletes get vaccinated.



They post on their social media that they're vaccinated.



Young athletes see these posts and learn about HPV and the vaccination.



Increased uptake in vaccination in women who play sport.

# IMPROVING UPTAKE

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# TASK FLOW OF SIGNING UP FOR SCREENING

Exploring the task flow of a new cisgendered female user signing up for the screening programme. Highlighting potential issues in the process.



# FORGETTING TO SIGN UP

Potential errors identified in this task flow include:

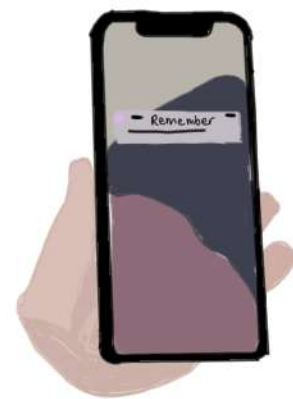
1. User forgets to sign up.
2. User doesn't know how to sign up.
3. User doesn't know they need to sign up.
4. User doesn't think it's important to sign up.

The author now explores methods by which these errors can be eliminated.

## 1. Forgetting to sign up



Handwritten note: Birthday cake / card delivered on your 25<sup>th</sup> birthday as a reminder to sign up.



Handwritten note: A text reminder to sign up once you're 25

Handwritten note: who sends this, if its cervical check can they not add you to the system/list?



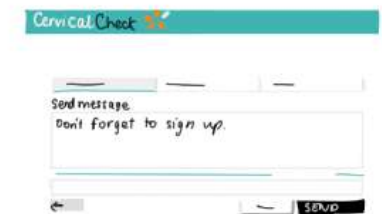
Handwritten notes: Can your GP add you to the list? Can the GP text?

Handwritten note: Send an automatic text to patients reminding them to sign up.



Handwritten note: The GP already has your number.

Handwritten note: Does the GP need patient consent to add them to cervical check list?

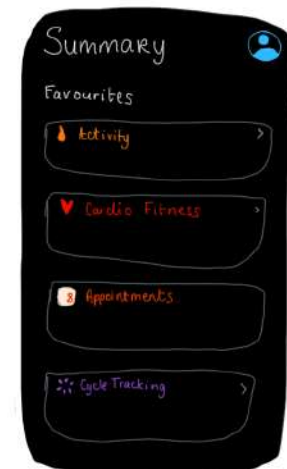
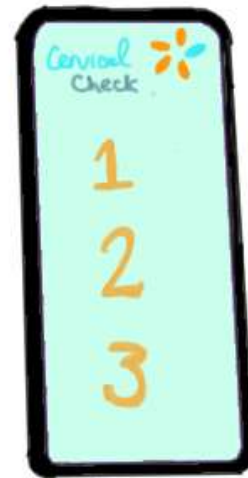


# FORGETTING TO SIGN UP

## 2. Don't know how to sign up



User gets a text reminder with a link to sign up.



Give the health app the ability to monitor appointments.



A healthy Ireland app that lets you organise appointments.

# FORGETTING TO SIGN UP

## 3. Don't know they need to sign up

The making every contact count (MECC) framework is used to optimise time spent by health professionals with patients to encourage healthy behaviour. This is a low cost way to improve client behaviour.



Encourage Doctors/nurses  
to mention the screening  
to patients during contact

## 4. Don't think it is important



Health care professionals  
using time together  
to raise awareness of  
the importance of screening



# SCREENING UPTAKE BARRIERS

Barriers to screening uptake have been identified as forgetting to schedule a smear test (Bosgraaf et al. 2014) and booking the test (Knops-Dullens et al. 2007).

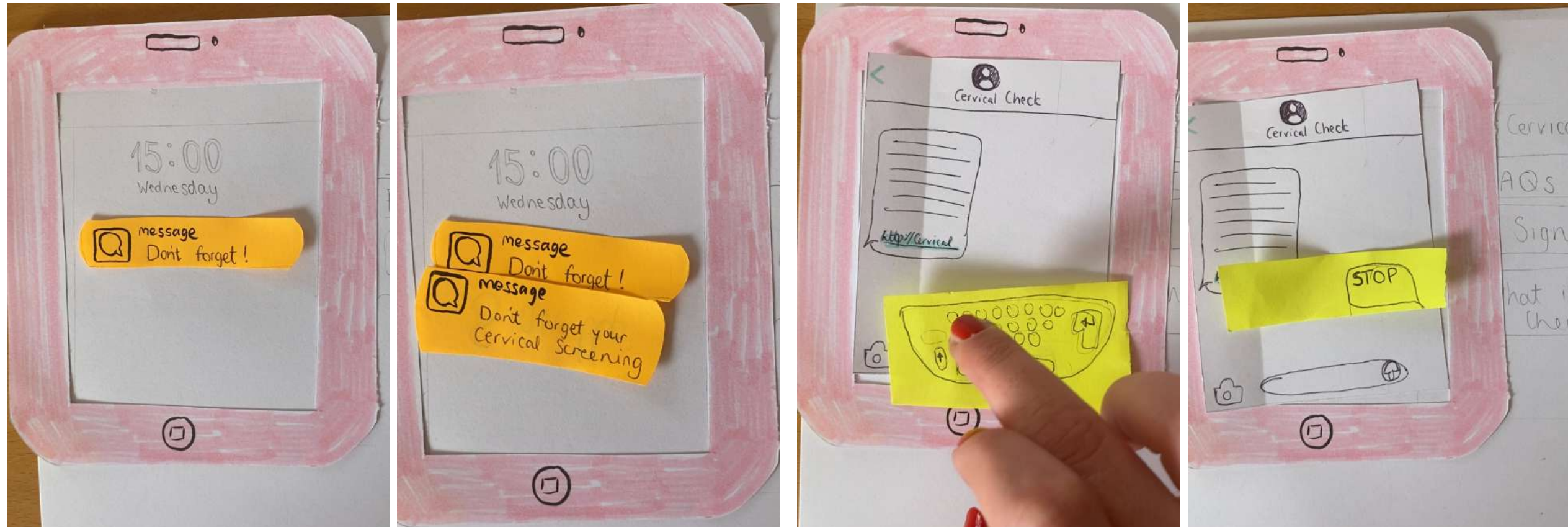
A number of studies note increased uptake of screening following text reminders. It has been identified as a success for first time bowel screening (Hirst et al. 2017) as well as first time breast checks (Kerrison et al. 2015).

In terms of CC it has been reported that text message reminders improve the uptake of screening, and in particular messages which were short and simple in terms of content (Huf et al. 2020). Again another study celebrates the use of text reminders in addition to education (Romaili et al 2020).

This information provides a number issues which can potentially be removed by design intervention.

# TEXT REMINDER

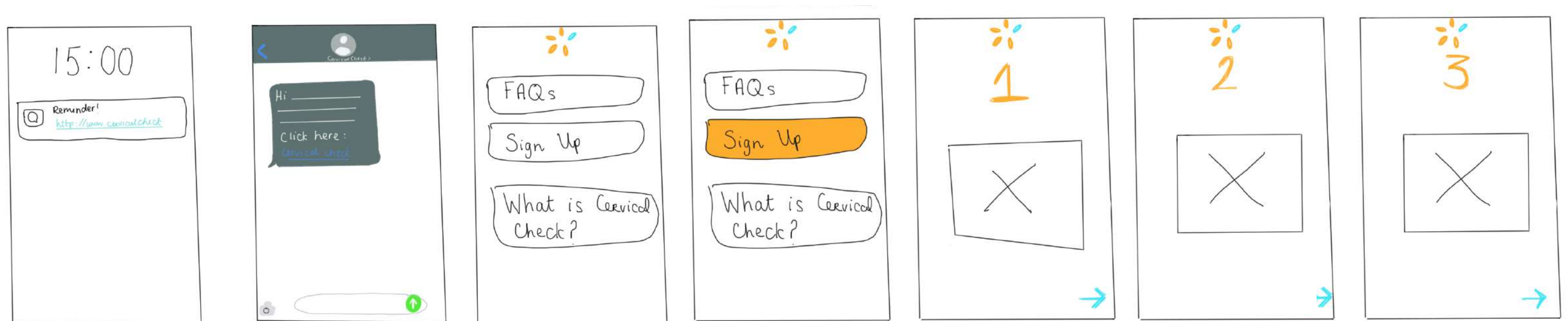
As research suggests, a reminder system would be efficient to increase uptake for cervical screening. What does a screening reminder system look like and how does a user move through it?



This run through of the text reminder, explores the user not wanting to receive any more messages from Cervical Check and replying STOP to opt out of the message chain.

# FORGETTING TO SIGN UP

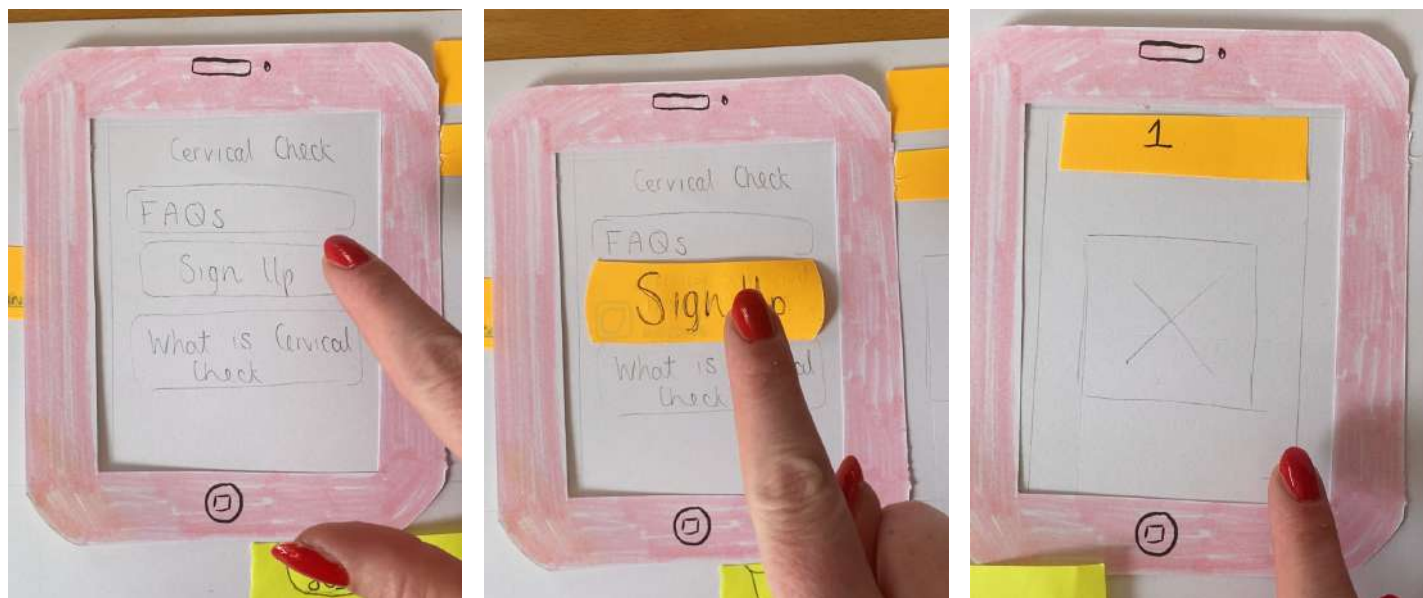
A text reminder system is optimal for reminding patients to attend their screening. Can this efficiency be translated into reminding users to sign up for the screening. Using some wireframing and low fidelity prototyping to help communicate this idea.



User receives a text message from cervical check when they turn 25, reminding them to sign up. They follow the link in the message to a step-by-step guide to signing up.

# FORGETTING TO SIGN UP

Using paper prototyping to identify how a user may work through a sign up reminder interface.



## Findings

The user works through the system opening the message, and starting the step by step sign up process. The designer noted it might be more efficient to have the sign up option at the start of the list and the FAQ at the bottom. User found the flow familiar and easy to operate.

# FORGETTING TO SIGN UP

By creating a digital solution to improve sign up the author works off the assumption that the user will have access to a smart phone, the internet and that they have a sufficient level of literacy. How might users without access to the internet or a smart phone be able to sign up and be reminded to sign up?



At sign up desk  
in health centers



In public libraries?  
schools?  
universities?  
workplaces?



# DON'T KNOW TO SIGN UP

If there were a help desk situated in public areas how would a user interact with it?



User goes to the shopping center.



They notice a new help desk in the center.



They approach the desk to see what it's for.



They see it is a sign up for CC screening and sign up.

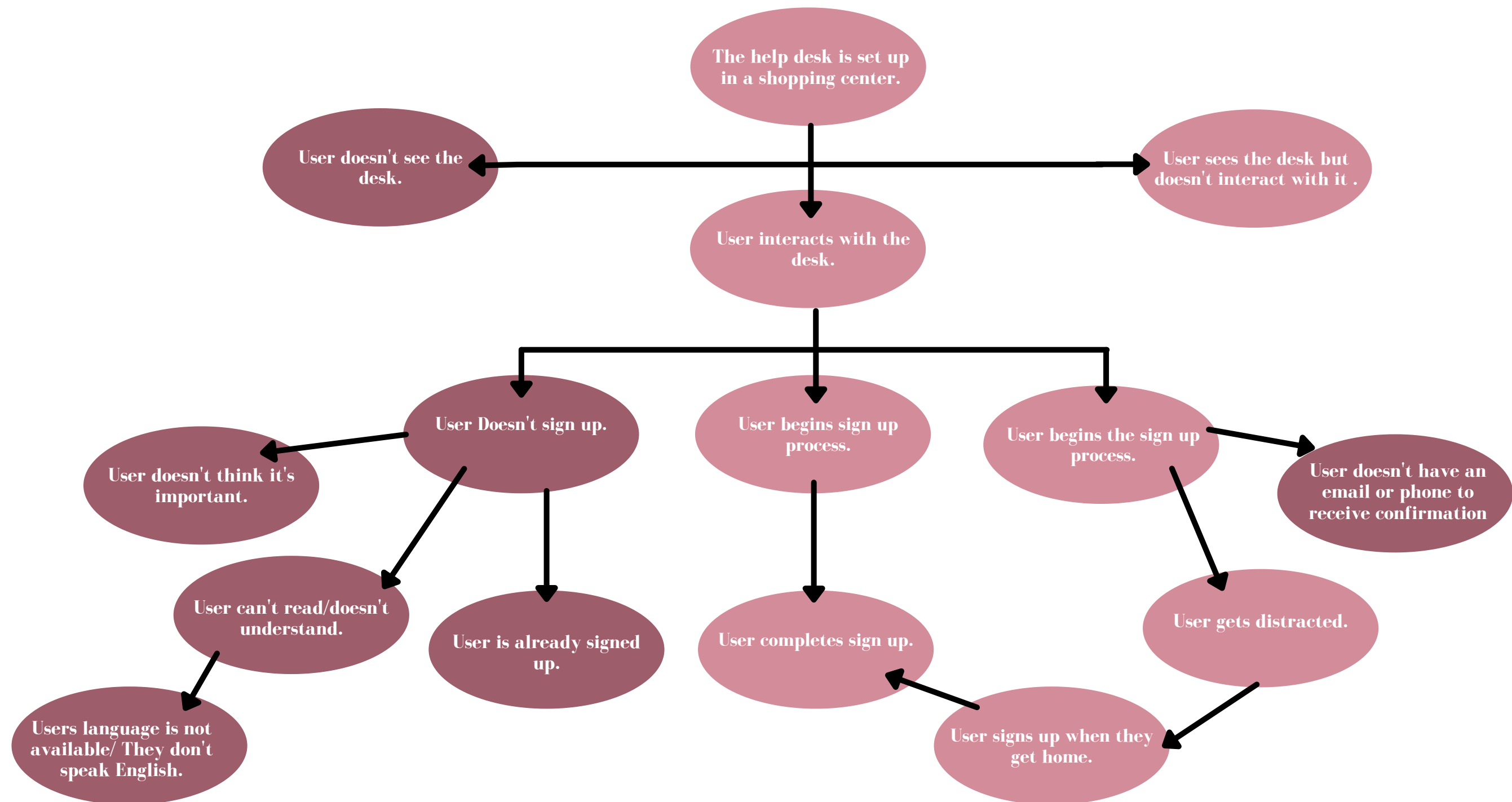


They get a confirmation of signing up and are told they'll get an appointment soon.

This storyboard depicts a user who has a phone using this platform to sign up. What if they have no phone? How can they get confirmation? Would a user with a phone even interact with this desk?

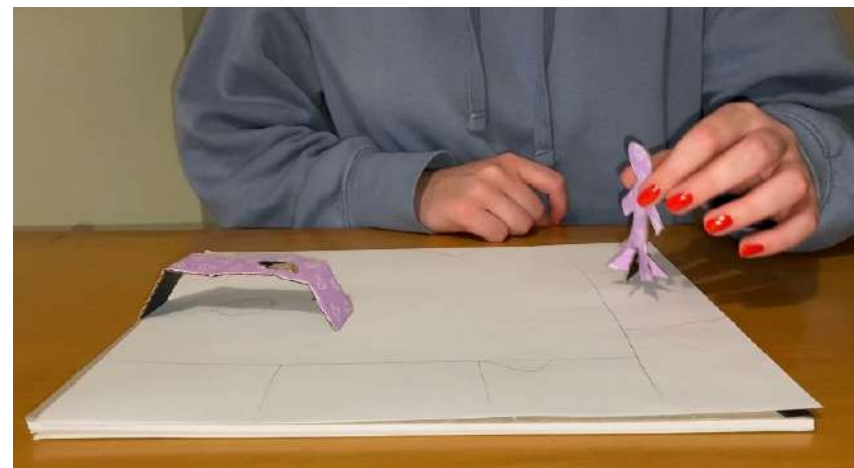
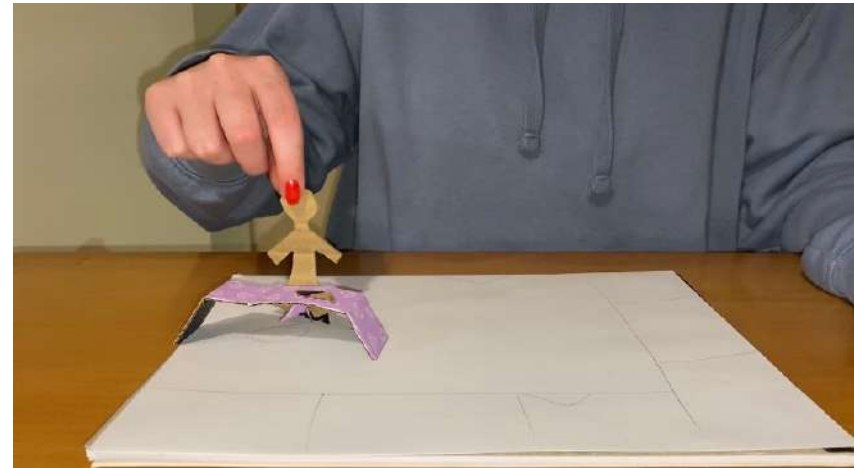
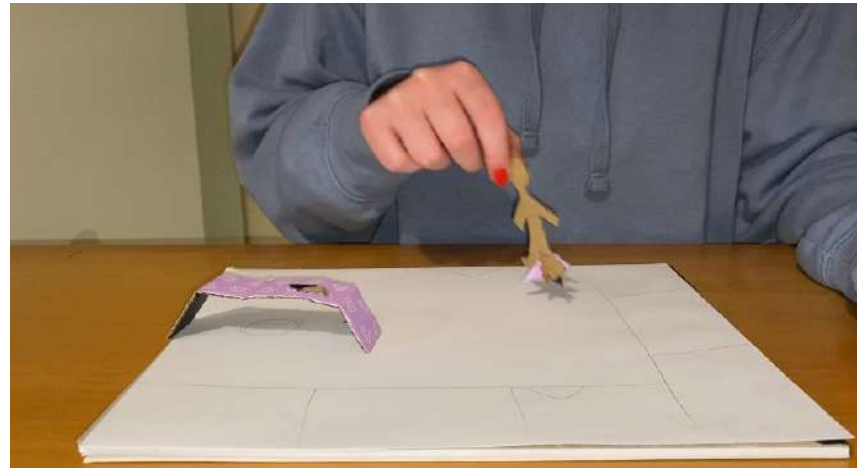
# PUBLIC SIGN UP DESK

What ways might a user interact with this that is not the optimal interaction. If they don't have a phone/if they can't read? Who are the extreme users? Highlighting issues with in a darker colour.



# PUBLIC SIGN UP DESK

Following the task flow which tracks the sign up the author carried out a desktop walkthrough to identify how different users would interact with the sign up desk. A number of potential users went through the service as if they were using it.



An assistant was used to walk the user through the service, to identify potential issues someone who is not familiar with the service may come across .

## **Findings**

The user required clear instructions as how to interact with the desk.

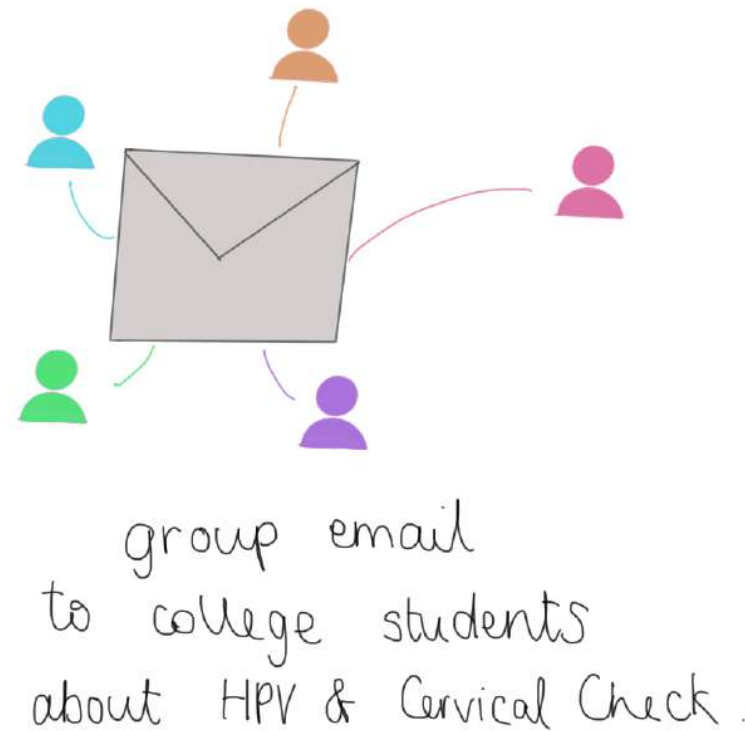
They suggested if the desk made noise it may be likely that users interact with it.

A number of scenarios were ran through with various characters, who interacted and completed the sign up, interacted and didn't and those who didn't interact at all.



# RAISING AWARENESS

There is research that suggests increasing education can improve self-efficacy and inclusion. It's thought that through improving awareness that it may increase service uptake (Sabates and Feinstein 2006).



a mobile unit that visits colleges doing HPV & STI checks.

Spotify Code like System where you scan stickers to give you info.



Cervical check code to scan.

Intercom announcement in shops.



# FILTERING IDEAS

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# IDEA FILTERING

Due to the volume of ideas generated a filtering process was created to reflect on ideas and assess them against the design guide to determine which ideas should be explored further. This opportunity was used to combine ideas which were promising on their own to create a product service system.

To begin the idea filtration, the designer uncovered some of their underlying biases that were present in their ideas. These biases were noted, and for future development they will be leading factors for consideration.

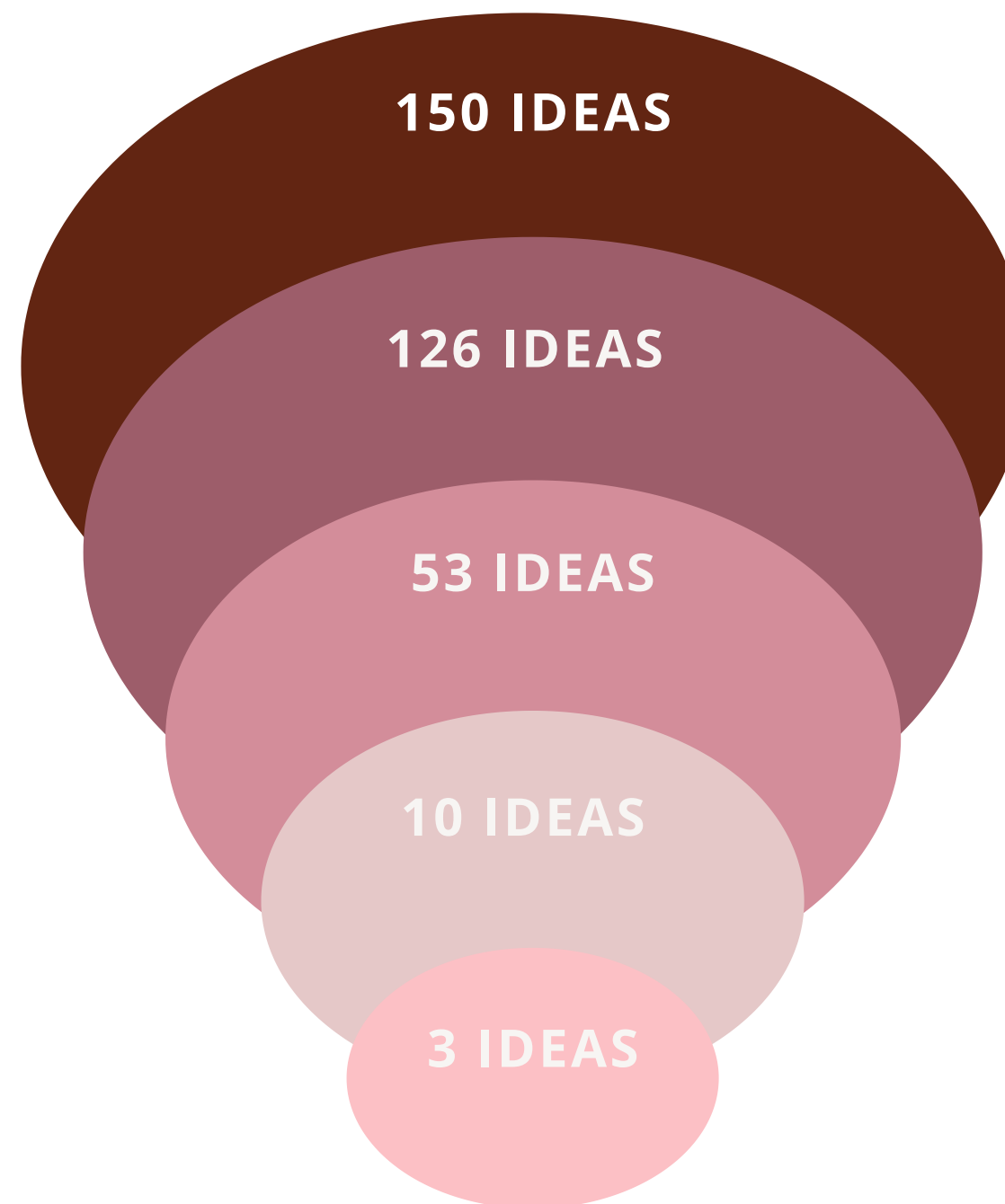
The ideas generated were compared against the needs they were answering, ideas which did not answer the need were eliminated.

The remaining ideas were considered in terms of reality, and whether or not they would be created within the scope of this project.

These ideas underwent a personal preference filtering stage, ideas that the designer was interested in developing were kept.

Finally the ideas were filtered based on a healthcare professionals opinion of the cost and time associated with the realisation of the idea.

## BIAS IDENTIFICATION



**Approach:** Examining the ideas generated, to identify biases.

**Major Factors:** Does this solution exclude people, is it assuming something?

**Approach:** Comparing the idea against the need it answers.

**Major Factors:** Does the idea answer the need?.

**Approach:** Considering what needs to occur for this idea to be feasible and if it is outside of the scope of the project.

**Major Factors:** Reality behind the actualisation of the idea.

**Approach:** Using quick decisions to determine personal interest in the idea.

**Major Factors:** Possibility for design to be inclusive, sustainable and intrigue the designer.

**Approach:** A healthcare professional uses intuition and professional experiences.

**Major Factors:** Cost and time of realising the idea.

# DESIGNER BIASES

## ***Technology Bias***

The issue of technology bias surfaced several times throughout the ideation process, with solutions generated relying on technology for their success. Ideas working on the basis of the user having a smart phone, and connection to the internet. Although the majority of people in the country have access to household internet (92%) (CSO Ireland 2020), and 77% use smart phones (Gibney and McCarthy 2020). The designer did however, make a few attempts to make the solutions more accessible by placing the solutions in public areas, for open usage. Even if everyone has access to the internet and to smart phones, 55% of adults have low digital skills (National Adult Literacy Agency 2020). This is important to recognise and mediate through design intervention, when filtering ideas there should be an obvious and successful attempt to make the chosen idea accessible through design. There is of course opportunity to remedy this bias, and insure that in the next stage of concept development that ideas are accessible in terms of technology.

## ***Literacy Bias***

A bias towards literacy levels also presented itself a number of times. In Ireland, 18% of adults, aged 16 to 65, score below a 1 on the literacy scale (National Adult Literacy Agency 2020). Ideas which require reading, and comprehension of written language are inaccessible to this population. The ideas as they are filtered, and as they are refined through concept development should consider literacy levels and be accessible to those with lower levels of literacy.

# IDEA FILTERING

The first round of filtering identifies whether or not the idea satisfies the need. A simple yes or no saw the elimination of the ideas which did not answer the need.

**150 Ideas**



**126 Ideas**

# IDEA FILTERING

After examining the need compliance of the ideas, the remaining ideas were examined with relation to fitting within the scope of the project. Ideas were given a yes or no in terms of the scope.

**126 Ideas**



**53 Ideas**

# IDEA FILTERING

After a scope review of the ideas, the next round of filtering spoke to the designers preferences. Whether or not the idea was something the designer was interested in pursuing. As identified in the previous chapter, the designers preferences are as follows.



## ***Universal Design***

Does this intervention allow for something which is easy to use, needing low physical effort, & flexible, etc,. ?



## ***Inclusive Design***

Is this intervention inclusive, is there a group of people who are unintentionally ostracised by this design and can they be included?



## ***Project Direction***

A combination of a product service would be most intriguing.



## ***Social Design***

Does this intervention make a difference for it's users in a positive way?



## ***Sustainability***

Can this solution be sustainable? Will it add extra waste to the environment, or can it potentially be sustainable?



## ***Circular Economy***

Is there opportunity to potentially include circular economy into this intervention?

# IDEA FILTERING

After a scope review of the ideas, the next round of filtering spoke to the designers preferences. Whether or not the idea was something the designer was interested in pursuing. Ideas were rated from 1-5 based on the following criteria.

1.	This idea is not inline with designers personal interests.
2.	This idea answers to one of designers personal interests.
3.	This idea answers to one or more of designers personal interests.
4.	This idea answers to more than one of designers interests and designer is interested in a solution.
5.	This idea answers to all of designers interests and the designer is invested in rectifying the need.



# NEEDS FILTERING - RESULTS

The scores from each of the filter categories were added up, and ideas with an overall score below 4 were eliminated.

**53 Ideas**



**10 Ideas**

# 10 IDEAS FOR FILTERING

After the personal preference round, 10 ideas remain. These ideas, categorised by the needs they satisfy can be seen below. It is worth noting that although ideas fit into one particular category here, it will be encouraged that they aim to encompass other needs too throughout concept development.

Using menstrual blood to detect HPV.  
A period pack with a HPV test included.  
Underpants that detect HPV infection.  
HPV tests that create an online community, empowering women to get their test.  
Legislation that makes HPV vaccination and information mandatory for every child.  
A HPV Vaccination workbook for children so they understand the importance of vaccination.  
A mobile unit that goes to colleges/workplaces and screens people.  
A text reminder system for attending screening.  
A text reminder system for new 25 year olds reminding them to sign up.  
Public sign up desk.

 Self Screening

 Equitable access

 Increasing uptake.

# IDEA FILTERING

The ideas that remained after the personal filtering process were then assessed in terms of a public health preference. An ex-public health manager assessed, and rated the ideas. The criteria by which they eliminated ideas is outlined below.

## ***Cost of Running the Programme (need) vs Cost of treatment of advanced disease***

Is the cost of this idea hugely expensive?

## ***Cost of Saving vs Programme (need) cost***

Does this idea cause subsequent savings, in terms of treatment, labour and death? How much is being saved by the idea and how much does the idea cost? If the idea costs more than the savings, what is the point?

## ***Psychosocial Impact***

What is the impact of this idea for social support, social status and the work force. What is the cost without this intervention, if someone is being treated, their social status may negatively be affected, they're out of work they are drawing social welfare. Some of these issues are immeasurable, but they were estimated by the healthcare professional.

## ***Political Issue***

What is the political impact of this intervention? The issue of CC is very much a political issue, especially at the moment. Much more women are affected by breast cancer than CC.

# NEEDS FILTERING - RESULTS

The scores from each of the filter categories were added up, and ideas with an overall score below 4 were eliminated.

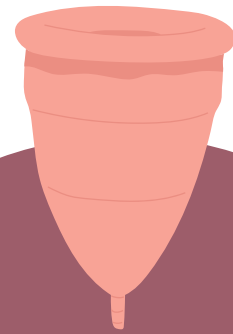
**10 Ideas**



**3 Ideas**

# FINAL CONCEPTS

After four rounds of filtering through ideas there are three remaining concepts which will be brought forward into the concept development phase, where the ideas will be explored and developed further.



## Menstrual Blood Test

This concept draws on research confirming that menstrual blood is an efficient biomarker for the detection of HPV (Wong et al. 2010; Lee et al. 2016; Wong et al. 2018).

This concept takes a user through the process from the collection of blood, to sending off the blood for analysis. The design intervention is a product service system, expanding existing methods of sampling menstrual blood and creating a new service for women to self screen and feel empowered in the process. Issues identified in research, including lack of self-trust are mitigated as the process is non-invasive and women are familiar with the process.



## Mobile Screening Unit

The mobile screening unit, is a nomadic screening centre which moves around the country stopping at colleges and workplaces offering to scan women over 25 and offering information to others.

This concept combats the issues highlighted with the sign up, including forgetting (Bosgraaf et al. 2014), having to book (Knops-Dullens et al. 2007), and not knowing. It also combats some of the issues with attendance, for example forgetting, the time constraints and having to take time off work/college.



## Period Pack

A period pack with a HPV test included could be given out to women to encourage self testing in between regular cervical screening sessions. Working as a period pack in school, it provides access to a wide range of users and creates a positive, shameless association with HPV testing.

Issues identified with HPV testing uptake throughout primary research also included embarrassment and lack of knowledge. This concept solves these issues with an inclusive empowering pack which aims to normalise HPV testing.



# REFLECTION

After four rounds of filtering through ideas there are three remaining concepts which will be brought forward into the concept development phase. As the author develops these ideas, they will refer back to the design guide and the needs statements. This will be done to ensure the project is focused to answering the needs, it is also beneficial to consider answering multiple needs through the concepts. There were reoccurring themes which presented themselves in the ideation generation including, behaviour, acceptance and information access which add to the research findings. These ideas will be considered holistically as the concepts are developed further.

The identification of the biases within the idea generation is crucial, as it became clear the designer has a technology and literacy bias. This is problematic from a point of view of inclusive design, and indeed the designers own interests of creating a social design, which is inclusive. The recognition of these biases make it easier to address them through concept development.

# CONCEPT DEVELOPMENT

CONCEPT FILTERING  
CONCEPT DEVELOPMENT  
CONCEPT PROOFING  
REGULATORY PATHWAY ASSESSMENT

# CONCEPT DEVELOPMENT

Following from the ideation phase, where over a hundred ideas were generated and filtered down into three concepts. This section will follow the partial development of the remaining three concepts and a decision to follow one particular concept through to its regulatory pathway assessment and a business case.

The ideation process could be prolonged indeed, however the time constraints of this project require the designr to move ahead on the basis that no decision is a failure (Zenios et al. 2010). By dwelling on the ideation phase any longer than the time constraints will restrict the flourishing of the concept.

This phase will compare the final three ideas from the previous chapter through a number of lenses including: Intellectual Property Prospects, the regulatory requirements and their potential Business Models.

Following on from this there will be an exploration of a single concept which will then undergo testing and iterative design.



# CONCEPT FILTERING

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INTELLECTUAL PROPERTY PROSPECTS  
REGULATORY ISSUES  
BUSINESS MODEL

# CONCEPT FILTERING

In order to filter the concepts from three down to one the author will explore the three remaining concepts through a selection of lenses. The lenses include their intellectual property prospects, to determine how well the idea may cope outside the constraints of this project in the future. Firstly the regulatory pathways will be explored. The concepts will also be considered in terms of their potential business model. Each of these practical lenses will be applied reflecting the profitability of the concept. However, the author is personally concerned with social design and the social impact that the design intervention may have, including whether or not it increases uptake of cervical screening and raises awareness of the importance of screening. The ideas will be rated as per the aforementioned criteria, however they will not be the deciding factors. The most important weighing factors will be the social impact of the design interventions and how well they align with the design guide.

# INTELLECTUAL PROPERTY

The intellectual property (IP) potential of a solution will determine external support engagement and funding from companies and indeed the university. The presence of patents for any of these ideas can hinder the development or success of a design intervention.

## ***Menstrual Blood Screening***

There are a number of published papers which cite menstrual blood as a suitable biomarker for detecting HPV infection (Lee et al. 2016; Budukh et al. 2018; Wong et al. 2018). As a result the idea of testing menstrual blood for HPV itself has no IP. Inventors have filed for and received patents for methods of obtaining vaginal samples to determine HPV presence (Tong 2003), and using menstrual blood to detect STI's (Tariyal 2017). There have also been patents filed for using pads to collect and analyse menstruation (Miller 2011) along with smart menstrual cups which can determine patient health through the amount and colour of collected blood (Hwang 2016). Design for women's health is a competitive space with many innovations surrounding menstrual blood as a determinant for female health. As far as the designer is concerned there are currently no patents or publications for a self screening HPV testing kit which uses menstrual blood as its biomarker and provides immediate results. Tariyal (2017) uses a device which filters out the blood cells to acquire the cervicovaginal fluid which is then sent to a lab for analysis. If a solution can use the blood and determine results immediately or without the need for an external lab the solution has potential to have strong IP.

## ***Mobile Cervical Screening Unit***

Several papers praise mobile screening for CC (Swaddiwudhipong et al. 1999; Mauad et al. 2010; Ferris et al. 2015) and is frequently used in some countries for increasing uptake (Paengchit et al. 2014; Hunt et al. 2018). Therefore, the idea itself, nor the unit would contain worthwhile IP. However, as mobile screening for CC does not exist in Ireland there is opportunity for the design of the service and the software involved and it is possible that novel software, or an identification process used may be patented.

## ***Period Pack with HPV kit***

The contents of this kit are spoken about in literature and have patents i.e., Tampons (Crawford and Waldman 2018; Billon et al. 2020) and pads (Janoowalla et al. 2020; Choi et al. 2021). Re-usable alternatives to these including: pads (Carstens 2005), tampon applicators (Agrawal 2014) and menstrual cups (Stoebe-Latham 2018) are all patented. HPV self-screening kits are also frequently mentioned in literature (Nelson et al. 2017; Tranberg et al. 2018) and patented inventions exist (Wallach 2000). Therefore, this concept has little room for IP development from the outset. Of course there is potential for software to be designed which could hold promising IP.

# REGULATORY ISSUES

Regulatory issues are of major importance for the success of new inventions and therefore identifying and understanding the complexities of the regulatory pathways can help determine which design is suitable within the scope of the project.

## ***Menstrual Blood Screening***

A menstrual blood screening kit is likely to be a class 1 device as it is likely to present minimal potential harm to users and is non invasive. Class one devices do not require clinical trials to prove the safety of the device.

They do however require:

The CE mark, from a certified body.

Registration with the HPRA.

Labelling per requirements.

## ***Mobile Cervical Screening Unit***

As this unit would be medium for people to get screened, and would be assisting a medical procedure it would be considered a class I medical device. Again class I devices will need a CE mark, they need to be registered with the HPRA and they need to meet any labelling requirements.

The fact the unit is mobile, if it is a motor unit it will need to be taxed, insured and have a CVRT certificate to be on Irish roads.

## ***Period Pack with HPV kit***

If this period pack consists of other products which are on the market, there should be no regulatory issues. Indeed the materials inside the kit will have to have their regulatory documentation and safety markings. There should also be instructions for use provided and labels and warnings should be displayed clearly on the products.

# BUSINESS MODEL

Identifying the potential business model for each concept is a suitable marker for whether or not a concept is worthwhile bringing forward. For instance a concept fits into a business model, particularly if there is an existing successful example of the model in the field the concept may be considered strong. If the business model makes the idea seem infeasible then it can be thoughtfully eliminated (Yock *et al* 2015).

## ***Menstrual Blood Screening***

The menstrual blood screening kit could be offered a number of ways, in particular as a subscription or a fee per use. With an emphasis on offering the product for free, there would need to be an emphasis on funding.

### *Fee per use*

Ensures that there is not a surplus of stock remaining as users would purchase the kit, and receive them. On the other hand free per use favours businesses with a high level of IP, as otherwise they can be subjected to high competition from other providers offering for cheap. As this doesn't exist at the moment the competition pool is small and therefore fee per use is an effective business model.

### *Subscription*

A subscription model would work well as the user could sign up for a year and get two packs at six months or sign up for longer periods of time. This would provide money to the company as soon as the initial sign up is completed, and if customer satisfaction is consistent and improving the customers are unlikely to cancel their subscription. However, they can be enticed by other companies offering the service for a lesser cost.

Ideally the opportunity to offer the menstrual blood screening would be the most favourable. As it would provide greater access to disadvantaged and marginalised groups. This would however, require a lot of funding and external support.

## ***Mobile Cervical Screening Unit***

For this to be accessible it would need to be funded by the government, and free for the users. It is likely the model would work in a similar way to the mobile breast check units. As the model for the breast check is effective its track record suggests this concept has a potentially successful business model.

## ***Period Pack with HPV kit***

This period pack could work in a number of ways, it could work as a fee per use model and for accessibility could offer an additional one-for-one model. Providing those who can't afford the pack with free kits. The fee per use model could be sponsored by workplaces and universities or users could purchase them online. It could also work as a subscription based model with users or workplaces signing up monthly, annually or biannually to receive the period pack..

# SOCIAL IMPACT

Identifying the potential social impact of the design interventions. The designer is particularly conscious of accessibility of the solutions and whether the solution is excluding any populations.

## ***Menstrual Blood Screening***

Using menstrual blood to screen women for HPV provides HPV screening with the potential to include any female who menstruates. Indeed it creates issues as the sample should be collected in a sanitary manner which may be difficult for populations without access to water. However, if the sample can be obtained from any of the various methods of period management, and not require an additional product it improves the accessibility and inclusivity of the design intervention. An issue raised in research was that of the pain associated with the CC screening. This non-invasive method would be more likely to be accepted due to the painless nature of collection.

## ***Mobile Cervical Screening Unit***

Although a screening unit increases uptake, unless it is in a central location it can be difficult to access for people without cars. This is also the case for rural areas and how they may find the location inaccessible.

## ***Period Pack with HPV kit***

Depending on the point of purchase, a period pack and HPV kit could be hugely accessible. If it was available in shops, workplaces and schools there would be a very large reach in terms of user demographics. If the kit had to be purchased it would of course be less accessible to members of lower income households, and other marginalised groups. However, if funded by the government this issue would no longer be of concern.

## ***Increasing uptake***

In order to increase uptake of CC screening, those who are currently excluded for what ever reasons must be accounted for. The users who are marginalised, due to low literacy levels, lack of education, lack of access and even fear of the CC screening process must be considered. By considering the social impact of the intervention, it can be estimated that the uptake would also increase. It is likely that providing a mobile screening unit would increase uptake in terms of ease of access. However, it would not cover users who are concerned about the screening process, or the visit to the doctor. The menstrual blood kit could act as a feeder system to get people involved in the Cervical Check programme.

# RAISE AWARENESS & PROJECT SCOPE

## ***Raise Awareness***

Each of the design interventions hold the possibility to raise awareness of the importance of cervical screening and the relationship between HPV and CC. It is likely that a mobile unit would raise awareness in the area surrounding the unit, at the time of its arrival and for the duration of its stay. The period pack and the menstrual blood screening allow opportunity to create an online buzz about a personal product. Encouraging sharing on social media to raise awareness.

## ***Project Scope***

In terms of the scope of the product it is important to keep in mind the timeframe of the project as well as the nature of the COVID-19 pandemic. Including the role it plays in limiting access to materials, machinery and users for testing. There is also room for consideration for the designers goals from this project and the desire to improve her product design skills while potentially designing a service for the first time which would be a welcomed challenge.








With these considerations in mind, the designer is least interested in designing the mobile screening unit, although it would bring the opportunity to create a service it does not challenge the designer to create a product service system in the way the other projects do.

On top of that the designer is most interested in the novel idea of using menstrual blood to test for HPV as there are currently no kits on the market which do so. There are kits to obtain cervical samples at home but none of them use menstrual blood as a biomarker.

# CONCEPT SCORING

After discussing the various concepts in terms of practical considerations and the ways in which each concept meets various aspects of the design guide the ideas are scored and a final concept is chosen to bring forward for concept development. Indeed ideas are not all lost and some aspects of concepts can be used to improve the final design intervention. The ideas are scored from 1-5.

Concept	IP Prospects	Regulatory Requirement	Business Model	Social Impact	Increasing Uptake	Raising Awareness	Project Scope	Score
1. Menstrual Blood	4	3	4	4	4	4	5	28
2. Mobile Screening	2	3	3	3	5	4	3	23
3. Period Pack	1	5	4	4	4	4	4	26

-  Does it potentially hold strong IP?
-  How complex are the regulatory requirements?
-  Does it have a potentially successful business model?
-  Will this be challenging for the designer?
-  Is there social impact for Irish women?
-  Will it increase uptake of screening?
-  Will it raise awareness of HPV and its link with CC?

After scoring the concepts, the highest scoring concept is the menstrual blood screening concept, and it will be brought forward for concept development.



# DESIGN GUIDE

In the research chapter the design guide introduced requirements for the design intervention. The menstrual blood screening kit answers the must haves and a number of nice to haves listed within the design guide.

It is vital that throughout the further development of this concept that the design guide is adhered to.

