A cross-sectional study of referrals to the ENT out-patients department in a Tertiary setting

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Otorhinolaryngology.

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Dedication

I dedicate this to my parents,

Jayantilal and Kiran Mistry,

who have always wanted me to shine bright.

Acknowledgments

I would like to thank God and my Guru HDH Mahant Swami
for his strength and blessings.

I would like to thank my family for their support and kindness.

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for their guidance and patience.

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Co-author declaration

Declaration: Student's contribution to article(s) and agreement of co-author(s)

I, **Heeral Jayantilal Bhaga (Mistry)**, student number **0403152D**, declare that this Research Report is my own work and that I contributed adequately towards research findings published in the article(s) stated below which are included in my Research Report.

Signature of Student _____ Date _____

Name of Primary Supervisor: Dr Natasha Morgado

Signature of Primary supervisor **Date: 23/11/2021**

Agreement by co-authors:
By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of his/her Thesis/Dissertation/Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for his/her degree purposes.

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Comments by primary supervisor:

Well done Dr Bhaga. An interesting topic that will help form guidelines for referral centres and reduce inappropriate referrals at the tertiary health care setting.

Chapter 1: Submissible Article

A cross-sectional study of referrals to the ENT out-patients department in a Tertiary setting.

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Abstract

Background: South Africa is historically plagued with social inequality resulting in challenges accessing healthcare. Streamlining referral systems may aid in providing appropriate and timely healthcare to patients, improving their quality of life. Ear nose and throat (ENT) conditions can account for up to 50% of GP referrals. Chris Hani Baragwanath Hospital (CHBAH) ENT services a substantial portion of the Gauteng population.

Method: This was a single center prospective cross-sectional study at the ENT OPD at CHBAH conducted over 6 weeks. Informed consent was taken thereafter a data sheet used to record patient details, employment status, pathology, duration, and appropriateness of referral. Patients excluded were those with incomplete details and where consent was denied. The clinical and epidemiological profile of new patients attending ENT Out-patient department (OPD) was analyzed and compared to international trends.

Results: The cohort of 200 patients had a wide age range of 79.89 years and mean of 26.9 years and predominantly female. Most patients were unemployed. Majority of referrals were from general doctors at primary health care centers. There was an even distribution of urgent and non-urgent referrals, most being non-malignant. The majority of cases were appropriately referred. A foreign body in the ear was the commonest diagnosis with 23 cases (11.5.0%)

followed by 15 cases (7.5%) of sensorineural hearing loss and 13 cases (6.5%) of recurrent tonsillitis.

Conclusion: Patients presenting to the ENT OPD at CHBAH were mostly female of lower socioeconomic status. The pathology seen is comparable with other upper- and lower-income countries.

Key words: hearing loss, foreign body.

Background

South Africa is historically a country plagued by inequality and as such access to and provision of healthcare is challenging. Streamlining referral systems may aid in providing timely healthcare to patients in need. Ear nose and throat conditions (ENT) may account for 50% of GP referrals. Chris Hani Baragwanath Academic Hospital (CHBAH) ENT services a large portion of the Gauteng population, providing efficient timely treatment will help to improve quality of life for many patients.

The South African Health care system consists of public and private health sectors. The public sector services most of the population and is built on a foundation of primary healthcare centers (PHC), which are the first port of entry into the healthcare system. The next tier is the district hospital where more sophisticated treatment is available. Tertiary level institutions and academic hospitals are where advanced diagnostic procedures and treatments are provided [1,2]. Only 38.7% of the health budget is spent on the public sector. Academic hospitals consume 30.65% of that budget, secondary and tertiary institutions 11% and 14% respectively. Academic institutions are considered tertiary institutions. Presently, Gauteng Province (GP) is home to 14.7 million inhabitants [3]. Many of whom are unemployed and are the primary users of the public healthcare system. Poorly resourced PHCs and lack of trained medical staff overload the tertiary institutions with unnecessary referrals [1]. There is a need to streamline healthcare service delivery and make it more efficient and accessible. Chris Hani Baragwanath Academic Hospital (CHBAH) is a tertiary care hospital, ranked the third largest hospital in the world. It is in Soweto in the Gauteng Province of South Africa. CHBAH is equipped with approximately 3 400 beds and 6 760 staff members [4].

Otorhinolaryngology encompasses a large variety of diseases which occur across all ages and races, regardless of socioeconomic status or gender [5]. Interestingly, some ENT conditions such as otitis media are much more common in lower socioeconomic groups compared to higher income groups, with an incidence as high as 60 percent of all ENT consultations [6]. Globally 65-330 million individuals are affected by chronic suppurative otitis media, with 60 % of these individuals having significant hearing loss. In Sub-Saharan Africa up to 50% of these children are under 10 years of age [5]. In

the paediatric population, ENT conditions account for 50% of all medical consultations [5]. In a study by Tshifularo and colleagues they showed that approximately 100% of HIV positive patients will present with head and neck manifestations in their lifetime, resulting in a higher burden of health in this population group [7]. In another study the authors showed oral diseases being the commonest ENT manifestation of HIV. Tonsillar hypertrophy being the most common disease [7].

Alherabi and colleagues found that 80% of patients presenting to a specialist ENT clinic had a general ENT condition that could be managed at a primary care or level one institution. This number overwhelms services provided at the tertiary institution [8]. John and colleagues noted that ENT referrals are the second most problematic cohort, mostly due to primary healthcare physicians not being able to tell which sub-specialty a patient belongs to [9]. The ENT clinic at CHBAH runs two days a week and services between 140-200 patients per day. Examples of referrals that can be managed at primary healthcare level include: wax impaction, uncomplicated allergic rhinitis, hearing aid malfunctions and submandibular gland abscesses secondary to dental pathology [10].

Our study aims to audit the referrals to CHBAH, stratify paediatric and adult referrals and identify referrals that could have been managed at primary healthcare level.

Our study also aims to document the conditions presenting to the ENT OPD. This will allow us to better understand disease profile in our setting and allocate limited resources accordingly. Include your introduction here

Methods

Ethics approval (M190912 MED19-07-040) was obtained from the University of the Witwatersrand Human Research Ethics Committee prior to collection of data. As well as clearance from the Baragwanath ENT department.

This study is a cross sectional study of referrals to the ENT OPD at CHBAH. The study was conducted over a six-week period from 1/12/2019 to 11/01/2020.

The study included all un-booked patients of all ages and gender that attended the OPD for treatment and diagnosis purposes. Patients who were excluded included patients who have been lost to follow up, i.e., patients who have been previously seen at the OPD but have not returned for a follow up appointment; all follow up patients and patients who had already been seen by an ENT in casualty. Patient details were recorded on a data sheet. The information recorded was gender, age, date of referral, final diagnosis, urgent or non-urgent as indicated on referral letter, employed or unemployed. In the case of paediatric patients whether the parents are employed or unemployed. Patient identifying information was removed to maintain confidentiality.

The data sheet was assessed by the principal researcher and the relevant data obtained. Two specified ENT consultants decided on whether the patient could have been managed at a PHC level or was appropriately referred. Two ENT specialists are used to reduce bias.

Results

The cohort of 200 patients contained a wide age range of 79.89 years and mean of 26.9 years with more women than men. Most patients were unemployed and had chronic illnesses. Referrals mostly came from general doctors at primary health care centres. There was an even distribution of urgent and non-urgent referrals, although most patients were seen for non-malignant conditions (95.5%). Most cases were appropriately referred.

There were 36 diagnoses made when the updated 2020 ICD-10 codes were applied to the various referrals in the cohort [ICD-10-CM Official Guidelines for Coding and Reporting FY 2020]. A foreign body in the ear was the commonest diagnosis with 23 cases (11.5.0%) followed by 15 cases (7.5%) of sensorineural hearing loss and 13 cases (6.5%) of recurrent tonsillitis. There were too many diagnoses by ICD-10 codes to assess in the cohort, therefore the diagnoses were grouped into 16 groups according to similarity and relevance. Please see Table 1 Descriptive characteristics for cohort (n=200 patients) and Figures 1: Diagnoses by ICD-10 and 2: Diagnoses by grouping. Conditions that had similar pathophysiology or a conditions that progressed to a chronic form were grouped together. Foreign body of ear and nose were grouped together. This was also done in other similar studies. This also made the number of patients significant. Conditions involving inflammatory conditions of the nose were grouped together. Abscess forming conditions were grouped together. Hearing loss of all causes were grouped together. Voice disorders were grouped together. Conditions benign conditions affecting the tonsil were grouped together. Otitis media chronic, acute, suppurative and non suppurutive were grouped together.

