Evaluation of Cellphone Based Otoscopy in Pediatric Patients

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Evaluation of Cellphone Based Otoscopy in Pediatric Patients Protocol

1. Important definitions

- **Trainee**= any resident physician, physician assistant student, medical student, or physician assistant who works in the Harriet Lane Clinic (Acute and/or Continuity Clinics) or Johns Hopkins Children's Center Pediatric Emergency Department.
- **Supervisor**= any attending physician, pediatric emergency medicine fellow, general pediatrics preceptor, nurse practitioner who works in the Harriet Lane Clinic (Acute and/or Continuity Clinics) or Johns Hopkins Children's Center Pediatric Emergency Department.
- **External Ear:** the anatomy of the ear that includes the external auditory meatus, ear canal, tragus, antitragus, and concha. This specifically does not include the lobule of the ear and the helix.
- **Direct Visualization:** the act of looking directly through a magnifying lens and seeing a non-digital image.
- **Indirect Visualization:** the act of looking at a screen attached to a magnifying lens and seeing a digital image.
- **Non-sensitive area anatomy:** Human anatomy that does not include the genitals or breasts.

2. Objectives

Aim 1: To establish whether a smartphone otoscope improves diagnostic accuracy of tympanic membrane (TM) pathology for trainees, compared to supervisor.

Aim 2: To determine whether smartphone otoscope improves diagnostic confidence of trainees, thereby reducing frequency of antibiotic prescriptions for AOM.

Aim 3: To determine whether there is a change in repeat exam rates by supervisors, comparing with/without Cellscope.

Aim 4: To determine whether trainees convert to traditional otoscope use during the weeks that Cellscope is available.

3. Study Procedures

a. Study design, including the sequence and timing of study procedures

This is a prospective, randomized, unblinded, controlled study in the Harriet Lane Clinic (HLC), the Johns Hopkins Children's Center pediatric primary care resident teaching practice and the Johns Hopkins Children's Center Pediatric Emergency Department (Peds ED). The HLC has clinics for acute care (e.g., sick visits) and continuity (e.g., well child and follow-up visits). We will purchase Cellscopes, iPhones, phone cases, and locking storage systems for each setting. There will be no direct collaboration between the study investigators and Cellscope related to this study. We will evaluate the above aims by block-randomizing in 2-week blocks: 1 week where the Cellscope will be available and 1 week where only traditional otoscopy will be available. Because residents rotate through the HLC and Peds ED in 2 and 4-week rotations, this will allow for the inclusion of the same trainees in each arm to act as their own control and ensure there is no use of the Cellscope during the traditional-only weeks. During Cellscope weeks, the traditional direct otoscopes will be available based on trainee/supervisor preference. During the traditional weeks, the Cellscope will not be available, thus the standard of care will not be changed during our study. iPhones will be secured with 6-digit numeric passcodes, in compliance with JHMI security standards. Recordings/images of external and middle ear structures will be obtained in a HIPAA compliant manner without collecting any PHI.

During Cellscope weeks, trainees and supervisors will be given access to the Cellscope and asked to use this tool for their otoscopic exams (research procedure). They will have full discretion of when an otoscopic examination is indicated, based on their existing practice and standard of care. We will then ask that the

trainees and supervisors each fill out an index card survey to record the following outcomes: agreement between trainee and supervisor using the OMgrade scale (validated otitis media diagnostic tool[1,2]), trainee confidence in exam, antibiotic prescription, need for conversion to traditional otoscopy, and whether a repeat exam was obtained. During the traditional weeks, the Cellscopes will be unavailable, locked in an enclosure, and traditional otoscopy (routine care) will be the only method available. The same index card survey will be completed by the trainees and supervisors. There will be no change to patient restraint, as described above.

b. Study duration and number of study visits required of research participants.
The study will last for between 9-12 months depending on the number of patients enrolled. Only one study visit is required per research participant. The same patient will be able to be included in the study multiple times if they present to the HLC or Peds ED on multiple occasions.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
This study will be unblinded. It is not possible to perform this study in a blinded manner given the obvious difference in the handheld hardware.

