PREVALENCE AND RISK FACTORS FOR PRIMARY SPEECH AND LANGUAGE DELAY AMONG CHILDREN ATTENDING SPEECH AND LANGUAGE THERAPY CLINIC AT MUHIMBILI NATIONAL HOSPITAL

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PREVALENCE AND RISK FACTORS FOR PRIMARY SPEECH AND LANGUAGE DELAY AMONG CHILDREN ATTENDING SPEECH AND LANGUAGE THERAPY CLINIC AT MUHIMBILI NATIONAL HOSPITAL.

By

Inocent Francis

A Dissertation submitted in Partial Fulfilment of the Requirements for the Degree of Master of Medicine (Otorhinolaryngology) at

Muhimbili University of Health and Allied Sciences

October 2024.

CERTIFICATION

The undersigned certify that they have read and hereby recommend for examination the dissertation entitled **" Prevalence and risk factors for primary speech and language delay (SLD) among the children attending Speech and Language Therapy clinic at Muhimbili National Hospital "** in partial fulfillment of the requirements for the degree of Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences.

……

Dr. Enica Richard

(Supervisor)

Date: ……

……

Dr. Rachel Mkumbo

(Co-Supervisor)

Date: ……

DECLARATION AND COPYRIGHT

I, Inocent Francis, declare that this dissertation is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature…… Date…….

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DEDICATION

To my lovely wife, Sr. Editha Furaha Richard, for her unwavering trust in me and my devoted kids, Ian and Eline; You inspire me to pursue greatness. To the best of my abilities, my late father Francis Mwita, and beloved mother Elizabeth Kasambala Charles, who persistently prays for me. To my brother, sisters, in-laws, and colleagues' friends, my perseverance was fueled by your prayers and support. This work is dedicated to all of you.

ABSTRACT

Background: Children's speech-language development is crucial for the acquisition of social and academic skills. The speech-language delay is diagnosed when the child follows a correct sequence of speech and language development but at a slow rate, therefore failing to reach the expected milestone of his/her age. The delay can be primary or secondary to other health conditions. In primary delay, there is no identified cause, however, several risk factors are attributable to its development. Male sex, extended use of electronic gadgets like Television **(TV)** and smartphones, and a family history of speech and language delays have all been recognized as common risk factors. Understanding these factors may help the development of preventive strategies and early intervention of the condition to prevent associated consequences like social and academic difficulties.

Objective: The purpose of this study was to identify the prevalence and risk factors for primary speech and language delay in children attending the Muhimbili National Hospital Speech and Language Therapy (SLT) clinic.

Methodology: A cross-sectional study was conducted from October 2023 to January 2024 among children aged 2 to 5 years attending a speech-language therapy clinic at Muhimbili National Hospital. For those who were recruited, their diagnoses were documented whether they had primary Speech and Language Delay (SLD) or not, and their corresponding parents/guardians were interviewed by using a structured questionnaire about the risk factors for primary SLD. Using Statistical Package for Social Sciences (SPSS) software version 23, data was analyzed, and the Chi-Square test was utilized to evaluate the relationship between variables. A p-value of less than 0.05 was regarded as statistically significant.

Results: A total of 77 participants were recruited, of which males were predominantly 44(57.4%) and the age group of 3 years had the highest proportion 31(40.3 %). Prevalence of Primary speech and language delay (SLD) was 19(24.7%) with male preponderance, and the highest prevalence was found in those aged 3 years 9(29.0%). Among the risk factors assessed; a positive family history of Primary SLD (p=0.01) and being raised by single mothers (p=0.02) were found to be significantly associated with Primary SLD, while several

risk factors which were found to be more prevalent in children with primary SLD, statistically were found to be insignificant.

Conclusion: Prevalence of Primary Speech and Language Delay (SLD) was found to be 24.7%. The risk factors found to be significantly linked to primary SLD, were being raised by a single mother and having a positive family history of primary speech and language delay while other risk factors demonstrated in other studies, in this study were found to be statistically insignificant.

Recommendation: Education about Primary Speech and Language Delay (SLD) and its risk factors to health care professionals and the public is an important preventive strategy. In addition, future studies with large sample size are important to assess further the relationship between primary speech and language delay and its risk factors.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
DEDICATION iv
LIST OF TABLES x
LIST OF FIGURES x
ABBREVIATIONS xi
DEFINITION OF TERMS xii
ABSTRACT v
CHAPTER ONE 1
1.0 INTRODUCTION 1
1.1 Background 1
1.2 Problem Statement 5
1.3 Rationale 5
1.4 Conceptual Framework 6
1.5 Research Questions 7
1.5.1 Specific Research Questions 7
1.6 Objectives 7
1.6.1 Broad objective 7
1.6.2 Specific objectives 7
CHAPTER TWO 8
2.0 LITERATURE REVIEW 8
2.1 Age-sex distribution of the study participants 8
2.2 Prevalence of primary speech and language delay (SLD) 9
2.3 Risk factors for primary speech and language delay (SLD) 10
CHAPTER THREE 13
3.0 METHODOLOGY 13
3.1 Study area 13

3.2 Study design 13
3.3 Study duration 13
3.4 Study population 13
3.5 Inclusion criteria 13
3.6 Exclusion criteria 13
3.7 Sample size estimation 14
3.8 Sampling technique 14
3.9 Data collection tool and piloting 14
3.10 Data collection technique 14
3.10 Description of study variables 15
3.11 Data analysis 15
3.12 Ethical Issues 15
3.13 Study Limitations 16
CHAPTER FOUR 17
4.0 RESULTS 17
4.1 Age-sex distribution of study participants 17
4.2 Prevalence of Primary Speech and Language Delay (SLD) 18
4.3 Risk Factors for Primary Speech and Language Delay (SLD) 19
CHAPTER FIVE 24
5.0 DISCUSSION 24
CHAPTER SIX 27
6.0 CONCLUSION AND RECOMMENDATIONS 27
6.1 Conclusion 27
6.2 Recommendations 27
REFERENCES 28
Appendix No. 1: Data collection tool (Questionnaire) 33
Appendix No. 2: Dodoso (Questionnaire-Swahili version) 37
Appendix No. 3: English Version Consent Form 41
Appendix No. 4: Swahili version informed consent form 43

Appendix No. 5: Ethical clearance 45
Appendix No. 6: Introduction letter.....47
Appendix No. 7: Permission letter for data collection.....48
Appendix No. 8: Similarity Index.....49

LIST OF TABLES

Table 1: Age-sex distribution of study participants.....17

Table 2: Prevalence of primary speech and language delay.....18

Table 3: Socio-demographic related risk factors for primary speech and language delay.....19

Table 4: Family-related risk factors for primary speech and language delay 21

Table 5: Environmental-related risk factors for primary speech and language delay.....22

LIST OF FIGURES

Figure 1: Conceptual Framework.....6

ABBREVIATIONS

AAP	American Academy of Pediatrics
IFG	Inferior Frontal Gyrus
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
ORL	Otorhinolaryngology
SLD	Speech and Language Delay
SLP	Speech and Language Pathologist
SLT	Speech and Language Therapy
SPSS	Statistical Package for Social Sciences
TV	Television

DEFINITION OF TERMS

Speech is the verbal expression of thoughts and ideas. It is the production of sounds by vocal cords and articulation by tongue and lips into meaningful words. These words have meaning in their respective languages**.**

Language is the use of words to communicate via agreed-upon symbols or signs of a specific community. Language symbols and signs are coded, and only those who share the same symbols and signs may communicate in their languages.

Speech and language delay (SLD) is defined as the failure of a child to meet anticipated milestones for speech and language during the active period for the development of speech and language. This important period is the first five years of life when a child's brain neuroplasticity is high and it is easy for him or her to learn and develop language.

