The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe

PRECIOUS MADZIMBE

1305779

A dissertation submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirements for the degree of Master of Science in Physiotherapy.

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DECLARATION

I, Precious Madzimbe, declare that **The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe** is my own work except where indicated by references. This dissertation is being submitted as fulfilment of the requirements for the degree of Master of Science in Physiotherapy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any other degree or examination at this or any other University or College.

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Mr Precious Madzimbe

Signed on……*21st* ……Day of ……. *February*…. 2022…… in ……
Johannesburg…..

DEDICATION

To all my patients, from whom the inspiration to carry out this research precipitated.

To my late inspirational grandmother Tsinzeni Madzimbe (1920-2004).

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LIST OF ABREVIATIONS

- **AAP** – American Academy of Paediatrics
- **ADLs -** Activities of Daily Living
- **aOR –** adjusted Odds Ratio
- **AR –** At Risk
- **ARSS -** At Risk Surveillance System
- **ASQ** - Ages and Stages Questionnaire
- **Bayley-II/BSID-II** - Bayley Scales of Infant and Toddler Development Second Edition
- **Bayley-III/BSID-III** - Bayley Scales of Infant and Toddler Development Third Edition
- **cART** - combination antiretroviral treatment
- **CCS** – California Children's Services
- **CDR-PQ -** Development Review–Parent Questionnaire
- **CI –** Confidence Interval
- **CLD** - Chronic lung disease
- **CNS** – Central Nervous System
- **Covid-19** – Corona virus disease
- **CP** – Cerebral Palsy
- **CPQCC** – California Perinatal Quality Care Collaborative
- **ECD** - Early Childhood Education
- **g –** grams
- **GAC** - General Adaptive Composite
- **GDD** - Global Developmental Delay

- **GMCD** - Guide for Monitoring Child Development
- **GMDS** - Griffiths Mental Development Scales
- **HIV** – Human Immunodeficiency Virus
- **HRI/HRIs** – High Risk Infant/High Risk Infants
- **HRIF** – High Risk Infant Follow-up
- **IUGR** - Intrauterine Growth Retardation
- **KIDS** - Kent Inventory of Developmental Skills
- **LBW** – Low Birth Weight
- **LMICs** - low-and-middle income countries
- **MCDI** - Minnesota Child Development Inventory
- **MDI** - Mental Development Index
- **MICS** – Middle Income Cluster Surveys
- **MoHCC** – Ministry of Health and Child Care
- **MRI** - Magnetic Resonance Imaging
- **NDD** – Neuro-Developmental Delay
- **NICU** - Neonatal Intensive Care Units
- **NNE** - Neonatal Neurological Examination
- **OR –** Odds Ratio
- **PEDS** - Paediatric Evaluation of Developmental Status
- **pH** - Potential Hydrogen
- **RDS** - Respiratory Distress Syndrome
- $\mathbf{r}_{xx}$ - reliability coefficients
- **SARS** – Severe Acute Respiratory Syndrome
- **SD/sd** – Standard Deviation

- **TORCH** - toxoplasmosis, rubella cytomegalovirus, herpes simplex and HIV
- **UNICEF -** United Nations International Children's Emergency Fund
- **VLBW** – Very Low Birth Weight

DEFINATION OF TERMS

- **Apgar score** – is a scoring system based on child's condition immediately after birth. It measures how well the child is immediately after birth to decide whether the child needs resuscitation or not. The scoring is done at the first and fifth minute after birth.
- **At Risk Surveillance System –** a follow up programme for babies with identified risk factors of developmental delay.
- **At Risk/High Risk baby –** Individual below the age of three years who has a greater possibility of experiencing developmental delay arising from identified biological and environmental factors (e.g. low birth weight of <2500 g in term babies).
- **Caesarean section/C-section –** delivery through a surgical procedure (incision in the abdomen)
- **Central Hospital** – a tertiary referral hospital. They offer specialised and super-specialised services.
- **Consanguinity/consanguineous marriage - a** union between partners who are second cousins or close relatives
- **Developmental delay -** is when a baby fails to attain expected developmental milestones for their age group. It can be mild (70-84 BSID-III composite score), moderate (55-69 BSID-III composite score) and severe (<55 BSID-III composite score)
- **Floppy baby** – a baby with very low muscle tone**.**
- **HIV exposure** – born to HIV positive mother
- **Jaundice** – excess bilirubin in blood causing yellowness in skin and eyes
- **Low birth weight** – birth weight of <2500 g

- **Neonatal convulsions/seizures** – fits in the early days of life
- **Risk factor** – something that increases the chance of developing a disease.
- **Severe jaundice** – high serum bilirubin requiring blood transfusion
- **Severe prematurity** – born <28 weeks of gestation
- **Very low birth weight** – birth weight <1500 g

CHAPTER 1: INTRODUCTION

1.1 Background and Need

Child development is the process by which a child grows from a helpless infant to an independent adult. The ability to perform specific tasks at a given age in comparison to the performance of the general population at that age is known as normal development. Development is categorized into domains which are cognitive, gross and fine motor skills, speech and language, socio-emotional and behavioural. If two or more of these domains are delayed, it is referred to as global developmental delay (Bellman et al., 2013). Developmental delay is when a child fails to attain expected developmental milestones for their age group (Karsimzadeh, 2005). There is strong evidence supporting good outcome when there is early identification and intervention of developmental delay (Bellman et al., 2013; Choo et al., 2019; Vitrikas, Savard & Bucaj, 2017). An estimate of 30 to 50% of developmental disorders are identified late at school going age, hence making any intervention less effective (Glascoe, 2000).

Early childhood development is a major global issue that has to be addressed. In the development of a child, the prenatal and postnatal periods are crucial (Lake, 2011). Globally, eight-point-four percent of children below the age of five have developmental disorders, 95% of which reside in low-and-middle income countries (LMICs). Sub-Saharan Africa has the highest prevalence of developmental delay which constitutes 73% of the global developmental delay (Olusanya et al., 2018).

Zimbabwe has a disability prevalence of seven percent, 25% of which are in children below the age of five (Ministry of Health and Child Care (MoHCC) & United Nations International Children's Emergency Fund (UNICEF), 2013). In Bulawayo, Zimbabwe, a cross-sectional study of 142 At Risk babies with Apgar score of ≤5 at five minutes of life were assessed at one year using BSID-I; 165 were assessed using the Neonatal Neurological Examination (NNE). Prevalence of 26% developmental delay was found using the BSID-I scale in children with low

Apgar score of ≤5 within the first five minutes of birth with confidence interval of 95% (Wolf et al., 1997).

Trauma, chemical exposures, micronutrient deficiencies, infections, consanguinity, increased birth order to older women, and hereditary illnesses are recognised risk factors for developmental disability in low-income nations. The contribution of these factors to the aetiology of developmental disability in LMICs is not fully documented. Most causes of developmental disabilities are known and most of them are preventable, but preventative measures are not fully implemented in developing countries (Durkin, 2002).

A sub-Saharan longitudinal, population based study by Donald et al. (2019) done on a South African population showed that children had developmental delay in the following domains: cognition (50.5%), receptive language (55.6%), expressive language (55.4%), fine motor (23.2%), and gross motor (38.4%) which is a significantly high proportion. Children who had greater than one domain affected constituted 55.3% and 10.2% of children had delay in all developmental domains. The study used a large sample size from the general population in which 734 babies were assessed using the BSID-III.

Developmental surveillance is "eliciting and attending to parents' concerns, making accurate and informative longitudinal observations on children, obtaining a relevant developmental history and promoting development" (National Health and Medical Research Council (NHMRC), 2002: 22). It is recommended to follow up At Risk (AR) babies such as preterm babies after discharge from Neonatal Intensive Care Units (NICU) for developmental screening. Early identification and intervention with therapies (such as physiotherapy, occupational therapy and speech therapy) are associated with a good developmental outcome (Kalia et al., 2009). The American Academy of Paediatrics (AAP) recommends that developmental delays be monitored at nine, 18 and 30 months of age using a standardized assessment method (Vitrikas et al., 2017).

Western standardised tools are not culturally adapted to the local settings. If culturally adapted, these developmental screening tools can easily identify developmental delay in regions where the services are not available. Lack of these culturally adapted developmental assessment tools leave

the magnitude of developmental problems unknown in developing countries. However, these Western developed assessment tools can be adapted to non-Western countries with good inter-rater and test retest reliability (Abessa et al., 2016).

The Bayley Scales of Infant and Toddler Development (BSID) is the Gold Standard developmental assessment tool and has been tried and tested in Bulawayo in assessing children with low Apgar scores. It was found to be comparable to the Neonatal Neurological Examination (NNE) tool and correctly classified level of child development in 94% of the cases (Wolf et al., 1997). It has been further tested in the black Zimbabwean population and adequately assessed development in HIV-exposed babies in Harare in the domains of motor, language and cognitive development (Hutchings & Potterton, 2013).

In Zimbabwe, the At Risk Surveillance System (ARSS) has been in use since the mid-1980s in public health. It is a paper-based system that follows up babies with known developmental delay risk factors such as severe neonatal jaundice. This surveillance system aims to identify children with neurological development conditions and disability in the first five months or latest twelve months of life. Children who are found to have developmental challenges are referred for early intervention (MoHCC, 2012).

Dzvukamanja et al. (2017) reviewed the ARSS in Chimhanda district, Zimbabwe and found that it was 88% acceptable, affordable (costing about US$2500 per months for the whole district), simple (the AR form took an average of 10 minutes to complete) and 97.7% useful. However, it was also found to be unstable (AR record forms were improvised by all 12 health facilities in the district), inefficient (as some cases took long to be reported and some were never reported) and insensitive (detects only 12.5% of AR babies) to a small extent. The study also detected a 21.1% prevalence of AR babies. A need for further training for health care professionals on the programme was identified.

1.2 PROBLEM STATEMENT

Zimbabwe does not have recent and comprehensive disability incidence and prevalence statistics for children at present (UNICEF, 2021). National and institutional statistics on AR babies are either not available or not up to date. Research on the prevalence of, and risk factors for developmental delay in children have been mainly done abroad and the findings cannot be generalised locally due to the uniqueness of the environment in which these babies are born and raised.

In 2019, United Bulawayo Hospitals started to fully implement the ARSS for early identification of developmental delay. However, due to the current economic meltdown, a significant number of parents do not arrive for their follow-up appointments due to failure to afford transport. As a result of that, statistical information on developmental outcome is lost. The hospital does not have a child developmental assessment kit, hence the severity of developmental delay of those who attend the follow-up clinic is unknown. Shortage of staff, lost statistical information due to the current use of manual medical records and inconsistencies to developmental assessments due to lack of a validated tool leaves developmental outcomes and risk factors unanalysed at this hospital. Since the severity of developmental delay and the risk factors involved in the ARSS at United Bulawayo Hospitals are not known, other Central Hospitals, which are yet to implement ARSS, have no reference studies from which to formulate follow-up policies.

It is therefore imperative to study and understand the profile of AR babies under the ARSS at a Central Hospital in Zimbabwe like United Bulawayo Hospital. Other local studies have focused on HIV exposure in Harare (Hutchings & Potterton, 2013) and low Apgar scores in children who were born in Bulawayo (Wolf et al., 1997) in relation to developmental delay outcome. Hence, the developmental outcome in babies with other risk factors remains undocumented in local literature.

1.3 RESEARCH QUESTION

What is the prevalence and severity of developmental delay in babies under the ARSS at United Bulawayo hospitals?

1.4 Aim

To determine the prevalence and severity of developmental delay in children under the ARSS at United Bulawayo Hospitals.

1.5 Objectives

1. To calculate the prevalence of developmental delay among children under two years of age enrolled in the ARSS at United Bulawayo Hospitals using the Bayley Scales of Infant and Toddler Development (BSID-III).

2. To determine the severity of developmental delay in children under the ARSS at United Bulawayo Hospitals.

3. To identify risk factors that are associated with developmental delay in children under the ARSS at United Bulawayo Hospitals.

1.6 SIGNIFICANCE OF THE STUDY

At present there is a paucity of information on the prevalence and severity of developmental delay in infants in Zimbabwe. If the prevalence and severity of developmental delay are ascertained, it helps to advise hospital administration on required rehabilitation staffing levels. It will also help to determine the types and quantities of rehabilitation equipment required to address the most commonly affected domains of development. Identification of the risk factors

would help us to know which of these risk factors are contributing most to developmental delay at the institution. This will enlighten the obstetricians and paediatricians on the extent of morbidity after delivery of At Risk babies and that will help in prioritisation of allocation of resources for prevention of modifiable risk factors. The information from this study will also add to the body of knowledge on infant development in Zimbabwe.

CHAPTER 2: LITERATURE REVIEW

This review of literature contains discussion of: At Risk/High Risk Babies, normal child development, developmental delay and its severity, developmental delay prevalence in the At Risk Babies, risk factors linked to developmental delay and child developmental assessments. The ARSS in the Zimbabwean context, the BSID-III (how to administer and interpret the results, its strengths and weaknesses) are discussed in this chapter. Since many children included in this study were born just before or during the Covid-19 era, literature on Covid-19 impact on child development was also explored.

The literature was searched on major online data bases (Cochrane Collaboration, PubMed, Ovid, Science Direct and Medline). Keywords used in the searches were: At Risk babies, High Risk Babies, developmental delay and risk factors for developmental delay in children, BSID-III assessment and severity of developmental delay. A search for hard copies was done at Wits University Health Sciences Library and United Bulawayo Hospitals Library.

Developmental delay and its risk factors warrant investigation as they are a contributor to disability in children. Early detection of developmental delays allows for early intervention that will lower the burden of disability.

2.1 At Risk/High Risk Babies

Any neonate with a high risk of mortality or morbidity (regardless of birth weight, gestational age, or size) in the first four weeks following delivery is classified as a High Risk infant (HRI). Preconception, prenatal, natal, or postnatal conditions or events that interfere with a normal delivery or obstruct extra uterine growth adjustment and development are examples of risk factors (CCS/CPQCC, HRIF-QCI, 2018).Long-term care, assessment, and education through a well-coordinated follow-up system are critical components of post-discharge treatment in HRIs.

Nurses are an important element of the professional team because they can identify HRIs, provide discharge education, and ensure follow-up referrals (Purdy & Melwak, 2012). Because of the higher risk of impairments and developmental delays, most programs have concentrated their efforts on long-term follow-up of the most susceptible group with birth weights <1500 g. (Yee & Rose, 2006).

Jodeiry et al. (2015) performed research in Iran with the goal of building and piloting an HRI surveillance system based on an action model, rather than a service package, for reformation and implementation across the country. This was a qualitative study, and the inclusion criteria for HRI into the national surveillance system were determined by a consensus of 12 medical professionals from diverse departments through focus group discussion. The following are the agreed-upon inclusion criteria:

- Birth weight <1500 g and/or gestation of <32 weeks
- Birth weight greater than 1500 grams or period of gestation which is greater than 32 weeks with the following conditions:
- Intrauterine Growth Retardation (IUGR)
- Antenatal or neonatal asphyxia (Arterial Blood Gases of the cord within the first hour: pH <7 or Apgar score <3 at the fifth minute)
- Continuous instability in the neonatal period like hypoxemia or acidosis, hypoglycemia, or persistent hypotension and resistant to vasopressors
- Persistent apnoea requiring the medical treatment at discharge
- Oxygen supplementation for more than 28 days during hospital admission or concomitant radiologic signs related to chronic lung disease (CLD)
- Persistent pulmonary hypertension of the new born diagnosed by echocardiography requiring treatment
- Seizures

- Intracerebral insult including: IVH Grade 2 or more, periventricular leukomalacia, neuro-developmental disorders of the Central Nervous System (CNS)
- Respiratory Distress Syndrome (RDS) managed by mechanical ventilator for >2 hours.
- Hypoglycemia: Two intervals blood sugar samples less than 40mg/dL and (50 after 24 hours)
- Polycythemia and partial exchange
- Surgery during the neonatal period
- Major congenital anomalies
- Infectious diseases such as toxoplasmosis, rubella cytomegalovirus, herpes simplex and HIV (TORCH syndrome)
- Neonates or mothers with systemic auto-immune disease
- Proven sepsis and osteomyelitis
- Intrauterine transfusion or hydrops fetalis
- Other difficulties leading to Central Nervous System (CNS) disorder as infection or hypotonia during discharge or hyper bilirubinemia at exchange transfusion level

The follow up is multidisciplinary comprising Coordinator, physician (neonatologist/fellow of neonatology/trained paediatrician), discharge nurse, follow-up clinic nurse, data analyser, ophthalmologist, audiologist, neuro-development specialist. The follow-up was supposed to continue until the child was five years old. In this pilot study, the BSID-III was recommended for developmental assessments for the High Risk Infants in preference to the Griffiths Mental Development Scales (GMDS). This study recommended implementing this follow-up study in the whole country.

2.2 Normal child development and developmental delay

The average rate of motor and mental growth at phases projected as developmental milestones is characterized as the developmental process in the early stage of extra uterine life (Scharf et al., 2016; Centers for Disease Control and Prevention, 2021). The term "developmental milestones" is used to define typical development in children and the milestones are included in routine testing methods for children. The ages at which these milestones are reached are then compared to the age ranges in which the majority of children achieve similar milestones (Scharf et al., 2016). The developmental process is influenced by a variety of factors (Molai, 2019; Pem, 2015). As a result, what is considered normal development has a wide range of variations (National Institute of Deafness and other Communication Disorders (NIDCD), 2015).

