

INTEGRATED INNOVATION FOR LARGE SCALE PROBLEMS: REDUCING HIV TRANSMISSION IN THE U.S. BY 2027

FINAL REPORT

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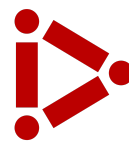


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1 Executive Summary

Looking to reduce the number of new HIV infections in the USA down to near zero in a decade, our team researched the problem through an extensive literature review, and a number of design methods such as speculative futures and co-design workshops. Of the many issues surfaced, such as the need for better education and less stigma around HIV, the emergence of new ways to treat and manage HIV, and different means of prevention, some facts stood out.

15% of those infected with HIV are unaware of this¹. Further, 30% of new infection is due to those unaware that they themselves are affected². This established that people not getting tested for HIV often enough is a problem that, if tackled, could lead to the most drastic reduction in the number of new HIV infections.

One of the biggest challenges to people getting tested frequently is a lack of awareness and access. In order to tackle this, our team proposes to co-package FDA approved home HIV rapid test kits along with condoms. This utilizes the existing brand value of a product that is already associated with sexual safety in order to raise awareness about testing, and enhance access. Our solution targets people who are at high-risk for HIV. To begin with, we will roll-out the co-packaged kits in high-risk communities to study the effectiveness of the solution. Initially, this would require effective marketing campaigns and support from local community organizations to build the excitement around the product and the idea of regular testing.

The existing testing methods include lab test prescribed by doctors which are expensive for those who are uninsured as well as a tedious process to get the test prescription. Home-test kits itself are expensive and just purchasing an HIV test kit from a store can be a scary experience for many. Both of these methods don't encourage regular testing, which is necessary to eliminate false negatives in the "window period" of 3 months from infection when the virus is almost undetectable.

The aim is to tap into 0.5% of overall condom sale in the US per year and co-package those condoms with subsidized HIV home-test kits. This ensures access to affordable home-test kits in high-risk communities. The proposal takes advantage of combining two FDA approved products, the condom and the home-test kit, and aims to use the condom brand's expertise in packaging and distribution. For the subsidies and funding, reaching out to foundations like Gates Foundation who have already pledged to improve access to HIV testing in developing countries is very promising and also the possibility of tapping into corporate social responsibility initiatives of several corporates in the US is another source of funding. The goal is to create a business model that breaks even and has the potential to sustain through funding and potential high-volume distribution.

¹ <https://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/HivTesting.html>

² <https://www.poz.com/article/transmission-cascade-26839-2100>

2 Background

2.1 Problem Description

HIV was discovered in 1983. Medical professionals assumed that the virus only affected the community of men who has sex with men. As the years went by, the virus infected people from other communities as well. Today, getting infected with HIV is a risk for any sexually active individual, or any individual who exchanges needles, regardless of their socio-economic level.

The World Health Organization estimates that "36.7 million people were living with HIV globally at the end of 2016. That same year, some 1.8 million people became newly infected, and 1 million died of HIV-related causes."³ In the United States only, the Center for Disease Control and Prevention (CDC) estimates "1,122,900 adults and adolescents were living with HIV at the end of 2015. Of those, 162,500 (15%) had not received a diagnosis."⁴

By its own nature, the HIV virus makes some communities more vulnerable than others. As the virus is transmitted by body fluids,⁵ Men who have Sex with Men (MSM) are the most vulnerable group. Transgender women are also vulnerable. They are closely followed by Black Heterosexual Women and Black Heterosexual Men. The CDC confirms this data.⁶

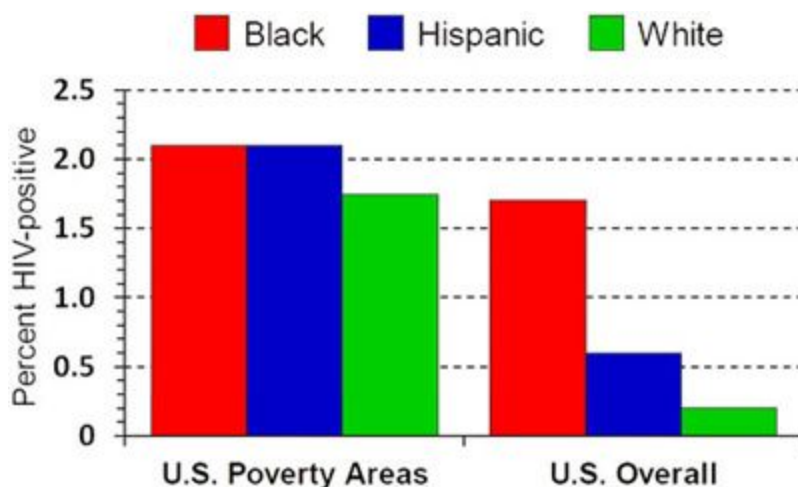


Figure 1 - HIV Prevalence Rate, by Race/Ethnicity⁷

³ World Health Organization website - HIV | <http://www.who.int/features/qa/71/en/>

⁴ CDC - HIV in the United States: At A Glance | <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>

⁵ "HIV is spread only in certain body fluids from a person infected with HIV. These fluids are blood, semen, pre-seminal fluids, rectal fluids, vaginal fluids, and breast milk." <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/20/48/the-basics-of-hiv-prevention>

⁶ <https://www.cdc.gov/hiv/group/poverty.html>

⁷ Image from the CDC article *Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States?* - <https://www.cdc.gov/hiv/group/poverty.html>

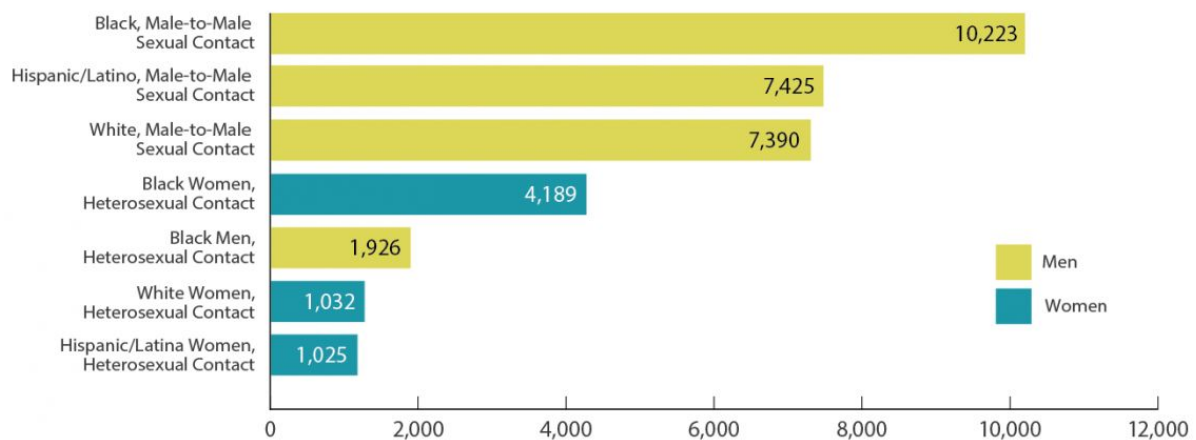


Figure 2 - New HIV Diagnoses in the United States for the Most-Affected Subpopulations⁸

In order to meet this project's goal of **reducing the number of new HIV infection to almost zero within a 10 year timeframe in the USA**, our team started by researching the problem space to get a better understanding of HIV in the United States. Three major challenges emerged from that research:

1. There have been significant medical advancements in the past few decades that are not fully utilized today to tackle this problem. Pre-Exposure Prophylaxis, or PrEP, can be used as a means of prevention for patients conscious of the risk they are at. Once a patient has contracted the HIV virus, Post-exposure Prophylaxis, or PEP, can be prescribed to patients to render the virus undetectable. Such medications have the means to drastically reduce the number of HIV positive individuals.
2. Knowledge is power. However, knowledge about HIV is not well spread enough. People engaging in high risk sexual activity are not always aware of the risks they are taking or the risk they represent for their sexual partners. This highlights a need to improve the access to education and create more awareness around HIV.
3. Statistics show that in underserved and high risk communities, infection rates are higher. This raises the question of the audience targeted by this project.

In order to properly tackle this large-scale and complex problem, we divided our work into four major modules: Opportunity analysis, Barriers to Solutions, Overcoming the Barriers, and Realizing the solution at scale.

⁸ <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>

2.1.1 Opportunity analysis

As a team, we started by analyzing the opportunities we could seize. In order to do this, besides the initial research necessary to understand the problem, we used a systems thinking approach, allowing us to list and take into account multiple aspects of the problem within the problem space.

No solution to a problem can be found without taking account the main stakeholders. In this case, they were mainly the medium and high risk communities, but also insurance companies, foundations, companies developing the relevant supply, the government, hospitals and clinics, and pharmacies.

