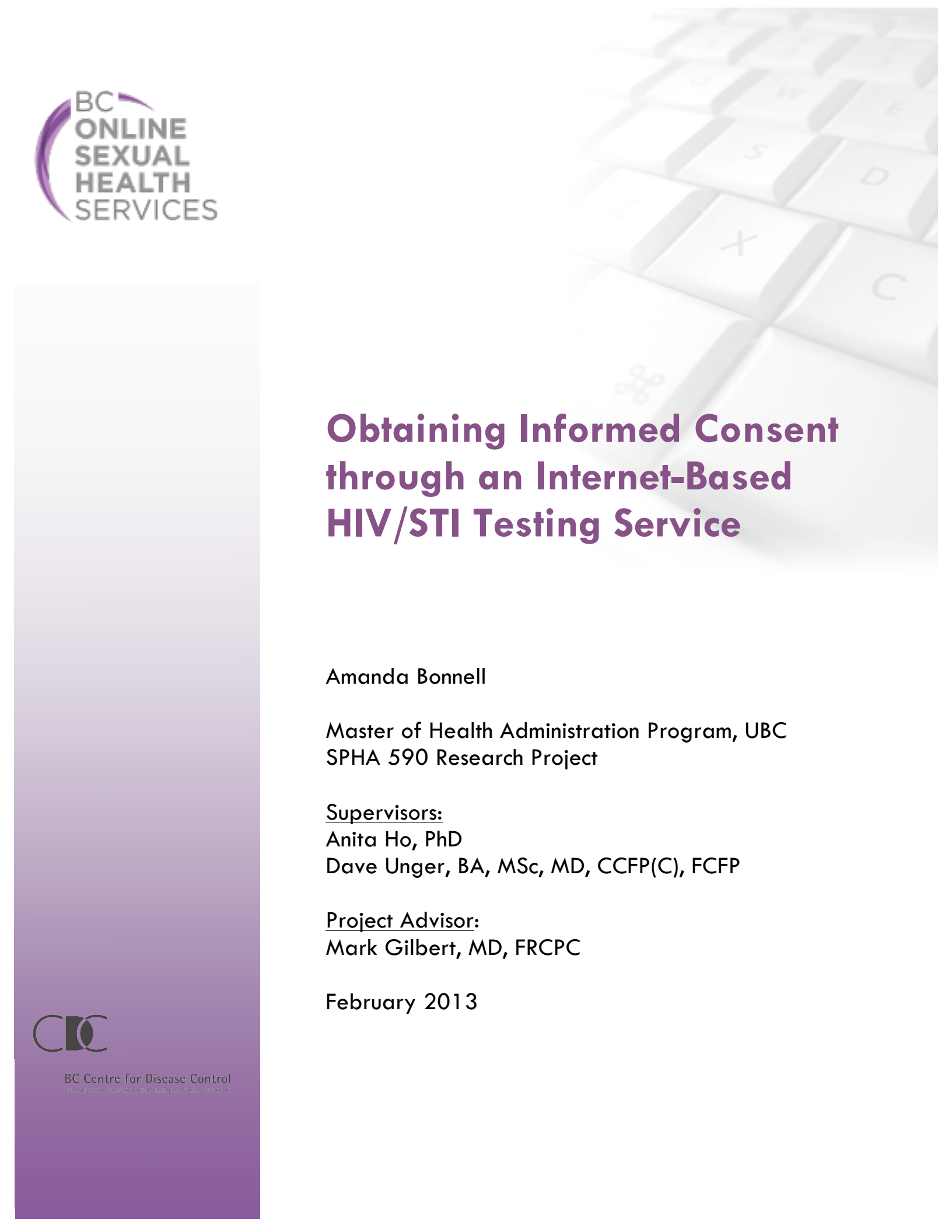




Obtaining Informed Consent through an Internet-Based HIV/STI Testing Service

Amanda Bonnell

Master of Health Administration Program, UBC
SPHA 590 Research Project

Supervisors:

Anita Ho, PhD

Dave Unger, BA, MSc, MD, CCFP(C), FCFP

Project Advisor:

Mark Gilbert, MD, FRCPC

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Background

The BC Centre for Disease Control publishes an annual surveillance report highlighting the prevalence of HIV and other STI's in the province. The 2011 report noted that the rate of chlamydia has been rising since 1998 but had shown a very small decrease that year to 255.5 per 100,000 people (representing over 11,000 cases that year).¹ Meanwhile, gonorrhea has increased to a rate of 34.3 per 100,000.¹ Statistics demonstrate that young adults under the age of 30 years old have the highest prevalence of chlamydia and gonorrhea, and there is a particular concern for adolescent females aged 15-19. Previously showing a downward trend, syphilis rates are showing a significant spike among BC's MSM (men who have sex with men) population at the end of 2012 to 4.2 cases per 100,000 people.¹ Affecting a wide range of ages (25-59 yrs old) the majority of syphilis cases noted were from Vancouver and Southern Vancouver Island.¹ Over 50% of the MSM cases of infectious syphilis also have an HIV co-infection.¹ Many sexually transmitted infections are asymptomatic, such as chlamydia and sometimes gonorrhea, and therefore can pose serious health risks, such as pelvic inflammatory disease or ectopic pregnancies, for the individual as well as their sexual partners if the infection goes unidentified and untreated.¹

Following provincial efforts to "STOP HIV", through additional funding for prevention, screening, and treatment programs, HIV rates are at their lowest ever (6.3 cases per 100,000 people), however, it is still of great importance to monitor and continue focused programming initiatives for the most at-risk populations in the Province.² HIV is a serious lifelong infection which causes a dramatic deterioration of a person's immune system and without treatment, 50% of HIV cases progress to AIDS within 10 years, defined by an extremely low CD4 T-cell count. Individuals infected with HIV/AIDS face grave susceptibilities to opportunistic infections, digestive and respiratory afflictions, and increased chance of various types of cancer. While still without a cure, there are many medications today that can support people diagnosed with an HIV infection that may prevent their disease advancement. Although still socially discriminated against in many communities, being HIV positive is no longer a definitive death sentence so testing is highly encouraged by public health leaders as a key step to normalising and reducing stigma and maintaining a healthy population. HIV may take time to be detected (i.e.: seroconvert) with a diagnostic test (known as the "window period") and can also be latent for a period of time once infected – sometimes even years – which can contribute to individuals spreading the infection if they have not been tested. Being aware of an HIV infection can also allow people to take precautions to reduce transmission to others.² Increased education and screening promotional campaigns have likely impacted the declining prevalence trends amongst most STIs and HIV.¹

Screening is a proven public health measure to mitigate the spread of disease and improve outcomes, although due to the nature of sexually transmitted infections, some people still feel uneasy about having such a test. Many feel embarrassed or uncomfortable discussing their sexual behaviours and potential exposures with healthcare providers, for fear of feeling judged or perhaps even blamed for their condition. Some simply find going to a walk-in clinic or having an appointment with their family doctor when they are asymptomatic an inconvenience and sometimes even costly if they must take time off work to have a test. Others face embedded cultural stigmatization if their family and/or community are not as open about sexuality as some other societies. In more remote areas of BC, this can be compounded with the lack of health resources available. Lastly, great anxiety around privacy and confidentiality of their actions and health status seem to be underlying reasons for why some individuals shy away from

preventative regular or even symptomatic screening for STIs. As such, provincial guidelines for HIV testing state that “it is essential that all HIV testing is voluntary, confidential, client-centred and occurs in a manner that is non-judgemental, reduces stigma, and maintains the human rights of clients (PHAC, 2006)”.³

