"PREVALENCE OF CHRONIC SUPPURATIVE OTITIS MEDIA IN PRIMARY SCHOOL CHILDREN IN ANTANANARIVO, MADAGASCAR."

A THESIS SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER IN EAR, NOSE AND THROAT – HEAD AND NECK SURGERY, AT THE UNIVERSITY OF NAIROBI 2009.

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Declaration.

I certify that this study is my original work and that it has not been presented for approval in any university.

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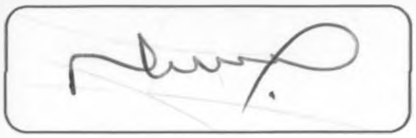
Signature: 

Date: 03/09/09

DEDICATION

"... Ary tamin'ny andro sabata no nanaovan'I Jesosy ny feta sy nampahiratany ny mason-dralehilahy..."

Jaona 9:14.

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LIST OF ABBREVIATIONS

CISCO	: Circonscription Scolaire
CSOM	: Chronic Suppurative Otitis Media
CT	: Computed Tomography
DREN	: Direction Regional de l'Education Nationale
FTM	: Foibe Taon-tsaritany Malagasy "Map maker"
HJRA	: Hopital Joseph Ravoahangy Andrianavalona
HOMI	: Hopital Militaire
SALFA	: SAmpan'asa Loterana momba ny FAhasalamana "Lutheran church health department"
TM	: Tympanic Membrane
UK	: United Kingdom
WHO	: World Health Organization

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PREVALENCE OF CHRONIC SUPPURATIVE OTITIS MEDIA AMONG PRIMARY SCHOOL CHILDREN IN ANTANANARIVO, MADAGASCAR.

A. ABSTRACT.

Chronic Suppurative otitis media is a major cause of hearing disability in developing countries having a profound effect on language development, scholastic performance and psychosocial interaction of children at varying ages.

Aim: To determine the prevalence of chronic suppurative otitis media among primary school children aged five years up to 14 years in Antananarivo.

Setting: Randomly selected primary schools in Antananarivo.

Study Design: Descriptive cross sectional study.

Methodology: Children in randomly selected primary schools had their medical history appraisal, otoscopic and audiological evaluation to verify the presence of features of chronic suppurative otitis media defined as persistent otorrhoea through a perforated ear drum for more than two weeks with or without hearing loss.

Results: Six hundred and twelve primary school children were reviewed, age range was 5 to 14 years (mean 9.05), thirteen had CSOM with prevalence of 2.12% ($p<0.05$) with predominance of male, 10 against 3 for female.

Conclusion: The primary school children in this specific study have prevalence of 2.12% of chronic suppurative otitis media with male preponderance. This prevalence is relatively low according to the low socioeconomic class of the study population.

B. INTRODUCTION.

The earliest known documentation of chronic suppurative otitis media (CSOM) was in the ancient Egyptians. Its capacity to provoke complications such as hearing loss, facial palsy and fatal complications like lateral sinus thrombophlebitis or meningitis merits to be considered seriously especially in Madagascar where no such study has been done in children (1).

A study was done in Madagascar among the general population in the Province of Antananarivo which showed that CSOM constituted 4.11% of the general population, and was responsible for 12.87% among the causes of hearing impairment (2). Similar studies in Kenya have shown prevalence rates of 1.1% (3).

Although hearing loss is a common feature of CSOM, the patient may first present to the clinician with a variety of complications including mastoid abscess, labyrinthitis, lateral sinus thrombosis or even intracranial complications. Consequently, the patient may be seen by specialists in other domains rather than the otolaryngologists.

No well designed study has been done to exclusively document the prevalence of CSOM among school children in Madagascar. Such data will be beneficial for Ministries of Health and Education. This study will form a basis for the National Program for Prevention of Deafness by Clinique Audiologique/ SALFA in Madagascar to plan an efficient prevention and management strategy.

I. THE APPLIED ANATOMY AND PHYSIOLOGY OF THE MIDDLE EAR.

The middle ear which is the main part of the entire ear affected by CSOM is composed of the tympanic membrane (TM) and the ossicles occupying the tympanic cavity. The anatomic design facilitates its role as an amplifier and transformer of sound signals before it is presented to the cochlear. This is exemplified by the arrangement of its ossicles, tympanic membrane, oval window and round window. It is instructive that the handle of malleus is longer than the long process of incus resulting in a lever effect on the final force delivered at the oval window by stapes. The continuity of this lever effect can be disrupted by cholesteatomatous erosion enhancing deafness. Secondly the size of the TM is 17 times larger than the oval window (55 square millimeters and 3.2 square millimeters respectively) lending it a hydraulic multiplying effect (4). The effective surface area of the TM is effectively reduced by the persistent perforation which is the hallmark of CSOM. Another effect of the defect on the TM is the removal of the protective baffle effect on the round window. The incident sound waves thus impinge simultaneously onto the oval and round window thus reducing the amplitude of the wave in the scala media and vestibuli.

The middle ear is connected to the nasopharynx via the Eustachian tube (figure 1). The importance of this structure in CSOM is two fold. First of all the middle ear transformer mechanism is most effective at the atmospheric pressure which is maintained by periodic opening of the Eustachian tube. Secondly, its shortness and horizontal posture and relatively larger diameter in children encourages the transmission of infection from the upper respiratory tree to the middle ear. Its swelling and blockage during the inflammatory process that punctuates CSOM encourages suppuration and otorrhoea. When the Eustachian tube is patent in the face of a perforated TM, the resultant mechanics allow free flow of fluids from nasopharynx to external meatus and vice versa. Consequently the middle ear is not protected from fluids like water from the river, swimming pool and even ingested fluids from the oropharynx that finds its way to the nasopharynx. These changes in the anatomical arrangement structures of the TM and the Eustachian tube perpetuate the infection of the middle ear.

Important relations of the middle ear include the external meatus which can be a source of recurrent infection. The medial wall near the aditus has a bulge that represents the lateral semicircular canal, round and oval window and the promontory which is a bulge of the basal coil of the cochlear (figure 2). The lateral semicircular canal is frequently eroded by cholesteatoma causing a positive fistula sign. The round and oval windows are also to a lesser extent the weak sites for such erosions. It is also to be appreciated that about 6% of the tube of Falopius (at least in Caucasians) are deficient exposing the facial nerve to any inflammatory processes, and that even when intact, the horizontal and descending segments of the intratemporal part of the facial nerve can be breached by erosive effect of the cholesteatoma. The mastoid air cells are a continuity of the middle ear cavity and extension of disease to these air cells can result in mastoiditis and abscess formation. The lateral sinus is located posterior to these air cells and infection can invade them causing thrombophlebitis which can further extend to the sagital sinus. The middle ear and the mastoid air cells are separated from the intracranial contents by tegmen tympani and tegmen antri, thin bony plates traversed by vascular channels which can act as conduits for infection to intracranial structures.

Histologically, the middle ear is composed of respiratory ciliated epithelium. However, infection transforms this epithelium to squamous or cuboidal type rendering it inefficient in clearing middle ear secretions.

Figure.1 **Right ear in coronal section showing the middle ear and its ossicles, medial and lateral boundaries (5).**

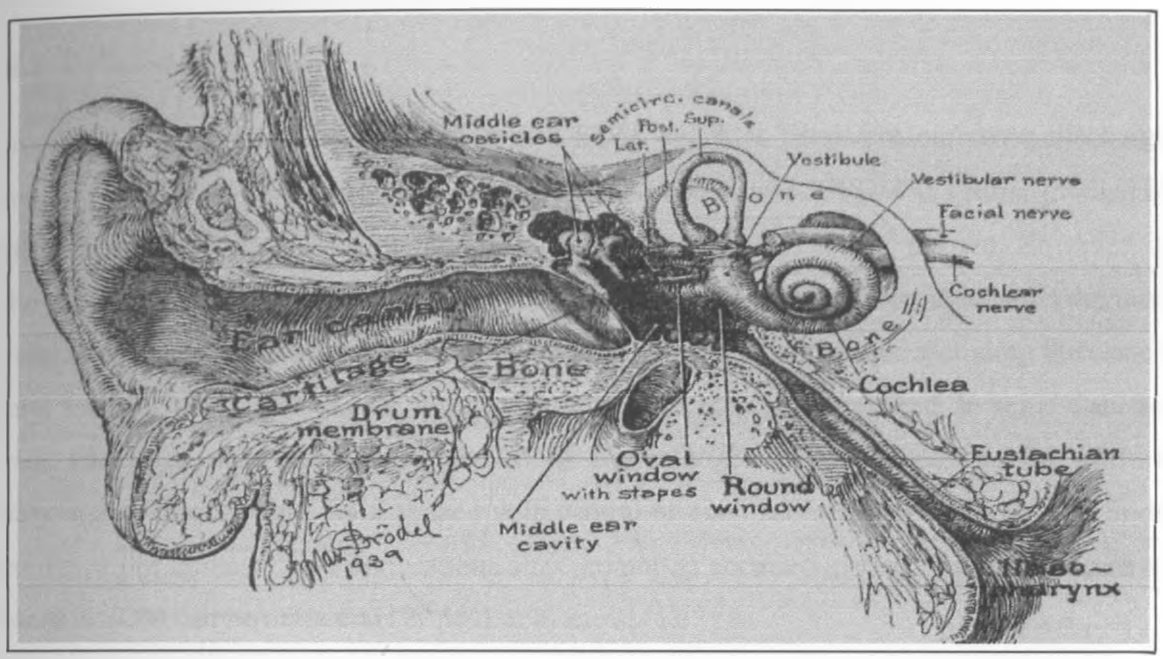
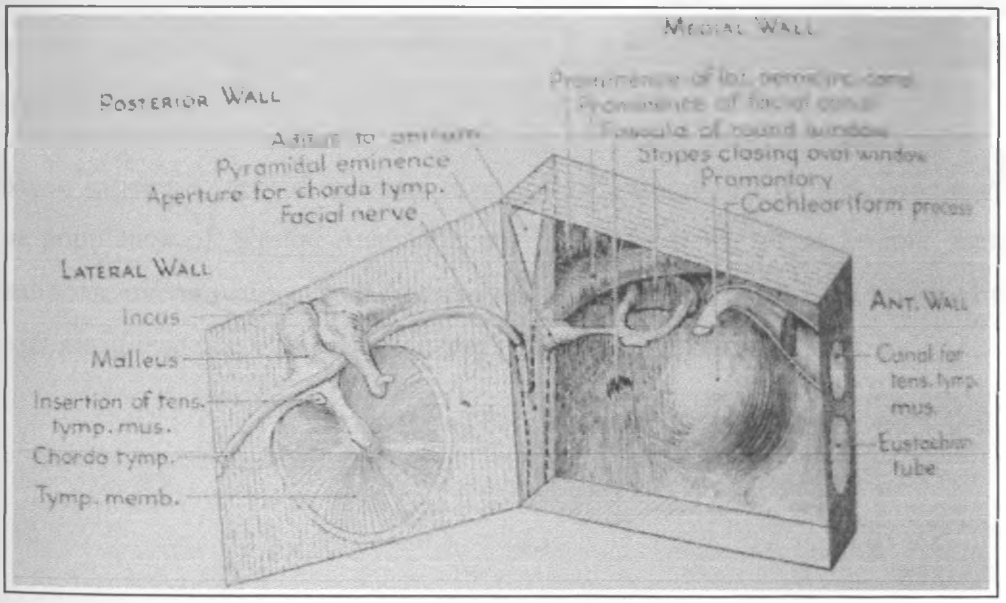