A primary speech and language delay is the kind of speech and language delay in which a child has a delay in speech and language with normal aspects of other developmental milestones such as motor, cognitive, behavioral, and social aspects. In other words, this is a child who has normal developmental milestones except for speech and language. Although the specific etiology is unknown, risk factors have been discovered that may contribute to its development.

Secondary speech and language delay is a type of speech-and-language delay caused by a known disorder that affects crucial areas required for normal speech and language development, such as the auditory system, the language center, or the muscles that produce speech.

A multilingual family environment is one in which three or more languages are spoken at the same time. For instance, consider a family in which English, Swahili, and Arabic are all spoken.

A nuclear family is a family that consists of parents and children only.

An extended family is a family that comprises in one household close relatives (such as grandparents, aunts, or uncles) in addition to a nuclear family

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Speech is the verbal expression of thoughts whereas language is an agreed system of symbols or signs used for communication. In other words, Speech is the production of words, whereas language is the use of these words or signs to communicate our needs. Language can be categorized as expressive or receptive, expressive involves the use of words or signs to communicate while receptive involves understanding communicated words or signs. Normal speech and language development is critical for proper social and academic skills acquisition in children (1–3).

Normal speech and language development in children occurs in stages, with progression from lower to higher stages being primarily determined by the child's health (hearing, intelligence, structural integrity), as well as family and early school experiences that provide a welcoming environment for learning. Normal speech starts with cooing, then babbling, and single-word development to word combinations, whereas normal language starts with comprehension and goes to communicating basic words to more complex thoughts. Furthermore, as a child ages, the proportion of his or her speech that should be comprehensible to a stranger in the absence of contextual cues increases. Milestones for this can be remembered by applying the "rule of fours": if the child's age in years is divided by four, the percent obtained is approximately equal to the quantity of speech that should be understandable. In this manner, a one-year-old, a two-year-old, a three-year-old, and a four-year-old should be 25%, 50%, 75%, and 100% understandable respectively. Therefore, failure of the child to achieve milestones appropriate for his or her age is interpreted as speech and language delay or disorder (1,4,5).

The term "speech and language delay" (SLD) refers to the inability to meet predicted milestones for speech and language during the active developmental stage of speech and language acquisition. It is when the child has normal speech and language of a chronologically younger age than the child’s age. The active period for the establishment of speech and

language is the first five years of life. It is crucial to address speech and language delays within this critical period for speech and language development because if the issue persists after this time, it has been linked to academic, attention, and social challenges (6,7).

Speech and language delays (SLD) are distinct from speech and language disorders. Speech and language delay occurs when there is slower development of an appropriate sequence of these milestones than predicted, whereas speech and language disorders occur when the development is unusual. (5).

Speech and language delays are classified as either primary (no known cause) or secondary (caused by another condition). In secondary SLD, identified disorders contributed to impaired proper development in speech and language. These disorders can affect hearing, language center, or muscles responsible for speech production. Among identified disorders are autism spectrum disorders, hearing loss, cerebral palsy, intellectual disability, and selective mutism. The correction of delay in the secondary type is difficult and requires intensive speech and language therapy sessions, in addition, primary causes such as hearing loss should be identified and treated as soon as possible for a better outcome (8–11).

Primary SLD, also known as developmental speech and language delay, occurs when a child has a delay in speech and language while having normal motor, cognitive, behavioral, and social skills. Identification and management of the problem is important and cost-effective as normal speech and language can be resumed effectively by speech and language interventions. Also, parents can provide therapy under the therapist's instructions at home with a similar outcome as one provided by the therapist in the clinic. If identified early, the prognosis is excellent and the child may achieve appropriate speech before the school registry (12,13).

Primary SLD has no known cause. However, certain risk factors for the condition's development have been identified. These factors can be classified as; a) Socio-demographic factors; Male sex, young parents, single parents, employed parents, low parent's education level b) Family factors; Raised in nuclear family and small family size, being firstborn, positive family history of SLD c) Environmental factors; Little time a child spent with mother, prolonged use of electronic devices like smartphones and Television (TV), multilingualism, a

child spent most of his/her time indoors, prolonged oral sucking habits (thumb or pacifier)(3,6,14–17)

Male gender has been linked to delayed speech and language development. The male vulnerability to delayed language development has been scientifically described as a result of sluggish nervous system maturation in boys and the negative effect of testosterone on the development of areas crucial for speech skills (18).

Those with delays in speech and language development have been found to have a positive family history. It has been shown that, nearly 20%–40% of patients with SLD have a positive family history, compared to 4% in the general population. The possible reason for these findings is due to the heritability of language problems as evidenced by twins' studies and the co-occurrence of language impairment with autoimmune disorders (19).

Environmental factors like prolonged Television (TV)watching or other electronic media like smart phones, tablets, etc. have been shown to contribute to improper language development. Scientifically TV watching during childhood has been found to have negative effects on frontopolar areas and inferior frontal gyrus (IFG) of the left side which are crucial brain sites for proper language development. Also, TV watching reduces child-caregiver communication interaction (dialogue) which is important in speech and language development. Due to negative impacts on language and other social aspects of life, American Academy of Pediatrics (AAP) recommends a time limit of 2 hours per day of total child's media time (20,21).

Thumb sucking and other non-nutritive sucking habits, such as the usage of pacifiers, are prevalent in young children and serve as an adjusting mechanism to the environment; nevertheless, this tendency usually stops spontaneously around 2 years. Prolonged sucking can cause decreased sensitivity of articulation parts of the oral cavity, which can contribute to speech delay, especially if it occurs between the ages of two and five when language development is most active (3).

Parental age influences the child's speech and language development. The younger the parent, the less linguistic stimulation their children receive, resulting in poor speech and language development (22). Children born to less educated parents have lower literacy and reading levels, reflecting their parents' educational background. These children were found to have delayed speech and language development (23).

Children raised by single parents are facing challenges in speech and language development. Literature has shown the importance of a child being raised by both parents, and each parent has a unique role in promoting timely and proper speech and language acquisition for their child. Fathers play a role in stimulating a child to express words through playfully repeating and imitating words while mothers enhance child comprehension through clarifying words spoken by the child. Therefore, the absence of one of the parents may affect proper and timely speech and language acquisition (24)

Few family members, a nuclear family, and busy parents affect parental-child interaction, which is essential for optimal speech development. A multilingual home setting confuses a child and impairs his or her capacity to master either language (25). The majority of risk factors are modifiable, therefore understanding these factors in preschool children will enable the establishment of effective prevention measures before the school registry.

1.2 Problem Statement

Changes in lifestyles in our society, affect the ways we raise our children. For example, the introduction of new technologies like TV, smartphones, and tablets affects child language development(26). Hence the magnitude of delay in speech and language acquisition among otherwise healthy children becomes evident(15). This problem is known as primary speech and language delay (SLD).

Primary SLD has been associated with problems like low IQ(27). This may later on affect a child's academic, behavioral, and social life(7). The Primary speech and language delay has no known cause, however, there are risk factors identified to be associated with the condition. Identification of these risk factors and modification of appropriate lifestyles are crucial for the condition's prevention and early improvement in those who are already afflicted because many of the risk factors are adjustable.

Currently, there is no study published yet in Tanzania about the magnitude and predisposing factors for primary speech and language delay. Therefore, this study aimed to establish the current situation of the problem in our setting.

1.3 Rationale

Provide evidence-based information regarding the magnitude and risk factors for Primary speech and language delay. The results of this study provided enlightenment to communities and healthcare professionals regarding the magnitude and risk factors for speech and language delays in otherwise healthy children who do not have underlying medical conditions such as hearing loss or seizure disorders

Guide the establishment of preventive strategies to combat the problem. Society may modify lifestyles to reduce the number of children suffering from the condition or reduce the progression of those who are in the early stages. The results also will help the Ministry of Health to know the magnitude of the problem, so may facilitate the expansion of the service to referral hospitals and enrollment of more speech and language pathologists (SLPs).

