INVESTIGATING KEY FACTORS THAT INFLUENCE QUALITY OF LIFE IN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PATIENTS IN THE CARDIAC CLINIC AT GROOTE SCHUUR HOSPITAL

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DECLARATION

I declare that:

Investigating key factors that influence Quality of Life in Implantable Cardioverter Defibrillator patients in the cardiac clinic at Groote Schuur Hospital

is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I have not previously submitted this work, or part of it, for examination at UNISA for another qualification or at any other higher education institution.

A L Luscombe

Signature

7 JUNE 2017

Date

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ABSTRACT

International studies have demonstrated that Implantable Cardioverter Defibrillators (ICDs) can have a significant impact on the Quality of Life (QOL) of patients. This is often due to factors that cause considerable psychological distress and has not been investigated in South Africa before. This research study thus investigated factors that influence QOL in patients with ICDs who are followed up in the Cardiac Clinic at Groote Schuur Hospital. The objectives were to describe demographic, clinical, ICD and patient support characteristics; to determine the prevalence of anxiety and depression; to assess QOL and to establish factors that influence depression, anxiety and QOL.

The method involved a quantitative approach and a descriptive, cross-sectional and correlational design. All eligible patients with ICDs from the Cardiac Clinic were invited to participate. Participants completed a Demographic and Clinical Questionnaire, the Hospital Anxiety and Depression Scale (HADS) and the SF-36v2 Health Survey. A descriptive analysis of frequencies and summary statistics were done, followed by a regression, comparison and correlational analyses.

A total of 70 patients (57 years mean, 65% male) participated in the study. The HADS mean score for anxiety was 6.50, SD 4.52 and for depression 4.96, SD 3.36. The SF-36v2 QOL Physical Component Summary (PCS) mean score was 43.83, SD 9.43 and the Mental Component Summary (MCS) was 47.81, SD 10.71. Factors associated with depression, anxiety and poor QOL included having more than 5 ICD shocks (appropriate or inappropriate). Patients who felt that the ICD influenced their lifestyle positively, was 10.46 times more like to have mental well-being.

This study showed that patients with ICDs managed in the state sector, is a vulnerable population. They often live far from hospital, have a high unemployment rate and a poor income. The HADS revealed that 21.4% of the patients had depressive symptoms and 28.6% fulfilled criteria for anxiety. The SF-36v2 revealed that the QOL of patients with ICDs was significantly lower than the norm, with regard to their physical and mental well-being. The study highlights the need for psychological and social support of patients living with ICDs.

Keywords: quality of life; implantable cardioverter defibrillator; sudden cardiac death; arrhythmia; anxiety; depression; HADS; SF36v2.

ABBREVIATIONS

ACC	Arrhythmia Care Co-ordinator
AED	Automatic External Defibrillator
AF	Atrial fibrillation
AHA	American Heart Association
BPS	Biopsychosocial
CASSA	Cardiac Arrhythmia Society of Southern Africa
ECG	Electrocardiogram
EPS	Electrophysiological Study
GSH	Groote Schuur Hospital
HADS	HADS Hospital Anxiety and Depression Scale
HRQOL	Health Related Quality of Life
HRS	Heart Rhythm Society
ICD	Implantable Cardioverter Defibrillator
MCS	Mental Component Summary
PACE	Prevent Arrhythmic Cardiac Events
PCS	Physical Component Summary
PTSD	Post Traumatic Stress Disorder
SCA	Sudden Cardiac Arrest
SCD	Sudden Cardiac Death
SF36	Short Form 36 item Health Survey
SFBT	Solution Focussed Brief Therapy
SWB	Subjective Well-Being
VA	Ventricular Arrhythmia
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

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CHAPTER 1

STUDY BACKGROUND

1.1 Research Topic

What are the key factors that influence Qualify of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) patients in South African (SA) context?

Establishing what constitutes QOL and what key factors impact it, may improve QOL in ICD patients. This research topic thus investigates QOL and factors that influence QOL of ICD patients in the cardiac clinic at Groote Schuur Hospital. The patients, who, after being diagnosed with a life-threatening cardiac condition, live with an ICD in their chest to prevent possible sudden cardiac death (SCD). This is the first such study in SA and it is thus delving into a foreign territory for psychological academic research in SA.

When a patient experiences a life-threatening arrhythmia (i.e. an abnormal heart rhythm) it can lead to sudden cardiac arrest (SCA) and possible SCD. The only successful treatment, as explained by the Heart Rhythm Society (HRS) (2016a), is rapid pacing and/or a powerful shock to the heart delivered by an electronic ICD device. The ICD paces or defibrillates the heart back to normal rhythm. This lifesaving but unpredictable and frightening treatment can have a dramatic impact on the functional and psychological aspects of a patient’s life. In a post on the MedHelp Communities Page (2011a) a subscriber exclaims: “I have an ICD and want it out now! I cannot take this in my body much longer. I told my doctor and he will not take it out. I wish I was dead at times”.

Although this statement may be an exception and contradictory to the miracle of the many lives saved and improved with ICD implantation, the fact remains that few people fully understand the mechanism and action of an ICD and even less realise the traumatic impact that it can have on the QOL of ICD patients (Dunbar et al, 2012). Studies have shown that living with an ICD may cause anxiety, depression, avoidance behaviour or post traumatic stress disorder (PTSD) (Thylén, Dekker, Jaarsma, Stromberg & Moser, 2014; Sears, Hauf, Kirian, Hazelton & Conti, 2011). A study to improve outcomes for ICD recipients, emphasised that for as long as the condition exists, underlying arrhythmias and ICD treatments may cause adverse psychological effects in patients and family members (Dunbar et al., 2012).

The concern that ICDs might have adverse psychological effects on patients was already highlighted in 2002 by Sears and Conti (2002) when they suggested that worldwide, routine consideration of psychosocial needs should be integrated into clinical care of ICD patients. In 2014, another study on QOL of a large cohort of ICD recipients continued to highlight that ICD specific factors should be addressed to improve outcomes (Thylén et al., 2014). This was followed by the 2015 European Society of Cardiology (ESC) guidelines for the management of patients with ventricular arrhythmias (VA) and the prevention of SCD that recommended that QOL issues be discussed before and during disease progression of all ICD patients (Priori et al., 2015).

The World Survey of Cardiac Pacing by Mond and Proclemer (2011) showed that ICD implantation rates have increased significantly internationally. This was despite resource constraints in developing countries like South Africa, which are limited by the lack of expertise and the high cost of an ICD device and its implantation especially in the public sector of SA which serves the majority of the South African population (Mond & Proclemer, 2011). It is crucial that key factors that influence QOL in South Africans with ICDs are identified to ensure optimal health outcomes in these patients. This study was therefore conducted on patients from the Cardiac Clinic at Groote Schuur Hospital (GSH) in Cape Town, in whom an ICD was implanted for a cardiac condition with potential life-threatening arrhythmias. GSH is the only, large tertiary care institution and public hospital in SA, that provides a full-time comprehensive cardiac electrophysiology service. The cardiac team has extensive experience and expertise in ICD implantation and care and therefore provides a suitable cross-section of the South African population living with an ICD.

It is important, however, to emphasise that living with an ICD can be a positive experience with intervention that can be lifesaving. The American Heart Association (AHA) (2016) highlights that ICDs can improve quality of life, prolong life and that one can live more confidently with an ICD if you understand the conditions that led to implantation, the device itself and what to expect from having it.

1.2 Motivation

For over 10 years I have been involved in ICD patient care as a parent and co-founder of PACE (Prevent Arrhythmic Cardiac Events), the first heart rhythm support organisation in South Africa. PACE was founded in 2004 with the aim of addressing the urgent need for support and education of individuals and families affected by arrhythmia. This involved improving patient QOL and preventing sudden cardiac death due to undiagnosed lethal arrhythmias.

As the CEO of PACE, I was involved in many support group meetings, interactions with patients, email correspondence and various other meetings with patients, doctors and families affected by arrhythmia. I became acutely aware that living with arrhythmia and an ICD can severely compromise QOL. Many patients were anxious and/or depressed, struggled to adjust to their drastic change in life style and were in desperate need of counselling. Other factors such as fear of shocks, difficulty accessing care, lack of understanding, language barriers, lack of support structures and low socioeconomic status, also emerged (Personal observation, 2000–2016). These patients' challenges to cope with their life-threatening arrhythmias and cardiac conditions motivated me to identify psychological factors that could improve the QOL of patients with ICDs.

I realized that research on the status and the factors that may impact QOL in ICD patients in South Africa was necessary as no data is yet available in South Africa. The cardiac clinic at GSH has subsequently agreed to support the research by providing arrhythmia care medical staff, the cardiac clinic facilities, patient data and any other necessary resources required to complete the study. Ultimately I hope that this study will encourage further research in South Africa that may benefit everyone affected by or involved in arrhythmia care.

1.3 Implantable Cardioverter Defibrillator (ICD)

The Heart Rhythm Society (2016a) describes cardiac arrhythmia disorders and explains that the human heart beats in a regular, co-ordinated rhythm between 60 and 100 beats per minute. During this regular synchronized rhythm each contraction of the heart pumps blood from the top chamber of the heart to the bottom chamber and from there to the rest of the body. The contractions are caused by a cycle of tiny electrical impulses in the heart. When the electrical impulses and subsequent cycle is disturbed, the heart will beat out of rhythm which may lead to a sudden episode of irregular heartbeats. This is called an arrhythmia.

The Heart Rhythm Society (2016b) further explains that an arrhythmia can occur anytime for a variety of reasons. The heart may beat too slow (bradycardia), too fast (tachycardia) or erratically. Some arrhythmias can potentially be imminently life-threatening. Ventricular fibrillation is a dangerous arrhythmia where the bottom chambers contract so fast and chaotically, that the heart cannot pump blood to the brain and rest of the body. This sudden, serious electrical malfunction of the heart's pumping action, will lead to sudden loss of consciousness, collapse and imminent sudden death if normal heart rhythm and beat is not restored immediately.

An unexpected chaotic arrhythmic episode resulting in no cardiac output is called sudden cardiac arrest (SCA) and will lead to sudden cardiac death (SCD) if arrhythmia is not defibrillated i.e. shocked back to a normal rhythm. Defibrillation can only be achieved by an automated external defibrillator (AED) or an internal ICD. The ICD is a small pocket watch sized battery-powered electronic device implanted under the skin often in the upper chest. Thin wires connect the ICD to the heart muscle. The ICD is programmed to monitor the electrical impulses of the heart beat and is able to restore normal heart rhythm by delivering an internal electrical shock, a powerful jolt, to the heart muscle to defibrillate it. Defibrillation by an ICD is therefore lifesaving in the management of ventricular fibrillation.

An ICD is thus usually implanted in patients diagnosed with episodes of sustained ventricular tachycardia, i.e. when the heart contracts very fast because of an abnormal electrical impulse arising from the bottom chambers of the heart, or who are at risk of ventricular fibrillation and SCA. This treatment is usually supplemented with medication and lifestyle changes for maximum benefit.

The Heart Rhythm Society (2016c) also state that SUDDEN CARDIAC ARREST must not be confused with a HEART ATTACK. A heart attack involves a blocked artery; the individual is conscious and usually experiences chest pain. A cardiac arrest involves sudden electrical chaos in the heart, sudden unconsciousness and no pain. An ICD shock is perceived as a terrifying prospect by many patients. This once again underscores that living with an ICD device can significantly impact QOL and that it is crucial to identify factors that may influence patient QOL.

1.4 Quality of Life (QOL)

Quality of life is negatively affected to such a degree, that in some cases, ICD devices are explanted, even at the risk of sudden death. Kovacs et al., (2006) report such a case where a patient was unable to manage the stress associated with multiple shocks delivered by the ICD. In another post on the MedHelp Communities Page (2011b), an ICD patient sadly laments that she knows that these things (ICDs) save people's lives but that it took her life away.

The World Health Organisation (WHO) (1997) defines QOL as "an individual's perception… a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment" (p.1). Sears and Conti (2002) also state that most researchers agree that "quality of life" is a generic term for a multi-dimensional health outcome in which biological, psychological, and social functioning are interdependent. QOL can also involve Health-Related Quality of Life (HRQOL) measures. HRQOL is a narrower concept which focuses on the effects of illness and specifically the impact that treatment may have on QOL. According to Noble (2014) HRQOL is a person's subjective perception of the impact of their ill health on daily life. This includes physical, psychological and social functioning. HRQOL is used interchangeably with QOL.

Many studies worldwide thus emphasize a multidisciplinary approach to improving healthcare and quality of life. The Kings Fund study state that many people with long-term physical health conditions also have mental health problems and that it may directly lead to considerable poorer health and quality of life (Naylor, Parsonage, McDaid, Knapp, Fossey & Galea 2012). Prince et al., (2007), state that there is no health without mental health and Stein, Williams and Kessler (2009) underscores this in their conclusion of the South African Stress and Health (SASH) survey. This could be especially relevant in patients living with a life threatening condition and an ICD.

Comprehensive literature reviews such as those of Arteaga and Windle (1995), Konstam, Colburn and Butts (1995) and Sears, Todaro, Saia and Conti (1999) show that ICD patient QOL can be quite good. But numerous studies since 1990 however, also show a high incidence of psychological disorders amongst these patients which negatively impact QOL (Kajanová, Bulava & Eisenberger, 2014). Sears and Conti (2003) found that between 24 and 38 percent of ICD patients show symptoms of anxiety and/or depression during the first year post implantation. Other particular distressing symptoms include Post Traumatic Stress Disorder (PTSD) (Sears, Hauf, Kirian, Hazelton & Conti 2011) agoraphobia and panic attacks (Godemann et al., 2004a). Other factors also related to psychological distress have been identified as age, gender, employment, ethnicity, ICD shocks, life style, recalls, type D personality and more (Lampert, 2013, Kajanová et al, 2014).

ICD implantations thus affect the biopsychosocial domains in various ways and Kajanová et al, (2014) stress that improving psychosocial outcomes in ICD patients are crucial. This has led to various studies and interventions such as of Cognitive Behaviour Therapy (CBT) which significantly reduces physiological distress (Sears et al., 2011). The British Heart Foundation's (BHF) Arrhythmia Care Co-ordinator (ACC) Service program also found that ACCs played a crucial role in improving QOL (Ismail & Lewin, 2010) while Dunbar et al. (2012) highlighted education, support and stress management as helpful interventions.

Identifying symptoms of distress, contributing factors and treatment options are crucial for optimum QOL in ICD patients but it needs to be understood in context especially in SA.

1.5 South African Context

South Africa has some of its own unique circumstances and factors that may influence QOL in ICD patients. This is primarily due to a long history of political struggles, economic challenges, social disparities, cultural complexities and psychological impacts (Coovadia, Jewkes, Barron, Sanders & McIntyre, 2009), (Bradshaw, 2008) The majority of South Africans have been exposed to inequality, poverty, neglect, prejudice and anxieties (Mayosi & Benatar, 2014). Health Care in SA has subsequently also been implicated and arrhythmia care has not been a priority. To address QOL in ICD patients in SA, it is thus crucial to understand South Africa's history, the current situation and the effect on healthcare.

In 2008, Okreglicki (2008), past electrophysiologist at GSH, highlighted arrhythmia care issues in South Africa. He stated that cardiac electrophysiology and an interest in arrhythmias have been neglected in SA while elsewhere in the world it has grown exponentially. He also stated that the South African public was under-served due to the lack of a basic Electrophysiology (EP) service and that awareness was crucial to begin to meet the needs of the people. Then in 2015, Scott Millar, (Scott Millar & Chin, 2015), Electrophysiologist, state: "While South Africa is somewhat better served than the rest of the continent, we still fall woefully short of international standards of access. The huge discrepancy in access to lifesaving treatment mirrors the many other inequalities in our society…" (p.162). The political situation in South Africa played a major role in general and health related QOL of South Africans. This was due to decades of an Apartheid policy of discrimination, segregation, dispossession, inequality and violent oppression of the majority of SA's population, the indigenous people. It led to dire poverty, social life destruction, multiple psycho-social problems and a long violent liberation struggle (Coovadia et al., 2009) (Bradshaw, 2008) (National Planning Commission, 2011). Living under such an extreme form of oppression has had a significant effect on the population's mental and physical health (Pascoe & Richman, 2009). It also led to general aggressive behaviour which underscores Bandura's study (Bandura, Underwood & Fromson, 1975) that found that dehumanisation leads to aggressive behaviour. The majority of South Africans have thus experienced ongoing violence and multiple traumatic events during their lives which added to the heavy burden of anxiety disorders like Post Traumatic Stress Disorder in SA (Atwoli et al., 2013).

Economically, most South Africans are still experiencing severe poverty and a struggle for life's basic requirements (Mayosi & Benatar, 2014). This includes a high unemployment rate of 27.1% in October 2016 (Trading Economics, 2016) and huge disparities in income while adequate healthcare services and access to all South Africans is also greatly lacking (Mayosi & Benatar 2014, Coovadia et al, 2009). Social development has also been hampered by apartheid policies as forced removals of the majority of the population have led to weakened family structures, poor education, language and communication challenges and widespread crime (National Planning Commission, 2011). Improving general QOL and HRQOL thus remains an ongoing challenge.

Cultural factors also play an important role in healthcare. There are various cultural groups in SA, but the majority of the population follow a traditional belief system and consult a traditional healer before going to a primary health practitioner (Truter, 2007). Cultural groups shape perceptions about illnesses and their treatments. Traditional healers and leaders can thus be very powerful (Benning, 2013). Traditional healers can thus play a vital role in healthcare. They are easily accessible, widely dispersed and know cultural norms and culture bound syndromes. Their advice is also believed and acted upon by community members (Sorsdahl et al., 2009). It is thus important to consider different cultural beliefs if health outcomes are to be maximised.

Healthcare in South Africa remains a challenge. It comprises of a public and private sector with services ranging from basic primary to highly specialised health care. The public system provides free tax funded health care to the majority of uninsured people (84 percent) but is chronically underfunded and understaffed. The private sector serves the wealthy 16 percent of the population who are on medical aid schemes, employs 70 percent of South Africa’s doctors and is far more effective (Mayosi & Benatar, 2014). Unfortunately many of the state hospitals are in a crisis, with infrastructures run down and dysfunctional as a result of underfunding, mismanagement and neglect according to Von Holdt (as cited in Mayosi & Benatar 2014, p. 1346).

Electrophysiology, a branch of cardiology that deals with the diagnosis and treatment of heart rhythm disorders, has also been neglected (Okreglicki, 2008). Today there is still a scarcity of Electrophysiologists in South Africa (Scott Millar & Chin, 2015). Fortunately, the medical society CASSA (Cardiac Arrhythmia Society of Southern Africa), and the patient awareness and support organisation PACE (Prevent Arrhythmic Cardiac Events), have made a significant difference in arrhythmia awareness, education, support and management of individuals with rhythm disorders (Okreglicki, 2008). These efforts have lightened the burden of the doctor, patient, carer and health care system alike although much still needs to be done.

1.6 Aim

The aim of this study is to explore factors that have an impact on the QOL of ICD patients. This involves obtaining an indication of the current QOL status of ICD patients, laying the foundation for further research and ultimately improving QOL in patients living with a life-threatening condition and an ICD implant. The rationale is that ICD implantations have increased dramatically worldwide (Scott Millar & Chin, 2015). This highlighted the significant impact that an ICD has on QOL. It resulted in a growing global need to identify factors that influence QOL and to implement strategies that will improve patient QOL.

Quality of life in ICD patients in SA is unknown and factors influencing QOL in SA have not been identified. SA would thus benefit from such a study as it may initiate strategies to improve QOL of ICD patients. Lastly, GSH Cardiac Clinic represents the general arrhythmia and ICD populations in SA and presents an ideal setting to initiate further research in SA.

Objectives will be to complete a descriptive analysis of Demographic, Clinical, ICD and Patient Support characteristics of the GSH ICD population, provide a descriptive analysis of Anxiety and Depression using the Hospital Anxiety and Depression Scale (HADS), an analysis of the QOL using the SF-36v2 Health Survey and a regression analyses that determine factors that influence Depression, Anxiety and QOL in the GSH ICD population.

1.7 Chapter Outline

Chapter one provides the study background by describing ICD devices, the QOL of patients living with a life-threatening condition and the study in the context of SA. Chapter two explores QOL research and a theoretical framework based on Maslow's Hierarchy of Needs Theory, Engel's Biopsychosocial (BPS) Model and Cleary's Health Related Quality of Life (HRQOL) Model. Chapter three provides a literature review on ICD implantations and patient QOL, symptoms, factors and solutions. It also provides a review on Health Care in the South African context from a political, economic and social perspective. Chapter four describes the methods used in this study. Chapter five presents the results of the study. Chapter six consists of the discussion and Chapter seven is the conclusion.

CHAPTER 2

THEORETICAL FRAMEWORK

The QOL concept and factors that constitute it, has a long and complicated history. As recently as 2004, a literature review by Church (2004), found little agreement with regard to QOL's meaning and measurement while in 2006, Michalos (cited in Sirgy et al., 2006) describe a multitude of social indicators that have developed over time that describe QOL.

In this study, the conceptual definition of QOL is as defined by The World Health Organisation (WHO) (1997): "an individual's perception… a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment" (p.1).

The operational definition of QOL in this study thus involves the patient's perception and satisfaction with their health, psychological state, social support and environment. The SF36v2 Health Survey, the Hospital Anxiety and Depression Scale, and the Demographic and Clinical questionnaire is thus appropriately being used to obtain a holistic assessment of QOL in the ICD patients.

QOL is clearly a multifactorial variable and demands a holistic approach to understand how QOL may be achieved. It thus leads this study to consider QOL research developments and elements of three QOL theories that acknowledge the influence of biological, psychological and social factors on QOL: Maslow's Hierarchy of Needs Theory, Engel's Biopsychosocial (BPS) Model and Wilson-Cleary's Model of HRQOL.

2.1 Quality Of Life Research: Past, Present, Future

The concept of QOL has its foundation in the search for social indicators. Social indicators describe QOL in statistical measures for subjective measures (feelings) or objective measures (pulse readings) according to Michalos (sited in Sirgy et al., 2006, p. 344). Endless combinations and variations of social indicators plus QOL evaluations over time, have often created confusion and great challenges for researchers (Ferrans, Zerwic & Larson, 2005).

The philosophical foundations of QOL research is also an endless debate. In general, it was aimed at ontology (what is it?), axiology (what good is it?) and epistemology (how do you know). In 1903 the philosopher Moore, (cited in Sirgy et al 2006, p. 352) asked: “I know it is satisfying, but is it (morally) good?” Plato c.360 B.C.E (cited in Sirgy et al 2006, p. 355) believed that reason and passion in harmony constitutes happiness while according to Tatarkiewicz (cited in Sirgy et al 2006, p. 355), Aristotle believed that to live and do well is happiness.

2.1.1 History of QOL Studies; a Sociological, Psychological and HRQOL Perspective:

Sociologists study social systems. Social indicators track changes, monitor social systems, evaluate interventions and forecast futures. To improve social indicators, QOL studies grew. The term QOL was not originally used yet measured since 1918 (Sewell 1940, cited in Sirgy et al 2006, p. 367). In 1930 multiple levels of living measures were encouraged. In 1960 social indicator research thrived and became part of surveys. In 1980 sociological QOL research looked hopeful according to Ferriss (cited in Sirgy et al 2006. p. 366).

With regard to the psychological perspective, Subjective Well-Being (SWB) measures provided subjective indicators of QOL and added to objective indicators (Pavot cited in Sirgy et al 2006, p. 383). The concept dates back to ancient Greece according to Diener (1984) (cited in Sirgy et al 2006, p. 384). Aristippus believed that pleasure creates happiness while Aristotle believed virtue the key according to Ryff and Keyes (1995) (cited in Sirgy et al 2006, p. 384). Recently Diener, Suh, Lucas & Smith (1999) defined SWB as emotional responses, domain satisfactions and global judgments of life satisfaction. Subjective experiences became a QOL indicator in the 20th century as humanism emerged and large QOL surveys were done in America by Andrews and Withey (1976) and Campbell, Converse and Rodgers (1976) (as cited in Sirgy et al., 2006, p386).

Most current SWB measures consist of multiple-item instruments and most theoretical approaches are bottom-up like Maslow’s Theory stating that humans all have basic needs to fill before being happy (Diener et al., 1999), or a top-down, where mechanisms such as personality traits can determine perceptions of SWB (McCrae & Costa, 1986).

HRQOL focused on the link between health and QOL. Aristotle (cited in Sirgy et al., 2006, p. 399) stated health's role in happiness as when he falls ill, it is his health but when he is hard up, it is money that's blamed for happiness. But QOL and health are always linked by treatment due to advances in medical technology. Technology impacts QOL so extremely that while survival is priority, QOL issues have become vital. Patients often question if QOL is worth the physical and emotional distress of a treatment and trading off quantity with QOL is a real issue according to Patrick (cited in Sirgy et al 2006, p. 399) which could be very relevant to ICD patients QOL.

2.1.2 Concepts and Measures: Concepts are often used interchangeably. But in general QOL is more comprehensive; SWB is more domain specific and HRQOL is more focused on health and health outcomes (Patrick cited in Sirgy et al 2006, p. 401). The Needs-Based Measures of Maslow (Maslow, 1943) has been widely used and reflects how health may interfere with a person's basic needs. Generic self-rated measures such as the Short-Form 36-item Health Survey (SF-36), Multiple Disease-Specific and HRQOL measures are also widely in use.

In summary, numerous social indicators for QOL have developed over time but descriptive and evaluative perspectives of QOL have become important (Michalos, 2006 cited in Sirgy et al, 2006, p. 347). According to Patrick (cited in Sirgy et al 2006, p. 407), the future of especially HRQOL assessments, will increasingly focus on descriptive and evaluative measures, how health influences and is influenced by the body and mind. This underscores that people's health status AND how they feel has become crucial in obtaining QOL.

2.2 Maslow's Theory of Hierarchy of Needs

Maslow's theory emphasises addressing basic needs in a hierarchical order to achieve QOL. Maslow's Theory of Hierarchy of Needs, also known as the Theory of Self-Actualization was developed in 1930 during research on how to obtain a good life. He published "A theory of Human Motivation" in 1943 that stated that human behaviour is ruled by the motivation of fulfilling a "hierarchy of needs", the ultimate level being self-actualization (Boeree, 2006). Maslow stated: "… goals (basic needs)… are related to each other and are arranged in a hierarchy of prepotency. When the most prepotent goal is realized, the next higher need emerges… Thwarting, actual or imminent, of these basic needs provides a psychological threat that leads to psychopathy” (Maslow, 1943).

Maslow’s theory of Self-Actualisation or motivation has been challenged on many fronts over the years. Hofstede (1984), criticised Maslow’s hierarchy for being culturally biased and argued that placing of self-actualization needs above self-actualization needs, reflects a western, individualistic values system which may not apply to other cultures.

According to Heylichen (1992), the definition of self-actualisation is confusing and that gratification of all needs is inadequate to explain self-actualisation. Heylichen (1992) thus reconstructed Maslow’s theory on the basis of a second-order, cognitive-system framework. He states that a hierarchy of basic needs is derived from the urgency of perturbations which an autonomous system must compensate in order to maintain identity.

This involves homeostasis, safety, protection, feedback and exploration. He thus redefines self-actualisation as competency to satisfy basic needs. Competence is material and/or cognitive and subjective. Material and/or cognitive incompetence during childhood creates subjective incompetence which in turn inhibits the further development of cognitive competence and thus self-actualisation.

Heylichen (1992) proposes that to promote self-actualisation, society needs democracy so that everybody can get what they need and that society needs to develop their own distinction systems to enhance their creative intelligence.

Although many elements of suggested reconstructions of Maslow’s theory may have merit, many studies still find Maslow’s hierarchical theory useful in understanding how QOL is achieved. As recent as 2013, Taormina and Gao (2013) measured satisfaction of Maslow’s needs and found that the satisfaction of each of the higher-level needs in their study was statistically predicted by the satisfaction of the need immediately below it in the hierarchy, as expected from Maslow's theory.

In 2003, a study by Ventegodt, Merrick and Anderson (2003), revisited Maslow’s theory and concluded that Maslow’s concept of self-actualization had a vital role in modern medicine.

Maslow explained that most chronic diseases often don’t disappear; the real change patients have for betterment may be personal development. Ventegodt et al (2003), continued that fulfilling Maslow’s needs can be explained in a simple and straightforward manner to any patient. The patient can incorporate it in his general plan of life and ultimately achieve better health and QOL. The usefulness of Maslow’s Theory in this study is thus clear as it potentially can point out which needs lack, which not and what can be done about it.

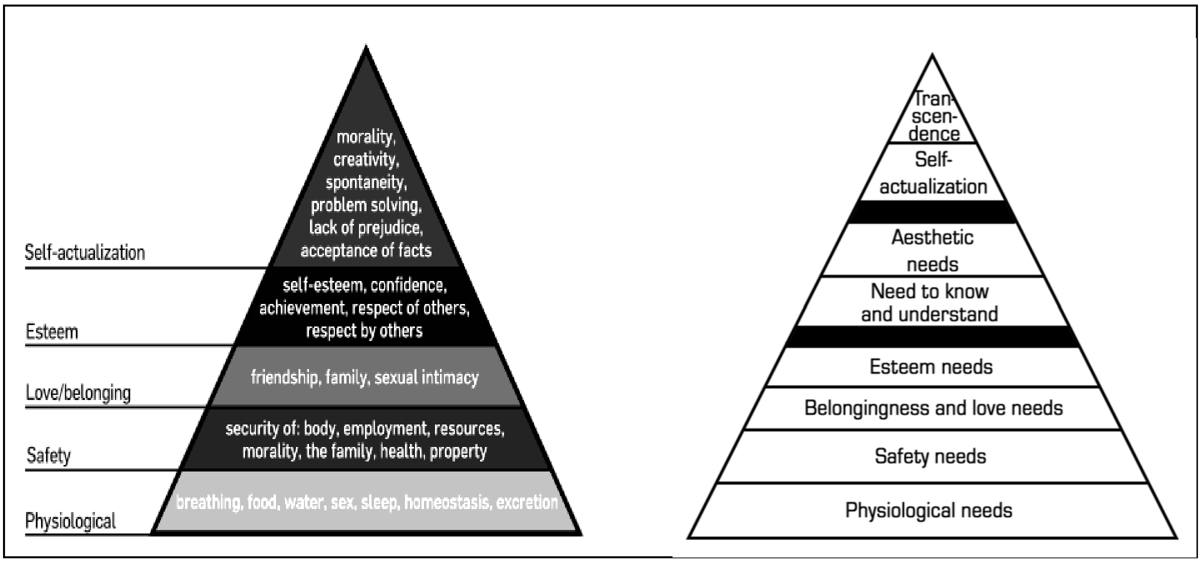
2.2.1 Abraham Maslow 1908-1970: Psychologist, Abraham Harold Maslow was born in New York in 1908. His parents were uneducated Jewish immigrants from Russia who encouraged academic success. Maslow married in 1928 and received his PhD in 1934 (Boeree, 2006). His studies focused on the healthy personality and the fulfilment of human potential. He believed that people find fulfilment and change through meeting basic human needs and through personal growth (Rice, 2014).

Maslow became a pioneer in the development of Humanistic Psychology which focused on positive human potential, self-actualization, the search for meaning and social change. He especially advanced the understanding of self-actualizing individuals which became the central theme of his work (Corey, 2013). Self-actualisation is realizing and expressing one’s own capabilities and creativity. As we take more responsibility for our own lives, our good qualities thrive and we are more free, powerful, happy and healthy (Ventegodt et al 2003).

Maslow died in 1970 but he continues to inspire millions (Hoffman, 2011). His theory, still widely used and the Journal of Humanistic Psychology which he co-founded are just a few areas in which his legacy continues (Corey, 2013).

2.2.2 Theory of Hierarchy of Needs: The theory originally consisted of five levels but later increased to eight levels (Figure 2.1).

Figure 2.1 Maslow's Hierarchy of Needs of 5 and 8 Levels



Deficit (D) Needs fill four levels. The first is PHYSIOLOGICAL needs: breathing, food, water, sex, homeostasis and excretion etc. The second is SAFETY needs: security of body, health, family, morality, resources, employment and property. The third is LOVE/ BELONGING needs: family, friendships and sexual intimacy etc. The fourth is ESTEEM needs: self-esteem, confidence, achievement, and respect of and by others which if not met, could be the root of most psychological problems. Maslow equates D-needs to homeostasis and humans genetically and instinctively aim to satisfy D-needs. They are felt but if they are met, cease to motivate. A threatening event can trigger a lower need causing a person to regress to that need until it is met. A major event, such as a family death, can also cause fixation on a need for the rest of the person's life if not dealt with (Rice, 2014)

Growth (G) Needs fill level five and six**.** Five is COGNITIVE: to know and understand and level six is AESTHETIC needs: symmetry, beauty and order (Ventegodt et al., 2003).

Being (B) Needs fill level seven and eight**.** Level seven, SELF-ACTUALIZATION is continuously present. Maslow identified some special needs of self-actualizers; they enjoy solitude, few close relationships, autonomy, are accepting of self and others, creative and often at one with nature or God. Lastly, level eight, SELF-TRANCENDENCE, is the highest awareness of being, feeling at one with the universe (Rice, 2014).