2.1.1.1 PEST Analysis

Understanding what was at stake for each of the groups of stakeholders was not straightforward. The process was however eased by doing a PEST analysis for each of the stakeholder categories. A PEST analysis focuses on the Political, Economical, Social and Technological external factors which could influence a timeline or a context. Here are the main points revealed by those analysis:

	Foundations	Community Organization	Tech Based Companies	Pharma Companies	Hospitals
Political	Influence policies	Community Insurance	New tech laws	Price reduction	Decrease in Funding
Economic	Provide housing	Localized donor	Affordable tech	Profit vs. Impact	Insurance / Physician cost
Social	Create Awareness	Encourage discussion	Data use	Focused intervention	Awareness for PreP
Technology	Invest in new technology	Information	Scale Fast	More accessible	Remote treatment

Figure 3 - Main outcomes of the PEST analysis relative to different stakeholders

2.1.1.1.1 Foundations

Foundations are mostly non-for-profit organizations that aim to reduce the number of HIV infections, provide better healthcare to HIV patients, invest in research for medication, etc. Various foundations focus on unique factors or some combination of factors that can address the problem. Their involvement in the cause can be highly visible and they receive funding through philanthropists, fund-raisers and other organizations. A few examples are San Francisco Getting to Zero, amfAR, AIDS Healthcare Foundation, etc. Below is the list of a few opportunities and threat for foundations from PEST Analysis:

Opportunities

- Act as the voice of HIV patients & ensure their needs reach the policy makers
- National AIDS Housing Coalition aims at providing housing to HIV patients

- Coordinating and spreading awareness in local areas so housing becomes a basic human right
- People in high risk zones are encouraged to get tested, but the high-risk zones also happens to be low income areas, who need financial support to get tested
- Foundations also work on creating increased awareness and in creating a comforting and safe environment for HIV patients to seek care.
- Awareness will make people more conscious of their decisions with substance use, sexual activities, and other forms of acquiring the virus
- Empower women from intimate partner violence which is a leading cause of HIV infection among African American women.
- Foundations create awareness about PrEP which helps prevent HIV infection by 92% in high risk areas
- The foundations also fund research in vaccines, medicines for suppressing the virus, etc.

Threats

- Inability to meet the growing demands with new patients if the price of the medicine keeps increasing
- When disparities are not considered and the resources are distributed equally, it gets challenging to address the real issue.
- Without insurance coverage, most would not get themselves tested until the symptoms starts showing up, which could be 10 years or so in a few cases and by then the HIV would have caused AIDS
- Possible neglect of a particular group or a factor by multiple foundations or too much focus for one aspect
- Failing to shift the strategy will be like fighting for a lost cause when technological advancements have already found the solution

2.1.1.1.2 Technology based companies

Technology based companies intervene in this space by either tackling the medical aspect of HIV or in ways that help people living with HIV. Medical tech companies look into new ways of testing to make tests more efficient, portable and affordable. Non-medical tech companies often look at the social aspect of HIV, but also offer in-home testing and treatment solutions. Below is the list of a few opportunities and threat for Technology based companies from PEST Analysis:

Opportunities

- Allow new technologies based on genome alteration to be developed in the future and treat more diseases than HIV
- Improve the way data can be anonymized and treatable
- Leaves more room for smaller companies or organisations to play a larger role
- Make tech affordable for low-income population
- More data made available to the scientific community
- Develop local solutions for the technology to work
- Knowledge is the best way yet to prevent the virus from spreading
- Use technology to educate people
- Drastically increase the number of tested people
- Providing people who seek help with an easier access to care and human contact

Threats

- If regulations are too conservative: Completely shut down HIV-related genome research
- If regulations are not conservative enough: the technology could be used to alter the genome to meet other needs (gender selection, ...)

- Increase inequalities when low-income groups cannot afford technology
- Digital trust also depends on the level of comfort with technology
- Increasing costs of dissemination and implementation of technology may not allow long term solution
- Focusing only on the populations at risk may prevent the information from reaching populations "safe" today but who may be at risk tomorrow
- Compromised data security
- Poor people at risk stay out of reach, even though the technology is getting cheaper
- Dividing people instead of bringing them together

2.1.1.1.3 Community based organizations (CBO)

Opportunities

- Community based insurance plans
- CBO-led affordable housing
- Free testing and PreP
- Clever marketing campaigns to reach non-traditional (eg. younger, less wealthy) donors
- More volunteers might have applicable software development skills to allow for custom technology solutions to be created for CBOs.
- Use incentives/social pressure/design to influence behavior
- Join and heighten conversations around identity & taboo topics
- Education/prevention measures through dating apps
- Get more people to use rapid vs. traditional testing
- Decrease stigma around PreP to increase use
- Integrate open-source tech in service delivery
- Connect providers with each other & clients via mobile technology
- Use data to understand transmission trends and medicine adherence

Threats

- When less people are insured, less people seek testing (for diagnosis) or care (for viral suppression)
- Have to please more people if there are more donors involved
- Software vulnerabilities if developed by amateurs
- Privacy issues/breaches with big data
- Riskier behaviors (ie. no condoms) if PreP feels too safe

2.1.1.1.4 Pharmaceutical companies

Pharmaceutical companies include public or private organizations that involve medical treatment. This ranges from research and testing to product development and promotion.

Opportunities

- Potential decrease in prices (US prices are currently 3x more expensive)
- Drugs can reach a wider audience
- Extra revenue can be put towards other resources like health workers and building medical infrastructure
- Extra money can be put towards lobbying and influence future laws passed
- Opportunities to invest or buy smaller generic drug producing companies
- Individual empowerment and protection
- Potential issues with not as developed research
- Treatment of HIV has a more targeted group, disease is now not as widespread
- More focused target of intervention
- Drug prices may decrease because of competition

- More accessibility of medication

Threats

- Less control over drug testing and regulation
- Less revenue goes to investments in more pharma research / resources
- Potential reduction in widespread drug treatment and prevention
- More competition from generic drug producers
- The trial may result in health issues - the drug is not 100% effective and may have other side effects
- Expensive drugs make it difficult to reach needed community
- People may not use pill because of the stigma
- Not as much knowledge about prevention methods
- Less people taking HIV tests
- Specific group is hard to reach (give prevention pills to)
- Other groups are less likely to help with resources
- Less money towards health services and resources

2.1.1.1.5 Hospitals

Opportunities

- Drugs becoming cheaper means procedures' overall costs go down
- Either profit margins for the hospital can increase without adding expense to the customer, or the cost to customer could go down, resulting in a greater volume of customers
- Better bargaining position with insurers and pharma
- Can expand area of coverage and number of services provided
- Can consolidate some services and cut costs
- People realise the effectiveness of prevention measures as they have had the opportunity to try them out
- Since hospitals have a lot of local knowledge, they can be active in collaborating with schools and community colleges for education
- Possibility of opening new facilities in high-risk communities.
- Train clinicians and specialists to know when to prescribe PrEP
- Can train non-specialists and nurses in the prescription of these drugs
- Collaboration with apps to spread information about programs and services offered by the hospital
- Could set up mobile testing units

Threats

- Less money from government on the fight against HIV
- More funds may be required from donors
- May have to pay more in taxes
- May have less to re-invest into research, community causes, etc
- May need to pay clinicians higher salary
- May not be able to accommodate all requests of patients
- Customers having more information will lead to more negotiation. Prices might have to be reduced

2.1.1.2 Planning the future with "What ifs ...?"

After understanding the stakeholders' connections to the problem space better, the team moved on to imagining futures using a very powerful technique based on "What ifs ...?". By considering more than 100 projections to the future, we were able to design four different scenarios. The "What ifs ...?" which helped us the most are:

- What if **everyone knew their status**?
- What if **more new infections** start happening?
- What if **all companies sponsored** & hosted **HIV testing events** for their employees?
- What if **doctors weren't afraid** of PrEP?
- What if we **lose funding** when pharma has less stakes?
- What if HIV **medication** was **free**?
- What if all **politicians worked together** without party lines?

A consolidation process over a few weeks allowed us to narrow down and define the four following scenarios:

1. Stigma around HIV disappears (preferred)
2. Loss of interest for HIV (neutral)
3. HIV positive individuals ostracized (pessimistic)
4. a more insidious virus (outlier)

2.1.2 Barriers to Solutions

Once the team had a better understanding of the problem space, we focused on designing interventions that would aid in achieving the vision and also envisioned scenarios that could be detrimental to the vision. Envisioning the negative scenarios help us be better prepared for such situations.

2.1.2.1 Exploring the futures with Backcasting

The process of backcasting allows to design a future without being bound to the political, economical, social or technological constraints of the present. By starting from the desired endpoint, i.e. the goal desired to be reached within the allotted time frame, thinking backwards towards the present allowed us to think of the milestones to be met and the interventions to be deployed over the years.