d. Justification of why participants will not receive routine care or will have current therapy stopped.
Standard of care is traditional direct otoscopy, as described above. We are using an equivalent method of otoscopy that allows the identical visualization of the external and middle ear structures. It will also be explicitly stated to providers that they can revert to traditional otoscopy if they feel that the Cellscope is not able to identify the needed structures.

e. Justification for inclusion of a placebo or non-treatment group.
N/A

f. Definition of treatment failure or participant removal criteria.
If any provider feels that the Cellscope is not able to appropriately identify the needed ear structures, that will be considered a failure of the Cellscope, and that provider will be able to immediately revert to a traditional otoscope. Furthermore, patients and guardians may opt for providers to use the traditional otoscope at any time. This will be tracked.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Resumption of traditional care, without any harm to the patient.

h. Informed Consent
If patients are interested in participating the trainees or supervisors will obtain informed verbal consent from the parent or legal guardian of the patient prior to examining the child. Explaining the study, obtaining consent, answering questions, and assessing parent and patient understanding is expected to take under 5 minutes, which is typical for a similar conversation clinical setting. A copy of the IRB protocol will be provided upon request. A waiver of written consent is requested because the consent document is the only record linking the subject and the research. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

i. Provider Training
Providers will be trained on setting up the Cellscope: attaching the case to the iPhone, attaching the Cellscope to the case, turning on the iPhone and unlocking it. They will also be trained on how to use the Cellscope application to record non-PHI containing images/videos. This training will be done by members of the study team who are proficient in using the device and app. This will occur in whatever clinical setting, in which they are assigned (Pediatric Emergency Room, Harriet Lane Acute Clinic, Harriet Lane Continuity Clinic). This will take place prior to them using the device on any patients for the purposes of this study or any other indication.

4. Inclusion/Exclusion Criteria

Inclusion:

- All trainees and supervisors
- All patients where otoscopy would traditionally be indicated, at the discretion of the clinical team
    - All ages included

Exclusion:

- None

5. Study Statistics

a. Primary outcome variable.

Aim 1:

A. Inter-rater reliability between trainee and supervisor utilizing the OMgrade scale

Aim 2:

A. Rates of patients who receive antibiotics
B. Levels of provider confidence in exam based on a standardized confidence measure

Aim 3: Rate of repeat exams by supervisors with and without Cellscope

b. Secondary outcome variables.

Aim 4: Rate of provider decided use of traditional otoscopy during Cellscope weeks

c. Statistical plan including sample size justification and interim data analysis.

Descriptive statistics will be performed to analyze our outcome measures in conjunction with Johns Hopkins BEAD Core statisticians.

1. Calculation of descriptive statistics such as mean, median, SD, range will be employed.
2. Examination of graphs such as outcome vs. time, scatterplots of two variables, Kaplan-Meier curves.
3. Estimation of differences between two groups with comparison by t-test or Mann-Whitney test.
4. Estimation and testing of within-person changes by matched t-test or Wilcoxon signed-rank test.
5. Multiple linear regression, logistic regression, or Cox proportional hazards regression.
6. Repeated measures models (usually requires the help of a statistician).
7. Comparison of proportions by the determination of kappa values will be employed.
8. Sample size will be calculated with an alpha of 0.05 and power of 80% to detect a change of 10%. We will have a minimum sample size of 392 subjects based on this calculation.

References:

1. Lundberg, T., Biagio, L., Laurent, C., Sandström, H. & Swanepoel, D. W. Remote evaluation of video-otoscopy recordings in an unselected pediatric population with an otitis media scale. *Int. J. Pediatr. Otorhinolaryngol.* **78,** 1489–1495 (2014).

2. Lundberg, T., Hellström, S. & Sandström, H. Development and Validation of a New Grading Scale for Otitis Media: *Pediatr. Infect. Dis. J.* **32,** 341–345 (2013).