2.2.3 ICD patient QOL and the Theory of Hierarchy of Needs:

In 1943 Maslow stated the importance of fulfilling the hierarchy of human needs by the following: “Any thwarting (ruining) or possibility of thwarting of these basic human goals, or danger to the defences which protect them, or to the conditions upon which they rest, is considered to be a psychological threat. With a few exceptions, all psychopathology may be partially traced to such threats. A basically thwarted man may actually be defined as a 'sick' man, if we wish” (Maslow, 1943).

And, still today, Ventegodt et al., (2003) continued to underscore Maslow’s statement. Their study concluded that patients can be empowered to improve their QOL if their needs are taken care of. Maslow’s Hierarchy of Needs is also a useful tool for doctors to mobilize a patients hidden potential. Ventegodt et al., (2003) urged doctors to support and facilitate a calm, safe space in which the patient can address past issues which may only surface during an illness.

In summary: With regard to Deficiency Needs (level one), fulfilling physiological needs such as eliminating pain may reduce bodily suffering. On level two, fulfilling safety needs such as implanting an ICD and providing accessible medical care can reduce anxiety. On level three, fulfilling love needs such as care and support can reduce depression. On level four, fulfilling self-esteem needs, such as self-respect can increase confidence to take control of one’s own life.

With regards to Growth Needs, level five, fulfilling cognitive needs such as understanding ourselves can increase joy. On level six, fulfilling aesthetic needs such as order, can increase stability and calm especially in a patient living with a life threatening condition. With regards to Being Needs (level seven), fulfilling self-actualisation needs can realize a patient’s full potential in areas the person was not aware of and on level eight, fulfilling transcendence needs can ultimately help us go beyond self-concern and live in life’s joyous moments.

Maslow’s theory clearly reminds us that meeting basic needs are vital in attaining QOL. It is also clear that it involves biological, psychological and social dimensions. The Biopsychosocial (BPS) Model of George Engel specifically focuses on those dimensions.

2.3 Biopsychosocial Model (BPS)

Engel’s BPS Model emphasises the major role the interactional system of levels (molecular to societal) play in QOL such as during a SCA. The Biopsychosocial (BPS) Model is a general theory on illness and healing developed by George Engel, internist and physician. Engel’s BPS concept was in contrast to the established Biomedical Model and published in 1977 entitled: "The Need for a New Medical Model: A Challenge for Biomedicine" (Engel, 1977). The paper contained Engel’s observation that actions at the biological, psychological, and social level are interrelated, that they exist along a continuum of natural systems and that the relationships affect both the process and outcomes of health care.

2.3.1 George Engel 1913-1999: George Engel was born in 1913, New York City. He completed his undergraduate degree in 1934 and received his medical degree from Hopkins in 1938. Engel interned at Mount Sinai Hospital, where physicians were incorporating psychosomatics into the clinical service and in 1946 he joined the new psychiatry department at Rochester University, with appointments in psychiatry and medicine.

“By the mid-1950’s Engel was one of the leading figures in psychosomatic studies. He was prominent in the American Psychosomatic Society, edited it’s journal and published numerous books and articles on the relation between emotion and disease, and on the incorporation of these ideas into medical training and clinical practice” (Engel, n.d.).

Ultimately Engel's ideas developed into the Biopsychosocial Model (Engel, n.d.). Engel criticised the Biomedical Model. He stated that a biochemical change does not translate directly into an illness and diverse factors, including at molecular, individual and social levels, may cause an illness. Biological change also does not show the meaning of symptoms to patients or which skills doctors need for treatment. He also stated that psychosocial factors are vital determinants of the severity/course of illness and that being sick, does not always equate to a biological change. Biological treatments are influenced by psychological factors and the patient-doctor relationship influences medical outcomes unlike inanimate subjects (Borrell-Carrió, Suchman & Epstein, 2004). Engel died in November 1999 after a prominent career but his legacy still living on.

2.3.2 Biopsychosocial Model (BPS): The Model involves biological, psychological and social factors (Figure 2.2). It exists along a hierarchical continuum of natural systems (Figure 2.3) and need equal concern to ensure optimum outcomes (Engel, n.d.).

Figure 2.2
Biopsychosocial Model

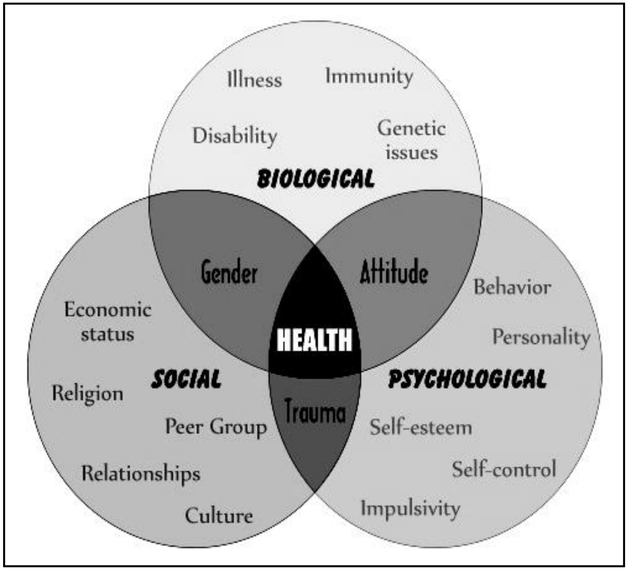
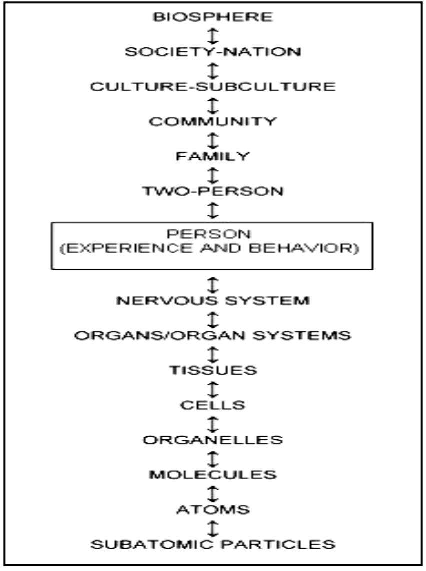


Figure 2.3
BPS Hierarchy of Natural Systems

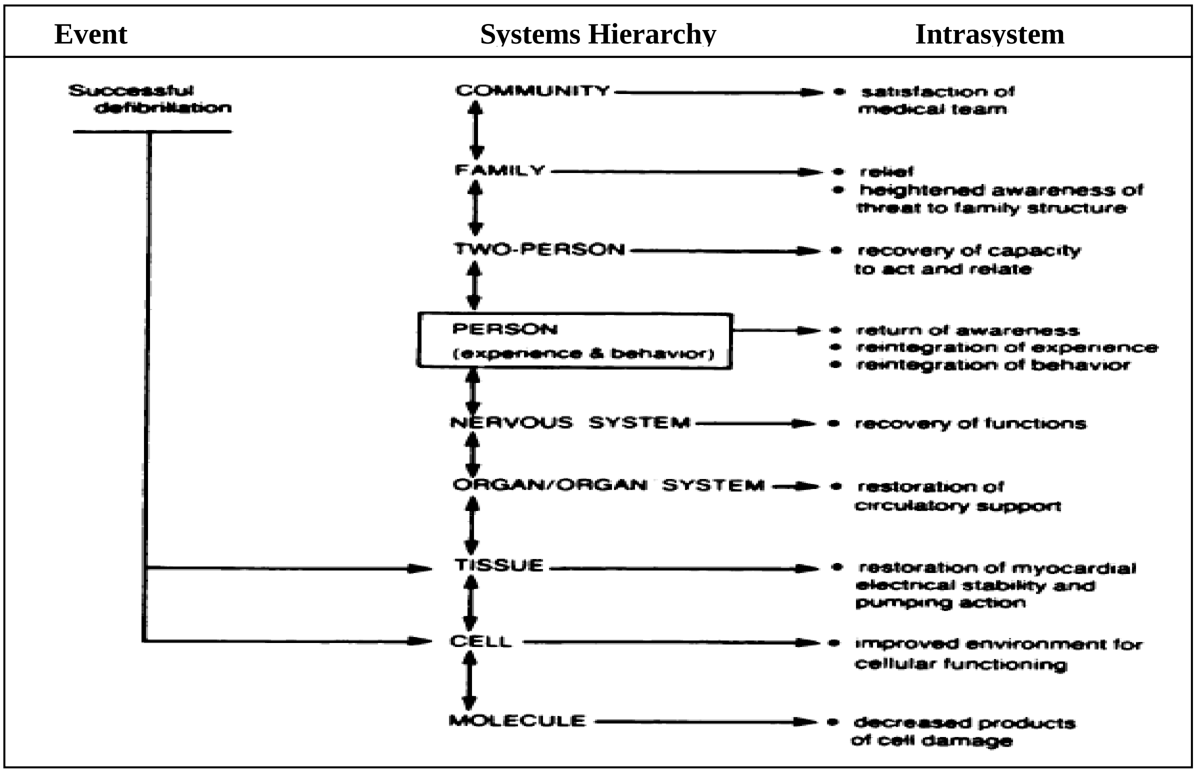


The biological dimension focus alone is not enough for illness to occur. Psychological and social aspects are crucial. Psychologically there may be an underlying mental condition contributing to an illness e.g. depression or even low self-esteem. The social dimension concerns the environment and various external factors e.g. religion, economic status or culture may play a role in the manifestation of an illness (Varnekar, 2016).

Engel suggests that factors need appropriate applications. When a patient has pain, anxiety may aggravate the pain without intervention for the anxiety. Psychological and social factors can thus be independent as well as biologically correlated (Engel, n.d.). Engel also state that disease and illness also manifest from cellular to organ, to person, to family, to society. The hierarchy of natural systems thus provide a broader understanding of disease processes, the levels of function and effect of doctor-patient relationships (Frankel et al., 2003, Engel, n.d.).

2.3.3 ICD patient QOL and the Biopsychosocial Model: Engel (1980) published the applicability of the BPS Model to emphasize the unity of medicine and physicianhood and how doctors can apply scientific methods to everyday patient care. The diagram shows the system level that a SCA affected and the impact up and down the hierarchy in a successful defibrillation event (Engel, 1980) (Figure 2.4).

Figure 2.4 Successful Defibrillation



The BPS Model is often used, especially in chronic illnesses and palliative care. It is seen as the foundation of health psychology and clinical health, public health, community health and critical health psychology are all based on the BPS model (Ventegodt et al., 2003).

Engel clearly highlighted the importance of psychological factors (Borrell-Carrió et al., 2004) and it could provide insight into the support ICD patients need.

2.4 Wilson-Cleary Conceptual Model of HRQL

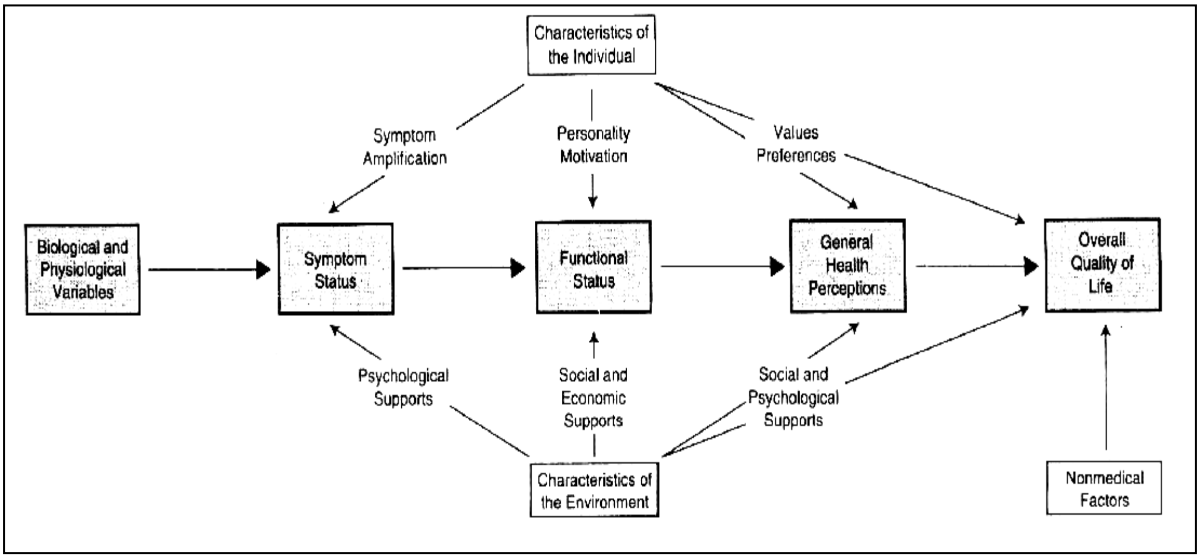
Wilson-Cleary's Model stresses the vital link between health and QOL on an increasingly complex continuum. To narrow the multiple definitions of QOL, HRQOL was introduced (Ferrans et al., 2005). QOL, although related to health, is also often affected by economic, political, cultural and spiritual factors but often ignored by doctors. HRQOL thus focuses on including these factors together with energy levels, pain, cognitive functioning and biological data Wilson and Cleary (1995). HRQOL describes a patients experience and adds vital data to biological assessments. HRQOL measures are proven to be valid, reliable, responsive to clinical changes, shorter and easier to understand and administer. It is thus increasingly being used according to Wilson and Cleary (1995).

The article by Wilson and Cleary (1995): "Linking Clinical Variables With Health-Related Quality of Life, A Conceptual Model of Patient Outcomes" presents a "…taxonomy of patient outcomes that categorises…patient outcomes according to the underlying health concepts they represent and proposes…causal relationships between different health concepts, thereby integrating the two models (Bio and QOL) of health…" Wilson and Cleary (1995, p. 59). They believed that the Biomedical Model's molecular, genetic and cellular mechanisms of disease relates to QOL components and needed to be linked.

A review by Bakas et al., (2012) on HRQOL models showed model popularity: Wilson and Cleary (16%), Ferrans and colleagues (4%) and World Health Organization (WHO) (5%) and recommended the Ferrans Model which updated the Wilson and Cleary's model with individual and environmental characteristics.

2.4.1 Wilson-Cleary Model: Description (Figure 2.5**):** The model is divided into five levels: biological/physiological factors, symptoms, functioning, general health perceptions and overall quality of life. Causal relationships between health concepts link clinical variables to HRQOL measures. From left to right of the model, the nature of the concepts shifts from the cell to the individual. It then moves to interaction of the individual with society. The measures exist on a continuum of increasing complexity. On one end there are biological measures and on the other more integrated measures such as physical functioning and general health perceptions. The arrows differentiate between measures of HRQOL and illustrate dominant causal associations.

Figure 2.5 Relationships among measures of patient outcomes in a HRQOL conceptual model.



Level one involves biological and physiological factors and are most commonly conceptualized, measured and applied in routine clinical practice. Assessment focuses on function of cells, organs, organ systems e.g. ejection fraction and any changes in cell functions that may influence health

Level two involves symptoms and are a patient's perception of an abnormal physical, emotional or cognitive state. Symptoms tend to be bidirectional and involve the organism as a whole. Physical symptoms are perceptions, feelings or beliefs about our body while psychological or emotional symptoms are feelings such as worry and fear. Even before a doctor is seen, a patient may feel a sensation such as pain or the influence of demographic and cultural factors. Patient reports thus express experiences from various sources.

Biological influences on symptoms are more complex. TB may have no symptoms while depression, with no biological origin, may have symptoms. Studies have shown that up to 80% of patients have no organic cause for their symptoms. Wilson and Cleary (1995) state that the inconsistency between biological and psychological factors demands that factors such as psychological, social, patient expectations and patient-doctor relationships need attention.

Level three refers to functioning measures that assess task performance ability. Determinants are symptom status, personality, motivation and a social and supportive environment. Wilson and Cleary (1995) thus suggest that disease-specific measures of symptoms as well as the biological factors shown by the symptoms will be good predictors of functioning.

Level four refers to General Health Perceptions (GHP) that is subjective and are amongst the best predictors of utilizing health services and mortality. GHP is related to biological factors but the clinical severity will differ. Functional status, emotional distress, dysphoria and social factors have been shown to influence general health perceptions while hypochondrias and somatisation were the strongest predictors of GHP (Barsky, Cleary & Klerman, 1992).

Level five refers to measure of overall quality of life and often assesses happiness with life. But according to Wilson and Cleary (1995) it should be related to HRQOL as measures of life satisfaction are often unstable as circumstances change, especially when health related.

Patient's preferences and values play an important role in understanding GHP and overall QOL. Patients often prefer to endure some symptoms instead of other more burdensome ones and patient assessments of the value of their state of health often indicate their HRQOL. With regard to psychological factors**,** many scales only measure distress, not how it impairs tasks. Depression could be classified as biological, a symptom or as psychological functioning, but all can have a causal relationship with variables at every level of the model. Psychological factors can thus greatly influence GHP and the other way round. Pain can cause depression and depression can cause pain, which illustrates that the model is bidirectional with many reciprocal associations (Wilson and Cleary (1995).

In 2005, Ferrans et al., (2005) revised the Wilson and Cleary HRQOL model. To make it more useful they expanded on how individual and environmental factors influence the biological domain and included a list of variables used to measure HRQOL. Ferrans et al., (2005) also elaborated on individual characteristics, symptom assessment, function optimization; the importance of GHP and that measuring patient values can provide vital data over time.

2.4.2 ICD patient QOL and the Wilson-Cleary Model of HRQOL: The Wilson-Cleary Model proposes a causal pathway that link clinical variables such as living with an ICD implant (an objective measurement) to QOL (a subjective experience). The pathway is reciprocal and underscores that overall QOL can influence as well as be an outcome of health status. It is thus useful to consider correlations between various variables. This starts with exploring factors that influence function and QOL.

Wilson and Cleary (1995, p. 63) concludes: "The development of treatment strategies requires that …we identify key factors that combine to determine function and QOL … and that we understand their relative importance and the degree to which they can be altered…We need to identify risk factors for poor health status … then…measurement of health status is likely to become an increasingly useful clinical tool." This study accordingly intend to identify factors related to health and QOL so that treatment strategies can be developed.

2.5 Conclusion

QOL and the many factors that influence QOL, has developed into a major concern in health outcomes. All three discussions emphasize that biological, psychological and social factors play a crucial role in health, health outcomes and QOL. Understanding the various theories and identifying possible factors that influence QOL is thus crucial in patient care. ICD patients living with an unpredictable life threatening condition are especially vulnerable.

Although this study primarily focuses on Maslow's theory of basic needs related to their biological, psychological and social domains, it is crucial to consider the impact of the BPS model's interrelated system of biopsychosocial issues and the HRQOL model's focus on the link between disease and QOL.

CHAPTER 3

LITERATURE REVIEW

This literature review provides an understanding and evaluation of factors that may influence Quality of Life in patients living with an ICD. Little is known about ICD QOL in the psychological field but it is a rapidly growing field. The following is thus reviewed: Sudden Cardiac Death (SCD), Implantable Cardioverter Defibrillator (ICD), QOL in ICD Patients, South African Context, Health Care in South Africa and Interventions.

3.1 Sudden Cardiac Death (SCD)

Understanding SCD is crucial. It has far too often been the first yet last sign of an underlying heart condition that triggered a lethal arrhythmia which lead to the SCD (Stecker et al., 2014). SCD is also the primary reason for inventing the ICD which in some cases could have corrected the lethal arrhythmias and prevented SCD.

Established SCD is an unexpected death with no obvious extracardiac cause. It is witnessed as a rapid collapse, or if unwitnessed, a collapse within 1 hour after the onset of symptoms. Probable SCD is when the unexpected death occured without obvious extracardiac causes within the previous 24 hours (Fishman et al., 2010). SCD has a huge impact on public health; worldwide it is one of the most common causes of mortality and implicates about 7 million deaths per year (Parakh, 2015). In the United States (US), up to 400 000 SCD's occur annually (Stecker et al., 2014) and in each country of Asia, SCD occurs in about 40 per 100,000 people per year (Murakoshi & Aonuma, 2013). In India, SCD contributes up to 10.3% of overall mortality (Parakh, 2015) and in Europe it ranges from 50-100 SCD's per 100 000 people (Fishman et al., 2010), In Moscow, SCD has reached 123.2 per 100 000 citizens per year (Makarov, Komoliatova, Fedina & Solokhin, 2011).

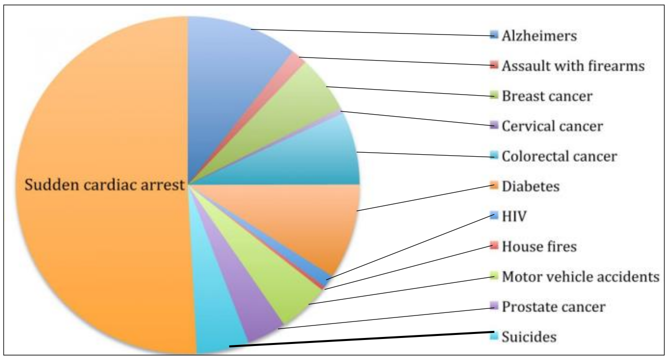
Kuriachan, Sumner and Mitchell (2015) broadly classify heart diseases that can cause SCD as ischemic heart disease; non-ischemic heart disease such as Hypertrophic Cardiomyopathy (HCM); electrical heart disease such as Long-QT and non-cardiac disease such as drug overdose. Although multiple causes exist, the immediate cause of SCD is usually ventricular fibrillation (VF) triggered by an underlying condition. VF is such chaotic electrical heart contractions; the heart only fibrillates and fails to pump. This condition is called a SCA. VF may be preceded by symptoms such as palpitations or syncope but VF is mostly sudden, with no symptoms and fatal. Fortunately some people may survive a SCA if the heart is rapidly defibrillated by an Automated External Defibrillator (AED) or ICD. The SCA is then called an aborted SCD or SCA and the person is referred to as a SCA survivor (Kuriachan et al., 2015).

SCA is the most extreme medical emergency and death or permanent brain injury will occur unless Cardiopulmonary Resuscitation (CPR) or defibrillation is started within minutes. SCA is defined as "…the sudden cessation of cardiac activity so that the victim becomes unresponsive, with no normal breathing and no signs of circulation… Cardiac arrest should be used to signify an event as described above, that is reversed, usually by CPR and/or defibrillation or cardioversion, or cardiac pacing. Sudden cardiac death should not be used to describe events that are not fatal" (Buxton et al., 2006). SCA has affected countless people; young, old and great athletes, many of whom appeared to be fit and healthy. In 2016, England's batsman, Taylor was suddenly forced to retire due to life-threatening cardiac symptoms (Charles, 2016). In the US, in 2011, about 326 200 people experienced out-of-hospital SCA and about 209 000 people suffered in-hospital SCA (Mozaffarian et al., 2015). In Europe, with 46 countries and about 730 million people, the incidence of SCA affected between about 350,000 and 700,000 people per year (Sans, Kesteloot & Kromhout 1997).

The incidence of SCA in Africa/South Africa is unknown. Countries in Africa find themselves at different stages of the epidemiological transition. Many countries, like South Africa, have reported a rising incidence of ischemic heart disease. According to the Global Burden of Disease in 2010, ischemic heart disease was responsible for more deaths in Africa than either rheumatic heart disease or hypertensive heart disease. With the introduction of antiretroviral therapy (ART), patients with HIV/AIDS are living longer and with the increasing atherogenic complications of ART, sub-Saharan Africa is facing an impending epidemic of cardiovascular and metabolic disease (Chin, 2015).

SCA survival depend on early recognition of SCA, high quality CPR, prompt defibrillation and effective post-resuscitation care (Nolan, Soar & Perkins, 2012). Being aware of symptoms such as a family history of SCA or SCD, chest pain, palpitations and/or syncope episodes are crucial in preventing SCD (Krishnaswamy & Askari 2015). Worldwide, ICD implantation has thus become the preferred treatment for individuals at risk of SCA/SCD.

Figure 3.1 SCA in the US 2011



(SOURCE: Sudden Cardiac Arrest Foundation, www.sca-aware.org).

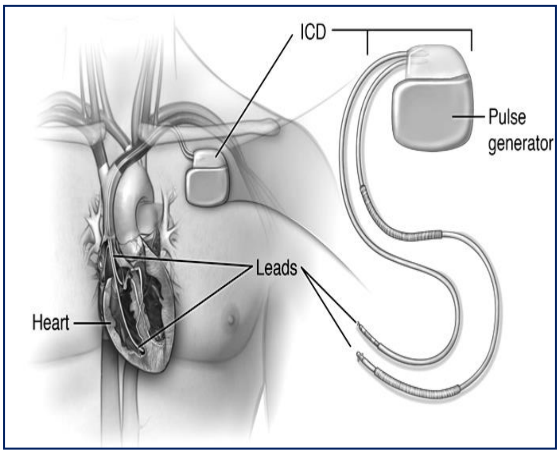
3.2 Implantable Cardioverter Defibrillator (ICD)

The ICD was developed by Dr. Mirowski, a pioneering cardiologist, and revolutionised the ability to prevent and treat SCA. Mirowski realized that SCD was often the first sign of a cardiac disease and it drove him to develop the ICD (Deyell, Tung & Ignaszewski, 2010).

3.2.1 History Mieczyslaw (Michel) Mirowski was born in 1924 in Warsaw, Poland. At age 15, during WW2, he fled to Russia and became the only family member to survive. He completed his medical degree in France in 1954 and later worked in Israel where he conceived the idea of an ICD after his good friend and colleague suddenly died from VF. In 1968, he moved to Baltimore where he and Mower, began to work on an ICD. After much perseverance, in 1975 the first ICD prototype emerged, small enough to be implanted in a dog (Mower, 1991). Overnight the ICD was brought into the forefront of cardiac research and the first successful human ICD implant occurred in 1980 (Mirowski et al., 1980). But besides the ICD, Mirowski is also celebrated for highlighting SCD and its huge impact on public health. He died in 1990 (Deyell et al., 2010).

3.2.2 Definition “An implantable cardioverter defibrillator (ICD) is a small, electronic device that continuously monitors the electrical activity of the heart. It is about the size of a stop watch and is usually inserted under the skin in the upper chest. It consists of a pulse generator and wires, called leads. The pulse generator contains the battery and a tiny computer. Wires connect the pulse generator to specific locations in the heart. (The ICD)… has many life-saving functions. Four key functions… (performed on the heart)… are anti-tachycardia pacing (ATP), cardioversion (light shock), defibrillation (stronger shock), and backup pacing” (Johns Hopkins Medicine, n.d.).

Figure 3.2 **ICD**



The ICD continues to improve rapidly. New models weigh as little as 90g and are less than 1cm thick (Deyell et al., 2010). They also have improved leads; battery life and monitoring capabilities.

In the most recent improvement, a subcutaneous ICD was developed. It ICD is placed subcutaneously in the body with leads that do not lie in the heart (De Maria, Olaru & Cappelli, 2015). All these advances has led to a greater acceptance and wider usage of ICDs by patients at risk of SCA (Welsenes et al.,2011; De Maria et al., 2015).

3.2.3 Prevalence After the first ICD implant in 1980, there was a growing awareness of arrhythmia and an associated increase in ICD implants. Between 1993 and 2006, 0.8 million people received ICDs in the US (Kurtz et al., 2010). In 2009, the largest survey to date, the 11th World Survey of Cardiac Pacing and Implantable Cardioverter Defibrillators were done and involved 61 countries and 328,027 ICDs. It showed a significant rise in ICD implants in all countries with the US the largest implanter (Mond & Proclemer, 2011). In 2013 at least one million Americans were living with ICD’s (Stephens, 2013) while in the United Kingdom (UK), in 2013 alone, there were nearly 6000 ICD implants (Raatikainen et al., 2015). In South Africa, over 150 patients had ICD implants by 2015, at Groote Schuur Hospital (GSH) alone.

3.2.4 ICD Indication ICD’s are implanted in patients diagnosed with life-threatening arrhythmias and a risk of SCD. In general there are two categories of patients who receive ICD’s; one is for primary intervention where patients are at risk of SCD but have not yet had an aborted SCA or life-threatening arrhythmias. Such patients may have ischemic heart disease, non-ischemic cardiomyopathy or an inherited condition. The other category is for secondary intervention where patients already experienced an SCA, life-threatening arrhythmias or sustained ventricular tachycardia (VT) (Deyell et al., 2010; Priori et al., 2015). Electrophysiologists or Cardiologists, with special interest in pacing, are responsible for ICD implantation, programming and long-term follow-up (Deyell et al., 2010; Priory et al., 2015).

3.2.5 Critical Appraisal A study in 1997 concluded that ICD therapy should be offered as first-line therapy to patients who suffered sustained VT or VF as it was superior to anti-arrhythmic drug therapy (Zipes et al., 1997). This transformed ICD implantation to a broad-reaching preventive therapy (Tung, Zimetbaum & Josephson, 2008). But ICD’s also brought along multiple complications. Pain, bleeding, cardiac perforation, infections, lead failures, inappropriate shocks, malfunctioning and psychological issues are just some (MEDSCAPE, 2016; Tung et al., 2008). Consequently, although the ICD is the most effective treatment for patients at risk, multiple studies recommend discussing various issues, especially factors that influence QOL, before, during and after ICD implantation in all patients (Priori et al., 2015; Kuriachan et al., 2015).

3.3 Quality of Life in ICD Patients

Living with arrhythmia and an ICD is a challenge that can be extremely debilitating for some patients. One study calls it “Living on a knife edge-…daily” and quotes a patient: “The fear NEVER goes away. Worry is not a strong enough word. I feel panic stricken ALL the time” (Withers et al., 2015). In one case an ICD was even explanted due to the stress associated with shocks (Kovacs et al., 2006). But without the ICD, VF or VT can be life threatening and therefore ICD implants have saved many lives; a multitude of clinical trials have shown the mortality benefits ICD’s (Bardy et al., 2005, Dunbar et al., 2012, Moss et al., 2004). Today it is seen as part of management of life-threatening arrhythmias (Bostwick & Sola 2011), either as a primary indication in those who have cardiac conditions putting as risk of VT or VF, or as secondary prevention in patients who have already suffered from previous VT or VF.

There is convincing evidence that an ICD can prolong life by treating life threatening arrhythmias (LTA) (Dickstein et al., 2008). Although many patients feel relieved and secure that the ICD is protecting their lives (Cesarino et al., 2011), there is also an increase in the prevalence of factors that influence the QOL of patients with ICDs (Kajanová, 2014; Godemann et al., 2004b).

Heterogeneity There has been an increase in ICD implants since 1990, partly due to the increased awareness of arrhythmias (Kajanová, 2014. Subsequently factors that influence QOL, in the heterogeneous patient population with ICDs, have been studied extensively (Sears & Conti, 2002, Godemann, et al., 2004b). Patients with ICDs have diverse medical histories, reasons for implantation, coping strategies and experiences (Thylén et al., 2014; Bostwick & Sola, 2007). Some patients had near-death experiences, some longstanding heart disease and some were apparently healthy before experiencing sudden dangerous arrhythmias. In some the course of the disease is relatively stable and in others it rapidly deteriorates (Bostwick & Sola, 2007). This is further confounded by multiple studies using diverse methodology, study designs, recruitment, assessment times and criteria (Holly & Sharp, 2011). Yet, despite the heterogeneity of this patient population, many studies have continued to find common overarching factors such as anxiety, depression and perception that influence their QOL (Dunbar et al., 2012; Shea, 2004; Kajanová, 2014). These factors appear to surface during various stages related to the cardiac event, diagnosis, information, treatment, home, family, coping, the future and the South African context. The factors also clearly seem to relate to Maslow's Hierarchy of Needs (Ventegodt et al., 2003) of physical, safety, support, esteem and actualization needs of patients with implanted ICDs.

3.3.1 Cardiac Event Any life-threatening cardiac event, especially when it involves fear, helplessness and/or horror can be extremely traumatic and trigger long term anxiety (Ford, Sears, Shea & Cahill, 2013; Humphreys, Lowe, Rance & Bennett 2016). But even arrhythmia symptoms such as palpitations and syncope can cause such anxiety and depression; it can significantly impact daily life (Withers et al., 2011). A history of myocardial infarction is thus strongly associated with poorer QOL (Thylén et al., 2014) and a SCA in an apparently healthy individual can be particularly devastating (Corrado, Bassa & Thiene, 2005). SCA survivors come close to death and often experience dissociation, a feeling of being dazed or having an out-of body experience (Ford et al., 2013). They realise their mortality, many fear dying suddenly after an SCA (Godemann et al., 2004a) and they often associate an ICD with a sign of death (Humphrey et al., 2016).

Previous studies have shown that patients with ICDs experience a much higher level of anxiety than the general population (Holly & Sharp, 2011; Thylén et al., 2014). These patients worry about their health, arrhythmias, the ICD, medication, information, family, the future and more (Flemme, Hallberg, Johansson, & Stromberg, 2011). Anxiety can become chronic and manifest in affective (fear, terror), cognitive (panic, worry, stress) behavioural (avoidance, phobias) or somatic (shallow breathing) disorders (Visser, Henderson, Mokgatlhe & von Krosigd, 2010). Fear can also become catastrophic (Shea, 2004) and Godemann et al., (2004a) found that panic disorders are 100 times higher in ICD patients than in the general population. It is clear that stress in ICD patients is very common (Dunbar et al., 2012; Shea, 2004) and a great concern as mental imbalances can increase the risk of cardiovascular disease and life-threatening arrhythmias (Carney, Freedland, Miller & Jaffe, 2002).