The following example presents the backcasting for the first of the four scenarios enumerated above:

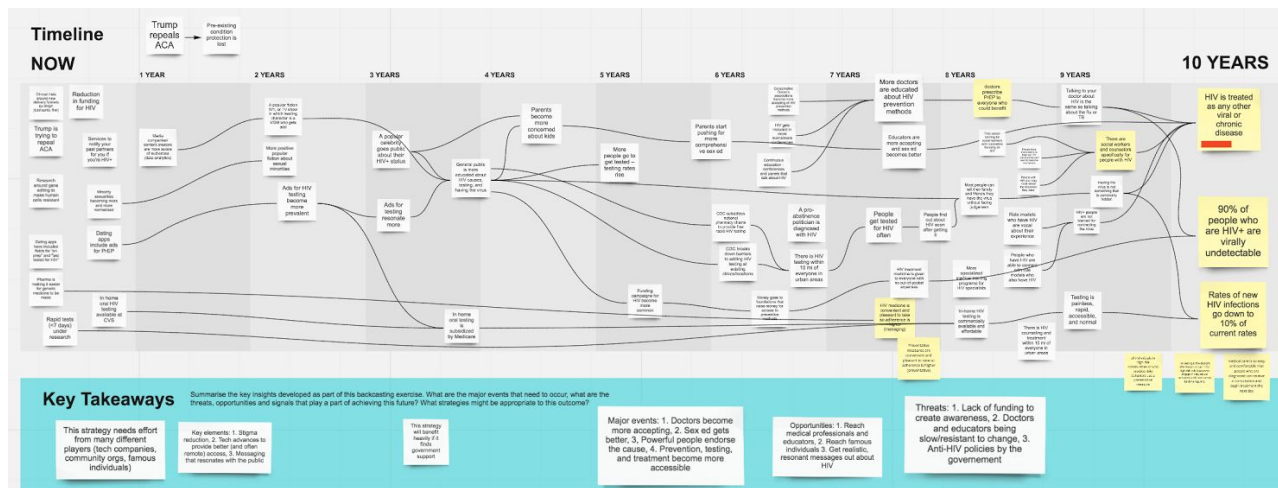


Figure 4 - Backcasting on the preferred scenario: *stigma around HIV disappears*

The first step is to set ambitious goals we would like to reach in 10 years.

"HIV is treated as any other viral or chronic disease"
"90% of people who are HIV+ are virtually undetectable"
"Rates of new HIV infections go down to 10% of current rates"

Thinking backwards implies determining the intermediate steps indispensable to reaching that goal. Among these are: (from the future back)

"People get tested for HIV often"
"More specialized medical training programs for HIV specialists"
"Educators are more accepting and sex ed becomes better"
"General public is more educated about HIV causes, testing, and having the virus"
"Ads for HIV testing become more prevalent"

Connecting those milestones and interventions to the present closes the loop and allowed the team to determine what direction to take to tackle the problem.

Similar backcastings were done on the three other scenarios. They can be found in the Appendix section of this report.

2.1.2.2 Imagining the future through Experiential Futures

Imagining and representing the future is a key aspect to designing steps to reach it. Here are the experiential futures each member of the team designed.

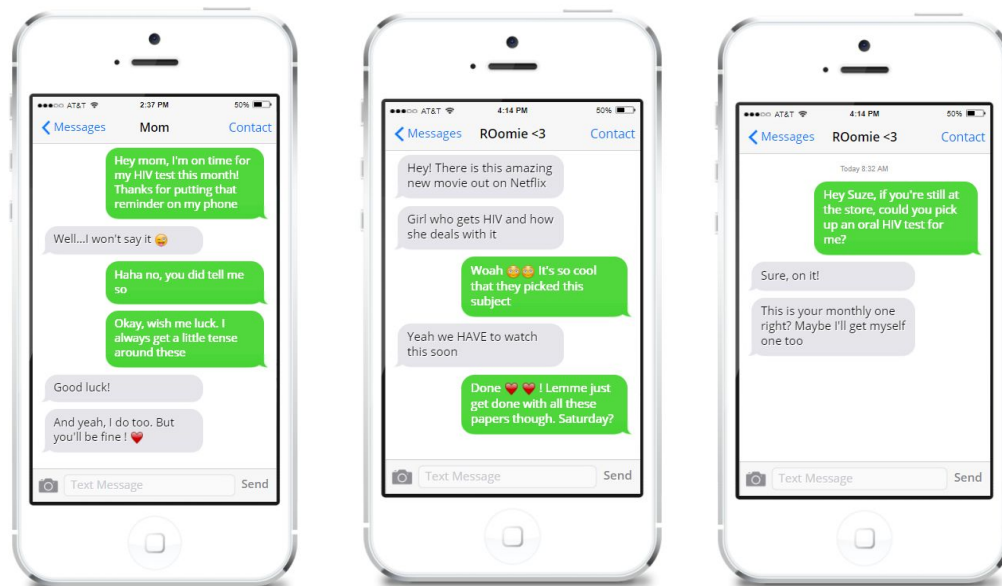


Figure 5 - Experiential Future designed by Aditi Chalisgaonkar
In this future, getting tested for HIV is common and not a taboo. People get tested on a regular basis and regularly talk about it with their parents or friends.



Figure 6 - Experiential Future designed by Michael James
In this future, getting tested is as easy as chewing gum. Testing would be integrated to several commonly used artifacts.

2.1.3 Synthesis and analysis

The details of each intervention from the backcasting and each experiential future led to four major areas in which interventions could be conducted:

- HIV education, which could be targeted towards both the general population and medical professionals who are not comfortable with or do not know about PrEP;
- HIV prevention, by encouraging the prescription and use of PrEP when it is safe as well as normalizing HIV by changing the way the disease is perceived and reducing stigma;
- HIV testing, by making testing for HIV a routine among the all segments of the population. This would also encourage early detection.

As the main goal of this research and project was to design and develop one single product, we narrowed down the interventions to the fields of HIV prevention and HIV testing as education would necessarily be part of an intervention in either of those areas.

At this point, the goal of the solution we were to design was to answer the following:

**In 2027,
anyone in the United States who
has a medium or high risk for contracting HIV will be diagnosed
in less than 3 months after transmission.**

2.1.4 Proposed interventions

To answer this, the team roughly designed two interventions focused on testing.

2.1.4.1 Self-diagnosis Testing Booth

The self-diagnosis testing booths were to be placed in stores like Walmart, Safeway, etc. where we can take advantage of the foot traffic who would already be visiting the store for various reasons. By providing a small space which is private, individuals can take advantage of the booths to test for various diseases like HIV, STI, flu, diabetes, etc. The idea of promoting testing for a range of infections and not just HIV reduces the stigma of using the booth and the fear of been noticed by someone while using the booth. Contrary to home testing kits, the booths aimed at providing very simple test procedures at lower costs and even considered subscriptions models to members who would sign up for an annual membership with access to multiple tests at a much more reduced cost.

2.1.4.2 Co-packaging HIV Home Test Kits

Co-packaging HIV home test kits with existing products was a great way to get the kits to the individuals. The possibility of co-packaging the test kit with existing sexual wellness products resonated the idea of taking responsibility for personal health more strongly. With effective subsidies for the cost of the co-packaged product more people will choose the co-packaged items to be more aware and safe. Products considered for packaging include condoms, sanitary pads, tampons, etc., which are branded for sexual wellness or hygiene.

2.2 Current Alternatives

There are several existing methods to get tested.

1. Lab tests - These include the very traditional lab test where the doctor prescribes the test and the individual takes it to the lab to get themselves tested. Unfortunately, doctors don't prescribe a HIV test unless there are some symptoms and it could be years before symptoms start surfacing. The lab test could be very expensive for people who do not have insurance.
2. Home-Test Kits - The existing home test kit cost around \$40 per unit and the experience of going into a store to get the kit can be very frightening for most of us. The test procedures are very elaborate. However, the advantage is that individuals can get themselves tested at the privacy of their own homes and can get the results within twenty minutes.

It is also important to note that there is usually a window period of 3 months from the infection for the tests to accurately indicate the status. There is a potential false negative situation when someone tests during the window period. Therefore it is even more important for testing to be made as a regular or a periodic practice than an one-time event.

3 Proposal

Our final proposal for this project is a co-packaged product which consists of an HIV rapid home-test kit (such as OraQuick) packaged along with condoms. We have chosen condoms for their existing association with sexual safety and self-care and this idea can be expanded to other products and services.

3.1 Products and Services

3.1.1 Product/Service Description

This product aims to normalize HIV testing by associating it and including it along with existing products which have already gained widespread acceptance in the market for their ability to provide sexual safety and as a means of self-care. The larger aim is to change the mindset of people - right now, most people get tested after a high-risk encounter and it is a scary experience. We hope to change this to a normalized and routine experience which people do frequently as an act of self-care.

Since sexual safety products are not limited to condoms, the team also discussed the possibility of co-packaging HIV home test kits along with other products such as oral contraceptive pills, lubricants, and even products which are sexual, such as menstrual products. This wide range of options gives the team to the ability to pivot if necessary, and also to scale to new product options with ease.

3.1.2 Product/Service Packaging

Initially, this idea was discussed as a co-selling idea, and this can have various connotations - an offer on condoms could subsidize the existing HIV test kit (with no co-packaging), the two products could retain their original packaging but be attached to each other, or the two products could be combined into a single, new, and cohesive package. After considering the advantages afforded by this last option (easier for people to associate with the condom brand) and the disadvantages (slightly higher buy-in barrier), it remains our choice of packaging.



Figure 7 : Co-packaged product

We envision the co-packaged product as having a cohesiveness with the parent brand so as to benefit from the brand associations. This also allows buyers in physical stores more discretion in buying an HIV home test kit than they are afforded today, as the current packaging (and safeguarding) of these kits are quite distinctive and eye-catching.

3.1.3 Product/Service Delivery

The two main strategies for the delivery and distribution of this product are physically through pharmacies as well as online through e-commerce websites.



Figure 8 : Physical Delivery - pharmacies such as CVS, RiteAid



Figure 9 : Online delivery - e-commerce websites

The team also explored some other options of delivery, such as handing out co-packaged kits for free along with condoms, free needles, etc.