Figure.2 **A diagrammatic scheme of the shape and the relationships of the middle ear structures (5).**



II. BACKGROUND.

II.1. Chronic suppurative otitis media.

II.1.1. Definition.

This study adopted the WHO definition as CSOM which is persistent otorrhoea discharging through a perforated tympanic membrane for at least two weeks. CSOM is further divided into 'safe' when cholesteatoma is absent and 'unsafe' when cholesteatoma is present. However, it is to be appreciated that the safe variety frequently involves the tubotympanic area while the unsafe variety is frequently located in the attico-antral area where vital structures including the ossicles, lateral semicircular canals and the intracranial structures are easily breached. In some Caucasian series, the attico-antral disease seemed to be characterized with attic perforation while the tubotympanic disease was characterized with central or even subtotal perforations. This finding is however not universal and perforations sites are not an accurate marker of the two variants of disease. CSOM can be unilateral (79.5%) or bilateral.(6)(7)(8)

II.1.2. Epidemiology.

A Study done in Israel showed that 0.039% of children 15years and younger are affected per year by CSOM, another study done in UK showed that 0.9% of children and 0.5% of adults have this disease (1).

The incidence appears to depend to some extent on race (more in Eskimos, American Indians, indigenous population of Alaska, Australian aboriginal children), socioeconomic factors, poor living conditions, overcrowding, poor hygiene and malnutrition (9). It is to be noted that these same factors are in evidence in the sub-Saharan Africa and Madagascar.

III. MIDDLE EAR AND CSOM.

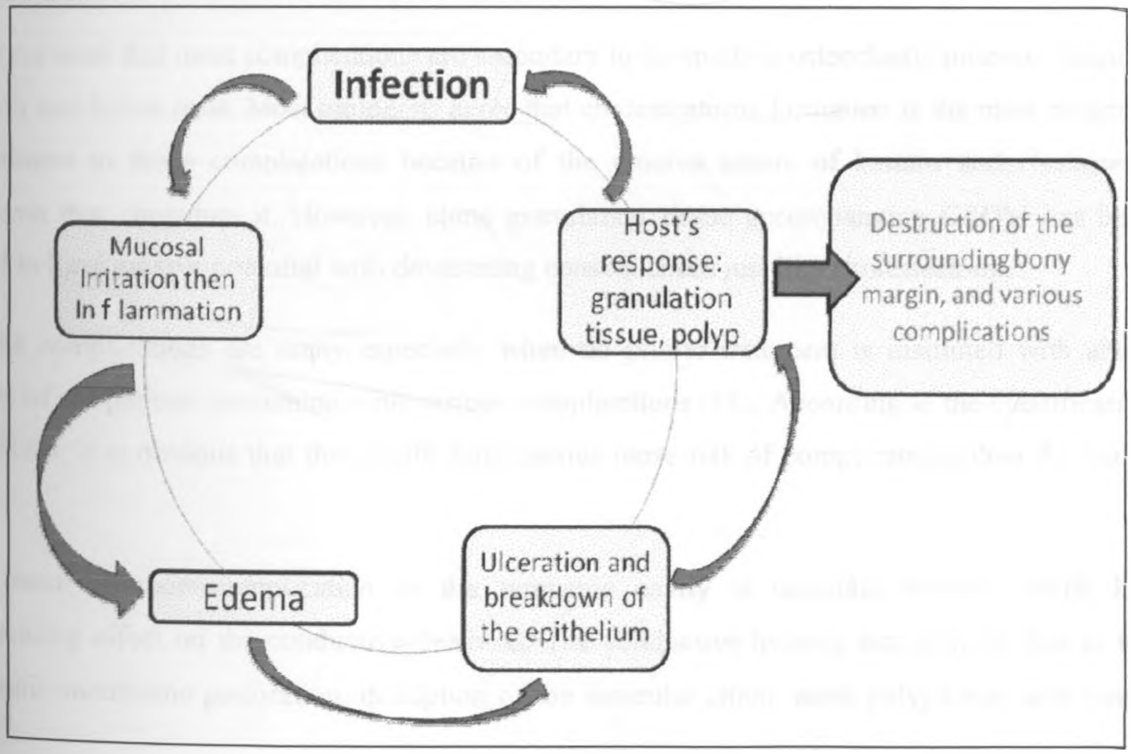
III.1. Pathophysiology.

Two theories concerning the middle ear infection have been proposed by different authors.

The first one proposes that the causative organisms gain access to the middle ear via the Eustachian tube. This process is facilitated by suction of infected mucous from the nasopharyngeal cavity into the middle ear secondary to a high positive pressure in the former on and the slightly lower intracavitary pressure in the middle ear (10).

The second theory concedes that the Eustachian tube theory, traumatic perforation of the tympanic membrane and inserted tympanostomy tubes are the initiators of acute otitis media and finally CSOM, but that the infection is exclusively maintained by recurrent entry of the causative organisms from the external ear through the resultant perforation on the tympanic membrane. Once the infection is established in the middle ear, a cyclic scenario will appear.

Figure.3 **Pathophysiology in CSOM.**



It would appear that these two arguments just explain the various roots of infection. One would appreciate that the recurrent otorrhoea frequently follow an upper respiratory tract infection as well as entry of dirty water into the ear via the external meatus. The argument is thus superfluous.

III.2. Microbiology.

Microbiologic findings of the CSOM show that the most commonly involved organisms cultured from the chronic otorrhoea are *Pseudomonas aeruginosa* (48-98%), *Staphylococcus aureus* (15-30%), *Proteus* species (10-15%), *Klebsiella pneumoniae* (10-21%), diphteroids. Anaerobes (including Bacteroids, Peptostreptococcus, Peptococcus) are isolated in 20-50% of cases while mycosis (Aspergillae and Candida species) are isolated in 25% (1). In many circumstances, multiple organisms are involved in what appears to be a symbiotic relationship. Tuberculous otitis media have also been noted in some circumstances. the acid fast bacilli gaining entry via the Eustachian tube from the infected sputum coughed into the nasopharynx from the lungs (11).

III.3. Complications and their management.

We have seen that most complications are secondary to destructive osteoclastic process, vascular erosion and halisteresis. Most otologists agree that cholesteatoma formation is the most common contributor to these complications because of the erosive nature of keratin and cholesterol elements that constitute it. However, some granulation tissue accompanying CSOM has been found to have erosive potential with devastating consequences just like cholesteatoma.

CSOM complications are many especially when no proper treatment is instituted with about 89 3% of the patients presenting with various complications (12). According to the classification of CSOM, it is obvious that the unsafe form carries more risk of complications than the 'safe' form .

The most common complication in the tympanic cavity is ossicular erosion which has aggravating effect on the conductive deafness. The conductive hearing loss may be due to the tympanic membrane perforation, disruption of the ossicular chain, aural polyps may also occur

obstructing the ear canal or a combination (13). Surgical removal of the disease with ossicular reconstruction mitigates the morbidity associated with decreased hearing loss. For further information about the hearing loss and its grading system, see annex 3.

Infection can also spread to the mastoid air cells resulting in mastoiditis or frank mastoid abscess. The abscess is initially subperiosteal but may eventually burst through the skin forming a persistent post auricular sinus.

Petrositis can occur when the disease spreads into the petrous apex, and can manifest as *Gradenigo's syndrome which presents with retro-orbital pain, aural discharge and abducens* palsy. This type of complication needs prompt investigations including CT scans and must be treated using systemic antibiotics and petrosectomy

Facial palsy can occur with or without cholesteatoma and must be explored surgically and the diseased mucosa and granulation removed.

Labyrinthitis may rapidly develop over an extended period of time. Here the infection spreads into the inner ear through the oval or the round window or through a semicircular canals exposed by bony erosion.