Delayed development is defined as slow to meet or not reaching the expected stage of development in ≥1 of the five developmental domains (motor, cognition, communication, adaptive skills and social-emotional) compared to the expected development for a child's age group (Choo et al., 2019; Vasudevan & Suri, 2017). The brain's vulnerability to insults is high in the early years after birth (Kuklina et al., 2004), leading to brain long-term functional and structural problems (Grantham-McGregor et al., 2007), affecting attainment of milestones in children. Cognitive, motor or communication development deficits resulting from insults to immature brain tissue often present later. The delays present as mild, moderate or severe.

2.3 Brain Development

This is the growth of the brain that begin three weeks after conception and continues for 30 years of life and occurs in phases: in utero, prenatal and post natal phases. Regions of the brain develop at different rates. The prefrontal cortex grows slowly and reaches maturity at about 30 years of age. There are several factors affecting brain development which includes early experiences, stress, psychoactive drugs, maternal and paternal stimulation, peer relationships, radiation therapy and ionizing radiation, intestinal flora and nutrition (Kolb, Mychasiuk & Gibb, 2013).

The first 1000 days of life are marked by fast rates of brain development. This is the best time for proper development, but it is also the time when the brain is most vulnerable (Innocenti, 2021). Sensory portions of the brain develop rapidly in babies, whereas higher-order cognitive areas of the brain continue to develop well into adolescence (Thompson, 2001).

2.3.1 Stages of brain development

Brain development occurs in stages which are neurogenesis, synaptogenesis, synapse pruning and myelination. Critical changes occur at each stage (Kolb et al., 2013).

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2.3.1.1 Neurogenesis

Within the first month after conception, the brain begins to grow. By six months of gestation, nearly all brain neurons are formed. Neurons migrate to specific areas of the brain to perform a specific function during neurogenesis (Tierney & Nelson, 2009).

2.3.1.2 Synaptogenesis

Neurons differentiate to fulfil specific functions, and synaptic connections are generated to allow cells to communicate. Synaptogenesis occurs throughout childhood, but far more connections are formed than are required. This provides the brain with enormous potential, but it also renders it ineffective (Thompson, 2001). Few synaptic connections exist at birth, but at four months, there is a quick burst of synaptogenesis, which is linked to an increase in visual awareness (Tierney & Nelson, 2009).

2.3.1.3 Synapse pruning and myelination

Unnecessary connections are pruned out during the pruning process. Experience plays a part in deciding whether or not connections are cut. The most frequently used connections are kept, while inactive connections are removed. As a result, a lack of stimulation might result in a permanent loss of function. For example, if the condition is not repaired early in childhood, long-term vision loss as a result of congenital cataracts in childhood could lead to the entire loss of underused visual pathways (Tierney & Nelson, 2009). Rapid expansion of cortical volume is found throughout foetal development and the first four postnatal months. However, myelination of sub-cortical white matter causes later increases in brain weight (Tierney & Nelson, 2009). White matter myelination occurs quickly after birth, and the adult pattern is visible by the end of the second year (Knickmeyer et al., 2008). Pruning is completed within 4-6 years of life (Tierney & Nelson, 2009).

2.3.2 Significance of stages of brain development to early intervention in developmental delay

The visual and auditory brain development in babies peaks at about two to four months of age, then slows down. The development of the receptive and expressive language centres (Wernicke's and Broca's area) peaks at around 7–10 months and then slows down (Grantham-McGregor,

2007). Anatomical and developmental changes in the visual cortex occur at the same time. The visual cortex achieves its maximal volume at four months (Tierney & Nelson, 2009). The frontal cortex and other cortical association areas grow more slowly (Tierney & Nelson, 2009). Higher cognitive function (prefrontal cortex) development peaks between the ages of 1-3 years (Grantham-McGregor, 2007). As a result, higher-functioning parts of the brain are the last to mature. The first two years of a child's life are clearly a key period in development as brain development is accelerated and motor and cognitive development are intensified (Lima et al., 2004).

Brain development up to the age of two years is important in neurodevelopmental disorders. According to studies, the total brain volume increases by 10% in the first year, when the infant brain is 72% of the adult volume. In the second year of life, brain volume scarcely increases by 15%. In the first year, gray matter volume increase by 149%; white matter and cerebellum volumes increase by 11% and 240%, respectively. The extraordinary cerebellum expansion in the first 12 months may explain the quick improvement in the baby’s balance and co-ordination (Knickmeyer et al., 2008).

The first five years following birth are crucial for the development of skills that will be required for future academic success. Math, reading, talking/listening, and self-discipline are examples of these abilities. Hence, developmental assessments at this critical time are important to allow timeous management. During this period, brain tissue is neuroplastic. Therefore, early intervention contributes to success due to the brain’s neuroplasticity during the first five years, making environmental interventions most beneficial at that stage. The early childhood years are a time of greatest risk and opportunity (Fernald et al., 2009).

2.4 Prevalence of developmental delay in At Risk/High Risk Babies

Globally, eight percent of children below the age of five have developmental disorders, 95% of which reside in LMICs. The highest prevalence of developmental delay is found in Sub-Saharan Africa, which constitutes 73% of the global developmental delay (Black et al., 2017; Olusanya et al., 2018).

A study by Ballot et al. (2012), which followed up very low birth weight babies in South Africa, reported BSID-III average scores in each subscale that were rather low, but within normal limits, according to a monitoring of babies with very low birth weight (VLBW) in South Africa. One-third of the patients were classified as being at high risk for developmental issues, scoring between 70 and 85 on the BSID-III. In this setting, VLBW infants belong to a High Risk group with a high chance of developing learning challenges at school and need to be put under surveillance. This study used a sample size of 106 patients. Children had an increased chance of scoring below normal on the BSID-III motor scale if they had a history of resuscitation at birth (Ballot et al., 2012).

An observational study on the developmental outcome of HRI in India was conducted by Chattopadhyay and Mitra (2015). Between January 2010 and June 2012, high-risk new-borns were tracked and assessed by child development specialists using standardised developmental assessment tools such as the Amiel-Tison method of tone assessment, the Denver Developmental Screening Tool II, and the Trivandrum Developmental Screening Chart. Developmental delay was identified and treatment was commenced for children having neuro-developmental delay (NDD). Children exhibiting visual, hearing, or speech impairment were placed in the developmental delay category. A total of 31.6% of the study population presented with developmental delay. The NDD prevalence was higher in babies with low birth weight <2500 g (but >2000 g), preterm <36 weeks gestation period and twins (Konje et al., 2018).

A study in rural China assessed 2514 babies sampled from the general population. The Chinese-modified Ages and Stages Questionnaire examined development in children aged six to 35 months. Of the total, 35.7% exhibited developmental delay. The 6-11 months age group had the largest proportion of delayed development of 48% and the age group 30-35 months had the least developmental delay proportion of 22.8%. The researchers recommended intervention measures to mitigate this high prevalence of developmental delay (Zhang et al., 2018).

When compared to HIV-exposed uninfected new-borns, HIV-exposed infected infants had a higher rate of developmental delay (Hutchings & Potterton, 2013; Mukherjee et al., 2019; Torre et al., 2012; Whitehead et al., 2014). A study in South Africa looked at 40 HIV-positive toddlers for developmental delays and found that 85% of them had gross motor delays, 12.5% had fine motor delays, and 82.5% had linguistic delays. This shows that developmental delay is very high in this At Risk category. The study assessed children aged 18–30 months using the BSID-II (Baillieu & Potterton, 2008). Vitrikas et al. (2017) reports developmental delay prevalence by domain as 1-1.5%, eight percent, 2-19% and 15% in cognitive, learning disability, speech/language and any delay respectively in United States of America in the general population. This shows that the prevalence of delay is less in the general population than in the At Risk population.

According to the findings of the aforementioned studies, the prevalence of developmental delay is substantial in babies with prenatal and postnatal risk factors, especially in LMICs. Delays in development can occur in any area of development.

2.5 Risk factors for developmental delay

There are many factors affecting child development. A risk factor is “a characteristic at the biological, psychological, family, community, or cultural level that precedes and is associated with a higher likelihood of problem outcomes” (O’Connell, Boat & Warner, 2009: 28). Risk factors for developmental delay can be classified into three categories.

2.5.1 Socioeconomic and environmental factors

Socioeconomic and environmental factors category, which includes low household income (Donald et al., 2019). Several studies established that stunted growth was linked to poor socioeconomic status of the child. Good nutrition is important for brain and physical development, which are important in achieving developmental milestones (Crookston et al., 2010; McDonald et al., 2012; Prado & Dewey, 2012; Sánchez-Vincitore & Castro, 2021; Zhang et al., 2018).

Early Childhood Development (ECD) is the development below the age of eight years. If a child is exposed to risk factors, irreversible changes to the brain's morphology and function may occur. Some of the risk factors affecting ECD include limited access to quality health and nutrition, low educational status of parents, depressed mothers, and lack of stimulation from parents. The risk factors are related, and the presence of one risk factor may increase the chance of the occurrence of another. For example, low socioeconomic status can result in a parent's educational status being low. These risk factors lead to a rise in cognitive and socio-emotional deficits (Jackson et al., 2017; Moriguchi & Shinohara, 2019). Ethnicity also contributes to developmental delay. Marginalised ethnic groups' development is negatively affected by the discrimination they suffer. Some ethnic groups carry rare mutated genes that affect child development (Cama & Sehgal, 2021; Kenyhercz & Nagy, 2021; Walker et al., 2011; WHO, 2018).

2.5.1.1 Nutrition

Poor nutrition affects child development (Pem, 2015). Maternal malnutrition can lead to IUGR which further leads to low birth weight. Globally, approximately 34% of babies below the age of five have stunted growth. (Kenyhercz & Nagy, 2021; Walker et al., 2011). Micronutrient deficiencies such as iron deficiency and iodine deficiency contribute to developmental delay (Walker et al., 2011). Iron deficiency causes anemia, which is a risk factor for developmental delay (Zhang et al., 2018).

Muhoozi et al. (2016) in their cross-sectional Ugandan study evaluated the influence of nutrition level on child development. A total of 512 babies aged 6–8 months were sampled and assessed for development using the BSID-III and the Ages and Stages Questionnaire (ASQ). The developmental assessment outcome was then compared to the nutritional status of the child, and poor nutritional status was found to be associated with developmental delay in motor, cognition and language development. Sharma et al. (2019) established a high odds ratio of developmental delay in babies who were never breastfed.

2.5.1.2 Exposure to toxic substances

Lead poisoning (Walker et al., 2011), as well as alcohol and smoking exposure during pregnancy (Carballo, 2015; Hendricks et al., 2020), are all harmful to children's development. Pesticides and environmental contaminants, for example, can enter the placenta and have a harmful impact on brain development. As a result, children may experience cognitive difficulties and attention deficiencies (Bellinger, 2018; Hirtz, Campbell & Lanphear, 2017). Environmental toxins can cause intellectual disability in 4–5% of cases (Liu et al., 2010).

2.5.1.3 Violence and institutionalisation

Violence (approximately 300 million children <5 years old are exposed to violence), institutionalization (which has cognitive and behavioural consequences on child development), and insufficient stimulation and learning opportunities have all been linked to developmental delays (Walker et al., 2011). Living away from home is linked to poverty and a lack of educational resources. There is also very little interaction with the workers of the institution. These situations have a negative bearing on child development (Morantz et al., 2013, Nelson et al., 2014).

2.5.1.4 Covid-19 pandemic impact on the development of children

The current Covid-19 pandemic environment significantly restricted children's opportunities, and this compromised the health development of many children (Singh, 2021). Stimulating and responsive environments are supportive of cognitive, language, emotional and social competency development. The environmental input effect enhances brain flexibility, making it easy to adapt. In this Covid-19 pandemic, serious injuries and deaths of children under one year of age increased by 40% (Bhopal & Fearon, 2021). Araújo et al. (2021) did a systemic review of literature to establish Covid-19 and other pandemics' impacts on children's development. The study found that Covid-19 caused a significant risk of morbidity and mortality in the global population. Children's health development risk factors were similarly high. The increased social isolation measures, nutritional risks, parental stress, suspension of classroom activities, stress exposure in unstructured homes, and deficiency of exercise activities are the factors that worsened with the arrival of Covid-19 found in the review of literature.

Mental and social stressing factors related to a novel disease pandemic (e.g. Covid-19) affect child development in the long-term (Wang et al., 2020). However, there is a paucity of reports that aim to identify the relationship between child health and the pandemics.

2.5.2 Maternal and child physical factors

Maternal and child physical factors that may impact negatively on child development include preterm delivery of less than 37 weeks, maternal HIV infection (exposure to antiretroviral therapy is a risk factor for developmental delay), maternal low haemoglobin (Hb) <10, maternal age and consanguinity (Abdel Khalek et al., 2018; Donald et al., 2019; Piske et al., 2018). Rare genetic disorders that affect development are prevalent in consanguineous marriages (WHO, 2018). Overall, these negative factors in the maternal history (e.g. obesity and multiple pregnancies) contributed significantly to developmental delay in children (Bajalan & Alimoradi,

2018; Kerstjens et al., 2013). Very low maternal age and very high maternal age beyond 35 years are associated with an increased risk of developmental delay (Falster et al., 2018). Compared to children born to HIV-uninfected mothers, babies born to HIV-infected mothers have a higher risk of developmental delays (Toledo et al., 2021).

In addition to these, other established risk factors for developmental delay are neonatal jaundice, sepsis, low birth weight and major congenital anomalies (Abdel Khalek et al., 2018; Jodeiry et al., 2015). A study by Kenyhercz and Nagy (2021) revealed that low birth weight of less than 1000g, retinopathy of prematurity, bronchopulmonary dysplasia and intraventricular haemorrhage were found to be postnatal causes of delayed cognitive development.

2.5.2.1 Infections

Various forms of infections are associated with developmental delay (Pem, 2015). HIV infection has been linked to developmental delays (Alford & Vera, 2018; Brackis-Cott et al., 2009; Chaudhury et al., 2017; Madlala et al., 2020). A South African study comparing developmental delays in HIV-infected neonates with HIV-uninfected children found that developmental delays were higher in the former group in both the motor and linguistic domains. At three and six months, the results were comparable. At six months, there was no significant difference in cognitive development between the two groups (Whitehead et al., 2014). Another study conducted in Zimbabwe found that HIV-exposed infected had a higher rate of developmental delays than HIV-exposed uninfected (Hutchings & Potterton, 2013). The Griffiths Scales of Mental Development were used to examine 68 HIV-exposed babies aged 3-5 years at a Johannesburg HIV clinic. A substantial developmental delay of 55.9% was discovered in the study. Speech, perception, and cognition were the most affected domains. The personal-social category was the least affected, with 13.4% experiencing significant delays. The research concluded that developmental delay is still present even though combination antiretroviral treatment (cART) is initiated early. Early initiation of cART lessens developmental delay (Potterton, Hilburn & Strehlau, 2016).

Malaria infections also contribute towards developmental delay (Walker et al., 2011). *Plasmodium falciparum* malaria causes placental inflammation that can cause IUGR and low birth weight, which will cause developmental delay (Rogerson et al., 2018; Weckman et al., 2021).

2.5.2.2 Intra uterine growth retardation (IUGR)

Intra uterine growth retardation is when the unborn baby's growth rate is slower than expected, with a foetal weight below the 10^{th} percentile of the population (Sacchi et al., 2018). It results from placental insufficiency in which the foetus is deprived of oxygen and nutrients, and this contributes to developmental deficits (Malhotra et al., 2019).

The brain can be damaged either before or after birth due to IUGR. Poor nutrition, toxins, and placental genes could all contribute to IUGR which is linked to low Apgar scores, low birth weight (LBW), and prematurity. All of these things are known to cause developmental delays (D. Sharma, Shastri & P. Sharma, 2016; Morsing, 2011).

2.5.2.3 Influence of child gender on developmental milestones

Male gender is prone to developmental delay in cognitive and motor development in AR babies e.g. preterm babies (Cho, 2010). Boys have a high prevalence of periventricular leucomalacia and intraventricular haemorrhage which are known causes of developmental delay (Tioseco et al., 2006). Boys also present with neonatal illnesses more than their female counterparts (Pongou, 2013; Rosenstock et al., 2013). Stunted growth due to poor nutrition, which mostly affects boys than girls, is also associated with increased developmental delay in boys compared to girls (Muhoozi et al., 2016).

Brain development is generally slower in boys compared to girls. Animal studies have shown that brain development in girls is faster due to hormonal levels. Magnetic Resonance Imaging (MRI) done on humans also indicates that brain matter volume reaches its peak at 10 years in girls and later in boys at 12 years of age. Girls also have higher dendritic volumes compared to boys. Female brain tissue is more neuroplastic and more likely to recover faster following a brain insult than male brain tissue. As the male brain matures slower than the female brain, it is more prone to insults compared to the female brain (Anderson, Spencer-Smith & Wood, 2011).

Another study conducted in Iran supports that boys have a significantly high risk of developmental delay. Boys had a 0.52 greater chance of having a developmental delay than girls. (Soleimani et al., 2018). Females are generally faster in development except for internalizing behaviours in the 1-6 years age group in Uruguay (Vásquez-Echeverría et al., 2021).

2.5.3 Maternal psychosocial risk factors

Maternal depression during pregnancy, maternal psychological distress, and lifetime intimate partner abuse are all examples of maternal psychosocial risk factors (Donald et al., 2019). Maternal mental health problems increase the chance of developmental delay in children (Donald et al., 2019; Marryat & Martin, 2010).

The other confounding variables influencing child development are difficult to identify and isolate. (Pivik et al., 2007). Therefore, developmental abilities vary across different populations because of these confounding variables.

2.6 Protective factors of developmental delay

A protective factor is defined as “a characteristic at the biological, psychological, family, or community (including peers and culture) level that is associated with a lower likelihood of

problem outcomes or that reduces the negative impact of a risk factor on problem outcomes." (O'Connell, Boat & Warner, 2009: 27). Socioeconomic and environmental variables, mother and child physical factors, and maternal psychosocial aspects are the three types of protective factors.