As technology has been deemed one of the most prominent influences today in our healthcare system, a movement towards online service delivery is a fitting progression and potentially revolutionary for managing our increasingly scarce healthcare resources.⁴ Society has already embraced the internet to offer new ways of shopping, banking, information seeking, and even finding relationships. Up until now, the internet has primarily served as a virtual encyclopedia for individuals to “do their homework” so to speak, on their own health questions and issues, as a supplement to seeking health services from clinicians in various settings. With an appetite for learning about their health through their own research, people are able to take a leading role in their health care decision-making, with or without providers. Unfortunately, very little research has examined the use of internet-based tools for patient “self-care” to assess patient satisfaction or outcomes.⁴

Using the internet as a vehicle for STI testing first began in the United States in 2003 with a site called “STDTest.org”, which was launched by the San Francisco Department of Health in response to a syphilis outbreak.^{5,6} This website invited anyone interested in syphilis testing to print out a requisition form and take it to one of many designated publicly-funded labs in San Francisco for blood to be drawn; testers could then log onto the system with their requisition number and a password to obtain their results.⁵ This service was anonymous and did not link with the public STI database to ensure confidentiality and promote uptake of testing.⁶ In STDTest.org’s first year, 218 tests were run and 13 people had reactive serologies (6 were diagnosed with new syphilis infections out of the 13), which demonstrated similar positivity as the municipal STI clinic and a new gay men’s health center.⁵ Content for the site was developed by a health educator and was reviewed by a committee of clinicians and prospective testers.⁵ Following suit, a team in Amsterdam developed a similar web service to respond to their own increase in syphilis prevalence.⁷ During its 15 month pilot, 93 website visitors printed their referral requisitions and proceeded to a lab to have a test.⁷ 10 online users tested positive (three reporting that they had never visited the STI clinic before).⁷ This team of investigators concluded that not only was syphilis testing through an online service feasible, but it was more successful in detecting early or latent syphilis amongst the MSM population than in-person clinical visits.⁷

Chlamydia testing jumped online next in Sweden and through Johns Hopkins University in the United States, although with a slightly different approach whereby clients could request or purchase home testing kits, prepare a self-collected specimen, and return to a local laboratory for analysis.^{6,8} In the US, clients were mailed swabs to self-administer to collect samples and mail back to the laboratory (thus not causing an influx of clinical provider visits for the screening program); tests showed a 10% prevalence in online clients as well as 1% prevalence for gonorrhea, and 86% of participants said they would use the internet program again.⁶ In Sweden, the goal was to try and sample broadly across the country’s population, so every inhabitant (population just over 256,000) was offered the opportunity to have a free at-home chlamydia test.⁸ Interested citizens received a urine specimen cup with instructions for how to sample and store before participants could obtain negative results online by entering a personal, confidential code, but if their urine specimen was positive for chlamydia, a message appeared telling them to print out a physician referral form to obtain treatment.⁸ Managed by a database, positive clients were reminded by email to access results after 2 weeks and then after three emails, were contacted by

phone.⁸ As a nation-wide initiative, 906 tests were performed with the majority of respondents between the ages of 20-24.⁸

As internet testing sites began to grow, Owens et al. (2010) looked at the various STI screening opportunities online and assessed their accuracy.⁹ Out of 27 international and national sites, only two mail-in urine specimen sites and one public health site kit yielded correct positive results.⁹ In addition, they found that the internet site hosts were difficult to reach and ask client-centred questions.⁹ These examples highlight some of the factors necessary for developing and delivering a successful online testing service including being operated by a credible public health or evidence-based medical centre, utilising accurate laboratory analysis rather than home testing kits, and ensuring opportunities for dialogue between client and health provider in support of their testing endeavours.

The Online Sexual Health Services Program (OSHSP) at the BC Center for Disease Control is currently developing a web application called *GetCheckedOnline* that will enable clients to access testing for HIV, chlamydia, gonorrhea, syphilis, and hepatitis C through a secured internet site. With a pilot scheduled to launch in 2013, this program aims to integrate clinical practice within a digital setting to increase accessibility to sexual health screening and treatment. Clients will be able to create a user profile, review information about the tests and infections, answer questions which describe their sexual behaviours and other risk factors for STI/HIV, and then print a lab requisition form for recommended tests, which they can take directly to a partnered specimen collection site. Essentially, users can eliminate the usual test-initiation step of having an appointment with a healthcare provider at a clinic or doctor's office. Rather, individuals can self-identify if they feel they need or want to be tested, and lead themselves through the process in the privacy of their own homes. Positive results will be routed to the Provincial STI/HIV Clinic as the central reporting center and online testers will be able to view negatives results through the web application, or receive a message to contact a BCCDC clinic nurse to receive positive results and follow-up or treatment if required.

While eliminating the need to interact with a provider will reduce barriers to testing for some clients (e.g., due to stigma associated with testing or privacy concerns), this also poses challenges in that it omits the traditional face-to-face patient-provider interaction wherein informed consent for testing is obtained. Testing information required for establishing informed consent is specified in the STI/HIV pre-test guidelines published by the BCCDC, and follows the UNAIDS/WHO 2004 principle that "the person having the test understands the purpose and benefits of the test, is prepared for positive results, understands the nature and type of test used, provides permission to be tested, is aware of where their personal information and test results will be stored, and is aware of (contact tracing) follow-up processes and services available if the test is positive".³ It states that the information can be given to the client either verbally or in writing such as a health file or pamphlet.³ The education, counseling, and consenting activities, which are required in current clinical practices, therefore must be translated to an online setting for this service.

An existing study protocol, approved by UBC's Behavioural Research Ethics Board (REB), is in place to support and inform the development of this new online STI/HIV testing service through various focus groups and interviews (an estimate of 60-120 participants was submitted to REB to capture numerous iterations of focus groups and interviews throughout the course of obtaining qualitative feedback for the *GetCheckedOnline* development). This particular project complements that study and addresses the practice of obtaining informed consent from online

clients through the web application, which has been designed to be in accordance with established STI pre and post-test guidelines and informed consent policy and legislation.^{2,10,11} Special attention was focused on investigating the users' experience and reactions to the informed consent page within the online system, and whether the information conveyed throughout the application is able to achieve an understanding from the patient analogous to that presented during an in-person clinical visit.

Objectives

Primary Objective:

This study was conducted to investigate whether the new online STI/HIV testing service, currently under development with the Online Sexual Health Services Program at the BC Centre for Disease Control, effectively meets legal and ethical requirements for obtaining informed consent. This was assessed by reactions of potential clients to the consent page within the website demonstration and their understanding of the reasons for the questions presented. A level of comprehension of the key ideas that constitute HIV/STI informed consent (as per the clinical guidelines)³ was explored. As part of this objective, I hoped to provide evidence that online testing clients accept and understand the differences between a self-initiated web-based health service compared with an in-person clinical encounter.

Secondary Objective:

While discussing the rationale and acceptance of the online informed consent page with prospective *GetCheckedOnline* clients, the second objective of this study was to take the opportunity to seek feedback from users on the graphic design/layout of the consent page. By presenting participants with slight design variations of the consent page, this investigation hoped to identify the more favourable characteristics of webpage construction that enhance the experience of the user when giving consent and then inform the ongoing development of the web application.

Methods

I had the good fortune to work with the Online Sexual Health Services Program team during my secondment at the BC Centre for Disease Control, and participate in the working group for *GetCheckedOnline*'s development project. In March 2012, an ethical review was performed by Ethicist, Dr. Dave Unger, who highlighted the requirement that clients who may use *GetCheckedOnline* truly understand how their testing experience will differ from an in-person clinical visit and suggested that the BCCDC team evaluate if prospective clients would be appropriately informed when asked to confirm online that they give consent for testing.¹² As the web application development continued with the BCCDC's IT vendor, it reached a point where usability testing is typically performed to ensure that users could navigate through hypothetical scenarios and identify any bugs or problems with the website infrastructure and programming. During usability testing, participants are invited to have a facilitated walkthrough and demonstration of the *GetCheckedOnline* site and perform typical tasks such as creating a user account, answering the risk assessment questionnaire, and providing informed consent. This created an ideal opportunity to explore the concept of informed consent after such a thorough demonstration of the site and hoped to address Dr. Unger's points raised in his ethical review of the web-based STI/HIV testing tool.