ABILITY TO TEST FOR HPV AT HOME

CONSIDER REASONS BEHIND POOR UPTAKE

ACCESSIBLE TO VARIOUS SOCIO-ECONOMIC BACKGROUNDS

CATER FOR VARIED VAGINA SIZES

LOW PHYSICAL EFFORT

CONSIDER VARIOUS LITERACY LEVELS

CONSIDER THE EMOTIONAL IMPACT OF SCREENING

EMPOWER WOMEN

ACCESSIBLE AND SUITABLE FOR USE IN LESS DEVELOPED COUNTRIES

PAINLESS SCREENING

AN EMPOWERING ONLINE COMMUNITY

SIMPLICITY OF OPERATION

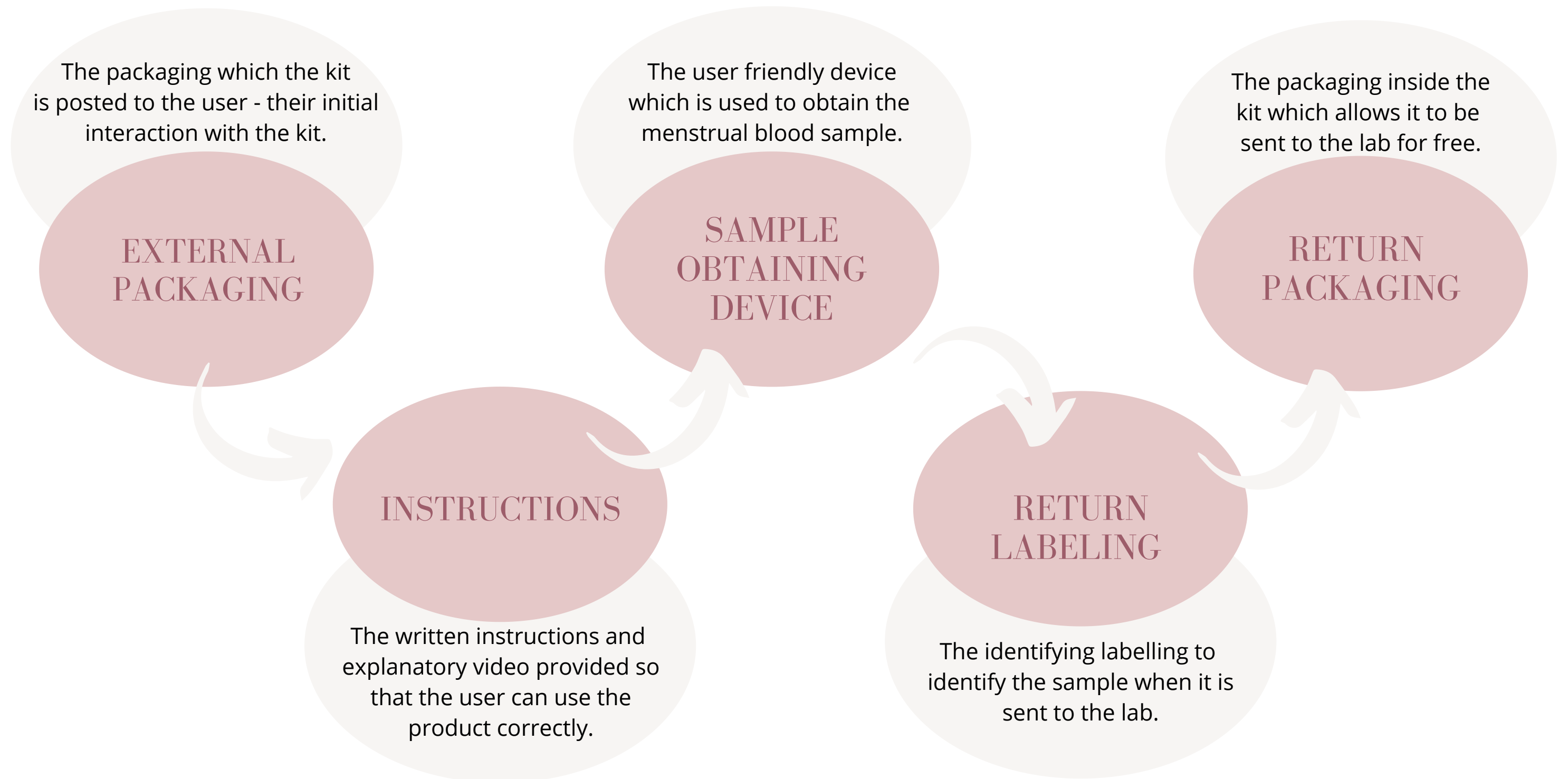
# CONCEPT DEVELOPMENT

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THE PRODUCT  
THE PACKAGING  
THE SERVICE  
THE WEBSITE

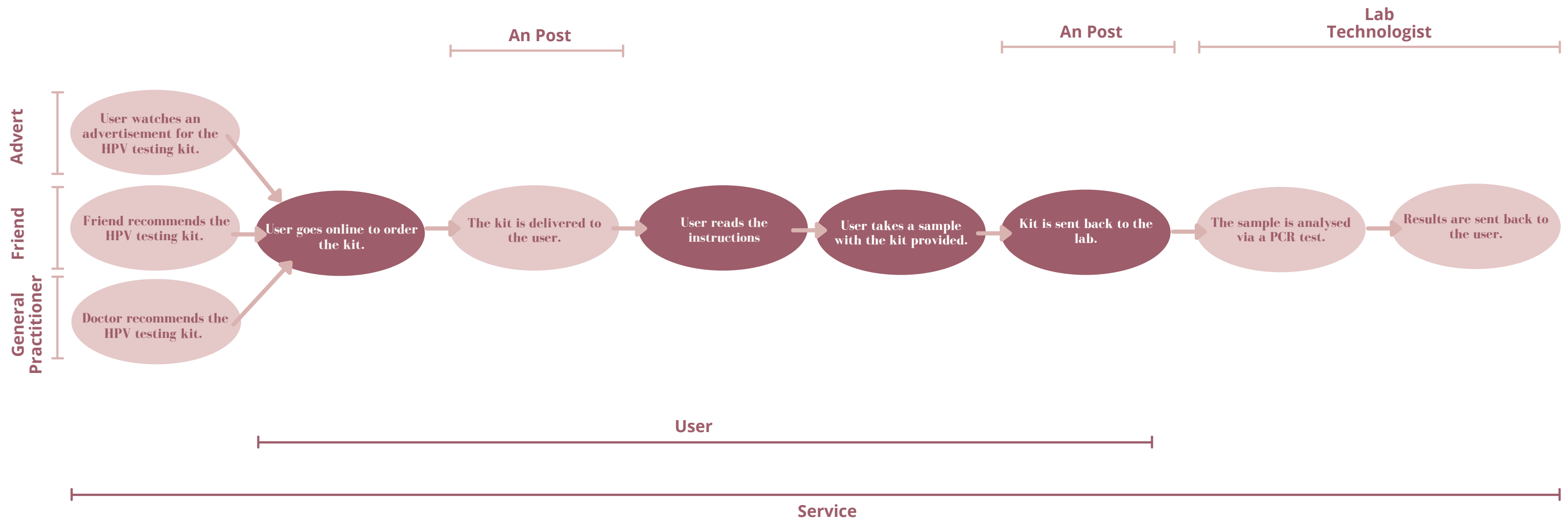
# WHAT IS IN THE KIT?

Before the designer can begin designing the service and the kit, the contents of the kit must first be identified. The designer will move forward and create a design intervention for the five components below as well as the site from which the device can be ordered.



# OVERVIEW OF THE PRODUCT SERVICE SYSTEM

The diagram below shows a growing service system for the menstrual blood testing kit. It highlights what the system will look like, what stakeholders are involved and which user touchpoints need to be designed.



After results are received the user joins the Cervical Check system and therefore the system finishes with their results.

# KNOWNNS AND UNKNOWNS

The prototyping process can give the concepts rigor, the work is then based in reality and not in assumptions made by the designer. Prototyping is important for creating human-centred design interventions (Soomro et al. 2021). This initial stage of prototyping exists in order to evaluate the concept. The prototype's purpose is to understand how people will experience the concept. Before prototyping questions will be established to decipher what is to be learned from the prototype. There are a number of unknowns which need to be identified through the prototyping process.

## Knowns

MENSTRUAL BLOOD IS A SUFFICIENT WAY TO DETECT HPV.

RATES OF HPV INFECTION ARE LIKELY TO BE HIGH BUT REGRESS IN 12-24 MONTHS.

THERE IS A MARKET GAP FOR USING MENSTRUAL BLOOD TO DETECT HPV

SELF SCREENING CAN INCREASE UPTAKE OF CC SCREENING.

WOMEN ARE INTERESTED IN SELF-SCREENING FOR HPV.

HPV CAN BE DETECTED THROUGH A PCR TEST.

USING MENSTRUAL BLOOD IS A NON - INTRUSIVE WAY TO DETECT HPV.

THERE ARE CONCERNS ABOUT PAIN & EFFICIENCY AROUND SELF-SCREENING.

THERE IS STIGMA AROUND CC & STI INFECTION.

## Unknowns

HOW IS THE SAMPLE OF MENSTRUAL BLOOD OBTAINED?

WHAT DOES THE PRODUCT LOOK LIKE?

HOW DO USERS GET IT?

WHERE DOES THE SAMPLE GO AFTER ITS COLLECTED?

WHAT IS INVOLVED IN THE UNBOXING?

HOW DOES IT TIE INTO EXISTING SYSTEMS?

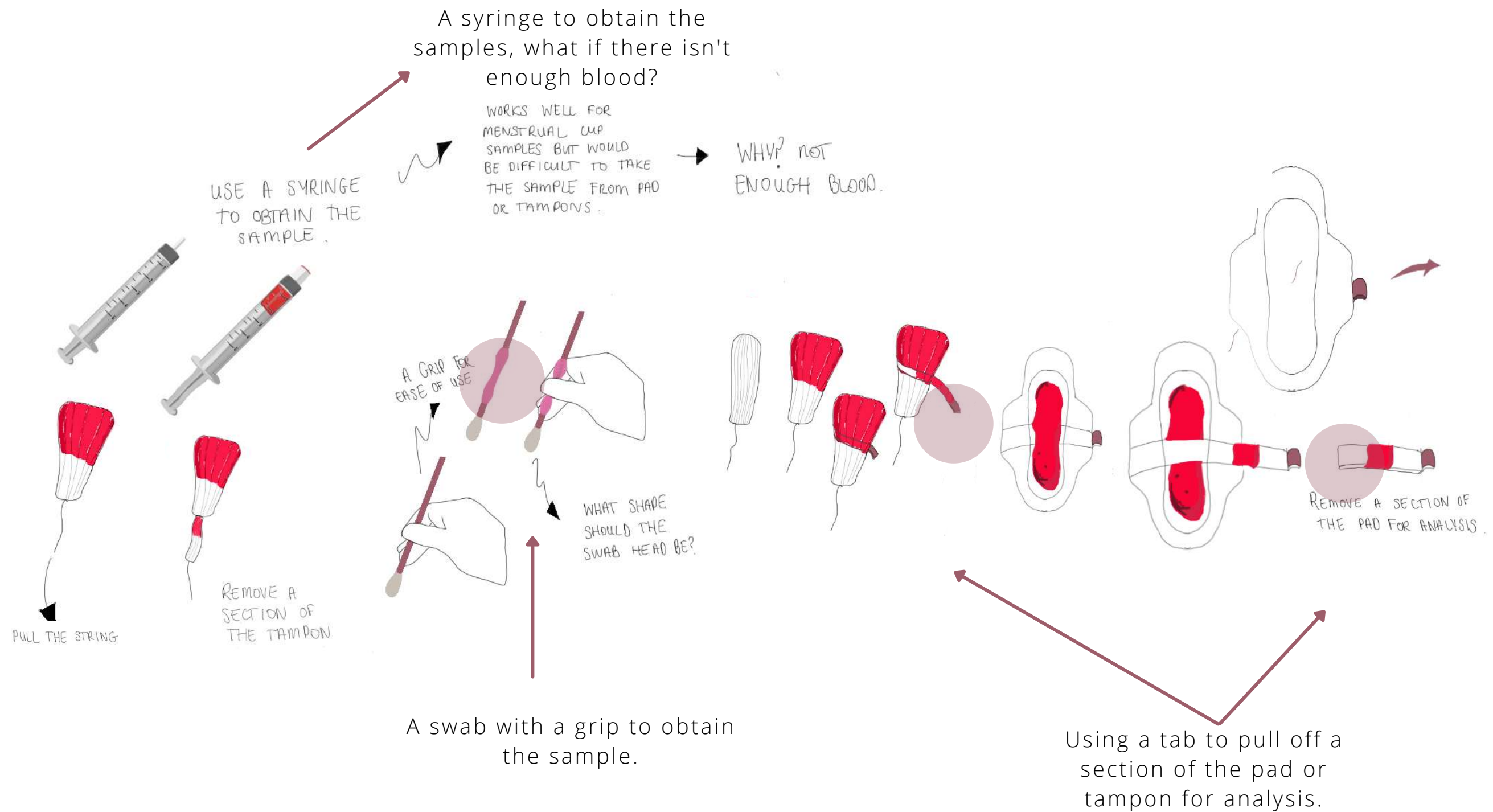
HOW IS THE SAMPLE ANALYSED?

WHAT DO THE INSTRUCTIONS LOOK LIKE?

WHAT DO USERS THINK?

# SAMPLE COLLECTION

The first unknown is how the sample will be collected. The designer uses sketching to explore some concepts. The most appealing aspect of using menstrual blood for determining HPV infection is the fact it can be obtained in a non-intrusive manner.



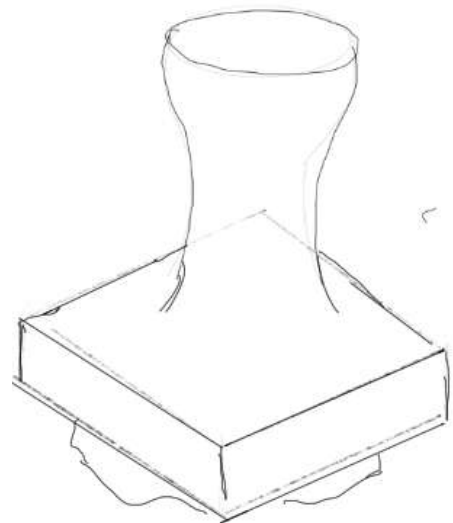
# SAMPLE COLLECTION

Sketching various methods of obtaining samples from the different period management products.

A reverse stamp that you use to obtain a sample.

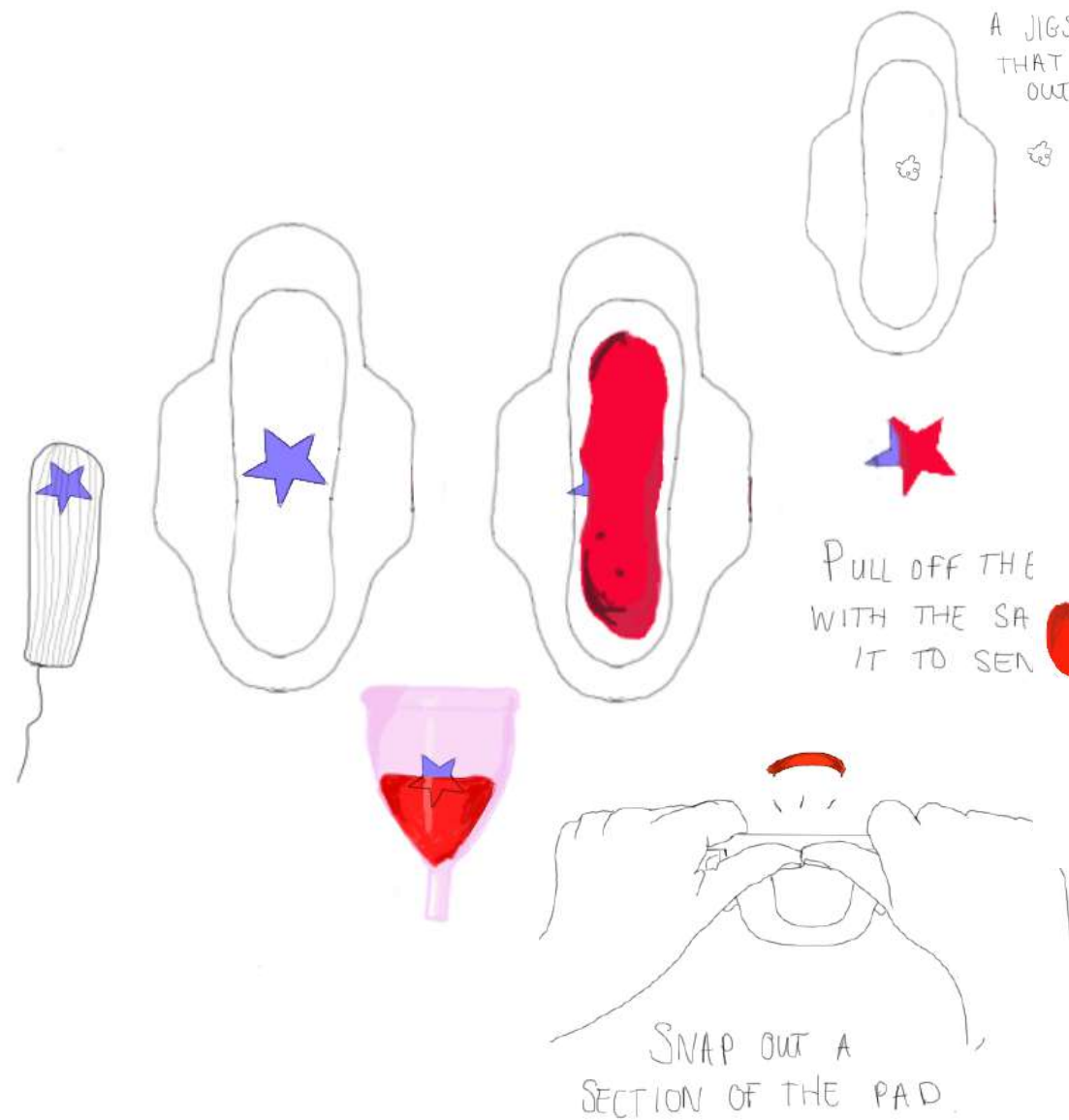
A needle like top that is exposed to the blood rather than taking up a large sample.

A STAMP TO COLLECT THE SAMPLE



STICK THE STICKER TO YOUR DEVICE

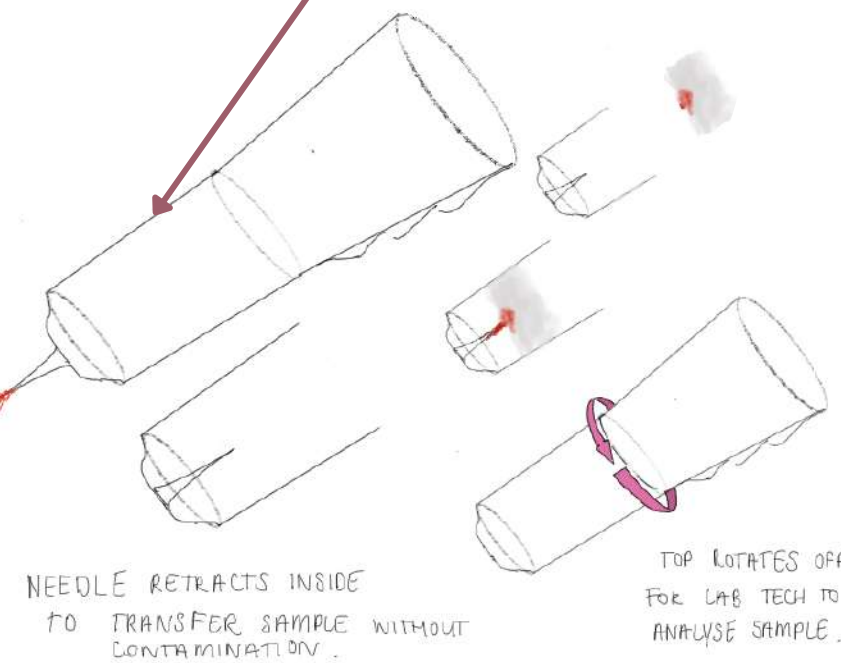
A pack of stickers which adhere to the menstrual management device, they're removed and sent to the lab for analysis.



A JIGSAW THAT GOES OUT.

PULL OFF THE WITH THE SA IT TO SEN

SNAP OUT A SECTION OF THE PAD.

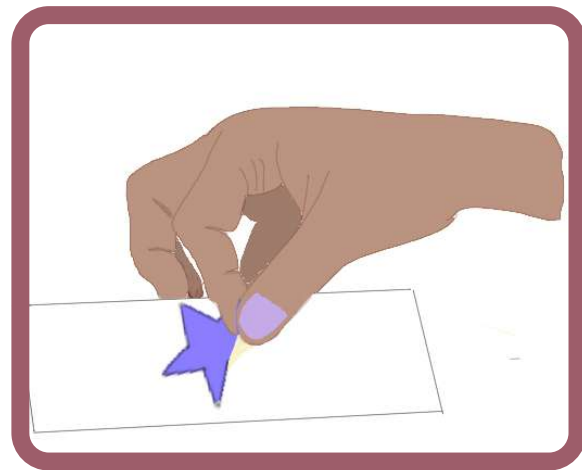


NEEDLE RETRACTS INSIDE TO TRANSFER SAMPLE WITHOUT CONTAMINATION.

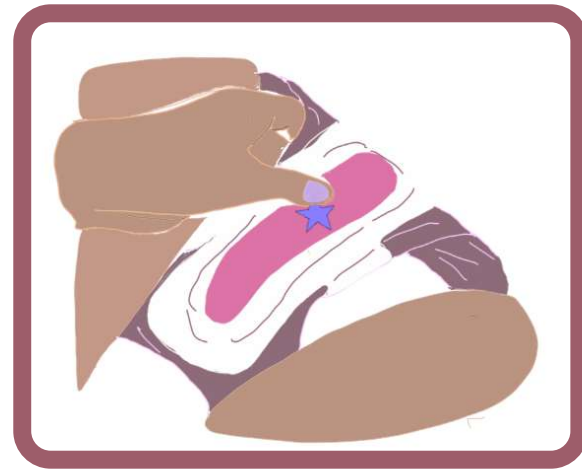
TOP ROTATES OFF FOR LAB TECH TO ANALYSE SAMPLE.

# SAMPLE COLLECTION

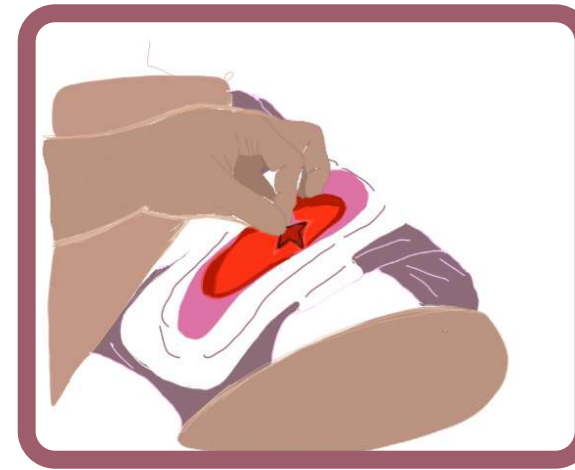
Exploring the idea of a sticker which adheres to the menstrual management product and is then removed and sent to the lab for further analysis. Using a storyboard to communicate the user interaction.



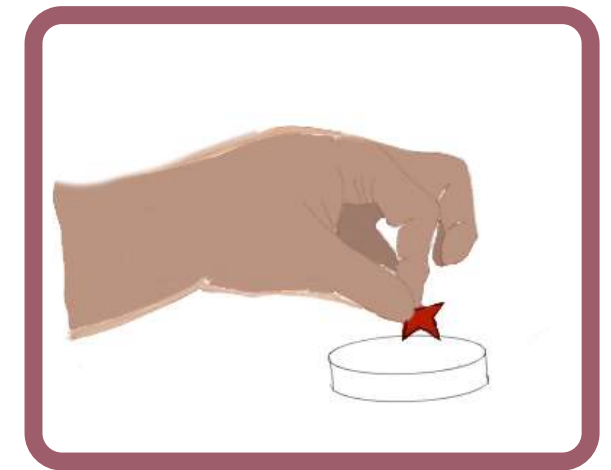
The user pulls off the sticker from the packaging.



The user attaches the sticker to the inside of their menstrual pad.



The next time the user goes to the bathroom, or changes their pad they remove the sticker.



The sticker is placed in the plastic container that comes with the kit and they can send it off for analysis.



# STICKERS

Through low fidelity mock ups, exploring how a user would interact with a sticker on their menstrual pad.



The user removed the sticker from its backing.



The user places the sticker down on the pad.



The user locates the sticker on the pad.



The user then removes the sticker from the pad.

## **User Feedback**

This is cool, but really messy. It is easy to put on but taking it off is so messy. It's all over my fingers and it's just annoying.

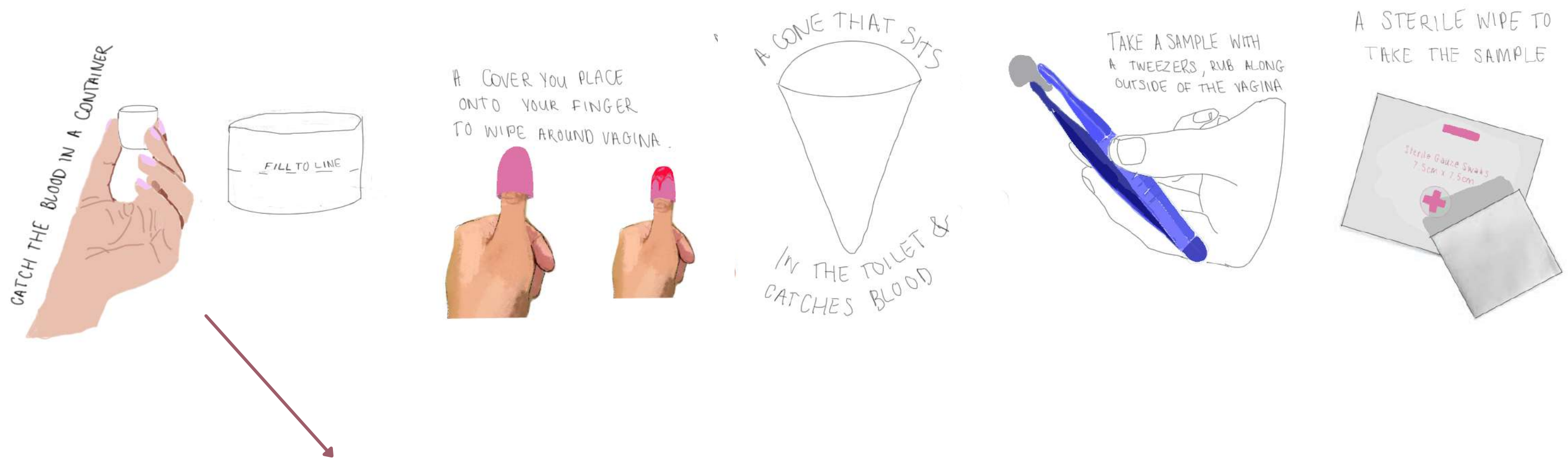
## **Findings**

User enjoyed the idea of this sticker, but the thought of its removal was messy and the user didn't think they would do it again.

It was also difficult to see the sticker on the pad once the 'blood' was on it.

# FIRST PRINCIPLES

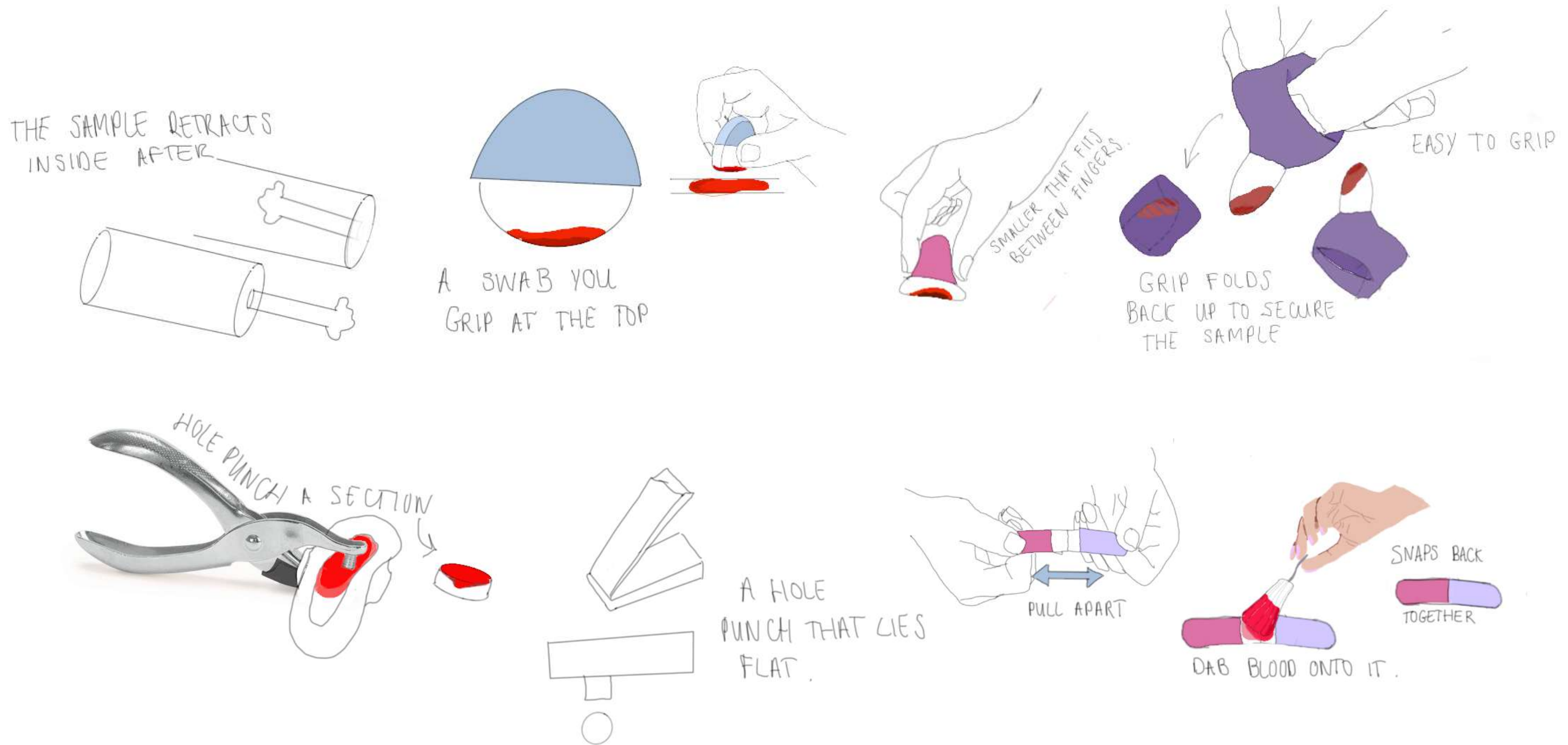
Returning to first principles to determine an effective way to obtain a sample of blood from a menstruating woman. Sketching solutions to this problem statement rather than designing a way to take the sample from the period management device as it should spark new more creative alternatives.



A small cup to catch drips of menstrual blood in.

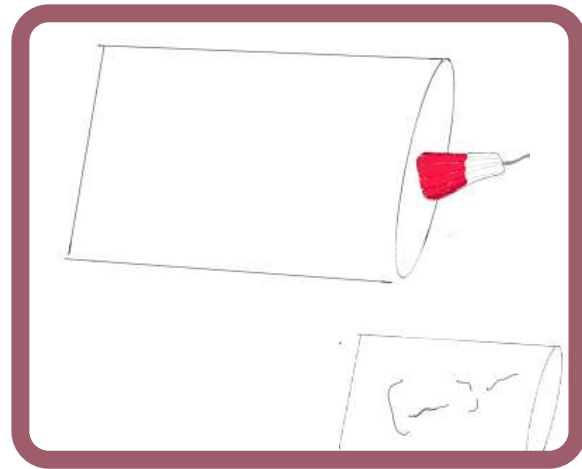
# FIRST PRINCIPLES

Exploring various handheld devices to obtain the sample from the vagina, or the menstrual pad/tampon.

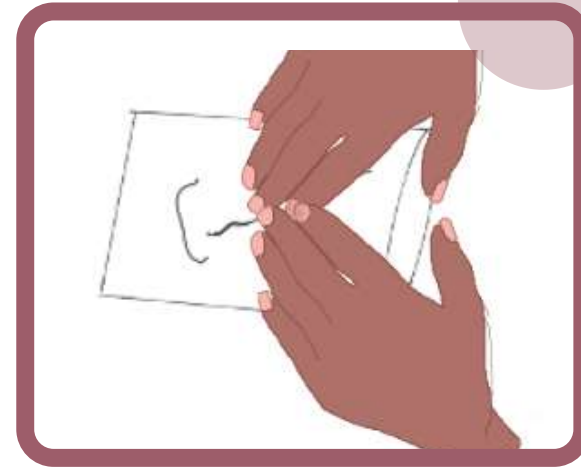


# STORYBOARDING

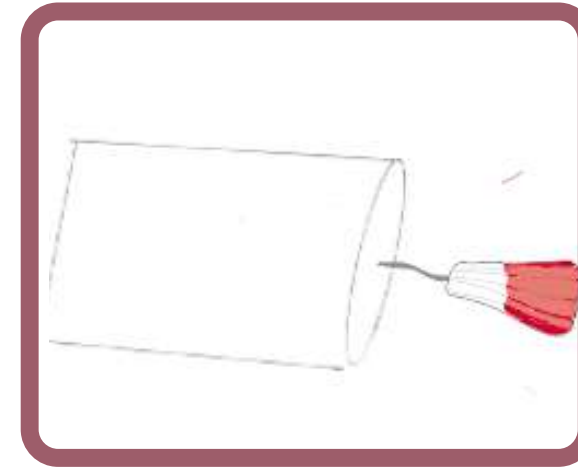
Storyboarding a use case where the packaging the device comes in could be used to take the sample. The circular mark, as with sketches signifies the designers preference for this idea. Designing the packaging to be intuitive to use and having the packing obtain the sample is very interesting and novel.



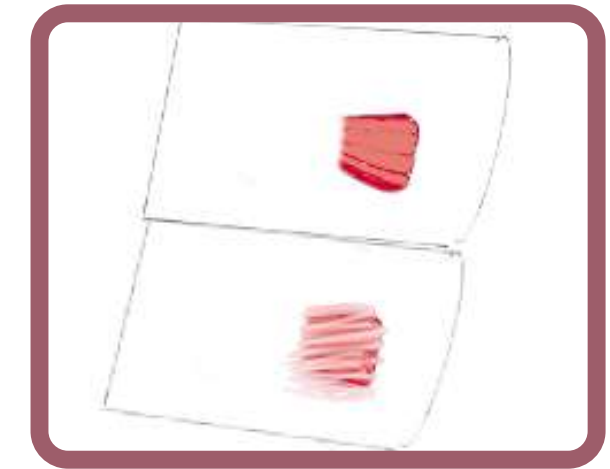
Insert the tampon into the packaging.



Press the packaging against the tampon.



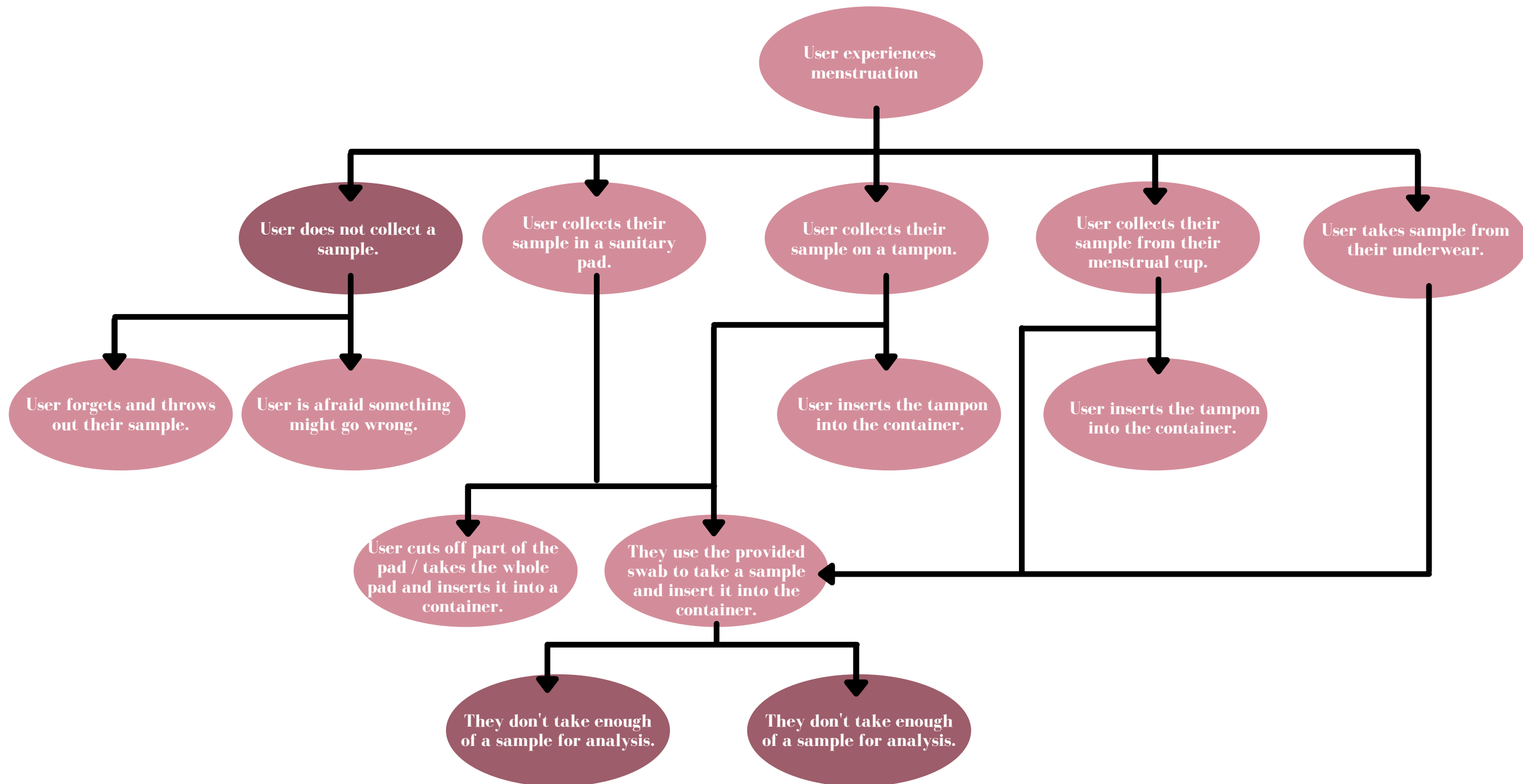
Remove the tampon and dispose of it.



The blood stamps to the inside of the packaging and can be cut open for analysis.

# SAMPLE COLLECTION

The initial sketches explored various methods of collection, depending on the chosen method of period management. If this is to be accessible, and inclusive it is likely that it should be one device which works for everyone. The designer explored a task flow of the sample collection. Identifying issues and highlighting them in a darker colour.



# SAMPLE COLLECTION

The task flow highlighted the various ways by which the sample may be collected and previous sketches surfaced the need for an inclusive tool that can obtain a sample from various period management devices. The designer returns to the tried and tested method of using a swab.

There is no intent to reinvent the wheel, after consulting with an expert on using menstrual blood for HPV detection they confirmed swabs to be efficient for obtaining and transporting samples (Wong 2021).

The goal of this product is to increase uptake of cervical screening. This means, marginalised groups need to be accounted for and research supports the idea of home testing to do this (Boggan et al. 2015; Nelson et al. 2017; Bernstein 2019). However, research highlights issues with the home testing kits not being trusted (Malone et al. 2020; Participant 03/U22 2021). Members of marginalised communities often struggle with trusting healthcare including healthcare workers (Calnan et al. 2006; Watkins et al. 2021).

With an issue such as trust it can be suggested that if the kit was similar to what the user expected, or what they were used to, they would be more likely to trust it (APA 2021).

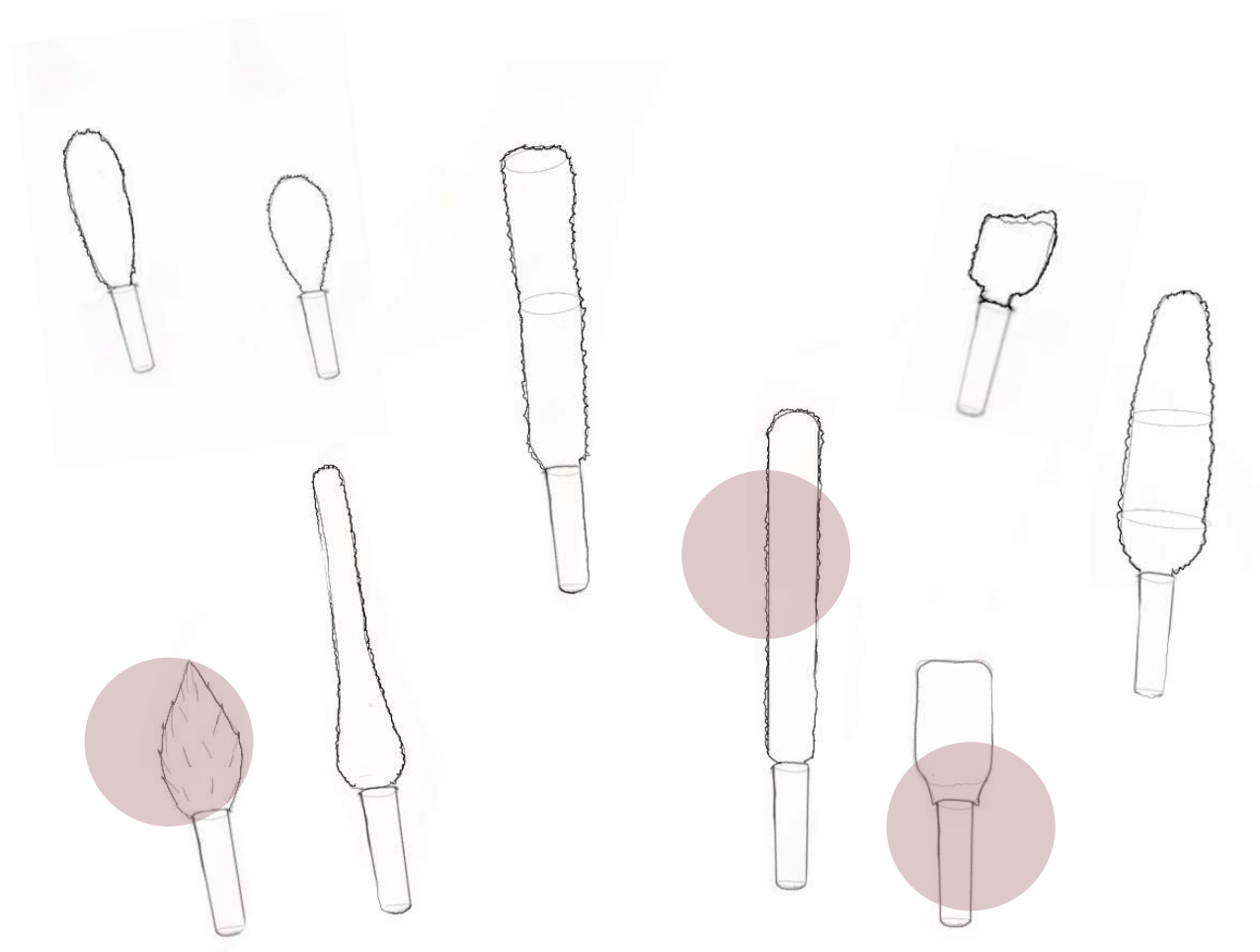
As well as considering the user who will be obtaining the sample the kit will be sent to the lab for analysis by a laboratory technologist. This user is important to keep in mind while designing the product. It is likely they will be conducting multiple tests and therefore speed and some familiarity will improve their efficiency.

A simplistic form is desired to create a user centred design. The product is also going to be offered to the users for free and therefore it is important to reduce costs where possible.

With this considered, the designer will pursue a design intervention which is similar to a swab which works best for the end users.

# SAMPLE COLLECTION

Firstly exploring different shapes for the head of the swab through sketching and sketch models. The highlighted shapes signify swab heads the designer likes.



A. B. Control. C. D. E.

# SWAB

After the initial prototypes were created the designer tested their ability to take up fluid from various surfaces. These prototypes were then discussed with a lab technologist who works with test samples daily. They talked the designer through the shapes and how they would access the sample from the swab for testing. The swab head should be easy to use, and work well to obtain samples on the part of the user carrying out the test as well as the lab technician who will be analysing the test. This discussion enlightened the designer to the tiny amount of the substance required for testing.

The designer carried out testing on the swab, with the successful test being substance transferred onto the swab easily. Along with obtaining any user feedback. Another important variable to note is how the user found the swab and if they liked it.



# TESTING THE SWAB

Testing the prototype swabs and their ability to take up the sample.



This head is the standard swab head for testing, here it is used as the control.



The swab is pulled along the sanitary pad to obtain the sample. It adheres well to the swab and it is easy to obtain this sample.



## **User Feedback**

This was easy to use, it slid across easily, but I was afraid I'd get the stuff on my hands.

## **Findings**

This swab works well but the distance between the sample and the grip should be elongated.



This is Swab Head A.



The swab is pulled along the sanitary pad and the integrity of the swab is spoiled. The sample obtained is plentiful and in the one palce.



## **User Feedback**

I like how it looked, but it came apart when I went to take the sample. It's hard to know if there is enough on the swab too.

## **Findings**

This swab is an interesting shape, and it was hypothesised that the sample would adhere to the raised surfaces and take more of the sample instead it was ruined. Perhaps this shape would work better if made from a different material. There needs to be a way to determine how much blood is needed for a viable sample.

# TESTING THE SWAB

Testing the prototype swabs and their ability to take up the sample.



This is swab head B.



As the swab pulled along the pad it came apart. However, a sufficient sample was acquired.



This is swab head C.



This swab slid along the pad easily but very little of the sample adhered to the head.

## **User Feedback**

I didn't get this one was I supposed to swipe it or dab it? I wanted to swipe it but it looked like it should be dabbed.

## **Findings**

This swab although effective caused confusion for the user and it lost its integrity when trying to obtain the sample.

## **User Feedback**

This one kind of moved the blood around it wasn't very good.

## **Findings**

This swab collected a small sample, but the user wasn't sure if it completed the job successfully.

# TESTING THE SWAB

Testing the prototype swabs and their ability to take up the sample.



This is Swab Head D.



This swab seemed too small but took up a large sample.



This is Swab Head E.



This head obtained a sufficient amount of the sample.

## **User Feedback**

This swab worked well it got the stuff on it but it seemed small so does it have too much on it?

## **Findings**

This swab was favourable but the size of it made the user feel like they were taking up too much of a sample. How do they know how much of a sample to take?

## **User Feedback**

This was good, it got the stuff on it easily but I got some on my finger, I think it's because I pushed down on it to get the stuff and my finger slid.

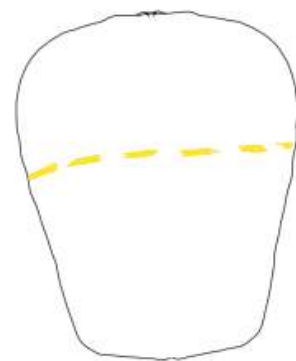
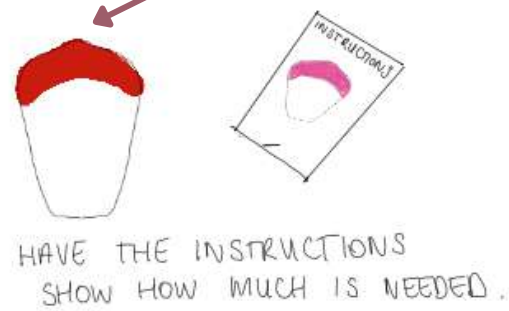
## **Findings**

This swab works well, however the users fingers slid onto the sample head, which would affect the sterility of the sample. The grip needs to be further away from the sample or have a mechanism to stop the user touching the head.

# HOW BLOODY MUCH

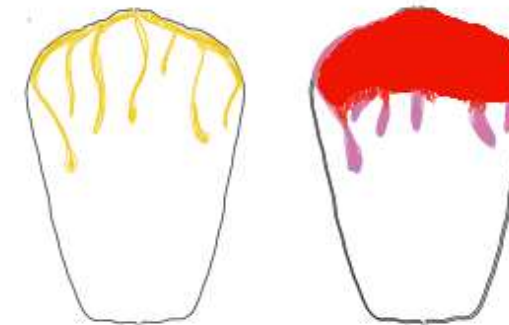
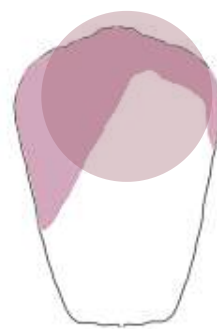
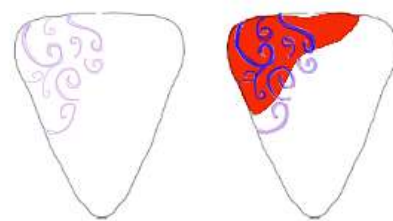
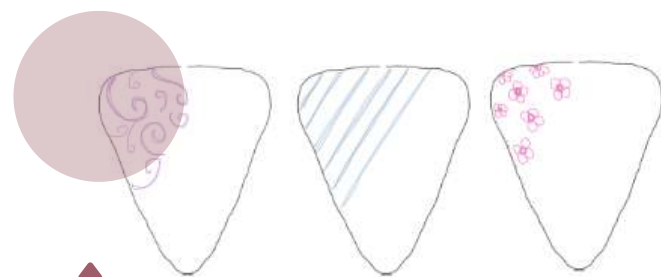
After testing the product with users, the feedback was gathered and an attempt to remedy, remove or redesign the issues was made. How does the user know they have acquired enough of a sample? This issue was identified in research when women felt they would be unable to take their own sample efficiently (Malone et al. 2020) and mirrored in primary research when women feared the same and that they would 'waste' someone else's time if they did it incorrectly (Participant 02/U25).