Serve as a foundation for further studies on primary speech and language delay. It also serves as one of the requirements for the award of a master's in medicine degree in Otorhinolaryngology at Muhimbili University of Health and Allied Sciences.

1.4 Conceptual Framework

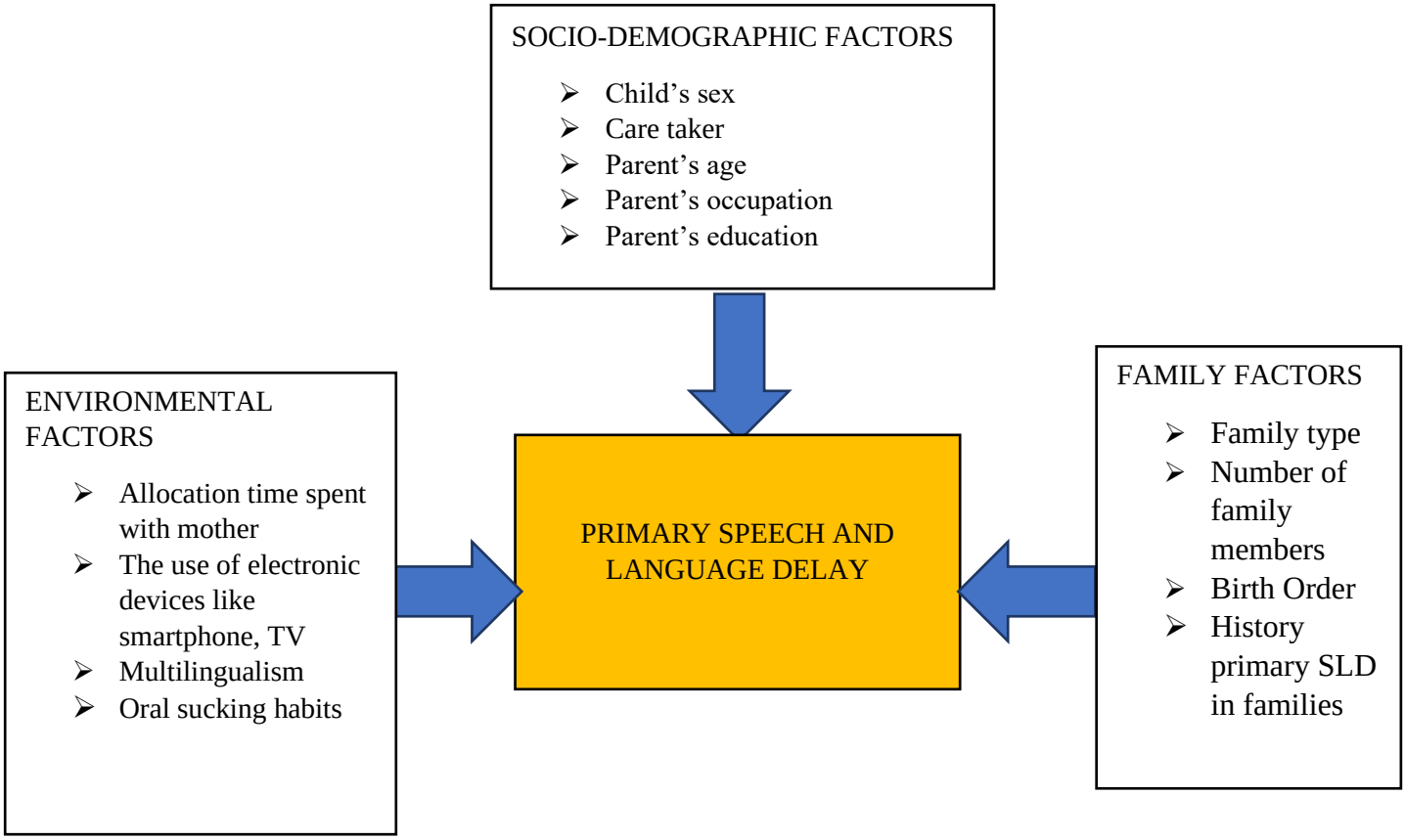


Figure 1: Conceptual Framework

1.5 Research Questions

1.5.1 Main Research Question

What is the prevalence and risk factors of primary speech and language delay (SLD) among the children attending Speech and Language therapy clinic at Muhimbili National Hospital?

1.5.1 Specific Research Questions

1. What is the prevalence of primary speech and language delay among the children attending the speech and language therapy clinic at Muhimbili National Hospital?

2. What are the risk factors for primary speech and language delay among the children attending the speech and language therapy clinic at Muhimbili National Hospital?

1.6 Objectives

1.6.1 Broad objective

To determine the prevalence and risk factors for primary speech and language delay (SLD) among the children attending Speech and Language Therapy clinic at Muhimbili National Hospital.

1.6.2 Specific objectives

1. To determine age-sex distribution among the children attending speech and language therapy clinic at Muhimbili National Hospital.

2. To determine the prevalence of primary speech and language delay among children attending speech and language therapy clinic at Muhimbili National Hospital.

3. To determine the risk factors for primary speech and language delay among children attending speech and language therapy clinic at Muhimbili National Hospital.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Age-sex distribution of the study participants

Age sex distribution seems too different in different studies; However, males predominate. The mean age of 150 children aged 2-11 years in Kumar et al's study was 5.65±2.66 years. Males made up almost two-thirds of the overall number of participants (3).In one of the studies done among under-fives, most of the participants were aged from 25 to 48 months; among them, those with speech and language delay had a mean age of 34±13 months. In this study, about 60 percent were males, with male to female 2:1 among affected ones(6).

In research conducted in Bangladesh, 68.5% of the 111 patients with speech and language delays were males, with the majority of patients aged 2 to 4 years. Male dominance could be attributed to the fact that being male is a substantial risk factor for SLD (14). Males also stand out in the Iraq study, accounting for about two-thirds of participants. The distribution was even across age groups, with a slightly higher (38.5%) in the 1-3 years category. Approximately 88% of those experiencing delays were also males (15)).

In a case-control study with a total of 42 cases and 42 controls, there was an average Age (months) of 65.9±36.08 among cases and 62.74±34.3 among controls. In this study, there were overall higher numbers of males compared to females (25). In a study conducted in Saudi Arabia with 1235 preschoolers aged 3 to 5, around a third (38.1%) of the participants were 3 years old, followed by 4 years old (10.2%), and the rest were 5 years old (28). In South Africa, the study was conducted on infants aged 6 months to 12 months, with males outnumbering females (55%). This was also seen among the patients with speech and language delay, of whom 54 percent were males (29).

2.2 Prevalence of primary speech and language delay (SLD)

Several researches on the prevalence of SLD have been conducted around the world. Prevalence has varied among studies due to different age groups and research settings. The prevalence was reported to be 11.9% in an Iraqi study of children under the age of seven who attended a Pediatric Psychiatry clinic in a tertiary hospital. The other study revealed a prevalence of 2.53% in children aged 1 to 12 years who attended pediatric outpatient clinics in India. The latter study's low prevalence may be attributed to the wide age range and research environment, which is a general Pediatric OPD clinic, as opposed to the previous study, which employs a psychiatry clinic, which is more likely to see children with speech and language delays (15,25).

The community-based study among 1235 preschool children in Saudi Arabia revealed a prevalence of approximately a quarter of the study sample (24.5%). The high prevalence in the study, as explained by the author, could result from an unsocial community lifestyle contributed by the effect of the hot climate in this area, causing individuals to spend more time indoors as opposed to outdoors (28).In the study done by Mondal et al among 200 children aged below 3 years in a tertiary hospital, a prevalence of 27% was found. According to the author, the higher prevalence could be due to the hospital level, since children who receive services in the hospital are more likely to experience a developmental delay (30).