After obtaining approval from UBC's Behavioural Research Ethics Board for the informed consent sub-study amended to the existing online testing protocol, (usability testing was coordinated with the Online Sexual Health Services Program team and the web application vendor. Individual face-to-face interviews were held with volunteer participants following a usability testing walkthrough of the new online STI/HIV system. Two rounds of usability testing/informed consent interviews took place – one over two days in October 2012 and another over two days in November 2012. The first group of participants in October were recruited through Craigslist, while the second group in November were recruited from a pool of BCCDC STI Clinic clients who had submitted their names to be contacted for participation in future research studies. As the team was keen to hold usability testing with a diverse group of potential website clients, preliminary screening was conducted for all Craigslist respondents to find a group with balanced gender, age, and testing experience. All participants were aged 19 years and older and were able to read and understand English. Each participant gave written informed consent for their involvement and received an honorarium for their time (\$25 cash plus \$25 iTunes gift card, funded through the BCCDC Online Services project budget).

Prior to each interview a written questionnaire was completed to obtain socio-demographic, testing experience, and computer access information. **(See Appendix A, Table 1, for summary of participant questionnaires).** *Note: 14 socio-demographic questionnaires are tallied in Table 1 but only 13 interview transcripts were used for analysis because one participant requested not to be tape-recorded. Field notes were used to capture the non-recorded interview responses.*

During usability testing, participants were presented with the version of the informed consent page, as it was built into the website at the time (Figure 1). With this version, there are eight statements which the user must check off before proceeding with the bottom blue button and printing their lab requisition. Each statement has the key bolded text visible, with the option for expanding to “more” explanations if the user wishes. The page is programmed to only allow one statement to be expanded at a time in order to not overwhelm the user with too much text.

Two additional versions were mocked up and provided in hard copy to participants during the last portion of their interviews to comment on their preferences in design and layout characteristics (Figure 2, 3). Participants were instructed to focus on the design, rather than the text, in each mock-up.

Figure 1: Informed consent page of GetCheckedOnline (current version)



GET
CHECKEDBC

A SERVICE PROVIDED BY THE BC CENTRE FOR DISEASE CONTROL

[About](#) [Contact](#) [Compliments & Complaints](#) [Lab Locations](#) [My Account](#) [Sign Out](#)

[↑ MY TESTS & RESULTS](#) [↑ MY TESTING HISTORY](#) [HOW IT WORKS](#) [STI TESTING](#) [PRIVACY](#)

Create Lab Form

Assessment 12Your TestsConsentPrint Lab Form

Consent to Testing

Before you print your lab form, there are a few things you need to know before you can consent to get sexually transmitted infection (STI) testing. Click on 'more' for more information about each statement.

☐

If I am under 19, I know I may consent to the STI testing without my parent or guardian's permission. [More](#)

☐

I understand I can get more information before I get tested. [More](#)

☐

I understand getting tested for STIs is voluntary. [More](#)

☐

I know what STI tests I am getting.
I understand that the STI tests recommended require a urine sample for chlamydia and gonorrhea, and a blood sample for syphilis, HIV and hepatitis C. If the test is done too soon, it may not be able to detect the infection and I will need to be retested after the 'window period' for each STI. I understand that GetCheckedBC does not offer all of the STI tests I might get if I went to an STI clinic. [Less](#)

☐

I know the benefits of getting STI tests. [More](#)

☐

I know the potential harms of getting STI tests. [More](#)

☐

I know a public health nurse will contact me with any positive results. [More](#)

☐

I understand GetCheckedBC is similar to, but not the same as, seeing a health care provider in person. [More](#)

Want to know more before you consent? [Learn more.](#)

I understand and would like to proceed with testing

[Cancel](#)

Figure 2: Alternative Informed consent page of GetCheckedOnline (# 1)

Difference: Informed consent page with different text box color treatment, and an “I Agree” statement for each point.

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About Contact Compliments & Complaints Lab Locations My Account Sign Out

MY TESTS & RESULTS MY TESTING HISTORY HOW IT WORKS STI TESTING PRIVACY

Create Lab Form Assessment 1 2 Your Tests **Consent** Print Lab Form

Consent to Testing

Before you print your lab form, there are a few things you need to know before you can consent to get sexually transmitted infection (STI) testing. Click on 'more' for more information about each statement.

I Agree I understand I can get more information before I get tested. [More](#)

I Agree I understand getting tested for STIs is voluntary. [More](#)

I Agree I know what STI tests I am getting.
I understand that the STI tests recommended require a urine sample for chlamydia and gonorrhea, and a blood sample for syphilis, HIV and hepatitis C. If the test is done too soon, it may not be able to detect the infection and I will need to be retested after the 'window period' for each STI. I understand that GetCheckedBC does not offer all of the STI tests I might get if I went to an STI clinic. [Less](#)

I Agree I know the potential harms of getting STI tests. [More](#)

I Agree I know a public health nurse will contact me with any positive results. [More](#)

I Agree I understand GetCheckedBC is similar to, but not the same as, seeing a health care provider in person. [More](#)

Want to know more before you consent? [Learn more.](#)

I would like to proceed with testing [Cancel](#)

Figure 3: Alternative Informed consent page of GetCheckedOnline (# 2)

Difference: Informed consent page with each statement bulleted and one single checkbox at the bottom.

GET CHECKEDBC
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About Contact Compliments & Complaints Lab Locations My Account Sign Out

MY TESTS & RESULTS MY TESTING HISTORY HOW IT WORKS STI TESTING PRIVACY

Create Lab Form Assessment 1 2 Your Tests **Consent** Print Lab Form

Consent to Testing

Before you print your lab form, there are a few things you need to know before you can consent to get sexually transmitted infection (STI) testing. Click on 'more' for more information about each statement.

- If I am under 19, I know I may consent to the STI testing without my parent or guardian's permission. [More](#)
- I understand I can get more information before I get tested. [More](#)
- I understand getting tested for STIs is voluntary. [More](#)
- I know what STI tests I am getting.
I understand that the STI tests recommended require a urine sample for chlamydia and gonorrhea, and a blood sample for syphilis, HIV and hepatitis C. If the test is done too soon, it may not be able to detect the infection and I will need to be retested after the 'window period' for each STI. I understand that GetCheckedBC does not offer all of the STI tests I might get if I went to an STI clinic. [Less](#)
- I know the benefits of getting STI tests. [More](#)
- I know the potential harms of getting STI tests. [More](#)
- I know a public health nurse will contact me with any positive results. [More](#)
- I understand GetCheckedBC is similar to, but not the same as, seeing a health care provider in person. [More](#)

Want to know more before you consent? [Learn more.](#)

☐ I understand all of the points above.

I would like to proceed with testing [Cancel](#)

Interviews were semi-structured with both guided and open-ended questions, seeking in-depth participant perspectives and reflections on their experience with the online informed consent page during their usability testing (*see Appendix B, Interview Guide*). Interviews were audio-recorded and independently transcribed to limit transcription bias. Participant identifiers were removed and transcripts have been encrypted and stored electronically. Having the interviews recorded also allowed for the natural flow of the discussion to occur between the participant and interviewer, creating opportunities for tangents which could provide valuable insight. A qualitative descriptive analytic approach was employed to summarize common opinions and responses to interview questions and provide feedback to the online STI/HIV testing service for structural or content adjustments before it is implemented. By relating participant responses to foundational and theoretical concepts around informed consent, this study draws conclusions around the acceptance and translational effectiveness of obtaining informed consent through an internet venue.