These high levels of anxiety can increase arrhythmias (Peacock & Wang, 2013) and the lethality of the arrhythmia (Stopper et al., 2007). Buckley and Shivkumar (2016) and Gray et al., (2007), state that a complex interaction exists between the heart and brain with regard to negative emotions. The autonomic nervous system changes the neuro-cardiac axis and a person's response to certain triggers. When there is a substrate for arrhythmia these effects can be detrimental (Buckley & Shivkumar, 2016) and be aggravated by Post Traumatic Stress Disorder (PTSD).

PTSD has become a great concern. Many studies have found an increase in PSTD in ICD patients (Edmondson et al., 2012; Habibovic et al., 2013a; Ladwig et al.,2008; Sears et al., 2011; Tagney, James & Albarran 2003; Tulloch, Greenman & Tasse 2015; Von Kanel, Baumert, Kolb, Cho & Ladwig 2011). PTSD is diagnosed if an individual has been exposed to a life-threatening event, has re-experiencing symptoms (constantly think or dream about the event, have flashbacks), arousal and reactivity symptoms (hyper vigilance, always on the lookout or jittery and easily startled), avoidance behaviour and cognition and mood symptoms (National Institute of Mental Health; Sears et al., 2011). Tagney et al., (2003), state that PTSD symptoms are very similar to the experiences of a SCA survivor. Sears et al., (2011) state that around 20% of ICD patients have PTSD and Von Kanel et al., (2011) even found that between 2 and 5.5 years post-ICD implantation, chronic PTSD increased with nearly one-fifth of patients newly diagnosed with PTSD. Von Kanel et al., (2011), found predictors for PSTD to be: having more than 5 shocks, being female, depression, peritraumatic dissociation, helplessness, alexithymia (deficit in describing feeling) and low education. Sears et al., (2011) conclude that it is important that electrophysiogists recognise PSTD symptoms in patients with ICDs and refer them for appropriate psychiatric and psychological management.

Maslow's first level focuses on basic physiological needs such as staying alive (Ventegodt et al., 2003) and clearly an event that threatens life gets priority over all other needs. To have quick access to emergency care could be crucial in decreasing anxiety.

3.3.2 Diagnosis Patients diagnosed with a life-threatening cardiac disease which has no cure and may also be genetic, is devastating and can provoke anxiety for the whole family (Corrado, Drezner, Basso, Pelliccia, & Thiene, 2011). It is also particularly traumatic for an apparently healthy sportsman to receive such a diagnosis (Tagney et al., 2003; Corrado et al., 2005). Denial of reality is one of the immediate reactions and the most primitive defence mechanism by patients (Grohol, 2016; Covino, Stern & Stern, 2011). Although denial is effective in the short term, it could jeopardize health care in the long term (Grohol, 2016).

Depression also soon sets in and it is not surprising that depression and anxiety are the most common factors that influence QOL in ICD patients (Dunbar et al., 2012; Kajanová et al., 2014; Sears et al., 2011). Prevalence of depression of up to 41% was found in various studies and reviews (Dunbar et al., 2012; Holly & Sharp, 2011; Kajanová et al., 2014). Multiple losses usually lead to depression and all ICD patients experience many physical, social and emotional losses. Patients react similar to the Loss and Grief Stage Theory of Kübler-Ross (Kübler-Ross, 1969) and experience denial, anger, bargaining, depression and acceptance of their disease (Humphrey et al., 2016). This process of loss, grief and mourning need to take place as patients and families adjust to uncertainty, loss of function in family members, loss of peace of mind, new diagnosis in relatives, the future and serious virtual and actual deaths (Skirton, 2008).

Many factors exacerbate depression. The prospects of living with an ICD to keep you alive with a painful shock leave patients vulnerable, powerless and insecure (Humphrey et al., 2016; Shea, 2004; Tagney et al., 2003). Added to this, they lament about disease progression, work prospects and life expectancy (Tagney et al., 2003). Detrimental coping behaviours may also manifest. Patients avoid risks; conceal concerns, isolate themselves and thus inevitably increase depression (Humphrey et al., 2016; Shea, 2004; Tagney et al., 2003). Added to this, there is a well-known association between depression and PTSD and depression is an important predictor of PTSD (Von Kanel et al., 2011). Studies have found that severe symptoms of depression may predict ICD shocks and contribute significantly to mortality (Whang et al., 2005; Habibovic et al., 2012). It is clearly vital to introduce effective coping mechanisms for vulnerable patients before depression sets in (Covino et al., 2011).

Receiving a life-threatening diagnosis challenges Maslow's safety needs level. Patients need predictability and order (Rice, 2014) and reliable medical care and support can be vital in alleviating depression.

3.3.3 Information It is vital to give timely, accurate and appropriate information for ICD patients. Many patients are in the stage of anger, fear and uncertainly after denial of their cardiac diagnosis (Kübler-Ross, 1969). A patient state: "The worst thing was a lack of information…anxiety levels are high because you need more information" (Withers et al., 2015). Minimising anger is vital. Lampert (2010) found that anger and strong emotions can trigger polymorphic, potentially life-threatening ventricular arrhythmias in vulnerable patients and thus increase shocks. Many patients find information too technical, too little, inappropriate, incorrect, given at the wrong time or in overload (Godemann, 2004b; Sears et al., 2011; Tagney et al., 2003). Some patients want to know more about the ICD before receiving it, (Bostwick & Sola, 2007) others want more individualized information and many want more information on coping skills at home (Tagney, 2003).

Eads, Sears, Sotile and Conti (2000) suggest that information can be one of the most effective methods of regaining a sense of control and patients who felt better prepared for living with the ICD had better medical and psychosocial outcomes (Dimitra, 2009). Dougherty, Thompson and Kudenchuk (2012) identified the period immediately after discharge as a vulnerable time emotionally and physically for ICD patients. Effective discharge planning and preparation of patients and families to address experiences and emotions when they at home are vital (Dougherty et al., 2012) especially as Tagney et al., (2003) found it very evident that patients bottle up their feelings and are desperate to talk to someone.

Information and communication is thus crucial as besides improving QOL, it will bolster problem-solving and coping strategies of ICD patients (Eads et al., 2000). Information relates to Maslow's need for safety. Adequate and appropriate information will help a patient feel safe and enable him to embrace Maslow's next level of love, belonging and support.

3.3.4 Treatment Once treatment starts, the patient may experience an added helplessness as he finally realizes he has no other option. The Loss and Grief Theory (Kübler-Ross, 1969) relates this to acceptance but concerns about their ICD continue and are strongly linked to depression and anxiety (Thylén et al., 2013). These concerns are important as the more uncertainty recipients experience early in the recovery process; the more difficult they adjust later (Mauro, 2008). Immediately post implant, patients may worry about the painful incision, the ICD's large size, position, protrusion, body sensations and discomfort (Humphreys et al., 2016). Eventually patients also worry about device failure, infections, lead complications and battery life while for many the device is a depressing reminder of their serious disease (Humphreys et al., 2016). In general factors such as pain (Thylén et al., 2013), medication, mobility (Tagney et al., 2003) and co-morbidities (Dunbar et al., 2012) influence QOL but the most significant impact on QOL is the ICD's shock or possible shock treatment (Sears et al., 2013).

Sear et al., (2013) state that after implantation, more than 20% of patients with ICDs have ICD related traumatic experiences. Some patients constantly seek for signs of an imminent ICD shock and feel in constant danger (Godemann, 2004a). Some patients even experience phantom shocks (Berg et al., 2013). This means that a patient perceives a shock but the memory of the ICD indicates that there was no shock. Flemme et al., (2011) also found that a life-threatening arrhythmia could have a greater impact than the ICD shock itself. But most patients seem to fear the anticipated pain of an ICD shock rather than the shock itself (Dunbar et al., 2012; Humphreys et al., 2016; Kamphuis, Leeuw, Derksen, Hauer & Winnubst 2003; Shea, 2004). Shocks are painful (described as being similar to being kicked by a horse), unpredictable and uncontrollable (Godemann, 2004a) and studies show that 5 or more shocks per year can severely impact QOL (Sears and Conti 2003; Thylén et al., 2014). Shocks leave patients fearful, vulnerable, uncertain, anxious and depressed. Two of the common repetitive safety behaviours due to fear of a shock, are that patients check their pulse or blood pressure more frequently than suggested and that they avoid activities that may raise their heart rate (Ford et al., 2013).

Patients realise that the ICD is no insurance for life and lose confidence in their safety (Humphreys et al., 2016). This is particularly relevant when leaving the relative safety of the hospital. Some patients develop agoraphobia, a fear of crowded spaces (Godemann, 2004a) and one female SCA survivor felt so vulnerable, she had to stay in close proximity of the emergency services while another wanted to make preparations for her burial (Humphreys et al., 2016). Many patients may thus continue to experience anxiety and depression which is compounded by the unpredictability of ICD shocks.

Every effort should be made to prepare a patient for living with an ICD. This includes ensuring ongoing support and when necessary, professional intervention. This stage also concerns Maslow’s need for safety. ICD patients need continuous reassurance and support to help them feel secure and achieve optimal QOL, especially at home.

3.3.5 Home At home patients are initially confronted by multiple practicalities and uncertainties that are dominated by the underlying fear of an ICD shock (Humphrey et al., 2016; Kajanová et al., 2014; Morken, Severinsson & Karlsen 2010; Tagney et al., 2003). Practical issues involve disease and ICD care, physical adjustment, daily routines, family roles, social networks and the future (Flemme et al., 2011). Patients often restrict their activities by working less, avoiding crowds and not plan far ahead. They also distract themselves by keeping so busy, they continue to live in denial and/or suppress their thoughts (Flemme et al., 2011). Some patients also avoid being alone in case of a shock and some travel less which also impacts their QOL (Heller, Ormont, Lidagoster, Sciacca & Steinberg, 1998; Lemon, Edelman & Kirkness, 2004).

Driving restrictions also significantly influence QOL. In some countries such in Canada (Simpson et al 2004), it is the law that you cannot drive commercially with an ICD and that you need to be shock free for at least 6 months before your driving license can be reinstated.

This can leave men in particularly feeling dependant, powerless and depressed (Humphrey et al., 2016; Shea, 2004; Tagney et al., 2003).

Uncertainty can have a major impact on QOL. Worldwide, in all cultures, studies have shown that incorporating uncertainty in daily life is a major concern for ICD patients (Morken et al., 2010). This behaviour is similar to patients of with other chronic diseases who need to accept uncertainty as normal (Flemme et al., 2011). Somatisation (psychological distress presenting as bodily symptoms) also influences QOL (Bostwick & Sola, 2011). Godemann, et al., (2004b) found that about 30% of somatic QOL indicators are determined by the patients' somatisation tendency. Patients with somatisation, feel tenser, worry more about their body/body signals and take them more seriously. This may call for intervention to address possible underlying issues (Barsky & Borus, 1995).

Going home can be frightening and adequate preparation is vital for the patient and family to adjust. Practical issues and uncertainty need to be addressed and support structures at home become vital. This care commitment correlates with Maslow's level of love and belonging. If the patient leaves the hospital with a sense of love and belonging, anxiety and depression will ease up and initiate a positive outlook on life.

3.3.6 Family Adjustment within the family structure is another significant challenge. The family fear an ICD shock or sudden death of a loved one. Families are often become over involved as they try and provide optimal support (Sears et al., 1999). But overprotection can cause a patient to feel dependant and insecure (Tagney et al., 2003). Patients subsequently often conceal their worries and fears. The situation gets worse when the patient also want to protect the family from worry especially if a member inherited the disorder. Unfortunately this may leads to isolation and increased levels of distress in a patient (Humphrey et al., 2016; Lemon et al., 2004).

The adjustment of the family to many other biopsychosocial uncertainties can also seriously threaten the stability of marriages, relationships, activities, roles and more (Shea, 2004). Added to this, studies have shown that age, gender, living status and work also influence QOL. Younger patients have a lower QOL, young adults have childbearing concerns but older adults appreciate the life-saving technology while women are more anxious and men struggle with loss of independence (Bostwick & Sola 2007; Thylén et al., 2014). Thylén et al., (2014) found that living alone is detrimental to QOL and many patients are anxious about their work prospects and financial security (Humphrey et al., 2016, Tagney et al., 2003).

Adjustment in the family system can implicate the whole family's QOL and may even require intervention. It demands good communication, support and patience but most of all, unconditional love. This stage clearly relates to Maslow's third level of love and belonging which lays the foundation for the continuously challenging issue of coping (Rice, 2014).

3.3.7 Coping It is clear that ICD patients need to cope with multiple and often long- term biopsychosocial factors. Studies have shown that resilience depends on having caring and supportive relationships within and outside the family (APA Help Centre). But many studies also stress the importance of personal disposition and that a pessimistic, negative or anxious attribution to life events can predict poorer QOL (Bostwick & Sola 2011; Godemann et al., 2004a; Sears et al., 2002). Studies have shown that a Type D (distressed) personality's negative perception can decrease QOL significantly (Habibovic et al., 2012; Kamphuis et al., 2003). Van den Broek et al., (2009) examined the combination of anxiety, depression and Type D personality as a predictor of VA in ICD patients. They found that personality changed the effect of emotional distress as anxiety predicted a 70% increase in risk of arrhythmia in Type D patients. Godemann (2004a), states that mood states related more closely to cognitive concepts than an objective distressing event. It is thus suggests that the high prevalence of ICD-related depression and anxiety can be due to perceived disabilities linked to daily activities or ICD discharges (Godemann, 2004a; Kamphuis et al., 2003).

Most ICD patients, besides feeling uncertain, feel out of control (Fricchione, Olson & Vlay 1989; Morken et al., 2010) due to the nature of their condition. They constantly strive to regain some control over their lives (Bostwick & Sola, 2007) and use strategies such as avoidance, denial, distraction and concealment of their fears in order to cope (Flemme, 2011).

Avoidance is especially prevalent in patients who have experienced a shock (Lampert, 2010). They avoid activities that they think may trigger a shock such as exercise and sex (Humphreys et al., 2016). Others avoid objects and places and some restrict ICD information to what they could cope with (Lemon et al., 2004). According to the classical conditioning theory, patients try to reduce anxiety by avoiding stimuli that they associate with a shock. This progressive avoidance behaviour can increase feelings of dysphoria (Humphreys et al., 2016) and eventually lead to poorer QOL (Godemann 2004b; Lemon et al., 2004).

Ultimately, coping depends on the disease status, the device and the individual's ability to cope and view the situation as a danger or an opportunity (Zayac and Finch, 2009). Referring patients for therapy if need be, is also vital in improving QOL outcomes. Coping relates to Maslow's fourth level of self esteem. Self esteem equates confidence and respect by to others, all which may increase the ability to cope and improve QOL (Rice, 2014).

3.3.8 Future ICD patients and their families are continuously challenged, from the cardiac event to the indefinite future. Disease progression, device longevity, funding, employment and having children are just some major concerns (Tagney et al., 2003). This is exacerbated by the patient efforts to cope with emotions and make sense out of a life suddenly changed.

Building resilience is vital. It involves making realistic plans and steps to carry them out. It also requires a positive view of oneself and one's strengths and abilities, competence in communication and problem solving; and being able to manage strong feelings and impulses (APA Help Centre). Supporting patients and intervening when necessary can help patients gain confidence and adapt to uncertainty (Flemme et al., 2011). Neimeyer (2006) state that "meaning making" in the wake of loss is important for post traumatic growth or positive adaptation. The patient is forced to create a new life story and reinvest in a new self-identity. This process follows acceptance, the last stage of the Grief Theory (Humphreys et al., 2016; Kübler-Ross, 1969) and also reflects Maslow's fifth level of actualization.

Ultimately actualization involves achieving one's full potential and transcending one's illness (Rice, 2014). This goal can be very meaningful for individuals affected by a life-threatening disease as they focus on being positive and happy in any given circumstance, as one patients said about his ICD: "… It's sort of having a good friend… it's nice to know it's there…" (Humphreys et al., 2016)

3.4 South African Context

SA has some of its own unique circumstances and factors that may influence QOL in ICD patients. This is primarily due to a long history of political struggles, economic challenges, social disparities, cultural complexities and psychological impacts. It has exposed the majority of South Africans to inequality, poverty, neglect, prejudice and anxieties (Coovadia, et al., 2009; Davidson, 2016; Mayosi & Benatar 2014). Health Care has subsequently also been implicated and arrhythmia care has not been a priority. To address QOL in ICD patients in SA, it is thus crucial to understand South Africa's history and current situation:

Okreglicki (2008), past Electrophysiologist and Director of the Cardiac Clinic at GSH state:

> "…for far too long in South Africa…electrophysiology and an interest in arrhythmias have been neglected while elsewhere it has grown exponentially. The South African public was under-served because of the lack of a basic EP service and awareness was crucial in helping to begin to meet the specific needs of our people."

Scott Millar and Chin (2015), Electrophysiologist, state the following in 2015:

> "While South Africa is somewhat better served than the rest of the continent, we still fall woefully short of international standards of access. The huge discrepancy in access to lifesaving treatment mirrors the many other inequalities in our society. "

South Africa is a democratic, multi ethnic, developing country situated at the most southern point of Africa. It has a population of approx. 51.8 million people with 5 ethnic groups of which 79.2% is Black, 8.9% White, 8.9% Coloured, 2.5% Asian and other 0.5% (Statistical Release, 2011). It has multiple cultures and 11 official languages with Zulu, Xhosa, Afrikaans and English mostly spoken. Nearly 80% of the population are Christians and up to 60% adhere to a traditional African religion. Most of the inhabitants have adopted a western lifestyle although many Africans in rural areas still practice African traditions (SA Info, 2012a.).

3.4.1 Politics The political situation in SA has played a major role in the QOL of the population. Since 1652 South Africa has endured a complicated history of wars and colonial oppression dominated by the “Apartheid” policy, the struggles to oppose it and its effect on society. It was only abolished in 1994, after 82 years and replaced by the majority vote (Coovadia et al., 2009). The Apartheid policy of discrimination, segregation, dispossession, inequality and violent oppression of SA’s indigenous people led to dire poverty, social life destruction, multiple psycho-social problems and a long violent liberation struggle (Coovadia et al., 2009). Black people were denied citizenship and millions were forcibly removed to rural areas (Coovadia et al., 2009). Racial classifications determined who could vote, where one could live or work or go to school and where funds are allocated (Coovadia et al., 2009).

The historical legacy of deeply entrenched racial discrimination in SA (James, 1997) has had a significant effect on mental and physical health (Moomal et al., 2009; Pascoe & Richman 2009; Williams et al., 2008). These effects include heightened stress responses, anxiety, depression, hypertension, increased cardiovascular reactivity (Pascoe & Richman 2009) and lower physical functioning (Harris et al., 2006). Moomal et al., (2009) underscores that exposure to chronic discrimination leads to a higher risk of psychiatric disorders and Williams et al., (2008) conclude that a growing body of research studies were finding that perceived discrimination is a significant health risk.

SA has also been subjected to extreme violence for decades. Altbeker (2007) stated in a review that compared violent crime with the rest of the world that “SA ranks at the very top of the world’s league tables for violent crime”. And today, in 2016, individuals still have to deal with ever present safety and security challenges. This situation can significantly impact patients QOL of patients with ICDs as Hamber and Lewis (1997) sees violence as a form of psycho-social trauma, a trauma which overwhelms an individual's coping resources (Hamber & Lewis, 1997) and create amongst other things; anxiety, depression and PTSD. Violence can leave a person feeling vulnerable, helpless and out of control in a world that is no longer predictable (Hamber and Lewis, 1997). Findings suggest that people's assumptive worlds are affected by traumatic events and the impact on their basic assumptions is still evident years after the event (Janoff-Bulman, 1989). Living with unpredictable shock treatments of an ICD can clearly exacerbate patients with ICDs QOL.

This “culture of violence” is deeply rooted in centuries of colonial, violent state oppression and institutionalised racism. This was compounded by migrant labour and influx control systems which damaged family structures and social cohesion. Individuals felt powerless and often used violence to assert power (Simpson, 1993). This relates to Bandura’s study that showed that dehumanization lead to aggression (Bandura et al., 1975). Hamber and Lewis (1997) concluded that this often displaced violence left many South Africans struggling to relate to other individuals due to broken trust. Grief and loss with added anger, vulnerability and suspicion left many South Africans challenged to cope daily (Hamber & Lewis, 1997).

General stress is thus very prevalent in SA. The first nationally-representative South African Stress and Health Study show that approx 30% of adults have experienced a DSM-IV disorder in their lifetime (Stein et al., 2009). A research study on multiple traumatic events and psychological distress in a nationally representative adult sample of SA, also showed high rates of trauma and that the majority of South Africans experience multiple traumatic events during their lives and subsequent high distress. This can take a toll on South Africans’ psychological health, and the study stresses the importance of considering traumatic events in the context of other traumas in SA (Williams et al., 2008; Atwoli et al., 2013).

Unfortunately Post Traumatic Stress Disorder is very prevalent in a country like SA that has experienced extreme political and social conflict with frequent public acts of violence. An analysis on trauma and PTSD in SA has shown that over 70% of the population was exposed to at least one potentially traumatic event. And that sudden unexpected deaths and witnessing (bystander effect) of traumatic events significantly added to the PTSD burden in SA (Atwoli et al., 2013). Symptoms of PTSD can be severe and long lasting (DSM-5, n.d.) and PSTD can thus play a major role in QOL considering that nearly 20% of ICD patients have PTSD according to (Sears et al., 2011).

3.4.2 Economy The economic situation also plays an important role in QOL. Twenty years post-apartheid, the majority of South Africans are still experiencing severe poverty. Apartheid policies of forced relocations, job reservations and low wages had a lasting impact on the majority of South Africans. Many still struggle for access to life’s basic requirements, and adequate housing, education, jobs, health care and ultimately better health and QOL (Mayosi & Benatar, 2014).

SA has the world's 25th-largest economy by GDP and the 33rd-largest labour force (SA Info, 2012b). During post-apartheid there was considerable economic growth, the black African middle class expanded and social grants to the poorest and unemployed was significantly increased (Mayosi & Benatar, 2014). In 2015 unemployment was at 25.0% (Statistics SA, 2015) and there is still a huge disparity in income with increased levels of inequality. 10% of South Africans earn 58% of the total annual national income while the bottom 70% combined earns only 17%. These are the widest figures in the world and are incompatible with improvement in population health (Mayosi & Benatar, 2014). The 2011 National Planning Commission (NPC) state that too few people work, school education for black people is poor, infrastructure is poor and the economy unsustainably resource intensive. Corruption levels are also high, SA is still a divided society and the public health system cannot meet demands or sustain quality health care (NPC, 2011). New economic programmes thus urgently need to address these concerns, which include healthcare access and services (Coovadia et al., 2009).

3.4.3 Social The history of SA had a major influence on its social development and structures. Discrimination and violent suppression of indigenous people caused millions of people to be forcibly removed to poorly located and impoverished rural areas (NPC, 2011). These areas lacked basic living requirements and infrastructures such as health care, support and transport services (Coovadia et al., 2009). Unemployment was high, disease rampant and QOL poor for the majority of South Africans. The migrant labour system subsequently became a vital means of income.

This severely weakened the crucial family structure, broke down traditions and diluted cohesion of the fragile communities. Many children grew up fatherless and boys especially suffered. Boys often missed the socialisation process into disciplined and responsible adults which often resulted in a life of crime and violence (Coovadia et al., 2009).

Deliberate poor education of black people also left many people illiterate and unemployable. This can have dire consequences as Commission on Social Determinants of Health (CSDH) (CSDH, 2008) states that there is a strong indication that a mother’s education determines a child’s health and survival (Caldwell, 1986; Cleland & Van Ginneken, 1988). The current dysfunctional education system is thus another persistent legacy of apartheid (Coovadia et al.,

2009) which significantly influenced QOL especially with regards to patient language and communication.

Language and communication proficiency have also been pivotal in health related QOL in SA. The Apartheid government established English and Afrikaans as dominant languages and neglected the indigenous languages of the majority such as Zulu and Xhosa. This hampered equitable and effective health delivery in SA and potentially directly influenced medical diagnosis, treatment, education and trust (Schlemmer & Mash, 2006).

Various studies highlight language barrier issues. Deumert's (2010) found that three public hospitals in SA showed that linguistic barriers between English/Afrikaans speaking providers and Xhosa speaking patients are deeply entrenched in the public health system and still affect health care fifteen years after the end of apartheid. Schlemmer and Mash (2006) and Levin (2006) also both found that language barriers may impact work efficiency, interpretations, ethical dilemmas, attitudes of patients and staff towards each other, satisfaction of care and cause cross-cultural misunderstandings. In a South African paediatric hospital where staff mainly spoke English and Afrikaans and patients mostly spoke Xhosa as their first language, parents had difficulties with understanding the doctors, making themselves understood and asking questions (Levin, 2006). Levin (2006) also found that parents tended to blame their own linguistic limitations rather than those of the doctors which highlight the need for doctors to be aware of communication issues.

Social development is thus vital in improving QOL in the challenged population of SA. This includes considering cultural issues which play a major role in SA.

3.4.4 Culture Cultural factors, especially cultural beliefs can significantly influence health in SA. A Disability Survey showed that 3% of the population stated 'bewitchment' as the cause of their disability (Department of Health (DOH), 2002). A rural study also found that 'bewitchment' got the blame for their tuberculosis caused patients to delay appropriate western health care (Wegner & Rhoda, 2015). Such incidences, the fact that more than 80% of the population associate with indigenous cultures and that up to 80% of people consult a traditional healer before going to a primary health practitioner (Truter, 2007), makes it vital to understand SA's cultural system and its influence on health and heath care.

Cultural groups are powerful. They meet the needs of safety, integrity and belonging (Kagawa-Singer & Chung, 2002) and ultimately shape perceptions on values, beliefs, norms and practices, as they are learned, shared and transmitted (World Health Organisation, 2004). These perceptions often determine how a patient describes symptoms, allow treatment and manages their illness.

SA has various cultural groups. The largest group, consisting of various ethnic groups such as the Zulu and Xhosa, practice a traditional culture. The minority groups such as the Dutch and English mostly practice a western culture (Mulaudzi, 2007; Truter, 2007). This cultural layout has been dominated for decades by white minority rule that westernized healthcare and established the dominant Christian religion. Today many African people practice a traditional belief system in combination with Christianity or Islam (Mulaudzi, 2007; Truter, 2007). The Indigenous Culture's concept of self-identity is collectivism. It is community based and kinship, rituals, spiritual relationships and responsibilities are inseparable from nature. This includes a belief in ancestral spirits, past lives, reincarnation and connectedness. Healing thus depend on recovering broken connections such as ancestors, nature or country which may require that an entire family be present in healing rituals (Benning, 2013).

This healing and divine guidance involve powerful spiritual leaders and traditional healers such as "sangomas" in the Zulu culture. They have a good relationship with patients and their families and act as physician, counsellor, psychiatrist or priest for anything from social problems to major illnesses (Truter, 2007).They are also more accessible than Western forms of health care as there are at least 200 000 Traditional Healers in SA (Abdool & Ziqubu-Page, 1994). They are widely dispersed, know cultural norms, culture bound syndromes and their advice is believed and acted upon by community members (Sorsdahl et al., 2009).

Understanding traditional beliefs are thus vital. Most black Africans attribute illness to superstitious causes such as magic and evil spirits which often imply tension between good/evil and harmony/ disharmony (Vaughn, Jacquez & Baker, 2009). Culture Bound Syndromes, which are conditions unique to specific cultures, is believed to reflect this tension and it is suggested that the syndromes may merely be local ways of explaining various problems and are not syndromes at all (Simons, 2001). Mood disturbances such as anxiety and depression are also not viewed as mental health problems but as social or moral problems. It is thus understandable that people believe that someone familiar with their past/present social ties such as a family member, spiritual/community leader or traditional healer are more equipped than western doctors to deal with their problems (Mulaudzi, 2007).

Symptom presentation can be difficult and somatisation is often used to show distress. This is common in collectivistic societies and people avoid expressing psychological complaints (Vaughn et al., 2009). Depression is especially difficult to detect. Some cultures like the Shona in SA and the Aborigines in Australia don’t have the word “depression”. The Aborigines simply use “Watjipa” which means homesickness. As a result, clinical presentations of depression or anxiety may differ significantly from the DSM-I description and lead to misidentification of distress (Kirmayer, 2001). The West’s universal approach to depression and other conditions, neglected culturally specific physical and somatic aspects of disease and customary rituals. This is particularly traumatic for people unable to complete a holistic healing process due to being separated from their land by apartheid laws (Benning, 2013).

Traditional health care in SA co-exists with modern health care and many patients use both systems. They see doctors as diagnosticians and treatment providers while traditional healers are problem solvers of the “body-mind” and spirits that caused the disease (Peltzer, 2009; Sewankambo & Katamba, 2009). SA has established a Traditional Medicine Directorate. This bodes well for traditional healers, western doctors and a culturally competent healthcare system. But to succeed, clinicians need to learn the differences in racial and ethnic backgrounds, improve their communication, accept that western belief systems will be challenge and learn that different levels of trust and respect exist (Davidson, 2016), as Meyer states.

3.5 Health Care in South Africa

Health Care in SA consists of a public and private sector and services range from basic primary care to highly specialised health care. The public system provides free tax funded health care to the majority of uninsured people (84 %) but is chronically underfunded and understaffed. The private sector serves the wealthy 16% of the population who are on medical aid schemes, employs 70% of South Africa's doctors and is far more effective (SA Info, 2012c). Although progress has been made post-apartheid to health care, access improved to services and 8.61% of the GDP spent on health in 2011, outcomes have remained poor (WHO, 2016). Many of the state hospitals are in a crisis and infrastructures are run down and dysfunctional, as a result of underfunding, mismanagement and neglect (Von Holdt cited in Mayosi et al., 2014).

Urgent post-apartheid priorities involve addressing the needs of the previously disadvantaged majority who are mostly affected by diseases of poverty e.g. infectious diseases HIV/AIDS and tuberculosis. These needs comprise of basic provisions such as fresh water, sanitation and primary health care (Mayosi et al., 2012).

Electrophysiology has been neglected in SA and in 2008 there were only a few Cardiac Electrophysiologist (EP) compared to at least 999 in 1998 in the USA (Okreglicki, 2008). In 2015, SA still has a scarcity of EP's. There are currently only 13 Electrophysiologists accredited by CASSA (Cardiac Arrhythmia Society of SA). Twelve work mostly in private practice and only one work in the academic/public sector. The ratio of EPs is thus around 1 for every 4.5 million of the population of SA (Scott Millar & Chin, 2015).

Access to arrhythmia care in South Africa and specifically access to ICDs in the public sector is thus limited by the lack of skilled personnel and financial constraints. This situation is aggravated by the lack of arrhythmia awareness, information and support. Fortunately, the medical society CASSA and the patient awareness and support organisation, PACE (Prevent Arrhythmic Cardiac Events) has made a significant difference in arrhythmia awareness, education, support, management of individuals with rhythm disorders (Okreglicki, 2008).

These efforts lightened the burden of the doctor, patient, carer and health care system alike.
But, albeit SA overcoming a myriad of challenges and making considerable advances since the democratic transition, the health and well-being of most South Africans remain challenged by a persistent burden of disease, social differences and inadequate human resources to provide care for a growing population (Mayosi et al., 2012). This especially

compounds the factors that influence the QOL of someone living with a life-threatening cardiac condition and an unpredictable shock device, the ICD.

3.6 Interventions

Sears et al., (2002) stated that ICD patients will always need assistance and/or intervention to adjust psychologically and that routine psychosocial need assessments by a multidisciplinary team should be integrated into clinical care of ICD patients. A comprehensive review, 10 years later by Dunbar et al., (2012) on the psychosocial responses and care of patients with ICDs and their families, underscores the importance of Sears's statement.

The basis of optimizing QOL in patients with ICDs starts with a holistic approach which involves comprehensive information/education and continuous psychological support by a skilled clinical care team (Lampert, 2013). Education begins at preimplantation with discussions on ICD benefits, limitations, concerns about its therapy and the impact on daily life (Dunbar et al., 2012; Kajanová et al., 2014; Thylén et al., 2013). Postimplantation involves preventing ICD shocks, especially inappropriate shocks, with drug therapy, ablation procedures and optimal ICD programming. Added to this, all patients and family members should know what to do after a shock (Kajanová et al., 2014). Other discussions should involve disease and wound care, activities, financial issues, support and educational resources, end of life issues and possible psychological issues (Humphreys et al., 2016; Kajanová et al., 2014; Lampert, 2013).

Routine screening for psychological issues such as anxiety, depression or possible PTSD, is crucial (Lampert, 2013). Dunbar et al., (2012) found that psycho-educational interventions that increase information and teach skills for living with an ICD has greatly reduced psychological distress and improved QOL (Dunbar et al., 2012). Cognitive Behavioural Therapy (CBT) has been very successful (Dunbar et al., 2012; Irvine et al., 2014; Kajanová et al., 2014; Maia et al., 2014) as has Solution Focused Brief Therapy (SFBT). SFBT is particularly effective for anxiety and depression. SFBT sessions are few; it is transferable across cultures and languages and can easily be used by medical staff (Franklin, 2015). Other successful interventions involve yoga (Buckley & Shivkumar, 2016), stress management (Dunbar et al., 2012), mindfulness (Humphreys et al., 2016).