On examination of the cohort for associated factors of appropriate referral, age was significant ($p=0.0434$) and paediatrics and adults ($p=0.026$) was significant. Duration was also significant ($p=0.028$). The grouping was very significant to appropriateness of referral ($p=0.001$). The other factors were not significant ($p>0.05$). Please see Table 2 and 3: Univariate relationship with appropriateness of referral.

To further investigate the appropriateness of referrals to CHBAH ENT clinic, we modelled the referred patients. There were 14 (7%) patients in our cohort who were inappropriately referred. A binary logistic regression model was designed to predict inappropriate referral. All predictor variables on exploratory (univariate) assessment were advanced from Table 2 into the model. None were excluded initially. The

prediction calculated the odds of an inappropriate referral. Manual intelligent modelling was used to design a binary logistic regression model. The advanced predictors that were unhelpful to the prediction were dropped from the model to create the most parsimonious design. Malignancy and duration were therefore dropped from the model. The final model included the age, gender, employment status, referring doctor, referring centre and urgency.

Logistic regression computed of an estimated adjusted odds ratio. Odds ratio is used as opposed to relative risks because the outcome of inappropriate referral was rare statistically defined as less than 10 percent. In our study inappropriate referral was 7% therefore estimates were reported as odds ratios [11]. The finding is that when a patient is a younger, unemployed male, who is privately referred for a non-urgent problem, the odds an inappropriate referral is 9.54. Please see Table 4: Binary logistic regression model for odds of inappropriate referral.

Discussion

The aim of this study was to determine the socio-economic and demographic, clinical characteristics and referral pattern of patients seen at the ENT OPD over a 6-week period. The study also aimed to quantify clinical conditions that are referred to the ENT department among paediatric and adult patients; also, to identify and quantify which referrals can be managed at primary healthcare level and to identify the prevalence of common pathology and compare it to international trends. South Africa is an upper-middle class country based on the World Bank classification [12]. There are many areas where there are those with all the wealth, and those who live in abject poverty. South Africa has the highest inequality in the world with the Gini Coefficient at 63 [12]. The above knowledge, we assume, may explain some of the results of our study when compared to other studies carried out in high income and low- and middle-income countries.

This study can be considered a snapshot of the demographics of the population of Gauteng. However, because of the small sample size, we may not be able to extrapolate to the entire Gauteng population, which is 15.1 million [13]. The most referred conditions in our study were hearing loss (14%), foreign body in the ear (11.5%) and recurrent tonsillitis (6.5%). These findings are in keeping with international developing world trends [9,14–16]. According to estimates by the WHO, 42 million people (> 3yrs old) have hearing loss, most frequently precipitated by otitis media [17]. Hearing loss is deemed by WHO to be a serious public health issue [17]. The increasing burden of hearing loss can be attributed to global population growth and improved life expectancy [17]. This can be an issue to further investigate for

preventable causes as 50% of all hearing loss is preventable [17]. The need for better community education should be explored.

The most common presenting condition in the adult population was chronic suppurative otitis media (CSOM), followed by Laryngopharyngeal reflux disease (LPRD) (5% and 4.5%). The prevalence of CSOM is in keeping with data published in other low- and middle-income countries such as Pakistan [18,19]. This contrasts with developed countries where the rate is less than 1% [20]. CSOM is an important cause of acquired hearing loss. Hearing loss leads to poor communication and poorer quality of life in adults. The complications of CSOM also add to the burden of disease [20].

The prevalence of LPRD ranges from 5-30% worldwide [21]. The prevalence found at CHBAH OPD is in keeping with the lower end of this prevalence rate. This may be explained in part by co- management with gastroenterologists. Many patients may be referred directly to gastroenterologist, who then onward refer to ENT. The diagnosis of LPRD is based on symptoms and on clinical findings. This may result in underdiagnosing if clinical findings are negligible.

A study by Ayotunde also found foreign body in paediatric patients to be one of the commonest causes for referral at 9.9% [16]. Our low numbers reflect the department policy of most foreign bodies in the ear and nose being removed in casualty rather than being referred to the ENT clinic. Otitis media was found to be a common cause for referral in children, followed by CSOM (12.2%) in the Dey study [19]. Our study showed only 0.02% of paediatric patients were referred for CSOM. CSOM is commonly treated at most PHC and only referred if not responding to treatment. The low numbers seen might be reflective of better access to clean water and healthcare. Our vaccination program may protect against certain pathogens.

Our primary healthcare facilities are managed by junior doctors and nurses. This is represented in our data as most new patients to our clinic were referred by these personnel. Referrals from primary healthcare facilities should ideally be referred to a secondary health facility before being referred to CHBAH. The primary reason to be seen at the secondary facility before coming to CHBAH, which is a tertiary care facility, is for simple conditions to be filtered out of the system. This would reduce the number of inappropriate referrals to and overloading of the tertiary institute. A large number of inappropriate referrals may indicate a lack of adequate equipment or medication at a secondary level. Secondary hospitals may also have fewer skilled professionals.

Most conditions referred were benign 189 (95.5%), with only 11 (5.5%) of the referrals being malignant. Head and neck cancers are the 6th most common malignancy in the world [22]. This is not reflected in our current study. This could be because many of our patients present in late stages and may be seen in casualty as emergency admissions. The low number of cancers also do not reflect the prevalence in our population as we are only seeing the cancers that cannot be managed at a

referral hospital. Finally, this low number may be due to the small size of our study as well as the short duration it was carried out over. Many studies conducted at tertiary hospitals were retrospective studies and had average sample size of over 500 patients, some in the thousands, as well as being carried out over more than 3 months [10,18,19].

Inappropriate referrals

The number of inappropriate referrals in our study was only 7%. Most studies referenced in our study showed approximately 31% of their referrals to be inappropriate. Even after intervention this percentage never dropped to below 10% [10,23]. In our study, factors that were most associated with inappropriate referrals included male gender and unemployment. Amongst the inappropriate referrals, 10 of those were paediatric and 8 of those were males. These children were brought in by primary caregivers. The most common reason for these referrals were wax impaction and recurrent tonsillitis. Wax impaction should be managed at PHC. Recurrent tonsillitis should have a trial of medical treatment before being referred to a speciality unit. Unemployment indicates poor socioeconomic status which predisposes to certain ENT condition [19,24].

Age

The age range was between 11 months and 80 years old with a mean of 26.9. The majority of referrals being adults, falling into this age range. Subsequently, 43% of referrals were patients aged under 18. This is in keeping with a study done in Uttar Pradesh (UP) in which, the most common presenting age group was between 21–30-year-olds [18]. In South Africa 28.6% of the population is younger than 15 years [3]. Gauteng has the highest percentage of people over 60 years at 24.1%. This percentage correlates with the finding that most of our patients were adults.

Gender distribution

The population of Gauteng, according to Stats SA, is mostly female at 51.1% [3]. This is reflected in our patient profile as most patients presenting to CHBAH ENT OPD were female. A report by Stats SA indicates that approximately 51,2% (approximately 30 million) of the population is female [3]. This finding was contrary to international trends where most studies had a male marginal predominance [10,15,18]. The latest UN stats showed that the ratio of HIV in woman to men is 1.5:1 [25]. Tshifularo showed that over 80% of HIV positive patients will present at least once for an ENT related illness [7]. This may explain our female predominance of patients attending our OPD. A study by Dey [19] carried out at a tertiary institute in the region of Dakar, services patients from similar socioeconomic backgrounds and HIV prevalence rates match to patients in our study. This study also showed a higher prevalence of female patients presenting to ENT outpatients department. The similarity in study settings

and HIV rates may explain the comparable findings. The commonest presenting complaint in males was foreign body ear (9), 8 of which were under 18 years of age. CSOM (6) and recurrent tonsilitis (6). The commonest presenting in females was also foreign body ear (14) with 9 being under 18 years of age. Following came recurrent tonsilitis (11) and LPR (7). These statistics are in keeping with most studies looked at in this study, these figures were common in both first and third world countries.