The second round of interviews was not originally planned, but the OSHSP team and I felt that, due to the minimal discussion, evident lack of content understanding and single-word answers during the first set of interviews, we could not be confident that the online informed consent page was acceptable to prospective clients, or met the ethical requirements for HIV/STI testing. Many interviewees needed to be prompted and lead, although this still provided very valuable feedback about which questions needed more two-way discussion and clarification. The most in-depth discussion occurred with two participants who responded to the Craigslist ad who had visited the BCCDC clinic before for testing. I felt that the sample size of the first round of interviews was too small and the population recruited was too broad and inconclusive, so we decided to hold another round of usability testing and informed consent interviews with participants recruited from our BCCDC clinic client pool since the online testing pilot would be launched only to that specific audience at first anyways. I felt that further discussion with round one participants would not contribute to this study's assessment of whether self-directed users of an STI/HIV testing website comprehend the informed consent material or accept its purpose, although future studies may want to explore certain demographic characteristics of the first participant group for feasibility of the *GetCheckedOnline* service beyond its proposed pilot phase. As the original and amended REB approvals did not indicate a precise number of focus groups/interviews or participants, and previous focus groups on the subject had been held with BCCDC clinic clients before captured within the ethics application already, a subsequent amendment was not necessary to hold a second round of usability testing and informed consent interviews with this more targeted audience. Although unintended in the initial design of this study, the second round of interviews with this more homogenous sample also explored whether previous testing experience and pre-and-post test conversations through our BCCDC clinic standard practices, was a factor in the acceptance and comprehension of the online service informed consent page and hence increased the confidence that ethical and clinical requirements are met with *GetCheckedOnline*.

Results

Participant Characteristics

During the first round of usability testing in October, 8 informed consent interviews were conducted (out of 10 scheduled; 2 participants did not show up as planned). Discussion varied greatly in response to the interview questions; duration ranged from 16 minutes to 45 minutes long, with an average of 32 minutes. This group of participants in October was comprised of 4 males and 4 females, aged 22 – 50, with a range of educational achievement from high school to

graduate school. The majority self-identified as heterosexual (6/8) and had been tested for HIV and STIs in the past year (6/8). A few participants (2/8) had visited the BCCDC STI clinic for their previous testing.

The second round of informed consent interviews (following usability testing) took place in November with 6 participants (out of 8 scheduled with 2 no-shows). This group was predominantly male (4/6) and most self-identified as heterosexual (5/6). All participants reported their education level at college/university and, due to the recruitment strategy, all had been tested for HIV and STIs in the past year at the BCCDC clinic. These last characteristics may be most important for understanding the difference in the responses between groups.

Interview Responses and Opinions

The interview was designed to have three distinct sections and objectives:

- 1) to gauge the initial response to the consent page, identify if any questions were unclear or problematic, and whether users understood the purpose of this step in the online testing process,
- 2) to describe users' understanding of the online process in comparison to a description or previous experience with an in-person clinical testing encounter, and,
- 3) to seek feedback about design preferences among three mocked-up versions of the consent page layout.

Possibly due to the mode of recruitment, the Craigslist group was quite diverse and achieving data-rich discussion proved to be very difficult. Some individuals were hesitant and shy, while others demonstrated comprehension difficulties with the interviewer's questions or were simply less articulate in their answers, using words like "yeah" and "okay" and "yes" or "no" without much dialogue. These responses were difficult to ascertain a true understanding from the participant or rather, issues such as communication skills that may impact consent. Some participant comments triggered concern that too little attention was paid on the website instructions. For example, when asked about their first impression of the consent page, one participant responded:

"Um, well, my first reaction was if I had to pick just one, like you know off the list. And even, well I guess I'm not the best at reading before I do (laughs)" (Interview #5)

Another participant responded with contradictions saying that he understood all the consent statements and that they were all very straightforward, yet when asked for an opinion about having a public health nurse contact him, responded:

"I didn't expect that but I just, who cares, 'cause you guys have your way of doing things right so I just, whatever." (Interview #8)

This individual continued to say, *"I was happy to just click on them all."* Throughout the interview it was clear that the consent page, for this participant, was more of a formality that he did not deem important to the process. Five interviewees expressed confusion or a lack of understanding of the material presented throughout the website, although most reported that they understood everything (yet could not demonstrate through probing questions). One person commented that they thought online testing was a good idea and said:

“Also it looks like you guys would be testing for more than the standard tests, because I’ve never gotten a blood test before for STDs and yeah so it just seems like it would be covering more.” (Interview #1)

This response is disconcerting in that, despite just completing the usability testing where they would have had a risk assessment questionnaire and seen a description of the recommended tests, this person did not understand what tests they would be receiving, which are normally performed and through which method of sample collection – which is a requirement for giving informed consent. One person did not remember seeing the consent page at all during their usability testing. This highlights one key ethical challenge of online informed consent – there is no way to be sure that internet-based testers have received all of the information deemed valuable for making such a decision about having an STI or HIV test without a health provider’s guidance and support.

These examples of interview discussion proved challenging to sufficiently conclude this study’s objectives, however a few participants in this group demonstrated a stronger understanding. When asked if one participant recalled when the site recommended someone to go to a clinic, she responded:

“If you’re experiencing symptoms or if your partner told you to, you know, “hey go get checked.” And for things like that, and for some things that it won’t test for also” (Interview #6)

Responses during the first round of interviews in this study with less experienced testers did not instil confidence that the information relayed through the website was well understood or that there were important differences in what could be achieved when testing online compared with seeing a health care provider in person. The non-BCCDC clinic participants did not recall or demonstrate awareness of some key aspects of informed consent – namely understanding what tests they would be receiving and recognizing circumstances where testing in-person may be recommended, such as when individuals are symptomatic or if they require additional tests that cannot be analysed from a blood or urine sample (such as swabs). Participants from the clinic client pool identified these differences without prompting or probing.

Looking more closely at the three sections of the interview, all participants were asked to comment on whether they read all of the questions on the consent page, which were familiar (and from where), which were surprising, which they did not understand, and which were possibly unnecessary. They were also asked if they felt that these questions were important to be asked in an online testing service.

Common responses were given within both groups of interviews to the first section of interview questions. Almost all participants who commented on previous testing experience during their interviews said that many of the questions on the consent page seemed familiar, although not necessarily laid out in the same manner. Many reported clicking on “more” to expand the additional text for the consent statements: “I know the potential harms of getting STI tests” and “I know a public health nurse will contact me about any positive results”. Interviewees questioned whether this was about actual physical harms of testing, such as needle sticks, and other more literal harms they were unaware of with testing. In one interview, the participant said that describing them as “harms” could be anxiety-causing itself (Interview #13). There was so much feedback about the potential harms statement after the first round of interviews, that it was raised

with the website development team and reworded to better reflect the idea of anxiety and potential emotional stress someone may feel when they have an HIV test. Responses to the public health nurse contacting them ranged from participants being surprised but not concerned, to one who raised a possible issue that this removed a potential online tester's comfort around anonymity. A few reported that they also clicked on "more" information for the last consent statement around online testing being similar to but not the same as an in-person clinic visit. One person (who had not had previous testing) said that she would want more information about that one because, *"umm.. Maybe I was expecting the same?"* (Interview #3).