2.6.1 Socioeconomic and environmental factors

2.6.1.1 Socio-demographics

Socioeconomic and environmental factors contribute towards normal development. Examples of developmental protective factors in children are engagement and connections with peers in religion and culture (Miller et al., 2020)**.** Other protective factors include high maternal education, birth weight and good socioeconomic status (Donald et al., 2019; Alam, Mansur & Barman, 2021). High maternal education is associated with less maternal depression, good nutritional status, quality child rearing environment and better access to intervention programmes (Dagvadorj et al., 2018; Donald et al., 2019; Ngure et al., 2014).

2.6.1.2 Nutrition

Malnutrition increases the chance of developing developmental delay (Saleem et al., 2021). Exclusive breastfeeding in the early months of life enhances cognitive development in addition to visual acuity. Fatty acids in breast milk seem to contribute significantly to brain tissue development (Pem, 2015; Walker et al., 2011). Breastfeeding provides essential nutrition that fights illnesses in childhood. This helps in the attainment of early developmental milestones and language (Oddy et al., 2011) and reduces the risk of neurodevelopmental problems (Horta, De Sousa & De Mola, 2018; Mahurin Smith, 2015; Saleem et al., 2021).

2.6.2 Maternal and child physical factors

Good health of the mother and child contributes positively towards child development (McDonald, 2016; Walker et al., 2011). Female gender and high birth weight are protective factors against developmental delay (Donald et al., 2019).

Maternal age above the age of 15 and up to the age of 30 is a protective factor for developmental delay. Parents in this age category are mature enough to take care of babies at the same time, not too old or too young to be susceptible to delivery complications (Falster et al., 2018). Babies born to HIV-uninfected mothers have a better chance of developing normally compared to children born to HIV-positive women (Piske et al., 2018). Well-nourished children have lesser chances of developing developmental delays compared to malnourished children (Chattopadhyay & Mitra, 2015).

2.6.3 Maternal psychosocial factors

Psychosocial factors such as caregiver positive emotions, sensitivity, and avoiding too much physical punishment also promote child development (Walker et al., 2011). Caregiver-child interactions are important in child development. Things such as talking and smiling at the baby help in building neural connections that make the child's brain strong. Child nurturing plays a significant role in child development (WHO, 2018).

2.7 At risk Surveillance System in the Zimbabwean context

The prevalence of disability in Zimbabwe was seven percent according to the 2013 disability survey (MoHCC, 2013) and increased to nine percent in 2018 according to the latest Poverty Income Consumption and Expenditure Survey. Twenty-five percent of these persons with disability are persons below the age of five years (Zimbabwe Multiple Indicator Cluster Survey (ZMICS), 2019).

At least one functional issue was observed in one out of every ten children aged 2-17 years. Children with disabilities of any kind are among the most marginalized groups. Discrimination faced is in the form of negative attitudes, inadequate legislation and policies; these children significantly have their rights to education, health and survival restricted (ZMICS, 2019).

From birth to age five, the ARSS, which is implemented by the MoHCC in Zimbabwe, tracks both prospective and established disabilities in children. Its primary goal is to identify two categories of risk:

a) Children at risk of developing disability identified for early referral and treatment for possible prevention and

b) Children with established disability who are at risk of developing complications (e.g. contractures) if left untreated who can benefit from rehabilitation services.

The target group for the ARSS is from birth to ≤5 years. In Zimbabwe, the national tracking system is currently identifying some At Risk indicators on the child health card, such as severe neonatal jaundice, delivery complications, and low birth weight among others. Developmental screening and surveillance through the ARSS are critical in detecting any delays and challenges in the child's physical, cognitive, emotional and social abilities. Early detection of developmental delay facilitates early treatment that optimises outcomes (King et al., 2010; Radecki et al., 2011). Without routine screening, only about 30% of babies having developmental challenges are identified before they reach what is termed ECD in Zimbabwe, alternatively referred to as kindergarten in other countries. This means that 70% cases are missed (MoHCC, 2021).

Indicators for At Risk (AR) cases in the ARSS are:

1. Severe neonatal jaundice

2. Apgar scores less than five (both at 1st and 5th minute post-delivery)

3. Severe prematurity with birth weight of <1500 g

4. A term baby with birth weight of <2500 g

5. Neonatal Malaria/Tuberculosis infections or Meningitis

6. HIV exposure

7. Neonatal seizures

8. Term infant with delivery complications e.g., severe birth asphyxia, birth trauma

9. Floppy baby (Hypotonia)

10. Baby didn't cry within 24 hours after birth

11. Baby didn't suck/poor sucking reflex within 24 hours after birth

If a child presents with any one of these 11 indicators stated, a green AR sticker is placed on the Road to health card of the baby as an entry point to the ARSS. This will allow follow up by the rehabilitation professionals in the early identification of neurological development challenges. If a neurological development delay is detected, a red R sticker is affixed on the child's card and rehabilitation treatment is initiated (MoHCC, 2012; MoHCC, 2021).

Dzvukamanja et al. (2017) evaluated the ARSS in Chimhanda Disrict, Mashonaland Central, Zimbabwe. This was a qualitative study in which 51 healthcare workers who were directly involved in the ARSS recruited using purposive sampling. The questionnaires administered by

the interviewer, comprehensive interview guide, records review and checklists were data collection tools used. On a five-point Likert scale, participants' knowledge of the ARSS was assessed. Although the majority of responders were knowledgeable on the age range covered by the ARSS, there was a need for additional training.

2.8 Child developmental assessment tools

According to the American Academy of Pediatrics, developmental assessment tools should look at every aspect of a child's development and be able to identify areas that are delayed, allowing for proper diagnosis, treatment, and referral (Lipkin & Macias, 2019; Weitzman & Wegner, 2015). The tool should also be culturally sensitive (Vitrikas et al., 2017). Several different types of developmental screening tools are used which are either standardised or non-standardised. The gold standard tools provide quality data, but may require extensive training of persons administering them. The degree of accuracy relies on the quality of test and its appropriateness to the study population (Fernald et al., 2009).

It is also important that developmental assessment instruments are validated across countries. A study by Ozturk Ertem et al. (2018) examined the Guide for Monitoring Child Development (GMCD) in four countries (South Africa, Turkey, Argentina and India) to determine its sensitivity and specificity. Developmental delay of 30% was established in four countries with a sensitivity and specificity of 0.71–0.94 and 0.69–0.82 respectively. The study found that the GMCD was accurate in predicting developmental delays in children from various nations. Mendonça and Fetters (2016) concluded that no single tool performed equally well across all cultures in their well-researched systematic analysis of cross-cultural validity of motor assessment methods. As a result, services may be referred insufficiently or excessively.

Parent questionnaires, such as the Ages and Stages Questionnaire (ASQ), the Minnesota Child Development Inventory (MCDI), the Paediatric Evaluation of Developmental Status (PEDS), the Parent Report of a Child's Abilities revised for preterm infants (PARCA-R), and the Kent Inventory of Developmental Skills, are examples of developmental assessment tools (KIDS).

These tools are intended to identify babies who require additional investigation (Johnson et al., 2006). Developmental screening instruments for child development are becoming common and are believed to have high degree of accuracy compared to previous estimates (Kerstjens et al., 2009). Significant disability can be better predicted by scores that are 3 SD below the average (Johnson et al., 2006). Some developmental screening tools being administered by trained cadres include but not limited to the Denver II screening test, Batelle Developmental Inventory and the Bayley-III Neuro-developmental Screener. However, these tools require effort and time for their administration and interpretation (Kerstjens et al., 2009).

The ASQ has been proven to work in a variety of cultures (Armijo, Schonhaut & Cordero, 2015; Kapci, Kucuker & Uslu, 2010; van Heerden et al., 2017). It has 40 items inclusive of parental questions. It has 86% and 85% sensitivity and specificity respectively. Child Development Review–Parent Questionnaire (CDR-PQ) is another tool which has been validated (Verhoeven et al., 2016) and has 32 questions and 99 additional items. It has a sensitivity and specificity of 68% and 88% respectively. Infant Development Inventory tool has not been validated. It has 85 items with sensitivity and specificity of 75-85% and 70-77% respectively. Parents' Evaluation of Developmental Status have been validated (Gustawan, Soetjiningsih & Machfudz, 2016) and has 10 items with sensitivity and specificity of 74-80% and 70-80% respectively. The developmental assessment tool should have a balance of sensitivity and specificity to minimize false positives and false negatives. A good tool should have a sensitivity of 70-80% and a specificity of 80% (Vitrikas et al., 2017).

Most of these tools were developed in Western countries and are culturally not adapted to the local setting and may not adequately measure developmental delay in the rural settings. Preliminary research in Malawi found that Western-developed tools were 97% trustworthy in gross motor, 91% in language, and 79% in fine motor, and that they fit well with logistic regression. Social items performed worse (51%) and were deemed culturally insensitive. To close the gap, the Malawian Developmental Assessment tool was developed. It demonstrated a high level of sensitivity and specificity of 97% and 82% respectively with more culturally appropriate social items (Gladstone et al., 2010).

A study by Milbrath et al. (2020) compared usability and adaptability of the ASQ and Cognitive Adaptive Test/Clinical Linguistic and Auditory Milestone Scale (CAT/CLAMS) in Limpopo, South Africa. The study reviewed that both tools needed language and cultural modifications to suit local needs as both tools were not locally developed. The ASQ was found to require less time to administer and its equipment was affordable compared to CAT/CLAMS.

2.9 The Bayley Scales of Infant and Toddler Development (BSID-III)

The BSID-III is an independently administered tool that evaluates developmental functioning in infants and toddlers aged one to 42 months. The BSID-III assesses cognitive, linguistic (receptive and expressive), motor (fine and gross), adaptive behaviour, and social-emotional development across five domains (Bayley, 2006: 3-9). These domains are significant in assessing children and in documenting developmental delays, according to the Individuals with Disabilities Educational Improvement Act (IDEA) of 2004. They also aid in the development of solutions (Individuals with Disabilities Education Improvement Act (IDEA), 2021). Historically, the BSID-III was regarded as the gold standard instrument for paediatric assessments and research. Its revision will continue to provide important information on developmental status of children (Weiss, Oakland & Aylward, 2010). The BSID-III was standardised using a demographically stratified sample of 1 700 children of age range 16 days – 43 months 15 days (Bayley, 2006: 31).

The BSID-II was the gold standard for child evaluation in research and clinical work, and it was a widely used standardised assessment tool (Campos et al., 2006; Gauthier et al., 1999; Rademeyer & Jacklin, 2013). The BSID-1 (issued in 1969) and BSID-II (launched in 1993) were replaced by the BSID-III (2006 edition). Concerns that the BSID-III might overestimate children's developmental status led to the release of the BSID-IV in 2019 (Bayley & Aylward, 2019).

The BSID-III is used to assess competence skills in children aged between one to 42 months and to detect deficits existing in the five main developmental domains and provide necessary information required for designing the management plan for developmental delay. In developing

the BSID-III, some items were removed from the BSID-II and some new items were added at the same time maintaining the nature and purposes of the Bayley Scales (Bayley, 2006: 1).

2.9.1 Developmental domains assessed by the BSID-III

Motor, language and cognitive domains were solely used to determine developmental delay in sub-Sahara Africa (Hutchings & Potterton, 2013). Similarly, these three composites were used in the South African study. The BSID-III tool is an appropriate instrument for use in the South African black population because there was a negligible difference between the black South African population and the US norms (Rademeyer & Jacklin, 2013).

The BSID-III has five scales:

Cognitive

Include information processing, habituation, memory etc. It is derived from sensory/perceptual and motivation. It assesses the child's memory and ability to habituate to auditory and visual stimuli (Bayley, 2006: 3-4).

Language

This describes communication. This can be in form of receptive and expressive.

a) Receptive communication
   Auditory acuity is assessed on child's ability to respond to sound, discriminate between sounds and to localize sound.
b) Expressive communication
   Child's ability to vocalise is assessed. Throaty sounds, babbling, speaking and gestures (non-verbal communication) form part of expressive language (Bayley, 2006: 5-6).

Motor

This describes movement, sensory integration, perceptual-motor integration, prehension and locomotion. It constitutes fine and gross motor:

a) Fine motor
   The child's coordination and control of eye movements are assessed.
b) Gross motor
   Child's locomotion (crawling, walking etc.) are assessed (Bayley, 2006: 6-7)

Socio-emotional

Describes the ability of establish relationships and express emotions (e.g. joyful intimacy, assertiveness etc.). Emotional function can be accurately observed and reported in a naturalistic environment (Bayley, 2006: 7-9).

Adaptive behaviour

These are functional skills required for independence in Activities of Daily Living (ADL). It looks at what the child actually does. A parent/primary caregiver completed questionnaire gathers the adaptive information required (Bayley, 2006: 9-10).

2.9.2 Cognitive, motor and language composites

The composites for these developmental domains have a mean of 100, the Standard Deviation of 15 and range from 40 to 160. The scaled scores are used to derive percentiles which are then converted composite scores (Bayley, 2006: 52).

2.9.3 Qualitative descriptions of BSID scores

All the developmental domains which he BSID-III assesses can be placed into seven classes based on the composite scores as follows:

Table 2.1 Qualitative Descriptions of composite scores for BSID-III developmental domains

Composite Scores	**Classifications**
≥130	-Very superior
120 - 129	-Superior
110 - 119	-High average
90 - 109	-Average
80 - 89	-Low average
70 - 79	-Borderline
≤69	-Extremely low

(Bayley, 2006: 108-114)

2.9.4 Reliability

The accuracy, consistency, and stability of test scores across varied settings are referred to as test reliability. The BSID-III instrument has high average reliability coefficients (r_{xx}) in all the five domains. The reliability coefficients are 0.91 (cognition), 0.87 (receptive language), 0.91

(expressive language), 0.86 (fine motor), 0.91 (gross motor), 0.93 (language) and 0.92 (motor). The reliability coefficients were even higher in Special Groups (At Risk of developmental delay, Down's syndrome, communication impairment, cerebral palsy (CP), pervasive developmental disorder, prenatal alcohol exposure, prematurity or low birth weight, small gestational age and birth asphyxia). The special groups had reliability coefficients 0.96 (cognition), 0.95 (receptive language), 0.96 (expressive language), 0.94 (fine motor) and 0.98 (gross motor) (Bayley, 2006: 55-67; Campos et al., 2006; Gauthier et al., 1999; van Baar, 2014).

2.9.5 Test-Retest stability

Test retest reliability is the nearness of the agreement between successive measurements when the same test is repeated under similar conditions (Vilagut, 2014). The BSD-III has high stability coefficients of 0.81 (cognition), 0.83 (receptive communication), 0.87 (expressive communication), 0.80 (fine motor), 0.82 (gross motor), 0.87 (language) and 0.83 (motor) (Bayley, 2006: 55-67).

2.9.6 Validity

2.9.6.1 Construct validity

This explains how well an instrument measures the domain it promises to measure (Polit & Beck 2012). The BSID-III instrument has a good level of validity, according to the research (Van Baar, 2014). Each object has a stronger relationship with the scale on which it is put than it does with other scales. The age scales correspond in a low to moderate range. Construct validity is supported by these substantial correlational tendencies. The BSID-III correlates with other instruments in a predictable fashion as well. With a correlation coefficient of 0.71, the BSID-III language composite and the BSID-II Mental Development Index (MDI) are significantly associated; the cognitive scale has a high correlation coefficient of 0.79 with the FSIQ (Bayley, 2006: 69-103).

When scales are used for diagnostic assessment in the clinical context in special populations such as children at risk of developmental delay, additional proof of validity is presented. All Bayley composites and subtests showed that At Risk children performed significantly worse than those in the control group. (Bayley, 2006: 69-103). In the context of our study, the tool was validated in special groups (e.g children with birth asphyxia) (Bayley, 2006: 84-103); and was previously used successfully for the Zimbabwean population by Hutchings and Potterton (2013) and detected developmental delay well in Zimbabwean children.

2.9.7 Strengths and weaknesses of the BSID-III

The strengths of the BSID-III are that the test items can be administered in a flexible manner, the tasks involved in the assessment are interesting and the behavioural rating scale is incorporated. It is also suitable for use by the interdisciplinary team. It has been used around the world including in many African countries (Potterton et al., 2009; Shead et al., 2010; Whitehead et al., 2014; Van Rie et al., 2008) which allows for comparison between studies.

Identified weaknesses were the kit layout, directions are not clarified and the materials used are not durable. Continuous improvements of the BSID aim to improve the weaknesses and retain its strength (Gagnon & Nagle, 2000). This instrument is not suitable in severely impaired child to get norm-referenced scores. For the very young age group 0-6 months it has low reliability (Bayley, 2006). It is also expensive, time consuming and require highly trained personnel to administer (Aylward, 2018). There is concern about BSID III overestimating children's abilities (Bos, 2013).

2.9.8 Classification of developmental delay

The severity of developmental delay is the degree of delay in development (Choo et al., 2019) and categorized into mild (functional age <33% below chronological age), moderate (functional age ranging 34%–66% of chronological age) and severe (functional age <66% of chronological age) (Mithyantha, Kneen, McCann & Gladstone, 2017). Significant developmental delay is when

child performance is ≥2SD below the average on norm-referenced age-appropriate standardised tests (conducted at a secondary or tertiary care setting) (Bellman et al., 2013).

The delay can affect one domain (isolated developmental delay) or >1 domain. A significant developmental delay in ≥2 domains affecting children <5 years is referred to as Global Developmental Delay (GDD) (Shevell et al., 2003).

