Assessing Dyspnea using Virtual Care during COVID-19 Pandemic (ADViC2) Research Study: Participant Consent Form

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Introduction:

You are invited to participate in a research study today. The purpose of this study is to investigate "The Roth Score", a new way to evaluate for shortness of breath using virtual care. This method may have the potential to approximate oxygen saturation, which is traditionally measured using a pulse oximeter. Your participation must be free and voluntary. You are free to stop this call and withdraw your participation at any time without providing a reason. You can ask to have your data removed from the study until we remove the linkage between your identification and your data, which will happen after we completed the 2nd study encounter approximately 7-10 days from today. Please be aware that this is a research study and the researchers are not providing you with health care services. We are contacting you today because we received a referral for you as part of the self referral process outlined in the study procedure below.

Background:
Telemedicine, or Virtual Care, is an evolving field that allows clinicians to provide care to patients in situations where an in-person assessment is not feasible or desirable. Due to the COVID-19 pandemic, many primary care clinicians (Family Physicians, Nurse Practitioners, Registered Nurses) are assessing their patients using telemedicine. Unfortunately, there is a lack of evidence-based clinical tools in supporting clinicians assessing patients virtually.

You are invited to participate in this research by phone or via an online platform called Doxy.me. You will be asked questions about your personal medical history, and then asked to perform the Roth Score, which is described below. The first visit will take approximately 30 minutes of your time, and the second visit will take approximately 15 minutes of your time. This research will likely take place within the comfort of your own home, or wherever you are safe to have a conversation when we contact you.

The research team consists of multiple people, who will have access to the data we collect from you. Please see the section above for details about our research team.

Inclusion and Exclusion Criteria:

1. <u>Inclusion Criteria</u>
    a. An adult (≥19-year-old) patient with shortness of breath possibly due to a respiratory reason.
    b. The participant has a healthcare encounter that documented the SpO_2
    c. The participant can provide informed consent.
    d. The participant can engage in assessments via a virtual care platform (i.e. has the appropriate equipment and technical skills, or has assistance from others).

2. <u>Exclusion Criteria</u>
    a. Anyone unable to provide informed consent.
    b. Anyone whose attending clinician or nurse feels they are not stable/well enough to participate in the study or require emergent transfer to a higher level of care.
    c. Anyone who has a chronic impairment (e.g. dysarthria, severe stuttering) that affects their ability to comprehend the researcher's instructions and perform the task required for a Roth Score assessment even at baseline.
    d. Anyone who has known congenital heart disease.
    e. Anyone pregnant.

f. Anyone who has an active cancer diagnosis
g. Anyone unable to engage in assessments via a virtual care platform (i.e. lacks the appropriate equipment and technical skills).
h. Anyone who is confirmed or suspected to have COVID-19.

Procedure:

A. Your clinical visit (this is how prospective participant are getting recruited to the study)

- If the nurse/clinician believes you to be a suitable fit for the study, the nurse/clinician will hand the information sheet to you and write your oxygen saturation number on it;
- Your nurse/clinician may also ask you to count from 1 to 30 in one breath (this step is optional);
- There are no identifiers on the information sheet, only the Sp02 number and the highest number you counted to
- You then calls or texts the research team directly via the information on the information sheet;
- If you are not interested in participating in the study further – you can recycle the information sheet;
- All further activities are done directly with the study team, and all other consent/information is collected directly from you (the participant).

B. Initial visit (approximately 30 minutes of your time)

Two members of our research team will contact you separately within two hours of your self referral to our study. You will be contacted via telephone first, and then provided with instructions on how to sign into our video telehealth platform. We will be collecting the following personal information from you: first name, age, sex, current location, past medical history, answers to a breathlessness scoring scale, your oxygen level (SpO2) and results of the Roth Score we will ask you to perform. To perform the Roth Score, you will be asked to take a deep breath in, and count from 1 to 30 in your native language as quickly as possible. Our team members will be documenting how long it takes for you to count to 30, or how long until you need to take your next breath. We will ask you to repeat this a second time once you have taken three deep breaths. We will compare the results of the Roth Score to your oxygen saturation level documented by your clinician.