All participants said that none of the consent page questions raised a barrier for them and would cause them to abandon testing online, except possibly the statement about a public health nurse contacting them. A few participants in the first round of interviews needed this statement explained to them (although this did not necessarily mean it was a potential barrier); but was not commented on as much in the second round, indicating that prior in-person pre-test conversations at the BCCDC clinic had conveyed the concept of contact tracing well already. A few participants suggested that the developers adjust the navigation of the site to allow users to go back to look at previous content information without having to redo their risk assessment questionnaire and consent page. Meanwhile, one person specifically commented that if people were able to navigate away from the page they may get lost and that pop-up windows are a poor option.

Nine out fourteen interviews commented that they expected to see a consent form in the web application, or were not surprised when they landed on that page in their usability testing. A few participants queried the consent statement confirming that STI testing is voluntary, some feeling it was strange to see, and another felt it was redundant since they had chosen to come to the site, create a user profile, and follow the steps provided up to that final page already. Every participant in both interview rounds said that they felt the questions on the consent page were important and that all points were necessary. When asked why they thought a consent page was included in the online testing tool almost all participants expressed their interpretation of the meaning of "informed consent" appropriately:

"Just to make sure that this is something you want to do, and just so that you know what you're getting into." (Interview #1)

"It's important because it seems natural in the progression of like the whole process that you're going to go through.double-checking, letting people know what's going to happen...some people like that to be told back to them – this is where we are, this is what we're going on, this is what we're going to do." (Interview #4)

"so that you know what you're doing or not doing." (Interview #5)

"I mean, it's not a light subject matter right? It's pretty important so it's good that you get people to acknowledge what they're doing and what they're signing up for." (Interview #10)

And lastly, a very pragmatic response:

"Because I'm skipping my doctor, yeah. Because I'm just going straight to a lab without getting my doctor to sign off on a form..." (Interview #12)

Three participants who saw informed consent as the BCCDC's safeguard or to reduce the organization's liability.

"It could be part of your guys' policy so to speak. You guys have to know this in case you get taken to court. Legal-wise." (Interview #2)

"crossing your t's and dotting your i's for you guys.... I don't know if there is any liability or anything... so it's like, they know what they're going for, you've told them what they're going for and that's that." (Interview #4)

Almost all respondents however, stated that the consent page was for both the client and the organization's benefit. One individual specifically applauded the language of the consent page being client-centred and was unlike any other consent page he'd seen before (Interview #11). Reinforcing results from the OSHSP's initial focus groups to identify prospective clients' perceived benefits, concerns and expectations of an online HIV/STI testing tool, participants in the informed consent interviews noted **convenience** and **privacy** as the key drivers for choosing online over an in-person clinic visit.¹³ Many commented that wait times to see a clinician in person are often long and can be costly to patients if they need to take time away from work to get tested. Some specifically said that *GetCheckedOnline* could help people who are embarrassed to have a test, and that this could be a good venue for teens who would not otherwise go to a clinic or see their family doctor (Interviews #4 and 6). One participant envisioned a scenario:

"If I were with my friend's daughter or whatever, sometimes they'll open up to me more than their mom and you know, then I can just say, 'Hey, you know if you're embarrassed you can go online'" (Interview #5)

The ability for minors to test online caught the interest of many participants. Everyone who commented on this opportunity for prospective clients under the age of 19 to test confidentially, without their parent's consent, was in favour. One said, *"I hope even a 14 year old can get tested without having their guardian's consent"* (Interview #9). All felt that as a particular audience, youth were less likely to go to a clinic to have an STI or HIV test.

Overall, participants recruited from the BCCDC STI clinics seemed to be relatively comfortable with the material presented on the *GetCheckedOnline* demo about STI/HIV testing and were able to comment on specific points within the consent page and relate it directly and correctly to clinically established pre-test information. BCCDC clinic-recruited participants had a clear advantage of being able to identify some of the key differences between testing online vs. having an in-person clinical encounter. For example, one participant noted:

"You know it's the other things that a nurse can provide that you're not going to get out of a Life Labs...I mean I went for HIV tests and while I was there the nurse says, 'by the way, do you want to get the gonorrhea, the syphilis, (and) the Chlamydia (test)?' And I went, 'yeah for sure'. And then she said 'oh but we checked out your care card and you started your Hep A and B inoculations but you haven't finished, we can finish them for you.' And I'm like 'Yeah!'" (Interview #9)

Another described:

“...you know, my experience like actually coming down and speaking with a nurse, they’ve actually been able to answer um, you know, questions that even a walk-in clinic doctor didn’t have satisfying answers to. Um, so I found had I not actually had that opportunity to come in and talk to a nurse, I might have had other questions that stay unanswered. So I mean, yeah it’s not complete.”

This person continued to advise:

“I think the most important thing would be to make people aware what the difference is between doing it online and going to see a nurse and what it’s not testing for. And like reasons, like almost reminding people why they might want to go see a nurse from a general health checkup kind of perspective.”(Interview #11)

One participant in the first group of interviews, who had been to the BCCDC clinic also pointed out that *“there’s times when it’s recommended that you actually see a person. ‘Cause there’s some things you can’t get tested for on the site, right?”* (Interview #7)

This level of understanding could be explained by differing practices in the BCCDC clinics where providers will spend approximately one hour per visit with each full STI screening to ensure a thorough pre-test discussion compared to often, brief interactions through walk-in clinics or outreach settings due to the nature of their business. Hence, the BCCDC participants’ previous knowledge contributed well to their understanding of the online service and its functional boundaries.

Layout

The last part of the interview asked participants to identify design characteristics that they liked about the consent page. Many described the site as, “simple”, “neat and easy to read”, “clean and uncluttered”, “precise”, and “put the relevant information front and centre.” Some said that they liked how users could expand each consent question to reveal “more” information, and that when you clicked on another, the previous one closed. Participants reported that they did not feel there were too many consent questions or that the consent page was not too long. When presented with two other versions (one using “I agree” buttons and with different box and color treatments; the other version with all the consent questions as bullet points and one checkbox at the bottom), the majority preferred the current version as it was built in the website (8 out of 14 participants). Five participants chose the “I agree” version, stating that using the words “I agree” (or “I understand” as one person suggested) felt more official, legal and straightforward. One person said that saying “I agree” reinforced the notion of free will (Interview #13).

One person preferred option three with the single checkbox of understanding for all of the consent points above. All other participants admitted that, like many other terms and conditions on websites, they would be less likely to read the content and would probably just skip to the bottom and select the checkbox regardless. It was nearly unanimous that, if the goal is to have clients read this important information, option three would not achieve that. Participants felt that having to check (or answer “I agree”) to each statement on the informed consent page, encouraged them to reach each, one by one. With a goal of translating an in-person practice of establishing informed consent to an online venue, the layout of the consent page greatly contributes to its acceptance and effectiveness. Clinicians, bioethicists, and the developers of *GetCheckedOnline* all agree that certain information around STI/HIV testing needs to be conveyed to users who are going to initiate and self-direct their online encounter, so it is

important to assess what design characteristics increases the readability and attention to the material presented for these clients to be truly informed.

Lastly, and possibly indicative of the diversity in experience and education of participants in the first round of interviews, three people suggested a glossary/dictionary, link, or tool-tip for users to be able to access if they did not understand a concept or word (such as the type of test or infection).

Discussion

This is evidently a very new way for patients to experience care. The final statement on the consent page reminding clients that *GetCheckedOnline* is similar to, but not the same as going to a clinic, is in line with the “e-Health Code of Ethics”, published in the Spring of 2000.¹⁴ The “e-Health Code of Ethics” is a document resulting from the e-Health ethics summit in Washington DC, and sets forth eight guiding principles for how people ought to receive health information and healthcare online: candor, honesty, quality, informed consent, privacy, professionalism, responsibility, partnering, and accountability.¹⁴ While the guideline around informed consent addressed the electronic storage and sharing of personal data, “professionalism” specifically advised that online services should inform their patients of the limitations of online health care.¹⁴ The varied responses from participants on their understanding of what services *GetCheckedOnline* could deliver vs. an in-person clinic appointment substantiate the need for the final point on the consent page to be expressed explicitly and fully to all users. As demonstrated through this study, many users did not click on “more” for all of the statements on the consent page, typically based on their previous knowledge about STI/HIV testing or simply because they chose not to read the expanded content. Yet if a web-based testing service is accessible to experience or inexperienced testers alike, specifying the differences and limitations to all clients is a fitting practice.