2.10 Role of physiotherapy in developmental delay

Neurodevelopmental treatment (NDT) is "a hands-on treatment approach used by physical therapists, occupational therapists and speech-language pathologists" (Physical Therapy Clinic, 2021). Physiotherapy in form of NDT help to improve developmental outcomes both in developmental delay without CP and developmental delay with CP. The Gross Motor Function Measure (GMFM) significantly improved after intervention in children with developmental delay and the improvement was maintained three months beyond intervention ($p<0.05$), and treatment of developmental delay is strongly recommended (Kyoung et al., 2017). Rapid brain development occurs in infancy, and interaction with the environment plays a crucial role. Therefore, early intervention should be considered (Sung, Shin & Park, 2013). Rehabilitation, injury factors, environment factors and age factors are important in recovery post brain insult (Anderson et al., 2011).

Hielkema et al. (2011) found a correlation between improved motor outcomes and caregiver coaching and challenging the child to self-produced motor activity for three months in At Risk babies in a study. This backs up the importance of physiotherapy in child development. The two alternative physiotherapy treatment modalities, COPing with and CAring for Infants with Special Needs (COPCA) and traditional infant physiotherapy, were compared. There two groups had similar outcomes.

Potterton et al. (2009) performed a randomised controlled experiment in South Africa to look into the efficacy of a stimulatory home program on child development in HIV-infected babies

aged <2.5 years. The BSID-II was used to examine the patients in the comparison and control groups. A stimulating home program was found to have a positive impact on child's cognition (p=0.010) and motor development (p=0.020).

2.11 Conclusion

Following a thorough review of the literature, it was determined that further research is needed on the prevalence of developmental delay and its associated risk factors in At Risk children in Africa, particularly in Zimbabwe. This will add to the body of knowledge on the subject.

The next chapter discusses the methodology or steps taken in carrying out this research. Instruments used and the way they were used will be also unpacked.

CHAPTER 3: METHODOLOGY

This chapter outlines the overall methodology that was used in this study. This includes the study design, study site and the participants, sampling procedure and the methods used to collect data, tools and measurements used, data management, statistical analysis approaches that were used to assess for associations and to estimate effect sizes and the study's ethical considerations.

3.1 Study design

The design used for this study was a descriptive cross-sectional study. It is quick and inexpensive type of study that gathers a lot of information from many participants. This study design determines the prevalence of, and risk factors for a medical condition and has been used previously in similar prevalence studies (Hakim et al., 2018; Setia, 2016).

3.2 Study site

The research was carried out at United Bulawayo Hospitals. This hospital was established in 1937. The hospital is one of the largest five central hospitals in Zimbabwe and is in Bulawayo, the second largest city in the country. It comprises of maternity, paediatric, medical, ophthalmology, orthopaedic and physiotherapy units under one administration. It is also a teaching hospital for the National University of Science and Technology. Babies born in the maternity unit with risk factors for developmental delay (e.g. low Apgar scores of <5 in the first five minutes after birth and low birth weight of <2500 g for full term babies) are enrolled into the ARSS by the physiotherapy department and are followed up by the same department together with the department of paediatrics to detect developmental challenges so that rehabilitation can be commenced early. The follow-up starts from when the child is two months of age and goes on up to the age of five years.

3.3 Study population

The study population was all babies between two months and five years enrolled in the ARSS between 2019 and 2020 at United Bulawayo Hospitals.

3.3.1 Inclusion criteria:

- Babies aged between two months and two years born at United Bulawayo Hospitals who had developmental delay risk factors and were enrolled in the ARSS between 2019 and 2020.

- Babies who attend routine clinic care with their primary caregivers.

- Babies with the primary caregiver who agreed to sign the consent forms to participate in the study.

3.3.2 Exclusion criteria:

- Babies with clinically apparent congenital deformities e.g. spina bifida.

- Babies already receiving physiotherapy treatment.

- Babies who were ill at the time of developmental assessment (Temperature >38^{O}C, signs of respiratory distress, etc.).

3.4 Study sample and sampling

A total of 160 babies who met the inclusion criteria were systematically selected from 271 babies who had been enrolled in the ARSS at United Bulawayo Hospitals between 2019 and

2020. The sample size was calculated using the Dobson formula with a 5% margin of error and 95% confidence level (RaoSoft Sample size calculator, 2016).

The systematic sampling procedure had a different random start each day (e.g. on the first day, every fourth baby with a start of baby number two was sampled; while on the second day, every fourth baby with a start of baby number one was sampled, etc.). This was repeated and continued until a sample size of 160 was attained. Sampling was done at the baby's scheduled appointments for a developmental check-up. This was based on a number assigned to each eligible baby on their arrival for appointments (baby to arrive first was given the first number and the one arriving last got the last number).

3.5 Measurement tools

3.5.1 Self-developed data collection tool

A data collection tool (**Appendix A**) was developed by the principal investigator to collect information from patient records (birth registers, baby cards), parents/caregivers (for obvious information that may be absent from records such as the baby's position of birth in the family) and developmental assessment findings. The research assistant was trained by the principal investigator to complete this form.

The data collection tool has three sections:

Section A

Captured the socio-demographic profile of participants. Items 1-16 were included.

Section B

Comprises a checklist of At Risk factors at birth on the At Risk Surveillance System. These were numbered 1-11.

Section C

This captured the summarised and interpreted BSD-III developmental assessment findings in categories numbered 1-3.

3.5.2 Validity and Reliability of the data collection tool

3.5.2.1 Content Validity

To enhance the content validity of the self-developed data collection tool, a panel of the multidisciplinary team (physiotherapists, occupational therapists, nurses and medical doctors) involved in Neuro-developmental clinic at United Bulawayo Hospitals were brought together to analyse the data collection tool together with objectives of the study and provide their input. All their recommendations and suggestions were factored in. The revised edition was sent to the supervisor who is a paediatric physiotherapy lecturer who constructively critiqued it again and the suggestions made were implemented. This led to the final draft which was distributed again to the multidisciplinary team and the supervisor who were satisfied with the final draft.

3.5.3 Bayley Scales of Infant and Toddler Development (BSID-III) tool

The BSID-III tool (**Appendix B**) was used in assessing development of each child. The tool can be administered in approximately one hour and assesses child development in 1-42 months age ranges. It assesses developmental domains such as cognitive, motor (both fine and gross) and language (both receptive and expressive) areas (Bayley, 2006). Scaled, composite, and growth scores, as well as percentile ranks, are the four types of norm-referenced scores on the BSID-III.

There are developmental age equivalents (for the subtests) and confidence intervals (for all measures) available (Bayley, 2006). The present study derived composite scores only for data analysis.

Babies were assessed as per their age group. Scores were calculated for cognitive, language and motor abilities. The rating scales for behaviour and socio-emotional were not used in this research. Cognitive, motor (gross and fine motor combined), and language (both expressive and receptive) composite scores were obtained. The BSID-III kit used in this study for developmental assessments was borrowed from the Wits Physiotherapy Department, and the principal investigator was trained on how to administer it by his supervisor. The supervisor is a paediatric physiotherapy professor with vast experience in administering the BSID-III tool. The BSID-III kit comprises toy-like items which are used in assessing child development by observing exploration.

The BSID is praised for its high accuracy in detecting developmental delay in other similar studies in Sub-Saharan Africa (Baillieu & Potterton, 2008; Drotar et al., 1997; McGrath et al., 2006; Potterton et al., 2009; Shead et al., 2010; Whitehead et al., 2014; Van Rie et al., 2008) with high validity and reliability described in Chapter two.

3.6 Research Procedure

3.6.1 Recruitment

Data collection was done during normal working hours, and participants were babies attending the ARSS at United Bulawayo Hospitals. One Hundred and sixty (160) participants who met the inclusion criteria were enrolled for the study. The principal investigator and his assistant were introduced to potential participants by the Sister in Charge of the Out Patient Department. Caregivers of infants attending the follow-up clinic who were systematically sampled were approached by the principal investigator. Caregivers of infants who met the study's inclusion criteria were informed about the research procedure. Potential participants were given enough

time to read the information sheet and consent form and to ask questions. Those who had queries had them answered to their satisfaction by the principal investigator. The study's purpose was clearly indicated on the information sheet, which also asked for their permission to have their child participate in the study [see **Appendix C** (English version)**, Appendix D** (Shona version) and **Appendix E** (IsiNdebele version)]. If interested in participating, the infants' caregivers were invited to take part in the study. They were requested to sign the consent forms to give their consent that their child participate in the study if they were still interested in taking part in the study. The principal investigator and the research assistant who are fluent in English, Shona and IsiNdebele explained the contents of the information sheet and consent form to caregivers.

Parents/guardians who signed a consent form were then escorted into the assessment room one by one. The research assistant recorded their demographic information and birth history obtained from caregivers and hospital cards. Any mental health conditions of mothers were also obtained from hospital cards under maternal health conditions. For preterm babies, a corrected age was calculated using the gestation age recorded on the child health card. Each child was then assessed using the BSID-III for approximately 60 minutes by the principal investigator while the caregiver helped in making the baby comfortable. The principal investigator communicated with the caregiver and the child in their mother language during developmental assessments which were conducted in a separate quiet room. Items were administered in the order recommended in the BSID-III administration manual. Participants were selected and assessed from the first quarter to the end of the second quarter of 2021 when Covid-19 challenges were being experienced in Zimbabwe.

3.6.2 Bayley Scales of Infant and Toddler Development Assessment Procedure

Developmental status was assessed on all the 160 infants using the BSID-III. This is a gold-standard observational development measure for children aged 1-42 months. Firstly, the participants' chronological age which determined the starting point in the test was calculated. The age corresponds to a letter of the alphabet as a starting point (the letters range from A to Q). The test was started in each subtest according to the tool's rules. The following reversal and discontinuance rules were then applied: at their age-specific beginning point, a kid should

receive a score of one for all three of the initial successive three items. In the event that this is not possible, the test should be restarted at the preceding age group's starting point. This went on until the child had mastered the first rule. When the child received five consecutive item scores of zero, the test was stopped (Bayley, 2006: 50-51). When babies were irritated, they were given a five-minute pause to eat or change their diapers if necessary. Those who had developmental delays were directed to the relevant medical professionals for assistance.

Developmental outcomes from assessments of babies development for the motor, language and cognitive aspects were captured in section C on the data collection tool, summarized as composite scores and developmental category (normal or delayed and severity where developmental delay was present).

Items in the kit were cleaned with 70% alcohol based sanitizer after each baby was assessed, one child was allowed in the assessment room at a time and the room was disinfected after each session in line with Covid-19 prevention protocols.

3.6.3 Data collection personnel

A research assistant helped the principal investigator with recording patient socio-demographic information and answering questions caregivers had on this research. She was trained by the principal investigator to record patient information.

The principal investigator administered the BSID-III and recorded the assessment findings. Prior to commencement of data collection, the principal investigator was trained on how to administer the BSID-III by his supervisor.

3.6.4 The Pilot study

The principal investigator received training in the use of the BSID-III from his supervisor at the University of the Witwatersrand's Department of Physiotherapy. During training, the data

collection sheet (**Appendix A**) and the BSID-III (**Appendix B**) were piloted on one patient (to minimize unnecessary exposure to patients as this was done at the peak of Covid-19) who was not included in the main study following the procedure prescribed for the main study and no adjustments were made to the tools as they were found to collect all the required information. The principal investigator conducted additional four assessments independently at United Bulawayo Hospitals, scored them and then discussed the scoring online with his supervisor. No changes were made as all the required information was fully captured. This pilot study followed the main study protocol, and it projected the time required for the collection of data to one hour for each patient.

3.7 Data collection

The principal investigator assessed 160 babies (118 babies <12 months and 42 babies >12 months but <24 months). There were no funding to send the assistant to South Africa for training, hence the principal investigator completed all of the tests. Assessments took approximately 60 minutes. Assessment, scoring and interpretation of delay in development were done in accordance with the BSID-III manual protocol. Raw scores were totalled at the end of each examination and then converted to scaled scores (Bayley, 2006: 108-109) and composite scores (Bayley, 2006: 109-110). The established composite scores were classified according to ranges: Normal (≥85), Mild (70-84), Moderate (55-69) and Severe (<55) to determine how the baby was performing (Johnson et al., 2014).

3.8 Data Management

Anonymised data was captured on Research Electronic Data Capture (REDCap) database tools hosted by the Wits University (Harris et al., 2009). A password protected computer accessible only by the principal investigator and his assistant was used.

3.9 Data analysis

Statistical package STATA (version 15.0 for Windows) software developed by StataCorp was used to clean data for errors of entry and to analyse data. Normally distributed continuous variables were summarized by the mean and standard deviation at 95% confidence interval (95% CI). Skewed data was described using mean and interquartile range. Prior to running regression models, the analysis followed a pre-determined strategy. The BSID-III measured the early childhood development outcome scores in three developmental domains which are motor (gross and fine combined), cognition and language/communication (expressive and receptive combined). Severity of developmental delay was classified based on the flowing BSID-III composite ranges: Normal (≥85), Mild (70-84), Moderate (55-69) and Severe (<55). We used a BSID-III cut-off score of less than 85 to define developmental delay leading to two categories of developmental delay (score <85) and no developmental delay (score ≥85) as in other studies (Baillieu & Potterton, 2008; Hutchings & Potterton, 2013; Potterton et al., 2009). The frequency with percentages was used for categorical data. Categorical variables association (association between risk factors and developmental delay) was tested and the Chi-square (X^2) test was used. A p-value of ≤0.05 indicated a strong association between the risk factor and developmental delay. In situations where the expected frequency was less than five in the cell, the Fischer exact test was used.

Separate logistic regression for each domain was used to analyse developmental delay outcome data. Odds ratio (OR) were presented with 95% Confidence Intervals (CI). Complete case analysis approach was used since we had no missing data. Initial models were adjusted for maternal level of education, child sex and child age (months) since they are factors proven to impact child development outcomes in all the three developmental domains. Other covariates, ranging from socio-demographic and environmental factors to maternal and child physical characteristics, were added in blocks. To reduce Akaike Information Criteria (AIC), covariates from each block were picked using the STATA 15.0 “gvselect” command. Only the subset of these variables that decreased the AIC were kept in mind for the next block (this would include an empty set, which would arise if no variables reduced AIC from the previous model).

The principal investigator analysed whether there was any interaction between child sex and the retained variable from the best-subsets when the final model that assessed the link between risk factors, protective variables, and each developmental outcome was run. Regression modelling decreased the AIC even more, allowing the principal investigator to see if the gender of the child affected the relationship between the developmental result and any of these variables. The principal investigator reported the multivariate final model with no interaction terms based on the outcomes of AIC. In measuring the global developmental delay outcome in each of the three domains of cognition, language (receptive and expressive combined), and motor (fine and gross combined), a similar process was used. Statistical expertise was sought from a biostatistician for the logistic regression. The data analysis is summarised in Table 3.1.

Table 3.1 Data Analysis table

Objective	Variables	Statistical test/s
1. To calculate the prevalence of developmental delay among children under two years of age enrolled in the ARSS at United Bulawayo Hospitals using the Bayley Scales of Infant and Toddler development (BSID-III).	Developmental delay (composite score <85)	Frequency and percentages
2. To determine the severity of developmental delay in children under the ARSS at United Bulawayo Hospitals.	Composite scores for the motor, language and cognitive development	Mean and standard deviation Chi-square test for association between categorical variables The frequency with percentages of different categories/severity of developmental delay
3. To identify risk factors that are associated with developmental delay in children under the ARSS at United Bulawayo Hospitals.	**See Appendix A**	Frequency and percentages Logistic regression – to identify the most important risk factors adjusting for confounding variables

3.10 Ethical considerations

The following steps were taken to ensure that the study met all ethical requirements:

- Unconditional Ethical clearance was obtained from the Wits University Human Research Ethics Committee (Medical) before data collection was commenced. Clearance number: M200869 (**Appendix F)**.

- Permission and proposal review was sought from the Medical Research Council of Zimbabwe following recommendations of Wits HREC and was granted before data collection commenced. Approval number MRCZ/B/2019 (**Appendix G**)**.**

- Permission was sought from the Clinical Director at United Bulawayo Hospitals and was granted (**Appendix J**).

- Permission was sought from the Head of Physiotherapy Department at United Bulawayo Hospitals and was granted (**Appendix K**).

- Caregivers of the children signed an informed written consent form (**Appendix C**) presented in laymen's language and translated to local languages (Shona – **Appendix D** and IsiNdebele – **Appendix E**). The Shona and Ndebele versions were back-translated to English language to check for consistency of the information. Since children involved were under two years, child assent forms were not applicable.

- Participation was voluntary.

- Participants were allowed to withdraw from participation without any prejudice and no explanation was required from them for taking such action.

- Data gathered is being kept anonymously (as code numbers were used on data collection sheets) and confidentially. The coded list of names is stored separate from the data collection sheets and is kept under lock and key. Computer data is password protected and can only be accessed by this principal investigator and his assistant.

- Child developmental assessments were done safely without any physical, psychological or social harm. Local Covid-19 protocols were adhered to and all equipment was cleaned with a disinfectant between participants.

- Children who were found to have significant developmental delay were given review dates to commence rehabilitation treatments on existing treatment days for those diagnosed of developmental delay.

- All ethical principles were strictly adhered to.

The results from this study were analysed and will be presented in chapter four. These will be in form of frequency tables, Venn diagram and logistic regression table which will be supported by interpretation and explanation notes.

CHAPTER 4: RESULTS

This chapter presents the results of this study. The children and their parents' demographic information is presented first and is followed by risk factors associated with developmental delay. The findings of the developmental assessments will be reported. Descriptive statistics were used in data analysis and are shown in the following tables with frequencies and percentages, means and standard deviations. Finally, the outcome of the logistic regression analysis is presented.