In acute serous labyrinthitis with acute onset of vertigo and hearing loss, surgical exploration via mastoidectomy to remove the infected tissue and systemic antibiotics are mandatory. The most lethal and harmful variant is acute suppurative labyrinthitis with profound sensorineural deafness, tinnitus and vertigo, with or without nausea and/or vomiting and nystagmus. Treatment is aggressive surgical debridement plus labyrinthectomy to prevent more serious complications and also antibiotics and cultures and sensitivities are advised. In most cases, the labyrinth is damaged and the patient ends with profound deafness and vestibular failure which are sequelae of labyrinthine sclerosis after bone remodeling.

Lateral sinus thrombophlebitis may occur by extension of the infection from the mastoid into the lateral sinus. The risk here is the release of thrombi causing extensive thrombophlebitis which may extend to superior sagital venous sinus destroying the arachnoid granulations and subsequently causing otitic hydrocephalus. Clinical signs may include alteration of the mental

status, seizures and fever. Mastoidectomy, drainage of the thrombus and culture-directed antimicrobial treatment are the first line management.

Intracranial extension of the disease may occur by direct or hematogenous spread causing meningitis, subdural or extradural abscess, brain abscess or even frank encephalitis. CT scans and lumbar puncture and microbiologic studies are crucial investigations in these intracranial complications. Principles of management include appropriate drainage procedures and antibiotic regimes guided by microbiologic studies. In all these instances, the primary focus of the disease must be simultaneously tackled in the form of tympanomastoidectomy either at the same sitting or sequentially.

It must be borne in mind that many variants of intracranial abscess are a notoriously silent disease and must be looked for. Since tegmen antri or tegmen tympani may be the portal of entry, the abscesses frequently occur in the temporal lobe or cerebellum. However, such abscesses may also be located in the frontal or parietal lobes and even in the contralateral cerebral hemisphere.

III.4. Cholesteatoma.

Known as characteristic epidermoid cyst containing keratin, there are two types (congenital and acquired) which are not different histologically. For any case, it is important to diagnose its presence and confirm it histologically because of its aggressive character.

Among the four types of congenital Cholesteatoma (cerebellopontine angle, petrous pyramid, jugular fossa and middle ear cleft), the Cholesteatoma of the middle ear cleft is the variant relevant to this study. Here, differentiating a congenital from acquired type is a challenge for the attico-antral region. However, in clinical practice, the vast majority of cholesteatomas in the middle ear cleft are secondary to CSOM. These CSOM acquired cholesteatomas most of the time arise from the pars flaccida in the attic region or the posterior part of the tympanic membrane thereafter extend everywhere in the middle ear. Presence of a Cholesteatoma in the attic region may be recognized by destruction of the lateral spur or "scutum", lateral attic wall, ossicles and erosion of the medial attic wall. The surgeon has to be aware always about the involvement of the facial canal and possibility of the labyrinthine fistula.

Diagnosis of acquired cholesteatoma is suspected by presence in the CT scan of non- dependent homogenous soft tissue mass in an appropriate location. For some situations such as encephalocele in the mastoid cavity, lateral sinus thrombosis and expansible lesion to the petrous apex, magnetic resonance, CT scan with contrast or magnetic resonance angiography are important imaging techniques.

III.5. Management of CSOM.

During the preantibiotic era, hot water, duck, grease, borax, cow milk, human milk, butter, sweet wine, other medicinal and behavioral treatments such as maintaining silence, avoiding fatigue, sun, strong wind and smoky room, were all experimented on treating CSOM.

Now, it has been proved that aural toilet is taking an immense role in treating the safe CSOM. It can be achieved by simple mopping or sucking the ear. The concept can also help elderly patient or others not fit for surgery. Removal of polyps or cauterization by silver nitrate of granulation tissues are part and parcel of management of CSOM (9).

Medical treatment is achieved mainly by antibiotic ear drops with or without steroids. Various types of powders such as boric acid with or without iodine, nystatin or cicatrin have also been tried. But the ototoxic effect of these preparations must be considered before use because some of them can give a sensorineural deafness. In our daily practice the most common topical eardrops used are fluoroquinolone with or without steroid (e.g. Ciprofloxacin) or aminoglycosides with or without steroid (e.g. Tobramycin).

If topical treatment associated to aural toilet has failed, systemic antibiotics should be started but at the same time continue with the topical and intensified aural toilet. Prior to this systemic therapy, culture should be obtained for sensitivity. It should be continued up to 3-4 days after the cessation of the otorrhoea. Fluoroquinolones, Piperacillin, Ceftazidime are the most useful among these antimicrobial agents.

Surgical management consists on repair of the perforated tympanic membrane to prevent a recurrent discharge and maintenance of infection via the external auditory meatus, to improve the hearing and the patient will be able to swim. Despite controversies about the age of operation, it is obvious that after the age of 12, the child is more cooperative for his/her postoperative care.

For unsafe CSOM where cholesteatoma is present, surgery is the treatment of choice if the patient is fit for it or if patient relatively young and techniques depend on surgeons' decision and experience.

Ossicular pathology and retraction pockets are treated by reconstruction and eversion or myringotomy respectively.

Mastoid revision surgery can be done for recurrent discharge. The mastoid cavity can also be obliterated by using a pedicled muscle flap, musculoperiosteal flap or mixture bone dust and water provided all disease has been eliminated.

C. LITERATURE REVIEW SPECIFIC TO THIS STUDY.

Apart from the hearing loss compromising the ability to communicate, language development, location of sound source and to appreciate stereo music, an affected child may also suffer psychologically from social stigma caused by draining pus from the affected ear.

Many studies have been done on the prevalence of CSOM in children but varying widely in their design and hence findings.

Ologe et al (8) did a study on Prevalence of chronic suppurative otitis media (CSOM) among school children in a rural community in Nigeria. One thousand, one hundred and thirty-five pupils were examined for CSOM in a rural community of Kwara State of Nigeria. The prevalence of CSOM was 7.30 %. The peak was seen among the age group of 2-5 years. Unilateral disease was most prevalent (79.5%); 99% of the pupils had tubotympanic disease. Active disease was observed in 27.7% of the cases of CSOM

Biswas et al (14) did a study on prevalence of CSOM among rural school going children, in Dhaka. Altogether 225 students aged 4-13 years from five primary schools and junior high schools of Magura district were interviewed and examined. Twenty eight (12.44%) children were found to have CSOM. Out of these 28 cases, 25 came from lower and 3 from middle income group families. No case of CSOM was found in higher income group family. In this study 73.33% mothers were not aware of CSOM. 60% mothers had no knowledge about treatment and sequelae of CSOM. Only (5.78%) people interviewed used cotton bud to clean ear while majority use unhygienic materials like matchstick, cloth with stick and chicken feathers. Treatment seeking pattern was observed in this study. 10.71% cases did not receive any treatment and remaining 89.29% received treatment of which 25% was from a general practitioner or Hospital and 7.14%, 35.71%, 10.71%, 10.71% received it from Kabiraj, Quack, Homeopathy doctor, and a chemist respectively However this study may not withstand statistic scrutiny because it does not give comparative composition of different economic strata in the general population.

In order to determine the prevalence of chronic suppurative otitis media (CSOM) in rural South Indian children, Rupa et al (15) conducted cross-sectional survey was conducted among 914 children (484 boys and 430 girls) from four primary schools and 12 nurseries of adjacent villages of North Arcot District of Tamil Nadu state. The preschool children were aged 2-5 years, while the ages of the primary school children ranged from 6 to 10 years. The overall prevalence rate of CSOM was found to be 6%. The disease was equally prevalent in preschool children (5.7%) and primary school children (6.2%). Cholesteatomatous ear disease was observed in 1.2% of children, those of the older age group having a slightly higher prevalence rate (1.5%) than the younger age group (0.7%). Parental beliefs and existing practices with respect to the disease are also presented.

Hatcher et al (3) found that Information on the prevalence of hearing impairment and related ear pathologies in children in sub-Saharan Africa is scarce. Five-thousand-three-hundred-sixty-eight children from 57 randomly chosen primary schools in Kiambu district (Kenya) were examined. Simple otoscopy was performed by clinical officers with specialty training in ENT, and hearing testing was performed by trained nurses, using a hand held field audiometer. Microbiological specimens were obtained from those children with CSOM. Two-point-four percent had at least one perforated tympanic membrane, and 1.1% had CSOM. There is evidence of a relationship between hearing impairment and both CSOM and wax obstructing the tympanic membrane. The most common organisms found were Pseudomonas spp. (34%), Proteus spp. (34%) and Eschericia coli (19%). These results are comparable with other studies in Africa and indicate a considerable burden of ear disease in Kiambu district, Kenya.

Piet Van Hasselt et al (2) in a study of the prevalence and causes of deafness and hearing deficits in the general population in Madagascar Antananarivo, found that among six thousands, six hundred and thirteen subjects, 4.1% had presented CSOM.

Minja et al (16) did a study in 802 primary school children in rural and urban Dar es Salaam, Tanzania, to determine the prevalence of otitis media, hearing impairment and cerumen impaction by otoscopy and pure tone audiometry. Ear disease was found in 222 (27.7%) of the children. One hundred and twenty six (15.7%) had cerumen impaction, 70 (8.7%) had sensorineural hearing loss and 21 (2.6%) had chronic suppurative otitis media. The prevalence of chronic suppurative otitis media (CSOM) was 9.44% among the rural school children and 1.3% among the urban school children, the difference being statistically significant. The low prevalence of chronic suppurative otitis media among the urban school children was ascribed to better medical services which facilitated early diagnosis and treatment of acute otitis media.