The unemployment rate in South Africa stands at 32.5% [26]. This is calculated using the economically active population and may not account for many others in rural communities. This can be expanded to 42.6% if including people who have stopped looking for work [26]. In keeping with this high number of unemployment in this country, 74.5% of patients seen at CHBAH ENT OPD had no source of income. The patients who were classified as having some source of income included those receiving government grants, parents that were employed and supported their children and pensioners who received a source of income. The majority of our patients fell into the lower socioeconomic band. The socioeconomic status does appear to influence the prevalence of disease and lack of access to specialist ENT services as shown by Fagan [22]. A lower socioeconomic status predisposes patients to a differing set of conditions especially in children, where poor nutritional status and overcrowded conditions can increase the risk of otitis media [16]. The rate of otitis media in our referrals is 10% but most of them are adults which may be attributed to our HIV pandemic rather than childhood factors. Lower income could also influence health seeking behaviours, with patients presenting later in the stage of their disease due to poor access to healthcare.

Over the 6-week period we had a total of 200 new referrals. The average being 33 new patients per week. These included patients presenting with acute as well as chronic conditions. This is more comparable to an out-patient department in a high-income country, where the average number of new patients per week ranges from 7 to 56 per week. This contrasts with a region in India, Uttar Pradesh where on average 487.5 new patients were seen per week at a university hospital [10,18]. This result may be explained by our tiered healthcare system where patients have to get referred from a primary or secondary HCF before being seen. Many of the patients may be filtered out. CHBAH ENT out-patient department also has a triage system in place that allows for non-urgent patients to be booked rather than seen the same day. Countries like England have NHS, where waiting periods to see a specialist can be up to 18 weeks [27].

Limitations

Data was collected via stats sheets, which were filled in by the treating doctors in the OPD, this may have led to under recording in a busy clinic. Inaccurate or incomplete records could not be included in the study.

Our study was conducted over a 6-week period. This is a relatively short time. A longer study period may have aided in indicating a more representative disease profile. Most of the referenced studies were carried out over a three-month period.

We did not include social factors such as occupation and tobacco consumption. Occupation is relevant to ENT especially since we are the biggest exporters of Gold and mining forms and integral part of our economy [28]. Mining exposure is linked to many ENT related illnesses. Long term exposure to gold mining is linked to oral and nasal cavity erosions as well as noise induced hearing loss [29]. Likewise, tobacco is also a risk factor as well as exacerbating factor for many ENT related conditions.

Consent is required for minors; some care givers were not comfortable with their details being recorded. This decreased our number of recorded patients. We did experience a number of language barriers in some cases, and even with the help of a translator and therefore could not adequately obtain consent from patients. These patients were also excluded from the study.

Finally, this study was only conducted at a single centre and therefore the results may not be generalisable to other regions or overall populations.

Conclusion

This prospective study was able to provide a snapshot of common ENT pathology encountered in a tertiary institute. Most of the patients seen were females from a lower socioeconomic background. The commonest pathology overall was hearing loss (14%), foreign body in the ear (11.5%) and recurrent tonsillitis (6.5%). These finding are in keeping with other developing world trends. The commonest pathology in the paediatric population was also foreign body in ear and nose. Our incidence of CSOM is lower than in other developing nations.

What is already known on this topic:

Hearing loss is the commonest presenting complaint to ENT

Head and neck cancers are the 6th most common cancer worldwide

What this study adds:

Gauteng has a lower than average incidence of chronic suppurative otitis media.

This study found a lower than expected number of patients presenting with malignancies to the out patients department.

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I would also like to thank Dr Y Atiya for his help along the way.

Competing interests

The authors declare no competing interest.

Authors' contributions

Heeral J. Bhaga 100 percent of write up

Natasha Morgado 75 percent editing and approval

Dipuo Masege 25 percent editing and approval

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Appendix and supplementary material

Tables

List of tables

Table 1: Descriptive characteristics for cohort (n=200 patients)						
Age	**Min - max**	**Mean**	**Q1**	**Q2 (Median)**	**Q3**	**Interquartile range**
	0.11 – 80.00	26.85	6	22	43.75	37.75
Paediatrics and adults	**Paediatrics**			**Adults**		
	86 *(43%)*			114 *(57%)*		
Gender	**Male**			**Female**		
	85 *(42.5%)*			115 *(57.5%)*		
Income	**Income**			**No income**		
	149 *(74.5%)*			51 *(25.5%)*		
Duration	**Acute**		**Subacute**		**Chronic**	
	36 *(18.0%)*		36 *(18.0%)*		128 *(64.0%)*	
Referring HCP	**Nurse**		**MBChB**		**Specialist**	
	40 *(20%)*		129 *(64.5%)*		31 *(15.5%)*	
Referring Centre	**Private/Prison**	**Primary**	**Secondary**		**Tertiary**	
	30 *(15.5%)*	103 *(51.5%)*	15 *(7.5%)*		52 *(26.0%)*	
Urgency	**Non urgent**			**Urgent**		
	101 *(50.5%)*			99 *(49.5%)*		
Benign/Malignant	**Benign**			**Malignant**		
	189 *(95.5%)*			11 *(5.5%)*		
Appropriate referral	**Appropriate**			**Inappropriate**		
	186 *(93.0%)*			14 *(7.0%)*		
ICD-10 code	**Diagnosis – see Figure 1**		**No**	**Group – see Figure 2**		**No**
H60.00	Abscess of external ear		8	Abscesses		10
L02.11	Cutaneous abscess of neck		2			
J35.3	Tonsils & adenoids hypertrophy		7	Adenotonsillar hypertrophy		7
J30.9	Allergic rhinitis		7	Allergic rhinitis and sinusitis		10
J32.9	Chronic sinusitis		3			
S02.2XXA	Closed fracture nasal bone		5	Closed fracture nasal bone		5
R04.0	Epistaxis		6	Epistaxis		6
T16	Foreign body in ear		23	Foreign body		28
T17.1	Foreign body in nostril		5			
K21.9	Gastro-oesophageal reflux without esophagitis		6	GORD without esophagitis		6
H90.2	Conductive hearing loss		5	Hearing loss		28
H90.3	Sensorineural hearing loss		15			
H90.6	Mixed conductive sensorineural hearing loss		8			
C80.1	Primary malignant lesion		11	Primary malignant lesion		11
R22.1	Neck lump or mass		10	Neck lump or mass		10
H65	Nonsuppurative otitis media		8	Otitis media		20
H66	Suppurative otitis media		12			
D37.036	Parotid disease		7	Parotid and tongue diseases		9
K14.8	Diseases of tongue		2			
J03	Acute tonsillitis		11	Tonsillitis		24
J03.91	Acute recurrent tonsillitis		13			
H81	Disorders of vestibular function		5	Vestibular and tympanum disorders		7
H72	Perforated tympanum		2			
R49.9	Voice and resonance disorder		4	Voice and resonance disorder		4
D14.1	Benign neoplasm of larynx		1	Other		15
D44.7	Paraganglia neoplasm		1			
G53	Cranial nerve disorders		2			
G96.01	Cranial cerebrospinal fluid leak		1			
H70	Mastoiditis		1			
H71	Cholesteatoma of middle ear		2			

H93.A	Pulsatile tinnitus	1		
Q17.0	Accessory auricle	1		
R68.2	Dry mouth	2		
R80.9	Delayed speech	1		
OBP13FZ	Trachea decannulation	1		
Z01.10	Normal ENT examination	1		

