CHUM

APPROUVÉ – CÉR CHUM

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INITIALES: YP

INFORMATION AND CONSENT FORM - USERS

Project Title : PHARMA-C Study: Community Pharmacy Screening for Hepatitis C

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Financing: **The project is not financed, but the testing material was obtained from Gilead Sciences Inc. and an AbbVie grant was received for the training of pharmacists.**

CHUM Project Number : **21.326**

INTRODUCTION

We are seeking your participation to conduct a community pharmacy screening for hepatitis C. Before agreeing to take part in this project and signing this information/consent form, please take the time to read, fully understand and consider the following information.

This form may contain words that you do not comprehend. We encourage you to ask your pharmacist any questions you may have and have them explain any words or information that is not clear.

NATURE OF THE PROJECT AND ITS OBJECTIVES

The hepatitis C virus causes an infection of the liver that can be transmitted mainly through blood (when sharing injection equipment, blood transfusions in some countries, non-sterile tattoos, high-risk sexual relations, etc.).

The infection is often symptomless, meaning that a person can be infected without experiencing any specific symptoms. Because of the absence of symptoms, many people will not be tested and will not know that they are infected. In the long term, severe health problems (cirrhosis, liver cancer) can occur if the infection is not treated.

It is therefore very important to detect hepatitis C and, above all, to treat it in order to avoid further complications.

Pharmacists in the community are valuable collaborators with physicians and try to make the best contribution to sustain health.

We found that screening was often late and deprived people of the opportunity to get treatment quickly to avoid complications. In this regard, the CHUM team of research pharmacists recruited pharmacists in Quebec. These collaborating pharmacists must then recruit users who wish to be tested for the hepatitis C virus at the pharmacy.

The test used to screen users is a small amount of blood taken from the tip of your finger (similar to measuring blood sugar levels). It has been approved by Health Canada since 1997 and has been shown to be over 98% effective in detecting hepatitis C. The result is available in 20 minutes. In the event of a positive result, it is important that your doctor be informed and be able to suggest a treatment to reduce or avoid any possible health problems.

The purpose of this project is to assess the feasibility of community pharmacy screening for hepatitis C and to contribute to the eradication of hepatitis C in Quebec, in line with the World Health Organization's objectives.

DURATION OF PARTICIPATION

The CHUM research team plans to involve a large number of pharmacies in Quebec to screen at least 500 people. In total, the project should last 12 months and your participation should require about 30 minutes of your time (no more than 60 minutes).

NATURE OF PARTICIPATION REQUIRED

If you agree to participate in the study, and after signing this form, you commit to:

- Performing the OraQuick® HCV test
- Ideally, we ask that you wait for the test result at the pharmacy (or ensure a method of communication to reach you and notify you of the result)

- Filling out a very short questionnaire about your appreciation of the testing service offered at the pharmacy (the questionnaire is available in paper form or online, depending on your preference).

PROJECT FLOW/PROCEDURES

The pharmacist has identified you as a potential hepatitis C candidate because he/she believes you have potential risk factors for hepatitis C infection.

If you have agreed to participate in the screening test, here is what will happen.

The pharmacist will see you at the pharmacy consultation desk. He or she will collect some of your information, such as your name, address, email, phone number, age, gender, country of origin, whether you have had a hepatitis C antibody test in the past, why you are being tested for hepatitis C at the pharmacy, the result of the hepatitis C test at the pharmacy. Moreover, the pharmacist will assign you a research participant code.

You must choose the best time to get tested (this can be done with or without an appointment, depending on your availability and that of the pharmacist).

The testing will be done as follows: the pharmacist will explain the procedure and will use the OraQuick® HCV test, which consists of taking a drop of blood from one of your fingertips. The pharmacist will collect the drop of blood with a swab and mix it with a solution. A small hepatitis C testing device will then be inserted into the solution (in which your blood has been mixed). It is this screening device that will reveal the presence or absence of hepatitis C antibodies in your blood.

You will have to wait for the results of the test, which should be available within 5 to 20 minutes.

During that time, the pharmacist could take a few minutes to discuss with you preventive measures related to your lifestyle.

If the test result is positive, you will need to authorize us to forward the result to your doctor. The pharmacist will also give you a copy of the test result, whether it is positive or not.

You should be aware, however, that hepatitis is a reportable disease and your pharmacist will have to report it to the appropriate public health authorities.

If you have not been able to wait at the pharmacy for the result, the pharmacist will try to reach you according to the contact information you have provided. If he/she cannot reach you, the pharmacist involved in this study may contact your attending physician or the person(s) you have designated to inform them of the result.

You will be asked to complete a short questionnaire about your experience with the hepatitis C screening test performed in pharmacy.

YOUR RESPONSIBILITIES AND IMPORTANT PRECAUTIONS THAT MUST BE TAKEN

By signing the consent form, you commit to:

- Get tested for hepatitis C.
- Wait for the results of the pharmacy screening test or ensure a reliable method of communication.

- Fill out the questionnaire about your experience with Hepatitis C testing in a pharmacy

RISKS AND DISCOMFORTS

You may feel a little pain when you get the needle in your fingertip. You may also feel some anxiety before receiving the test result or after a positive result.

A positive test result does not necessarily mean that you are sick. It means that your body has already encountered the virus. It could be a past infection that has been resolved. The pharmacist will then refer you to your doctor or a clinic to confirm the result with a blood test.

Your pharmacist will listen to your concerns and can answer all your questions.

You can refuse to answer a question, refuse to continue the screening test or even terminate your participation at any time.