Aasham et al (17), during an audiometric screening conducted in Dhofar region in Oman, among first-year preparatory-school children, found that none of the 1894 pupils had otitis media with effusion or sensorineural hearing loss. Six children (0.32%) had impacted wax, 4 (0.21%) chronic suppurative otitis media and 2 (0.11%) dry perforation of eardrum.

D. JUSTIFICATION OF THE STUDY.

Although CSOM per se is not a fatal disease it can give many social, educational and psychosocial sequelae as well as life threatening complications by spreading to vital structures.

This study will be helpful because:

1. No study focusing on the prevalence of the CSOM among school children has been done in Madagascar.

2. The data from such study would be used for building a strategy for the prevention of deafness programs and sensitization of health workers and the population at large on the serious consequences of CSOM.

D. OBJECTIVES.

IV. General objective.

To determine the prevalence of CSOM among primary school children in Antananarivo.

V. Specific objectives.

1. To determine the age and sex distribution of children presenting with CSOM.
2. To determine the severity of hearing loss associated to CSOM.
3. To determine complications secondary to the CSOM apart from hearing loss.
4. To determine the socioeconomic status of the study population for future reference.

VI. Inclusion criteria and Exclusion criteria.

VI.1. Inclusion criteria.

Pupils aged five up to 14 years old in the randomly selected primary schools for whom consent have been obtained.

VI.2. Exclusion criteria.

Pupils whose were declining physical examination and those who do not have consent.

F. METHODOLOGY.

VII. Study design.

This was a descriptive cross-sectional study.

VIII. Setting.

In Madagascar, children start primary school from the age of five years. Our study population will consist of all pupils from the randomly selected schools aged between five and 14. The people of Madagascar are still referred to as Malagasy, composed of mixed African, Arab and Asian descent, and most practice traditional religious beliefs or a combination of Christian and indigenous beliefs. Malagasy (of Malayo-Polynesian origin) is the primary language of the island, although French is spoken among the educated population. The population pyramid is such that almost 50% are under 14 years of age.

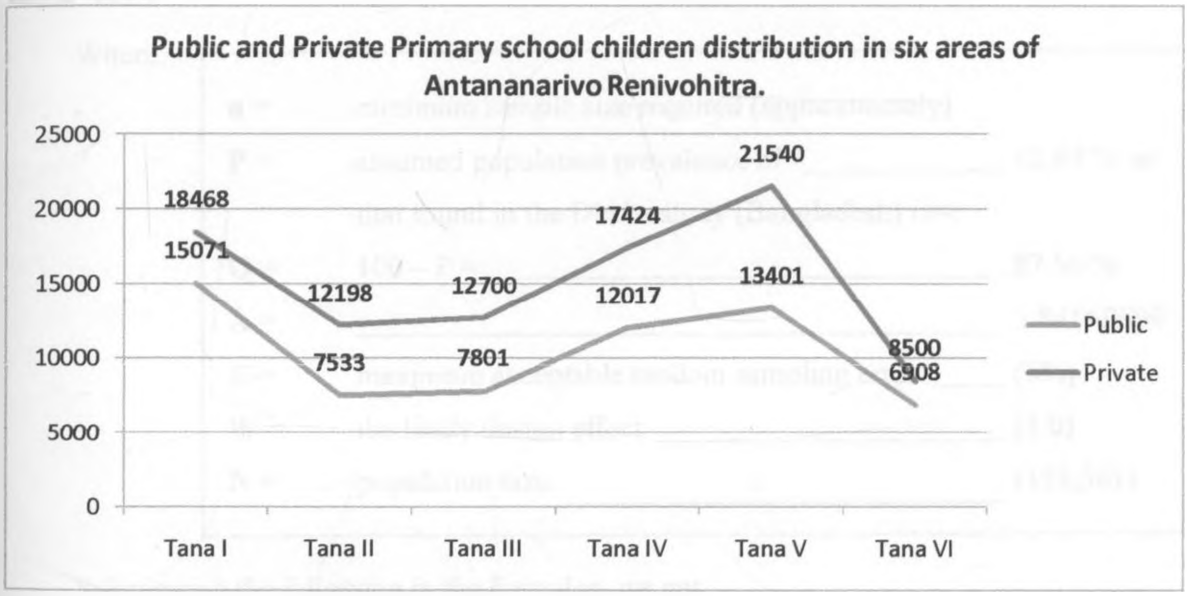
"Antananarivo Capital" or Antananarivo Renivohitra or Antananarivo Ville is one of the eight Districts of Analamanga Region. The latter is the capital of Madagascar. Antananarivo Renivohitra district is composed of six communes. Antananarivo covers 16,911 km² and has a population of 2,650,000. It has the highest population density in Madagascar of 157/km². Majority of the residents are mixed class people.

There are 2,904 primary schools in the region of Analamanga with an average student population of 500,645 which constitutes 18.89% of the general population.

In total, the primary school children in Antananarivo Renivohitra represent 30.67% of pupils in the region of Antananarivo with total of 573 primary schools (18). 92 of these schools (62,713 pupils) are public with 481 of them (with a capacity of 90,830 pupils) being privately run by the government. Randomly selected primary schools out of the 573 primary schools shall provide the subjects for the study in Antananarivo Renivohitra precisely because of its accessibility and the high density of its population.

The distribution of the Primary School Children in Antananarivo on whom the random selection was done is as shown in figure 4.

Figure 4. Distribution of the primary school children in Antananarivo Renivohitra.



X. Sample size.

To calculate the required sample size for this study, sampling fraction (n/N), and the design effect (W) are taken into consideration (19).

The sample size is therefore, calculated from the following formula:

$$n = \frac{A}{E^2 + A/N}$$

Where;

n =	minimum sample size required (approximately)	
P =	assumed population prevalence of that found in the Dhaka study (Bangladesh) (14)	12.44 %, as
Q =	100 – P =	87.56 %
A =		3.8416PQW
E =	maximum acceptable random sampling error	(5%)
W =	the likely design effect	(3.0)
N =	population size.	(153,561)

Substituting the following in the formulae, we get,

$$n = \frac{3.8416 \times 0.12 \times 0.88 \times 3}{0.0025 + (1{,}217/\ 153{,}561)}$$

= 486.8 = **487 pupils** are the minimum sample size.

XI. Sampling Procedure.

Three stage clusters sampling was used. A cluster was considered to consist of each primary school in the district of Antananarivo Renivohitra and was be assigned an identification number.

XI.1. First Stage.

In the first stage, each school with number of its pupils was listed in a random order.

XI.2. Second Stage.

This involved entering the numbers into a box.

XI.3. third stage.

Random selection of the schools was done in this final stage. The school with its identification number was withdrawn by a blind folded person.

The total number of pupils from the randomly selected schools had to be equal to or more than the minimum sample size (20).

The first randomly selected school(s) constituted the unit(s) of observations and represented the schools in Antananarivo Renivohitra.

In this study, the 573 primary schools including both public and private were numerated on small paper (1 to 573), one blind folded person was asked to pick randomly from one box. The number **"25"** was picked, which turned out to be l'Ecole Primaire Publique d'Ambodifiakarana, Isotry".

This primary school has 724 pupils according to information from the DREN.

Although, the school registrar showed 644 pupils. During the study, only 615 children were present during the study. The reasons for the absence could not be immediately established.

Three pupils aged 15 years old were excluded (exclusion criteria) from the study because of failure to satisfy the inclusion criteria. Therefore, the total number of pupils examined was 612, far above the minimum random sample size.

XII. Materials and Equipment Used

1. Questionnaire (Annex 1)
2. Audiogram form (Annex 2)
3. Referral letter (Annex 3)
4. Consent form (Annex 4)
5. Sound level meter
6. Audiometer "type Interacoustic AS 208 portables".
7. Aural speculums
8. Crocodile forceps
9. Otoscopes
10. Batteries
11. 512 Hz Tuning fo
12. Wax probes
13. Suction equipment.
14. Syringing equipment set
15. Foreign body hooks
16. Warm water container
17. Kidney dishes
18. Towels
19. Ceruminolytic drops
20. Instrument container
21. Cotton,
22. Disposable gloves,
23. Surgical spirit

XIII. Procedures.

XIII.1. Study period.

Since Madagascan education system, for the year 2008 – 2009 was scheduled to start on September 22nd, 2008 and end on July 3rd, 2009 and the academic year is divided into 6 terms (see Annex 5), the ideal time for our study was during the second bimester of the year 2008-2009, November 10th to December 22nd 2008.

The data collection lasted for 15 days with an average of 42 students being examined per day. A further two days was needed for statistical assessment Data collection consisted of:-

- 1. Sensitization of the school authority and the teachers (few hours)
- 2. Data collection
- 3. Verification of the files (every evening before leaving the school)

XIII.2. Preliminary preparations.

1. Permission was obtained from the relevant administrative authorities as well as the relevant Malagasy and Kenyan ethical and regulatory institutions. Permission to carry out the study was also obtained from 'Chef de la CISCO" representing the education authority and "le Medecin Chef' (The Director of Medical Services) representing the health authority.

2. Special map provided by FTM (Foibe Taontsarin-tany Malagasy) of the study area was used as guide for the study. The study team was composed of the principal investigator, the clinical audiology team and the school authorities (Directors and Teachers).