In Africa, the study done in South Africa among infants ranging from 6 months to 12 months, the prevalence of delay was 13%. This study utilizes the samples of 201 participants from three different clinics. The author addressed the significant prevalence within such a short age range by stating that the majority of the infants were exposed to risk factors for speech delay(29). Currently, no data found for the prevalence of primary speech and language delay in Tanzania.

2.3 Risk factors for primary speech and language delay (SLD)

Primary speech and language delay has been linked to various risk factors in the literature. Being male has been shown by several works of literature to be significantly linked to primary speech and language delay. In the study conducted by Saeed et al., being male (p-0.037) was found to be significantly associated with primary speech and language delay (15)). Being a boy was also found to be associated with primary SLD in the study conducted in Saudi Arabia with a p-value of 0.001 (28). Other studies that support this finding were; The study done by Mondal et al (p=0.04), Sharifa et al (p=0.034), and the study done in South Africa in which the association was strong with a p-value of 0.003 (6).

A positive family history of primary speech and language delay has been shown by several studies to be associated with primary speech and language delay. In the study done in Saudi Arabia, a positive family history was found to be associated with primary SLD with a p-value of less than 0.001 (28). The study done in Bangladesh among 120 under-fives (40 cases and 80 controls) found that a family history of speech delay (p=0.000) to linked to primary SLD. It was also found that children with a positive family history of primary SLD were more affected in the study done by Aboufaddan et al (p=0.001) and Mondal et al (p<0.01) (6 ,30, 31). Contrary to many other studies, in the study done by Fouzia et al; the family history of primary SLD was not a statistically significant risk factor(p=0.078) (14).

Time the parents spend with children has been shown to affect language development, the less time, the poorer the speech development. In a case-control study done in Bangladesh it was also found that children who spent less than eight hours per day with their mother had more speech and language delay(p=0.006). The parental employment has been shown to have negative effects on the child's speech and language development. In Africa, a case-control study found that working dads and mothers had significantly higher rates of language delay than controls (57.3% compared to 47.3%, p=0.021 for fathers) (12% vs 3.3%, p=0.005 for moms). In one study children raised by employed parents had more speech delays (p=0.042) which could be resulted of little time the parents spent with their kids (6, 28, 31). Additionally, children raised by single parents have been shown to exhibit more delays than

those raised by both parents due to lack or little time the children can spent with single parents due to busy schedule (24) .

Viewing television (TV) has been found to have a harmful impact on speech and language development. A cross-sectional study was conducted in Korea to evaluate the association between TV viewing and communicative delay in children aged 24 to 30 months. After adjusting for all cofounders, children who watched more than 2 hours but less than 3 hours of TV had a 2.7-fold higher risk of language delay (RR = 2.74, 95% CI: 1.13-6.65) than those who watched less than 1 hour of TV. Those who watched TV for more than 3 hours had a threefold (RR = 3.03, 95% CI: 1.12-8.21) increased risk ($p < 0.05$). It was also revealed that the risk of language delay rose with the amount of time spent watching TV ($p = 0.004$) (26). Fouzia et al also showed usage of electronic gadgets such as mobile phones, televisions, and others to have a significant association with speech and language delay (p-value 0.043) (14). A cross-sectional study conducted at Lahore General Hospital's speech therapy clinic agreed with previous studies that prolonged electronic device use was significantly linked to language delay ($p=0.043$) (3). However, In the study conducted by Saeed et al Television (TV) watching (p-0.58) had no significant association with speech and language delay (15).

The environment that supports a child's social interaction plays a role in proper speech and language development. In one study being a child alone was found to be significantly linked to the development of primary speech and language delay ($p=0.015$), the other study found that firstborn was also more affected, with cases having considerably higher first birth orders than controls (61.3% vs 38.7%) (p-value less than 0.001) (6 ,31). Literature has shown that playing with peers is more important for optimal language development than playing by oneself (p-value of less than 0.001) (28). In contrast, in one study it was found that children raised in a family with more than 4 members (OR = 1.5), and a joint family (Odds Ratio = 1.5), indicated a trend toward association with the development of primary speech delay, though not statistically significant (30).

The age of the child's father and mother influences the child's proper speech and language development. The younger the parents and older parents the poor child's speech and language development. In the study done in Bangladesh the parents with ages below 20 years or over 40 years their children had speech and language delays significantly (p=0.014) more than those with ages in between. In another study language delay was also observed to be considerably higher among infants born to mothers aged 18 years or younger (43%), and women aged 35 years or older (15%), than in those born to mothers aged 19 to 34 years (10%; Fisher's exact test, p=0.035) (14, 29).

Multilingual family environment (P value of 0.001) was found to be significantly associated with speech and language delay in a study conducted at Somaiya Medical College, Hospital and Research Centre in Mumbai. Another study conducted at Lahore General Hospital's speech therapy clinic supports the concept of the multilingual family environment being more in common in children with primary speech delay, in addition, prolonged thumb or pacifier sucking was also found to be a barrier to proper speech and language development (3, 25). Currently, no data found about risk factors for primary speech and language delay in Tanzania.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study area

The study was carried out at the Speech and Language Therapy (SLT) clinic of Muhimbili National Hospital in the Ilala city council of Dar es Salaam. The hospital receives referral patients from around Tanzania's mainland, Zanzibar, and neighboring countries.

Speech and Language Therapy is the unit in the ORL department, whereas, in Tanzania, MNH is the only government facility that provides SLT services. Speech-language therapy unit has 1 Otorhinolaryngologist, two SLPs, and 3 Speech assistant nurses. There are three rooms in which the services are provided, five days a week from Monday to Thursday for children while Friday is for adult cases. There are an average of 82 children every month, whereby 32 are new cases and 50 for follow-up.

3.2 Study design

A hospital-based cross-sectional study was employed.

3.3 Study duration

It was a 3-months study, from October 2023 to January 2024.

3.4 Study population

All children who attended the Speech and Language therapy clinic at MNH during the study period.

3.5 Inclusion criteria

All children from the age of 2 to 5 years attended the SLT clinic during the study period whose parents/guardians signed informed consent.

3.6 Exclusion criteria

Critical ill patients.

3.7 Sample size estimation

The Yamane formula was used because the study aimed to determine the prevalence(proportion) of the unknown population's behavioral characteristics (32).

Sample size n

$$= \frac{N}{(1+N£^2)}$$

£=margin of error 5%=0.05

N= 96, the average number of new cases of children attending the SLT clinic at MNH in three months obtained from a pilot study.

$$n= \frac{96}{1+96X0.05^2}$$

n=77

Therefore, the minimum sample size n was 77.

3.8 Sampling technique

Non-probability convenience sampling was employed. Each patient who met the inclusion criteria was recruited.

3.9 Data collection tool and piloting

Structured questionnaires consisting of the patient's age, sex, and risk factors were used as a tool. The tool was pre-tested before commencing data collection.

3.10 Data collection technique

The structured questionnaires were administered to parents/guardians whose children were included in the study.

3.10 Description of study variables

3.10.1 Independent variables

These were age, sex, and risk factors for primary SLD.

3.10.2 Dependent variables

Primary speech and language delay.

3.11 Data analysis

The data obtained was evaluated for accuracy, consistency, and completeness and then analyzed using SPSS software version 23. Variables were analyzed and presented using frequency distribution tables. The chi-square test was used to assess the relationship between variables. P value less than 0.05 was considered statistically significant.

3.11.1 Descriptive Analysis of Variables

Tables were used to present statistics of the measured sample and variables. Frequencies were used to evaluate variables. Mean and standard deviation were determined for quantitative variables.