The instructions should hold information, but it should be easy to determine how much is needed without the instructions.



SCAN A QR CODE ON INSTRUCTIONS TO WATCH VIDEO.

PATTERN APPEARS IN PRESENCE OF BLOOD.



This pattern feature would be a welcomed change from usual clinical swabs.

The swab should have a guide so users know how much blood they need.

This doesn't help the user determine how much blood is needed.

# SAMPLE COLLECTION

After exploring the various heads for the swab the designer moves onto the grip. The HSE were running a trial for home STI testing kits which the designer ordered. The vaginal swab which came with the kit was a standard swab. The picture below shows the size of the handle, which is difficult to grip and seen as the swab is sterile the neck of the swab should not be touched. This makes the swab difficult to manoeuvre.



The design of the handle must consider the user taking the sample but it must not get in the way for the pathologist or lab technician who will be testing the sample. By testing the handle with both of these users it should account for the user centred design the author is aiming for. The designer hypothesised that the grip should be lengthened to allow for the various ways users may hold the device.



The book 'The measure of man' by Henry Dreyfuss, inspires a lot of modern day ergonomic design. In this book he lists the maximum force and resting angle of the hand to be 35 degrees and that the circumference should be around .5 cm. The design of the standard swab accounts for this, however the length of the grip is not ergonomic.



In addition, the swab neck will not need to be as long as photographed here as the sample will not be obtained from the inside of the vagina, rather the tampon, menstrual cup, underwear or sanitary pad. Feedback did suggest a longer neck than the 5cm prototype so testing will need to take place to determine the best length for the neck.

# GETTING TO GRIPS

With the intention of making the grip more ergonomic the designer created sketch models to test with users in order to identify which shape was preferred.

The cylindrical shape was soft and difficult to grip. Perhaps ribbed edges would improve it.



This grip has an indent at the top which makes it comfortable for both hands. The base heavier making it feel more sturdy.



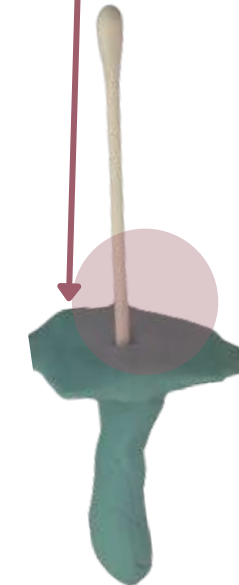
This semi circular shape made a first good impression but the range of motion was limited and the user thought they would be too close to the pad or sample.



This cylindrical shape much like the first was soft and difficult to grip it was also noted to be too short.



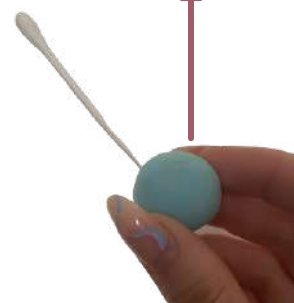
This grip has an umbrella top to prevent the user touching the stem. The stalk was too short.



The rectangular grip with raised edges and ends was comfortable and suited multiple grips and right and left hands.



This circular shape was 'fun' but the users 'fingers got too close to the stick' and would have contaminated it.



This grip had an indent and was comfortable when held as intended but did not suit being held in the left hand.



There is a very prominent indent in this grip which works well when held correctly but is not suited to be held any other way.



This grip was easy to hold however it was too short.



# GETTING TO GRIPS; PROFESSIONALLY

After testing the grips with the user, the designer contacted a professional lab technologist and tested the grips.

The lab technologist enlightened the user to the fact that the majority of swabs used for PCR testing are often snapped in half when sent back to the lab.

The swab tends to have a perforated area to allow the user to easily break off the swab head from the body.



This is a polystyrene (PS) neck with a break point at 45mm suitable for vaginal swabs (TSC 2021)



This is a plasticised paper breakpoint shaft (45mm) with a cotton mini-tip (TSC 2021).



This a PS (breakpoint at 45mm) shaft with Viscose Tip in peel pouch (TSC 2021).

The most suitable swabs for this product are either the plasticised paper or the PS one which both come in peel pouches.

# THE SWAB

Upon completing user testing with both users and lab technologists, feedback from the technologist suggested the swab itself did not need a grip. Further research uncovered the best type of swabs to use for PCR testing.

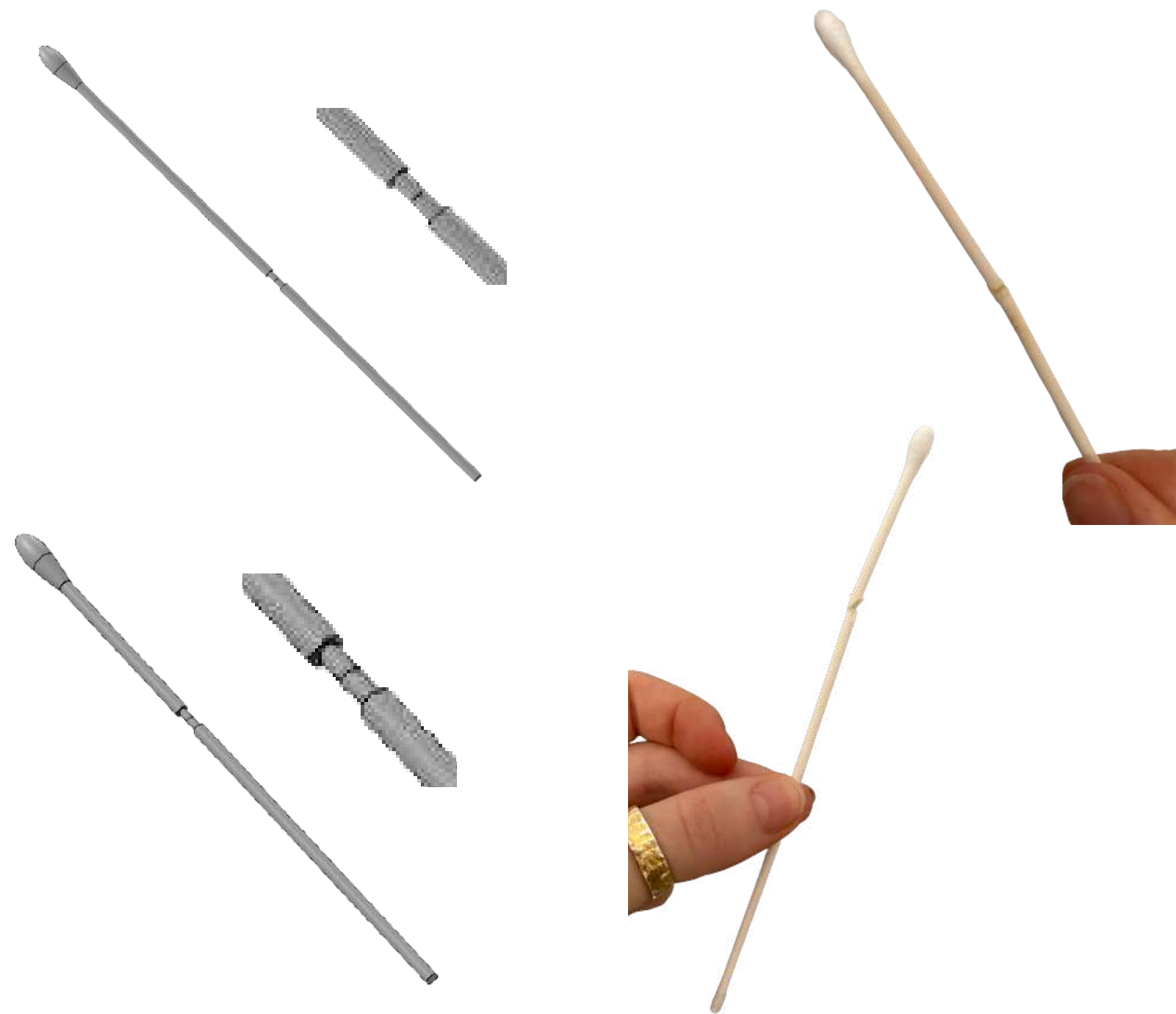
During project discussions the issue of accessibility in terms of the size of the kit were raised - questioning would people miss out on this kit if it did not fit in a standard envelope and wasn't suitable to be posted in the letterbox. This question and research supporting standard swabs for PCR testing Swabs are cheap, safe and effective methods of collecting samples for PCR testing (Mimori et al. 2002; Ghatak et al. 2013; Wong 2021). PCR testing is effective on menstrual blood (Wong et al 2018). These facts provide enough evidence to make the swab as simplistic as possible. The simplicity will also reduce cost when it comes to funding the product to provide it for free. Having an off the shelf swab means the device will have been validated by the regulatory bodies and will be fit for use in this product. It will also match up well with laboratory procedures.

There were a number of iterations the designer created and printed for testing. The 3D printing of nasal swabs has been successful for the diagnosis of COVID-19 (Ford et al. 2020; Oland et al. 2021) and was trusted by healthcare professionals and patients (Williams et al. 2020). It is hypothesised that 3D printing could potentially be suitable for acquiring samples of menstrual blood.



# TESTING THE SWAB

Using Solidworks, the designer created a 3D CAD model of a swab, the designer had intended on printing the swab, however access to the 3D printer was limited due to COVID-19 Restrictions. Instead the designer made prototypes at home to test. After testing design iterations were made and the new design was prototyped and tested.



## ***User Feedback***

It felt fine in my hand, but then I pressed it too hard and it broke,

## ***Findings***

The swab broke in half as the user went to obtain the sample. The designer hypothesised it was because the snapping section was in the centre and if it were towards the top of the swab it would be more stable.

## ***User Feedback***

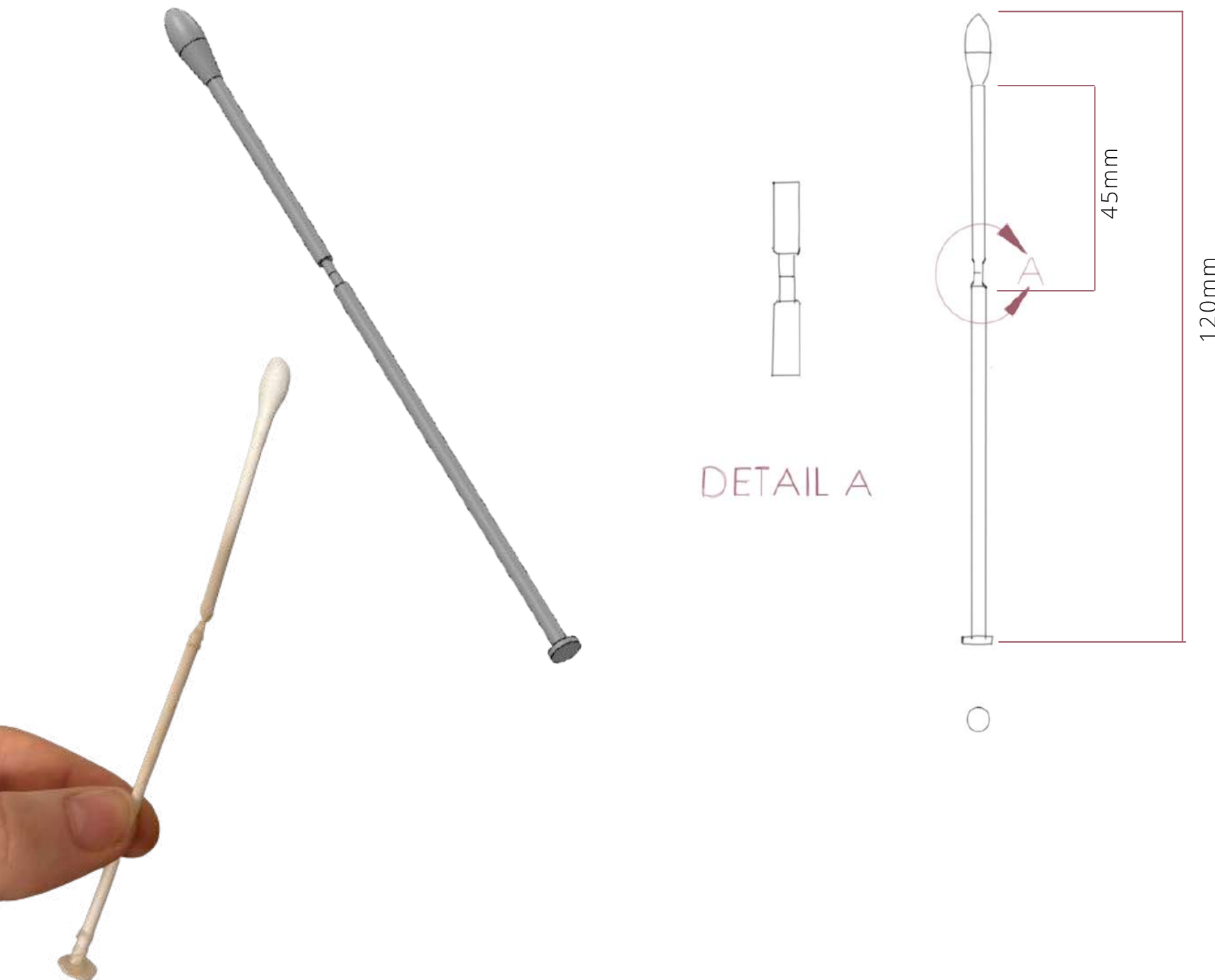
This was better it didn't break and felt like it was stronger.

## ***Findings***

This swab was more stable for obtaining the sample.

# THE SWAB

After taking the user feedback into consideration the designer added a base to the swab.

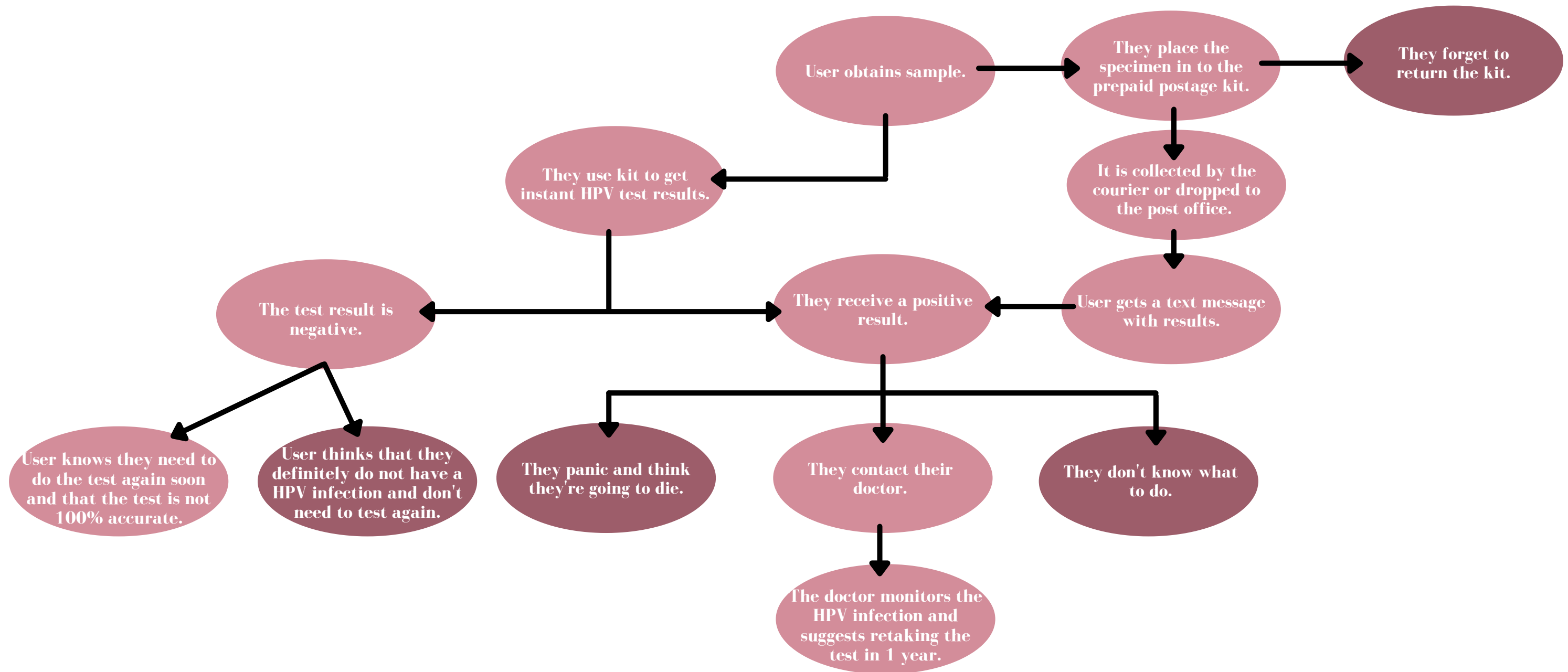


## **Findings**

At this stage the designer presented the project, and this particular swab to a panel of design experts and peers. Feedback from a member of the panel spoke to the 3D printing of the device. Whether it was actually the most cost effective option when compared with using standard off the shelf swabs. It was decided based off this feedback that the swab could be an off the shelf product to save on cost. In addition to this, although swabs are suitable to be 3D printed they are then required to be tested individually which can be costly, compared to an off the shelf product which would already be verified (Gallup et al. 2020). This feedback came from a panel of experts, who are listed in the DesignHistoryFile/1.Design Inputs/Design Team.

# SAMPLE COLLECTION

Once the sample is collected what are the subsequent steps? Using a task flow to map the process following sample collection. This task flow highlights potential issues in a darker colour, these issues will be addressed.



# SAMPLE COLLECTION

Using a journey map to explore the users motivations and their experience with the sample collection process.



## ACTIVITIES

User receives their kit in the post and unboxes it to read the instructions.

User goes to the bathroom to remove their tampon to obtain the sample.

User holds the tampon by the string and tries to swab it but it keeps moving. She has to hold the tampon up higher to get the sample on the swab.

User holds the swab in one hand and disposes of the tampon with the other. Then they put the swab into its container and wash their hands.

User inserts the container with their details on it into the pre-paid package and brings it to the post office.



## MOTIVATIONS

User knows the importance of diagnosing CC early, and saw an ad for this product online.

Eager to try the new kit, they go to the bathroom to take the sample from their tampon.

User knows she needs to take the sample but can't get it. She reluctantly grabs the tampon to hold it still.

User is frustrated but they know they must complete the test or it was pointless.

User knows that even though it was frustrating it will be for the best when they get the results.



## EMOTIONS

Intrigued, optimistic and excited by the packaging they read the instructions to find out how it's done.

Interested to see how it works and excited to try it .

Frustrated that she couldn't get it without touching the tampon. Disgusted she had to touch it.

User is frustrated but happy that it is over and they will have their results soon.

User is relieved the test is completed. They're annoyed that they couldn't get immediate results.



## BARRIERS

The user can't read or doesn't understand the instructions. User receives the product before/after their period and forget to use it.

User hasn't had the tampon in long enough for it to collect blood. User throws out the tampon and forgets to take the sample.

User is not comfortable touching the tampon to get the sample. User doesn't like the feel of the tampon. User contaminates the kit because there is nowhere to rest it.

The user contaminates the swab by putting it down on a surface before inserting it into the container. User doesn't complete the test because they're frustrated.

User is frustrated and tells her friends not to get this test. They don't post the results. They don't fill in their details and won't be able to get their results.

# REFRAMING AND NEW PROBLEMS

Upon completing the task flow and the journey mapping, giving thought to the issues which occurred can be beneficial, some of these issues included:

***The user receiving a HPV positive test and panicking.***

***The user learning they have no HPV in their sample and thinking they do not have HPV and do not ever need to be tested again.***

Both of these issues are potentially harmful. Causing unnecessary stress for the user, or indeed adding to misinformation if left unaddressed. These issues can be mediated through labelling, educating the user on the importance of frequent testing and giving them clear helpful guidelines following a positive result. The designer will explore options for these considerations and then design them to fit into the system.

Other issues which surfaced, which may not be resolved easily with labelling adjustments include:

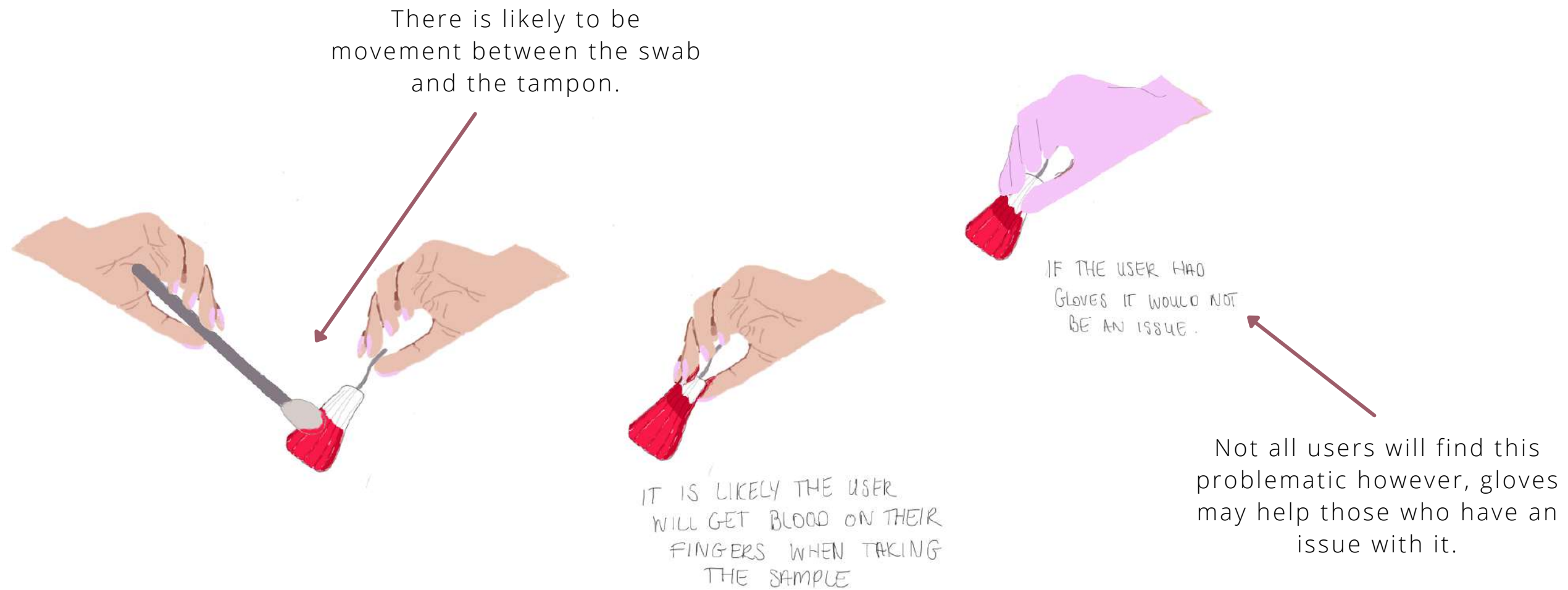
***How can you obtain a sample from a tampon with ease?***

***How does the test relay personal details to the lab technician?***

***How can you ensure samples are sent to the lab before they 'go out of date'?***

# TAMPON SAMPLE

How can a user obtain a sample from their tampon?



It is worth noting the sample does not need to be obtained from the tampon itself it could be taken from the toilet bowl or the vagina.

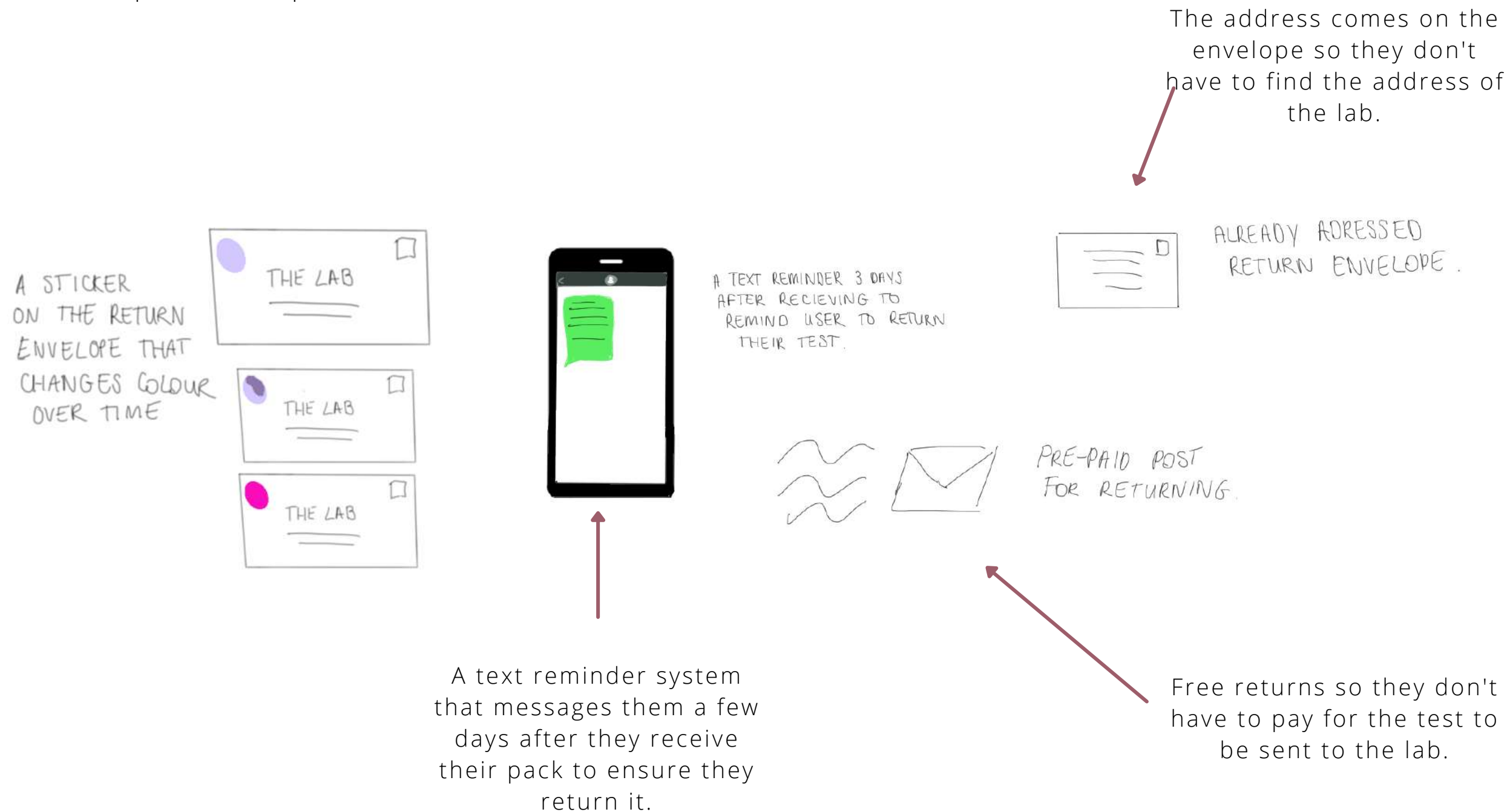
# PERSONAL DETAILS

How do you communicate the personal details with the lab technician.



# RETURNING THE TEST

How can you encourage the returning of the test? In terms of transport, infectious diseases are organised into two categories. HPV fits into the second category - B and therefore the rules around transportation are less stringent according to the WHO the outer packaging must read 'exempt human specimens' (WHO 2010) .





# WHERE DOES THE SAMPLE GO?

The idea that a user could obtain a sample and receive results almost immediately is promising. It is known that Polymerase Chain Reaction (PCR) testing is valuable for the detection of HPV (Stevens et al. 2007). However, PCR testing creates copies of the DNA and contamination is extremely likely, this leads to false positives in testing (Villa and Denny 2006). Real time PCR or Qualitative PCR (qPCR) can provide rapid and sensitive results (Kralik and Ricchi 2017) which is beneficial for the detection of HPV in menstrual blood . The author could not find any research which suggested or supported instantaneous results from the qPCR testing. When used with menstrual blood the samples were sent to the lab. One company Biomeme, has developed software for real time PCR testing. They have streamlined the chemistry process, creating a portable lab that can be used by people who are not specifically trained, and can return results in between one to two hours. Their software is an open architecture and developers can apply to test the software and Biomeme can create lyophilised strips from the collected assays (Biomeme 2021). These strips can be used in the field and could potentially be used to test menstrual blood for HPV. This technology could be used to provide HPV home testing products to users.

The main issue this creates is accessibility, the product is portable and could be seen to be accessible but when examined further it becomes apparent that the sample must be placed into a thermocycler. While the results from commercially available portable thermocyclers are promising (Wee et al. 2020), they are costly. Efforts have been made to create affordable PCR tests (Mendoza 2018), however the issue still remains that this equipment is expensive and therefore not suitable for personal occasional usage.

# MENSTRUAL BLOOD 101

How exactly is the DNA within the menstrual blood replicated to find the HPV infection? Exactly how much blood is required and will the dried blood work? These burning questions surfaced in discussions about this project and they need to be addressed. This concept must work well, and be easy to use, it has to create a trust between the user and the world of cervical screening. It is likely that this be their first experience with screening, and therefore they must have a positive experience to continue to engage with regular screening, and other screening services offered by the HSE.

## ***How is DNA replicated to find HPV infection?***

As discussed before the PCR test identifies the presence of HPV in the samples. The PCR test works by using enzymes - polymerase to assemble new DNA from template DNA and nucleotides (Redig 2021).

## ***How much blood is required, will dry blood work?***

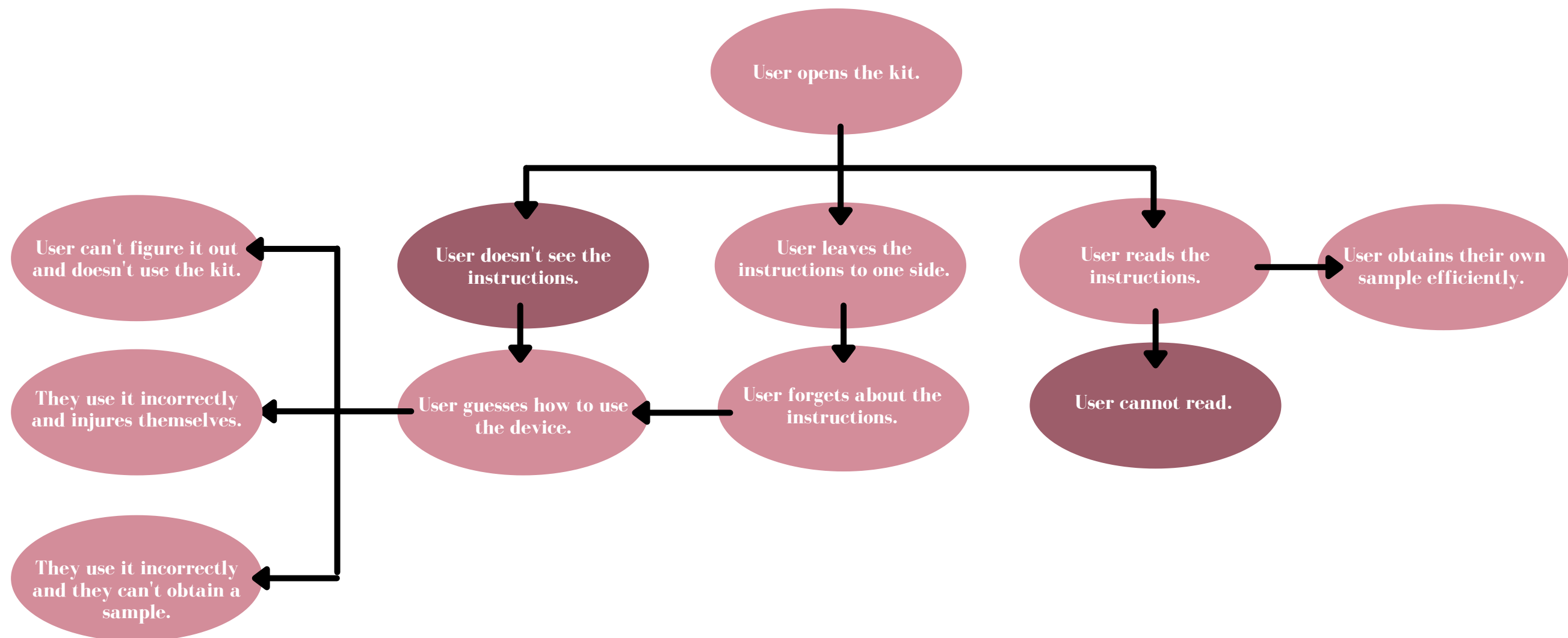
The designer reached out to Wong, who has been leading research into using menstrual blood as a biomarker for HPV detection (Wong et al. 2010; Wong et al. 2018). Wong clarified that a small amount of blood was required, and that the dried blood is most efficient for transport. While fresh blood is good, it can be difficult to obtain and the DNA within the dried blood would be sufficient for a number of days (Wong 2021). This information from Wong, was received in an email interaction which is listed in the *DesignHistoryFile/01.DesignInputs/Dr.WongEmails*.

## ***Prepping for PCR***

Considering the test is going to be sent back to the lab the product must conform to the standards required. Specimen samples are required to be in a sealed container and leak proof plastic bag for transport (UoI Healthcare 2021). Dry sample swabs are generally cut to length and inserted into a sterile container, where a viral sample solution is not available (NHS 2021). A viral sample solution is a liquid which preserves the sample. In research examining menstrual blood as the biomarker, the sample has not required a sample solution for preservation. For instance, the pad was contained in a zip lock bag before a 1cm x 1cm square was removed for analysis (Lee et al. 2016). However, this took place as part of a pilot trial, and if it was going to be completed on a regular basis the process would need to be streamlined for the laboratory staff.

# INSTRUCTIONS FOR USE

Mapping the typical flow of users as they interact with the instructions.



Indeed the instructions are required to be informative, easy to follow and accessible. Perhaps, the instructions could be integrated into the sample swab so they are not disregarded.

# INSTRUCTIONS FOR USE

Designing the Instructions for use, how can they be easy to follow and informative for the user?

## ***Literacy In Ireland***

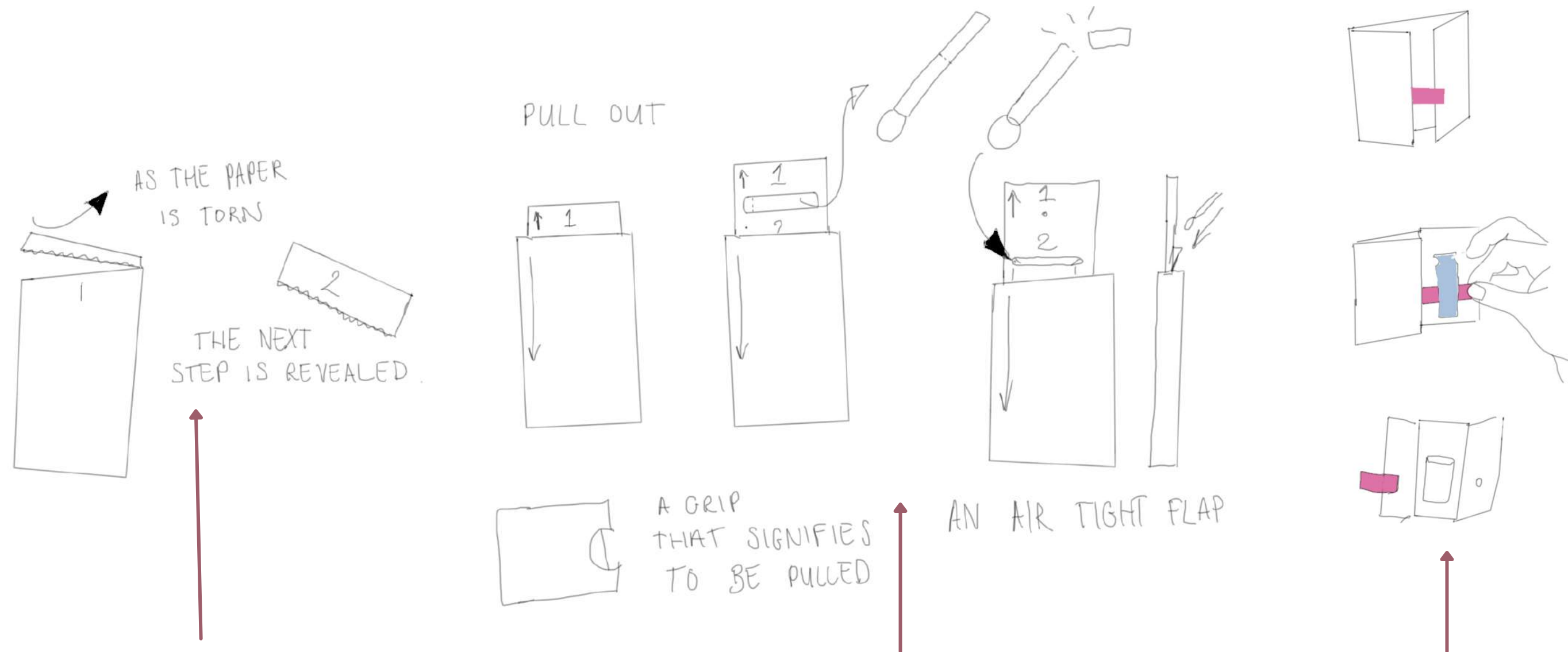
It is worthwhile taking another look at the literacy levels in Ireland and ensuring the instructions are accessible to the widest variety of people possible. Again to increase the uptake of cervical screening, those who have low attendance groups must be accounted for. Members of marginalised groups, including travellers have a lower level of education than the general population (CSO 2016 b). Research into experiences of traveller women and health show that they often have low uptake of services due to low literacy levels (Jackson et al. 2017). It is apparent that they have lower literacy, but that this often acts as barrier to interacting with health services. Therefore the accessibility of the instructions is of huge importance. There is also a high population of non-English speaking people living in Ireland so where possible the instructions should not rely on written text, rather other ways to communicate the requirements.

## ***Analogue Usability***

For the consideration of those with lower levels of literacy or without English as a first language the designer looks to user interface (UI) usability techniques to ensure the instructions are learnable and reduce risk for error. The number of principles for usability vary 5 (Idler 2021), 7 (Story 1998), 10 (Nielsen 2005), however the basics remain the same. It needs to be intuitive to use, easy to remember and difficult to make mistakes. Other than that the design should be minimal, and match the real world. The existence of the principles make for a neat checklist to ensure the design is usable. Nielsen has established a heuristics evaluation which will be applied to the design to solidify the instructions as being usable.

# OUT OF BOX EXPERIENCE

A previous sketch described a way to obtain the sample through the packaging. The designer explores other ways to combine the instructions with the sample collection for ease of use. Focusing on reducing the opportunity for error.



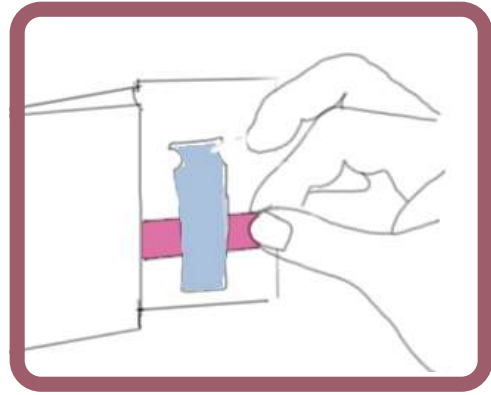
Packaging is pulled to reveal the next step - minimising room for error

Packaging slides apart step-by-step to reveal the components as they are needed - controlling error.

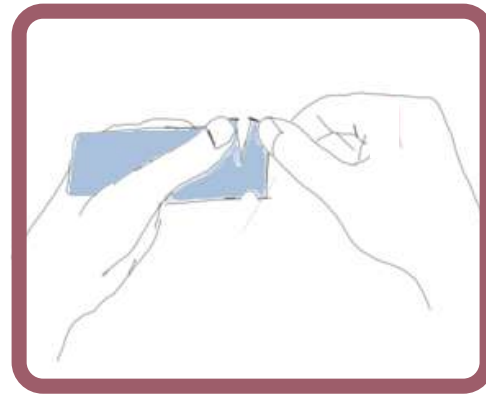
A tab on the side could indicate to the user to pull open a trifold packaging.

# OUT OF BOX EXPERIENCE

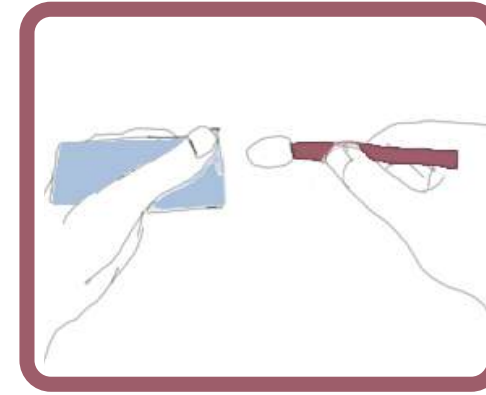
Exploring the trifold packaging from the previous page through a storyboard and prototype.



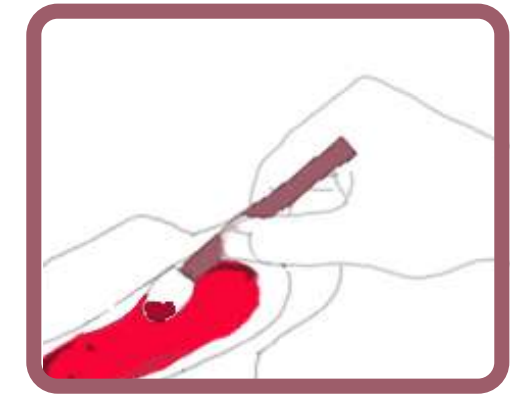
User pulls the tab. To open the packaging.



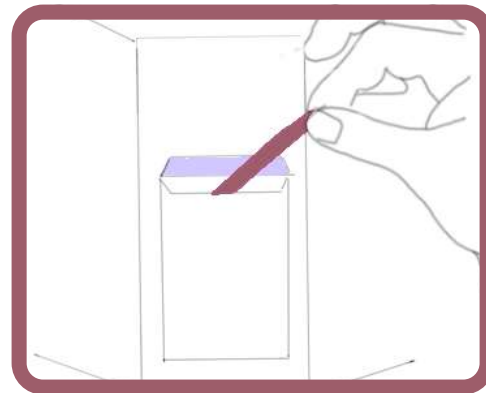
User tears open the instructions..



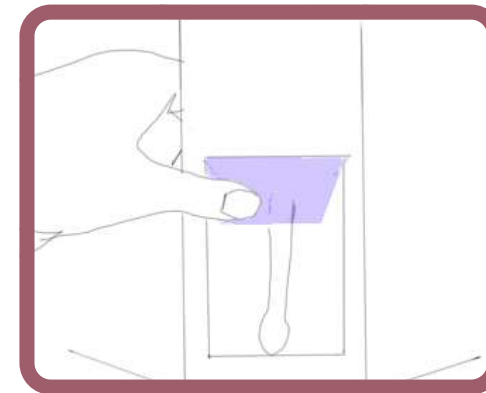
User removes the swab.



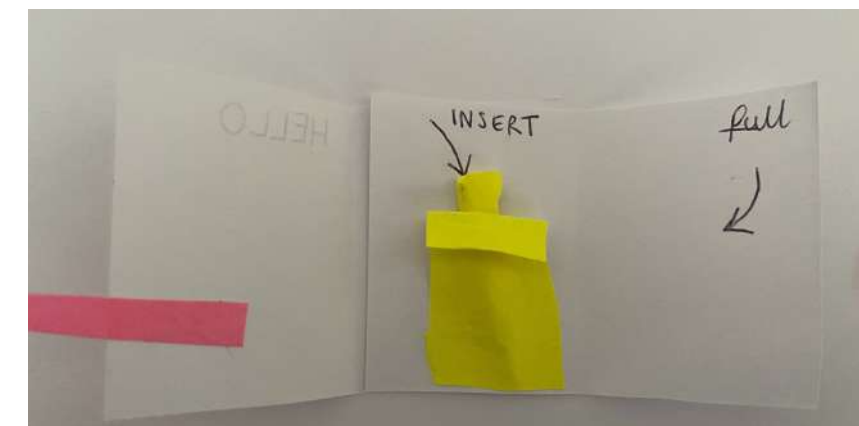
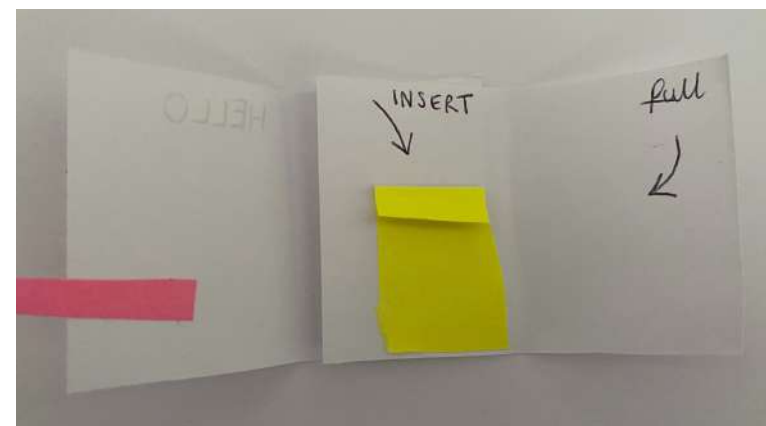
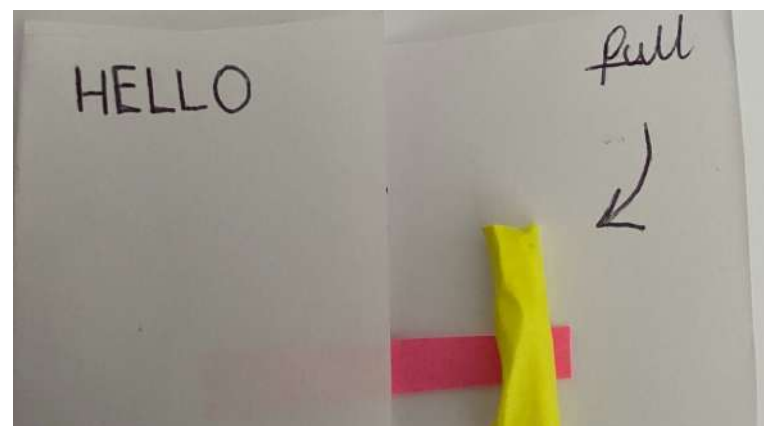
User takes a sample of the blood.



User places the swab into the pocket.

