Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

_____ _____

Katherine Wilcox Date

Community Pediatric Acceptability Study

By

Katherine Wilcox

MPH

Epidemiology

_____ [Chair's signature]

Dr. Jesse Jacob

Committee Chair

_____ [Member's signature]

Dr. Wilbur Lam

Committee Member

_____ [Member's signature]

Dr. Andrea Shane

Committee Member

Community Pediatric Acceptability Study

By

Katherine Wilcox

B.S. in Biology

University of Alabama

2013

Thesis Committee Chair: Jesse Jacob, MD

An abstract of

A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of
Master of Public Health
in Epidemiology

2015

Abstract

Community Pediatric Acceptability Study

By Katherine Wilcox

Ear infections cause increased health expenditures and antimicrobial prescriptions in children. Optimal diagnosis requires visualization of the eardrum. Interpretation of an otoscopic examination is limited by an individual's assessment that cannot be seen by anyone other than the person holding the otoscope. Physicians often advise parents to wait and watch for symptoms to abate before giving antibiotics, known as watchful waiting. An attachment employing the technology and light source of a smartphone to capture images of the ear canal and eardrum allows for documentation and sharing of images.

We conducted an observational crossover study of patients aged 0.5 to 18 years with symptoms suggestive of an otic source, including discomfort, fever, rhinorrhea, cough, or otalgia. Six participating physicians were randomized to use the smartphone or conventional otoscope for the first study month, and changed to the opposite device for the next month, alternating between devices for 4 months. Parents of children examined with the smartphone otoscope were shown images taken during the exam. All participating parents completed a baseline assessment within one day of the initial examination, an interim visit questionnaire for any follow-up visits during that month, and a follow up assessment 30 days later.

Of 337 eligible patients, 75 (22%) were enrolled, 7 (2%) completed interim questionnaires, and 62 (18%), completed both baseline and follow up questionnaires. Thirty (48%) were prescribed an antibiotic at baseline assessment. Odds of receiving a prescription were lower with the smartphone otoscope compared to the conventional otoscope (OR = 0.24, P = 0.05). There was no significant difference in the total number of parents who waited > 24 hours to fill their child’s antibiotic prescription or in the completion rates of antimicrobial course by otoscope device. Thirty-four (94%) of 36 parents of children examined with the smartphone reported that images of their child’s ear helped them to understand management of their child’s ear infection. Results of our single center study suggest that a smartphone otoscope is acceptable to parents and shared visualization by parents and clinicians of the otic examination may improve the ability to optimally manage otitis media.

Community Pediatric Acceptability Study

By

Katherine Wilcox

BS in Biology

University of Alabama

2013

Thesis Committee Chair: Jesse Jacob, MD

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of
Master of Public Health
in Epidemiology

2015

Acknowledgements

We would like to thank the staff of Pediatric Physicians, PC, in Roswell and Alpharetta, GA, specifically Drs. Biggs, Brown, Fedack, Kelly, Muench, and Stebbins, for their assistance in data collection. We also appreciate the contributions of the parents and children who participated in our study, who made the completion of this study possible. Thank you to Cellscope Inc. for providing smartphone attachment devices for the use of the study.

I would like to thank Drs. Shane, Lam, and Jacob for all of their time and input in helping me to complete this study and this thesis. Thank you to my family, and friends for providing support throughout this process.

Table of Contents

Background

Acute otitis media (AOM), defined as acute inflammation in the middle ear, is a leading reason for health encounters and antimicrobial prescriptions in young children worldwide (1,2). In the first three years of life, over 90% of children will have one or more episodes of AOM (3). Internationally, 709 million cases of AOM are estimated to occur annually and approximately 2.8 billion dollars are spent annually in care of children with AOM in the United States (4). Additional unmeasured costs and inconvenience arise when children miss school and parents miss work to care for children. Diagnosis of AOM is often dependent on limited visualization of an uncooperative child's ear canal and tympanic membrane that may be suboptimal for diagnosis (1). Consequently, AOM may be inappropriately diagnosed when visualization of the tympanic membrane (TM) is not ideal.

Importance

The majority of antimicrobial prescriptions written for children are to address AOM, though many of these infections are viral and antibiotics are not indicated (3). Over 90% of children diagnosed with AOM in the United States receive a prescription for antibiotics, resulting in approximately 15 million prescriptions each year (5). In 2013, the Centers for Disease Control (CDC) released an Antibiotic Resistance Threat report that estimated that approximately half of antibiotic prescriptions in the United States are unnecessary and inappropriate (6). Parental expectation also increases the pressure for providers to prescribe antibiotics for children with AOM (7). Fifty percent of parents have a

pre-visit expectation for antibiotics, and in 34% of these consultations, physicians perceive an expectation for an antibiotic (8).

Physicians may advise parents of children with mild to moderate AOM to employ watchful waiting, where the parent is advised to withhold the antibiotic prescription until symptoms worsen. Educating the parent on the subject of watchful waiting, as well as the ability to explain the decision to prescribe or not prescribe an antibiotic, aided by photos or video of the ear canal, could significantly increase the parents' compliance with the provider's decision and aid in joint decision making (9,10). Improved methods of visualizing the tympanic membrane, including the capability to capture still images and video of otoscopy, could be beneficial in improving the diagnosis of AOM by facilitating comparison of images over time, as well as justifying medical decision making.

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. These guidelines advocate for active and ongoing involvement by both clinician and parent, and emphasize visualization of the tympanic membrane in diagnostic and management decisions. While ideal from a guideline perspective, the ability to visualize the tympanic membrane in an often uncooperative child may further be compromised by the inability of more than one individual to view the tympanic membrane (1,11,12).

In 2015, a prospective clinical trial comparing the use of an attachment that converts a smartphone into a digital otoscope (smartphone otoscope) to the use of a conventional otoscope found that the use of a smartphone otoscope in the pediatric

emergency department changed the final diagnosis a significant number of times, including clinically relevant changes to and from AOM. It also enhanced TM visualization as reported by participating resident and attending physicians (12). Another prospective study in 2015 employing the use of the smartphone otoscope found that the smartphone otoscope captured images at least as clearly as those captured using a conventional, conventional camera-fitted otoscope, with the added ability to record video images. Parents acknowledged that the ability to view their child's tympanic membrane aided in their understanding of their child's care (13).

Goals of the current study

The smartphone otoscope (CellScope Oto, www.CellScope.org) device is a clip-on attachment that converts a smartphone into a digital otoscope by employing the technology and light source of a smartphone to capture reproducible images and video of the middle ear and tympanic membrane, with the ability to send images and video to an electronic medical record to facilitate the possibility of remote diagnosis. Video capture of multiple images improves the diagnostic capability over a single still image as it allows a more complete view of the tympanic membrane and optimizes three-dimensional image capture (12,13). The ability to share tympanic membrane images captured with a smartphone otoscope has the potential to impact care by improving both reliability and validity of the diagnosis, as well as enabling comparison of images from the same child over time, and reassuring a parent who may have expectations that their child's otitis media will be managed with an antibiotic.

This study has two aims and two hypotheses:

Specific Aim 1: To assess the impact of smartphone otoscope use on antimicrobial

prescribing practices for otitis media among pediatric primary care providers in a community practice, we will perform a randomized cross-over observational study in which pediatric providers will alternate monthly between standard of care use of a smartphone or conventional otoscope. We will compare antimicrobial prescribing, prescription filling and antimicrobial course completion among children examined by a physician assigned to standard of care use of a smartphone or a conventional otoscope.

Hypothesis 1: Pre-assigned use of a smartphone otoscope by pediatricians in a primary care practice to manage AOM will result in decreased antimicrobial prescribing and decreased prescription filling with decreased antimicrobial course completion by parents compared with examinations conducted with a conventional otoscope.

Specific Aim 2: To compare parental acceptability of management of their child's acute otitis media, we will administer a questionnaire within 2 days of their child's assessment, at an interim assessment if it occurs, and 4 weeks following the initial assessment.

Hypothesis 2: Use of a smartphone otoscope by pediatric clinicians in a primary care practice to diagnose and manage children with otitis media will result in increased acceptability among parents of their child's management, compared with the acceptability of parents whose children are managed by a provider using a conventional otoscope.

Methods

Study Population

Children from 6 months up to 18 years of age at the time of assessment who were evaluated at one of two offices of a community-based pediatric practice during February – May 2015 for an otic complaint, including discomfort, fever with or without otalgia, rhinorrhea, cough, or otalgia were eligible for enrollment. Pediatricians provided parents of eligible children with study information. A child was eligible to be enrolled once in a single 4-week study period, and only one child per family could be enrolled.

Setting

Subjects were recruited from two locations of a private community suburban pediatric practice in suburban Atlanta, Georgia. Physicians rotate between 2 office locations and have over 10,000 documented patient encounters in the last 3 years.

Device

The smartphone otoscope attachment used in data collection is composed of a plastic case with a slide-on magnifying lens and fiber optic illumination system (Figure 1). It aligns with the smartphone's camera and uses the phone's light source. With the attachment, the camera of the smartphone is able to focus on the tympanic membrane. Using a software application, the ear canal and tympanic membrane can be seen on the screen of the phone in a similar field of view to that seen through the eyepiece of a conventional otoscope.

Data Collection

We conducted a prospective, observational cross-over study. Following a

scheduled training session led by the study coordinator, as well as a pilot month (January 2015) of data collection to acclimate physicians to the smartphone otoscope, 3 of the 6 participating clinicians were assigned using a random number generator to use either a smartphone otoscope or conventional otoscope for all otic examinations on all children for a one month period. At the end of each 1-month period, the clinicians crossed over to the opposite device (either a conventional analogue otoscope or smartphone otoscope), and opposite of the one used in the previous 1-month period. Physicians were provided with smartphones and otoscope attachments for each period that they were assigned to use a smartphone otoscope device. At the conclusion of the 4-month study period, each clinician had used each device for a 2 month period, alternating between devices after each study month (Appendix I).

When assigned to use the smartphone otoscope, clinicians shared images of the child's ear examination with the patient, if developmentally appropriate, and parent or guardian at the time of the encounter. Diagnosis and management plans including antimicrobial prescriptions issued were documented in an electronic medical record.

At the time of study contact 24-48 hours following the clinical encounter of interest, the study coordinator described the study and the informed consent elements verbally. If the parent/guardian expressed verbal consent, the coordinator administered a 9-question baseline enrollment questionnaire via telephone. Attempts to contact families were limited to 3.

Study Assessments

The research component of the Community Pediatric Acceptability Study (CPAS) study included the following data collection instruments for parents

(Appendix II):

1. The baseline questionnaire collected demographic information, the child's history of ear infections in the last 12 months, and assessed parental acceptability of the smartphone otoscope device (if used during that visit) and their understanding of the physician's treatment plan.

2. If applicable, subsequent visit questionnaire assessing parental acceptability of the smartphone otoscope (if used during that visit) and their agreement with the physician's decisions and treatment plan during that visit.

3. The follow up questionnaire administered 30 days following date of completion of baseline questionnaire consisting of a 7-question, Likert-style questionnaire assessing whether or not their child received a prescription for an antimicrobial for AOM, if the prescription was filled, and if filled was the course completed.

Verbal responses were recorded and manually transcribed into an electronic deidentified database, coded, and then imported into Statistical Analysis Software (SAS) version 9.4, Cary, NC. (SAS) for analysis. It was not expected that the use of one device would have an effect on the use of the other device; therefore a wash-out period was not incorporated.

The study was approved by the Institutional Review Board at Emory University with a waiver for written informed consent. Parents were compensated for their time devoted to study procedures following completion of the follow up questionnaire.

Statistical Methods

Data analysis was completed using Statistical Analysis Software (SAS) version 9.4, Cary, NC. Parental acceptability was examined by study month and device. To account for sparse data for children without a history of otitis media, the coded variable for history of ear infection (0, 1, 2, 3, 4, 5+) ear infections reported in the last year) was categorized as 0-1, 2, and 3+ ear infections. Due to sparse data in the month of May, the variable documenting study visit month was also combined to make two categories (February/March and April/May). Prescription rates were defined as the number of antimicrobial prescriptions issued by participating physicians per study month.

Chi-square analyses of differences in antimicrobial prescription rates, antimicrobial prescription filling rates, antimicrobial prescription completion rates, parental acceptance of the smartphone otoscope, and exchangeability of patients in the smartphone and conventional otoscope groups, were conducted to measure any demographic differences between the smartphone and conventional otoscope groups. Logistic regression models were fitted to determine if the patient's age, history of ear infections, or device used, influenced the physician's decision to prescribe an antibiotic, the parent's decision to administer that antibiotic, and antibiotic course completion.

Results

Study Population

Three hundred and thirty seven children were eligible for study enrollment during the study period from February 1, 2015 to May 31, 2015: 75 (22%) of parents completed the baseline assessment, 7 of those 75 (9%) completed subsequent visit assessments, and 62 (83%) completed both baseline and follow-up questionnaires. Data collected from those who completed both the baseline and follow-up assessments were analyzed.

Data was collected from 13 (17%) parents who completed the baseline, but not the follow up questionnaire. The children of 7 (54%) were examined with the smartphone otoscope, and the children of 6 (46%) with the conventional otoscope. Of the 7 examined with the smartphone otoscope, 5 parents reported that images seen during the exam helped them to understand the management decision, and 2 (29%) parents reported that they did not know if seeing the images helped them to understand the management of their child's ear issue.

Children whose parents completed both the baseline and follow up assessments had a mean age of 2.7 years (standard deviation (SD) = 1.5 years, range 0.5 to 15 years), and a median age of 2 years (interquartile range (IQR) = 2). Twenty-six (42%) had been examined with the conventional otoscope, and 36 (58%) had been examined with the smartphone otoscope. There were no significant differences in age at enrollment between those who had been examined with the conventional compared with the smartphone otoscope ($Z = 827$, $P = 0.91$), or between those given a prescription for antibiotics and those who were not ($Z = 858.5$, $P = 0.91$). The difference in reported ear infections in the

last year between those seen with the smartphone otoscope and the conventional otoscope (Z = 810, P = 0.89), and the difference in number of reported antibiotic prescriptions in the last year (Z = 811, P = 0.91) between device groups was also not statistically significant (Table 1, Figure 2).

Antibiotic Prescription Rates

Monthly prescription rates differed for those examined with the smartphone and conventional otoscope (Table 2, Figure 3). Thirty (48%) subjects were prescribed an antibiotic at the time of ear examination. Overall prescription rate was lower in the smartphone otoscope group than in the conventional otoscope group (15 (42%) vs. 15 (58%), P = 0.09). A child with a history of 2 ear infections in the last year was more likely to have been prescribed an antibiotic than a child with 0-1 infections (odds ratio OR= 18.2, 95th confidence interval (CI) (2.0, 162.6)), and a child with 3 or more infections reported in the last year was also quite likely to be prescribed an antibiotic in comparison to those who reported 0-1 infections in the last year (OR = 65, 95th CI (6.5, 648.1)). There was no significant association between the use of the device alone and a reduction in the monthly prescription rate (OR = 0.4, 95th CI (0.14, 1.2)). The age of the child did not have an effect on receipt of an antibiotic prescription (OR = 0.92, 95th CI (0.7, 1.3)). The odds of being prescribed an antibiotic in the past month were different between the smartphone and conventional otoscopes (OR = 0.24, 95th CI (0.06, 0.99)), and in the history of ear infections (2 infections vs. 0-1: OR = 18.2, 95th CI (2.0, 162.6), 3-4 infections vs. 0-1: OR = 65, 95th CI (6.5, 648)). Those who were examined with the conventional otoscope were approximately 4 times more likely to receive a prescription

for antibiotics than those examined with the smartphone otoscope (OR = 4.1, 95th CI (1.0, 16.9)).

Antibiotic Use

Thirty (48%) of subjects were prescribed an antibiotic; 15 (50%) were examined with the smartphone otoscope group and 15 (50%) with the conventional otoscope. Three (20%) of the 15 parents of children examined with the smartphone otoscope and 3 (20%) of the 15 parents of children examined with the conventional otoscope were advised to watch and wait before administering the antibiotic. Three (100%) parents advised to watch and wait in the smartphone otoscope group reported that they were comfortable watching and waiting, in comparison to 2 out of 3 (67%) parents of children in the conventional otoscope group. Parents of children who were examined with a smartphone otoscope were more likely to wait one day or more before filling their child's prescription (4 (29%) vs. 2 (14%), P = 0.65) (Figure 4). Children who were prescribed an antibiotic who were examined with a smartphone otoscope were also more likely to complete their antibiotic course than those who were examined with the conventional otoscope (12 (79%) vs. 9 (60%), P = 0.43)(Figure 5). Of the 36 children examined with the smartphone otoscope, 15 (42%) were prescribed an antibiotic. Ten (67%) parents reported that they waited less than 24 hours before filling their child's prescription, and 4 (27%) reported that they waited more than 24 hours before filling their child's prescription. No parents reported that they chose not to fill their child's prescription. One parent reported that they did not know how long they waited until filling the child's prescription

Parental Acceptability

Of the 36 parents whose children were examined with the smartphone otoscope, 34 (94%) reported that the physician showing them images of the exam helped them to understand management decisions. Two (6%) remaining parents reported that they did not know if the images helped with understanding management. Twenty-seven (75%) parents reported that seeing the images obtained during the otoscopic exam with the smartphone otoscope made them feel more comfortable about the antibiotic recommendations for their child, and 9 (25%) reported that they did not know if the images helped. All parents reported that they would be comfortable using the smartphone otoscope themselves at home to examine their child, with training or direction from a physician. Eight (22%) parents of children examined with the smartphone otoscope reported that their child had a reaction to seeing images of their ear during the exam, 20 (56%) reported that their child did not have a reaction to the images from the smartphone otoscope, and 8 (22%) reported their child was not old enough to respond.

Discussion

The ability to view images taken during the exam may result in increased parental acceptability and comfort with the physician's decision to prescribe. If the parent feels that they are making a joint decision with the physician, they could be more likely to follow their recommendations. The lower rates of antibiotic prescribing and fewer prescriptions filled by parents of children who were examined with a smartphone otoscope may be related to their parent's ability to visualize the appearance of the child's middle ear. The ability to visualize tympanic membrane anatomy during the exam may have influenced the length of time parents waited before filling their child's prescription; parents with the ability to see their child's ear canal were more likely to wait to fill the prescription. The ability to better understand the severity of their child's ear issue may also have influenced whether or not the parent ensured the completion of their child's prescription.

Strengths and Weaknesses

Our results are subject to several limitations. The small sample size limits the generalizability of our results, and reduces power. The enrollment response rate of less than 30% of eligible children may have biased results to support a more favorable outcome. We do not know how the parents who did not respond (68%) felt about the smartphone otoscope device. Additionally, we do not have data about the children of those parents pertaining to prescription filling or antibiotic completion. The study period was also limited to 4 months of data collection, with physicians using each device for only 2 months. Rates of prescription differed between physicians, due in some part to

some physicians working more regularly and seeing more patients than others. The data for the month of May was sparse, but may have been a true reflection of the number of infections seen by the practice that month.

Future Directions

The use of the smartphone otoscope resulted in lower rates of antibiotic prescription and the device was well accepted by parents of patients. The implications of sharing imagery captured during the exam supports a movement towards parental understanding and involvement in management decisions of their children with otitis media.

References

1. Lieberthal, A, Carroll, A, Chonmaitree, T, et al. Clinical practice guideline: The Diagnosis and Management of Acute Otitis Media. Pediatrics 2013;131(3): e964-999.
2. Haggard, M. Poor adherence to antibiotic prescribing guidelines in acute otitis media—obstacles, implications, and possible solutions. European Journal of Pediatrics 2011;170(3):323–332.
3. Tähtinen, P, Laine, M, Huovinen, P, et al. A placebo-controlled trial of antimicrobial treatment for acute otitis media. New England Journal of Medicine 2011;364(2): 116-126.
4. Monasta, L, Ronfani, L, Marchetti, F, et al. Burden of Disease Caused by Otitis Media: Systematic Review and Global Estimates. PLoS ONE 2012;7(4): e36226.
5. Spiro, D, Tay, K, Arnold, D, et al. Wait-and-see prescription for the treatment of acute otitis media: A randomized controlled trial. Journal of the American Medical Association 2006;296(10):1235-1241.
6. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Available from: http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf
7. Pshetizky, Y, Naimer, S, Shvartzman, P. Acute otitis media: A brief explanation to parents and antibiotic use. Family Practice 2003;20(4):417-419.
8. Mangione-Smith, R, McGlynn, E, Elliott, M, et al. Parent expectations for antibiotics, physician-parent communication, and satisfaction. JAMA Pediatrics 2001;155(7):800-806.

9. McCormick, D, Chonmaitree, T, Pittman, C, et al. Nonsevere acute otitis media: A clinical trial comparing outcomes of watchful waiting versus immediate antibiotic treatment. Pediatrics 2005;115(6):1455-1465.
10. Trepka, M, Belongia, E, Chyou, P, et al. The effect of a community intervention trial on parental knowledge and awareness of antibiotic resistance and appropriate use in children. Pediatrics 2001;107(1):e6.
11. Hansen, M, Howlett, J, Del Mar, C, et al. Parents' beliefs and knowledge about the management of acute otitis media: A qualitative study. BMC Family Practice 2015;16(82).
12. Richards, J, Gaylor, K, Pilgrim, A. Comparison of traditional otoscope to iPhone otoscope in the pediatric ED. American Journal of Emergency Medicine 2015; 33(8):1089-1092.
13. Rappaport, K, McCracken, C, Beniflah, J, et al. Assessment of a smartphone otoscope device for the diagnosis and management of otitis media. Clinical Pediatrics 2015. pii: 0009922815593909. [Epub ahead of print] No abstract available. PMID: 26156976
14. SAS Institute Inc. 2013. Base SAS® 9.4 Procedures Guide. Cary, NC: SAS Institute
Inc.

Tables

Table 1. Characteristics of subjects participating: Pediatric patients seen in Roswell and Alpharetta, Georgia, from February to May 2015

	All Participants (n=62)		Seen with Smartphone Oto (n=36)		Seen with Conventional Oto (n=26)		*P* Value
	No.	%	No.	%	No.	%	
Mean Age (SD) (years)	2.7 (1.5)		2.7 (1.6)		2.7 (1.5)		0.91
Median Age (IQR) (years)	2.0 (2.0)		2.0 (2.0)		3.0 (2.0)		
Number of ear infections in last 12 months							0.90
1-2	24.0	38.7	12	33.3	4	15.4	
3-4	17.0	27.4	11	30.6	12	46.2	
5+	7.0	11.3	4	11.1	6	23.1	
0	14.0	22.6	9	25.0	5	19.2	
Number of antibiotics in last 12 months							0.91
0	17.0	27.4	11	30.6	6	23.1	
1-2	0.0	25.8	10	27.8	10	38.5	
3-4	15.0	32.3	8	22.2	7	26.9	
5+	10.0	24.2	7	19.4	3	11.5	

Table 2. Proportion of patients prescribed an antibiotic by device

	All Participants (n=62)		Seen with Smartphone Oto (n=36)		Seen with Conventional Oto (n=26)	
	No.	**%**	**No.**	**%**	**No.**	**%**
Month						
February	10	62.5	4	50.0	6	75.0
March	7	35.0	4	28.6	3	50.0
April	13	68.4	8	72.7	5	62.5
May	5	71.4	1	33.3	4	100.0

Figures and Figure Legends

Figure 1. Pictures of the smartphone otoscope device. In combination with the app, device controls focus, illumination, and zoom, as well as image and video transmission.

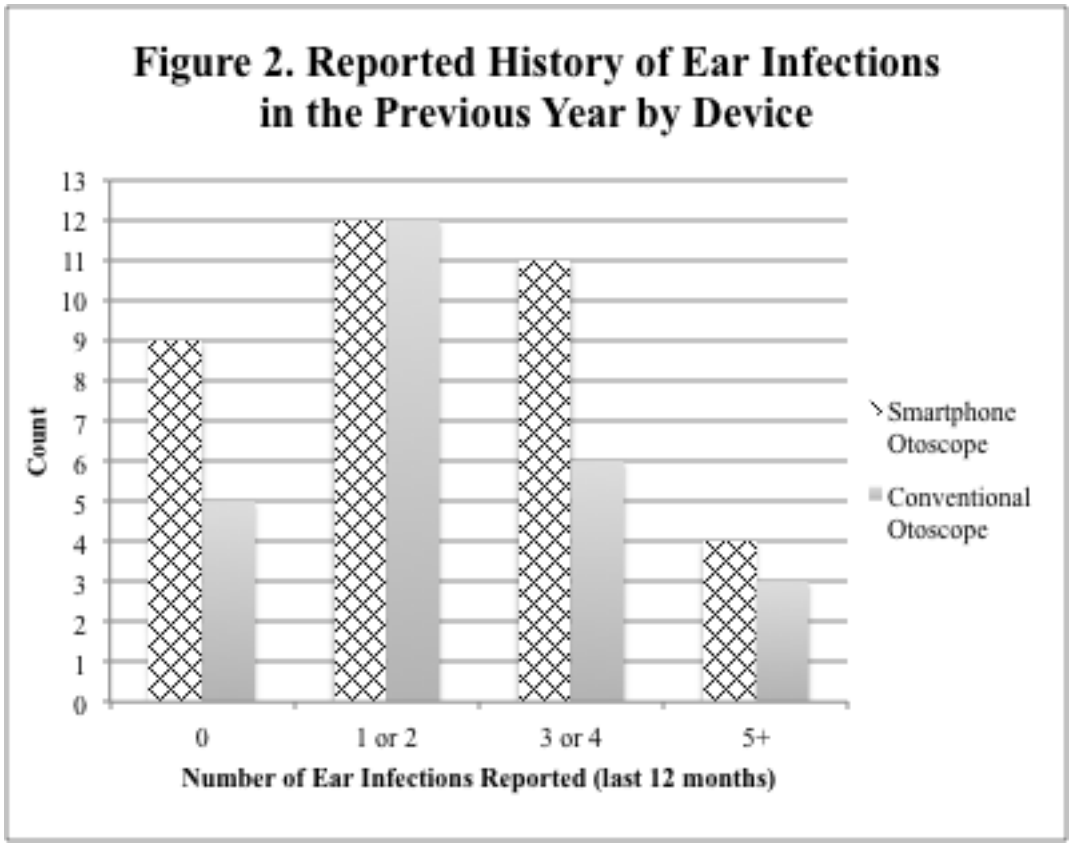

Figure 2. Ear Infections Reported in the Last Year: Classified by Device

	Ear Infections Reported			
	0	1 or 2	3 or 4	5+
Smartphone Otoscope	9	12	11	4
Conventional Otoscope	5	12	6	3

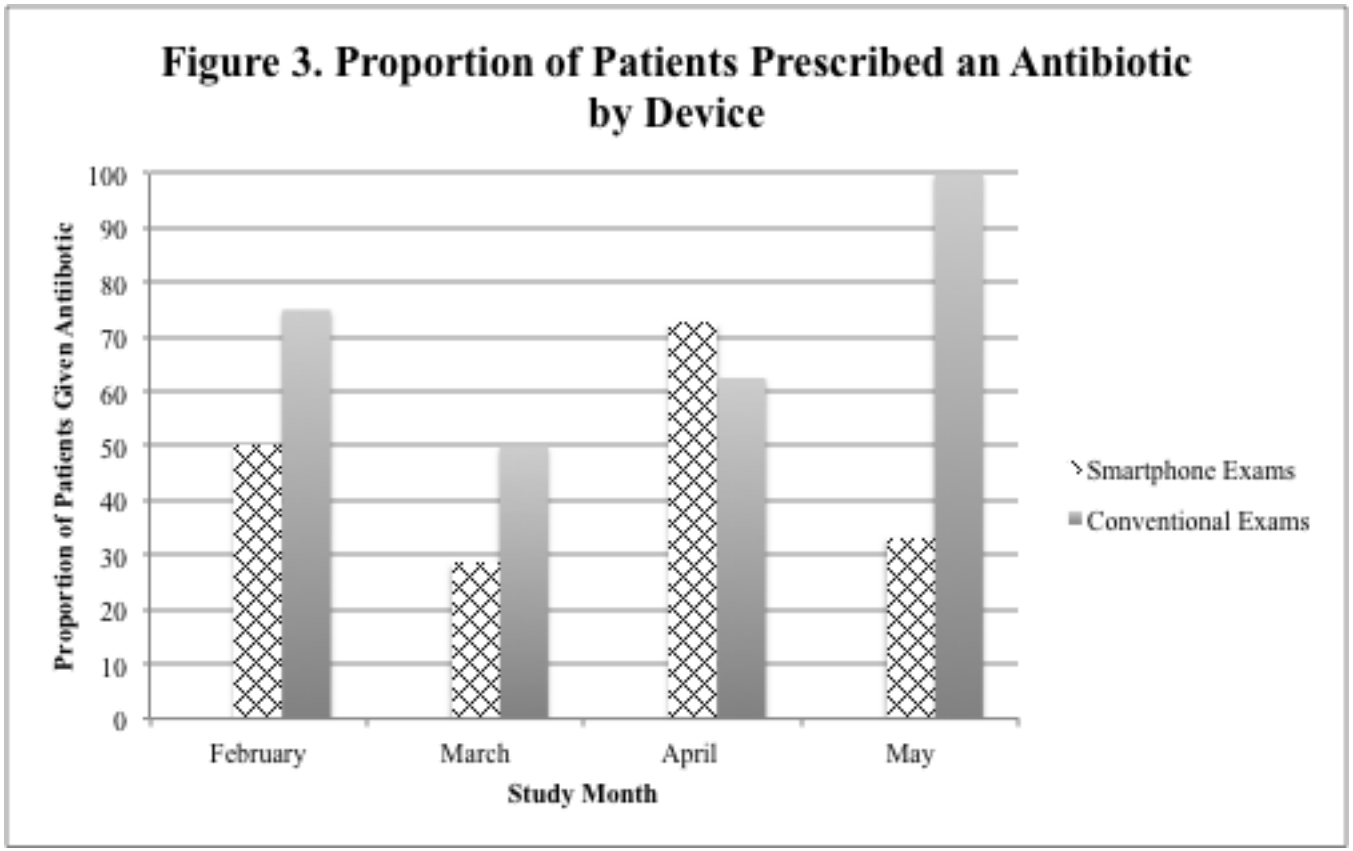

Figure 3. Proportion of Patients Prescribed Antibiotic, by Device

	Smartphone Exams	*Conventional Exams*
February	50	75.0
March	28.6	50.0
April	72.7	62.5
May	33.3	100.0

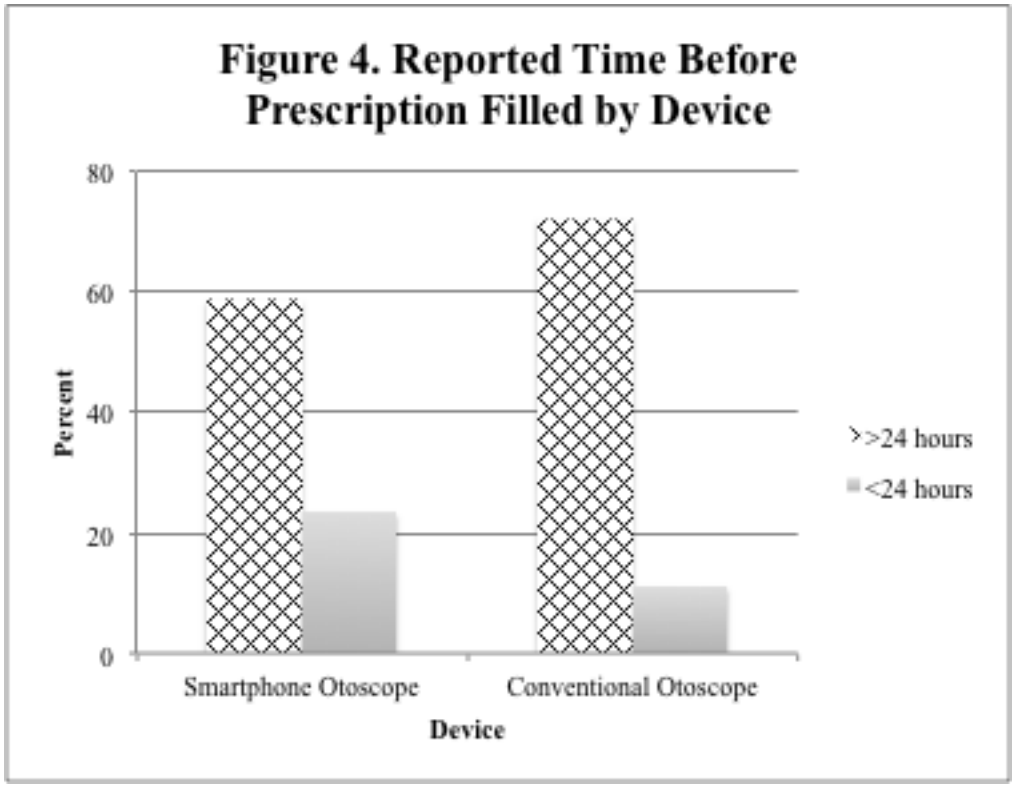

Figure 4. Reported Time Before Prescription Filled

	Time before Filling Prescription	
Group	>24 hours	<24 hours
Smartphone Otoscope	58.8	23.5
Conventional Otoscope	72.2	11.1

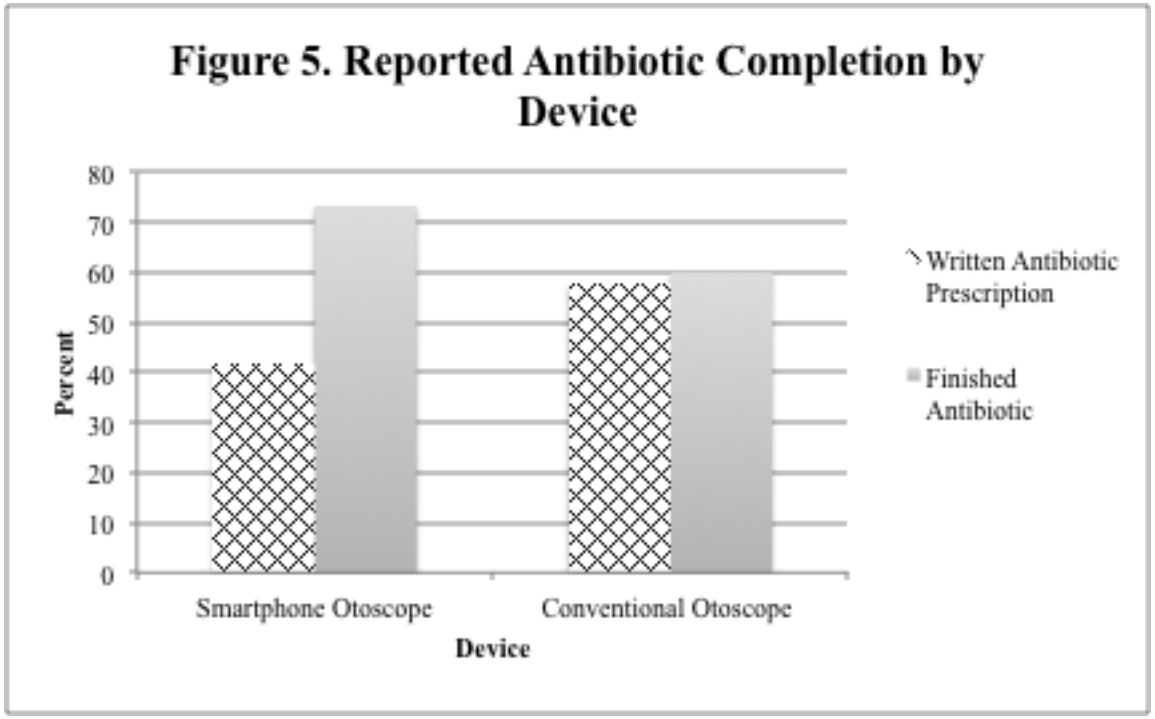

Figure 5. Reported Antibiotic Completion

	Smartphone	*Conventional Otoscope*
Written Antibiotic Prescription	41.7	57.7
Finished Antibiotic	73.3	60

Appendices

I. Physician Randomization

CPAS Physician Group Assignment

Physicians randomized to groups using online random number generator

Month 1 (Feb 2015)

Smartphone: Physician A, Physician B, Physician C
Conventional: Physician D, Physician E, Physician F

Month 2 (March 2015)

Smartphone: Physician D, Physician E, Physician F,
Conventional: Physician A, Physician B, Physician C

Month 3 (April 2015)

Smartphone: Physician A, Physician B, Physician C
Conventional: Physician D, Physician E, Physician F

Month 4 (May 2015)

Smartphone: Physician D, Physician E, Physician F
Conventional: Physician A, Physician B, Physician C

II. Study Questionnaires

Community Practice Acceptability Study (CPAS)
Baseline Assessment

1. Child's age on date of assessment:_____

2. How many ear infections has your child had in the past 12 months?
   ☐ **0** ☐ **1-2** ☐ **3-4** ☐ **5+**

3. How many different times did your child take antibiotics for an ear infection in the past 12 months?
   ☐ **0** ☐ **1-2** ☐ **3-4** ☐ **5+**

4. Did your child's pediatrician give your child a prescription for antibiotics for an ear infection and then ask you not to fill it?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

5. Did your child's pediatrician use a smartphone otoscope to examine your child's ears?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

   IF RESPONSE TO QUESTION 5 IS "NO" END QUESTIONNAIRE.

6. If your child's provider used the smartphone otoscope, did seeing the images help you to understand your pediatrician's decision about care of your child's ear complaint today?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

7. If your child's provider used the smartphone otoscope, did seeing the images on the smartphone otoscope help you to feel more or less comfortable about antibiotic recommendations for your child's ear complaints?
   ☐ **More** ☐ **Less** ☐ **Don't know** ☐ **Not applicable**

8. a. Did your child have a reaction to seeing photos or video of his/her ear?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not age appropriate**
   ☐ **Not applicable**
   b. IF YES, please describe your child's comments:
   _____
   _____

9. Would you feel comfortable using a smartphone otoscope to look in your child's ear and take still photos or video?

   ☐ **Yes** ☐ **No** ☐ **Don't know**

10. Other comments: _____

Smartphone Otoscope Community Practice Acceptability Study (CPAS)
Subsequent Visit Assessment

1. Date of encounter: _____ ☐ **Don't know**

2. Reason for visit: _____
   ☐ **Follow-up visit for ear pain or symptoms**
   ☐ **Visit for new problem not related to ears**
   ☐ **Scheduled well child visit**
   ☐ **Other (please specify):_____**
   ☐ **Don't know**

3. Date of previous encounter: _____ ☐ **Don't know**

4. Reason for previous encounter:
   ☐ **Follow-up visit for ear pain or symptoms**
   ☐ **Visit for new problem not related to ears**
   ☐ **Scheduled well child visit**
   ☐ **Other (please specify):_____**
   ☐ **Don't know**

5. a. Has your child taken antibiotics for an ear infection since your child's last visit?
   ☐ **Yes** ☐ **No** ☐ **Don't know**

   5.b. **If yes, antibiotic name _____**
   ☐ **Cannot recall** ☐ **Not applicable**

6. Did your child's pediatrician show you images of your child's ear during this visit?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

IF NO, END QUESTIONNAIRE

7. Did seeing images of your child's ears help you to understand the decisions made about your child's care?
   ☐ **Yes** ☐ **No** ☐ **Don't know**
   ☐ **Not applicable**

8. Other comments: _____

Community Practice Acceptability Study (CPAS)
Follow-Up Antimicrobial Use Assessment

1. Was your child prescribed an antibiotic for an ear infection in the last 4 weeks?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

2. Were you advised to watch and wait before filling your child's prescription for antibiotics for your child's ear infection?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

3. Did you feel comfortable watching and waiting before filling the prescription?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

4. If your child's pediatrician used a smartphone otoscope, did you feel more comfortable watching and waiting before filling the prescription after seeing images of your child's ear?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

5. How long did you wait before filling your child's prescription?
   ☐ **Less than 1 day** ☐ **Less than 1 week** ☐ **More than 1 week**
   ☐ **Don't know** ☐ **Not applicable**

6. Did you give your child antibiotics for his/her ear infection?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

7. Did your child finish the prescribed course of antibiotics recommended by your child's pediatrician?
   ☐ **Yes** ☐ **No** ☐ **Don't know** ☐ **Not applicable**

III. Tabulated Questionnaire Data

CPAS Baseline Assessment																			
1. Child's age on date of assessment (years)																			
	<1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
62	14	11	4	5	3	4	4	3	0	4	2	3	0	0	4	1	0	0	0
2. How many ear infections has your child had in the last 12 months																			
	0	1 to 2	3 to 4	5+															
62	14	23	17	8															
3. How many different times did your child take antibiotics for an ear infection in the last 12 months																			
	0	1 to 2	3 to 4	5+															
62	16	21	15	10															
4. Did your child's pediatrician give your child a prescription for antibiotics for an ear infection and then ask you not to fill it?																			
	Yes	No	Don't Know	N/A															
62	6	46	0	10															
5. Did your child's pediatrician use a smartphone otoscope to examine your child's ears?																			
	Yes	No	Don't Know	N/A															
62	36	26	0	0															
6. If your child's provider used the smartphone otoscope, did seeing the images help you to understand your pediatrician's decision about care of your child's ear complaint today?																			
	Yes	No	Don't Know	N/A															
62	34	0	2	26															
7. If your child's provider used the smartphone otoscope, did seeing the images on the smartphone otoscope help you to feel more or less comfortable about antibiotic recommendations for your child's ear complaints?																			
	More	Less	Don't Know	N/A															
62	27	0	9	26															
8. a. Did your child have a reaction to seeing photos or video of his/her ear?																			
	Yes	No	Don't Know : age appropri	N/A															
62	8	21	0	7	26														
8.b. IF YES, please describe your child's comments:																			
	Kind of gross but cool	She thought it was really cool	"Wow that's cool"	Interesting	Cool	Cool	Cool	Cool	Cool	Weird	Wow what is t Eew there's blood in there	Cutting edge							
9. Would you feel comfortable using a smartphone otoscope to look in your child's ear and take still photos or video?																			
	Yes	No	Don't Know	N/A															
62	36	0	0	26															

CPAS Subsequent Visit Assessment

Count	Study ID	Date	Reason for Visit	Date of Previous Visit	Reason for Previous Visit	Antibiotics Since Last Visit	Antibiotic Name	Shown Images During Exam	Images Helped
1	133A	3.14.15	F-up ear pain	Don't Know	Ear pain	Yes	Cefdinir	Yes	Yes
2	192A	3.11.15	F-up ear pain	3.2.15	Ear pain	Yes	Omnicef	Yes	Yes
3	224A	3.18.15	F-up ear pain	3.9.15	Ear pain	Yes	Amoxicillin	No	N/A
4	287A	3.25.15	F-up ear pain	3.21.15	Drainage, fever	Yes	Omnicef	N/A	N/A
5	326A	4.21.15	F-up ear pain	4.7.15	Ear pain, fever	No	N/A	No	N/A
6	342A	4.30.15	F-up ear pain	4.13.15	Ear pain	No	N/A	Yes	Yes
7	207A	3.26.15	F-up ear pain	3.5.15	Ear pain	Yes	Amoxicillin	Yes	Yes

CPAS Follow-up Antimicrobial Use Assessment					
1. Was your child prescribed an antibiotic for an ear infection in the last 4 weeks?					
	Yes	No	Don't Know	N/A	
62	37	25	0	0	
2. Were you advised to watch and wait before filling your child's prescription for antibiotics for your child's ear infection?					
	Yes	No	Don't Know	N/A	
62	6	27	4	25	
3. Did you feel comfortable watching and waiting before filling the prescription?					
	Yes	No	Don't Know	N/A	
62	5	1	4	52	
4. If your child's pediatrician used a smartphone otoscope, did you feel more comfortable watching and waiting before filling the prescription after seeing images of your child's ear?					
	Yes	No	Don't Know	N/A	
62	5	0	3	54	
5. How long did you wait before filling your child's prescription?					
	Less than 1 day	Less than 1 week	More than 1 week	Don't Know	N/A
62	24	6	0	3	29
6. Did you give your child antibiotics for his/her ear infection?					
	Yes	No	Don't Know	N/A	
62	32	2	4	24	
7. Did your child finish the prescribed course of antibiotics recommended by your child's pediatrician?					
	Yes	No	Don't Know	N/A	
62	21	9	5	27	