3.11.2 Determining the prevalence of primary SLD

This was obtained by running the frequency of children aged 2 to 5 years diagnosed with Primary SLD (numerator) to all children aged 2 to 5 years attending the SLT clinic (denominator).

3.11.3 Assessing risk factors of primary SLD

Risk factors obtained from the data were summarized and analyzed before being presented in frequency tables. The relationship between risk factors and primary SLD was assessed, a p-value of less than 0.05 was considered statistically significant.

3.12 Ethical Issues

Ethical clearance was obtained from the MUHAS Ethical Committee and permission to perform the study was acquired from MNH. Before enrollment of each child in the study, written informed consent was obtained from the study participant's parent/guardian.

Participants were not identified by their names instead; patients' hospital registration numbers were used to ensure confidentiality.

3.13 Study Limitations

This study involved only children who attended SLT clinic; therefore, the sample size cannot be representative of all children in the general population.

CHAPTER FOUR

4.0 RESULTS

4.1 Age-sex distribution of study participants

A total of 77 participants were enrolled in the study. There was a higher proportion of males 44(57.4%) with male to female ratio of 1.3:1. The mean age was 3.6 years with a standard deviation of 0.8 years. The highest proportion of participants 31(40.3%) was observed in those aged 3 years (Table 1).

Table 1: Age-sex distribution of study participants

Age(years)	Sex		
	Male n (%)	**Female n (%)**	**Total n (%)**
2	3(50.0)	3(50.0)	6(7.8)
3	17(54.8)	14(45.2)	31(40.3)
4	16(57.1)	12(42.9)	28(36.4)
5	8(66.7)	4(33.3)	12(15.5)
Total	44(57.1)	33(42.9)	77(100.0)

4.2 Prevalence of Primary Speech and Language Delay (SLD)

Prevalence of Primary speech and language delay was 19(24.7%). Prevalence in males was 12(27.3%) while in females was 7(21.2%). The highest prevalence was found in those aged 3 years 9(29.0%). The observed differences were not statistically significant (p>0.05) (Table 2).

Table 2: Prevalence of primary speech and language delay according to age and sex

		Primary SLD			p-value
		Yes n (%)	**No n (%)**	**Total n (%)**	
Age(years)	2	1(16.7)	5(83.3)	6(7.8)	0.48
	3	9(29.0)	22(71.0)	31(40.3)	
	4	8(28.6)	20(71.4)	28(36.4)	
	5	1(8.3)	11(91.7)	12(15.5)	
Sex	Male	12(27.3)	32(72.7)	44(57.1)	0.54
	Female	7(21.2)	26(78.8)	33(42.9)	
Total		19(24.7)	58(75.3)	77(100.0)	

4.3 Risk Factors for Primary Speech and Language Delay (SLD)

4.3.1 Socio-demographic related risk factors for Primary Speech and Language Delay

Primary SLD was 10(42.9%) among the children raised by single mothers, while it was 9(17.9%) among those raised by both parents. This difference was statistically significant (p = 0.02). Primary SLD was most prevalent among the children born to the youngest fathers 7(36.8%) and mothers 1(33.3%) compared to other age categories. Children born to fathers with primary or below-level education were observed to have the highest primary SLD 4(30.8%) compared to other educational levels. Among children born to employed fathers, primary SLD was 9(22.0%), while it was 10(27.8%) among the children born to self-employed fathers. Primary SLD was highest among children born to mothers with education above the secondary level 12(34.3%), compared to lower education levels. Primary SLD was the least prevalent 5(18.5%) among children born to housewives compared to those born to employed or self-employed mothers. These observed differences were not statistically significant (Table 3).

Table 3: Socio-demographic related risk factors for primary speech and language delay

Socio-demographic-related risk factors	Primary SLD			p-value
	Yes n (%)	No n (%)	Total n (%)	
Caretaker				
Single Mother/Female guardian	10(42.9)	46(57.1)	56(72.7)	0.02
Both parents/guardians	9(17.9)	12(82.1)	21(27.3)	
Father/Male guardian's age (years) at childbirth				
Up to 30 years	7(36.8)	12(63.2)	19(24.7)	0.33
31 to 40	9(22.5)	31(77.5)	40(51.9)	
>40 years	3(16.7)	15(83.3)	18(23.4)	

Father/Male guardian's education level				
Primary or below	4(30.8)	9(69.2)	13(16.9)	
Secondary level (Form IV)	6(25.0)	18(75.0)	24(31.2)	0.83
Above the secondary level	9(22.5)	31(77.5)	40(51.9)	
Father/Male guardian's occupation				
Employed	9(22.0)	32(78.0)	41(53.2)	0.55
Self-employed (Business Owner)	10(27.8)	26(72.2)	36(46.8)	
Mother/Female guardian's age (years) at childbirth				
Up to 20 years	1(33.3)	2(66.7)	3(3.9)	
21 to 30 years	14(28.6)	35(71.4)	49(63.6)	0.46
>30 years	4(16.0)	21(84.0)	25(32.5)	
Mother/Female guardian's education level				
Primary or below	3(15.8)	16(84.2)	19(24.6)	
Secondary level (Form IV)	4(17.4)	19(82.6)	23(29.9)	0.20
Above the secondary level	12(34.3)	23(65.7)	35(45.5)	
Mother/Female guardian's occupation				
Employed	6(27.3)	16(72.7)	22(28.6)	
Self-employed (Business Owner)	8(28.6)	20(71.4)	28(36.4)	0.65
Housewife	5(18.5)	22(81.5)	27(35.0)	
Total	19(24.7)	58(75.3)	77(100.0)	

4.3.2 Family-related risk factors for Primary Speech and Language Delay (SLD)

Primary SLD was 17(25.0%) among children raised in nuclear families, while for the children raised in extended families, primary SLD was 2(22.2%). The proportion of primary SLD was 12(33.3%) among children raised in families with less than or equal to 4 members and 7(17.1%) among children raised in families with more than 4 members. Primary SLD was 9(26.5%) among firstborns and 10(23.3%) among those who were not firstborns. All these observed differences were not statistically significant (p values were > 0.05). Primary SLD was more prevalent among children with a positive family history of primary SLD in first-degree relatives 4(80.0%) than those with a negative history 15(20.0%), and this difference was statistically significant (p = 0.01) (Table 4).

Table 4: Family-related risk factors for primary speech and language delay

Family-related risk factors	Primary SLD			p-value
	Yes n (%)	No n (%)	Total n (%)	
Type of family				
Nuclear family	17(25.0)	51(75.0)	68(88.3)	0.86
Extended family	2(22.2)	7(77.8)	9(11.7)	
Number of family members				
Less than or equal to 4	12(33.3)	24(66.7)	36(46.8)	0.09
More than 4	7(17.1)	34(82.9)	41(53.2)	
Order of birth				
Firstborn	9(26.5)	25(73.5)	34(44.2)	0.74
Not firstborn	10 (23.3)	33(76.7)	43(55.8)	
Family history of primary speech and language delay (first-degree relatives-parents and siblings)				
Yes	4(80.0)	1(20.0)	5(6.5)	0.01
No	15(20.8)	57(79.2)	72(93.5)	
Total	19(24.7)	58(75.3)	77(100.0)	

4.3.3 Environmental-related risk factors for Primary speech and language delay (SLD)

Primary SLD was 7(25.9%) among children who spent less than 8 hours per day with their mothers, and among those who spent equal to or more than 8 hours per day with their mothers, primary SLD was 12(24.0%). The proportion of primary SLD among children with prolonged time spent on electronic devices was 5(16.7%) and 14(29.8%) among children who do not use or spend less than 2 hours per day on these devices. Among children with prolonged sucking habits, 4(26.7%) had primary SLD, while children without prolonged sucking habits had 15(24.2%). No child was found to have primary SLD among those living in a multilingual family environment, but 19(25.3%) of children without a multilingual family environment had primary SLD. Primary SLD was 10(27.0%) among children attending daycare centers, while it was 9(22.5%) among children who do not attend daycare centers. Of the children who stay indoors, primary SLD was 5(23.8%), and among children who play outside with others, primary SLD was 14(25.0%). However, all these differences were statistically insignificant (p-values > 0.05) (Table 5).