3.1.4 Product/Service Support

Any product relating to health, and specifically one relating to such a sensitive topic requires post-purchase support. To this end, we have envisioned some measures:

- Training customer support personnel to answer queries such as 'Can I test negative even if I have HIV?' and 'I just tested positive, what do I do next?'. These queries have to be handled in a sensitive manner - apart from the facts, anticipating and appropriately reacting to a caller's emotional state is crucial.
- Clinic locators - if people do test positive, or if they wish to consult a trained doctor for any reason, they should be able to find relevant information (cost, insurance coverage, wait time) in a simple and convenient manner. This could be through printed maps, and also through prompts to maps and resources online

3.2 Key Metrics

Some key metrics which can help identify whether this idea is achieving the desired goals are:

- Number of products sold/handed out
- Surveys to estimate the number of products used
- Topics surfaced in calls and queries coming to phone helplines

3.3 Costs and Finances

As we begin with co-packaging, the two key components are the HIV test kit and the condoms. Oraquick In-Home HIV Test Kit costs approximately 40 USD per test in store like Walmart, CVS, etc. Amazon sells a set of three test kits for 67 USD. Assuming the ability to buy from the manufacturer itself at discount based on volume, we believe 12 USD would be the cost of a single HIV home test kit.

Unit Economics

To encourage the condom users to purchase the co-packaged product, the price of the bundled product can only be 10% higher than the condom itself.

Assuming the average price for a pack of condoms to be 20 USD, co-packaging the condom with HIV home test kit can now be sold at 22 USD.

Average price for a pack of condoms	20 USD
Projected price for co-packaged product	22 USD
Cash inflow towards home test kit	$22 - 20 = 2$ USD
Cost of a home test kit	12 USD
Deficit	10 USD

Therefore for every co-packaged we would need 10 USD to support the cause. Apart from getting bulk pricing for test kits from manufacturers, we will look towards foundations with aligned objectives to fund this product. Recognizing the importance of testing, Gates Foundation⁹ has entered into an agreement to provide 20M USD over a period of four years to take HIV tests at affordable prices to developing countries.

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<https://globenewswire.com/news-release/2017/06/27/1029393/0/en/OraSure-Technologies-to-Drive-Accelerated-Adoption-of-OraQuick-HIV-Self-Test.html>

Apart from foundations, other ways of reducing this expense include

- OraQuick subsidizing the price further
- Condom brands being willing to pay for the additional cost as a social responsibility initiative.
- Funding from insurance (since the objective of preventing HIV infections is a shared one)
-

We would not need FDA approval on the components themselves. We could take an expedited process to simply get the new packaging approved.

450 million condoms¹⁰ are sold in the United States every year. We would like to address at least 0.5% of this market share to begin with. Assuming there are at least 20 condoms in a pack, we are looking at 11250 packs of condoms to be co-packaged with a HIV home test kit.

Phase ▾	Sales (Co-packaged Units) ▾	Entity ▾	Cost ▾	Funding ▾
P1	2000	Home Test Kit	\$ 20,000	\$ 24,000
		Marketing	\$ 2,000	
		Operations Set Up	\$ 2,000	
P2	2500	Home Test Kit	\$ 25,000	\$ 27,500
		Marketing	\$ 1,250	
		Operations	\$ 1,250	
P3	3250	Home Test Kit	\$ 32,500	\$ 35,750
		Marketing	\$ 1,625	
		Operations	\$ 1,625	
P4	3500	Home Test Kit	\$ 35,000	\$ 38,500
		Marketing	\$ 1,750	
		Operations	\$ 1,750	
Total	11250			\$ 125,750

Thus, it is evident that the bulk of the cost is required to subsidize the HIV home test. Marketing and operations costs do need to be budgeted for, but are much smaller than the cost of HIV home tests. As technology advances, and possibly if the sales numbers for OraQuick increase, home tests are likely to become more affordable, reducing the bulk of the costs involved in this proposal

4 Proof Of Concept Outcome

4.1 Key Concepts

The business model generation matrix was used to visualize the key concepts involved in the solution.

Value Proposition

Rebrand HIV tests so they fit into the product ecosystem of condoms and emphasise the idea of self-care. Providing a safe and private way to get themselves tested and encourage regular testing as a behavior through reduced cost and increased access to the testing kit.

¹⁰ <http://www.encyclopedia.com/medicine/divisions-diagnostics-and-procedures/medicine/condom>

Customer Segment

Mainly male population between the ages 16 and 34. The underlying reasons to purchase a condom include safe sex, avoiding pregnancy, etc. Tapping into this market includes individuals from all economic backgrounds and varied education levels. Although the use of the condom is not universal, the success of this co-packaged product will allow us to scale the idea to other sexual wellness products too in the future.

Key Partners

The main partners are the condom brand and the home test kit manufacturers themselves. Others include doctor's clinics, community organizations, planned parenthood centers, and other social organizations who can highly promote the initiative. Foundations are also the key partners who can help us raise funds and/or subsidize the cost of the co-packaged units.

Key Activities

Activities including rebranding the co-packaged unit. With both the condom and the test kit being FDA approved, there would not be a need to go through FDA approval for packaging the two together. However, there will be the need for operations set up and effective distribution in high-risk communities, to begin with. Marketing campaigns are essential to build the initial excitement about the product and get the idea across, so as many people are will to use the product. The theme of "Know Yourself" and advantage of self-care should be included well in the marketing messages. Counseling and post-sale support are also crucial.

Key Resources

The idea aims to exploit most of the existing resources as taking advantage of the condom brands' distribution channel and packaging facilities and building relationships for the condom brand and the home test kit manufacturers to work together. There is also a possibility to tap into the corporate social responsibility initiatives of several related organizations.

Customer Relationship

The customer support includes answering queries about the use of the home test kit, and also any queries related to results and further consultation. Since most of the sexual wellness products are places in aisles closer to the pharmacy, it will also be beneficial to train support staff in-store to answer a few of these queries.

Channel

Distribution is currently aimed through in-store facilities like Walmart, CVS, Safeway, etc. to begin with, especially in the high-risk communities, and eventually add online distribution as there is an increasing tendency to buy condoms online due to the anonymity e-commerce offers.

Cost

The cost is discussed in detail in section 3.3

Revenue

The business model is focused on break-even sustainable solution than making profits. The idea is to use grants and funds and to take advantage of potential high volume distribution to create a sustainable business model.

4.2 Prototyping and Testing

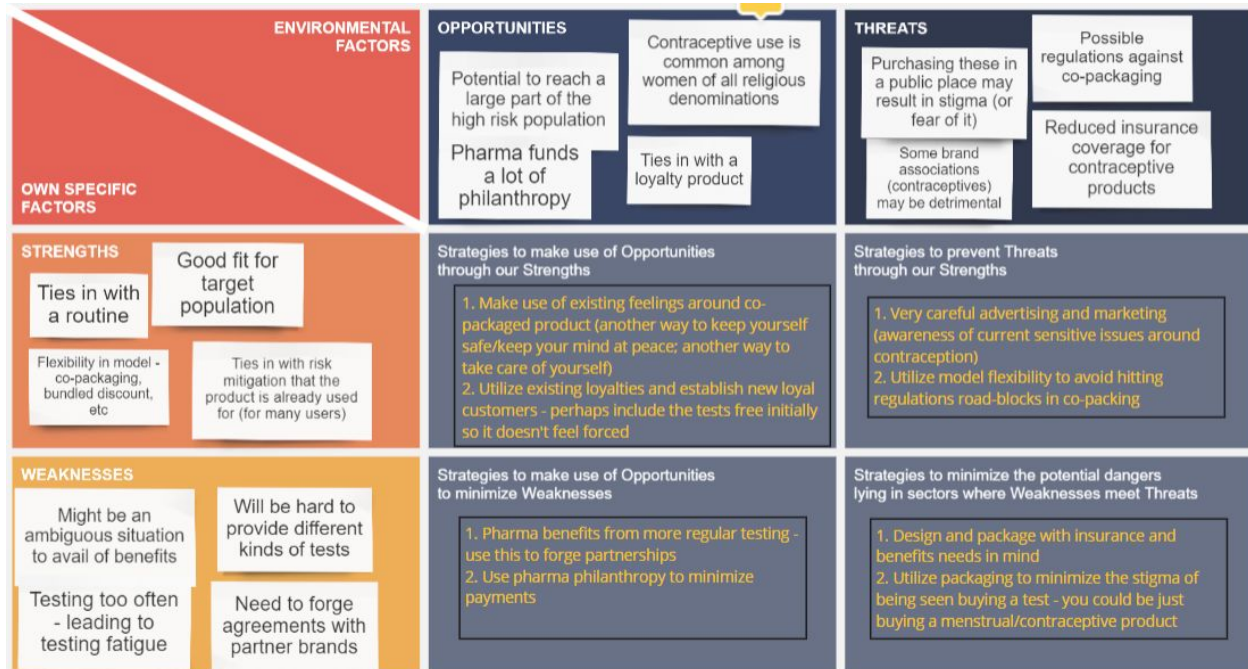


Figure 10 : SWOT Analysis

A SWOT Analysis for the project (indicated in the picture above) revealed the following risks.