4.1 Socio-demographic characteristics

A total of 271 babies identified with risk factors for developmental delay in 2019 and 2020 at United Bulawayo Hospitals were enrolled in the ARSS. Of these 160 (59%) babies aged between 2 and 24 months who met the inclusion criteria were systematically invited to participate in the study. All the 160 enrolled babies, of whom 94(58.7%) were males, had the BSID-III assessment completed. The maternal demographic and characteristics for those children completing three domains of the BSID-III (cognition, language and motor) are presented in tables 4.1 and 4.2.

The mean age for the mothers was 30.2(sd: 5.4) years, 90% of them were married whilst 10% were either widowed or not married. The level of education of at least secondary education was high at 83% for the mothers and 82% for the fathers. At least one parent was employed in 85% of families. However, there was low medical aid cover for the children at only 25.6%. The majority stayed in urban areas with 74.4% of them staying in high density suburbs of Bulawayo City. Only 5.6% stayed in a rural area. Most mothers had a good mental health status at the birth of the child, 98.1%, table 4.1.

Table 4.1: Socio-demographic characteristics

(n=160)

Variable	
Maternal age in years (Mean, SD)	30.2(5.4)
Marital status of mother n(%):	
Married	144(90.0)
Widowed	5(3.1)
Single	11(6.9)
Education: secondary and above n(%):	
Mother	
Yes	133(83.1)
No	27(16.9)
Father	
Yes	131(81.9)
No	18(11.2)
Not indicated	11(6.9)
At least one parent employed: n(%)	
Yes	137(85.6)
No	23(14.4)
Medical aid cover for the child: n(%)	
Yes	41(25.6)
No	119(74.4)
Residential area: n(%)	
Urban: High density	119(74.4)
Low density	32(20.0)
Rural	9(5.6)
Maternal mental health status at birth of child: n(%)	
Good	157(98.1)
Poor	3(1.9)

Table 4.2 shows the characteristics of children who completed the BSID-III assessment. Their mean age was 8.6(sd: 6.4) months. One-quarter (25.5%) of the babies were born to primigravid mothers and 30.6% were preterm (<37 weeks' gestation). Less than half (42.5%) of the babies

were delivered through normal vaginal delivery. Exclusive breast feeding was relatively high with 135 (84.4%) of the children exclusively breastfed for the first six months.

Table 4.2: Characteristics of babies who completed BSID-III developmental assessment (n=160)

Variable	
Child sex: n(%)	
Male	94(58.7)
Female	66(41.3)
Child age in months (Mean, SD)	8.6(6.4)
Position of birth in family: n(%)	
First	44(25.5)
Second	61(38.1)
Third or more	56(34.4)
Preterm (<37 weeks of gestation): **n(%)**	49(30.6)
Mode of delivery: n(%)	
Normal vaginal delivery	68(42.5)
Forceps delivery	9(5.6)
Vacuum extraction	10(6.3)
Emergency C-Section	73(45.6)
Birth head circumference (cm), Mean, [Range]	34.2[28 - 54]
Birth length (cm), Mean, [Range]	47.8[29 – 58]
Birth weight (grams), Mean [Range]	2718.7 [1020 - 4150]
Mode of feeding in first 6 months: n(%)	
Exclusive breastfeeding	135(84.4)
Bottle feeding	19(11.9)
Solids	6(3.7)

4.2 Risk factors for developmental delay

Table 4.3 shows the risk factors for developmental delay at birth. Of the 160 babies, a total of 49(30.6%) were preterm babies, with 47(29.4%) having been HIV-exposed, 42(26.3%) having had Apgar scores <5 at both 1st and 5th minute. A total of 34(21.3%) were recorded to have had experienced severe neonatal jaundice.

Table 4.3: Risk factors (in the ARSS inclusion criteria) for developmental delay at birth (n=160)

Variable	**n(%)**
Severe neonatal jaundice	34(21.3)
Apgar scores <5 (both at 1st and 5th minute after birth)	42(26.3)
Severe prematurity (birth weight <1500 g)	14(8.8)
Term baby with birth weight <2500 g	12(7.5)
Neonatal Malaria/Tuberculosis/Meningites infections	18(11.2)
HIV exposure	47(29.4)
Neonatal convulsions	11(6.9)
Term baby with delivery complications	14(8.8)
Preterm (<37 weeks of gestation)	49(30.6)

4.3 Child development assessment outcomes

4.3.1 Child development outcome mean scores during the first 24 months

Table 4.4 shows child development outcomes in the three domains. On composite scores, girls exhibited higher scores than boys which translated to significant mean lower score differences for boys compared to girls. Higher percentages of poor development outcomes (i.e. a composite score below 85) were observed for boys compared to girls.

Table 4.4: Child development outcome mean composite scores during the first 24 months (n=160)

Developmental subscale	**Total n=160**	**Male n=94**	**Female n=66**	**p-value**
Motor:				
Mean score (sd)	77.4(18.9)	73.0(18.9)	83.7(17.2)	0.001
Poor motor outcome, n(%)	96(60.0)	68(72.3)	28(42.2)	
Language:				
Mean score(sd)	78.7(17.0)	75.6(18.7)	83.1(13.0)	0.003
Poor language outcome, n(%)	91(56.9)	63(67.0)	28(42.4)	
Cognition:				
Mean score(sd)	77.0(16.4)	74.3(17.2)	80.9(14.6)	0.006
Poor cognitive outcome, n(%)	108(67.5)	72(76.6)	36(54.6)	

4.3.2 Child development delay outcome classification by severity

Table 4.5 shows developmental delay classification by severity for the children in the ARSS at United Bulawayo Hospitals. Girls were significantly more likely to score in the normal category.

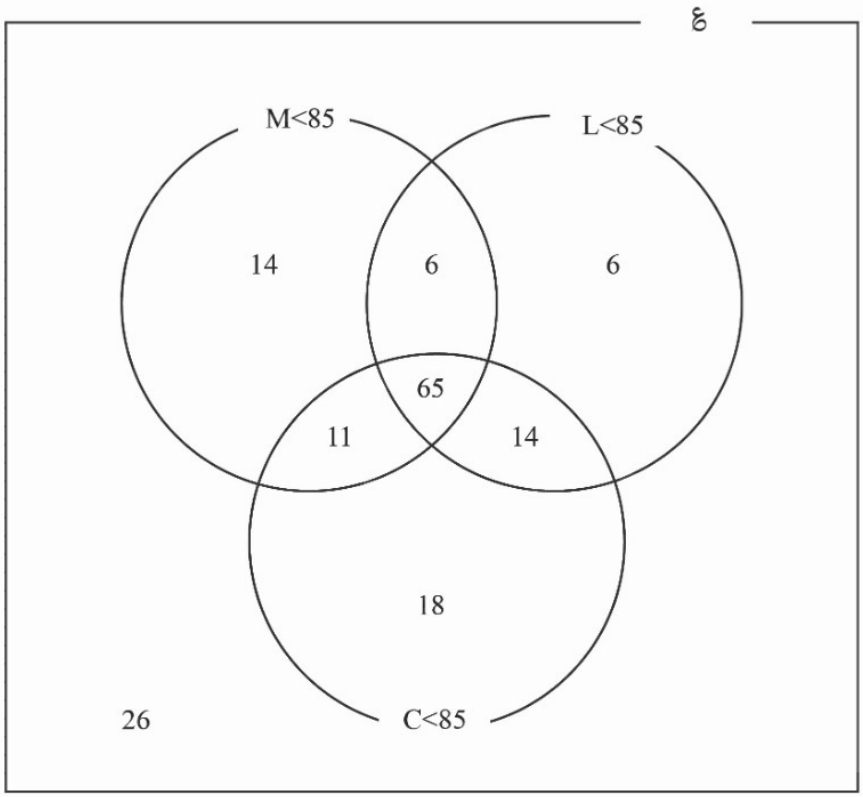
Table 4.5: Child development delay outcome classification by severity according to composite score.

Developmental subscale	**Total n=160**	**Male n=94**	**Female n=66**	**p-value**
	n(%)	n(%)	n(%)	
Motor:				
Normal (≥85)	64(40.0)	26(27.7)	38(57.6)	0.001
Mild delay (70 – 84)	40(25.0)	26(27.7)	14(21.2)	
Moderate delay (55 – 69)	36(22.5)	27(28.6)	9(13.6)	
Severe delay (<55)	20(12.5)	15(16.0)	5(7.6)	
Language:				
Normal (≥85)	69(43.1)	31(33.0)	38(57.6)	0.001
Mild delay (70 – 84)	43(26.9)	29(30.8)	14(21.2)	
Moderate delay (55 – 69)	33(20.6)	19(20.2)	14(21.2)	
Severe delay (<55)	15(9.4)	15(16.0)	-	
Cognition:				
Normal (≥85)	52(32.5)	22(23.4)	30(45.5)	0.006
Mild delay (70 – 84)	62(38.8)	38(40.4)	24(36.4)	
Moderate delay (55 – 69)	46(28.7)	34(36.2)	12(18.2)	
Severe delay (<55)	-	-	-	

4.3.3 Child development delay outcome classification by affected domain

A total of 134/160 (83.7%) children among those assessed were categorized as having developmental delay in at least one domain. The Venn diagram below (Fig 4.1) shows the

categorization among the three developmental domains. A total of 96/160 (60.9%) were categorized as having motor delay, 91/160 (56.8%) as having language delay while 108/160 (67.5%) had delay in cognitive development. Overall, 96 children from the 160 (60.0%) were classified as having delay in ≥2 domains; the combination of language and cognitive delay was the most common, with 79 children (49.4%). There were 65 children (40.6%) who were delayed in all the three domains. A total of 14 children (8.6%) had motor delay only, six children (3.8%) had language delay only and 18 children (11.3%) had delay in cognitive development only.



Key: ℰ = Total number of babies assessed using BSID-III = 160
M<85 = Set of babies with a composite score of less than 85 in Motor
L<85 = Set of babies with a composite score of less than 85 in Language
C<85 = Set of babies with a composite score of less than 85 in Cognition

Fig 4.1 Venn diagram showing domains affected by developmental delay

4.4 Risk and protective factors for child development

Logistic regression modelling was used to identify risk factors for developmental delay in each of the three domains. Compared to girls, boys were at increased risk of developmental delay in all domains in bivariate analyses, and these associations held when adjusted for confounders in the multivariable model, with: cognitive delay (adjusted odds ratio [aOR] 4.3; 95% CI 1.8 – 10.2, p=0.001), receptive language delay (aOR 2.4, 95% CI 1.1 – 5.3, p=0.034) and motor delay (aOR 4.6, 95% CI 2.1 – 10.2, p<0.001). Increased age since birth was associated with apparent and significant language and motor delay in both girls and boys. The logistic regression results are depicted in table 4.6 below.

Table 4.6: Associated risk and protective factors for developmental domain outcome for composite score

	Cognition		Language		Motor	
	Unadjusted OR [95% CI]' p-value	Adjusted OR [95% CI], p-value	Unadjusted OR [95% CI], p-value	Adjusted OR [95% CI]' p-value	Unadjusted OR [95% CI] p-value	Adjusted OR [95% CI] p-value
A priori factors						
Child sex: Boy	2.7 [1.4 – 5.4] P=0.004	4.3 [1.8 – 10.2] P=0.001	2.8 [1.4 – 5.3] P=0.002	2.4 [1.1 – 5.3] P=0.034	3.5 [1.8 – 6.9] P<0.001	4.6 [2.1 – 10.2] P<0.001
Child age			1.1 [1.05 – 1.2] P<0.001	1.1 [1.05 – 1.2] P<0.001	1.1 [1.01 – 1.13] P=0.014	1.1 [1.01 – 1.15] P=0.023
Physical factors						
Head circumference			1.2 [1.1 – 1.4] P=0.007	1.1 [0.98 – 1.32] P=0.075		
Birth weight (<2500 g)					2.5 [0.96 – 6.74] P=0.06	5.9 [1.7 – 20.4] P=0.005
Delivery mode Vacuum extraction Emergency C-section					2.5 [0.6 – 10.4] P=0.215 2.8 [1.4 – 5.7] P=0.004	2.4 [0.5 – 11.4] P=0.288 4.1 [1.8 – 9.5] P=0.001
Risk factors at birth						
Both Apgar scores <5	2.1 [0.9 – 4.8] P=0.078	4.6 [1.4 – 15.6] P=0.014	2.3 [1.1 – 5.0] P=0.029	2.4 [1.01 – 5.64] P=0.05		
Severe prematurity (birth weight <1500 g)	0.1 [0.03 – 0.4] P=0.001	0.1 [0.04 – 0.6] P=0.006	0.2 [0.1 – 0.7] P=0.011	0.3 [0.1 – 1.4] P=0.118		
Term baby with delivery complications			11.3 [1.4 – 88.9] P=0.021	17.1 [2.8 – 146.7] P=0.01		
Socioeconomic factors						
At least one parent working	0.47 [0.2 – 1.1] P=0.095	0.2 [0.1 – 0.5] P=0.004				
Maternal age	0.8 [0.7 – 0.8] P<0.001	0.8 [0.7 – 0.9] P<0.001				

4.4.1 Child physical factors at birth

In the multivariable final model, lower birth weight and born through an emergency caesarean section were associated significantly with lower developmental composite scores or higher odds of delay in the motor domain. Children born with a lower weight (<2500 grams) were nearly six times at risk of motor developmental delay (aOR 5.9; 95% CI: 1.7 – 20.41, p=0.005) while those who had been delivered through an emergency caesarean were more than four times at risk of motor developmental delay when compared to those who were delivered through normal vaginal delivery (aOR 2.4; 95% CI: 1.8 – 9.5, p=0.001). Those with increased head circumferences had language developmental delays, however, this was not significant.

4.4.2 Child birth conditions

Child conditions at birth which were risk factors for lower developmental scores or higher odds of delay included Apgar scores <5 (both at 1st and 5th minute after birth). This was associated with cognition developmental delay of more than 4 times (aOR 4.6; 95% CI: 1.4 – 15.6, p=0.014) compared to children born with normal Apgar scores. Also, these children were more than twice at risk of higher odds of language delay (aOR 2.4; 95% CI: 1.01 – 5.64, p=0.05) compared to children with normal Apgar score measurements at birth. Increased birth weight was associated with significant greater scores and lower odds for developmental delays in this sample. However, severe prematurity with a birth weight <1500 g significantly reduced the risk of cognitive developmental delay in the sample very slightly (aOR 0.1; 95% CI: 0.04 – 0.56, p=0.006). Those children who had delivery complications were at very much higher risk of language developmental delay of up to 17 times more (aOR 17.1; 95% CI: 2.8 – 146.7, p=0.01) compared to children with no delivery complications.

4.4.3 Socioeconomic factors and developmental delay

Good socioeconomic status and older maternal age were protective factors for reduced risk of cognitive delay. Having at least one of the child's parents employed was significantly associated with higher composite scores and reduced risk of cognitive developmental delay (aOR 0.2; 95% CI: 0.04 – 0.54, p=0.004) compared to children with both parents not employed. Older maternal age significantly reduced the risk of child's cognitive development delay (aOR 0.8, 95% CI: 0.7 – 0.9, p<0.001).

4.4.4 Developmental delay in all three domains

A total of 65(40.6%) children had developmental delay in all three domains. Of these, most were boys, 54(83.1%). Neonatal convulsions, (aOR 5.6; 95% CI: 1.2 – 25.7, p=0.03), an Apgar score of <5 at both 1st and 5th minute after birth, (aOR 2.6; 95% CI: 1.1 – 5.8, p=0.02) and being a boy, (aOR 7.1; 95% CI: 3.2 – 15.7, p<0.001) were risk factors for developmental delay in all the three domains.

4.5 Conclusion

In line with the aims and objectives of the study, the following results were found:

Prevalence of developmental delay

A total of 134/160 (83.7%) children among those assessed were categorized as having developmental delay in at least one domain.

Severity of developmental delay

In motor development, 40(25%) of children assessed had mild delay, 36(22.5%) had moderate delay, 20(12.5%) had severe delay and 64(40%) were normal.

With respect to language development, 43(26.9%) had mild delay, 33(20.6%) had moderate delay, 15(9.4%) had severe delay and 69(43.1%) were normal.

In cognitive development, 62(38.8%) had mild delay, 46(28.7%) had moderate delay, none had severe delay and 52(32.5%).

Risk factors for developmental delay

Risk factors in the inclusion criteria for the ARSS at United Bulawayo Hospitals which babies in this study presented with are severe neonatal jaundice (21.3%), Apgar scores <5 (both at 1st and 5th minute) (26.3%), severe prematurity with birth weight of <1500 g (8.8%), term baby with birth weight <2500 g (7.5%), neonatal Malaria/Tuberculosis/Meningitis (11.2%), HIV-exposed (29.4%), neonatal convulsions (6.9%), term baby with delivery complications (8.8%) and preterm babies with <37 weeks of gestation (30.6%).

Of the risk factors identified in our sample, the following contributed to developmental delay: severe neonatal jaundice, Apgar scores <5 (both at 1st and 5th minute), severe prematurity, HIV exposure, neonatal convulsions and term baby with delivery complications.

The most important risk factors in the ARSS associated with developmental delay in all three domains found are neonatal convulsions, (aOR 5.6; 95% CI: 1.2 – 25.7, p=0.03) and an Apgar score of <5 at both 1st and 5th minute after birth (aOR 2.6; 95% CI: 1.1 – 5.8, p=0.02). In addition to these, being a boy (aOR 7.1; 95% CI: 3.2 – 15.7, p<0.001) was also an important risk factor for developmental delay in all the three domains.