Table 2: Univariate relationship with appropriateness of referral (n=200 patients)							
		Appropriate			Analysis		
		No	Yes		T value	P value	
Age	Observed	186	14				
	Mean	17.10714	27.59306				
	Mean diff	-10.49592					
	Std. Error	4.570624	1.634271		-1.7210	**0.0434**	
	Std. error diff	6.092996					
	Std. dev.	17.10171	22.28848				
	95%CI lower	7.232911	24.36886				
	95%CI upper	26.95137	30.81727				
		Appropriate			**Analysis – Fishers exact / Pearson's**		
		No	**Yes**	**Total**	**Chi²**	**df**	**P value**
Paediatrics and adults	Paediatrics	10	76	86	4.9638	1	**0.026**
	Adults	4	110	114			
	Total	**14**	**186**	**200**			
Gender	Female	4	81	85	1.1951	1	0.274
	Male	10	105	115			
	Total	**14**	**186**	**200**			
Income	No income	12	137	149	0.9965	2	0.318
	Income	2	49	51			
	Total	**14**	**186**	**200**			
Duration	Acute	3	33	36	7.1477	2	**0.028**
	Subacute	6	30	36			
	Chronic	5	123	128			
	Total	**14**	**186**	**200**			
HCP	Nurse	5	35	40	3.5394	2	0.316
	MBChB	6	123	129			
	Specialist	3	28	31			
	Total	**14**	**186**	**200**			
Centre	Private	0	30	30	3.7811	3	0.286

	Primary	9	94	103			
	Secondary	2	13	15			
	Tertiary	3	49	52			
	Total	**14**	**186**	**200**			
Urgency	Non	11	141	152	0.0546	1	0.815
	Urgent	3	45	48			
	Total	**14**	**186**	**200**			
Benign Malignant	Benign	14	175	189	0.8761	1	0.349
	Malignant	0	11	11			
	Total	**14**	**186**	**200**			
Grouping of diagnoses	Abscesses	4	6	10	37.8136	15	**0.001**
	Adenotonsillar hypertrophy	0	7	7			
	Allergic rhinitis and sinusitis	0	10	10			
	Closed fracture nasal bone	0	5	5			
	Epistaxis	0	6	6			
	Foreign body	0	28	28			
	GORD without esophagitis	0	6	6			
	Hearing loss	0	28	28			
	Primary malignant lesion	0	11	11			
	Neck lump or mass	0	10	10			
	Otitis media	2	18	20			
	Parotid and tongue diseases	0	9	9			
	Tonsillitis	5	19	24			
	Vestibular and tympanum disorders	0	7	7			
	Voice and resonance disorder	0	4	4			
	Other	3	12	15			
	Total	**14**	**186**	**200**			

Table 3: Other univariate relationships (n=200 patients)

		Gender			Analysis – Fishers exact / Pearson's		
		Male	Female	**Total**	**Chi²**	**df**	**P value**
Benign or Malignant	Benign	79	110	189	0.6911	1	0.406
	Malignant	6	5	11			
	Total	**85**	**115**	**200**			
		Gender			**Analysis – Fishers exact / Pearson's**		
		Male	Female	**Total**	**Chi²**	**df**	**P value**
Income	No income	64	85	149	2.2606	1	0.323
	Income	21	30	51			
	Total	**85**	**115**	**200**			
		Gender			**Analysis – Fishers exact / Pearson's**		
		Male	Female	**Total**	**Chi²**	**df**	**P value**
Duration	Acute	13	23	36	0.8276	2	0.661
	Subacute	15	21	36			
	Chronic	57	71	128			
	Total	**85**	**115**	**200**			
		Gender			**Analysis – Fishers exact / Pearson's**		
		Male	Female	**Total**	**Chi²**	**df**	**P value**
Urgency	Non	64	88	152	0.0404	1	0.485
	Urgent	25	27	48			
	Total	**81**	**115**	**200**			
		Paediatrics and adults			**Analysis – Fishers exact / Pearson's**		
		Paediatric	Adults	**Total**	**Chi²**	**df**	**P value**
Duration	Acute	19	17	36	3.7811	2	0.286
	Subacute	18	18	36			
	Chronic	49	79	128			
	Total	**86**	**114**	**200**			
		Paediatrics and adults			**Analysis – Fishers exact / Pearson's**		
		Paediatric	Adults	**Total**	**Chi²**	**df**	**P value**

Urgency	Non	65	87	152	0.0145	1	0.517
	Urgent	21	27	48			
	Total	**86**	**114**	**200**			
		Otitis media			**Analysis – Fishers exact / Pearson's**		
		No	Yes	**Total**	**Chi^2**	**df**	**P value**
Paediatrics and adults	Paediatrics	81	5	86	2.9376	1	0.068
	Adults	99	15	114			
	Total	**180**	**20**	**200**			

Table 4: Binary logistic regression model for odds of inappropriate referral (n=200 patients)							
Number of observations = 200. Residual df = 189				BIC = -923.7126			
Link function: g(u) = ln(u/(1-u)) [Logit]				Variance function: V(u) = u*(1-u) [Bernoulli]			
Predictor		**Odds Ratio**	**Std. Err.**	**Z**	**P>|z|**	**95% CI lower**	**95% CI upper**
Age							
Younger versus	Older	1.02811	0.0177103	1.61	0.108	0.9939779	1.063414
Gender							
Male versus	Female	0.5579932	0.3596846	-0.91	0.365	0.1577397	1.973862
Employment							
No income	Income	1.657343	1.366003	0.61	0.540	0.3294894	8.336496
Health care professional							
Nurse	MBChB	2.300845	1.667014	1.15	0.250	0.556125	9.519237
	Specialist /therapist	0.703648	0.8936218	-0.28	0.782	0.0583906	8.479455
Centre							
Private versus	Primary	0.5400414	0.6088462	-0.55	0.585	0.0592621	4.92127
	Secondary	0.1758948	0.2228375	-1.37	0.170	0.0146853	2.106797
	Tertiary	1	-	-	-	-	-
Urgency							
Non-urgent versus	Urgent	1.303932	0.9605461	0.36	0.719	0.3077615	5.524533
Constant							
Constant		**9.541683**	11.91025	1.81	0.071	0.8262781	110.1853

Figures

List of figures

Figure I: Diagnoses by ICD-10 (n=200 patients).

Figure II: Diagnoses by grouping (n=200 patients).

