

Pediatric Emergency Department Smartphone Otoscope Study (PED-Oto)

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PED-Oto Study

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2. Abstract:

Acute otitis media (AOM), defined as acute inflammation in the middle ear, is a leading cause of health encounters and antimicrobial prescriptions in children worldwide. In the first three years of life, 80% of children will have one or more episodes of AOM. Internationally, 709 million cases of AOM are estimated to occur annually and approximately 2.8 billion (2006) dollars are spent annually in the United States. Diagnosis of AOM is often dependent on a brief view of the tympanic membrane in an uncooperative child's ear canal that may be suboptimal for diagnosis. As a consequence, AOM may be inappropriately diagnosed when visualization of the tympanic membrane (ear drum) is not optimal. Improved methods for visualizing the tympanic membrane including capturing still images and recording video of the ear exam would be beneficial in the diagnosis and management of otic complaints including acute and chronic otitis media.

A smartphone otoscope (CellScope-Oto) is a pocket-size attachment that employs the technology and light source of a smartphone to capture reproducible images of the ear canal and tympanic membrane. Previous studies with this device demonstrated that images taken with both the smartphone otoscope and a camera-fitted conventional analogue otoscope were equivalent with respect to image quality (IRB00057321)² and that the smartphone otoscope was acceptable as an educational and diagnostic tool to health professional students (IRB00066495). A pilot study with a similar design to this study conducted in two offices of an ambulatory pediatric clinic demonstrated a trend toward decreased antimicrobial prescription filling among families whose children were examined with the smartphone otoscope (IRB00074526) compared to those who were examined with a conventional otoscope. To further assess this trend, we propose an evaluation of the impact of device use on antimicrobial prescribing for children with an otic complaint in a pediatric emergency department (PED) setting.

We hypothesize that use of a smartphone otoscope with the capability to capture still images and video will reduce the rate of antimicrobial prescribing by emergency department clinicians for otic complaints in children presenting for care in pediatric emergency department settings.

The Pediatric Emergency Department Oto Study (PED-Oto) will be conducted as a

randomized control study in two affiliated children's hospital emergency departments. Twenty volunteer clinicians will be randomly assigned to use either a smartphone otoscope or a conventional otoscope for all otic examinations for a 6-month period. Study outcomes will include:

- 1) rates of antimicrobial prescribing by the clinicians randomly assigned to use a smartphone otoscope compared to the rates of antimicrobial prescribing by the clinicians using a conventional otoscope.
- 2) rates of otitis media or otitis externa diagnoses by the clinicians randomly assigned to use a smartphone otoscope compared to the rates of otitis media or otitis externa diagnoses by the clinicians using a conventional otoscope.
- 3) clinician acceptability of the assigned otoscopic device.

Data will be abstracted via retrospective review of the electronic medical record of encounters in which an otoscopic exam was performed as part of the diagnostic evaluation. We plan to enroll 20 clinicians for the 6-month study period; 10 who will be randomly assigned to use a smartphone otoscope for the 6-month study period and 10 who will be assigned to use a conventional otoscope for all otoscopic exams. Use of a smartphone otoscope has the potential to optimize clinician ability to manage otic complaints, visualize the tympanic membrane, and support antimicrobial stewardship.

3. Introduction and Background:

Acute otitis media (AOM), defined as acute inflammation in the middle ear, is a leading cause of health encounters and antimicrobial prescriptions in children worldwide. In the first three years of life, 80% of children will have one or more episodes of AOM incurring burden to both the individual and the healthcare system. The diagnosis of AOM is often dependent on a brief glance into an uncooperative child's ear canal and incomplete visualization of a tympanic membrane that may be suboptimal for diagnosis. Improved methods of visualizing the tympanic membrane including the capability of capturing still images and video otoscopy (ear exam) have demonstrated an impact on the management of children with otic complaints.

In February of 2013, The American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) released revised clinical practice guidelines for the diagnosis and management of uncomplicated AOM in children that emphasize visualization of the tympanic membrane in making a clinical diagnosis of AOM. The guidelines further recommended judicious use of antimicrobials and advocates for active and ongoing involvement by both clinician and parent¹.

A pocket-size smartphone attachment that employs the technology and light source of a smartphone to capture reproducible images of the external ear canal and tympanic membrane was developed. Images and video capture of multiple images improves diagnostic capability facilitating a more complete view of the tympanic membrane and optimizing three-dimensional image capture. Digital images captured with the device may be incorporated into electronic medical records, facilitating documentation and review over time, an important aspect in the management of pediatric otic conditions.

The smartphone otoscope device has been evaluated in several settings to assess

function and application. A single-center prospective study published in 2015 (IRB00057321)² found that images from the smartphone otoscope device were of comparable quality to those obtained from a camera-fitted device when subsequently reviewed by blinded pediatricians, emergency medicine pediatricians, and an otolaryngologist. The majority felt photographic documentation for diagnosing acute otitis media would reinforce their decision to defer antibiotic administration. A second study assessing acceptability of a smartphone otoscope compared to a conventional wall-mounted otoscope among medical students, nurse practitioner students, and physician-assistant students noted support for the smartphone device for both learning how to conduct the otic exam and for future patient care (IRB00066495). The students concurred that the smartphone otoscope enhanced tympanic membrane view and diagnostic precision, was easy to use, and preferred it over a traditional otoscope when using the devices to examine each other in an educational setting. A study among resident and attending physicians found good correlation between otitis media diagnoses when resident and attending physicians used conventional and smartphone otoscopes in an emergency department setting³. The physicians also agreed that the smartphone otoscope enhanced tympanic membrane view and diagnostic precision, was easy to use, and preferred it over a traditional otoscope. A study conducted in a neurotrauma clinic found a preference for a smartphone otoscope for use in medical education and diagnostic capabilities⁴.

This study has two proposed hypotheses and subsequent aims:

Hypothesis 1: Use of a smartphone otoscope by pediatric clinicians in a pediatric emergency department setting for otic examinations will result in decreased rates of antimicrobial prescribing for presumptive otic infections, compared to rates of providers using a conventional otoscope.

Specific Aim 1: To compare antimicrobial prescribing practices for otitis media among pediatric emergency care clinicians, we will perform a randomized control trial study in which pediatric clinicians will be randomly assigned to use either a smartphone otoscope or a conventional otoscope for 6 months when an otic examination is performed.

Hypothesis 2: Pediatric emergency care clinicians will express a greater acceptability for use of a smartphone otoscope for the examination of children than use of a conventional otoscope.

Specific Aim 2: To compare pediatric emergency department clinician acceptability of use of a smartphone otoscope with that of a conventional otoscope, we will assess clinician satisfaction and challenges experienced with each device during the study period with a written questionnaire.

4. Objectives:

To address the specific aims stated above, we will utilize a **randomized control study design** to compare antimicrobial prescribing practices of pediatric emergency department clinicians for encounters in which an otic examination is performed while using the smartphone otoscope to those clinicians using a conventional otoscope. (*Specific Aim 1*). Pediatric emergency care clinicians will be surveyed to assess acceptability of smartphone otoscope use compared to conventional otoscope use during the 6-month study period (*Specific Aim 2*).

5. Study Design and Methods:

We propose a randomized, controlled study. The smartphone otoscope will be used in clinical care in the same manner as a conventional otoscope. Twenty volunteer Pediatric Emergency Department clinicians will be randomized to use either the smartphone otoscope or a conventional otoscope for 6 months for all non-traumatic patient otoscopy (ear examinations). In the event that a clinician assigned to use the smartphone otoscope device is unable to use the assigned smartphone otoscope device, s/he will be able to use a conventional otoscope for the examination that cannot be completed with the smartphone otoscope, with documentation to the study team of the reason that the smartphone otoscope could not be used on a study log. The study log, stored in a locked file cabinet, will be reviewed by a member of the study staff in real time to troubleshoot equipment challenges and to monitor study progression. The option to use a conventional otoscope device by clinicians assigned to use of the smartphone device will ensure that clinical care is not adversely impacted in the event of smartphone device malfunction or another situation that makes smartphone otoscope device not feasible.

All encounters in which an otic examination is performed for a non-traumatic chief complaint will be considered to be eligible to be included in the study. Eligible encounters will be tracked by having the clinician place a patient identification sticker on a log sheet. The log sheet will contain the physician study ID number, date and times of shift, patient sticker and a notation if a clinician substituted a conventional otoscope for the smartphone otoscope device. The study log sheet will be stored in a locked file cabinet, accessible only to study staff. The electronic medical record will be retrospectively accessed, based on the medical record number listed on the study log sheet to collect study-relevant information (**PED-Oto EMR Abstraction Form**) including age of patient, history of otitis diagnoses, past antimicrobial prescription use, antimicrobial prescribed, duration of antimicrobial prescribed, and instructions given specifying the conditions under which to initiate an antimicrobial, if given. Personal identifiers will be maintained only as necessary to link the encounter to the medical record for extraction of study-related information. All information will be recorded in a password protected electronic database. Paper copies of the study log will be stored in a locked file cabinet. Access to both electronic and paper copies of study information will only be granted to study staff.

