Western Medicine&Dentistry
Division of Emergency Medicine
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Title of Project: Calibration and Validation of Low-Cost 3D Printed Pulse Oximeter

Principal Investigator: Dr. Tarek Loubani, MD, CCFP (EM)

Co-Investigators: Dr. Melanie Columbus, PhD, Mrs. Kristine Van Aarsen, MSc

Background & Purpose

You are invited to participate in a research study to validate a low-cost 3D printed pulse oximeter. A pulse oximeter is a sensor device placed on the finger to measure oxygen levels in the blood. All healthy, non-smoking adults over the age of 18 are eligible to participate in this study. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to understand why the study is being conducted and what it will involve. Please take the time to review it carefully and feel free to ask questions if anything is unclear or there are words/phrases that you do not understand.

The purpose of this study is to calibrate and validate a low-cost 3D printed pulse oximeter that measures oxygen levels in the blood.

Calibration is the process by which data is collected from a pulse oximeter and another method (blood sampling from your artery) so that the raw data from the pulse oximeter can be translated into clinically usable values (percent of oxygen in a patient).

Validation is the process by which the calibration process is checked to ensure that the end-result (the oxygen values) are accurate when compared to a gold standard device.

Measurements from the experimental pulse oximeter will be compared to a gold standard – the pulse oximeter currently used in the emergency department at London Health Sciences Centre (LHSC). The experimental pulse oximeter can be manufactured at a fraction of the cost of currently employed devices and may be a cost-effective alternative for hospitals and clinics in both the developed and developing worlds.

You are being asked to help calibrate a new low-cost 3D printed pulse oximeter. This means that the data taken from you will be used to calculate equations that will translate the pulse oximeter's raw data into clinically useful values. Your participation in the study involves completion of the study protocol. All study procedures will be conducted in the emergency department at Victoria Hospital and University Hospital at LHSC by an experienced emergency physician (EP). 50 participants will be recruited in order to calibrate the 3D printed pulse oximeter.

You will have an arterial catheter (a plastic tube that looks and behaves like an IV tip) inserted into the radial artery of your wrist by the EP for accurate blood oxygen level measurements. This procedure is just like putting in an intravenous line, but into one of your arteries. Risks include pain at the wrist or temporary problems with blood

supply to the hand. Two blood samples will be taken at the beginning of the study. The experimental, 3D printed pulse oximeter will then be placed on your finger in addition to a pulse oximeter currently used at the hospital on a different finger on the same hand. Readings from both of these devices will be compared under different oxygen conditions. You will then be fitted with a breathing mask which will deliver a mix of nitrogen and oxygen at progressively different ratios under careful monitoring by the EP. Blood oxygen levels will be measured until a pulse oxygen saturation of 70% is achieved. Approximately two milliliters of blood (half a teaspoon) will be drawn for every 5% drop in blood oxygen saturation from 100% to 70% up to a maximum of 20milliliters (4 teaspoons). If you experience chest pain, low blood pressure, fast heart rate, unstable vitals or become symptomatic, we will discontinue the experiment and restore normal oxygen saturation levels immediately. The EP will be monitoring you closely, and you will be placed on monitors that follow your heartrate through stickers on your chest and your blood pressure using a blood pressure cuff. Once the endpoint has been reached, normal oxygen levels will be restored. Arterial blood samples will be drawn and oxygen saturation will be measured throughout. This study takes approximately 60 minutes to complete. This phase of the study will require approximately 50 volunteers.

This study is part of an unfunded research project being under taken by Dr. Tarek Loubani of Western University. Should you require any further information, please feel free to contact: Dr. Tarek Loubani (tlouban@uwo.ca), Carrie Wakem (carrie.wakem@lhsc.on.ca) or Melanie Columbus (melanie.columbus@lhsc.on.ca) at 519-685-8500 ext 55014.

Risks & Benefits

Risks associated with this study include pain and discomfort during the catheter insertion process. You may also experience low blood pressure, increased heart rate, chest pain, become symptomatic, or reach a pulse saturation of 70%. Risks of catheterization include temporary occlusion of bloodflow from that artery (there is another artery that supplies the same area) (19.7%); bruising; bleeding (0.53%); and, rarely, minor infection (0.72%) or major infection (0.13%). You will be assessed for any of these complications by the EP and treated accordingly in the emergency department if there are any injuries related to this study.

You may not benefit personally from the study. Participation in this study will not impact your clinical course, academic status or employment. Results of this study may benefit society by validating a low-priced pulse oximeter whose design is freely available which may impact emergency rooms in both the developed and developing worlds. You will not be compensated for your participation in this study.

Participation in this study is voluntary. You may refuse to participate or withdraw at any point in the study without impact on your clinical course, employment or academic status. If you withdraw, any data collected may also be withdrawn at your request.

Confidentiality

Your results will be stored in a locked cabinet in a secure office, will be viewed only by members of the research team, and will be destroyed at the completion of this study. If the results of this study are published, your name will not be used and no information that discloses your identity will be released or published. You do not waive any legal rights by participating in this study. Data will be retained for a period of 15 years after publication in a secure place, after which time it will be disposed of in a secure manner (e.g. shredded or electronically deleted).

Qualified representatives of the following organizations may look at the study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).
Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of the University of Western Ontario Health Sciences Research Ethics Board that oversees the ethical conduct of this study

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute, (519) 667-6649

Should you require any further information, please feel free to contact: Dr. Tarek Loubani (tlouban@uwo.ca), Carrie Wakem (carrie.wakem@lhsc.on.ca) or Melanie Columbus (melanie.columbus@lhsc.on.ca) at 519-685-8500 ext 55014.

Thank you,

Dr. Tarek Loubani, MD, CCFP (EM)
Assistant Professor
Schulich School of Medicine and Dentistry
Western University

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Consent to Participate

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I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

_____	_____	_____
Participant Signature	Participant Name (Printed)	Date

_____	_____	_____
Signature of Person Obtaining Informed Consent	Person Obtaining Informed Consent (Printed)	Date