Being adequately informed and routinely screened for psychological issues, may prepare everyone for eventualities, lessen anxiety/depression and improve QOL significantly (Dunbar et al., 2012; Kajanová et al., 2014). The Scientific Statement from the American Heart Foundation by Dunbar et al., (2012) had the ultimate goal of improving the identification and care of psychosocial distress in patients with ICDs to maximize benefits of their ICDs. This is supported by studies such as Wilson & Cleary (1995) who stated that treatment strategies depend on identifying factors that influence function and QOL so that risk factors can be adapted and health improved. This is ultimately also what this study hope to initiate.

3.7 Summary

This literature review found that worldwide, there is a high prevalence of SCD and SCA and that ICD's are increasingly being implanted. It also found that multiple interrelated factors influence QOL in ICD patients. Cardiac Events and Shock Treatments are key medical factors. Anxiety and depression are of the most common psychological impact factors. Information and support are of the most important practical impact factors. Politics and culture are of the most significant factor impacting South Africans. Personal disposition is a key underlying factor. Health Care in SA indeed faces many challenges but this review shows that interventions can successfully improve QOL outcomes in ICD patients.

ICD Patients and their families thus need a holistic approach: appropriate information, routine assessments, timely interventions and continued support. Maslow's theory of needs are clear: physiological needs refer to clinical intervention; safety needs refer to information and ICD treatment; love and belonging needs refer to support from doctors, family and friends; self-esteem needs refer to coping skills, and self-actualising needs refer to acceptance and transcendence beyond the disease. The patient ultimately finds peace within himself.

CHAPTER 4

RESEARCH DESIGN

The purpose of this study was to establish the quality of life of patients with ICDs, and to investigate factors that may influence their quality of life. This study ultimately endeavours to improve the care of patients with ICDs in South Africa, as well as lay the foundation for future research in this area.

The research design is a crucial part of a research study as it has to maximise the validity of the findings to ensure sound conclusions (Mouton & Marais 1990.) The design has to be valid, coherent and a clear guide for the research process (Terre Blanche, Durrheim & Painter 2006). This study involved a positivistic paradigm and a quantitative approach. Descriptive and correlational studies were done to determine data frequencies, means, relationships and key factors related to QOL and surveys with questionnaires provided statistical data.

4.1 Research Paradigm

The research paradigm suitable for this study was positivism. Positivism focuses on measureable realities and this study aimed to observe and / or / measure factors that influenced QOL before further meanings were explored. A research paradigm is the philosophical assumption and shared belief systems that influence the kinds of knowledge researchers seek and how they interpret the evidence they collect (Morgan, 2007). It is the core of a researchers thinking and practice and impacts the research question and the way it is studied. This involves dimensions of ontology (what exists), epistemology (how to understand it) and methodology (how to study it) (Terre Blanche et al., 2006).

From an ontological perspective, the positivist views reality as realism with stable objective facts to explain patterns of human behaviour. This leads to large studies and statistical and numerical data as this study has used. From the epistemological perspective, the positivist is objective and in this study, the researcher was objective and detached from the participant by only handing out questionnaires. From a positivistic, methodological perspective; the study was quantitative and used statistical techniques such as determining correlations, while it also used questionnaires (Creswell 2003).

The advantages of a positivistic approach are that it relies on well-known elements of philosophy of knowledge but the disadvantages are that it has a broad approach to knowing and a less direct connection to research (Morgan 2007). Advantages were evident in this study. The study had a clear statistical focus from the outset; the approach suited the relatively large amount of data, provided easily comparable data and could be replicated.

Disadvantages were that the positivistic approach was inflexible and that it was weak in understanding social processes. In one case, a patient spontaneously provided meaningful QOL information while completing the questionnaires but the information could not be included in the study as there was not an appropriate question. Deciding exactly what variables had to be investigated and how to investigate them was thus essential to get an accurate description of ICD patient QOL.

4.2 Research Objectives

The research objectives of the design was to perform
a) a descriptive analyses of the demographic, clinical and ICD information of the study cohort, as well as the patient support characteristics in means and frequencies
b) a descriptive analysis of the Hospital Anxiety and Depression Scale (HADS) in means and frequencies
c) an analysis of the SF-36v2 Health Survey and quality of life using summary statistics,
d) regression analyses that determine factors that influence depression, anxiety and QOL.

The study population on which the above statistical analysis would be performed was patients with ICDs who were followed up at Groote Schuur Hospital.

The study objectives were greatly influenced by the literature review, own observations and the theoretical framework of Maslow (see chapter 2). Literature showed that factors such as ICD shocks, age, gender, ICD indication and information often influenced QOL (Kajanová et al., 2014) and that these factors caused anxiety, depression or even post traumatic stress

(Sears et al 2011). From personal experience and involvement in the PACE Support Organisation, patients with ICDs in South Africa showed needs such as ICD awareness of the general population, ICD education, support and counselling (Own Observation). It was clear that meeting basic needs to optimise QOL was fundamental. This reflected Maslow's theory of Hierarchy of Needs. Maslow's theory was thus a suitable theoretical framework to establish if some factors that influence ICD patient QOL are associated with Maslow's basic needs.

4.3 Type of Study

The research design of this study was quantitative, descriptive, cross-sectional and correlational. Three questionnaires were competed.

Quantitative research emphasizes objective measurements and statistical analysis of numerical data which is collected through surveys and questionnaires. It has been used globally in numerous studies to assess patients with ICDs (Kajanová et al., 2014), (Thylén et al., 2014). Creswell (2014) suggests that quantitative research is the best approach for identifying factors that may influence outcomes and for understanding predictors. This underscored the appropriateness of its use in this study.

Statistical analyses of the data and results are often arranged in tables, charts or figures (Terre Blanche et al., 2006). Quantitative studies are also based on large sample sizes that are representative of the population. Good quantitative research can thus generalize results across groups of people, explain a particular phenomenon (Babbie 2010) or allow for making comparisons of different situations (Terre Blanche et al., 2006). Quantitative studies can also be replicated or repeated due to the high reliability or consistency of quantitative research.

This study used this approach as the objectives were to determine frequencies of variables such as ICD shocks and associations of variables such counselling and anxiety. The approach thus provided numerical data on demographics, clinical status, general health, anxiety and depression. This enabled the researcher to classify features, count them and construct statistical models to explain what was observed (Babbie 2010**)**.

Quantitative research allows for large samples and thus more than 70 patients could be invited to participate. This enhanced the generalisability of the findings to the broader population at GSH. The approach also allows for summarizing large amounts of information. The large amount of data, the objectivity and accuracy of the results due to the statistical methods, enhanced comparison with similar studies and possible replication (Babbie 2010). Lastly the approach reduced a complex problem of an unknown amount of factors, to a limited number of variables. This was ultimately one of the main aims of this study when doing the regression analyses (University of Surrey Library).

Limitations of quantitative research are that results may be humanly insignificant. The measures may miss detail such as recent trauma that may have influenced a response (Babbie 2010), (Terre Blanche et al., 2006). Such events were thus noted in the study if possible. Another limitation was the inflexibility. It limits detail on behaviour and may not reflect people's real feelings. In this study, the invitation stressed that the project was to benefit everyone. Lastly, personal bias was also avoided as the researcher's role was only to hand out the questionnaires and not be subjectively involved with the participant.

Descriptive researches' key aim is to describe and it can describe what exists with respect to status and situational variables. It also describes phenomena through measures on relationships or establishes associations between variables (Terre Blanche et al., 2006).
Descriptive research can cater for large samples which may enable valid estimates of a generalised relationship between variables. Subjects are only measured once and structured questionnaires are generally used (Babbie 2010). Descriptive research can thus, as a pre-cursor to more focused studies on ICD patient QOL, provide valuable recommendations for further research (Polit & Hungler1999).

The research design also involved a cross-sectional approach as the investigation was done in one point in time. This added to the time and cost effectiveness of the research study (Mann 2003). According to Mann (2003), cross sectional studies are the best to determine prevalence, are quick, study multiple outcomes and are useful at identifying associations for more rigorous cohort or randomised control studies. Mann (2003) also stated that prevalence is vital as it may influence a particular diagnosis and the predictive value of an investigation.

Advantages were that subjects were not deliberately exposed or treated in the study so ethical difficulties never arose. Only one group was used, data collected only once and multiple outcomes was studied which made it so suitable for this study (Mann 2003).

A correlational study was also done to test for the correlation between ICD patients and QOL. This was done to determine the degree to which a relationship exists between two or more variables; positive, negative or no correlation. Correlations do not represent causal relationships between two variables. It is one criterion of causality as sometimes the observed correlation is the incidental result of other casual relationships, involving other variables (Babbie 2008) and thus only allows for general predictions.

Strengths of a correlational study are that they are quick, easy and describe strength of relationships. The researcher can determine relationships without randomly assigning participants to conditions. With its predictive capabilities, as with large a sample size, you can use one variable to predict the other when there is a strong correlations between the two. Limits are that correlations don't equal causation and can be misused (Psychteacher). It cannot explain the behaviour and a third variable could always influence the two variables measured.

This study did a survey using questionnaires as they are quick and easy and are of the most common methods used in psychological research. Validity and reliability of the research both depend on properly constructed questionnaires while external reliability is important when aiming for generalisability (Terre Blanche et al., 2006). The development of questions by researchers can lead to false representation, where the data actually reflects the view of the researcher instead of the participating subject and preset answers will not always reflect how people really feel as in some cases it may only be the closest match (Babbie, 2010).

4.4 Setting

The study was conducted at the Cardiac Clinic in Groote Schuur Hospital, Western Cape. GSH is an academic health care centre and a public hospital and is known as the training ground for some of South Africa's best doctors, surgeons and nurses.

As the only South African public hospital that offers Electrophysiology, patients from all over South Africa come to the Groote Schuur Cardiac Clinic for arrhythmia related treatments. They comprise of various age groups, genders, cultures, ethnic groups and socio-demographic backgrounds. Consultants, cardiology registars and technologists provide patients with ICDs regular follow-ups at the Cardiac Clinic. There are many different reasons for ICD implants and patients' health statuses can vary from very good to very poor. But patients living with an ICD have one thing in common; they live with an invasive device which can at any moment shock their heart.

The Cardiac Clinic had adequate areas and seating where the patients were able to complete their questionnaires. Patients found the setting comfortable and familiar and readily participated in the research while waiting for their checkups.

4.5 Sampling

Ethical clearance and compliance was attained with the Policy for Research Ethics from the department of Psychology at UNISA (Appendix 1). Secondly, ethical clearance was obtained from the University of Cape Town (UCT)(HREC REF: 672/2015) (Appendix II). Permission was then obtained from the Department of Cardiology at GSH to conduct the study at the Cardiac Clinic (Appendix III).

The study included all patients with ICD implants aged 18 years and older in the Cardiac Clinic at GSH who agreed to take part in the study. Patients with ICDs who are followed up at GSH are representative of the broader ICD population in SA as it is the only public hospital in SA that provides a comprehensive cardiac electrophysiology service to a cross-section of the South African population. The sample consisted of diverse ages, gender, cultures and socio-economic backgrounds. Representative samples are important in descriptive surveys used to estimate the properties of populations or make inferences. But even if the sample is not representative in a statistical sense, it may show many issues likely to be transferable to similar contexts (Terre Blanche, 2006).

It was estimated that the Cardiac Clinic have an ICD patient population of approximately 150 patients but full participation was unlikely due to contact and time challenges. Convenience, non-probability sampling was used to select the patients because contactibility of the patients were unpredictable. This meant that all ICD patients at GSH were invited to participate but participation depended on the availability and contactability of the patients.

The process of recruiting patients was as follow: Senior Consultant and Electrophysiologist at GSH, Dr Ashley Chin, identified the ICD patients while the principal investigator recruited the patients. Personal or telephonic contact was made with patients before and after being invited to ensure that they understood the study and had the required decision-making capacity. All patients were on the invite list but a number of patients could not be contacted due to incorrect contact details. Consent was obtained by a formal invitation and signed consent form. This was done by hand, post or email. If any participants were experiencing a stressful period, their participation was postponed if possible and noted as such.

The information in the invitation explained the purpose and benefits of improving arrhythmia care and the methods and process of completing short questionnaires. It also gave the assurance of confidentiality in that questionnaires was anonymised by assigning numbers, that data was stored securely in Cardiac Clinic at GSH and access was only permissible to the advising specialist and principal investigator. Patients were also informed of their withdrawal rights and ensured of the freedom to withdraw at any time. Contact details were also provided.

4.6 Data Collection

Data collection was done by completing the following questionnaires:

1) The Demographic and Clinical Questionnaire
2) the HADS 14-item Hospital Anxiety and Depression Scale
3) the SF - 36v2 Health Survey QOL Questionnaire

The questionnaires were a practical way of collecting quantitative data from a large amount of people in a short time and relative cost effective way. The data collection process involved that over 150 copies of each questionnaire printed in English with extra questionnaires in Zulu, Xhosa and Afrikaans. A questionnaire was then put into an envelope for each potential participant. The envelope and questionnaire was marked with a unique code to ensure anonymous and identification of the potential participant. Envelopes were filed and kept at the Cardiac Clinic until the patients arrived.

A detailed patient list was initially compiled with all available contact details. In the process it was found that many ICD patients had problematic contact details.

Secondly contact was made with patients every Tuesday at the Cardiac Clinic when they came for their appointment and unfortunately some patients did not arrive for their appointment. Thirdly patients were contacted telephonically and fourthly, in some cases questionnaires were sent by email to complete.

The completion method involved paper and pen or electronic completion. Translation and interpretation were provided if necessary. Most questionnaires were completed on Tuesdays when patients came to the Cardiac Clinic for appointments. Other patients completed them via email or at home.

Completed questionnaires were kept in the Cardiac Clinic's Electrophysiology filing cabinets. Questionnaires were anonymous, only identified with a number. The number was linked to a master list of the individuals' names and this link was only accessible to the investigators. Anonymised data will be stored in the cardiac clinic. If the researcher left the study, one of the other investigators may complete the study. Any unexpected findings was discussed and dealt with in consultation with their doctor.

The context that the research took place in was strongly focussed on a research team effort. Dr. Chin, the principle researcher, the ICD technologists and the questionnaire assistants were mostly well known to the patients and everyone was motivated and committed to the research project. Participants were reminded that the study was about assessing their QOL and that their own objective responses were most important. The researcher or assistant thus remained objective and only clarified questions when necessary. Email or telephonic completion received the same objective approach.

In general, most questions were enthusiastically answered and the study well received.

4.7 Measuring Instruments

4.7.1 Demographic and Clinical Questionnaire (Appendix V)

A Demographic and Clinical Questionnaire had to be developed to determine characteristics and issues related to key factors that influence QOL in the ICD patient population.

The first step was to review literature on similar studies. This highlighted various important issues such as medical access, coping skills, counselling, support and number of shocks (Kajanová et al 2014) and was subsequently integrated in the questionnaire. Secondly, questions were drawn and added from 15 years of my personal experience as an ICD carer. Thirdly, ICD patients, Electrophysiologists, counsellors and medical staff reviewed the questions and added some questions to the draft.

All questions had to be short and concise. They also had to be simple, direct, not leading, applicable to all and not vague. The length of the questionnaire also had to be kept to a minimum. The questions were then assembled under Demographic Data (Personal data, Education, Home/Location, Coping, Support, Medical Support, Shocks) and Clinical Data (Diagnosis, ICD and Shock information) and finally drafted into closed questions.

The response format consisted of the closed questions which was dichotomous and multiple choices. Answers were completed by crossing one answer in the appropriate box. Lastly, the questionnaire was completed by a few respondents to check for major inaccuracies. Data obtained was then coded, entered on the computer and cleaned before it was analysed in collaboration with a statistician.

4.7.2. HADS 14-item Hospital Anxiety and Depression Scale (Appendix VI)

Anxiety and depression symptoms are commonly found in ICD patients according to various studies (i.e. Dunbar, 2012; Kajanová et al., 2014; Sears et al., 2002; Thomas, Friedmann, Kao, Inguito & Metcalf, 2006). Worldwide, multiple studies have thus used the HADS questionnaire to assess anxiety and depression in ICD patients (i.e. Thylén et al., 2014; Pedersen et al., 2004; Pedersen et al., 2007; Mastenbroek et al., 2014).

In South Africa a few studies have used the HADS but no study has established normative data for the general South African population. One study did though research wording effects and factor structure of the HADS in HIV/AIDS patients in SA and supported the use of the HADS in SA as a valid and reliable means to screen for mental health problems (Wouters, Booysen, Ponnet & Van Loon, 2012). Another found that the HADS is useful in under-resourced and under-staffed settings while still being robust. It can be administered by clerical hospital staff in a busy outpatient clinic and only takes 2 to 5 minutes to complete. It can also easily be scored after completion and make data immediately available (Boermeester & Berard, 1998).

HADS is a 14 item scale. 7 Items relate to depression and 7 items to anxiety. Each item on the questionnaire is scored from 0-3 and this means that a person can score between 0 and 21 for either anxiety or depression. The HADS uses a scale and therefore the data returned from the HADS is ordinal. Researchers have explored cut-off points for anxiety or depression and identified a cut-off point of 8/21 for anxiety or depression. For anxiety (HADS-A) this gave a specificity of 0.78 and a sensitivity of 0.9. For depression (HADS-D) this gave a specificity of 0.79 and a sensitivity of 0.83. Threshold values were set at: None:<8; Doubtful: 8-10; Definite: >10 (Zigmond & Snaith 1983).

The HADS has been found to be a simple and reliable instrument for detecting states of depression and anxiety in the setting of a hospital medical outpatient clinic while the anxiety and depressive subscales have also been found to be valid measures of severity of the emotional disorders (Zigmond & Snaith 1983), (Bjelland et al 2002).

An extensive literary review by Bjelland et al., (2002) on the validity of the HADS found that it performed well in assessing symptom severity and caseness of anxiety disorders and depression in both somatic, psychiatric and primary care patients and in the general population. A large study by Thylén et al, (2014) also underscored its validity in community and medical practice setting.

According to a report by GL Assessments (2011) the HADS is also especially quick and cost-effective in assessing cardiac patients for anxiety or depression which makes it appropriate for use in this study. The HADS was obtained from GL Assessment in the United Kingdom.

4.7.3 **SF-36v2 Health Survey** (Appendix VII)

The SF-36v2 Health Survey is a multipurpose, short-form health survey and developed due to the need of assessments of medical outcomes. It assesses functional health and well-being from a patient’s perspective. Lembcke, 1952 (cited in OPTUM 2017) wrote 50 years ago that the best measure of quality is not how well or frequently medical service is given, but how closely the result approaches the basic objectives of prolonging life, relieving distress, restoring function and preventing disability.

The survey is a generic measure of health status, as opposed to one that targets a specific age, disease, or treatment group. It has proven useful in surveys of general and specific populations, in comparing the relative burden of diseases and in differentiating the health benefits produced by a wide range of treatments (OPTUM, 2017). The SF-36 is considered one of the best generic self-reporting instruments which concentrates on a dimensional approach to QOL and have been tested in an array of diseases according to Joshi, Nau, & Kalsekar, 2001 (cited in Möller, Smit & Petr, 2000). Schneidermann (2011) also concludes that the SF-36 gave more detailed information about HRQOL than the EQ-5D measurement.

The SF-36 has been used worldwide (more than 41 million surveys and 170 translations (OPTUM)) in spite of many countries having no general population norm. The survey has often been used in developed countries such as in Europe (Magnusson et al., 2016), North America (Thomas, Friedmann, Kao, Inguito & Gottlieb, 2006) and New Zealand (Newall, Lever, Prasad, Homabrook & Larsen, 2007). It has also been used in developing countries such as in Asia (Francis et al., 2006) and South America (Cesarino et al., 2011).

Studies that have used the SF-36 in SA are limited (O’Keefe & Wood, 1996). There is also no normative data for the general population of South Africa (Kastien-Hilka, Rosenkranz, Sinanovic, Bennet & Schwenkglenks 2017; Schneidermann, 2011). Yet, there is nothing much more appropriate to use in this study as the SF-36 is the most common tool used to assess QOL in ICD patients according to many studies (i.e. Cesarino et al., 2011; Church, 2004; Francis, Johnson & Niehaus, 2006; Kamphuis et al., 2003; Thomas, 2006). It may thus allow for useful comparison and contributions to ICD QOL research.

The SF-36 was developed in the United States and is based on the 1998 general population norms. It also uses norm-based scoring (NBS). In NBS, each scale is scored to have the same average (50) and the same standard deviation (10), meaning each point equals one-tenth of a standard deviation. Without referring to tables of norms, this method makes it is clear that whenever an individual respondent's scale score is below 45, or a group mean scale score is below 47, health status is below the average range. NBS ultimately simplifies interpretation (Manual SF36).

The 36-item questionnaire measures functional health and well-being from the patient's point of view. It provides scores for eight health domains as well as psychometrically-based physical component summary (PCS) and mental component summary (MCS) scores. Scores are from 0 to 100 (worst to best). Norm-based scoring (NBS) are used and each scale is scored to have the same mean (50) and standard deviation (10).

For each dimension, the score represents the mean of item values from the subject when all the items were completed. It is in likert scale format and available in South African languages. The SF-36 is a practical, a reliable and valid measure of physical and mental health, can be done in 10 minutes.

Content validity was confirmed by systematic comparisons that indicate that the SF-36 includes eight of the most frequently represented health concepts in the measurement of health-related quality of life (Ware, 2000). Internal and construct validity of the SF-36 instrument have also been confirmed through numerous studies such as Petr, 2000; Petr, 2001; Möller & Petr, 2002 (cited in Möller & Smit, 2004).

In general, it has been documented in more than 2000 publications. It has been proved to be very useful in measuring HRQOL in general and specific populations; in patients with acute and chronic diseases, and in clinical practice, various situations and circumstances (Ware, 2000).

The scales encompass physical and mental scales:

- Physical scales:
  - (1) Physical functioning
  - (2) Role physical
  - (3) Bodily pain
  - (4) General health
- Mental health scales:
  - (1) Vitality
  - (2) Social functioning
  - (3) Role emotional
  - (4) Mental health.

The PCS relates at its lowest to major limitations in self care; physical, social and role activities; severe body pain; constant tiredness and a poor health rating. At its highest, there are no physical limits, disabilities or decrements in well-being; a high energy level and an excellent health rating. The MCS relates at its lowest to frequent psychological distress, great social and role disability due to emotional problems and a poor health rating. At the highest, it relates to positive affect; no psychological distress and limitations in social and role activities due to emotional problems and health is mostly rated as excellent.

The eight domains are described as follow: Physical functioning (PF) such as self-care, walking and exercise; Role-Physical (RP), how much role activities are limited by physical health; Bodily Pain (BP) such as intensity, duration, frequency and limitations due to pain; General Health (GH) beliefs and values of the person’s health; Vitality (VT), energy levels and absence of tiredness; Social Functioning (SF) such as how much the person develops and maintains social relationships; Role-Emotional (RE) which refers to how much role activities are limited by emotional problems and Mental Health (MH), a person’s emotional, cognitive and intellectual status.

The SF-36v2 Health Survey was obtained from OPTUM (2017) who provided a license to download the QualityMetric Health Outcomes Scoring Software 4.5.

4.8 Data Analyses

Data analyses firstly involved preparing the data (Research Methods, n.d). The data was coded and each question was assigned a code. Secondly the data was entered on an excel spreadsheet. The top row represented the questions and the left column, the unique participant number. Finally the data was cleaned, checked for errors and corrected. The data was then transferred to the SF-36v2 Software Program, as well as the statistical packages SPSS and Stata.

The analyses involved:

1. A descriptive analysis of Demographic, Clinical, ICD and Patient Support characteristics
2. A descriptive analysis of the Hospital Anxiety and Depression Scale (HADS)
3. An analysis of the SF-36v2 and QOL in the population using summary statistics
4. A univariate and multivariate analysis that determine factors that influence QOL, Anxiety and Depression.

A descriptive analysis of the Demographic, Clinical, ICD and Patient Support data was performed, to determine the frequencies of categorical variables and means and standard deviations for continuous variables. Similarly, HADS anxiety and depression data was analysed to determine the means and standard deviations of the scores, as well as frequencies of anxiety or depression (as determined by a score of > 8 on the HADS anxiety and HADS depression scales). Thirdly the analyses determined the quality and internal consistency of the SF-36v2 data as well as the frequency, means, standard deviations and QOL of the data.

Univariate and multivariate regression analyses were done to determine the key factors that influence QOL, anxiety and depression amongst patients in this study. A regression model was fitted with QOL as the dependent variables and various chosen variables as the predictors or independent variables. Predictors were selected based on previous research (Humphreys et al 2016, Godemann et al 2004) and model assumptions and fit were evaluated.

4.9 Validity and Reliability

Coherence, validity and reliability of the research design play a vital role in the evaluation of the design. Design Coherence is a basic principle of a good research design. It refers to the degree to which various elements of the design fit together within the framework provided by the research paradigm (Terre Blanche et al 2006). Design coherence was achieved in this study as it adhered to a positivistic stance throughout.

Design validity, also a basic principle of a good research design refers to the degree that the research conclusions are sound and accurately reflect what we were studying (Terre Blanche et al 2006). Internal validity is achieved by identifying plausible rival hypotheses and eliminating their impact. In this study alternative considerations such as co-morbidities were measured to determine their influence. To maximise internal validity, measures with good psychometric properties (standardised, reliable and valid scales) such as the HADS and SF36 were also used as measures.

External validity, also called generalisability, is highly valued by descriptive research (Terre Blanche et al 2006). Generalisability refers to the extent to which it is possible to generalize from the data of the study to the broader population. In this study external validity was acceptable in that convenience, non-probability sampling was done, the sample population was 70 (50%) out of 150 possible patients which made it representative on the GSH ICD population and the measure (HADS, SF-36v2) was representative of QOL measures.

Reliability is highly valued by positivists and is the degree to which the results are repeatable and consistent (Terre Blanche et al 2006). This applies to measurement reliability and the final outcome. The measurement used in this study, the HADS and SF36, has shown to be reliable and were thus conducive to a sound outcome.

4.10 Ethics

Ethical considerations were crucial and before the study commenced. Firstly ethical clearance and compliance was attained with the Policy for Research Ethics from the department of Psychology at UNISA (Appendix 1). Secondly, ethical clearance was obtained from the

University of Cape Town (UCT) (Appendix II). Permission was then obtained from the Department of Cardiology at GSH to conduct the study at the Cardiac Clinic (Appendix III). During the study, Dr Chin, Consultant Electrophysiologist at the Cardiac Clinic would be involved either in an advisory or investigating capacity. The Cardiac Clinic Staff was subsequently informed about the study, its commencement and their involvement.

All qualifying ICD patients in the Cardiac Clinic were then identified invited to participate and informed that they needed to sign a consent form. Participants were also informed that they would only be involved in the study once and only for approximately 45 minutes to complete 3 questionnaires. The completion would be done in the Cardiac Clinic before or after appointments or at home. All participants were informed and ensured of autonomy and dignity through voluntary informed consent and confidentiality. Confidentiality was maintained by assigning anonymised numbers to the participants and keeping the administration securely in the Cardiac Clinic. Nonmaleficence was ensured for no harm was done. Benefice was also ensured as the benefits of improved QOL and patients care is stressed while risks are minimised by providing a counsellor if need be. Justice was upheld as all participants would benefit in future.

Collaborative partnerships were also established as medical staff at GSH, ICD patients and the researcher together developed the research. Social value and scientific validity was ensured as patients, medical staff and families would gain knowledge and possible intervention to improve ICD QOL. Fair selection was adhered to as all ICD patients over 18 at GSH are invited. Lastly, informed consent included the right to withdraw without risking medical attention and care and respect for participants was to be ongoing.

4.11 Strengths and Limitations

The strengths of this research design were that it provided a large amount of data in a cost effective way. Structural factors such as age could be analysed, documentation on the measures were available and the standardised approach allowed for replication. It was also useful for identifying variables and hypothetical constructs which can be further investigated through other means. Hypotheses about causation can be generated and tested in analytical studies in the future. Limitations of the study were that it could not identify causes that influence QOL but for this study, it could lay the foundation for further research. Self-reported information may also have been inaccurate or incomplete but participants have been made aware of that. Results may have masked or ignored underlying factors but an indication of the general status of QOL of ICD patients was obtained.

4.12 Summary

In summary, using a positivistic, quantitative approach and a descriptive, cross-sectional and correlational research design was a time and cost effective way to identify factors that influence QOL in ICD patients before larger studies are done. The design set a foundation for further investigation especially to investigate specific causes.

Internal validity was maximised by measuring possible alternative explanations such as co-morbidities and by using standardised, valid and reliable scales to obtain sound results. External validity, thus representativeness and generalisability, was maximised by inviting all ICD patients at GSH and using convenience sampling. Reliability or consistency was also achievable as the study could be repeated at other Cardiac Clinics in SA by using the appropriate measures and a standardized approach.

“Research design is about balancing the need for valid findings with the need to conduct practically feasible research” (Terre Blanche et al 2006). Research design is thus crucial from beginning to end and can make or break the study.

CHAPTER 5

RESULTS

A total of 70 ICD patients were invited. Everybody completed the three questionnaires involved in the study. Results provide a descriptive analysis of demographic, clinical, ICD and patient support characteristics; a descriptive analysis of the sample according to the HADS survey; an analysis of the QOL of ICD patients according to the SF-36v2; and lastly, factors that influence depression, anxiety and QOL according to a regression analyses.

5.1 Demographic, Clinical, ICD (Table 5.1) and Patient Support characteristics (Table 5.2), are presented in means or (frequencies) and standard deviations (SD) or percentages (%).

Table 5.1 Demographic, Clinical and ICD Characteristics for the total sample, n=70(100%)

	Mean or (Number)	*SD or (%)*
Demographics		
Age	57.0	13.16
Male	(46)	(65.7)
Ethnicity Coloured	(39)	(55.7)
Afrikaans speaking	(35)	(50.0)
Living with spouse/partner	(38)	(54.3)
Completed High School	(49)	(70.0)
Unemployed	(35)	(50.0)
Travel time over 1 hr to GSH	(31)	(44.3)
Emergency Unit close to home	(48)	(68.6)
Knows an emergency number	(47)	(67.1)
Clinical		
Ischemic Heart Disease	(30)	(42.9)
ARVC	(11)	(15.7)
DCM	(13)	(18.6)
ICD duration 1-5years	(30)	(42.9)
ICD duration > 5years	(28)	(40.0)
Previously documented VT	(55)	(78.6)
Secondary indication for ICD implant	(60)	(85.7)
SCA first sign of cardiac disease	(18)	(25.7)
ICD		
Reported > 5 shocks	(18)	(25.7)
Shock worse than symptoms before or after	(21)	(30.0)
Frequent palpitations	(13)	(18.6)
Preoccupied with cardiac disease	(11)	(15.7)
Always aware of possible shock	(41)	(58.6)
Nothing prepares them for a shock	(20)	(28.6)
Fear that ICD might fail	(7)	(10.0)

The age of patients in this study ranged from 23 to 87. The mean age was 57 and the standard deviation was 13.162. The sample was predominantly male 46(65%). Ethnicity mostly comprised of Coloured 39(55%) and White 20(28%) participants. Language was predominantly Afrikaans 35(50%) and English 31(44%) (see Table 5.1).

Most patients lived with their spouse or partner 38(54%) and 21(30%) with family. 49(70%) of the patients completed high school education. 35(50%) were unemployed, 14(20%) were employed, 1(1.4%) was a student and 20(28.6%) were retired. 30(42%) fell into low-income category (one to four thousand Rand p.m) and 20(28.6%) had no income. Only 11 out of 70 patients had an income above four thousand rand p.m. 38(54%) owned their own property. 46(65%) of patients reported that they found transport easy to GSH but 31(44.3%) take more than one hour to travel to GSH. Most patients 48(68%) reported having an Emergency Unit close to home and 47(67%) had a phone number to dial in an emergency (see Table 5.1).

In this cohort, 30(42.9%) had ischemic heart disease, whereas dilated cardiomyopathy (DCM) of unknown aetiology was found in 13(18.6%) of the patients. Arrhythmic Right Ventricular Cardiomyopathy (ARVC) affected of 11(15.7%) patients (see Table 5.1).

30(42.9%) had their ICD for 1-5 years, whereas 28(40.0%) had their ICD for more than 5 years. The indication for ICD implantation was secondary in 60(85.7%) of the patients. These patients are survivors of a life-threatening event such as ventricular tachycardia or ventricular fibrillation. 55(78.6%) of the patients in this study had a previously documented event of ventricular tachycardia (VT). In 18(25.7%), sudden cardiac arrest was the first sign of their cardiac disease, whereas in 35(50%) of the patients, their SCA occurred after they were diagnosed with a cardiac condition (see Table 5.1). 28(40%) of the ICD patients reported no shocks but 18(25.7%) had more than 5 shocks since implantation. Although most patients 26(37.1%) cannot decide what is worst about a shock, 21(30%) said that the actual shock was worse than the prodrome prior to the shock. Although 25(35.7%) reported no palpitations, 30(42.9%) reported a few palpitations and 13(18.6%) reported frequent palpitations.

36(51.4%) were pre-occupied with their cardiac disease. 41(58.6%) were always aware of a possible shock. Knowledge prepares most patients 27(38.6%) for a shock but 20(28.6%) said nothing prepares them. 7(10%) reported that they fear ICD failure (see Table 5.1).

Patient Support Characteristics are presented in frequencies and percentages (%) (Table 5.2).