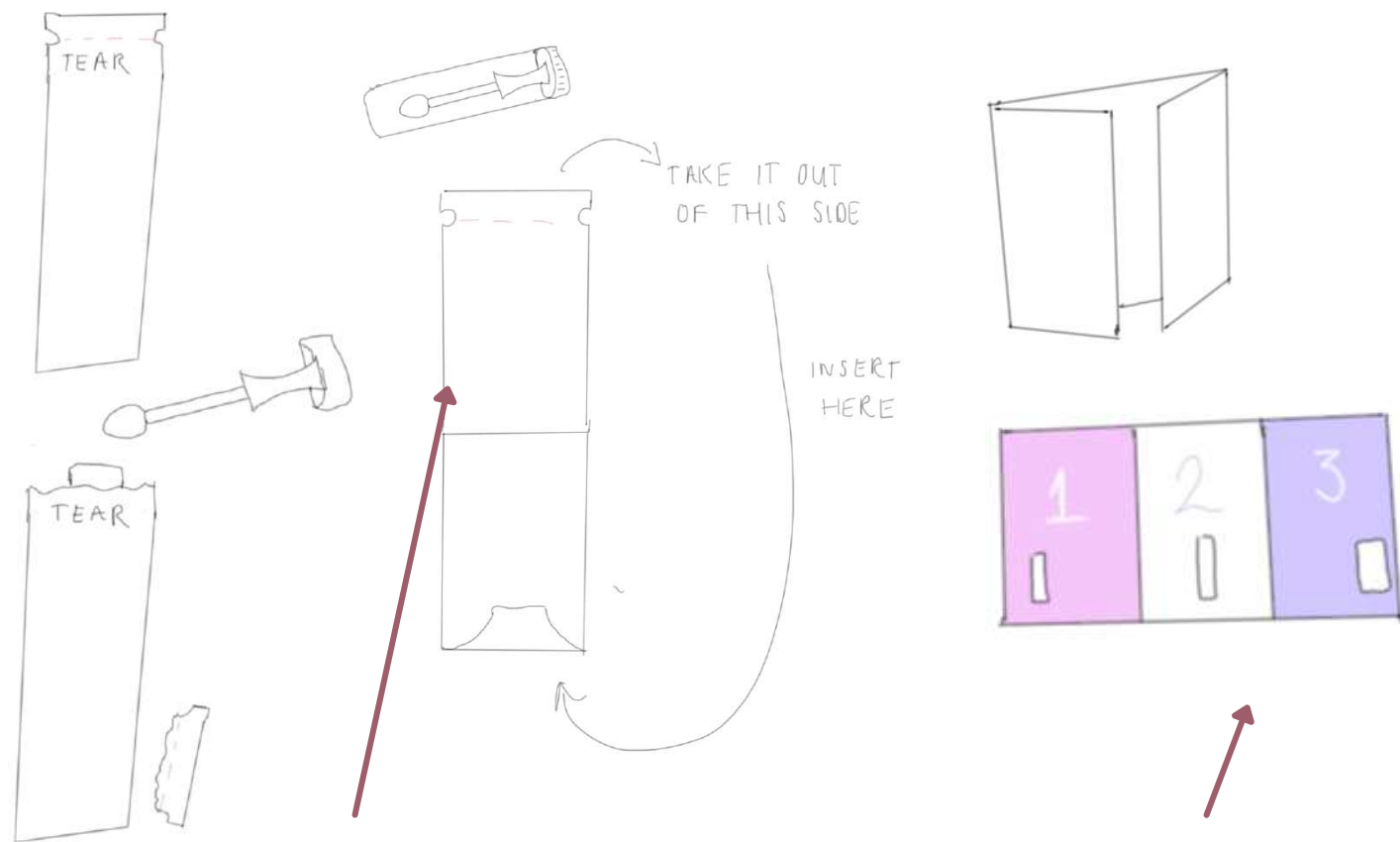


User seals the packaging.



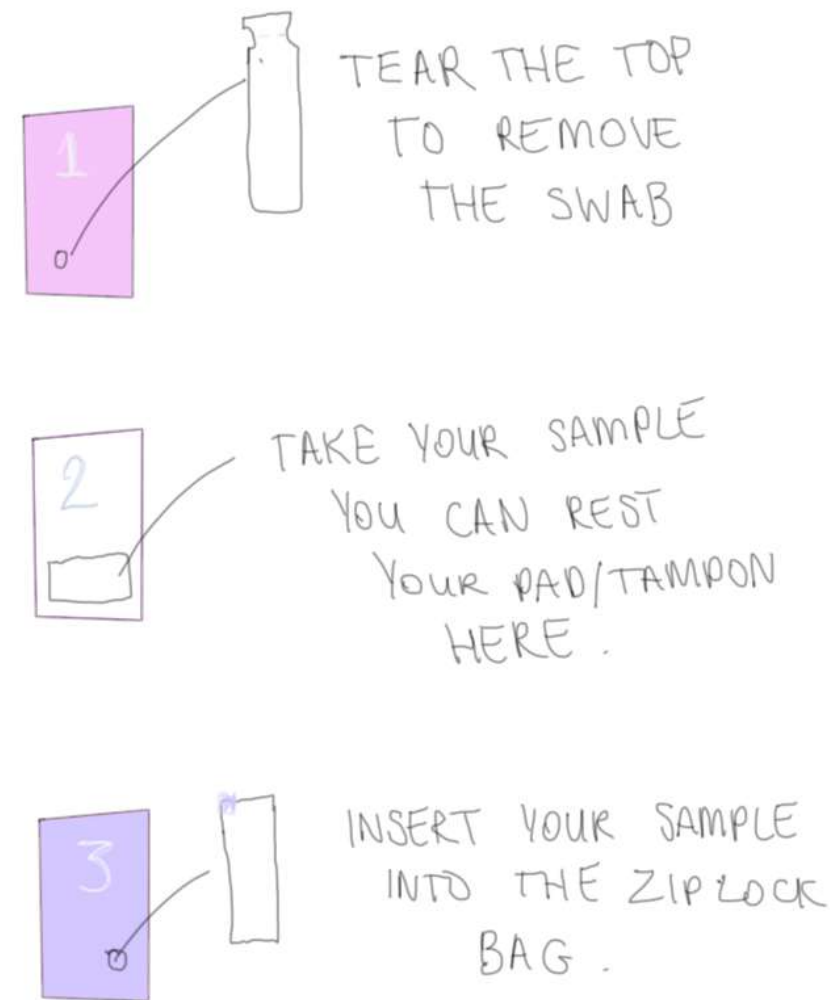
# OUT OF BOX EXPERIENCE

The designer continues to sketch packaging to make obtaining the sample a simple error free process.



The packaging is torn at the top and the swab is inserted in the base.

Packaging that folds out and each step has its own section and colour.



TEAR THE TOP TO REMOVE THE SWAB

TAKE YOUR SAMPLE YOU CAN REST YOUR PAD/TAMPON HERE.

INSERT YOUR SAMPLE INTO THE ZIP LOCK BAG.

Packaging with instructions in the middle and a tear side to take the swab out and a seal side to put the sample back in.



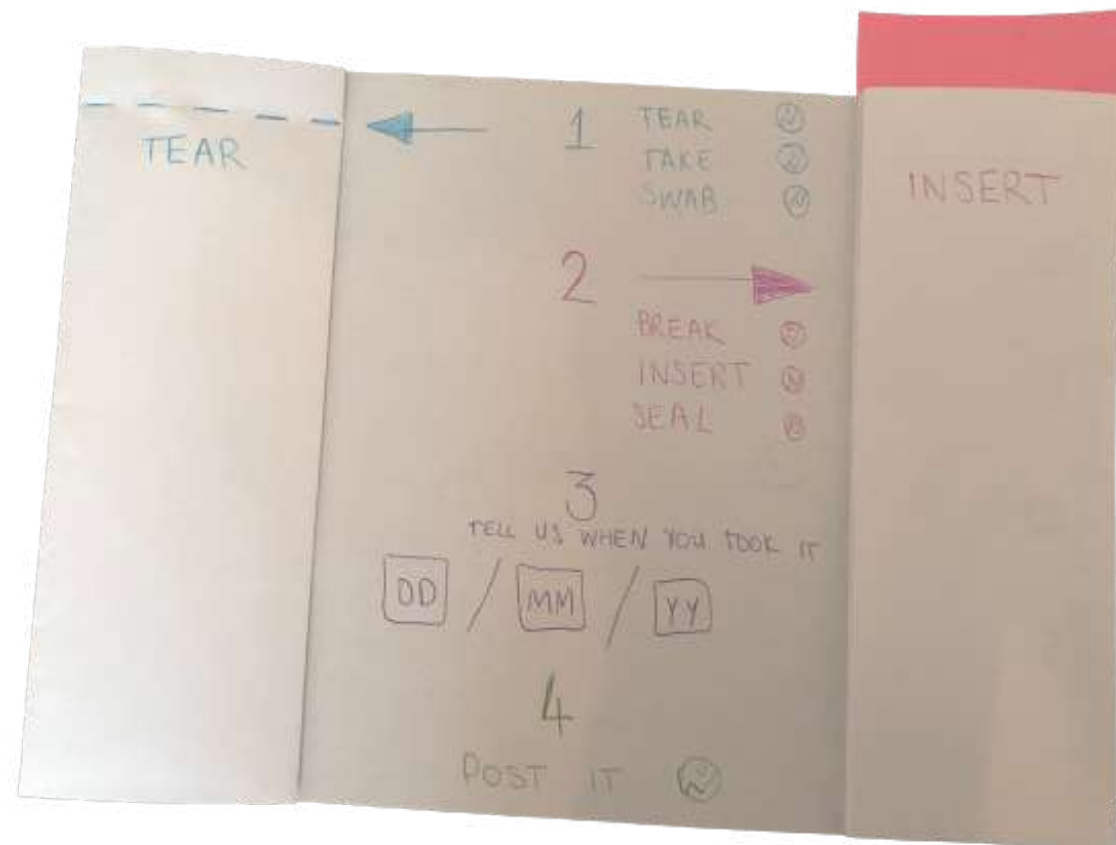
TAKE SWAB OUT.

PUT SWAB IN PINK SIDE

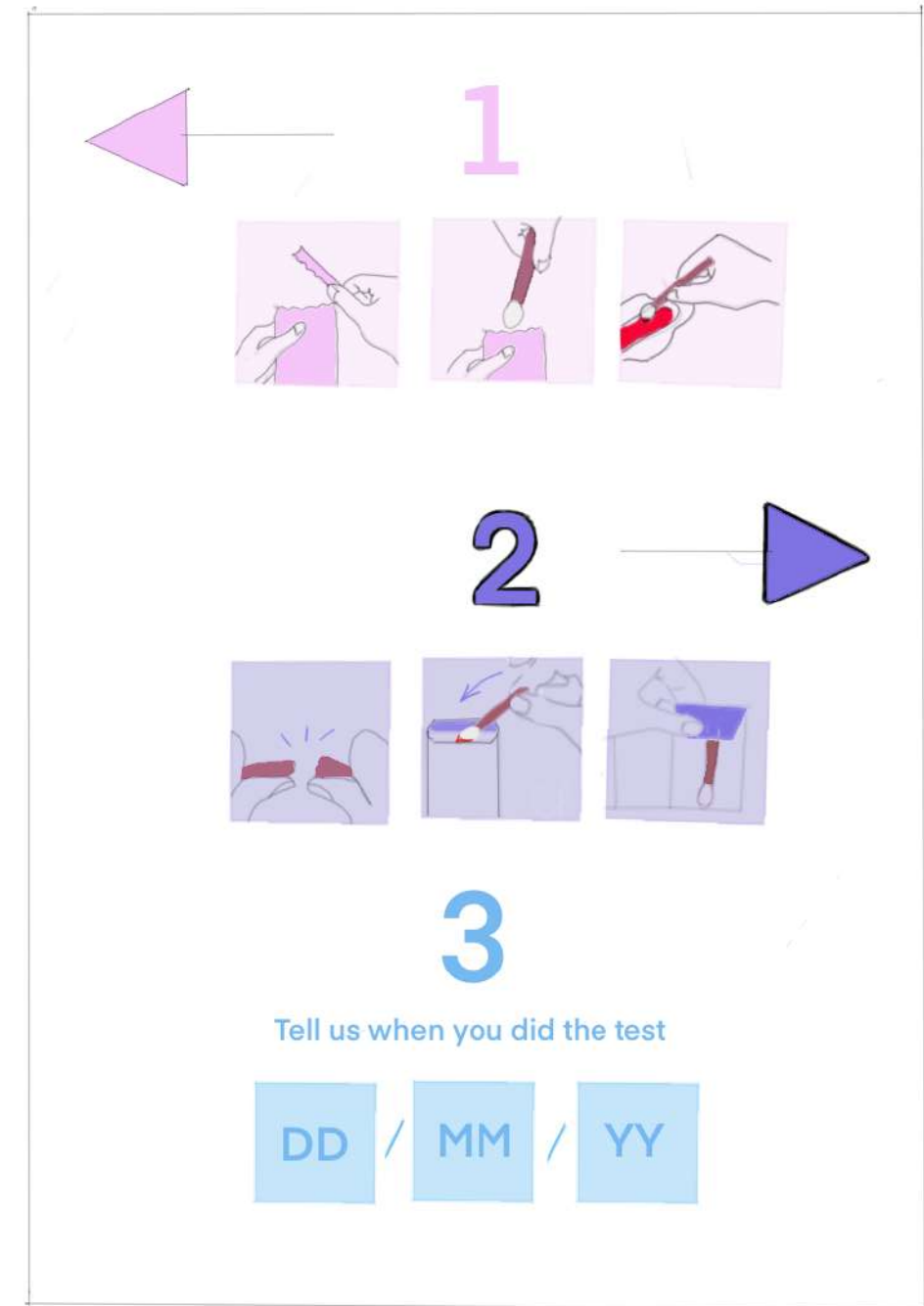
FOLD FLAP OVER

# INSTRUCTIONS FOR USE

Exploring the three sectioned packaging where one side tears off and the opposite side is sealed for sterility. There was a particular emphasis on graphic representation of the instructions rather than written instructions due to the aforementioned issue with literacy. These instructions require testing to identify whether or not they are comprehensible without text. The designer created a sketch model of the packaging to identify what it would look like and then made a CAD graphic representation of it.



This instructional sketch has 4 instructions and gaps for the graphic representation of the instructions. It also has text on it, mostly single word descriptions on it, however without looking at the literacy levels in Ireland and exactly what level of comprehension is out there the emphasis should be on graphics.

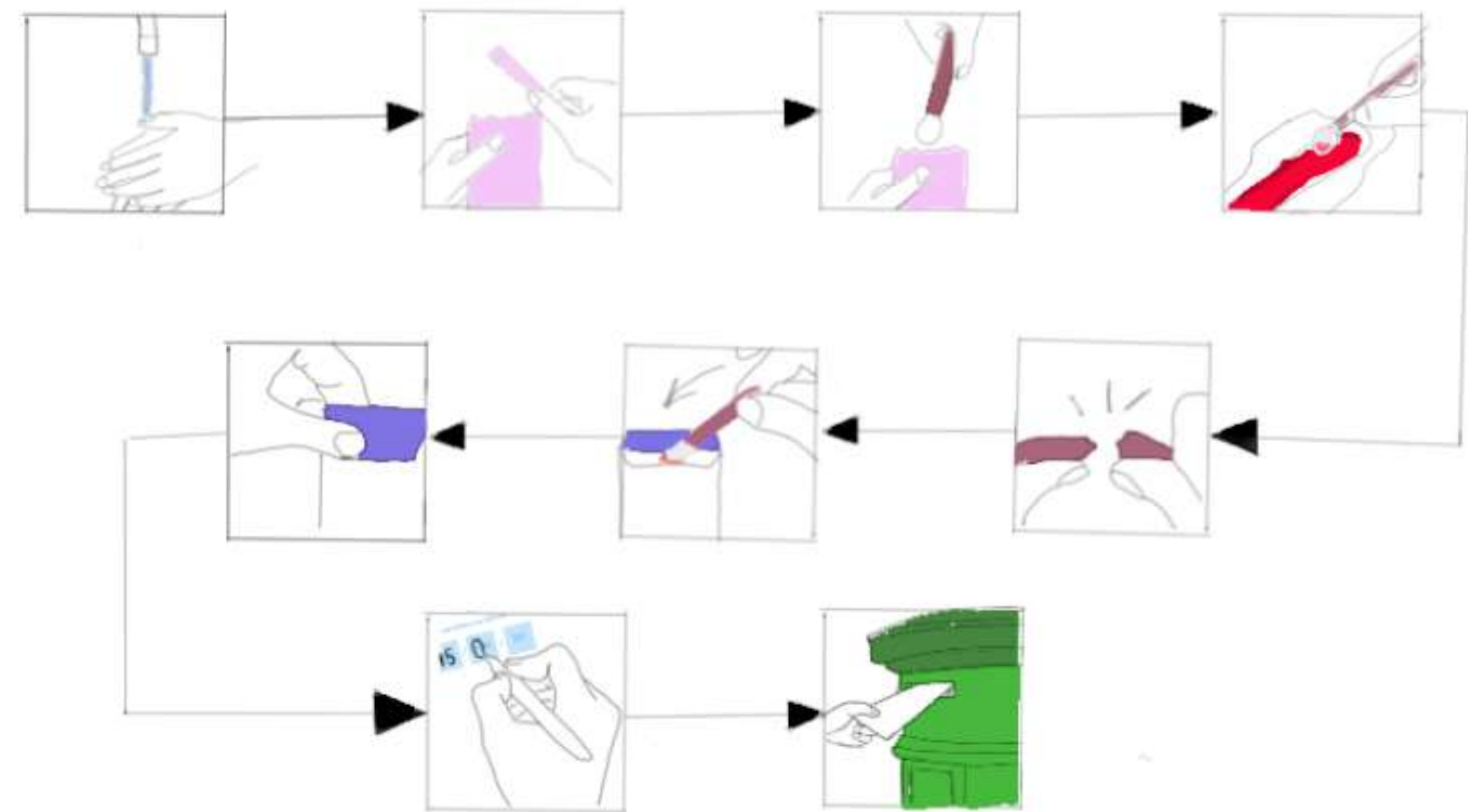


This representation focuses on graphic representation and the purple 2 and arrow are bolded, to account for colour blind users. They can differentiate by the bolding rather than the colour.



# INSTRUCTIONS FOR USE

After testing the packaging with the user the designer went back to the drawing board to decide how the instructions could be communicated more clearly and if there was a way to include what to do after the sample was collected somewhere on the packaging. To test these icons, the designer gave them to a participant who had not used the product before to see if they could identify what the icons meant. The designer added one icon 'clap hands' to keep the participant on their toes.



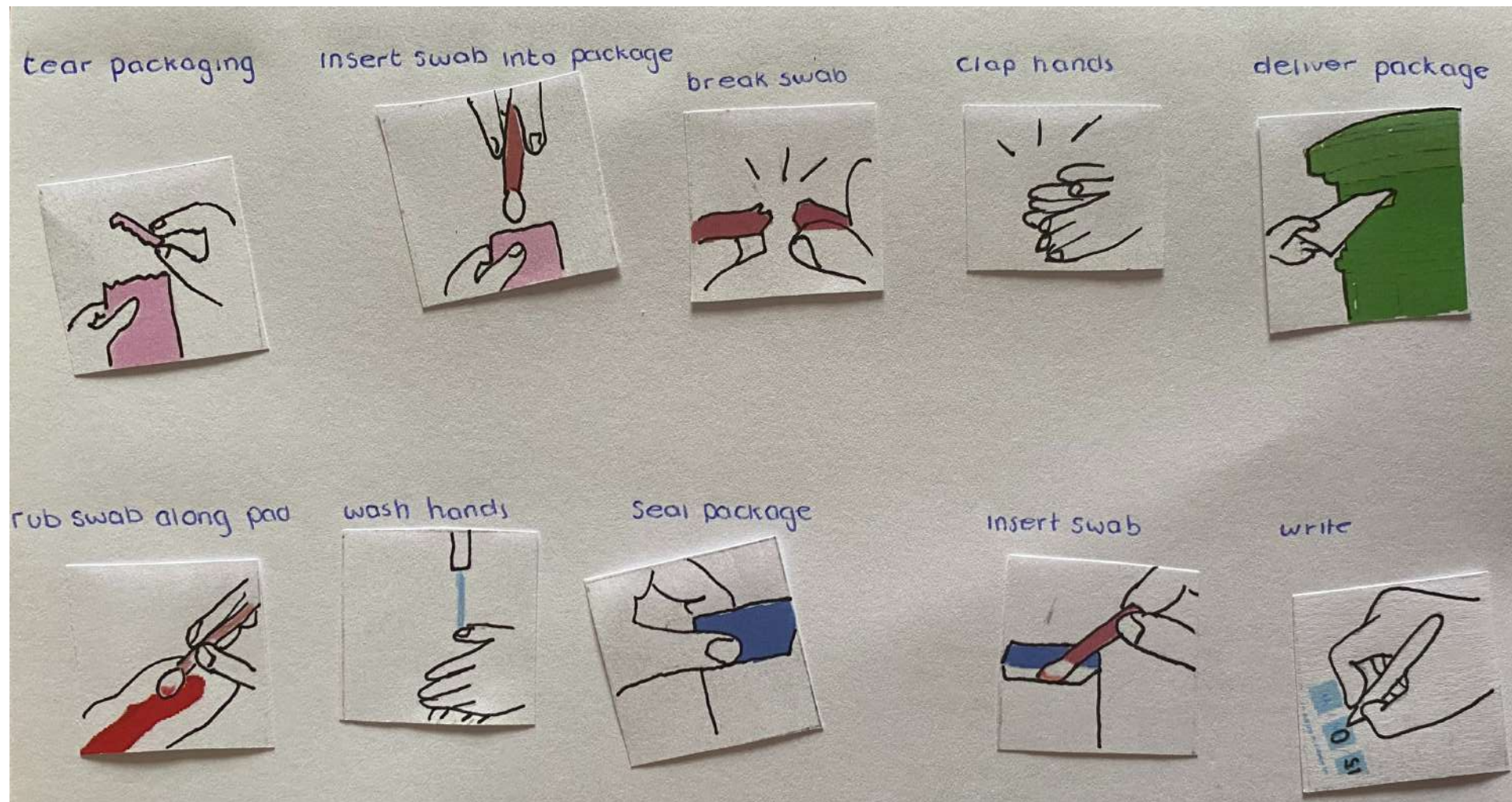
## **Task**

Write down the meaning of the icon above it.

## **Purpose**

Understanding how the icon is perceived by someone who has not used the product before.

# INSTRUCTIONS FOR USE



## **User Feedback**

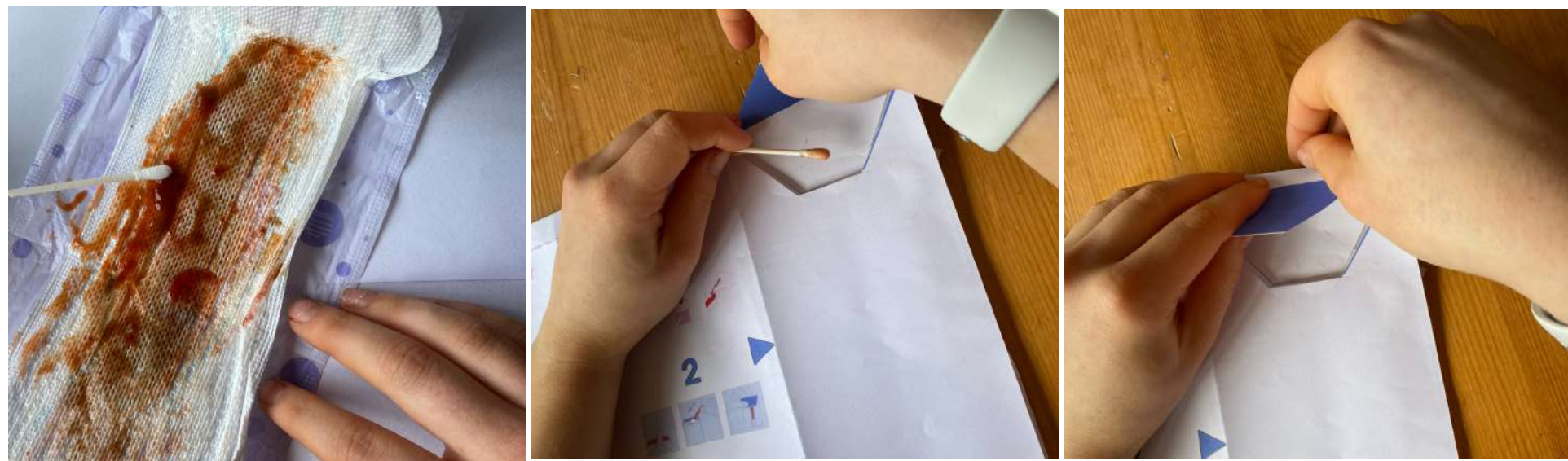
I messed up the second one but when I saw the second last one I knew it was wrong. I guessed the seal package one, I didn't understand that one and the last one I said write but I didn't know what needed to be written.

## **Findings**

The icons are comprehensible but the test should be replicated to ensure other users understand it as well. The user did question the clap hands icon and its relevance which worked well. The insert and remove swab icons should have directional arrows to avoid confusion.

# OUT OF BOX EXPERIENCE

This design contains graphics and icons rather than written language to convey how to use the test so that it may be accessible. This test is to identify the ability of a user to work through the packaging and get feedback about the process.



## **User Feedback**

I liked this packaging, I knew what was going on and what I needed to do. Those pictures are kind of hard to see though.

## **Findings**

The user found the packaging size too large for the purpose of the testing. They found it difficult to see the graphics on the colourful backgrounds.

They were able to move through the process quickly and efficiently without major issues. The swab was inserted with the head at the tear line so the user removed the swab by it's head which is incorrect and needs to be addressed. Another issue is the sterility of the pocket the sample is being returned into. It should be lined with a material which will not harm the integrity of the sample.

# PACKAGING

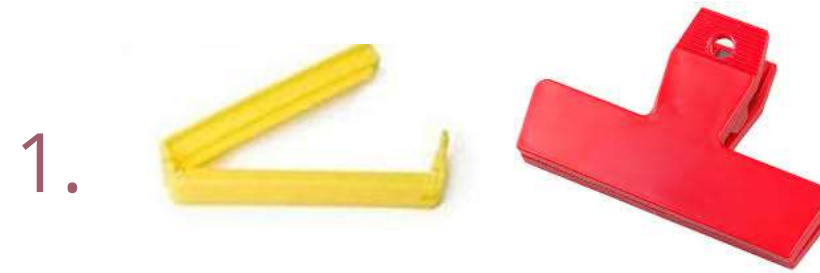
Upon identifying the users ability to make their way through the packaging it is important to recognise that the seal for the packaging needs to be secured and identifying a way of ensuring it is sealed.

1. Methods of sealing the bag shut like a clip are effective but create a lot of waste, unless they are recycled in the lab.

2. Bags with zip locks or drawstrings on them would be useful and suitable for holding the sample.

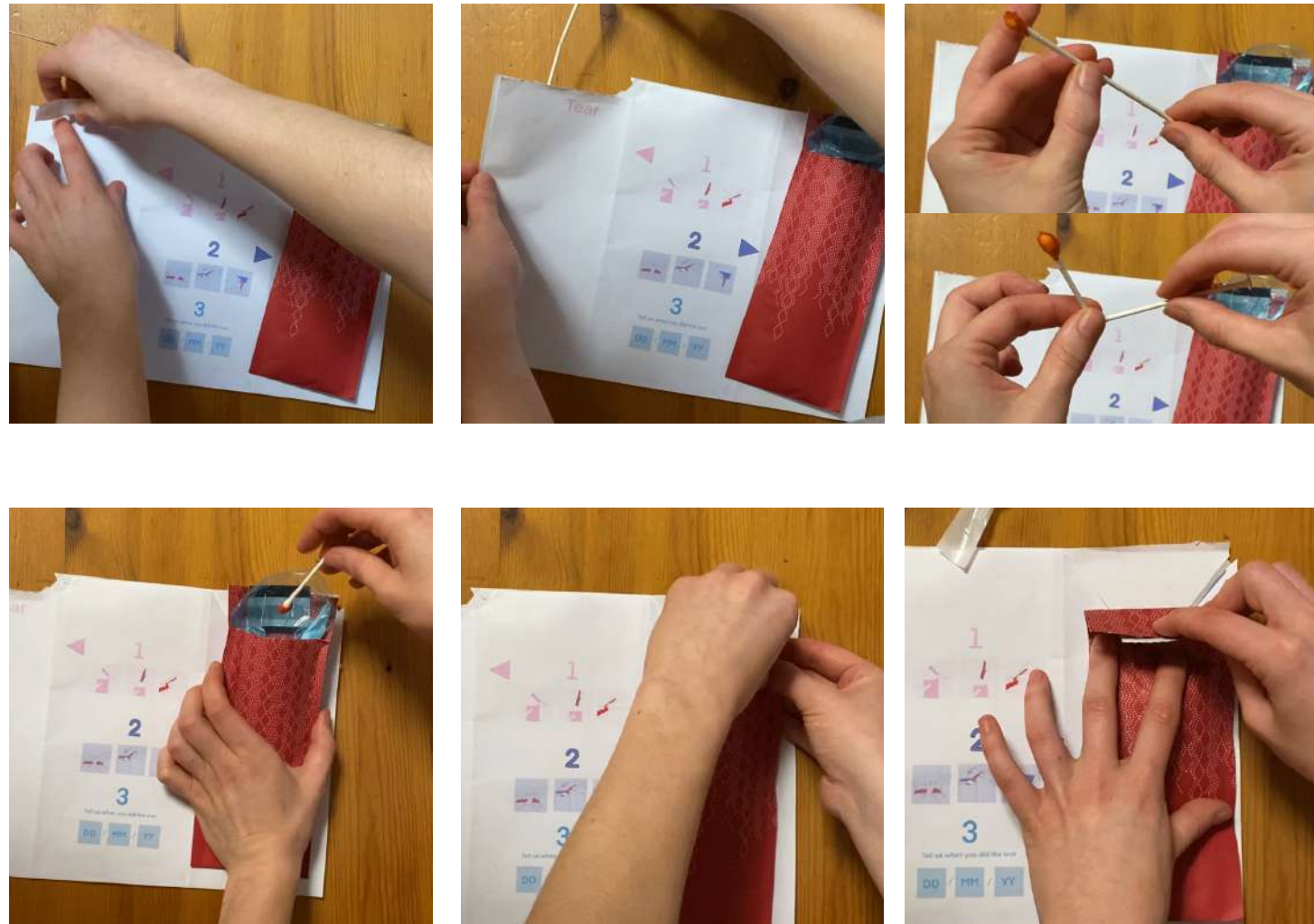
3. Methods of sealing which use extra products, for instance heat sealing are highly effective but too expensive to include in a kit.

4. The method of peeling and sealing an envelope would work very well as it is cheap and easy.



# PACKAGING

Following the user feedback, the designer creates another version of the packaging. This time the designer ensures the swab is sitting correctly with the base at the top of the pack and has a plastic layer in the receiving end of the packaging. There were also adjustments made to the graphic instructions to ensure they were readable. This time the test would examine the ability of a user who is not familiar with the product, to comprehend the instructions.



## **Task**

Testing a seal for the packaging.

## **Purpose**

Identifying the ease of use of the seal and noting any feedback.

## **User Feedback**

This seal was easy to use and its like other seals on packages so it was handy enough to know what to do.

## **Findings**

The user spoke highly of the method of sealing the sample. The designer however is concerned about reducing the waste involved and removing a protective layer is additional waste.

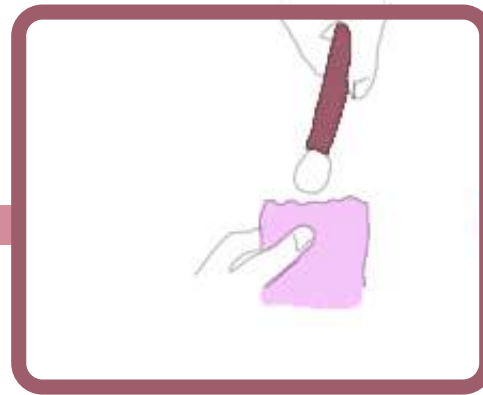
The solution examined in the final picture was perhaps to remove the sample section of the packaging and have the remainder of the packaging as recyclable or compostable.

# THE PRODUCT IN USE

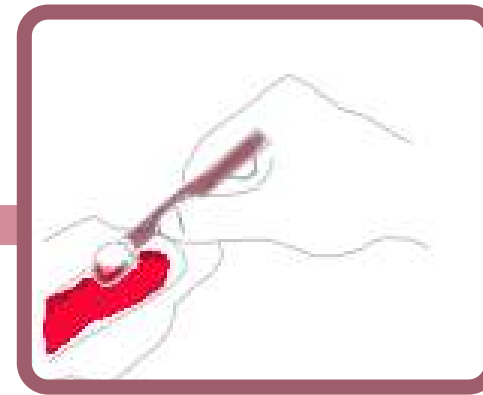
Storyboarding the users interaction with the product



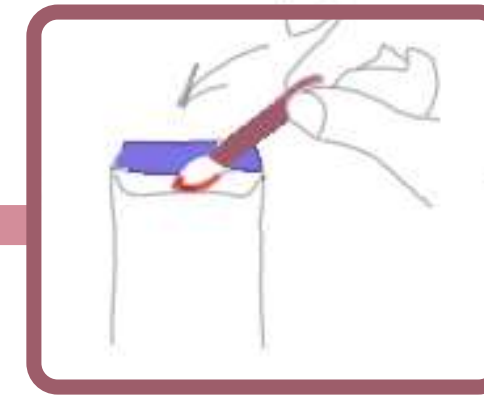
The user tears along the perforated edge to reveal the swab.



They remove the swab.



They wipe the swab along the menstrual pad.



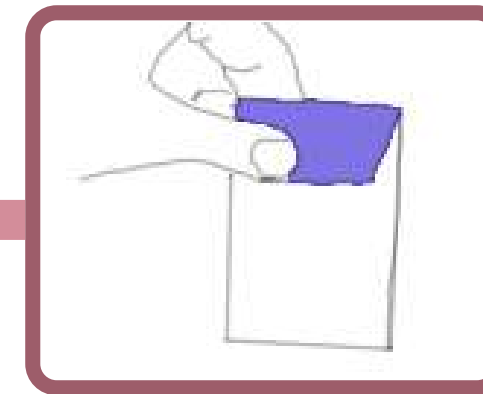
They insert the swab into the other side of the pack.



They post the envelope in the post box.



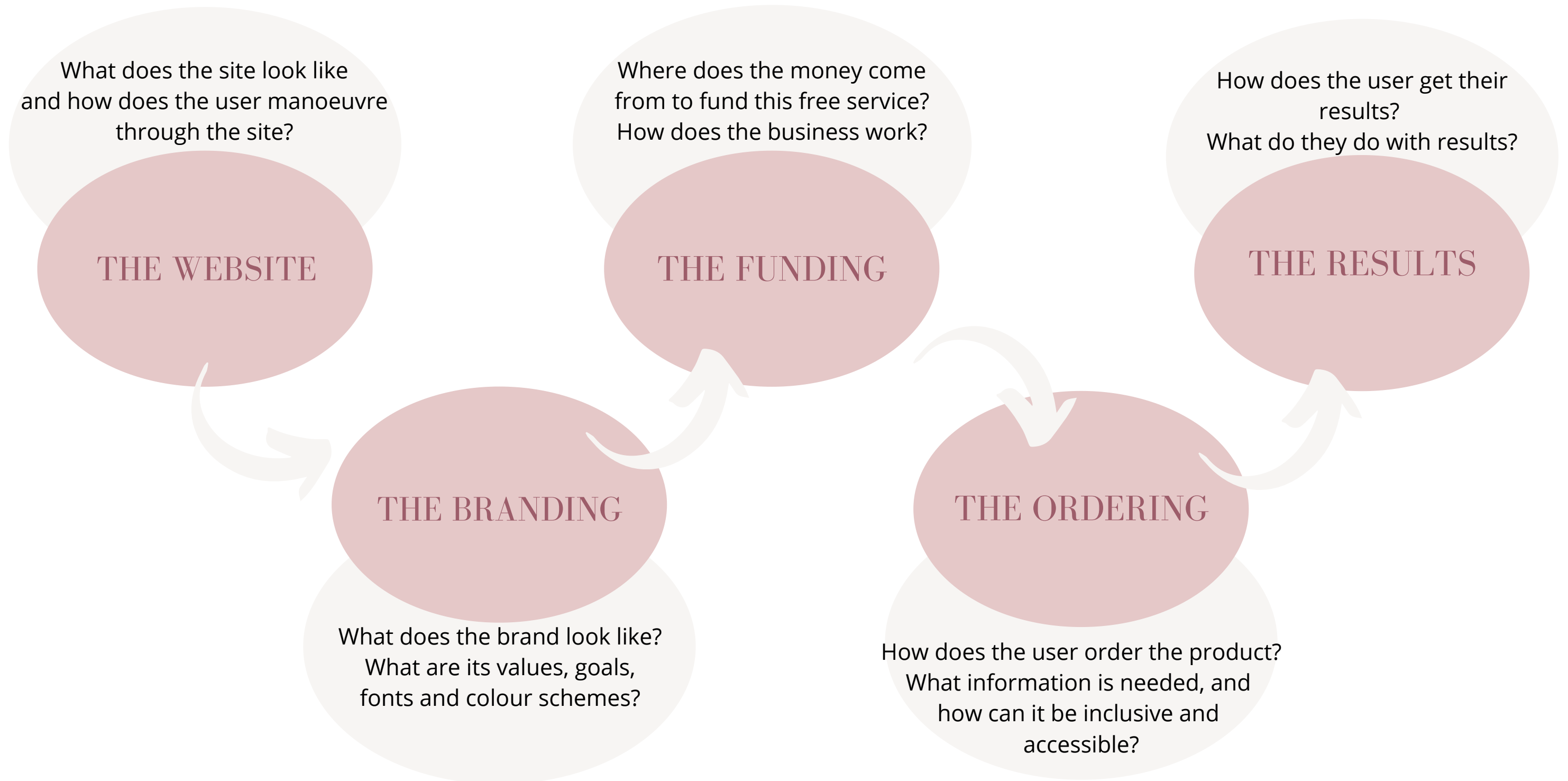
User fills in the date the sample was taken.



User reseals the packaging and finishes in the toilet.

# THE SERVICE

With a solid idea of the kit, having tried and tested the testing kit and the packaging it's time to move onto the five touchpoints for the service that are to be designed.

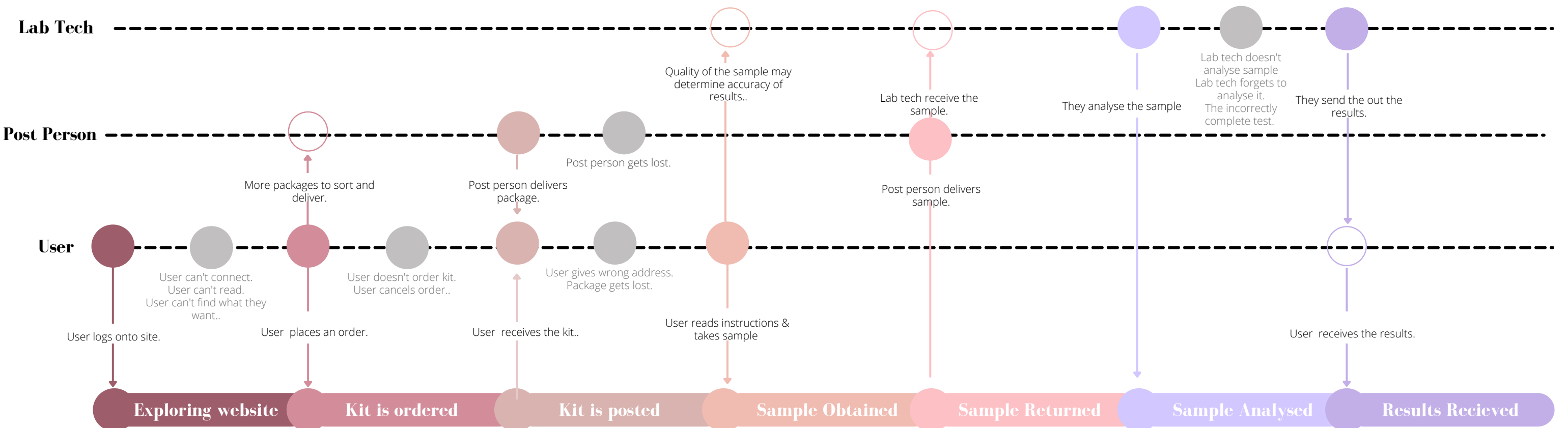


# LIFECYCLE MAPPING

Lifecycle mapping, focuses on goals, users and tasks. It maps various users regardless of where they interact with the service (Unqiu Li 2018). It highlights users performing actions, being impacted and when they have a decision or an option. Here the tasks are colour coded and the interactions the user and the lab technician will have are noted. Decisions or alternative routes are marked in grey.

**KEY**

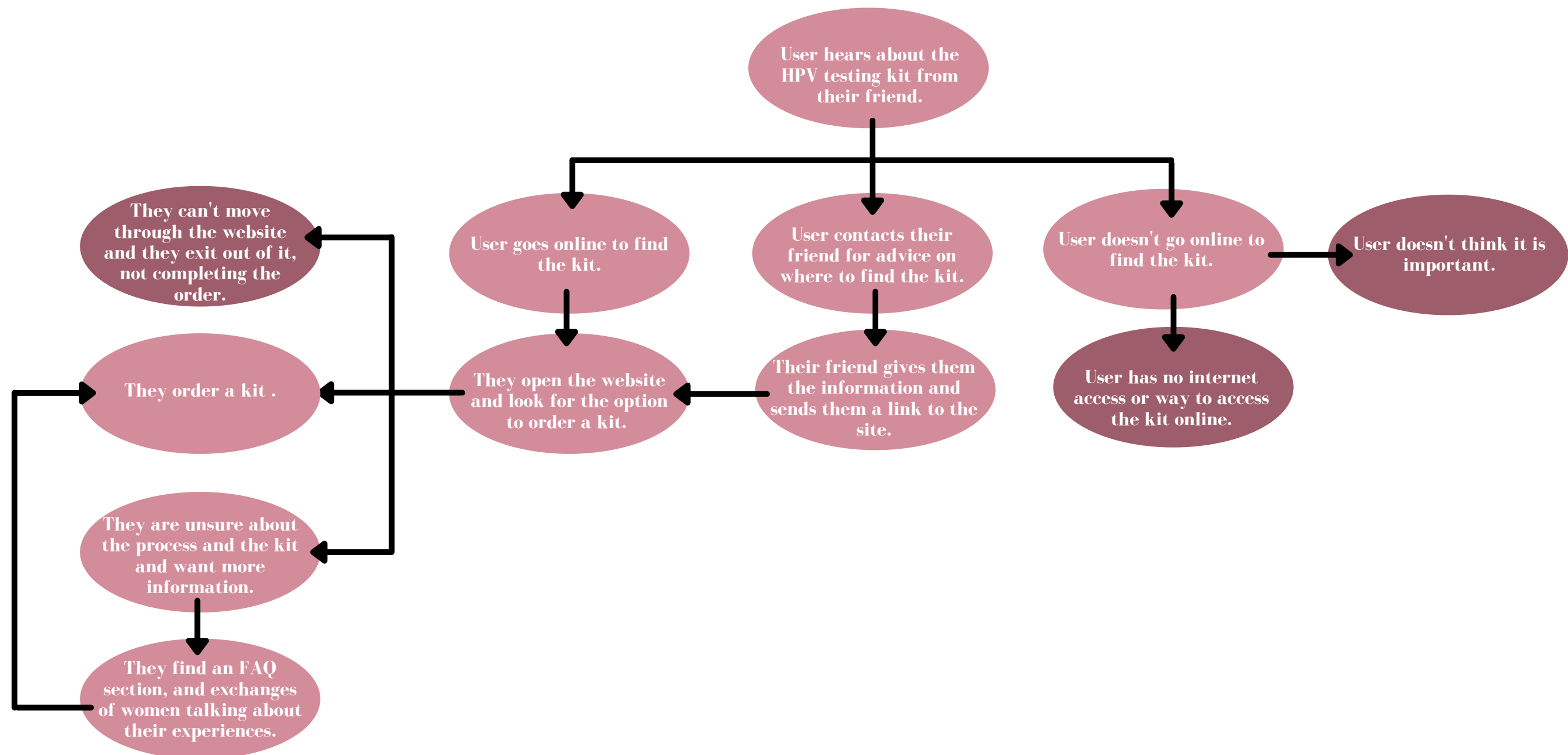
- Action Performed
- Actor Impacted
- Options/Alternatives





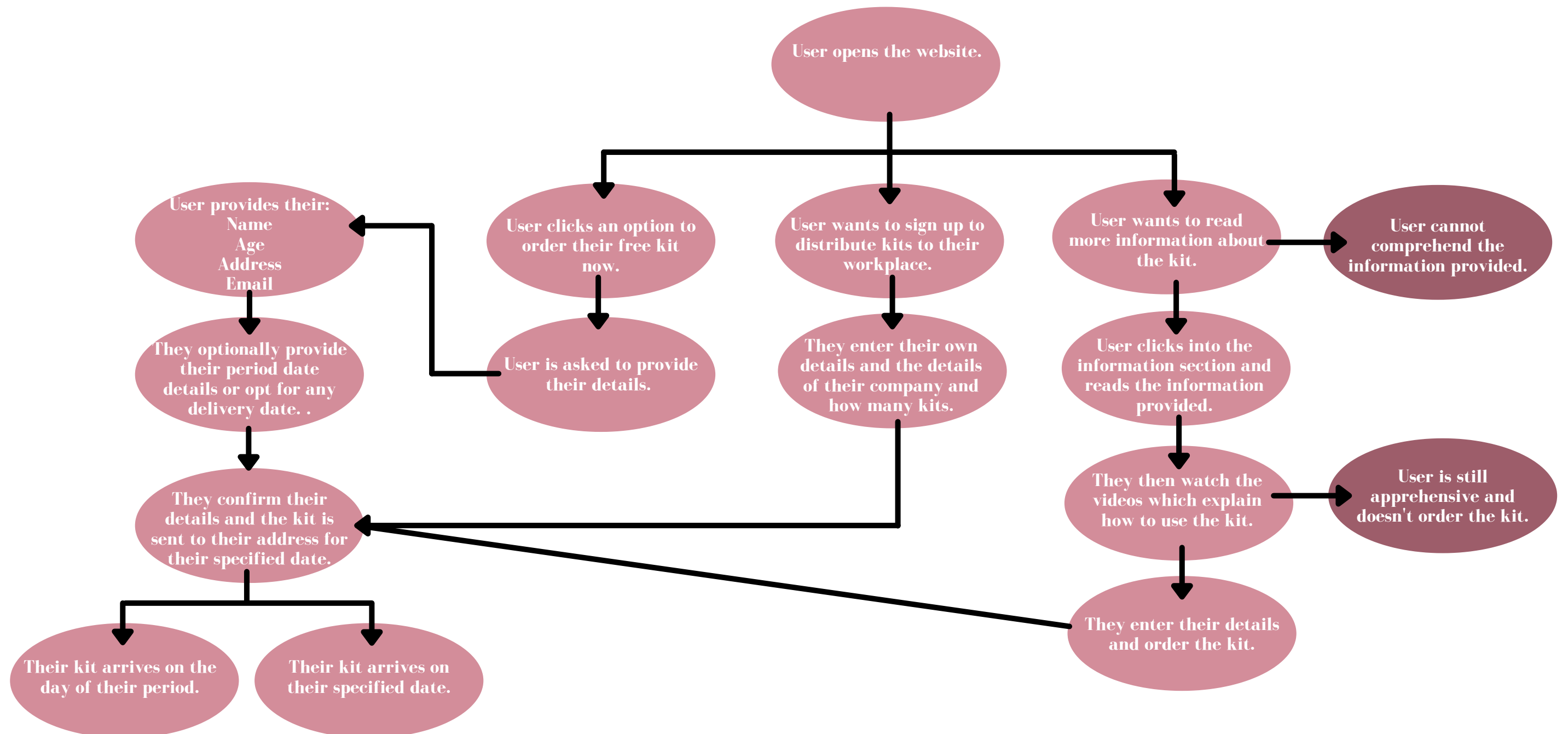
# PURCHASING PATHWAYS

It is beneficial to identify the ways in which it can be provided to customers and what the service as a whole looks like. To do this the author will use task flows and then apply a service blueprint to identify key aspects of this service. This task flow highlights the issue of accessibility, the designer will address this later on in the process book.