Interview discussions and the design aspect of having a statement with the ability to expand “more” information highlights an important concept about how much information to provide at one time (so as not to overwhelm the reader), and which information is absolutely necessary to convey in order to achieve an acceptable standard and satisfy professional responsibilities. While clinicians and health agencies have professional and ethical duties to convey information deemed important for a patient/client to make an informed decision about their health care, each individual person has a personal responsibility to seek out and receive such information. There is no way for a clinician to ensure saturation of information or even that the individual wants certain knowledge, but care providers and clinical services such as this one do need to give access to all information so that clients can inform themselves accordingly. I feel that *GetCheckedOnline* balances this practice well and results from this study show a variation in users around how much information they each want to consume when testing online.

Common response from participants that the informed consent page was for the benefit of clients “to make sure they knew what they were doing”, provides confidence that the BCCDC’s *GetCheckedOnline* service is client-centred in how they deliver testing and the information related to it, rather than simply aiming to meet the legal and ethical needs of a host health agency. A team at St. Jude’s Children’s Hospital in Memphis, Tennessee, attempted to develop an online tool for the families of pediatric oncology patients to inform them about the consent process for medical treatment and research, found it “challenging to deliver accurate information to people unfamiliar with medical terminology.”¹⁵ This rings true with the request from some participants in

this study to have a glossary/tool tip available to help them understand unfamiliar words in the website. St. Jude's proceeded in building their online tool under a premise that, to place the patient needs anywhere but at the forefront of the design would dilute the purpose of informed consent.¹⁵ It also meets BC's legislative "duty to communicate in an appropriate manner to the individual's skills and abilities."¹⁰

It is in this spirit that client-initiated, online STI/HIV testing epitomizes the principle of "autonomy" in healthcare. Informed consent is at the cornerstone of patient autonomy because we cannot expect people to be the drivers of their own healthcare if they do not have all the information a "reasonable person would need to make a decision".¹⁰ In Hebert's ethical guide for physicians (1996), he states that "informed consent is best obtained by having a discussion with the patient to elicit his or her preferences regarding treatment."¹⁶ He continues to say that "we should strive to ensure that our patients' choices are true expressions of their autonomy."¹⁶ Arguably, although some information communicated on the website consent page was not consumed by the user, it was available to those who did choose to click on "more" if they wished. Again, the client was the driver of their experience, so we must accept that as autonomous choice and acknowledge that some individuals will want to know more, and others less, before making their decisions. Collste (2002), sees medical information delivered online to patients as a "means to enhancing their autonomy".¹⁷

There seems to be a trade-off between Autonomy and Beneficence/Non-maleficence in healthcare ethics – the more autonomy that is embodied in healthcare practices, the less assurance a clinician may have that patients are doing what's in their best interests and aren't at risk of any, otherwise avoidable, harm. As was demonstrated, not all potential testers understood or sought out the information provided to them about having an STI/HIV test online, so it is possible that a web-based testing medium can open up potential harms by eliminating the in-person discussions with health care providers (which often can intervene or explore individualised risks together). If we prioritize autonomy however, it is still of clients' own free will and choice to proceed with testing without consuming certain information provided, and therefore ethically sound. Three participants related the consent page to affirming that the individual was acting of their own "free will" (Interviews #3, 6, and 13). This is an extremely promising comment if the innovative service delivery of online testing aims to instil autonomy in patients. After all, "autonomous patients are those capable of exercising deliberate and meaningful choices, choices consistent with their own values."¹⁶ There will always be tension between autonomy and beneficence/non-maleficence because clinicians do not want paternalistic practices to determine how they deliver care.

Overall, the consent page contributed to the "trust" users had in the site. Four participants explicitly said that they saw the statements on the consent page as "trust building." One even described it as follows:

"It made me feel really safe. It made me feel safe because it made it seem like you guys really wanted me to be protected. And wanted me to know what I was getting involved with an not trying to confuse me or trick me or coerce me into getting tested. It really pushed the whole feeling of free will, I'm here because I want to be here for myself...."
(Interview #13)

Another participant who said that consent was being asked because, "you just want us to know what we're getting into," felt that this step legitimized the site and made it more

“trustworthy”(Interview #6). In Collste’s article, *The Internet doctor and medical ethics (2002)*, he proposes that “if trust is based on competence rather than care, it is possible that even the Internet consultation could be of this kind.”¹⁷ In other words, the integrity of the information portrayed and the confidence that users have in the hosting organization could establish the same level of trust as an interpersonal encounter. Some participants commented that having the BCCDC logo visible on the site lent to the trustworthiness of the online testing service. In an online medium, one’s capacity to give informed consent is assumed by the very act of a client self-identifying to obtain medical care, in this case choosing to pursue STI and HIV testing and navigating the website to create an account and complete the risk assessment questionnaire to find out what tests are recommended for them. Making the web service available to minors under the age of 19 without requiring consent from their parent or guardian to seek out STI/HIV screening and potential treatment recognizes their unique needs for care and privacy. Minors are discussed uniquely in clinical guidelines and legislation with regards to their capacity to give informed consent.^{10,11,12,18} Society accepts that communicable disease screening and treatment can be laden with stigma, shame, embarrassment, and avoidance and hence, recognizes that minors are vulnerable and have special needs. They may need and wish to access services of this nature without involving their parents or guardians. Clinicians struggle with balancing their guiding ethical principle of beneficence (which may impel them toward more paternalistic medical practices) with that of respect for autonomy and respecting that the child very likely is making purposeful and informed decisions about their behaviours and healthcare. This is often referred to as the “mature minor” and acknowledges that, although not necessarily at the chronological age of a legal adult, youth can understand and make decisions about their medical conditions.¹⁸

As a tech-savvy generation, conditioned towards instant gratification, *GetCheckedOnline* undeniably opens doors for minors to seek sexual health care. Forkner-Dunn (2003) states, “we have arrived at the era of the impatient patient. Patients demand immediate convenient access to a high level of personalised health care: they want it their way, and they want it now.”⁴ The participant in interview #6 highlighted this shift in control, noting:

“I’m pretty sure young people rely more on the internet to find things. And they want it, they want the results now kind of thing, and they don’t want to have to go through all the different places they can get tested. Nor, I’m pretty sure, nor are they going to go to their home doctor... and some people might not have a doctor, they might have to go through their walk-in clinics that are either impossible to find or you’re going to be waiting for the next six hours when you’re there.”

A poll cited in Forkner-Dunn’s paper on internet-based self-care proposed that patients who used the internet to find health information felt more empowered and had an enriched relationship with their physician because of their increased engagement in their care.⁴ Furthering the principle of autonomy, this suggests that, through internet-based health services, patients are no longer simply recipients of privileged information shared by knowledgeable and powerful clinicians; they are active researchers and consumers of the information they wish to have, and they can look to a health care provider as a facilitator and partner rather than just a gatekeeper with medical authority. However results from this study (such as the participant who navigated the website and reported that they did not remember seeing the consent page) also identifies a common learned behaviour that seems to be prevalent in many online services – people know how to use websites to achieve a specific goal or action without necessarily reading or understanding the content provided for them. In fact, websites are designed and tested for “usability” – or the way individuals of varying literacy and backgrounds can achieve the purpose of the site. With

competing bioethics principles, it is challenging that this behaviour may occur with internet-based health services.