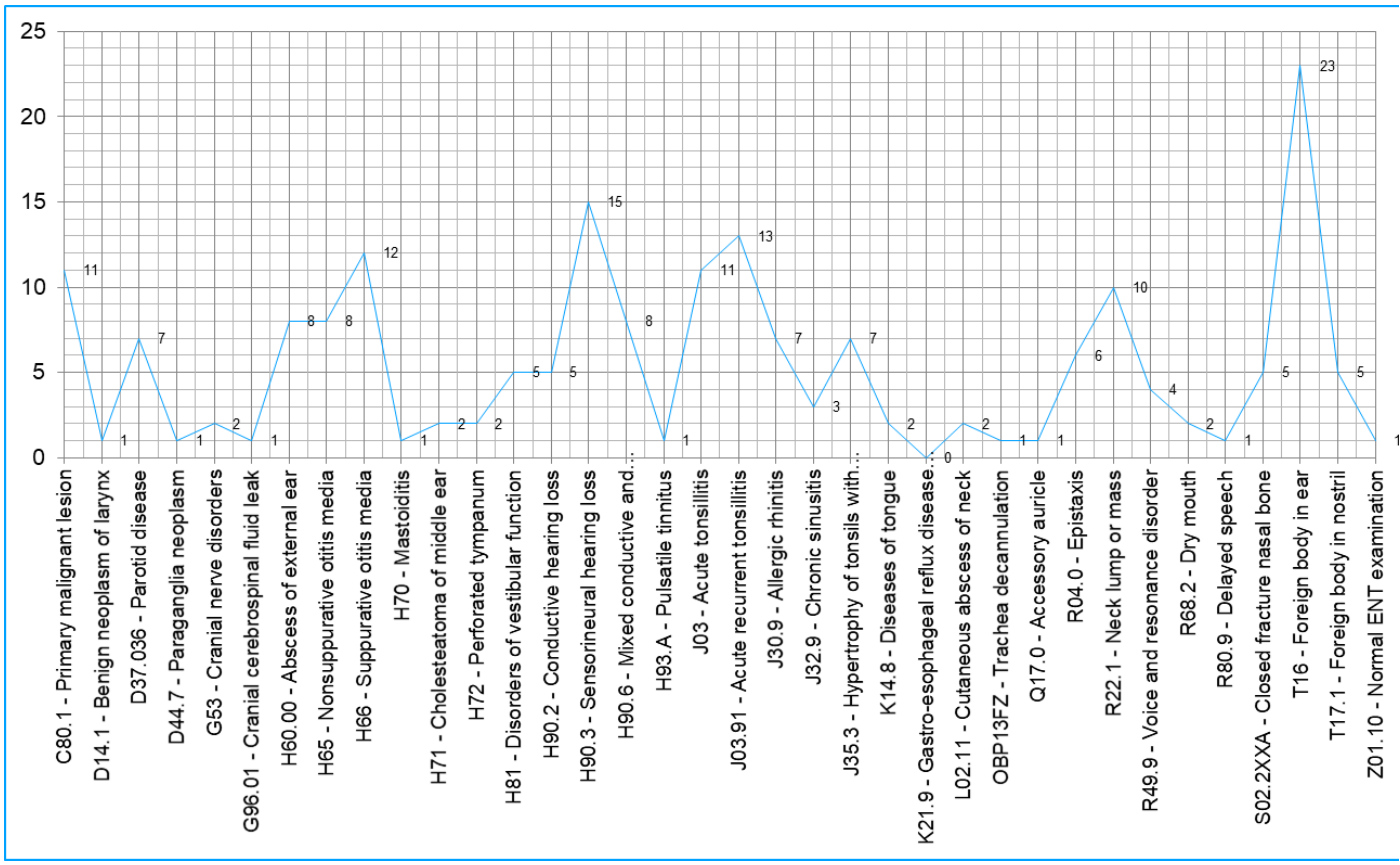

Figure 1: Diagnoses by 36 ICD-10 codes (n=200 patients).

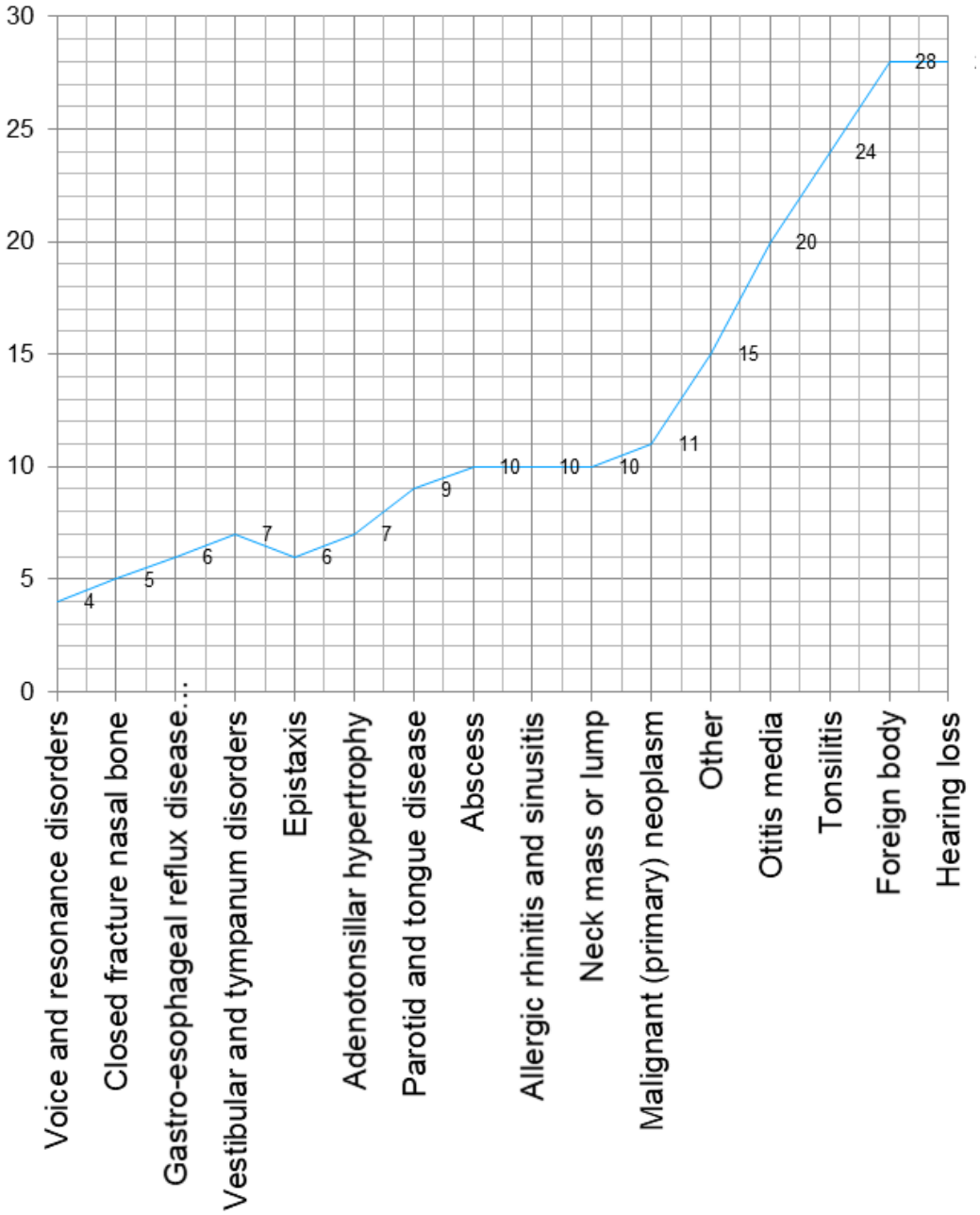

Figure 2: Diagnoses by 16 groups (n=200 patients).

Chapter 2: Protocol with extended literature review

Introduction

Health Care systems in South Africa:

The South African Health care system consists of public and private health sectors. The public sector is built on a foundation of primary healthcare centres (PHC), which are the first port of entry into the healthcare system, whereas in the private sector patients have direct access to their preferred service provider. In the public sector following PHCs, the next tier is the district hospital where more sophisticated treatment is available. Finally, comes tertiary level institutions and academic hospitals where advanced diagnostic procedures and treatments are provided (1). A study by Gray and colleagues has shown that the public sector services the majority of the population (2). Surprisingly only 38.7% of the health budget is spent on the public sector. Academic hospitals consume 30.65% of that budget, secondary and tertiary institutions 11% and 14% respectively. In addition, the study indicates an uneven distribution of resources, with urban areas receiving a greater proportion than poorer rural areas, as well as maldistribution between levels of care (2).

Presently, Gauteng Province (GP) is home to 15.1 million inhabitants (3). Many of these inhabitants are unemployed and are the primary users of the public healthcare system. The appropriate starting point-of-care for these patients would be the PHCs, with referral on to more specialized clinics if indicated. However, many level one health care facilities are led by nursing staff with no doctors available, whilst other level one health care facilities have junior doctors whose knowledge of certain disciplines is limited. Many of the PHC facilities do not have adequate medication, they are not well resourced and some do not have access to laboratory services (1). Patients would then have to be referred to the next level of care. Some patients, knowing that this is the case, may bypass level one facilities and present directly to tertiary centers, further over burdening this level of care. Poorly resourced PHCs and lack of adequately trained medical staff overload the tertiary institutions with unnecessary and incorrect referrals. There is a need to streamline healthcare service delivery and make it more efficient and accessible.

Otorhinolaryngology encompasses a large variety of diseases which occur across all ages and races, regardless of socioeconomic status or gender (4). Interestingly, some Ear Nose and Throat (ENT) conditions such as otitis media are much more common in lower socioeconomic groups compared to higher income groups, with an incidence as high as 60 % of all ENT consults (5). Globally 65-330 million individuals are affected by chronic suppurative otitis media, with 60 % of these individuals having significant hearing loss. In Sub-Saharan Africa up to 50% of these children are under 10 years of age (4). In the paediatric population, ENT conditions account for 50% of all medical

consultations (4). Studies conducted in Africa have shown that the commonest ENT pathology in children is otitis media and the commonest in adults is hearing loss (6,7).

The HIV epidemic has resulted in a greater need for access to healthcare. This is particularly true for ENT conditions. A South African study has shown that approximately 100% of HIV positive patients will present with head and neck manifestations in their lifetime, resulting in a higher burden of health in this population group (8). A Gauteng based study showed oral diseases being the commonest ENT manifestation of HIV. Tonsillar hypertrophy being the most common disease (9).