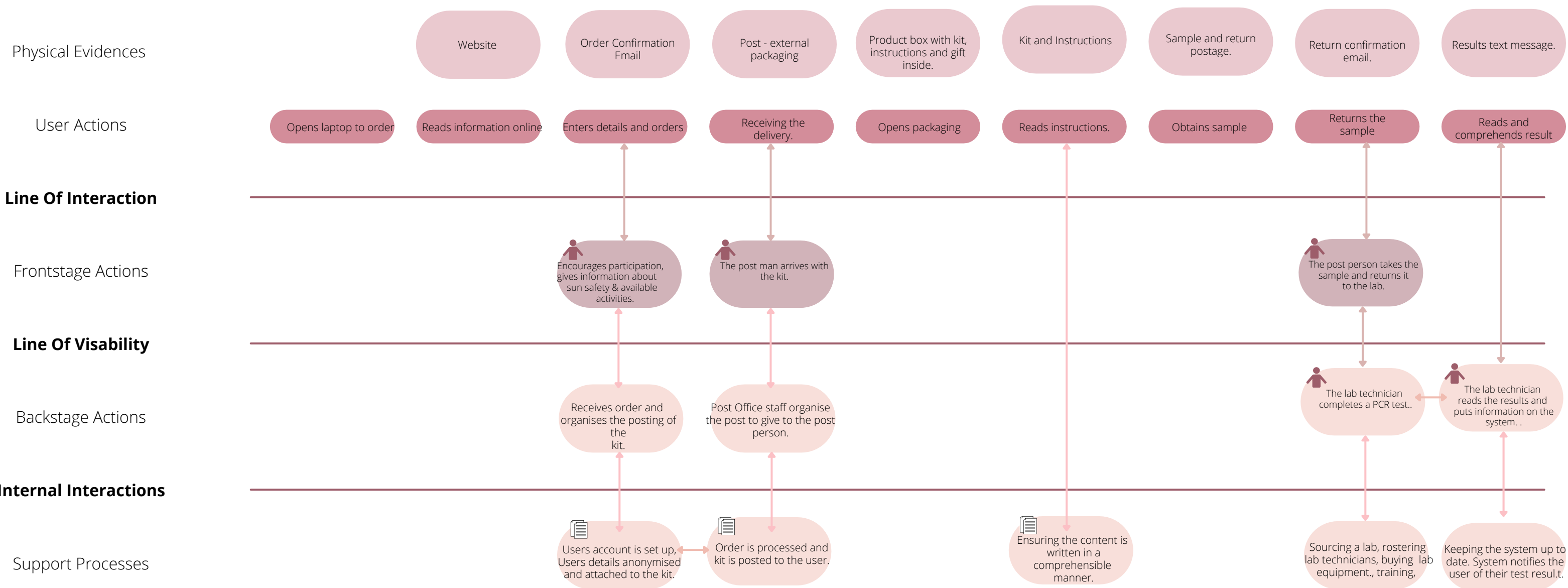
# PURCHASING PATHWAYS

Identifying issues in the previous task flow allows for improvement. This task flow will follow the user as they move through the website. As one of the aforementioned issues cites inability to move through the site.



# SERVICE BLUEPRINT

Service blueprints are extensions of journey maps which add depth to show relationships and dependencies between frontstage and backstage processes (Stickdorn et al. 2018). It is focused on service innovation within human-to-human and human-to-technology boundaries (Bitner et al. 2008).

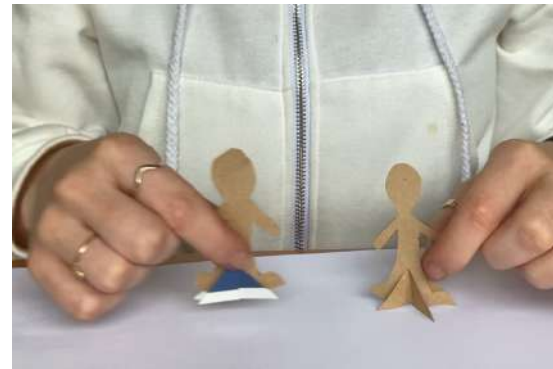


# DESKTOP WALKTHROUGH

Following the service blueprint, the designer moved users through the system in the form of a desktop walkthrough to identify problem areas in order to make the service more efficient.



The user orders the kit online.



The post person delivers the kit to the user.



The user returns the kit to the post office.

## **Task**

Use this service.

## **Purpose**

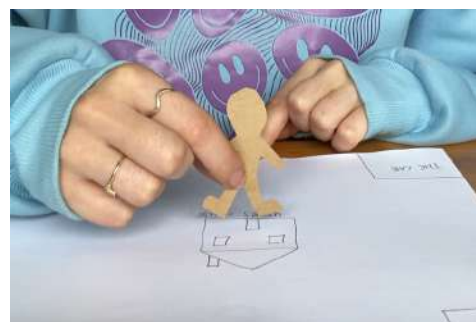
Identify any missing touchpoints, users or any issues with the service.

## **Findings - Walkthrough 1**

This walkthrough featured a perfect situation a user ordering online and being delivered their package. It highlighted the need for a 3rd person, the lab technologist.

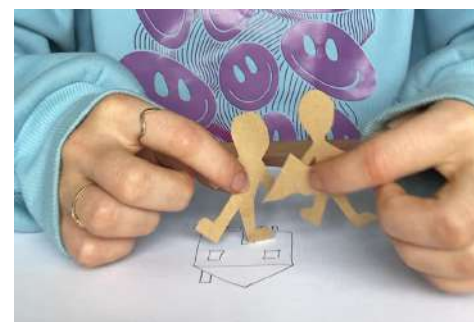
## **Findings - Walkthrough 2**

This walkthrough surfaced the issue of the post box and post office being far away from the user, so they waited until the next time they were in the town to post it. It also explored the post man loosing the package, not returning the package and not understanding the kit. There needs to be consideration given to the posting of the sample for those outside towns, particularly with the increasing risk of rural post offices closing down due to retiring postmasters (McCurry 2021).



The user orders the kit online.

- The order is not processed and never arrives.



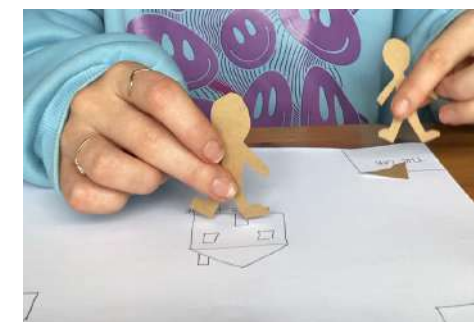
The post person delivers the package.

- The user does not understand the kit.



The user returns the package to the post office.

- The person does not return the kit.

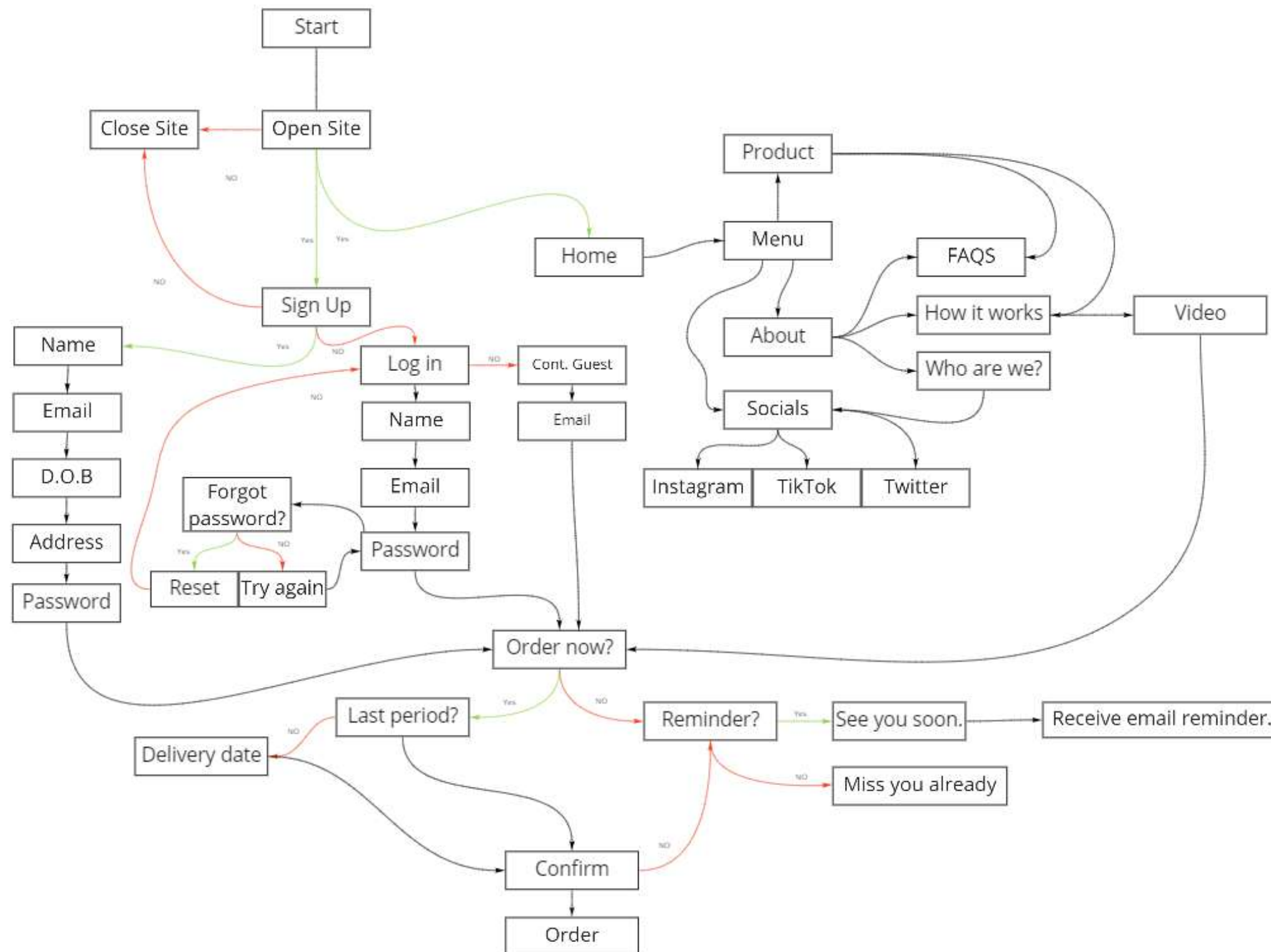


The post person delivers the kit to the lab.

- The kit gets lost in transit.

# WEB PAGE FLOW CHART

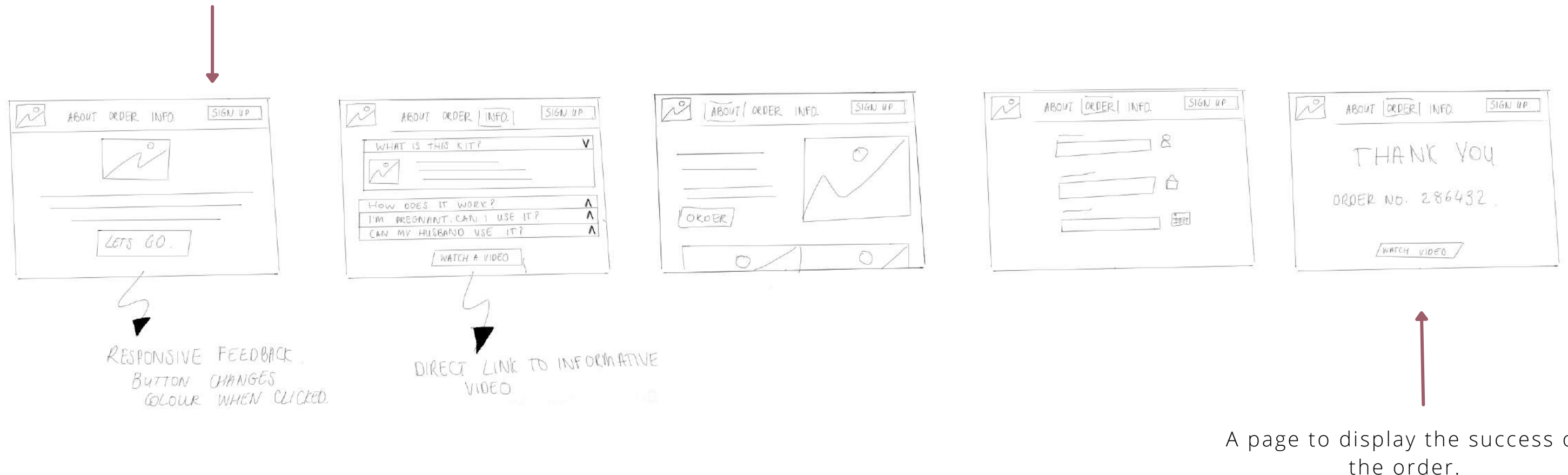
Before diving into the design of the website, the first thing the designer will do is explore, similar to the previous task flows, how the user might move through the website. This includes decision cross-roads and opportunities for error. With a flow chart to refer to the creation of wireframes will be easier.



# SKETCHING SCREENS

The flow chart enabled the designer to identify different uses for the website and various ways to interact with it. The designer builds on this information by sketching various screens to begin visualising the website.

A home or landing screen that has a picture of the product and two shortcut buttons to ordering the kit or signing up cervical check.



Research into internet usage in Ireland revealed that in 2018, 88% of people accessed the internet on their phone (CSO 2018). Based on this information the designer has focused on creating the website in 'mobile format' as if it were used on a phone, as it will likely be accessed.

# PAPER PROTOYPING

Following on from the development of the flow chart, the designer began paper-prototyping, and working through the prototypes with the user. The user feedback is easier to action at this stage than when the mock-ups and interactive prototypes have been created.



## **Task**

Open the site and order a kit.

## **Purpose**

This test is to watch the user as they make their way through the site, noting any mistakes, questions and confusion.

## **User Feedback**

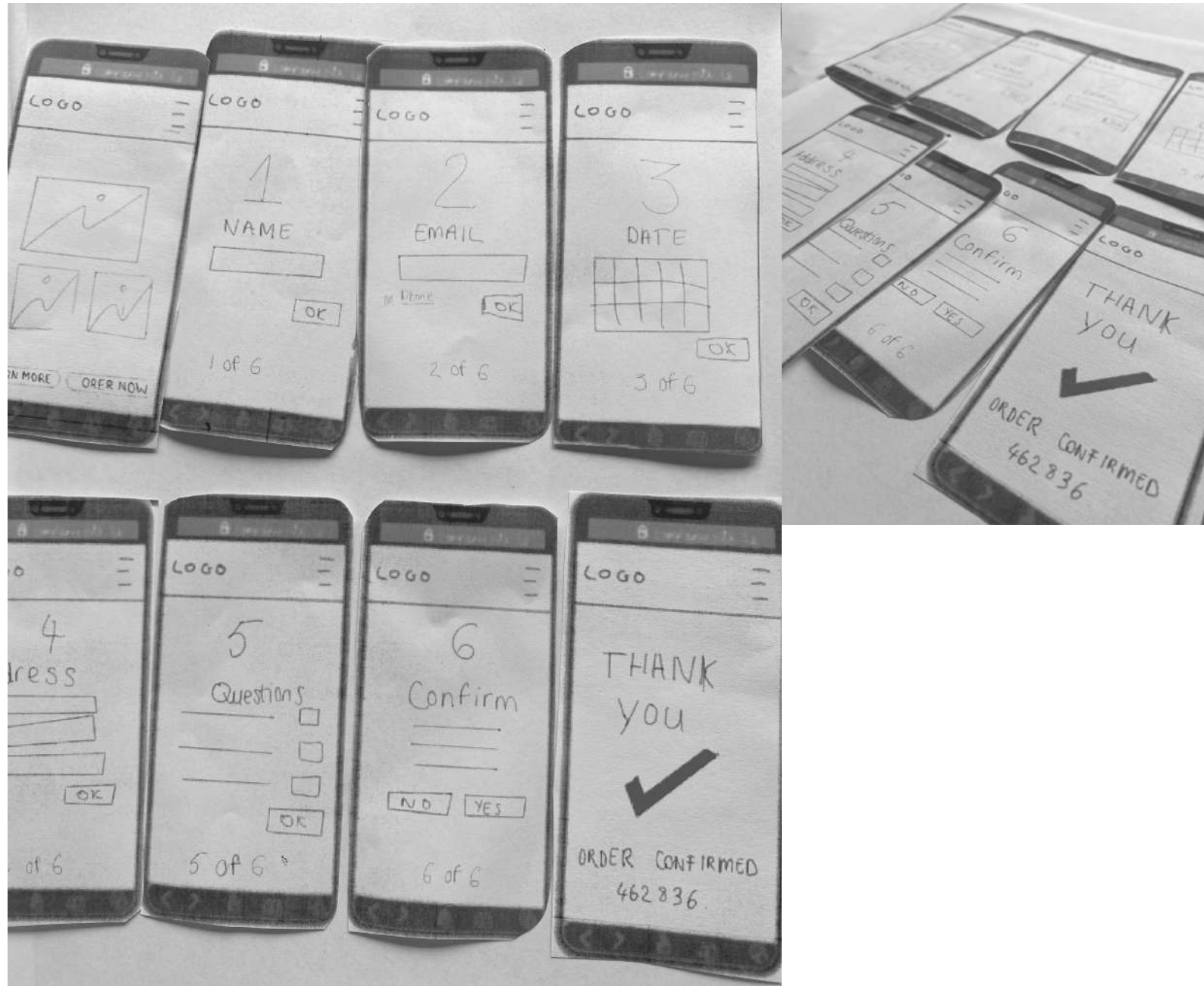
The user found the task easy to complete. They said that they'd feel disheartened if they didn't know how much information was needed, if they couldn't scroll to the end to see how long it would take.

## **Findings**

There should potentially be a call to action on the landing page, it would move users more smoothly through the site. There should also be a confirmation page prior to the thank you page where the user confirms their details and order.

# PAPER PROTOYPING

Using the feedback provided by the user - stating the process should be simpler as well as the designers thoughts the landing page should have a call to action, the screens were redesigned and tested again.



## **Task**

Open the site and order a kit.

## **Purpose**

Watching the user move through after making the adjustments suggested in the previous iteration.

## **User Feedback**

The user found the task easy to complete again, they preferred this version to the last however they thought the lower section of the screen reading where they were in the process was small and would have preferred tabs at the top.

## **Findings**

This iteration makes a big jump from the landing page to ordering, without confirming that you want to order beforehand, perhaps offering the video explanation to watch before ordering the kit.



# PAPER PROTOYPING

As with this iterative stage of the design process, the feedback and findings were actioned to create another paper prototype to work through with the user.



## **Task**

Open the site and order a kit. Watch the video before you order the kit.

## **Purpose**

Watching the user move through the site again, after making design changes as suggested in the previous testing.

## **User Feedback**

The user found accessing the video easy. They asked whether the learn more button would lead them to the video. They found this representation of the item tabs above to be confusing and said they had preferred the earlier iteration. When offered both, they still preferred the tracker down the bottom.

## **Findings**

The video works well as an option before ordering the kit. The user prefers the tracker to determine how many more pages are left rather than the tab at the top.

# USER TESTING

After working with the user to redesign the paper prototype, the prototype was updated and uploaded onto an app called Marvel as a low fidelity digital prototype. The sketches are linked to each other to allow the user to seamlessly transition between the screens. Using this app made the prototype portable and provided a link which allowed other users to test the device.



## **Task**

Work through the site and order a kit. Speaking aloud through the process.

## **Purpose**

Observing different user groups move through the site including men using it for their partners to gain new perspectives to make the app easier to use

## **User Feedback**

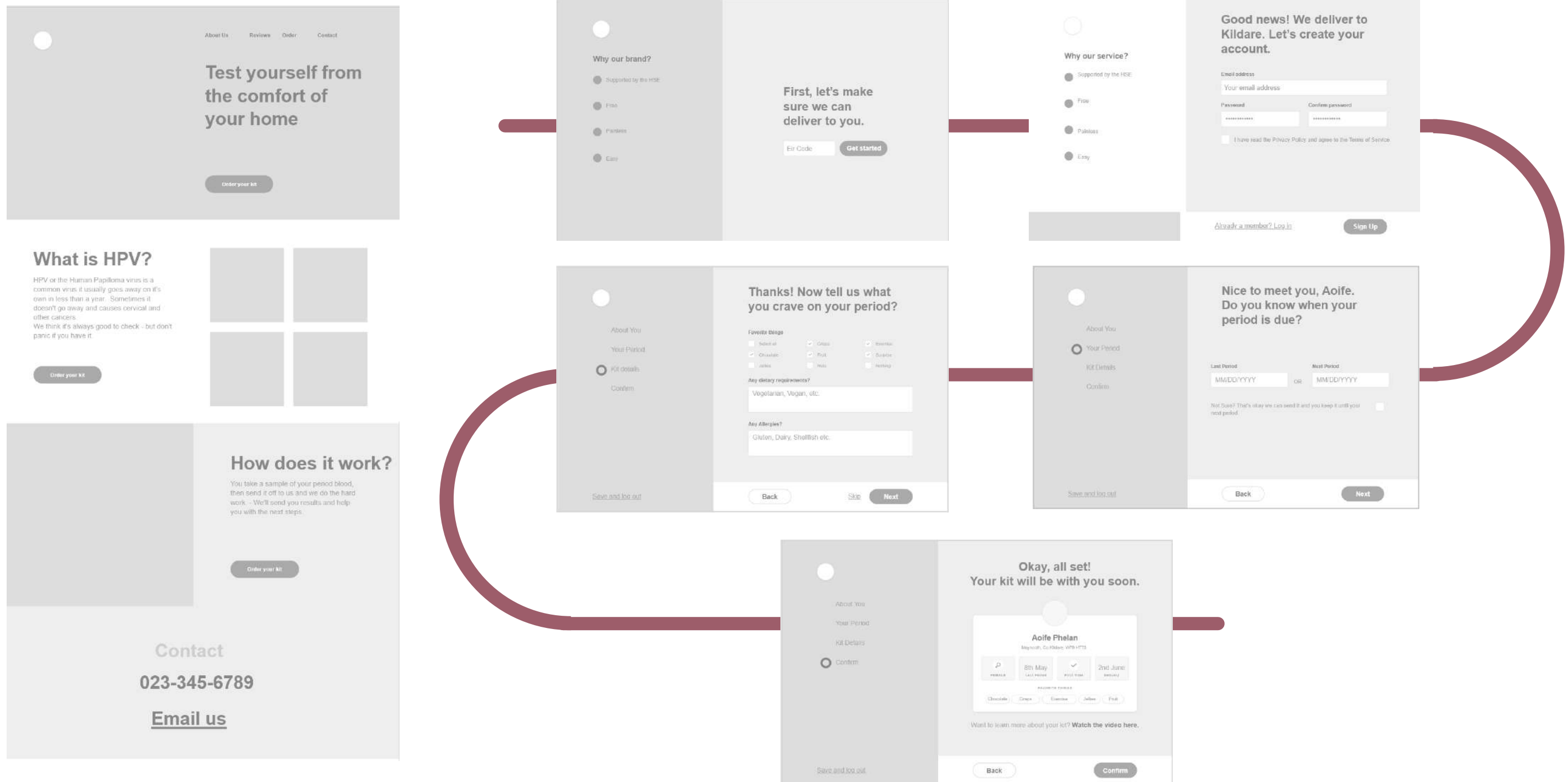
The users found it easy to follow through the site and had no complaints. One user mentioned the font was hard to read. Another user noted the double numbered steps was confusing and one number would be better than the two.

## **Findings**

There was an issue with font size, but upon further questioning it became apparent that the particular user had the font on their phone settings larger than the normal font. If it were an actual site it would have also appeared larger for this user to see. The marker for the stage in the process should be changed from two numbers to one.

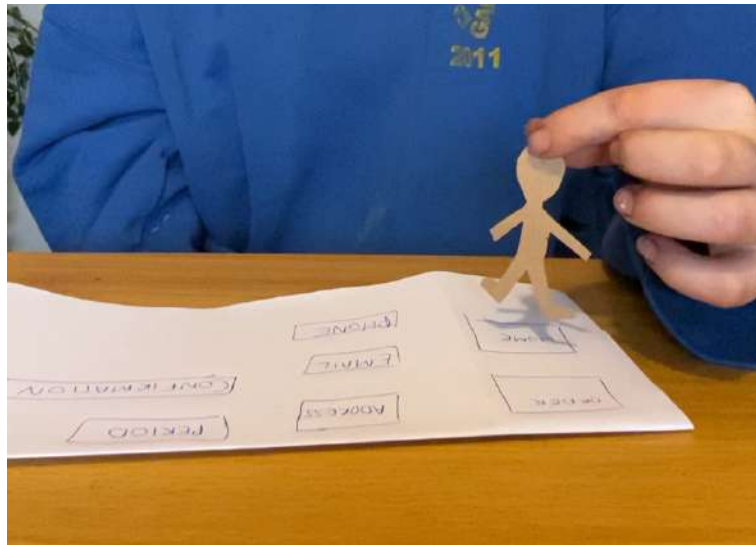
# WIREFRAMING

After user testing the paper prototypes and gathering feedback, the designer begins to create the layout for the website via wireframing. Returning to the desktop sized screens as that is generally the standard format, the screens will be modified for use on mobile phones once the desktop screens have been created.



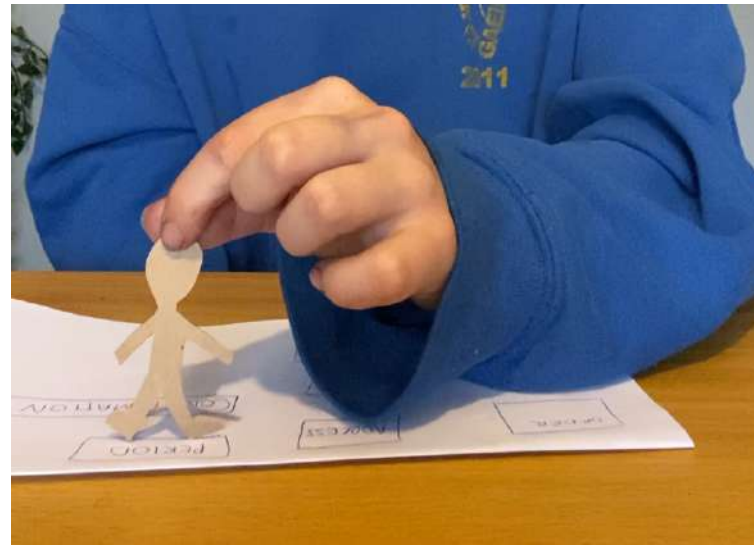
# WALKTHROUGH

Completing a desktop walkthrough to understand how the user may interact with the service.



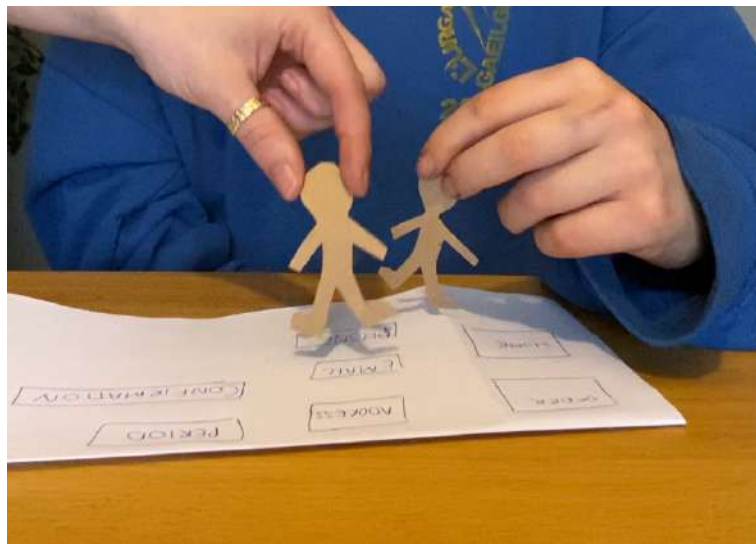
The user signs up to the site to order a kit.

- 1.They don't know about the site
- 2.They have no phone number.



The user follows the steps and successfully orders the kit.

- 1.1They did not order a kit.
- 2.1They could not order a kit.



The advocate informs the user about the site and aids them with sign up.

- 1.They are not interested.



The advocate provides the user with an address and phone number to use.

- 1.1They do not sign up.

## **Task**

Walk through using the site as a user.

## **Purpose**

Understand who may have difficulties with the service and what they may be.

## **Walkthrough 1 - Findings**

This walkthrough (the top) highlighted concerns of knowledge about the service, how does the user know? Some solutions included GPs or Public Health Nurses (PHN) informing users. Another option which was presented was that of patient advocates, members of the community that could be educated to encourage others to order and use the kit.

## **Walkthrough 2 - Findings**

A second walkthrough (at the bottom) discussed a patient/community advocate walking the user through the site and offering an address and phone number for the user to avail of while ordering their kit.

# THE BUSINESS

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BUSINESS MODEL CANVASES  
VALUE NETWORK MAPPING  
SWOT ANALYSIS  
PESTLE ANALYSIS  
BRANDING

# CIRCULAR ECONOMY

## ***Circular Economy***

Currently most products follow a take-make-dispose system (Stahel 2016), taking raw materials, making products and disposing of them with little or no regard for the products following its use. This linear economy is harmful for both the environment and society. A closed loop would create a system which is designed to be restorative or regenerative (MacArthur 2013), although it is argued that it is more restorative than regenerative (Morseletto 2020). The closed-loop model for production and consumption is an effective alternative which aims to address some of the harm associated with the linear economy (Daou et al. 2020). This closed loop most often referred to as a circular economy (CE), and is a viable, sustainable and most importantly an unavoidable alternative to the linear economy (Sariatli 2017).

## ***The sustainable development goals***

CE aids the implementation of the sustainable development goals (SDG) (Schroeder et al. 2019). The United Nations (UN) outlined 17 development goals to action over a period of the 15 years which address areas crucial to the planet and humanity (UN 2016). As per the design guide set out at the end of the research chapter, the designer intends on creating a socially responsible, ethical, and sustainable design intervention. These characteristics can be solidified if the intervention meets some of the SDGs.

## ***Circular Economy and Sustainability***

It is important to note, that although often assumed to be sustainable circular economy is not equivalent to environmental sustainability (Haupt and Hellweg 2019). For instance energy demand for recycling increases with the rate of recycling and can offset the environmental benefits of recovering this secondary material (Haupt et al. 2018). In order to combat this it is essential to identify what happens once the loop is closed, what the material substitutes are and indeed if the loop is ethical.

With all things considered the designer will examine the circular economy surrounding the menstrual blood screening kit.

# CIRCULAR ECONOMY

After introducing the concept of circular economy, and identifying the designers desire to consider it in design it is useful to explore how this product service system considers the environment in its design.

## ***Energy Efficient Web Design***

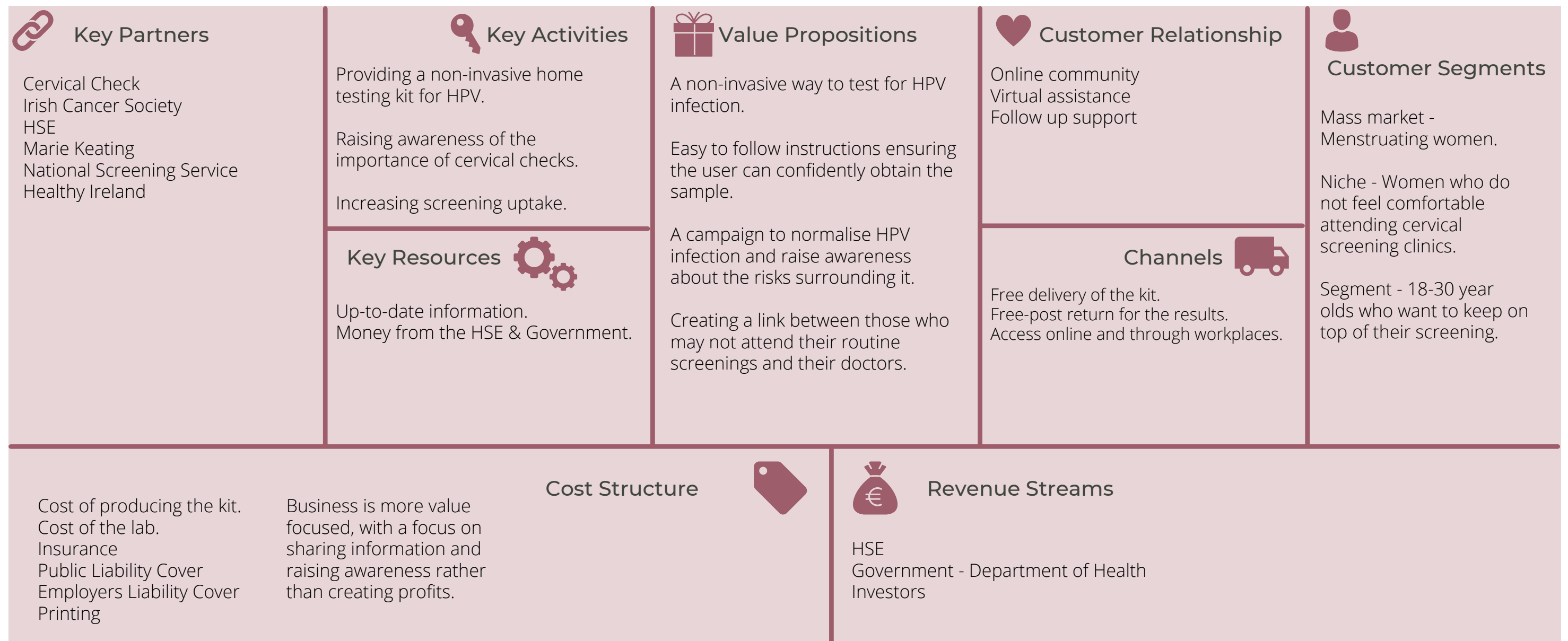
The carbon footprint of a website comes from the electricity required to run the site. Ways to reduce the energy consumption include: blocking bots, using Search Engine Optimisation (SEO) and insuring images are the correct size and only used when they're needed (Greenwood 2019). Most benefits lie in optimising the code, and reducing the amount of JavaScript used on the site (North 2021). The majority of these interventions can be considered later on in the design process as the designer meets with computer scientists and those who would be writing the code. In terms of design intervention, the designer will reduce the number of images on the site, the user will also explore SEO in the next chapter.

## ***Material and End Of Life***

With an intention to consider the environment in the design of the product, thought must be given to material choices and their properties. The major concern within this product is that of the swab once it has a sample specimen on it. Typically this biological waste is incinerated which causes concern of pollutants being released into the atmosphere(Sajjad et al. 2020). By reducing the waste which is contaminated the designer can reduce the waste which must be incinerated. The ability to tear apart the excess packaging from where the sample is inserted aids this process. That way the excess can be recycled.

# BUSINESS MODEL CANVAS

The business model canvas (BMC) has been praised for its simplicity, visual representation, and usefulness. The BMC is limited in that it does not account for external forces such as competition nor does it allow for detailed description (Coes 2014). The business model canvas gives an over-view of the business. This particular version highlights the need for greater income in order to follow the demand.

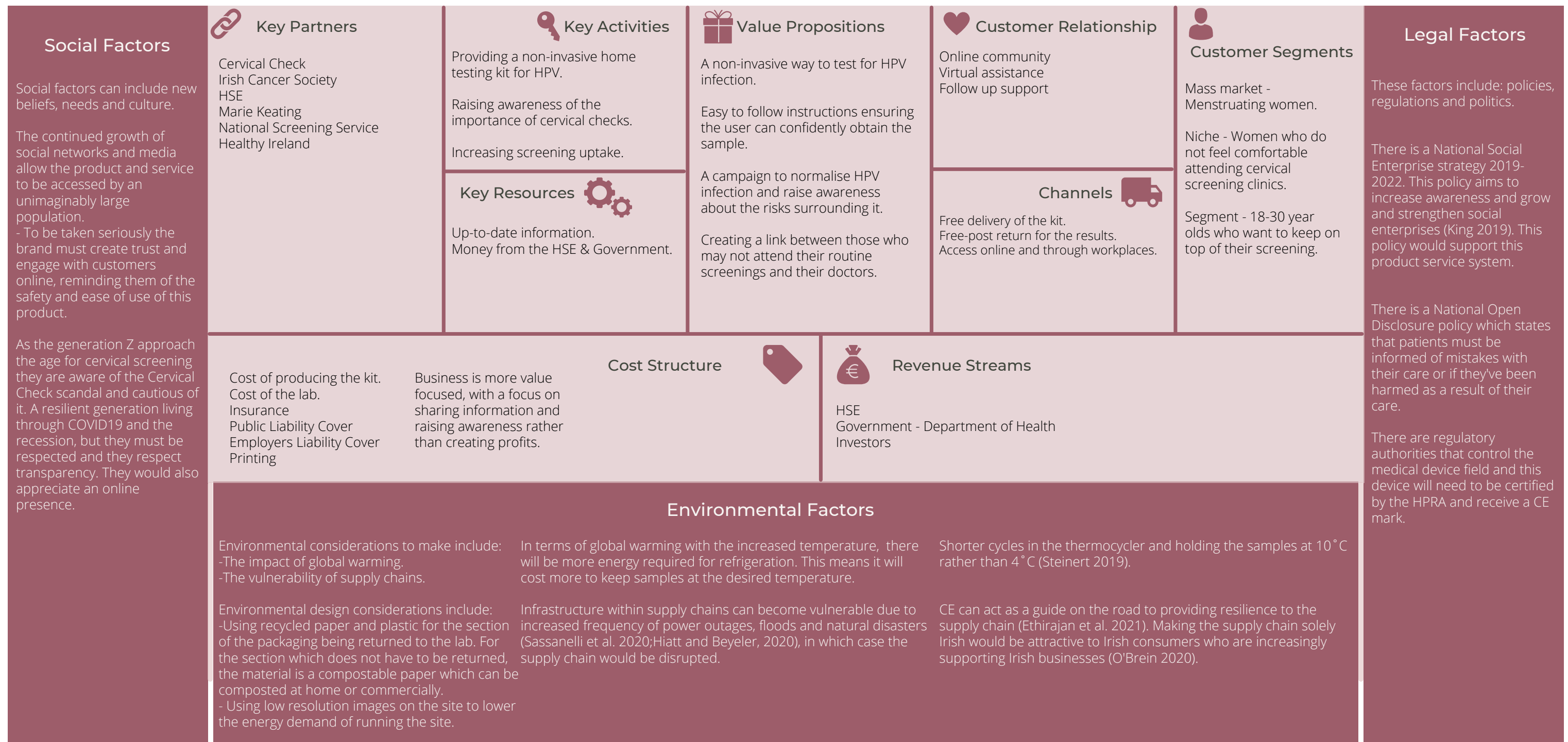


The next iteration of the BMC should explore social and environmental factors.



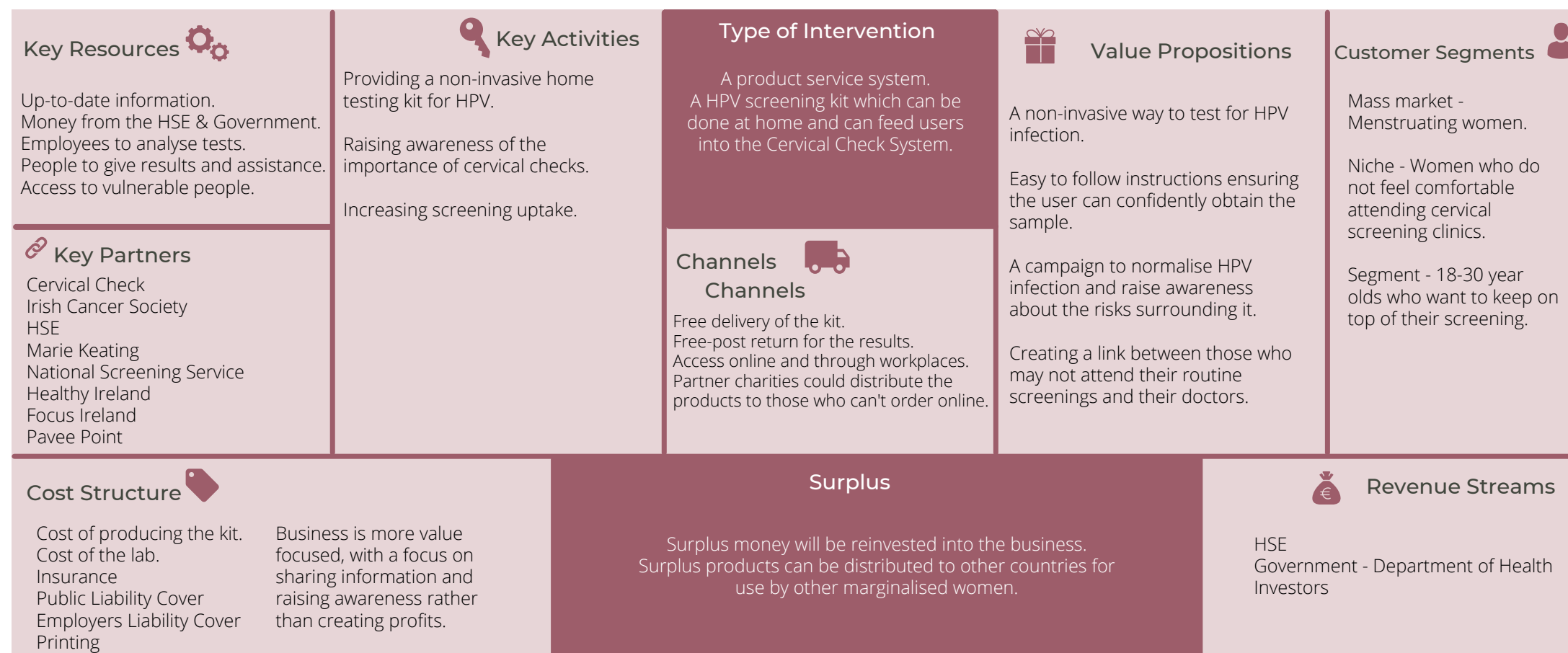
# THE ECOCANVAS

The eco canvas is a holistic tool which considers environmental and social impacts of an intervention. It allows its users to create a unique circular value proposition (Daou et al. 2020). The eco canvas builds upon the previously completed business model canvas. The Eco canvas accounts for social, environmental, economic and legal factors.



# THE SOCIAL BUSINESS MODEL CANVAS

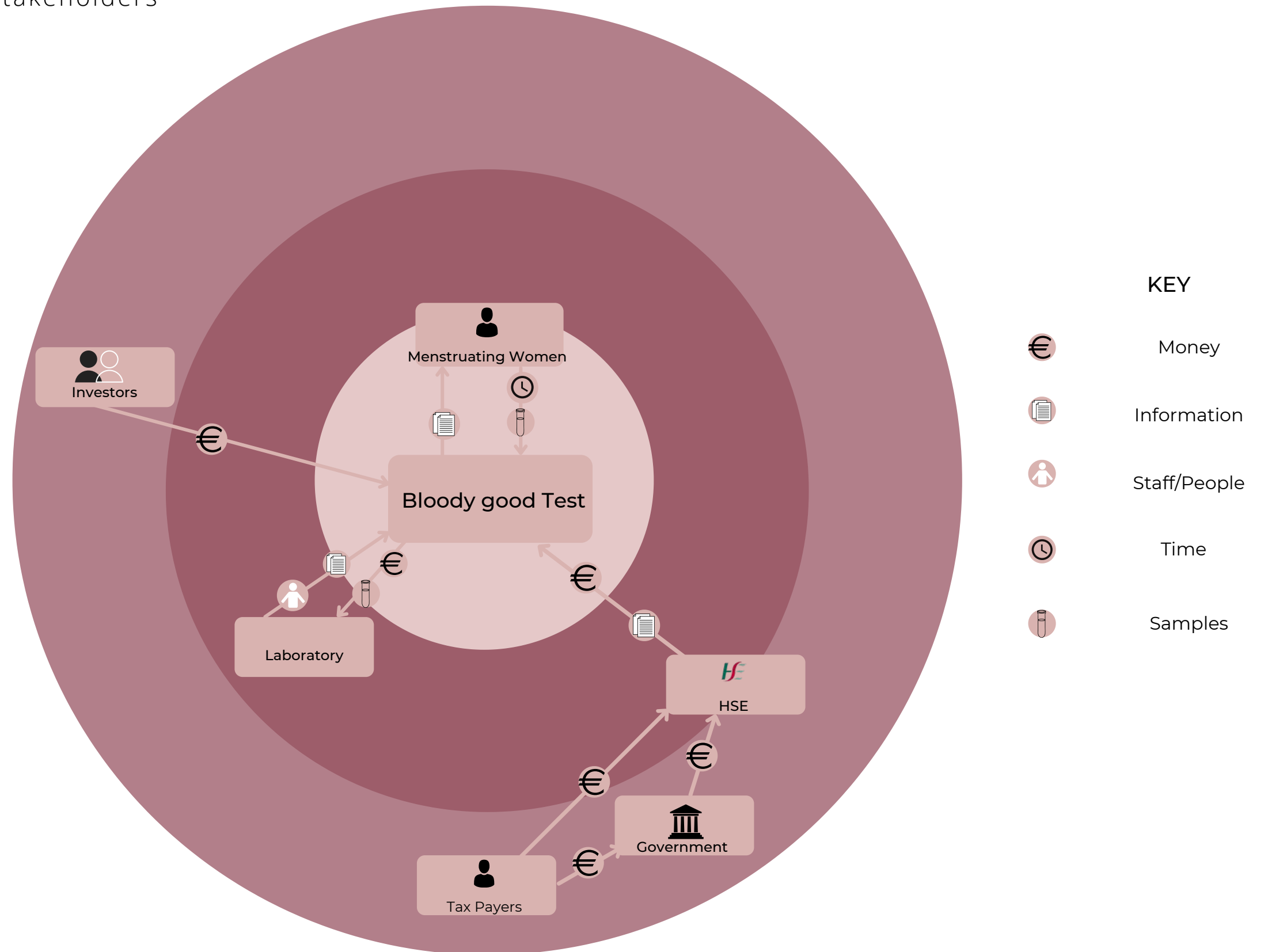
Upon completion of the business model canvas and the eco canvas it has become apparent that perhaps the most suitable model to follow is that of the social business model. This is because this design intervention focuses on social design rather than income and profit. This canvas considers what is done with surplus products and what exactly the intervention is. Using the basis of the business model the designer slotted in the new categories to create the social business model canvas (Social Innovation Lab 2013).



This BMC iteration highlights the fact the intervention is a social design, and it is not for profit. The surplus is reinvested into the company and its channels to grow the reach of the social business.

# VALUE NETWORK MAPPING

Upon mapping the business model, it is useful to map who is involved in the service, where value comes from and which stakeholders play important roles.



# SWOT ANALYSIS

With a vision of the business it is useful to address the competitive environment around this service. The designer will use a SWOT analysis to identify the strengths, weaknesses, opportunities and threats this business might have.

## Strengths

Ease of use of the product.  
Focus on accessibility and inclusion.  
Non invasive method of testing.  
Unique testing.  
Business is not ran by the HSE so increased consumer trust.

S

W

## Weaknesses

Screening is not always accurate, risk of false positives.  
Difficult to access users who have no residence.  
Not being purchased, reliant on funding.  
If uptake is not increased funding will stop.

## Opportunities

Increase in home testing kit popularity.  
Increased funding in technology for prevention and treatment.  
Potential support from the HSE and Cervical check to obtain hard to reach users who may otherwise not engage with the CC screening.

O

T

## Threats

Potential for another scandal which would disrupt the market again.  
Huge competitors in this space who could use their customer trust and money to compete.  
Following COVID-19 there is likely to be a crash and government money/funding may be low.

# PESTLE ANALYSIS

After completing a SWOT analysis another useful tool used to address the competitive environment is a PESTLE analysis. This looks at political, economic, social, technological, legal and environmental factors.

**P**

## Political

Irish cervical cancer scandals which negatively impacted the trust of Irish women in the screening process " (Dyer 2020).

Cervical screening policies frequently highlight the benefit of intervention but downplay the risks (Pienaar et al. 2019).

The misguided presumption of HPV to be a female disease has caused the feminisation of HPV and the HPV vaccine.

The burden of CC on women has made the prevention of HPV primarily a female concern (Daley et al. 2017).

**E**

## Economic

A study in Sweden cited self screening for HPV to be more cost effective than midwife collected samples (€ 229,446 vs. € 782,772) (Aarnio et al. 2020).

Another study supports HPV self screening to be cost effective if it increases population coverage (Mezei et al. 2017).

**S**

## Social

283,960 women between 15-24 in the 2016 census. Positive net migration and natural increase has resulted in a 1.1% increase in population in 2020.

There is currently a one-size-fits-all approach to health systems and investments should be made to improve health literacy in Ireland (Marshall et al. 2012).

A European health literacy survey found 10% of respondents had inadequate health literacy and 29.7% had problematic health literacy (Doyle et al. 2012).