These findings will be discussed in the following chapter. The discussion will involve comparing and contrasting our findings with results of other similar studies.

CHAPTER 5: DISCUSSION

This chapter discusses findings of this study in relation to those recorded in previous similar studies. Results are discussed in the sequence they are presented in the results chapter. Strengths and limitations of the study are highlighted. Recommendations for future research and clinical practice are also made.

The study aimed to determine the prevalence, severity and risk factors for developmental delay in children under the ARSS at United Bulawayo Hospitals. The study provides directly measured developmental delay data and confirmed a high prevalence rate of developmental delay. The findings of this study also highlight the severity of developmental delay as well as important risk factors.

This research established a developmental delay of 83.7% in babies attending the ARSS. In motor development, the majority (25%) had mild motor delay; in language development, mild delay group dominated with 26.9% each; the majority (38.8%) had mild delay in cognition. The most important risk factors associated with developmental delay in all three domains were low Apgar scores of <5 both at 1st and 5th minute, neonatal convulsions and being a boy. These results are discussed under the following subheadings:

5.1 Developmental delay among children in the ARSS at United Bulawayo Hospitals

5.1.1 Prevalence of developmental delay

A substantial prevalence of at least one domain of developmental delay among the three domains has been reported in this sample in 83.7% of participants, a figure that is much higher than in

previous other reports elsewhere (Black et al., 2017; Chattopadhyay & Mitra, 2015). This can be explained by the fact that all of the children included in this study were all known to have risk factors for development. Furthermore, 56.9% of the infants had language developmental delay with 60% having motor developmental delay and 67.5% having cognitive developmental delay. Overall, our study reveals that 40.6% of infants had developmental delay in all three domains. Another study by Abdel Khalek et al. (2018) showed that 38% of their sample had motor developmental delay (lower than what this study found), 63.3% of the participants had speech delay (which is the same as the findings of this study when rounded to the nearest 10) and two percent of the cases had cognitive delay (this was far below the findings of this study). The differences can be attributed to the fact that our study investigated developmental delay in babies with known risk factors and some had multiple risk factors for developmental delay, unlike other studies which investigated developmental delay in the general population. Different settings could have also contributed to the differences as the child nurturing environment is known to contribute towards child development (Walker et al., 2011; WHO, 2018).

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Prevalence of developmental delay in three domains assessed was higher than the findings of Donald et al. (2019) which recorded 10.2% developmental delay in all domains assessed. This significant difference could be due to the fact that her study looked at developmental delay in the general population, while our study focused on developmental delay in High Risk babies.

The Covid-19 movement restrictions were associated with high nutritional risks (Araújo et al., 2021) which might have contributed to developmental delay in children in our study, as most of the studies compared to this study were conducted outside the Covid-19 era. Poor nutrition due to lockdowns is most likely to have affected children in our study due to high informal employment in our Zimbabwean context which was hugely affected with Covid-19. This made it difficult for most parents to put food on the table. Covid-19 also caused lower clinic visits, this has negatively impacted on child development.

The Harare study (Hutchings & Potterton, 2013) showed that among children who were HIV-exposed, 64.29% had cognitive delay, 60.71% had language delay and 53.57% had motor delay at two years of life, which was significantly higher than the developmental delay of children not exposed to HIV. This is comparable to our findings. This may be because our sample was exposed to HIV as well as other risk factors for developmental delay at birth.

Another previous study in Bulawayo that looked at developmental delay in babies with low Apgar scores found that 29% had developmental delay. The study assessed 142 babies with low Apgar scores using the BSID-I (Wolf et al., 1997). It was a longitudinal study that followed the babies up to three years unlike our study which was a cross-sectional study. The study also investigated one risk factor, while our study investigated all the 11 risk factors in the ARSS, of which some babies presented with more than one risk factor increasing the probability of them developing developmental delay.

5.1.2 Severity of developmental delay

On classification for severity of developmental delay, significant delay (moderate and severe combined) in motor development were observed in 35% in this sample, which is lower than 77.5% reported by Baillieu and Potterton (2008) in HIV-infected children. Similarly, for cognitive developmental delay, a lower proportion was observed in significant developmental delay with 28.7% compared to over 50% reported in other studies (Baillieu & Potterton, 2008; Potterton et al., 2009). These differences can be attributed to inclusion of several risk factors in this study compared to other studies that included HIV alone as a risk factor. Infection by HIV contribution to developmental delay is multifactorial due to the impact of the virus itself, exposure to ARVs, condition of the caring mother and many others (Hutchings & Potterton, 2013; Potterton, Hilburn & Strehlau, 2016).

Ballot et al. (2012) reported severe cases of developmental delay in three-point-seven percent. This is lower than the severe cases reported in our study. The differences can be attributed to the fact that Ballot et al. (2012) study investigated developmental delay babies with very low birth weight only while our study investigated developmental delay in several risk factors, and some babies included in our study had multiple risk factors.

5.1.3 Risk factors for developmental delay

In our sample, key factors associated with developmental delay in all three domains at <24 months of age included male gender, having experienced neonatal convulsions and having an Apgar score of <5 both at 1st and 5th minute after birth. Our findings are similar to the related literature in highlighting these as some of the risk factors for developmental delay in the three developmental domains. The risk factors were similar to those identified by Donald et al. (2019).

Gender

Compared to an observational birth cohort in South Africa, boys performed poorly compared to girls who had significantly lower composite scores in all the three developmental domains. Correspondingly, boys had increased risk of developmental delay in each of these developmental delays (Donald et al., 2019). This is similar to our study findings and in other studies that explored developmental performance in children exposed to developmental delay risk factors at birth that as described in a large multicounty study assessed over a period time (Weber et al., 2017), although the children were aged between 3–5 years.

Abdel Khalek et al. (2018) reported 68.7% male cases and 31.3% female cases of developmental delay. The male dominance to developmental delay is in tandem with this current study.

Neonatal Seizures

Neonatal seizures were associated with delayed development in all three domains (40.6% had delayed development in all the three domains in our study). Seizures are known to contribute towards developmental delay (Chattopadhyay & Mitra, 2015). Another study that looked at developmental delay in 120 children with neonatal seizures found that 43% had global developmental delay (Garfinkle, 2011). The findings are similar to ours.

Seizures commonly cause neurologic dysfunction in infants. They are known to cause brain injury or worsen existing brain injury (Lai et al., 2013; Volpe, 2008). The high developmental delay in three domains prevalence in our study support this known contribution of seizures to neonatal brain damage.

Apgar scores

Apgar scores of <5 both at 1^{st} and 5^{th} minute after birth were associated with developmental delay in all three domains. It was associated with cognitive developmental delay of more than four times. They were also more than twice at risk of language developmental delay. Low Apgar scores of ≤5 define birth asphyxia (Locatelli et al., 2020), which is a known cause of hypoxic-ischemic encephalopathy (HIE) which causes neurological problems and CP (American College of Obstetricians and Gynecologists, 2014; Graham, 2008; Sharma, 2019).

Prematurity

In other studies, children born prematurely were at a higher risk of developmental delay in all three domains (Donald et al., 2019). Prematurity is a well-established risk factor for developmental delay (Ballot et al., 2012; de Kieviet et al., 2009). Uniquely, our study established that babies born with severe prematurity (birth weight <1500 grams) had significantly reduced risk of cognitive developmental delay. This difference can be attributed to the fact that our study sample was drawn from babies born at a central hospital with specialised neonatal units where maximum neonatal care is rendered to preterm babies. This is different from Donald et al., 2019 study in which the sample was drawn from a periurban setting, with low socio-economic profiles where minimum neonatal care of preterm babies is highly likely.

Jaundice

Children with severe neonatal jaundice significantly contributed to developmental delay in our sample. This is similar to the findings from other studies (Abdel Khalek et al., 2018; Chattopadhyay & Mitra, 2015; Cox, Potterton & Rosie, 2020).

HIV exposure

HIV exposure was found in 29.4% of our sample. Babies showed significant developmental delay in our sample. This is well supported by other studies in sub-Saharan Africa which concluded that HIV exposure contributes to child developmental delay, although developmental delay is more in HIV infected babies compared to HIV uninfected babies born to HIV infected mothers (Hutchings & Potterton, 2013). Our sample constituted only HIV uninfected babies born to HIV positive mothers due to the effective Prevention of Mother-to-Child Transmission programmes at our setting. HIV uninfected babies born to HIV infected mothers in our study had

low prevalence of developmental delay. This is similar to Hutchings and Potterton findings in which HIV-exposed and uninfected had none in the motor development delay category, and a very low developmental delay of three-point-one percent in cognition and 12.5% in language were reported.

Delivery complications

Babies who had delivery complications were at a very high risk of language developmental delay up to 17 times more compared to children with no delivery complications. Delivery complications such as difficult labour are fully established causes of developmental disorders due to the bearing they have on fetal distress and asphyxia (Gomes et al., 2015; Hadjkacem et al., 2016; Polo-Kantola et al., 2014). In a similar study conducted in India, a high developmental delay odds ratio was also reported in babies with a history of delivery complications (Sharma, 2019).

Child physical factors

Factors that were clearly identified as significantly associated with risk for poor motor developmental delay outcome include those that represent the child's physical health at birth. These included child's lower birth weight. Increased age after birth was also found to be associated with increased delay in motor and language both in boys and girls. This could be because these domains are easy to assess as the child gets older and deficiencies are easily picked up. The contribution of weight is similar to the study findings by Abdel Khalek et al. (2018) in which very low birth weight was associated with developmental delay.

Our study also established that those children born with increased head circumference had increased risk of language developmental delay. This is similar to previous studies which established increased developmental delay in social skills and language in babies with macrocephaly (Lainhart et al., 2006).

Maternal factors

Older maternal age was associated with significant reduction in cognitive development delay in our study. This supports evidence from literature that vulnerability to developmental challenges is reduced with increasing maternal age from 15 years to 35 years. This age related advantage lapse beyond 35 years (Falster et al., 2018; Trillingsgaard & Sommer, 2016).

Socioeconomic factors

In our sample, key factors that were associated with positive cognitive development at <24 months of age included better socio-economic status and older maternal age. A child born to parents with at least one of them employed exhibited a very strong protective factor that reduced the odds of cognitive developmental delay in this group of At Risk children, followed by older maternal age.

Social determinants importance on childhood development is fully described (Britto et al., 2017; WHO, 2018). Our findings are similar to those of Donald et al. (2019) in the South African population, who discovered that good socioeconomic standing was protective against poor developmental delay. The socioeconomic status in our study tallies with typical African population from similar studies in Sub-Saharan Africa.

Mode of delivery

Other similar studies also reported an increased developmental delay in children born through caesarean section, although it was in the hearing/receptive language domain (Smolkin et al., 2013; Xiao et al., 2015). The majority of studies reported no difference in babies born through Caesarean section and those born normally (Asztalos et al., 2016; Joseph et al., 2015; Kimura et al., 2017; Robson et al., 2015; Zhu et al., 2014). However, this risk factor was not established in our study.

Sepsis and neonatal infections

Sepsis and neonatal infections have been identified as risk factors for developmental delay in previous studies (Cox et al., 2020; Durkin, 2002; Chattopadhyay & Mitra, 2015), but these were not significant factors in our study. This can be attributed to the very few children who presented with these factors in our study. In addition to that, limited laboratory support to ascertain the severity of sepsis might have excluded potential candidates for the ARSS and possibly included mild cases of sepsis in the ARSS at the study centre.

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Most important risk factors

This study's most important risk factors were low Apgar scores of <5 in the first five minutes, neonatal convulsions, and being a boy. These were different from Abdel Khalek et al. (2018) in the study done in Egypt that investigated developmental delay in children born with At Risk factors. They discovered that babies with cyanosis (OR 16.391), LBW (OR 6.147), parental consanguinity (OR 5.489), first birth order (OR 4.048), urban residence (OR 3.702), and neonatal jaundice (OR 2.518) had significantly higher odds of developing delayed milestones in

the logistic regression model. This can be attributed to different settings, which is North Africa and Southern Africa. In Zimbabwe, consanguinity is extremely rare.

Environmental stimulus and care are other important predictors of developmental delay established in rural China (Zhang et al., 2018). This can still be attributed to different settings which have different environmental stimulus.

5.2 Strengths of this study

The following strengths of this study were identified:

- The research involved a comprehensive data collection procedure by a paediatric physiotherapist who received adequate training in administering the BSID-III tool. The principal investigator was able to communicate with the caregiver and child in their home language and was able to communicate effectively and assess the child's speech and language responses accurately.

- Child development assessments used the BSID-III which is the gold standard tool for developmental assessment in our study context. The BSID is used for comprehensive developmental assessments and has been used frequently and successfully in southern Africa (Hutchings & Potterton, 2013; Potterton et al., 2009; Shead et al., 2010; Whitehead et al., 2014; Van Rie et al., 2008). Children had a comprehensive assessment during this study that would have been unlikely were it not for this study and parents/guardians were conscientized of their child's developmental milestones in depth.

- A large sample size of 160 participants was used in this study. This resulted in more statistically significant results. This study has a much larger sample size than some earlier

studies on development in At Risk populations in Sub-Saharan Africa (Ballot et al., 2012; Hutchings & Potterton, 2013; Potterton et al., 2009; Shead et al., 2010).

5.3 Limitations of this study

The following weaknesses of this study were identified:

- This study data is from one site only, hence the results cannot be generalised for the rest of the country.

- As a cross-sectional study on a limited age group, we are not able to draw longer-term conclusions.

- Socio-emotional and adaptive behaviour domains were not assessed in this study.

- Despite being recognised as the gold standard and potentially being the most suitable available assessment tool, the BSID-III has not been formally validated in the Zimbabwean context and some cultural biases may exist.

- Limited laboratory support to ascertain the severity of jaundice and sepsis might have excluded potential candidates for the ARSS and possibly included mild jaundice and sepsis in the ARSS at the study centre.

5.4 Implications of the study

The results imply that developmental delay is high in children under the ARSS at United Bulawayo Hospitals, hence there is need to routinely assess children in the ARSS to allow early detection and intervention of developmental challenges.

Detection of developmental delay in cognition, language and motor implies that an interdisciplinary approach is required in assessing and management of these developmental deficits (i.e. physiotherapists to deal with the motor challenges, occupational therapists and psychologists to deal with cognitive issues, speech and language therapists to deal with the lag in language development).

If recommendations from this study are implemented this is likely going to reduce the burden of developmental delay. Since the most important risk factors are singled out (low Apgar score of <5 both at 1st and 5th minute after birth, neonatal convulsions and being a boy), targeted meticulous follow-up of children presenting with these three risk factors can be implemented to ensure they are never missed in the ARSS.

5.5 Recommendations

5.5.1 Clinical Recommendations

- Apgar scores of <5 both at 1st and 5th minute after birth, neonatal convulsions and being a boy contributed to developmental delay in all three domains. Therefore, children falling into these three categories should be closely monitored using the BSID-III while the rest of the babies can be screened using a cheaper and faster tool such as the ASQ.

- There is a need to improve antenatal, natal, perinatal and postnatal care to reduce the risk factors for developmental delay.

- The ARSS is useful in detecting early developmental delay. Hence, MoHCC should allocate more resources to this important programme so that it is sustained.

- The BSID-III is a useful developmental assessment tool for children; therefore, training rehabilitation personnel in its administration is highly recommended, and the MoHCC should budget for it annually.

- The BSID-III requires more time with the child during assessment (at least an hour). In that regard, adequate staff should be assigned to the developmental assessment clinics.

- Since the developmental assessments were done at an interdisciplinary clinic, those babies found to have developmental issues or other medical conditions were reported to their referral points since the services were under one roof. From that observation during this research, it is strongly recommended that all child developmental follow-up clinics be interdisciplinary.

5.5.2 Recommendations for Further Research

- A longitudinal study is recommended to follow the babies up to five years to determine the percentage of babies who graduate from this five-year follow-up period without developmental delay and to determine those who will require physiotherapy treatment or assistive devices beyond the age of five.

- To include all the five central hospitals in Zimbabwe so that the results become a true reflection of the At Risk Surveillance System in Zimbabwe.

- Local researchers to develop or adapt a developmental assessment tool in the African context that can be afforded in poor settings, as the BSID-III is expensive and is not available in Zimbabwean hospitals.

- Future research should explore socio-emotional and adaptive behaviour aspects of development that were missed by this research.

Conclusions emanating from his study will be presented in the next chapter. This will be in the form of important messages that answer the research question of this study.

CHAPTER 6: CONCLUSION

National and institutional statistics on AR babies are either not available or not up-to-date in the Zimbabwean setting. Research on the prevalence of, and risk factors for developmental delay in children have been mainly done abroad, and the outcome findings cannot be generalised locally due to the uniqueness of the birth environment in which these babies are born.

The aim of this study was to determine the prevalence and severity of developmental delay in children under the ARSS at United Bulawayo Hospitals. This was achieved by conducting a cross sectional study in which 160 infants aged one to 42 months were assessed by the principal investigator using the BSID-III.

For each child who was systematically sampled into this study, socio-demographic profile and risk factors for developmental delay were captured from caregivers and patient hospital cards. This was followed by a thorough developmental assessment by a paediatric physiotherapist. Children's developmental scores on the BSID-III scale were categorised into normal development, mild, moderate and severe developmental delay.

The study objectives were met and revealed the following:

Prevalence of developmental delay

The prevalence of developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals was found to be 83.7%; of whom 60.0% were classified as having delay in ≥2 domains.