Table 5.2 Patient Support Characteristics for the total sample, n-70(100%)

Patient Support	***Number***	***(%)***
Accept ICD	(63)	(90.0)
Faith as support	(60)	(85.7)
Prayer as coping	(47)	(67.1)
Counselling always important	(22)	(31.4)
Family affected by members condition	(20)	(28.6)
Protective family	(28)	(40.0)
Lifestyle influence positive	(30)	(42.9)
Less independent	(27)	(38.6)
Family understand ICD	(40)	(57.1)
Community don't understand ICD	(31)	(44.3)
Specialist easily contactable	(35)	(50.0)
GSH Nurse supports enough	(44)	(62.9)
GSH service excellent	(47)	(67.1)
GP are updated	(38)	(54.3)

Patient Support characteristicts show that most patients accepted their ICD implant 63(90%). 60(85.7%) valued their faith and 47(67.1%) use prayer as a means of support. Most patients were supported by their spouse or partner 39(55.7%), or family 14(20%). 49(70%) reported that their support base was sufficient but that support groups were important 45(64.3%). 56(80%) had no councelling and 22(31.4%) felt counselling was always important.

20(28.6%) of the patients felt that their families were also affected by their cardiac condition. 28(40%) felt that their families were over-protective. 30(42.9%) reported that their lifestyles were influenced positively by the ICD however, 41(58.6%) felt less independent. In this cohort, 40(57.2%) reported that their family and friends knew what an ICD was and 31(44.3%) felt that the community was sufficiently knowledgeable.

The specialist was easily contactable for 35(50%) of the patients and 48(68.6%) reported sufficient consultation time. 37(52.9%) felt that nurses and doctors should provide equal support. 44(62.9%) felt that nurses provide enough support. GSH service was rated excellent by 47(67.1%) and 54(77.1%) thought the staff was knowledgeable. 38(54.3%) of the patients felt that General Practicioners (GPs) have adequate knowledgable about ICDs.

5.2 Descriptive analysis of the Hospital Anxiety and Depression Scale (HADS).

The HADS survey assesses anxiety and depression in a non-psychiatric population (Noonan, Zhu & Mak 2016). It has 2 subscales namely anxiety and depression, both with 7 items. The scale are in a self-report format, are based on relative frequency of symptoms and use a four point Likert scale ranging from 0 (not at all) to 3 (very often indeed). Responses are summed to provide separate scores, each of anxiety and depression scales have a score range of 0-21 (Snaith 2003; Noonan, Zhu & Mak 2016).

A higher score indicates a greater probability of depression or anxiety. A cut-off point of 8/21 for the Anxiety subscale gives a specificity of 0.78 and a sensitivity of 0.90. A cut-off point of 8/21 for the Depression subscale gives a specificity of 0.79 and a sensitivity of 0.83 (Zigmond & Snaith 1983).

Anxiety and Depression of the ICD study sample are presented in numbers and percentages (%), and means and standard deviations (SD) using summary statistics (Table 5.3) (Appendix IX).

Table 5.3 HADS Anxiety and Depression Scores n=70(100%)

HADS A score (Anxiety)	**Mean**	6.50	**SD**	4.52
Anxiety score>8	**Number**	20	**(%)**	(28.6)
HADS D score (Depression)	**Mean**	4.96	**SD**	3.36
Depression>8	**Number**	15	**(%)**	(21.4)

The mean score for anxiety in the HADS survey was 6.5, with a standard deviation of 4.52. 20 patients (28.6%) in this study fulfilled criteria for anxiety according to the HADS survey, i.e. had a score score of more than 8.

The mean score for depression in the HADS survey was 4.96, with a standard deviation of 3.37. The HADS survey revealed that 15 (21%) of the patients had depressive symptoms, i.e. they had a score of 8 or more in the survey.

5.3 Analyses of the SF36v2 Health Survey/QOL using summary statistics (Appendix X).

Results provide the following:

a) SF-36v2 Data Quality Evaluation Report
b) Scores for total sample
c) Percentage sample whose scores were above, at or below the norm
d) First Stage Positive Depression Screening: % at Risk

a) SF-36v2 Data Quality Evaluation Report: The SF36v2 ICD Patient QOL project analyses were done by the QualityMetric program. There were a total number of 70 records in the project and it included the Health Transition (HT) item. Data Quality Indicators appear to be satisfactory. Indicators that included failed items or scales were Consistent Responses (91.4%), Internal Consistency (94.3%) and Discriminant Validity (95.5%) (see Table 5.4). Details are in Appendix X.

Table 5.4 SF-36v2 Data Quality Evaluation Report

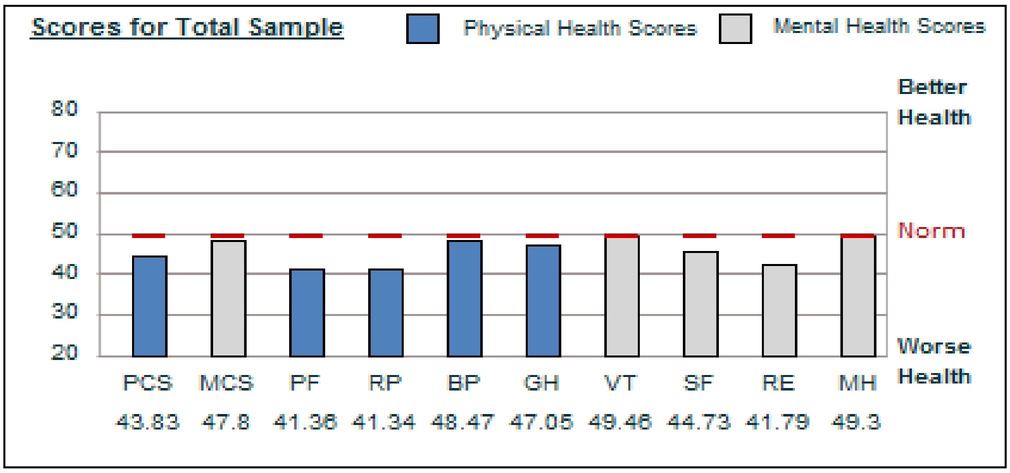
Data Quality Indicators:		*Satisfactory*	*Norms*
1. Completeness of Data...................... Items with 5% or more missing values: NONE	100.0%	YES	90
2. Responses within Range.................... Items with 5% or more out-of-range values: NONE	100.0%	YES	100
3. Consistent Responses......................	91.4%	YES	90
4. Estimable Scale Scores.......................			
Estimable without Missing Data Estimation (MDE)	100.0%	YES	90
Estimable with Half-Scale MDE	100.0%		
Estimable with Full MDE	100.0%		
5. Item Internal Consistency Items that failed internal consistency test: GH02 GH04	94.3%	YES	90
6. Discriminant Validity Items that failed discriminant validity test: GH02 VT03 VT04 SF02	95.5%	YES	80
7. Reliable Scales Scales that failed reliability criteria: NONE	100.0%	YES	100

NOTES: Definition of Data Quality Indicators: 1. Percentage of completed responses (within range) divided by the total possible number of responses (items*N). This calculation includes the Health Transition (HT) item. 2. Percentage of item responses within the range of response codes printed on the questionnaire. This calculation includes the Health Transition (HT) item. 3. Percentage of subjects with no inconsistent responses on the Response Consistency Index (score= 0). 4. Percentage of subjects for whom all scales are computable with and without application of SF-MDE. 5. Percentage of items that correlated (corrected for overlap) 0.40 or higher with their hypothesized scale. 6. Percentage of items that correlated significantly higher with their hypothesized scale than with competing scales. score. 7. Percentage of scales with Cronbach's Alpha coefficients greater than or equal to 0.70.

b) Scores for total sample

Both the physical and mental component summary means for the total sample (n = 70), scored below the norm. The graph displays the average summary measure and scale scores for the sample. Higher scores indicate better functioning and well-being. Norm-based scoring (NBS) was used and each scale is scored to have the same mean (50) and standard deviation (10). Each point is one-tenth of a Standard Deviation. Scores range from 20-70 (Graph 5.1).

Graph 5.1 Scores for Total Sample



The Mental Component Summary (MCS) had a mean of 47.81 (39% below the norm). The Physical Component Summary (PCS) had a mean of 43.83 (51% below the norm). Role Physical was the lowest with a mean of 41.34 (64% below the norm). Vitality was the highest with a mean of 49.46 (31% below the norm) (see Table 5.5).

Table 5.5 Scores for total sample: mean, SD and % below the norm

	MEAN	**(SD)**	**(%) below Norm**
Physical Component Summary (PCS)	43.83	9.43	(51)
Mental Component Summary (MCS)	47.81	10.71	(39)
Physical Functioning (PF)	41.36	9.89	(60)
Role Physical (RP)	41.34	10.73	(64)
Body Pain (BP)	48.47	11.95	(43)
General Health (GH)	47.05	10.43	(41)
Vitality (VT)	49.46	9.92	(31)
Social Functioning (SF)	44.73	10.69	(47)
Role Emotional (RE)	41.79	12.09	(56)
Mental Health (MH)	49.30	10.66	(29)

ABBREVIATIONS: PF = Physical functioning , RP = Role physical, BP = Body pain , GH = General Health, VT = Vitality, SF = Social functioning , RE = Role emotional, ME = Mental health.

c) % Sample whose Scores are Above, At or Below the Norm.

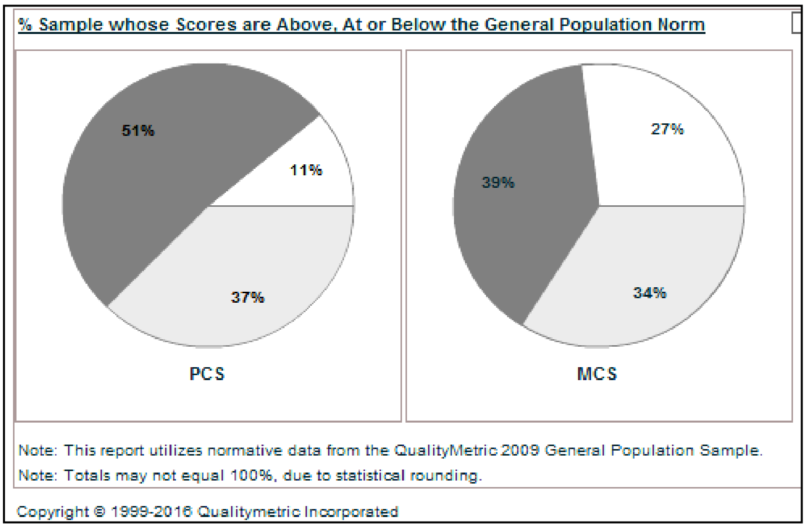
Pie charts display the percentage of respondents that are Above, At or Below the norm. Above, At or Below analyses are done by comparing each respondent's score to the norm.

Categories are defined by computing confidence intervals which reside above and below the average summary measure score. Confidence intervals serve as boundaries to indicate the amount of distance a score can vary from the norm before it is considered significantly better or worse with a certain degree of confidence and are derived from each measure's reliability and average dispersion.

Each measure has its own set of confidence intervals and a 95% confidence interval was used for category definition. When a score is greater than the upper measure confidence interval, he is considered to have an above average score compared to the general population norm. A lower score is considered below average. A score within both upper and lower confidence intervals is considered average compared to the norm (QualityMetric 2000).

The first set of pie charts display the percentage Physical Component Summary and the Mental Component Summary Above, At or Below the norm. 51% of the sample was below the PCS norm and 39% was below the MCS norm (Table 5.6).

Table 5.6 % Scores Above, At or Below the norm


% Sample whose Scores are Above, At or Below the General Population Norm

Note: This report utilizes normative data from the QualityMetric 2009 General Population Sample.
Note: Totals may not equal 100%, due to statistical rounding.

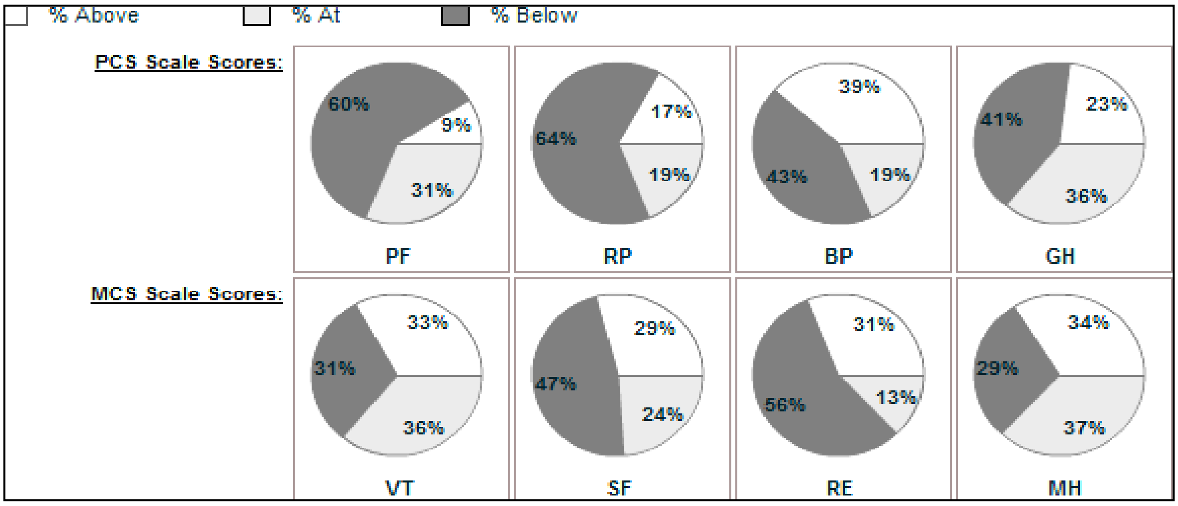
Scores

above ☐
at ▨
below ■

the general population norm

The next set of pie charts display the percentage of the PCS and MCS Scale Scores Above, At or Below the norm (Table 5.7).

Table 5.7 PCS and MCS Scale Scores: % Above, At and Below the Norm



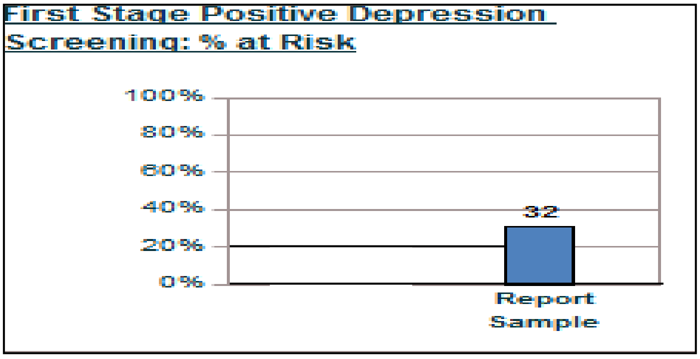
PCS Scale Scores show that in Role Physical (RP), 64% of patients were below the norm. In Physical Functioning (PF) 60% scored were below the norm. Bodily Pain (BP) was 43% below the norm and General Health (GH) was 41% below the norm. MCS Scale Scores show that in Role Emotional (RE) 56% scored below the norm. In Social Functioning (SF), 47% was below the norm, in Vitality 31% was below the norm and in Mental Health, 29% was below the norm.

d) First Stage Positive Depression Screening: % at Risk

A positive first stage depression screening score is defined as a mental component summary (MCS) score less than or equal to 42.

The results also showed that 32% of the ICD patients are at risk of First Stage Positive Depression (Bar Graph 5.2).

Bar Graph 5.2 % at Risk for Depression



5.4 Regression analyses that determined factors that influenced depression, anxiety and Quality of Life.

Table 5.8 Univariate and multivariate analysis for factors associated with depression.

Variable	**Univariate analysis**			**Multivariate analysis**	
	OR (95% CI)	p-value	LR test p-value	OR (95% CI)	p-value
Number of ICD shocks					
< 5 shocks	0.86 (0.17 – 4.28)	0.851	0.031	0.54 (0.07 – 3.98)	0.542
> 5 shocks	4.80 (1.17 – 19.64)	0.029		4.29 (0.64 – 28.80)	0.133
Inappropriate shocks	6.96 (1.49 – 32.53)	0.014	0.037		
Reported palpitations					
Often	6.13 (1.33 – 28.21)	0.020	0.001	1.71 (0.21 – 14.09)	0.616
Seldom	0.81 (0.18 – 3.62)	0.780		0.85 (0.12 – 6.02)	0.874
Preoccupied with cardiac condition	6.13 (1.42 – 26.33)	0.015	<0.001	4.29 (0.65 – 28.22)	0.130
Constant fear that ICD may fail	4.13 (1.16 – 14.62)	0.028	0.020	1.05 (0.19 – 5.76)	0.956

Level of significance p-value = 0.05

Patients in whom the ICD had delivered more than five shocks since implantation were 4.80 times more likely to be depressed than patients who had no shocks (*P* = 0.029). Those who experienced inappropriate shocks were 6.96 times more likely to be depressed (*P* = 0.014). Patients who reported frequent palpitations were 6.13 times more likely depressed than those who were asymptomatic (*P* = 0.020). Patients who reported that they were preoccupied with their cardiac condition were 6.13 times more likely depressed than those who accepted their cardiac condition. (*P* = 0.015). Patients who constantly feared that their ICD could fail were 4.13 times more likely depressed than patients who had confidence in their ICD (*P* = 0.028) (Table 5.8).

Table 5.9 Univariate and multivariate analysis for factors associated with anxiety.

Variable	**Univariate analysis**			**Multivariate analysis**	
	OR (95% CI)	p-value	LR test p-value	OR (95% CI)	p-value
Female gender	4.75 (1.57 – 14.34)	0.006	0.005	20.51 (1.62 – 259.11)	0.020
Number of ICD shocks					
< 5 shocks	2.47 (0.62 – 9.79)	0.198	0.032	0.25 (0.01 – 4.32)	0.338
> 5 shocks	6.00 (1.47 – 24.45)	0.012		2.89 (0.11 – 78.60)	0.529
Inappropriate shocks	9.50 (1.95 – 46.20)	0.005	0.005	0.76 (0.05 – 12.15)	0.848
Reported palpitations					
often	18.40 (2.96 – 114.31)	0.002	0.001	1.61 (0.09 – 27.65)	0.741
seldom	5.75 (1.12 – 29.41)	0.036		46.68 (1.29 – 1690.03)	0.036
Preoccupied with heart					0.016
most of the time	18.38 (2.75 – 122.94)	0.003	0.003	449.93 (3.05 – 66301.31)	0.133
sometimes	4.62 (0.92 – 23.22)	0.063		10.78 (0.48 – 239.59)	
Constant fear that ICD may fail	3.81 (1.25 – 11.60)	0.019	0.015	13.82 (0.96 -198.94)	0.054
Cardiac arrest first sign of disease	3.20 (0.92 – 11.11)	0.067	0.056	7.53 (0.73 – 78.14)	0.091

Level of significance p-value = 0.05

In this study, females with ICDs were 4.75 times more likely have anxiety than males (*P* = 0.006). Patients who reported more than 5 shocks since ICD implantation were 6 times more likely to have anxiety (*P* = 0.012) whereas patients in which the ICD delivered less than 5 shocks were 2.47 more likely to be anxious (*P* = 0.198). Patients who reported inappropriate shocks were 9.50 times more likely to have anxiety (*P* = 0.005). Patients who complained of frequent palpitations were 18.40 times more likely to have anxiety than asymptomatic patients (*P* = 0.002). Similarly, patients who reported to be preoccupied with their cardiac diagnosis were 18.38 times more likely to have anxiety (*P* = 0.003). Patients who feared that their ICD might fail were 3.18 times more likely to have anxiety (*P* = 0.019). Patients who have a Sudden Cardiac Arrest (SCA) as the first sign of cardiac disease were 3.20 times more likely to have anxiety even though it was not statistically significant because *P* = 0.067 (Table 5.9).

Table 5.10 Univariate and multivariate analysis for factors associated with physical well-being.

Variable	**Univariate analysis**			**Multivariate analysis**	
	OR (95% CI)	p-value	LRtest p-value	OR (95% CI)	p-value
Employment					
unemployed	0.07 (0.01 – 0.34)	0.001	<0.001	0.10 (0.01 – 0.81)	0.031
retired	0.40 (0.10 – 1.64)	0.205		0.45 (0.07 – 2.96)	0.404
Frequent palpitations	0.64 (0.21 – 1.97)	0.439	<0.001	0.38 (0.09 – 1.59)	0.185

Level of significance p-value = 0.05

Patients who were unemployed were less likely to have physical well-being as measured by the SF-36 test (OR 0.07 (*P*= 0.001).

Patients who had frequent palpitation were less likely to have physical well-being however, it is not significant because the *P* = 0.439.

Table 5.11 Univariate and multivariate analysis for factors associated with mental well-being

Variable	Univariate analysis			Multivariate analysis	
	OR (95% CI)	p-value	LR test p-value	OR (95% CI)	p-value
Less independent					
Yes	0.30 (0.10 – 0.90)	0.032	0.048		
Somewhat	0.28 (0.07 – 1.12)	0.071			
Lifestyle influence					
Positively	10.46 (1.16 – 94.48)	0.037	0.049	7.72 (0.66 – 90.31)	0.104
Don't know	2.67 (0.19 – 36.76)	0.464		2.83 (0.15 – 53.44)	0.487
Equally	5.14 (0.55 – 48.37)	0.152		7.67 (0.55 – 106.75)	0.130
Patients who were not sure if they had inappropriate shocks	0.21 (0.05 – 0.85)	0.029	<0.001	0.19 (0.03 – 1.20)	0.077
Experience palpitations					
Often	0.17 (0.03 – 0.92)	0.039	0.021	0.48 (0.05 – 4.87)	0.534
Seldom	0.81 (0.28 – 2.34)	0.694		0.63 (0.15 – 2.61)	0.521
Preoccupation with cardiac condition					
Most of the time	0.14 (0.02 – 0.82)	0.029	0.036	0.41 (0.05 – 3.63)	0.420
Sometimes	0.36 (0.12 – 1.07)	0.066		0.46 (0.10 – 2.15)	0.326
Fear of ICD failure	0.32 (0.12 – 0.87)	0.025	0.022	1.0 (0.21 – 4.41)	0.965

Level of significance p-value = 0.05

Patients who feel less independent are less likely to have mental well-being as measured by the SF-36 score. On the contrary, patients who felt that the ICD has influenced their lifestyle positively, was 10.46 times more likely to have mental well-being according to the SF 36. Patients who were not sure if they had inappropriate shocks were less likely to have mental well-being (OR 0.21, *P* = 0.029). Patients who frequently experienced palpitations were less likely to have mental well-being (OR 0.17, *P* = 0.039). Those who were reported to be preoccupied with their cardiac condition most of the time were unlikely to have mental well-being (OR 0.14, *P* = 0.029). Patients who fear that their ICD will fail were less likely to have mental well-being, as determined by the SF-36 score (OR 0.32, *P* = 0.025).

CHAPTER 6

DISCUSSION

ICD patients in the cardiac clinic at Groote Schuur Hospital appear to be a very vulnerable population. This was evident from the results which showed demographic, clinical, ICD and patient support concerns; high levels of anxiety and depression, and low levels of physical and mental well-being.

It was interesting, but not surprising, that factors associated with depression, anxiety and low mental-being, were mainly ICD related. Other factors involved being female, frequent palpitations, heart pre-occupation, unemployment and loss of independence. Also interesting was that patients who experienced their ICD as a positive influence were much more likely to have mental well-being.

6.1 Results in perspective

Putting the results in perspective is interesting as this is the first ICD study in SA and there is no South African general population norm for the HADS or SF-36 QOL measures. A comparison with related studies in other developing countries is thus insightful.

In Colombia, a developing country, HADS normative values for the general population were found to be similar to the general population values in Europe (Hinz, Finck, Gomez, Daig & Glaesner, 2013). When comparing Colombia's population means and South Africa's ICD sample means, SA showed higher anxiety and depression values. As this is expected in ICD patients, the reliability and generalisability of the HADS is promising (See Table 6.1)

Table 6.1 HADS Means: Colombia general population and SA ICD sample

	HADS A score (Anxiety)		HADS D score (Depression)	
	Mean	SD	Mean	SD
South Africa	6.5	4.52	4.96	3.36
Colombia	4.61	3.64	4.3	3.91

In Brazil, another developing country, SF-36 normative values were established for the general population and an ICD population sample.

In the general population of Brazil, Cruz, Fleck, Oliveira, Camey, & Polanczyk, (2013) found that in comparison to Turkey and other developed countries, Brazil scored lower means but slightly higher means than Croatia, also a developing country, (Sersic & Vuletic, 2006).

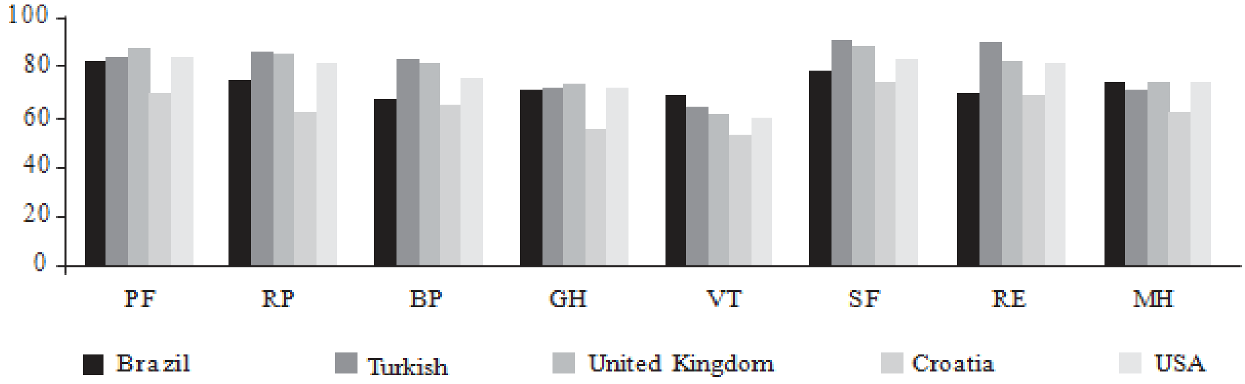
In Sao Paulo, Cesarino et al., (2011) investigated QOL in ICD patients from the Outpatient Cardiology Clinic of a teaching hospital using the SF-36. The results showed that according to the SF-36 norms, their study presented lower scores for physical and emotional profiles.

A comparison between the SF-36 scores of ICD patients in South Africa and Brazil; and the normative data for the general population of Brazil, show that both ICD populations are below the norm of the general population of Brazil.

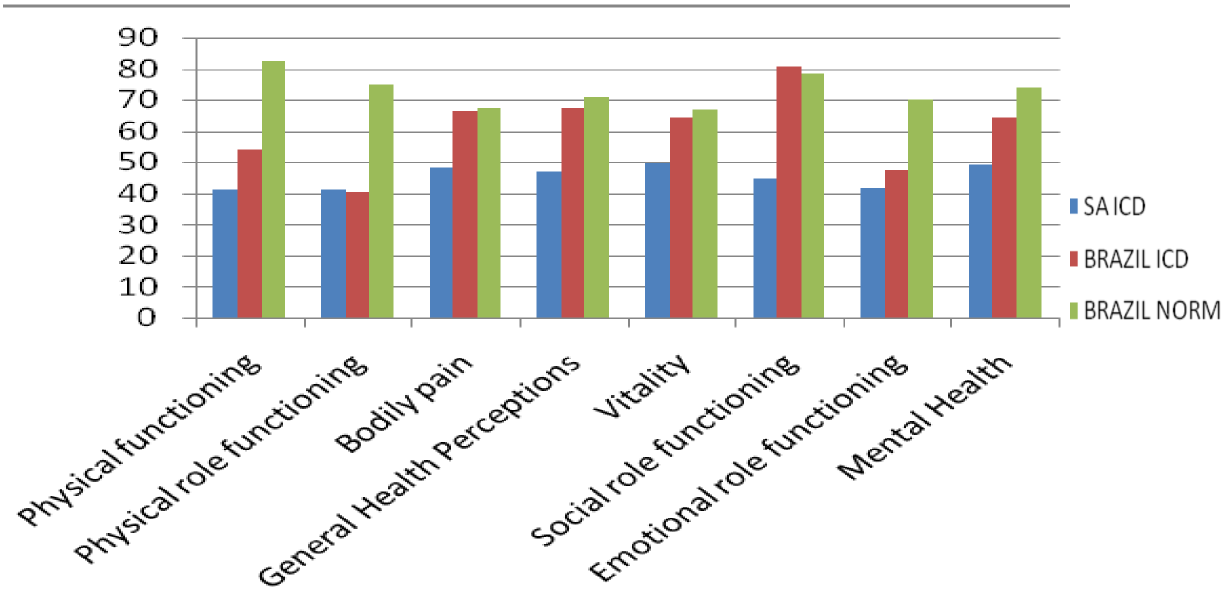
This may suggests that ICD patients in SA and Brazil, as in the rest of the world, have sub-optimal QOL and that the HADS and SF-36 Health survey is a useful tool all over the world to assess and compare QOL in ICD patients.

Bar Graph 6.1 show means scores of SF-36 domains in the general population of Brazil and other countries (Cruz et al., 2013) and Bar Graph 6.2 compare mean scores of SF-36 domains in ICD patient samples in SA and Brazil with the SF-36 general population norm of Brazil.

Graph 6.1 Means scores of SF-36 domains in the general population of Brazil and other countries.



Graph 6.2 Comparison of mean scores of SF-36 domains in the general population of Brazil and ICD patient samples of SA and Brazil.



6.2 Demographic, Clinical, ICD and Patient Support Characteristics

Demographic characteristics showed that the ICD patient population sample in SA had an average age of 57 and that 65.7% were men. The population was thus younger and enrolled more women compared to other studies such as Thylén et al., (2014) with an average age of 66 (80% male) and Godemann et al., (2004b) with an average age of 60 (86% male).

With regard to patient support structures, 16% of the patients had no spouse, partner or family which may have been detrimental to their QOL (Thylén et al., 2014). Although 70% of the sample had high school education, 23% had primary education or below. Although no significant education associations with QOL were found in this study but it is important to be aware that the lack of education can have dire consequences on QOL (CSDH, 2008). According to Schlemmer & Mash, (2006), language and communication proficiency directly influences effective diagnosis, treatment, education and trust in health delivery.

Unemployment can also directly influence QOL (Mayosi & Benatar, 2014). This was underscored in this study as the high level of unemployment (50%) was found to be associated with lower physical well-being. The percentage of the low income status in this study (42.9% earn less than four thousand rand per month) is also a concern as it may also have contributed to the low QOL scores. Concerns such as long term financial security, high ICD replacement and care costs, and possible job losses are particularly stressful (Humphrey et al., 2016; Tagney et al., 2003; Mayosi & Benatar, 2014).

Another factor that may impact QOL is health care access (Humphrey et al., 2016). Although 65.7% of the patients said transport to GSH was easy, it took 44.3% of the patients over one hour to travel to GSH. This could create great anxiety as ICD shocks are frightening, unpredictable and could demand quick medical attention. This anxiety could be aggravated by the fact that 31.5% of the patients don't have an emergency unit close to home nor an emergency number (32.9%) saved. Access is especially vital due to GSH being the only South African public hospital that offers a full-time electrophysiology service. This in total exacerbated a very vulnerable population group, a situation which SA has been trying to address (Mayosi & Benatar, 2014).

Clinical characteristics show that Ischemic Heart Disease (42.9%), Dilated Cardiomyopathy (18.6%) and ARVC (15.7%) are most prevalent cardiac conditions in the study population and that 78.6% presented with Ventricular Tachycardia (VT). It is important to be aware that these diseases, especially chronic diseases, affect QOL in their own right and may contribute to impaired well-being. This highlights the importance of a holistic approach to improving QOL.

42.9% of the patients had their ICD implants for 1-5 years and 40.0% had it for more than 5 years. Longer duration can impact QOL and increase PTSD (Von Kanel et al., 2011) thus being aware of psychological symptoms is vital. In this study, 25.7% of the patients experienced sudden cardiac arrest as the first sign of their cardiac condition. This can be particularly devastating in apparently healthy individuals and is thus a predictor of anxiety. Such patients demand accurate monitoring of physiological distress symptoms (Corrado, Bassa & Thiene, 2005). Furthermore, indication for ICD implantation was in most cases secondary (85.7%). That is due to resource constraints in an economically challenged SA (Mayosi & Benatar, 2004). This could also explain the high incidence of depression and anxiety as many patients would have experienced a SCA or a lethal arrhythmia before they received their ICD.

ICD related characteristics of the study population show that 60% of the patients had shocks; 34.3% had between one and five shocks and 25.7% had more than five shocks. This study supports the findings of Thylén et al. (2014) and Sears & Conti (2003) in that patients who experienced more than 5 shocks had impaired quality of life. Similar to the study by Sears & Conti (2003) this study showed that inappropriate shocks had a significant impact on quality of life. Intervention to decrease recurrent VT and ICD shocks is thus crucial. This may involve medication, VT ablation and/or ICD reprogramming and may significantly improve overall QOL (Dunbar et al., 2012).

The shock delivered by the ICD can be so traumatic that it is not surprising that 82.9% of the population, albeit 58.6% are always and 24.3% are sometimes aware of getting a possible shock. Dunbar et al. (2012) explains that most patients seem to fear the anticipated pain of the shock rather than the shock itself. In this study population only 10% feared the time before the shock, 30% feared the actual shock and 52% feared everything equally. In this

study 18.6% of the patients often experienced palpitations. Flemme et al., (2011) pointed out that a life-threatening arrhythmia could have a greater impact than the shock itself.
Pre-occupation with their cardiac condition by 67.1% of the study population is thus also not surprising. In this study, 52.9% of patients had confidence in the device and did not fear failure of the ICD.

