

# **A retrospective study investigating risk factors for sudden unexpected death in the young**



by

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# Declaration

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## Abstract

Sudden unexpected death in the young (SUDY) is the unanticipated demise of individuals aged between 1 and 40 years. In South Africa, these deaths are referred for forensic investigation. The primary aim of this study was to retrospectively investigate the frequency of known risk factors in SUDY cases admitted to Salt River Mortuary in Cape Town and explore differences between males and females. There were 1 088 SUDY cases identified with 0.9% (10/1 088) missing files. Reviewed cases were n=1 078, 62.6% (675/1 078) males, and 37.4% (403/1 078) females; 83.5% (901/1 078) adults and 16.4% (177/1 078) children, accounting for 5.6% of total admissions between 1 January 2010 and 31 December 2015. Despite the predominance of males, significantly more females (61.8%) were obese ( $p < 0.05$ ). At least one primary medical condition was present in 53.7% of cases, with the leading conditions being tuberculosis (11.9 % of adult males), epilepsy (11.7% of adult males; 10.3% of female children), HIV (10.7% of adult females) and asthma (11.1% of male children). In the subset of the study population where information was available, before death, 74% of individuals were reported to have experienced prodromal symptoms; 37.6% of males and 32.4% of females did not seek medical intervention following symptoms. Information regarding a family history of sudden death was known in 237/1078 cases. In 3.2% of these cases, a family history of sudden death was reported. Significantly more males than females reported the use of tobacco, alcohol, and other illicit drugs ( $p < 0.05$ ). More females were unemployed ( $p < 0.05$ ). Interventions based on lifestyle modification, social support, pharmacologic needs, and awareness should be targeted at individuals with the above profiles, especially those with a family history of sudden death, as they may be high-risk groups. Findings from this study contribute new and relevant local reference data for SUDY risk profiles of males and females admitted to Salt River Mortuary.

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# **Dedication**

This work is dedicated to my friend, late Eseohe Odiase Ituah- for the life we shared.

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## **Abbreviations**

AIDS – acquired immunodeficiency syndrome

BMI – body mass index

CHD – coronary heart disease

COD – cause of death

COPD – chronic obstructive pulmonary disease

CVD – cardiovascular disease

FPO – Forensic Pathology Officers

FPS – Forensic Pathology Services

HIV – human immunodeficiency virus

HBP – high blood pressure

HREC – human research ethics committee

ICD – international classification of diseases

SAPS – South African Police Service

SCD – sudden cardiac death

SCDY – sudden cardiac death of the young

SRM – Salt River Mortuary

SUD – sudden unexpected death

SUDA – sudden unexpected death in adults

SUDC – sudden unexpected death in childhood

SUDEP – sudden unexpected death in epilepsy

SUDY – sudden unexpected death in the young

TB – Tuberculosis

UCT – University of Cape Town

WHO – World Health Organisation

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# Chapter 1: Literature Review

## 1.1 Introduction

### 1.1.1 Sudden unexpected death in the young

For many reasons, the death of an individual can be devastating. Abrupt death occurring in seemingly healthy persons with non-fatal medical conditions is considered sudden and unexpected (Pelemo et al. 2014). In forensics, sudden and unexpected death (SUD) is defined as the unforeseen death of an individual without an apparent cause (Mason, 1995). As per the International Classification of Disease (ICD), the World Health Organisation (WHO) defines any non-violent death within 24 hours from the onset of acute symptoms in a person without a prior fatal condition as sudden and unexpected (WHO, 1992). There are many definitions of SUD; however, the shared premise is that death is usually rapid without an external cause (Byard, 2010). When SUD occurs in victims between childhood and early to middle adulthood particularly within the age group of 1 and 40 years, it is referred to as "sudden unexpected death in the young" (SUDY) (Drory et al. 1991).

Internationally, the mortality rate of SUDY in individuals between 1 and 35 years is estimated at 0.43 per 100 000 persons per annum (Morentin et al. 2003). A statistical review revealed an international incidence rate of SUD in individuals younger than 18 years of age as 1.9 per 100 000 deaths (Burns et al. 2020). The above rates led to SUD-related cases being considered a scientific and public health issue (Thurman et al. 2014). In the United States (US), SUDY accounts for 300 000 to 400 000 (121 per 1 000 000) deaths annually (Kuriachan et al. 2015). The incidence was shown to be higher in males (76 per 100 000) than in females (45 per 100 000) (Kuriachan et al. 2015). In 2009, 1.9% (48 033) of 2 437 163 deaths in the US were persons 18 years and below. In South Africa

and the same year, the corresponding number was 11.85% (69 878) of total deaths (579 711) in South Africa (Statistics South Africa, 2011).

SUDY may consist of three categories; the sudden death of (1) a seemingly healthy person, (2) a person displaying mild symptoms, or (3) a person with established chronic but stable conditions (Byard, 2010). In developing countries like South Africa, poor socio-economic status, inability to recognise prodromal symptoms, and a lack of health care facilities in communities may contribute to the prevalence of SUDY (Kruger, 2017). Cardiovascular diseases like cardiomyopathy, congenital coronary artery disorders, and hypertension are major causes of SUDY (Klitzner, 1990). Other causes of SUDY may include infections (Puranik et al. 2005), malignancies (Barranco et al. 2021; Alotaibi et al. 2022), haemorrhage (Alotaibi et al. 2022), and disorders such as immunologic and hematologic death, endocrine, gastrointestinal, and metabolic diseases (Fan & Xu, 2022).

Since these diseases are both phenotypically and genetically heterogeneous, often, SUD might be the first sign of a hereditary disease (Hertz et al. 2016; Bagnall et al. 2017). Therefore, in victims of SUDY, sudden death may expose the genetic basis of the phenomenon in surviving relatives and patients with clinical abnormalities (Scheiper-Welling et al. 2021). However, in some SUDY cases, no single apparent cause of death may be established even after a routine autopsy (Puranik et al. 2005; Van Deventer et al. 2016).

Risk factors for SUDY may be environmental, genetic, and health-related (Waldron et al. 1996; Reinier et al. 2006; Lewis et al. 2016; Kruger et al. 2018), with the most common being comorbid conditions and illnesses such as asthma, human immunodeficiency virus (HIV), tuberculosis (TB) and epilepsy (Kruger et al. 2018). Evaluating and accurately

identifying a wide range of these determinants can serve as valuable tools for designing interventions specific to local populations.

Housing, education level, occupation, and availability of financial and psychological support have been shown to have significant relationships with SUDY (Waldron et al. 1996; Reinier et al. 2006). Therefore, SUDY may result when many factors have compromised an individual's health. The incidence of SUDY is reportedly higher amongst individuals and groups with certain conditions and lifestyles, including unemployment, poor education, chronic illness, and smoking (Reinier et al. 2006).

With the right interventions, SUDY can be prevented amongst high-risk populations (Kintzle & Bride, 2010). The issues surrounding SUDY, including prevention measures, are being evaluated worldwide (Vaartjes et al. 2009), and understanding the risk factors associated with SUDY can be a complex and daunting task. To better understand SUDY, a case registry was established in the US in 2010, describing a standard process for investigating deaths and archives data and samples for surveillance and research purposes. Risk factors using these data have been established to guide interventions (Burns et al. 2017).

This chapter will discuss SUDY and its associated risk factors in the different categories of individuals previously identified as vulnerable groups. It will focus on SUDY victims that have undergone a forensic post-mortem examination. Information on risk factors for SUDY is essential to identify vulnerable populations at risk, allow preventative measures to be put into place, and increase the understanding of the SUD (Bagnall et al. 2016).

## **1.2 Medico-legal investigation of SUDY**

The approach toward SUDY investigation has been observed to vary between regions (Winkel et al. 2012). For instance, in British Columbia, Canada, all paediatric deaths are reported to the coroner (Lim et al. 2010). In Denmark, when death is sudden and unexpected, it is mandated by law that a standardised medico-legal external examination is performed (Winkel et al. 2017). Although all SUDY cases must be investigated by the Forensic Pathology Service (FPS) in South Africa, there are still inconsistencies in investigating and reporting SUDY nationally and locally (Bennett et al. 2019). In a 2-year retrospective study, it was observed that post-mortem examinations varied amongst SUD victims at the Salt River Mortuary (SRM) in the Western Cape (Kruger, 2017).

For SUDY investigation, the case history, autopsy findings, and clinical information history must be considered before an opinion regarding the cause of death is provided. Within South Africa, SUD cases are referred for medico-legal investigation for the cause of death determination. They are considered potentially unnatural under the National Health Act (Act 61 of 2003) until proven otherwise. The forensic pathologist might retrieve relevant evidence through a multi-staged process, including examinations of the scene of death, reviewing clinical and social information, examining the body, and interpreting results from ancillary investigations.

The SRM is one of the major mortuaries servicing the Western metropole of the City of Cape Town (Department of Health, Western Cape Government). Despite the forensic relevance of the SRM, there is a limited representation of SUDY cases admitted to this mortuary published in the literature. Hence, more studies should be conducted in the SRM



setting to generate data that would inform locally relevant conversations and formulate interventions for preventative measures of SUDY in South Africa.

## **1.3 Risk Factors**

The Google Scholar database was searched for this review, using the keywords; Risk factors, Sudden Unexpected Death, Sudden Death, Salt River Mortuary, Sudden Death in the Young, and Sudden Death in Children. The search was limited to articles written in the English language. Additionally, the reference lists of generated articles were further screened for articles relating to risk factors and SUDY. Overall, a total of 60 articles were used to compile this section.

### **1.3.1. Clinical and disease-related risk factors**

Disease-associated risk factors for SUDY may include coronary heart diseases, hypertension, diabetes mellitus, and a positive family history of SUD and diseases (Lewis et al. 2016). Other common clinical-related risk factors which have been identified in past research are comorbid conditions (Lewis et al. 2016) and body mass index (BMI) > 30 kg/m<sup>2</sup> (Nanavati et al. 2014). In the South African population, in addition to heart disease, epilepsy, asthma, TB, and HIV/AIDS have been identified as common medical conditions prevalent amongst victims of SUD (Tiemensma, 2010).

A study in Australia and New Zealand from 2010 to 2012, observed that 40% of SUDY cases were linked to cardiac conditions, including coronary diseases (24%) and inherited cardiomyopathies (16%). In 13% of the unexplained cases in the cohort, a follow-up genetic screening of family members revealed an inherited cardiovascular disease (Bagnall

et al. 2016). The findings of Bagnall et al. (2016) highlighted two important risk factors of cardiac disease and family history in the population of New Zealanders and Australians, which are consistently reported in the literature.

Tan et al. (2005) suggested that relatives of SUDY victims may be at higher risk for SUDY because of an increased chance of shared genetic information and lifestyle. Clinical profiles of at-risk individuals for SUDY may lead to decisions capable of informing lifestyle modifications and recognising early symptoms or illnesses (Vaartjes et al. 2009). Early recognition of prodromal symptoms plays a vital role in SUDY prevention (Drory et al. 1991). Identification of risk factors in cases of SUDY has shown the potential to prevent recurrence of SUDY in the relatives of these victims (Vaartjes et al. 2009), because treatable diseases such as atherosclerosis and other inherited disease increase the risk of SUDY; thus, early intervention can avoid SUDY occurrence (Vaartjes et al. 2009).

### **1.3.2 Demographic risk factors**

Several studies have shown differences in the prevalence of SUDY for different biological sexes (Vaartjes et al. 2009). A study on SUDY in the Netherlands reported that a higher percentage of males from their study population had epilepsy and atherosclerotic coronary diseases as the cause of death compared to females (Vaartjes et al. 2009). However, for individuals where causes of death were cardiomyopathy and conduction disorders, the prevalence was higher in females (Vaartjes et al. 2009).

Although there was an equal distribution of sudden unexpected death in childhood (SUDC) cases (1 – 18 years) between males and females at the Pretoria Medico-legal Laboratory, South Africa (Van Deventer et al. 2016), the overall incidence of SUDY is generally higher

in males than females, with an increased prevalence with age (Vaartjes et al. 2009). Sudden death in young people often occur due to cardiovascular diseases, making cardiovascular one of the causes associated with SUDY (Eckart et al. 2011). The incidence of cardiovascular diseases, however, differ between men and women. Some studies hypothesised that from a clinical perspective, differences might be due to the female endogenous oestrogen hormone (Mendelsohn et al.1999). Stampfer et al. (1991) and Barrett-Connor (1997) describe this phenomenon as the oestrogen effect. The oestrogen effect in females may increase vasodilation, inhibit the development of atherosclerosis, and control the responses to injuries of the blood vessels (Farhat et al. 1996). Animal studies also observed an increased life span amongst oestrogen-treated male mice (Fontana & Partridge, 2015) and castrated male humans (Min & Park, 2012).

The male sex has also been described as a contributing factor to infectious and immune disorders related to SUDY. It was suggested that in males, the absence of a second X chromosome, which contains significant immune-related genes, may increase the susceptibility of males to infections (Bianchi et al. 2012), and infectious disorders are commonly associated with SUDY (Parham et al. 2003).

Furthermore, differences exist in the healthcare-seeking attitude of young men and women due to their socialisations (Vanheusden et al. 2009). Epidemiological evidence indicates consistently lower medical consultation rates for men than women, especially in emotional and depressive disorders (Möller-Leimkühler, 2000). Delayed presentation for a medical consult may lead to fatality.

### **1.3.3 Socio-economic factors**

From a social and economic perspective, research highlights the role certain social backgrounds, statuses, and lifestyles may play as a predisposing factor to SUDY. For example, Waldron et al. (1996) indicated the health effect of marital status. The authors hypothesised that married and unemployed women, as a result of the alternative social and financial support marriage provides, showed seemingly better health trends than unmarried and unemployed women. Likewise, Lewis et al. (2016) supported this notion and suggested marriage as a protective factor from SUDY; in their study, only 1.5% of participants were married and had died in the presence of a spouse. Being single has been linked with risky behaviour, morbidity, and mortality in men (Burman et al. 1992).

SUD may be related to poverty, as seen in the higher occurrence amongst rural and meagre income earning families (Reinier et al. 2006). Low economic status has been evaluated as a predisposing factor associated with SUD (Reinier et al. 2006). Low income earning may be reflected in the type of residence, education level, and combined family annual income. In most instances, the factors mentioned above can influence the level of responsiveness towards prevention interventions for SUDY (e.g., recognition of symptoms and knowledge of when to seek medical assistance). Vulnerable families may also expose their loved ones to risk factors in ways they do not know about. Natural consequences of social deprivation and vulnerability may include SUDY. Furthermore, informal settlements and crowded living, which are often indicators of poverty, are reported as independent risk factors for SUDY due to limited access to quality health facilities, awareness, and inadequate protection from natural elements. With readily available quality medical care response systems in place, it is thought that SUD can be reduced (Lown & Ruberman, 1970).

Behavioural patterns and responsiveness, level of knowledge concerning SUDY, and underlying aetiology may also predispose individuals; in a study of one thousand women, over 70% of the women did not discuss heart diseases with their doctors (Mosca et al. 2000). This under-reporting attitude might be because, in some women, signs of cardiovascular diseases may be similar to symptoms of minor illnesses. Heart diseases may go unrecognised for a long time (Goldberg et al. 1998). Heart diseases are also silent killers (Balwan & Kour 2021) - they often present suddenly. Patients might not know they have a heart disease until a sudden heart failure because of the absence of symptoms.

Other lifestyle-related risk factors, such as poor diet (Fontana & Partridge, 2015) may account for minor roles in SUDY victims because the exposure to risk factors usually manifests and translate into clinical hazards later in life (Winkel et al. 2017). Obesity a likely consequence of poor diet and lifestyle, has been associated with victims of SCDY (Finocchiaro et al. 2018; Goel et al. 2020). One independent approach seeking a holistic perspective found the prevalence of coronary artery disease significantly higher in obese individuals (23%) than in non-obese individuals (10%). From their study, about one in four young patients with obesity showed coronary artery disease (Finocchiaro et al. 2018), a leading cause of SUD. The burden of disease in patients with diabetes (44%), ischemic heart (23%) and certain types of cancer (41%) are attributed to overweight and obesity (Antwi et al. 2013). Thus, excess adiposity is considered a chronic disease with serious health challenges.