Risk Analysis for Threats:

1. The partner's brand image could hurt that of the HIV tests
2. The public nature of buying menstrual and contraceptive products might turn people away from buying these
3. The bundling might make it hard for people who need to avail the benefits to pay for testing
4. If this increases the price suddenly from the existing one, loyalty might be lost
5. Insurance payouts might be tricky to navigate in this situation

Risk Analysis for Opportunities

1. There is already a lot of branding associated with existing products. This can be utilized
2. Possibility to target medium to high-risk population specifically
3. This could help spread awareness to other related groups, such as partners of those using this product
4. Small test runs can be conducted to assess desirability, especially since the original products already has such extensive reach
5. With the right packaging, this can prompt users as to when it is to be used, instead of relying on their memory

User testing included questionnaires to in-store personnel, online surveys, and interviews to understand the pros and cons of the product.

4.3 POC Summary

The key takeaways from user testing include:

1. Need to ensure the affordable cost of the co-packaged product.
2. Allow a new product line with themes like "Know Yourself" rather than disturbing existing brand value of the condoms which is usually tied to themes like being adventurous etc.,
3. Pilot in high-risk communities and measure the success of the initiative before rolling out nationwide.
4. Be prepared to pivot with co-packaging with another product for better impact.
5. Improve relationship with foundations for better funding.

5 Roll out Plan

5.1 Implementation and Rollout Plan Strategy

The overall strategy can be broken up into three phases. The initial 1-2 year period is planned to be a time for growing excitement about the product. This time is crucial for the brand image so the co-packaged product can receive a positive response from the public. The first step in this phase is to contact stakeholders such as the Gates Foundation, Oraquick, Durex, Trojan and Pharmaceutical companies in order to receive initial investments. This money will go towards brand development and micro-pilots that will be launched in three different cities. At the same time, plans for the co-packaging idea will be submitted to the FDA so the approval process can begin. After a few months, initial prototypes will be edited after feedback is received from initial users. The next phase will be to inspire more stakeholders, such as Amazon, to invest in the product. This goal can help the product scale to more cities and influence users and potential customers. The final phase from 6 to 10 years will be to look for new product avenues. This can push the product to new demographics and secondary customer segments by partnering with other products besides condoms. This moment will be the push to normalization because the OraQuick test will be prevalent and become a more common practice with current routines people are already familiar with.

Beginning Section of Rollout Gantt Chart:

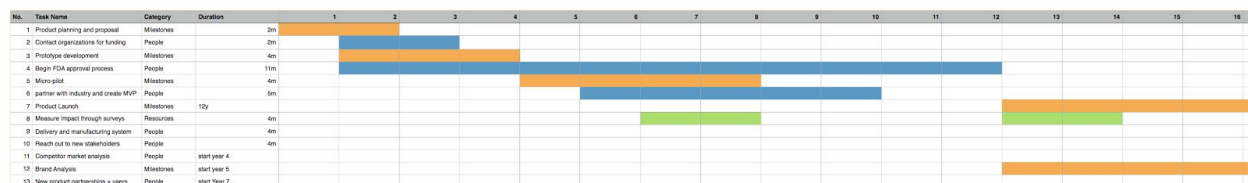


Figure 11: Gantt Chart Development (See Appendix)

5.2 Assumptions and Constraints

One binding factor is the nature of the Oraquick test. Because this is an existing product that is out of our control, we will have to comply with the company's constraints. The test only can give accurate results 3 months after the disease is contracted, and developing a new product that can defy this timeline would require a longer and more expensive process. The product can only remain as a mobile box, unless changed by Oraquick. Under this constraint, the co-packaged product aims to develop a system of testing normalization. This reaches to overcome the extended timeline and accuracy of results. The product can also be either actively bought by a customer or passively received at a clinic or as an extra defaulted item. In addition, people who normally use condoms have a lower chance of

infection. This does not address the high-risk group of individuals that may not even be aware they are at risk of contracting HIV. However, the goal of the co-packaged product is to make associations between sexual activity and knowledge of HIV status. If both practices become more closely related, more people will have this perception and the practices may permeate to other groups. The focus is on the culture of sexual activity and HIV; changing the culture and language can greatly influence personal routine.

The public reaction to the product is an assumption driving the timeline. Unfortunately, this perception has one of the largest impacts on stakeholder relationships, funding, development and scaling ability. If the product does not receive a positive response, there is no way the product development can continue. However, the flexibility of branding and marketing can help alleviate this issue. By gauging customer responses and feedback, the design can be adjusted to correlate to their preferences. This allows for a fast turnaround and alignment. In addition, this can be adjusted as many times as necessary and can assimilate well with changing trends over time. For example, current trends of self-care and wellness are prevalent but may not be in the future. These cultural values may become altered with ongoing world events and happenings.

5.3 Schedule of Activities

T0 + 2 months - initial product planning and proposal will be developed

This process will develop the story around the product idea. This can be used to inspire stakeholders and funding.

T0 + 3 months - ensure funding from foundations and organizations

Companies such as the Gates Hillman Foundation, Gilead, Durex, Trojan, Oraquick, AIDS Free Pittsburgh, US AID and other foundations will be contacted with a project proposal. This proposal will be used to inspire members to see the value of investing in the co-packaged product. This initial fund will help to jump start initial pilot studies and design development.

T0 + 3 months - start designing

Initial prototypes will be developed. This will iterate on product look and feel, system integration, and follow up services.

T0 + 8 months - launch micro-pilot study with prototypes

The prototypes will be deployed in three different cities. Small groups of people will be selected to try out the product and provide feedback on its use and connotation.

T0 + 10 months - partner with industry and create MVP

After feedback from the pilot studies, stronger connections will be made with interested stakeholders. This will be able to develop a strong foundation and relationship to ensure funding and resources.

1 year - LAUNCH - gain FDA approval and begin promoting product

Once Federal approval is officially granted for the product. Small marketing campaigns at local drug stores and public areas will promote the product. In addition, online campaigns will be developed and targeted to people in the chosen pilot cities. This aims to inform more people about the product and begin to change perceptions on testing connotations. This moment is crucial because it will immediately show how people respond to the product and will reveal how branding may need to be shifted.

1y + 3m - Figure out impact - through surveys and other methods

Users will be contacted to fill out surveys and evaluation methods on the product.

This will help to provide more information on the public's perception and reaction to

- the co-packaged product.
- T0 + 2y - flush out delivery and manufacturing system
Initial feedback will help guide what customers are looking for, and how that could align to the manufacturing process. This step aims to research the potential scalability of the idea to then apply to other potential cities.
- T0 + 3y - establish relationships with delivery companies, such as Amazon
Once credibility is established, larger companies may become more interested in co-packaging and will be able to supplement funding. This can push the product to larger market segments across the United States.
- T0 + 4y - market analysis to search for competitors
Reflection on how the product exists in the market and how other companies are responding to the product idea can provide information and evaluate its success.
- T0 + 5y - Brand analysis
Based on market and customer reaction, a brand analysis can provide an opportunity to shift branding again.
- T0 + 7y - look for new types of product partnerships and user-base
Partner with new products and reaching new customer segments can increase the scale of the project and influence more people's perception of HIV, testing, and sexual health.

5.4 Performance Monitoring

Initial pilot studies can use co-design methods to develop a product that would interest the customer. This would provide helpful feedback to see what connotations are initially present. After the launch, a larger product release can be conducive to customer review surveys to see a wider segment of perception and reaction to the product. Qualitative methods can be used in conjunction with quantitative methods of analysis in order to understand the user experience. This can also be carried out with stakeholders in order to understand how that might compare with customer response. Demographic surveys and city-based user analysis can also be helpful with performance monitoring in order to understand trends in perception.

The net impact of the product can also be evaluated through product awareness. The amount of reduced HIV infections may not immediately occur, so other methods should be evaluated in order to understand the impact of the product.

5.5 Adjustments and Contingencies

Flexibility is baked into the co-packaging service. This allows for a fast readjustment if the public response does not align with projected reactions. The product connotation and branding are crucial to the success of the product. This image is the most powerful symbol that can influence the Oraquick test use. This image is also reflected in the other stakeholders involved, whether they are funding the initiative or are actively a part of the face of the product. This image will influence whether companies will want to continue having a relationship and continue funding. As the timeline continues, new relationships may become available, so it is important to stay aware of the market. In addition, some self-reflection should occur to monitor for biases or misaligned incentives that may influence the products ultimate goal. This is very plausible because of the product's heavy reliance on external stakeholders.

6 Anticipated Impact

Excitement and Growth

In the short term, initial funding relationships with a subset of relevant stakeholders and pilots in select cities will build excitement about the distribution of home tests (HTs) through co-packaging. It will also validate the concept and offer insights for improvement.

Stakeholder Inspiration

In the medium term, the outcomes of the pilots will provide evidence that will fuel discussions with further stakeholders, particularly funding sources. Pharmaceutical companies (pharma) who develop and sell treatment medications such as Antiretroviral Therapy (ART) will recognize home testing as an area of opportunity for identifying new HIV cases, see co-packaging with condoms as a novel and viable channel, and offer funding to subsidize the cost of HTs because new diagnoses mean new needs for medication. Condom manufacturers, particularly smaller innovative organizations, will recognize the value in building trust with their customers with a more holistic emphasis on self-care and sexual health, see including HTs as a key way to do so, and agree to help subsidize the HTs and collaborate on co-packaging for both economics and corporate social responsibility (CSR) motivations. Health insurance companies will also recognize the value of HTs in leading to earlier diagnoses and the effect this could have on their bottom line by reducing the level of care and medication necessary to achieve viral suppression, therefore working to subsidize and/or cover all or part of the additional cost of packaging HTs with condoms. OraQuick sees the business and social good potentials of this collaboration and co-packaging and is a friendly and engaged partner. Community-based organizations (CBOs) and foundations see the potential in the intervention and help to expand the program to their cities of interest as well as explore their own approaches to distributing and subsidizing HTs.