3. Introductory visits were done to the selected schools before the onset of the study exercise. This was followed by familiarization, sensitization and recruitment of the school authorities in the study. A pretest was done by the coordinators and the principal investigator to enable the school authorities to know what to expect and plan for. Efforts were made not to interfere with the core school learning activities

4. Lists of pupils for all classes were established before the screening through the help of the school authorities.
5. Recording of the demographic data of the children was done with the help of the class teachers by using the English version of modified WHO EARFORM (Annex 1).
6. The study subjects then underwent clinical examination of the ears via otoscopy, tuning fork tests and pure tone audiometry.

XIII.3. Definitive procedures.

XIII. Otoscopic examination.

Otoscopic examination was done as briefly summarized below:

a. The procedure was preliminarily explained to each subject who was assured of the painless nature of the examination. The examination was done in both ears starting with the normal ear where relevant.

b. Examination began with the inspection of the pinna, pre-auricular and post-auricular areas for any abnormalities.

c. Otoscopy was carried out using a battery powered otoscope. The pinna was gently pulled upwards and outwards (backwards only in young children) and the speculum of the otoscope gently inserted into the canal with the instrument held between the thumb and index finger with the ulnar aspect of the hand resting gently against the subject's cheek or neck.

d. The external auditory canal and tympanic membrane was then inspected and findings recorded in the proforma (annex 1).

Pupils found to have CSOM, were re-examined, in case of active discharge which made visualization of the TM difficult. Aural toilet was then done using cotton wool carefully under clear vision and the ear reexamined. Likewise, pupils presenting wax or foreign bodies underwent syringing or removal by hook respectively.

XIII.3.2. Audiological examinations.

The tuning fork and pure tone audiometric procedures were explained and done to the subject as described in standard textbooks in otolaryngology. Summarized below are the actual procedures carried out.

a. Tuning fork tests.

The 512 Hz tuning fork was used to determine the position of Rinne and Weber tests.

Rinne Test.

The tuning fork prong was gently struck at a point about one third from its free end on the examiner's forearm near the olecranon. After confirming that the prongs were vibrating, the tuning fork was held with its acoustic axis coincident with the anatomical axis of the external auditory meatus of the subject within 2 cm of the meatal opening without touching the ear (Air conduction). The subject was then asked if he/she could hear the sound produced by the tuning fork. The fork was then immediately transferred and base pressed firmly against the mastoid process. The fork was held for 2 seconds with counter pressure applied to the opposite side of the head with the other hand (Bone conduction). The subject was asked whether he/she could hear the tuning fork sound and if this sound was louder or quieter than when it was at the external auditory meatus. When the sound perceived by Air Conduction is louder than Bone Conduction, the test is positive. When the BC is louder than AC the test is negative. Negative Rinne test suggests conductive deafness of over 10dB.

Weber Test.

The examiner applied the vibrating tuning fork to the forehead in the midline. The subject was asked to indicate if any sound was heard and whether it was heard in the middle of the head, in both ears equally, or directed to the right or left. Lateralization or centralization of the sound was then noted. Lateralization of the Weber to the affected ear confirms conductive deafness. Lateralization to the opposite ear suggests false Rinne negative which may indicate severe mixed or sensorineural deafness on the affected ear.

b. Pure tone audiometry.

a. A quiet classroom was chosen in each school and the ambient noise was measured by a sound level meter (42dB). Doors and windows of the classroom were closed to reduce background noise. The screening procedure was then be explained and demonstrated to the children in Malagasy language.

b. The test subject was made to sit comfortably on the chair by the audiologist.

c. Continuous and not pulse sound was presented via a supraaural earphone. The pupil's ear under test was exposed to a pure tone at 50dB and the child would indicate the whole duration of the stimulus. The stimulus was repeated for at least two times. If no response was elicited, the stimulus would be increased by 20dB and repeated until the response was well heard by the pupil. The sound level was thereby reduced in 5 dB steps until the pupil could not hear. The lowest sound level in terms of decibels was taken as the true threshold at that frequency.

d. Screening was performed at a tone 1, 2 and 4 kHz frequencies by using Audiometer "type Interacoustic AS 208 portables".

e. Subjects who failed to hear the screening tone at any of the frequencies would undergo further audiometric testing for thresholds to determine the severity of the hearing impairment.

f. Results were recorded in the audiogram form (annex 2). Type of hearing loss was be defined by using the WHO grading system.

Thus, the severity of hearing loss was determined by using only air conduction pure tone thresholds and tuning fork test results.

All detected ear problems were recorded and treated and if necessary referred for further attention to the appropriate health facility. Other health problems during the study were referred to the relevant clinics for further clinical investigations by using the referral letter (annex 3).

XIII.4. Personnel.

- Principal investigator:
  - Dr RAKOTONIAINA Liva Claude.

- Supervisor, Co-Supervisor:
  - Pr OBURRA Herbert.
  - Pr RAKOTO Fanomezantsoa (ENT Consultant HOMI).

- Audiology clinic Team:
  - *Dr RANDRIANARISOA Theodore (Doctor Audiologist).*
  - 1 doctor
  - 2 nurses.
  - *2 audiometrists.*
  - 1 driver.

- School authorities:
  - *Director.*
  - Teachers.

XIII.5. Data processing and analysis.

From the questionnaire, the data was transferred to a coded sheet and analyzed by using Statistical Package for Social Sciences version 11.0 and Software Microtable5 with aid of a statistician. Results were presented in text, tables, histograms and graphs.

The time duration between sensitization and data analysis was six weeks.

G. ETHICAL ISSUES.

1. At the school level, community consent was obtained from the Director of each school after consultation with the parents.
2. Arrangements were made for appropriate treatment or referral for survey subjects found to have survey related or other diseases.
3. The results and recommendations of this study will be available for use to Madagascar government, WHO and the entire medical fraternity through the relevant presentations such as official reports, reputed journals, conferences and formal media.
4. Information obtained from the study will be kept confidential at all times.
5. There was no cost implication for participating in the study.
6. No pupil was penalized for refusing to participate in the study.

H. QUALITY CONTROL.

Questionnaire was pretested before the data collection and appropriate changes made.

All audiological equipment was calibrated before the onset of the study.

Periodic random sampling of the already examined subjects were reexamined to ascertain the consistency of results.

I. LIMITATIONS OF THE STUDY DESIGN.

Interpersonal differences could have occurred during the measurements. These were minimized by random cross checking of results between the examiner teams.

J. RESULTS.

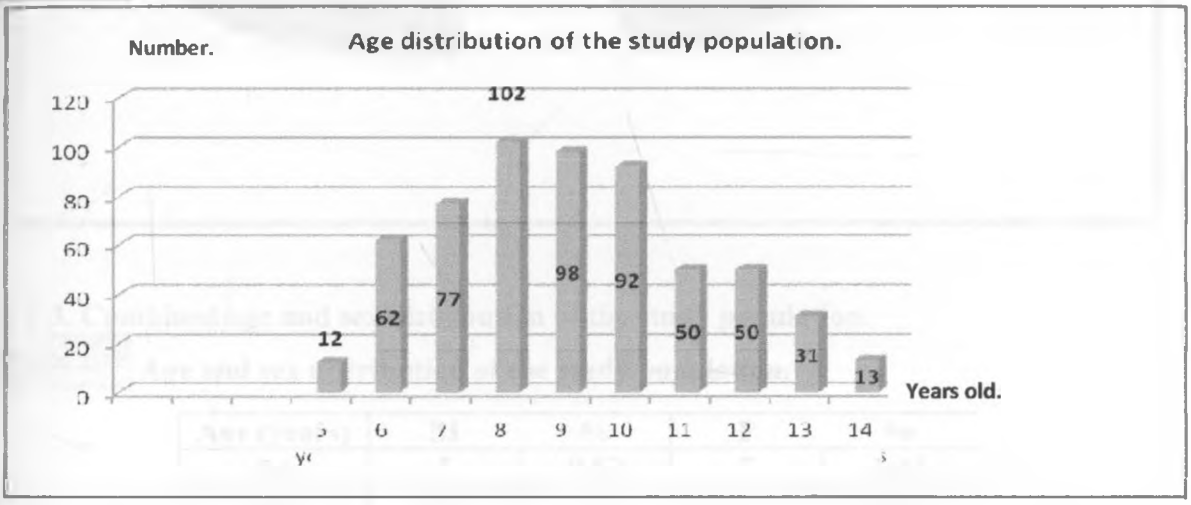
XIV. DEMOGRAPHIC DATA OF THE STUDY POPULATION.

There were a total of 612 children.

XIV.1. Age distribution of the study population.

As can be seen in the histogram in figure 5, the commonest age group was 7-10 years (63.52%) with average at 9.05 years.