Some other lifestyles include smoking and drug-abusing culture. Acute and chronic alcoholism and drug combined effects may contribute to injuries or falls. Some studies have reported cigarette smoking as one of women's most significant risk factors for sudden

cardiac death (SCD) (Slone et al. 1978; Talbott et al. 1981; Albert et al. 2003). In one study, a history of cocaine use was seen in 35% of the study population aged 20 to 40 years (Shen et al. 1995). In another study by Schwartz et al. (1991), amongst subjects who died within the last decade of the study (1980 -1989), 33% (nine cases) of the 27 cases had a history of cocaine abuse as documented in the community medical records. Six of the nine individuals died from cardiovascular diseases, while the cause of death in the other three was undetermined. It is postulated that amongst cocaine abusers, SUD may be due to the complex interactions that occur between the potentially lethal substance and body mechanisms (Shen et al.1995); these interactions may be similar to ventricular arrhythmia, which appear in the presence of substrates that facilitate rhythm disturbances (Shen et al. 1995). Additionally, in the first phases of withdrawal in cocaine abusers, silent myocardial ischemia is likely to occur (Nademanee et al. 1989).

### **1.3.4 Infection and SUDY**

Acute and aggressive presentation of infections in individuals may lead to SUDY. Infectious disorders commonly associated with SUDY include myocarditis, meningitis, septic shock, and gastroenteritis (Parham et al. 2003). Internationally, infections affecting the respiratory and central nervous systems are among the most prevalent causes of SUDY (Taggart & Craver, 2006). Also, in South Africa, there is a prevalence of death associated with infection in young individuals. The main leading causes of death in this population are infectious diseases such as pneumonia, TB, HIV/AIDS (Statistics South Africa, 2017). Similarly, Kruger (2017) observed infection as the leading cause of sudden death in all age groups at the SRM, South Africa.

Since most clinical conditions result in a compromised immune system, many individuals with comorbid and underlying health conditions become susceptible to infection (Listing et al. 2013). Chronic comorbid conditions such as heart diseases, cancer, and diabetes occur in up to 65% of sepsis patients (Angus et al. 2001). Different types and sources of infections are a leading cause of sepsis, a lethal condition (Esper et al. 2006). Therefore, it is not uncommon for infections to occur in people with underlying health issues, as poor health status may increase the risk for SUD due to infections (Listing et al. 2013).

Furthermore, lifestyle behaviours manifested in hygiene habits relating to substance abuse, such as drug infusion and user-specific paraphernalia sharing (razors, bottles, syringes), increase the transmission rate for infections like HIV/AIDS and TB (Musshoff et al. 2010). Alcohol and illicit drugs may also lead to significant alterations in the immune system, leading to an increased risk for infection and an increase in the consequences of already existing infections (Cooper et al. 2007).

## **1.4 Rationale**

SUDY is a burden in South Africa, yet there is a lack of published data on SUDY in local contexts (Van Deventer et al. 2016). The lack of information is problematic because different regions in South Africa have differing and unique social, cultural, and economic lifestyles that can influence the prevalence of SUDY per region. Therefore, local research on risk factors in SUDY is necessary to avoid generalisations and provide data relevant to the specific population in question.

While research on SUD in South Africa is increasing, little exists in the literature concerning risk factors associated with SUDY, specifically between the ages of 1 year and

40 years (Tiemensma & Burger, 2012; Van Deventer et al. 2016). A few studies have investigated sub-groups of this population, such as children (Van Deventer et al. 2016), adults (Tiemensma, 2010), and all age groups (Kruger, 2017). However, none has investigated the complete age range defined as young (ages 1 to 40 years), and no study has explicitly focused on risk factors associated with SUDY in the Western Cape, South Africa.

This research will focus on the differences between males and females as they pertain to the social and disease-associated factors studied in this work. Considering the analysis of SUDY risk factors through the lens of sex disparities is of significant interest because a sex-sensitive approach would provide more comprehensive and inclusive data (Eifert et al. 2014), that will aid the understanding of the local nuances of SUDY within male and female groups and facilitate the tailoring of targeted interventions in the future. As established earlier in this chapter, males and females may exhibit different genetic and psychosocial traits regarding their predisposition toward SUD. The role biological sex plays in these deaths will thus improve the quality of community-based interventions. Countries such as the US have shown success with interventions of a similar nature. For instance, in a community-based intervention study, the socio-demographic, physiological, and psycho-social characteristics associated with positive changes in cardiovascular disease (CVD) risk factors were prospectively examined during a 6-year multiple risk factor study (Winkleby et al. 1994). In their research, a positive shift in risk factors score was observed in 69% of the respondents during the intervention, wherein 83% were older adults with the highest perceived risks. The lowest proportion of positive changes (42%) was in the least educated, most likely of Hispanic descent, and had the least health knowledge and self-efficacy scores. The differing groups who responded to the community



CVD interventions further illustrated the need for specific interventions targeted at different ages, socio-economic, and cultural demography.

In response to the gap mentioned above regarding community-based local studies on risk analysis in the Western Cape, a project on SUDY at the University of Cape Town was launched in 2019, to investigate causes and risk factors for SUDY at SRM. The information gathered in this project will supplement other similar ongoing studies in the Division of Forensic Medicine and Toxicology (HREC: 211/2019, HREC: 171/2020, and HREC: 232/2021) to contribute toward a 10-year meta-analysis of SUDY at SRM. This project will help identify trends and help make projections, conclusions, and relevant recommendations regarding SUDY at SRM.

## **1.5 Aims and objectives**

This study aimed to explore the risk factors associated with SUDY cases admitted to Salt River Mortuary between 2010 and 2015. The specific objectives of the study were:

- i. To determine the number of SUDY admissions in Salt River Mortuary during the proposed period.
- ii. To describe known social, demographic, and clinical risk factors for SUDY in this population.
- iii. To analyse the differences in these observed risk factors between males and females.

# **Chapter 2: Methodology**

## **2.1 Study population and study design**

This study was a quantitative cross-sectional study involving a retrospective case folder review. The study population comprised all cases aged one year – to 40 years old admitted to SRM between 1 January 2010 and 31 December 2015 for medico-legal investigation under the circumstances that the death was sudden and unexpected. This study received ethical approval from the Faculty of Health Sciences, University of Cape Town (UCT) Human Research Ethics Committee (HREC REF 242/2021) (Appendix C). Permission was also obtained from the Head of the Division of Forensic Medicine and Toxicology to access the SRM autopsy database and related records (Appendix D).

## **2.2 Data collection**

The Office Autopsy Database (HREC: R036/2014), where autopsy records from the SRM are stored, was filtered to identify relevant cases. The medico-legal case files were retrieved for each of the cases. The folders contained the (i) FPS laboratory contemporaneous form (LAB. 27), used to accession and collect information on the basic demographics of the deceased per the laboratory procedure, (ii) SUD questionnaire (FPS006a/b) that documents the medical history, general information and circumstances surrounding the death of the individual for adults and children, respectively, and, (iii) post-mortem reports which record relevant observations and details of the autopsy examination such as post-mortem time, and the autopsy findings.

The demographic information, medical history, and social history variables (Table 2.1 and 2.2) were collected into a standardised data collection sheet. The data validation function in Microsoft Excel was used to define the value limits of data capture lists. The validation ensured data quality and controlled spelling mistakes and improbable figures. Additionally, an independent researcher collected a subset (10%) of the data again to ensure accuracy. After data collection, case numbers were replaced with unique study numbers to deidentify the information and maintain confidentiality.

**Table 2.1: Variables, Variable type, and Method of Data Capture for all data collected in the study**

<b>Variable category</b>	<b>Variables</b>	<b>Variable type</b>	<b>Method of Data Capture</b>
Demographic information	Age at death	Numerical	Range (1-40 years)
	Sex	Categorical	Male, Female, Unknown
	Bodyweight	Numerical	Range
	Body height	Numerical	Range
Circumstances at death and post-mortem details	Date of death	Categorical	dd/mm/yyyy
	Scene of death	Categorical	House, Shack, Road, Waterbody, Medical centre, Railway track, Open land, Other.
	Alleged manner of death	Categorical	Unnatural Natural Undetermined Under investigation Unknown Missing Not reported
	Cause of death outcome (COD)	Categorical	Free text (as reported by the pathologist)
	COD Determined/Undetermined	Categorical	Determined Undetermined
Social history	Occupation	Categorical	Employed, Unemployed,

			Economically inactive.
	Type of housing	Categorical	Formal, Informal, Unknown.
	Substance abused by deceased	Categorical	Alcohol, Illicit drugs, Tobacco products, pharmaceutical products, Combination of substances, Traditional medicine, Unknown, None. Other (Specify: _____)
	Mother's educational qualification <sup>a1</sup>	Categorical	Primary, Secondary, Tertiary, Unknown
	Marital status of mother (primary caregiver) <sup>a2</sup>	Categorical	Single, Married, Unknown, Not reported, Missing.
Clinical history	Symptoms before death	Categorical	None, Unknown, Chest pain, Fitting, Holding head in pain, Abdominal pain, Severe headaches, Nose bleeds, Foaming at mouth, Breathlessness, Paralysis of limbs, Vomiting, Diarrhoea, Other (Specify: _____)
	Did the deceased seek medical care following symptoms?	Categorical	Yes, No, Unknown, Missing, Not reported, N/A.

	Pre-existing chronic /acute illness in deceased	Categorical	Diabetes, Epilepsy, Asthma, Cancer, High blood pressure, Heart problems, Kidney problems, HIV exposure, TB exposure, Allergies, Mental disease, Malaria, Other (Specify: _____)
	Family history of illness or sudden death	Categorical	Heart disease, Asthma, Cancer, Epilepsy, Sudden death, Other (Specify: _____) None Unknown
Other	Was the body identified?	Category	Unknown, No, Yes.
	Ancestry <sup>b</sup>	Categorical	European, African, Asian, Mixed, Unknown.

<sup>a1</sup> and <sup>a2</sup> Data on maternal history was only collected for children aged 1 to 5 years at the time of death.

<sup>b</sup>Data on ancestry was only collected for undetermined cases, where a molecular autopsy may be helpful.

## 2.3 Age categorisation

In this study, the ages of the individuals were broadly grouped into adults (18 - 40 years) and children (1 - 17 years). Further, for analysis, the age categorisation was subdivided where relevant. The subdivision was done to analyse variables that may be influenced by age socially. The variables included maternal information for children, substance use, and employment status. For substance use, the children category was subdivided into the following: (i) younger children (1 – 9 years) and (ii) early adolescence (10 – 17 years) (Assopardi, 2018), and for the adults: (i) late adolescence/early adulthood (18 – 21 years) (Assopardi, 2018) and (ii) older adulthood (21 to 40 years). Additionally, due to the

overlap of tertiary school age with early adulthood and working-class age, the adult category was subdivided into (i) younger adults and (ii) older adults for the 'employment' variable.

Lastly, the two variables used to collate maternal data were : (i) maternal educational qualification and (ii) maternal marital status. These data were only available for children who were five years and below.

## **2.4 BMI categorisation**

In this study, the BMI ( $\text{kg/m}^2$ ) classification was used to estimate body weight status as Dwyer et al. (2015) recommended for medical research. The four categories for the BMI grouping in accordance with the National Institutes of Health (NIH), (1998) are as follows: (i) underweight ( $<18.5\text{kg/m}^2$ ), (ii) normal weight ( $18.5\text{kg/m}^2 - 24.9\text{kg/m}^2$ ), (iii) overweight ( $25\text{kg/m}^2 - 29.9\text{kg/m}^2$ ), and (iv) obese ( $\geq 30\text{kg/m}^2$ ). It is acknowledged that the BMI categories may not be sufficient for markers of body weight status in children which is age and sex dependant. However, to facilitate analysis across all ages up to 40yrs, these generalised markers were chosen.

## **2.5 Cause of death categorisation**

In this study, the causes of death reported by the pathologist in the post-mortem reports were further regrouped for analytical processes during data collation. The classification was done in line with a previous study which is a part of the 10-year meta-analysis project on SUDY at SRM. Maintaining consistency with previous studies was essential to ensure comparable data for the larger project.

## **2.6 Data analysis**

The data were analysed using inferential and descriptive statistics. Inferential statistical tests performed in this study were the Chi-squared test and Mann-Whitney test for categorical and numerical variables, respectively. A post hoc analysis for Pearson's chi-squared test was applied to correct for multiple testing. A p-value of 0.05 was considered to be statistically significant. For the post hoc testing, to control type 1 error rate, the p-values estimates for each chi-square value were compared against the adjusted Bonferroni corrected p-values and interpreted (Beasley & Schumacker, 1995; Garcia-Perez & Nunez-Anton, 2003). The statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS) software (version 27).

Microsoft Excel (version 16.58) was used for the graphical representation of the data. The data were summarised using percentages, graphs, and tables. Due to missing data, the denominator for percentages varies according to the available data for each variable described. A tabular representation of the summarised data containing the number of cases for which data were available is presented for each variable in appendix (A).

# Chapter 3: Results

## 3.1 SUDY at SRM 2010 to 2015

From January 2010 to December 2015, 19 410 bodies were admitted to SRM for post-mortem investigation during the six-year study period. SUDY cases accounted for 5.6% (n=1 088/19 410) of the caseload. There was an overall decrease in SUDY cases from 2010 to 2015 (Table 3.1), with an average of 181 SUDY cases per annum in the six years. Case files from 0.9% (n=10/1 088) of the identified SUDY were missing, and consequently, data from these cases could not be obtained and were not included in further analyses.



**Table 3.1:** Frequency of SUDY cases by sex per study year at SRM (2010-2015).

<b>Year</b>	<b>SUDY males cases; n (% of SUDY cases)</b>	<b>SUDY females' cases; n (% of SUDY cases)</b>	<b>Total SUDY cases</b>	<b>Annual admissions (n)</b>	<b>Percentage of SUDY cases relative to annual admissions</b>
2010	157 (67.4%)	76 (32.6%)	233	2963	7.2%
2011	130 (60.5%)	85 (39.5%)	215	2904	7.4%
2012	97 (60.2%)	64 (39.8%)	161	3045	5.3%
2013	109 (67.3%)	53 (32.7%)	162	3347	4.8%
2014	93(63.3%)	54(36.7%)	147	3461	4.3%
2015	89 (55.6%)	71 (44.4%)	160	3690	4.3%
<b>Total</b>	<b>675 (62.6%)</b>	<b>403 (37.4%)</b>	<b>1 078</b>	<b>19410</b>	<b>5.6%</b>

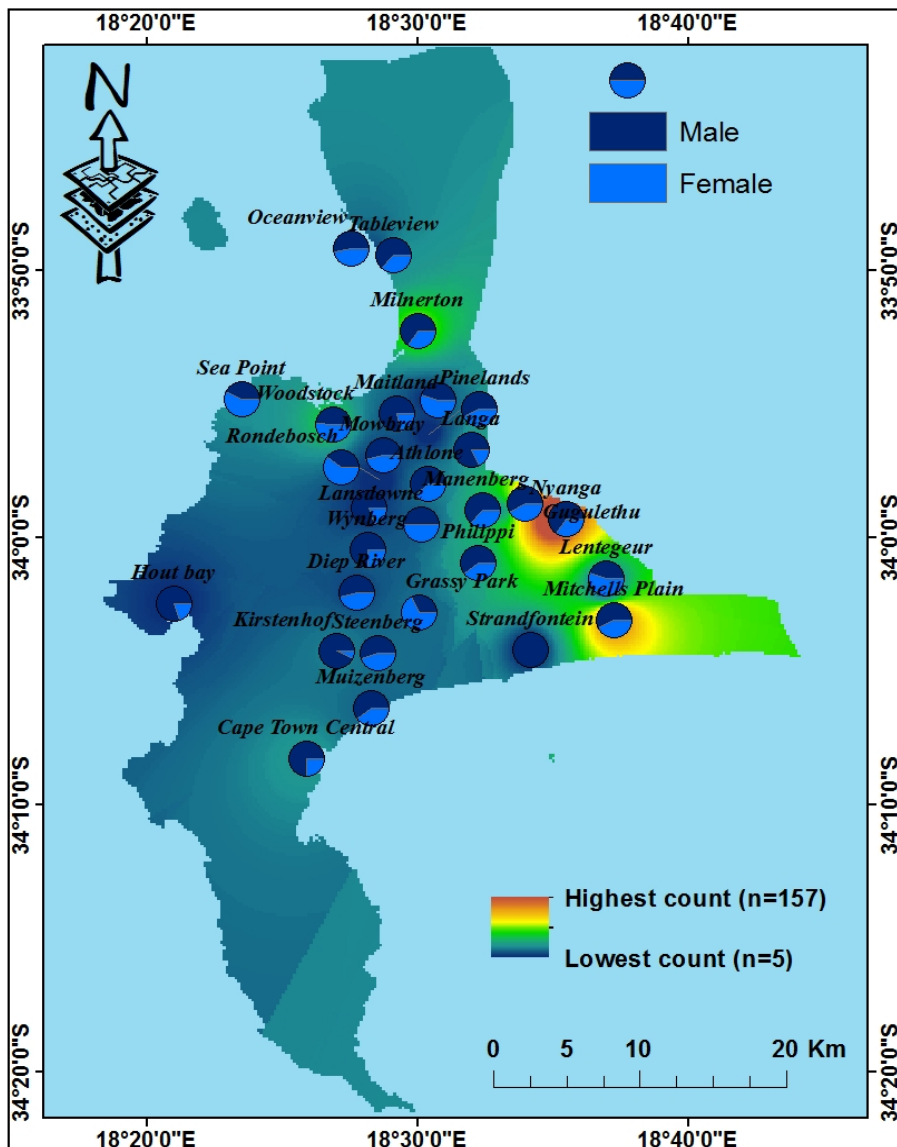
## 3.2 Demographics of the study

### 3.2.1 Sex

Males comprised 62.6% (n=675/1 078) of the SUDY cases. In each of the years, males comprised the majority of SUDY cases, with males increasing from 67% in 2010 to 73% in 2015 (Table 3.1).