While providing a venue for marginalised individuals or people with great concern for confidentiality and stigmatization, GetCheckedOnline does deliver a valuable service, although from an ethical perspective, perhaps these individuals are the ones who could benefit the most from an in-person clinical visit that could help to foster confidence in the healthcare system rather than provide a “workaround” for it. Forkner-Dunn (2003) noted that although “eHealth technologies” could potentially reach the underserved or unreachable populations who could benefit greatly from such an option, that group is the least likely to access the technologies.⁴ Since her article, the “digital divide” as Forkner-Dunn referred to it has undeniably diminished, yet 30% of participants interviewed in this informed consent study responded that they did not have access to a private printer in order to be able to print out a lab requisition to utilise the new web-based testing service. All but one, however, had access to private email and a computer. If we are hoping to launch this service to a more marginalised population, the concern around access to an internet-based web service still remains.

“When HIV testing is client-initiated and/or occurs in settings with broader STI service mandates such as youth clinics, STI clinics, outreach settings, or community-based services more in-depth client-centred discussions are recommended.”³ This point in the provincial HIV pre- and post-test guidelines identifies some considerable limitations with an online testing venue, for example, it eliminates the opportunity for the healthcare provider to assess the situations where the client may have been exposed to HIV and determine if there are “any issues of power, abuse, or other contextual factors” that may be increasing their risk or “affect their ability to act on (their) knowledge of status.”³ This interaction with a clinician also can serve as a gateway to “relevant harm reduction supplies, referrals, and resources” – something that health professionals would likely deem one of the more important aspects of their interaction with a patient.³ During a working group meeting with the Online Sexual Health Services Program team, the topic of power based or marginalised relationships came up with regards to whether information pertaining to sexual abuse should be added to the web application. It was felt that trying to reach specific situations like this may dilute and distract from the key messages around STI testing in general for the majority of the target audience. The team wanted to keep the content neutral and generalizable to be able to evaluate the pilot. Unfortunately, an online STI/HIV screening service will not be able to deliver all the services that an individualised in-person visit can between a client and a clinician. However, it is hoped that if results are positive and a conversation takes place between the client and a nurse at the BCCDC, either in person or by telephone, that some of these concerning situations and issues could be addressed at that time.

GetCheckedOnline does not intend to replace the post-test counselling, connection with treatment, and follow-up that comes with a positive result. Currently, the results page will post negative results only and advise clients to contact the clinic if their tests results are either positive or indeterminate. This process in the web application is supported by the CDC Atlanta’s, *Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings*, which states:

“HIV-negative test results may be conveyed without direct personal contact between the patient and the healthcare provider... HIV-positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff...Active efforts are essential to ensure that HIV-infected

patients received their positive test results and linkage to clinical care, counseling, support, and prevention services.”¹⁹

Receiving a positive HIV result can be “complex and life-changing,” which is why GetCheckedOnline leaves the result delivery to a more protective and supportive process.³ This aligns with the ethical principle of nonmaleficence, whereby simply posting a positive result on the webpage could instigate great harm to the client if they cannot cope with this news or need support in accessing follow-up care. It is possible also, that simply seeing a message on their online results page advising the client to contact the clinic, creates anxiety and assumption that the results are not favourable. This is where *GetCheckedOnline* reconciles the principle of respect for autonomy with non-maleficence by maximizing choice in how to get tested but minimizing harm when it comes to receiving results. It is also possible, that clients could choose *not* to contact the clinic for their results...which could pose ethical challenges for clinicians who have received positive tests from the lab and may not have contact information to reach out to the online tester to link them with treatment. Although, some clients may still react to hearing the news in person in various ways, and possibly reject any further support or treatment. The ethical responsibility is to try and partner with them in both receiving their result and dealing with the next steps, regardless of the mode in which they have a test. It may be prudent to have a clinic or nurse contact number and open invitation for web testers to make an appointment at the BCCDC STI clinic on the results page, whether the tests are negative or positive. Those who feel that they could benefit from a discussion, such as if their negative result was a “close call” or indicative of a larger concern, may reach out if the invitation was made.

Scarcity of resource management potentially provides the greatest value from an online testing tool that can offer streamlined and self-managed care for those who have already had the benefit of prior STI/HIV pre-test counselling and support through the process, or those who are interested in routine testing rather than if they are symptomatic or were recently exposed to an infection. This was noted in the first interview:

“Well there’s quite a bit of information on the website, but I don’t think anything really compares to going to a doctor, and I think if you need to go to a doctor then you should go to a doctor. But it’s really good like it said for people who don’t have any symptoms and just want to get tested to make sure.” (Interview #1)

With lengthy wait times in sexual health clinics, contrasted with the brevity and pace of appointment in walk-in clinics (i.e.: 5minutes), and even the number of people without a family doctor (see interview #9), *GetCheckedOnline* provides a complementary, rather than substitute care option for STI/HIV testing. In accordance with supply and demand theory, this could result in a significant increase in testing province-wide as it provides alternative testing opportunities to those who cannot or wish not to access in-clinic resources. As one BCCDC client participant commented in regards to the current lead time for a clinic appointment, “*now I called and it was like 3 weeks waiting period. What could have happened in 3 weeks... wholly cow!*” (Interview #9). While clinical guidelines around education and offering support to patients waiting for tests or receiving a positive diagnosis aim for beneficence, the number of clients turned away due to wait times in specialised clinics defeats that principle. The goal when faced with shrinking healthcare budgets and constrained resources should be to appropriately streamline individuals who can access care through expert and legitimate self-service mediums, leaving the rate-limiting in-person appointments for those who require more education, support, and treatment.

Recommendations

Implementation and program evaluation

- Focus the upcoming pilot on audiences who test frequently as part of their regular sexual health maintenance. Results showed a greater understanding of online testing limitations and awareness of when in-person care is required among experienced testers – specifically those who had attended the BCCDC STI clinics.
- Further research is likely needed on knowledge translation through a website and whether HIV/STI pre-test counselling information can be effectively conveyed to inexperienced testers.
- Further consideration around the feasibility of *GetCheckedOnline* for marginalised, remote, and at-risk populations is warranted. These individuals may not have access to the technology, or may still face stigmas and barriers going to a lab in their community. Most importantly, from an ethical standpoint, healthcare resources should be focussed on higher-risk, underserved or more difficult to reach populations because of the value-added care only accessible from in-person clinical encounters. While some may argue that testing online is better than not testing at all, more marginalised groups who test online could miss out on opportunities for additional medical or emotional support and/or harm reduction supplies.
- Continue usability testing with minors to explore whether this tool is appropriate for their needs and level of maturity and understanding. As youth are often at higher-risk for contracting STIs, and have many barriers to in-person testing, this vehicle for screening and treatment could result in a much lower incidence in infection amongst this population.
- Ensure that success of the pilot is not met with reduced human, clinical resources in the BCCDC STI clinics and partner programs. As one participant expressed,

“And I guess one thing I would be very sad to see is if something like an online testing form basically means like less health care providers. If it’s replacing health care providers then I don’t think it would be a good thing.” (Interview #11)

As was evident through this study, the services offered by public health and specialised sexual health nurses cannot be imitated or replaced by an online testing service. In fact, I would expect that, through the pilot, nursing hours may need to be increased to accommodate the telephone conversations and follow-up appointments for treatment of clients who test positive for STIs online. With wait times in the BCCDC STI clinic up to three weeks sometimes, it is very likely that volume would increase if some regular or frequent clients choose to test online instead of in-person, thus freeing up appointment availability for others.