RISKS OF CONFIDENTIALITY BREACH

There may be a greater risk of confidentiality breach if you use your personal email address to communicate with a member of the study team. Unsecured email is not a safe method of communication. The content of an unsecured email can be seen by anyone with access to your email account and/or the device you use to send it.

RISKS ASSOCIATED WITH PREGNANCY

Pregnant women cannot participate in the study because the OraQuick® HCV test has not been validated for this population. However, the test is still safe for the female or the fetus. Any woman of childbearing age who wishes to participate in the research project must confirm with the pharmacist if she is pregnant. If she is pregnant, she will not be able to participate in the project.

BENEFITS

By participating in this project, you will help advance the implementation of the hepatitis C screening program in pharmacies. This will potentially improve the accessibility of this screening to all Quebecers in the future and possibly contribute to the elimination of hepatitis C.

There are medications that are easily administered and completely cure the disease within a few weeks.

CONFIDENTIALITY

During your participation in this study, the research team will collect, in a research file, your personal information that is required to meet project objectives.

Only the research team and your pharmacist will know your identity. Your first and last name will only be included in the signed consent form. The following information will be collected by the pharmacist: your age, gender, country of origin, reason for testing, whether you have any ongoing risk factors for Hepatitis C, current and past Hepatitis C test results, if applicable. You will be assigned a unique code. All of this data will be de-identified (i.e. your first and last name will be kept in separate files from the data that will be analyzed).

In addition, the result of the screening test will be kept in your file at the pharmacy. Your file is only accessible by the pharmacy team.

If the result of the screening test at the pharmacy is positive, it must be reported to public health because hepatitis C is a notifiable disease. Afterwards, you will be asked to have a blood test to confirm the result of the screening test done in the pharmacy. This blood test can be done by a nurse in a hospital, clinic or CLSC. If the blood test confirms that you have hepatitis C, you will be referred to a physician who will be able to do a complete evaluation and initiate treatment.

Your pharmacist will forward the data collected to the research team. The data collected and the signed consent forms will be kept in a safe place at the CHUM Research Centre. The researchers responsible for this project will not share your data with anyone. This research data will be kept for at least 10 years after the end of the study by the researchers in charge of this study.

The research data may be published or discussed scientifically, **but you will not be identified.**

REPORTING THE OVERALL RESULTS

The results of this study will be made available to you if you request them from the researcher in charge at the end of the study. You can make this request at the following e-mail address: pharmac.vhc.chum@ssss.gouv.qc.ca.

PROJECT FUNDING

This is a not-for-profit project. The OraQuick® HCV tests were obtained from Gilead Sciences Inc. either through the *Testing Program points of service* or through grants to cover only the acquisition costs.

Collaborating Pharmacists will receive free training through the AbbVie educational grant to properly equip and train them.

These companies have no role in the design and conduct of the study (collection, management, analysis, interpretation of data; preparation, review or approval of the manuscript). They therefore have no influence on our decisions or on future decisions in providing care for a user who has a positive screening test.

COMPENSATION

You will not receive financial compensation for your participation in this research. However, the pharmaceutical service and the screening test will be provided free of charge.

IN CASE OF HARM

By agreeing to participate in this research project, you do not waive any of your rights and you do not release the researcher responsible for this research project, the pharmacist and the institution from their civil and professional liability.

VOLUNTARY PARTICIPATION AND RIGHT OF WITHDRAWAL

Your participation in this project is entirely voluntary. You are therefore free to refuse to participate. You may withdraw at any time to ensure that your data is not included in our publication.

If you wish to withdraw, contact your pharmacist. The research team will destroy the data associated with your assigned unique number.

IDENTIFICATION OF CONTACTS

Please refer to your pharmacy's opening hours to verify staff availability.

If you have any questions about your rights as a participant in this study or if you have any complaints or comments, you can contact your pharmacist directly, the research team by e-mail (pharmac.vhc.chum@ssss.gouv.qc.ca) or the CHUM's local service complaints and quality commissioner at 514-890-8484.

APPROVAL BY THE RESEARCH ETHICS COMMITTEE

The CHUM Research Ethics Committee has given its ethical approval to the research and will ensure its follow-up.

SIGNATURE

I have read the information and consent form. The research project and this information and consent form have been explained to me. My questions have been answered and I have been given sufficient time to make a decision. After consideration, I agree to participate in this study under the conditions stated in this form.

I authorize the study pharmacist to inform my assigned physician of my participation in this project and to provide him/her with any relevant information (including the result of the hepatitis C test, whether negative or positive):

❑ Yes ❑ No

Name and details of assigned doctor:

Details:

I agree that the person listed below may be contacted by my study pharmacist to follow up on my health status if I cannot be reached:

❑ Yes ❑ No

Name and details of contact person:

Details:

Name (in printed form)	Signature of participant	Date

SIGNATURE OF PERSON OBTAINING CONSENT, IF DIFFERENT FROM THE RESEARCHER IN CHARGE OF THE RESEARCH - COLLABORATING PHARMACIST

I have explained the proposed research and this information and consent form to the participant and have answered the related questions he/she has asked me. I agree with the research team to respect what has been agreed upon in the information and consent form and to give a signed and dated copy to the participant.

Name (in printed form)	Signature of person obtaining consent (collaborating pharmacist)	Date

RESPONSIBLE INVESTIGATOR UNDERTAKING - SIGNATURE UPON RECEIPT OF FORM SIGNED BY USER AND COLLABORATING PHARMACIST

I certify that this information and consent form has been explained to the participant and that any questions the research subject had have been answered.

Name (in printed form)	Signature of responsible researcher	Date