**T**

## Technological

There have been advances in PCR testing and there are ways to complete PCR testing in a much quicker timeframe (Biomeme 2021) and the results are promising (Wee et al. 2020).

**L**

## Legal

Medical devices are required to have many certifications including CE marks and approval from the HPRA. They are also subjected to auditing and testing.

**E**

## Environmental

As mentioned earlier, climate change creates the issue of vulnerability within supply chains (Sassanelli et al. 2020;Hiatt and Beyeler, 2020).

# BRANDING

With an understanding of the product, the service as a whole and the value being offered to customers, this concept is in a suitable position to examine branding and reconnecting with the design guide to ensure it aligns with the customer needs as identified in the research phase.

Key words within the design guide that are repeated include: Empower, Accessible and Consider. The product and service were both designed to empower women and be accessible to large varieties of women. It is also considerate of literacy and emotional impact. Therefore the branding should reflect these three themes, or goals.



# BRANDING

The designer explored the world of femhealth, taking inspiration from patterns, fonts and colours. Having a look at both menstrual products and HPV kits enlightened the designer to a number of interesting points.

The designer had hypothesised that pink might make up the majority of the products. While there were many, there was also a focus on blues and greens. The designer in line with personal preferences selected menstrual brands which were either social enterprises or concerned about sustainability.

This research evoked a mindfulness towards using femhealth or women's health as terminology in consideration of transmasculine people (Sisters&Sisters 2020). The designer took aspects about the branding which were pleasant and has highlighted them on the right hand side of this page. These aspects will be drawn from in the journey to branding for this kit.



(Freda 2021)



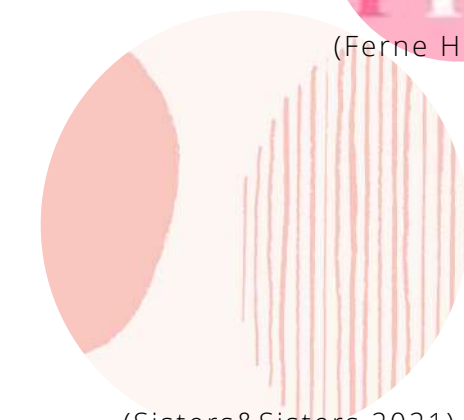
(Callalay 2021)



(DAME 2021)



(Ferne Health 2021)



(Sisters&Sisters 2021)

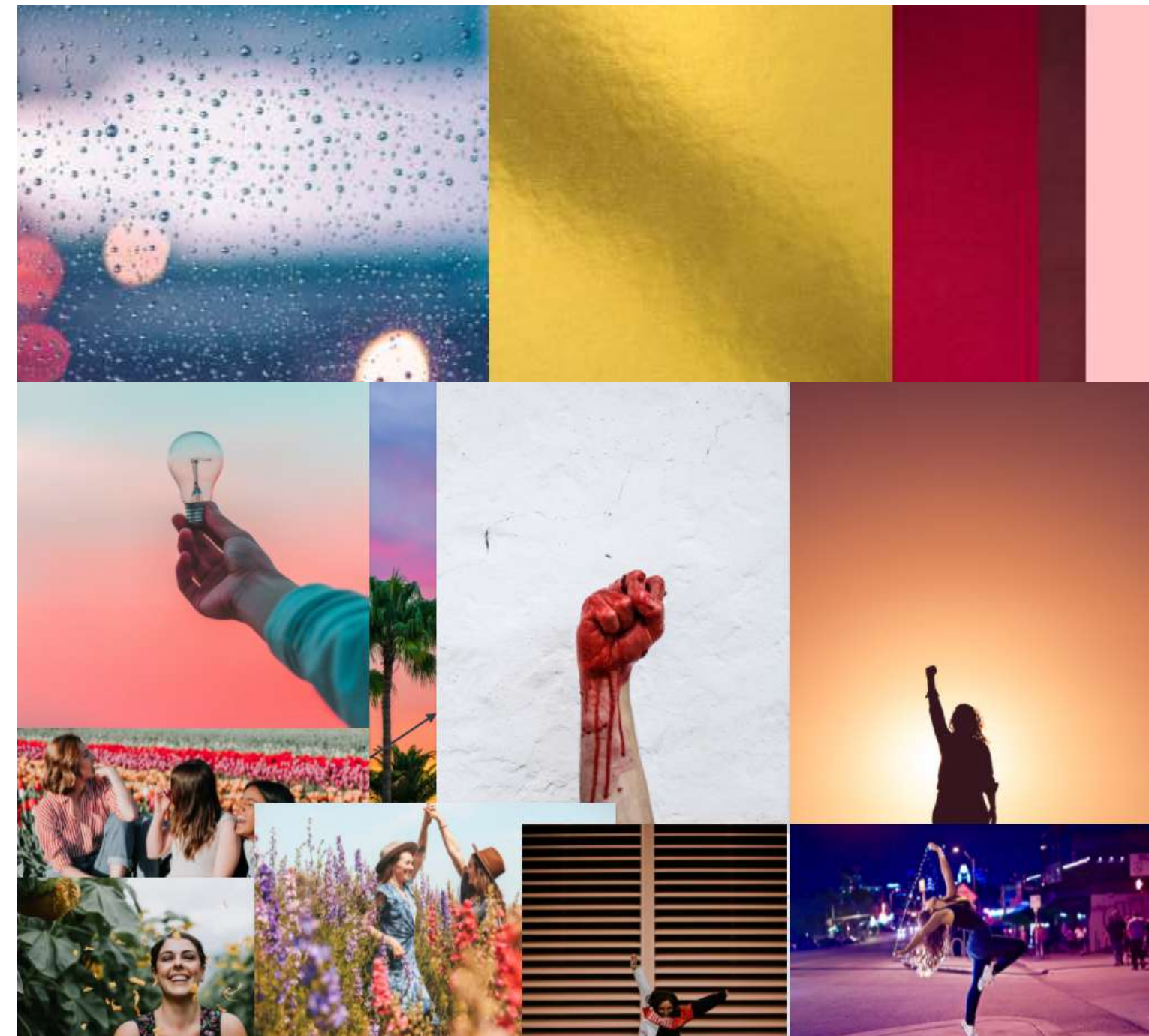
# BRANDING

Empowering - Accessible - Considerate. After defining the brand values and taking inspiration from menstrual health products the designer created a mood board. The board aimed to capture the brand values in imagery and colour.

The images are bright and engaging. The brand is providing a service which needs to be trusted and welcoming. The hands in the air can be viewed as empowering imagery and the lightbulb is for hope and creativity. The kit is about women being empowered to do their own self screening, without the barriers of doctors appointments and the fear of cervical screening.

The colour choices here are of huge importance as colour can be seen as a non-verbal way of communicating with the consumer (Pyrozhenko and Zotova-Sadylo 2017).

Research suggests that in marketing, the colour blue creates a sense of trust for the consumer (Su et al. 2019). This occurs in both physical products and websites (Alberts and van der Geest, 2011). This is exactly what is required - a sense of trust between the service and the user. This use of blue was also seen in many of the products in the previous page.



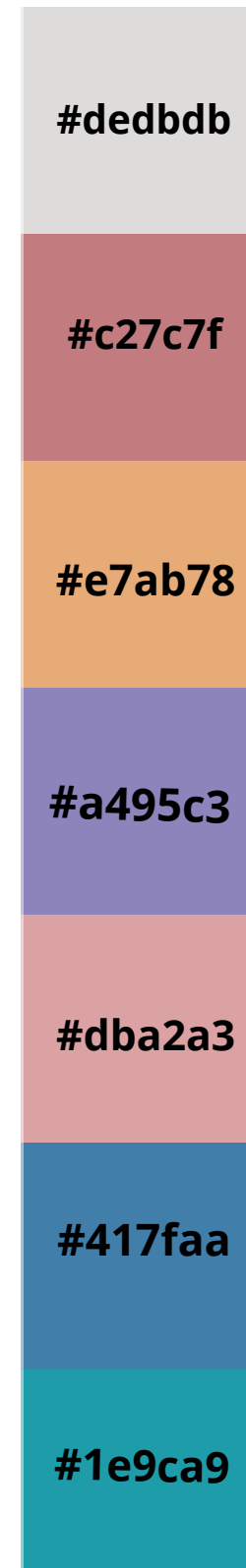


# COLOUR THEORY

Indeed relying on colour theory is difficult because it is mostly subjective and depends on where the service will be offered. This is because colours can have different meanings in different countries (Aslam 2006) for instance purple is a colour of love in the US and China (Jacobs et al. 1991) while it is attributed to fear in Japan and anger in Mexico (Hupka et al. 1997). The importance of colour choice remains and often incorrect colour choices can be seen as accomplices to the strategic failure of a product or service (Bellizzi et al. 1983).

Bright colours are likely to grab and hold more attention than duller colours on packaging (Hawkins et al. 2009). Therefore the use of bright colours should be considered.

In order to appear trustworthy the research supports using blue, and to grab attention colours should be bright. This colour pallet is a suitable combination and will be used for the branding of the product and service. The design will carry out user testing once the whole brand is established. This will be to understand what emotions are surfaced by the brand and if they are as intended.



# THE NAME

The designer completed a brainstorming session to name the brand. Taking inspiration from the freedom of self screening, the comfort of home and the inclusivity of the concept. The designer first explored different buzz words and how they are represented in different languages as well as how they are communicated in mythology. After some searching the research moved towards existing women's health products and there are a number which feature women's names, Yas, Lola, Eve, etc,. This movement is something the author enjoys. Consumers frequently anthropomorphize products, they give them humanlike characteristics (Epley et al. 2007) and tend to fit them into the box of gender (Van Tilburg et al. 2015). It has been reported that products and companies which have strong senses of gender within their brand are often received better than those who don't (Lieven et al. 2014).

There is also a lot to be said for a name which a user can pronounce. Research supports the idea that if a user cannot pronounce a brand name they are less likely the name has less of an impact on the user (Bao et al. 2008). Especially with an emphasis on the literacy levels of the users it is important to keep the name short and familiar.

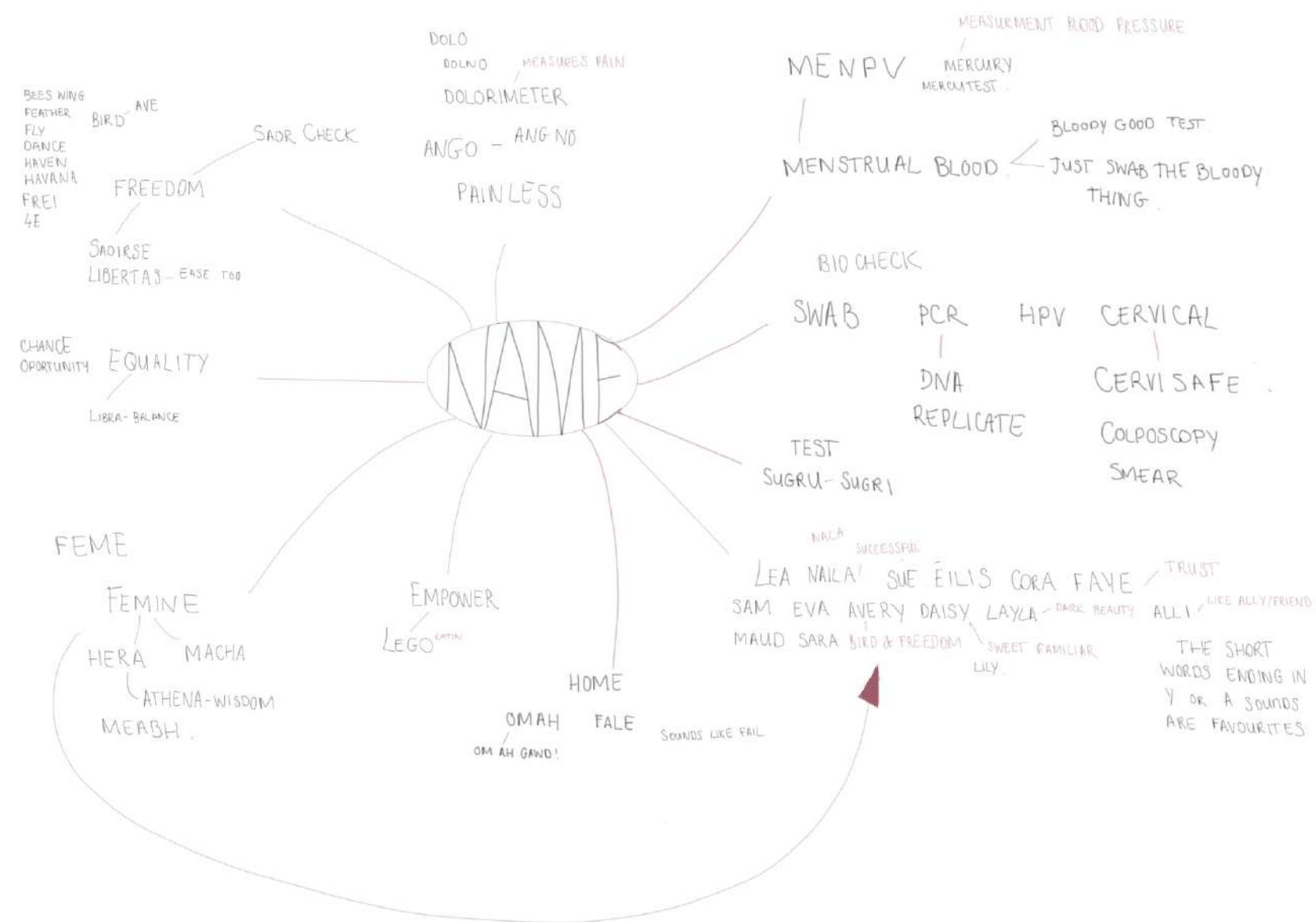
The designer had a preference for the names which ended in Y or with A/E sounds.

The favourite names were as follows:

## ***Daisy - Layla - Nala***

The designer asked a number of potential users which of the names were their favourite and the results are seen below.

Name	Score
1. Daisy	8
2. Layla	3
3. Nala	10



# THE LOGO

Next the designer began exploring simplistic fonts and lettering for the name. The designer is looking for a crisp accessible design and believes a font will work well to do that. Again users are shown the various fonts and they are asked to choose their favourites. Below marked with the coloured circles are users choices. These three choices were fed back to them and their decision was made. They had chosen Yeseva One, and the designer then paired the font with other fonts for a suitable font pairing. The designer wanted to communicate the fact this test was based on blood, and did so with the tag line and a splash of blood behind the font.

NALA NALA Nala  
NALA *Nala* Nala NALA  
NALA NALA *Nala* Nala  
*nala* NALA *Nala* Nala  
NALA *Nala* NALA  
NALA *Nala* NALA



# BRANDING THE KIT

After establishing the brand logo, and colours the designer took to designing the instruction leaflet.

In order to discover what the feelings the branding evokes for users the designer will carry out a desirability test. Sending the branding to participants and getting them to select words from a large list, and giving them the opportunity to come up with their own words to. This will test the branding and will see if users perceive the branding in the same way it is intended.

Common words used to describe the brand were:

***Feminine - Beauty - Health - Calm - Safe - Comfortable***

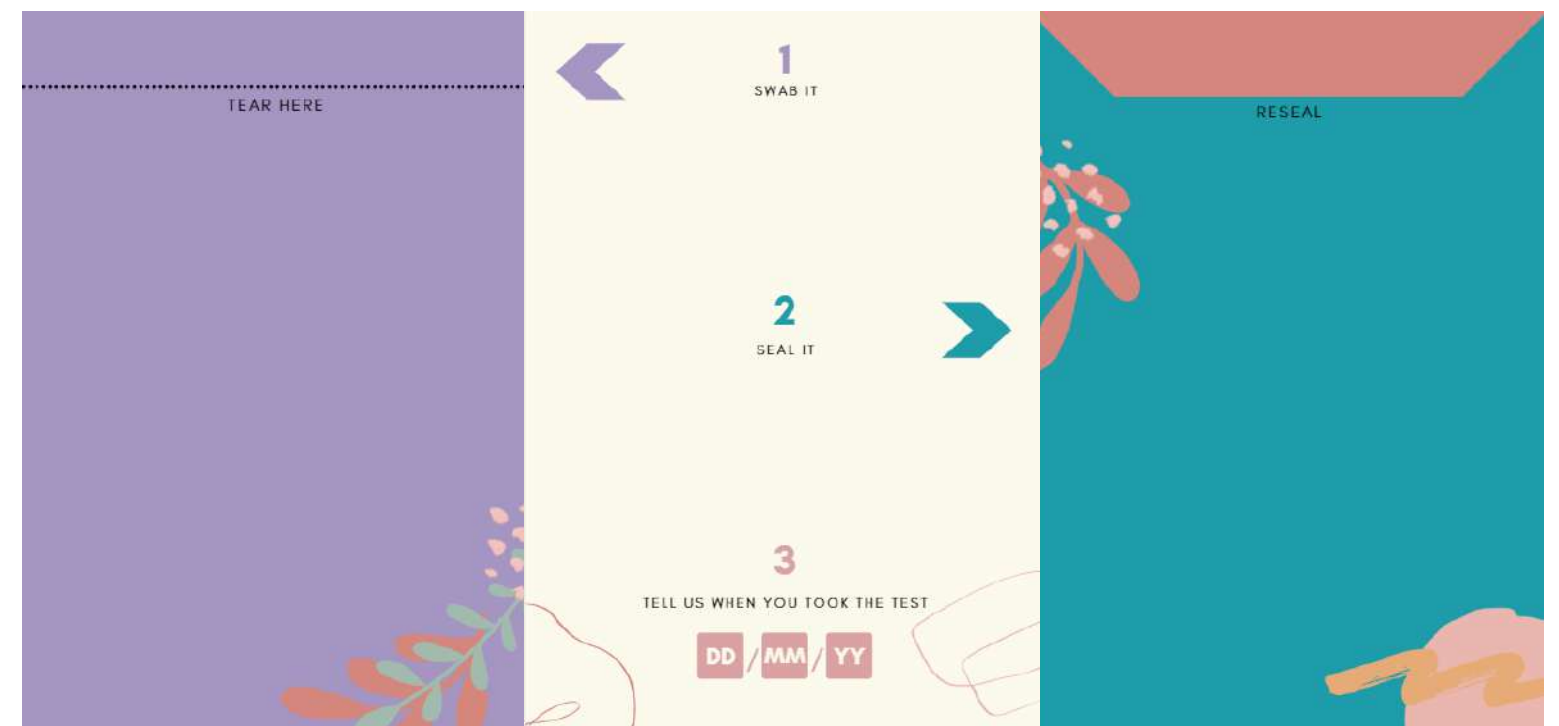
Less common words used were:

***Nature - Independent - Modern - Warm - Happy***

Words only used by one participant:

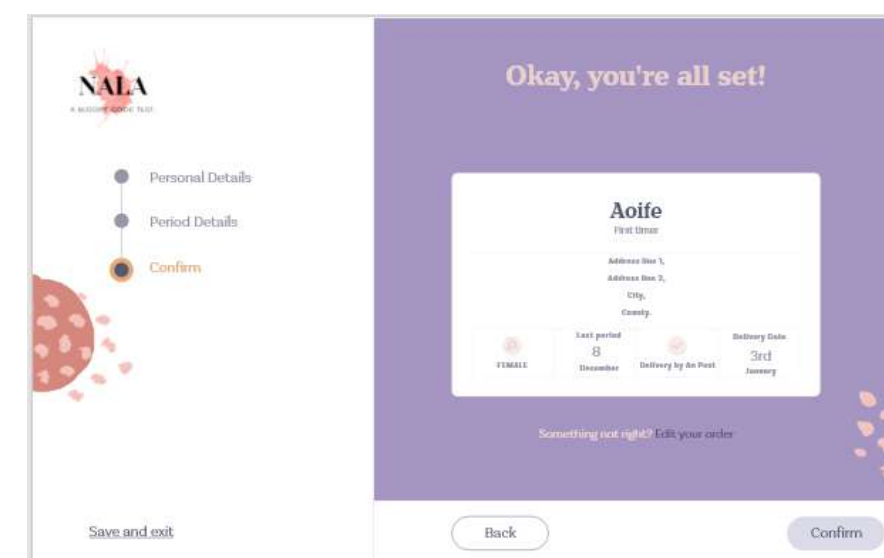
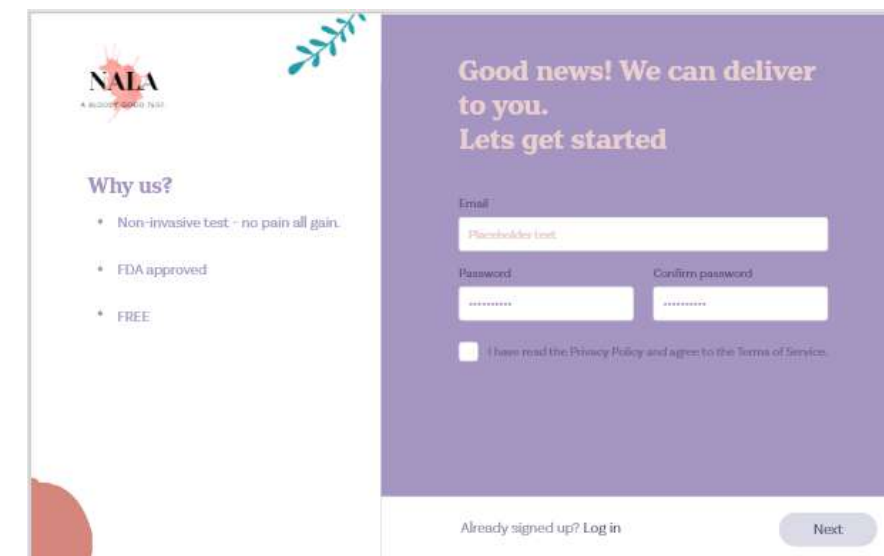
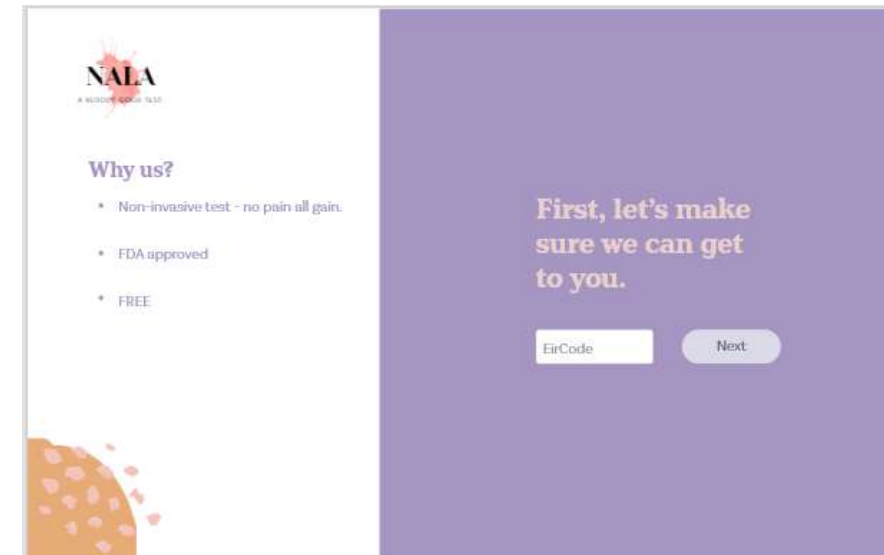
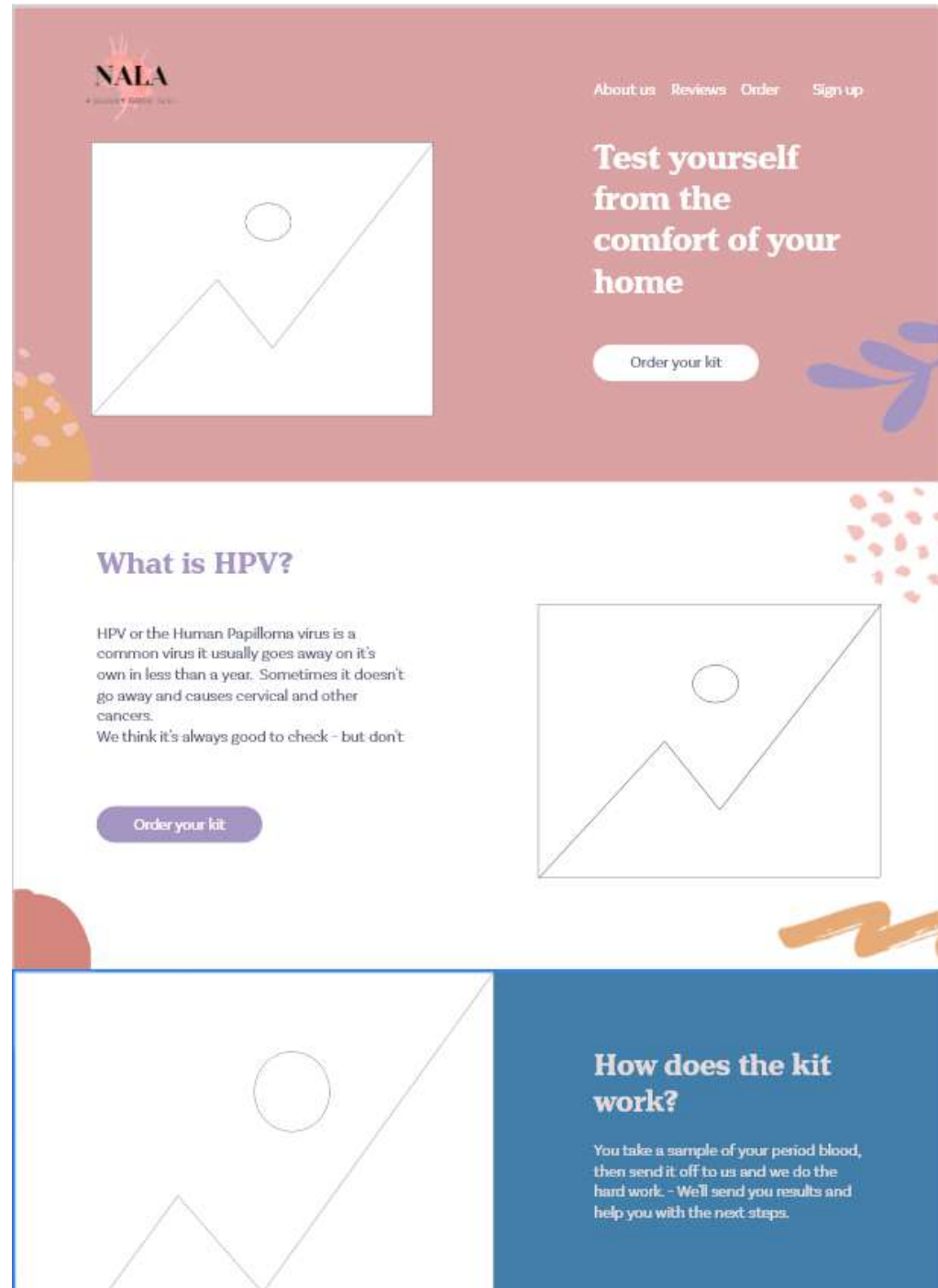
***Chic - Witty - Aesthetic***

On all levels users positively engaged with the branding. Nobody mentioned empowerment, but multiple participants suggested safety and calm which implies the safety of this product which is a big success.



# BRANDING THE SITE

Applying the branding to the website, before completing user testing on the website.



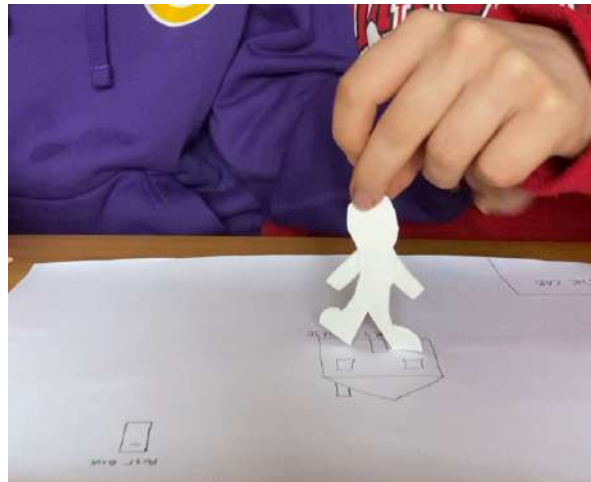
# CONCEPT PROOFING

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RISK ASSESSMENT  
MATERIAL SELECTION  
DESIGN GUIDE  
VALIDATION

# COGNITIVE WALKTHROUGH

Completing a cognitive walk-through of a user ordering a kit online and then using it. The goal of the walk-through is to identify potential issues and suggest design modifications.



The user orders the kit.

1. It does not arrive.



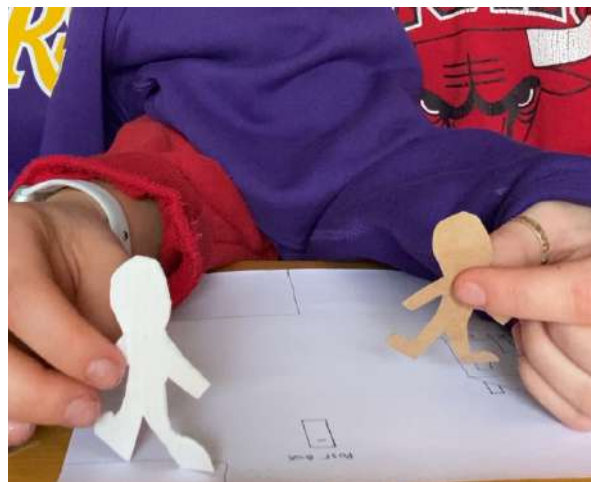
The kit is delivered to the user.

2. They don't return it
3. They take a bad sample.



The kit is delivered to the lab.

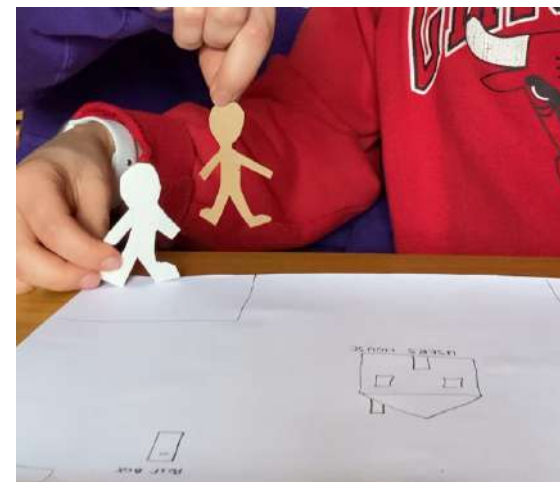
- 2.1. It does not arrive.
- 3.1. The sample cannot be analysed.



The user orders the kit to their current address.



The user moves to a different address.



The kit is delivered to the wrong address.

## **Task**

Walkthrough the Service

## **Purpose**

Identify any missing touchpoints, users or any issues with the service. Include walkthroughs of homeless users, and members of the travelling community.

## **Findings - Walkthrough 1**

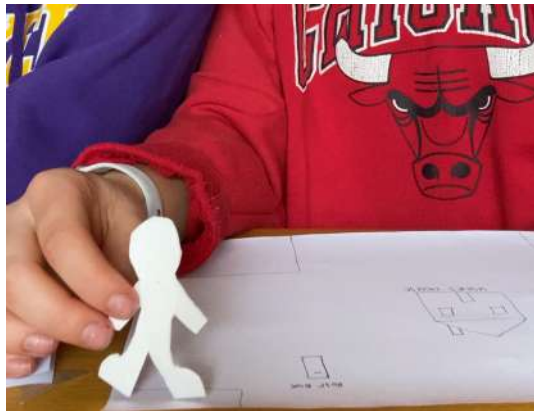
This scenario explored a number of potential issues - kit getting lost - user not returning the kit - user does not get the kit they ordered. The suggested intervention was a feedback system, tracking the package, reminding the user to post the package and easily re-ordering the package if it does not arrive.

## **Findings - Walkthrough 2**

This scenario saw a member of the travelling community order the kit, but in between their ordering they had moved. This is an issue and the user may not have an address in the first place to sign up with. Suggestions were - the ability to change address on the order or ordering it to a local shop/building.

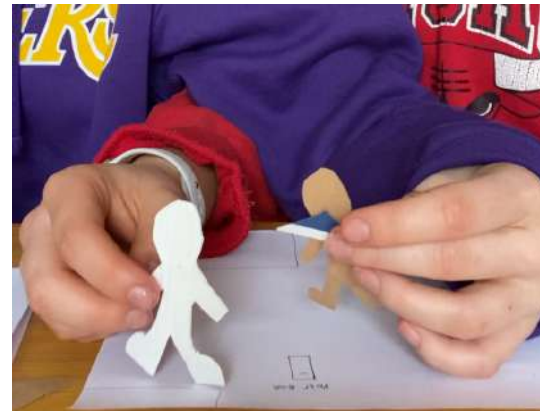
# COGNITIVE WALKTHROUGH

Completing a cognitive walk-through of a user ordering a kit online and then using it. The goal of the walk-through is to identify potential issues and suggested design modifications.



The user cannot order the kit.

- 1.They have no phone
- 2.They have no internet

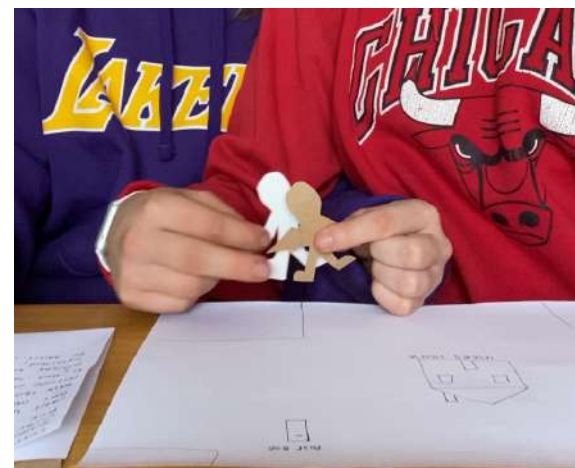


An unprovoked kit is delivered to their residence.

- 3.They ignore it.
- 4.They don't understand it



A member of the agency orders a kit for a service user.



The kit arrives and the staff member explains the kit to the user.



The issue of results arises as the service user has no phone but the staff member cannot receive the results- GDPR

## **Task**

Walkthrough the Service

## **Purpose**

Exploring another scenario with a member of the travelling community and homeless women who engage with homeless services.

## **Findings - Walkthrough 3**

If the user has no phone or no internet connection, and they don't engage in services how can they be accessed?

- The public health nurse could issue an unprovoked kit.

## **Findings - Walkthrough 4**

The staff member orders the kit for the user, but they may not understand the context of the kit if this is done without consulting them, or they may not be interested. An issue arose that the service user didn't know where the post box was so couldn't return the kit and made the staff member do it. Another issue was the results and if the user didn't have a phone how could they get results. The suggested remedy was a letter.



# COGNITATIVE WALKTHROUGH-IDENTIFYING RISKS

From the walk through, risks have been identified, and risk management methods have also been identified. Scoring the risks 1-5 where 1 is a lower risk. In terms of severity, a high scoring risk will be one which impacts the users comprehension of the instructions and interaction with the product. Multiplying likelihood X occurrence X severity gives an RPN, a risk priority number. Which identifies which risks are most important to manage.

Risk	Likelihood	Occurrence	Severity	RPN
1. User does not complete the test.	3	2	5	30
2. User does not return the test.	3	3	5	45
3. User has no internet to order the kit.	2	1	4	8
4. User has no address to get the kit delivered to.	2	1	4	8
5. User has no phone to receive their results.	2	1	5	10
6. User has moved from the address given with the order.	1	1	2	2

## Risk Mediation

1. Ensure the test is engaging and easy to use.
2. Give a reminder via text to the user within 24 hours of receiving the test.
3. Provide a way to order the kit in shops/doctors offices/libraries.
4. Give an option to pick up the kit from shops/doctors.
5. Provide the option of receiving results via text or a letter.
6. Give the option to change delivery location after/ allow pick up from shop.

# MATERIAL SELECTION

Material selection is of huge importance, especially finding the balance between environmentally friendly material choices and biocompatibility. The materials for the swab will be based on existing products and requirements for PCR testing. The material selection for the packaging will be explored using the CES software to identify cheap, environmentally sustainable, suitable materials.

## ***The Swab***

Using cotton or nylon swabs is a suitable method of collecting samples for PCR testing (Adamowicz et al. 2014). Research supports cotton swabs to be more efficient than nylon swabs (Brownlow et al. 2012). Based on the studies which test menstrual blood for HPV using sections of the menstrual pads (Wong et al. 2010; Lee et al. 2016; Budukh et al. 2018; Wong et al. 2018b) it can be determined that a dry cotton swab is a suitable material for collection of the menstrual blood.

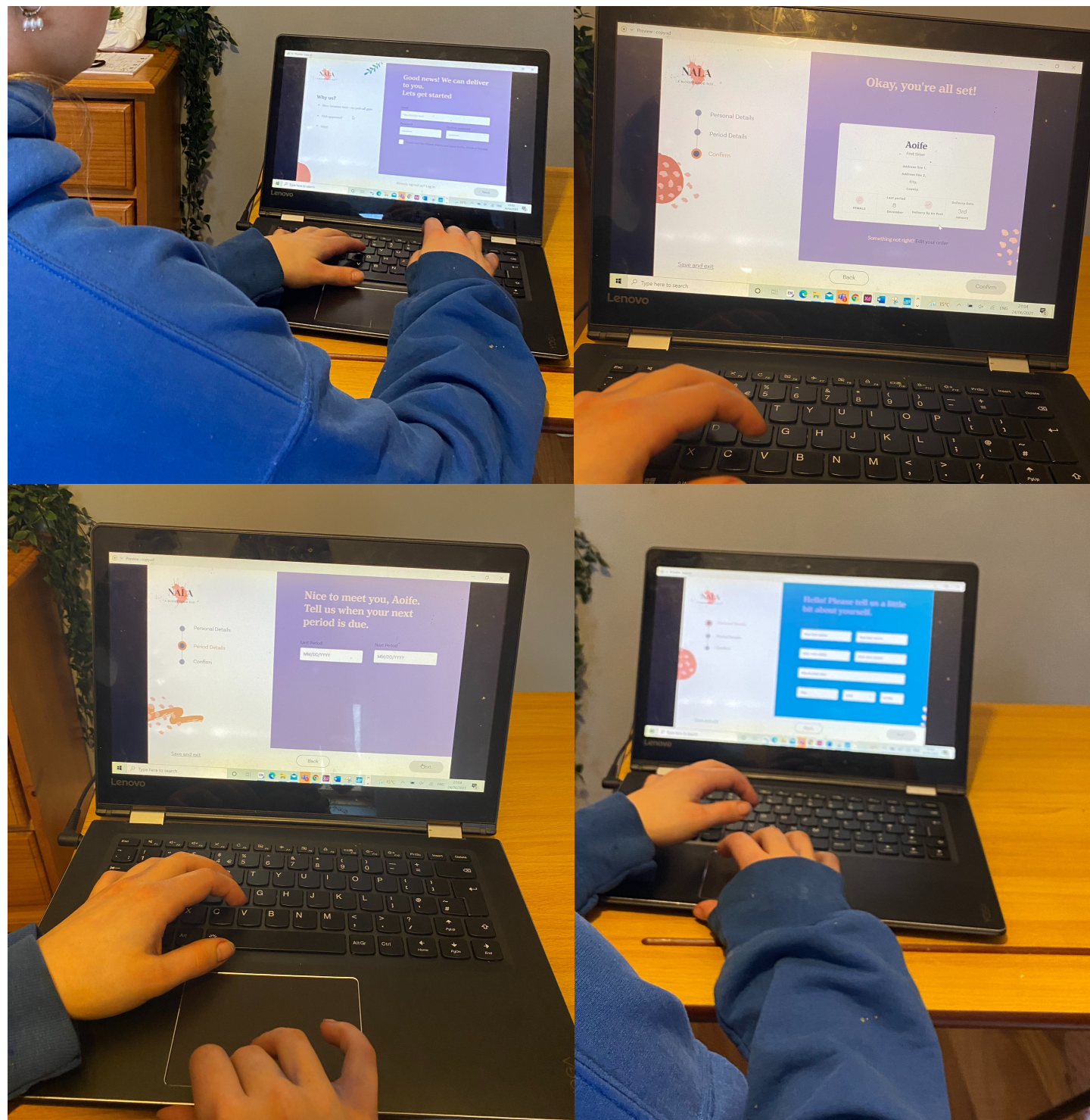
In terms of sustainability a wooden handle would be a favourable option. However, wooden handles are not widely accepted due to the fact they may contain substances that inactivate some viruses and inhibit PCR testing (CDC 2021). The handle is often made from polypropylene (PP). PP is one of the most widely recycled materials in Ireland and therefore the section of the swab which is snapped off can be recycled.

## ***The Packaging***

The packaging is the perfect item to design to be sustainable. There are a number of options including using biodegradable materials for the packaging and using recycled paper. Paper itself is typically biodegradable when it has not been treated with chemicals. If this packaging were to be made from recycled paper and then be composted it would be sustainable. The paper could be recycled again however with each cycle the fibres shorten and only last about 5 cycles. It is tempting to want to compost the product due to the high cost of recycling, however it is necessary to consider if all paper is composted the need for virgin material increases and as it does deforestation increases (Carter 2021).

# ROLEPLAYING

A participant user makes their way through the site and afterwards they fill in a questionnaire.



## **Task**

Work through the site and order a kit.

## **Purpose**

Observing a user work through the site and having them evaluate their experience afterwards.

## **User Feedback**

The user found it easy to move through the site however, some of the filler text inside boxes was hard to read. The user admired the colour and appearance of the website. User was able to recall what was on the site afterwards and felt confident that they had ordered the kit successfully.

# USER EVALUATION

This is the evaluation questionnaire the participant filled in. The responses are based on the likert scale, and the questions are inspired by a validated a mobile health (mHealth) questionnaire (Zhou et al. 2019).

## Review Sheet – Website Evaluation

**Directions:** Work through the website and complete this evaluation based on your experience. Circle the appropriate numbers and provide at least two specific pieces of feedback.

5. Strongly agree 4. Agree 3. No opinion 2. Disagree 1. Strongly disagree

### Ease of Use

I found it very easy to work through this website.

5	4	3	2	1
---	---	---	---	---

### Scoring

5

### Feedback

This looks really good and its so funky. I liked the side and how I could see what part I was filling out.

### Error

I found it very easy to fix my mistakes when/if I made them.

5	4	3	2	1
---	---	---	---	---

5

The bloody good test slogan is really clever.

### Satisfaction

I found the site provided information to let me know the progress of my action.

5	4	3	2	1
---	---	---	---	---

4

### Usefulness

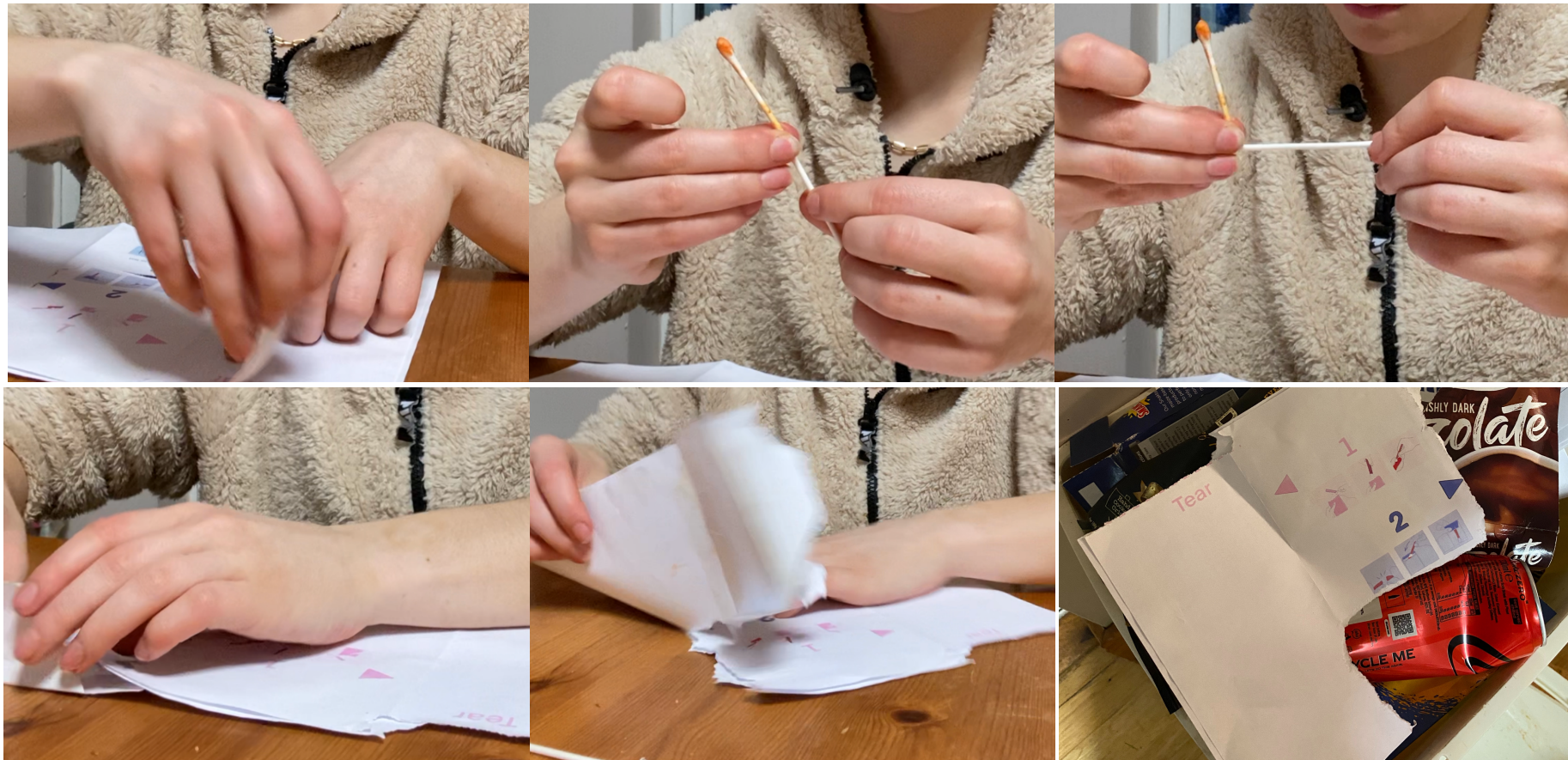
This site would be useful for ordering the HPV Kit.

5	4	3	2	1
---	---	---	---	---

3

# ROLEPLAYING

A participant user makes their way through using the device afterwards they fill in a questionnaire.



## **Task**

Use the kit to take a HPV sample.

## **Purpose**

Observing a user using the kit and having them evaluate their experience afterwards.

## **User Feedback**

The user found the kit easy to use and the instructions easy to follow. However, the user found ripping the packaging very difficult.

## **Findings**

The designer is of the opinion that a more realistic packaging needs to be created and tested. This packaging should then be used on a wider user group if possible. Assessing how various user groups move through the packaging. The designer suggests a human factors style usability on a number of users to properly evaluate the quality of the instructions. These issues will be addressed in the following chapter.

# USER EVALUATION

As with the previous evaluation the user filled in the evaluation sheet after completing the roleplaying exercise.

## Review Sheet – Kit Evaluation

**Directions:** Work through the website and complete this evaluation based on your experience. Circle the appropriate numbers and provide at least two specific pieces of feedback.

5. Strongly agree 4. Agree 3. No opinion 2. Disagree 1. Strongly disagree

### Ease of Use

I found it very easy to open the kit.

5	4	3	2	1
---	---	---	---	---

### Scoring

4

### Comments

The paper is really nice and its mad how easy the instructions were even though there weren't any words.

### Error

I knew what to do with the kit.

5	4	3	2	1
---	---	---	---	---

4

I think if I thought blood was gross then I'd find this hard to use even though I didn't have to touch the blood.

### Satisfaction

I enjoyed using the kit.

5	4	3	2	1
---	---	---	---	---

4

### Usefulness

I found the instructions helpful for taking the HPV sample.