Web application design/development

- Proceed with informed consent page design which asks the user to select a checkbox for each individual statement and then a summary consent button on the bottom
- Users responded favourably to the neutral tone, language and simplicity of the website content and consent page.
- Keep the option to see “more” for all questions except the final question about understanding the difference and limitations of testing through an online service rather than through an in-person clinical encounter with a nurse or physician – that statement

should be fully expanded at all times. It was felt that this point was important enough to display all content that reminds online clients what they are and are not achieving through the online modality. It may be prudent here to explicitly remind users of the STIs that cannot be tested for through this service.

Limitations

As online STI and HIV testing is an extremely new endeavour (in Canada especially), there are many limitations to this initial study exploring the practice of obtaining informed consent through a digital environment. Experiential knowledge will always play a factor in how much content is sought out and absorbed by users navigating websites. Less experienced testers found it challenging to reflect on relatively new information after only a quick exposure, meanwhile, experienced testers had difficulty speculating what they would do if they did not yet have their previous knowledge around pre-HIV-test information. Due to the varied level of understanding among a broad group of participants, it was not only disingenuous but likely a disservice to follow the structured interview as an impartial representative for the *GetCheckedOnline* project. As such, it was not possible to answer definitively and concretely if the website was able to attain informed consent from prospective users. What it was able to confirm, was that all study participants had very similar versions of what informed consent meant to them and why the website was seeking it.

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Appendix A: Description of participants (n=14)

Variable	October group*		November group**	
	n	%	n	%
Age range (years)				
20-29	3	37.5%	1	16.7%
30-39	3	37.5%	2	33.3%
40-49	1	12.5%	1	16.7%
50-59	1	12.5%	2	33.3%
Gender				
Male	4	50.0%	4	66.7%
Female	4	50.0%	1	16.7%
2-Spirit	-	0.0%	1	16.7%
Sexual Orientation				
Heterosexual	6	75.0%	5	83.3%
Homosexual	1	12.5%	1	16.7%
Bisexual	1	12.5%	-	0.0%
Highest Level of Education Completed				
Elementary school	-	0.0%	-	0.0%
High school	2	25.0%	-	0.0%
Trade/vocational school	1	12.5%	-	0.0%
College/university	3	37.5%	6	100.0%
Graduate school	1	12.5%	-	0.0%
Have you ever been tested for HIV?				
Yes	6	75.0%	6	100.0%
No	1	12.5%	-	0.0%
Have you ever been tested for a sexually transmitted infection (STI) other than HIV?				
Yes	7	87.5%	6	100.0%
No	1	12.5%	-	0.0%
Have you been tested for HIV or STIs in the past year?				
Yes	6	75.0%	6	100.0%
No	2	25.0%	-	0.0%
Have you ever visited a BCCDC STI clinic (655 West 12th Avenue or Bute Street clinic)?				
Yes	2	25.0%	6	100.0%
No	6	75.0%	-	0.0%
Do you have access to a printer where you can print personal information?				
Yes	5	62.5%	4	66.7%
No	3	37.5%	2	33.3%
Do you have access to a computer where you can use the internet or e-mail in private?				
Yes	7	87.5%	6	100.0%
No	1	12.5%	-	0.0%

* October interview participants were recruited through a posting on *Craigslist*

**November interview participants were recruited through an email to registered clients at the BCCDC STI clinics who reported they were interested in future research studies

Appendix B: Interview Guide

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Internet STI/HIV Testing: Informed Consent – One-on-One Interview Guide

Note: The following is an outline of proposed topics and questions to be asked during one-on-one interviews. The precise content of the interview guide will be determined iteratively throughout the development of GetCheckedBC. During the interviews, this will be used not as a “script,” but as **guide**. Thus, the format of the interviews will allow for natural patterns of conversation to emerge, encouraging open and genuine dialogue around the topic of providing informed consent through an online service delivery model.

Opening: Participant will be welcomed. The interviewer will describe the purpose and scope of the interview. Items from the study consent form (e.g., confidentiality, voluntary nature of the interview, right to pass on any question, etc.) will be reviewed and discussed as needed.

Item	Question	Objective
	I'd like to talk to you about the consent page that you saw during your usability testing for GetCheckedBC. Now that you've walked through the website, please try to imagine that you are now using the GetCheckedBC service yourself, or how you think someone else may respond to it. <i>Present print-out (or screen shot) of consent page from usability testing session.</i>	
1	What was your first impression when the page was displayed to you on the website? <i>(probing question)</i> How did you feel when you were asked to select each statement in agreement? <i>(probing question)</i> How much time did you spend at this page when exploring the website?	Gauge initial reaction to consent page/process
2	Did you read through all of the questions? If no, which questions did you skip over and why?	Determine if consent questions read, and reasons why not
3	Were any of the questions surprising to you? If so, which were surprising and why?	Identify questions which are confusing, problematic, superfluous, etc. (which require revision/reconsideration)
4	Were any of the questions familiar to you? If so, where have you heard them or been asked them before?	
5	Were there any questions that you did not understand? If so, which ones? Please explain.	

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6	Why do you think that these questions were asked? <i>(probing question)</i> Do you think they are important? <i>(probing question)</i> Who do you think they are important for?	Assess how user conceptualizes the consent process (e.g., is it consistent with clinical expectations around informed consent?)
7	Were there any questions that you thought were not necessary / not important? Which ones? Please explain.	Similar objective as Q3-5; also assess perspective on aspects of consent criteria that are of value to the user
Typically, with an in-person clinic visit, a healthcare provider will discuss the process, risks and benefits of testing, and what will happen once you receive your results. They will also be able to answer your questions and make recommendations for future tests or assist you with any supports you may wish to pursue. Using this practice as a reference point, I'd like to ask you about how well you think these discussions can be achieved in the online setting, and how we can ensure that you, as the user, understand all of the necessary information before getting a test.		
8	Can you think of some reasons why people may wish to test online instead of in-person through a doctor or nurse?	
9	Do you think the same standards of consent should apply in an online model for testing compared with a clinical model? Why or why not? <i>(may need to explain "consent" to participant if they are unclear)</i> <i>(probing question if necessary)</i> Do you think consent is necessary for a voluntary online testing service?)	Describe users' expectations in terms of translating in-person consent requirements to an online setting
10	Do you feel that you received sufficient information throughout the website pages (or could identify where to find the information) in order to answer the consent questions before printing your lab requisition? (if no, which questions may need to be better explained or have more information in the relevant sections of the website?)	** KEY QUESTION Assess whether user can adequately identify necessary online pre-test information to provide informed consent before testing
11	Did any of the questions, or the consenting page in general, cause you to reconsider your choice to pursue online testing? If yes, please describe.	Evaluate whether any items on consent page pose barriers to users

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12	Were there any questions that you would have liked to have asked that weren't addressed throughout the site pages? If you had a question to ask before proceeding with your online testing requisition, was it indicated how you could do so?	Identify areas where pre-test information or online testing process is lacking or confusing
Now to finish up our discussion, I'd like to ask for some feedback regarding the layout/design of the consent page in the site. Please remember that we are still developing this model, and we've invited you here to help with that, so don't be shy in telling us if there are things that you don't like or don't think will work.		
13	What are your first impressions of the design of this page? What aspects do you like/dislike?	Gauge impressions of layout of consent page
<i>Present mock-ups of alternative designs for consent page</i>		
14	Would either of these design ideas be more appealing to someone who may use this service? What aspects of these do you like/dislike?	Assess appeal of alternative designs
15	Do you have any suggestions for how we can encourage potential clients to read the information on this page? (suggestion if prompting needed: color, layout, hyperlinks)	
16	Is there anything that we've missed in our discussion today? Is there anything that has come to mind that you've wanted to say but didn't get a chance to say?	Final question
E	Thank participants, provide honoraria and have them sign receipt, remind of contact info found on study consent page if they wish to provide further feedback	