### 3.2.2 Geographical distribution

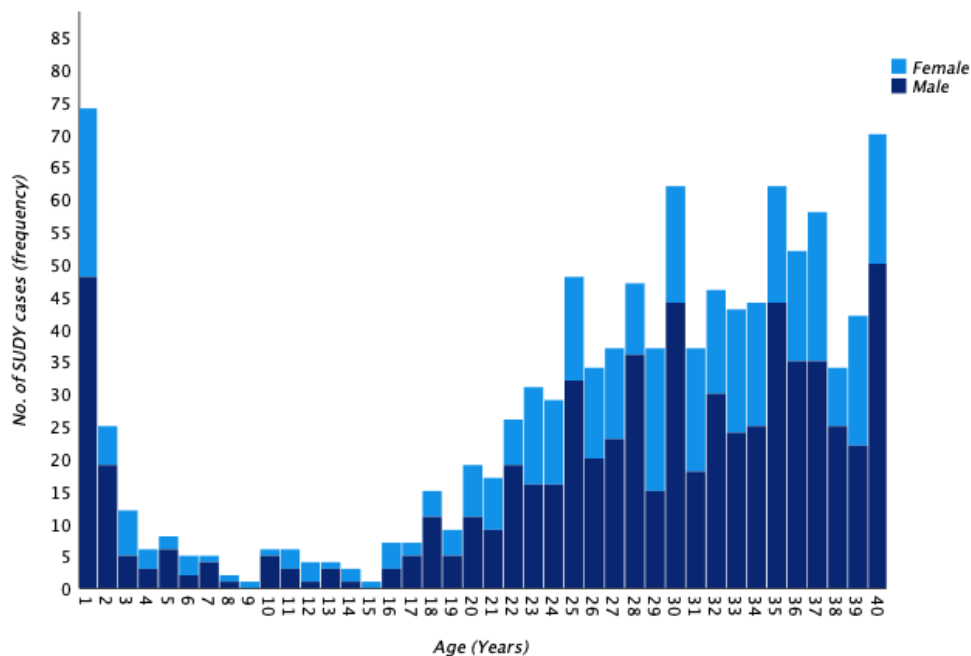
From 2010 – to 2015, the majority of the SUDY cases admitted into SRM were reported from three South African Police Service (SAPS) stations, namely, Nyanga (15%; 158/1066), Mitchells Plain (11%; 113/1066) and Gugulethu (9% 97/1066) SAPS stations. These three areas account for over a third (35%) of all SUDY cases in this study. The heat map in Figure 3.1 below shows the approximations of the areas where deaths occurred.



*Figure 3.1: Heatmap of geographical region comprising the drainage area of SRM and SUDY cases reported per SAPS police station (2010 – 2015).*

### 3.2.3 Age

Children made up 16.4% (n=177/1078) of the study population. There were 61.6% (n=109/177) males and 38.4% (n= 68/177) females. Adults comprised 83.5% (n= 901), of which 62.8% (n= 566/901) were males and 37.2 % (n= 335/901) were females. The median age was  $30 \pm 11.40$  years for the study population,  $29 \pm 11.17$  years for females, and  $30 \pm 11.51$  for males. The differences in the median age for males and females were not statistically significant ( $p=0.425$ ).

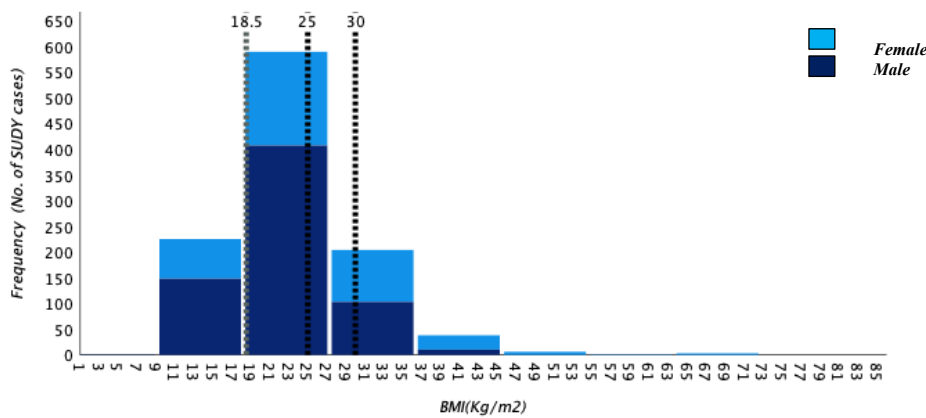


*Figure 3.2: Age distribution by sex for SUDY cases reported at SRM (2010 – 2015).*

### 3.2.4 Body mass index

For the BMI variable, there was only 93.7% (n=1010/1078) of data available. The BMI distribution among males and females varied significantly. Out of the available data, there were 16.83% (n=170/1010) obese individuals. Overall, more females, 61.2% (n=104/170) were obese. Whereas 38.3% (n=66/170) males were obese. Nearly a quarter of the

population were under-weight (23.3%; 236/1010). In the adult category, there was a significant difference in the proportion of the BMI of males and females ( $p<0.001$ ), with females having a significantly higher BMI than males. More males had a normal weight ( $n=284$ ; 70%) while more females were obese ( $n=99$ ; 61.5%). There was no association between BMI and sex for children ( $p=0.473$ ).



**Figure 3.3:** BMI distribution by sex for SUDY cases reported at SRM (2010 – 2015). Trendlines represent BMI classification of underweight ( $\leq 18.5$ ), normal (18.5 - 25), overweight (25 – 29.9), and obesity ( $\geq 30$ ).

### 3.3 Clinical history

#### 3.3.1 Symptoms before death

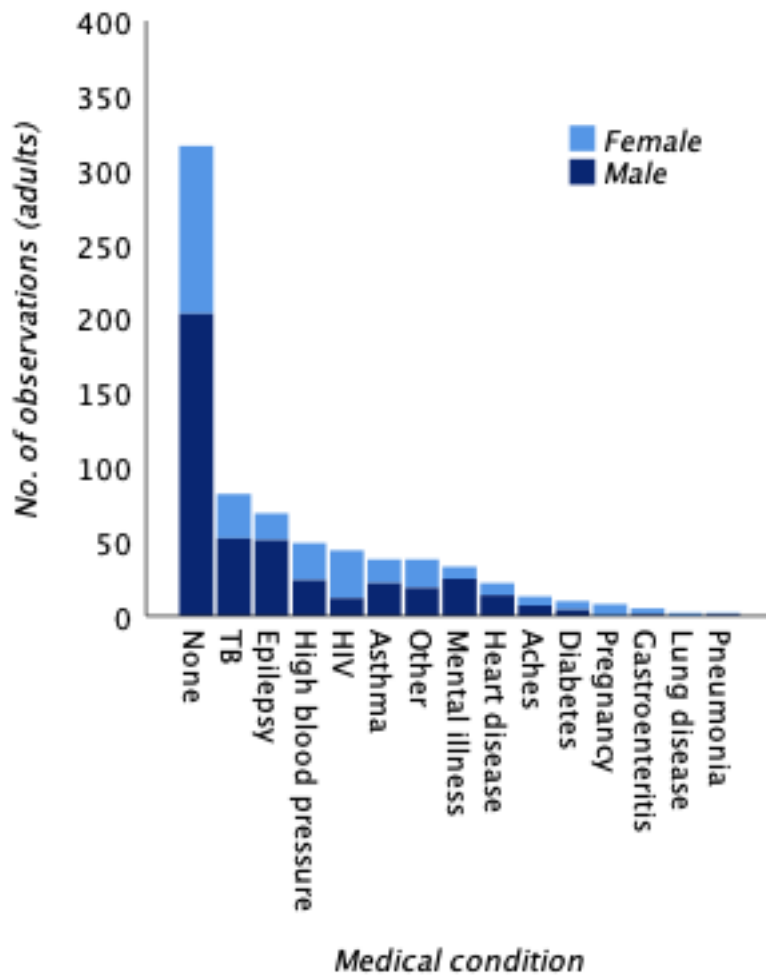
Data on medical symptoms experienced before death were reported in a subset of 70.5% ( $n=760/1078$ ) out of the entire cases. Of the 760 cases with available data, 74% ( $n=563/760$ ) of individuals reported to have experienced one or more prodromal symptoms, such as abdominal pain, headaches, flu-like symptoms, nausea, fitting, diarrhoea, and nose bleed around the time of their death.

### **3.3.1.2 Medical-seeking behaviour**

Following symptoms that presented around the time of death, there were 49.7% (n=536/1 078) cases where data was available on whether medical health was sought or not. Out of these 536 individuals who experienced symptoms before death, according to the available information, 35.4% (n=190/536) of individuals did not seek medical intervention. Wherein, 32.4% (73/225) were females and 37.6% (117/311) were males who did not seek medical care. There was no significant difference ( $p=0.380$ ) in the proportion of males and females who did not seek medical care.

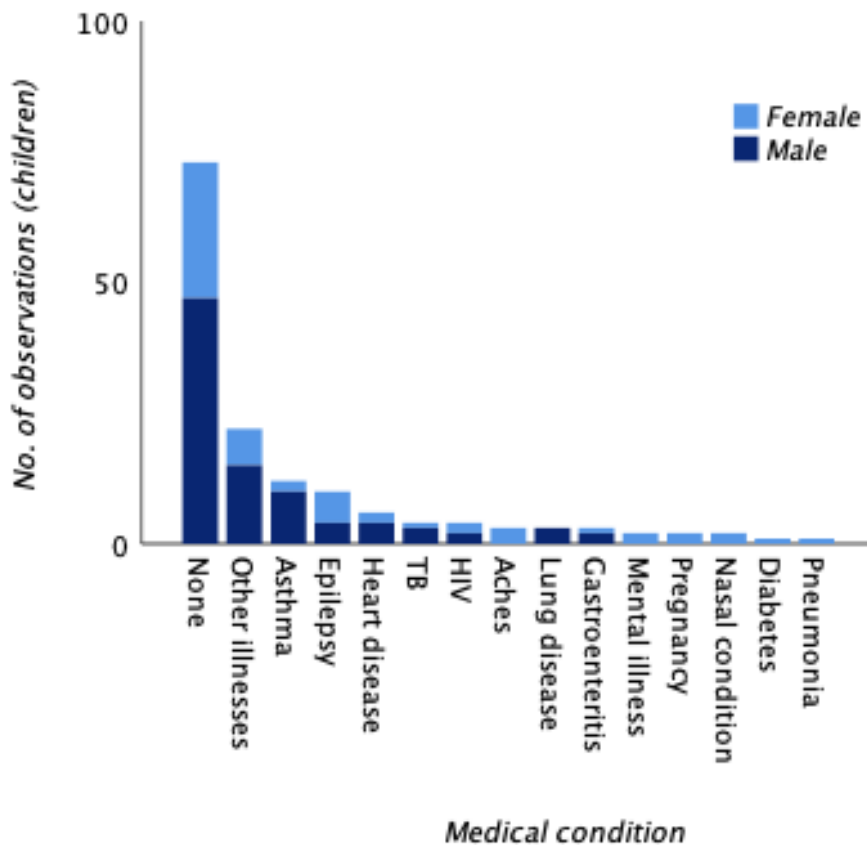
### **3.3.2 Pre-existing medical condition**

There were 78% (n=841/1 078) cases where medical history was documented; 53.7% (n=452/841) of these cases were reported to have experienced at least one chronic illness during their lifetime, out of which 9.3% (n=42/452) had existing comorbid conditions. In adults (n=734), TB 11.9% (n=52/436) and epilepsy 11.7% (n=51/436) were the most common illness among males, while in females HIV, 10.7% (32/298) was the most dominant (Figure 3.4).



**Figure 3.4:** Pre-existing medical condition by sex in adult SUDY cases reported to SRM (2010 -2015).

In children, asthma was documented in 11.1% (n=10/90) of male children, and epilepsy was reported in 10.3%(n=6/58) of female children (Figure 3.5).



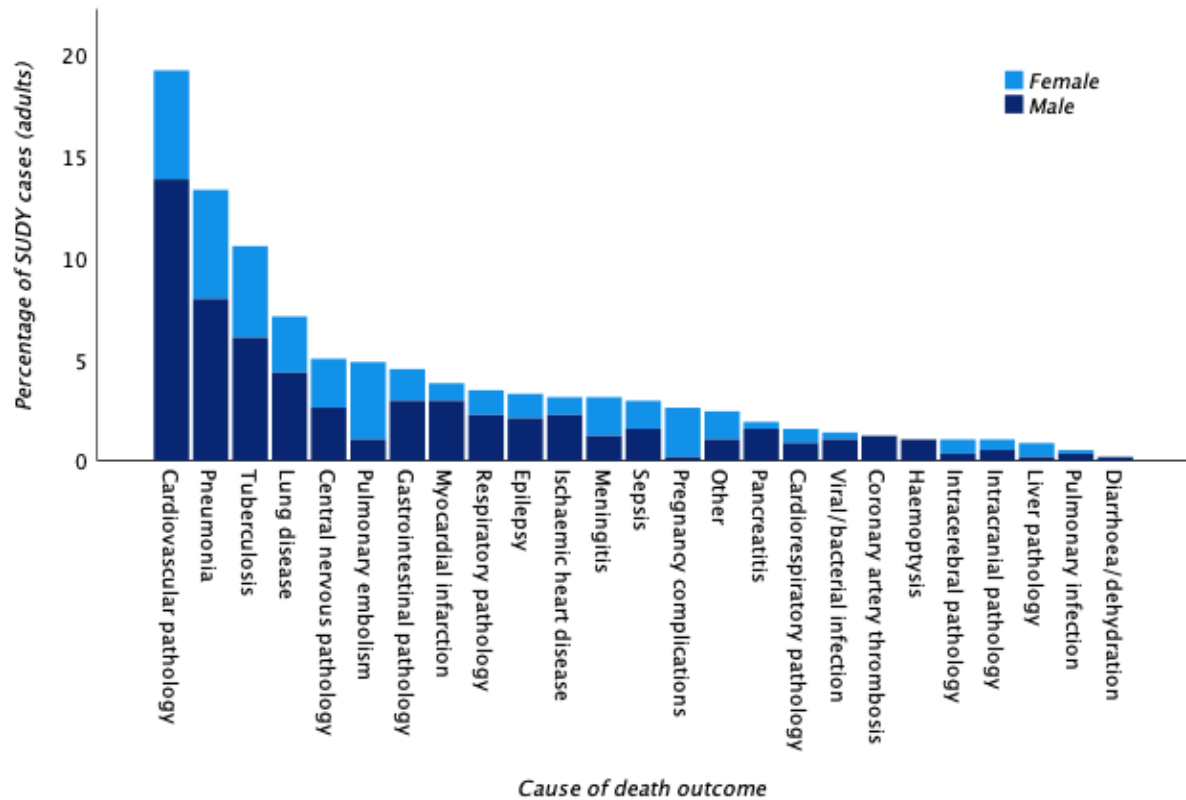
**Figure 3.5:** Pre-existing medical condition by sex in children SUDY cases reported to SRM (2010 -2015).