5	4	3	2	1
---	---	---	---	---

3

# PCA ANALYSIS

The designer next completes a Perception, Cognition, Action analysis of the concept. Completing this PCA analysis of the task of the user working through the kit. This can help identify human factors errors which may occur in order to improve the design of the kit.

**Perception-** What the user senses.

**Cognition-** What the user knows, computes, decides.

**Action-** How the user responds to the situation.

**Potential Errors-** The possible ways in which the task may go wrong.

**Critical Task -** Tasks which effect the care of the patient if not completed.

Task	Perception	Cognition
1. User enters their details and orders the kit.	1. Sees the website	1. Decides to order. Knows their details. Knows their last period.
2. User takes the packaging out of external envelope.	2. Sees the external/internal packaging. Feels the packaging.	2. Knows to take the packaging out of the external packaging.
3. User reads the instructions.	3. Sees the instructions. Feels the instructions.	3. Knows how to read. Comprehends the informational icons.
4. User tears the packaging and removes the swab.	4. Sees the instructions. Feels the packaging. Feels the swab.	4. Knows how to tear along the perforated edge.
5. User runs the swab along their menstrual pad.	5. Sees the swab and the pad. Feels the swab and the pad. Sees blood.	5. Knows how to swab along the pad. Knows how much blood to take.
6. User snaps the swab in half.	6. Sees the swab with blood on it. Feels the swab.	6. Knows how to break the swab..
7. User inserts the swab head into the other side of the packaging.	7. Sees the swab and the packaging. Feels the swab and the packaging.	7. Understands which side of the swab to put into the packaging.
8. User seals the packaging closed.	8. Sees the packaging and the reseal sticker. Feels the sticker.	8. Knows how to seal the packing. Knows they have to seal the packaging.
9. User writes the date on the packaging.	9. Sees packaging, pen and box for date. Feels the pen.	9. Knows the date. Knows how to write.
10. User posts the kit in the post box.	10. Sees the packaging and the post box. Feels the packaging and post box.	10. Decides to post. Knows where the post box is.

Action	Potential Errors	Critical Task?
1. Types details. Presses order. Opens the website.	1. Enter wrong details.	1. YES - If they don't enter their details they won't get the kit.
2. Tear the packaging. Pull the kit out from the external packaging.	2. Tears the internal packaging.	2. YES - If the user doesn't open the packaging they cannot use the test.
3. Reads the instructions.	3. Misinterprets the instructions.	3. NO - User could potentially complete the task without reading instructions.
4. Pulls the packaging apart. Pulls out the swab.	4. User cannot tear the packaging.	4. YES - If the user does not open the packaging they cannot get the swab.
5. Holds swab. Holds pad still. Rubs the swab off the pad.	5. Does not get any blood on the swab..	5. YES - If the user does not take a sample the test cannot be completed.
6. Holds the swab. Squeezes swab. Pulls swab apart. Breaks swab.	6. Drop the head of the swab when trying to break it.	6. NO - If the swab does not break the sample can still be analysed.
7. Hold the swab, drop the swab into the packaging. Hold packaging open.	7. Drop the swab outside the packaging.	7. YES- If the swab is not inserted into the packaging it cannot be analysed.
8. Pull off the seal. Push the packaging together.	8. Rip the seal.	8. YES- If the seal is not closed the sample can be compromised.
9. Pick up pen. Hold pen. Write the date.	9. User puts the wrong date down.	9. NO - The test can still be completed without a date, it may be innacurate.
10. Go to the post box. Lift package into post box. Push into post box.	10. User forgets to post it.	10. YES - If the kit is not posted the sample cannot be analysed.

# THE DESIGN GUIDE

Returning to the design guide to ensure it has been satisfied and identifying any room for further development.

## ***Test For HPV at home***

This test is fully suitable for use at home or on the go.

## ***Consider reasons behind poor uptake***

Reasons including: trust, low literacy, fear of mistakes and pain have all been considered and designed for.

## ***Accessible for various socio-economic backgrounds***

The kit has been tested to be accessible for various socio-economic backgrounds including homeless and traveller women.

## ***Cater for varied vagina sizes***

The fact this does not require the vagina to be swabbed means it successfully caters for varied vagina sizes. It's applicability to various period management devices make it inclusive for different levels of flow.

## ***Low physical effort***

There is very low physical effort involved: the tearing is along perforated edges, the swab can be done gently and the swab is broken easily,

## ***Consider literacy levels***

The instructions contain mostly visual images to include those with low literacy levels. The wording used is in line with very basic written English.

## ***Consider emotional impact of screening***

The screening process can be very stressful, but by linking the users up with Cervical check at the end of the service and providing support the burden of the screening can be alleviated.

## ***Empower Women***

The service empowers women, allowing them to take control of their own screening.

## ***Suitable for use in lesser developed countries***

The simplicity of this kit, allow it to be used in other countries. It will be cheap to replicate. Issues to be considered however are: access to PCR testing labs, cultural attitudes towards menstruation and cultural attitudes towards women and health.

## ***Painless***

Due to the nature of the test using menstrual blood it does not have to be inserted into the user and should therefore not cause pain.

## ***Empowering online community***

This could be achieved with funding and marketing, however the opportunity to achieve it is very much attainable.

## ***Simplicity***

Again, this kit works because it is simple, and difficult to mess up. There is no difficult or complex screening process needed, just a simple swab of menstrual blood.



# VALIDATION - THE SWAB

The final aspect of the concept proofing which will be explored is the validation, ensuring that the products and processes can be replicated to the same standard time and time again. Firstly, the designer explores the validity of the swab, due to the nature of the product being off-the-shelf, the testing has already been completed and the product has been validated.

## **Drop Test**

It has been considered that the swab would not need to undergo drop testing, as the swab is designed to be broken in half so there is no concern if the device drops, as it can still be used when broken in half.

## **Durability**

A longitudinal study tested the durability of clinical performance of self-screening for HPV. The results highlighted the superiority of HPV self-screening compared with visual inspection, and it was found to be on par with cytology over the course of five years (Zhang *et al.* 2018). In a study addressing menstrual blood for collection of HPV samples results found the sensitivity compared with the gold standard was 83% and the specificity was 99%. For identifying CIN lesions the sensitivity was 83% and the specificity was 95% (Budukh *et al.* 2018)

## **Biocompatibility**

Cotton fibres which have been coated with fabricated silver nanoparticles (SNPs) are biocompatible, environmentally friendly and cost effective (Kashid *et al.* 2017). The sample will be suitable for testing provided it is placed in a sealed plastic bag (Lee *et al.* 2016) or sealed paper packaging (Budukh *et al.* 2018) after collection.

# THE WEBSITE

Secondly, the designer must assess the validity of the website and a key factor in this is indeed usability. The way by which the designer has chosen to assess the usability of the site is through a validated an mHealth questionnaire (Zhou *et al.* 2019). The questions can be seen in the tables below. This questionnaire was designed for an mHealth app, but with a few modifications it could be applicable to the website.

## Ease Of Use

1. The site was easy to use.
2. It was easy for me to learn how to use the site.
3. The navigation was consistent when moving between pages.
4. When I made a mistake it was easy to recover.

## Interface and Satisfaction

5. I like the interface of the site.
6. The information was well organised so I could find what I was looking for..
7. The site provided information to let me know the progress of my action.
8. Provide a way to order the kit in shops/doctors offices/libraries.
9. I would use this site again.
10. Overall, I am satisfied with this site.

## Usefulness

11. This site would be useful for ordering a HPV kit..
12. The site improved my access to health services.
13. This site has all the functions I expected it to have.
14. Give a reminder via text to the user within 24 hours of receiving the test.
15. Provide a way to order the kit in shops/doctors offices/libraries.
16. Give an option to pick up the kit from shops/doctors.

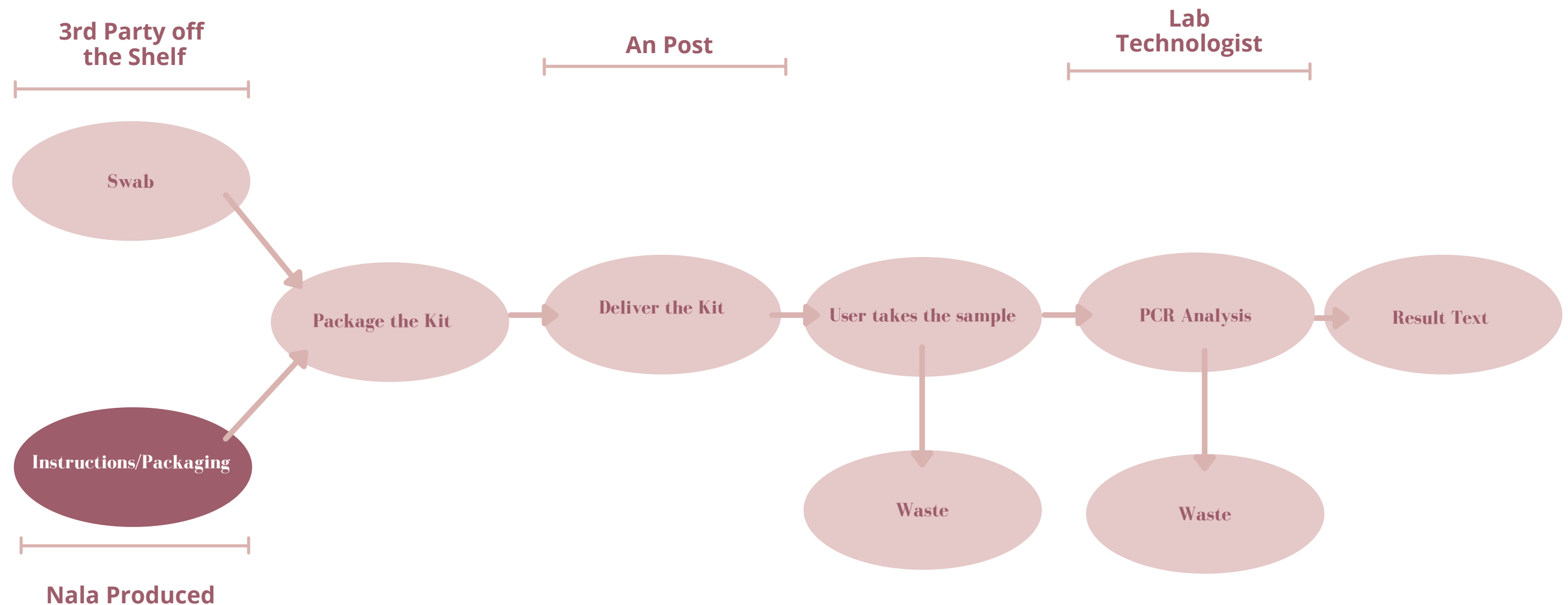
# REGULATORY PATHWAYS

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RISK ASSESSMENT

# REGULATORY PATHWAYS

In order to best prepare the product service system for integration with existing systems, the regulatory requirements of the product and service both need to be considered. The designer will do this by exploring existing protocol for similar products and processes. The designer will also explore the medical device regulation requirements set out by the HPRA. Below is a map which highlights the touchpoints which are required to be regulated. The lighter colour are existing, approved products and services. The darker colours represents the non-approved touch points for which regulatory pathways need to be identified.



# SWAB SAMPLE PROTOCOL

## ***Transporting Samples***

HPV is a category B sample of an infectious disease, and the rules of its transportation are less strict than those of category A infectious diseases. According to the WHO the outer packaging must read 'exempt human specimens' (WHO 2010) .

## ***Sample Disposal***

A yellow container must be used to dispose of the swab sample as it is visibly soiled with blood (Stericycle 2021).

## ***Classification***

The author finds the swab to be a class I medical device, as it is non-invasive. Although with any uncertainty surrounding the classification of the device a notified body should be contacted (European Commission 2010).

## ***Regulatory Bodies***

Within Ireland the swabs must be approved by the HPRA. They are responsible for the regulation of medical devices on the Irish market and are designated as a CA for medical devices in Ireland (HPRA 2020). Any product which will be sold in Europe is required to have a CE conformity mark.

# PCR TESTING PROTOCOL

As mentioned in literature (Wong *et al.* 2018) uses the QIAamp DNA Mini Kit for analysis of the blood samples. There is an established protocol which has been validated and approved (Qiagen 2016) and this protocol is therefore sufficient to use as a bench mark. The protocol for PCR testing is as follows:

1. Cut tissue ( $\leq 25$  mg) into small pieces and place in a 1.5 ml microcentrifuge tube. Add 180  $\mu$ l Buffer ATL and 20  $\mu$ l Proteinase K, mix by vortexing and incubate at 56°C until completely lysed (1–3 h). Vortex occasionally during incubation.
2. Add 200  $\mu$ l Buffer AL. Mix thoroughly by vortexing for 15 s.
3. Incubate at 70°C for 10 min. Briefly centrifuge the tube to remove drops from the lid.
4. Add 200  $\mu$ l ethanol (96–100%). Vortex for 15 s. Briefly centrifuge the tube to remove drops from the lid.
5. Pipet the mixture onto the QIAamp Mini spin column (in a 2 ml collection tube). Centrifuge at 6000 x g (8000 rpm) for 1 min. Discard the flow-through and collection tube.
6. Place the QIAamp Mini spin column in a new 2 ml collection tube and add 500  $\mu$ l Buffer AW1. Centrifuge at 6000 x g (8000 rpm) for 1 min. Discard the flow-through and collection tube.

7. Place the QIAamp Mini spin column in a new 2 ml collection tube and add 500  $\mu$ l Buffer AW2. Centrifuge at full speed (20,000 x g; 14,000 rpm) for 3 min. Discard the flow-through and collection tube.

8. *Recommended:* Place the QIAamp Mini spin column in a new 2 ml collection tube (not provided) and centrifuge at full speed for 1 min. This eliminates the chance of possible Buffer AW2 carryover.

9. Place the QIAamp Mini spin column in a new 1.5 ml microcentrifuge tube (not provided), add 200  $\mu$ l Buffer AE or distilled water and incubate at room temperature for 1 min. Centrifuge at 6000 x g (8000 rpm) for 1 min to elute the DNA.

10. *Optional:* Repeat step 10 for increased DNA yield with a further 200  $\mu$ l Buffer AE or distilled water.

This protocol must be met when the samples are being analysed by PCR testing.

# MEDICAL DEVICE REGULATION

The IFUs and website both require identifying the path for medical device regulation. Some of the key requirements for medical device regulation are listed below as per the HPRA medical device regulation reference list (HPRA 2017). The designer intends to explore the regulatory paths and what is required for the approval of the NALA kit.

There are a number of abbreviations in the regulatory table below, an introduction to them before reading the table may be beneficial for the reader: *Quality Management System (QMS), Risk Management System (RMS), Person Responsible for Regulatory Compliance (PRRC), Post Market Surveillance (PMS), Field Safety Corrective Actions (FSCA), General Safety and Performance Requirements (GSPR), Instructions for Use (IFU).*

## Qualification & Classification

Is the product a medical device under MDR?

Is the product a Class I medical device under MDR?

Is your Class I device up classified under MDR?

## Processes and Systems

Is there a QMS established, documented, implemented and maintained?

Is there an RMS established, documented, implemented and maintained?

Is there a clinical evaluation planned, conducted and documented?

Is there a PRRC identified within the organisation?

Is there financial coverage/liability for defective devices put in place?

Is there a PMS system documented and in place including a PMS plan?

Is there a system for reporting incidents and FSCA in place?

## Conformity Assessment and CE marking

Is the GSPR fulfilled?

Is the technical documentation drawn up and requirements fulfilled?

Is the IFU, packaging and labelling requirements fulfilled?

Is a clinical investigation required?

Is Notified Body assessment required? (sterile/measuring/reusable)

Is the Declaration of Conformity drawn up?

Is the CE mark affixed?

## Other Requirements

Is your distributor informed the device is on the market under new Regulations?

Is there appropriate traceability within the supply chain?

# QUALIFICATION & CLASSIFICATION

The designer will now explore the IFUs and the website under the four aforementioned categories. Beginning with qualification and classification.

## ***Classification***

The new medical device regulation (MDR) applies to accessories to medical devices (European Commission 2021). The packaging, considering it holds the device and gives instructions for the device can be considered an accessory.

The software on the other hand does not qualify as a medical device as it does not meet the definition of software or Medical Device Software (MDSW) according to Section 2 (Definitions and Abbreviations) of the Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR (MDCG 2019).

## ***Instructions for Use***

Class I and IIa devices are not required to have IFUs if the device can be safely operated without them. The designer is of the impression however, that the user would require the instructions to carry out the screening efficiently. It is also typically recommended that they are included (The European Commission 2021).



# PROCESSES & SYSTEMS

There are a number of processes and systems which are required to be in place for the regulation of medical devices.

## **Quality Management System**

It is a structured system of procedures and processes which covers aspects of design, manufacturing, supplier management, risk management, complaint handling, clinical data, storage, distribution and product labelling (Oriol 2018).

## **Risk Management System**

This system consists of a number of steps including; establishing the framework, defining intended use, identifying hazards and hazardous situations, estimating risk, evaluating and controlling the risk, evaluating the overall risk acceptability, risk management overview and compiling production and post production information (Speer 2021).

## **Person Responsible for Regulatory Compliance**

This is a requirement which ensures the team or company have a regulatory expert available to them (Wyler 2020).

## **Financial Coverage**

When applying for regulation for medical devices the designer/company or university must have liability insurance. Due to their liability for all claims with regard to their product (HDI 2019).

## **Post Market Surveillance**

The Following is a list of what is generally to be included in a PMS report:

- Background of the device
- Regulatory history
- Description, and indications for use
- Purpose of the PMS plan
- PMS plan objectives and hypothesis
- PMS design
- Patient population (include inclusion and exclusion criteria for patients)
- Statistically justified sample size calculation,
- Primary and secondary endpoints including definitions, success criteria for the study, a list of expected adverse events of complications, and an agreement to collect unexpected adverse events
- Descriptions of the follow-up schedule, length, and assessment procedures
- Relevant data collection forms and description of data collection procedures and statistical analysis
- Reporting schedules for interim and final reports
- Interim and final data analyses
- Milestones/timeline elements

(Brown 2020).

## **Field Safety Corrective Actions**

This is an action taken by the manufacturer to prevent death or injury to patients and can include: the return of a medical device to the supplier, device modification, device exchange, device destruction (HPRA 2021).

# CONFORMITY ASSESSMENT & CE MARKING

As a third section for exploration the designer looks into the conformity assessment section of the regulatory pathway.

## **General Safety and Performance**

The GSPR sees that the device does what it is intended to do, and is made with the correct materials and that the materials also do what they are intended to do. This is in general, in terms of design, manufacture and supplied information (Qualion.d).

## **Instructions for Use Requirements**

The instructions are to follow the guidelines set out in *Annex I* of the *MDR (EU) 2017/745 Regulation*. This is the way by which the manufacture provides details of the composition and operation of the product, and indicates the safety warnings. The use of symbols must be in compliance with the MDR. From 2025 the medical devices labelling must include a Unique device identification (UDI) which increases its traceability throughout the supply chain, in order to be able to act promptly in case of need (Thema 2021).

## **Notified Body Assessment**

As mentioned before the notified body in Ireland is the HPRA. An email can be sent to the HPRA at [devices@hpra.ie](mailto:devices@hpra.ie) for applications for designation or extensions.

## **Declaration of Conformity**

It is an essential document under the MDR and the following information must be included in it:

- Manufacturer's or the authorized representative's name, address and Single Registration Number (SRN)
- Statement that the manufacturer alone accounts for the declaration of conformity
- Basis-UDI-DI
- Product and trade name, product code, catalogue number and other references, allowing product identification and traceability, intended purpose and, if necessary, a photograph
- Risk class of the device
- Statement that the device is in conformity with the MDR and other applicable EU legislation, that require a declaration of conformity
- References to applied common specifications
- If applicable name and identification number of the notified body, description of the conformity assessment procedure
- Place and date of issue, name and function of the signatory, indicating for, and on behalf of whom, that person signed, as well as signature.

(Matousek 2018).

## **CE mark Affixation**

The mark must be *visible, legible* and *indelible*. It should consist of the letters CE. Both letters should have the same vertical dimension and be no smaller than 5mm (Europa 2021).

# SUPPLY CHAIN TRACEABILITY

Finally in terms of supply chain traceability, the designer already mentioned the need for a UDI (Thema 2021). Medical device traceability is achieved through maintaining adequately detailed records in relation to the sourcing and supply of medical devices.

They are required to identify to a competent authority:

- To whom they have directly supplied a device, including healthcare professionals, institutions and sales representatives
- Who has directly supplied them with a device.

The distributor is required to keep records for ten years after the last device has been placed on the market.

These records are likely to include:

- Copies of invoices relating to the receipt and supply of a medical device
- Copies of orders relating to the receipt and supply of a medical device
- A list of approved medical device suppliers and details of the relevant medical devices
- A list of approved customers, for example economic operators, health institutions and healthcare professionals, including contact details of those to whom medical devices were supplied
- Records of checks carried (for example, labelling checks for CE marks) and the approval of medical devices into saleable stock.

The distributor is also responsible for preventing falsified medical devices from being introduced into the supply chain.

## ***Eudamed***

This is the IT system developed by the European Commission to implement the MDR and IVDR. It includes six modules:

- Actor registration, including a single registration number (SRN)
- UDI/device registration
- Notified bodies and certificates
- Clinical investigations and performance studies
- Vigilance and post-market surveillance
- Market surveillance

(HPRA 2021).

# DESIGN IMPLEMENTATION

DESIGN REFINEMENT  
USER TESTING  
MARKET RESEARCH  
DISCUSSION & CONCLUSION  
FINAL DESIGN

# DESIGN REFINEMENT

---

REFINING THE PACKAGE  
REFINING THE SITE

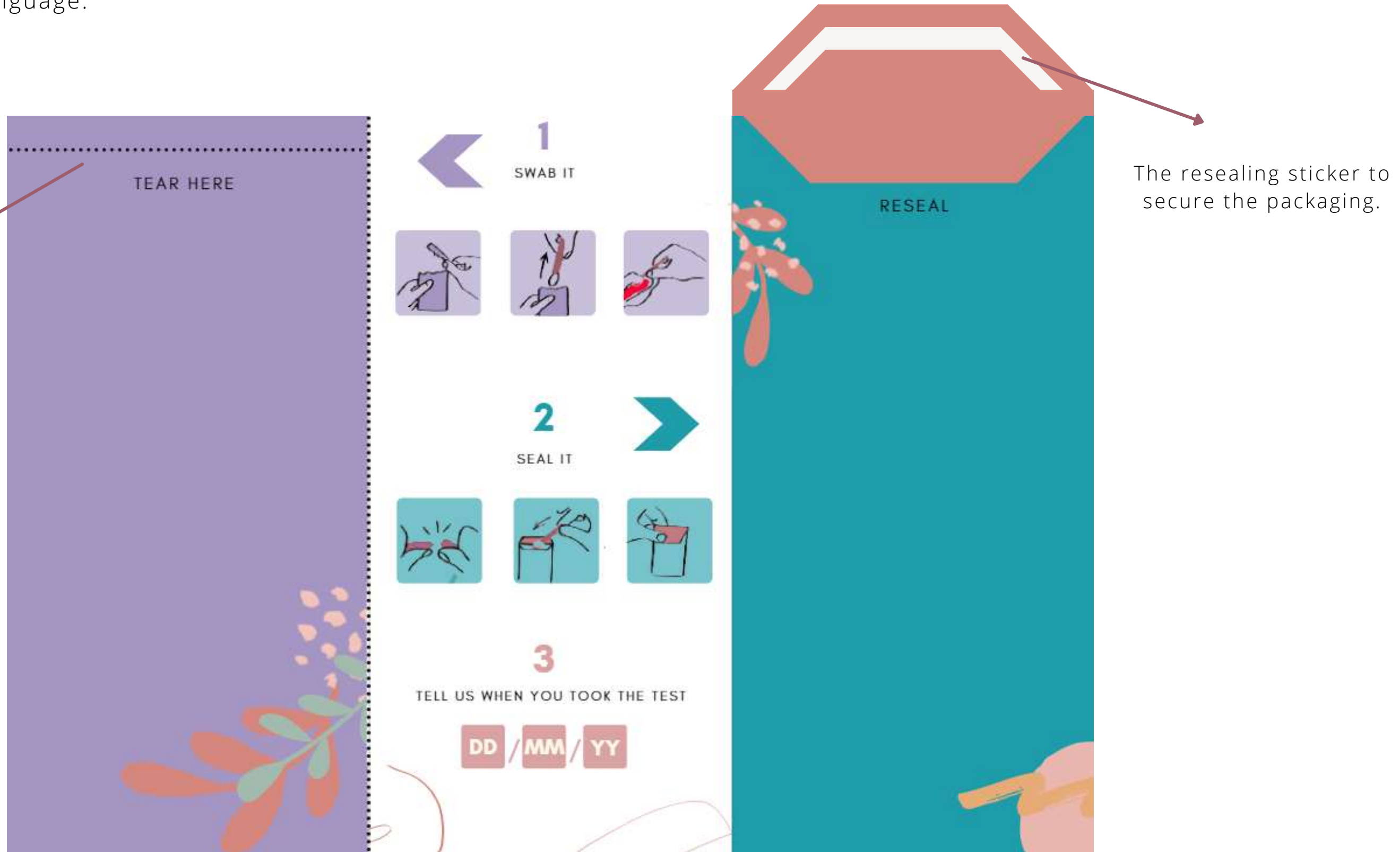
# REFINING THE DESIGN

Following on from the previous chapter, there are a number of aspects of the design intervention which are yet to be confirmed. For instance the closure of the packaging, and its final design. In addition to this the transition from this service into the cervical check service should be made concrete. The handover should be airtight to prevent women falling through the gap, these women need to make the connection from this design intervention to the Cervical Check services in place in Ireland. As with the previous chapter this will be reached by designing - testing - and refining the intervention.

# REFINING THE DESIGN

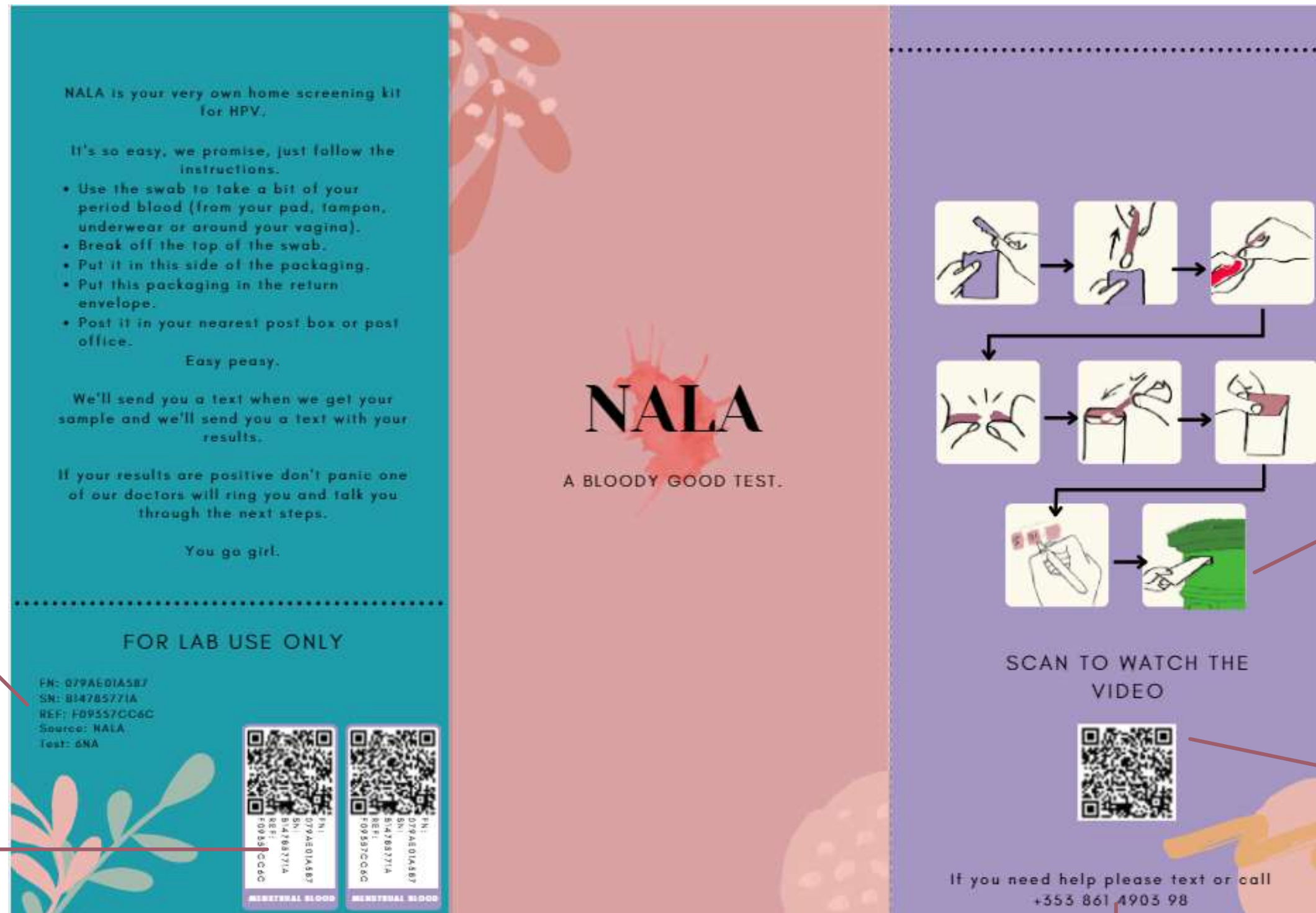
To begin refining the packaging the designer adds the icons to the printed packaging and adds explanatory text in simplistic language.

A dotted line to signal to the user where to tear. The dotted line is perforated for ease of tearing.



# REFINING THE DESIGN

This is the reverse side of the packaging. This packaging will be printed and tested with users to gather feedback.



Lab Identification details.

ID Stickers for the lab technician to transfer to the PCR test samples.



# TESTING THE PACKAGING

The designer then tested this packaging with the user.



## **Task**

Work through this packaging and follow the steps.

## **Purpose**

Observing someone using the packaging to identify any issues or changes which need to be made.

## **Findings**

The user was able to move through the packaging without concern. Feedback from a senior designer highlighted the potential need for an additional descriptive icon in the instructions. There was a comment made about the clarity of the text too, which should be addressed. As well as this the packaging needs to be more secure and include the section for sealing.

# REFINING THE DESIGN

Feedback from testing highlighted a need for additional icons for instructions and to perhaps reassess the accompanying text.

NALA is your very own home screening kit for HPV.

It's so easy, we promise, just follow the instructions.


- Use the swab to take a bit of your period blood (from your pad, tampon, underwear or around your vagina).
- Break off the top of the swab.
- Put it in this side of the packaging.
- Put this packaging in the return envelope.
- Post it in your nearest post box or post office.

Easy peasy.

We'll send you a text when your sample arrives.

We'll send you another text with your results.

If your results are positive don't panic one of our doctors will ring you and talk you through the next steps.



## **Task**

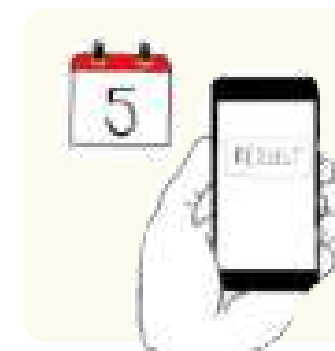
Read through and speak aloud while moving through the instructions.

## **Purpose**

Measuring the success of the additional icon and the new instructional text.

## **Findings**

The user was read the text without any issues and had no difficulty understanding. The new icon caused some confusion, the user suggested having an icon that gave an idea of when the results might be back.



# REFINING THE DESIGN

The previous iteration of the packaging raised concern of the user peeling off the QR code intended for the laboratory technician. Two solutions were provided by the designer.

1. Give the illusion that the sticker is smaller than it actually is, making it difficult for users to take it off out of curiosity.

2. Have the sticker blend into the packaging and have the QR code on the reverse side, not visible to the user.

These techniques were tested to see which one worked best at deterring the user from peeling the sticker.

1.



2.

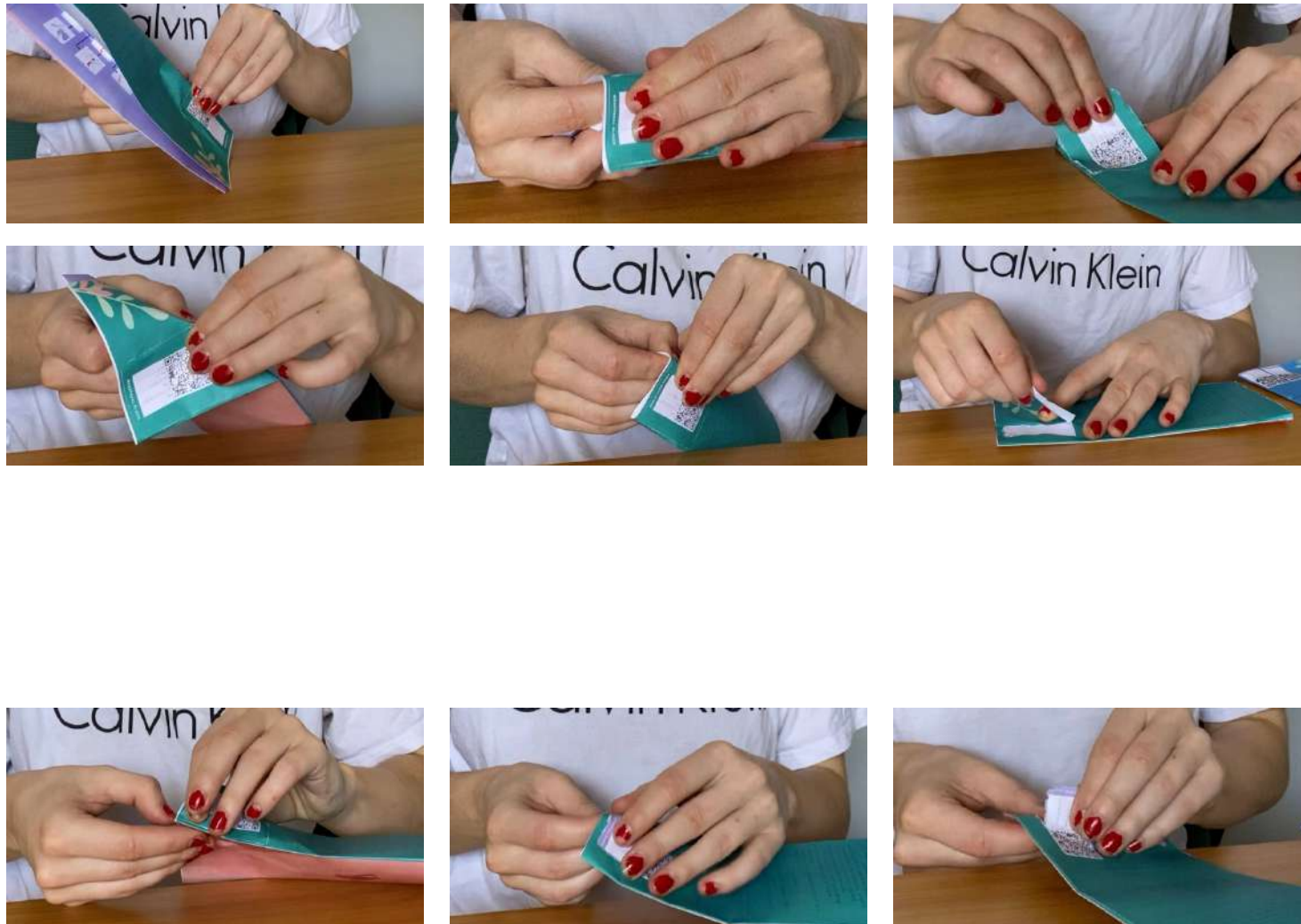


3.



# REFINING THE DESIGN

Testing these stickers with users, to identify whether the lab technician would experience difficulty when they have to remove the stickers.



## **Task**

Locate and remove the stickers.

## **Purpose**

Testing whether or not a user (lab technician) would be able to remove the stickers from the kit.

## **Findings**

The user successfully removed the blue and purple stickers however the sticker without the QR code was forgotten about. The sticker with the blue surrounding colour took a number of attempts to remove (the top 6 images) when compared with the purple sticker (lower 3 images).

While it can be suggested the sticker without the QR code visible may be the best option to deter the user it is difficult for the lab tech to use and therefore the designer decided to move forward with the blue sticker as it was tricky to remove and therefore may deter the patient, however with a prompt and some practice it would be easy for the lab technologist to use.

# RETURN PACKAGING

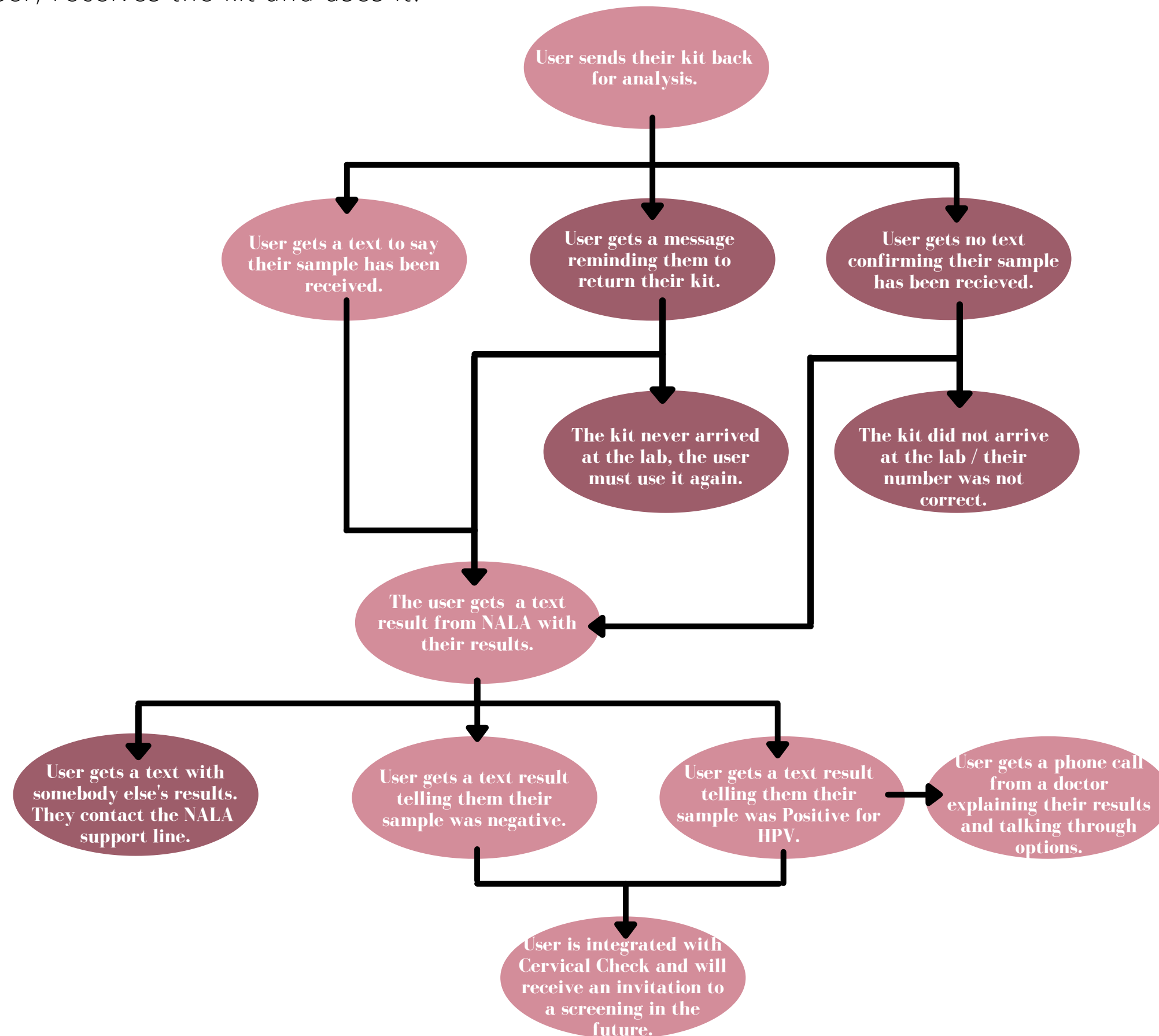
As mentioned in the previous chapter, there are requirements for the external return envelope as it will contain a biological sample. The return packaging is pictured below. On the rear of this packaging there is a QR code which can be scanned on arrival to the lab to send a notification to the user.



After some consideration the designer decided that a paper envelope may not be suitable for the transport of the biological substance. As it could leak or get wet and spill through the paper. For this reasoning the designer has decided to have the packaging as a biodegradable mailer which is an alternative to plastic.

# WHAT HAPPENS NEXT?

The designer creates a task flow to analyse what could happen after the user, receives the kit and uses it.

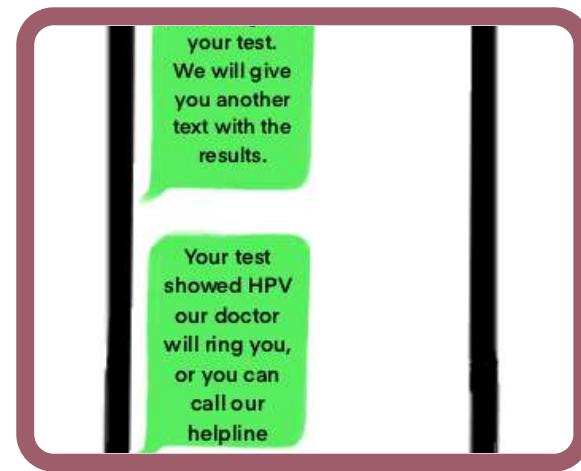


# WHAT HAPPENS NEXT?

This storyboard below depicts the steps following the self testing kit. It has taken shape as a result of the task flow which precedes it.



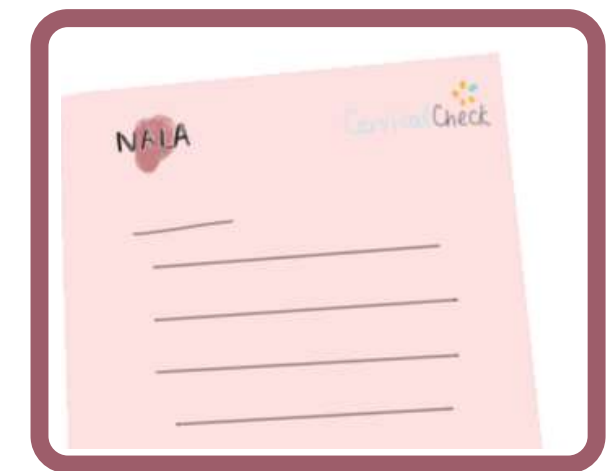
User receives a text confirming their sample has been received.



User receives a second text message result with a positive result.



They get a phone call from a health professional who talks them through what it means.



The user will get a reminder to take the test again in 6 months, or be invited in for a screening.

# ENVIRONMENTAL CONSIDERATIONS

As the designer has mentioned previously and per the design guide, the design must be environmentally conscious. A number of design decisions have been made to make this product sustainable. Firstly, the website is designed to be energy efficient. This is achieved by a low number of images, embedding videos into the site and through SEO.

## **SEO**

SEO refers to improving a site to increase its visibility when people are searching for services products or terms related to the site. The visibility of the site in search results often determines the amount and frequency of visitors to the site (Search Engine Land 2019). There are typically three types of SEO that strategies focus on:

- *On-page SEO* – The content on the sites pages and improving it to boost the websites ranking based on keywords.
- *Off-page SEO* – Links directing to the website from elsewhere. Backlinks from reputable sources will increase trust within search algorithms.
- *Technical SEO*- The site code and the backend architecture behind the site (Fortin 2021).

## **Energy Efficiency and SEO**

SEO essentially aids users finding the information they want quickly and easily. Successful SEO results in people spending less time browsing the web looking for information, and visiting the sites they don't need. Therefore, less energy is consumed (Greenwood 2019).

## **NALA and Energy efficient SEO**

In order to create and maintain an energy efficient website the SEO must be considered. There are a number of ways the designer intends on incorporating to ensure site uses as little energy as possible:

- Embed the informative video to the website rather than hosting it on the site.
- Remove images where possible, and optimise images for the web where it is not possible.
- Use a hosting company for the site which is operated ethically and uses renewable energy *e.g. fatcow.com*.
- Maintain a site with a reduced number of elements as it will be quicker to load.
- Improve and frequently update the keywords used to locate the site.

(Ratcliff 2021).

In terms of environmental considerations for the kit itself there are a number of design decisions which have been made.

- The packaging is made from recycled paper. This reduces the need for virgin materials during production.
- The packaging is not treated with a wax coating, and therefore is suitable for recycling.
- The packaging rips to allow the user recycle the side of the packaging which is not required to be returned.
- The return envelope is made from a compostable plastic alternative.



# USER TESTING

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DESIRABILITY  
USABILITY  
HEURISTICS EVALUATION

# DESIRABILITY TESTING

A desirability test is used to determine what users think of the intervention, and how they perceive it. Users were given a selection of cards with adjectives on them and they were asked to select a number of cards which resonated with them with relation to the design. A full list of the adjectives can be found in the appendix, and is based off the Microsoft desirability toolkit (Benedek and Miner 2002).



## **Task**

Select cards which you think best describe the design intervention.

## **Purpose**

Identifying how the kit and site appear to users.

## **Findings**

The participants selected a number of cards which they found appropriate including:

- Attractive
- Approachable
- Easy to use
- Intuitive
- Personal
- Simplistic
- Time-saving
- Trustworthy

A host of positive words were chosen, which reflected the need for the product to be easy to use. The fact the participants used these words to describe the design innovation means the design guide has been satisfied in terms of ease of use.

# USABILITY TESTING

Usability testing is important for the validity of a product. To insure that it can be used and that it does what it is supposed to do. The author will complete a shortened usability test based on the FDA standard test. The report for the test in its entirety exists in the designhistoryfile/03.Validation/UsabilityReport. However, the designer has chosen some key findings for discussion in this process book.

In conclusion to the usability report: Nala, the website and kit, as a class one medical device has been found to be safe and effective for its intended users, use cases and use environments.

The human factors evaluation methods used included a PCA analysis, FMEA analysis, actual use testing and as a heuristic's evaluation. All results from these evaluations showed no serious risks apart from disengagement and failure to return the test, both of which saw a low risk of occurrence. These risks have been mediated through labelling. Minor and Negligent risks reported are also infrequent. Validation testing saw no critical task use errors and based on this the NALA kit and site is found to be safe and effective for its intended use. Modifications to the user interface including the instructions for use are not necessary for the safe and effective use of this product. The remaining residual use related risks are greatly outweighed by the benefits provided by the use of this device.

# USABILITY REPORT

## **Intended Users**

Identifying user groups and meaningful differences in capabilities between user groups which could affect user interactions with the device.

User groups identified were:

1. women 25-30 with literacy levels above 3.
2. Women 25-30 with literacy levels below 2 on the 5 point scale.

Identified factors for the users included:

1. Vision
2. Dexterity
3. Previous Experience
4. Comfort with bodily fluids.
5. Period Flow
6. Literacy

Key issues included cultural views of periods, which may impact comfort with their menstrual blood, the flow of menstrual blood and their ability to collect a solid sample and then indeed their literacy.

The flow can be minimal as only a small amount of blood is required for testing, literacy is considered in the lack of written instructions. The comfort with bodily fluids is tricky, but because this kit works with existing period management it does not require any foreign objects being inserted into the vagina. Nor does it require the user to touch their blood or discharge.

## **Intended Use**

- Intended to be used as a screening test for HPV.
- Intended to be used to swab a menstrual blood sample.
- Intended to be returned to the lab within 72 hours.
- Intended that the swab is inserted directly into the packaging after collecting the sample.
- Intended that user reads instructions or is familiar with the device before use.

## **Operational Context**

- No formal training.
- It is used in a bathroom.
- Should not be opened for long before use.
- Device should not be placed on dirty surfaces prior to sample collection.
- User should clean their hands before and after using the device.