Figure 5. **Age distribution of study population.**

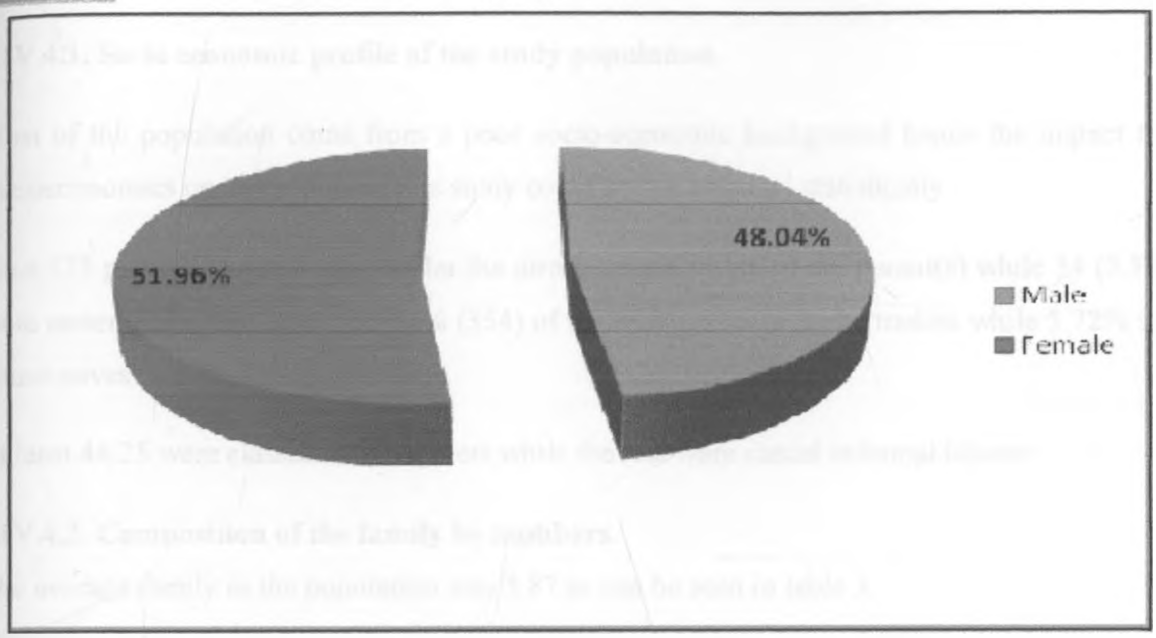


XIV.2. Sex distribution of the study population.

The sex distribution suggested a preferential female pupil school enrolment rather than that of the male. About 51.96% were females.

It was not however clear whether this was an accurate conclusion because this figure has yet to be compared the to the Malagasy national census population pyramid which was not readily available to the investigators at the material time.

Figure 6. **Sex distribution of the study population.**



XIV.3. Combined age and sex distribution of the study population.

Table 1. **Age and sex distribution of the study population.**

Age (years)	M	%	F	%
5 y	5	0.82	7	1.14
6 y	23	3.76	12	6.86
7 y	44	7.19	38	6.21
8 y	43	7.03	63	10.29
9 y	52	8.50	52	8.50
10 y	50	8.17	47	7.68
11 y	28	4.57	22	3.59
12 y	23	3.76	28	4.57
13 y	21	3.43	10	1.63
14 y	5	0.82	9	1.47
	294	**51.96**	**318**	**48.04**

XIV.4. Socioeconomic data.

XIV.4.1. Socio economic profile of the study population.

Most of the population come from a poor socio-economic background hence the impact from socioeconomics on any aspect of this study could not be assessed statistically.

Thus 575 pupils (94.41%) were under the direct responsibility of the parent(s) while 34 (5.59%) were under guardians. About 57.84% (354) of the mothers were pretty traders while 5.72% were house wives.

At least 44.25 were classified as hawkers while the rest were casual informal laborer.

XIV.4.2. Composition of the family by numbers.

The average family in the population was 5.87.as can be seen in table 3.

XV. SPECTRUM OF EAR AILMENTS IN THE STUDY POPULATION.

Apart from CSOM many pupils were found to have other ear ailments that needed attention. Table 3 shows the nature of such ear problems.

Table 2. **Ear problems distribution.**

Age (years)	Otitis media variants	Wax	Foreign body	Dry perforation	Other	Total
5	0	3	0	1	0	**4**
6	1	15	0	0	0	**16**
7	4	25	1	2	0	**32**
8	3	35	0	2	4	**44**
9	5	26	1	1	3	**36**
10	4	28	2	2	1	**37**
11	3	5	0	2	1	**11**
12	4	13	0	0	1	**18**
13	4	6	0	2	0	**12**
14	1	2	0	0	0	**3**
Total	**29**	**158**	**4**	**12**	**10**	**213**
%	**13.62**	**74.18**	**1.88**	**5.63**	**4.69**	**100.00**

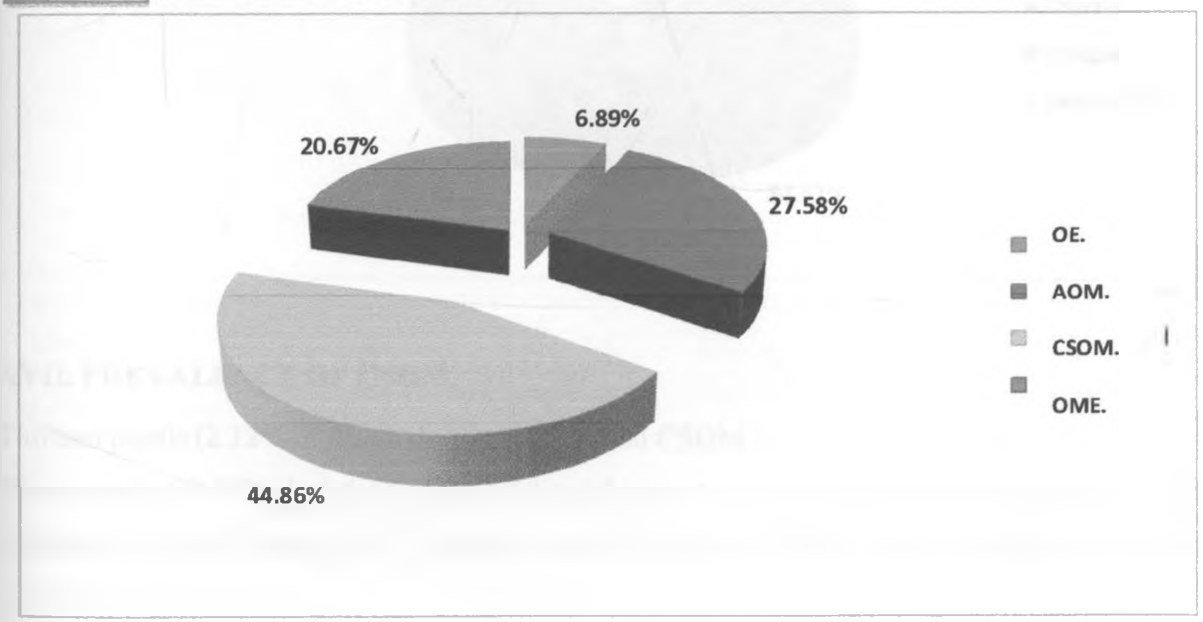
213 out of 612 children (34.80%) had ear problems, and the most common ear problem was wax, followed by otitis and dry perforation of the tympanic membrane.

Impacted wax was the most common ear problem, occurring in 158/213 of the pupils having ear problems study population followed by all forms of otitis media in 29 pupils (13.61%). Preauricular sinuses, skin tags and pigmentation disorders constituted the 4.69%.

XV.1. Variants of Otitis media.

About 4.41% of the study population had some variant of otitis media. Otitis media per se represented 12.6% of those with ear ailments. The variants of otitis media found in the study population are as shown in Fig 7.

Figure 7. Spectrum of Otitis Media.



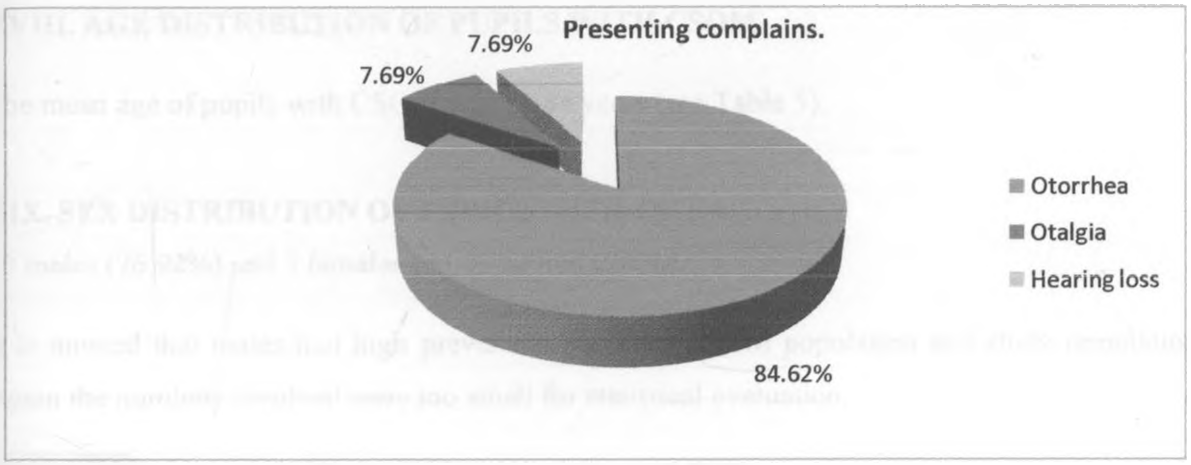
K. RESULTS SPECIFIC TO CSOM.

XVI. Presenting complains.

Otorrhoea was the main complaint in the vast majority of pupils followed by hearing loss and otalgia is shown in figure 8. The duration of Otorrhoea varied from four weeks to many years, this source of information being subjective could not be authenticated.

11/13 (84.61%) were aware of their symptoms, and only 2 were already on treatment.

Figure 8. **Presenting complaints during examination.**



XVII. PREVALENCE OF CSOM.

Thirteen pupils (2.12% of the study population) had CSOM.

Three pupils (23.07%) had the CSOM on the right ear, 4 (30.79%) on the left ear and 6 (46.14%) bilaterally. In total 19 ears (of 13 patients) were involved by CSOM which translates to 1.55% of 1,224 the examined ears.

Table 4. **The statistical test. One-Sample T: CSOM.**

Variable	N	Mean	St Dev	SE Mean	90%CI	T	P
CSOM	10	1.300	1.059	0.335	0.686; 1.914	-2.45	0.037

(Test of mu = 2,12 vs not = 2,12)

The test statistic, T, for H0 : $\mu = 2,12$ is calculated as -2,45.