Access at Scale

In the long term, the collaboration and funding from major stakeholders, such as pharma, condom manufacturers, health insurers, and OraQuick, allow for surplus funds which are used to distribute free co-packaged condoms and HTs at non-commercial venues, such as clinics, public nightlife venues, House and Ball communities, black Prides, and possibly religious organizations. This essentially pro-bono distribution will specifically target black and latino communities in cities with a greater than average incidence of HIV transmission and undiagnosed individuals. Towards the end of this phase, all high-risk individuals will have access to a free HIV HT at least once every three months. However, due to stigma and a lack of awareness, not all relevant individuals will seek this opportunity.

Normalcy

The ultimate vision for the intervention is that the integration of HTs with condoms, a less stigmatized product, will decrease stigma around at-home HIV testing, and eventually HIV testing in general. While high-risk individuals have the greatest need for access to free or almost free HTs, co-packaging with condoms, particularly popular name brands such as Durex or Trojan, will increase the visibility of the virus to non-high-risk individuals, such as to name the largest group, heterosexual males. This bundling would increase testing among this population, but more importantly increase their awareness of HIV as a still-present issue while also framing HIV home-testing as a normal, preventative, minor, and positive activity through the pairing with condoms and the simple and joyful branding and visual design of the packaging itself.

Alternatives

Once the primary intervention is proven effective, scalable, and sustainable for HIV, and assuming STD home testing will become available, STD testing could be also co-packaged with condoms and/or HIV HTs.

Another deviation or expansion would be pairing HIV HTs with other sexual health or pleasure-related products. These may include lubricants, PrEP, birth control pills, birth control devices, or morning-after pills.

7 Next Steps and Recommendations

With this intervention, the next immediate step would be to gain the support of foundation to obtain funding support. After collaborating with the foundation, reaching out to corporations to tap into their corporate social responsibility budget would be the next step. Approaching multiple condom manufacturer brands to get buy-in from them and striking an acceptable proposal will be beneficial in obtaining buy-in from Oraquick.

There is also great opportunity to extract insights and components from this intervention to inform similar projects. Putting the emphasis on co-packaging to the side for a moment, CBOs, particularly clinics, and foundations could focus on distributing free or highly subsidized HTs to high-risk individuals when they come in for routine care or attend concentrated venues, such as Pride or House and Ball communities. The insights presented about the aligned interests of pharmaceutical companies and health insurers to increase regular HT usage would still apply. In some ways, this deviation could even more pointedly reach racial, ethnic, and gender identity minorities at high-risk who may currently purchase condoms at a store or online less often or not at all.

Beyond the specific proposals outlined here, we feel strongly that the methodologies included in this course and outlined in the report could contribute great value to CBOs, foundations, governmental agencies, and, most acutely, cooperative bodies made up of many individual organizations. In particular, a consideration of current and future environmental forces through a PEST (politics, economics, social, and technical) analysis is a great way to understand the status quo and begin to peer into the future. Additionally, opening up the problem and opportunity spaces by considering alternative futures is a useful way to think outside of current practices and limitations and, from our vantage point, seems as though it would be a novel yet impactful practice for many local CBOs and foundations. To do this, we would suggest engaging various stakeholders to generate “what if” scenarios then applying the method of backcasting to define preferred, disowned, neutral, and wildcard outcomes then working backward to imagine how they could come about. We found this exercise useful not only to see into the future but largely to define other ways of approaching our current reality and identifying the biggest roadblocks we and our community partners felt were intractable but potentially significantly impactful. Simple experiential futures activities, such as writing postcards from the future, have great potential not only to allow for “time travel” to a future state within an organization but also as a cultural intervention to influence and hopefully change how a community thinks about the present and the possible futures they desire.

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9 Appendix

1. **PEST Analysis**

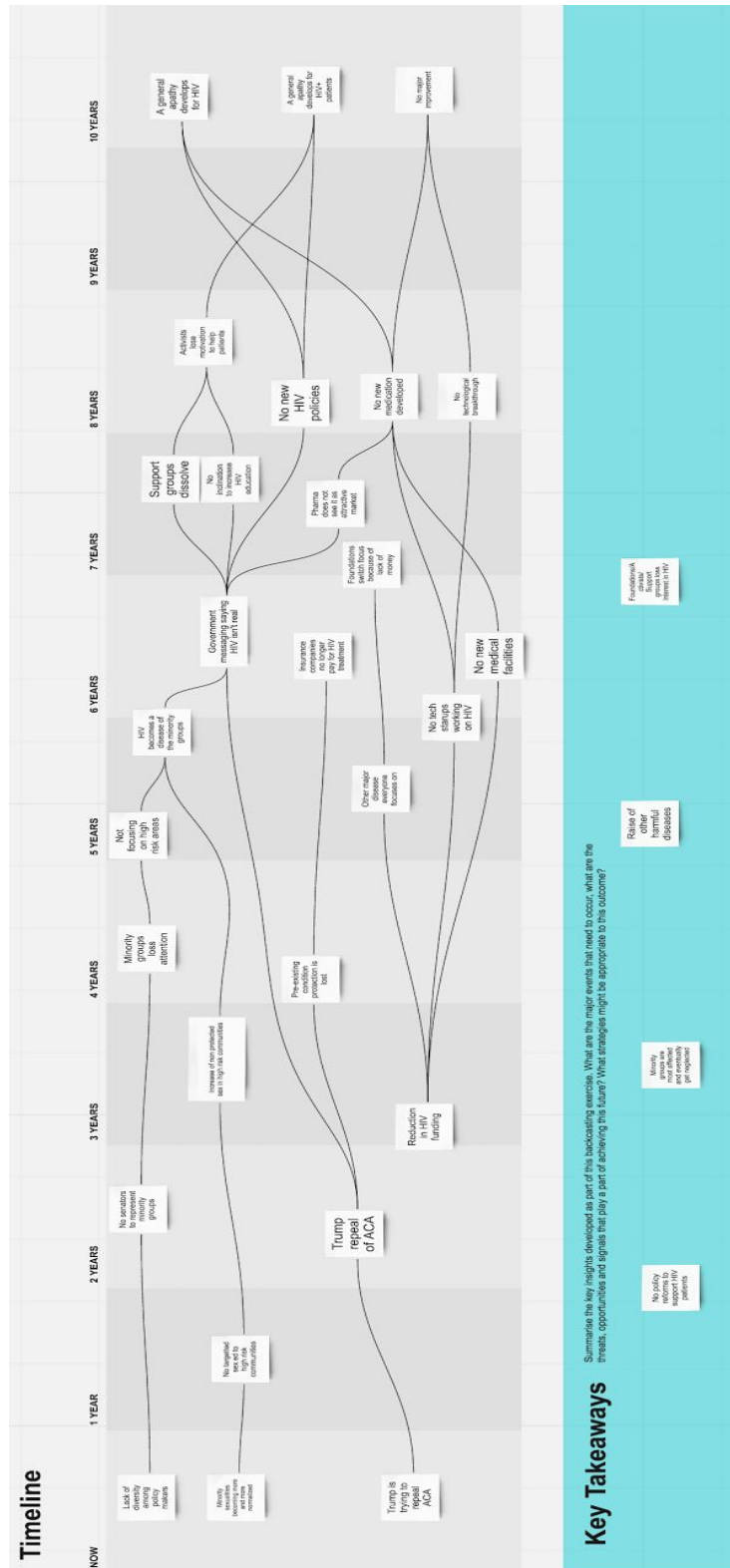
2. **Backcasting**

a. Preferred Scenario:

- https://realtimeboard.com/app/board/o9J_k0S7hm4=/

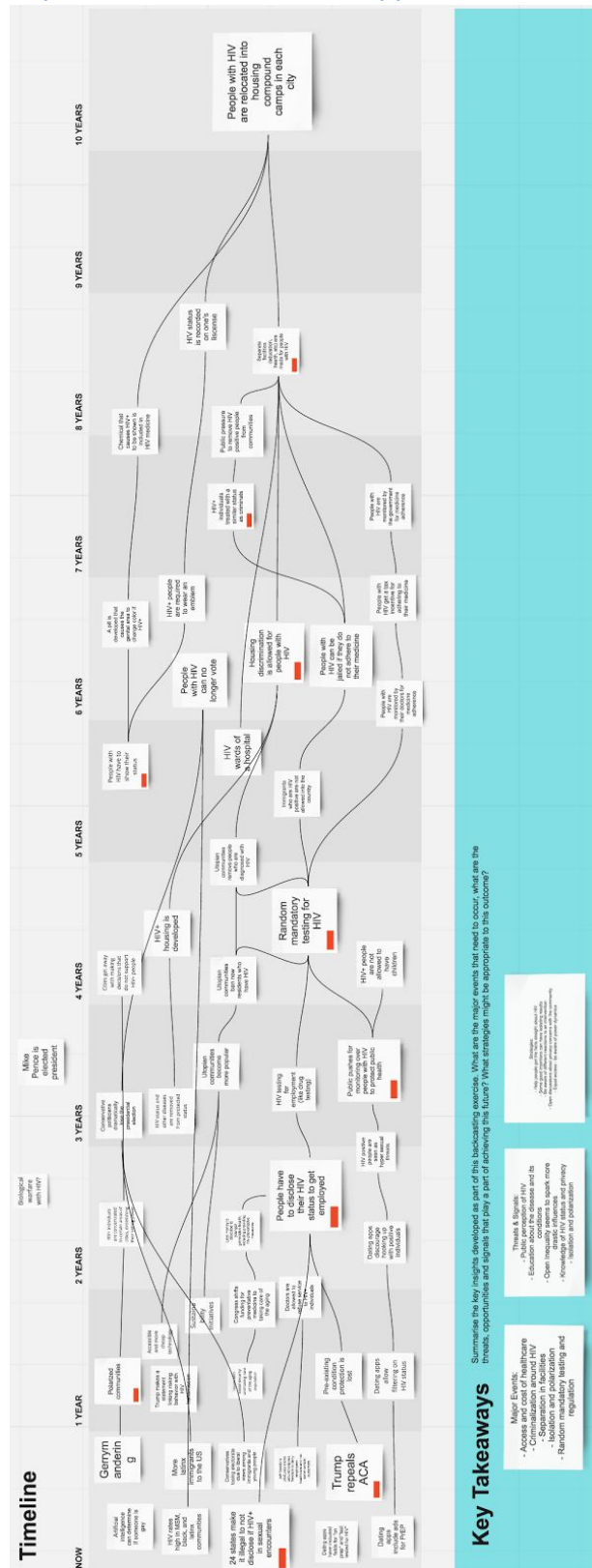
b. Backcasting - Scenario 2: Neutral
(https://realtimeboard.com/app/board/o9J_k0S7hhc=)

(https://realtimeboard.com/app/board/o9J_lk0S7hhc=)

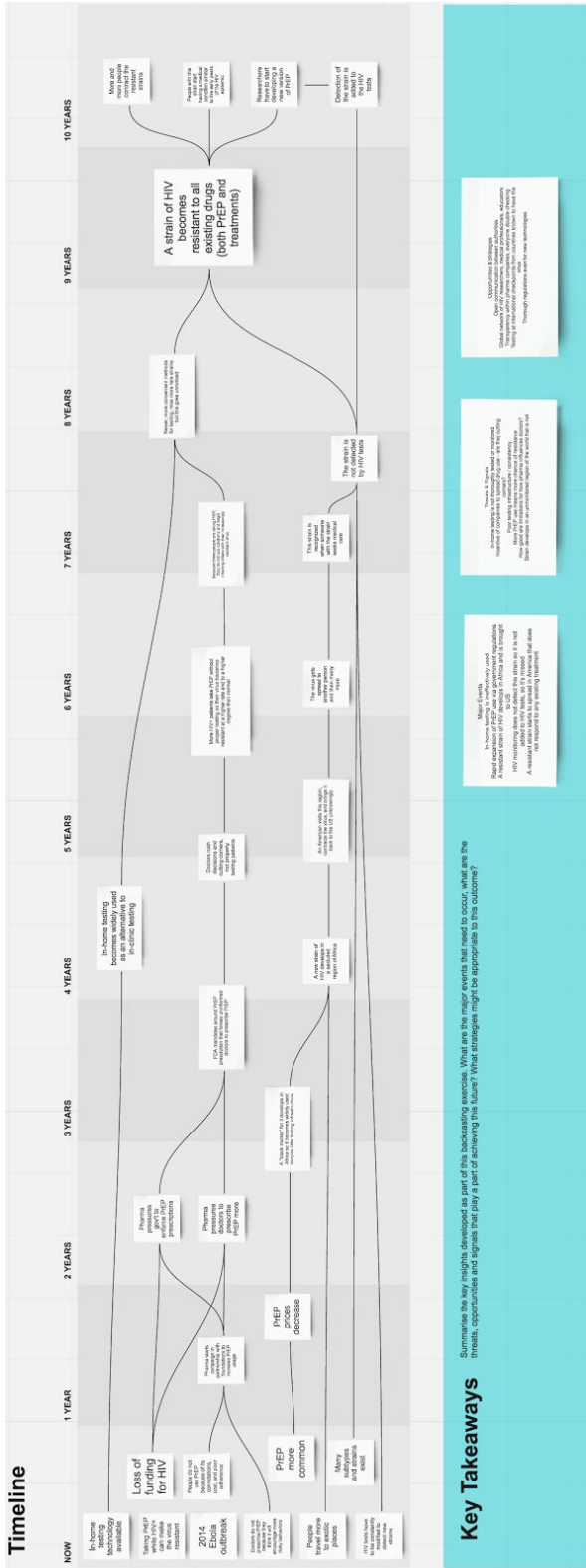


c. Backcasting - Scenario 3: Disowned
https://realtimeboard.com/app/board/o9J_k0S7hhc=

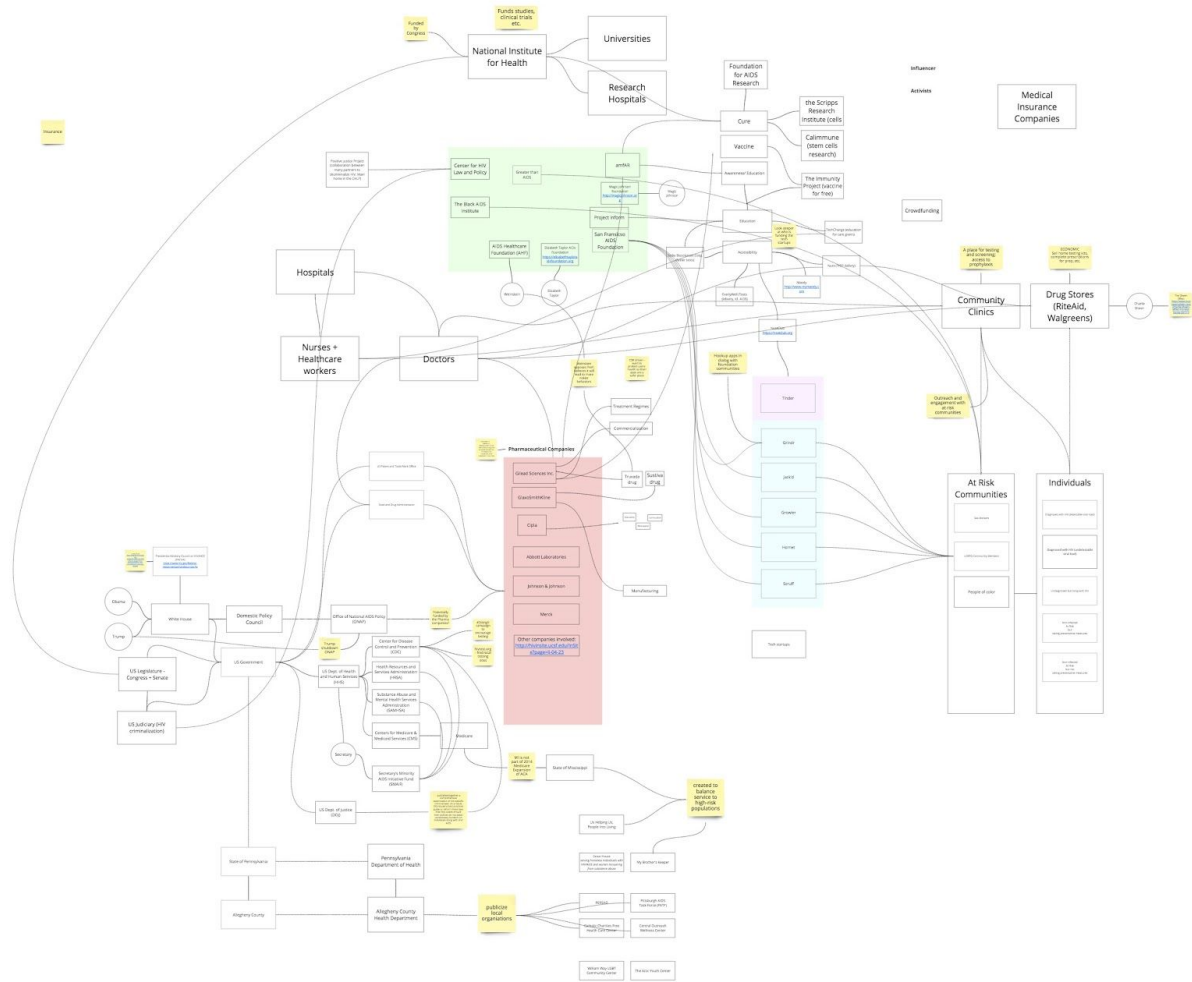
Age Group	Percentage
18-24	28%
25-34	22%
35-44	18%
45-54	15%
55-64	12%
65-74	8%
75-84	5%
85+	2%