## **Use Environments**

Exploring two potential use environments as a bathroom at home and a public toilet and identifying factors including:

- Temperature
- Lighting
- Sanitation
- Distraction
- Distance to sink
- Space

## **Intended Training**

There is no formal training for users of this device, however there are in depth instructions for use (IFUs) enclosed in the device packet. The instructions fold out and provide descriptive imagery.

# FMEA

After identifying users the usability report analyses tasks in understand how the user will move through the kit. After identifying the tasks and risks the designer can complete a FMEA.

Task	Risk
1. Read instructions.	1. User does not understand the IFU's
2. Wash hands.	2. User doesn't use soap.
3. Rip Packaing	3. User can't tear the packaging.
4. Remove the swab.	4. Swab falls on the floor.
5. Obtain the sample.	5. Swab breaks when obtaining the sample.
6. Break the Swab.	6. Swab doesn't break
7. Re-insert swab into packaging.	7. The swab is inserted into the wrong side.
8. Wash Hands.	8. User doesn't use soap.
9. Reseal the Packaging.	9. Packaging doesn't stay sealed.
10. Fill out the date.	10. User does not fill in the date.
11. Insert into return packaging.	11. User returns the wrong side.
12. Post the sample.	12. User forgets to return the packaging.

Risk	Likelihood	Occurrence	Severity	RPN
1. User does not understand the IFU's	2	2	5	20
2. User doesn't use soap.	3	3	2	18
3. User can't tear the packaging.	2	1	4	8
4. Swab falls on the floor.	2	1	4	8
5. Swab breaks when obtaining the sample.	2	1	1	2
6. Swab doesn't break	1	1	1	2
7. The swab is inserted into the wrong side.	2	1	3	6
8. User doesn't use soap.	3	3	2	18
9. Packaging doesn't stay sealed.	2	1	3	6
10. User does not fill in the date.	2	1	1	2
11. User returns the wrong side.	1	1	5	5
12. User forgets to return the packaging.	2	1	5	10

# HEURISTICS EVALUATION

As part of the usability report the designer completed a heuristic evaluation to indicate the usability of the kit. The evaluation contained 12 heuristics for consideration (Privitera 2019). Suggestions were made per the HE75 document (AAMI 2018).

Heuristic	Description
Consistency	Users should not wonder whether different words, situations, or actions mean the same thing.
Visibility	Visibility of system state: Feedback and information display keeps users informed.
Match	Match between system and world: The way they see the system should match the model they have
Minimalist	Extra information is not needed it slows the user down.
Memory	Minimize memory load: Users should not have to memorize a lot to be able to complete the task.
Feedback	Informative feedback: Users actions should be met with prompt and informative feedback.
Flexibility	Different users learn and use the interface differently. Allow flexibility to enhance performance
Message	Error messages should help user to understand, learn from and recover from the error.
Error	Interfaces should prevent errors from happening in the first place.
Closure	Users should be clearly notified about the completion of a task.
Undo	Errors should be recoverable or reversible.
Language	The language should be understandable by the intended users.
Control	Make the user confident they are in control not the other way around.
Document	Help and documentation: Always provide help when needed

Task	Usability Issue	Heuristic Violated	Recommendations
Use swab to obtain sample	Don't know if the sample is enough	Closure	Section 4.4.2 – If a sufficient amount is not obtained the user is notified.
	The swab breaks.	Flexibility	Section – 4.3.4 The user should be informed that it is okay if the swab breaks.
Break Neck of swab	User can't break the swab.	Control	Section – 4.3.4 The user know that not breaking the neck is okay.
Return Packaging	User forgets to return the sample.	Closure	Section 4.4.2 – User may forget to return the packaging and that measures should be in place to ensure it does not happen.
		Message	

# MARKET RESEARCH

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INDUSTRY OVERVIEW  
TARGET MARKET  
COMPETITORS

# MARKET RESEARCH

With a defined final concept, it is worthwhile identifying the market in which this design intervention will operate. There has been consideration given, in previous chapters to the market space. In the research chapter this consideration focused widely on women's health with relation to CC screening and HPV vaccination. In the previous chapter a more specific examination was given to the competitive space surrounding the design intervention. Thought was given to political, environmental and economic factors. Now the designer will explore in more depth the industry, the target market, competitors, finally the designer will offer a forecast of how the intervention may succeed and ways by which it may fail.

The designer will complete market research by exploring areas including

*Industry Overview - Target Market - Competitors*



# INDUSTRY OVERVIEW

In the research chapter the designer first discussed the market size, along with trends and drivers within this market. The designer will have another look at these characteristics of the industry space which NALA will operate in.

## **Market Size**

### *Worldwide*

CC is the 4th most prevalent cancer in women worldwide. In 2018, about 570,000 women were diagnosed with the disease, and an estimated 311,000 women died from CC (WHO 2020). The global market size for the treatment of CC was estimated at USD 6.2 billion in 2018 and is expected to expand (GrandviewResearch 2018).

### *Ireland*

CC is the 9th most common cancer in Ireland, and annually around 300 women are diagnosed with CC. It accounts for about 90 deaths (HSE 2019). CC most commonly affects women between 25 - 65, and which in 2016 included 1,290,774 Irish women (CSO Ireland 2016). The Irish population is also increasing (Worldometer 2021). Data relating to the cost of CC for the HSE is lacking, however comparing data of the NHS can be considered a sufficient benchmark. The cost of CC in the UK is 21.1m annually (Salter 2014).

It is apparent that there is a large market both in Ireland, and worldwide for the screening of CC.

## **Market Trends**

The author suggests a trend towards self-testing for HPV. This was supported in primary research and secondary research (Harper et al. 2002; Boggan et al. 2015). Data suggests that there will be an increase in the adoption of home testing for HPV (BusinessWire 2020). There has been an increase in companies providing self screening kits for HPV (Ferne Health 2021; Eve 2021).

## **Market Drivers**

There has been an increased awareness regarding care, prevention and treatment of CC. Genetic factors, and weak immune systems have been linked to the growth of the CC diagnostics and therapeutics market (Research and Markets 2020). Increase in R&D expenditure in oncology is also likely to provide growth for the market (GrandviewResearch 2018).

## **Market Restraints**

The stigmatised nature of the disease, can also hinder the growth of the market, as patients are less likely to attend their follow up clinics due to their embarrassment and or anxiety relating to the disease (Milner and McNally 2020).

# TARGET MARKET

Following from an overview of the general marketplace. The designer moves into exploring the specific target market. For this exploration the designer will pay specific attention to the Irish population.

## **Market Size**

As previously mentioned this product aims to serve women aged between 25-65 of which there are 1,290,774 Irish women (CSO Ireland 2016).

## **Demographics**

While a large portion of the target customers are women of a regular economic background a number of them will belong to marginalised groups. These marginalised groups include, traveller women and homeless women. With specific efforts to make NALA accessible to these women, they are key within the demographic of customers.

## **Location**

The customers will be based in Ireland for the most part, services and support for reaching members of marginalised groups are abundant in areas such as Dublin, Cork and Galway cities. However, these women are everywhere. The postal service An Post, and Public health nurses will help reach the women who may be in rural areas.

## **Behaviours**

While there has been low uptake in CC screening recently, the general population have quite good uptake of CC services. However, it is the women who do not engage with the services who are cause for concern and will benefit most from this intervention.

These women often do not engage with the services for lack of trust (Calnan et al. 2006; Watkins et al. 2021) and often their own low literacy levels (Jackson et al. 2017). In general research highlights issues with the home testing kits not being trusted (Malone et al. 2020; Participant 03/U22 2021). Issues of trust appear to affect the uptake of self screening for healthcare. That is why there has been an emphasis upon increasing trust and making this product simple to operate.

# COMPETITORS

Another key consideration to make when analysing the market is that of the competitors. Who is currently in the market, and what is their situation? A suitable framework for analysing competitors is Porters 5 Forces (Dobbs 2014). This measures threat of new entry, threat of substitution, competitive rivalry as well as the bargaining power of buyers and suppliers.

## ***Threat of New Entry***

New entrants to the market space are typically determined by the level of entry barriers. In this particular competitive space barriers include the cost of entry. For instance this product service system is to be offered for free and therefore has high costs as the customer is not paying. The complex regulatory pathways for self testing kits may also be a barrier to entering this competitive space. This can be of particular concern if a competitor does not have or requires a patent for their technology. This increased cost is a heightened barrier for entry.

## ***Threat of Substitution***

In terms of substitution the fact the product service system will be offered for free means there would be a high switching cost if a user were to switch to a competitors paid product. The switching cost would reduce the threat of substitution. If users were to substitute the product for the Cervical Check programme that could be considered a success for NALA and would not be seen as a threat of substitution.

## ***Bargaining power of Buyers***

Buyers in this case can be one of the following:

1. Users
2. Third Party Buying for Users
3. Funding Body

In any case the buyers are looking for the cheapest cost where they are funding it otherwise they are expecting it to be free. Therefore, they have a lot of bargaining power because if it is not free it is unlikely to be purchased.

## ***Bargaining power of Suppliers***

The suppliers in this case can be one of two parties:

1. The supplier of the swabs to NALA.
2. The supplier of NALA.

In each case the suppliers do not hold an extensive amount of bargaining power.

1. The swabs can be provided by a large number of companies and therefore these companies have low bargaining power.
2. The product service system holds a more significant bargaining power as it would be the only non-invasive self screening method of HPV detection used in the country. This means there are not a wide range of substitutes for consumers. However, the fact the product will be given to customers for free reduces most of the bargaining power.

## ***Competitive Rivalry***

Most competitors offer pricey alternatives or free alternatives which are not user friendly. If NALA was to be backed by the HSE and the Government it would have a clear competitive advantage.

# DISCUSSION & CONCLUSION

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KEY FINDINGS  
INTERPRETATIONS  
IMPLICATIONS  
LIMITATIONS  
RECOMMENDATIONS

# KEY FINDINGS

The strategic focus for this project was: How do young women understand and experience, Cervical Screening and HPV vaccination, and how do we include their opinions and attitudes in a design solution? The key findings from the primary and secondary research, which underpin this design intervention are:

- CC is largely attributed to HPV infection, which can naturally regress over time without turning into CC.
- Women under 25 are likely to have HPV infections which naturally regress, and the over treatment of these young women can lead to fertility issues.
- Self-screening methods increase uptake in CC.
- Women do not trust their ability to self-screen.

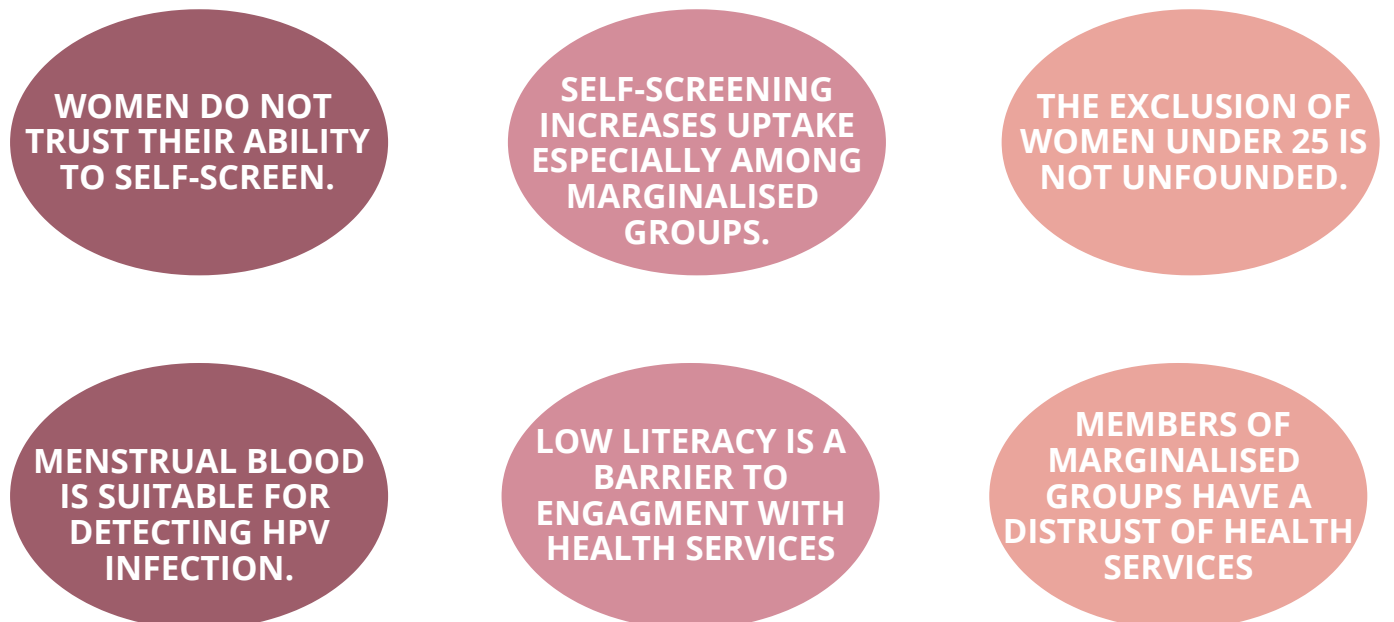
The designer, following this research created a list of 325 needs. These needs were filtered down to 6 needs. The designer considers these needs to be gaps for exploration through design thinking.

- Need for self-screening which is user friendly.
- Need to address sexual health stigma
- Need to ensure CC treatment does not cause infertility.
- Need for equitable access to the vaccination and information.
- Need to triage relatives of CC patients.
- A need to improve uptake of cervical screening and the treatment procedure.

Focusing on the need to improve uptake of screening delivered more key findings:

- Menstrual Blood is a suitable biomarker for detection of HPV.
- Low literacy levels can be seen as a barrier to engagement with health services.

These findings aided the development of NALA as it is now known. NALA is a self-screening test which uses menstrual blood to detect HPV. The kit has very little written text and the instructions are graphic representations with an informative video accessory.



# INTERPRETATIONS & IMPLICATIONS

## ***Interpretations***

While this research began with a focus on the exclusion of under 25s from the cervical screening programmes around the world, it became apparent that although these women would like to be included, there is little dissatisfaction with their exclusion. There is an abundance of research which suggests screening under 25's does not reduce the rates of cervical cancer, and there is a high chance of detecting abnormalities within the cervix of this age group (McAllum et al. 2011; Landy et al. 2014; Taghavi et al. 2017). Research also states that most HPV infections naturally regress (Brianti et al. 2017).

This pivoted the research into increasing uptake among women focusing on the designer's interest in accessibility and ensuring that the design intervention would be suitable for a wide range of women. The designer focused on creating a self-screening kit, and Wong's research into menstrual blood shaped the kit (Wong et al. 2010; Wong et al. 2018b; Wong et al. 2018a). It allowed the kit to use a non-invasive method for obtaining the sample which would be painless, and simplistic.

Using design thinking, ideas were generated, filtered, and developed into the existing screening kit. Through the iterative process of designing-testing-refining NALA made its way from an initial blue sky sketch of using menstrual blood to detect HPV to solid research supporting the idea, to finally, a kit which facilitated the concept.

## ***Implications***

This research builds on the idea that women do not object to self-screening for CC (Harper et al. 2002), however they do have concerns about the process. It adds to the existing research which implies women do not always trust healthcare systems, particularly Cervical Check (Dyer 2018).

The designer suggests a practical solution to the fear of cervical screening, fear of pain and the distrust of users ability to self-screen. The design intervention is supported by research which shows self-screening to increase uptake (Boggan et al. 2015; Reisner et al. 2017).

The design intervention uses Wong's research into menstrual blood for HPV detection (2019) and builds a self-screening using this technology. It appears to be the first to suggest that the process for screening does not need elaborately designed interfaces, that it should be simple and trustworthy, and should not isolate potential users due to low literacy levels.

While previous research has repeatedly highlighted the positives and negatives of self-screening (Nelson et al. 2017; Ngure et al. 2017; Kobetz et al. 2018), it has failed to acknowledge or suggest an applicable solution, as presented in this process book.

# LIMITATIONS & RECOMMENDATIONS

## ***Limitations***

The scope of this research and design intervention was restricted by time constraints and access to users for testing. The time allocated for the study, hindered the development of an integration protocol for users of NALA, which would join them to existing systems. While it could be suggested that once the users are interacting with the existing system that they will continue to engage with it, this study does not account for fall out and disengagement after the initial link with Cervical Check. Another limitation of this design research and subsequent intervention, is the inability of the designer to test with multiple end users. Particularly the failure to test with vulnerable users or members of marginalised groups hinders the validity of the usability claims for these groups.

## ***Recommendations for Future Work***

Further research could be undertaken to establish effective integration with existing systems and maintaining the engagement of marginalised groups with these systems. Future research could investigate the roll out of a similar system and how it could be adjusted for use in other countries and among different cultures. Going forward, more user testing should be completed on user populations specifically the more vulnerable and marginalised members of society to ensure this kit is suitable for the end user.

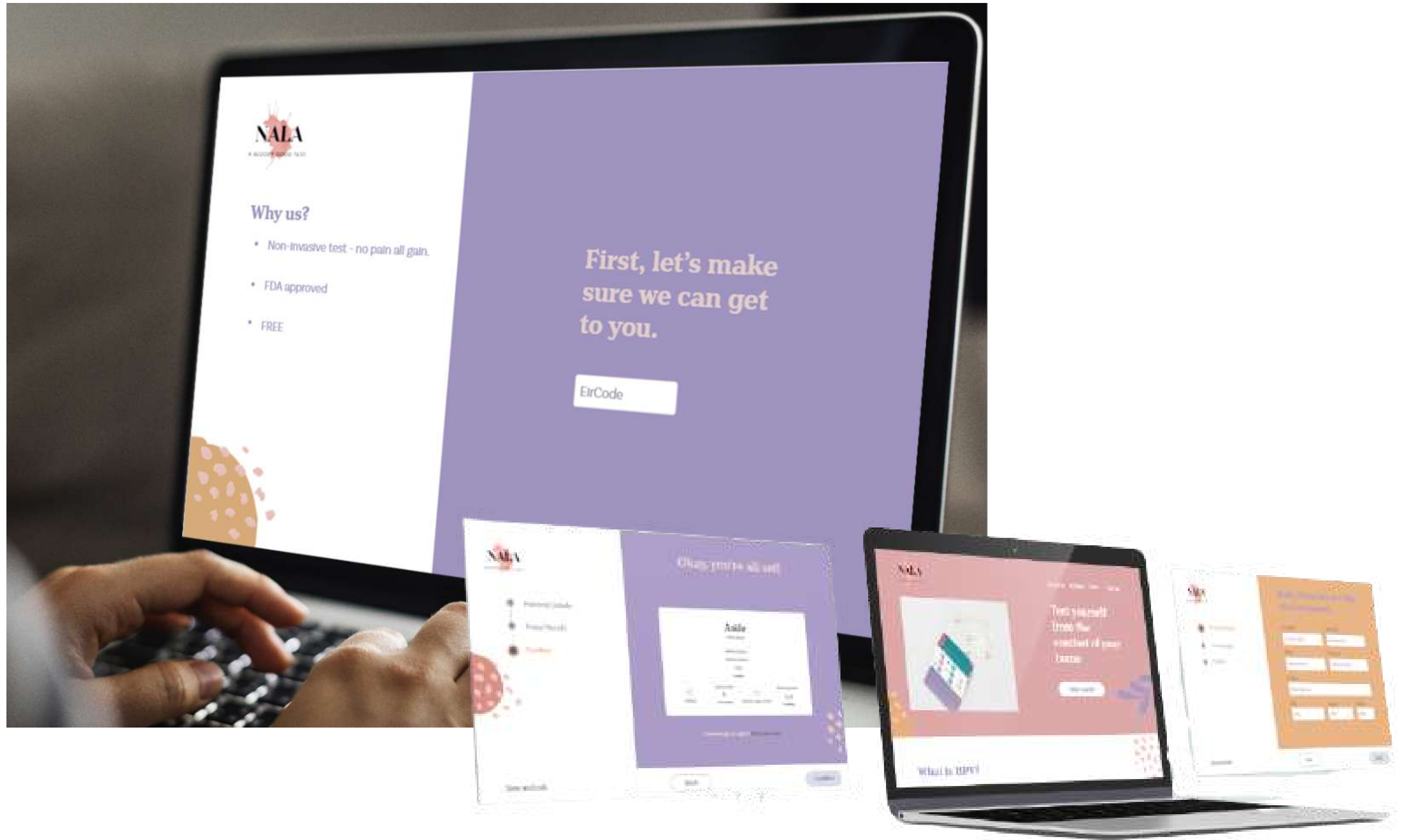
# FINAL DESIGN

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THE KIT  
THE WEBSITE  
THE STORYBOARD



# THE WEBSITE



# THE KIT

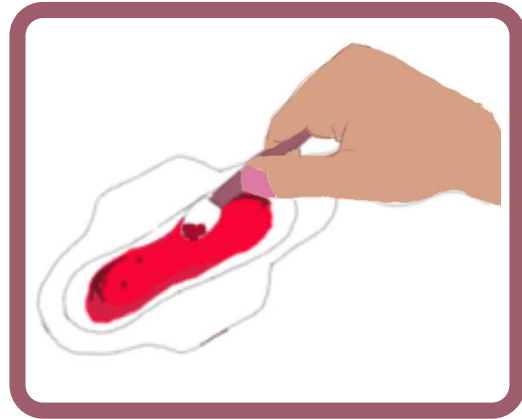


# STORYBOARDING

Storyboarding the use of the kit. The light pink story line depicts a typical user who may have a carer and or may not have access to a phone or internet.



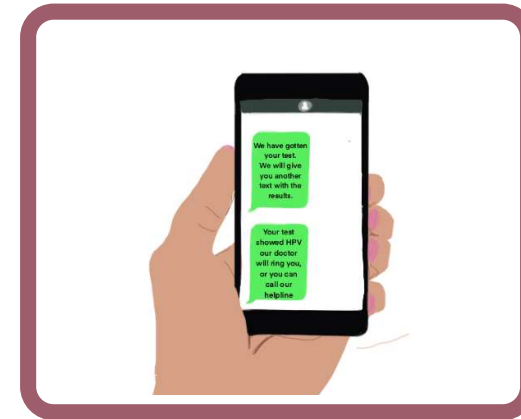
User or carer opens the website and orders the kit.



The user receives the kit, follows the instructions and takes the sample.



They put the sample back into the kit, and post it in the post office.



The user receives a text message with their results.



A doctor rings the user and explains their results.



The post man collects the sample.



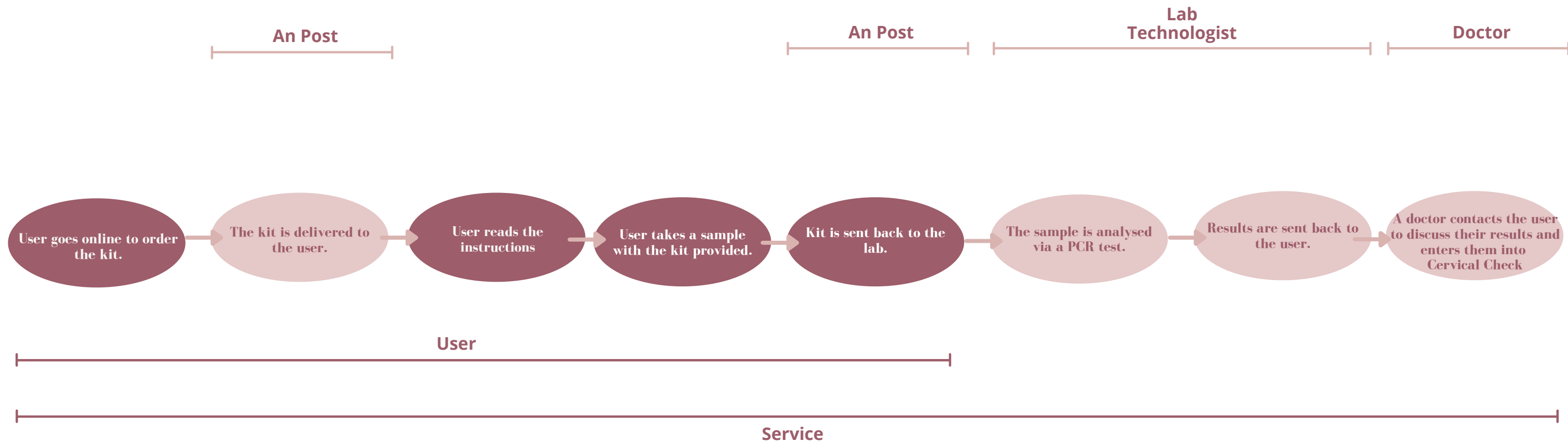
The user receives a letter with their results.



The user receives a notification of a doctors appointment to discuss their results.

# OVERVIEW

An overview of the design intervention suggested to address the need for increasing uptake of cervical screening, with an emphasis on underserved and marginalised communities.



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# APPENDIX

**APPENDIX 1- ETHICS**

**APPENDIX 2 - CODING**

**APPENDIX 3 - OBSERVATION PROBLEM NEEDS**

**APPENDIX 4 - DESIRABILITY TESTING**

# APPENDIX 1- ETHICS

## Ethics Approval

Approval was granted on the 8th of February 2021.

Faculty of Science and Engineering Ethics Committee  
Expedited Form for  
research involving human participants

### 1: Applicants Details Form Must Be Typed

Principal Investigator name (ie supervisor): Dr. Muireann Mc Mahon
Principal Investigator email: Muireann.mcmahon@ul.ie
Student name: Doireann Peelo Dennehy
ID number: 20127383
Email address: 20127383@studentmail.ul.ie
Programme of study: Design for Health and Wellbeing
FYP, MSc or PhD Dissertation: MSc
Working title of study: HPV and cervical cancer; feelings, opinions and attitudes.
Period for which approval is sought: <b>Start Date:</b> Date of approval <b>End date:</b> 25/07/2021

### 2. Human Participants

Does the research proposal involve

- Working with participants over 65 years of age? Yes  No
- Any person under the age of 18? Yes  No
- Adult patients? Yes  No
- Adults with psychological impairments? Yes  No
- Adults with learning difficulties? Yes  No
- Relatives of ill people (e.g. parents of sick children) Yes  No
- Adults under the protection/control/influence of others (e.g. in care/prison)? Yes  No
- People who may only have a basic knowledge of English? Yes  No
- Hospital or GP patients (or HSE members of staff) recruited in medical facility Yes  No

### 3. Subject Matter

Does the research proposal involve:

- Sensitive personal issues? (e.g. suicide, bereavement, gender identity, sexuality, fertility, abortion, gambling)? Yes  No
- Illegal activities, illicit drug taking, substance abuse or the self reporting of criminal behaviour? Yes  No
- Any act that might diminish self-respect or cause shame, embarrassment or regret? Yes  No
- Research into politically and/or racially/ethnically and/or commercially sensitive areas? Yes  No

### 4. Procedures

Does the research proposal involve:

- Use of personal records without consent? Yes  No
- Deception of participants? Yes  No
- The offer of large inducements to participate? Yes  No
- Audio or visual recording without consent? Yes  No
- Invasive physical interventions or treatments? Yes  No
- Research that might put researchers or participants at risk? Yes  No
- Storage of results data for less than 7 years? Yes  No

## 5 Research Project Information

**5a Give a description of the research. (Give details of what you and the participant will be doing for this study)**

Cervical cancer is one of the most prevalent cancers in the world (Chrysostomou *et al.* 2018) with the second highest prevalence and mortality in women aged 15 – 44 in Europe (Nunes *et al.* 2020). In recent years, there have been multiple public incidents of cervical cancer screening scandals, and discrimination on young Irish women for these screenings (Murry 2018). Including false negative results, and exclusion of young women who do not meet the age threshold. Although research has shown that it is increasingly likely to find abnormal results in women under 25, and the increased risk of overtreating lesions (Sasieni 2009). The lack of inclusion of under 25's in smear testing, along with reduced access in disadvantaged areas is concerning. Young women under 25 are vulnerable to potential precancerous cervical lesions (Bano, *et al.* 2008), and therefore should be included in the screening process.

There have been scientific advances in the form of vaccinations for HPV viruses which can be linked cervical cancers. There are also technological advances in the form of new methods of screening, and home screening kits. There is little to no emphasis on the wellbeing of those diagnosed with cervical cancer, or those with abnormal smear results. Even though testing HPV-Positive with normal cytology is associated with anxiety (McBride 2020). I am proposing a qualitative study with some basic statistics, hoping to interview <30 women and private healthcare professionals who specialise in gynecology to understand values, ideas and beliefs about cervical cancer screening, with a focus on opportunities to include under 25's and allow cervical cancer screening be accessible to disadvantaged areas. These interviews will take place over MS teams. I also plan on carrying out a survey to identify the current knowledge of members of the general healthy population and their attitudes towards cervical cancer and its screening process. This survey will be created via Microsoft forms and will be distributed to participants via Facebook, Instagram, and email. Data gathered will be analyzed to identify areas for improvement.

### References

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## Ethics Approval

The yellow highlighted sections are amended based on feedback from the ethics committee.

*Gynecology and Reproductive Biology*, 139(1), 86-89, available: <http://dx.doi.org/https://doi.org/10.1016/j.ejogrb.2007.08.020>.

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5b Will the participants be recorded? Yes X No

If Yes will the recordings be Video  Audio X

Why is recording required?

Recording is required to subject the qualitative data gathered during the study to analysis, and to verify the data with interview participants to ensure a subsequent write-up is accurate and rigorous. **Once analysis is complete and interviews have been transcribed, the recordings will be destroyed.**

5c Will a prototype be developed? Yes  No

5d How many participants will be involved?

<30 for interviews and <300 for surveys

5e How do you plan to gain access to /contact/approach potential participants?

Due to COVID-19 restrictions, all sampling methods will take place remotely. The sampling method will involve surveys via Microsoft Forms and interviews via Microsoft Teams. This sample will be that of a purposive sample, research suggests

S&EEC Form, October 2019

that purposive style is efficient for sampling specific groups online (Gentles *et al.* 2015). Recruitment will be via posts on the researcher's social media accounts, via Twitter, Facebook, and Instagram. Social media is seen to be efficient for recruitment of hard to reach populations (Topolovec-Vranic and Natarajan 2016). Issues may arise with regard to participants answering questions quickly and randomly as they are self-administered, but data collected does not answer the questions seriously or at all will be excluded from the analysis (Necka *et al.* 2016). Social media provides an effective method of recruitment based on a wide variety of variables and will be time and cost efficient (Boas *et al.* 2020). For the interviews, women will be recruited online from social groups which cater to gynecology and women's health. There will be 30 women recruited. Previous design research through my MSc module 'Design Research' has provided me with continued access to Gynecologists. Therefore, I will recruit participants from this sample, and no HSE staff will be used. Five of these healthcare professionals will be recruited for interviews. They will be recruited via a phonecall, where they will be provided the relevant information and asked if they would like to partake in the research. They have expressed their interest in helping with future projects in the past.

### References

Boas, T.C., Christenson, D.P. and Glick, D.M. (2020) 'Recruiting large online samples in the United States and India: Facebook, mechanical turk, and qualtrics', *Political Science Research and Methods*, 8(2), 232-250.

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# APPENDIX 1- ETHICS

**5f What are the criteria for including/excluding individuals from the study?**

Inclusion criteria: female, between 18-24, able to consent.

OR

Able to consent, current or past experience working in women's health or cervical cancer screening, these participants may be **male or female**.

Exclusion: Male, out of age range or unable to consent OR no experience in women's health/cervical cancer screening. **Women who have had cervical cancer.**

**5g Have arrangements been made to accommodate individuals who do not wish to participate in the research? (NB This mainly relates to research taking place in a classroom setting)**

Yes  No  N/A

If Yes

Please state what these arrangements are.

**5h Can you identify any particular vulnerability of your participants other than those mentioned in section 2?**

**There will be no vulnerable participants involved in this study.**

**5i Where will the study take place? (If in UL please state where)**

This study will take place via Microsoft Teams due to the COVID 19 pandemic.

**5j What arrangements have you made for anonymity and confidentiality? (How will participants be referenced in the final report)**

Data collected will be treated with confidentiality and participants treated with anonymity. The research will be GDPR compliant. At the beginning of the research, participants can freely enter the research, after being informed of what is involved with taking part, e.g., information collected regarding opinions and attitudes towards Cervical Cancer. Once fully briefed they can ask further questions or give their consent. Information about the storage and anonymity of the data will be given. The participant will also be informed that they can withdraw from the study, for any reason, at any time. Participants' data will be processed with the sole intention of achieving the research objective. All data will be anonymized as it is collected. In a written academic paper at the end of the year, if data is to be used, identities of participants' will be anonymized by pseudonyms. **The anonymization of the data will involve a coding system e.g. CS\_Survey01 and CS\_Interview01. (CS- Cervical Screening and 01 – participant 1).** The storage of the data will be stored on a password protected university computer, in a locked room.

**5k What are the safety issues (if any) arising from this study, and how will you deal with them?**

It is not expected that any safety issues will arise, due to the distanced nature of participant interaction and the consideration for anonymity and confidentiality.

**5l All data must be stored for 7 years following completion of the project.**

**How do you propose to store the information once the project is completed? Will the file/computer be password protected? (Information must not be stored on student's PC or on a USB Key)**

All data regarding to the study will be stored on a password protected university computer, operated by Muireann McMahon and located in room FG021.

**Where will the information be stored (room number):** FG021

# APPENDIX 1- ETHICS

S&EREC No. 2021\_01\_04S&E

**5m Insurance Cover**

Insurance cover is required for all research carried out by UL employees. Principal Investigators/Supervisors should carefully view the University's 'Guidelines on Insurance Cover for Research' document and the University's Insurance cover to ascertain if their proposed research is covered. These documents are available at [www.ul.ie/insurance](http://www.ul.ie/insurance).

Where any query arises about whether or not proposed research is covered by insurance, the Principal Investigator/Supervisor must contact the University's Insurance Administrator at [cliona.donnellan@ul.ie](mailto:cliona.donnellan@ul.ie) to confirm that the required level of insurance cover is in place.

Please indicate by way of signature that the research project is covered by UL's insurance policies:

*Muiran McMahon*

PI/Supervisor signature: \_\_\_\_\_



INFORMATION SHEET

To Whom it may concern,

My name is Doireann Peelo and I am currently undertaking a masters of Design for Health and Wellbeing at the University of Limerick under the supervision of Dr. Muireann Mc Mahon. The title of my proposed research is "HPV and Cervical Cancer; feelings, opinions and attitudes." The purpose of this project is to explore via interviews and surveys women's, and health care professionals' opinions and attitudes towards cervical cancer, it's prevention, screening and treatment. In order to understand knowledge levels of the sample and to offer a design solution to problems which are identified during the research. These interviews will take place on Microsoft Teams and will last no longer than 45 minutes.

There are no expected risks involved with your participation in the study. You do of course have the right to withdraw from the study at any stage or not to participate at all. I will ask to record the audio of the interview, this audio will be destroyed once it has been transcribed. The audio will be anonymised at source and in any analysis or write up of the data. You have the option to access the transcribed data if you wish, to ensure your voice as the participant has been accurately conveyed. Your information will be kept confidential and in line with GDPR standards.

To participate in this study, you must be between the ages of 18 and 65.

If you have further questions regarding this research, please feel free to get in touch with either myself or my supervisor using the email addresses listed below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 237719

Yours sincerely,

Doireann Peelo

Student Name: Doireann Peelo Dennehy Email address: 20127383@studentmail.ul.ie	Supervisor Name: Dr. Muireann McMahon Department: School of Design Telephone Number: Email address: muireann.mcmahon@ul.ie
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**5n Please attach the relevant information documents and complete the following checklist to indicate which documents are included with application**

Participant Information Sheet	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Participant Informed Consent Form	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Parent/Guardian Information Sheet	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Parent/Guardian Informed Consent Form	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
School Principal Information Sheet	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
School Principal Informed Consent Form	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Teacher Information Sheet	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Teacher Consent Form	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Child Protection Form (must be included if dealing with <18 year olds)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Questionnaire & Explanatory Cover Letter	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Interview/Survey Questions	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Recruitment letters/Advertisements/Emails, etc.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

**6. Declaration**

The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it. I undertake to abide by the guidelines outlined in the UL Research Ethics Committee guidelines <http://www.ul.ie/researchethics/>

I undertake to inform S&EEC of any changes to the study from those detailed in this application.

Student: 20127383	Name: Doireann Peelo Dennehy Signature:	Date: 03/01/21
Principal Investigator*:	Name: Dr. Muireann McMahon Signature: <i>Muiran McMahon</i>	Date: 05/01/21

# APPENDIX 1- ETHICS



S&EREC No. 2021\_01\_04S&E

## Faculty of Science & Engineering ETHICAL CONSENT FORM

### Consent Section:

I, the undersigned, declare that I am willing to take part in research for the project entitled “HPV and Cervical Cancer; feelings, opinions and attitudes.”

- I declare that I have been fully briefed on the nature of this study and my role in it and have been given the opportunity to ask questions before explicitly consenting to participate.
- The nature of my participation has been explained to me and I have full knowledge of how the information collected will be used.
- I am aware that my data may be used in reports and published output relating to this research (e.g. journal publication) but that I will not be identifiable in these reports or output.
- I am also aware that my participation in this study may be recorded (audio) and I agree to this. However, should I feel uncomfortable at any time I can request that the recording equipment be switched off. The recordings will be destroyed once they have been transcribed.
- I fully understand that there is no obligation on me to participate in this study
- I fully understand that I am free to withdraw my participation at any time without having to explain or give a reason
- I am also entitled to full confidentiality in terms of my participation and personal details
- I declare that I am between the ages of 18 and 65

Signature of participant

Date

S&EEC Eform, October 2019



S&EREC No. 2021\_01\_04S&E

## Faculty of Science & Engineering DATA PROTECTION CONSENT FORM

### Consent Section:

I, the undersigned, declare that I am freely giving specific, informed and an unambiguous consent to the University to process my Personal Data for the purposes of undertaking the research project entitled HPV and cervical cancer; feelings, opinions and attitudes.

- |   |                          |                          |
|---|--------------------------|--------------------------|
| • I declare that I have read and fully understand the contents of the Research Privacy Notice, which is appended at Appendix 1 of this Consent form and I explicitly consent to my personal data being processed in line with this Research Privacy Notice. | Yes                      | No                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |
| • I explicitly consent to the University contacting me as part of current or similar future research and holding my contact details on its database for the purpose of contacting me.   | Yes                      | No                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |

Signature

\_\_\_\_\_  
Name of participant [IN CAPITALS]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

S&EEC Eform, October 2019

# APPENDIX 1- ETHICS

S&EREC No. 2021\_01\_04S&E



Recruitment Message **(Survey)**

Are you a woman? Are you 18 – 25? Do you have 10 minutes to spare? I'd love to hear from you.

My name is Doireann Peelo and I am currently undertaking a MSc Design for Health and Wellbeing at the University of Limerick.

I'm doing some research about HPV and Cervical cancer, and I would love your feedback and opinions.

There should be no risks for this study, but you can of course choose not to finish the survey at any stage, or not to participate at all. Your answers will be anonymised through the survey, so I won't know who does the survey.

If you have any further questions regarding my research, or if you would like to be contacted for an interview do not hesitate to contact me at the email below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 237719

Look forward to hearing from you,

Doireann Peelo  
Email: [20127383@studentmail.ul.ie](mailto:20127383@studentmail.ul.ie)

S&EEC ~~Eform~~ October 2019

S&EREC No. 2021\_01\_04S&E



Recruitment Message **(Interview)**

Are you a woman or a health professional with a speciality in gynaecology? Are you over 18? Do you have 40 minutes to spare? I'd love to hear from you.

My name is Doireann Peelo and I am currently undertaking a MSc Design for Health and Wellbeing at the University of Limerick.

I'm doing some research about HPV and Cervical cancer, and I would love your feedback and opinions.

There should be no risks for this study, but you can of course choose not to finish the interview at any stage, or not to participate at all. With your permission, the audio of interview will be recorded. This audio is to ensure your voice and opinions are correctly interpreted and will be used to transcribe the interview afterwards. Once this transcription has taken place the audio will be destroyed. The data recorded will be anonymized and you will have the opportunity to review the transcribed data if you wish.

If you have any further questions regarding my research, do not hesitate to contact me at the email below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 237719

Look forward to hearing from you,

Doireann Peelo  
Email: [20127383@studentmail.ul.ie](mailto:20127383@studentmail.ul.ie)

**Interview consent form:**

<https://forms.office.com/Pages/ResponsePage.aspx?id=JLmEALQ6FkGSUZk59pXITKT7n9ju0VZBtgoAGqHzc71UQ0FHVFRRQ0JUMTE0Q1e3RTVaVkk5UTZIMC4u>

S&EEC ~~Eform~~ October 2019

# APPENDIX 1- ETHICS

S&EREC No. 2021\_01\_04S&E



## Survey Questions

<https://forms.office.com/Pages/ResponsePage.aspx?id=JLmEALQ6FkGSUZk59pXITKT7n9ju0VZBtqoACqHxc7UUMJCMt6KQIVBTTJTVFFCMVUMfpLVY5Uj4u>

What age are you? (18/19/20/21/22/23/24/25+) 25+ will bring them to end of form

What is your understanding of HPV? (Open ended)

Did you learn about HPV or cervical cancer in school? (Yes/No/Unsure)

Do you think there is sufficient information available if you want to learn about cervical cancer and HPV? (Yes/No/Unsure)

Where would you look to find this information? (Open ended)

Have you received the HPV vaccine? (Yes/No/Unsure)

(If No) Why not? (Parental Objection / Lack of Information / Didn't seem important / Friends weren't getting it / Nobody explained it to me/ Other)

(If Yes) Why did you get the vaccine?

(If Yes) Did you receive the vaccine in school? (Yes/No)

(If No) Where did you receive the vaccine? (Open ended)

What information was given to you prior to receiving (or being offered) the vaccine?

What you know about the link (if any) between HPV and cervical cancer? (open ended)

Where did you find or learn this information? (open ended)

Have you ever been offered a cervical smear test? (Yes/No/Can't Remember/Prefer not to say)

Do you think smear tests are necessary? (Yes/No/ Prefer Not to say)

How would you feel if you were told your smear test was abnormal? (Open ended)

What is your understanding of an abnormal result? (Open ended)

What emotions does the word 'ABNORMAL' surface for you? (Open ended)

How would you rate the impact of Irish Cervical Screening Program under the following:

Knowledge- "The program has equipped me with adequate knowledge" rate between 1 – 6 (1 No knowledge – 6 Very Knowledgeable)

Behaviour- "The program has made me more likely to present for regular screening" 1 – 6

Attitude- "The program has made me confident about timely medical interventions"

What is the rationale for not currently giving under 25's smear tests? (Open Ended)

Do you think under 25's should be entitled to free cervical smear tests? (Yes/No/Indifferent)

(If yes) Why?

(If no) Why not?

In your opinion what type of person doesn't get a smear test?

Who do you think might miss out on education about cervical cancer and HPV?

What in your opinion is the most spoken about cancer in Ireland?

What in your opinion most advertised cancer in Ireland?

Why do you think this particular cancer is advertised so much in Ireland?

If you consent to being contacted with relation to any of your answers, please leave your email here...

S&EEC Eform, October 2019

S&EREC No. 2021\_01\_04S&E



## Interview Questions for Female Participants

(Semi Structured to allow for individual tailoring and to keep conversation flowing)

In the last year why did you present to the GP?

Do you frequently google symptoms online?  
- Based on these search results do you self-diagnose?

Have you ever had a cervical smear? (Talk me through it) (How did you feel)

Would you go for a cervical smear?

Did you receive the HPV vaccine? (Did you get any information beforehand) (Where did you get)

What do you know about cervical cancer & HPV?

What are your concerns for cervical screenings?

How would you feel about using your own cervical screening kit?

S&EEC Eform, October 2019

# APPENDIX 1- ETHICS

S&EREC No. 2021\_01\_04S&E



## Interview Questions for Gynaecologists

**(Semi Structured to allow for individual tailoring and to keep conversation flowing)**

Talk me through the cervical screening procedure-

What is the screening process looking for?

Are there any other ways to identify abnormal cells?

Are the screenings accurate?

What can be done to improve accuracy/what makes them so accurate?

What type of patients do you regularly see?

Why are under 25's not included in the cervical screening scheme?

What would be the benefits/issues of including these women?

How often do you see nervous patients?

What would you say their biggest concerns are?

What do you do to combat these concerns?

Would it be possible for patients to carry out home smears?

What would a home smear kit look like?

What would the home smear kit be looking for?

# APPENDIX 2 - CODEBOOK

## ***Codebook for thematic analysis.***

The Codebook for the interviews:

**Agency**

**Distrust in Healthcare**

**Attitudes**

**Gender**

**Education**

**Knowledge / Information Acquisition**

- *Friends* - *Google /Online* - *Family*

**Ability to Self-Test**

The Codebook for the Surveys:

**Mixing up vaccine and HPV**

**Information sources**

- *Google* - *Parents* - *School* - *Gossip* - *Didn't care*

**Negative Emotions**

**Sexualisation**

**Catholicism**

**Stigma**

**Negative Prejudice**

**Fear**

**Causality**

The codebook is available at this link:

**[https://ulcampus.sharepoint.com/:w:/s/MScDesignforHealthWellbeing-DoireannPeeloDennehy/EU\\_96iO2kWJCmM1GpQ\\_F8VEBxxLm56Fs\\_QikVEd5HAuWig?e=hFlhOS](https://ulcampus.sharepoint.com/:w:/s/MScDesignforHealthWellbeing-DoireannPeeloDennehy/EU_96iO2kWJCmM1GpQ_F8VEBxxLm56Fs_QikVEd5HAuWig?e=hFlhOS)**



# APPENDIX 3 - OPN

## ***Observation Problem Need - Filtering Criteria***

The observation - problem - need filtering was completed in an excel file available below.

The contents in the excel file are as follows.

Sheet 1 - Observation/Problem/Need Identification

Sheet 2 - Filtering 1 Patient/Provider Impact & Treatment Landscape

Sheet 3 - Filtering 2 Personal Preference

Sheet 4 - Filtering 3 Healthcare provider Preference

Sheet 5 - filtering 4 Market Research

The excel file is available at this link:

**<https://ulcampus.sharepoint.com/:x:/s/MScDesignforHealthWellbeing-DoireannPeeloDennehy/EQT0z9bsae5Nm4RKkESZCO8BxYMw3PDZZJ8iAKdv95lthg?e=GXdXAX>**

It is also available in the designhistoryfile/0.Feasibility/OPN.

# APPENDIX 4 - DESIRABILITY TESTING

## *List of words used for desirability testing.*

- Accessible
- Advanced
- Annoying
- Appealing
- Approachable
- Attractive
- Boring
- Business-like
- Busy
- Calm
- Clean
- Clear
- Collaborative
- Comfortable
- Compatible
- Compelling
- Complex
- Comprehensive
- Confident
- Confusing
- Connected
- Consistent
- Controllable
- Convenient
- Creative
- Customizable
- Cutting edge
- Dated
- Desirable
- Difficult
- Disruptive
- Distracting
- Dull
- Easy to use
- Effective
- Efficient
- Effortless
- Empowering
- Energetic
- Engaging
- Entertaining
- Enthusiastic
- Essential
- Exceptional
- Exciting
- Expected
- Familiar
- Fast
- Flexible
- Fragile
- Fresh
- Friendly
- Frustrating
- Fun
- Gets in the way
- Hard to Use
- Helpful
- High quality
- Impersonal
- Impressive
- Incomprehensible
- Inconsistent
- Ineffective
- Innovative
- Inspiring
- Integrated
- Intimidating
- Intuitive
- Inviting
- Irrelevant
- Low Maintenance
- Meaningful
- Motivating
- Not Secure
- Not Valuable
- Novel
- Old
- Optimistic
- Ordinary
- Organized
- Overbearing
- Overwhelming
- Patronizing
- Personal
- Poor quality
- Powerful
- Predictable
- Professional
- Relevant
- Reliable
- Responsive
- Rigid
- Satisfying
- Secure
- Simplistic
- Slow
- Sophisticated
- Stable
- Sterile
- Stimulating
- Straight Forward
- Stressful
- Time-consuming
- Time-Saving
- Too Technical
- Trustworthy
- Unapproachable
- Unattractive
- Uncontrollable
- Unconventional
- Understandable
- Undesirable
- Unpredictable
- Unrefined
- Usable
- Useful
- Valuable