Chris Hani Baragwanath Academic Hospital (CHBAH) is a tertiary care hospital, ranked the third largest hospital in the world. It is located in Soweto, south of Johannesburg in the Gauteng Province, South Africa. CHBAH is equipped with approximately 3 400 beds and 6 760 staff members. The hospital is also a teaching hospital for the University of the Witwatersrand (10).

The Outpatient Department:

The outpatient department (OPD) provides diagnosis and care for patients who do not require immediate hospital admission. Previously, OPDs were designed for people with healthcare concerns who would visit the hospital for diagnosis or treatment purposes and would not necessarily require a bed or to be admitted for overnight care. However, currently outpatient departments offer a wider range of treatment services, diagnostic tests and minor surgical procedures (11). Many patients are examined and given treatment as outpatients. These patients may require admission to hospital later. Upon discharge from hospital, patients may attend the outpatient clinic for follow-up treatment (11).

ENT OPD:

The ENT OPD is one of the many specialist clinics available at large tertiary hospitals. The ENT outpatient clinic offers services to patients suffering from ear, nose, and throat ailments ranging from, but not limited to, acute or chronic hearing loss, dizziness and tinnitus, acute and chronic sinusitis to more complex diseases such as head and neck cancers. The consultant usually supervises a small team of specialist trainee doctors. The patient may be seen by any member of the ENT team. Due to unforeseen complexity of patient problems, patients may on occasion not be seen at their allocated appointment time and will be seen as soon as possible (11). In the case of hearing concerns, the audiologist may evaluate the patient, assess the ear and conduct an audiological test prior to the patient being seen by the ENT specialist, which is not ideal (11).

The aims of an ENT outpatient department are to see patients that need follow up for previous admissions or appointments and to provide access to patients who need to be seen timeously, not as acute emergencies (12). Consultation in the outpatient

setting constitutes a considerable proportion of an otolaryngologist's workload. Timely access into the clinic is critical to high quality patient care (13). Inappropriate referrals negatively influence high quality patient care. The problems that inappropriate referrals cause to the ENT outpatient's department are highlighted by Cox and colleagues (14). This results in overburdening the outpatient department, longer waiting times and less time spent per patient (2). Hoare and colleagues have shown that inappropriate referrals to secondary care increase waiting times, consume resources and can be harmful to patients (15). Urgent patients may end up waiting longer than necessary as they are in the same queue as the chronic patients.

On an average clinic day at the ENT OPD at CHBAH, there are on average five to seven doctors attending to about 140 patients per clinic: doctor patient ratio of 1: 20-28. These doctors attend to patients consisting of new referrals and follow up patients. Paediatric and adult patients are seen in the same clinic. The average waiting time at CHBAH ENT OPD is three hours. Patients are informed of this on arrival (10). The clinic often runs past closing hours due to the high volume of patients consulted. This results in patients having to make a second trip to the hospital to collect medication from the pharmacy or to have special investigations performed. This inefficiency of service results in additional costs to the patients.

Alherabi and colleagues found that 80% of patients presenting to a specialist ENT clinic had a general ENT condition that could be managed at a primary care or level one institution (16). This number overwhelms services provided at the tertiary institution. Although many of their cases were referred as emergency or semi-emergency, many of these cases were found not be and most cases could have waited until the next day. The study found that true emergency cases were otitis externa and middle ear otitis, epistaxis, vertigo, and facial injuries (16). It was established that appropriate referrals were more likely to come from a general practitioner than an accident and emergency unit within the hospital or other local hospitals (16). Primary healthcare physicians are often the first physician to evaluate patient symptoms and initiate treatment, thus deciding and coordinating referrals is an essential aspect of primary care. John and colleagues noted that ENT referrals are the second most problematic cohort, mostly due to primary healthcare physicians not being able to tell which sub-specialty a patient belongs to (17). Otolaryngologists have been found to be the third most common specialty to which family physicians referred patients (17). Otitis media, sinusitis, and hearing loss were the most common reasons for otolaryngology referral (17). The role of gatekeepers in ensuring appropriate referrals to secondary care facilities has been highlighted by Ang and colleagues (18). The study found that well-resourced facilities or having more experienced doctors lowered the number of referred cases (18).

Rationale and objectives

According to the World Health Organization (WHO), "The goal of a health information system is often narrowly defined as the production of good-quality data. However, the ultimate goal is more than this – it is to produce relevant information that health system stakeholders can use for making transparent and evidence-based decisions for health system interventions" (19). Apart from the referrals CHBAH receive from other hospitals in the province, there are many referrals from surrounding provinces and furthermore, neighbouring countries. On average, the ENT clinic services 140-200 patients per day (on two days a week). Paediatric and adult patients are seen in the same clinic. Some of the referrals may be managed at the primary healthcare level (16). Examples of referrals that can be managed at primary healthcare level include wax impaction, uncomplicated allergic rhinitis, hearing aid malfunctions, submandibular abscesses secondary to dental pathology (12).

Our study aims to evaluate the referrals to CHBAH, stratify paediatric and adult referrals and identify referrals that could have been managed at primary healthcare level.

Our study also aims to document the conditions presenting to the ENT outpatient department. This will allow us to better understand disease epidemiology in our setting. Resources could be better distributed between paediatric and adult patients. The hospital would save on unnecessary use of resources and clinicians could then give more attention to the patients that need to be managed at a tertiary level.

This study could also be used to formulate protocols for the referring doctors or nurses. This will help them treat conditions that can be managed at a primary setting and guide them on appropriate referrals (12). Referral management should not focus solely on reducing demand, but on ensuring that the right patients receive the right care, at the right time (20).

Materials and Methods

Study location

The study will be conducted at the Chis Hani Baragwanath Academic Hospital outpatients' department, in Soweto, Johannesburg, South Africa. It is a tertiary level hospital that is academically affiliated to the University of Witwatersrand.

Study period

The investigation will be conducted over a period of six weeks from 1/12/2019 to 11/01/2020.

Study population

The study includes all un-booked patients that attend the CHBAH ENT OPD for treatment and diagnosis purposes.

Inclusion criteria

All first-time attendees to the ENT OPD at CHBAH.

1. all age groups.
2. male and female.

Exclusion criteria

1. Patients who have been lost to follow up, i.e., patients who have been previously seen at the OPD but have not returned for a follow up appointment.
2. Follow up patients.
3. Patients who have already been seen by an ENT in casualty.
4. Incomplete details on the data sheet

Data collection

Subjects were identified as follows:
Patients who do not have pre-booked appointments (henceforth referred to as walk-ins) are screened on all clinic days. The doctor doing the screening is usually the most senior doctor available. The Screened patients are then given a booking date if they non urgent. Examples are nonacute hearing loss, chronic rhinosinusitis. Urgent or semi urgent conditions are seen on the same day. These conditions are usually life threatening or need treatment in a semi urgent fashion such as cancerous conditions.

The ENT OPD already has a data sheet which we will modify to include age, new or repeat patients and employed or unemployed. In the case of paediatric patients whether the parents are employed or unemployed. The current data sheet had the following variables: name, hospital number, diagnosis, and if any procedures were performed.

Patients will first be informed of the study and what details would be required. They will then be counselled about remaining anonymous and about what the aims of the study are. If they agree to the requirements then they will be asked to sign a consent form. In the case of minors the primary caregiver will be asked for permission. The consent form will then be signed by a witness.

The data sheet will be assessed by the principal researcher and the relevant data obtained. Only new patient's data is recorded. This includes diagnosis, age and employment status. Two specified ENT consultants will decide on whether the patient could have been managed at a PHC level or is appropriately referred. Two ENT specialists are used so as to reduce bias. This will be done by using the data sheet. The reason for referral and final diagnosis will be compared and then used to

determine if the patient requires tertiary level ENT care. The source of referral will also help determine whether the referral centre would have been able to render the required service or not.

Patients' information will be recorded anonymously. Patients will only be identified by a study number. The data will be collected over the specified period and analysed using the STATA program.