Patient support characteristics showed that faith and prayers helped patients cope (85.7%). Prayer (20.0%) and knowledge (38.6%) prepared patients for a shock which underscores the importance of adequate information for the patient. This highlights faith's role in health outcomes (Coruh, Ayele, Pugh & Mulligan, 2005). Patients also felt that their spouse or partner (55.7%) and family (20%) provided the best emotional support, which underscores the valuable role of family support (Shea, 2004). This may have contributed to the fact that 70% felt their support network was big enough.

Previous studies have shown the benefit of counselling on the quality of life of patients with ICDs. (Sears & Conti, 2002) Although 94.3% and 64.3% of patients in this study considered counselling and support groups important, 80% of patients with ICDs reported not have had any counselling. This highlights the need for counselling and support groups. Furthermore, 64.3% of the patients felt that their families were greatly affected by their cardiac condition. 70% felt that their families were over-protective, which has previously been shown to be detrimental to QOL (Sears et al., 1999; Tagney et al., 2003). 58.6% also felt less independent which men particularly struggle with (Bostwick & Sola 2007; Humphrey et al., 2016).

Knowledge and information is vital in managing a cardiac condition. In this population, only 57.1% felt that their families and friends understood what an ICD does, and that they felt that only 25.7% of the community understood what an ICD does. Not feeling understood with regard to your condition could also significantly undermine QOL (Dunbar et al., 2012).

Regarding health care services, 50% of the population felt that their specialist was easily contactable and 68.6% experienced enough consultation time and that GSH had excellent service (67.1%). Patients also felt that GSH hospital staff was knowledgeable about ICD's (77.1%) but only 54.3% felt their family doctor was up to date with ICD's. This may reflect on the healthcare system in SA that needs urgent attention (Mayosi & Benatar, 2004).

6.3 Anxiety and Depression Characteristics

The Hospital and Anxiety Depression Scale (HADS) showed that 28.6% of the population had anxiety and 21.4% of the population had depression. This indicates that nearly a third of the study population suffer from moderate to severe anxiety and depression. This is similar to many other studies that found elevated scores of anxiety and depression in patients with ICD's. Pedersen et al., (2007) showed anxiety in 30.0% in 182 ICD patients, Crossmann et al., (2010) showed 24.0% in 119 patients while Pedersen et al., (2004), showed 42.0% in 221 ICD patients. With regard to depression, Pedersen et al., (2004), showed 29.0% depression in 221 patients, Tzeis et al., (2011) showed 21.0% in 236 patients and Mastenbroek et al., (2014), showed 25.1% in 430 ICD patients. This underscores the great need for psychological and psychiatric support in these patients.

6.4 Physical and Psychological Well-being Characteristics

The SFv2 Health Survey showed that patients with ICDs managed at GSH scored below the norm. The physical component summary (PCS) scored a mean of 43.83 with a standard deviation of 9.43 and was 51% below the norm. The mental component summary (MCS) scored a mean of 47.81 with a standard deviation of 10.71 and was 39% below the norm.

Role physical (41.34) and physical functioning (41.36) was the lowest in the PCS. Role emotional (41.79) and social functioning (44.73) was the lowest scores in the MCS. It was also found that 32% of the patients were at risk of first stage positive depression. In Brazil (Cesarino et al., 2011), a developing country like SA, QOL was scored in an ICD study of 50 patients. The score means were: role physical 40.5, physical functioning 54.1, role emotional was 47.3 and social functioning was 80.5. This was thus similarly low (except for social functioning) which underscores the need to improve QOL in ICD patients.

Role physical refers to the degree that physical problems interfere with a task such as a job and physical functioning refers to activities like exercise. The low scores (mean of 43.83) may be associated with physical problems that interfere with lifestyle, driving, employment and more (Shea, 2004; Kamphuis 2003).

Role emotional refers to the degree that emotional problems interfere with a job and social functioning refers the degree of socialization. These low scores (mean of 47.81) may be associated with anxiety and depression related mostly to ICD concerns as have been found in multiple studies (Lampert, 2013; Godemann, 2004b; Kajanová et al., 2014).

6.5 Factors that significantly influenced depression, anxiety, physical and mental QOL.

A univariate and multivariate analysis for factors associated with depression, anxiety, physical QOL and mental QOL highlighted the major impact of the ICD.

Depression and anxiety was mostly significantly associated with ICD related factors (*P* value of 0.05 and less). Interesting was that the values were slightly more significance for anxiety. This may underscore the anxious provoking nature of living with an ICD especially regarding shocks.

Table 6.2 P-value comparison of variables associated with depression and anxiety

Variable	P-Value	
	Depression	Anxiety
Number of ICD shocks > 5	0.029	0.012
Inappropriate shocks	0.014	0.005
Often reported palpitations	0.02	0.002
Preoccupied with cardiac condition	0.015	0.003
Constant fear that ICD may fail	0.028	0.019
Level of significance p-value = 0.05		

Depression in patients were associate with receiving more than five shocks, (*P* = 0.029), having inappropriate shocks (*P* = 0.014), often reporting palpitations (*P* = 0.02), being pre-occupied with their cardiac condition (*P* = 0.015) and constant fearing that the ICD may fail (*P* = 0.028). Many studies have identified similar ICD factors related to depression (i.e. Thylén et al., 2014; Tomzik, Koltermann, Zabel, Willich & Reinhold., 2015, & Thomas et al., 2006).

Anxiety in patients was associated with similar ICD factors as in depression but one exception was a significant association (P=0.006) between anxiety and being female. Females were 4.75 times more likely to have anxiety than males. This is similar to other ICD studies (Thylén et al., 2014; Dunbar et al., 2012) and underscores the support females need. Many females are caretakers and caregivers and their identity can be threatened by actual and perceived activity limitations due to the ICD implant. This is beside the anxiety due to their underlying heart condition (Walker, Campbell, Sears, Glenn & Conti, 2004).

ICD concerns significantly associated with anxiety were: experiencing more than 5 shocks ($P = 0.012$); inappropriate shocks ($P = 0.005$); frequent palpitations ($P = 0.002$); a pre-occupation with the cardiac condition ($P = 0.003$) and a constant fear that their ICD might fail ($P = 0.019$). Sudden cardiac arrest as the first sign of their cardiac condition is very likely to cause anxiety ($P = 0.067$) but is not significant in this study. SCA is however a great concern. SCA can be devastating (Corrado et al., 2005) and many patients fear dying suddenly after a SCA. It is thus understandable that panic disorders and agoraphobia are frequent side effects of ICD treatment (Godemann et al., (2004a).

Low physical well-being was found to be more likely in patients that were unemployed ($P = 0.001$) and experienced frequent palpitations ($P = 0.001$). This is not surprising as a study by Mastenbroek et al., (2015) found that being unemployed was one of seven stable trajectories that influence ICD patient physical health status. Many studies (i.e. Flemme et al., 2011; Humphrey et al., 2016) also found that patients post-implantation are often physically challenged with issues such as health care, returning to work or driving. In this study, 50% of the ICD patient sample is unemployed which underscores the importance of addressing related issues. This is complicated as unemployment in SA is high in the general population and challenges to address it numerous (Mayosi & Benatar, 2014).

Palpitations, also associated with low physical well-being, are rapid strong or irregular heartbeats. It can have a major influence on physical well-being and some patients even modify behaviours to avoid palpitations (Lampert, 2016). Stress, palpitations, unemployment and physical well-being could thus impact each other greatly and in multiple ways.

Mental well-being was influenced negatively by feeling less independent (*P* = 0.032), having inappropriate shocks, experiencing palpitations frequently, pre-occupation with their cardiac condition and the fear that the ICD might fail during an arrhythmia. These factors echoed the major impact of ICD's on QOL in study and as described by Kamphuis et al., (2003). On the contrary, patients who felt that the ICD influenced their lives positively were 10.46 times more likely to have improved mental well-being. Literature often highlight that a positive attitude can improve QOL (Bostwick & Sola, 2011; Godemann et al., 2004a; Sears et al., 2002) and this may be applicable to some patients in this study.

An evaluation of the measuring instruments in this study showed that a few questions in the Demographic and Clinical Questionnaire were a bit challenging. There may have been too many questions, some questions were unclear and some answering options were not available. Sometimes patients could also not decide on one answer because they felt all answers were relevant. This required the assistant to clarify the question or suggest to the participant to take more time to make a decision. It is also clear that in developing a questionnaire that a level of researcher imposition exists. As principle researcher I was ultimately responsible for making decisions and assumptions of what is important. In the process I may have missed some important information.

The HADS was well received and enthusiastically completed as it was clear, concise and short. The SF-36v2 questions were sometimes confusing and needed clarification. Assistance was sometimes required when there were too many questions or options in one section.

In general, the questionnaires were well received by most patients. It provoked much thought for them and they were eager to engage in further discussions regarding their health, experiences and lives.

Theoretical Background

The results of this study showed that the population's low scores on anxiety, depression and QOL were mostly associated with ICD related concerns such frequent shocks, inappropriate shocks and possible ICD failure. Being symptomatic, i.e. having frequent palpitations, also impacted on depression and anxiety rates. In improving QOL, Maslow's theory of unmet basic needs and/or elements of Engel's BPS model and Wilson Cleary's HRQOL model may thus be useful.

Maslow's Hierarchy of Needs: physiological, safety, support, esteem and self actualisation may provide a practical approach to improving QOL. Ventegodt et al., (2003), explained that most chronic diseases don't disappear and that the real change for betterment may be personal development. He felt that Maslow's theory may be explained in a simple manner to provide better QOL.

In a hierarchical order, physiological health needs in patients with ICDs depend on cardiac disease management i.e. minimising palpitations; safety needs depend on ICD functioning, appropriate information and access to emergency care; support needs depend on readily available medical, family and community support; esteem needs depend on independence and self-actualisation needs depend on being able to come to terms with a new life.

Elements of Engels Biopsychosocial (BPS) Model are also clear in this study. A cardiac arrest for example causes multiple levels of interactions: from a life threatening event to defibrillation, to the effect on the family and vice versa. Wilson and Cleary's HRQOL Model that stress the link between health and QOL is also evident as this study shows how significantly living with a cardiac disease can impact QOL.

Thus although Engel and Cleary have meaningful elements, Maslow's theory ultimately provides a practical method to improving QOL in a step-wise approach.

CHAPTER 7

CONCLUSION

7.1 LIMITATIONS

As a first study in South Africa, the study had some limitations. Contacting patients were problematic and the sample size may have been compromised. Lengthy time lapses between appointments and patients that sometimes don't turn up proved a challenge. Fortunately, in some cases, patients could complete their questionnaires at home. But in the end, some contact details could not be obtained and finding more than 70 patients became impossible due to time constraints.

The Demographic and Clinical Questionnaire had to be developed. This may need reviewing as some questions were ambiguous or unnecessary. These questions were not considered in the results. Other disadvantages of the questionnaires were that there was no way to tell how truthful a respondent was or if they understood all the questions correctly. Some participants could have tried to please the researcher, lied to make them look better or had mistaken memories. The study outcomes could also have been affected by closed-ended questionnaires which may have hampered the real meaning people attached to their answers.

Any event outside the study which could have influenced the test procedures would have been noted and patients, whose emotions were stirred following questionnaire completion, would have been referred to an appointed counsellor. This never occurred as all participants were enthusiastic to share their thoughts and feelings about living with an ICD.

Although caution should be taken regarding the results of this study and that it may not be generalized to groups of ICD-recipients, the results were similar to what studies internationally commonly found.

7.2 RECOMMENDATIONS

The results showed that although the study population was content with healthcare service at GSH, they still had underlying anxiety, depression and a low QOL. This was mostly associated with ICD related concerns. Addressing ICD related concerns are thus crucial. This should include reducing appropriate and inappropriate shocks; providing adequate and appropriate information; and establishing accessible counselling and support pre and post ICD implantation. Other factors are also vital. This includes careful assessment of the impact of the cardiac event; a sensitive approach to the diagnosis; appropriate and adequate information and education; skilled healthcare services; practical preparation for home care; continuous family/other support; coping strategies and skills and realistic future planning. This will all add to improving QOL.

Further investigations into the QOL of patients with ICDs in South Africa will thus make a significant difference to everyone affected by or involved in ICD and arrhythmia care.

7.3 CONCLUSION

This study has shown that patients with ICDs at the GSH Cardiac Clinic are a very vulnerable population. Their QOL is significantly low and there is a high level of anxiety and depression. The main factors that influenced QOL in this study were ICD related. But many other factors: the cardiac event, the diagnosis, information, treatment, home, family, coping and their future prospects may also have impacted their QOL.

Ultimately, an ICD can save your life but this study underscores the need for increased clinical care, education, counselling and support. Meeting basic physical and psychological needs of patients with ICDs is clearly fundamental in improving QOL. After all there can be “no health without mental health” (Stein, Williams & Kessler, 2009).

Ultimately, a little support allows every individual to
embrace their inner strength, talents and awesomeness
creating a confidence and calm; a knowing,
that will survive any life challenge

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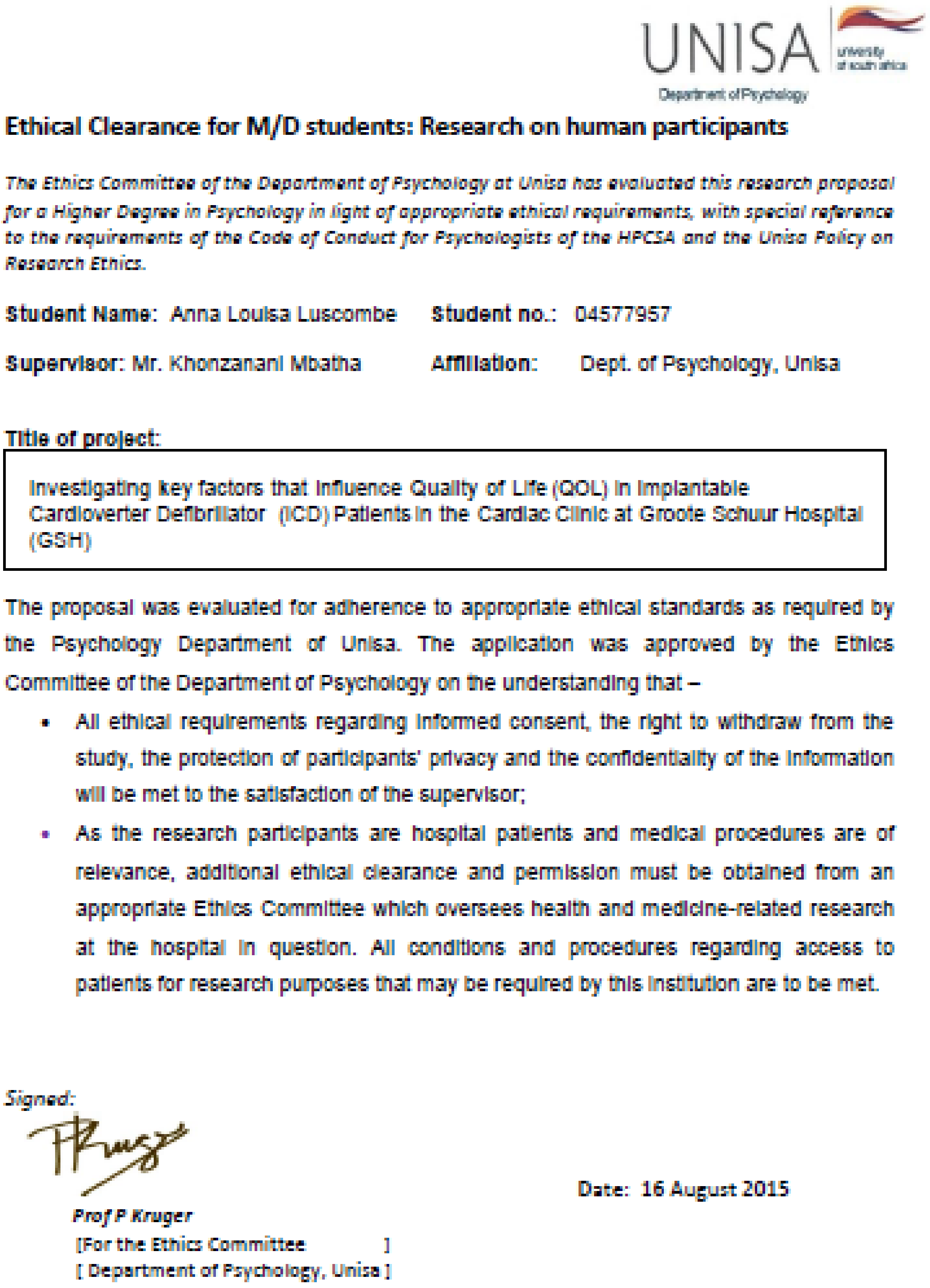
Appendix 1 – Ethical Clearance Letter (UNISA)



UNISA university of south africa
Department of Psychology

Ethical Clearance for M/D students: Research on human participants

The Ethics Committee of the Department of Psychology at Unisa has evaluated this research proposal for a Higher Degree in Psychology in light of appropriate ethical requirements, with special reference to the requirements of the Code of Conduct for Psychologists of the HPCSA and the Unisa Policy on Research Ethics.

Student Name: Anna Louisa Luscombe **Student no.:** 04577957

Supervisor: Mr. Khonzanani Mbatha **Affiliation:** Dept. of Psychology, Unisa

Title of project:

Investigating key factors that influence Quality of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) Patients in the Cardiac Clinic at Groote Schuur Hospital (GSH)

The proposal was evaluated for adherence to appropriate ethical standards as required by the Psychology Department of Unisa. The application was approved by the Ethics Committee of the Department of Psychology on the understanding that –

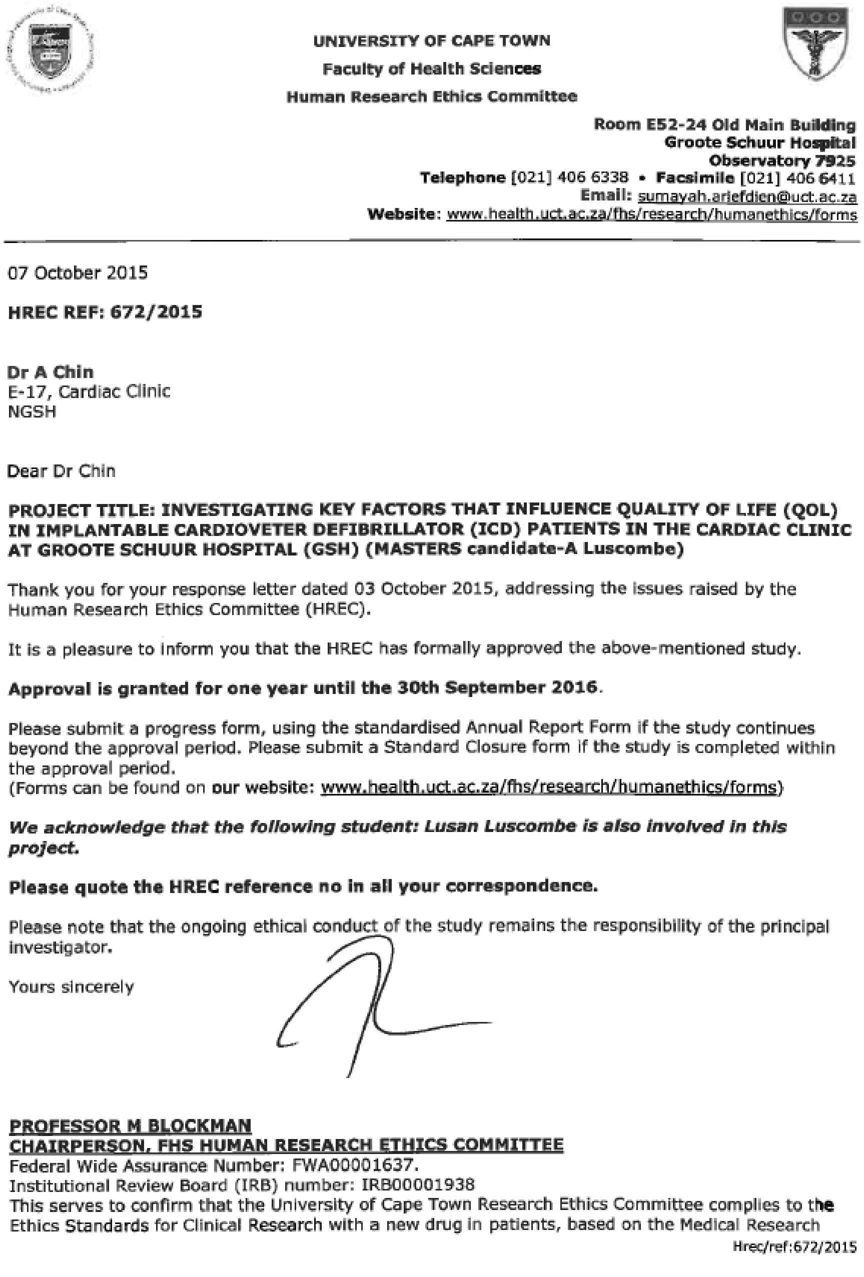
- All ethical requirements regarding informed consent, the right to withdraw from the study, the protection of participants' privacy and the confidentiality of the information will be met to the satisfaction of the supervisor;
- As the research participants are hospital patients and medical procedures are of relevance, additional ethical clearance and permission must be obtained from an appropriate Ethics Committee which oversees health and medicine-related research at the hospital in question. All conditions and procedures regarding access to patients for research purposes that may be required by this institution are to be met.

Signed:

Prof P Kruger
[For the Ethics Committee]
[Department of Psychology, Unisa]

Date: 16 August 2015

Appendix 11 – Ethical Clearance Letter (UCT)



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

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

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07 October 2015

HREC REF: 672/2015

Dr A Chin
E-17, Cardiac Clinic
NGSH

Dear Dr Chin

PROJECT TITLE: INVESTIGATING KEY FACTORS THAT INFLUENCE QUALITY OF LIFE (QOL) IN IMPLANTABLE CARDIOVETER DEFIBRILLATOR (ICD) PATIENTS IN THE CARDIAC CLINIC AT GROOTE SCHUUR HOSPITAL (GSH) (MASTERS candidate-A Luscombe)

Thank you for your response letter dated 03 October 2015, addressing the issues raised by the Human Research Ethics Committee (HREC).

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

Approval is granted for one year until the 30th September 2016.

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)

We acknowledge that the following student: Lusan Luscombe is also involved in this project.

Please quote the HREC reference no in all your correspondence.

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

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research

Hrec/ref:672/2015

Appendix 111 – Cardiac Clinic Authorization

Letter of Authorisation from the Cardiac Clinic Groote Schuur Hospital

Professor and Chair Division of Cardiology
University of Cape Town & Groote Schuur Hospital
Cardiac Clinic
Observatory

8 September 2015

UCT ETHICS
University of Cape Town
Cape Town

UNISA Student AL Luscombe 4577957
RE: Research Study
Investigating Key factors that influence Quality of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) Patients in the Cardiac Clinic at Groote Schuur Hospital (GSH)

Herewith I, Professor Ntsekhe, Head of the Cardiac Division at Groote Schuur Hospital, give Lusan Luscombe, MA Research student from UNISA, authorisation to conduct her research study at the Cardiac Clinic in Groote Schuur Hospital.

The study will involve all Implantable Cardioverter Defibrillator (ICD) patients from the Cardiac Clinic who have agreed to participate in the study. Their participation will involve one completion 3 different Quality of Life questionnaires.

The Cardiac Clinic at Groote Schuur Hospital (GSH) will support the research by providing use of the Cardiac Clinic facilities, arrhythmia care medical staff, patient data access and any other resources necessary to complete the study.

Yours sincerely,

Professor Mpiko Ntsekhe

Mpiko Ntsekhe MD PhD FACC
Professor and Chair Division of Cardiology
University of Cape Town & Groote Schuur Hospital

Tel: +27214046084
Fax: +27214487062

Appendix 1V - Informed Consent Letter

Invitation to participate in the research study:
Identify Key factors that influence Quality of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) patients in the Cardiac Clinic (CC) at Groote Schuur Hospital (GSH).

INFORMATION SHEET and INFORMED CONSENT FORM
PART 1: Information Sheet

INTRODUCTION: As a parent of 2 children with ICD's I have been involved in ICD patient care for more than 10 years. I realised that to improve QOL and care of ICD patients, we need to identify the key factors that influence their QOL. Together with UNISA and the GSH Cardiac Clinic Doctors and Staff we invite all ICD patients to join us in exploring ICD patient QOL and care to benefit everyone involved. Principal Investigator: Lusan Luscombe

1. PURPOSE: The purpose of this study is to identify key factors that influence Quality of Life in ICD patients in the Cardiac Clinic at Groote Schuur Hospital.
2. BENEFITS: The study may benefit all ICD patients and carers as it may increase ICD awareness, improve ICD care, enhance ICD patient QOL, save more lives and initiate further research.
3. RISKS: No risks are foreseen but a counsellor may attend to emotional concerns if need be.
4. PARTICIPANT SELECTION: We are inviting all ICD patients over the age of 18 registered at the GSH Cardiac Clinic to participate in the research project.
5. 3 QUESTIONNAIRES: Easy, short questions will provide 1: Demographic and Clinical data 2: Health and Well-being data 3: Anxiety and Depression data. The questions are not distressing, quick to complete and only require ticking a box.
6. WHERE: Questionnaires will be completed at the Cardiac Clinic E17 in GSH before a consultation or at home if need be.
7. RESULTS: The results will be given to any participant on their request.
8. CONFIDENTIALITY: Total confidentiality and privacy is ensured by only entering a number for each participant and no personal identifiable details will be released. All information will be stored in the GSH Cardiac Clinic for at least 5 years. Access is only permissible to Dr. Chin (Co-Supervisor), the Principal Investigator, the research ethics committee and regulatory authorities whom will check that the study has been done correctly. You can also arrange with your doctor to see and correct your information if need be. If the results are published, your identity is kept confidential.
9. VOLUNTARY PARTICIPATION: Participation is voluntary and non participation or withdrawal will not influence future care. Every participant has the right to withdraw at any stage and in particular unforeseen circumstances, the research project may be terminated early.
10. PROCESS: 1. ICD patients are invited by hand, post or email to participate.
    2. Participants return signed consent form and discuss the study if need be.
    3. Participants complete questionnaires at the Cardiac Clinic or at home.
    4. Completion may take about 30 minutes.
    5. Collection will be by hand, post or email.
    6. Results will be provided on request.
11. CONTACT: For any questions please contact:

Electrophysiologist:	Dr Ashley Chin	021 404 6084	Email: ashley.chin@uct.ac.za
Principal Researcher:	Lusan Luscombe	082 7800 739	Email: lusanlusan@gmail.com
UCT FHS Human Research Ethics Committee:	Professor Mark Blockman	021 406 6338	Email:sumayah.ariefdien@uct.ac.za

PART 2: Informed Consent Form

Number:

1. I hereby agree to participate in the research study that identifies Key factors that influence Quality of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) patients in the Cardiac Clinic (CC) at Groote Schuur Hospital (GSH).
2. The purpose of the study has been explained to me and I understand what is expected of my participation.
3. The study may benefit all ICD patients and carers as it may increase ICD awareness, improve ICD care, enhance ICD patient QOL, save more lives and initiate further research.
4. No risks are foreseen but a counsellor may attend to emotional concerns if need be.
5. 3 Easy, short questionnaires will provide 1: Demographic and Clinical data 2: Health and Well-being data and 3: Anxiety and Depression data. The questions are not distressing, are quick to complete and only require ticking a selected box.
6. I understand that the results will be given to me on request.
7. I understand that my answers will remain confidential.
8. I understand that I am participating voluntary without being forced or penalised in any way to do so. I also understand that I may withdraw at any point should I not want to continue and it will not influence future care.
9. I have received the telephone number of a person to contact should I have any questions.
10. I understand that the research must be approved by the Research Ethics Committees of the University of Cape Town and the University of South Africa.
11. I have read the foregoing information, or it has been read to me.

Print Name of Participant ____

--------------------------------------- -------------------------------------

Signature: Participant Date:

<u>If illiterate</u>

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

*Print name of witness*______________________ *AND* *Thumb print of participant*

Signature of witness ________________________

Date ______________________

CONTACT: Electrophysiologist: Dr Ashley Chin 021 404 6084 Email: ashley.chin@uct.ac.za
Principal Researcher: Lusan Luscombe 082 7800 739 Email: lusanlusan@gmail.com
UCT FHS Human Research Ethics Committee: Professor Mark Blockman 021 406 6338
Email:sumayah.ariefdien@uct.ac.za

Number:

Appendix V-DEMOGRAPHIC AND CLINICAL QUESTIONNAIRE

Investigating key factors that influence Quality of Life (QOL) in Implantable Cardioverter Defibrillator (ICD) Patients in the Cardiac Clinic at Groote Schuur Hospital (GSH). Welcome! Thank you for exploring Quality of Life in ICD patients. Remember all information remains confidential and anonymous

Choose **ONE** option only. Please cross your answer like this:

male	☒ female

1	*AGE*					
2	*GENDER*	male	female			
3	*ETHNICITY*	African	Asian	Coloured	Indian	White
4	*LANGUAGE*	Afrikaans	English	Xhosa	Zulu	other
5	*LIVING WITH*	spouse/partner	family	friends/other	alone	
	EDUCATION					
6	*EDUCATION*	primary school	high school	diploma	degree	none
7	*EMPLOYED*	yes	no	student	retired	
8	*INCOME PER MONTH*	below 1000	1000 - 4000	4000 - 10 000	Above 10 000	none
	HOME / LOCATION					
9	*RESIDENCE*	own property	rent	informal dwelling	share	
10	*TRANSPORT IS EASY TO HOSPITAL*	yes	no	sometimes		
11	*TRAVEL TIME to Groote Schuur Hospital*	less than 30 minutes	less than 1 hour	over 1 hour		
12	*IS A 24HR CRISIS CLINIC CLOSE BY*	yes	no	don't know		
13	*YOU HAVE AN EMERGENCY NUMBER*	yes	no			
	COPING					
14	*BEST COPING STRATEGY*	pray	meditate	withdraw	ignore	share
15	*DO YOU ACCEPT YOUR CONDITION*	yes	somewhat	no		
16	*HOW IMPORTANT IS FAITH*	most	somewhat	not	don't know	
17	*YOUR BEST EMOTIONAL SUPPORT*	spouse/partner	children	community	self	family
18	*SIZE OF YOUR SUPPORT NETWORK*	big enough	too small	don't know	none	
19	*DO YOU FEEL LESS INDEPENDENT*	yes	somewhat	no		

	SUPPORT				
20	*HAVE YOU HAD COUNSELLING*	yes professional	yes lay	no	other
21	*WHEN IS COUNSELLING MOST IMPORTANT*	before ICD implant	after implant	always	sometimes don't know
22	*ARE SUPPORT GROUPS IMPORTANT*	yes	no	sometimes	don't know
23	*IS YOUR FAMILY GREATLY AFFECTED BY YOUR CONDITION*	yes	somewhat	no	
24	*IS YOUR FAMILY OVER-PROTECTIVE*	yes	no	sometimes	don't know
25	*HOW DOES YOUR ICD MOSTLY INFLUENCE YOUR LIFESTYLE*	negatively	positively	don't know	equally
26	*DO CLOSE FAMILY AND FRIENDS UNDERSTAND what an ICD does*	yes	no	a little	
27	*DOES THE COMMUNITY UNDERSTAND what an ICD does*	yes	no	a little	don't know