The P-value of this test, or the probability of obtaining more extreme value of the test by chance if the null hypothesis was true, is 0,037. This is the attained significance level. Thus, there is moderate evidence against the null hypothesis in favor of the alternative (0,01<P<0,05).

Therefore, H0 is rejected if we take the commonly value of $\alpha = 0,05$ which is greater than P-value. A 90% confidence interval for the population mean, μ, is (0,686 ; 1,914)

We have noticed that the majority of the study population was from poor families and further statistical analysis could not be established.

XVIII. AGE DISTRIBUTION OF PUPILS WITH CSOM.

The mean age of pupils with CSOM was 10.84 years (see Table 5).

XIX. SEX DISTRIBUTION OF PUPILS WITH CSOM.

10 males (76.92%) and 3 females (23.08%) had CSOM.

It is noticed that males had high prevalence for both CSOM population and study population. *Again the numbers involved were too small for statistical evaluation.*

Table 4. **Age and sex distribution of pupils with CSOM.**

		Sex	
Age	**Number**	**Male**	**Female**
8 years	2	1	1
9 years	2	2	0
10 years	1	1	0
11 years	3	1	2
12 years	2	2	0
13 years	2	2	0
14 years	1	1	0
	13	**10**	**3**

XX. TYPE AND SEVERITY OF HEARING LOSS ASSOCIATED WITH CSOM.

Among the 32 children having hearing loss, 13 (40.62%) children had CSOM.

As shown in Table 6, 11 ears had associated moderate hearing loss while 8 ears had slight hearing loss. No ear presented with severe or profound hearing loss.

Many CSOM pupils had conductive hearing loss with few having sensorineural hearing loss which could not be ascertained because of the mode of screening. For the same reasons, mixed hearing loss could not be verified.

XXI. SEVERE COMPLICATIONS OF CSOM.

For both, pupils having previous CSOM or the ones with CSOM currently, no pupil gave a history or presented with features suggestive of postauricular swelling and pain (mastoid abscess), vertigo, tinnitus or severe headaches, seizures, loss of consciousness or relevant surgery suggestive of intracranial complications. However the presence of pupils with sensorineural hearing loss suggesting labyrinthitis is noted.

XXII. Actions taken to remedy prevailing medical conditions after findings.

For the impacted ear wax, syringing was done immediately after examination and the child reviewed a few days later. Medications and advice for hearing aids were availed to relevant cases. Cases with other common illnesses (including dermatological conditions, diarrhoea, respiratory tract infections, suspected malaria) were also referred to the nearest suitable health facility.

Referral for further audiological work up and eventual elective surgery in government hospitals were done for cases of CSOM. Table 7 gives a summary for such actions taken during the study.

Table 5. Actions needed.

Age (years)	Syringing	Medication	Hearing aid	Referral for further medical attention		Others	No action
				Urgent	Non-urgent		
5	3	0	0	0	1	0	9
6	17	1	0	0	0	0	47
7	27	5	0	0	3	1	50
8	33	5	2	0	4	0	67
9	28	5	1	0	5	0	67
10	29	1	0	0	4	1	66
11	9	4	0	0	4	0	35
12	15	4	0	0	3	0	34
13	6	3	0	0	4	0	22
14	3	1	0	0	1	0	11
	170	**29**	**3**	**0**	**29**	**2**	**408**

L. DISCUSSION

This was the first study on the prevalence of CSOM in Primary school pupils in Madagascar. The only documented study in otological problems in Madagascar was on causes of deafness in the general population where the prevalence of CSOM was found in 4.1% in the general population comprising rural and urban subjects (2).

According to this current study, 2.12% pupils in an urban public primary school were found to have CSOM. This finding is low when considered to other studies done in other third world countries (8,14,15). This finding must however be seen in the right perspective for two intriguing reasons. Firstly, this study was done in an urban setting. One would expect health delivery facilities to be at least more easily available to an urban community done in a rural setting. Secondly, this was a public school whose enrolment is expected to comprise of the poorer echelons of the society and indeed the section of the study assessing the socioeconomic status of the pupils showed that nearly all of them were living below the United Nation definition of poverty line.

One finding of interest in Antananarivo is that there is preferential enrolment of pupils in private rather than public schools. The genesis of this phenomenon needs to be clarified, whether this preferential enrolment is due to lack of basic public utilities including schools or whether the two categories of school are a real definition of the socioeconomic divide between the two groups of schools. It is only after this issue is clarified that further studies can be designed to give a comprehensive picture of the national prevalence of CSOM in Madagascar in both private versus public schools setting and rural versus urban areas settings.

The role of different variants of otitis media (29 pupils) in causation of ear morbidity that needed medical attention as exemplified in Table 4. It is instructive that 13 of these 29 pupils had CSOM, still emphasizing the significant role of CSOM in causing otological morbidity. It should be mentioned also that the prevalence of the otitis media with effusion might be underestimated during the study because of the screening method. The prominence of impacted ear wax as a finding was not given further attention in this study because its role as a cause of morbidity was not appreciated and the subject was not one of the objectives of this study.

In the age group of the pupils studied here, CSOM was most active between 8 and 13 years. This is contrary to studies done elsewhere where the peak age of presentation is below 5 years (8,15). The preponderance of the male sex in the prevalence of otitis media is similar to studies elsewhere. Again it must be emphasized that due to the small size of CSOM cases, this finding can only considered as a trend whose statistical significance is yet to be ascertained (1).

The morbidity of CSOM as expressed by severity of hearing loss and the attendant complications in this study are mild when compared to studies elsewhere (16). In this study, CSOM cases presented with mild to moderate hearing loss. There were no cases of severe to profound hearing losses. Likewise apart from few cases suggestive of sensorineural hearing loss, lack of severe complications including mastoid abscesses, facial nerve palsy and intracranial complications is noted. Again, the few numbers of CSOM detected does not mitigate this finding.

The table 4 shows the spectrum of ear diseases found in the study population, apart from CSOM. It is logical that any future programs dealing with control or prevention of CSOM in Madagascar must appreciate the magnitude of other causes of otological morbidity. The findings outlined on this table put the CSOM in its right perspective as far as its role in public health otology is concerned.

M. CONCLUSION.

In conclusion, this study has shown that the prevalence and morbidity of CSOM at least in a public urban school in Antananarivo/Madagascar is as low as 2.12%. The same low prevalence of expected severe complications was also noted.

N. RECOMMENDATIONS.

1. There is need to sensitize the school authorities and the general public of the morbidity of CSOM and other ear affections as a whole.

2. Further studies involving larger population samples in different geographical and socioeconomic settings are needed to determine a comprehensive picture of the prevalence and morbidity of CSOM in Madagascar.

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Annex 1.

SCHOOL & CLASS :

No in the study :

PERSONAL INFORMATIONS

Name & Surname :
Age :
Gender :

FAMILY, SOCIAL HISTORY

Parent occupational : Mother: Father: Guardian:
Cooking mode :
Number of the family members :
Other ear problems at home :

CURRENT EAR DISEASE: √ **for YES** ☐ **X for NO** ☐

Yes/No :
If Yes, specify :

Duration :

PAST MEDICAL HISTORY ☐ √ **for YES** ☐ **X for NO**

Medical conditions :

		R	L		R	L
Previous CSOM	:	☐	☐			
Presence of hearing loss :	before the CSOM:	☐	☐	During or After CSOM	☐	☐

Surgical history on ear or head :

Other illness :

EXAMINATION √ **for YES** ☐ **X for NO**

BASIC EAR ASSESSMENT:

		R	L		R	L
- **Pain**	:	☐	☐			
- **Auricle**	: Normal:	☐	☐	Anomalie:	☐	☐

		R	L
- **External ear canal** :			
o Normal	:	☐	☐
o Inflammation	:	☐	☐
o Wax	:	☐	☐
o Foreign body	:	☐	☐
o Otorrhoea	:	☐	☐

	R	L
o Fungi :	☐	☐
o Not seen :	☐	☐

- **Eardrum** :

	R	L
o Normal :	☐	☐
o Perforation :	☐	☐
o Dullness or retraction:	☐	☐
o Red and bulging :	☐	☐
o Not seen :	☐	☐

- **Middle ear** :

	R	L
o Normal :	☐	☐
o Otorrhoca :	☐	☐
o Not seen :	☐	☐

- **Other findings (specify)** :

HEARING EXAMINATION:

	R	L
- **Tuning fork test : RINNE** : + for positive, - for negative	☐	☐
WEBER : **MM** for midline, **L** for lateralize	☐	☐

- **Pure tone audiometry** : (attached)

SUMMARY:

	R	L
- **Ear disease**:		
o Wax : _____	☐	☐
o Foreign body : _____	☐	☐
o Otitis : Externa: _____	☐	☐
Media : Acute: _____	☐	☐
Chronic suppurative:	☐	☐
Serous (with effusion):	☐	☐
o Dry perforation of tympanic membrane : _____	☐	☐
o Other : _____	☐	☐
- **Genetic conditions** : _____	☐	☐
- **Non infectious conditions** : _____	☐	☐
- **Undetermined cause** : _____	☐	☐

ACTION NEEDED

- **No action needed** :
- **Action needed** :
  - o Syringing :
  - o Medication :
  - o Hearing aid :
  - o Surgery referral : *Urgent :
    *Non-urgent :
  - o Others :

Annex 2.