The data sheet has the following variables (Appendix A):
Study number assigned to patient
Age
Gender
Employment status
Final diagnosis
Urgent vs Non-Urgent Case
Appropriate for tertiary level care

A representative sample of patients attending ENT OPD was determined to have a minimum of 200 patients. This was determined in consultation with the statistician to demonstrate a snapshot of the patients attending CHBAH ENT OPD.

Data analysis and presentation

Apple numbers (version 10.0 2018) was used for data storage; retrieval and selection and STATA program for data analysis summary statistics and comparison of sample means. Descriptive statistics will be used to describe the results. The prevalence of disease was calculated using the chi square equation with a confidence interval of 95%. A p value of less than 0.05 will be considered significant.

Ethics committee approval

Ethics approval (M190912 MED19-07-040) was obtained from the University of the Witwatersrand Human Research Ethics Committee prior to collection of data. As well as clearance from the Baragwanath ENT department. Confidentiality was maintained as no patient names were published or used. The data obtained did not influence whether the patient was seen or not. All data was stored on a password protected database, to which only the principal researcher has access.

Funding

No funding will be required, as the information will be obtained from the ENT OPD stats sheet. The funding for printing and collating data sheets will be undertaken by the researcher.

Timing

	March 2018	April-July 2018	October 2018-March 2019	27 Sept - 8 November 2019	December2019 - January 2020	Jan2021- April2021	February – March 2021
Literature Review							
Protocol Preparation							
Protocol Assessment							
Ethics Application							
Data Collection							
Data Analysis							
Write up							

Potential limitations

1. Data recording - this may be hindered by poor handwriting on the data collection sheet.
2. Incomplete data sheets.
3. Incorrect diagnosis.
4. Some diseases are seasonal which may bias the data, as referrals for allergic rhinitis tend to occur more frequently in the spring.
5. Cross sectional studies only show prevalence at a set point in time, it may not be representative of the total prevalence of the disease in South Africa.

Expected outcomes

Based on the foundational knowledge provided, the expected outcomes are to determine:

1. The total number of new referrals to the CHBAH ENT outpatient department in the given time period.
2. The commonest conditions patients are referred for.
3. The gender distribution of pathology.

4. The incidence of various ENT diseases in paediatric and adult age groups.
5. The relationship between employment status and prevalence of disease.

If the screening consultants are of the opinion that the case could be treated at a primary healthcare facility, then it will be deemed inappropriate.
We may also be able to compare this study's epidemiological trends with international populations.

Publishing intentions

I intend to publish the findings of the study in an appropriate peer-reviewed journal.

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Chapter 3: Appendices

Appendix A – Data collection sheet

Number	age	gender	date of referral	Employment status y/n	urgent/non urgent indicated on letter	Final Diagnosis	Appropri referral?

Appendix B – Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Heeral Jayantilal Bhaga (Mistry)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190912 MED19-07-040

NAME: (Principal Investigator)	Dr Heeral Jayantilal Bhaga (Mistry)
DEPARTMENT:	Neurosciences Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A cross sectional study of referrals to the ENT Outpatients department in a tertiary setting
DATE CONSIDERED:	27/09/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Natasha Morgado and Dr Dipuo Masege
APPROVED BY:	Dr C Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/11/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

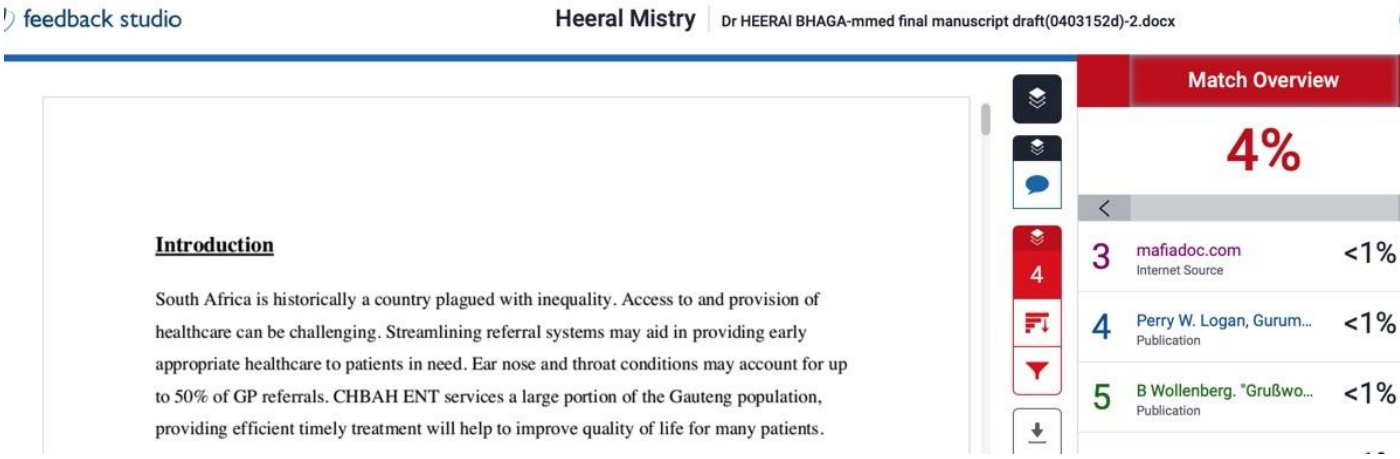
DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed September and will therefore be due in the month of September each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C – Turn-it-in originality report



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Assignment title:	Final Similarity Report
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File name:	Dr_HEERAl_BHAGA-mmed_final_manuscript_draft_280403152...
File size:	294.68K
Page count:	18
Word count:	4,052
Character count:	21,481
Submission date:	10-Nov-2021 10:55AM (UTC+0200)
Submission ID:	1698636449

Appendix D – Plagiarism declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I **Heeral Jayantilal Bhaga** (Student number:0403152D) am a student registered for the degree of FCORL MMED_ in the academic year _2021_.

I hereby declare the following:

- - I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- - I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- - I have followed the required conventions in referencing the thoughts and ideas of others.
- - I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- - I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: 

Date: 11/ 11/ 2021

Appendix E - Consent

PARTICIPANT CONSENT SHEET

Project Title: **A Cross sectional study of referrals to the ENT Outpatients department in a Tertiary Setting**

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study I am free to speak to any of these contacts.

Contact details:

Heeral Bhaga, telephone no. 083 502 2110 or by e-mail at heeral28@yahoo.com

Dr N. Morgado, on telephone no.0836516093, or by e-mail at natasha.morgado1@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____
Date: _____
Place: _____
Signature or mark _____

Witnessed by:

Name of Witness: _____
Signature: _____
Date: _____

PARTICIPANT ASSENT SHEET FOR MINORS*

Project Title: **A Cross sectional study of referrals to the ENT Outpatients department in a Tertiary Setting**

1. I have been given a Participant Information Sheet for Minors, which explains what this study is about;
2. The study was explained to me and I understand what will happen if I take part;
3. I was given time to ask any questions I wanted to and was happy with the answers I was given;
4. I understand that I will not benefit from the study, should I agree to take part. I also understand that I will not be paid to take part in the study; taking part will not cost me anything either;
5. I have been given a range of contact details, repeated below, should I require further information at a later stage, or have any cause for concern over anything which is done to me during the study; and
6. I understand that even if I agree to take part in the study, I can change my mind later and stop being a part of the study
7. My parent(s) or guardian(s) know that I have been invited to take part in the study. They agree that I may do so, but the decision to take part is also mine.

Contact details:

Heeral Bhaga, telephone no, 083 502 2110, or by e-mail at heeral28@yahoo.com

Dr Morgado, on telephone no.083 651 6093, or by e-mail at natasha.morgado1@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____
Date: _____
Place: _____
Signature or mark _____

Name of Parent or Guardian: _____
Date: _____
Place: _____
Signature or mark _____

Witnessed by:

Name of Witness: _____
Signature: _____
Date: _____

* Defined as being persons under the age of 18

Appendix F – Author guidelines (Pan African Medical Journal)
Research Manuscript templates

Maximum length: 4000 words in main text (i.e., excluding abstract, references, legends, tables and figures), 4 tables/figures maximum, and a structured abstract of 250 words plus up to 50 references.