There was a significant association between sex and pre-existing medical conditions ( $p < 0.001$ ). Although there were more males overall than females, more females in the adult category experienced the following illnesses: gastroenteritis 80% ( $n=4/5$ ), HIV 72.7% ( $n=32/44$ ), diabetes 60% ( $n=6/10$ ), and high blood pressure 50.1% ( $n=25/49$ ). However, the observed difference was only significant for HIV ( $p < 0.001$ ). Also, as seen in figure 3.5 above, in the children category, of the medical illnesses experienced before death, significantly more females ( $p=0.035$ ) than males, had epilepsy 60% ( $n=6/10$ ), mental illness 100% ( $n=2/2$ ), diabetes 100% ( $n=1/1$ ) and body ache 100% ( $n=3/3$ ) wherein only body aches, was significantly different ( $p=0.021$ ).

### 3.3.3 Cause of death outcome

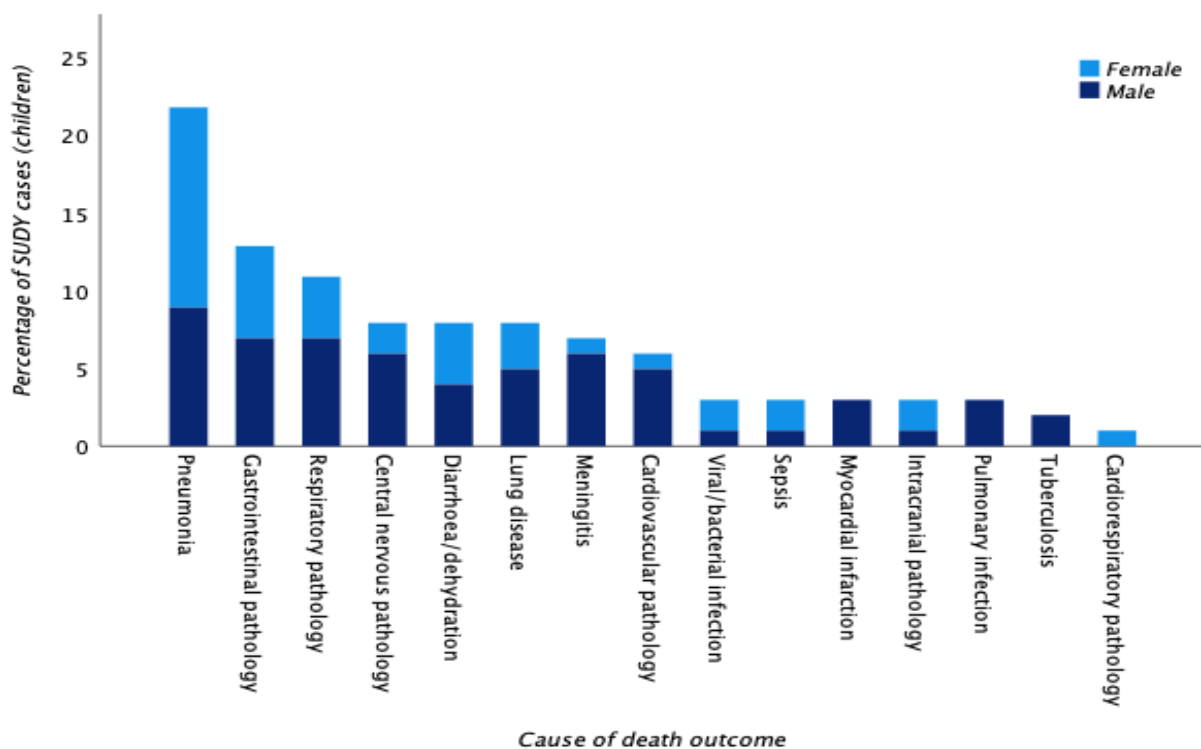
Available data where cause of death was reported was 99.5% (n=1 073/1078). After autopsy, the cause of death remained undetermined in 17.5% (n=70/401) of female cases and 22.6% (n=152/672) of male cases. The cause of death in some cases was reported as natural causes without being further specified; 14.9% (n=60/401) and 17.9% (n=120/672) in females and males, respectively. The leading cause of death was CVD, 23.3% (n=80/344) in adult males, and in females, 13.2% (n=31/234), followed by infectious disease, pneumonia, 13.2% (n=31/234) in females and 13.4% (46/344) in males, and TB, 11.1% (26/234) in females and 10.2% (35/344) in males. Pneumonia, gastrointestinal pathology, and other respiratory pathology accounted for the highest percentages of death causes in the children category (Figure 3.6).





**Figure 3.6:** Cause of death outcome by sex in adult SUDY cases reported to SRM (2010 -2015).

There was a significant association between the cause of death and sex in adults ( $p < 0.0001$ ). Specifically, there were significantly more men ( $p = 0.002$ ); 72.1% ( $n = 80/344$ ) who died of CVD than females, while significantly more females died of pulmonary embolism ( $p = 0.008$ ); 78.6% ( $n = 22/234$ ). Also, there was a significant association between the cause of death and pre-existing illness ( $p = 0.001$ ). However, there was no significant association between sex and cause of death in children ( $p = 0.235$ ).



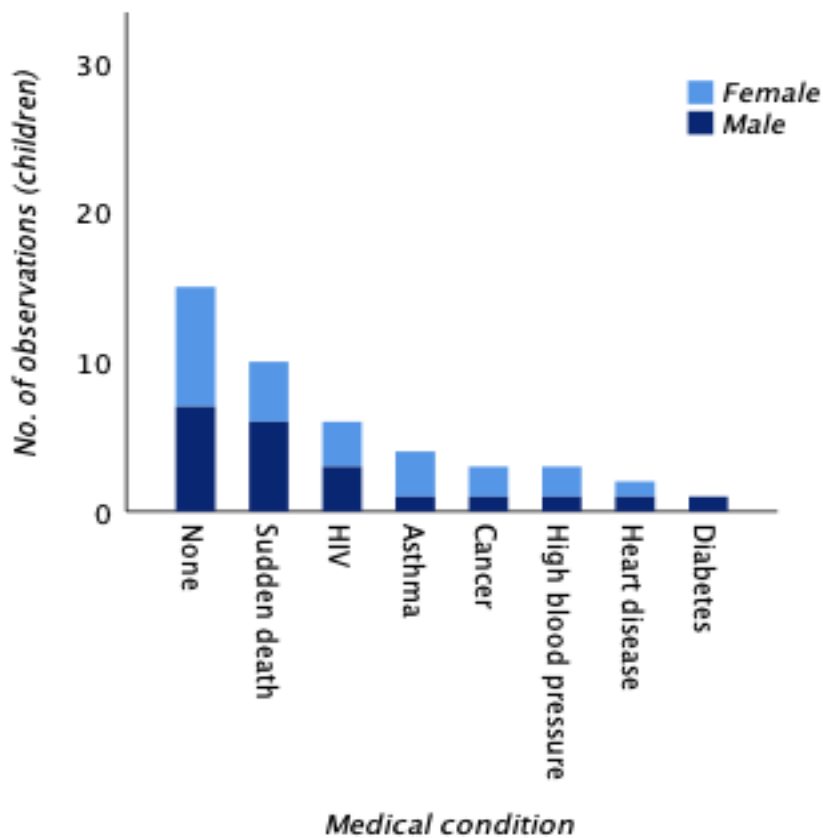
**Figure 3.7:** Cause of death outcome by sex in children SUDY cases reported to SRM (2010 -2015).

*Table 3.2: Proportion of COD by organ system for SUDY cases at SRM (2010-2015).*

<b>Organ system</b>	<b>No. of cases (n)</b>	<b>% (=n/1078)</b>
Respiratory	278	25.8
Circulatory	198	18.4
Nervous	94	8.7
Multiple organs	81	7.5
Digestive	71	6.6
Reproductive	14	1.3
Immune	5	0.5
Muscular	1	0.1
Urinary	1	0.1
Integumentary	1	0.1
Undetermined	270	25
Not specified	34	3.2
Missing information	30	2.8

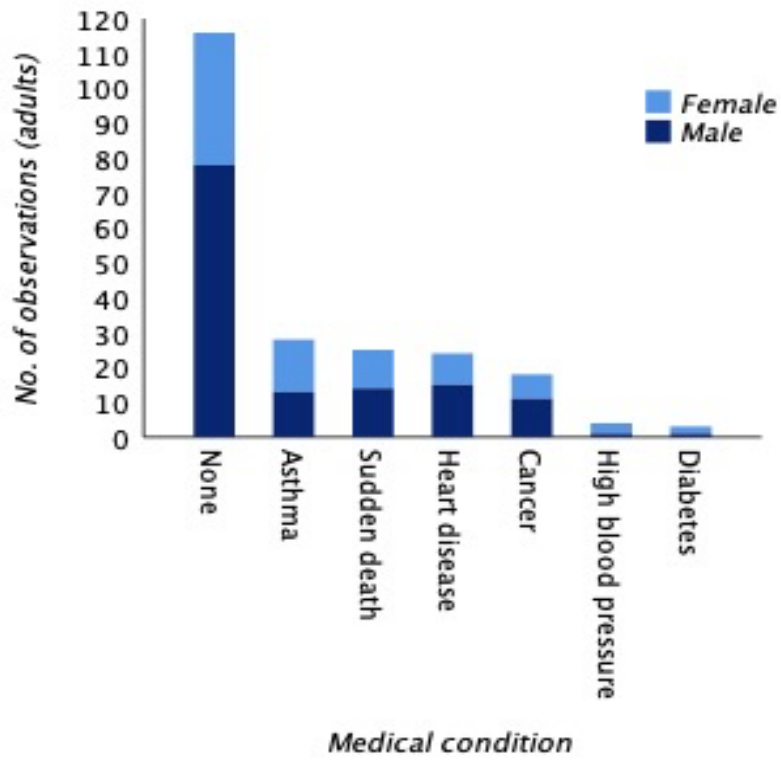
### **3.3.4 Family history of illness or sudden death**

The number of cases where data pertaining to family history of illness or sudden death were available was 22% (n=237/1 078). Of these cases, 55.3% (n=131/237) had neither a history of sudden death nor illness in their family. In 22% (n=11/50) of children, one or more family members had previously died a sudden death, wherein 54.5% (n=6/11) were males (Figure 3.8).



**Figure 3.8:** Medical conditions of family members of children SUDY cases reported to SRM (2010 -2015).

For the adult category, in 12% (n=21/180) (Figure 3.9), one or more family members had previously died a sudden death, wherein 52% (n=11/21) of them were males (Figure 3.9). There was no significant difference between sex and family history of illness in children ( $p=0.880$ ) and adult categories ( $p=0.251$ ). There was no significant association between family history and pre-existing illness ( $p=0.05$ ).



**Figure 3.9:** Medical conditions of family members of adult SUDY cases reported to SRM (2010 -2015).

## 3.4 Social history

### 3.4.1 Maternal history of children $\leq$ 5 years

#### 3.4.1.1 Maternal educational qualification

The reported data for the educational qualification of mothers/caregivers was 62% (n=78/125) (Table 3.3). Over half, 74.4% (n=58/78), of the mothers of children five years and below were educated up to secondary level (Table 3.3). Only 1.3% (n=1/78) of the mothers were reported to have no formal educational qualification (Table 3.3). The others, 19.2% (n=15/78) and 5.1% (n=4/78), had a primary and tertiary level qualification, respectively (Table 3.3).

**Table 3.3:** Maternal education data for SUDC (under five years) admitted into SRM (2010-2015).

<b>Educational qualification</b>	<b>Frequency (n)</b>	<b>Percentages</b>
None	1	1.3%
Primary education	15	19.2%
Secondary education	58	74.4%
Tertiary education	4	5.1%

#### 3.4.1.2 Maternal marital status

The available data for the marital status of mothers/caregivers was 81% (n=102/125) (Table 3.4). Mothers' marital status were reported as married or single. There were more married mothers 71.6% (n=73/102) than single mothers 28.4% (n=29/102) (Table 3.4).

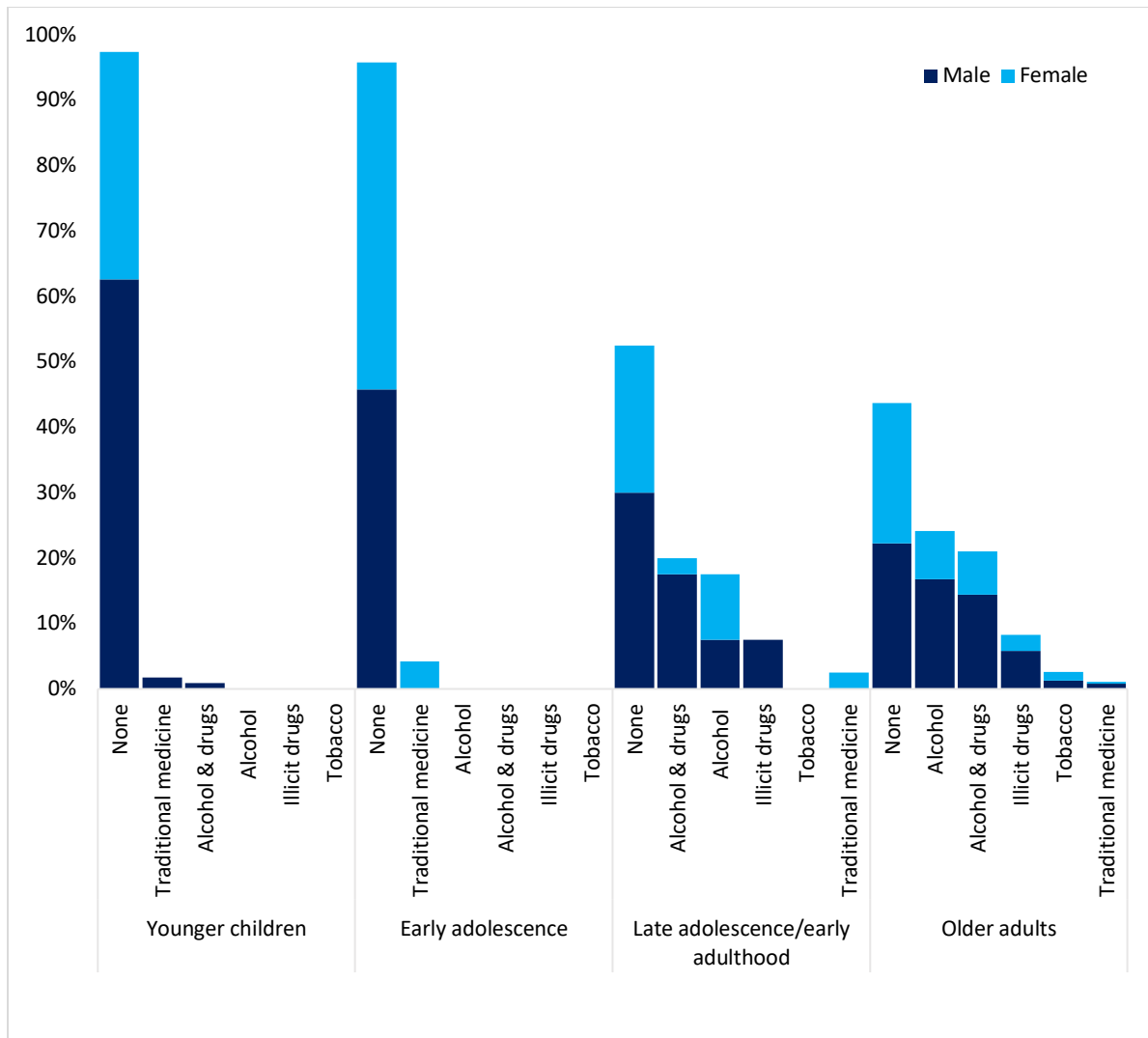
**Table 3.4:** Maternal marital status data for SUDC (under five years) admitted into SRM (2010-2015).

Marital status	Frequency (n)	Percentages
Single	73	71.6%
Married	29	28.4%

There was no association ( $p=0.494$ ) between maternal education and medical seeking behaviour for children five years and below, as well as marital status and medical seeking behaviour  $p=0.670$ .