C. Follow-up visit (approximately 15 minutes of your time)

One of our team members will contact you within 7-10 days following the initial study visit. There will be only one follow-up visit. Our research team members want to know whether or not you have had any additional clinical encounters for the same concern that you had with the original clinical encounter. If yes, we would like to know details about the additional clinical encounter including: location, setting (e.g. primary care, emergency room), and date and time. We will also ask you if you needed to be admitted to hospital, encountered any negative outcomes, or were tested for COVID-19 since your appointment with your primary care clinician.

Potential Harms:

You may experience worsening of your symptoms (e.g. shortness of breath, dizziness, or cough) during our initial study visit. The amount of discomfort is not expected to be out of proportion to other clinical maneuvers, such as taking a deep breath in to listen to your chest. We do not expect any significant negative outcomes during study.

You have the option to stop participating in the study at any time if you are feeling uncomfortable and/or experiencing any symptoms. You do not have to answer any questions that you are uncomfortable answering.

Potential benefits:
The results of our study may provide more evidence to assist primary care clinicians optimize the way they provide virtual care/telemedicine to their patients.

Confidentiality and Privacy :
We are taking numerous steps to ensure your confidentiality. The information we collected today will be stored in a secure research database. Any identifying information linking you to your data will be permanently destroyed after the follow-up visit in about 14 days.

To use doxy.me our research assistant will provide you the study doxy.me web address. You will enter this into your internet browser to start your session. You will not need to register, login, or download anything, but you will need to provide your name and check in for your appointment, and allow your browser to use your webcam and microphone (having a webcam and microphone is a criteria of participation).
• Doxy.me states that they do not store patient data.
• Doxy.me does not record any video or audio calls or save any chat messages at any time for any reason.
• Doxy.me may collect by itself or through third parties: Cookies; IP addresses; domain names of the computers utilized by the users; URL addresses and other Usage Data; unique device identifiers for advertising (Google Advertiser ID or IDFA, for example).
• The Data collected by doxy.me is processed at their operating offices outside of Canada. As such, there is a possibility that information about you that is gathered may be accessed without your knowledge or consent by the U.S. government in compliance with the former Patriot Act (now the USA Freedom Act).

Unless you are currently in an ambulatory site of a healthcare facility (e.g. emergency department), we will be collecting the address of your current physical location for safety precaution. The address of your current physical location will be kept on a transitory note without any identifying information. The transitory note will then be destroyed immediately after the call. All study data will be held in Canada and never transferred outside of Canada. By consenting, you have not waived any rights to legal recourse connected to research-related harm. If you do decide to participate and then change your mind later, you can withdraw without any consequences or explanation. If you do withdraw from the study, we will ask you if we can still use your collected data. The data that we collect about you will be anonymized, that is we will have no way to find out which are your data, after the follow-up visit in about 14 days. Therefore, we will not be able to remove your data after that point.

Project Results:
We hope to share the results of this project with the medical community in a peer-reviewed journal. No identifying patient information will be included in the journal article. If interested, you will be able to read about the results of the study from this article.

You have the right to exit the research at any time for any reason. Participating in this study does not waive any of your legal rights to research related harm.

Please indicate your agreement with the following:

- ☐ I have read and understood the information in this consent form.
- ☐ I have been able to ask questions and have had satisfactory responses to my questions.
- ☐ I understand that my participation in this study is voluntary.
- ☐ I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- ☐ I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- ☐ I understand that there is no guarantee that this study will provide any benefits to me.
- ☐ I authorize access to my health information as described in this consent form.
- ☐ I consent to participate in this study.
- ☐ A copy of this consent form is available at http://advicstudy.ca

By providing a verbal consent and continuing with the study encounter, I am providing my consent to participate in this study.