Title page - This page should states: a) The title of the paper (include the study design if appropriate; for example: A versus B in the treatment of C: a randomized controlled trial; X is a risk factor for Y: a case control study), b) Authors names (full name - no qualification, no abbreviations). **Strictly follow this order: First Name, Middle name (if ever), Last Name. E.g.: Paul Kevin Akuna**), c) institution(s) of origin, d) Corresponding author plus his/her address, telephone and fax number, e-mail address, e) Word count (for both abstract and the main text)

Abstract - The abstract of the manuscript should not exceed 250 words and must be structured into separate sections: **Background:** the context and purpose of the study; **Methods:** how the study was performed and statistical tests used; **Results:** the main findings; **Conclusion:** brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract.

Keywords. Up to ten keywords should be provided at the end of the Abstract. The keywords should be Medical Subject Headings (MeSH®) Terms. Use the MeSH on Deman Tool to help suggest keywords.
Abbreviations a list of abbreviations is not accepted. Define abbreviations the first time they are used in the text and use them thereafter. No abbreviations in the abstract except for vary know ones.

Background The background section should be written from the standpoint of researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a very brief statement of what is being reported in the article.

Methods Sufficient information should be given to permit repetition of the experimental work. This should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate.

Results - The Results should be stated concisely without discussion and should not normally contain any references. The same data should not be presented in figures and tables. Do not repeat all the data that is set out in the tables or figures in the text; emphasize or summarize only important observations.

Discussion - The Discussion should deal with the interpretation of the results and not recapitulate them. We encourage authors to write their Discussion in a structured way, as follows:a) statement of principal findings; b) strengths and weaknesses of the study; c) strengths and weaknesses in relation to other studies; d) discussion of important differences in results; e) meaning of the study; f) unanswered questions and future research.

Limitations - Always acknowledge the potential the limitations of your study that and how they impact or influence the interpretation of the findings from your research, the generalizability, applications to practice, and/or utility of findings.

Conclusion - The conclusion should provide a brief summarize of the key findings, potential implications and the way forward.

***What is already known on this topic*:** include a maximum of 03 bullet points on what is already known on this topic.

***What this study adds*:** include a maximum of 03 bullet points on what your study adds.

Acknowledgements - Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study. The role of a medical writer must be included in the acknowledgements section, including their source(s) of funding. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements. Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

Competing interest - Authors are responsible for recognizing and disclosing conflicts of interest that might bias their work. They should acknowledge in the manuscript all financial support for the work and other personal connections. Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'. When completing your declaration, please consider the following questions:

Financial competing interests

- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
- Do you have any other financial competing interests? If so, please specify.

Non-financial competing interests

- Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.
- If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions - In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals(URM) of the International Committee of Medical Journal Editors (ICJME) recommends the following criteria for authorship (Learn more about the URM on Authorship and Contributorship):

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

References - References must be numbered consecutively, in square brackets (like this [1], or this [2,3] or even this [4-7]), in the order in which they are cited in the text, followed by any in tables or legends. Reference citations should not appear in titles or headings. Each reference must have an individual reference number. Preferably, limit the number of references to 50. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission. We encourage authors to use a recent version of EndNote (version 5 and above) or Reference Manager when formatting their reference list, as this allows references to be automatically extracted. Examples of the PAMJ reference style are shown below. Please take care to follow the reference style precisely; references not in the correct style may be retyped, necessitating tedious proofreading.

We strongly advocate the use of **Zotero**, a free and open source reference management software which is a very good alternative to expensive software like Reference Manager or EndNote.

- Download output style (PAMJ.os) for **Reference Manager**.
- Download output style (PAMJ.ens) for **EndNote**.
- Download output style (PAMJ.csl)) for **Zotero**.

Manuscripts not formatted according to the PAMJ style will be returned to the authors. An example is provided below (note the use of the dot after the author list, the title, the journal and the date).

1. Kirikou Thomas, Doe JA, Shaba KV, Kashawa Tuma. A sample of the PAMJ reference style as shown on the journal website. J Hist Fant. 2006; 76(11):204-212
2. Kirikou Thomas, Doe JA, Shaba Kevin, Kashawa TB. Another sample of the PAMJ reference style: as shown on the journal website. J Hist Fant. 2006; 76(12):212-228
3. Kirikou TA, Doe John, Shaba KV, Kashawa TB. Another sample of the PAMJ reference style: as shown on the journal website. J Hist Fant. 2006; 76:212-228

Formatting book references: Use the format below to reference a book
Author of the book. Title of the book. Year of publication. Publisher Location. Publisher name
Example: Fleiss JL. Statistical methods for rates and proportions - 3rd edition.

2003. Hoboken. J Wiley
NB: Note the use of dots to separate the sections of the book reference.

Formatting web references: Use the format below to reference a web page or a web site
Author of the page. Name of the source (if any). Year of data. url. Date link accessed
Example: SAS Institute. SAS 9. http://support.sas.com/software/index.htm. Accessed 10 April 2005
NB: Note the use of dots to separate the sections of the web reference.

Supplementary material/Appendices (if any) - Submit any supplementary material to the editorial office bye email. The editorial office can also decide which material will be published as supplemental material.

Tables (if any) - General instructions for tables.

- Append tables at the end of your manuscript, after the reference section
- Maximum 3 tables per articles. If more tables are required, it will have to be justified
- Each table should fit on one page. No table overlapping over several pages. So no matter the size of the table, make sure it can comfortably fit on a single page (portrait or landscape)
- Elements inside the table should be contained within cells.

Download samples of correctly formatted tables (Microsoft Word 2002-2003, *.DOC): **Table 1**, **Table 2**.

Figures (if any) - General instructions for figures.

- Include a legend for your images inside the main text, after the reference section
- Should be provided as separated files during the manuscript submission. Do not embed images within the main text.
- Major image formats are accepted excluding BMP. (JPEG, PNG, TIFF)
- Provide high resolution images, not tiny thumbnails. Image of poor quality will be rejected.
- The size of the uploaded image is limited to 4 MB.
- Avoid unnecessary large borders on your figure or image. Click below to see examples of good and bad images.

Examples of good and bad image with borders (Click on the images to enlarge)

Files must be named with the three letter file extension appropriate to the file type (eg: .jpeg, .png). You will be asked to provide figure labels during the submission process. (The label is the small comment that usually goes with the figure. Example: **Figure 1:** Prevalence of diabetes in the study population aged 18 years and above. Findings of the TRICARE Diabetes Study, Uganda, 2006.)
If you use excel to generate your graph, avoid 3D, crowded axes, colored background, strong grid etc.. Use Tahoma font (size 10 maximum) for all items in your graphs (Title, legend, axes etc..). Expand your Excel graph to obtain a large image, copy and paste it in Paint (Microsoft Paint), crop any white border and save the image as PNG or JPEG. Submit this image for your manuscript (don't forget to include the legends for each figure inside the main manuscript) Look at an acceptable **formatted Excel graph here**. See the detailed sample instructions for a **nicely formatted Excel graph here.**

Title of manuscript

The names and affiliations of the authors: The names should be completed, no abbreviations and in the order: First Name Middle Name Last Name. It is important that the name be spelled in that order; this is how they will be submitted to PUBMED
The name and email address of the corresponding author.

Abstract

Should be limited to the sections: Introduction, Methods, Results , Conclusion

Introduction

Include your introduction here

Methods

Include your methods here

Results
Include your results here

Discussion
Include your discussion here

Conclusion
Include your conclusion here

What is already know on this topic
Include at least 2 points of what is already known on this topic

What this study adds
Include at least 2 points of what your study adds

Competing interests
Declare any competing interests here. If there are no competing interests to declare us the mention: The authors declare no competing interest.

Authors' contributions
Specify the contribution to the work and write-up of the manuscript for each person listed as author

Acknowledgements (if any)
If any, mention it here

Tables and figures (if any)
List all tables and figures (if any) included in the manuscript, with their detailed legend: Example. Note that Tables should be included at the end of the manuscript, after the reference section.
Table 1 : XXXX
Table 2 : XXXXX
Figure 1 : XXX
Figure 2 : XX
Etc..

References

Include your reference list here. Ensure that the list if formatted according to the journal standards

Include all the tables here, listed numerically