https://realtimeboard.com/app/board/o9J_k0S4ekY=



3. Influencer Motivations Map

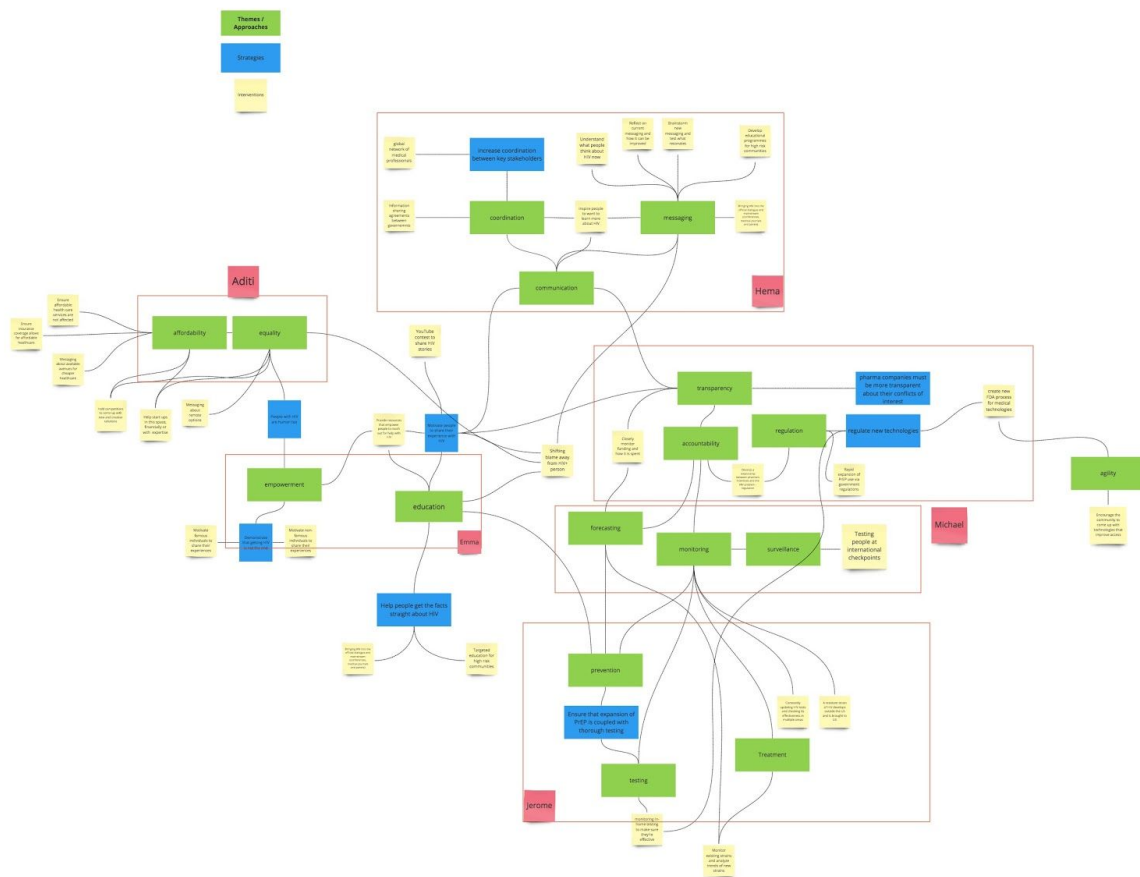


4. Photos and documentation from the workshops



Marsha and Adrian hard at work crafting the future | Silicon Valley team

5. Organizing Strategies and Intervention Method Options



6. Opportunities considered for intervention

■ One time HIV vaccination administered like flu shots in walk-in clinics and other public areas. there should not be any cost associated with the vaccine to the patients. When the vaccine is administered in a common place, it is viewed with less reluctance than if a person has to go a clinic to get the vaccine.

■ HIV medication can be made easy to consume and patients can get refillable prescription through online or other means that would save them a hospital visit. This will encourage patients to take their medication more consistently. Also treating the prescription as a prescription for birth control pill, slightly takes the taboo away from purchasing the medicine.

■ Every individual should report their HIV status to government every year. This will be seen as a mandatory activity that everyone has to go through and will reduce the suspicion when someone wants to get themselves tested for HIV.

■ This can be tackled by educating the parents early on, perhaps by introducing HIV education for parents as part of Parental education or a continuation of that, once the child is born, at the pediatrician, or in professional events such as "Quality of Work Life" weeks

■ Create an AA (Alcoholic Anonymous) for AIDS to increase the number of support groups. This could also be a first opportunity for HIV+ persons to do their “coming out”

■ Hold a competition for short stories/short films/pieces in other media for realistic portrayals of HIV. Allow anonymous submissions

■ Push for a day within the HIV awareness month that’s for testing awareness. Perhaps there could even be a day every month for this (eg: first Saturday every month/ the 3rd of every month, etc)

■ Make early detection testing the norm. There are a few medical trials currently going on which first test someone with a normal test (usually an oral test). If they return negative on that test, meaning no antibodies were detected, their blood is then used for a viral load test (which looks for presence of HIV RNA), which is able to identify the virus in as few as six days after exposure (although 21 days is recommended for the best results). If at all HIV testing sites this two stage process was established, more recent instances of the virus could be identified, diminishing new transmissions.

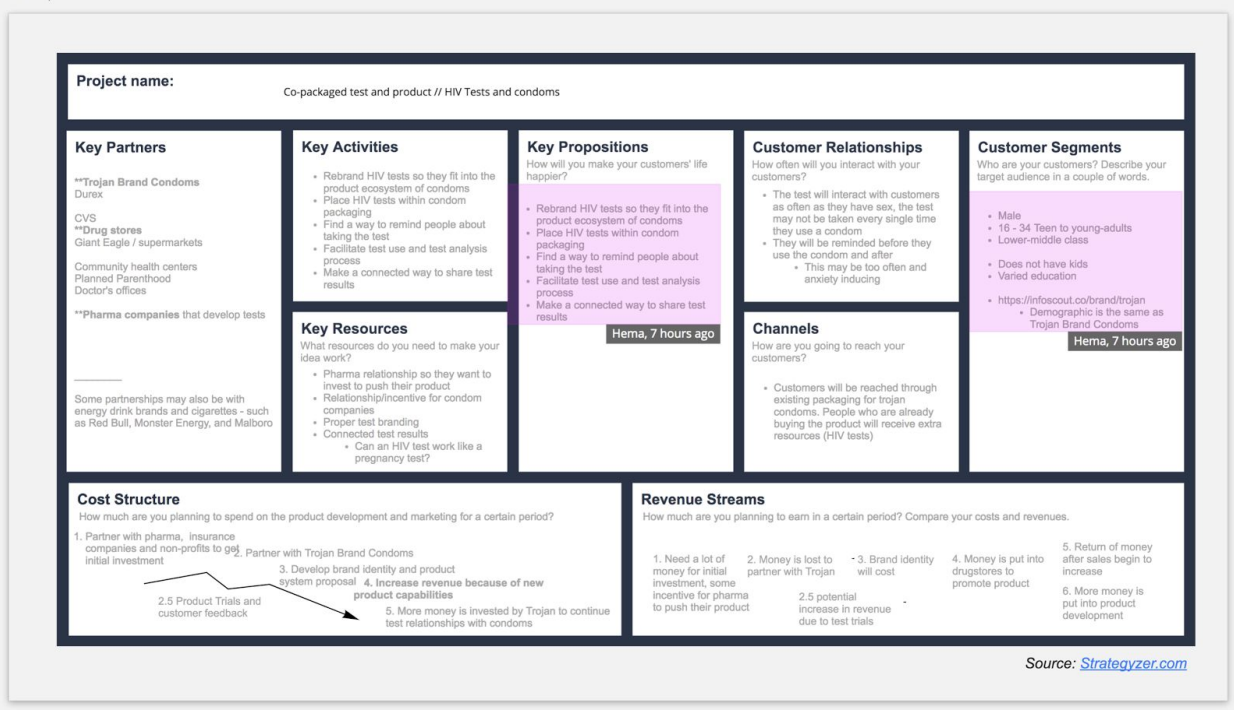
■ Get data from a data wholesaler about physicians’ prescription rates for PrEP, PEP, and treatment medications. Identify physicians who systematically prescribe each of these medications much less or not at all. Make these medications available to the patients of these physicians by opening HIV clinics in these areas or advertising existing clinics in these areas. A more tactical approach might place advertising at or near the offices of these physicians or explore digital marketing, through social media or dating apps. However, specifically target patients of these physicians may be illegal due to privacy regulations and also violate privacy norms, alienating patients.

■ Bundling the various service interactions across the continuum of care into a single service would greatly reduce the possibility of someone breaking medication adherence and losing contact with their physician. This bundling should apply to both in-person, phone, and digital

touchpoints. There are particular opportunities at the time of notification, during the period immediately after before medication begins, and then onwards, through medication to suppression and beyond to maintain suppression.

■ One solution is to begin changing the connotations around sex. The idea to open or include in spas STI testing kits, or other products that equate body health and sex health. Testing can maybe be connected to a self-care routine. This allows for potential normalization while keeping privacy around HIV status. People won’t have to seek out testing as much and are more exposed to options.

7. Business Model Canvas



8. Prototype Survey - [Link](#)

9. User Interview Questionnaire - [Link](#)

10. Rollout Plan and Gantt Chart Development:

