

***TELEHEALTH FOR PRIMARY HEALTH  
CARE EAR DISORDERS:  
A STUDY IN VIDEO-OTOSCOPY***

**by**

**Leigh Biagio**

Submitted in partial fulfilment of the requirements for the degree  
D. Phil (Communication Pathology)

In the Department Speech-Language Therapy & Audiology  
Faculty of Humanities  
University of Pretoria

Supervisor: Prof De Wet Swanepoel

Co-Supervisor: Prof Claude Laurent

June 2014

# CONTENTS

<b>LIST OF TABLES</b> .....	<b>4</b>
<b>LIST OF FIGURES</b> .....	<b>5</b>
<b>LIST OF APPENDICES</b> .....	<b>6</b>
<b>ACKNOWLEDGMENTS</b> .....	<b>7</b>
<b>ABSTRACT</b> .....	<b>8</b>
<b>ORIGINAL PAPERS</b> .....	<b>9</b>
<b>ABBREVIATIONS</b> .....	<b>10</b>
<b>1 INTRODUCTION</b> .....	<b>11</b>
1.1 Background .....	11
1.2 Ear disease.....	11
1.3 Otitis media .....	12
1.4 Telehealth .....	15
1.5 Models of service delivery .....	16
1.6 Video-otoscopy within telehealth clinics .....	18
1.7 Rationale.....	19
<b>2. METHOD</b> .....	<b>21</b>
2.1 Research objectives .....	21
2.2 Research design and methods .....	23
2.3 Ethical considerations .....	26
<b>3. STUDY I: Asynchronous video-otoscopy by a telehealth facilitator</b> .....	<b>29</b>
3.1 Abstract .....	29
3.2 Introduction.....	30
3.3 Materials and methods .....	32
3.3.1 Population.....	32
3.3.2 Data collection.....	32
3.3.3 Data analyses.....	34
3.4 Results .....	35
3.5 Discussion .....	38
3.6 Conclusion.....	41
3.7 Acknowledgements .....	42
3.8 References .....	42
<b>4. STUDY II: Video-otoscopy recordings for diagnosis of childhood ear disease using telehealth at primary health care level</b> .....	<b>46</b>
4.1 Abstract .....	46

4.2	Introduction.....	46
4.3	Materials and methods .....	48
4.3.1	Otomicroscopic examination.....	49
4.3.2	Video-otoscopy recordings.....	50
4.3.3	Equipment .....	51
4.3.4	Asynchronous assessment.....	51
4.3.5	Analyses .....	52
4.4	Results.....	53
4.5	Discussion .....	57
4.5.1	Quality of video-otoscopy recordings .....	57
4.5.2	Diagnostic accuracy using video-otoscopy recordings .....	58
4.6	Conclusion.....	60
4.7	Acknowledgements .....	60
4.8	References .....	61
<b>5.</b>	<b>STUDY III: Paediatric otitis media at a primary health care clinic in South Africa.....</b>	<b>64</b>
5.1	Abstract .....	64
5.2	Introduction.....	65
5.3	Method .....	67
5.3.1	Population.....	67
5.3.2	Data collection.....	68
5.3.3	Data analysis .....	68
5.4	Results .....	69
5.5	Discussion .....	71
5.6	Conclusion.....	75
5.7	References .....	75
<b>6.</b>	<b>SUMMARY AND CONCLUSIONS .....</b>	<b>79</b>
6.1	Summary of study findings .....	80
6.2	Clinical implications .....	81
6.3	A telehealth model for primary health care diagnosis of ear disease .....	82
6.4	Study strengths and limitations .....	85
6.4.1	Study strengths .....	85
6.4.2	Study limitations .....	86
6.5	Recommendations for further research .....	87
6.6	Conclusion.....	88
<b>7.</b>	<b>REFERENCES.....</b>	<b>90</b>
<b>8.</b>	<b>APPENDICES .....</b>	<b>97</b>

## LIST OF TABLES

<b>TABLE 2.1</b>	Summary of studies I to III displaying article title, objectives and journal .....	22
<b>TABLE 2.2</b>	Research design and methods summary for studies I to III .....	24
<b>TABLE 2.3</b>	Ethical principles applied to formulation of research design, participant selection and recruitment procedures, and data collection and analysis procedures.....	27
<b>TABLE 3.1</b>	Video-otoscopy image grading for images acquired by the otolaryngologist and facilitator .....	36
<b>TABLE 3.2</b>	Otologic diagnoses made using face-to-face otoscopy and asynchronous otoscopy using video-otoscopy images acquired by an otolaryngologist and facilitator .....	36
<b>TABLE 3.3</b>	Comparison of asynchronous assessment of video-otoscopy images acquired by the otolaryngologist and facilitator .....	36
<b>TABLE 3.4</b>	Sensitivity, specificity and diagnostic odds ratios for asynchronous video-otoscopy using images acquired by an otolaryngologist and facilitator .....	37
<b>TABLE 3.5</b>	Concordance (%) of face-to-face otoscopy and asynchronous video-otoscopy using images acquired by an otolaryngologist and a clinic facilitator .....	37
<b>TABLE 4.1</b>	Asynchronous grading of video-otoscopy recordings acquired during the first and second week of data collection.....	53
<b>TABLE 4.2</b>	Onsite diagnoses made by the otologist using otomicroscopy compared to asynchronous diagnoses made by the otologist and GP using video-otoscopy recordings .....	55
<b>TABLE 4.3</b>	Concordance of asynchronous diagnosis using video-otoscopy recordings by the otologist and GP compared to onsite otomicroscopy .....	55
<b>TABLE 4.4</b>	Concordance of asynchronous diagnosis using video-otoscopy recordings between and within the otologist and GP .....	56
<b>TABLE 4.5</b>	Sensitivity, specificity, positive and negative predictive values (%) for normal and abnormal classifications of asynchronous video-otoscopy recordings as assessed by an otologist and GP.....	56
<b>TABLE 5.1</b>	Caregiver report of symptoms of otologic disorder over two weeks prior to otomicroscopy .....	69
<b>TABLE 5.2</b>	Obstruction of the tympanic membrane during otomicroscopic examination .....	70
<b>TABLE 5.3</b>	Otologic status as diagnosed by otomicroscopy .....	70
<b>TABLE 5.4</b>	Otologic status as diagnosed by otomicroscopy excluding participants and ears where a diagnosis could not be made .....	71

## LIST OF FIGURES

<b>FIGURE 3.1</b> Video-otoscopy image of a normal tympanic membrane .....	35
<b>FIGURE 3.2</b> Video-otoscopy image of a tympanic membrane with inflammation over pars flaccida and over handle of malleus indicating early stage of acute otitis media .....	35
<b>FIGURE 4.1</b> Hearing telehealth clinic facilitator completing video-otoscopy recording for a child.....	50
<b>FIGURE 4.2</b> Video-otoscopy recordings rated poor quality as a function of participant age.....	54
<b>FIGURE 6.1</b> Flowchart of proposed telehealth model for primary health care diagnosis of ear disease .....	83

## LIST OF APPENDICES

<b>APPENDIX A</b>	Study I participant information form .....	97
<b>APPENDIX B</b>	Study I participant consent form.....	99
<b>APPENDIX C</b>	Study I onsite otoscopy data sheet .....	101
<b>APPENDIX D</b>	Study I video-otoscopy images remote data sheet .....	103
<b>APPENDIX E</b>	Study II and III caregiver information sheet.....	105
<b>APPENDIX F</b>	Study II and III caregiver consent form .....	107
<b>APPENDIX G</b>	Study II and III onsite otomicroscopy data sheet .....	109
<b>APPENDIX H</b>	Study II video-otoscopy recordings remote data sheet .....	111
<b>APPENDIX I</b>	Postgraduate committee and research ethics committee approval letter .....	113
<b>APPENDIX J</b>	Witkoppen Health and Welfare Centre permission letter .....	115

## ACKNOWLEDGMENTS

Firstly to my academic colleagues and friends:

- To De Wet: I can't promise that I am now more logical than when I started this process but I think I can say I am considerably less long-winded and convoluted. Thank you for your most wonderful supervision, which never failed to make me think a little further. I can only hope I learn to supervise students one day as well as you do.
- To Claude: Thank you for your friendship, enthusiasm and constant drive for perfection. Your dedication and hard work has been an inspiration.
- To Bart for the continuous encouragement and for luring me into academia!
- To Thorbjörn, my co-author and fellow PhD student, for his constant encouragement and for his largely misplaced faith in me.
- To Bola: Thank you for your patience and huge support during study I.
- To Jay for pointing out the missed thought that makes all the difference to an article.

And to my family:

- To Hennie: My work and my achievements mean nothing unless you are there for me to share this with. You give me so much more strength and belief in myself than I thought I was capable of.
- To my parents: Mon and dad, thank you for your unwavering support and for rushed opinions on my writing. Thank you for being proud of me – it makes me try harder and be better! Love you lots.
- To my grandparents – it's done! You never questioned whether it was possible but only wanted to know when ;) xxx
- To Dale and Mia: my siblings, love you and thank you for the support!
- To my friends: for all the hugs and smiles that mean so much more to me than you will ever know.

## ABSTRACT

The study examined the effectiveness of asynchronous video-otoscopy by a telehealth facilitator, for diagnosing ear disease in an underserved community at a primary health care clinic.

**Study I** explored whether video-otoscopy images by a facilitator provided accurate asynchronous diagnosis. Onsite otoscopy was performed by an otolaryngologist on 61 adults. Video-otoscopy images were taken by the facilitator with no formal health care training, and by the otolaryngologist. Images were uploaded to secure server from which the otolaryngologist rated and made a diagnosis six weeks later.

More otolaryngologist acquired images (83.6%) were graded as acceptable or better than facilitator images (75.4%). Moderate concordance was measured between asynchronous diagnosis from video-otoscopy images acquired by the otolaryngologist and facilitator ( $\kappa = 0.596$ ). Lack of depth perception was considered a limitation of video-otoscopy images.

**Study II** investigated asynchronous video-otoscopy recordings made by a facilitator in children at primary health care. Onsite otomicroscopy of 140 children (2-16 years) by an otologist was the gold standard. Video-otoscopy recordings were completed by a facilitator. Four and eight weeks later, an otologist and general practitioner asynchronously graded and made a diagnosis from online recordings.

Video-otoscopy recording quality was acceptable or better in 87% of cases. Asynchronous diagnosis from recordings was not possible for 18% of ears. There was substantial agreement between asynchronous video-otoscopy and onsite diagnoses ( $\kappa = 0.679-0.745$ ). Variability of asynchronous diagnosis accuracy was similar to inter- and intra-rater diagnostic variability.

**Study III** examined the point prevalence of otitis media in the children from study II. Onsite otomicroscopy was completed by an otologist.

Prevalence of otitis media was 24.8%, with OME the most prevalent (16.5%). Despite AOM prevalence of 1.7%, caregivers reported otalgia for 7.4% of children within two weeks of assessment. Caregivers did therefore not typically seek medical opinion for



otalgia. Lack of medical opinion is problematic as the sample demonstrated high CSOM prevalence (6.6%).

A telehealth facilitator with limited training was capable of acquiring good quality video-otoscopy measures in children and adults. Asynchronous video-otoscopy recordings may be used within a telehealth clinic in a primary health care clinic to reduce morbidity and mortality associated with CSOM.

## ORIGINAL PAPERS

- Biagio, L., Swanepoel, D. W., Adeyemo, A., Hall, J. W. III, & Vinck, B. (2013). Asynchronous video-otoscopy with a telehealth facilitator. *Telemedicine and e-Health*, 19(4), 252–258. doi:10.1089/tmj.2012.0161
- Biagio, L., Swanepoel, D.W., Laurent, C., & Lundberg, T. (2014). Video-otoscopy recordings for diagnosis of childhood ear disease using telehealth at primary health care level. *Journal of Telemedicine and Telecare*. 20(6), 300-306. doi:10.1177/1357633X14541038
- Biagio, L., Swanepoel, D. W., Laurent, C., & Lundberg, T. (2014). Paediatric otitis media at a primary health care clinic in South Africa. *South African Medical Journal*, 104(6), 431–435. doi:10.7196/SAMJ.7534

## ABBREVIATIONS

AOM	Acute otitis media
ASHA	American Speech-Language-Hearing Association
CBM	Christian Blind Mission
CI	Confidence interval
CSOM	Chronic suppurative otitis media
GP	General Practitioner
HIV	Human immunodeficiency virus
HPCSA	Health Professions Council of South Africa
NPD	Not possible to diagnose
OME	Otitis media with effusion
TB	Tuberculosis
UNAIDS	United Nations programme on HIV/AIDS
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organisation

# 1 INTRODUCTION

## 1.1 Background

A worldwide drop in mortality rates and rise in life expectancy have increased society's attention on reducing disability and handicap, including deafness and hearing impairment (Goulios & Patuzzi, 2008). Hearing loss ranks as the number one cause of disability globally with 10% of the global population presenting with a mild or greater hearing loss (World Health Organization [WHO], 2006, 2010). Adult-onset hearing loss is ranked thirteenth amongst the leading causes of the global burden of disease, and ninth in terms of years of healthy life lost as a result of disability (Lopez, Mathers, Ezzati, Jamison, & Murray, 2006; Mathers & Loncar, 2006). More than half the global burden of hearing impairment may be caused by preventable ear disease, specifically chronic suppurative otitis media (CSOM; Acuin, 2004). If untreated, where secondary complications are possible, ear disease may lead to sensorineural hearing loss.

## 1.2 Ear disease

The WHO classifies ear disease into three categories: diseases of the external ear; diseases of the middle ear and mastoid; and diseases of the inner ear (Centre for Disease Control and Prevention, 2013). Diseases of the external ear include disease of both the pinna and the external auditory meatus. The external auditory meatus may present with cerumen impaction, a foreign object, otitis externa or exostosis (Silverberg & Lucchesi, 2011). Middle ear disease includes Eustachian tube disorders, otitis media, cholesteatoma, otosclerosis and other ossicular disorders (Swarts et al., 2013; Yoon, Patricia, Kelley, & Friedman, 2012). Tympanic membrane pathologies fall under middle ear disease, and may include conditions such as myringitis, myringosclerosis, retraction pockets and perforations (Jung et al., 2013; Yoon, Patricia et al., 2012). Mastoiditis is a secondary complication of otitis media. Inner ear diseases include disorders of both the cochlear and the vestibular system (Verhoeff, van der Veen, Rovers, Sanders, & Schilder, 2006).

Otitis media is the most common of the ear diseases and the most common childhood disease (Freid, Makuc, & Rooks, 1998). Eighty percent of children will have developed acute otitis media (AOM) at least once before three years of age (Teele, Klein, & Rosner,

1984). AOM represents the most common cause of physician visits for sick children and the major reason for the prescription of antibiotics for children in developed countries (Freid et al., 1998; Teele et al., 1984). The pervasiveness of otitis media poses a challenge in many populations around the world (Daly et al., 2010).

### **1.3 Otitis media**

Otitis media is the inflammation of the middle ear without any reference to the aetiology or the pathogenesis (Bluestone et al., 2002). AOM, otitis media with effusion (OME), and CSOM are different forms of otitis media. OME, the most common type of otitis media, is defined as inflammation of the middle ear in which fluid is present in the middle ear space with the absence of signs and symptoms of acute infection in which the tympanic membrane is intact (Bluestone et al., 2002). The effusion may be watery, thick and mucoid, purulent, or a combination of these. OME may occur spontaneously, or may follow an episode of AOM (Lieberthal et al., 2013; Morris & Leach, 2009). AOM presents as inflammation of the middle ear in conjunction with rapid onset of one or more signs of acute infection, such as otalgia, otorrhea, fever or irritability (Bluestone et al., 2002; Lieberthal et al., 2013; Rovers, Schilder, Zielhuis, & Rosenfeld, 2004). The tympanic membrane is then opaque, inflamed, with limited or no mobility; it may be bulging in the presence of an intact tympanic membrane, or there may be a tympanic membrane perforation (Bluestone et al., 2002; Morris & Leach, 2009). The natural course of AOM shows a high rate of spontaneous recovery (Rosenfeld & Kay, 2003; Rovers et al., 2004; Rovers, 2008).

OME is the mildest form of otitis media and CSOM is the most severe. CSOM is a form of otitis media in which there is a chronic inflammation of the middle ear and mastoid, a non-intact tympanic membrane with or without retractions and recurrent otorrhea (Bluestone et al., 2002; Verhoeff et al., 2006; WHO/CIBA Foundation, 1998). Children with CSOM may have presented with past episodes of OME, AOM with perforation, and finally a progression to CSOM (Morris & Leach, 2009). There are varied opinions on the point in time when AOM becomes CSOM, the definition of chronic otorrhea varying from longer than two weeks to three months (Acuin, 2004; Bluestone et al., 2002; Morris et al., 2005; WHO/CIBA Foundation, 1998). CSOM is also the type of otitis media most likely to persist without treatment (Morris & Leach, 2009). The most common sequela of CSOM is hearing loss (van der Veen et al., 2006). CSOM produces mild to moderate conductive

hearing loss because of tympanic membrane perforation and/or ossicular malfunction in more than 50% of cases (Acuin, 2004). The conductive hearing loss caused by otitis media may lead to behavioural changes and delays in communicative development (Daly et al., 2010; Teele et al., 1984).

CSOM may also occasionally lead to additional suppurative complications such as erosion of the walls of the middle ear and mastoid cavity, facial palsy, labyrinthitis, meningitis, acute mastoiditis, with or without sensorineural hearing loss (Acuin, 2004; Jung et al., 2013; Netto, da Costa, Sleifer, & Braga, 2009; Rovers, 2008; Verhoeff et al., 2006). Complications from CSOM can be permanently disabling and potentially dangerous or even fatal (Acuin, 2004).

The epidemiology of otitis media is complex, with risk factors involving multiple host-related factors (age, race, sex, allergy, immune-competence, craniofacial abnormalities, genetic predisposition) and environmental factors (recurrent upper respiratory infections, seasonality, day care, siblings, tobacco smoke exposure, lack of breast feeding, low socioeconomic status), which are considered important in the occurrence, recurrence, and persistence of middle ear disease (Casselbrant & Mandel, 2003; Daly et al., 2010; Hoffman et al., 2013; Morris & Leach, 2009; Rovers et al., 2004; Rovers, 2008). The Eustachian tube plays a central role in otitis media as it is the port of entry to the middle ear for pathogens from the nasopharynx, and is also important in clearing middle ear secretions (Rovers et al., 2004; Swarts et al., 2013).

History of otitis media is in itself also considered a risk factor for the development of future episodes of the disease. Children with OME suffer from up to five times more episodes of AOM than those without OME (Alho, Oja, Koivu, & Sorri, 1995). The peak incidence of AOM occurs during the second half of the first year of life and decreases with age (Teele, Klein, & Rosner, 1989). Inadequate antibiotic treatment, poor access to medical care and poor hygiene and nutrition are also associated with otitis media (Casselbrant & Mandel, 2003; Daly et al., 2010). CSOM prevalence was halved over a ten year period in Maori children in New Zealand by improving housing and access to health care (WHO/CIBA Foundation, 1998). The predisposition of certain races for CSOM, such as the South-western American Indians, Australian Aborigines, Greenlanders, and Alaskan Eskimos, is well documented (Acuin, 2004; Hoffman et al., 2013; Morris et al., 2005).

HIV positive children are more prone to, and more severely affected by otitis media than immunocompetent children (Miziara, Weber, Araújo Filho, & Pinheiro Neto, 2007). An estimated 3 million of the 3.3 million children worldwide who are HIV positive (0 - 14 years of age) live in sub-Saharan Africa (UNICEF, 2013). Of the sub-Saharan countries, South Africa presents with the second highest prevalence of new HIV infections in children (UNAIDS, 2013). HIV status is therefore likely to be an important factor in the prevalence rates of paediatric otitis media in South Africa.

The nature of the burden of otitis media differs greatly between developed and developing countries. The incidence of AOM in Sub-Saharan African, South Asia and Oceania is two to eight times higher than in other areas of the world (Monasta et al., 2012). In 1998 the WHO reported that the prevalence of CSOM in Africa was classified as high (WHO/CIBA Foundation, 1998), with Sub-Saharan Africa presenting with the second highest global incidence of CSOM (Monasta et al., 2012). Together with India, Sub-Saharan Africa accounts for most deaths from otitis media complications (Acuin, 2004). Tiedt et al. (2013) reported a high prevalence of complications associated with CSOM in South African children below 13 years of age with CSOM who attended a specialist clinic at a tertiary hospital.

In South Africa, only three studies assessed the prevalence of otitis media, the latest of which was completed over 20 years ago (Halama, Voogt, Musgrave, & van der Merwe, 1987; Nel, Odendaal, Hurter, Meyer, & Van der Merwe, 1988; Prescott & Kibel, 1991). The CSOM prevalence varied considerably amongst the aforementioned studies however, with rates of 0.3% to 6% of the paediatric population. Variation in CSOM definitions made comparison between studies difficult though. OME prevalence rate, which was most frequently reported by all South African studies, also fluctuated from 3.8% to 12% (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991). These studies selected rural populations, with many of the poor socioeconomic conditions associated with otitis media, but focused on school aged children (Halama et al., 1987; Prescott & Kibel, 1991) as opposed to younger children who are more prone to otitis media (Casselbrant & Mandel, 2003). Additionally, otoscopy, rather than otomicroscopy, was used previously to diagnose middle ear pathology. Otomicroscopy demonstrates better sensitivity and specificity than either otoscopy or pneumatic otoscopy (Lee & Yeo, 2004), and is therefore likely to provide a more accurate diagnosis and classification of otitis media. Also, no

studies on otitis media prevalence have previously been performed at primary health care clinics in South Africa.

Despite the diverse risk factors and influences, otitis media is largely preventable, and can be effectively managed through medical and surgical approaches (WHO/CBM, 2013). The WHO states that half of all cases of hearing loss are avoidable through primary prevention (WHO, 2013a). Knowledge of the prevalence of otitis media, especially of the most severe form of the disease, is important in determining management protocols (Casselbrant & Mandel, 2001; Morris & Leach, 2009). In a community where CSOM prevalence is low, the disease will generally resolve without treatment or complications. However, early medical intervention is indicated in communities where more than 4% of children experience CSOM, considered a high-risk population (Morris & Leach, 2009). With prevalence rates in sub-Saharan Africa reportedly 4% or higher (Acuin, 2004; Prescott & Kibel, 1991) early medical intervention is essential. However estimates place one otolaryngologist for approximately 250,000 to 7.1 million people in sub-Saharan Africa (Fagan & Jacobs, 2009). Early diagnosis of middle ear pathology is therefore particularly important in this, an area where hearing health services and hearing health professionals are very limited (WHO, 2013a).

Utilising innovations in technology and the growth in connectivity allows for the implementation of services through telehealth models which hold significant promise for improving access to hearing health care services in underserved regions such as sub-Saharan Africa (Eysenbach, 2001; Krumm, Ribera, & Schmiedge, 2005; Swanepoel, Olusanya, & Mars, 2010; Swanepoel, Clark, et al., 2010).

#### **1.4 Telehealth**

Telemedicine is the application of telecommunications technology to deliver professional medical services at a distance by linking clinician to patient; or clinician to clinician for assessment, intervention, and/or consultation (American Speech-Language-Hearing Association [ASHA], 2005a; Swanepoel & Hall, 2010). Telehealth is the expansion of telemedicine, to include applications across the full spectrum of the health sciences (ASHA, 2005a). The Health Professions Council Of South Africa defines telehealth as an exchange of health care information at a distance in order to facilitate, improve and

enhance clinical, educational and scientific health care and research, particularly to the underserved areas of South Africa (HPCSA, 2008).

Telehealth may be employed to overcome barriers related to access to services caused by distance, unavailability of specialists and/or subspecialists, and impaired mobility of patients (ASHA, 2005a). Telehealth offers the potential to extend clinical services to rural, remote, and underserved populations, and culturally and linguistically diverse populations. As such, it is the position of ASHA that telehealth is an appropriate model of service delivery for the profession of audiology and is designated as tele-audiology (ASHA, 2005a).

## **1.5 Models of service delivery**

Three distinct telehealth practice models are recognized namely store-and-forward (asynchronous), clinician interactive (synchronous), and self-monitoring/testing (Agency for Healthcare Research and Quality, 2001). A combination of both synchronous and asynchronous approaches may also be useful in some settings (Krumm, 2007).

The store-and-forward telehealth model is an asynchronous, noninteractive form of telehealth during which clinical data is collected, stored, and forwarded for later interpretation (ASHA, 2005b). Store-and-forward telehealth systems have the ability to capture and store digital still or moving images of patients, as well as audio and text data (Agency for Healthcare Research and Quality, 2001). The store-and-forward model does not require for the client and clinician to be available at the same time. Examples of store-and-forward applications in audiology include transmission of audiological data such as hearing screening results, auditory brainstem responses, otoacoustic emissions recordings and audiograms (ASHA, 2005b; Krumm, 2007). The use of store-and-forward applications with automated testing and calibration procedures may be the most appropriate model for providing tele-audiology services in sub-Saharan Africa in order to enhance time- and cost-efficiency (Swanepoel, Olusanya, et al., 2010).

Clinician-interactive telemedicine services are real-time clinician-patient interactions that, in the conventional approach, require face-to-face encounters between a patient and a health care provider (Agency for Healthcare Research and Quality, 2001). Clinical hearing



evaluation and intervention can be performed in real-time (i.e. synchronously) through devices operated remotely, using computer application sharing combined with videoconferencing (Swanepoel, Olusanya, et al., 2010). Remote control software applications permit the clinician to control computers and their peripherals, such as otoacoustic emission systems located at consumer sites (ASHA, 2005b). The synchronous technology can also include adjustment of amplification devices, including hearing aids and cochlear implants (ASHA, 2005b). The advantage of remote control computing is that the clinician can test the patient directly without an intermediate technician or facilitator. However, synchronous telehealth service delivery is not always possible, due to time constraints of the staff involved. Synchronous diagnosis also requires high speed broadband connectivity which is often unavailable in areas such as sub-Saharan Africa (International Telecommunication Union / United National Educational Scientific and Cultural Organization, 2013).

Self-monitoring / testing telehealth services enable health care providers to monitor physiologic measurements, test results, images, and sounds, usually collected in a patient's residence or a care facility (Agency for Healthcare Research and Quality, 2001). Patients with chronic illnesses, and patients with conditions that limit their mobility often require close monitoring and follow up with the aim of early detection of problems (Agency for Healthcare Research and Quality, 2001). One application hereof is self-assessment of hearing sensitivity to identify hearing-impaired patients in a cost effective manner that requires little clinician involvement (Ho, Hildreth, & Lindsey, 2009).

The field of audiology, and therefore also of hearing telehealth, encompasses prevention, assessment, and rehabilitation of hearing, auditory function, balance, and other related systems (Swanepoel & Hall, 2010). An examination of the tympanic membrane and ear canal is essential in the assessment of ear disease and hearing loss (Eikelboom, Mba, Coates, Atlas, & Gallop, 2005). The video-otoscope has extended the capabilities of the traditional otoscope as a tool for tympanic membrane examination, allowing digitized images or recordings of the ear canal and tympanic membrane to be reviewed, stored, archived, and transmitted via internet (via e-mail attachments, or uploaded on a central, secure database) for medical specialist opinion. The video-otoscope, used within a telehealth program, has the potential to provide specialist care to people in rural and remote areas (Mba, Eikelboom, Atlas, & Gallop, 2003).

## 1.6 Video-otoscopy within telehealth clinics

Studies comparing video-otoscopy with conventional face-to-face otoscopy examination concluded that images are equivalent in quality to standard face-to-face otoscopy, with 75% to 82% judged to be of adequate quality or better (Lundberg, Westman, Hellström, & Sandström, 2008; Pedersen, Hartviksen, & Haga, 1994; Smith, Perry, Agnew, & Wootton, 2006). Importantly, for the purpose of validation of use of video-otoscopy within a tele-audiology program, studies have demonstrated average to good diagnostic concordance between otoscopy and video-otoscopy images (Burgess et al., 1999; Eikelboom et al., 2005; Kokesh et al., 2008; Patricoski et al., 2003).

Previous research has reported on the use of video-otoscopy for telehealth applications within underserved communities (Eikelboom et al., 2005; Kokesh et al., 2008; Patricoski et al., 2003; Smith et al., 2006). The study by Eikelboom et al. (2005) made use of images taken by an experienced video-otoscopist, rather than clinic facilitator or health care worker. The exact qualification of the video-otoscopist was, however, not clarified. The study also used the participant's clinical history, audiometric and tympanometric data in order to help the otolaryngologist make a retrospective diagnosis using the images. One study made use of video-otoscopy images taken by individuals with no formal health care training, rather than nurses or health care workers (Kokesh et al., 2008). Kokesh et al. (2008) evaluated video-otoscopy images taken by a community health care worker. Concordance between the diagnoses of two otolaryngologists based on asynchronous evaluation of video-otoscopy images acquired by a health care worker was substantial ( $\kappa = 0.70$ ) compared to 'near perfect' concordance during face-to-face otoscopy ( $\kappa = 0.83$ ), which served as the gold standard. The population was, however, limited to children attending follow-up appointments following tympanostomy tube placement. The use of a closed sub set of participants is likely to have improved the resulting diagnostic concordance. A dearth of research therefore exists regarding the diagnostic validity of video-otoscopy images taken of a heterogeneous group of patients by a facilitator within a hearing telehealth clinic in an underserved community.

The lack of depth perception was identified as a limitation of asynchronous video-otoscopy images (Kokesh et al., 2008; Patricoski et al., 2003). Smith, Dowthwaite, Agnew and Wootton (2008) made use of real-time telehealth video conferencing for otolaryngological diagnosis which included synchronous video-otoscopy examination

performed by a paediatrician. Diagnosis made via telehealth principles was reportedly equivalent to onsite examination in 99% of cases with 93% agreement on surgical management decisions.

In an earlier study, Smith et al. (2006) did evaluate the use of asynchronous video-otoscopy recordings completed by a nurse in a sample of 58 paediatric patients taken from a population at high risk of developing chronic ear disease. A panel of otolaryngologists compared the diagnosis and management recommendations made during the original onsite appointment with that using video-otoscopy recordings and the participant history. The panel judged 75% of video-otoscopy recordings to be adequate. The diagnosis was comparable in 81% cases with agreement on clinical management decisions in 76% of cases. Variations in intra-observer agreement were noted in 5% to 10% of cases. The otolaryngologists commented that the three dimensional video-otoscopy recording demonstrated variations in light reflection patterns produced by movement over an atrophic and retracted ear drum, which increased the accuracy of diagnosis. This suggests that the video-otoscopy recording was effective in addressing the lack of depth perception noted with video-otoscopy images. Although Smith et al. (2006) confirmed that video-otoscopy recordings are useful for the assessment of common otologic conditions, there were some limitations in methodology. The authors used a consensus panel to judge level of agreement and clinically significant differences, rather than independent specialists who were blinded to the others' assessment. Additionally, the video-otoscopy recordings were acquired by a research nurse, who may not be available in remote hearing telehealth clinics.

Video-otoscopy data therefore demonstrates potential for remote diagnosis in children and adults. Previous research has used a hearing telehealth clinic facilitator to acquire video-otoscopy but participants were limited to a post-tympanostomy tube placement. It is not yet known whether diagnostic accuracy of asynchronous interpretation of video-otoscopy data compared to onsite assessment will be as high for patients with diverse ear disease in a primary health care clinic. Further research is therefore required regarding the diagnostic validity of video-otoscopy images or recording taken of a heterogeneous group of patients by a hearing telehealth clinic facilitator.

## **1.7 Rationale**

Otitis media is a frequently occurring, yet preventable, childhood disease associated with a high degree of morbidity and impaired quality of life (Schuerman, Borys, Hoet, Forsgren, & Prymula, 2009). Otitis media places a considerable economic burden on health care resources (Schuerman et al., 2009). This is especially true in sub-Saharan Africa where specialist hearing health services are very limited (Fagan & Jacobs, 2009).

Telehealth may be used to overcome the many barriers to access to services (Swanepoel & Hall, 2010). Video-otoscopy may be used effectively within a telehealth context to assist in early identification of otitis media. A telehealth clinic facilitator with no formal health care education may be trained to acquire video-otoscopy measures (Kokesh et al., 2008). Once uploaded to a central server, remote specialist otolaryngologists may be able to access and make a diagnosis from asynchronous video-otoscopy measures from anywhere in the world.

It is imperative to note that the use of telehealth does not remove any existing responsibilities in delivering services, including adherence to the Code of Ethics, Scope of Practice, national laws and HPCSA policy documents on professional practices (ASHA, 2005a; HPCSA, 2008). Therefore, services delivered via hearing telehealth must adhere to the same level of quality as services delivered onsite (American Speech-Language-Hearing Association, 2005a).

The current research project was therefore initiated in light of the high prevalence of otitis media in developing countries, lack of health personnel to accurately diagnose ear disease for appropriate early treatment in these regions and the potential of telehealth to increase access to care when utilising a local facilitator.

The following question was therefore posed: *What is the effectiveness of asynchronous video-otoscopy images and recordings, acquired by a telehealth facilitator, for diagnosing ear disease at a primary health care clinic in an underserved community?*

## **2. METHOD**

### **2.1 Research objectives**

When formulating the research question related to health care delivery, clarification of the definitions of effectiveness and efficiency may be of value. Goodman (2004) states that efficacy refers to the probability of benefit to individuals in a defined population from a service or medical technology applied for a given medical problem under ideal conditions of use. Effectiveness on the other hand is defined as the benefit (e.g. to health outcomes) of using a technology or service delivery model for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home (Goodman, 2004). Similarly, Brook and Lohr (1985) state that effectiveness has all the attributes of efficacy except one: it reflects performance under ordinary, rather than ideal conditions, by the average practitioner for the typical patient.

With reference to the aforementioned definitions, the aim of the present study was formulated as follows: To evaluate the effectiveness of asynchronous video-otoscopy images and recordings, acquired by a telehealth facilitator, for diagnosing ear disease at a primary health care clinic in an underserved community. Three studies were designed to address the three main research objectives, for submission to three ISI accredited peer-reviewed journals upon completion. The three studies are summarised in Table 2.1 according to proposed titles, objectives, and journal for submission.

**Table 2.1 Summary of studies I to III displaying article title, objectives and journal**

<b>Study</b>	<b>I</b>	<b>II</b>	<b>III</b>
<b>Title</b>	Asynchronous video-otoscopy by a telehealth facilitator	Video-otoscopy recordings for diagnosis of childhood ear disease using telehealth at primary health care level	Paediatric otitis media at a primary health care clinic in South Africa
<b>Objectives</b>	<p>The study investigated whether video-otoscopy images taken by a telehealth clinic facilitator are sufficient for accurate asynchronous diagnosis by an otolaryngologist within a heterogeneous population.</p> <ol style="list-style-type: none"> <li>Determine and compare the quality of video-otoscopy images taken by an otolaryngologist and by the clinic facilitator.</li> <li>Determine and compare the diagnostic accuracy of onsite otoscopy, video-otoscopy images taken by an Otolaryngologist, and video-otoscopy images taken by the clinic facilitator.</li> <li>Determine and compare the sensitivity and specificity for normal and abnormal classifications of asynchronous video-otoscopy images acquired by the otolaryngologist and by the clinic facilitator.</li> </ol>	<p>The study investigated otologist and general practitioner (GP) interpretations of asynchronous video-otoscopy recordings made by an ear and hearing telehealth clinic facilitator, compared to onsite otomicroscopy, in a paediatric population</p> <ol style="list-style-type: none"> <li>Determine the quality of video-otoscopy recordings.</li> <li>Determine the diagnostic accuracy using video-otoscopy recordings.</li> </ol>	<p>The study examined (using otomicroscopy) the point prevalence of otitis media in a paediatric population in a primary health care clinic in South Africa.</p> <ol style="list-style-type: none"> <li>Determine the point prevalence of participants that presented with cerumen.</li> <li>Determine the point prevalence of the different types of otitis media.</li> <li>Determine the point prevalence of participants where a diagnosis could not be determined.</li> </ol>
<b>Journal</b>	Telemedicine and e-Health	Journal of Telemedicine and Telecare	South African Medical Journal
<b>Publication status</b>	<p>Accepted and published:            Biagio, L., Swanepoel, D. W., Adeyemo, A., Hall, J. W. III, &amp; Vinck, B. (2013). Asynchronous video-otoscopy with a telehealth facilitator. <i>Telemedicine and e-Health</i>, 19(4), 252–258.            doi:10.1089/tmj.2012.0161</p>	<p>Accepted and published:            Biagio, L., Swanepoel, D.W., Laurent, C., &amp; Lundberg, T. (2014). Video-otoscopy recordings for diagnosis of childhood ear disease using telehealth at primary health care level. <i>Journal of Telemedicine and Telecare</i>. 20(6), 300-306.            doi:10.1177/1357633X14541038</p>	<p>Accepted and published:            Biagio, L., Swanepoel, D. W., Laurent, C., &amp; Lundberg, T. (2014). Paediatric otitis media at a primary health care clinic in South Africa. <i>South African Medical Journal</i>, 104(6), 431–435. doi:10.7196/SAMJ.7534</p>

## **2.2 Research design and methods**

Table 2.2 presents a summary of the study design, participant selection criteria, sampling method, sample size, equipment and apparatus and data collection material for each of the three studies completed.

**Table 2.2 Research design and methods summary for studies I to III**

<i>Study</i>	<b>I</b>	<b>II</b>	<b>III</b>
<i>Title</i>	Asynchronous video-otoscopy by a telehealth facilitator	Telehealth for primary health care: A video-otoscopy study of paediatric ear disease	Paediatric otitis media at a primary health care clinic in South Africa
<i>Study design</i>	Quasi-experimental within subject comparative research design using quantitative data (Baldwin & Berkeljon, 2010; Kaplan, 1987)		Non-experimental, descriptive research design using quantitative data (Kaplan, 1987; Trochim, 2006)
<i>Participant selection criteria</i>	<ul style="list-style-type: none"> <li>• Participants must be registered patients of the Witkoppen Health and Welfare Centre.</li> <li>• Both male and female participants will be included.</li> <li>• Participants may have normal hearing or any degree of hearing loss.</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• Participants must be 18 years of age or older.</li> <li>• The individual must be able to read or understand English, Venda, Zulu, Xhosa, Pedi or Northern Sotho.</li> <li>• The individual must have signed the Informed Consent Form (Appendix B).</li> </ul>		
<i>Participant sampling</i>	Convenience sampling (Hussey, 2010)		
<i>Participant description</i>	61 adults (age range = 18–61 years; average age, 39.5±10.3 years; 80.3% female)	140 children aged two to 16 years (age range = 2-15.8 years; mean age = 6.4± 3.5 years; 44.3% female)	
<i>Sample size</i>	240 still video-otoscopy images (120 images acquired by the facilitator; 120 images acquired by the otolaryngologist)	Otomicroscopy completed for 136 participants (272 ears). Video-otoscopy recordings completed for 269 ears	Otomicroscopy completed for 136 participants (272 ears)



<p><b><i>Equipment and apparatus</i></b></p>	<ul style="list-style-type: none"> <li>• Welch Allyn Digital MacroView Video Otoscope WA-23920-Set, with Reusable ear specula.</li> <li>• Welch Allyn Viewer (version 1.1.2.0) is the software that allows visualisation of the video otoscopy images.</li> <li>• Netbook computer (Acer Aspire One PC, Windows XP).</li> <li>• Dropbox (version 1.1.35) is the software that links patient data together via a single web-based folder.</li> </ul>	<ul style="list-style-type: none"> <li>• Leica M525 F40 surgical microscope with a 6:1 zoom magnification (1.2 to 12.8x) and 300-watt xenon fibre optic illumination, with reusable ear specula.</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• Laptop (Lenovo Thinkpad 2.0 T420 Core i5, running Windows 7).</li> <li>• AMH-EUT Dino-Lite Pro Earscope (USB) with a 3, 4 or 5mm speculum</li> <li>• Dropbox (version 1.1.35) is the software that links patient data together via a single web-based folder.</li> </ul>
<p><b><i>Data collection material</i></b></p>	<ul style="list-style-type: none"> <li>• Participant information form (Appendix A).</li> <li>• Individuals willing to participate in the study will be given an informed consent form (Appendix B) to complete and return.</li> <li>• Onsite otoscopy data sheet (Appendix C).</li> <li>• Video-otoscopy images remote data sheet (Appendix D) for remote grading and diagnosis of asynchronous video-otoscopy images.</li> </ul>	<ul style="list-style-type: none"> <li>• Caregiver information form (Appendix E).</li> <li>• Caregivers willing to allow their children to participate in study were given an informed consent form (Appendix F) to complete and return.</li> <li>• Onsite otomicroscopy data sheet (Appendix G)</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• Video-otoscopy recording remote data sheet (Appendix H) for remote grading and diagnosis of asynchronous video-otoscopy recordings.</li> </ul>

## 2.3 Ethical considerations

The research project was approved by the Postgraduate Committee of the Faculty of Humanities of the University of Pretoria on 13 September 2011, and by the Research Ethics Committee of the Faculty of Humanities of the University of Pretoria on 20 October 2011 (see Appendix I). Permission was also obtained from Witkoppen Health and Welfare Centre to conduct the current research project at the clinic (see attached Appendix J).

The South African National Health Act (2007) states that medical and health care research is subject to ethical standards that promote respect for all human beings and protect their health and rights. In keeping with this statement, the current study will be initiated and conducted within the framework of the ethical guidelines set out in the Guidelines of Practice in the Conduct of Clinical Trials in Human Subjects in South Africa (South African Department of Health, 2000) and in the South African National Health Act (2007). The individual principles presented in these documents are listed and discussed below in Table 3 as they were applied to the current study.

**Table 2.3 Ethical principles applied to formulation of research design, participant selection and recruitment procedures, and data collection and analysis procedures (South African Department of Health, 2000; South African National Health Act, 2007)**

Principle	Application to study
<p><i>The right, safety and wellbeing of the participants are the most important considerations and should prevail over interest of science and society. Foreseeable risks and inconveniences should be weighed against the anticipated benefit for participants and society. A study should only be initiated and continued if the anticipated benefits justify the risks.</i></p>	<p>There are no risks involved for the participants of this study with the only inconvenience being the extra time spent at the clinic. The telemedicine model replaces the traditional personal encounter between patient and clinician but the advantages hereof must not be at the cost of quality. The benefit for the population in question is verification of the accuracy and cost efficiency of a novel service delivery model. Cost effectiveness is one of the cornerstones of the South African National Health Act (2007). The participants were not exposed to unusual stress or embarrassment. The video-otoscopy image or recording allowed both participants and caregivers to see any pathology diagnosed. The video-otoscope served as a good counseling tool with specialist doctors on hand at the local clinic to explain the findings and recommendations made. The benefit hereof was frequently expressed by participants / caregivers.</p>
<p><i>Research or experimentation on an individual may only be conducted after the participant has been informed of the objectives of the research or experimentation and any possible positive or negative consequences on his or her health.</i></p>	<p>There was no direct benefit to the participants but also no risks involved. An information form (Appendix A or E) was presented to all individuals who were potential participants in the study or to the caregivers of potential participants. The information form described the broad purpose and rationale of the study, what participation would involve and participant rights. Individuals were encouraged to ask any questions they may have had regarding the study or regarding their rights as participants / caregivers of participants in the study.</p>
<p><i>The health care provider must also, where possible, inform the individual in a language that the individual understands, and in a manner which takes into account the individual's level of literacy.</i></p>	<p>The hearing telehealth clinic facilitator, having been recruited from the community that the clinic serves, is fluent in six languages. As such, she was able to translate and answer any questions that potential participants / caregivers may have. This ensured understanding of the information and consent forms. The information and consent forms were also read aloud if necessary to the potential participants / caregivers by the researcher or facilitator in order to overcome any limitations in levels of literacy. The participants were also encouraged to ask any questions they may have had regarding the aims and objectives of the study, or their rights as participants / caregivers of participants in the study.</p>
<p><i>Freely given informed consent should be obtained from every participant prior to clinical trial participation.</i></p>	<p>Freely given informed consent was obtained from every participant through use of the informed consent form as presented in Appendix B. This enabled the researcher to acquire written consent from each participant / caregiver prior to the assessment.</p>
<p><i>The participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.</i></p>	<p>This principle was stated in the informed consent form (Appendix B) and was reiterated verbally in the participant's / caregiver's home language prior to commencement of the assessment session.</p>
<p><i>The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).</i></p>	<p>Participant confidentiality was ensured as data was reported using an alphanumeric code. The identity of the participant represented by this code was known only to the researcher. Access to online data folders, which was also marked with only the alphanumeric code, was restricted to the four researchers only.</p>

***A preliminary study should be conducted in compliance with the protocol that has received prior institutional review board / independent ethics committee approval.***

The Research Ethics Committee of the Faculty of Humanities of the University of Pretoria gave approval for the study.

***Participants have the right to know their health status and researchers are obligated to disseminate results in a timely and competent manner.***

The facilitator and researcher conveyed the results of hearing assessment to participants directly after completion of audiometry. The facilitator was trained on how to convey the information and on what information to provide, with the researchers on hand to answer any questions. For the majority of participants, the facilitator was able to interpret results in the participants' home language.

### **3. STUDY I: Asynchronous video-otoscopy by a telehealth facilitator**

#### **3.1 Abstract**

**Objective:** The study investigated whether video-otoscopy images taken by a telehealth clinic facilitator are sufficient for accurate asynchronous diagnosis by an otolaryngologist within a heterogeneous population.

**Material and Methods:** A within-subject comparative design was employed with 61 adults recruited from patients of a primary health care clinic. The telehealth clinic facilitator had no formal health care training. Onsite otoscopy examination performed by the otolaryngologist was considered the gold standard diagnosis. A single video-otoscopy image was recorded by the otolaryngologist and facilitator from each ear, and the images were uploaded to a secure server. Images were assigned random numbers by another investigator and six weeks later, the otolaryngologist accessed the server, rated each image and made a diagnosis without participant demographic or medical history.

**Results:** A greater percentage of images acquired by the otolaryngologist (83.6%) were graded as acceptable and excellent, compared to images recorded by the facilitator (75.4%). Diagnosis could not be made from 10.0% of the video-otoscopy images recorded by the facilitator compared to 4.2% taken by the otolaryngologist. A moderate concordance was measured between asynchronous diagnosis made from video-otoscopy images acquired by the otolaryngologist and facilitator ( $\kappa = 0.596$ ). The sensitivity for video-otoscopy images acquired by otolaryngologist and facilitator was 0.80 and 0.91 respectively. Specificity for images acquired by otolaryngologist and facilitator was 0.85 and 0.89 respectively, with a diagnostic odds ratio of 41.0 using images acquired by the otolaryngologist and 46.0 using images acquired by the facilitator.

**Conclusion:** A trained telehealth facilitator can provide a platform for asynchronous diagnosis of otological status using video-otoscopy in underserved primary health care settings.

## 3.2 Introduction

Advances in science and technology have historically significantly impacted health care delivery. Various authorities have recognised this trend, suggesting that health practices incorporate new norms and standards which serve the interests of the international community, and align themselves with current realities of global health (Eysenbach, 2001; Fagan & Jacobs, 2009; Swanepoel, Clark, et al., 2010). The reality of hearing health in sub-Saharan Africa is that there are approximately 250,000 to 7.1 million people per otolaryngologist (Fagan & Jacobs, 2009). The WHO indicated the number of audiologists in developing countries as between one audiologist per 0.5 million people to one per 6.25 million (WHO/CIBA Foundation, 1998). Ironically, more than 80% of people with moderate to profound hearing loss live in low- and middle-income countries, such as those in sub-Saharan Africa, where hearing health professionals, and subsequently hearing health services, are either completely absent or very limited (WHO, 2013a). Consequently, a new, innovative means of bringing hearing health services to people, such as telehealth, should be investigated as a high priority (Swanepoel & Hall, 2010). The global revolution in connectivity and continuing advances in technology mean that hearing health delivery through telehealth is becoming increasingly possible to underserved regions (Motsoaledi, 2010; Swanepoel, Clark, et al., 2010).

The video-otoscope is an example of technology that extends the capabilities of the conventional otoscope as a tool for ear canal and tympanic membrane examination, allowing digitized images of these to be reviewed, stored, archived, and transmitted for medical specialist opinion. The video-otoscope, incorporated into a hearing telehealth program, has the potential to allow provision of specialist care to people in rural and remote areas (Aronzon, Ross, Kazahaya, & Ishii, 2004; Mbao et al., 2003).

Previous studies concluded that video-otoscopy images are equivalent in quality to face-to-face otoscopy (Lundberg et al., 2008; Mbao et al., 2003; Patricoski et al., 2003; Pedersen et al., 1994; Swanepoel & Hall, 2010). A comparison of four video-otoscopes found that three of the four systems yielded images rated as adequate or better for at least 80% of the images (Mbao et al., 2003). Previous studies reported 75 to 82% of video-otoscopy images respectively were judged to be adequate, good, very good or excellent in quality (Lundberg et

al., 2008; Smith et al., 2006). Importantly, for the purpose of validation of video-otoscopy within a hearing telehealth clinic, studies have demonstrated average to good diagnostic concordance between conventional otoscopy and video-otoscopy images (Burgess et al., 1999; Eikelboom et al., 2005; Kokesh et al., 2008; Patricoski et al., 2003).

Three studies have made use of video-otoscopy for telehealth applications within underserved communities (Eikelboom et al., 2005; Kokesh et al., 2008; Patricoski et al., 2003). Patricoski et al. (2003) compared the diagnosis made from microscopic examination of ears post tympanostomy tube placement with that made from asynchronous video-otoscopy images taken by a nurse. Diagnostic concordance between the aforementioned methods indicated substantial agreement with kappa values ranging from 0.67 to 0.76. Using an experienced video-otoscopist to acquire video-otoscopy images, Eikelboom et al. (2005) reported significant correlations between image quality and age of the participant, and between clinically important observations of the tympanic membrane during face-to-face otoscopy and asynchronous evaluation of video-otoscopy images. In addition, significant diagnostic agreement was demonstrated, although the referral rate after asynchronous assessment was 4 to 16% higher than those in made in the field. The study emphasized the importance of the participant's clinical history, audiometric and tympanometric data in order to assist the otolaryngologist in making an asynchronous diagnosis using the images.

Kokesh et al. (2008) evaluated video-otoscopy images taken by a community health care worker but, as with the study of Patricoski et al. (2003), the population was limited to children attending follow-up appointments following tympanostomy tube placement. Concordance between the diagnoses of two otolaryngologists based on asynchronous evaluation of video-otoscopy images was substantial ( $\kappa = 0.70$ ) compared to near perfect concordance during face-to-face otoscopy ( $\kappa = 0.83$ ), which served as the gold standard. Despite the aforementioned studies there is still a dearth of investigations on the diagnostic validity of video-otoscopy images taken from a heterogeneous group of patients. In particular no validation studies on video-otoscopy images taken by a telehealth clinic facilitator, without formal tertiary education, in a typical hearing telehealth program in an underserved community has been reported.

Early diagnosis of middle ear pathology is particularly important as otitis media is responsible for a significant burden of disease in developing countries in which access to

medical care is limited (Klein, 2000). Complications from untreated middle ear pathology include sensorineural hearing loss, ossicular chain disruption or fixation, perforation of the tympanic membrane, retraction pockets, mastoiditis, and even meningitis (Berman, 1995b; Klein, 2000; Mbao et al., 2003). HIV-infected children with low T4 lymphocyte counts have a nearly 3-fold increased risk of recurrent acute otitis media (Barnett, Klein, Pelton, & Luginbuhl, 1992). Video-otoscopy conducted via telehealth to primary health clinics in underserved areas may contribute to the prevention of complications from middle ear pathology, and to significant improvement in the health and quality of life.

In light of the importance of early diagnosis of middle ear pathology in developing countries, and the lack of evidence on diagnostic validity of video-otoscopy images taken from a heterogeneous population by individuals without formal hearing health care training the current study was initiated. The study investigated whether video-otoscopy images taken by an onsite telehealth clinic facilitator are sufficient for accurate asynchronous diagnosis by an otolaryngologist within a heterogeneous clinic population.

### **3.3 Materials and methods**

#### **3.3.1 Population**

The project was conducted following approval from the institutional ethics committee. A within-subject comparative research design was employed with a sample of 61 consenting adults (age range = 18 to 61 years; average age =  $39.5 \pm 10.3$  years; 80.3% women) recruited from registered patients of the primary health care clinic, where a hearing telehealth clinic was established in 2010. The primary health care clinic serves as a specialist centre for HIV and TB treatment. *No distinction was made regarding the reason for clinic attendance when recruiting participants over the four day data collection period.*<sup>1</sup>

#### **3.3.2 Data collection**

The telehealth hearing clinic facilitator had no formal health care or other tertiary training. Onsite training of the facilitator was provided on how to perform conventional otoscopy and take video-otoscopy images over a two day period. Training included participant positioning, visual inspection of external ear, appropriate hand position, manipulation of direction of speculum, focus adjustment, image capture, video-otoscope software use, and equipment

---

<sup>1</sup> Added to dissertation in response to external examiner recommendations after publication of article



sterilisation. Data collection which included acquisition of case history, face-to-face otoscopy examination, acquisition of video-otoscopy images by the otolaryngologist and facilitator was completed over four consecutive days.

A Welch Allyn Digital MacroView video-otoscope WA-23920-Set, with a 3, 4 or 5mm speculum, was used to acquire the video-otoscope images. The video-otoscope was attached to a Netbook computer (Acer Aspire One PC) running Windows XP Service Pack 2 via a USB video cable. The Welch Allyn Viewer (version 1.1.2.0) software was used to visualise the video-otoscopy images. The images were saved as 24 bit colour (16.7 million colours) PNG images with a resolution of 1280 x 1024 pixels. The conventional otoscopy was performed with a Heine mini3000<sup>®</sup> fibre optic otoscope with 3, 4 and 5mm disposable specula.

Participants were interviewed to obtain biographical information and history of ear ache, ear discharge, hearing loss, tinnitus, balance information and any other relevant information offered. A single video-otoscopy image was then recorded by the telehealth clinic facilitator from each ear. Subsequently an experienced otolaryngologist, who was not present during acquisition of images by the clinic facilitator, performed conventional, face-to-face otoscopy examination, to document tympanic membrane surface structure, thickness, colour, position and to make a diagnosis. This was followed by recording of video-otoscopy images from each ear of the same participant. This onsite otoscopy examination by the otolaryngologist was considered the gold standard diagnosis.

The video-otoscopy images were assigned random numbers by the first author. The images were then uploaded to a secure server. Six weeks later, the otolaryngologist, who was blinded to the randomised images, accessed the secure server and assessed the video-otoscopy images by completing an evaluation form on the server for each image. The otolaryngologist assessed the images without the benefit of relevant participant history or demographic information. The delay in assessment was included to counter the possible effect of memory of images and previous diagnosis made in order to eliminate clinician bias. The overall image quality was graded (0 to 2) with reference to image focus, light, obscuring objects and composition (Lundberg et al., 2008). A grading of 0 indicated that the image quality was not acceptable, and it was not possible to assess the tympanic membrane. An image graded 1 indicated an acceptable image quality, enabling evaluation of the status of the tympanic

membrane. An excellent video-otoscopy image was graded 2, indicating high image quality, with tympanic membrane easily assessable. Otoscopy findings related to tympanic membrane surface structure, thickness, colour and position, as well as the concluding diagnosis were documented. The aforementioned data collection order was maintained during data collection for all participants. One participant did not consent to acquisition of video-otoscopy imaging of one ear by either the facilitator or otolaryngologist due to reported discomfort. Two other video-otoscopy images were lost due to software error. The remaining 240 video-otoscopy images, 120 video-otoscopy images taken by a facilitator and 120 taken by the otolaryngologist, were randomly numbered from one to 240.

### 3.3.3 Data analyses

Descriptive statistics were used to describe the mean image quality rating for images taken by the otolaryngologist and by the telehealth clinic facilitator, and the frequency with which the tympanic membrane surface structure, thickness, colour and position could be evaluated (Trochim, 2006). By classifying the diagnosis as normal or abnormal, the sensitivity and specificity of video-otoscopy images acquired by the facilitator and by the otolaryngologist was calculated with reference to face-to-face otoscopy examination by the otolaryngologist as the ‘gold standard’.

The Chi-Square statistic of independence could not be used to compare conventional otoscopy to the video-otoscopy images as, under the assumption that the null hypothesis is true, the cells displayed an expected frequency count of less than five. The odds ratio, as a statistic of independence for nonparametric data, was used to compare conventional otoscopy to the video-otoscopy images. As a measure of test performance, the odds ratio combines sensitivity and specificity with accuracy as a single indicator (Glas, Lijmer, Prins, Bonsel, & Bossuyt, 2003).

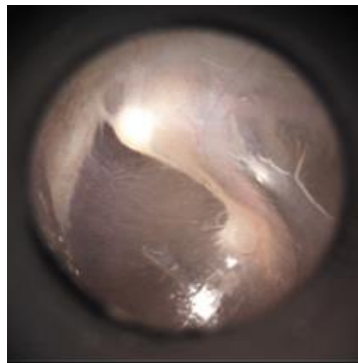
Kappa statistic ( $\kappa$ ) was used to quantify diagnostic concordance between video-otoscopy images acquired by the facilitator and by the otolaryngologist. The diagnostic concordance was based upon the range in which kappa statistic matches: “poor agreement” ( $\kappa < 0.00$ ), “slight agreement” ( $\kappa = 0.01-0.20$ ), “fair agreement” ( $\kappa = 0.21-0.40$ ), “moderate agreement” ( $\kappa = 0.41-0.60$ ), “substantial agreement” ( $\kappa = 0.61-0.80$ ), “almost-perfect agreement” ( $\kappa = 0.81-1.00$ ; Shrout, Spitzer, & Fleiss, 1987). Diagnostic concordance between face-to-face

otoscopy and otoscopy assessment of video-otoscopy images, acquired by the otolaryngologist and facilitator, were determined.

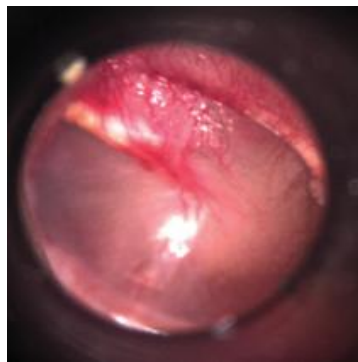
### 3.4 Results

The case history of the sample population included 29.5% with previous history of ear ache, 4.9% with discharge, 42.6% with hearing loss, 42.6% with tinnitus, 18% with balance problems and 14.8% had other related complaints.

Examples of the video-otoscopy images are presented in figures 3.1 and 3.2.



**Figure 3.1 Video-otoscopy image of a normal tympanic membrane**



**Figure 3.2 Video-otoscopy image of a tympanic membrane with inflammation over pars flaccida and over handle of malleus indicating early stage of acute otitis media**

According to the distribution of the asynchronous video-otoscopy image grading (Table 3.1) a larger percentage of the images acquired by the otolaryngologist (83.6%) were graded as acceptable and excellent, compared to the images (75.4%) recorded by the facilitator.

**Table 3.1 Video-otoscopy image grading for images acquired by the otolaryngologist and facilitator (n = 120 ears)**

Image grading	Otolaryngologist images (%)	Facilitator images (%)
0 Unacceptable	15.0	23.4
1 Acceptable	24.2	29.2
2 Excellent	60.8	47.4

According to the distribution of the asynchronous video-otoscopy image grading (Table 3.1) a larger percentage of the images acquired by the otolaryngologist (83.6%) were graded as acceptable and excellent, compared to the images (75.4%) recorded by the facilitator.

**Table 3.2 Otologic diagnoses made using face-to-face otoscopy and asynchronous otoscopy using video-otoscopy images acquired by an otolaryngologist and facilitator (n = 120 ears)**

	Otoscopy (%)	Otolaryngologist images (%)	Facilitator images (%)
Normal	76.2	72.5	62.5
Wax in canal	12.3	10.8	15.0
Chronic suppurative otitis media	5.7	5.0	4.2
Otitis media with effusion	3.3	4.2	5.8
Exostosis	0.8	1.7	0.8
Foreign body in canal	0.8	0.8	0.8
Otomycosis	0.8	0.8	0.8
Image not reliable to make diagnosis	N/A	4.2	10.0

Table 3.2 indicates that the majority of ears assessed using otoscopy and video-otoscopy was judged to be normal. A diagnosis could not be made from 10.0% of images recorded by the facilitator compared to 4.2% of images recorded by the otolaryngologist.

**Table 3.3 Comparison of asynchronous assessment of video-otoscopy images acquired by the otolaryngologist and facilitator (n = 120 ears)**

	Frequency with which characteristics of TM could be assessed		Concordance* between asynchronous video-otoscopy images
	Otolaryngologist images:	Facilitator images:	Kappa value
TM surface structure	81.1	71.3	0.693
TM translucent / opaque	81.1	72.1	0.574
TM colour	82.8	73.0	0.512
TM position	77.9	68.9	0.484
Diagnosis	-	-	0.596

*Asymp. std. error = Asymptotic standard error; TM = tympanic membrane*

*\*Concordance between asynchronous assessment of images acquired by the otolaryngologist and facilitator.*

Table 3.3 indicates that the characteristics of the tympanic membrane could, on average, be assessed asynchronously in 80.7% of images acquired by the otolaryngologist, and in 71.3% of images acquired by the facilitator. The Kappa value indicates a substantial agreement on the asynchronous judgement of surface structure of the tympanic membrane between the images acquired by the otolaryngologist and facilitator ( $\kappa = 0.693$ ), and moderate agreement on judgements of tympanic membrane texture, colour and position ( $\kappa = 0.574, 0.512$  and  $0.484$  respectively). A moderate agreement ( $\kappa = 0.596$ ) between diagnoses made from images acquired by the otolaryngologist and facilitator was found.

**Table 3.4 Sensitivity, specificity and diagnostic odds ratios for asynchronous video-otoscopy using images acquired by an otolaryngologist and facilitator (n = 120 ears)**

Face-to-face otoscopy	Sensitivity		Specificity		Diagnostic odds ratio
		(95% CI)		(95% CI)	
Otolaryngologist images	0.80	(0.61 to 0.91)	0.91	(0.83 to 0.95)	41.00
Facilitator images	0.85	(0.68 to 0.94)	0.89	(0.80 to 0.94)	46.00

(CI = confidence interval)

Comparable sensitivity and specificity scores for asynchronous video-otoscopy using images acquired by the otolaryngologist and facilitator were evident when compared to conventional face-to-face otoscopy (Table 3.4). The odds ratio indicate marginally better diagnoses from video-otoscopy images taken by the facilitator compared to images taken by the otolaryngologist with face-to-face otoscopy as the gold standard.

**Table 3.5 Concordance (%) of face-to-face otoscopy and asynchronous video-otoscopy using images acquired by an otolaryngologist and a clinic facilitator (n = 120 ears)**

Face-to-face otoscopy	Asynchronous video-otoscopy concordance	
	Otolaryngologist images	Facilitator images
Diagnosis = Normal	87.2	76.6
Diagnosis = Abnormal	75.0	82.1

There was a high concordance between the diagnosis made from face-to-face otoscopy, and diagnosis made from asynchronous video-otoscopy using images acquired by the otolaryngologist and the facilitator (Table 3.5). For ears identified as normal by face-to-face otoscopy, a greater diagnostic concordance was measured between otoscopy and video-otoscopy images taken by an otolaryngologist (87.2% concordance) than between otoscopy and video-otoscopy images acquired by a facilitator (76.6% concordance). The reverse was true for ears judged by face-to-face otoscopy to be abnormal. A higher diagnostic

concordance for video-otoscopy images acquired by the facilitator (82.1%) than for video-otoscopy images acquired by the otolaryngologist (concordance = 75.0%) was calculated.

### 3.5 Discussion

In the present study, 83.6% of asynchronous video-otoscopy images acquired by the otolaryngologist, and 75.4% of video-otoscopy images acquired by the facilitator were rated as acceptable or excellent. This is comparable to previous studies that reported 75% to 82% of video-otoscopy images judged to be acceptable or better in quality (Kokesh et al., 2008; Lundberg et al., 2008; Mbao et al., 2003; Smith et al., 2006). Comparable quality ratings between previous studies and the video-otoscopy images taken by the facilitator images in the current study are particularly noteworthy since the aforementioned studies reported on video-otoscopy images taken by an otolaryngologist, a nurse or a community health practitioner, all of whom had formal tertiary education in health care compared to the clinic facilitator with no formal health education. However, a greater number of video-otoscopy images taken by the facilitator were judged to be unacceptable in quality (23.4%) compared to the images taken by the otolaryngologist (15.0%). And a diagnosis could not be made from 10.0% video-otoscopy images acquired by the facilitator compared to 4.2% taken by the otolaryngologist. Experience and additional training may reduce the amount of poor quality images and the amount of images that could not be used to make a diagnosis, as was observed by Lundberg et al. (2008) who reported an improvement in image quality over time as a function of experience. Other studies suggested taking multiple video-otoscopy images of each ear, rather than relying on a single image (Eikelboom et al., 2005). This approach is likely to decrease the amount of referrals for repeat assessment, or for specialist evaluation due to poor video-otoscopy image quality. Other strategies may include taking brief video clips of the ear canal and tympanic membrane for asynchronous interpretation.

Despite the lower quality grading of the video-otoscopy images acquired by the facilitator compared to the otolaryngologist, agreement of characteristics of the tympanic membrane between images acquired by the otolaryngologist and by the facilitator of the same ear ranged from moderate to substantial ( $\kappa = 0.484$  to  $0.693$ ). This agreement is, in fact, similar to previously reported overall interpersonal agreement between two otolaryngologists' for the same asynchronous video-otoscopy images ( $\kappa = 0.49$  to  $0.66$ ; Lundberg et al., 2008). The

lowest concordance was measured in respect of the position of the tympanic membrane as judged from images taken by the otolaryngologist and by the facilitator of the same ear ( $\kappa = 0.484$ ). For both the images acquired by the otolaryngologist and by the facilitator, the characteristic of the tympanic membrane which could be assessed with the lowest frequency was the position of the tympanic membrane. This suggests that noticing mild retraction of the tympanic membrane may be more difficult from a still image compared to a face-to-face otoscopy examination, which may be related to apparent lack of depth perception afforded by two dimensional video-otoscopy images. A negative middle ear pressure is characterized by retraction of the tympanic membrane, prominence of the lateral process of the malleus, a more horizontal orientation of the manubrium of the malleus, and increased mobility of the tympanic membrane when the insufflation creates negative pressure in the external ear canal (Fireman, 1997; Berman, 1995a).

Although prominence of the lateral process of the malleus and orientation of the malleus can be observed using video-otoscopy images, the assessment of mobility of the tympanic membrane requires either pneumatic otoscopy or tympanometry to elicit the required response. A retracted tympanic membrane is typically apparent through use of interactive binocular microscope examination (Patricoski et al., 2003) or pneumatic otoscopy. Typically, in field face-to-face otologic assessment, medical, demographic and social history, in conjunction with techniques such as tympanometry and pure tone audiometry would be used in addition to video-otoscopy or conventional otoscopy. The use of an otoscope alone, even by experienced physicians, may demonstrate unsatisfactory sensitivity and specificity for identifying a retracted tympanic membrane (Cantekin et al., 1980). Therefore the use of two dimensional video-otoscopy images alone, without additional measurements, demographic information, social or medical history, may exhibit poor diagnostic concordance compared to face-to-face otoscopy.

The lack of depth perception afforded by video-otoscopy images was mentioned by previous studies (Kokesh et al., 2008; Patricoski et al., 2003). The use of video pneumatic otoscopy may address the difficulty in identifying a retracted tympanic membrane while being appropriate for use within a hearing telehealth clinic (Cho, Lee, Lee, Ko, & Lee, 2009; Lee et al., 2011). Using video pneumatic otoscopy and quantitative analysis of the degree of movement of the umbo of the malleus, Cho et al. (2009) reported correlation between tympanograms and, amongst other middle ear pathologies, negative middle ear pressure.

Although otitis media with effusion may occur spontaneously because of negative middle ear pressure (Rosenfeld et al., 2004), the identification of a retracted tympanic membrane may not be highly significant within a primary health care environment in a rural or underserved area.

In the present study the Kappa value indicated moderate concordance between asynchronous diagnosis made from video-otoscopy images acquired by the otolaryngologist and by the facilitator ( $\kappa = 0.596$ ). Higher diagnostic concordance between face-to-face otoscopy and video-otoscopy images acquired by either an otolaryngologist or a community health care practitioner, and between two otolaryngologists evaluating video-otoscopy images was reported in previous studies ( $\kappa = 0.64$  to  $0.76$ ; Kokesh et al., 2008; Patricoski et al., 2003). The difference in diagnostic concordance may be attributable to the fact that a nurse acquired the video-otoscopy images in the study by Patricoski et al. (2003;  $\kappa = 0.67$  to  $0.76$ ). Additionally, both Kokesh et al. (2008) and Patricoski et al. (2003) reported on a closed set of diagnostic possibilities as all participants were evaluated after tympanostomy tube placement. In the current study, participants were randomly selected from the patients that attended the primary health care clinic. The population sampled in the present study can be expected to increase diagnostic possibilities and, consequently, decrease diagnostic concordance. In addition to the heterogeneous population, the otolaryngologist in the present study was requested to make an asynchronous diagnosis using video-otoscopy images without the benefit of demographic information, social or medical information. Previous studies provided the diagnosing otolaryngologist with included relevant medical history in support of the video-otoscopy images (Kokesh et al., 2008; Patricoski et al., 2003). Against this background, the moderate diagnostic concordance demonstrated in the current study between asynchronous diagnosis using only video-otoscopy images taken by an otolaryngologist and a facilitator is encouraging.

Percentage diagnostic concordance has been reported in previous studies using microscopy and video-otoscopy. In post tympanostomy tube placement examinations diagnostic concordance was reported to be 76 to 85% (Kokesh et al., 2008; Patricoski et al., 2003). This is comparable to the 87.2% concordance for the otologic diagnosis of normal ears using video-otoscopy images (87.2 and 76.6% of images acquired by the otolaryngologist and facilitator respectively), and for the diagnosis of abnormal ears (otolaryngologist images = 75.0%; facilitator images = 82.1%).



The sensitivity (video-otoscopy images acquired by otolaryngologist = 0.80; images acquired by the facilitator = 0.85<sup>2</sup>), specificity (video-otoscopy images acquired by otolaryngologist = 0.91<sup>3</sup>; images acquired by the facilitator = 0.89) and indicators of accuracy (diagnostic odds ratio = 41.0 using otolaryngologist images and 46.0 using facilitator images) measured in the current study are acceptably high. In fact, sensitivity and specificity values in the current study were comparable to those reported on binocular microscopy performed by a paediatric otolaryngologist (sensitivity = 88.0%; specificity = 89%), which was higher than the sensitivity and specificity of values of both pneumatic otoscopy and tympanometry (Rogers, Boseley, Adams, Makowski, & Hohman, 2010). *The higher sensitivity reported for diagnosis using the facilitator acquired images may have been the result of the larger number of images where a diagnosis could not be made compared to the otolaryngologist acquired images.*<sup>4</sup> The sensitivity, specificity and accuracy values for asynchronous video-otoscopy images acquired by the hearing telehealth clinic facilitator compared to conventional face-to-face otoscopy in the present study were achieved from a heterogeneous population without the benefit of demographic, social or medical history. The population in question is, however, adult, and may not necessarily generalizable to a paediatric population. Further research is required to ascertain whether sensitivity, specificity and accuracy values would be as promising in a less compliant patient population. *Additionally, the use of the same otolaryngologist that acquired the video-otoscopy images to evaluate the images remotely may have biased the results, despite the delay between onsite and asynchronous assessment introduced to minimize this.*<sup>5</sup>

### 3.6 Conclusion

Video-otoscopy images acquired by an otolaryngologist and by a trained hearing telehealth clinic facilitator are equally effective for asynchronous diagnosis by an otolaryngologist compared to conventional face-to-face otoscopy. More poor quality video-otoscopy images were acquired by the facilitator (24.6%) than by the otolaryngologist (16.4%). This may however improve with additional training and experience. Performance of asynchronous video-otoscopy compared to face-to-face otoscopy was similar to previous reports. The apparent lack of depth perception was highlighted as a possible disadvantage of a single

---

<sup>2,3,4,5</sup> Added to dissertation in response to external examiner recommendations after publication of article

video-otoscopy image, but is unlikely to have a significant impact on clinical diagnosis of pathologies. Multiple images or brief video clips of patients' ears may improve diagnostic concordance. Using a hearing health telemedicine facilitator trained in video-otoscopy can provide a platform for asynchronous diagnosis of otological status using video-otoscopy in underserved primary health care settings. Video-otoscopy may have a significant role to play in the early detection of middle ear disease and in the prevention or timely management of life-threatening pathology in developing countries.

### 3.7 Acknowledgements

The authors would like to thank Ms Violet Mugodo, Dr Jean Bassett and the rest of the Witkoppen Health and Welfare Clinic management, staff and patients for their help and support during data collection for this research project.

### 3.8 References

- Aronzon, A., Ross, A. T., Kazahaya, K., & Ishii, M. (2004). Diagnosis of middle ear disease using tympanograms and digital imaging. *Otolaryngology - Head and Neck Surgery*, *131*(6), 917–920. doi:10.1016/j.otohns.2004.07.012
- Barnett, E. D., Klein, J. O., Pelton, S. I., & Luginbuhl, L. M. (1992). Otitis media in children born to human immunodeficiency virus-infected mothers. *The Pediatric Infectious Disease Journal*, *11*(5), 360–364. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/1352871>
- Berman, S. (1995a). Otitis media in children. *The New England Journal of Medicine*, *332*(23), 1560–1565. Retrieved from <http://www.nejm.org/doi/full/10.1056/NEJM199506083322307>
- Berman, S. (1995b). Otitis media in developing countries: Review article. *Pediatrics*, *96*(1), 126–131.
- Burgess, L. P., Holtel, M. R., Syms, M. J., Birkmire-Peters, D. P., Peters, L. J., & Mashima, P. A. (1999). Overview of telemedicine applications for otolaryngology. *The Laryngoscope*, *109*(9), 1433–1437. doi:10.1097/00005537-199909000-00014

- Cantekin, E. I., Bluestone, C. D., Fria, T. J., Stool, S. E., Beery, Q. C., & Sabo, D. L. (1980). Identification of otitis media with effusion in children. *The Annals of Otolaryngology, Rhinology and Laryngology*, 89(3 Pt 2), 190–195. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/6778304>
- Cho, Y.-S., Lee, D.-K., Lee, C.-K., Ko, M. H., & Lee, H.-S. (2009). Video pneumatic otoscopy for the diagnosis of otitis media with effusion: A quantitative approach. *European Archives of Oto-Rhino-Laryngology*, 266(7), 967–973. doi:10.1007/s00405-008-0839-x
- Eikelboom, R. H., Mba, M. N., Coates, H. L., Atlas, M. D., & Gallop, M. A. (2005). Validation of tele-otology to diagnose ear disease in children. *International Journal of Pediatric Otorhinolaryngology*, 69(6), 739–744. doi:10.1016/j.ijporl.2004.12.008
- Eysenbach, G. (2001). What is e-Health. *Journal of Medical Internet Research*, 3(2), e20. doi:10.2196/jmir.3.2.e20
- Fagan, J. J., & Jacobs, M. (2009). Survey of ENT services in Africa: Need for a comprehensive intervention. *Global Health Action*, 2, 1–8. doi:10.3402/gha.v2i0.1932
- Fireman, P. (1997). Otitis media and Eustachian tube dysfunction: Connection to allergic rhinitis. *The Journal of Allergy and Clinical Immunology*, 99(2), S787–S797. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9042072>
- Glas, A. S., Lijmer, J. G., Prins, M. H., Bossel, G. J., & Bossuyt, P. M. M. (2003). The diagnostic odds ratio: A single indicator of test performance. *Journal of Clinical Epidemiology*, 56(11), 1129–1135. doi:10.1016/S0895-4356(03)00177-X
- Klein, J. O. (2000). The burden of otitis media. *Vaccine*, 19 Suppl 1, S2–S8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11163456>
- Kokesh, J., Ferguson, A. S., Patricoski, C., Koller, K., Zwack, G., Provost, E., & Holck, P. (2008). Digital images for postsurgical follow-up of tympanostomy tubes in remote Alaska. *Otolaryngology - Head and Neck Surgery*, 139(1), 87–93. doi:10.1016/j.otohns.2008.04.008
- Lee, J. K., Cho, Y.-S., Ko, M. H., Lee, W. Y., Kim, H.-J., Kim, E., ... Hong, S. H. (2011). Video pneumatic otoscopy for the diagnosis of conductive hearing loss with normal tympanic membranes. *Otolaryngology - Head and Neck Surgery*, 144(1), 67–72. doi:10.1177/0194599810390917

- Lundberg, T., Westman, G., Hellström, S., & Sandström, H. (2008). Digital imaging and telemedicine as a tool for studying inflammatory conditions in the middle ear - Evaluation of image quality and agreement between examiners. *International Journal of Pediatric Otorhinolaryngology*, 72(1), 73–79. doi:10.1016/j.ijporl.2007.09.015
- Mbao, M. N., Eikelboom, R. H., Atlas, M. D., & Gallop, M. A. (2003). Evaluation of video-otoscopes suitable for tele-otology. *Telemedicine Journal and e-Health*, 9(4), 325–331.
- Motsoaledi, A. P. (2010). Address by the South African minister of health. In *1st Southern African Telemedicine Conference*. Cape Town: South African Medical Research Council. Retrieved from [http://www.mrc.ac.za/pressreleases/2010/telemed\\_doh\\_minister2010.htm](http://www.mrc.ac.za/pressreleases/2010/telemed_doh_minister2010.htm)
- Patricoski, C., Kokesh, J., Ferguson, A. S., Koller, K., Zwack, G., Provost, E., & Holck, P. (2003). A comparison of in-person examination and video otoscope imaging for tympanostomy tube follow-up. *Telemedicine Journal and e-Health*, 9(4), 331–345.
- Pedersen, S., Hartviksen, G., & Haga, D. (1994). Teleconsultation of patients with otorhinolaryngologic conditions. A telendoscopic pilot study. *Archives of Otolaryngology - Head and Neck Surgery*, 120(2), 133–136. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8297568>
- Rogers, D. J., Boseley, M. E., Adams, M. T., Makowski, R. L., & Hohman, M. H. (2010). Prospective comparison of handheld pneumatic otoscopy, binocular microscopy, and tympanometry in identifying middle ear effusions in children. *International Journal of Pediatric Otorhinolaryngology*, 74(10), 1140–1143. doi:10.1016/j.ijporl.2010.06.015
- Rosenfeld, R. M., Culpepper, L., Doyle, K. J., Grundfast, K. M., Hoberman, A., Kenna, M. A., ... Yawn, B. (2004). Clinical practice guideline: Otitis media with effusion. *Otolaryngology - Head and Neck Surgery*, 130(5 Suppl), S95–S118. doi:10.1016/j.otohns.2004.02.002
- Shrout, P. E., Spitzer, R. L., & Fleiss, J. L. (1987). Quantification of agreement in psychiatric diagnosis revisited. *Archive of General Psychiatry*, 44, 172–177.
- Smith, A. C., Perry, C., Agnew, J., & Wootton, R. (2006). Accuracy of pre-recorded video images for the assessment of rural indigenous children with ear, nose and throat conditions. *Journal of Telemedicine and Telecare*, 12(7), 76–80. doi:10.1258/135763306779380138

Swanepoel, D. W., Clark, J. L., Koekemoer, D., Hall, J. W. III, Krumm, M., Ferrari, D. V, ...  
Barajas, J. J. (2010). Telehealth in audiology: The need and potential to reach  
underserved communities. *International Journal of Audiology*, 49(3), 195–202.  
doi:10.3109/14992020903470783

Swanepoel, D. W., & Hall, J. W. III. (2010). A systematic review of telehealth applications in  
audiology. *Telemedicine and e-Health*, 16(2), 181–201. doi: 10.1089=tmj.2009.0111

Trochim, W. M. (2006). Research methods: Knowledge base. *Web centre for social research  
methods*. Retrieved September 11, 2010, from  
<http://www.socialresearchmethods.net/kb/index.php>

World Health Organization / CIBA Foundation. (1998). *Prevention of hearing impairment  
from chronic otitis media* (pp. 1–32). London, UK.

World Health Organization. (2013). Deafness and hearing impairment: Fact sheet. World  
Health Organization. Retrieved July 10, 2013, from  
<http://www.who.int/mediacentre/factsheets/fs300/en/>

## **4. STUDY II: Video-otoscopy recordings for diagnosis of childhood ear disease using telehealth at primary health care level**

### **4.1 Abstract**

We studied the diagnoses made by an otologist and general practitioner (GP) from video-otoscopy recordings on children made by a telehealth facilitator. The gold standard was otomicroscopy by an experienced otologist. A total of 140 children (mean age 6.4 years; 44% female) were recruited from a primary health care clinic. Otomicroscopic examination was performed by an otologist. Video-otoscopy recordings were assigned random numbers and stored on a server. Four and eight weeks later, an otologist and a GP independently graded and made a diagnosis from each video recording. The otologist rated the quality of the video-otoscopy recordings as acceptable or better in 87% of cases. A diagnosis could not be made from the video-otoscopy recordings in 18% of ears for whom successful onsite otomicroscopy was conducted. There was substantial agreement between diagnoses made from video-otoscopy recordings and those from onsite otomicroscopy (first review: otologist  $\kappa=0.70$  and GP  $\kappa=0.68$ ; second review: otologist  $\kappa=0.74$  and GP  $\kappa=0.75$ ). There was also substantial inter-rater agreement ( $\kappa=0.74$  and  $0.74$  at the two reviews) and intra-rater agreement ( $\kappa=0.77$  and  $0.74$  for otologist and GP respectively). A telehealth facilitator, with limited training, can acquire video-otoscopy recordings in children for asynchronous diagnosis. Remote diagnosis was similar to face-to-face diagnosis in inter- and intra-rater variability.

### **4.2 Introduction**

Telehealth has been proposed as a means of bringing ear and hearing health services to people in underserved regions (Swanepoel & Hall, 2010; Swanepoel, Clark, et al., 2010). The nature of the otitis media burden, as the most common ear disease, differs greatly between developed and developing countries (Monasta et al., 2012; WHO, 2013b). AOM incidence in sub-Saharan African, South Asia and Oceania is two to eight times higher than in other world regions (Acuin, 2004). The prevalence of CSOM in Africa was classified as high by the WHO with sub-Saharan Africa presenting with the second highest global incidence of CSOM (Monasta et al., 2012; WHO / CIBA Foundation, 1998). Unfortunately, estimates of

otolaryngologists available to serve populations in sub-Saharan Africa vary from 1 to every 250,000 to 7.1 million people (Fagan & Jacobs, 2009; WHO, 2013b). Early diagnosis and subsequent treatment of ear disease is therefore particularly difficult to achieve, because hearing health services and hearing professionals are very limited (WHO, 2013a)

Specialist services may potentially be extended to rural and underserved areas by use of video-otoscopy used within a telehealth framework (Swanepoel & Hall, 2010). By incorporating video-otoscopy in telehealth clinics, digitized images or recordings can be stored and forwarded to otolaryngologists anywhere in the world for asynchronous assessment (Biagio, Swanepoel, Adeyemo, Hall, & Vinck, 2013; Lundberg et al., 2008; Swanepoel & Hall, 2010). In the absence of otolaryngologists, GPs, as first line physicians, may be required to make diagnoses from video-otoscopy recordings (Lundberg et al., 2008). Use of video-otoscopy within telehealth programs has been reported using video-otoscopy images and recordings, and through both synchronous and asynchronous methods of evaluation (Biagio et al., 2013; Eikelboom et al., 2005; Kokesh et al., 2008; Patricoski et al., 2003; Pedersen et al., 1994; Smith et al., 2005, 2008, 2006). Previous studies have demonstrated that asynchronous video-otoscopy images are equivalent in quality, and offer average to good diagnostic concordance, with onsite otoscopy (Eikelboom et al., 2005; Kokesh et al., 2008; Lundberg et al., 2008; Mbao et al., 2003; Patricoski et al., 2003; Pedersen et al., 1994; Smith et al., 2008; Swanepoel & Hall, 2010).

In a recent study, video-otoscopy images in adult patients were acquired by an ear and hearing telehealth facilitator with no formal health care education (Biagio et al., 2013). Asynchronous diagnosis from video-otoscopy images yielded moderate concordance with onsite diagnosis made by the same otolaryngologist. A limitation of video-otoscopy images was identified as the lack of depth perception, which may well be addressed by making video-otoscopy recordings of a few seconds in length (Biagio et al., 2013; Kokesh et al., 2008).

Both synchronous and asynchronous video-otoscopy recordings were employed by Smith et al. (2006, 2008). These authors reported a higher diagnostic concordance between onsite otoscopy and synchronous, compared to asynchronous diagnosis using video-otoscopy recordings. Synchronous diagnosis is not always possible however, due to time constraints of specialists, and even time differences between locations. Synchronous diagnosis requires high

speed broadband connectivity which is also unavailable in areas such as sub-Saharan Africa. Video-otoscopy recordings in the study by Smith et al. (2006, 2008) were acquired by a paediatrician or a research nurse, neither of whom are likely to be available in remote health clinics.

The capture of video-otoscopy information at primary health care level may be completed by a telehealth facilitator with limited or no formal health training (Biagio et al., 2013). Utilising telehealth facilitators to acquire video-otoscopy for remote asynchronous interpretation may be a powerful tool to identify pathology early, and make appropriate recommendations whilst avoiding excessive waiting times and costs related to travelling (ASHA, 2005; Biagio et al., 2013). This is particularly important for children in remote areas who may be more prone to ear disorders such as otitis media (Acuin, 2004; Morris & Leach, 2009).

In studies comparing asynchronous diagnosis using video-otoscopy, conventional otoscopy has usually served as the gold standard reference (Biagio et al., 2013; Smith et al., 2006). The most ideal method under which an ear examination may be performed is considered to be through use of an operating otomicroscope with an ear canal free of cerumen (Aronzon et al., 2004). In clinical practice this is rarely available to a clinician (Patricoski et al., 2003). Nevertheless, the selection of otomicroscopy instead of conventional otoscopy is expected to provide a more accurate gold standard for comparison of diagnostic concordance with video-otoscopy recordings.

The aim of this study was therefore to investigate otologist and general practitioner interpretations of asynchronous video-otoscopy recordings made by an ear and hearing telehealth clinic facilitator, compared to onsite otomicroscopy, in a paediatric population. Video-otoscopy interpretations by a GP were included due to the limited number of otolaryngologists available in sub-Saharan Africa leaving diagnosis to GPs in many cases (Fagan & Jacobs, 2009; WHO, 2013b).

### **4.3 Materials and methods**

The study followed a within-subject comparative design and was conducted following approval from the institutional ethics committee at the University of Pretoria. A convenience



sample of 140 children aged two to 16 years of age (range 2 to 15.8 years; mean age  $6.4 \pm 3.5$  years; 44.3% female) were recruited from a primary health care clinic. Witkoppen Health and Welfare Centre is a primary health care clinic that provides services to the Diepsloot community north of Johannesburg, South Africa.

Diepsloot is a densely populated, poor socio-economic settlement with estimates suggesting that more than 90% of the population is unemployed (Carruthers, 2008). There is no hospital in Diepsloot despite a very high prevalence rate of HIV and associated TB infections (Carruthers, 2008).

Participants were recruited from the entire paediatric population attending the clinic irrespective of reason for attendance. Caregivers were informed of the procedure and were required to give consent before any data collection commenced. Biographical information and history of ear ache, ear discharge or hearing loss during the two weeks prior to participation in the study was then recorded.

#### **4.3.1 Otomicroscopic examination**

Otomicroscopy was completed of participants' ears by an experienced otologist (>35 years of practice). Onsite otomicroscopy examination was considered the gold standard diagnosis. Cerumen was removed manually in order to obtain a clear view of the tympanic membrane. Cerumen removal was discontinued if any discomfort was noted. Thereafter, observations regarding ear canal obstruction, presence of any discharge, tympanic membrane patency, translucency and position, as well as the concluding diagnosis were documented.

Diagnosis of tympanic membrane status was based on visual otomicroscopic examination alone, without objective assessment of the tympanic membrane mobility. The types of otitis media were classified as either AOM, OME or CSOM. Classification of the types of otitis media were recorded according to the following criteria: AOM diagnosis was based on clinical data (e.g. rapid onset of fever, otalgia, or irritability for less than one week) and otomicroscopic findings of either a bulging intact tympanic membrane, or a wet, contourless, perforated tympanic membrane (Bluestone et al., 2002). Diagnosis of OME was based on suspicion of sero-mucoid or serous effusion in the middle ear (completely filled or air-fluid level or bubbles), with an intact tympanic membrane without symptoms of acute infection (Bluestone et al., 2002). CSOM diagnosis was made based on the presence of perforation,

deep not fully visible retraction pocket or cholesteatoma) with or without purulent discharge (Acuin, 2004).

#### 4.3.2 Video-otoscopy recordings

Following otomicroscopy, video-otoscopy recordings of nine to 33 seconds in length each (mean 25.6 s) were completed by an ear and hearing telehealth clinic facilitator from each ear of participants. The facilitator had no formal health care or tertiary education. Prior to data collection onsite training was provided over a two day period by the otologist on how to conduct video-otoscopy recordings. Training included participant positioning, visual inspection of external ear, appropriate hand position, manipulation of direction of speculum, focus adjustment, recording capture, video-otoscope software use, and equipment cleansing.

Data collection, which included acquisition of case histories, onsite otomicroscopy result and acquisition of video-otoscopy recordings by the facilitator (see Figure 4.1), was completed over a period of two weeks.



**Figure 4.1** Hearing telehealth clinic facilitator completing video-otoscopy recording for a child

### 4.3.3 Equipment

Otomicroscopy was done using a Leica M525 F40 surgical otomicroscope with a 6:1 zoom magnification (1.2 to 12.8x) and 300-watt xenon fibre optic illumination. An AMH-EUT Dino-Lite Pro Earscope (USB), with a 3, 4 or 5mm speculum was used to acquire the video-otoscopy recordings (Figure 1). The Dino-Lite Pro made use of a LED light, a magnification rate of 10 to 20x, a frame rate 30 frames per second and 1.3 megapixel resolution. The Dino-Lite Pro video-otoscope was attached, via a USB video cable, to a Lenovo ThinkPad 2.0 running Windows 7 via USB 2.0 interface. DinoCapture 2.0 software (AnMo Electronics Corporation) version 1.2.7 was used to record and view the video-otoscopy recordings. The recordings were saved as WMV files and ranged from 0.85 to 7.61 MB in size (mean = 3.6 MB).

### 4.3.4 Asynchronous assessment

After data collection was completed, video-otoscopy recordings, the participant's demographic information and case history based of ear ache, discharge and perceived hearing loss were uploaded to a secure server, using a web-based file hosting service (Dropbox). Recordings were assigned random numbers by an independent investigator prior to the first asynchronous evaluation (review one) and again prior to the second asynchronous evaluation (review two). Four and eight weeks after onsite data collection, an otologist (the same otologist who performed onsite otomicroscopy) and a GP, who were blinded to the randomised numbering of recordings, accessed the server. Each rater was required to independently grade the video-otoscopy recordings, to make observations regarding ear canal obstruction, presence of secretion, tympanic membrane patency, translucency and position, and diagnosis from each video recording. The overall image quality was graded (0 to 2) with reference to image focus, light, cerumen and composition (Lundberg et al., 2008). A grading of 0 indicated that the image quality was not acceptable, and it was not possible to assess the entire tympanic membrane and to set a diagnosis. An image graded 1 indicated an acceptable image quality, enabling evaluation of the status of the tympanic membrane. An excellent video-otoscopy image was graded 2, indicating high image quality, with tympanic membrane easily assessable.

The asynchronous assessments were logged on an electronic spread sheet and uploaded to the server once completed. The delay in asynchronous assessment was included to counter the

possibility of a memory effect of onsite diagnoses made. The second asynchronous assessment four weeks after the first allowed for assessment of intra-rater correspondence.

#### 4.3.5 Analyses

Descriptive statistics were used to describe the mean recording quality rating for video-otoscopy recordings and the frequency with which ear canal obstruction and presence of secretion was identified, as well as the tympanic membrane patency, translucency and position (Trochim, 2006). The frequency of diagnosis of the different types of otitis media was also measured. For analysis of ears where an asynchronous diagnosis could not be made, labelled as not possible to diagnose (NPD), participants were divided into a younger and an older age group. The two groups represented preschool children (2 to 5 years of age) and children in formal education (6 to 16 years of age). Comparisons between the number of undiagnosed ears and the age group were made using Pearson's chi-squared test with a probability of 5% considered to be significant. Pearson's chi-squared test was also used for comparing the quality grading of video-otoscopy recordings acquired during the first and during the second week of data collection.

Kappa statistic ( $\kappa$ ) was used to quantify concordance of diagnosis made from onsite otomicroscopic examination and asynchronous video-otoscopy recordings, inter- and intra-rater concordance of asynchronous and diagnosis from video-otoscopy recordings. For calculations of diagnostic concordance between onsite examination and video-otoscopy recordings (i.e. sensitivity, specificity, positive and negative predictive values;  $n=176$  ears), the ears where a diagnosis could not be made by either assessment method were excluded from the calculations. For inter- and intra-rater concordance ( $n = 249$  ears), the ears where a diagnosis could not be made during asynchronous assessment were excluded from the kappa calculations. The concordance was based upon the range in which kappa statistic matches: “poor agreement” ( $\kappa < 0.00$ ), “slight agreement” ( $\kappa = 0.01-0.20$ ), “fair agreement” ( $\kappa = 0.21-0.40$ ), “moderate agreement” ( $\kappa = 0.41-0.60$ ), “substantial agreement” ( $\kappa = 0.61-0.80$ ), “almost-perfect agreement” ( $\kappa = 0.81-1.00$ ; Landis & Koch, 1977).

By classifying the diagnosis as normal or abnormal, the sensitivity, specificity, positive and negative predictive value of asynchronous diagnosis from video-otoscopy recordings

acquired by the facilitator was calculated with reference to otomicroscopic examination by the otologist as the ‘gold standard’.

#### 4.4 Results

Four participants did not co-operate for onsite otomicroscopy. Otomicroscopy was therefore completed for 136 participants (272 ears). One of the 136 participants did not co-operate for video-otoscopy in either ear, while another participant did not allow video-otoscopy to be completed in one ear. Therefore video-otoscopy recordings were carried out on 135 participants, and 269 ears.

**Table 4.1 Asynchronous grading of video-otoscopy recordings acquired during the first and second week of data collection (R1 – Review 1; R2 – Review 2)**

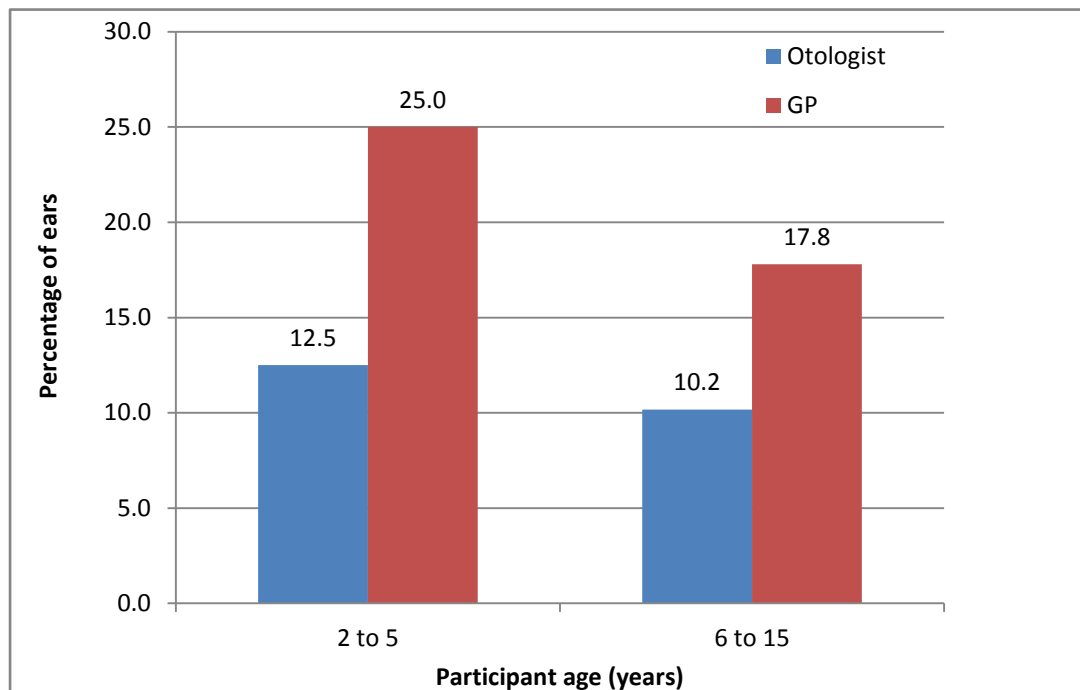
Recording grading	Week 1 (%) (n = 134 ears)				Week 2 (%) (n = 135 ears)				Total (%) (n = 269 ears)			
	Otologist		GP		Otologist		GP		Otologist		GP	
	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2
<b>0 Unacceptable</b>	14.2	13.4	22.4	26.1	11.9	12.6	22.2	26.7	13.0	13.0	22.3	26.4
<b>1 Acceptable</b>	79.1	84.3	51.5	49.3	77.0	79.3	47.4	40.7	78.1	81.8	49.4	45.0
<b>2 Excellent</b>	6.7	2.3	26.1	24.6	11.1	8.1	30.4	32.6	8.9	5.2	28.3	28.6

During asynchronous assessment, the otologist graded video-otoscopy recordings as unacceptable in 13% of ears for the first and second review whilst the GP graded 22.3% and 26.4% unacceptable for the two review sessions, respectively (Table 4.1). To examine whether experience improved the quality of recordings by the facilitator, video-otoscopy gradings were assessed separately for recordings acquired during the first and second week of data collection (Table 4.1). Both the otologist and the GP judged more video-otoscopy recordings as excellent in quality in the second compared to the first week of data collection (otologist mean number of excellent ratings for each review 4.5% and 9.6% for week one and two respectively; GP mean number of excellent ratings 25.4% and 31.5% respectively). This was true at both the first and second review sessions. The improvement in quality ratings between the first and second week of data collection was not statistically significant however ( $p > 0.05$ ; Chi-squared test).

Mean intra-rater agreement at review one and two, was 87.0% and 73.6% on recordings labelled as either acceptable or excellent for the otologist and GP respectively. Inter-rater

agreement on video-otoscopy recordings graded as either acceptable or excellent was 76.6% for review one, and 72.1% for review two. Disagreement on ratings of video-otoscopy recordings as poor was noted in 9% to 13% of ears for review one and two respectively. Inter-rater agreement on video-otoscopy recordings graded as either acceptable or excellent was 76.6% for review one, and 72.1% for review two.

Poor video-otoscopy recordings were more common in younger children (2 – 5 years of age), compared to older children (6 -15 years of age) for both raters (Figure 4.2), but was not statistically significant ( $p > 0.05$ ; Chi-squared test).



**Figure 4.2** Video-otoscopy recordings rated poor quality as a function of participant age (n = 269 ears)

During onsite assessment, manual cerumen removal was deemed necessary and attempted for 36.0% of participants (23.5% of ears) in order to obtain a clear view of the tympanic membrane for otomicroscopic diagnosis. After reasonable attempts were made to remove any cerumen without causing discomfort, cerumen still partially or completely occluded the ear canal in 12.9% of participants for either or both ears (7.7% of ears) preventing a diagnosis from being made (Table 4.2). During asynchronous diagnosis, the inability of the otologist and GP to make a diagnosis was due to partial or complete occlusion of the ear canal (due to

lack of visualisation of the entire tympanic membrane), or poor video-otoscopy recording quality. At review one and two respectively, the otologist was unable to make a diagnosis in 24.9% and 23.4% of ears. The GP was unable to make a diagnosis for 27.5% and 26.8% of ears at asynchronous review one and two, respectively. Asynchronous diagnosis from video-otoscopy recordings could therefore not be made from a mean (calculated from mean between reviews of both raters) 18% of ears for whom successful onsite otomicroscopy was conducted.

**Table 4.2 Onsite diagnoses made by the otologist using otomicroscopy compared to asynchronous diagnoses made by the otologist and GP using video-otoscopy recordings (R1 – Review 1; R2 – Review 2)** The values shown represent percentages of participants (% ears)

	Onsite diagnosis n = 136 (272 ears)	Asynchronous diagnosis n = 135 (269 ears)			
	Otologist (%)	Otologist (%)		GP (%)	
		R1	R2	R1	R2
<b>Normal</b>	65.5 (75.8)	63.0 (58.4)	68.1 (62.1)	65.9 (58.0)	69.6 (60.6)
<b>Otitis media:</b>	21.6 (16.5)	25.2 (16.7)	20.8 (14.5)	20.0 (14.5)	17.1 (12.6)
<b>AOM</b>	1.4 (0.7)	0.0 (0.0)	1.5 (0.7)	0.7 (0.4)	1.5 (0.7)
<b>CSOM</b>	5.8 (4.8)	9.6(6.7)	8.9 (6.3)	7.4 (4.8)	5.2 (4.1)
<b>OME</b>	14.4 (11.0)	15.6 (10.0)	10.4 (7.5)	11.9 (9.3)	10.4 (7.8)
<b>NPD</b>	12.9 (7.7)	11.8 (24.9)	11.1 (23.4)	14.1 (27.5)	13.3 (26.8)

*AOM = acute otitis media; CSOM = chronic suppurative otitis media; OME = otitis media with effusion; NPD = not possible to diagnose*

Otitis media was identified in 12.6% to 16.7% of ears, with OME being the most common type of otitis media (7.5% to 10.0% of ears), followed by CSOM (4.1% to 6.7% of ears). The otologist reported a larger number of ears with CSOM during asynchronous assessment (mean number of ears with CSOM diagnosed at review one and two 6.5%) compared to either onsite otomicroscopy (CSOM of 4.8% of ears) or asynchronous video-otoscopy assessment by the GP (mean CSOM ears 4.5%).

**Table 4.3 Concordance of asynchronous diagnosis using video-otoscopy recordings by the otologist and GP compared to onsite otomicroscopy (n = 176 ears; R1 – Review 1; R2 – Review 2)**

		Concordance between asynchronous video-otoscopy recordings	
		Kappa value	Asymp. std. error
<b>R1</b>	<b>Otologist</b>	0.702	0.070
	<b>GP</b>	0.679	0.074
<b>R2</b>	<b>Otologist</b>	0.740	0.068
	<b>GP</b>	0.745	0.069

*Asymp. std. error = Asymptotic standard error*

There was substantial agreement between asynchronous video-otoscopy diagnoses compared to onsite otomicroscopic diagnoses (Table 4.3). A slightly higher diagnostic concordance was found at review two for both the otologist ( $\kappa = 0.740$ ) and for the GP ( $\kappa = 0.745$ ) than for review one (otologist  $\kappa = 0.702$ ; GP  $\kappa = 0.679$ ).

**Table 4.4 Concordance of asynchronous diagnosis using video-otoscopy recordings between and within the otologist and GP (n = 249 ears; R1 – Review 1; R2 – Review 2)**

		Concordance between asynchronous video-otoscopy recordings	
		Kappa value	Asymp. std. error
Inter-rater diagnosis	R1	0.737	0.040
	R2	0.735	0.040
Intra-rater diagnosis	Otologist	0.773	0.038
	GP	0.737	0.040

*Asymp. std. error = Asymptotic standard error*

Agreement between diagnosis made using asynchronous video-otoscopy recordings was substantial between raters ( $\kappa = 0.737$  and  $0.735$  at review one and two) and within raters ( $\kappa = 0.773$  and  $0.737$  for otologist and GP respectively; Table 4.4).

**Table 4.5 Sensitivity, specificity, positive and negative predictive values (%) for normal and abnormal classifications of asynchronous video-otoscopy recordings as assessed by an otologist and GP (n = 176 ears; R1 – Review 1; R2 – Review 2)**

		Sensitivity	Specificity	Positive predictive value	Negative predictive value
Otologist	R1	79.3	93.2	69.7	95.8
	R2	75.9	95.9	78.6	95.3
	Mean	77.6	94.6	73.8	95.5
GP	R1	72.4	95.2	75.0	94.6
	R2	72.4	98.0	87.5	94.7
	Mean	72.4	96.6	80.8	94.7

Specificity and negative predictive values were higher than sensitivity and positive predictive values for asynchronous video-otoscopy interpretations for both raters (Table 4.5). The sensitivity of the asynchronous interpretation of the video-otoscopy recordings was slightly better for the otologist (mean sensitivity of 77.6%) than for the GP (mean sensitivity of 72.4%). Slightly higher positive predictive values were determined from the GP evaluation of asynchronous video-otoscopy recordings (positive predictive value of 80.8%) compared to those of the otologist (positive predictive value of 73.8%).



## 4.5 Discussion

### 4.5.1 Quality of video-otoscopy recordings

Video-otoscopy recordings acquired by the telehealth facilitator were rated as acceptable or better in quality for 73.6% to 87.0% of cases by the otologist and GP. This is comparable to the proportion of adequate video-otoscopy cases acquired by a nurse and an otolaryngologist in previous studies (viz. 75% to 85% recordings judged to be adequate in quality; Biagio et al., 2013; Smith et al., 2006). The similarity in quality judgements reported by the current study and in previous studies are of consequence for three reasons. Firstly, the telehealth facilitator who captured the video-otoscopy recordings had no formal health care training unlike the health care personnel used in earlier studies (Biagio et al., 2013; Smith et al., 2006). Secondly, video-otoscopy recordings in the current study were found to be equivalent in quality compared to the video-otoscopy images acquired previous (Biagio et al., 2013). Thirdly, the present study targeted a paediatric population who were likely to be less cooperative than the adult population of Biagio et al. (2013).

The number of video-otoscopy recordings rated excellent by the otologist and GP was higher (albeit not significantly) for recordings acquired during the second week and may suggest a learning effect with increased experience by the facilitator (mean excellent gradings by otologist in week one increased from 4.5% to 9.6%; mean excellent gradings by GP increased from 25.4% to 31.5%). An improvement in quality of video-otoscopy images acquired over time was also demonstrated by Lundberg et al. (2008). The quality of video-otoscopy recordings is likely to be impacted by the amount of training and level of proficiency of the person acquiring the recordings, which, ultimately, affects the diagnostic accuracy of video-otoscopy recordings as a means of asynchronous diagnosis of ear disease.

Asynchronous diagnosis from video-otoscopy recordings could not be made from 18% of ears for whom successful onsite otomicroscopy was completed in the current study. This may be attributable to several factors including poor video quality, insufficient visualisation of the entire tympanic membrane, and / or partial occlusion of the ear canal by cerumen. In previous studies, when the entire tympanic membrane could not be visualised, Eikelboom et al. (2005) and Biagio et al. (2013) reported the presence of partial or total cerumen occlusion rather than stating that a diagnosis could not be made. Kokesh et al. (2008) remarked that images were discarded due to poor image quality or cerumen but did not indicate how many. Use of

cerumen removal strategies is likely to reduce the number of undiagnosed ears from asynchronous video-otoscopy if they are performed prior to the recording. Providing a cerumenolytic a few days earlier may facilitate both manual removal of the cerumen, and removal using syringing. Furthermore cerumen removal may be performed by a nurse at a clinic immediately prior to video-otoscopy recording.

Poor video-otoscopy image quality or a lack of sufficient information was reported as the reason for being unable to diagnose 14% of ears in the study by Patricoski and colleagues compared to 18% in the current study (Patricoski et al., 2003). In a previous study, Biagio et al. (2013) reported a lower number of ears where asynchronous diagnosis could not be made from video-otoscopy images acquired by a telehealth facilitator in adult subjects (10% of images). This difference may in part be attributable to participant age (paediatric versus adult participants) and consequent variability in co-operation.

#### **4.5.2 Diagnostic accuracy using video-otoscopy recordings**

Agreement between onsite otomicroscopy and asynchronous evaluation of video-otoscopy recordings in the present study was substantial ( $\kappa = 0.679-0.745$ ) and equivalent to concordance previously reported using video-otoscopy images and otoscopy ( $\kappa = 0.64-0.76$ ; Kokesh et al., 2008; Patricoski et al., 2003). The correspondence of concordance scores suggest that the telehealth facilitator in the present study, with no formal health care training, was capable of acquiring video-otoscopy recordings comparable to personnel with formal health care education who completed video-otoscopy in previous reports (Kokesh et al., 2008; Patricoski et al., 2003).

Validity of asynchronous diagnoses in this study is supported by similar correspondence with onsite otoscopy reported by Smith and colleagues where a nurse completed the video-otoscopy recording (Smith et al., 2006). Agreement in diagnosis was 81% and agreement on clinical management recommendations was 76% (Smith et al., 2006).

Intra-rater concordance was substantial for asynchronous diagnosis using video-otoscopy recording (otologist  $\kappa = 0.773$ ; GP  $\kappa = 0.737$ ), which corresponds to previous findings using asynchronous video-otoscopy images (Kokesh et al., 2008; Patricoski et al., 2003). The substantial inter-rater concordance between the asynchronous diagnoses made in the present study suggests good agreement between diagnosis made by the otologist and the GP. Inter-

rater concordance measured was equivalent to that reported in previous research between otolaryngologists (Kokesh et al., 2008; Patricoski et al., 2003). The inter- and intra-rater concordance in this study was also similar to the diagnostic concordance between onsite otomicroscopy and remote diagnosis. This suggests the variability of remote diagnosis, using video-otoscopy recordings, is similar to typical diagnostic variability that can be expected within and between clinicians.

Video-otoscopy recordings could be used for asynchronous diagnosis to correctly identify ears without pathology more often in the current study (specificity 94.6% and 96.6% for otologist and GP respectively) than was previously reported for asynchronous diagnosis from video-otoscopy images (specificity = 89%; Biagio et al., 2013). Negative predictive values for normal ears in the current study were equally high (negative predictive value 95.5% and 94.7% for otologist and GP respectively). Sensitivity values in the present study (sensitivity 77.6% and 72.4% for otologist and GP respectively) were lower than was previously reported for asynchronous diagnosis using video-otoscopy images however (sensitivity 80% and 85% for images acquired by an otolaryngologist and telehealth facilitator respectively; Biagio et al., 2013). *Direct comparison between the present study and our previous study (Biagio et al., 2013) are limited by different participant ages (adults and paediatric populations) and different gold standards (otoscopy and otomicroscopy). Never-the-less the lower sensitivity measured in the current study may be attributable to the increased difficult in diagnosing pathology in paediatric compared to adult ears. In addition, the smaller number of participants evaluated in our earlier study, with comparably less ears with pathology, may have contributed to the difference in sensitivity scores.*<sup>6</sup>

Video-otoscopy recordings may pose several advantages above video-otoscopy images for asynchronous diagnosis. Video-otoscopy recordings provide the possibility of pausing, rewinding and reviewing the recording several times, an opportunity rarely granted by a child. Compared to video-otoscopy images, video-otoscopy recordings appear to afford better depth perception as it offers several, dynamic angles of the tympanic membrane compared to a single still video-otoscopy image (Biagio et al., 2013; Kokesh et al., 2008). Asynchronous diagnosis by the otologist compared to onsite assessment indicated slightly more CSOM ears. This may reflect the advantage afforded by asynchronous assessments allowing several

---

<sup>6</sup> Added to dissertation in response to external examiner recommendations after publication of article

reviews with no time pressure as is the case when conducting onsite otomicroscopy with young children. Another advantage is that both the child and caregiver are able to see the ear canal and ear drum, providing good counselling and learning opportunities. In one case, a child co-operated willingly for video-otoscopy by the telehealth facilitator but not for the otomicroscopic examination. Video-otoscopy may be a less intimidating assessment for some children. Additionally a telehealth facilitator, who would likely originate from the community the clinic serves, and who speaks the child's home language, may also be perceived as less threatening than a doctor. The video-otoscope selected for the present study was portable and easy to operate with some training. In comparison with a surgical otomicroscope, the video-otoscope is significantly less expensive. By increasing the telehealth facilitator's training and supervising period, the number of acceptable quality video-otoscopy recordings may increase, with fewer ears left undiagnosed after asynchronous assessment.

#### **4.6 Conclusion**

A telehealth facilitator with limited training was capable of acquiring good quality video-otoscopy recordings in a paediatric sample for asynchronous diagnosis. Asynchronous video-otoscopy recordings have high intra- and inter-rater reliability for diagnoses made by an otologist and GP. Remote diagnosis was equivalent to inter- and intra-rater variability. However, asynchronous diagnosis could not be made for close to one in five paediatric video-otoscopy recordings due to residual cerumen in the ear canal or poor video-quality. Increasing the telehealth facilitator's training and supervising period and applying cerumen management strategies prior to video-otoscopy recordings may reduce the number of ears left undiagnosed after asynchronous assessment.

#### **4.7 Acknowledgements**

The authors would like to thank Ms Violet Mugodo, the hearing telehealth clinic facilitator, Dr Jean Bassett, Executive Director of Witkoppen Health and Welfare Clinic, as well as the clinic staff and patients for their help and support during data collection for this research project. We are also grateful to Mr Headley Isserow at Tecmed, Midrand, South Africa, for providing the Leica otomicroscope used for on-site diagnoses, and to Dr Dirk Koekemoer,

GeoAxon, for his continued support. Partial funding from the National Research Fund of South Africa is gratefully acknowledged.

## 4.8 References

- Acuin, J. (2004). *Chronic suppurative otitis media: Burden of Illness*. World Health Organisation (pp. 1–83). Geneva, Switzerland. Retrieved from [http://www.who.int/pbd/deafness/activities/hearing\\_care/otitis\\_media.pdf](http://www.who.int/pbd/deafness/activities/hearing_care/otitis_media.pdf)
- American Speech-Language-Hearing Association. (2005). *Audiologists providing clinical services via telepractice: Position statement*. American Speech-Language-Hearing Association. doi:10.1044/policy.PS2005-00029
- Aronzon, A., Ross, A. T., Kazahaya, K., & Ishii, M. (2004). Diagnosis of middle ear disease using tympanograms and digital imaging. *Otolaryngology - Head and Neck Surgery*, 131(6), 917–920. doi:10.1016/j.otohns.2004.07.012
- Biagio, L., Swanepoel, D. W., Adeyemo, A., Hall, J. W. III, & Vinck, B. (2013). Asynchronous video-otoscopy with a telehealth facilitator. *Telemedicine and e-Health*, 19(4), 252–258. doi:10.1089/tmj.2012.0161
- Bluestone, C. D., Gates, G. A., Klein, J. O., Lim, D. J., Mogi, G., Ogra, P., ... Tos, M. (2002). Definitions, terminology, and classification of otitis media. *Annals of Otolaryngology and Laryngology*, 111, 8–18.
- Carruthers, J. (2008). Dainfern and Diepsloot: Environmental justice and environmental history in Johannesburg, South Africa. *Environmental Justice*, 1(3), 121–126. doi:10.1089/env.2008.0526
- Eikelboom, R. H., Mba, M. N., Coates, H. L., Atlas, M. D., & Gallop, M. A. (2005). Validation of tele-otology to diagnose ear disease in children. *International Journal of Pediatric Otorhinolaryngology*, 69(6), 739–744. doi:10.1016/j.ijporl.2004.12.008
- Fagan, J. J., & Jacobs, M. (2009). Survey of ENT services in Africa: Need for a comprehensive intervention. *Global Health Action*, 2, 1–8. doi:10.3402/gha.v2i0.1932
- Kokesh, J., Ferguson, A. S., Patricoski, C., Koller, K., Zwack, G., Provost, E., & Holck, P. (2008). Digital images for postsurgical follow-up of tympanostomy tubes in remote Alaska. *Otolaryngology - Head and Neck Surgery*, 139(1), 87–93. doi:10.1016/j.otohns.2008.04.008

- Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics*, 33(1), 159–174. Retrieved from <http://www.jstor.org/stable/2529310>
- Lundberg, T., Westman, G., Hellström, S., & Sandström, H. (2008). Digital imaging and telemedicine as a tool for studying inflammatory conditions in the middle ear - Evaluation of image quality and agreement between examiners. *International Journal of Pediatric Otorhinolaryngology*, 72(1), 73–79. doi:10.1016/j.ijporl.2007.09.015
- Mbao, M. N., Eikelboom, R. H., Atlas, M. D., & Gallop, M. A. (2003). Evaluation of video-otoscopes suitable for tele-otology. *Telemedicine Journal and e-Health*, 9(4), 325–331.
- Monasta, L., Ronfani, L., Marchetti, F., Montico, M., Brumatti, L. V., Bavcar, A., ... Tamburlini, G. (2012). Burden of disease caused by otitis media: Systematic review and global estimates. *PloS One*, 7(4), 1–12. doi:10.1371/journal.pone.0036226
- Morris, P. S., & Leach, A. J. (2009). Acute and chronic otitis media. *Pediatric Clinics of North America*, 56(6), 1383–1399. doi:10.1016/j.pcl.2009.09.007
- Patricoski, C., Kokesh, J., Ferguson, A. S., Koller, K., Zwack, G., Provost, E., & Holck, P. (2003). A comparison of in-person examination and video otoscope imaging for tympanostomy tube follow-up. *Telemedicine Journal and e-Health*, 9(4), 331–344. doi:10.1089/153056203772744653
- Pedersen, S., Hartviksen, G., & Haga, D. (1994). Teleconsultation of patients with otorhinolaryngologic conditions. A telendoscopic pilot study. *Archives of Otolaryngology - Head and Neck Surgery*, 120(2), 133–136. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8297568>
- Smith, A. C., Dowthwaite, S., Agnew, J., & Wootton, R. (2008). Concordance between real-time telemedicine assessments and face-to-face consultations in paediatric otolaryngology. *The Medical Journal of Australia*, 188(8), 457–460. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/18429711>
- Smith, A. C., Perry, C., Agnew, J., & Wootton, R. (2006). Accuracy of pre-recorded video images for the assessment of rural indigenous children with ear, nose and throat conditions. *Journal of Telemedicine and Telecare*, 12(7), 76–80. doi:10.1258/135763306779380138
- Smith, A. C., Williams, J., Agnew, J., Sinclair, S., Youngberry, K., & Wootton, R. (2005). Realtime telemedicine for paediatric otolaryngology pre-admission screening. *Journal of Telemedicine and Telecare*, 11(Suppl. 2), 86–89. doi:10.1258/135763305775124821

Swanepoel, D. W., Clark, J. L., Koekemoer, D., Hall, J. W. III, Krumm, M., Ferrari, D. V, ... Barajas, J. J. (2010). Telehealth in audiology: The need and potential to reach underserved communities. *International Journal of Audiology*, 49(3), 195–202.

doi:10.3109/14992020903470783

Swanepoel, D. W., & Hall, J. W. III. (2010). A systematic review of telehealth applications in audiology. *Telemedicine and e-Health*, 16(2), 181–201. doi: 10.1089=tmj.2009.0111

Trochim, W. M. (2006). Research methods: Knowledge base. *Web centre for social research methods*. Retrieved September 11, 2010, from

<http://www.socialresearchmethods.net/kb/index.php>

World Health Organization. (2013a). *Deafness and hearing impairment: Fact sheet*. World Health Organization. Retrieved July 10, 2013, from

<http://www.who.int/mediacentre/factsheets/fs300/en/>

World Health Organization. (2013b). *Multi-country assessment of national capacity to provide hearing care* (pp. 1–49). Geneva, Switzerland. Retrieved from

[www.http://www.who.int/pbd/deafness/en](http://www.who.int/pbd/deafness/en)

World Health Organization / CIBA Foundation. (1998). *Prevention of hearing impairment from chronic otitis media* (pp. 1–32). London, UK.

## **5. STUDY III: Paediatric otitis media at a primary health care clinic in South Africa**

### **5.1 Abstract**

#### **Background**

No published studies on prevalence of paediatric otitis media at primary health care clinics in South Africa are available.

#### **Objectives**

The study used otomicroscopy to examine the point prevalence of otitis media in a paediatric population in a primary health care clinic in South Africa.

#### **Methods**

A sample of 140 children aged two to 16 years (mean age = 6.4 years; 44.1% females) were recruited from patients of the primary health care clinic. Otomicroscopy was completed for each ear of the participants by a specialist otologist using a surgical microscope.

#### **Results**

Cerumen removal was necessary for 36.0% of participants (23.5% of ears). OME was the most frequent diagnosis for the participants in which a diagnosis could be made (16.5%). CSOM was diagnosed in 6.6% of children and was the most common type of otitis media in participants 6 to 15 years of age. AOM was only diagnosed in the younger, two to five year old, age group (1.7%). Otitis media was significantly more prevalent for younger (31.4%) compared to older children (16.7%).

#### **Conclusion**

CSOM prevalence, as classified by WHO, was high for children at this primary health care clinic. Consequently diagnosis, treatment and subsequent referral protocols may need to be reviewed to prevent CSOM complications.



## 5.2 Introduction

Otitis media is a pervasive childhood disease posing significant health care challenges (Daly et al., 2010). Estimates suggest 80% of children will have developed AOM at least once before three years of age (Teele et al., 1989). A global incidence study reported an AOM incidence rate of 10.9% (Monasta et al., 2012). The true incidence of OME is difficult to estimate as *individuals with OME may<sup>7</sup> be asymptomatic*. Furthermore, most screening studies determine the presence of middle ear fluid without differentiating between AOM and OME (Casselbrant & Mandel, 2003). An analysis of previous studies estimated point prevalence of middle ear effusion on screening tests as 20.0% (Casselbrant & Mandel, 2003). With regard to the most severe form of otitis media, namely CSOM, the global incidence is 4.8%. CSOM is estimated to contribute to more than half to the global burden of hearing impairment (Acuin, 2004).

The burden and population characteristics of otitis media differ greatly between developed and developing world regions. India and sub-Saharan Africa account for most deaths from complications arising from otitis media (Acuin, 2004). The incidence of AOM in sub-Saharan Africa, South Asia and Oceania is two to eight times higher than in the remaining world regions (Monasta et al., 2012), with the Aboriginal population demonstrating the highest incidence (Casselbrant & Mandel, 2003). Sub-Saharan Africa presents with the second highest incidence of CSOM (Monasta et al., 2012).

The epidemiology of otitis media, and reason for regional incidence and prevalence differences, is complex, with risk factors involving multiple host-related factors (age, gender, race, allergy, immune-competence specifically related to HIV status, malnutrition, craniofacial abnormalities, genetic predisposition) and environmental factors (upper respiratory infection, seasonality, day care, siblings, tobacco smoke exposure, breast feeding, socioeconomic status; Casselbrant & Mandel, 2003; Daly et al., 2010; Monasta et al., 2012; Morris & Leach, 2009). HIV positive children are more prone to and more severely affected by otitis media than immunocompetent children (Miziara et al., 2007). An estimated 3 million of the 3.3 million children worldwide who are HIV positive (0-14 years of age) live in sub-Saharan Africa (UNICEF, 2013). Of the sub-Saharan countries, South Africa presents with

---

<sup>7</sup> Added to dissertation in response to external examiner recommendations after publication of article

the second highest prevalence of new HIV infections in children (UNAIDS, 2013). HIV status is therefore likely to be important factor in the epidemiology of otitis media prevalence rates in South Africa.

Despite the diverse risk factors and influences, *complications of*<sup>8</sup> otitis media are largely preventable, and can be effectively managed through medical and surgical approaches (Morris & Leach, 2009). However, knowledge of the prevalence of otitis media, especially of the most severe form of the disease, namely CSOM, is important in determining treatment protocols (Morris & Leach, 2009). In a community where CSOM prevalence is low, the disease will generally resolve without treatment or complications (Morris & Leach, 2009). However, early medical intervention is indicated in communities where CSOM prevalence rates are greater than 4.0%, which is considered a high risk population (Acuin, 2004; Morris & Leach, 2009).

The WHO has classified the prevalence of CSOM in Africa amongst children and adults as high, estimated to be between 3 to 6% (Acuin, 2004). Estimates of otitis media in South Africa, which are included in recent global prevalence studies completed by Acuin (2004) and Monasta et al. (2012) are based on only two studies (Halama et al., 1987; Prescott & Kibel, 1991). One additional study provided an indication of prevalence of only OME in South Africa (Nel et al., 1988). Estimates of the point prevalence of otitis media in the rural populations targeted varied from 6.5 to 18% amongst South African studies (Nel et al., 1988; Prescott & Kibel, 1991). OME was reported most frequently by all studies (paediatric prevalence of 3.8 to 12.0%), with CSOM evidenced in 0.3 to 6.0% of the paediatric population (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991). Variations in CSOM definition make comparison between studies difficult though.

Previous South African studies investigating otitis media prevalence selected rural populations, with many of the poor socioeconomic conditions associated with otitis media, but focused on school aged children (Halama et al., 1987; Prescott & Kibel, 1991) as opposed to younger children who are more prone to otitis media (Casselbrant & Mandel, 2003). Otoscopy, rather than otomicroscopy, was used previously to diagnose middle ear pathology. Otomicroscopy however demonstrates better sensitivity and specificity than either otoscopy

---

<sup>8</sup> Added to dissertation in response to external examiner recommendations after publication of article

or pneumatic otoscopy (Lee & Yeo, 2004), and is therefore likely to provide a more accurate diagnosis and classification of otitis media. No studies on otitis media prevalence have been performed at primary health care clinics in South Africa. The current study therefore examined (using otomicroscopy) the point prevalence of otitis media in a paediatric population in a primary health care clinic in South Africa.

## **5.3 Method**

### **5.3.1 Population**

The investigation was conducted following approval from the institutional ethics committee. A consecutive sample of 140 children aged two to 16 years (age range = 2 to 15.8 years; mean age =  $6.4 \pm 3.5$  years; 44.3% females) were recruited from registered patients of the primary health care clinic. Witkoppen Health and Welfare Centre is a primary health care clinic that provides services to the Diepsloot community north of Johannesburg, South Africa.

Diepsloot is a densely populated settlement made up of Government subsidised housing, brick houses built by landowners, and shacks made from scrap metal, wood, plastic and cardboard (Carruthers, 2008). Estimates suggest that more than 90% of the over 150 000 population is unemployed, with many families lacking access to basic services such as running water, sewage and rubbish removal. Despite a very high prevalence rate of HIV and associated TB infection there is no hospital (Carruthers, 2008).

Witkoppen Health and Welfare Centre serves as a specialist centre for HIV and TB treatment. In 2012 the clinic had 95,521 patient visits. Of the children ( $\leq 14$  years) that attended the clinic in 2012, and whose caregivers consented, 4.0% tested positive for HIV. The participants were recruited from the entire paediatric population attending the clinic for any purpose, whether it was a routine clinic appointment, or for chronic or acute treatment. Caregivers were required to provide written consent after being informed (verbally and in writing) of the study objectives and methods. Although the typical annual paediatric HIV prevalence of patients of the Witkoppen clinic that consented to HIV testing was known, HIV status for each of the participants of the study was not recorded because ethical clearance did not allow for this. Caregivers and children were interviewed immediately prior to otomicroscopy to obtain biographical information and history of earache, ear discharge or hearing loss during the two weeks prior to participation in the study.

### 5.3.2 Data collection

Otomicroscopy was completed for each ear of the participants by a specialist otologist using a Leica M525 F40 surgical microscope. Observations regarding ear canal obstruction, presence of secretion, tympanic membrane patency, translucency and position, as well as the concluding diagnosis were documented. Onsite data collection continued over the course of two weeks.

The following diagnosis and classification of the types of otitis media was observed. The diagnosis of AOM was based on clinical data of otalgia and otomicroscopic findings of opacity and bulging of the intact tympanic membrane (Bluestone et al., 2002). The diagnosis of perforated AOM was based on a wet, swollen and contourless ear drum. The diagnosis of OME was based on evidence of sero-mucoid effusion in the middle ear (completely filled or air-fluid level or bubbles), with an intact tympanic membrane without symptoms of acute infection (Bluestone et al., 2002). CSOM diagnosis was made based on evidence of a perforation or cholesteatoma with or without purulent discharge (Acuin, 2004).

### 5.3.3 Data analysis

Four participants did not co-operate for otomicroscopy. Otomicroscopic examinations could be completed on 136 participants (272 ears). Descriptive statistics were used to describe the frequency with which the caregivers reported otologic symptoms, the presence of cerumen, and otologic status of otitis media for the age groups two to five years, and six to 15 years. The two age groups were delineated into these groups to represent preschool children (2 – 5 years of age) and children in formal education (6 to 15 years of age). Descriptive statistics on otologic status were presented for participants and ears respectively. A participant was classified as ‘normal’ when an otologic diagnosis of ‘normal’ was made on otomicroscopy in both ears. When a diagnosis could not be made by otomicroscopy due to partial or complete obstruction of the external ear canal, the ear was classified as ‘undetermined’. If a participant presented with ‘undetermined’ in one or both ears, the participant was classified as ‘undetermined’. Descriptive statistics on otologic status were also completed excluding ears where a diagnosis could not be made in one or both ears. Comparisons of otologic status (for data including and excluding ‘undetermined’ ears) between age groups, gender, and left and right ears were made using Pearson's chi-squared test with a probability of 5% considered to be significant.

## 5.4 Results

Table 5.1 presents the symptoms and complaints of otologic disorders for the two weeks prior to evaluation, as disclosed by the participants' caregivers. Caregivers indicated that 7.4% of participants presented with earache, 5.2% with discharge and 6.6% with possible hearing loss. Earache and discharge for participants aged two to five years were reported almost twice as often compared to participants aged six to 15 years (Table 5.1).

**Table 5.1 Caregiver report of symptoms of otologic disorder over two weeks prior to otomicroscopy (n=136)**

	2 to 5 yrs (%)	6 to 15 yrs (%)	Total (%)
<b>Earache</b>	9.2	5.0	7.4
<b>Hearing Loss</b>	2.6	11.7	6.6
<b>Discharge</b>	6.6	3.3	5.2

Cerumen removal was necessary for 36.0% of participants (23.5% of ears) in order to obtain a clear view of the tympanic membrane for otomicroscopic diagnosis. Cerumen was removed manually in this study and was halted in the event of any discomfort. Cerumen removal was required for 39.5% of 2 to 5 year old participants (23.7% of ears), and for 31.7% of participants aged six to 15 years (23.3% of ears). Cleaning was not possible for a greater number of participants aged two to five years (14.5% of participants), than those aged six to 15 years (10.0% of participants). Table 5.2 presents the percentage of participants and ears with no, partial and complete obstruction of the tympanic membrane by cerumen (after manual cerumen removal as far as was possible without causing discomfort) at the time of otomicroscopic diagnosis of middle ear status.

**Table 5.2 Obstruction of the tympanic membrane during otomicroscopic examination**

Subjects	2 to 5 yrs (%) <i>n</i> =76	6 to 15 yrs (%) <i>n</i> =60	Total (%) <i>n</i> =136
<b>Bilateral obstruction</b>			
None	30.3	46.7	37.5
Partial	44.7	23.3	35.3
Complete	0.0	1.7	0.7
<b>Unilateral and complete</b>	9.2	10.0	9.6
<b>Unilateral obstruction</b>			
Partial	13.2	11.6	12.5
Complete	2.6	6.7	4.4
Ears	2 to 5 yrs (%) <i>n</i> =152	6 to 15 yrs (%) <i>n</i> =120	Total (%) <i>n</i> =272
None	38.8	55.8	46.3
Partial	55.9	34.2	46.3
Complete	5.3	10.0	7.4

The diagnosis of otologic status was reported for both ears and participants (Table 5.3). Cerumen could not be removed, and otomicroscopic diagnosis of middle ear status could consequently not be made in one or both ears of 12.9% of participants. A diagnosis of otologic status could not be made in either ear of three participants.

**Table 5.3 Otologic status as diagnosed by otomicroscopy**

Participants	All <i>n</i> =136	2 to 5 yrs <i>n</i> =76	6 to 15 yrs <i>n</i> =60	Male <i>n</i> =75	Female <i>n</i> =61		
Normal	66.9	60.5	75.0	61.4	72.1		
Otitis media:	20.6	27.7	11.7	25.3	16.4		
AOM	1.5	2.6	0.0	1.3	1.6		
CSOM	5.1	4.0	6.7	6.7	4.9		
OME	14.0	21.1	5.0	17.3	9.9		
Undetermined	12.5	11.8	13.3	13.3	11.5		
Ears	All <i>n</i> =272	2 to 5 yrs <i>n</i> =152	6 to 15 yrs <i>n</i> =120	Male <i>n</i> =150	Female <i>n</i> =122	Left <i>n</i> =136	Right <i>n</i> =136
Normal	75.8	71.1	81.6	72.0	81.4	75.7	75.7
Otitis media:	16.5	21.0	10.9	19.3	11.8	17.7	15.5
AOM	0.7	1.3	0.0	0.7	0.8	1.5	0.0
CSOM	4.8	3.3	6.7	5.3	4.2	4.4	5.2
OME	11.0	16.4	4.2	13.3	6.8	11.8	10.3
Undetermined	7.7	7.9	7.5	8.7	6.8	6.6	8.8

AOM = acute otitis media; CSOM = chronic suppurative otitis media; OME = otitis media with effusion

Table 5.4 presents the otologic status for the paediatric sample but excluded ears where a diagnosis could not be made due to partial or complete cerumen obstruction. Diagnosis by otomicroscopic examination indicated otitis media to be significantly more prevalent for the younger participants (31.4%) compared to the older participants (16.7%;  $p=0.034$ ; Chi-squared test). OME was the most frequently diagnosed pathology for participants of two to five years of age (23.9%), while CSOM was most commonly diagnosed for participants of six

to 15 years of age (9.3%). AOM was only diagnosed in the younger age group (3.0% of participants two to five years of age).

Otitis media was equally distributed between right and left ears. More male participants presented with otitis media (29.2%) than female participants (18.5%) but the difference was not statistically significant ( $p > 0.05$ ; chi-squared test).

**Table 5.4 Otologic status as diagnosed by otomicroscopy excluding participants and ears where a diagnosis could not be made**

Participants	All <i>n</i> =121	2 to 5 yrs <i>n</i> =67	6 to 15 yrs <i>n</i> =54	Male <i>n</i> =65	Female <i>n</i> =54		
Normal	75.2	68.6	83.3	70.8	81.5		
Otitis media:	24.8	31.4	16.7	29.2	18.5		
AOM	1.7	3.0	0.0	1.5	1.8		
CSOM	6.6	4.5	9.3	7.7	5.6		
OME	16.5	23.9	7.4	20.0	11.1		
Ears	All <i>n</i> =251	2 to 5 yrs <i>n</i> =140	6 to 15 yrs <i>n</i> =111	Male <i>n</i> =137	Female <i>n</i> =110	Left <i>n</i> =127	Right <i>n</i> =124
Normal	82.1	77.1	88.3	78.8	87.3	81.1	83.1
Otitis media:	17.9	22.9	11.7	21.2	12.7	18.9	16.9
AOM	0.8	1.4	0.0	0.7	0.9	1.6	0.0
CSOM	5.2	3.6	7.2	5.9	4.5	4.7	5.6
OME	11.9	17.9	4.5	14.6	7.3	12.6	11.3

AOM = acute otitis media; CSOM = chronic suppurative otitis media; OME = otitis media with effusion

## 5.5 Discussion

Establishing regional otitis media prevalence rates are important when determining *management*<sup>9</sup> protocols (Morris & Leach, 2009). The point prevalence of OME in the current study population (excluding undetermined participants) was 16.5%, which is the highest of current reports in South Africa (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991). It is also higher than Non-Aboriginal OME prevalence in Asia Pacific (prevalence 1.14 to 13.8%; Mahadevan et al., 2012), but still considerably lower than bilateral OME prevalence for Aboriginal children (viz. 31%), which presents with the highest OME prevalence rate in the world (Mahadevan et al., 2012).

A higher prevalence of OME for male participants was found in the current study although it was not statistically significant ( $p > 0.05$ ; chi-squared test). Previous research on gender differences have reported divergent findings with some demonstrating statistically significant

<sup>9</sup> Added to dissertation in response to external examiner recommendations after publication of article

higher prevalence in male children, while others found no gender differences (Casselbrant & Mandel, 2003; Teele et al., 1989). The findings of the current study support that of Teele et al. (1989) who found that OME was associated with male rather than with female children. Although HIV status was not assessed in participants enrolled in the current study, the primary health care clinic targeted in the current study reported a new HIV prevalence rate of 4% amongst the children 14 years and younger in 2012. This is higher than the national HIV prevalence rate in South Africa of 2.4% for babies tested at six weeks of age (reported between March 2012 to February 2013; Gauteng Provincial Department of Health, 2013). Individuals with HIV are known to be more prone to, and more severely affected by, otitis media than seronegative children (Shapiro & Novelli, 1998). HIV status may therefore have contributed to OME point prevalence measured, and in the more severe form of otitis media, namely CSOM.

In this study, the prevalence of CSOM for the total paediatric sample (excluding undetermined participants) was 6.6%, which is classified by the WHO as high (Acuin, 2004), and is similar to previous estimates of CSOM prevalence in sub-Saharan Africa (Acuin, 2004). The CSOM prevalence of 9.3% measured amongst six to 15 year olds in the current study would be rated as the 'highest' prevalence according to the WHO classification system (Acuin, 2004). The higher CSOM prevalence for older children was anticipated as the pathology and sequelae develop from long-term, chronic middle ear inflammation. Differences in the terminology and definitions used in previous studies do make comparisons problematic. Perforations of tympanic membrane can be associated with either AOM or CSOM. Prescott & Kibel (1991) did not report on CSOM but described the prevalence of perforated tympanic membranes in the study (viz. 6.0% of participants), which was comparable to the CSOM prevalence of the total sample of the current study (viz. 6.6% of participants). The CSOM prevalence in primary school children reported in the current study and that of Prescott and Kibel (1991) is considerably higher than that of previous South African studies (Halama et al., 1987; Nel et al., 1988). Formal health care institutions, albeit different levels of health care, were sampled in the current studies and in the study by Prescott and Kibel (1991), which may explain the higher CSOM prevalence compared to the school populations targeted by Nel et al. (1988) and Halama et al. (1987). In a recent study on the otological, audiological and bacteriological findings in children with CSOM in a tertiary hospital in South Africa, HIV infection was present in 54.6% of participants with CSOM (Tiedt et al., 2013). As the health care clinic sampled is a specialist HIV centre, the HIV rate



among participants may therefore have contributed to the higher CSOM prevalence in the current study compared to that of Halama et al. (1987) and Nel et al. (1988)

From the sample of 272 ears, only two ears (0.8%) were identified with AOM in the present study (1.7% participants excluding participants where a diagnosis could not be made). As may be expected given that AOM prevalence decreases with age, the two participants diagnosed with AOM fell within the age group two to five years of age (Teele et al., 1989). Previous South African studies did not distinguish between active AOM, OME and ‘previous evidence’ of AOM (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991). A study performed on 2430 five to eight year old children in rural Swaziland reported a lower point prevalence of AOM of 0.007% (Swart, Lemmer, Parbhoo, & Prescott, 1995). This is, however, comparable to the prevalence of AOM in the group six to 15 years of age (AOM prevalence for 6 to 15 year old children = 0.0%). The exclusion of children younger than five years of age in the study by Swart et al. (1995) may account for the lower prevalence compared to the current study (AOM prevalence of present study = 1.7%). A recent study for a group of 15 718 children in India reported an AOM point prevalence rate of 0.65% (Chadha, Sayal, Malhotra, & Agarwal, 2013). The point prevalence reported by Chadha et al. (2013) is also lower than was found in the current study, but, children younger than five years of age were also excluded.

Timing of *spring*<sup>10</sup> data collection and possible seasonal influences on AOM as a complication of chronic allergic rhinitis, may also have played a role in AOM point prevalence measured in the present study (Daly et al., 2010; Green, 2005). However, the expression of allergic rhinitis in South Africa is mainly that of a persistent disease, especially inland, where grass pollens, are present for significant periods of time (Green, 2005). What was noteworthy was that caregivers of 7.4% of the participants reported their children complained of earache within two weeks of the assessment. This suggests that caregivers may not seek medical opinion in response to episodic otalgia, but may rather adhere to fixed clinic visit schedules. Additionally the rapid spontaneous recovery rate for AOM (80% within two to three days; Rosenfeld & Kay, 2003) mean that a point prevalence study, such as the current study, is likely to underestimate actual occurrence of AOM (Monasta et al., 2012).

---

<sup>10</sup> Added to dissertation in response to external examiner recommendations after publication of article

Although not the most common finding on otomicroscopy, the presence of complete occlusion of the ear canal due to impacted cerumen was higher in the present study (prevalence of unilateral and bilateral complete obstruction from cerumen = 15.5%) than in the studies by Chadha et al. (2013) and Swart et al. (1995; prevalence of complete cerumen obstruction = 7.93%, 8.6%, 7.5% respectively). The rate of cerumen impaction found in the present study was, however, similar to the previous finding for a sample of South African school children, where impacted cerumen was reported in 14% of paediatric participants (Prescott & Kibel, 1991).

CSOM point prevalence measured in the present study has implications for *management*<sup>11</sup> protocols. In low risk populations, OME and AOM are conditions that mostly resolve without treatment or complications (Morris & Leach, 2009). Although beyond the scope of the current research, intervention paradigms may have to be reassessed in the light of the categorization of the high CSOM prevalence in the paediatric population sampled according to WHO criteria (Acuin, 2004). Many of the risk factors that are attributed to high rates of CSOM can be identified in the population sampled, including short-term breast feeding, overcrowding, poor hygiene, poor nutrition, exposure to tobacco, wood and charcoal smoke (Casselbrant & Mandel, 2003). Caregivers need to be informed of the high prevalence of complications of otitis media amongst children in the community, the impact of hearing impairment caused by CSOM, and should be encouraged to seek medical advice for any symptoms of ear disease. Other measures that may reduce the burden of otitis media include routine otologic screening of school-children and increased referral of children with recurrent ear disease for specialist opinion (Chadha et al., 2013). Further research using strict CSOM diagnostic criteria is required to determine if the prevalence rates measured in the current study are typical of primary health care clinics in underserved communities in South Africa.

*Generalizability of the findings of this study may be influenced by factors such as the population sampled, namely the urban community with low socio-economic status; seasonal variation in otitis media prevalence rates; and that the clinic attended by participants was a specialist HIV treatment site.*<sup>12</sup> Limitations to the current study included a smaller sample of participants compared to previous otitis media prevalence studies in South Africa (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991). With larger participant numbers,

---

<sup>11,12</sup> Added to dissertation in response to external examiner recommendations after publication of article

stratification of the sample across age groups would be possible. Future studies on the prevalence of OME in a paediatric sample at primary health care levels in South Africa would also be improved by careful documentation of additional disease and treatment regimes, especially those related to HIV and TB status.

## 5.6 Conclusion

No studies on otitis media prevalence have previously been performed at primary health care level in underserved paediatric populations in South Africa. Otitis media was significantly more prevalent for younger (31.4%) compared to older children (16.7%). The current study found an OME point prevalence of 14.7% for children between 2 and 15 years of age with a CSOM prevalence of 6.6%, which is classified by the WHO as being high (Acuin, 2004). The lack of timely medical intervention, together with the presence of environmental risk factors for otitis media, may explain the high rate of CSOM identified. With CSOM prevalence rates at a primary health care clinic being so high the *management*<sup>13</sup> and subsequent referral protocols may need to be reviewed to prevent complications.

## 5.7 References

- Acuin, J. (2004). *Chronic suppurative otitis media: Burden of Illness*. World Health Organisation (pp. 1–83). Geneva, Switzerland. Retrieved from [http://www.who.int/pbd/deafness/activities/hearing\\_care/otitis\\_media.pdf](http://www.who.int/pbd/deafness/activities/hearing_care/otitis_media.pdf)
- Bluestone, C. D., Gates, G. A., Klein, J. O., Lim, D. J., Mogi, G., Ogra, P., ... Tos, M. (2002). Definitions, terminology, and classification of otitis media. *Annals of Otology Rhinology and Laryngology*, *111*, 8–18.
- Carruthers, J. (2008). Dainfern and Diepsloot: Environmental justice and environmental history in Johannesburg, South Africa. *Environmental Justice*, *1*(3), 121–126. doi:10.1089/env.2008.0526
- Casselbrant, M. L., & Mandel, E. M. (2003). Epidemiology. In R. M. Rosenfeld & C. D. Bluestone (Eds.), *Evidence based otitis media* (2nd ed., pp. 147–162). Chicago: BC Decker.

---

<sup>13</sup> Added to dissertation in response to external examiner recommendations after publication of article

- Chadha, S. K., Sayal, A., Malhotra, V., & Agarwal, A. K. (2013). Prevalence of preventable ear disorders in over 15 000 schoolchildren in northern India. *The Journal of Laryngology and Otology*, *127*(1), 28–32. doi:10.1017/S0022215112002691
- Daly, K. A., Hoffman, H. J., Kvaerner, K. J., Kvestad, E., Casselbrant, M. L., Homoe, P., & Rovers, M. M. (2010). Epidemiology, natural history, and risk factors: Panel report from the Ninth International Research Conference on Otitis Media. *International Journal of Pediatric Otorhinolaryngology*, *74*(3), 231–240. doi:10.1016/j.ijporl.2009.09.006
- Gauteng Provincial Department of Health. (2013). *Annual Report 2012/13* (Vol. 4, pp. 1–404). Retrieved from [http://www.health.gpg.gov.za/Documents/Annual report 2013 Gauteng Department of Health.pdf](http://www.health.gpg.gov.za/Documents/Annual%20report%202013%20Gauteng%20Department%20of%20Health.pdf)
- Green, R. J. (2005). Allergic rhinitis in South African children: There is something new in the air. *South African Family Practice*, *47*(6), 28–31.
- Halama, A., Voogt, G. R., Musgrave, G. M., & van der Merwe, C. A. (1987). Prevalence of otitis media in a Venda village. *South African Medical Journal*, *71*(9), 577–579. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/3576407>
- Lee, D.-H., & Yeo, S. (2004). Clinical diagnostic accuracy of otitis media with effusion in children, and significance of myringotomy: Diagnostic or therapeutic? *Journal of Korean Medical Science*, *19*, 739–743.
- Mahadevan, M., Navarro-Lochin, G., Tan, H. K. K., Yamanaka, N., Sonsuwan, N., Wang, P.-C., ... Vijayasekaran, S. (2012). A review of the burden of disease due to otitis media in the Asia-Pacific. *International Journal of Pediatric Otolaryngology*, *76*(5), 623–635. doi:10.1016/j.ijporl.2012.02.031
- Miziara, I. D., Weber, R., Araújo Filho, B. C., & Pinheiro Neto, C. D. (2007). Otitis media in Brazilian human immunodeficiency virus infected children undergoing antiretroviral therapy. *The Journal of Laryngology and Otology*, *121*(11), 1048–1054. doi:10.1017/S0022215107006093
- Monasta, L., Ronfani, L., Marchetti, F., Montico, M., Brumatti, L. V., Bavcar, A., ... Tamburlini, G. (2012). Burden of disease caused by otitis media: Systematic review and global estimates. *PloS One*, *7*(4), 1–12. doi:10.1371/journal.pone.0036226
- Morris, P. S., & Leach, A. J. (2009). Acute and chronic otitis media. *Pediatric Clinics of North America*, *56*(6), 1383–1399. doi:10.1016/j.pcl.2009.09.007

- Nel, M., Odendaal, W., Hurter, M., Meyer, S., & Van der Merwe, A. (1988). Die voorkoms en aard van gehoorprobleme en middelloorpatologieë by 'n groep swart stedelike kinders in graad I. *The South African Journal Communication Disorders*, 35, 25–29.
- Prescott, C. A. J., & Kibel, M. A. (1991). Ear and hearing disorders in rural grade 2 (Sub B) schoolchildren in the western Cape. *South African Medical Journal*, 79(2), 90–93. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/1989096>
- Rosenfeld, R. M., & Kay, D. (2003). Natural history of untreated otitis media. *The Laryngoscope*, 113(10), 1645–1657. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/14520089>
- Shapiro, N. L., & Novelli, V. (1998). Otitis media in children with vertically-acquired HIV infection: the Great Ormond Street Hospital experience. *International Journal of Pediatric Otorhinolaryngology*, 45(1), 69–75. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9804022>
- Swart, S. M., Lemmer, R., Parbhoo, J. N., & Prescott, C. A. (1995). A survey of ear and hearing disorders amongst a representative sample of grade 1 schoolchildren in Swaziland. *International Journal of Pediatric Otorhinolaryngology*, 32(1), 23–34. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/7607818>
- Teele, D. W., Klein, J. O., & Rosner, B. (1989). Epidemiology of otitis media during the first seven years of life in children in greater Boston: A prospective, cohort study. *The Journal of Infectious Diseases*, 160(1), 83–94. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2732519>
- Tiedt, N. J., Butler, I. R. T., Hallbauer, U. M., Atkins, M. D., Elliott, E., Pieters, M., ... Seedat, R. Y. (2013). Paediatric chronic suppurative otitis media in the Free State Province: Clinical and audiological features. *South African Medical Journal*, 103(7), 467–470. doi:10.7196/SAMJ.6636
- UNAIDS. (2013). *UNAIDS report on the global AIDS epidemic 2013* (pp. 1–198). Retrieved from [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS\\_Global\\_Report\\_2013\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf)
- UNICEF. (2013). *Towards an AIDS-free generation - Children and AIDS: Sixth stocktaking report* (pp. 1–88). New York. Retrieved from

[http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20131129\\_stocktaking\\_report\\_children\\_aids\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20131129_stocktaking_report_children_aids_en.pdf)

## 6. SUMMARY AND CONCLUSIONS

According to the WHO half of all cases of deafness and hearing impairment are avoidable through prevention, early diagnoses and management (WHO, 2010). As the most severe form of otitis media, CSOM contributes significantly to the global burden of hearing loss and disease associated with a high degree of morbidity and impaired quality of life (Acuin, 2004). AOM represents the most common cause of physician visits for sick children and the major reason for the prescription of antibiotics for children in developed countries (Freid et al., 1998; Teele et al., 1984). The pervasiveness of otitis media poses a challenge in many populations around the world (Daly et al., 2010).

The complications of otitis media are largely preventable though, and can be effectively managed through medical and surgical approaches (WHO / CBM, 2013). Knowledge of the prevalence of otitis media, especially of the most severe form of the disease, is important in determining treatment protocols (Casselbrant & Mandel, 2001; Morris & Leach, 2009). In 1998 the WHO classified the prevalence of CSOM in Africa as high (WHO / CIBA Foundation, 1998), with Sub-Saharan Africa presenting with the second highest global incidence of CSOM (Monasta et al., 2012). Together with India, Sub-Saharan Africa accounts for most deaths from otitis media complications (Acuin, 2004). However estimates place one otolaryngologist for approximately 250,000 to 7.1 million people in sub-Saharan Africa (Fagan & Jacobs, 2009). Early diagnosis of middle ear pathology is therefore particularly important in this, an area where hearing health services and hearing health professionals are very limited (WHO, 2013a).

Telehealth may be used to overcome the many barriers to access to services. The video-otoscope has extended the capabilities of the traditional otoscope as a tool for tympanic membrane examination, allowing digitized images or brief video recordings of the ear canal and tympanic membrane to be reviewed, stored, archived, and transmitted via internet (via e-mail attachments, or uploaded on a central, secure database) for medical specialist opinion. Utilising telehealth facilitators to acquire video-otoscopy for remote asynchronous interpretation may be a powerful tool to identify pathology early, and make appropriate recommendations whilst avoiding excessive waiting times and costs related to travelling (ASHA, 2005a; Biagio et al., 2013). This is particularly important for children in remote

areas who may be more prone to ear disorders such as otitis media (Acuin, 2004; Morris & Leach, 2009).

The current study therefore examined the effectiveness of asynchronous video-otoscopy images and recordings, acquired by a telehealth facilitator, for diagnosing ear disease when used within a hearing telehealth clinic in an underserved community at a primary health care clinic.

## 6.1 Summary of study findings

Video-otoscopy used within a hearing telehealth clinic was proposed to extend specialist services to underserved areas and to expedite early identification of otitis media. Study I demonstrated that a facilitator without formal health care education, with limited training, was capable of acquiring sufficient quality video-otoscopy images in an adult population for asynchronous diagnosis. The initial study noted, as did previous studies (Kokesh et al., 2008; Patricoski et al., 2003), that video-otoscopy images did not permit depth perception. It was consequently surmised that this limitation may be overcome through use of video-otoscopy recordings.

Study II established that telehealth facilitator acquired video-otoscopy recordings yielded substantial concordance with onsite otomicroscopy ( $\kappa = 0.679-0.745$ ) for paediatric patients. The high diagnostic concordance is consequential as study II targeted a paediatric population who were likely to be less cooperative than the adult population of study I. There was also substantial inter-rater agreement ( $\kappa=0.74$  and  $0.74$  at the two reviews) and intra-rater agreement ( $\kappa=0.77$  and  $0.74$  for otologist and GP respectively). Pertinently, the variability of the accuracy of asynchronous diagnosis using video-otoscopy recordings was similar to typical inter- and intra-rater diagnostic variability.

A diagnosis from video-otoscopy recordings could not be made from 18% of ears in which successful onsite otomicroscopy was completed. This may have been due to poor video quality, insufficient visualisation of the entire tympanic membrane or partial occlusion of the ear canal by cerumen. Increasing the telehealth facilitator's training and applying cerumen



management strategies prior to video-otoscopy recordings may reduce the number of ears left undiagnosed after asynchronous assessment.

When the prevalence of otitis media was examined in Study III in the underserved paediatric population sampled, the overall otitis media prevalence was 24.8%. OME was the most prevalent type of otitis media (16.5%). Despite an AOM prevalence of 1.7%, caregivers reported otalgia for 7.4% of children within two weeks prior to assessment. It was apparent that caregivers did not typically seek medical opinion on episodic otalgia but adhered to fixed clinic appointment schedules. The lack of medical opinion on otalgia is not problematic in a population with low prevalence of CSOM, as the disease generally resolves without treatment or complications (Morris & Leach, 2009). However, the population targeted demonstrated high CSOM prevalence (6.6%) according to WHO criteria (Acuin, 2004). Early medical intervention is indicated in communities where CSOM prevalence rates are greater than 4.0% (Acuin, 2004; Morris & Leach, 2009). The high CSOM prevalence rates measured therefore has implications for primary health management protocols in this community.

## **6.2 Clinical implications**

In light of the high CSOM prevalence in the paediatric population sampled, intervention paradigms may have to be reassessed. Caregivers need to be informed of the high prevalence of complications due to otitis media amongst children in the community, the impact of hearing impairment caused by CSOM, and should be encouraged to seek medical advice for any symptoms of ear disease. To further address the burden of CSOM, routine otologic screening of preschool and school-aged children is recommended, with increased referral of children with recurrent ear disease for specialist opinion (Chadha et al., 2013).

Identification and consequent treatment of otitis media can be expedited through use of video-otoscopy images or recordings for remote diagnosis. A telehealth facilitator without formal health care education, working within a hearing telehealth clinic at a primary health care clinic in an underserved area may be trained to perform video-otoscopy. Video-otoscopy acquired by a hearing telehealth facilitator with limited training is capable of acquiring good quality video-otoscopy recordings in adults and children. Asynchronous diagnosis could not be made for close to one in five paediatric video-otoscopy recordings due to residual cerumen

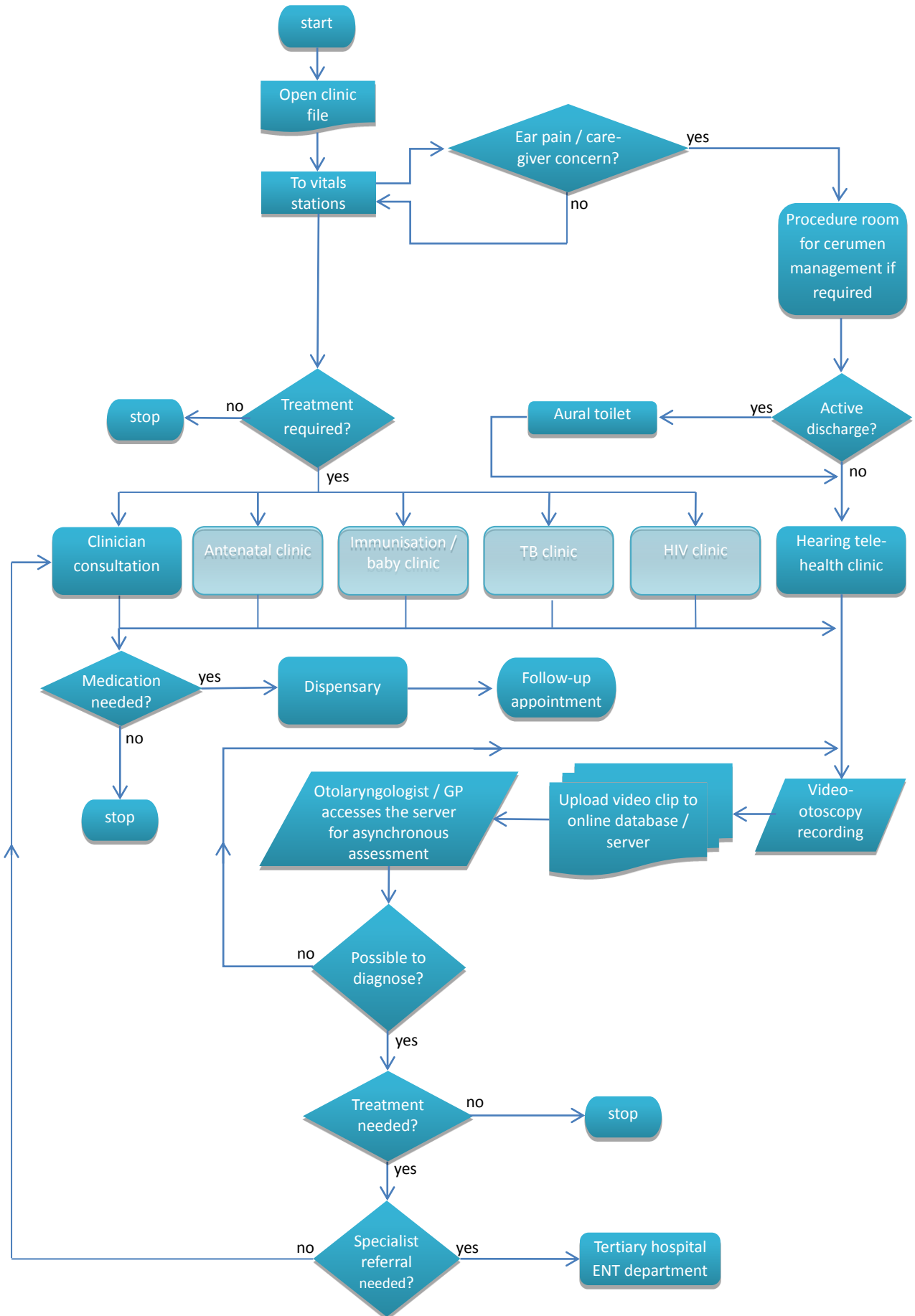
in the ear canal or poor video-quality. The number of ears left undiagnosed after asynchronous assessment may be reduced by increasing the telehealth facilitator's training and supervised period, and by applying cerumen management strategies prior to video-otoscopy recordings.

Video-otoscopy recordings appear to afford better depth perception as it offers several, dynamic angles of the tympanic membrane compared to still video-otoscopy images (Biagio et al., 2013; Kokesh et al., 2008). Video-otoscopy recordings provide the possibility of pausing, rewinding and reviewing the recording several times, an opportunity rarely granted by a child. Video-otoscopy recordings could therefore be used to enable both the child and caregiver are able to see the ear canal and ear drum, hereby providing good counselling and learning opportunities.

Two different video-otoscopes were used in the study. Compared to the Welch Allyn Digital MacroView video-otoscope used in study I, the AMH-EUT Dino-Lite Pro Earscope selected for video-otoscopy recordings in study II was easier to operate with some training, was lighter in weight (Welch Allyn = 95g; Dino-Lite = 90g) and was less expensive (Welch Allyn = ±805USD; Dino-Lite = ±400USD). In comparison with a surgical otomicroscope, the gold standard, the Dino-Lite Pro earscope is significantly less expensive.

### **6.3 A telehealth model for primary health care diagnosis of ear disease**

The conclusions drawn from studies I, II and III were utilised to develop and propose a model for diagnosis of ear disease using telehealth principles at primary health care level. Figure 6.1 depicts the service delivery model proposed.



**Figure 6.1** Flowchart of proposed telehealth model for primary health care diagnosis of ear disease

After collecting their existing file or opening a new file patients at primary health care clinics are then typically directed to one of the following vitals stations: general, chronic, TB or HIV vitals stations. Here, the patient's history form is completed and the patient's weight, blood pressure and blood glucose is measured by an auxiliary nurse. The auxiliary nurse may then enquire about any otalgia, and whether there is any caregiver or patient concerns regarding ears or hearing. If any otalgia or concern is reported, the patient should be sent to the procedure room where any cerumen is removed. Nursing personnel would be advised to make use of manual removal techniques instead of syringing due to the high prevalence of CSOM measured in at least the paediatric population of a primary health care clinic. Removal of any cerumen that completely or partially occludes the view of the tympanic membrane should be performed as thoroughly as possible without causing discomfort. If any active discharge is noted by the nursing staff, an aural toilet may be performed prior to referral for video-otoscopy. If no purulent discharge is noted, patients would be sent to the hearing telehealth clinic after cerumen management. If no concerns about ear disease or hearing are reported to the auxiliary nurse at the vitals stations, patients would generally be examined by one of the onsite primary health care clinicians. If ear disease is identified, patients can also be directed by the clinician to the hearing telehealth clinic.

The hearing telehealth clinic facilitator who receives the patient should ideally be selected from the community in which primary health care clinic serves to avoid any possible language or cultural differences impeding communication and service delivery. In addition to an initial onsite training period by an otolaryngologist or GP, feedback after asynchronous assessment should be given continuously with periodic repeat onsite instructions. A continuous training schedule will ensure that a high level of expertise in video-otoscopy recording is developed and maintained over time. Training should include patient positioning, visual inspection of the external ear, appropriate hand position, manipulation of direction of speculum, focus adjustment, recording capture, video-otoscope software use and equipment cleansing.

The hearing telehealth clinic facilitator would then use a PC or laptop based video-otoscope to acquire a video-otoscopy recording of approximately 30 seconds. If necessary, multiple recordings may be completed. The video-otoscopy recordings, the participant's demographic information and case history can then be uploaded to a server or online database, using a file transfer service such as Dropbox. In order to ensure confidentiality and anonymity, this

information may be labelled using only the patient's file number. Additionally access to the Dropbox folder would be restricted to only the clinic facilitator and the clinicians involved in asynchronous diagnosis from video-otoscopy recordings.

Otolaryngologists or GPs at tertiary health institutions or in private practice may then access the server and download patient data for asynchronous diagnosis. In severely under-resourced environments it may also be feasible to investigate using voluntary assistance by otolaryngologists from other countries employed in public health or private practice who are willing to volunteer their time and expertise. The diagnosis and treatment recommendation, if any, may then be uploaded to the server, using the patient file number as identifier. Alternatively the diagnosis and recommendations together with the patient identifier may simply be emailed to the hearing telehealth clinic facilitator. In the event of treatment recommendations, the patient may be referred either to the onsite clinician, to the dispensary, or to a tertiary health clinic for onsite otologic assessment. A follow-up appointment at the hearing telehealth clinic and with the clinicians would be required hereafter to determine the impact of treatment.

If a diagnosis cannot be made, the otolaryngologist or GP may request that the telehealth clinic facilitator repeat video-otoscopy recording. The facilitator will be required to liaise to recall the patient to the hearing telehealth clinic.

Video-otoscopy recordings may be stored on the server for reference purpose or comparison at follow up assessment. This may further aid in effective management of otitis media and other ear disease. The recordings marked with the diagnosis could also serve as a training resource for onsite clinicians, and for remote otolaryngologists and GPs.

## **6.4 Study strengths and limitations**

### **6.4.1 Study strengths**

Strengths of the current studies included the following:

- The age of participants in study I, and in studies II and III differed as participants were adults and children respectively. The populations targeted in all three studies were nevertheless drawn from a heterogeneous population attending the primary

health care clinic. This ensured ecological validity to facilitate generalization of the findings to other primary health care settings. This is in contrast to previous research on video-otoscopy within a telehealth program where assessments were limited to children attending follow-up appointments following tympanostomy tube placement (Kokesh et al., 2008; Patricoski et al., 2003).

- In study II, otomicroscopy was the gold standard to which diagnostic accuracy of asynchronous assessment of video-otoscopy recordings were compared. Previous research using video-otoscopy within a telehealth clinic often referenced conventional otoscopy (Lundberg et al., 2008; Smith et al., 2006). The ideal method of ear examination is by use of an operating otomicroscope with the ear canal free of cerumen (Aronzon et al., 2004). In practice this is rarely available to a clinician (Patricoski et al., 2003). Nevertheless, the use of otomicroscopy instead of conventional otoscopy should provide a more accurate gold standard for comparison of diagnostic concordance with video-otoscopy recordings, and improved construct validity.
- Due to the limited number of otolaryngologists available in sub-Saharan Africa, GPs are frequently relied on to make otologic diagnosis (Fagan & Jacobs, 2009; WHO, 2013b). As such, study II included video-otoscopy interpretations by a GP, in addition to otologist interpretations. In so doing, the GP's perspectives are also considered, which has not been done in previous research on video-otoscopy for telehealth. The addition of the GP perspective also contributed to the validity of the study.
- Reliability of clinician interpretations was ensured in study I and II by introducing repeat asynchronous assessment four weeks after the first. The two successive assessments allowed for calculation of test-retest reliability (intra-rater concordance). By including asynchronous assessment of video-otoscopy recordings by a GP in addition to that of the otologist for study II, inter-rater reliability could also be calculated with reference to the gold standard.

#### **6.4.2 Study limitations**

Limitations of the current studies included the following:

- Results for studies I and II were comprised largely of normal ears with only a limited number of ears with pathology.

- The TB and HIV status of children in the study on otitis media prevalence (study III) was not documented. This limited the conclusions that could be drawn with regard to contribution of TB / HIV prevalence on otitis media prevalence in the community selected.
- The primary health care clinic sampled is a specialist HIV centre. The prevalence rates of otitis media, particularly of CSOM, may have inflated prevalence rates measured. This also hinders generalisation of prevalence rates to the other regions in South Africa.
- Children under two years of age were not included in study III. The peak incidence of AOM occurs during the second half of the first year of life and decreases with age (Teele et al., 1989). As such, paediatric otitis media prevalence, especially AOM prevalence in the target community, may be underestimated.
- The inclusion of a smaller sample of participants in study III compared to previous otitis media prevalence studies in South Africa (Halama et al., 1987; Nel et al., 1988; Prescott & Kibel, 1991) may have influenced the prevalence rates measured in the current study.
- The limited training offered to the hearing telehealth facilitator in studies I and II is not necessarily representative of a telehealth service with experienced clinic facilitators who have received on-going training over several months or years.
- Studies I and II do not represent an assessment of an on-going program using video-otoscopy within a hearing telehealth services. Consequently, the long-term experience, difficulties and impact of such a program was not considered.

## 6.5 Recommendations for further research

The following recommendations for future research related to the current study findings are made:

- Paediatric otitis media prevalence studies which include children below two years of age are recommended to confirm true paediatric prevalence rates.
- Future studies on the prevalence of OME in a paediatric sample at primary health care levels in South Africa would also be improved by documentation of additional disease and treatment regimes, especially those related to HIV and TB status.

- Further research using larger sample sizes and strict CSOM diagnostic criteria is required to determine if the prevalence rates measured in the current study are typical of primary health care clinics in underserved communities in South Africa.
- It is necessary to validate the use of video-otoscopy recordings taken by a telehealth clinic facilitator on children younger than two years of age.
- Establishment and longitudinal evaluation of routine use of video-otoscopy recordings acquired by a telehealth facilitator in hearing telehealth clinics should follow this study.
- The long term contribution of video-otoscopy as a method of asynchronous diagnosis on CSOM prevalence should be documented to determine the impact of this tool on otitis media burden.
- Establishment of an online network of GPs and otolaryngologists is recommended to provide rapid feedback on asynchronous video-otoscopy recordings before the child leaves the clinic. This is an important due to the distances that patients in sub-Saharan Africa may be required to travel to the closest primary health care clinic. The time between clinic appointments may therefore not be conducive to early identification of otitis media. A research project may be designed to test the effectiveness of a hearing telehealth network, leading to a longitudinal study on the effect hereof on CSOM prevalence in the areas served.

## 6.6 Conclusion

Video-otoscopy used within a hearing telehealth clinic was proposed to extend specialist services to underserved areas and to expedite early identification of otitis media. A telehealth facilitator with limited training was capable of acquiring good quality video-otoscopy images and recordings in a paediatric and adult sample for asynchronous diagnosis. The accuracy of remote diagnosis of otologic status using asynchronous video-otoscopy recordings was equivalent to inter- and intra-rater variability. Video-otoscopy recordings seem to address the apparent lack of depth perception found with video-otoscopy images. Asynchronous video-otoscopy images or recordings may therefore be used within a hearing telehealth clinic at primary health care institutions to reduce morbidity and mortality associated with CSOM complications. The paediatric population at the primary health care clinic sampled presented with high CSOM prevalence rates. CSOM management and referral protocols may therefore



need to be reviewed to prevent CSOM complications. Utilising telehealth facilitators to acquire video-otoscopy measurements for remote asynchronous interpretation may therefore be a proficient tool for early identification of pathology, especially in underserved areas of sub-Saharan Africa where the prevalence of CSOM is high.

## 7. REFERENCES

- Acuin, J. (2004). *Chronic suppurative otitis media: Burden of Illness*. *World Health Organisation* (pp. 1–83). Geneva, Switzerland. Retrieved from [http://www.who.int/pbd/deafness/activities/hearing\\_care/otitis\\_media.pdf](http://www.who.int/pbd/deafness/activities/hearing_care/otitis_media.pdf)
- Agency for Healthcare Research and Quality. (2001). *Telemedicine for the medicare population: Summary, evidence report / Technology assessment: Number 24*. Rockville, Maryland: Agency for Healthcare Research and Quality (US). Retrieved from <http://text.nlm.nih.gov/fters/directBrowse.pl?collect=epc&dbname=telesum>
- Alho, O.-P., Oja, H., Koivu, M., & Sorri, M. (1995). Chronic otitis media with effusion in infancy: How frequent is it? How does it develop? *Archives of Otolaryngology - Head and Neck Surgery*, *121*(4), 432–436. doi:10.1001/archotol.1995.01890040056009
- American Speech-Language-Hearing Association. (2005a). *Audiologists providing clinical services via telepractice: Position statement*. *American Speech-Language-Hearing Association*. doi:10.1044/policy.PS2005-00029
- American Speech-Language-Hearing Association. (2005b). *Audiologists providing clinical services via telepractice: Technical report*. *American Speech-*. doi:10.1044/policy.TR2005-00149
- Aronzon, A., Ross, A. T., Kazahaya, K., & Ishii, M. (2004). Diagnosis of middle ear disease using tympanograms and digital imaging. *Otolaryngology - Head and Neck Surgery*, *131*(6), 917–920. doi:10.1016/j.otohns.2004.07.012
- Baldwin, S., & Berkeljon, A. (2010). Quasi-experimental design. In N. J. Salkind (Ed.), *Encyclopedia of research design* (pp. 1172–1177). Thousand Oaks, California: Sage Publications, Inc. Retrieved from <http://0-www.sage-reference.com.innopac.up.ac.za/view/researchdesign/n353.xml>
- Barnett, E. D., Klein, J. O., Pelton, S. I., & Luginbuhl, L. M. (1992). Otitis media in children born to human immunodeficiency virus-infected mothers. *The Pediatric Infectious Disease Journal*, *11*(5), 360–364. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/1352871>
- Berman, S. (1995a). Otitis media in children. *The New England Journal of Medicine*, *332*(23), 1560–1565. Retrieved from <http://www.nejm.org/doi/full/10.1056/NEJM199506083322307>
- Berman, S. (1995b). Otitis media in developing countries: Review article. *Pediatrics*, *96*(1), 126–131.
- Biagio, L., Swanepoel, D. W., Adeyemo, A., Hall, J. W. I., & Vinck, B. (2013). Asynchronous video-otoscopy with a telehealth facilitator. *Telemedicine and E-Health*, *19*(4), 252–258. doi:10.1089/tmj.2012.0161
- Biagio, L., Swanepoel, D. W., Laurent, C., & Lundberg, T. (2014). Paediatric otitis media at a primary healthcare clinic in South Africa. *South African Medical Journal*, *104*(6), 431–435. doi:10.7196/SAMJ.7534
- Bluestone, C. D., Gates, G. A., Klein, J. O., Lim, D. J., Mogi, G., Ogra, P., ... Tos, M. (2002). Definitions, terminology, and classification of otitis media. *Annals of Otolaryngology and Laryngology*, *111*, 8–18.

- Brook, R. H., & Lohr, K. N. (1985). Efficacy, effectiveness, variations, and quality: Boundary-crossing research. *Medical Care*, 23(5), 710–722. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/3892183>
- Burgess, L. P., Holtel, M. R., Syms, M. J., Birkmire-Peters, D. P., Peters, L. J., & Mashima, P. A. (1999). Overview of telemedicine applications for otolaryngology. *The Laryngoscope*, 109(9), 1433–1437. doi:10.1097/00005537-199909000-00014
- Cantekin, E. I., Bluestone, C. D., Fria, T. J., Stool, S. E., Beery, Q. C., & Sabo, D. L. (1980). Identification of otitis media with effusion in children. *The Annals of Otolaryngology, Rhinology & Laryngology*, 89(3 Pt 2), 190–195. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/6778304>
- Carruthers, J. (2008). Dainfern and Diepsloot: Environmental justice and environmental history in Johannesburg, South Africa. *Environmental Justice*, 1(3), 121–126. doi:10.1089/env.2008.0526
- Casselbrant, M. L., & Mandel, E. M. (2001). The genetics of otitis media. *Current Allergy and Asthma Reports*, 1, 353–357.
- Casselbrant, M. L., & Mandel, E. M. (2003). Epidemiology. In R. M. Rosenfeld & C. D. Bluestone (Eds.), *Evidence based otitis media* (2nd ed., pp. 147–162). Chicago: BC Decker.
- Centre for Disease Control and Prevention. (2013). International classification of diseases, tenth revision: Clinical modification (ICD-10-CM). Retrieved May 19, 2014, from <http://www.cdc.gov/nchs/icd/icd10cm.htm>
- Chadha, S. K., Sayal, A., Malhotra, V., & Agarwal, A. K. (2013). Prevalence of preventable ear disorders in over 15 000 schoolchildren in northern India. *The Journal of Laryngology and Otolaryngology*, 127(1), 28–32. doi:10.1017/S0022215112002691
- Cho, Y.-S., Lee, D.-K., Lee, C.-K., Ko, M. H., & Lee, H.-S. (2009). Video pneumatic otoscopy for the diagnosis of otitis media with effusion: A quantitative approach. *European Archives Of Oto-Rhino-Laryngology*, 266(7), 967–973. doi:10.1007/s00405-008-0839-x
- Daly, K. A., Hoffman, H. J., Kvaerner, K. J., Kvestad, E., Casselbrant, M. L., Homoe, P., & Rovers, M. M. (2010). Epidemiology, natural history, and risk factors: Panel report from the Ninth International Research Conference on Otitis Media. *International Journal of Pediatric Otorhinolaryngology*, 74(3), 231–240. doi:10.1016/j.ijporl.2009.09.006
- Eikelboom, R. H., Mba, M. N., Coates, H. L., Atlas, M. D., & Gallop, M. A. (2005). Validation of tele-otology to diagnose ear disease in children. *International Journal of Pediatric Otorhinolaryngology*, 69(6), 739–744. doi:10.1016/j.ijporl.2004.12.008
- Eysenbach, G. (2001). What is e-Health? *Journal of Medical Internet Research*, 3(2), e20. doi:10.2196/jmir.3.2.e20
- Fagan, J. J., & Jacobs, M. (2009). Survey of ENT services in Africa: Need for a comprehensive intervention. *Global Health Action*, 2, 1–8. doi:10.3402/gha.v2i0.1932
- Fireman, P. (1997). Otitis media and eustachian tube dysfunction: Connection to allergic rhinitis. *The Journal of Allergy and Clinical Immunology*, 99(2), S787–S797. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9042072>
- Freid, V. M., Makuc, D. M., & Rooks, R. N. (1998). Ambulatory health care visits by children: Principal diagnosis and place of visit. *Vital and Health Statistics*, 13(137), 1–23.

- Gauteng Provincial Department of Health. (2013). *Annual report 2012/13* (Vol. 4, pp. 1–404). Retrieved from [http://www.health.gpg.gov.za/Documents/Annual report 2013 Gauteng Department of Health.pdf](http://www.health.gpg.gov.za/Documents/Annual%20report%202013%20Gauteng%20Department%20of%20Health.pdf)
- Glas, A. S., Lijmer, J. G., Prins, M. H., Bonsel, G. J., & Bossuyt, P. M. M. (2003). The diagnostic odds ratio: A single indicator of test performance. *Journal of Clinical Epidemiology*, *56*(11), 1129–1135. doi:10.1016/S0895-4356(03)00177-X
- Goodman, C. S. (2004). *HTA 101: Introduction to health technology assessment*. Virginia, USA. doi:10.1016/j.jacr.2009.01.025
- Goulios, H., & Patuzzi, R. B. (2008). Audiology education and practice from an international perspective. *International Journal of Audiology*, *47*(10), 647–664. doi:10.1080/14992020802203322
- Green, R. J. (2005). Allergic rhinitis in South African children: There is something new in the air. *South African Family Practice*, *47*(6), 28–31.
- Halama, A., Voogt, G. R., Musgrave, G. M., & van der Merwe, C. A. (1987). Prevalence of otitis media in a Venda village. *South African Medical Journal*, *71*(9), 577–579. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/3576407>
- Health Professions Council Of South Africa. (2008). *Booklet on tele-medicine: Draft document of the human rights, ethics and professional practice committee of the Health Professions Council of South Africa*.
- Ho, A. T. P., Hildreth, A. J., & Lindsey, L. (2009). Computer-assisted audiometry versus manual audiometry. *Otology & Neurotology*, *30*(7), 876–883. doi:10.1097/MAO.0b013e3181b120d0
- Hoffman, H. J., Daly, K. A., Bainbridge, K. E., Casselbrant, M. L., Homøe, P., Kvestad, E., ... Vernacchio, L. (2013). Panel 1: Epidemiology, natural history, and risk factors. *Otolaryngology - Head and Neck Surgery*, *148*(4 Suppl), E1–E25. doi:10.1177/0194599812460984
- International Telecommunication Union / United National Educational Scientific and Cultural Organization. (2013). *The state of broadband 2013: Universalizing broadband. A report by the Broadband Commission* (pp. 1–104). Geneva, Switzerland. Retrieved from <http://www.broadbandcommission.org/Documents/bb-annualreport2013.pdf>
- Jung, T. T. K., Alper, C. M., Hellstrom, S. O., Hunter, L. L., Casselbrant, M. L., Groth, A., ... Spratley, J. (2013). Panel 8: Complications and sequelae. *Otolaryngology - Head and Neck Surgery*, *148*(4 Suppl), E122–E1243. doi:10.1177/0194599812467425
- Kaplan, R. M. (1987). *Basic statistics for the behavioural sciences*. Boston: Allyn and Bacon.
- Klein, J. O. (2000). The burden of otitis media. *Vaccine*, *19 Suppl 1*, S2–S8. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11163456>
- Kokesh, J., Ferguson, A. S., Patricoski, C., Koller, K., Zwack, G., Provost, E., & Holck, P. (2008). Digital images for postsurgical follow-up of tympanostomy tubes in remote Alaska. *Otolaryngology - Head and Neck Surgery*, *139*(1), 87–93. doi:10.1016/j.otohns.2008.04.008
- Krumm, M. (2007). Audiology telemedicine. *Journal of Telemedicine and Telecare*, *13*(5), 224–229. doi:10.1258/135763307781458912
- Krumm, M., Ribera, J., & Schmiedge, J. (2005). Using a telehealth medium for objective hearing testing: Implications for supporting rural universal newborn hearing screening programs. *Seminars in Hearing*, *26*(01), 3–12. doi:10.1055/s-2005-863789

- Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics*, *33*(1), 159–174. Retrieved from <http://www.jstor.org/stable/2529310>
- Lee, D.-H., & Yeo, S. (2004). Clinical diagnostic accuracy of otitis media with effusion in children, and significance of myringotomy: Diagnostic or therapeutic? *Journal of Korean Medical Science*, *19*, 739–743.
- Lee, J. K., Cho, Y.-S., Ko, M. H., Lee, W. Y., Kim, H.-J., Kim, E., ... Hong, S. H. (2011). Video pneumatic otoscopy for the diagnosis of conductive hearing loss with normal tympanic membranes. *Otolaryngology - Head and Neck Surgery*, *144*(1), 67–72. doi:10.1177/0194599810390917
- Lieberthal, A. S., Carroll, A. E., Chonmaitree, T., Ganiats, T. G., Hoberman, A., Jackson, M. A., ... Tunkel, D. E. (2013). The diagnosis and management of acute otitis media. *Pediatrics*, *131*(3), e964–e999. doi:10.1542/peds.2012-3488
- Lopez, A. D., Mathers, C. D., Ezzati, M., Jamison, D. T., & Murray, C. J. L. (2006). Global and regional burden of disease and risk factors, 2001: Systematic analysis of population health data. *Lancet*, *367*(9524), 1747–1757. doi:10.1016/S0140-6736(06)68770-9
- Lundberg, T., Westman, G., Hellström, S., & Sandström, H. (2008). Digital imaging and telemedicine as a tool for studying inflammatory conditions in the middle ear - Evaluation of image quality and agreement between examiners. *International Journal of Pediatric Otorhinolaryngology*, *72*(1), 73–79. doi:10.1016/j.ijporl.2007.09.015
- Mahadevan, M., Navarro-Lochin, G., Tan, H. K. K., Yamanaka, N., Sonsuwan, N., Wang, P.-C., ... Vijayasekaran, S. (2012). A review of the burden of disease due to otitis media in the Asia-Pacific. *International Journal of Pediatric Otolaryngology*, *76*(5), 623–635. doi:10.1016/j.ijporl.2012.02.031
- Mathers, C. D., & Loncar, D. (2006). Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Medicine*, *3*(11), e442. doi:10.1371/journal.pmed.0030442
- Mbao, M. N., Eikelboom, R. H., Atlas, M. D., & Gallop, M. A. (2003). Evaluation of video-otoscopes suitable for tele-otology. *Telemedicine Journal and E-Health*, *9*(4), 325–331.
- Miziara, I. D., Weber, R., Araújo Filho, B. C., & Pinheiro Neto, C. D. (2007). Otitis media in Brazilian human immunodeficiency virus infected children undergoing antiretroviral therapy. *The Journal of Laryngology and Otology*, *121*(11), 1048–1054. doi:10.1017/S0022215107006093
- Monasta, L., Ronfani, L., Marchetti, F., Montico, M., Brumatti, L. V., Bavcar, A., ... Tamburlini, G. (2012). Burden of disease caused by otitis media: Systematic review and global estimates. *PloS One*, *7*(4), 1–12. doi:10.1371/journal.pone.0036226
- Morris, P. S., & Leach, A. J. (2009). Acute and chronic otitis media. *Pediatric Clinics of North America*, *56*(6), 1383–1399. doi:10.1016/j.pcl.2009.09.007
- Morris, P. S., Leach, A. J., Silberberg, P., Mellon, G., Wilson, C., Hamilton, E., & Beissbarth, J. (2005). Otitis media in young Aboriginal children from remote communities in Northern and Central Australia: A cross-sectional survey. *BMC Pediatrics*, *5*(27), 1–10. doi:10.1186/1471-2431-5-27
- Motsoaledi, A. P. (2010). Address by the South African minister of health. In *1st Southern African Telemedicine Conference*. Cape Town: South African Medical Research Council. Retrieved from [http://www.mrc.ac.za/pressreleases/2010/telemed\\_doh\\_minister2010.htm](http://www.mrc.ac.za/pressreleases/2010/telemed_doh_minister2010.htm)

- Nel, M., Odendaal, W., Hurter, M., Meyer, S., & Van der Merwe, A. (1988). Die voorkoms en aard van gehoorprobleme en middeloortpatologiee by 'n groep swart stedelike kinders in graad I. *The South African Journal Communication Disorders*, 35, 25–29.
- Netto, L. F. S., da Costa, S. S., Sleifer, P., & Braga, M. E. L. (2009). The impact of chronic suppurative otitis media on children's and teenagers' hearing. *International Journal of Pediatric Otorhinolaryngology*, 73(12), 1751–1756. doi:10.1016/j.ijporl.2009.09.033
- Patricoski, C., Kokesh, J., Ferguson, A. S., Koller, K., Zwack, G., Provost, E., & Holck, P. (2003). A comparison of in-person examination and video otoscope imaging for tympanostomy tube follow-up. *Telemedicine Journal and E-Health*, 9(4), 331–344. doi:10.1089/153056203772744653
- Pedersen, S., Hartviksen, G., & Haga, D. (1994). Teleconsultation of patients with otorhinolaryngologic conditions. A telendoscopic pilot study. *Archives of Otolaryngology - Head and Neck Surgery*, 120(2), 133–136. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8297568>
- Prescott, C. A. J., & Kibel, M. A. (1991). Ear and hearing disorders in rural grade 2 (Sub B) schoolchildren in the western Cape. *South African Medical Journal*, 79(2), 90–93. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/1989096>
- Rogers, D. J., Boseley, M. E., Adams, M. T., Makowski, R. L., & Hohman, M. H. (2010). Prospective comparison of handheld pneumatic otoscopy, binocular microscopy, and tympanometry in identifying middle ear effusions in children. *International Journal of Pediatric Otorhinolaryngology*, 74(10), 1140–1143. doi:10.1016/j.ijporl.2010.06.015
- Rosenfeld, R. M., Culpepper, L., Doyle, K. J., Grundfast, K. M., Hoberman, A., Kenna, M. A., ... Yawn, B. (2004). Clinical practice guideline: Otitis media with effusion. *Otolaryngology - Head and Neck Surgery*, 130(5 Suppl), S95–S118. doi:10.1016/j.otohns.2004.02.002
- Rosenfeld, R. M., & Kay, D. (2003). Natural history of untreated otitis media. *The Laryngoscope*, 113(10), 1645–1657. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/14520089>
- Rovers, M. M. (2008). The burden of otitis media. *Vaccine*, 26 Suppl 7, G2–G4. doi:10.1016/j.vaccine.2008.11.005
- Rovers, M. M., Schilder, A. G. M., Zielhuis, G. A., & Rosenfeld, R. M. (2004). Otitis media. *Lancet*, 363(9407), 465–473. doi:10.1016/S0140-6736(04)15495-0
- Schuerman, L., Borys, D., Hoet, B., Forsgren, A., & Prymula, R. (2009). Prevention of otitis media: Now a reality? *Vaccine*, 27(42), 5748–5754. doi:10.1016/j.vaccine.2009.07.070
- Shapiro, N. L., & Novelli, V. (1998). Otitis media in children with vertically-acquired HIV infection: the Great Ormond Street Hospital experience. *International Journal of Pediatric Otorhinolaryngology*, 45(1), 69–75. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9804022>
- Shrout, P. E., Spitzer, R. L., & Fleiss, J. L. (1987). Quantification of agreement in psychiatric diagnosis revisited. *Archive of General Psychiatry*, 44, 172–177.
- Silverberg, M., & Lucchesi, M. (2011). Common disorders of the external, middle, and inner ear. In J. Tintinalli, J. Stapczynski, O. Ma, D. Cline, R. Cydulka, & G. Meckler (Eds.), *Tintinalli's emergency medicine: A comprehensive study guide* (7th ed.). New York: Mc Graw-Hill. Retrieved from <http://0->

accessmedicine.mhmedical.com.innopac.up.ac.za/content.aspx?bookid=348&Sectionid=40381723.

- Smith, A. C., Douthwaite, S., Agnew, J., & Wootton, R. (2008). Concordance between real-time telemedicine assessments and face-to-face consultations in paediatric otolaryngology. *The Medical Journal of Australia*, 188(8), 457–460. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/18429711>
- Smith, A. C., Perry, C., Agnew, J., & Wootton, R. (2006). Accuracy of pre-recorded video images for the assessment of rural indigenous children with ear, nose and throat conditions. *Journal of Telemedicine and Telecare*, 12(7), 76–80. doi:10.1258/135763306779380138
- Smith, A. C., Williams, J., Agnew, J., Sinclair, S., Youngberry, K., & Wootton, R. (2005). Realtime telemedicine for paediatric otolaryngology pre-admission screening. *Journal of Telemedicine and Telecare*, 11(Suppl. 2), 86–89. doi:10.1258/135763305775124821
- South African Department of Health. A policy on quality in health care for South Africa. , Government Gazette (2000). Pretoria: Government Printer. Retrieved from [www.doh.gov.za/docs/policy/qhc.pdf](http://www.doh.gov.za/docs/policy/qhc.pdf)
- South African National Health Act, 2003. Regulations relating to research on human subjects. , Government Gazette (2007). Pretoria. Retrieved from <http://www.info.gov.za/view/DownloadFileAction?id=72155>
- Swanepoel, D. W., Clark, J. L., Koekemoer, D., Hall, J. W. I., Krumm, M., Ferrari, D. V., ... Barajas, J. J. (2010). Telehealth in audiology: The need and potential to reach underserved communities. *International Journal of Audiology*, 49(3), 195–202. doi:10.3109/14992020903470783
- Swanepoel, D. W., & Hall, J. W. I. (2010). A systematic review of telehealth applications in audiology. *Telemedicine and E-Health*, 16(2), 181–201. doi:DOI: 10.1089=tmj.2009.0111
- Swanepoel, D. W., Olusanya, B. O., & Mars, M. (2010). Hearing health-care delivery in sub-Saharan Africa - A role for tele-audiology. *Journal of Telemedicine and Telecare*, 16(2), 53–56. doi:10.1258/jtt.2009.009003
- Swart, S. M., Lemmer, R., Parbhoo, J. N., & Prescott, C. A. (1995). A survey of ear and hearing disorders amongst a representative sample of grade 1 schoolchildren in Swaziland. *International Journal of Pediatric Otorhinolaryngology*, 32(1), 23–34. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/7607818>
- Swarts, J. D., Alper, C. M., Luntz, M., Bluestone, C. D., Doyle, W. J., Ghadiali, S. N., ... Tideholm, B. (2013). Panel 2: Eustachian tube, middle ear, and mastoid - Anatomy, physiology, pathophysiology, and pathogenesis. *Otolaryngology - Head and Neck Surgery*, 148(4 Suppl), E26–E36. doi:10.1177/0194599812472631
- Teele, D. W., Klein, J. O., & Rosner, B. (1989). Epidemiology of otitis media during the first seven years of life in children in greater Boston: A prospective, cohort study. *The Journal of Infectious Diseases*, 160(1), 83–94. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2732519>
- Teele, D. W., Klein, J. O., & Rosner, B. A. (1984). Otitis media with effusion during the first three years of life and development of speech and language. *Pediatrics*, 74(2), 282–287.
- Tiedt, N. J., Butler, I. R. T., Hallbauer, U. M., Atkins, M. D., Elliott, E., Pieters, M., ... Seedat, R. Y. (2013). Paediatric chronic suppurative otitis media in the Free State

- Province: Clinical and audiological features. *South African Medical Journal*, 103(7), 467–470. doi:10.7196/SAMJ.6636
- Trochim, W. M. (2006). Research methods: Knowledge base. *Web centre for social research methods*. Retrieved September 11, 2010, from <http://www.socialresearchmethods.net/kb/index.php>
- UNAIDS. (2013). *UNAIDS report on the global AIDS epidemic 2013* (pp. 1–198). Retrieved from [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS\\_Global\\_Report\\_2013\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf)
- UNICEF. (2013). *Towards an AIDS-free generation - Children and AIDS: Sixth stocktaking report* (pp. 1–88). New York. Retrieved from [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidpublication/2013/20131129\\_stocktaking\\_report\\_children\\_aids\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidpublication/2013/20131129_stocktaking_report_children_aids_en.pdf)
- Van der Veen, E. L., Schilder, A. G. M., van Heerbeek, N., Verhoeff, M., Zielhuis, G. A., & Rovers, M. M. (2006). Predictors of chronic suppurative otitis media in children. *Archives of Otolaryngology - Head and Neck Surgery*, 132, 1115–1118. doi:10.1001/archotol.132.10.1115
- Verhoeff, M., van der Veen, E. L., Rovers, M. M., Sanders, E. A. M., & Schilder, A. G. M. (2006). Chronic suppurative otitis media: A review. *International Journal of Pediatric Otorhinolaryngology*, 70(1), 1–12. doi:10.1016/j.ijporl.2005.08.021
- World Health Organization. (2006). Primary ear and hearing care training manuals. Geneva: World Health Organisation.
- World Health Organization. (2010). Deafness and hearing impairment. Geneva: World Health Organisation.
- World Health Organization. (2013a). Deafness and hearing impairment: Fact sheet. World Health Organization. Retrieved July 10, 2013, from <http://www.who.int/mediacentre/factsheets/fs300/en/>
- World Health Organization. (2013b). *Multi-country assessment of national capacity to provide hearing care* (pp. 1–49). Geneva, Switzerland. Retrieved from [www.http://www.who.int/pbd/deafness/en](http://www.who.int/pbd/deafness/en)
- World Health Organization / CBM. (2013). *Millions of people in the world have hearing loss that can be treated or prevented*. Retrieved from <http://www.who.int/pbd/deafness/news/Millionslivewithhearingloss.pdf>
- World Health Organization / CIBA Foundation. (1998). *Prevention of hearing impairment from chronic otitis media* (pp. 1–32). London, UK.
- Yoon, Patricia, J., Kelley, P. E., & Friedman, N. R. (2012). Ear, nose, & throat. In W. W. Hay Jr, M. J. Levin, R. R. Deterding, M. J. Abzug, & J. M. Sondheimer (Eds.), *Current diagnosis & treatment: Pediatrics* (21st ed.). New York: Mc Graw-Hill. Retrieved from <http://0-accessmedicine.mhmedical.com.innopac.up.ac.za/content.aspx?bookid=497&Sectionid=40851685>



## **8. APPENDICES**

### **APPENDIX A**

#### **Study I participant information form**



Date:

**Researcher:** Leigh Biagio  
**Tel:** 012 420 6774  
**Fax:** 08660 85398  
**Email:** leigh.biagio@up.ac.za

Dear Participant

We are conducting research to evaluate a tele-otology service in primary healthcare. As part of the research, the effectiveness of video-otoscopy images used in an asynchronous method of service delivery will be evaluated. To evaluate and improve services, patient information will be used as part of an ongoing research project.

As patients of the Witkoppen tele-audiology clinic, your consent is required to allow us to use the information collected during your hearing assessment. Your consent is voluntary and all information will be kept confidential and no personal identifying information will be documented at any stage. A unique code will be assigned to each participant instead of using names. You also have the right to withdraw from the study at any stage should you prefer to do so without any negative consequences to you.

The research project will involve an Ear, Nose and Throat Specialist and a trained audiology clinic facilitator looking into your ears with an otoscope, and taking a digital picture of your ear drums with a video otoscope. You will also be asked a few hearing and ear related questions. This should only take between 15 to 20 minutes.

All research data will be kept for 15 years at the University of Pretoria for archiving and future research purposes but will be stored without any personal identifying information. The results of the study will be used to complete a doctoral study, used for publication of an article in a scientific journal and for conference papers.

Your consent will be sincerely appreciated. If you agree to participate, please sign the informed consent form. If you have any questions or concerns, please do not hesitate to contact the researcher.

Kind regards,

Leigh Biagio  
Researcher

Prof De Wet Swanepoel  
Research supervisor

Prof Bart Vinck  
HOD: Speech-Language Therapy &  
Audiology

Communication Pathology Bldg R3-5  
University of Pretoria  
PRETORIA 0002  
Republic of South Africa

Tel: +27 12 4202304  
Fax: +27 12 4203517

[dewet.swanepoel@up.ac.za](mailto:dewet.swanepoel@up.ac.za)  
[www.up.ac.za](http://www.up.ac.za)

**APPENDIX B**

**Study I participant**

**consent form**



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Humanities  
Department of Speech-Language Therapy & Audiology

Date:

*Researcher:* Leigh Biagio  
*Tel:* 012 420 6774  
*Fax:* 08660 85398  
*Email:* leigh.biagio@up.ac.za

### INFORMED CONSENT FORM

## *Telehealth for primary health care: A video-otoscopic study of ear disease*

Please complete the following:

Name and surname: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Age: \_\_\_\_\_

I have received information about the study and have also had the opportunity to ask questions regarding the study and also received answers to any questions I may have asked. I understand that my identity will be kept confidential and that the data will be reported using an alphanumerical code only. I hereby agree to participate in this project and acknowledge that the data will be used for research purposes. I am aware that I may withdraw from this project, at any time, should I wish to.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Communication Pathology Bldg R3-5  
University of Pretoria  
PRETORIA 0002  
Republic of South Africa

Tel: +27 12 4202304  
Fax: +27 12 4203517

[lewis.swanson@up.ac.za](mailto:lewis.swanson@up.ac.za)  
[www.up.ac.za](http://www.up.ac.za)

**APPENDIX C**

**Study I onsite otoscopy**

**data sheet**

**VIDEO-OTOSCOPYY - CLINICAL ONSITE EXAM SHEET**

<b>PATIENT CODE</b>	
---------------------	--

<b>AGE</b>	
------------	--

<b>GENDER</b>	Male	Female
---------------	------	--------

<b>OCCUPATION</b>	
-------------------	--

<b>EAR COMPLAINTS</b>
-----------------------

<b>EAR ACHE</b>	Yes	No
-----------------	-----	----

<b>EAR DISCHARGE</b>	Yes	No
----------------------	-----	----

<b>HEARING LOSS</b>	Yes	No
---------------------	-----	----

<b>TINNITUS</b>	Yes	No
-----------------	-----	----

<b>BALANCE PROBLEMS</b>	Yes	No
-------------------------	-----	----

<b>OTHER RELEVANT INFO</b>	
----------------------------	--

<b>OTOSCOPY FINDINGS</b>
--------------------------

<b>RIGHT EAR</b>
------------------

<b>SURFACE STRUCTURE OF TM</b>	
--------------------------------	--

<b>THICKNESS OF TM</b>	
------------------------	--

<b>COLOUR OF TM</b>	
---------------------	--

<b>POSITION OF TM</b>	
-----------------------	--

<b>DIAGNOSIS</b>	
------------------	--

<b>LEFT EAR</b>
-----------------

<b>SURFACE STRUCTURE OF TM</b>	
--------------------------------	--

<b>THICKNESS OF TM</b>	
------------------------	--

<b>COLOUR OF TM</b>	
---------------------	--

<b>POSITION OF TM</b>	
-----------------------	--

<b>DIAGNOSIS</b>	
------------------	--

**APPENDIX D**

**Study I video-otoscopy images**

**remote data sheet**

**VIDEO-OTOSCOPY - REMOTE GRADING EXAM SHEET**

IMAGE CODE	
------------	--

IMAGE RELATED COMPONENTS		
Grade	Label	Description
2	Excellent	Excellent image quality and easy to assess the status of the TM
1	Acceptable	Possible to assess the status of the TM
0	Not acceptable	Not possible to assess the status of the TM

	<b>GRADE</b>	<b>0</b>
FOCUS		Good focus
LIGHT		Good light
OBSCURING OBJECTS		No obscuring objects
COMPOSITION		Important anatomic structures of TM is visible

**OTOSCOPY FINDINGS**

	YES/NO	Explanation
SURFACE STRUCTURE OF TM		Surface structure of TM can be assessed (smooth/rough)
THICKNESS OF TM		Thickness of TM can be assessed (translucent/opaque)
COLOUR OF TM		Colour of TM can be assessed
POSITION OF TM		Position of TM can be assessed
DIAGNOSIS		



**APPENDIX E**

**Study II and III caregiver  
information sheet**



Date:

**Researcher:** Leigh Biagio  
**Tel:** 012 420 6774  
**Fax:** 08660 85398  
**Email:** leigh.biagio@up.ac.za

Dear Participant

We are conducting research to evaluate a hearing telehealth service in primary health care. As part of the research, the effectiveness of video-otoscopy recordings (video clips) used in an asynchronous method (ie. uploaded to a secure online server from where specialists anywhere in the world can evaluate the images) of service delivery will be evaluated. To evaluate and improve services, patient information will be used as part of an ongoing research project.

As patients of the Witkoppen tele-audiology clinic, your consent is required to allow us to use the information collected during your hearing assessment. Your consent is voluntary and all information will be kept confidential and no personal identifying information will be documented at any stage. A unique code will be assigned to each participant instead of using names. You also have the right to withdraw from the study at any stage should you prefer to do so without any negative consequences to you.

The research project will involve an otologist looking into your ears with an otomicroscope, after which a trained telehealth clinic facilitator will take a short video recording of your child's ear drums with a video-otoscope. You will also be asked a few hearing and ear related questions. This should only take between 15 to 20 minutes.

All research data will be kept for 15 years at the University of Pretoria for archiving and future research purposes but will be stored without any personal identifying information. The results of the study will be used to complete a doctoral study, used for publication of an article in a scientific journal and for conference papers.

Your consent will be sincerely appreciated. If you agree to participate, please sign the informed consent form. If you have any questions or concerns, please do not hesitate to contact the researcher.

Kind regards,

Leigh Biagio  
Researcher

Prof De Wet Swanepoel  
Research supervisor

Prof Bart Vinck  
HOD: Speech-Language Therapy &  
Audiology

**APPENDIX F**

**Study II and III caregiver  
consent form**



Date:

*Researcher:* Leigh Biagio  
*Tel:* 012 420 6774  
*Fax:* 08660 85398  
*Email:* leigh.biagio@up.ac.za

**INFORMED CONSENT FORM**

***Telehealth for primary health care: A video-otoscopic study of ear disease***

**Please complete the following:**

Caregiver's name and surname: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Child's name and surname: \_\_\_\_\_

Child's age: \_\_\_\_\_

I have received information about the study and have also had the opportunity to ask questions regarding the study and also received answers to any questions I may have asked. I understand that my child's identity will be kept confidential and that the data will be reported using an alphanumeric code only. I hereby agree to allow my child to participate in this project and acknowledge that the data will be used for research purposes. I am aware that I may withdraw my child from this project, at any time, should I wish to.

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

**APPENDIX G**

**Study II and III onsite**

**otomicroscopy data sheet**

**VIDEO-OTOSCOPYY - CLINICAL ONSITE EXAM SHEET**

PATIENT CODE			
--------------	--	--	--

AGE	
-----	--

GENDER	Male	Female
--------	------	--------

<b>EAR COMPLAINTS</b>
-----------------------

EAR ACHE	Yes	No
----------	-----	----

EAR DISCHARGE	Yes	No
---------------	-----	----

HEARING LOSS	Yes	No
--------------	-----	----

<b>OTOSCOPY FINDINGS</b>
--------------------------

<b>RIGHT EAR</b>			
	None	Partial	Complete
Earcanal obstruction?			
	Yes	No	
Secretion			
	Intact	Perforated	
TM patency			
	Translucent	Opaque	
TM translucency			
	Normal	Retracted	Bulging
POSITION OF TM			

DIAGNOSIS	Normal	SOM	AOM	CSOM	Other: _____
DIAGNOSTIC DESCRIPTION	_____				

<b>LEFT EAR</b>			
	None	Partial	Complete
Earcanal obstruction?			
	Yes	No	
Secretion			
	Intact	Perforated	
TM patency			
	Translucent	Opaque	
TM translucency			
	Normal	Retracted	Bulging
POSITION OF TM			

DIAGNOSIS	Normal	SOM	AOM	CSOM	Other: _____
DIAGNOSTIC DESCRIPTION	_____				

**APPENDIX H**

**Study II video-otoscopy recordings**

**remote data sheet**

Recording	Ear Complaints in past 2 weeks			Asynchronous rater:							
	Ear Ache	Discharge	Hearing loss	GRADE	Obstruction	Secretion	TM patency	TM translucency	TM position	Diagnosis	Other comments
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											



## **APPENDIX I**

### **Postgraduate committee and research ethics committee approval letter**



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Humanities  
Office of the Deputy Dean

26 October 2011

Dear Prof Swanepoel,

**Project:** Telehealth for community-based hearing health care: a systematic evaluation  
**Researcher:** L Biagio  
**Supervisor:** Prof DCD Swanepoel  
**Department:** Communication Pathology  
**Reference Number:** 94256838

Thank you for the application that was submitted for review.

The content of the application was approved by the **Postgraduate Committee** on 13 September 2011 and by the **Research Ethics Committee** on 20 October 2011 (Please refer to the comments that are attached). Data collection may therefore commence, based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

The manner in which the project will be presented for examination is however a subject of on-going discussion between the faculty and the department.

The Committee requests you to convey this information to the researcher.

We wish you success with the project.

Sincerely



**Prof John Sharp**  
**Chair: Postgraduate Committee &**  
**Research Ethics Committee**  
**Faculty of Humanities**  
**UNIVERSITY OF PRETORIA**  
**e-mail: john.sharp@up.ac.za**

## **APPENDIX J**

### **Witkoppen Health and Welfare Centre permission letter**



*Association Incorporated Under Section 21  
Reg. No. 96/00404/08  
Non-profit Organisation Reg. No. 001-244NPO  
PBO Reg. No. 930009674*

Ms L Biagio  
leighbiagio@gmail.com

---

**Postal Address**  
P O Box 2472, Fourways, 2055  
**Telephone**  
+27 11 705 2438 / +27 11 467 3158  
**Medical Centre Fax**  
+27 11 465 7896  
**Administration Fax**  
+27 086 671 9674 or  
**Welfare Centre Fax**  
+27 11 467 8543  
**E-mail**  
info@witkopp.co.za

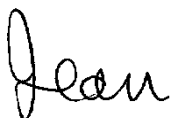
30 July 2010

Dear Leigh

This letter serves to confirm that you have my permission to use data gathered from your work at Witkopp Health & Welfare Centre in your work towards your PhD in tele-audiology through Pretoria University.

I understand that the study will entail describing the prevalence of otitis media amongst the paediatric population at Witkopp Health and Welfare Centre, as well as the evaluation of asynchronous video-otoscopy images and recordings acquired by the trained facilitator of the tele-audiology clinic at Witkopp Health and Welfare Centre. I understand that voluntary participation in the study will be requested from registered patients and from the caregivers of registered patients of the Centre and that the participants' anonymity will be protected at all times.

Kind regards



DR JEAN BASSETT (MBChB UCT)  
EXECUTIVE DIRECTOR

---

**Directors**

G Japhet, M Khoza, R Smith, A Christie, L Holding,  
P Tlhabi, J F Bassett (Executive Director),  
D M Franklin (Chairman)