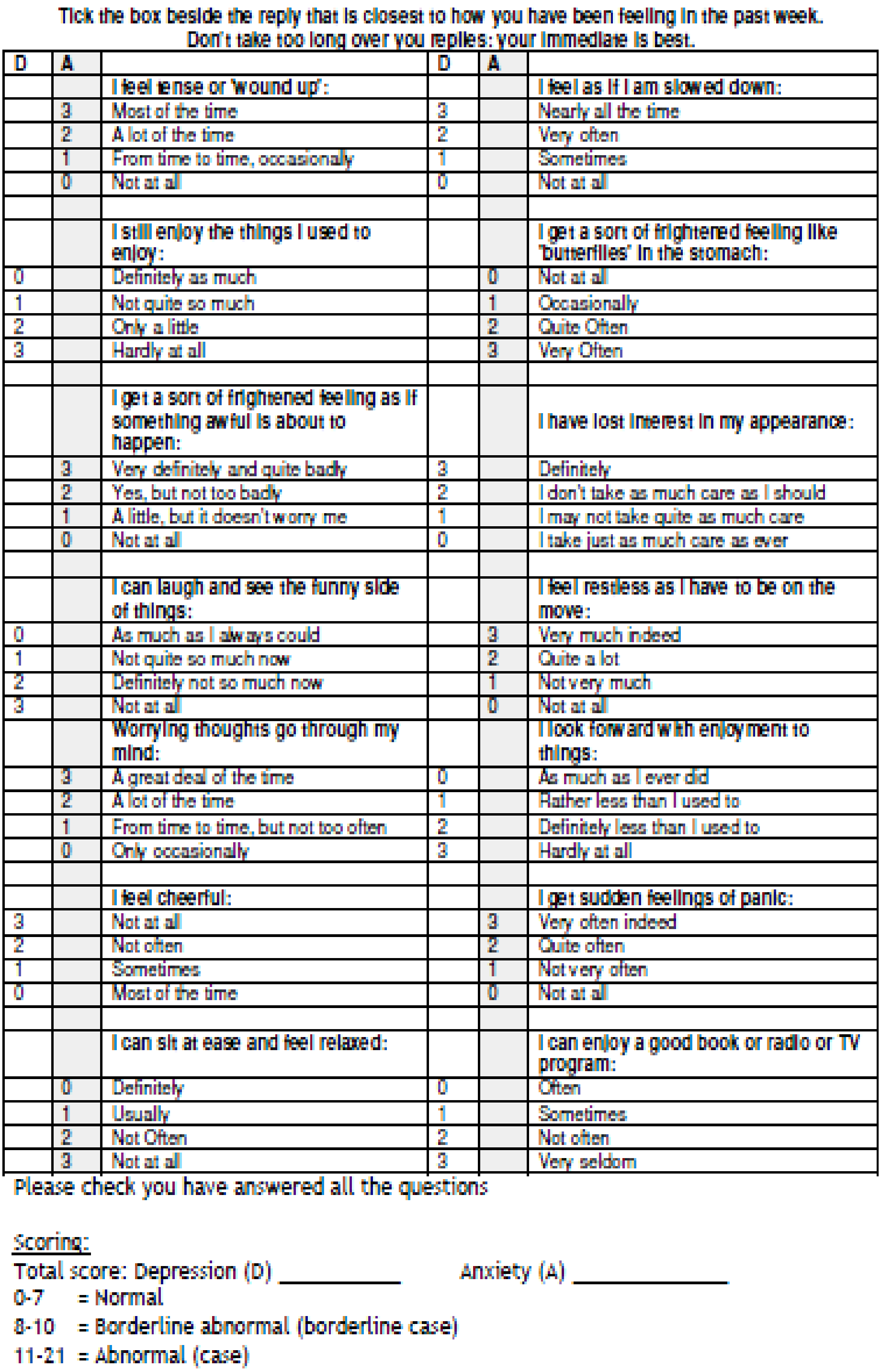
Number:

	MEDICAL SUPPORT				
28	*IS YOUR SPECIALIST EASILY CONTACTABLE*	yes	sometimes	no	
29	*DO you have ENOUGH CONSULTING TIME*	yes	sometimes	no	
30	*SHOULD NURSES PROVIDE MORE EMOTIONAL SUPPORT than DOCTORS*	yes	equal	no	don't know
31	*DO NURSES PROVIDE ENOUGH EMOTIONAL SUPPORT*	yes	somewhat	no	
32	*SERVICE AT GSH IS*	excellent	good	poor	
33	*IS YOUR FAMILY DOCTOR UP TO DATE WITH ICD's*	yes	no	don't know	a little
34	*IS THE HOSPITAL STAFF KNOWLEDGABLE ABOUT ICD'S*	yes	no	don't know	a little

	SHOCKS				
35	*NUMBER OF SHOCKS SINCE IMPLANT*	none	less than 5	more than 5	
36	*HAVE YOU HAD INAPPROPRIATE SHOCKS*	no	one	more than 1	don't know
37	*WHAT IS THE WORST*	arrhythmia before shock	the shock	time after a shock	equal don't know
38	*DO YOU GET ARRHYTHMIAS/palpitations*	never	often	seldom	don't know
39	*ARE you PRE-OCCUPIED WITH your HEART*	most of the time	sometimes	no	
40	*ARE YOU ALWAYS AWARE THAT YOU MAY GET A SHOCK*	yes	sometimes	no	
41	*What BEST PREPARES you for a SHOCK*	knowledge	emergency plan	meditation/prayer	nothing
42	*DO YOU FEAR ICD FAILURE*	always	sometimes	never	

	CLINICAL DATA				
43	*DIAGNOSIS*	Ischemic heart	ARVC DCMO	HCM Brugada	Idiopathic Congenital
44	*HOW LONG HAVE YOU HAD AN ICD*	less than 1 yr	1 - 5 yrs	more than 5 yrs	
45	*ARRHYTHMIA*	none	VT	VF	n/a
46	*INDICATION*	primary	secondary		
47	*WAS CARDIAC ARREST FIRST SIGN OF DISEASE*	yes	no	n/a	
48	*CO-MORBIDITY*	no	yes		

Appendix V1 - HADS Anxiety and Depression Scale



Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			I feel as if I am slowed down:
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			I get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			I have lost interest in my appearance:
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			I feel restless as I have to be on the move:
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			I look forward with enjoyment to things:
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			I get sudden feelings of panic:
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			I can enjoy a good book or radio or TV program:
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

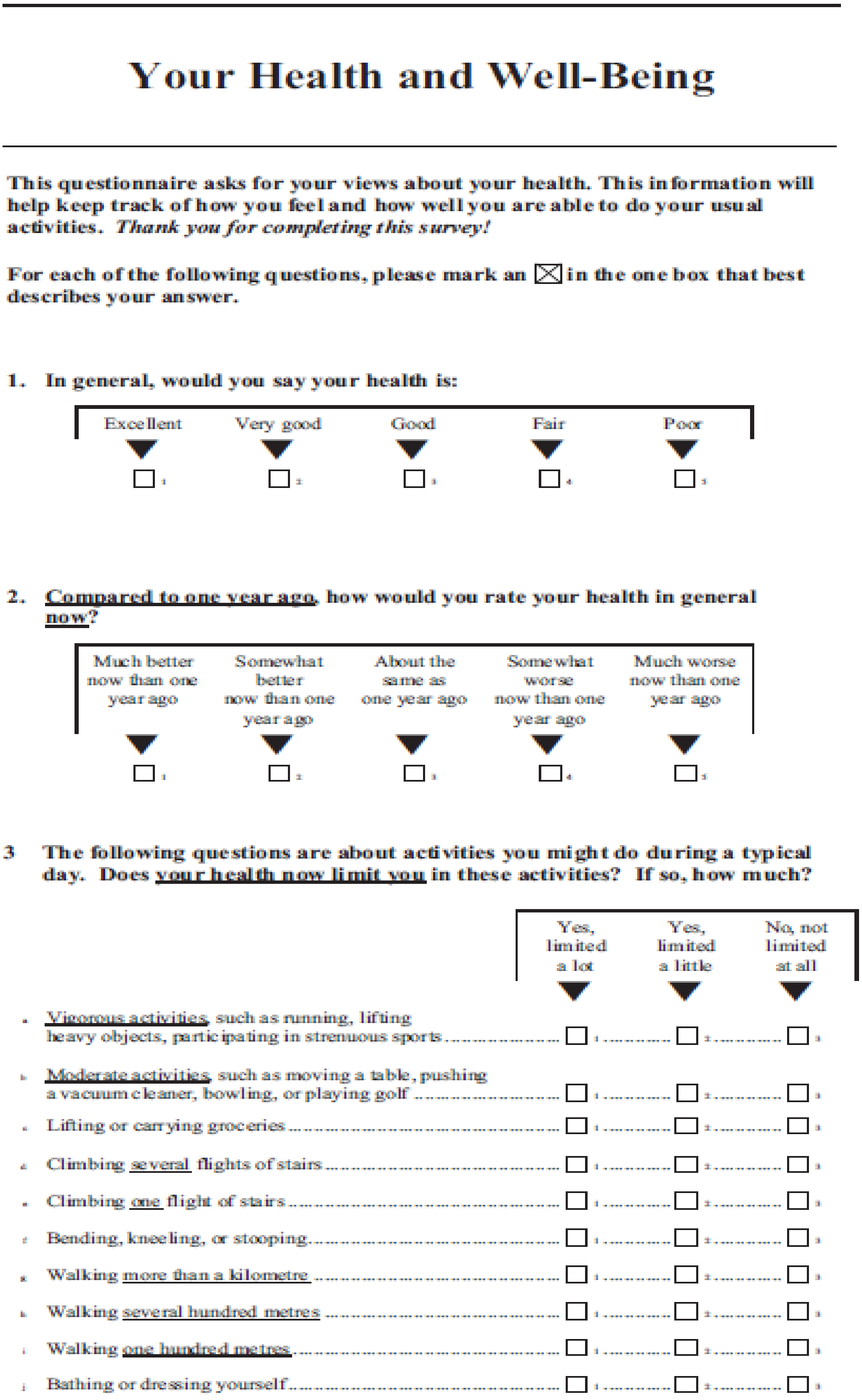
Total score: Depression (D) ___________ Anxiety (A) _____________

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

Appendix V11 - SF-36v2 Health Survey



Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h Walking several hundred metres	☐ 1	☐ 2	☐ 3
i Walking one hundred metres	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Have you had a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Have you felt worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Have you felt tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

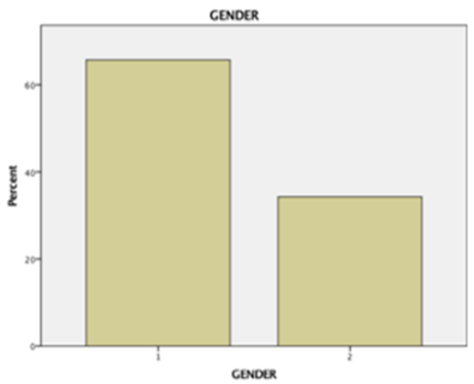
Appendix V111 - Demographic and Clinical Results

FREQUENCIES DEMOGRAPHICAL DATA

GENDER

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	46	65.7	65.7	65.7
	2	24	34.3	34.3	100.0
	Total	70	100.0	100.0	

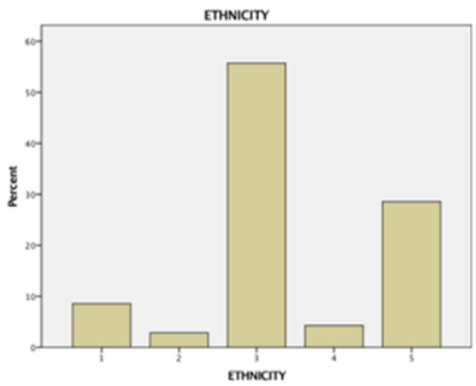
1Male 2Female



ETHNICITY

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	6	8.6	8.6	8.6
	2	2	2.9	2.9	11.4
	3	39	55.7	55.7	67.1
	4	3	4.3	4.3	71.4
	5	20	28.6	28.6	100.0
	Total	70	100.0	100.0	

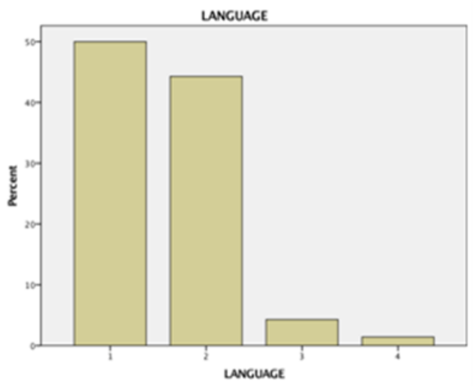
1African 2Asian 3Coloured 4Indian 5White



LANGUAGE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	35	50.0	50.0	50.0
	2	31	44.3	44.3	94.3
	3	3	4.3	4.3	98.6
	4	1	1.4	1.4	100.0
	Total	70	100.0	100.0	

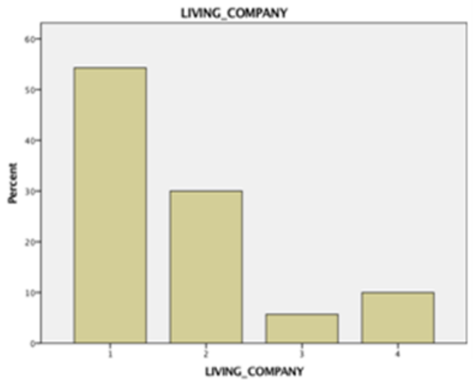
1Afrikaans 2English 3Xhosa 4Zulu



LIVING_COMPANY

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	38	54.3	54.3	54.3
	2	21	30.0	30.0	84.3
	3	4	5.7	5.7	90.0
	4	7	10.0	10.0	100.0
	Total	70	100.0	100.0	

1Spouse/partner 2Family 3Friends/other 4Alone

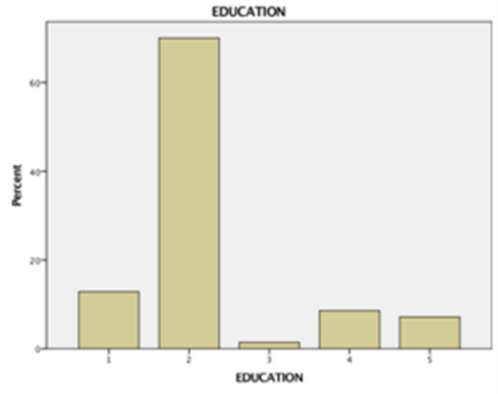


FREQUENCIES DEMOGRAPHICAL DATA

EDUCATION

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	12.9	12.9	12.9
	2	49	70.0	70.0	82.9
	3	1	1.4	1.4	84.3
	4	6	8.6	8.6	92.9
	5	5	7.1	7.1	100.0
	Total	70	100.0	100.0	

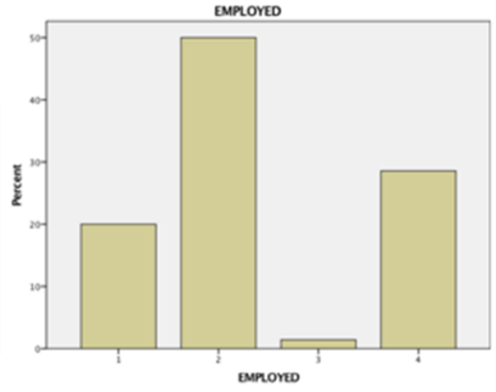
1Primary 2High 3Diploma 4Degree 5None



EMPLOYED

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	14	20.0	20.0	20.0
	2	35	50.0	50.0	70.0
	3	1	1.4	1.4	71.4
	4	20	28.6	28.6	100.0
	Total	70	100.0	100.0	

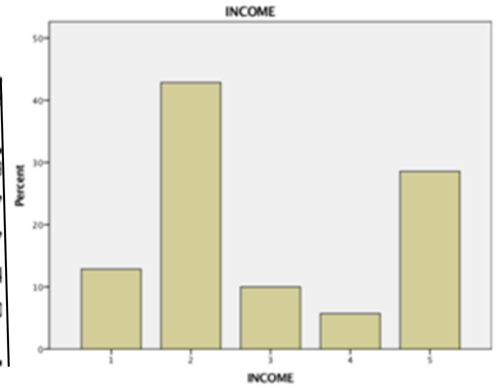
1Yes 2No 3Student 4Retired



INCOME

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	12.9	12.9	12.9
	2	30	42.9	42.9	55.7
	3	7	10.0	10.0	65.7
	4	4	5.7	5.7	71.4
	5	20	28.6	28.6	100.0
	Total	70	100.0	100.0	

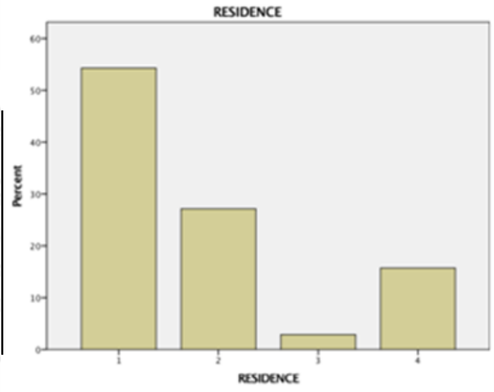
1.Below 1000 2.1000-4000 3.4000-10000 4.Above 10000 5.None



RESIDENCE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	38	54.3	54.3	54.3
	2	19	27.1	27.1	81.4
	3	2	2.9	2.9	84.3
	4	11	15.7	15.7	100.0
	Total	70	100.0	100.0	

1own property 2Rent 3Informal 4Share

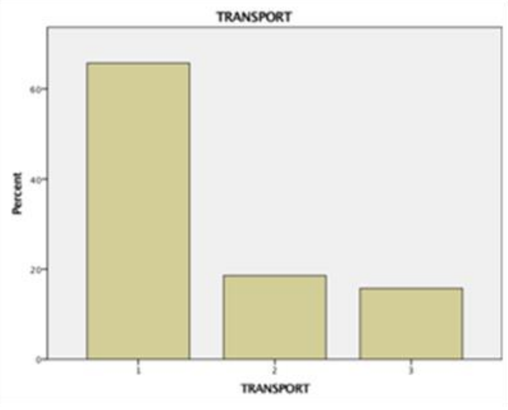


FREQUENCIES DEMOGRAPHICAL DATA

Transport is easy is GSH

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	46	65.7	65.7	65.7
	2	13	18.6	18.6	84.3
	3	11	15.7	15.7	100.0
	Total	70	100.0	100.0	

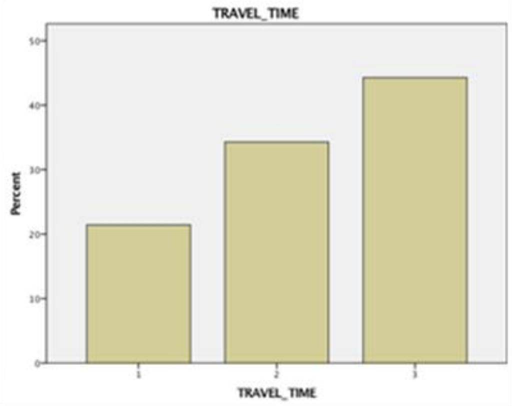
1Yes 2No 3Sometimes



Travel time to GSH

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	15	21.4	21.4	21.4
	2	24	34.3	34.3	55.7
	3	31	44.3	44.3	100.0
	Total	70	100.0	100.0	

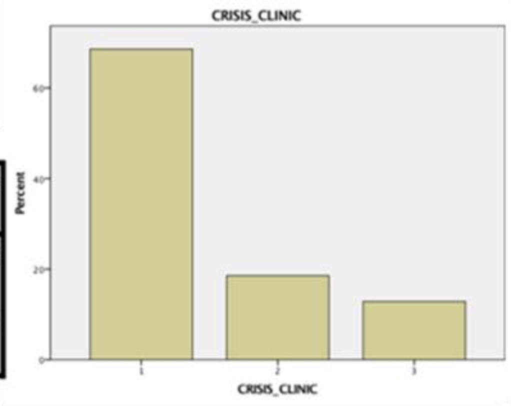
1Less than30 min 2Less than 1 hr 3Over 1 hr



Is a 24hr Emergency Unit nearby

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	48	68.6	68.6	68.6
	2	13	18.6	18.6	87.1
	3	9	12.9	12.9	100.0
	Total	70	100.0	100.0	

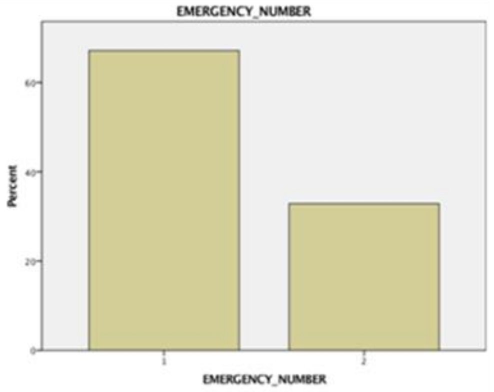
1Yes 2No 3Dont know



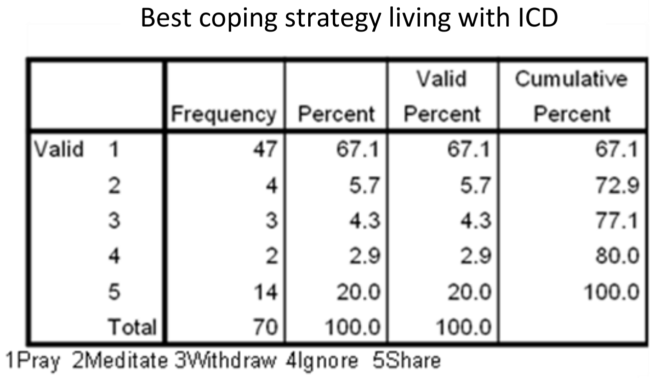
You have an emergency number

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	47	67.1	67.1	67.1
	2	23	32.9	32.9	100.0
	Total	70	100.0	100.0	

1Yes 2No



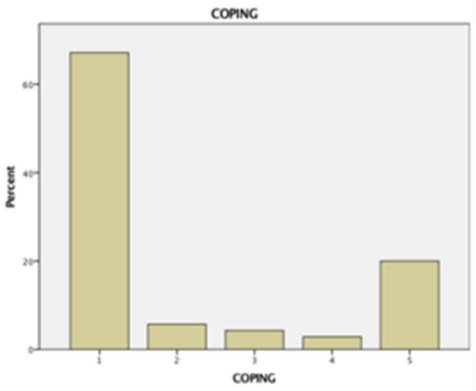
FREQUENCIES PATIENT SUPPORT DATA

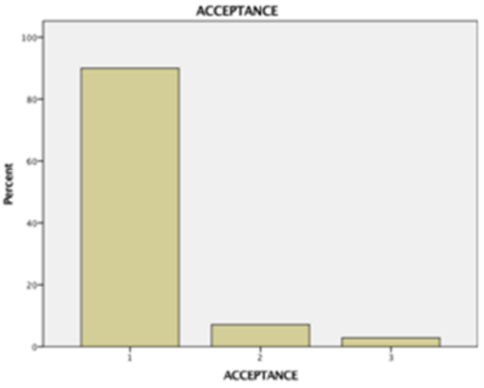


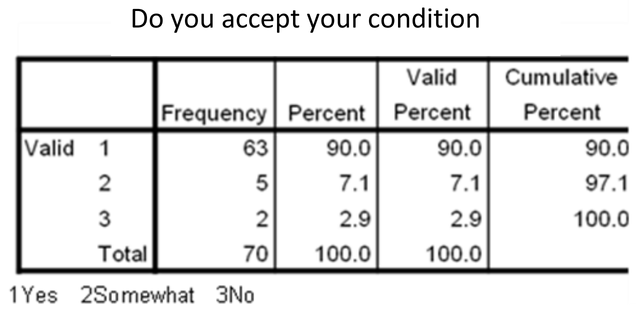
Best coping strategy living with ICD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	47	67.1	67.1	67.1
	2	4	5.7	5.7	72.9
	3	3	4.3	4.3	77.1
	4	2	2.9	2.9	80.0
	5	14	20.0	20.0	100.0
	Total	70	100.0	100.0	

1Pray 2Meditate 3Withdraw 4Ignore 5Share



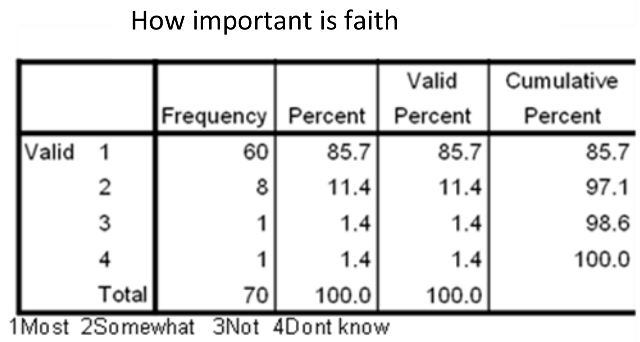




Do you accept your condition

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	63	90.0	90.0	90.0
	2	5	7.1	7.1	97.1
	3	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

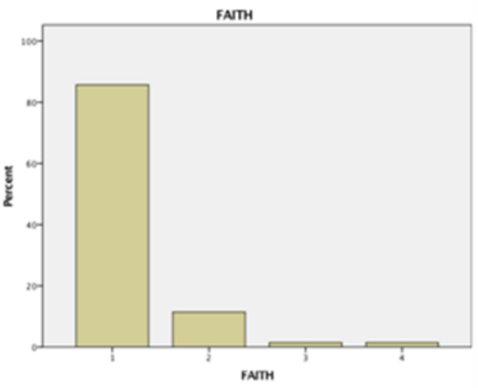
1Yes 2Somewhat 3No

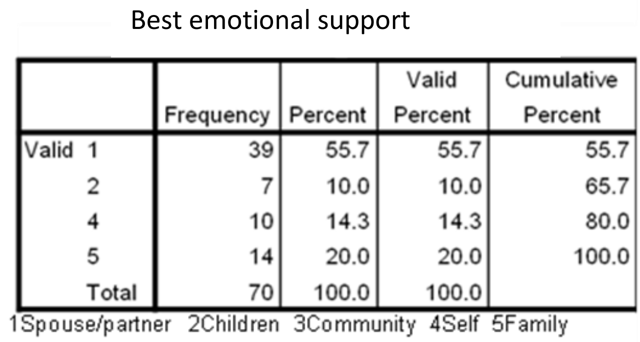


How important is faith

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	60	85.7	85.7	85.7
	2	8	11.4	11.4	97.1
	3	1	1.4	1.4	98.6
	4	1	1.4	1.4	100.0
	Total	70	100.0	100.0	

1Most 2Somewhat 3Not 4Dont know

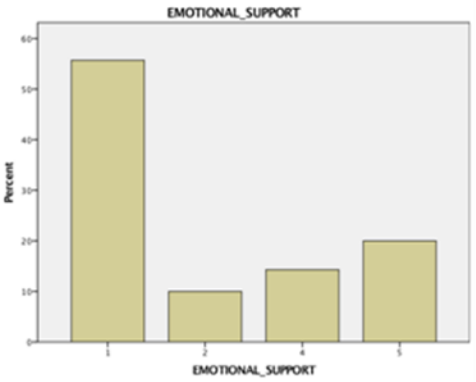




Best emotional support

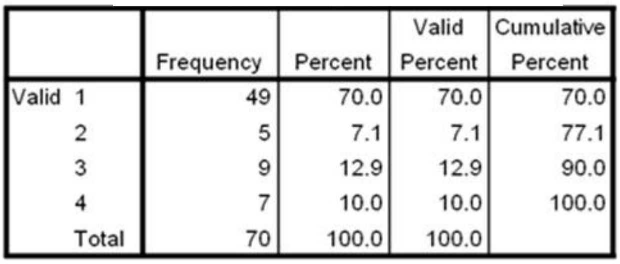
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	39	55.7	55.7	55.7
	2	7	10.0	10.0	65.7
	4	10	14.3	14.3	80.0
	5	14	20.0	20.0	100.0
	Total	70	100.0	100.0	

1Spouse/partner 2Children 3Community 4Self 5Family



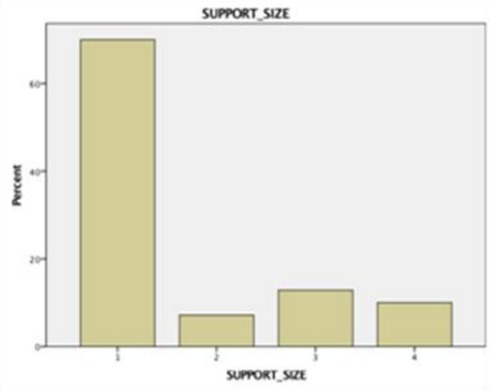
FREQUENCIES PATIENT SUPPORT DATA

Size of your support network

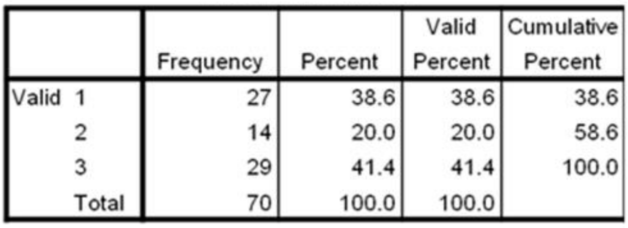


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	49	70.0	70.0	70.0
	2	5	7.1	7.1	77.1
	3	9	12.9	12.9	90.0
	4	7	10.0	10.0	100.0
	Total	70	100.0	100.0	

1Big enough 2Too small 3Dont know 4None

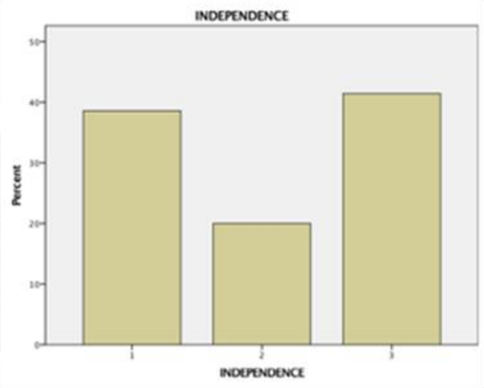


Do you feel less independent

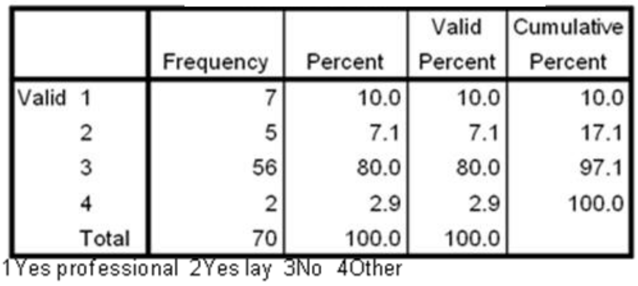


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	27	38.6	38.6	38.6
	2	14	20.0	20.0	58.6
	3	29	41.4	41.4	100.0
	Total	70	100.0	100.0	

1Yes 2Somewhat 3No

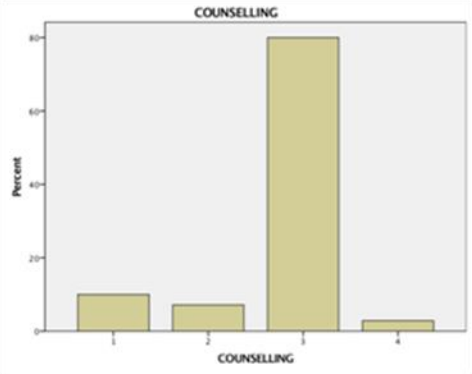


Have you had counselling

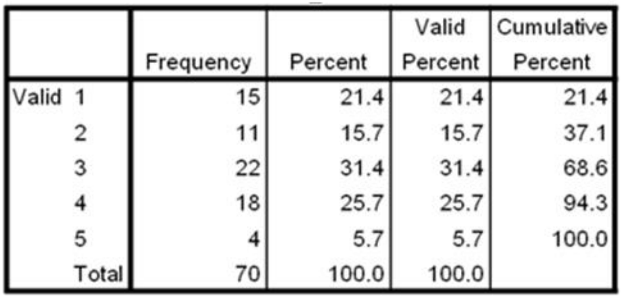


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	7	10.0	10.0	10.0
	2	5	7.1	7.1	17.1
	3	56	80.0	80.0	97.1
	4	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

1Yes professional 2Yes lay 3No 4Other

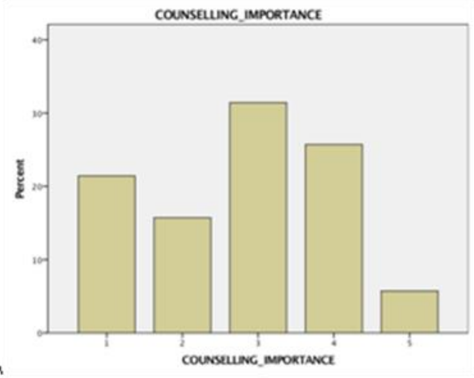


When is counselling important



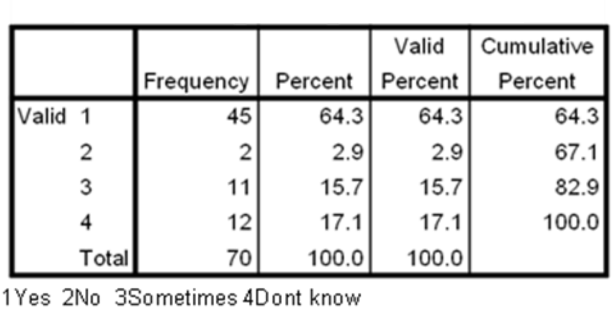
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	15	21.4	21.4	21.4
	2	11	15.7	15.7	37.1
	3	22	31.4	31.4	68.6
	4	18	25.7	25.7	94.3
	5	4	5.7	5.7	100.0
	Total	70	100.0	100.0	

1Before implant 2After implant 3Always 4Sometimes 5Dont know



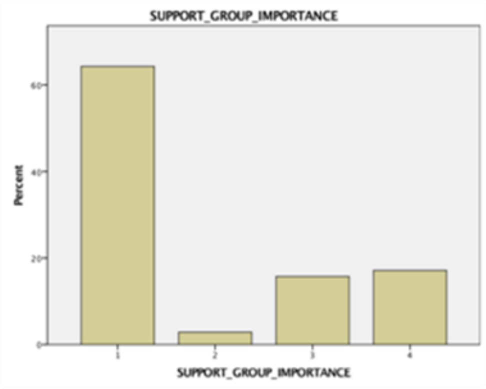
FREQUENCIES PATIENT SUPPORT DATA

Are support groups important

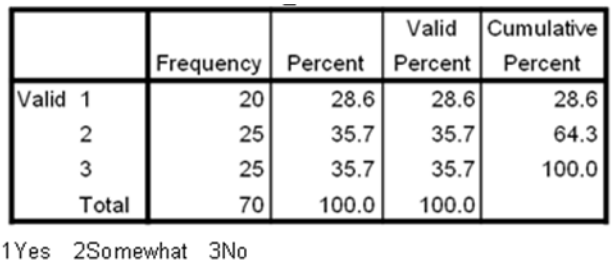


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	45	64.3	64.3	64.3
	2	2	2.9	2.9	67.1
	3	11	15.7	15.7	82.9
	4	12	17.1	17.1	100.0
	Total	70	100.0	100.0	