### 3.4.2 Substance use

Information regarding substance use was available in 58.4% ( $n=630/1\ 078$ ) of cases. There was reported use of tobacco, alcohol, traditional medication, and other illicit drug substances amongst adults. 63% ( $n=241/384$ ) of males and 45% ( $n=110/246$ ) of females used at least one of the substances mentioned above (Figure 3.10). More men consumed alcohol ( $p=0.01$ ). In the older adult category (21 – 40 years), men had a significantly high rate of substance consumption ( $p<0.001$ ) compared to females. There was no significant association between sex and substance use ( $p=0.135$ ) in the younger adults. Only 2.6% ( $n=3/115$ ) of younger children were reported to have used traditional medication and a combination of alcohol and drugs, of which 100% ( $n=3/3$ ) were male (Figure 3.10). Also, in the early adolescence category (10 – 17 years), 7.7% ( $n=1/13$ ) used traditional medication; this individual was a female and the only female in this group (Figure 3.10). For the younger children (1 – 10 years) and early adolescence categories, there were no significant differences between sex and substance use ( $p = 0.440$ ) and ( $p=0.347$ ), respectively.



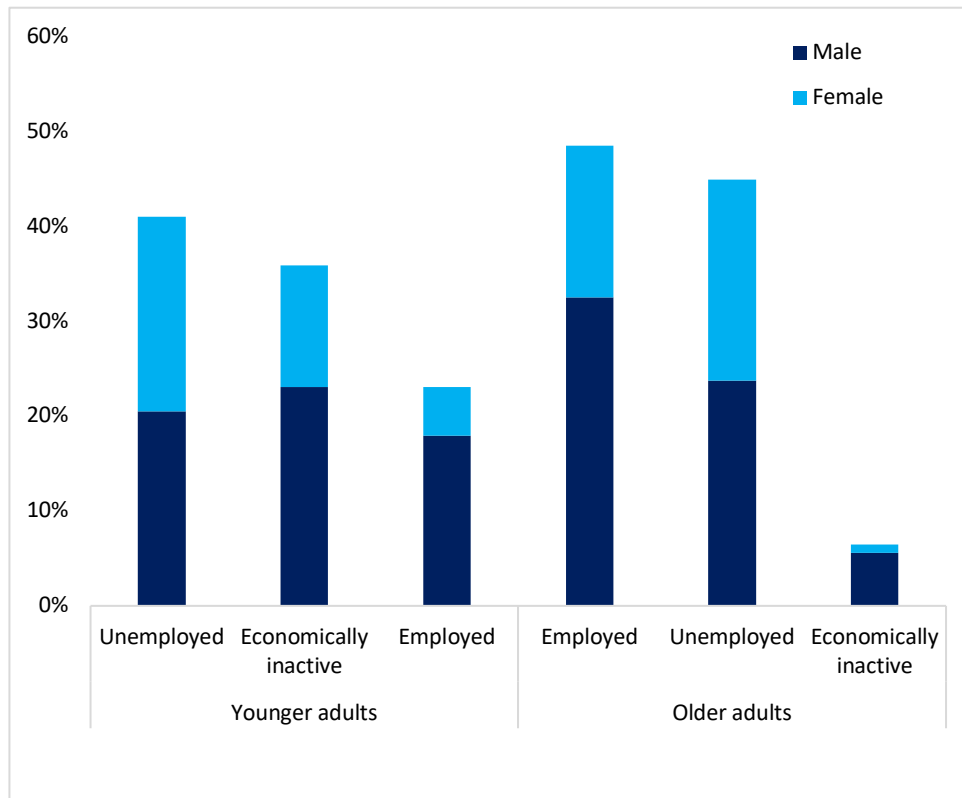
**Figure 3.10:** Substance use by sex in categories of younger children (1 -9 years), early adolescence (10 - 17 years, younger adults (18- 21) and older (22 -40) and older adult (22 – 40 years) SUDY cases at SRM (2010 -2015).

### 3.4.3 Employment

Out of 55.2% (n=595/1078) adult cases with employment status reported, 46.9% (n=279/595) of adults were employed, while 44.7% (n=266/595) were unemployed. Additionally, 8.4% (n=50/595) were economically inactive due to health challenges, schooling, disabilities, and incarceration. Significantly more females than males were unemployed ( $p < 0.001$ ). The unemployment rate was 55.5% (n=126/227) for the females,



and 38% (n=140/368) for males, with more males 10.8% (n= 40/368) than females 4% (n=9/227) in the older adult group economically inactive (Figure 3.11). Additionally, there was a significant association between employment status and substance use ( $p<0.001$ ).

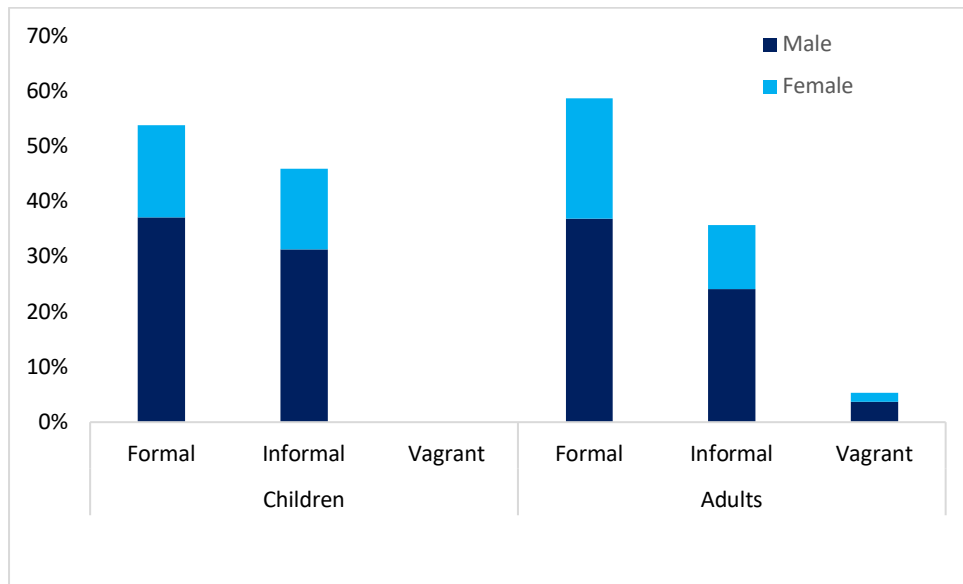


**Figure 3.11:** Employment status of younger (18 -21 years) and older (22 -40) adult SUDY cases by sex reported to SRM (2010 -2015).

### 3.4.4 Type of housing

In 58% (308/532) of cases where data were available for the type of housing, the decedents lived in formal settlements, 38% (202/532) in informal houses specified as shacks and shebeens, and 4% (23/532) as vagrants (Figure 3.12). Most individuals in both age and sex categories lived in formal houses. There was no significant association between sex and

type of housing in children ( $p=0.900$ ) and adults ( $p=0.500$ ) categories. There was an association between employment status and housing ( $p<0.001$ ).



**Figure 3.12:** Type of housing occupied before death by children and adult SUDY cases reported to SRM (2010 -2015).

# Chapter 4: Discussion

## 4.1 Burden of SUDY at SRM

Risk factors play a crucial role in the prediction and prevention of SUDY. This study explored known clinical, social, and demographic risk factors previously associated with SUDY in cases referred to SRM in the Western Cape of South Africa from 2010 to 2015. This was motivated by the lack of empirical data pertaining to these variables in the SUDY population in South Africa. The study also sought to highlight the differences in these risk factors between males and females to compare the influence of sex in the development and course of the risk conditions investigated.

SUDY comprised 5.6% of the total caseload of admissions at SRM through the six-year study period. Although 5.6% may seem like a small proportion of the total figures, SUDY could be consequential because of its rippling effect on surviving relatives, society, and a country's economy. From the results, the rate of SUDY admissions into SRM decreased by 2.9% from 2010 to 2015.

It is challenging to directly compare these numbers to international and local studies dealing with SUDY because of the variations in their inclusion criteria and the overlapping age categorisations. However, in Western Cape, the study by Tiemensma (2010) is the closest comparable published empirical data that shows an indication of the burden of SUDA (a subset of SUDY) at SRM relative to Tygerberg FPS in the Western Cape. Tiemensma (2010), reports an average of 40.6 cases per year for the adult, nearly four times the annual admission for adult cases in this current study. The number of SUDC and SUDA cases will be discussed further in the context of other studies in section 4.2.3 below titled 'Age'.

## **4.2 SUDY population demography**

### **4.2.1 Sex**

As mentioned, there was an overall decrease (2.9%) in the SUDY rate by 2015. Despite this decrease, the percentage of male SUDY cases increased by 6%. Also, the majority (62.6%) of SUDY cases in this study were males. Yet, the 2011 census reports the sex ratio in Cape Town as 51.1% female to 48.9% male (Stats, SA, 2011). This disproportion in the sex ratio of SUDY cases is similar to other studies. In one SUDA study on sex comparison in France, the males comprised 69.1% (n=369) (Naneix et al. 2015). Another population-based prospective study investigating the risk factors for SUD in men and women, at the end of 26 years, found that 2.14% (146/2336) of men and 1.7% (50/2873) of women died suddenly (Schatzkin et al. 1984). As discussed in chapter 1 (section 1.3.2), some hypotheses have been proposed to explain the high number of male SUDY cases, and these will be discussed concerning the risk factors presented below.

### **4.2.2 Geography**

Over one-third of cases (35%) were reported from Nyanga, Mitchells Plain, and Gugulethu SAPS stations, making them the three leading hotspots for SUDY deaths admitted into the SRM within the study period (Figure 3.1). The SAPS stations approximate the actual location of deaths as most deaths did not occur at the police station but rather in the vicinity closest to that SAPS station. The townships and neighbouring suburbs where most of the deaths were reported are mainly informal in nature, with many informal houses, minimal social benefit, poor living standards, and a compromised lifestyle. According to the 2011

census, in Nyanga, which had the highest number of reported SUDY cases in this study, 74% of households had a monthly income of R 3200 or less at the time (Stats, SA, 2011). Socio-economic status has been shown to predict health outcomes and quality of life; hence, low socio-economic status is associated with sudden death (Reinier et al. 2011). In the US and Canada, the incidence of SUDY was higher in poorer neighbourhoods due to individual risk factors such as compromised living standards and delays in seeking hospital care (Foraker et al. 2008).

### **4.2.3 Age**

Although there were more adults (n= 901; 83.5%) in the study, death rates were highest among children aged one year (n= 74) and adults aged 40 years (n= 72) at the time of death. Globally, infectious diseases, including pneumonia, diarrhoea, and malaria, are a leading clinical risk factor for deaths in under-fives (UNICEF, 2021). Similarly, pneumonia was a leading cause of death in children in this study. Research has shown that 60% of children who die suddenly are toddlers between 1 and 4 years (Kinney et al. 2009). In 2018 the US centres for disease control and prevention reported sudden deaths among 392 children equating to 1.4 deaths per 100 000 toddlers, and the majority aged between 1 and 4 years. In a local study on SUDC in Pretoria medico-legal laboratory, South Africa, from 2007 -2011, children between 1 and 5 years also constituted the majority (51%) of all cases (children aged 1 -18 years) investigated (Van Deventer et al. 2016).

Not many studies on SUDY have included individuals aged 40 years at the time of death. However, Tiemensma and Burger (2012), in their research on SUDA, noted the highest death rates in the category of decedents aged 30 years to 39 years (14.1%), followed by those within the 40 to 49 years (12.3%) category. Furthermore, in another study

investigating SUDY under 40 years of age, the incidence of SUD increased with age (Vaartjes et al. 2009). In the current study, there was an overall increase in the number of deaths as the age advanced. While it is not well understood why the chances of SUDY increase with age, there are various well-documented reasons for the SUD of children under five and in the early phase of their lives. A few of these include infection, unrecognised congenital malfunctions (Wren, 2002), and syncope (McLeod, 2001).

#### **4.2.4 Body mass index**

Despite the disproportionate ratio of males to females in the study population, amongst women, the rate of obesity was significantly higher (61.2%) than among men (38.8%), particularly in adulthood (Figure 3.3). Often, the first manifestation of coronary heart disease (CHD) in women is SCD. Similarly, worldwide, the proportion of adults with a BMI  $\geq 25$  kg/m<sup>2</sup> has increased in the last 33 years, from 28.8% to 36.9% in men and 29.8% to 38.0% in women (Plourde et al. 2014). Compared to lean individuals, obese men have a 2.6-fold increased risk of SCD, whereas women have a 5.8-fold increased risk (Plourde et al. 2014).

In adulthood, overweight and obesity are major risk factors associated with SUD (Chiuve et al. 2015), with about 2.8 million people dying annually due to being overweight (Parratte et al. 2014). Sometimes obesity may result due to metabolic disorders (Engin, 2017). In other individuals, the condition could be secondary to excessive food craving and consumption caused by a genetic predisposition (Perju-Dumbrava et al. 2017).

In theory, obesity, a well-established risk factor for SCD, is preventable (Perju-Dumbrava et al. 2017). Therefore, measures such as proper exercise, healthier diets and early medical

interventions could be implord in order to reduce the prevalence of overweight and obesity in young individuals.

### **4.3 Clinical factors**

After the first year of life, 10% of paediatric deaths are sudden. In children, approximately 50% of SUDs are secondary to a pre-existing illness, most commonly epilepsy, asthma, and CVD (Wren, 2002). The findings of this study were in keeping with the high frequency of these three illnesses amongst children, with asthma, epilepsy, and heart disease being the most common pre-existing illnesses (Figure 3.5). Asthma is a common disease among young South Africans, especially those living in low-income areas (Yakubovich et al. 2016). A study in Denmark reported SCD (63%) and fatal asthma attacks (27%) as the predominant causes of death in young persons with uncontrolled asthma (Gullach et al. 2015). Children and young people with recurring episodes of wheezing and tight chest symptoms must be monitored and evaluated periodically for asthma.

In addition to the above-mentioned common conditions that existed during the lifetime of decedents, HIV was also predominant in adults, especially females (10.7%). Among the adults with HIV, 72.3% were women (Figure 3.4). The high numbers of infectious diseases like TB seen in this study (Figure 3.4) may be, in part, secondary to HIV infection since TB infections are considered opportunistic infections (Wilkinson & Davies 1997; Fenner et al. 2013; Scott et al. 2017). TB prevalence amongst SUD victims in Cape Town, South Africa, is high (Osman et al. 2021). However, most of the TB detected during autopsies were diagnosed post-mortem, thus, eliminating the chances of early treatment and death prevention in patients (Osman et al. 2021).

In a setting with high burdens of HIV and TB, individuals should be educated on the symptoms of these infectious diseases to encourage testing and medical care. Considering the prevalence of HIV in South Africa (Karim et al. 2009), it may be beneficial for the SRM to adopt HIV testing as a routine test during autopsies, especially for high-risk groups. Without measures like post-mortem HIV testing, the actual impact of HIV on SUDY may be underestimated. Guided by proper ethical adherence, including end-of-life confidentiality, post-mortem testing may increase the awareness of family members of the deceased and further reduce the risk of SUD. Also, in a forensic setting, HIV post-mortem tests may be helpful for epidemiologic, academic, medical, and legal investigations (Ridgway et al. 2017), as HIV not diagnosed and accurately managed may be the reason for compromised health leading to SUDY (Kuemmerle et al. 2021).

In this study, after TB (11.2), epilepsy (9.4%) was the second most common condition in the adult cases (Figure 3.4). SUD has reportedly increased by 24- to 28-fold in people with epilepsy when compared to the general population (Tomson et al. 2016). Sudden unexpected death in epilepsy (SUDEP) mainly occurs in individuals with refractory epilepsy and presents in approximately 30% of epileptic patients (Tomson et al. 2016). Within the Western Cape, specific interventions to reduce the risk of SUD tailored toward public health campaigns, such as the encouragement of the regular intake of prescribed seizure medications and the supervision during sleep hours of individuals with nocturnal seizures to such patients.

### **4.3.1 Cause of death outcome**

In this study, CVD was the number one cause of death in adults, primarily in males. CVD was over three times more common in men than women (Figure 3.6). This may, in part,



be attributable to the age range considered in this study, as men tend to experience CVD at a much earlier age than women (Weidner, 2000). Also, psycho-social, and behavioural factors such as depression resulting from social roles, emotions, and attitudes may influence the sex disparities observed in CVD (Möller-Leimkühler, 2022).

It is reported that CVD in Africa is primarily non-ischemic (Damasceno et al. 2012; Lozano et al. 2012). However, South Africa has reported a rising incidence of ischaemic heart disease (Damasceno et al. 2012). Results from this present study distinguish between ischemic and non-ischemic, of which non-ischaemic causes were the most dominant cause of death. Therefore, given the findings of this study and a parallel increase in the incidence of CVD across South Africa (Bradshaw et al. 2003), the trend of SCD in young people may worsen if current trajectories do not change.