Severity of developmental delay

From the total number of children found to be developmentally delayed, cognitive delay was identified in 67.5%; of whom 38.8% presented with mild delay, 28.7% had moderate delay and none was severe in cognition. Fifty-six-point-nine percent of children assessed presented with language delays; 26.9% were mild, 20.6% were moderate and 9.4% were severe. In terms of motor development, 60% of infants assessed presented with delayed development; 25% were mild, 22.5% were moderate and 12.5% were severe.

Risk factors for developmental delay in ARSS at United Bulawayo Hospitals

Out of 11 risk factors which form the inclusion criteria for enrolling children into the ARSS, children assessed at United Bulawayo hospitals presented with the following risk factors: severe neonatal jaundice, Apgar scores <5 (both at 1^{st} and 5^{th} minute), severe prematurity with birth weight of <1500 g, term baby with birth weight <2500 g, neonatal Malaria/Tuberculosis/Meningitis infections, HIV exposure, neonatal seizures and term baby with delivery complications. The most important risk factors in our sample associated with developmental delay in all three domains were low Apgar score of <5 in the first five minutes, neonatal seizures and being a boy. These risk factors are similar to those found in the literature.

The findings of this study support the need for ongoing developmental monitoring and assessment of infants at United Bulawayo Hospitals. The inclusion of an interdisciplinary rehabilitation team is strongly recommended to effectively address developmental delay in motor, language and cognition. There is a need for further research to add to the evidence base and support advocacy efforts for the ARSS in Zimbabwe.

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APPENDICES

Appendix A - Data Collection Sheet

Data collection sheet (To be completed by the assessing physiotherapist)

NB: Fill in spaces provided and tick applicable where options are given

Code no: …….. **Date**: ……..

A. Socio-demographic profile

1. Age (Months)……
2. Sex: M☐ F☐
3. Birth Head circumference (cm): ……..
4. Birth length (cm): ……..
5. Position of birth in the family (e.g. 1st born): 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐ Other☐
6. Mode of delivery: NVD☐ Forceps Delivery☐ Vacuum extraction☐ Elective C-section☐ Emergency C-section ☐ Perimortem C-section ☐
7. Gestational age at birth (weeks): ……..
8. Maternal age at birth (years): ……
9. Maternal mental health status (from medical records): Good☐ Bad☐
10. Mode of feeding in the first 6 months of life: Breastfeeding☐ Bottle feeding ☐ Solids☐
11. Residential area: Urban - High density☐ Low density ☐ Rural ☐
12. Marital status of mother: Married ☐ Divorced ☐ Widowed ☐ Single parent☐
13. At least one of the parents is working YES☐ NO ☐
14. Parents level of education attended – Mother: Primary☐ Secondary☐ Tertiary☐ Father: Primary☐ Secondary☐ Tertiary☐
15. Number of Children in the family: 1 child ☐ More than 1 child ☐

16. Medical aid cover for the child YES☐ NO ☐

B. <u>Risk factor(s) at birth on the At Risk Surveillance System</u>:

1. Severe jaundice in the first week of life YES ☐ NO ☐
2. Apgar scores less than five (both in 1 minute and 5 minutes after birth)YES☐ NO ☐
3. Severe prematurity with birth weight less than 1500 g YES ☐ NO ☐
4. Term baby with birth weight less than 2500 g YES ☐ NO ☐
5. Neonatal Malaria/Tuberculosis infections or Meningitis YES ☐ NO ☐
6. HIV exposed YES ☐ NO ☐
7. Neonatal convulsions/seizures YES ☐ NO ☐
8. Term infant with delivery complications e.g. severe birth asphyxia, birth trauma YES☐ NO ☐
9. Floppy baby (Hypotonia) YES ☐ NO ☐
10. Baby does not cry for more than 24 hours after birth YES ☐ NO ☐
11. Baby does not suck for more than 24 hours after birth YES ☐ NO ☐

C. <u>Developmental assessment</u> (to be summarised from Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) developmental assessment findings).

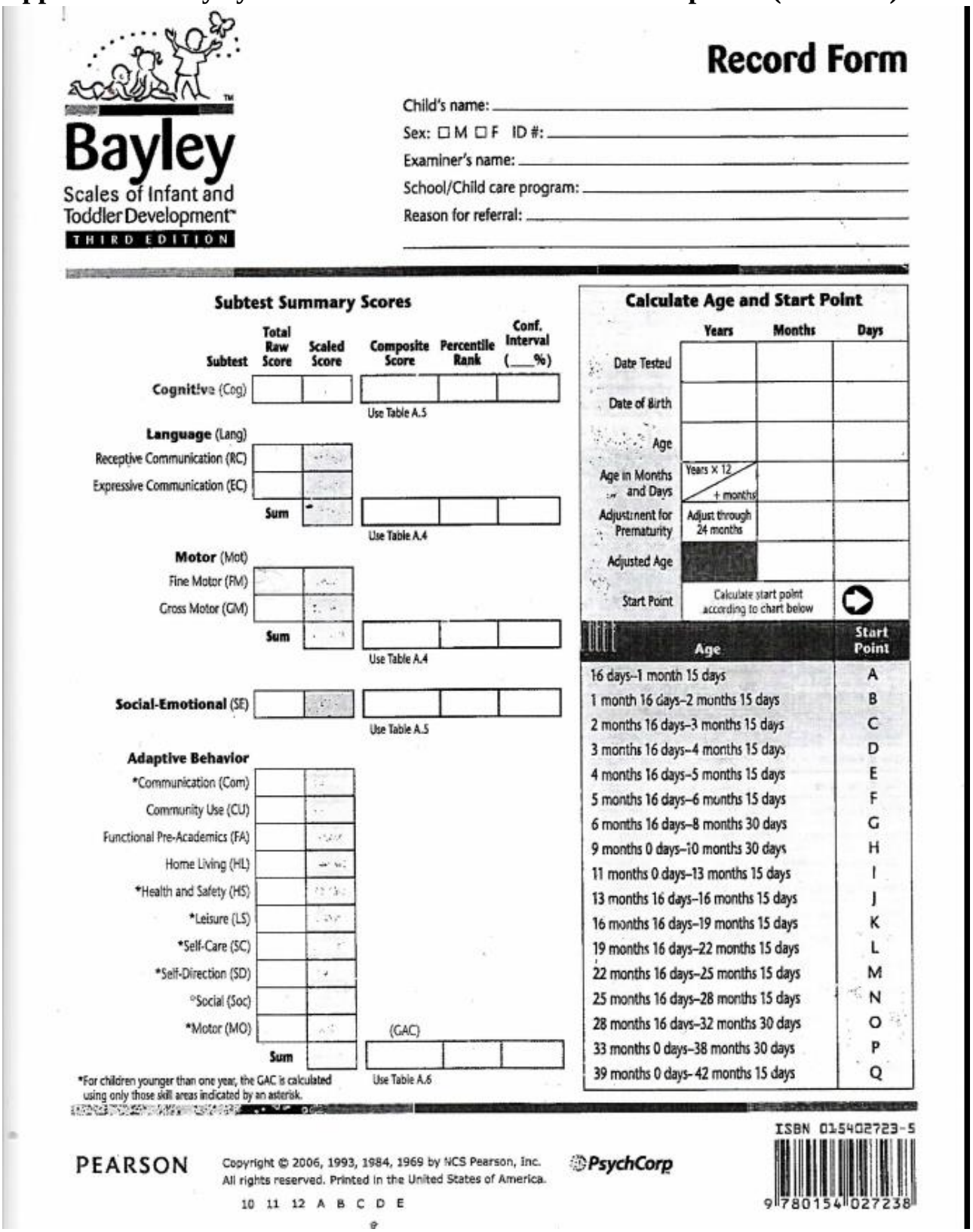
1. Developmental assessment outcome: No delay ☐Cannot be ascertained at present ☐ Delay is present☐
2. The severity of developmental delay if present: Mild ☐ Moderate ☐ Severe ☐ Normal ☐
3. Areas of development affected:

   Motor (Fine & Gross combined) – YES ☐ NO ☐ Composite score: …

Language (Receptive & expressive combined) – YES ☐ NO ☐ Composite score: …

Cognition – YES ☐ NO ☐ Composite score: …

Appendix B - Bayley Scales of Infant and Toddler Development (BSID-III)



Bayley
Scales of Infant and Toddler Development™
THIRD EDITION

Record Form

Child's name: _____

Sex: ☐ M ☐ F ID #: _____

Examiner's name: _____

School/Child care program: _____

Reason for referral: _____

_____

Subtest Summary Scores

Subtest	Total Raw Score	Scaled Score	Composite Score	Percentile Rank	Conf. Interval (___%)
Cognitive (Cog)					
			Use Table A.5		
Language (Lang)					
Receptive Communication (RC)					
Expressive Communication (EC)					
Sum					
			Use Table A.4		
Motor (Mot)					
Fine Motor (FM)					
Gross Motor (GM)					
Sum					
			Use Table A.4		
Social-Emotional (SE)					
			Use Table A.5		
Adaptive Behavior					
*Communication (Com)					
Community Use (CU)					
Functional Pre-Academics (FA)					
Home Living (HL)					
*Health and Safety (HS)					
*Leisure (LS)					
*Self-Care (SC)					
*Self-Direction (SD)					
*Social (Soc)					
*Motor (MO)			(GAC)		
Sum					
			Use Table A.6		

*For children younger than one year, the GAC is calculated using only those skill areas indicated by an asterisk.

Calculate Age and Start Point

	Years	Months	Days
Date Tested			
Date of Birth			
Age			
Age in Months and Days	Years × 12 + months		
Adjustment for Prematurity	Adjust through 24 months		
Adjusted Age			
Start Point	Calculate start point according to chart below		➔

Age	Start Point
16 days–1 month 15 days	A
1 month 16 days–2 months 15 days	B
2 months 16 days–3 months 15 days	C
3 months 16 days–4 months 15 days	D
4 months 16 days–5 months 15 days	E
5 months 16 days–6 months 15 days	F
6 months 16 days–8 months 30 days	G
9 months 0 days–10 months 30 days	H
11 months 0 days–13 months 15 days	I
13 months 16 days–16 months 15 days	J
16 months 16 days–19 months 15 days	K
19 months 16 days–22 months 15 days	L
22 months 16 days–25 months 15 days	M
25 months 16 days–28 months 15 days	N
28 months 16 days–32 months 30 days	O
33 months 0 days–38 months 30 days	P
39 months 0 days–42 months 15 days	Q

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Appendix C - English - Information sheet and Informed consent form

Appendix C: English - Information sheet and Informed consent form

Information Sheet

Study Title: **"The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe"**

Principal investigator: Mr Precious Madzimbe [Paediatric Physiotherapist, BSc Physiotherapy (Hons) - UZ, PGD Physiotherapy (Paeds) – UCT, SA]

Contacts: +263 775 424 570, 1307559@students.wits.ac.za

Hello! I am a University of the Witwatersrand Masters in Physiotherapy degree student. Currently, I am carrying out research titled: **"The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe".** The study will help to understand the prevalence, severity and risk factors of developmental delay in children on follow-up at United Bulawayo Hospitals. The findings of the study will help in scaling up preventative measures of developmental delay once risk factors are clearly described and equipping the rehabilitation department based on the prevalence of developmental delay.

This information helps you to understand the purpose, benefits and risks of this study. You are asked to provide information for this study. You were chosen to participate in this study because your child is at risk of developing developmental delays. Information will be obtained from your child's medical records, you will be asked some questions to fill in the missing information and to verify some of the recorded information and your child will be assessed to see if they have a developmental delay or not.

If you decide to participate, you will be required to provide the child's hospital record book, you will be asked to supply certain information where possible if not clear in the records. This will be followed by child assessment. The whole process will take at most 1 hour 30 minutes. Assessing the child is the one that takes most of the time. The assessment will be done once.

There are no known risks for taking part in this study and there are no direct benefits for taking part in this study. Indirect benefits are that findings of the study will help in preventing risk factors and sourcing equipment for the rehabilitation of children with developmental delay if risk factors and prevalence of developmental delay become known.

If you are willing to participate in this study by signing this consent form, your child's information will be kept confidential and will not be disclosed to third parties. Your personal information can be disclosed with your permission. It can only be disclosed without your permission if required by law. Research Ethics Committees such as the Medical Research Council of Zimbabwe (MRCZ) and the University of Wits Human Research Ethics Committees and my examiners may copy or inspect research records for quality assurance and data analysis.

Participation in this study is voluntary. If you decide not to take part or withdraw in the middle of the study, you can do so without any prejudice. You are not required to give explanation for taking such actions. No monetary expenses will be incurred in participating or not participating in this study. The assessment will be longer than usual as a different assessment tool is being used, hence refreshments will be provided at the end. Please feel free to ask any questions and take your time to fully understand the contents of this document. If you feel that you have been treated improperly, feel free to contact the Medical Research Council of Zimbabwe on +263 (242) 791792 or +263 772 433 166.

Consent form:

By signing this document, you are agreeing that your child should participate in this study and accepting that you have read and understood the contents of the information sheet attached and had adequate time to go through it and ask questions. You will get a duplicate of this consent form for you to keep.

Name of research participant parent/ legal guardian (print name): ……

Name of research participant (print name): ……...

Signature of the participant: ……Date: ……...

Witness' name (if required): ……Signature: ……Date: ……...

Thank you for consenting to take part in this research.

Appendix D - Shona - Zvizere pamusoro petsvagurudzo uye gwaro rewiririrano nevachapinda mutsvagiridzo

ZVIZERE PAMUSORO PETSVAGURUDZO

Musoro Wetsvagurudzo: **"The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe"**

Mutsvagurudzi Mukuru: Mr Precious Madzimbe [Paediatric Physiotherapist, BSc Physiotherapy (Hons) - UZ, PGD Physiotherapy (Paeds) – UCT, SA]

Nhamba dzenhare uye kero yetsamba dzepadandemutande: +263 775 424 570, 1307559@students.wits.ac.za

Hevoi! Ndiri mudzidzi pachikoro cheUniversity of the Witwatersrand. Ndirikuita zvidzidzo zve*Masters in Physiotherapy*. Parizvino ndiri kuita tsvagurudzo pamusoro unoti: ***"The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe".*** Tsvagurudzo iyi iripo pakuda kunzwisisa zvinoita kuti vana vasakura nomazvo tichatarisa zvinotarisirwa kuitwa nemwana pazera rake uye kuti kukanganisika kunenge kwakanyanya zvakadii muvana vari kuteererwa nechinangwa chokuda kuona makurire avarikuita pachipatara cheUnited Bulawayo Hospitals. Zvichabuda mutsvagurudzo iyi zvichabatsira kudzivirira zvinokanganisa kukura kwevana. Tichinge tave kuziva kuti dambudziko iri rakanyanya zvakadii uye kuti chii chinonyanyokonzera, zvichabetsera kuisa midziyo inoshandiswa nevatwasanudzi venhengo dzomuviri muzvipatara yakakwana.

Gwaro rino rinobatsira kuti munzwisise zvakanakira kana kuipira tsvagurudzo ino. Munokumbirwa kupa zvamunoziva zinodiwa mutsvagurudzo ino. Masarudzwa kuti mupinde

mutsvagurudzo ino nokuti mwana wenyu akaonekwa kuti ari munjodzi yokuti anogona kusanyatsokura zvinotarisirwa. Zvizere pamusoro pemwana wenyu zvichatorwa kubva mumabhuku ake ekuchipatara, muchazobvunzwawo mibvunzo kuzadzisa zvinenge zvisimo mumabhuku emwana asi zvichidiwa mutsvagurudzo uye kuona kuti zvakanyorwa mumabhuku aya zvinoenderana here nezvamunoziva pamusoro pemwana.

Kana mukabvuma kupinda mutsvagurudzo iyi, muchakumbirwa bhuku remwana rekuchipatara uye mobvunzwa imwe mibvunzo pamusoro pemwana kubvira pakuzvarwa kwake uye kuti mujekese zvezvimwe zvinonga zvakanyorwa. Mushure mezvo, mwana achaongororwa. Izvi zvose zvinogona kutora awa rimwe nechidimbu. Kuongorora mwana ndikwo kuchatora nguva yakanyanyoreba. Mwana achaongororwa kamwe chete.

Hapana njodzi irikuzivikanwa inogona kusangana nemwana wenyu kana akapinda mutsvagurudzo ino uyezve hamubhadharwe kupinda mutsvagurudzo ino. Zvichabuda mutsvagurudzo ino ndizvo zvichabetsera mukudzivirirwa kwematambudziko anokanganisa kukura kwemwana uye kuwandudzwa kwemidziyo ingangodiwa muzvipatara kutwasanudzisa nhengo dzomuviri wevana. Ndokunge zvizere zvave kuzivikanwa pamusoro pevana vanenge vasingagoni kuita zvavanotarisirwa kuita pazera ravo.

Kana mabvuma kupinda musarudzo nekusaina gwaro rewiririrano, zvizere pamusoro pemwana wenyu zvichachengetwa pakavanzika uye hazvisi kuzoshambadzwa zvichibudisa zita remwana. Izvi zvinogona kubuda chete kana imi mbune muchinge mazvibvumira. Zvinogona hazvo kuburitswa imimi musina kuzvibvumira kana zvichinge zvakumbirwa nevemutemo. Masangano anotarisa kuitwa kwetsvagurudzo akaita *seMedical Research Council of Zimbabwe (MRCZ)* ne*University of Wits Human Research Ethics Committees* uye vanoongorora bvunzo dzezvandichanyora pamusoro petsvagurudzo ino ndivo vevamwe vanogona kutarisa izvozvo kuona kuti tsvagurudzo iri kuitwa nemazvo here.