Information collected as part of the PED-Oto study:

1. Line listing of patients seen per shift by participating study clinicians and record

of device substitution, **PED-Oto Device Use**.

2. Electronic record medical record review of encounters in which an otoscope device was used as reported by study-participant clinicians. Encounters related to ear trauma will be excluded. The **PED-Oto EMR Abstraction Form** will be completed retrospectively by a member of the study staff.
3. At the conclusion of the 6 month study period, the 10 pediatric emergency department clinicians randomly assigned to use the smartphone otoscope device will complete a written questionnaire to assess their comfort level, ease of use, and preference for or against the otoscope device. This assessment will be known as the **PED-Oto Clinician Assessment**.

6. Participant selection:

The subjects in this study will be 20 randomly selected pediatric emergency care clinicians who perform care at one or both locations (Egleston or Hughes Spalding) of a tertiary care pediatric hospital system. Subjects will agree to random assignment to either a smartphone otoscope device or a conventional otoscope device for the 6-month study period. Informed consent will be obtained from each participating clinician prior to the initiation of the study by a member of the study staff. Study participants will be asked to: 1) compile a list of patient encounters that included an otoscopic examination for a non-traumatic indication for each shift worked during the study period, 2) document and report episodes of care in which the assigned otoscopic device could not be used on a study-eligible otoscopic examination, 3) the 10 clinicians assigned to use the smartphone otoscope will be asked to complete an end of study assessment, the **PED-Oto Clinician Assessment**.

This study presents no more than minimal risk to the subjects. The greatest risk is the loss of privacy by the participating clinicians. There is likely no direct benefit from participation in the study for the individual clinicians. Clinicians assigned to the smartphone otoscope arm will be permitted to keep the clip-on otoscopic device, without the loaned iPhone, as compensation (approximate retail value \$79) for the time and effort related to instruction of device use and completion of study-related documentation. Clinicians assigned to use a conventional otoscope will be given a \$50 gift card at the completion of the study period. Completion of the 6-month study period will be required for compensation.

7. Statistical analysis:

Statistical analyses will predominantly be descriptive with assessments of means, medians, standard deviations, and statistical tests to correlate device and rates of antimicrobial prescribing practices within and among clinicians. Twenty clinicians (10 assigned to the smartphone otoscope intervention and 10 to conventional otoscopy) will participate in the six month study, with a combined 1000 encounters over the 6-month study period. Allowing for drop out, incomplete data collection and other study related issues, we anticipate that we will have usable assessments from 800 encounters.

8. Adverse event reporting:

As this study does not pose more than a minimal risk to subjects, it is unlikely that there

will be a need to discontinue the study due to adverse effects. Rates of completed clinician assessments as well as reports of study related issues will be reported in real time to study staff. Adverse events will be recorded and reported using standard IRB documentation. Progress reports for each 6-month study period will be presented as requested from the funding source.

9. Data and safety monitoring plan (DSMP):

The data safety and monitoring plan will consist of periodic review of the clinician assessments by study staff during which research and study issues will be reviewed. Due to the minimal risk nature of the study, an independent data and safety monitoring committee will not be convened. Standards for stopping procedures will be observed in the case of an adverse event. Study staff will immediately be convened and the issues will be addressed on an urgent basis.

10. Device information:

The device is manufactured by CellScope, Inc. The device is not FDA approved for the indication and there is no IDE. The trade name is the CellScope-Oto and it is considered to be a non-significant risk device. This device is class 1, 510(k) exempt. 21 CFR Part 874 (ear, nose, and throat devices) includes Regulation Number 874.4770 (Otoscope), a Class I, 510(k) exempt device only when used in the external ear canal. When used in the external ear canal, a premarket notification application and FDA clearance is not required before marketing an otoscope in the U.S. This is a reusable device that is used with a single use disposable ear tip that is placed in the external ear canal. The research team is responsible for device maintenance. Any parts of the device having contact with human subjects will be topically disinfected between subject use or discarded after single use. The study team or clinician will keep the device on the person or locked in a research team office. The study team is responsible for tracking use of the device and dispensing the device.

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