Table 5: Environmental-related risk factors for primary speech and language delay

Environmental-related risk factors	Primary SLD			p-value
	Yes n (%)	No n (%)	Total n (%)	
Allocation time spent with mother/female guardian				
Less than 8 hours/day	7(25.9)	20(74.1)	25(32.5)	0.51
Equal to or more than 8 hours/day	12(24.0)	38(76.0)	52(67.5)	
Time used per day on electronic devices (TV watching, gaming with phone/tab or computer)				
None/ less than or equal to 2 hours/day	14(29.8)	33(70.2)	47(61.0)	0.19
>2hours/day	5(16.7)	25(83.3)	30(39.0)	

Prolonged (> 2 years) thumb or other fingers sucking/pacifier use				
Yes	4(26.7)	11(73.3)	15(19.5)	0.84
No	15(24.2)	47(75.8)	62(80.5)	
Multilingual family environment				
Yes	0(0.0)	2(100.0)	2(2.6)	0.41
No	19(25.3)	56(74.7)	75(97.4)	
Attending daycare centers				
Yes	10(27.0)	27(73.0)	37(48.1)	0.64
No	9(22.5)	31(77.5)	40(51.9)	
Interactions with nearby peers				
Stay indoor only	5(23.8)	16(76.2)	21(27.3)	0.91
Plays with other peers outdoor	14(25.0)	42(75.0)	56(72.7)	
Total	19(24.7)	58(75.3)	77(100.0)	

CHAPTER FIVE

5.0 DISCUSSION

Primary speech and language delay is an emerging problem in children due to lifestyle changes in our society, prevention and early recognition are important to avoid its later consequences to the child's life like poor interaction and academic skills. This study aimed to assess the burden and risk factors of this developmental delay among children within the critical period for speech and language development to get a real picture of the situation in our setting. The study involved 77 participants of which the majority were males and the age group with the highest number of participants was 3 years. This distribution of age and sex among participants is similar to the study done by Fadhili et al in Saudi Arabia (28).

Primary speech and language delay prevalence was found to be 24.7% in this study. This finding is higher compared to the studies done by Sunderajan et al in general Pediatric clinics and Saeed et al in Pediatric Psychiatric clinics ((15,25). The high prevalence could be due to different settings as the current study was done in a speech and language therapy clinic that provides services to this kind of patient; Therefore, they are more likely to attend the clinic for services This finding alarms us since it shows that our society is burdened by the condition under study; early preventive measures should be taken to lessen the negative effects.

According to the current study, the highest prevalence of primary speech and language delay was found in children aged three years old; which is consistent with research done in Saudi Arabia (28). This finding can be explained by the fact that a child's speech and language are nearly completely developed at this age (they should be 75% comprehensible), making it simple for parents and guardians to spot abnormalities (1). In terms of sex, males were predominant among the affected ones; this finding is consistent with most of the studies ((3,6,14,15,29). The male preponderance has been linked with slow speech and language centers maturation due to the effects of testosterone (18).

The exact cause of primary SLD is not known however, various factors have been identified to increase the likelihood of its occurrence. The current study assessed these factors and several findings were found. Being raised by a single mother was statistically significantly (p=0.02)

associated with primary SLD; another study with corresponding findings showed approximately two-thirds of those with delays were raised by their mothers only (3). This makes sense because each parent plays a different role in helping their child acquire speech and language in a timely and appropriate manner. The mother plays a major role in the child's comprehension of words, and the father plays a major role in the child's ability to express words. As a result, the absence of one parent has an impact on the child's development of speech and language (24). Additionally, sharing parental responsibilities amongst parents increases the likelihood that the parents will interact with their kids; however, single mothers are overburdened with dual-parent responsibilities, which results in little time spent with the children, which impacts the development of speech and language (33).

Primary speech and language delay was more common in children who spent less than eight hours a day with their mothers and less common in children born to housewives when compared to children born to mothers who were employed or self-employed. These findings are consistent with a study conducted among children under five years old by Tanjina et al. These results emphasize the significance of parent-child interaction for speech and language development (6).

A positive family history of primary speech and language delay in first-degree relatives was found to be significantly associated ($p=0.03$) with primary SLD. This finding agrees with many studies ((6,15,25,28,30,31) which showed the significance of positive family history in the development of primary SLD. The reason for this relationship could be due to the heritability of primary SLD through single nucleotide polymorphism of several genes (34).

Although some previous studies reported a significant association between primary SLD and prolonged use of electronic devices ((3,6,14,26) ; this study showed no association between the two. The lack of association could be due to the comparison group used, which was children with speech and language disorders other than primary speech and language delay which may share the same risk in one way or another, a better comparison group may yield different findings. This explanation may also account for the lowest prevalence of primary speech and language delays among children who stay indoors and those living in a multilingual family environment. Further studies are essential to assess this relationship.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study showed a significantly high prevalence (24.7%) of Primary speech and language delay in our setting, with boys being more affected than girls. The only two risk factors that were found to be significantly linked to primary SLD were growing up with a single mother and having a positive family history of primary speech and language delay. Several risk factors were shown to be more common in patients with primary speech and language delay; however, these findings were statistically insignificant.

6.2 Recommendations

To provide education about primary speech and language delay and its risk factors to health care professionals and the public. This is important preventive strategy and can be achieved through Seminars, instructional outreach to peripheral healthcare facilities, and media advertising—including radio, television, and newspapers.

Children raised by single mothers and those with a positive family history of primary speech and language delay should be raised in an environment that supports social interaction. In case when the children show signs of speech and language delay, early intervention should be considered.

Future studies with large sample sizes. These will aid in further assessment of the association of risk factors and primary speech-language delay.

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APPENDICES

Appendix No. 1: Data collection tool (Questionnaire)

A. INITIAL INFORMATION

PATIENT'S HOSPITAL REG NO…….

AGE……

SEX……

DIAGNOSIS: PRIMARY SLD (TICK WHERE APPROPRIATELY) **YES** **NO**

□ □

B. SOCIO-DEMOGRAPHIC RELATED RISK FACTORS

Caretaker	**Response (Put a tick (√) accordingly)**
Both parents/guardians	
Father/Male guardian only	
Mother/Female guardian only	
Father/Male guardian's age (years) at childbirth	
Up to 30 years	
31 to 40	
>40 years	
Father/male guardian's education level	
Primary or below	
Secondary level (Form IV)	
Above the secondary level	

Father/Male guardian's occupation	
Employed	
Self-employed/Business	
Mother/Female guardian's age (years) at childbirth	
Up to 20 years	
21 to 30 years	
>30 years	
Mother/Female guardian's education level	
Primary or below	
Secondary level (Form IV)	
Above the secondary level	
Mother/Female guardian occupation	
Employed	
Self-employed (Business Owner)	
Housewife	

C. FAMILY RELATED RISK FACTORS

Type of family	**Response**
Single family	
Joint family	
Number of family members	
Less than or equal to 4	
More than 4	
Order of birth	
Firstborn	
Not firstborn	
Family history of primary speech and language delay (first-degree relatives- parents and siblings)	
Yes	
No	

D. ENVIRONMENTAL RELATED RISK FACTORS

Allocation time spent with Mother/Female guardian	**Response**
Less than 8 hours/day	
Equal to or more than 8 hours/day	
Time used per day on electronic devices (tv watching, gaming with phone/tab or computer)	
None/ less than or equal to 2 hours/day	
>2hours/day	
Prolonged (> 2 years) thumb or other fingers sucking/pacifier use	
Yes	
No	
Multilingual family environment	
Yes	
No	
Attending daycare centers	
Yes	
No	
Interactions with nearby peers	
Stay indoor only	
Plays with other peers outdoor	

Appendix No. 2: Dodoso (Questionnaire-Swahili version)

A. TAARIFA ZA AWALI

NAMBA YA USAJILI…….