Another major cause of death in adults and children was pneumonia, comparable with data from a previous study by Smith et al. (2011) and Burns et al. (2020). The researchers observed pneumonia and other respiratory infections cause more child deaths than other diseases. Pneumonia results from malnutrition, limited access to proper health care (Bryce et al. 2005), and household pollutants released from unprocessed cooking fuel and tobacco smoking (Cliff, 1992; Capello & Pili 2018). Since these factors are mainly thought to be influenced by poverty, pneumonia is higher in informal settlements (Ekaru et al. 2012). Thus, the preponderance of pneumonia as a COD was anticipated in this study as a substantial number of decedents had a history of drugs and smoking (Figure 3.10).

### **4.3.2 Family history of SUD and illness**

In the cases where the information available, a previous SUD in the family was the second most prevalent condition documented in the adult SUDY cases after asthma (Figure 3.9). The three most commonly known family history conditions found in children were a previous history of SUD of family member(s), HIV, and asthma (Figure 3.8). HIV and CVD were also the prevalent familial conditions of sudden cardiac death in the young (SCDY) victims in a different study conducted at the University of Johannesburg, South Africa (Bakkum et al. 2011). In their study, significant correlations existed between sex and family history of illnesses like CVD ( $r = 0.377$ ;  $p = 0.008$ ). According to White et al. (2015) the odds of having a family history of SCDY are significantly higher for females than males. This assertion was in contrast to findings in this study, in that there was no correlation between sex and family history of sudden death or illness.

In the present study, out of the available information, there was a reported history of SUD among relatives of decedents in 3.2% of cases, over half the rate found in a similar study by White et al. (2015) in Michigan. In their study, adults with a family history of SCDY were estimated to be 6.3%, of which 5% of the affected relatives were between the ages of 1 and 39 years (White et al. 2015). Furthermore, observational studies have suggested that a parental history of SUD increases one's risk of dying suddenly (Kaikkonen et al. 2006). All of these findings indicate that a history of SUD and certain illnesses may constitute a genetic predisposition contributing to SUDY (Mestroni et al. 1999; Tan & Judge, 2012).

## 4.4 Social factors

The effect of alcohol on SUDs is seldomly discussed. In about 6% (35/601) of SUDA cases, death was attributed to alcohol toxicity in the Western Cape (Tiemensma, & Burger, 2012). Alcohol is reported as the most abused substance in the Western Cape, having a prevalence of about 39% to 64% for lifetime alcohol use across households in the Western Cape (Tiemensma, & Burger, 2012). Likewise, the most consumed substance in this study was alcohol, followed by illicit drugs. About 1% of younger children, 38.5% of younger adults, and approximately 44% of older adults had a history of alcohol consumption (Figure 3.10). Although more males had a history of using alcohol in this study, the differences were insignificant.

Although alcohol consumption cannot infer abuse or consumption rate, excessive alcohol/drug use is a leading risk factor for sudden deaths in young people globally (Murray & Lopez, 2013). Varying drug tolerance thresholds in individuals due to genetic differences in the rate of metabolism may be responsible for toxicity and the lethal effect of alcohol in certain persons (Edenberg, 2007).

Also, from the results, it is observed that the number of young people reported to have indulged in substance use does not quite capture entirely the social problem of drug abuse or the reality internationally (Wu et al. 2003; Ettorre & Miles, 2004) and across provinces in South Africa (Parry et al. 2004; Harker et al. 2008). An international study revealed that 1 in 4 adolescents living in America smoked, and one-third consumed alcohol (Wu et al. 2003). In the SRM deaths not due to chemicals or other external factors such as illicit substances are classified as natural deaths which was a major premise for inclusion in this study. The disparity of similar studies reports on drug toxicity may be due to such classification parameters.

The data collated from this study represent the reports from the decedents' relatives who provided the required information to the FPS and not on post-mortem alcohol test results. Thus, information generated were based on “hearsay” information. Therefore, the fact that the population of younger adults seems to be relatively small might not necessarily mean that individuals in this age category do not indulge in the consumption of substances, as there was a marked difference between the figures observed versus existing information on the prevalence of illicit drug use amongst young South Africans reported in the literature (Madu & Matla, 2003; Peltzer et al. 2010). Family members may be unaware of whether the decedent was involved in any substance use. Thus, the low rates reported may also be due a lack of knowledge of whether the deceased engaged in substance or due to families deliberately withholding such information for fear of reporting illegal substance use due to the legal, social, and religious implications.

Additionally, in terms of other social factors considered in this study, multiple associations were seen from the results (Appendix B). Significant associations were observed in the correlation between employment versus substance abuse and residential area and type (Appendix B). Employment status, substance use, and housing type have been linked to the health and mental well-being of individuals in society (Fryers et al. 2005; Compton & Shim, 2015). While substance use may be linked to unemployment, as seen in this study (Appendix B), drug use increased significantly among participants who were employed full-time (Wu et al. 2003). It is quite a complex interplay of many factors regarding how social factors may link to SUDY. However, an increased deprivation of social benefits such as employment, education, and quality housing has previously been associated with mortality from all causes, including cardiac pathology, infections, and smoking-related

diseases (Eames et al.1993). Thus, particular lifestyles and social factors may lead to a build-up of interrelated consequences for mortality in the young.

## **4.5 Limitations and challenges of the study**

From the risk factors analysed in this study, the factors BMI, age and sex, were certain factors, other factors were mainly identified by evaluating information available in a fraction of the study population, that was collected by a layperson from a layperson, thus, the accuracy of these information cannot be verified.

This research was a retrospective study. Therefore, there were a few limitations and challenges encountered in the different phases due to the use of secondary data. The data was sometimes missing or of poor quality, particularly for the earlier years in this study. Therefore, information in this study has to be interpreted with caution as information for most of the variables was only available for a fraction of the study population. There were either no data or an unclear representation of information for some variables due to illegible handwriting and inconsistent information provided for some cases. However, attempts were made to reach pathologists and use electronic records for updated information to limit the effects of missing data. When pathologists could not be reached, or the required information remained unavailable, the outcome was a reduction in data volume and quality. Though, as the study years progressed from 2010 to 2015, the data quality improved in completeness and consistency. Also, the questionnaires used in the post-mortem investigation were more defined and organised. During the research phase, little can be done to control for missing or poorly reported information. Handwritten documentation affects data collection at the academic research stage. To improve the

quality of scientific research in the future, the FPS should consider migrating to digital documentation for information gathering so that future researchers do not encounter the same challenges. Also, in a study such as this, the data quality is likely to be affected by the disorienting effect of SUDY experienced by relatives of decedents; recall bias can result in the omission of essential details and subjective or inaccurate responses when providing information.

In addition to the concerns on data representation, as stated in chapter 2, some captions in the current FPS questionnaire form are either too vague or non-specific, and as such, do not quite represent the details of the actual information for most of the variables. For example, in the cause of death variable, the interpretation is limited because the unclear representation impedes the interpretation of whether the observed risks had any relevance to the cause of death or not. Furthermore, the cause of death variable in this study was classified as per previous research in the ongoing larger 10-year project to maintain consistency and not necessarily in the most optimal manner.

Another challenge encountered in this study was the continued use of the term N/A across the questionnaire forms, mostly when the information required was non-clinical, i.e., social and household related. In forensics, investigations require as much information regardless of whether such information is directly linked to an incidence. This is because the details could have a significant impact during investigations.

Lastly, in the FPS laboratory contemporaneous (LAB. 27) form, only the age, in figure, of individuals was reported without providing the actual dates of birth. Such representation might be flawed by an unintended misreporting from relatives due to ignorance or the overestimation or underestimation of the actual age of the deceased. Furthermore,

reference data in South Africa and the Western Cape comparable to this study was limited primarily because of the age category and spectrum of risk factors covered. An attempt to overcome this was made by assessing many variables for children and adults separately. In addition to available local research, comparable findings from similar international studies were also utilised. Additionally, the years for this study may seem outdated; however, the included years were deliberate to provide baseline data to which more recent data can later be compared. This data contributes to a 10-year meta-analysis of SUDY at SRM and forms an integral part of the larger project.

## **4.6 Conclusion and recommendations**

This study analysed risk factors evidenced in literature to impact SUDY amongst males and females. As earlier mentioned, SUDY is a multifactorial outcome. Therefore, any young person can experience SUDY. Still, the risk factors such as BMI, age, comorbid conditions, consumption of substances of abuse, and family history of certain illnesses or SUD are known to increase its chances.

In this study, most of the SUDY cases were adult males. However, the highest number of SUDY victims were males aged one-year-old and 40 years at the time of death. Therefore, males in these ages may be more vulnerable to SUDY than other age groups. Also, the primary COD were CVD in adult males and pneumonia across all age groups. With targeted awareness and interventions, clinical conditions can be managed. Efforts around the prevention of SUDY can be most effective when information surrounding the cause of death is accurate and available (Bryce et al. 2015).

This study also showed that significantly more females (61.2%) were obese, implying obesity might pose a greater risk for SUDY in females than males. There should therefore be a drive to promote lifestyle changes in women to improve diet, exercise, stress, and sleep. Another highlight from this study includes a high number of individuals, 74% (n=563/760), out of the available data, reported to have experienced prodromal symptoms such as fever, breathlessness, and fits before death; with such high numbers of persons experiencing symptoms, caregivers, family members, health workers, and the public, if well-educated on the responsibility of first responders at scenes of emergencies at home, in public places, and health facilities, may save more lives.

In summary, as earlier stated, the SUDY rate was highest among children aged one year at the time of death, with asthma, epilepsy, and heart disease being the most common pre-existing medical conditions. The three most commonly known family history conditions found in children were a previous history of SUD of family member(s), HIV, and asthma.

For the adult population, death rate was highest among individuals aged 40 years at the time of death. The most common pre-existing conditions experienced were TB, epilepsy, HIV and Obesity in adult females. Additionally, CVD was the number one cause of death, followed by pneumonia in the adult group.

Though Pneumonia was a leading cause of death in children and a major cause of death in adult categories, some of the above factors may be irrelevant when considering the cause of death outcome as the factors such as family history of illness and pre-existing conditions were not measured against specific causes of death. Therefore, while this study looked at the overall prevalence of risk factors in an autopsy population, there were no further in-depth analyses to evaluate the exact cause of death and risk factors identified in individual cases. The results can



therefore not be applied to the entire study population due to the heterogenous largely non-specific causes of deaths observed.

This research covered SUDY cases as a whole; future researchers could exclusively analyse the clinical and lifestyle history of victims of SUDEP and SCD since many individuals experienced cardiac and epileptic conditions before death. Additionally, the process of information collection by the FPO's is another major area to be analysed, as data is compromised when medical history is misrepresented due to the use of clinically incorrect or vague terminologies often relayed by the lay relatives during questionnaire data entry. The current FPS questionnaire form should therefore be critically reviewed and refined to allow for researchers and pathologists obtain more descriptive and accurate information this will enable advancement in the information gathering processes at the SRM and by extension will enable better research outputs. Thus, accurate clinical standardized terminologies should be used to describe and capture medical conditions including causes of death. To achieve this, the FPS should consider training ad-hoc staff members involved in interfacing with relatives of the deceased on how best to relay and collect information in line with best practices.

Finally, resources should be channeled towards mediums that advocate for lifestyle modification and community and self-based care management for the high-risk groups identified in this study. The government, healthcare actors, and local policy-makers must consider utilising research data specific to communities to create relevant policies for the same areas.

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## Appendix A: Data collection variable table

*Table Ai: Summary of variable list for available data*

Variable	Output	Number of cases (n)	Percentage (%) (n/available data)
Age (years)		<b>Available data = 1084</b>	
	1	61	5.6
	2	24	2.2
	3	12	1.1
	4	6	0.6
	5	8	0.7
	6	5	0.5
	7	5	0.5
	8	2	0.2
	9	1	0.1
	10	6	0.6
	11	6	0.6
	12	4	0.4
	13	4	0.4
	14	5	0.5
	15	4	0.4
	16	8	0.7
	17	8	0.7
	18	20	1.8
	19	11	1.0
	20	19	1.8
	21	17	1.6
	22	26	2.4
	23	32	3.0
	24	29	2.7
	25	48	4.4
	26	34	3.1
	27	37	3.4
	28	47	4.3
	29	37	3.4
	30	46	4.2
	31	44	4.1
	32	44	4.1
	33	62	5.7

	34	44		4.1		
	35	62		5.7		
	36	52		4.8		
	37	58		5.4		
	38	34		3.1		
	39	42		3.9		
	40	70		6.5		
<b>Sex</b>	<b>Output</b>	<b>Number of cases (n)</b>		<b>Percentage (%) (n/available data)</b>		
		<b>Available data = 1078</b>				
	Males	67		62.6		
	Females	40		37.4		
<b>SAPS station</b>	<b>Output</b>	<b>Number of cases (n)</b>		<b>Percentage (%) (n/available data)</b>		
		<b>Available data = 1066</b>				
			<b>Male</b>	<b>Female</b>		
	Athlone	29	18	11	2.7	
	Atlantis	44	33	11	4.1	
	Cape Town Central	32	24	8	3.0	
	Claremont	10	8	2	0.9	
	Diep River	13	7	6	1.2	
	Fishoek	7	6	1	0.7	
	Grassy Park	22	7	15	2.1	
	Gugulethu	97	56	41	9.1	
	Hout bay	10	8	2	0.9	
	Kensington	11	5	6	1.0	
	Kirstenhof	27	25	2	2.5	
	Langa	32	26	6	3.0	
	Lansdowne	18	9	9	1.7	
	Lentegeur	9	4	5	0.8	
	Maitland	19	15	4	1.8	
	Manenberg	32	20	12	3.0	
	Milnerton	68	44	24	6.4	
	Mitchells Plain	11	3	65	48	0.6
	Mowbray	13	7	6	1.2	

	Muizenberg	20	12	8	1.9	
	Nyanga	15	8	103	55	14.8
	Oceanview	15	8	7	1.4	
	Other	22	14	8	2.1	
	Philippi	33	20	13	3.1	
	Phillipi East	40	27	13	3.8	
	Pinelands	7	4	3	0.7	
	Rondebosch	5	2	3	0.5	
	Sea Point	28	12	16	2.6	
	Steenberg	22	12	10	2.1	
	Strandfontein	6	6	0	0.6	
	Tableview	31	19	11	2.9	
	Woodstock	53	26	27	5.0	
	Wynberg	20	15	5	1.9	
<b>BMI</b>	<b>Output</b>	<b>Number of cases (n)</b>			<b>Percentage (%) (n/available data)</b>	
		<b>Available data = 1010</b>				
			<b>Male</b>	<b>Female</b>		
	Underweight	232	157	75	23.0	
	Normal	448	311	137	44.3	
	Overweight	160	98	62	15.8	
	Obese	170	66	104	16.8	
<b>Employment</b>	<b>Output</b>	<b>Number of cases (n)</b>			<b>Percentage (%) (n/available data)</b>	
		<b>Available data = 595</b>				
			<b>Male</b>	<b>Female</b>		
	Unemployed	16	8	8	2.7	
	Employed	8	7	1	1.3	
	Economically inactive	13	8	5	2.2	
	Unemployed	249	133	116	41.8	
	Employed	271	183	88	45.5	

	Economically inactive	38	33	5	6.3
<b>Housing</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 532</b>			<b>Percentage (%)</b> <b>(n/available data)</b>
			<b>Male</b>	<b>Female</b>	
	Formal	307	197	111	57.4
	Informal	202	137	65	38.3
	Vagrant	23	16	7	4.4
<b>Medical seeking behaviour</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 536</b>			<b>Percentage (%)</b> <b>(n/available data)</b>
			<b>Male</b>	<b>Female</b>	
	Individuals who sought medical intervention	346	194	152	64.6
	Individuals who did not seek medical intervention	190	73	117	35.4
<b>Substance use</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 630</b>			<b>Percentage (%)</b> <b>(n/available data)</b>
			<b>Male</b>	<b>Female</b>	
	Individuals who did not engage with substance of abuse	279	156	123	44.3
	Individuals who engaged with substance of abuse	351	241	110	55.7
<b>Pre-existing condition (Adults)</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 734</b>			<b>Percentage (%)</b> <b>(n/available data)</b>
			<b>Male</b>	<b>Female</b>	

