

**Feasibility of obtaining pulse oximetry readings from the
oropharynx**

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	1/5/2024	6.0 – addition of baseline data collection	No
2	4/2/2024	Changing this to a multi-center study to add OU summer research student	No

1.0 Study Summary

Study Title	Feasibility of obtaining pulse oximetry readings from the oropharynx
Study Design	Prospective, non-blinded comparative study
Primary Objective	To compare pulse oximetry readings from an oximeter on a finger to those obtained from an oral airway or a tongue blade with a pulse oximeter probe attached.
Secondary Objective(s)	To compare the pulse oximetry reading (oxygen saturation) with that obtained from an arterial blood gas (measured by co-oximetry).
Research Intervention(s)/ Investigational Agent(s)	There will be no change in anesthetic management or use of investigational pharmacological agents.
IND/IDE #	None
Study Population	Patients scheduled for a surgical procedure that requires invasive monitoring of arterial blood pressure (placement of an arterial cannula).
Sample Size	100
Study Duration for individual participants	60 minutes
Study Specific Abbreviations/ Definitions	SpO ₂ = oxygen saturation ABG = arterial blood gas

2.0 Objectives

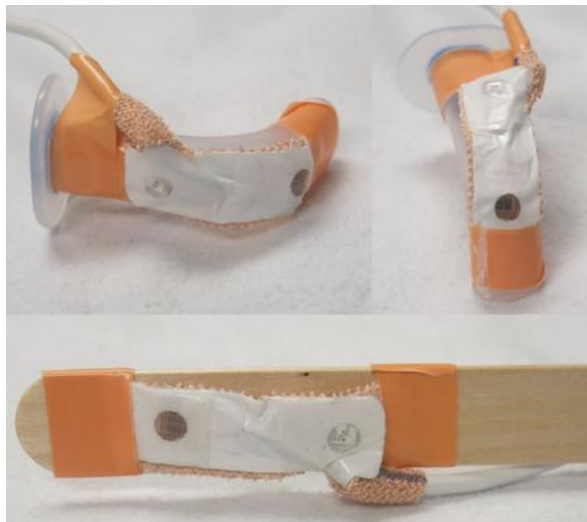
- 2.1 The primary objective of this study is to evaluate the feasibility of obtaining a pulse oximetry reading from the oropharynx with a standard oximeter probe that has been attached to an oral airway or a tongue blade.
- 2.2 The secondary objective is to compare the pulse oximetry reading (oxygen saturation) with that obtained from an arterial blood gas (measured by co-oximetry).

3.0 Background

- 3.1 Pulse oximetry is non-invasive monitoring technology that allows the continuous assessment of oxygen saturation (SaO₂) in the arterial bed. It has become a standard of care to monitor oxygenation and assess respiratory function in patients in various clinical settings including the operating room and the ICU.¹⁻³ Pulse oximetry estimates arterial oxygen saturation by measuring the differential absorption of light at 2 wavelengths (660 nm and 940 nm) in human tissue beds.⁴ In routine clinical practice, the pulse oximeter probe is wrapped around a finger or toe. As the presence of pulsatile flow is necessary for effective functioning of the pulse oximeter, absent or inaccurate readings may be obtained

during low perfusion states, which may occur during shock, critical illness, or other comorbid conditions.

- 3.2 Patient or monitor-related issues may interfere with the ability to obtain a plethysmograph and accurate readings from the pulse oximeter include motion artifact, interference from ambient light or skin pigmentation, hypothermia, peripheral vasoconstriction, low perfusion, or decreased cardiac output.⁵⁻⁸ To overcome such problems, novel pulse oximeters have been developed and technology improved to allow for more accurate measurements in the presence of low perfusion states, vasoconstriction, and during patient movement. Additionally, various alternative sites have been evaluated for pulse oximetry including the nasal ala, earlobe, and forehead.⁸⁻¹¹ While these alternative sites especially the forehead may be effective during low perfusion states, extensive burns or scarring may preclude their use, other investigators have suggested the possibility of using the oropharynx, larynx, trachea or esophagus for oximetry.¹²⁻¹⁶ These sites may offer advantages given the maintenance of perfusion in these areas during low perfusion states.
- 3.3 Given the need for continuous assessment of oxygenation in these critically ill patients and clinical scenarios, alternative sites for measurement of pulse oximetry may be needed to provide optimal care. We have recently had anecdotal clinical experience in two challenging patients, one with peripheral vasoconstriction and a low cardiac output state and another with lack of access to a routine monitoring site (finger, toe, ear or nose) due to extensive burns that impeded our ability to use pulse oximetry. To allow for pulse oximetry monitoring, we used a pulse oximeter attached to an oral airway in one patient and to a tongue blade in another to allow for clinical care (figures 1). In both patients, the pulse oximetry functioned but we were not able to compare it to a peripheral value.