UMRI(MIAKA)……

JINSI……

TATIZO: KUCHELEWA KUONGEA (WEKA ALAMA YA VYEMA PANAPOHUSIKA)

NDIO HAPANA

□ □

B. VIATARISHI VYA KIDEMOGRAFIA

Mwangalizi wa motto	**Majibu (Weka alama ya vyema √ panapohusika)**
Wazazi wote/Walezi wote	
Baba mzazi/ mlezi pekee	
Mama mzazi/mlezi pekee	
Umri (miaka) wa baba mzazi/mlezi wakati wa kuzaliwa motto	
Kuzaliwa mpaka miaka 30	
Miaka 31 hadi 40	
Zaidi ya Miaka 40	
Kiwango cha elimu cha baba mzazi/mlezi	
Kutokwenda shule/shule ya msingi	

Shule ya sekondari (Kidato cha nne)	
Zaidi ya sekondari	
Kazi ya baba mzazi/mlezi	
Mwajiriwa	
Kujiajiri (kumilik biashara)	
Umri (miaka) wa mama mzazi/mlezi wakati wa kuzaliwa mtoto	
Kuzaliwa mpaka miaka 20	
Miaka 21 hadi 30	
Zaidi ya miaka 30	
Kiwango cha elimu cha mama mzazi/mlezi	
Kutokwenda shule/shule ya msingi	
Shule ya sekondari (kidato cha nne)	
Zaidi ya shule ya sekondari	
Kazi ya mama mzazi/mlezi	
Mwajira	
Kujiajiri (kumiliki biashara)	
Mama wa nyumbani	

C. VIATARISHI VYA KIFAMILIA

Aina ya familia	**Majibu (Weka alama ya vyema √ panapohusika)**
Familia baba, mama na Watoto tu	
Familia ya baba, mama, Watoto na ndugu wa karibu	
Idadi ya wanafamilia	
Wanne au pungufu	
Zaidi ya wane	
Mpangilio wa kuzaliwa	
Wakwanza	
Sio wa kwanza	
Historia ya tatizo la kuchelewa kuongea katika familia (dada, kaka au wazazi)	
Ndio	
Hapana	

D. VIHATARISHI VYA KIMAZINGIRA

Muda anaotumia mtoto akiwa na mama mzazi/mlezi	**Majibu (Weka alama ya vyema √ panapohusika)**
Chini ya masaa 8 kwa siku	
Masaa nane au Zaidi	
Muda anaotumia mtoto kwa siku (kuangalia tv, kucheza gemu kwenye simu ya mkononi/tabuleti au compupyta)	
Hakuna/ Masaa mawili au pungufu	
Zaidi ya masaa mawili	
Kunyonya kidole gumba /vidole au chuchu bandia kwa zaidi ya miaka miwili	
Ndio	
Hapana	
Matumizi ya lugha tatu au zaidi kwenye familia	
Ndio	
Hapana	
Kuhudhuria kituo cha kulea watoto wakati wa mchana (day care centers)	
Ndio	
Hapana	
Mahusiano na watoto wa Jirani	
Anakaa ndani tu	
Anacheza na Watoto wa Jirani	

Appendix No. 3: English Version Consent Form

UHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

DIRECTORATE OF RESEARCH AND PUBLICATIONS.

INFORMED CONSENT FORM

NO---------- DATE----------

Consent to be a participant in a research study

Greetings. I am Dr Inocent Francis, a postgraduate student of Master of Medicine in Otorhinolaryngology (MMED-ORL) at Muhimbili University of Health and Allied Sciences. I am researching the Prevalence and risk factors for primary speech and language delay among children attending the SLT clinic at Muhimbili National Hospital.

Purpose of the study: To determine the Prevalence and risk factors for primary speech and language delay among children attending Speech and Language Therapy clinic at Muhimbili National Hospital.

Participants of the study: All Parents/Guardians with children aged 2 to 5 years will be included in this study.

Confidentiality: There will be no need for names because the patient's hospital registration number will be used to identify all participants. The information gathered during data collection will be maintained in a strictly restricted closed environment to which only the principal investigator will have access, and it will be destroyed once the dissertation has been completed and accepted for the award of my postgraduate degree.

Risk: Participating in the study is not likely to cause any damage.

Benefits: The research findings will identify how big the problem is, raise community awareness about predisposing factors, and facilitate prevention strategies.

Withdrawal right: The decision to participate in this study is entirely up to you. You have the right to decline participation and leave instantly, even after signing the consent form. It is not forbidden to refuse to answer any of the questionnaire's questions.

Whom to Contact: If you have any matters or questions concerning the research, please contact the people listed below:

1. Dr Inocent Francis-Principal investigator (Phone no 0744 839 762, Email: innocentfrancis180@gmail.com or P.O.BOX 65001 Dar es Salaam)

2. Dr Enica Richard-Supervisor (Phone no 0754 307 717, Email: eningowi18@gmail.com or P.O. BOX 65001, Dar es Salaam,)

3. Dr. Rachel Mkumbo-Co supervisor (Phone no 0754 618 222, Email: RachelMkumbo43@gmail.com or P.O.BOX 65001 Dar es salaam)

4. Dr Nahya Salim (Muhimbili University Senate Research and Publications Committee chairperson) through P.O.BOX 65001, Dar es Salaam, for any issues concerning ethics during the study.

Declaration

I agree without being forced that I …… read all contents in this form and completely understood. The questions I had have all been explained and answered, and I have agreed to be a participant in this study.

Participant's signature ……. Participant's phone no……

Principal Investigator/Assistant Investigator signature…….

Appendix No. 4: Swahili version informed consent form

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA TAFITI NA UCHAPISHAJI

Idhini ya kushiriki kwenye utafiti

Namba---------- Tarehe----------

Naitwa Dr Inocent Francis, mwanafunzi wa shahada ya uzamili ya udaktari idara ya maskio, pua na koo Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili.

Lengo la utafiti huu: Lengo ni kuangalia ukubwa wa tatizo na mambo yanayochangia kuchelewa kuongea kwa Watoto wanaotibiwa katika kitengo cha matibabu ya magonjwa ya kuongea na mawasiliano Hospitali ya Taifa ya Muhimbili.

Usiri: Washiriki wa utafiti huu hawatataja majina yao badala yake namba za usajili hospitalini zitatumika.

Washiriki: Ni wazazi au walezi wenye watoto wenye matatizo ya kuchelewa kuongea kuanzia miaka miwili hadi mitano. Washiriki watajibu maswali yahusianayo na mambo yaliyochangia watoto wao kachelewa kuongea.

Madhara ya utafiti huu: Katika utafiti huu hakuna madhara yatarajiwayo.

Faida za utafiti huu: Matokeo yatakayopatikana kutokana na huu utafiti yatasaidia kujua ukubwa wa tatizo pia kuongeza uelewa kwa jamii juu ya mambo yanayochangia watoto kuchelewa kuongea, uelewa huu utasaidia kuzuia au kupunguza tatito hili.

Kujitoa kwenye utafiti: Ushiriki wako katika utafiti huu ni hiyari, unayo haki ya kujitoa katika utafiti huu wakati wowote na maamuzi yako hayataathiri kiwango cha huduma atakachopewa mgonjwa.