	Asthma	38	22	16	5.2
	Body ache	13	7	6	1.8
	Diabetes	10	4	6	1.4
	Epilepsy	69	51	18	9.4
	Gastroenteritis	5	1	4	0.7
	HBP	49	24	25	6.7
	Heart disease	22	14	8	3.0
	HIV	44	12	32	6.0
	Lung problem	2	0	2	0.3
	Mental	33	25	8	4.5
	Nasal	3	1	2	0.4
	None	316	203	113	43.1
	Other	38	19	19	5.2
	Pneumonia	2	1	1	0.3
	Pregnancy	8	0	8	1.1
	TB	82	52	30	11.2
<b>Pre-existing condition (Children)</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 149</b>			<b>Percentage (%) (n/available data)</b>
			<b>Male</b>	<b>Female</b>	
	Other	22	15	7	14.9
	Asthma	12	10	2	8.1
	Epilepsy	10	6	4	6.8
	Heart disease	6	4	2	4.1
	TB	4	3	1	2.7
	HIV	4	2	2	2.7
	Aches	3	0	3	2.0
	Lung problem	3	3	0	2.0
	Gastroenteritis	3	2	1	2.0
	Mental illness	2	0	2	1.4
	pregnancy	2	0	2	1.4
	Nasal Condition	2	0	2	1.4
	Diabetes	1	0	1	0.7
	Pneumonia	1	0	1	0.7
None	73	47	26	49.3	
<b>COD (Adults)</b>	<b>Output</b>	<b>Number of cases (n)</b> <b>Available data = 578</b>			<b>Percentage (%) (n/available data)</b>

		Male	Female	
Cardiovascular pathology	111	80	31	19.2
Cardiorespiratory pathology	9	5	4	1.6
Central nervous pathology	29	15	14	5.0
Coronary artery thrombosis	7	7	0	1.2
Diarrhoea/dehydration	1	1	0	0.2
Epilepsy	19	12	7	3.3
Gastrointestinal pathology	26	17	9	4.5
Haemoptysis	6	6	0	1.0
Intracerebral pathology	6	2	4	1.0
Intracranial pathology	6	3	3	1.0
Ischaemic heart disease	18	13	5	3.1
Liver pathology	5	1	4	0.9
Lung disease	41	25	16	7.1
Meningitis	18	7	11	3.1
Myocardial infarction	22	17	5	3.8
Other	14	6	8	2.4
Pancreatitis	11	9	2	1.9
Pneumonia	77	46	31	13.3
Pregnancy complications	15	1	14	2.6
Pulmonary embolism	28	6	22	4.8
Pulmonary infection	3	2	1	0.5
Respiratory pathology	20	13	7	3.5
Sepsis	17	9	8	2.9
Tuberculosis	61	35	26	10.6
Viral/bacterial infection	8	6	2	1.4



COD (Children )	Output	Number of cases (n)			Percentage (%) (n/available data)
		Available data = 101			
	Cardiorespiratory pathology	1	0	1	1.0
	Cardiovascular pathology	6	5	1	5.9
	Central nervous pathology	8	6	2	7.9
	Diarrhoea/dehydration	8	4	4	7.9
	Gastrointestinal pathology	13	7	6	12.9
	Intracranial pathology	3	1	2	3.0
	Lung disease	8	5	3	7.9
	Meningitis	7	6	1	6.9
	Myocardial infarction	3	3	0	3.0
	Pneumonia	22	9	13	21.8
	Pulmonary infection	3	3	0	3.0
	Respiratory pathology	11	7	4	10.9
	Sepsis	3	1	2	3.0
	TB	2	2	0	2.0
	Viral/bacterial infection	3	1	2	3.0

*\*Below are abbreviations and their meaning from table Ai above.*

*COD – cause of death*

*HIV – human immunodeficiency virus*

*TB – Tuberculosis*

*HBP – high blood pressure*

## Appendix B: Summary of p-values for risk factors

*Table Bi: Summary of risk factors and their respective p-values*

	Risk factors	P-value		
		Adults	Children	
<b>i</b>	BMI	0.001*	0.473	
	Preexisting medical condition	0.001*	0.03*	
	COD	0.002*	0.235	
	Family history	0.251	0.880	
	Type of housing	0.5	0.9	
	Employment	0.001*	-	
		0.00*, 0.135	0.347, 0.440	
	Medical seeking behaviour	0.38		
	Age	0.425		
	<b>ii</b>	COD and preexisting medical condition	0.001	
		Family history and preexisting illness	0.05	
Employment and substance abuse –		0.001*		
<b>iii</b>	Mother's education and medical seeking $\leq 5$	0.494		
	Mother's marital status and medical seeking $\leq 5$	0.670		

The asterisks (\*) indicate levels of statistical significance.

i association between risk factors versus sex in children and adult categories.

ii association between two risk factors.

iii association between maternal factors versus medical seeking in  $\leq 5$  age category.



## Forensic Pathology Services

## SUD Questionnaire

## FORENSIC PATHOLOGY SERVICE

**To be completed in all individuals 5 years of age and younger who have died suddenly and unexpectedly.**

FPS laboratory \_\_\_\_\_ WC \_\_\_\_\_

Name of baby \_\_\_\_\_

### Part 1: Scene Questionnaire and Observations

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_

**Name of Forensic Pathology officer:** \_\_\_\_\_

#### **1. A: Who gives the history/ information in this case e.g. mother / father / granny / grandpa / other relative (give details)**

Name:	Relationship:
Address:	Contact telephone number:
ID Number or Date of Birth:	

#### **1. B: Deceased's Details**

Full name:	
Home Address:	
Age:	Date of birth:
Race:	Gender:

#### **1. C: Person(s) at/called to the scene and relationship**

Name/relationship	Date	Time
Name/relationship	Date	Time
Name/relationship	Date	Time
Name/relationship	Date	Time
Police response/name	Date	Time
Paramedic response/name	Date	Time

When was the death certified/by whom		Date	Time
Was the deceased taken to hospital? If yes, provide name of hospital		Yes	No
Name of hospital:			
Date of arrival:		Time of Arrival:	
Name of doctor seen / declared death: (Comment: Get copies of doctors notes)			
Was the deceased's resuscitated or treated by the paramedics? If Yes, get copies of the ambulance voucher		Yes	No
<b>1. D: Household environment at scene:</b>			
Place (dwelling) where the deceased lived at time of death:	House	Shack	Other (specify)
Number of rooms and bedrooms within household?	Bedrooms		Total rooms:
Number of individuals living in household?	Adults:	Children:	Total:
Is there enough fresh air circulating through the room in which the deceased was found?	Yes	No	
Are there odours present in the room where the deceased slept? If Yes, specify	Yes	No	
Was there peeling paint in the room in which the deceased slept?	Yes	No	
Was the peeling paint anywhere near the deceased's food?	Yes	No	
Was the room damp and/or fungal (mould) present within household?	Yes	No	
Did people smoke cigarettes within the household?	Yes	No	
Are there any pets in the household? If Yes, provide type and number	Yes	No	
Provide a brief history of the events leading up to death:			
Is there any suspicion of foul play? If Yes, please describe below		Yes	No
List items retained by FPO at scene (e.g. medications, syringes, clothing etc.)			

Comments by FPO who attended scene:

Date:	Signature of deponent:
-------	------------------------

I certify that the above answers to the questionnaire at the scene was taken down by myself and that the deponent has acknowledged that he / she knows and understands the contents hereof.

Date \_\_\_\_\_ Time: \_\_\_\_\_ Place: \_\_\_\_\_

Signature of Forensic Pathology Officer: \_\_\_\_\_

<b>Part 2: Facility Questionnaire</b>	
<b>Date:</b> _____	<b>Time:</b> _____
<b>Name of Forensic Pathology officer:</b> _____	

<b>2. A: Who gives the history/ information in this case</b> <b>Ideally to be provided by mother, legal guardian or primary caregiver</b>	
Name: _____	Relationship: _____
Address: _____	Contact telephone number: _____
ID Number or Date of Birth: _____	

<b>2. B: Deceased's Details</b>	
Full name: _____	
Home Address: _____	
Age: _____	Date of birth: _____
Race: _____	Gender: _____

<b>2. C: Circumstances of death / details about events before death</b>		
1. When was the baby last seen alive?	Date	Time
2. Who last saw the baby alive? Name and relationship	_____	
3. When was the baby found dead?	Date	Time
4. Who found the baby dead at the scene? Name and relationship	_____	
5. Was the deceased's body moved when found dead? If Yes, provide details below	Yes	No
_____		
_____		
_____		
6. Was the deceased ill prior to death?	Yes	No
a) If Yes, Was the deceased taken to doctor, hospital, clinic, pharmacy or traditional healer for treatment? Indicate which option(s) and dates below	Yes	No
_____		
_____		
_____		
_____		
b) If deceased was ill and not taken to doctor or clinic, provide reasons why?		
_____		

c) Provide names of medication given to deceased (including traditional). FPO to retain all medications for pathologist.					
7. Where was the baby found dead	Bed	Cot	Couch	Floor	Other
Other:					
8. Did the baby sustain any injuries – e.g. by falling or being hit: If yes:				Yes	No
a) When did it happen?					
b) How did it happen?					
c) Where did it happen?					
d) What did the caretaker do about it?					
9. a) On what surface was the baby placed to sleep?	Bed	Couch	Cot	Floor	Other
b) Specify Other:					
c) If Bed/cot, Indicate mattress type.	Foam Rubber	Inner Spring	Other (specify):		
10.a) Was there a pillow present under the head?				Yes	No
b) If Yes, was the face pressed against pillow		Yes	No	Don't know	
11.a) In what position was the deceased's body found?	Back	Stomach	Side (R/L)	Other	
b) Specify Other:					
c) In what position was the deceased's face found?	To side (R/L)	Face up	Face down	Other	
d) Specify Other:					
e) Was there anything covering the deceased's head or face?		Yes	No	Don't Know	
f) If Yes, provide details.					
12. Was the head, neck or chest squashed or wedged between any objects?		Yes	No	Don't know	

If Yes, provide details				
13. Did the deceased use a dummy (pacifier)?	Yes	No	Don't know	
14.a) Did the deceased sleep in the same bed as the mother, father or another person?	Yes	No	Don't know	
b) If Yes, describe position	In the arms	Alongside	On Chest	
c) Number of people that slept in same bed with deceased?				
d) Was anyone found laying on top of deceased (overlay)?	Yes	No	Don't know	
15. Did the mother or anyone in the house smoke while the deceased slept on the night/day of death?	Yes	No	Don't know	
16.a) Did the mother/caregiver use alcohol before going to bed with the baby on the night/day the baby was found dead?	Yes	No	Don't Know	
b) If Yes, Indicate what and how much?				
17.a) Did the mother/caregiver use drugs before going to bed with the baby on the night/day the baby was found dead?	Yes	No	Don't know	
b) If Yes, Indicate what and how much				
18.a) Did the mother/caregiver give the baby medication on the night/day of death?	Yes	No	Don't know	
b) If Yes, Indicate what medication and how much.				
17.a) When was the deceased last fed?		Date	Time	
b) What was the deceased fed?				
<b>2. D: About the baby</b>				
1.a) Where was the baby born?	Hospital	Clinic	Home	Other
b) Name of clinic/hospital, or specify other				
2.a) How was baby born?	Normal Vaginal delivery	Caesarian Section	Forceps or Ventouse	
b) Indicate reason for Caesarian Section or assisted delivery				
3. Birth weight		4. Birth Length		
5. Specify number of weeks gestation and indicate term	Weeks:	Preterm	Full Term	Post-dates (overdue)
6. Did the deceased receive Kangaroo care (skin to skin contact)?			Yes	No
7.a) Was the baby	Exclusively Breast fed	Exclusively Bottle fed	Mixed Bottle and Breast fed	
b) Provide name of Formula Milk				
c) Was boiling water used to make the bottle?			Yes	No
d) Provide names of any other foods used to feed deceased.				
8. Does the mother have the clinic card? If Yes, make copies for pathologist. If No, ask family to bring to facility.			Yes	No
9.a) Are the immunizations up to date for age?			Yes	No
b) If No, provide reasons				



10. Was the deceased sick before it died?	< 24 hours	1 day to 2 weeks	> 2 weeks	Never
Cold or Runny Nose				
Coughing				
Diarrhoea (Runny tummy)				
Unusually restless or irritable				
Crying more than usual				
Change in appetite or feeding				
Vomiting				
Seizures or fits				
Fever or Warm to touch				
Lethargic, floppy, no energy				
Cyanotic (Blue) or suddenly stop breathing				
11.a) Did the deceased come into contact with someone who was sick in the past 2 weeks?			Yes	No
b) if Yes, provide details of sickness and who the person was:				
12.a) Is the deceased known to be allergic to anything?			Yes	No
b) If yes, what?				
13.a) Did the deceased visit another province or country prior to the death?			Yes	No
b) If yes, provide details of where and when.				
14. What did the baby wear when it died? (list clothing)				
<b>2. E: About the mother</b>				
1. Is the mother			Single	Married
				In relationship
2.a) Is the mother employed?			Yes	No
b) If Yes, what works does she do?				
3. Age of the mother?				
4. What standard of schooling did she achieve?				

5.a) Is the mother the primary caregiver	Yes	No
b) If No, who is caregiver and why?		
6. Was she on contraception before she fell pregnant?	Yes	No
7. Did she take iron and vitamin tablets during her pregnancy?	Yes	No
8. Did she receive antenatal care?	Yes	No
9. Did the mother have diabetes in the pregnancy?	Yes	No
10. Did the mother have high blood pressure in pregnancy	Yes	No
11. Did the mother gain weight adequately in pregnancy?	Yes	No
12.a) Was she diagnosed with any illness during the pregnancy e.g. HIV?	Yes	No
b) If Yes, What?		
13.a) Was the mother on any medication during the pregnancy?	Yes	No
b) If yes, what medication:		
14.a) Were there any difficulties during the delivery?	Yes	No
b) If yes, what?		
15.a) Were there any problems with the baby after the delivery?	Yes	No
b) If yes, what?		
16.a) Was any specific instruction given about specific health care for the baby?	Yes	No
b) If yes, what?		
17.a) Was she depressed after the pregnancy?	Yes	No
b) If Yes, is she on any treatment?		
18.a) How many children does she have?		
b) How old are they?		
c) Do they all have the same father?	Yes	No
d) If No, provide details		
e) Do they all live with her?	Yes	No
f) If No, Provide reasons why?		

g) Are they all healthy?				Yes	No	
h) If No, provide details						
i) Do any of the children have learning disability?				Yes	No	
19.a) Did the mother smoke during the pregnancy?				Yes	No	
b) If yes, how many cigarettes per day?						
c) Does the mother smoke after the pregnancy?				Yes	No	
d) Does the mother know that smoking harms the unborn baby?				Yes	No	
20.a) Did the mother drink alcohol during the pregnancy?				Yes	No	
b) What did she drink?		Beer	Wine	Spirits	Other	
c) Other:						
d) How often did she drink?		Daily	Weekly	Occasionally		
e) How much did she drink?						
f) Does the mother drink after the pregnancy?				Yes	No	
g) Does the mother know that alcohol harms the unborn baby?				Yes	No	
21.a) Did the mother use drugs?				Yes	No	
b) What drugs did she use?	Cannabis	Cocaine	Heroin	Mandrax	Tik	Other
c) Other:						
d) How often does she use drugs?		Daily	Weekly	Occasionally		
22. Does the husband/partner drinks?				Yes	No	
23. Do the parents of the mother drink?				Yes	No	
24.a) Did the mother have a previous baby that died suddenly?				Yes	No	
b) If yes, how many died?						
c) At what age did they die?						
d) Was a PM done?				Yes	No	
e) If yes, Provide details as to when it was done, where it was done and what the cause of death was.						
25.a) Did the mother have a previous stillbirth?				Yes	No	
b) If Yes, provide details						
<b>2. F: Household environment</b>						
1.a) Was the following in the room where the deceased slept to heat the room?		Electric heater	"Galley"	Fire	Other	





## Forensic Pathology Services

## SUDA Questionnaire

To be completed for all individuals over 18 years of age who should die suddenly and unexpectedly.