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15. Pal SK, Kyriacou PA, Kumaran S, Fadheel S, Emamdee R, Langford RM, Jones DP. Evaluation of oesophageal reflectance pulse oximetry in major burns patients. *Burns.* 2005;31:337-41.
16. Brimacombe J, Keller C, Margreiter J. A pilot study of left tracheal pulse oximetry. *Anesth Analg.* 2000;91:1003-6.

4.0 Study Endpoints

- 4.1 The primary endpoint is comparing pulse oximetry readings from an oximeter on a finger to those obtained from an oral airway or a tongue blade with a pulse oximeter probe attached.

- 4.2 The secondary endpoint is comparing the pulse oximetry reading with that obtained from an arterial blood gas.

5.0 Study Intervention/Investigational Agent

- 5.1 The only novel intervention is the use of the pulse oximeter in the oropharynx on either an oral airway or a pulse oximeter. No change in the anesthetic technique will be required during the study. As a single ABG is required, the study will include only patients scheduled for a surgical procedure that requires invasive monitoring of arterial blood pressure (placement of an arterial cannula).

6.0 Procedures Involved*

- 6.1 This is a prospective study that will compare the values from the peripheral pulse oximeter on a finger, toe, foot or hand with the that from the oropharyngeal oximeter. We will also compare the saturation from the ABG with that obtained from the oropharyngeal oximeter.
- 6.2 The study cohort will include patients requiring anesthetic care and in whom an indwelling arterial cannula will be placed for the surgical procedure. The arterial cannula will not be placed for the purpose of the study. A standard pulse oximeter will be placed on an extremity and the oropharyngeal on a tongue blade or oral airway will be placed into the oropharynx. An ABG will be obtained and the saturations from the two pulse oximeters noted at the time the ABG is obtained. Additionally, the saturations from the two oximeters will be recorded every 2 minutes for 30 minutes (total of 15 pairs of values). After that time, the oropharyngeal oximeter will be removed.
- 6.3 Along with the oxygen saturations and ABG results, the following baseline information will be collected from EPIC: DOB, height, weight, BMI, sex at birth, ASA status, race, ethnicity, surgical procedure, and comorbidities.
- 6.4 Regardless of the sites that they are placed, there is a very low risk of a minor burn from the pulse oximeter. As the oropharyngeal oximeter will be in place for only 30 minutes, we believe that the risk is very low or non-existent.
- 6.5 The saturation values from the two oximeters as well as the ABG value will be recorded on a data sheet in the operating room. The research team will transfer the data to REDCap.

7.0 Data and Specimen Banking*

- 7.1 There are no plans to bank data for future use.

8.0 Sharing of Results with Subjects*

- 8.1 Results will not be shared with subjects.

9.0 Study Timelines*

- 9.1* An individual study subject's participation in the study should last no more than 1 hour. All study subjects should be enrolled with 1 year of the start of the study. The study data will be analyzed, a manuscript written, and the study completed within 12 months of the end of the study.

10.0 Inclusion and Exclusion Criteria*

- 10.1* Individuals will be screened for eligibility by reviewing the surgery schedule in EPIC and speaking with the attending anesthesiologist.
- 10.2* Inclusion criteria: ASA 1-5 patients undergoing a surgical procedure with general anesthesia and requiring an invasive arterial cannula.
- 10.3* Exclusion criteria:
- Patients in whom an arterial cannula is not indicated for the surgical procedure
 - Patients in whom a peripheral pulse oximeter value cannot be obtained
 - Patients in whom an invasive arterial cannula cannot be placed
 - Patients with any type of intra-oral pathology or injury
 - Patients in whom access to the oropharynx is restricted or not feasible for any clinical reason

11.0 Vulnerable Populations*

- 11.1* We will include children, but will not include any other vulnerable population.
- 11.2* The subjects will not be exposed to greater than minimal risk.
- 11.3* Parents/legal guardians will be asked to sign informed consent and children over the age of 9 years will provide assent.

12.0 Local Number of Subjects

- 12.1* 100 patients.

13.0 Recruitment Methods

- 13.1* Potential subjects will be recruited in the surgical preoperative area on the day of the surgery. The research team will contact the guardian/parents and obtain written consent. Written assent will also be obtained from age appropriate patients.
- 13.2* The patients to be recruited are those who are scheduled for surgery under general anesthesia in the NCH operating rooms.
- 13.3* Using EPIC, the research team will check the patients scheduled for planned surgery in the NCH operating rooms.
- 13.4* Subjects will not be paid.

14.0 Withdrawal of Subjects*

14.1 Although there are no anticipated circumstances under which subjects will be withdrawn from research without their consent, the PI can withdraw subjects if deemed necessary

15.0 Risks to Subjects*

15.1 Although not likely, there may be a potential risk for breach of patient health information. All study related procedures are non-invasive; however, when used in clinical practice there have been rare reports of minor burns from the use of pulse oximetry at any site.