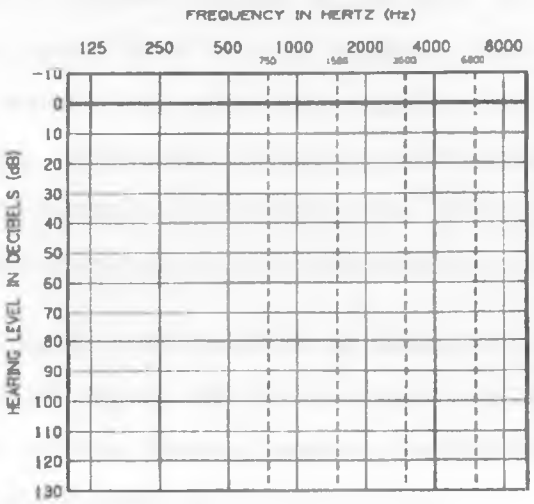
SCHOOL & CLASS :

No in the study :

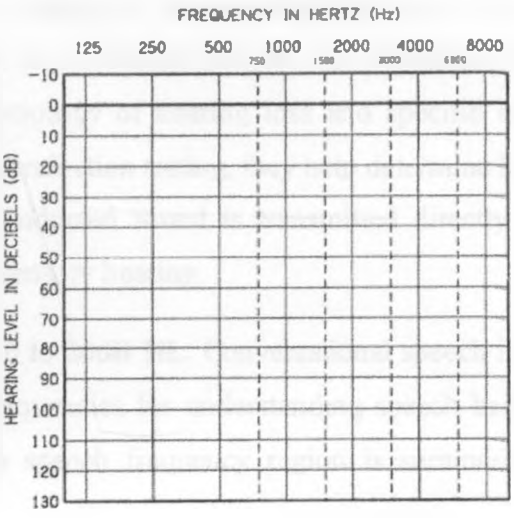
PERSONAL INFORMATIONS

Name & Surname :
Age :
Gender :

RIGHT EAR



LEFT EAR



PURE TONE AVERAGE:

RIGHT EAR LEFT EAR

WHO Grading system

Grade 0 None		25 dB or less	No/ slight problems Hears whispers
Grade 1 Slight		26 – 40 dB	Hears/ repeats words in Normal voice at 1m
Grade 2 Moderate	Child:	31 – 60 dB	Hears/ repeats words in Raised voice at 1m
Grade 3 Severe		61 – 80 dB	Hears words shouted into the Better ear
Grade 4 *Profound*		81 dB or more	Cannot hear/ understand shouted voice

[Average 0.5, 1, 2, 4 kHz in better ear]

Annex 3.

Hearing assessment by Pure Tone Audiometry

Pure tone audiometry is the most common measurement of hearing sensitivity according to the American Academy of Pediatrics.

The pure tone screening is considered important, because even slight abnormalities in hearing acuity can reduce the intelligibitlity of speech message and cause learning problems in children. Signals are delivered through air and bone. Air conduction assesses the function of the entire auditory system from the most peripheral aspect to the central portion. Air conduction testing alone provides little information regarding the etiology of hearing loss and specific auditory pathology. When used in conjunction with bone conduction testing, they help determine both the type and severity of the hearing loss. Bone conducted sound is transmitted directly to the cochlea and is thought to be a better reflection of sensory hearing.

The clinically normal region on an audiogram is 0 to 20dB HL. Conversational speech is in the 40-50db HL region; with the most significant frequencies for understanding speech being 500 through 4000Hz. Hearing sensitivity within the speech frequency region is summarized by means of calculating the pure-tone average.

Audiometric results are valid only when the patient's responses are caused by stimulation of the test ear. Crossover occurs when the acoustic energy presented to one ear can stimulate the non-test ear, resulting in obtained responses, which represent the performance of the non-test rather than the test ear. The main mechanism of crossover is presumed to be bone conduction stimulation caused by vibration of the earphone cushion against the skull at high stimulus intensity levels. The amount that crosses over is a reflection of attenuation. The interaural attenuation of air-conducted tones varies from 40 to 80dB depending on whether ear inserts or headphones are being used. Interaural attenuation values are also frequency dependent, being smaller for low frequencies and higher for high frequencies. Interaural attenuation values for bone conduction can occur even at about 0dB for bone conduction signals. A pass is defined as correct responses to signals at all frequencies in both ears whereas a fail will be recorded if no response to one or more frequencies in at least one ear is obtained.

Masking is the audiometric technique used to eliminate responses by the non-test ear whenever air and bone conduction stimulation exceeds interaural attenuation. An appropriate noise is presented to the ear not being tested when the stimulus is presented to the test ear. The level of masking noise must exceed the threshold for that ear. Excess levels of masking noise must be avoided in order to prevent crossover from the masking noise.

Regardless of the type, hearing loss can be defined in terms of Decibels lost. The table below shows the grades of hearing impairment currently used by WHO (1991) from none, slight, moderate, severe to profound. Moderate, severe and profound hearing impairment in the better ear define the group of people having disabling hearing impairment. WHO uses disabling hearing impairment in the estimation of global deafness and hearing impairment for the global burden of disease rankings.

Hearing loss can be defined by using the following grading system.

WHO Grading system

Grade 0 None		25 dB or less	No/ slight problems Hears whispers
Grade 1 Slight		26 – 40 dB	Hears/ repeats words in Normal voice at 1m
Grade 2 Moderate	Child:	31 – 60 dB	Hears/ repeats words in Raised voice at 1m
Grade 3 Severe		61 – 80 dB	Hears words shouted into the Better ear
Grade 4 Profound		81 dB or more	Cannot hear/ understand shouted voice

[Average 0.5, 1, 2, 4 kHz in better ear]

Annex 4.

REFERRAL LETTER "LETTRE D'EVACUATION"

(French version)

MINISTERE DE LA SANTE
MINISTRY DE L'EDUCATION

"Prevalence of CSOM in primary school children in Antananarivo."

Cet eleve a ete vu pendant l'enquete intitulee "prevalence of chronic suppurative otitis media in preimary school children in Antananarivo".

Ecole/ Lieu: .....

DATE: .....

NOM: .....

AGE: .....

EVACUE a : .....

POUR (Motif): .....

Le Medecin

(English version)

MINISTRY OF HEALTH
MINISTRY OF EDUCATION

"Prevalence of CSOM in primary school children in Antananarivo."

This pupil has been seen during the study about prevalence of chronic suppurative otitis media in preimary school children in Antananarivo

School/ Location: .....

DATE: .....

NAME: .....

AGE: .....

REFERRED TO: .....

REASON: .....

DOCTOR

Annex 5.

CONSENT

GENERAL INFORMATION

We would like to seek community consent from you (Director), the school board and parents in this study aimed at finding out the prevalence of chronic suppurative otitis media in primary school children in Antananarivo. Chronic discharge from the ear can negatively affect a child's school performance and may result in the affected children dropping out of school because of the hearing loss and other fatal complications. These children may also have problems understanding their teachers in class and inattention.

WHAT IS INVOLVED IN THIS STUDY?

In this study, we will examine the children's ears and do hearing tests. Examination of ears and the hearing tests have no danger to the children though they may experience some discomfort. Children will not be given any form of medication before they undergo these examination and tests. This study will only include those children whose parents do not object to the procedures in this study and children who will agree to be examined.

ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

Children who are found to have survey related or other diseases will be treated at the screening site or referred to the appropriate health facility for treatment.

This study will help in building an strategy for the prevention of the serious complications associated with the ear disease and for the prevention of deafness. And data would also be used as a basis for public health for sensitization about the seriousness of such pathologic ear condition.

WHAT ABOUT CONFIDENTIALITY?

Information obtained in this study will be kept strictly confidential.

WHAT IS THE COST?

There is no cost for participating in this study

RIGHTS OF PARTICIPANTS

Taking part in this study is voluntary. Children or their parents may choose not to take part or may leave the study any time. Leaving the study will not result in any penalty.

(English version)

CONSENT

I ..... ID No: .....

Director of ..... School

Of ..... do hereby give community consent for the children in my school to be included in the study on the prevalence of chronic suppurative otitis media in primary achool children in Antananarivo.

The nature of the study has been explained to me by

Dr/Mr/Mrs .....

and I have not promised any material gain to give this consent.

Signature Date: __/ __/ __

(Malagasy version)

FANEKENA

Izaho .... Kar. laharana: .....

Talen'ny sekoly .....

eto ..... dia manao izao fanekena foibe izao hoa n'ny mpianatra ato amin'ny sekoly mba ho isan'ireo ho hadihadiana hahafantarana ny tahan'ny mpianatra voan'ny "tsitongandronono" amin'ny mpianatra ambaratonga fototra eto Antananarivo Renivohitra.

Ny fizotran'ny fanadihadiana dia efa voazavan'

Atoa Dr/Atoa/Ramatoa .....

ary izany dia tsy hisy fandraisana na fampanantenana tambiny.

Sonia Daty: __/ __/ __

Annex 6.

Calendar of year 2008-2009 for

primary and secondary schools in Madagascar.

	STUDY PERIOD	HOLIDAYS
Beginning:	**september 22nd 2008**	
Field period.		**03/11/2008 to 09/11/2008 "Toussain"**
	10/11/08 – 22/12/08	
		23/12/2008 to 11/01/2009 "Xmass"
	12/01/09 – 22/02/09	
		23/02/2009 to 01/03/2009
	02/03/09 – 05/04/09	
		06/04/2009 to 19/04/2009 "Easter"
	20/04/09 – 07/06/09	
		08/06/2009 to 14/06/2009
	15/06/09 – 24/06/09	
		25/06/2009 to 28/06/2009 "Independence day"
End	**29/06/09 – 03/07/09**	
Exam period		**03/07/2009 to 20/08/2009**