Kupinda mutsvagurudzo ino kuzvidira kwenyu. Kana mukafunga kubuda mutsvagurudzo ino, makasununguka. Hapana murango wamunopihwa uye hazvikanganisi ukama hwenyu neni kana nechipatara. Munogona kubuda pasina kupa chikonzero kuti mabudirei. Hapana zvamuchanzi mubhadhare kupinda mutsvagurudzo ino uye hamuripiswe kana mukasarudza kusapinda mutsvagurudzo ino. Ongororo yemwana ichatora nguva yakati rebei kupfuura zvamakajaira nokuti zvichange zvichishandiswa zvakasiyana nezvange zvichimboshandiswa kumashure. Naizvozvo muchapihwa zvokudyira-dyira nokunwira-nwira kwekupedzisira. Ivai vakasununguka kubvunza mubvunzo kuti munzwisise zvizere zviri mugwaro rino. Kana musina kugutsikana pamusoro petsvagurudzo ino, zivisai veResearch Council of Zimbabwe panamba dzenhare dzinoti: +263 (242) 791792 kana *+263 772 433 166*.

GWARO REWIRIRANO

Pamuchasaina gwaro rino, munenge muchibvumira kupinda mutsvagurudzo ino uye kubvuma kuti manzwisisa zvose zviri mugwaro rino. Zvichireva zvekare kuti mawana nguva yakakwana yokuverenga gwaro pamusoro petsvagurudzo ino uye kubvunza mibvunzo. Muchapiwa mufananidzo wegwaro rino wamuchazvichengetera moga.

Zita remutariri wemwana azvipira kupinda mutsvagurudzo ino (nyora zita zvinoverengeka): …….....

Zita remwana arikupinda mutsvagurudzo: ……..

Siginecha yako: ……..… Zuva, mwedzi negore: ……....

Zita rechapupu (kana chichidiwa): …….. Siginecha: ……..

Zuva, mwedzi negore: ….....

Ndatenda chaizvo nekubvuma kwenyu kupinda mutsvagurudzo ino.

Appendix E - IsiNdebele - Ugwalo olukhuluma okunengi ngenhlolisiso yethu kanye logwalo lwesivumelwano

Ugwalo olukhuluma okunengi ngenhlolisiso yethu

Isihloko Sesifundo: ***"The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe"***

Umhlolisisi Omkhulu: *Mr Precious Madzimbe [Paediatric Physiotherapist, BSc Physiotherapy (Hons) - UZ, PGD Physiotherapy (Paeds) – UCT, SA]*

Inombolo: +263 775 424 570, 1307559@students.wits.ac.za

Salibonani! Ngingumfundi weKolishi le Witwatersrand ngiyenza i*Masters* ye*Physiotherapy*. Okwakhathesi ngiphanda ulwazi ngephepha elilesihloko esithi *"**The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe".*** Inhlolisiso le izasincedisa ukuzwisisa ukuthi kwande kanganani, kubi okunganani njalo lokuthi kuyini okungenza othile abelakho lokhu kuphuza ukufikisa izibanga zokukhula ebantwaneni esibelaphayo/avasebhukwini lethu esibhedlela seUnited Bulawayo Hospitals. Impumela yaleli phepha izasiza ekwandiseni izindlela zokuvikela ukuphuza ukufikisa izibanga zokukhula ebantwaneni uma izinto ezibeka engcupheni zichaziwe ngokucacileyo futhi zihlomisa abezempilakahle *kuRehabilitation Department* ngokukhangela imbangela yokuphuza ukufikisa izibanga zokukhula ebantwaneni.

Isivumelwano lesi senzelwe ukuzwisisa izinjongo, uncedo kanye lezingozi kuphepha leli. Ukhethwe ukuthi ufake imbono yakho ngodaba lolu. Ukhethwe ukuthi ubambe iqhaza kulolu daba ngoba ingane yakho isengozini yokuphuza ukufikisa izibanga zokukhula. Ulwazi lolu luzatholakala encwadini zomntwana ezesibhedlela. Uzobuzwa imibuzo eyehlukeneyo lapho

okuyabe kusilele khona encwadini zomntwana ezesibhedlela futhi ingane zizohlolwa ukubona ukuthi ingabe iphuza ukufikisa izibanga zokukhula noma cha.

Uma uvuma ukuphatheka kuloludaba, kuzamele usinike ugwalo lomtwana lwesibhedlela. Uzacelwa njalo ukuba usinike imininingwane ethile uma ingekho loba ingakhanyi kuhle emabhukwini. Lokhu kuzolamdelwa yikuhlolwa kwengane. Lokhu kuzathatha ihola elilemizuzu engu *30* (*1hour 30minutes*). Ukuhlola ingane yikho okuzathatha ithuba elinengi.

Akula ngozi ezaziwayo ngokuphatheka kulolu daba and akula nzunzo eziqondene lokuphatheka kudaba lolu. Inzuzo ongayithola kunhlolisiso le yikuthi izosiza ekuvikeleni izingozi kanye namathuluzi okuthola amandla okuvuselelwa kwezingane eziphuze ukufikisa izibanga zokukhula uma izici zengozi kanye nokwanda kokuphuza ukufikisa izibanga zokukhula kwaziwa.

Uma uzimisele ukuphatheka kulolu gwalo ngokusayina ifomu lokuvuma, imininingwane yengane yakho izogcinwa iyimfihlo njalo ngeke ivezwe kwabanye abantu. Imininingwane yakho ingavezwa ngokuvuma kwakho. Ingavezwa kungela mvumo yakho uma kudingwa ngu mthetho. Amakhomithi okuziphatha afana le *Medical Research Council of Zimbabwe (MRCZ*) le *University of Wits Human Research Ethics Committees* kanye labahloli bami bavunyelwe ukuhlola amarekhodi ukuze kuqiniswe ikhwalithi lokuhlaziya i*data*.

Ukuphatheka kuloludaba yikuzithandela kwakho. Uma uthatha isinqumo sokuhlanganela kuloludaba noma ukuphuma ngaphakathi kwesifundo, uvumelekile kungela okubambayo noma ozakubandlulula. Akula izindleko zezimali ezifunakalayo noma ezizatholakala ngokuphatheka noma ukungaphatheki kuloludaba. Ukuhlola kuzathatha ithuba elide ngoba kuzasetshenziswa izakhali ezehlukeneyo ngokunjalo sizalinika iziphuzo ekucineni. Lizizwe likhululekile ukubuza lokhu elingakuzwisisiyo. Uma uphathwe ngendlela engakuthokozisiyo ukhululekile ukuxhumana labe *Medical Research Council of Zimbabwe* kunombolo ezithi: +263 (242) 791792 kumbe *+263 772 433 166.*

Ugwalo lwesivumelwano

Ngokusayina (faka isivumelano) ku phepha leli, livuma ukuphatheka kulolu daba lokuba libalile njalo laba lolwazi ngokuqukethwe lapha, njalo ubulesikhathi sokuhlolisisa lokubuza imibuzo eyehlukeneyo lapho ongazwisisi khona ngodaba lolu. Uzathola elinye laleli phepha njalo uzayenelisa ukuzigcinela lona.

Ibizo loncedisa umchwephetshi (Bhala ngamabala amakhulu):

……...

Ibizo lomama: ……..

Isiginetsha yomama/Legal guardian: ……..…Ilanga: ……..…...

Ibizo lomfakazi (uma edingeka): ……Isiginetsha: ……

Ilanga: ……...

Siyabonga ngokuvuma ukusisiza kunhlolisiso yethu.

Appendix F – HREC (MEDICAL) clearance letter

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Mr P Madzimbe

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200869

NAME: (Principal Investigator)	Mr P Madzimbe
DEPARTMENT:	School of Therapeutic Sciences Department of Physiotherapy Medical School University
PROJECT TITLE:	*The prevalence of, and risk factors for, developmental delay amongst children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe*
DATE CONSIDERED:	2020/08/28
DECISION:	Approved unconditionally
CONDITIONS:	Unconditional approval issued on 2021/03/17
SUPERVISOR:	Professor J Potterton
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/10/08

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **August** and therefore reports and re-certification will be due in the month of **August** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

18.03.2021

Appendix G – Medical Research Council of Zimbabwe Clearance letter

Telephone: 08644073772/791193
E-mail: mrcz@mrcz.org.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazowe Street
P. O. Box CY 573
Causeway
Harare

MRCZ/B/2019

APPROVAL

26 October, 2020

Precious Madzimbe
United Bulawayo Hospitals
Physiotherapy Department
Box 958
Ascort, Bulawayo

RE: The prevalence of, and risk factors for, development delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe.

Thank you for the application for review of research activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review: -

- Completed MRCZ 101 new application form
- Study protocol
- Data collection tools

- **APPROVAL NUMBER : MRCZ/B/2019**

This number should be used on all correspondence, consent forms and documents as appropriate.

- **TYPE OF MEETING : EXPEDITED**
- **APPROVAL DATE : 26 October, 2020**
- **EXPIRATION DATE : 25 October, 2021**

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ offices should be submitted three months before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.
- **MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.
- **QUESTIONS**: Please contact the MRCZ on Telephone No. (0242) 791193, 0864407377203 or by e-mail on mrcz@mrcz.org.zw

Other

- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.
- In addition to this approval, all clinical trials involving drugs, devices and biologics (including other studies focusing on registered drugs) require approval of Medicines Control Authority of Zimbabwe (MCAZ) before commencement

Yours Faithfully

.....

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2020 -10- 26
APPROVED
P.O. BOX CY 573 CAUSEWAY HARARE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

Appendix H – Approval of title letter

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050

Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

08 September 2020
Person No: 1305779
PAG

Mr P Madzimbe
United Bulawayo Hospitals
St Lukes Road
Ascort
958
Zimbabwe

Dear Mr Precious Madzimbe

Master of Science in Physiotherapy: Approval of Title

We have pleasure in advising that your proposal entitled *The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix I – Change of title of research letter

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050

Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

08 September 2020
Person No: 1305779
TAA

Mr P Madzimbe
United Bulawayo Hospitals
St Lukes Road
Ascort
958
Zimbabwe

Dear Mr Precious Madzimbe

Master of Science in Physiotherapy: Change of title of research

I am pleased to inform you that the following change in the title of your Dissertation for the degree of **Master of Science in Physiotherapy** has been approved:

From:

To: **The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix J – United Bulawayo Hospitals Clinical Director approval letter

Physiotherapy Department
United Bulawayo Hospitals
Box 958
Bulawayo

05 August 2020

The Clinical Director
United Bulawayo Hospitals
Dear Sir,

RE: A request to carry out a research study at UBH titled: 'The prevalence of, and risk factors for, developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe'

I am a University of the Witwatersrand student doing MSc Physiotherapy Degree, also working as a physiotherapist at UBH, who hereby requests to undertake the above-stated study at your institution. The study is in fulfilment of the MSc Physiotherapy Degree. **The research will commence late this year or early next year depending on the COVID situation**, hoping that the physiotherapy department would have resumed operations and COVID-designated hospitals would have been completed. The research aims to identify the developmental outcome of babies on the At Risk Surveillance System which is done by UBH Physio Department. The results of the study will be made available to your office. Children will be assessed on their existing routine treatment review dates hence they won't be exposed unnecessarily. For details of the study find attached research protocol summary.

The institutional permission grant is a requirement for the research ethics clearance and MRCZ application which is in progress. Looking forward to your permission grant.

Regards,

Precious Madzimbe, Mr

Paediatric Physiotherapist (+263 775 424 570, 1305779@students.wits.ac.za)

CLINICAL DIRECTOR
UNITED BULAWAYO HOSPITALS
Approved
05 AUG 2020
P.O. BOX 958, BULAWAYO
ZIMBABWE

Appendix K - United Bulawayo Hospitals Physiotherapy HOD approval letter

Telephone (263) (09)252111-9
Fax No. (263) (09) 237284
Website: www.ubh.org.zw
E-mail:info@ubh.org.zw
All Correspondence to be addressed to the:
CHIEF EXECUTIVE OFFICER
UNITED BULAWAYO HOSPITALS
P O BOX 958
BULAWAYO.
ZIMBABWE

ZIMBABWE

MINISTRY OF HEALTH AND
CHILD WELFARE
UNITED BULAWAYO HOSPITALS
PHYSIOTHERAPY &
OCCUPATIONAL THERAPY
ST LUKES WAY
ASCOT
BULAWAYO.
ZIMBABWE

24 August 2020

Dear Mr P Madzimbe

RE: PERMISSION GRANT FOR THE RESEARCH TITLED: 'THE PREVALENCE OF, AND RISK FACTORS FOR, DEVELOPMENTAL DELAY AMONG CHILDREN UNDER THE AT RISK SURVEILLANCE SYSTEM AT UNITED BULAWAYO HOSPITALS, ZIMBABWE'

The physiotherapy department have granted you permission to carry out the above stated study using children on physiotherapy follow-up. I wish you a successful research project.

Regards.

MOYO S. Mrs
Chief Therapist
United Bulawayo Hospitals

UNITED BULAWAYO HOSPITALS
CHIEF THERAPIST
24 AUG 2020
P. O. BOX 958, BULAWAYO
ZIMBABWE

Appendix L – Editor's letter

48 Catherine Berry

Illanda

Bulawayo, Zimbabwe

11 November 2021

To whom it may concern

RE: The prevalence of, and risk factors for developmental delay among children under the At Risk Surveillance System at United Bulawayo Hospitals, Zimbabwe

This serves to inform that I thoroughly went through the above document in checking for grammar, language usage, logic and consistency in its hard copy. It is up to the author to accept or reject the supposed changes suggested. The original author has the mandate to interact with the said comments as he finalises the text.

Author and Institution:

Precious Madzimbe

Department of Physiotherapy, University of the Witwatersrand

Degree:

MSc Physiotherapy

Sincerely

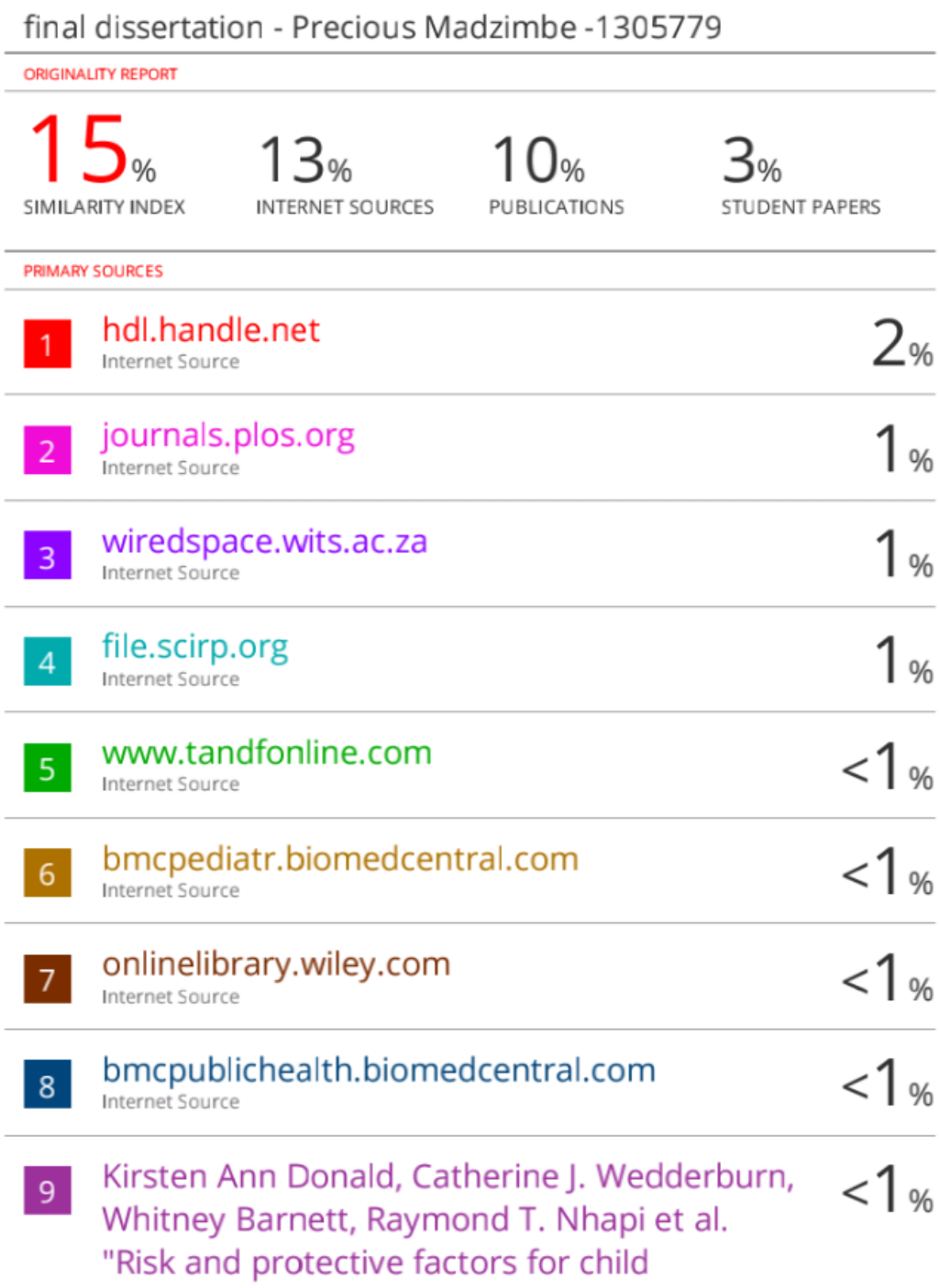
……

Dr RONNIE MWATSVERUKA

MBChB – UZ, DCH (Aus), Dip HIV Med (SA)

Paediatrics Department, United Bulawayo Hospitals

Appendix M – Turnitin Report



final dissertation - Precious Madzimbe -1305779

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