16.0 Potential Benefits to Subjects*

16.1 There are no direct benefits to the subjects.

17.0 Data Management* and Confidentiality

17.1 Statistical analysis and data presentation will include a calculation of the absolute difference of the pulse oximetry values of the two devices in comparison to each and in comparison to the saturation from the ABG.

17.2 Research records will be stored in a locked cabinet and password protected computer. Only certified research personnel will be given access to identifiable subject information.

17.3 Following publication of study results, research records will be stored for a period of 6 years after study closure and then will be destroyed by placing in a secure shredding bin.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 The study will be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

20.0 Compensation for Research-Related Injury

20.1 Not applicable.

21.0 Economic Burden to Subjects

21.1 There will be no costs to the subjects.

22.0 Consent Process

- 22.1 The consent process will begin in the preoperative surgery unit on the day of surgery, by PI, sub-investigators, study coordinators, and/or trained research staff.
- 22.2 The study will be thoroughly explained to the patient and their family. There will be ample time allotted for questions and answers. An explanation of voluntary participation will take place, and the family will be asked if they are interested in participating in the study. If the patient and their parent(s), or legal guardian agrees to participate they will be asked to sign consent and assent form. The patient will then be enrolled in the study with the understanding that they can elect to stop the study and be withdrawn from the study at any time.

23.0 Process to Document Consent in Writing

- 23.1 We will be following “SOP: Written Documentation of Consent (HRP-091).”

24.0 Setting

- 24.1 Potential subjects will be identified from the surgery schedule in Epic and recruited from the pre-op area of the surgery unit.
- 24.2 Research procedures will be performed in the operating room during anesthetic care.

25.0 Resources Available

- 25.1 We will need approximately 20 minutes per patient to explain the research protocol, obtain consent, and enroll patients. The Department of Anesthesiology & Pain Medicine has 2 research coordinators/RNs and 4 research associates who will be enrolling subjects for this study. All study staff will be trained regarding the study procedures. Before the study starts, the involved personnel will be informed by e-mail and during a pre-study meeting about the study protocol, the research procedures, research member’s duties, and functions.

26.0 Multi-Site Research*

- 26.1 NCH IS participating in multi-site research.
- 26.2 OU will be a relying site solely for the purpose of adding their medical student as study staff for the summer. No subjects will be enrolled at OU.
- 26.3 Subjects will only be recruited and enrolled at NCH.
- 26.4 No data will be exchanged with OU. All data will be maintained at NCH.
- 26.5 NCH investigator IS the LEAD investigator in the study.
- 26.6 OU will be notified in writing when the study closes.

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

- ☒ Name
- ☐ Complete Address
- ☐ Telephone or Fax Number
- ☐ Social Security Number (do not check if only used for ClinCard)
- ☒ Dates (treatment dates, birth date, date of death)
- ☐ Email address , IP address or url
- ☒ Medical Record Number or other account number
- ☐ Health Plan Beneficiary Identification Number
- ☐ Full face photographic images and/or any comparable images (x-rays)
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- ☐ Device Identifiers and Serial Numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Other number, characteristic or code that could be used to identify an individual
- ☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

- ☒ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the [HRP-900, HIPAA AUTHORIZATION](#) form.)
- ☒ Protocol meets the criteria for waiver of authorization. (Attach the [HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST](#) form.)
- ☐ Protocol is using de-identified information. (Attach the [HRP-902, DE-IDENTIFICATION CERTIFICATION](#) form.) (Checked "None" in 1.0 above)
- ☐ Protocol involves research on decedents. (Attach the [HRP-903, RESEARCH ON DECEDENTS REQUEST](#) form.)
- ☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

***Find the HIPAA forms in the [IRB Website Library, Templates](#).**

Attach the appropriate HIPAA form on the “Local Site Documents, #3. Other Documents”, page of the application.

3.0 How long will identifying information on each participant be maintained?

Identifying Data will be retained for 6 years after the research is complete as this meets both HIPAA & OHRP regulations.

4.0 Describe any plans to code identifiable information collected about each participant. None

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

- ☒ Research records will be stored in a locked cabinet in a secure location
- ☒ Research records will be stored in a password-protected computer file
- ☐ The list linking the assigned code number to the individual subject will be maintained separately from the other research data
- ☒ Only certified research personnel will be given access to identifiable subject information

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)

Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

- ☒ Demographics (age, gender, educational level)
- ☒ Diagnosis
- ☒ Laboratory reports
- ☐ Radiology reports
- ☐ Discharge summaries
- ☒ Procedures/Treatments received
- ☒ Dates related to course of treatment (admission, surgery, discharge)
- ☐ Billing information
- ☒ Names of drugs and/or devices used as part of treatment
- ☐ Location of treatment
- ☐ Name of treatment provider
- ☐ Surgical reports

- ☒ Other information related to course of treatment
☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.

Demographics need to be recorded to describe the patient characteristics of the study cohort for publication of these data in scientific journals. Diagnosis and procedures need to be assessed for inclusion criteria.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No