Mawasiliano wakati wa utafiti: Pale ikitokea kuna shida yoyote au maswali, wasiliana na wafuatao;

1. Dr Inocent Francis-Mtafiti mkuu (Sanduku la posta 65001 Dar es Salaam, Namba ya simu ya mkononi 0744 839 762, Barua pepe: innocentfrancis180@gmail.com)

2. Dr Enica Richard-Msimamazi (Sanduku la posta 65001, Dar es Salaam, Namba ya simu ya mkononi 0754 307 717, Barua pepe: eningowi18@gmail.com)

3. Dr. Rachel Mkumbo-Msimamizi (Sanduku la posta 65001 Dar es salaam, Namba ya simu ya mkononi; 0754 618 222, Barua pepe: RachelMkumbo43@gmail.com)

4. Dr. Nahya Salim (Mwenyekiti wa Kamati ya Tafiti na Machapisho wa Chuo Kikuu chaAfya na Sayansi Shirikishi Muhimbili) kwa mambo yanayohusisha maadili, kupitia sanduku la posta 65001, Dar es salaam.

Tamko

Nakubali bila kushurutishwa kwamba mimi……. nimesoma na kuelezewa kwa undani na maswali yangu yamejibiwa kwa ufafanuzi na ninakubali kuwa mshiriki wa huu utafiti.

Saini ya mshiriki---------- Namba ya simu ya mkononi ya mshiriki……

Saini ya mtafiti mkuu/Saini ya mtafiti msaidizi----------

Appendix No. 5: Ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1897 Date: 08/09/2023

MUHAS-REC-09-2023-1897
INOCENT FRANCIS
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE AND RISK FACTORS FOR PRIMARY SPEECH AND LANGUAGE DELAY AMONG CHILDREN ATTENDING SPEECH AND LANGUAGE THERAPY CLINIC AT MUHIMBILI NATIONAL HOSPITAL

Reference is made to the above heading,

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 08/09/2023
EXPIRATION DATE OF APPROVAL: 08/09/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this cross sectional study is to determine Prevalence and risk factors for primary speech and language delay among children attending speech and language therapy clinic at Muhimbili National Hospital.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee



Appendix No. 6: Introduction letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.174/2021

18th September, 2023

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is Inocent Francis with Reg. No. HD/MUH/T.174/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Otorhinolaryngology.

As part of his studies, he will be doing an elective research titled: **"Prevalence and Risk Factors for Primary Speech and Language Delay Among Childen Attending Speech and Language Therapy Clinic at Muhimbli National Hospital."** he is being supervised by Dr. Rachael Mkumbo from MNH and Dr. Enica Richard from MUHAS.

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Inocent Francis

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix No. 7: Permission letter for data collection

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/510 Date: 29th September, 2023

Head Department,
Otorhinolaryngology
Muhimbili National Hospital

Received 04/10/2023

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Innocent Francis**
Title	**"Prevalence and Risk Factors for Primary Speech and Language Delay Among Children Attending Speech and Language Therapy Clinic at MNH".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Enica Richard (MUHAS)
Co - Supervisor	Dr. Racheal Mkumbo (MNH)
Period	29th September, 2023 to 30th April, 2024

Approval has been granted to the above mentioned student to collect data at MNH. **A final study report should be lodged with Clinical Research, Training and Consultancy Unit.** Dissemination of study findings to MNH stakeholders shall be overseen by **Dr.** Racheal Mkumbo (MNH) Co – supervisor.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Yours Sincerely,

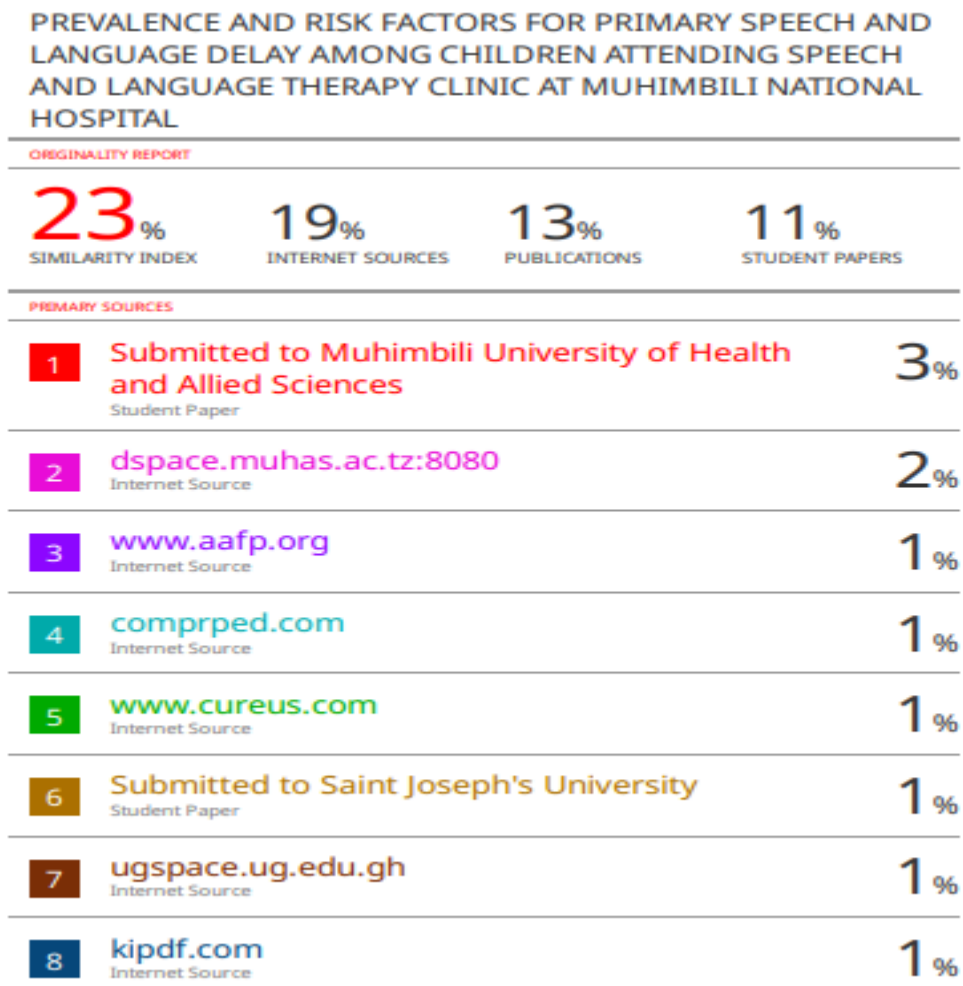
Dr. Deus Buma
For: Head of Clinical Research, Training and Consultancy Unit

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT * MUHIMBILI NATIONAL HOSPITAL * P. O. Box 65000 DAR-ES-SALAAM

c.c DSS
c.c Dr. Racheal Mkumbo
c.c **Innocent Francis**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz

Appendix No. 8: Similarity Index



PREVALENCE AND RISK FACTORS FOR PRIMARY SPEECH AND LANGUAGE DELAY AMONG CHILDREN ATTENDING SPEECH AND LANGUAGE THERAPY CLINIC AT MUHIMBILI NATIONAL HOSPITAL

ORIGINALITY REPORT

23%	19%	13%	11%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to Muhimbili University of Health and Allied Sciences Student Paper	3%
2	dspace.muhas.ac.tz:8080 Internet Source	2%
3	www.aafp.org Internet Source	1%
4	comprped.com Internet Source	1%
5	www.cureus.com Internet Source	1%
6	Submitted to Saint Joseph's University Student Paper	1%
7	ugspace.ug.edu.gh Internet Source	1%
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