FPS laboratory \_\_\_\_\_

WC \_\_\_\_\_

### Part 1: Scene Questionnaire and Observations

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Name of Forensic Pathology officer: \_\_\_\_\_

#### 1. A. Details of the person being interviewed.

E.g. husband / wife / son / daughter / mother / father / brother / sister / other relative

Name:	Relationship:
Address:	Contact telephone number:
ID Number or date of birth:	

#### 1. B: Deceased's details

Full Name of deceased:	
Home Address:	
Age of deceased:	Date of birth of deceased:
Race of deceased:	Sex of deceased:

#### 1. C: Person(s) at/called to the scene and relationship

Name/relationship	Date	Time
Name/relationship	Date	Time
Name/relationship	Date	Time
Police response/name	Date	Time
Paramedic response/name	Date	Time
When was the death certified/by whom	Date	Time
Was the deceased taken to hospital? If yes, provide name of hospital	Yes	No

Name of hospital:			
Date of arrival:		Time of arrival:	
Name of doctor seen / declared death: (Comment: Get copies of doctors notes)			
Was the deceased's resuscitated or treated by the paramedics? If Yes, get copies of the ambulance voucher		Yes	No
<b>1. D: Household environment:</b>			
Place where deceased adult lives: If Other, please specify		House	Shack
Did the deceased live alone?		Yes	No
Did anyone witness the death? If Yes, Whom? Provide name.		Yes	No
Are you aware of what the deceased did prior to death? If Yes, specify below.		Yes	No
Fits:		Yes	No
Breathlessness:		Yes	No
Foaming at the mouth:		Yes	No
Grabbing of chest:		Yes	No
Number of bedrooms in dwelling:			
Is the room where the deceased lived well ventilated?		Yes	No
Was the room locked from the inside?		Yes	No
Odour(s) present in the room the deceased slept in?		Yes	No
Peeling paint in the room the deceased slept in?		Yes	No
Medication present on the scene? If Yes, provide details and retain medication for pathologist.		Yes	No
Alcohol or Drugs present on the scene? If Yes, provide details		Yes	No
Did the deceased call a friend/someone prior to death? If Yes Whom		Yes	No
Are there pets in the house? If yes – type and number?		Yes	No
Was there a heater or open fire/gas heater/ galley blik or other heating device in room where deceased slept?		Yes	No



<b>2. A: Details of the person being interviewed.</b>		
<b>E.g. husband / wife / son / daughter / mother / father / brother / sister / other relative</b>		
Name:	Relationship:	
Address:	Contact telephone number:	
ID Number or date of birth:		
<b>2. B: Deceased's details</b>		
Full Name of deceased:		
Home Address:		
Age of deceased:	Date of birth of deceased:	
Race of deceased:	Sex of deceased:	
<b>2. C: Circumstance of death and details about the events before death</b>		
When was the deceased last seen alive?	Date:	Time:
Who last saw the deceased alive?		
When was the deceased adult found dead?	Date	Time
Who found the deceased adult dead at the scene?		
Relationship of finder		
Age of finder		
Did anyone witness the death? If yes, what did the deceased do prior to death?	Yes	No
Fits	Yes	No
Held the head	Yes	No
Breathlessness	Yes	No
Foaming at the mouth	Yes	No
Grabbing of chest	Yes	No
Other- Describe		
Did the deceased sustain any injuries at the time of death? If Yes, describe how it happened?	Yes	No



Was the deceased ill? If yes: What was wrong?	Yes	No	
For what length of time was he ill			
	<24 hrs	1 day -2 wks	
Did the deceased suffer from any of the following chronic diseases?			
Diabetes	Yes	No	
Epilepsy	Yes	No	
Asthma	Yes	No	
Cancer (If yes, provide site of Cancer)	Yes	No	
High blood pressure (Hypertension)	Yes	No	
Heart problems	Yes	No	
Kidney problems	Yes	No	
HIV	Yes	No	
TB	Yes	No	
Allergies	Yes	No	
Mental disease	Yes	No	
Malaria	Yes	No	
Urinary problems	Yes	No	
Did the deceased visit a doctor, clinic, pharmacist or traditional healer for illness?	Yes	No	
When (date and time)	Date	Time	
Did the deceased use the medication as prescribed?	Yes	No	
Contact details of individual or clinic visited			
Was the deceased admitted to a hospital for the illness?	Yes	No	
When (date and time)	Date	Time	
Name of Hospital and attending doctor (get hospital notes/folder of admission)			
Was the deceased taking any medication including chronic medication? If yes, List medication and indicate if medication retained for pathologist	Yes	No	
Did the deceased vomit? If Yes, For how long did the deceased vomit?	Yes	No	Don't Know
	Days	Weeks	Months

How many times per day did the deceased vomit when most severe?				
How did the vomit look like? If Other, provide details		Coffee	Blood	Other
Did the deceased complain of abdominal pain? If Yes, For how long did the deceased have abdominal pain?		Yes Days	No Weeks	Don't know Months
Did the deceased have abdominal distension/swelling? For how long did the deceased have abdominal distension/swelling?		Yes Days	No Weeks	Don't know Months
Was there a period of a day or longer during which the deceased could not pass stool?		Yes	No	Don't know
Did the deceased have difficulty or pain when swallowing?		Yes	No	Don't know
Did the deceased complain of headaches? If Yes, For how long did the deceased have headaches?		Yes Days	No Months	Don't know Years
Was the headaches severe?		Yes	No	Don't know
Did the headache improve upon lying down?		Yes	No	Don't know
Did the deceased have a stiff or painful neck? If Yes, Did the deceased have mental confusion? For how long did the deceased have mental confusion?		Yes Yes Days	No No Months	Don't know Don't know Years
Did the mental confusion start suddenly within a single day or slowly over many days?		Single day		Many days
Did the deceased become unconscious? If Yes, For how long was the deceased unconscious?		Yes Min	No Hours	Don't know Days
Did the unconsciousness occur suddenly or gradually over time?		Suddenly		Gradually
Did the deceased have convulsions/fits? If Yes, How long did the convulsions last for?		Yes	No	Don't know
To your knowledge, how many times did the deceased convulse?				
Was the entire body stiff during the convulsion?		Yes	No	Don't know
Did the deceased have weakness or paralysis of the body? If Yes,		Yes	No	Don't know
Was the weakness or paralysis involving	Entire Body	One side of body	Lower limbs only	Other
For how long did the deceased have this weakness or paralysis		Days	Months	Years
Did the weakness or paralysis occur suddenly or gradually over time?		Suddenly		Gradually

2. D: SURGICAL HISTORY				
Did the deceased have an operation/s? If Yes, complete table below		Yes	No	Don't know
DATE	HOSPITAL/CLINIC	NATURE OF PROCEDURE		

<b>2. E: TRAVEL HISTORY</b>		
Did the deceased travel outside the Province OR Country?	Yes	No
If Yes, Specify where and for how long?		
<b>2. F: FAMILY HISTORY OF ILLNESS</b>		
Heart disease	Yes	No
Hypertension	Yes	No
Diabetes Mellitus	Yes	No
Asthma	Yes	No
Cancer	Yes	No
Sudden death	Yes	No
If family members passes away from any of these illness, indicate at what age and which family member.		
<b>2. G: TRAUMA HISTORY</b>		
Was the deceased injured in an assault or in any accident?	Yes	No
If Yes, provide details as to when it occurred and what was specifically injured.		
Did the person need admission to hospital after the injury?	Yes	No
How was the person after the incident?	Well	Unwell
If the deceased remained unwell after discharge from hospital, provide details why and for how long.		
<b>2. H: SOCIAL HISTORY</b>		
Did the deceased consume alcohol?	Yes	No
If yes, what?	Beer	Spirits
	Wine	Papsak
		Other
Indicate how much?		

And how often (daily, weekly, occasionally)						
Did the deceased regularly use drugs?				Yes	No	Don't know
If yes, what?	TIK	Mandrax	Dagga	Cocaine	Heroin	Other
How often (daily, weekly, occasionally)						
Describe Other:						
Did the deceased use alcohol or on the day/night of death?				Yes	No	Don't know
If Yes, specify what and how much?						
If the deceased is female, is she pregnant				Yes	No	Don't know
If Yes, ask about antenatal clinic attendance						
What clinic						
Was she on contraception				Yes	No	Don't know
If Yes, name of contraceptive:						
Did the deceased smoke cigarettes?				Yes	No	Don't know
How many packs per day? (Pack = 20 cigarettes)						
<b>2. I: EMPLOYMENT HISTORY</b>						
Was the person employed?					Yes	No
If yes, what did he/she do?						
Did the person ever work in a mine?				Yes	No	Don't know
History of an animal/insect/snake bite				Yes	No	Don't know
History of Bee sting				Yes	No	Don't know

<b>COMMENTS TO PATHOLOGIST FROM THE FORENSIC OFFICER WHO INTERVIEWED:</b>


<b>ITEMS RETAINED DURING THE INTERVIEW</b>

Date: _____	Signature of deponent: _____
-------------	------------------------------

I certify that the above answers to the questionnaire was taken down by myself and that the deponent has acknowledged that he / she knows and understands the contents hereof.

Date \_\_\_\_\_ Time: \_\_\_\_\_ Place: \_\_\_\_\_

Signature of Forensic Pathology Officer: \_\_\_\_\_

Department of Health, Forensic Pathology Laboratory



**UNIVERSITY OF CAPE TOWN**  
**Faculty of Health Sciences**  
**Human Research Ethics Committee**



**Room G50- Old Main Building**  
**Groote Schuur Hospital**  
**Observatory 7925**  
**Telephone [021] 406 6492**

**Email:** [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za)

**Website:** [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

20 April 2021

**HREC REF: 242/2021**

**Dr L Heathfield**

Division of Forensic Medicine & Toxicology

Falmouth Building -FHS

Email: [laura.heathfield@uct.ac.za](mailto:laura.heathfield@uct.ac.za)

Student: [Oghogh001@myuct.ac.za](mailto:Oghogh001@myuct.ac.za)

Dear Dr Heathfield

**PROJECT TITLE: A RETROSPECTIVE STUDY INVESTIGATING RISK FACTORS FOR SUDDEN UNEXPECTED DEATH IN THE YOUNG' -MPHIL CANDIDATE: OGHENEOCHUKO OGHENECHOVWEN-sub-study linked to 211/2019**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.**

**Approval is granted for one year until the 30 April 2022.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

***The HREC acknowledge that the student: - Miss Oghenechuko Oghenechovwen will also be involved in this study.***

**Please quote the HREC REF 242/2021 in all your correspondence.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely




**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE**

Federal Wide Assurance Number: FWA00001637.  
Institutional Review Board (IRB) number: IRB00001938  
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.



## FHS016: Annual Progress Report / Renewal

<b>HREC office use only (FWA00001637; IRB00001938)</b>			
<b>This serves as notification of annual approval, including any documentation described below.</b>			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30.4.23
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee			Date Signed 28/3/22

**Note:** Please email this form and supporting documents (if applicable) in a combined pdf-file to [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za).

Please clarify your plan for research-related activities during COVID-19 lockdown.

Please use the latest form found on our website:

<http://www.health.uct.ac.za/fhs/research/humanethics/forms>

Comments to PI from the HREC

### Principal Investigator to complete the following:

#### 1. Protocol information

Date (when submitting this form)	26 March 2022		
HREC REF Number	242/2021	Current Ethics Approval was granted until	30 April 2022
Protocol title	A retrospective study investigating risk factors for sudden unexpected death in the young		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
If yes, could you please provide the HREC Reference number for all sub-studies? <b>Note:</b> A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Laura Heathfield		
Department / Office Internal Mail Address	Reception, Division of Forensic Medicine and Toxicology, Falmouth building (entrance 3, level 1), Medical School, Anzio Road, Observatory		





1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

**Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates.

(Please send electronic copy for full committee review to hrec-submission@uct.ac.za)

**If yes in 1.2 please complete section 1.3 below for invoicing purposes**

**1.3 Ethics Renewal Fee**

Please (tick ✓) appropriate box for billing purposes:

<u>Submission Type</u>	<u>Description</u>	<u>New fee (Vat Incl.)</u>	<u>tick ✓</u>
<i>Research funded solely from UCT departmental/divisional/group budget</i>	Annual evaluation of research progress report for re-certification	R0,00	<input type="checkbox"/>
<i>Non-sponsored student research for degree purposes at UCT/Other Universities &amp; Colleges</i>	Annual evaluation of research progress report for re-certification	R0,00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R7000,00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	R3 710.00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R6000.00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	R1 500,00	<input type="checkbox"/>

**NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.**

**Please provide details for Invoicing, either complete section 1 or 2 :**

**1. Invoice billing – Directly to Sponsor**

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	
Contact person	
Telephone number	



Email Address	
<b>2. Internal Journal Billing:</b>	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

## 2. List of documentation for approval

None
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## 3. Protocol status (tick ✓)

<input type="checkbox"/>	Open Enrolment
<input type="checkbox"/>	Closed to enrolment (tick ✓)
<input type="checkbox"/>	Research-related activities are ongoing
<input type="checkbox"/>	Research-related activities are complete, long-term follow-up only
<input checked="" type="checkbox"/>	Research-related activities are complete, data analysis only
<input type="checkbox"/>	Main study is complete but sub-study research-related activities are ongoing
<input type="checkbox"/>	Study is closed → Please submit a Study Closure Form (FHS010)

## 4. Enrolment

Number of participants enrolled to date	N/A
Number of participants enrolled, since last HREC Progress report (continuing review)	N/A
Additional number of participants still required	N/A

## 5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	N/A
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## 6. Cumulative summary of participants

Total number of participants who provided consent	N/A
Number of participants determined to be ineligible (i.e. after screening)	N/A



Number of participants currently active on the study	N/A
Number of participants completed study (without events leading to withdrawal)	N/A
Number of participants withdrawn at participants' request (i.e. changed their mind)	N/A
Number of participants withdrawn by PI due to toxicity or adverse events	N/A
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	N/A
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	N/A
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	N/A

### 7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:

This study is a retrospective review of medico-legal case folders from 2010 – 2015. All data collection is complete and data analysis is ongoing.

### 8. Protocol violations and exceptions (tick ✓ all that apply)

<input checked="" type="checkbox"/>	No prior violations or exceptions have occurred since the original approval
<input type="checkbox"/>	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
<input type="checkbox"/>	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

### 9. Amendments (tick ✓ all that apply)

<input type="checkbox"/>	No Prior amendments have been made since the original approval
<input checked="" type="checkbox"/>	Prior amendments have been reported since the last review and have already been approved
<input type="checkbox"/>	New protocol changes/ amendments are requested as part of this continuing review (See note below)

**Note:** If new protocol changes are being requested in this review, please complete an amendment form (FHS006).



Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

**10. Adverse events**

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.

N/A

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?

Yes                       No                       Not applicable

If yes, please describe:

**11. Summary of Monitoring and Audit Activities (tick ✓)**

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?

Yes                       No                       Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?

Yes                       No                       Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

Agency Name		Report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable
		DSMB report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?

Yes                       No

If yes, please explain:

**12. Level of risk (tick ✓)**

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:



<input type="checkbox"/>	Increased
<input type="checkbox"/>	Decreased
<input checked="" type="checkbox"/>	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

-

**13. Insurance**

Please confirm that valid no fault insurance is still in place? (tick ✓)

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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If yes, please complete the following:

Insurer's name:			
Policy no.		*Coverage Period:	

*For UCT sponsored studies please liaise the Insurance office via [fhs.sponsorship@uct.ac.za](mailto:fhs.sponsorship@uct.ac.za) regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.*

**14. Statement of conflict of interest**

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
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If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):

**15. Signature**

My signature certifies that the above is complete and correct.

Signature of PI		Date	26 March 2022
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Acting Head of Division: Division of Forensic Medicine and Toxicology

Dr Yolande van der Heyde

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Level 1, Entrance 3
Anzio Road
Observatory
Tel: +27 (0) 21 406 6821 E-mail: yolande.vanderheyde@uct.ac.za
Internet: www.forensicmedicine.uct.ac.za

22 April 2021

To whom it may concern,

As the Acting Clinical Head of the Division of Forensic Medicine and Toxicology, I grant permission for the following researchers to have access to Salt River Mortuary records and/or samples (as specified below) for the research project as stipulated:

Principal Investigator: Dr Laura Heathfield (Staff number: 01426764)
Co-investigators: Mr Calvin Mole
Student: Oghenechuko Oghenechovwen (Student number: Oghogh001)
Project Title: A Retrospective Study Investigating Risk Factors for Sudden Unexpected Death in the Young

Access to:

Table with 2 columns: checkbox, description. Includes items like 'The autopsy allocations', 'The Office Autopsy Database and related records', and various forensic pathology services.

For the data collection period of 20/04/2021 to 31/12/2021

Signature of Dr Yolande van der Heyde

Dr Yolande van der Heyde (Signature)

22/04/2021

Date (dd/mm/yyyy)