1Yes 2No 3Sometimes 4Dont know

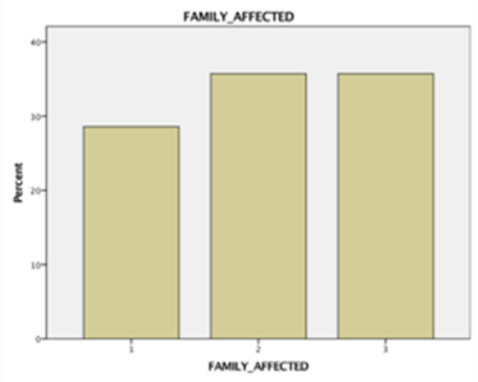


Is your family greatly affected by your condition

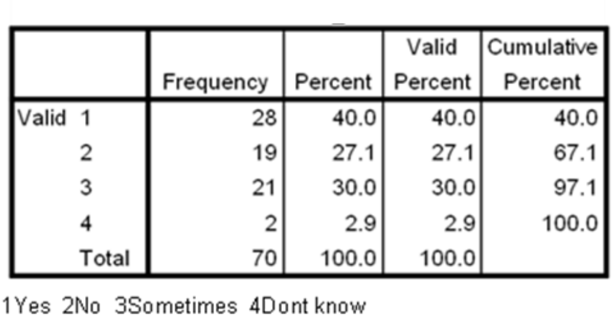


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	20	28.6	28.6	28.6
	2	25	35.7	35.7	64.3
	3	25	35.7	35.7	100.0
	Total	70	100.0	100.0	

1Yes 2Somewhat 3No

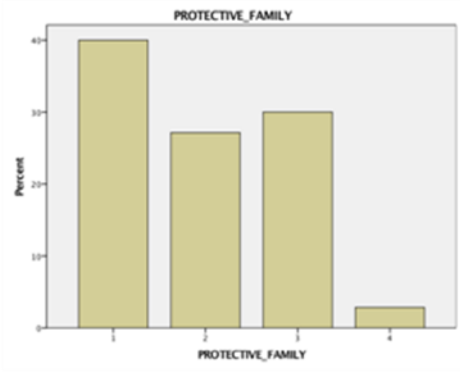


Is your family over-protective

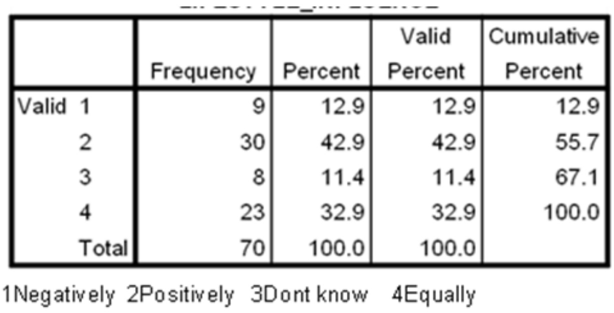


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	28	40.0	40.0	40.0
	2	19	27.1	27.1	67.1
	3	21	30.0	30.0	97.1
	4	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

1Yes 2No 3Sometimes 4Dont know

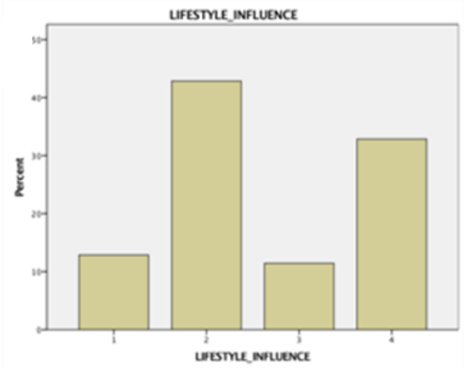


How does your ICD mostly influence your lifestyle



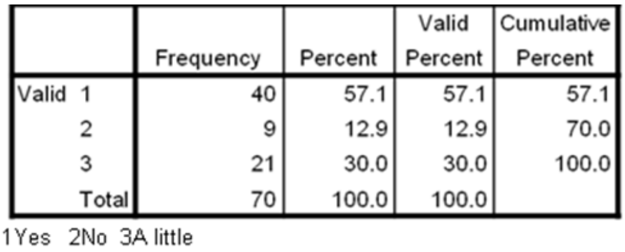
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	12.9	12.9	12.9
	2	30	42.9	42.9	55.7
	3	8	11.4	11.4	67.1
	4	23	32.9	32.9	100.0
	Total	70	100.0	100.0	

1Negatively 2Positively 3Dont know 4Equally



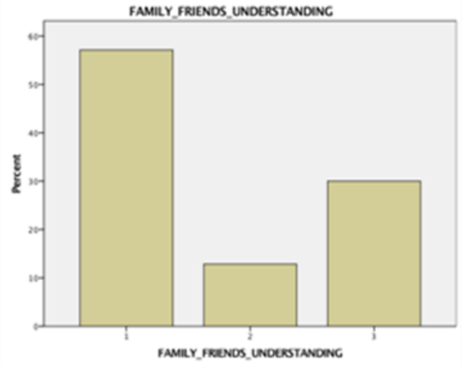
FREQUENCIES PATIENT SUPPORT DATA

Do close family and friends understand what an ICD does

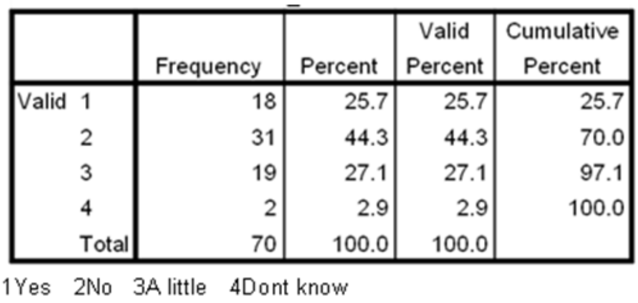


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	40	57.1	57.1	57.1
	2	9	12.9	12.9	70.0
	3	21	30.0	30.0	100.0
	Total	70	100.0	100.0	

1Yes 2No 3A little

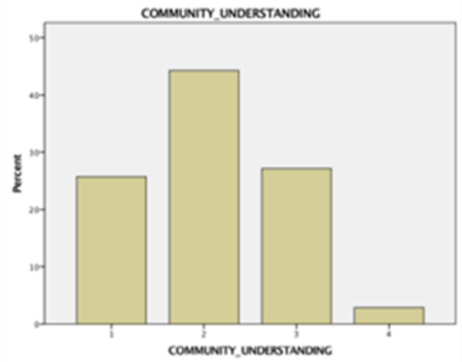


Does the community understand what an ICD does

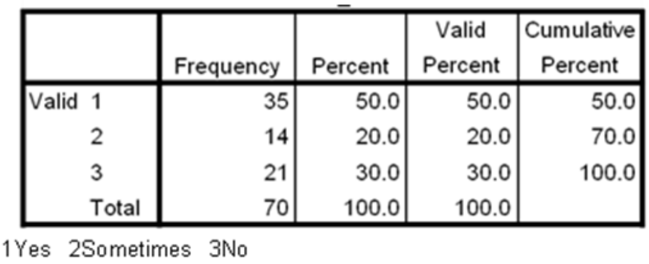


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	18	25.7	25.7	25.7
	2	31	44.3	44.3	70.0
	3	19	27.1	27.1	97.1
	4	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

1Yes 2No 3A little 4Dont know

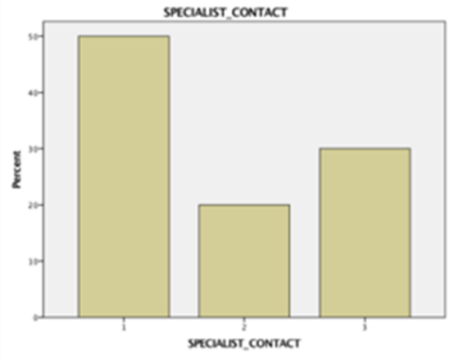


Is your specialist easily contactable

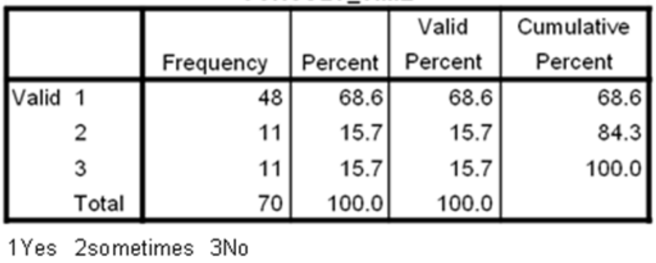


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	35	50.0	50.0	50.0
	2	14	20.0	20.0	70.0
	3	21	30.0	30.0	100.0
	Total	70	100.0	100.0	

1Yes 2Sometimes 3No

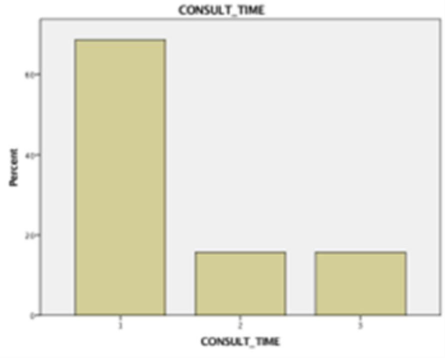


Do you have enough consulting time



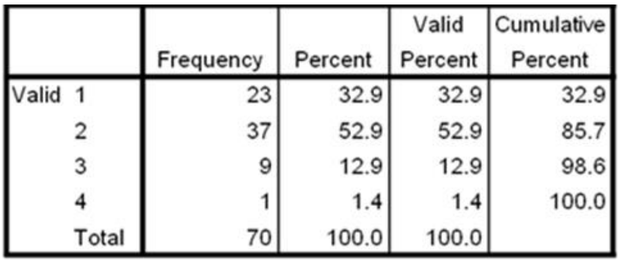
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	48	68.6	68.6	68.6
	2	11	15.7	15.7	84.3
	3	11	15.7	15.7	100.0
	Total	70	100.0	100.0	

1Yes 2sometimes 3No



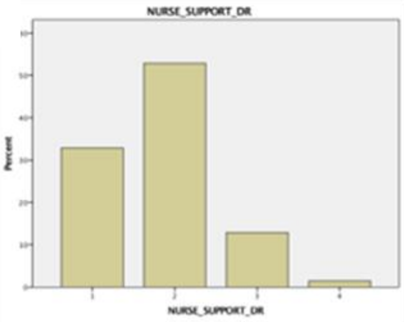
FREQUENCIES PATIENT SUPPORT DATA

Should nurses provide more emotional support than doctors

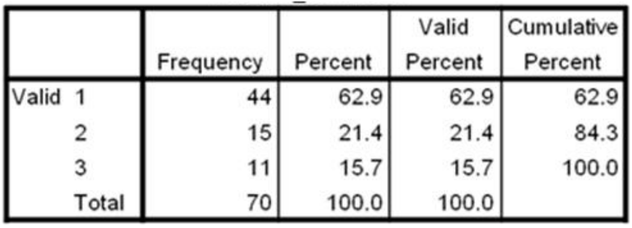


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	23	32.9	32.9	32.9
	2	37	52.9	52.9	85.7
	3	9	12.9	12.9	98.6
	4	1	1.4	1.4	100.0
	Total	70	100.0	100.0	

1Yes 2Equal 3No 4Dont know

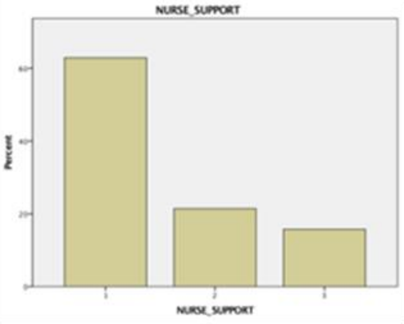


Do nurses provide enough emotional support

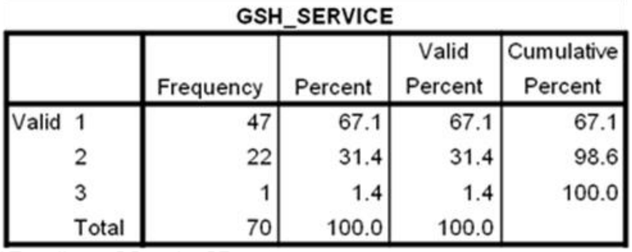


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	44	62.9	62.9	62.9
	2	15	21.4	21.4	84.3
	3	11	15.7	15.7	100.0
	Total	70	100.0	100.0	

1Yes 2Somewhat 3No

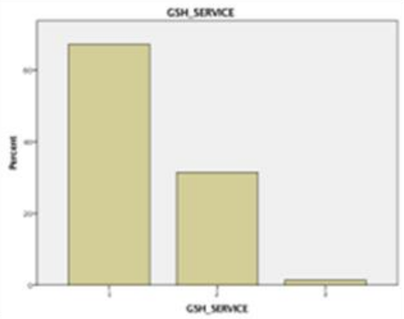


GSH_SERVICE

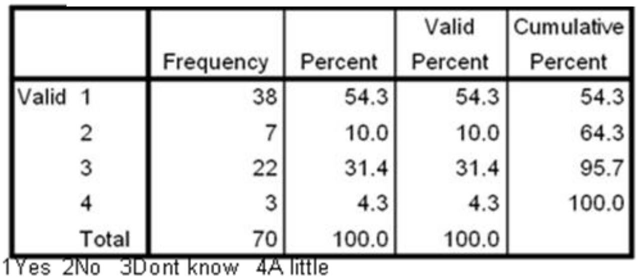


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	47	67.1	67.1	67.1
	2	22	31.4	31.4	98.6
	3	1	1.4	1.4	100.0
	Total	70	100.0	100.0	

1Excellent 2Good 3Poor

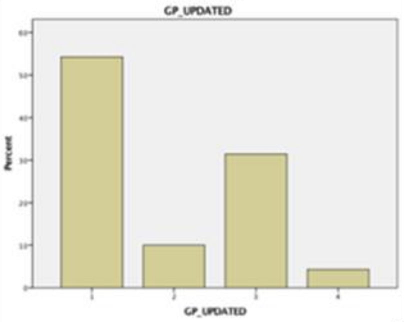


Is your family doctor up to date with ICD’s

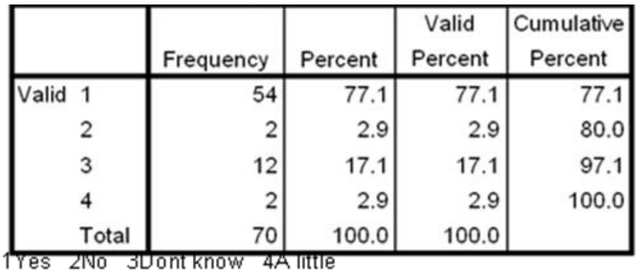


		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	38	54.3	54.3	54.3
	2	7	10.0	10.0	64.3
	3	22	31.4	31.4	95.7
	4	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

1Yes 2No 3Dont know 4A little

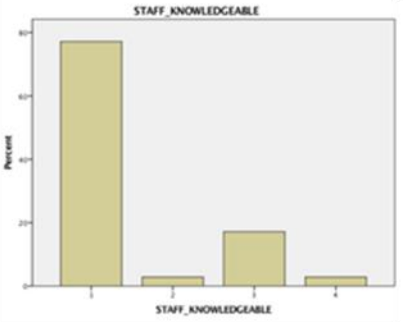


Is the hospital staff knowledgeable about ICD’s



		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	54	77.1	77.1	77.1
	2	2	2.9	2.9	80.0
	3	12	17.1	17.1	97.1
	4	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

1Yes 2No 3Dont know 4A little

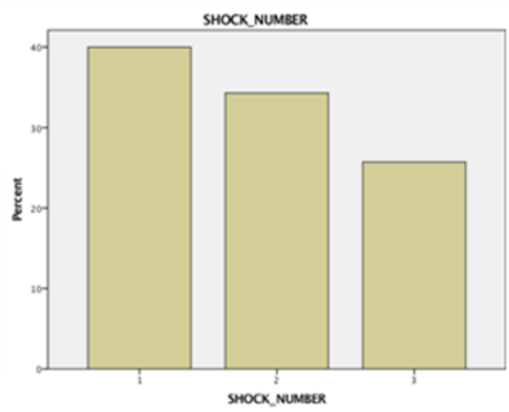


FREQUENCIES ICD DATA

SHOCK_NUMBER

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	28	40.0	40.0	40.0
	2	24	34.3	34.3	74.3
	3	18	25.7	25.7	100.0
	Total	70	100.0	100.0	

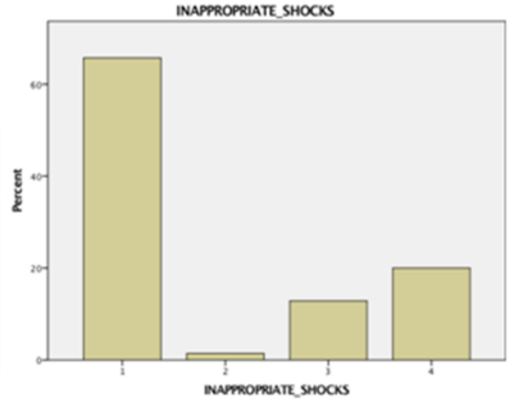
1None 2Less than 5 3More than 5



INAPPROPRIATE_SHOCKS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	46	65.7	65.7	65.7
	2	1	1.4	1.4	67.1
	3	9	12.9	12.9	80.0
	4	14	20.0	20.0	100.0
	Total	70	100.0	100.0	

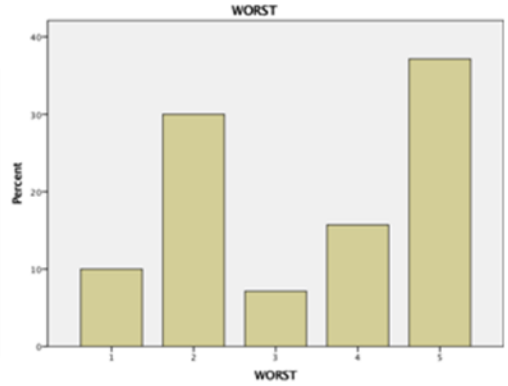
1No 2One 3More than one 4Dont Know



What is worst

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	7	10.0	10.0	10.0
	2	21	30.0	30.0	40.0
	3	5	7.1	7.1	47.1
	4	11	15.7	15.7	62.9
	5	26	37.1	37.1	100.0
	Total	70	100.0	100.0	

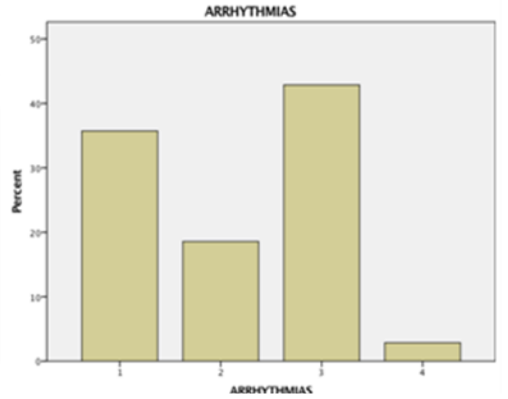
1Arrhythmia before shock 2The shock 3Time after shock
4Equal 5Dont know



Do you get palpitations

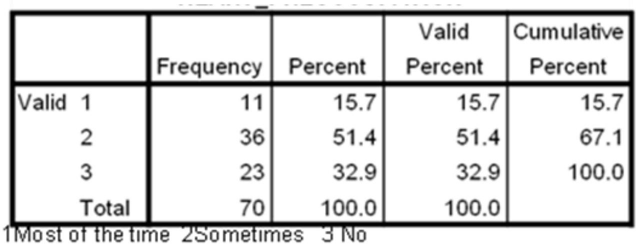
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	35.7	35.7	35.7
	2	13	18.6	18.6	54.3
	3	30	42.9	42.9	97.1
	4	2	2.9	2.9	100.0
	Total	70	100.0	100.0	

1Never 2 Often 3Seldom 4Dont know



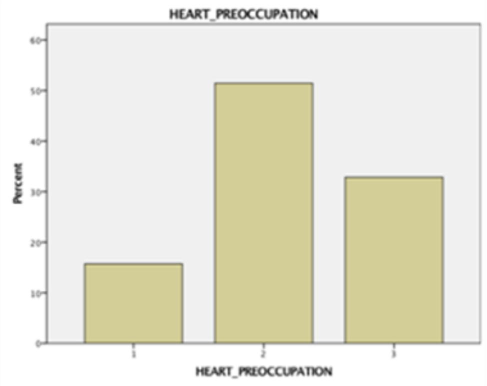
FREQUENCIES ICD DATA

Are you pre-occupied with your heart

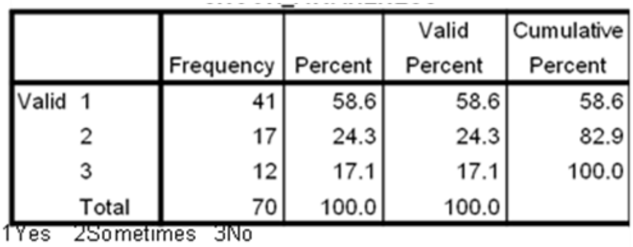


	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 1	11	15.7	15.7	15.7
2	36	51.4	51.4	67.1
3	23	32.9	32.9	100.0
Total	70	100.0	100.0	

1Most of the time 2Sometimes 3 No

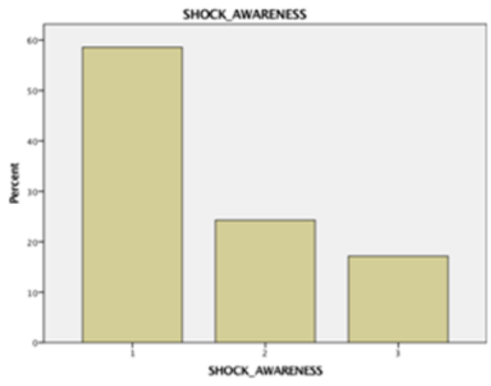


Are you always aware that you may get a shock

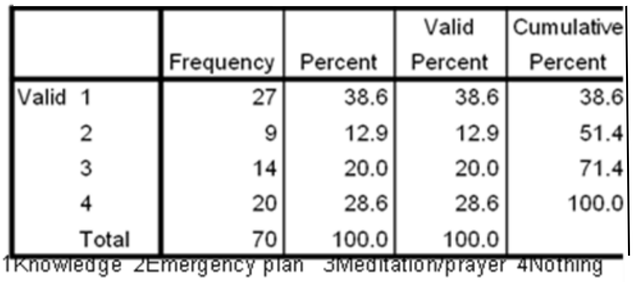


	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 1	41	58.6	58.6	58.6
2	17	24.3	24.3	82.9
3	12	17.1	17.1	100.0
Total	70	100.0	100.0	

1Yes 2Sometimes 3No

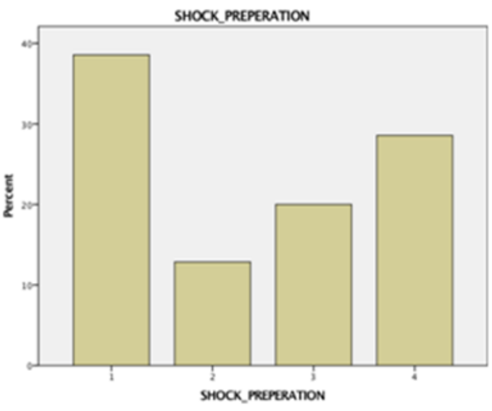


What best prepares you for a shock

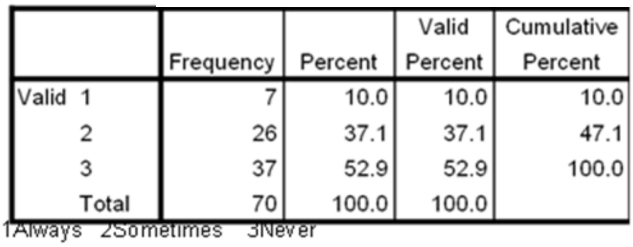


	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 1	27	38.6	38.6	38.6
2	9	12.9	12.9	51.4
3	14	20.0	20.0	71.4
4	20	28.6	28.6	100.0
Total	70	100.0	100.0	

1Knowledge 2Emergency plan 3Meditation/prayer 4Nothing



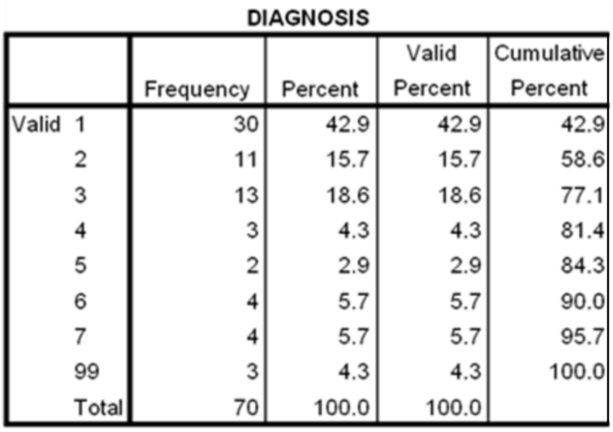
Do you fear ICD failure



	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 1	7	10.0	10.0	10.0
2	26	37.1	37.1	47.1
3	37	52.9	52.9	100.0
Total	70	100.0	100.0	

1Always 2Sometimes 3Never

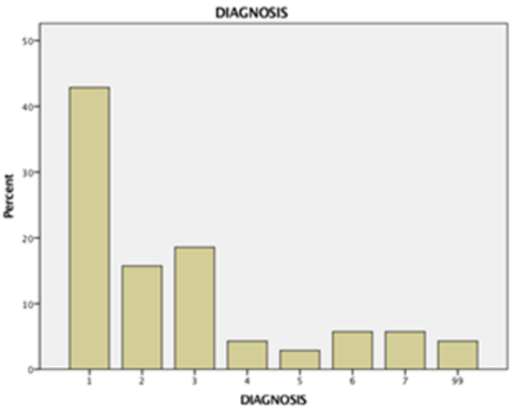
FREQUENCIES CLINICAL DATA

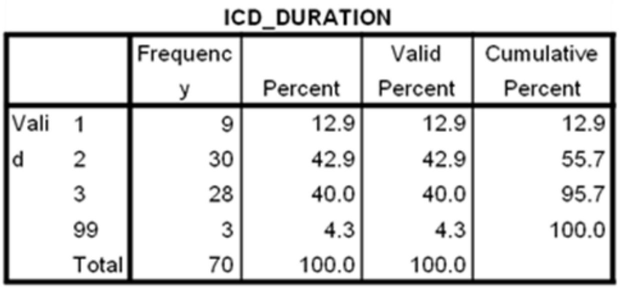


DIAGNOSIS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	30	42.9	42.9	42.9
	2	11	15.7	15.7	58.6
	3	13	18.6	18.6	77.1
	4	3	4.3	4.3	81.4
	5	2	2.9	2.9	84.3
	6	4	5.7	5.7	90.0
	7	4	5.7	5.7	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

1Ischeamic heart disease 2ARVC 3DCMO 4HCM 5Brugada
6Idiopathic 7Congenital heart disease 99Unknown

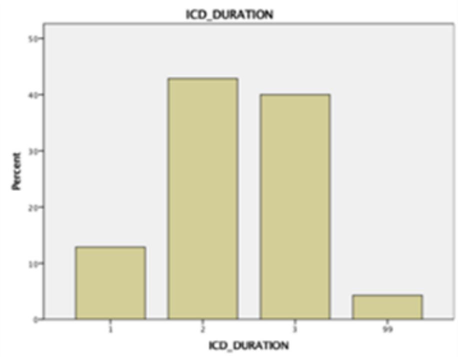


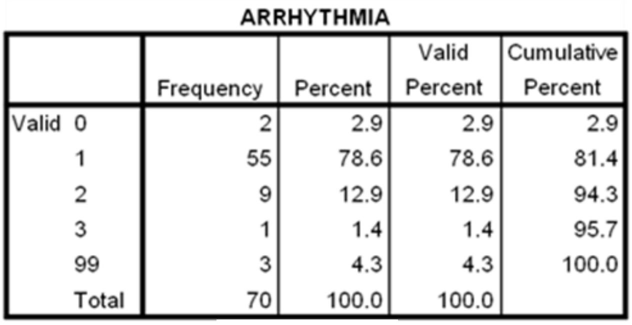


ICD_DURATION

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	12.9	12.9	12.9
	2	30	42.9	42.9	55.7
	3	28	40.0	40.0	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

1Less than 1 year 2Between1-5 Years 3More than 5 years
99Unkown

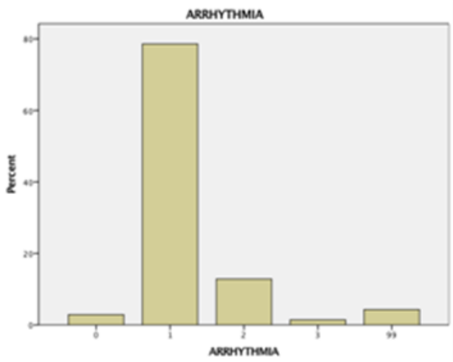




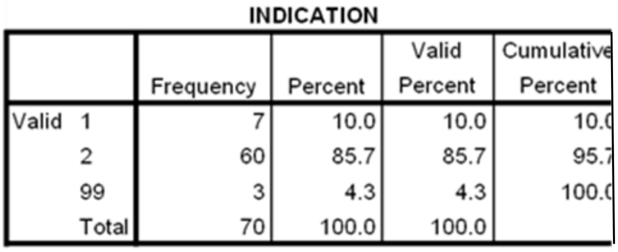
ARRHYTHMIA

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	2	2.9	2.9	2.9
	1	55	78.6	78.6	81.4
	2	9	12.9	12.9	94.3
	3	1	1.4	1.4	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

0None 1VT 2VF 3 N/A 99Unknown



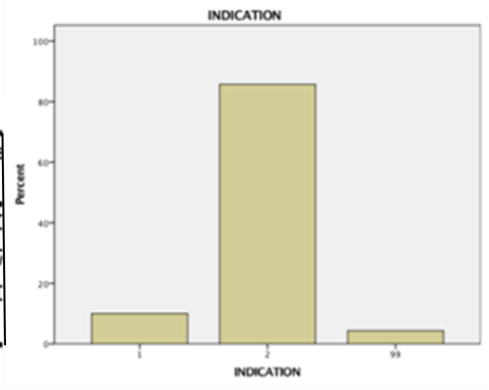
FREQUENCIES CLINICAL DATA

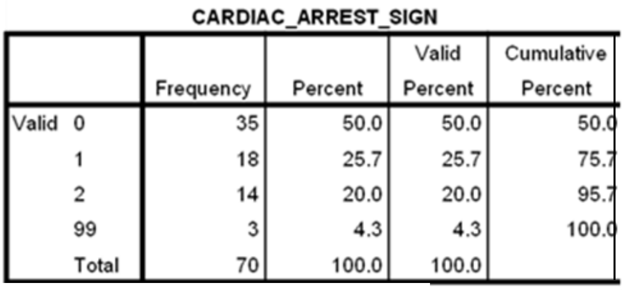


INDICATION

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	7	10.0	10.0	10.0
	2	60	85.7	85.7	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

1Primary 2Secondary 99Unknown

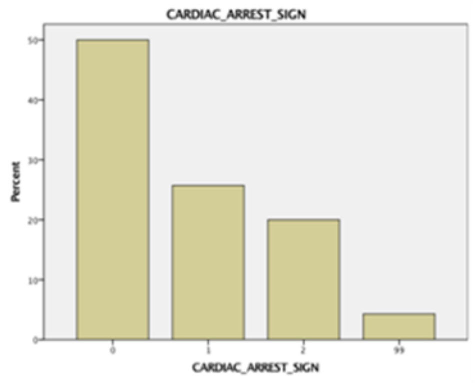


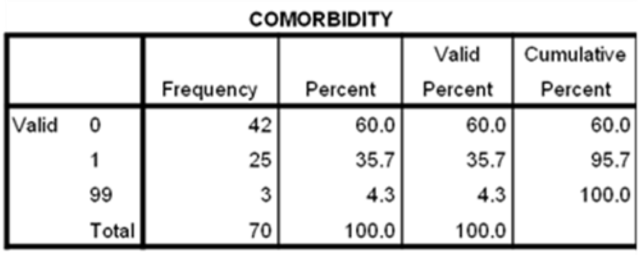


CARDIAC_ARREST_SIGN

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	35	50.0	50.0	50.0
	1	18	25.7	25.7	75.7
	2	14	20.0	20.0	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

0 No 1Yes 2N/A 99Unknown

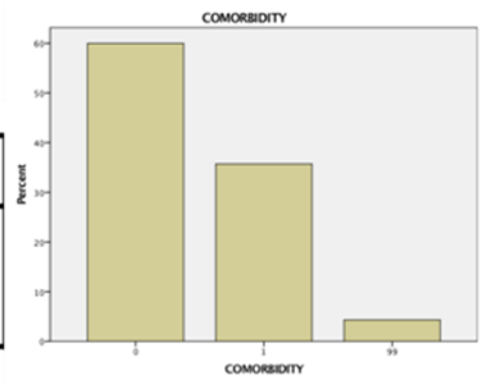




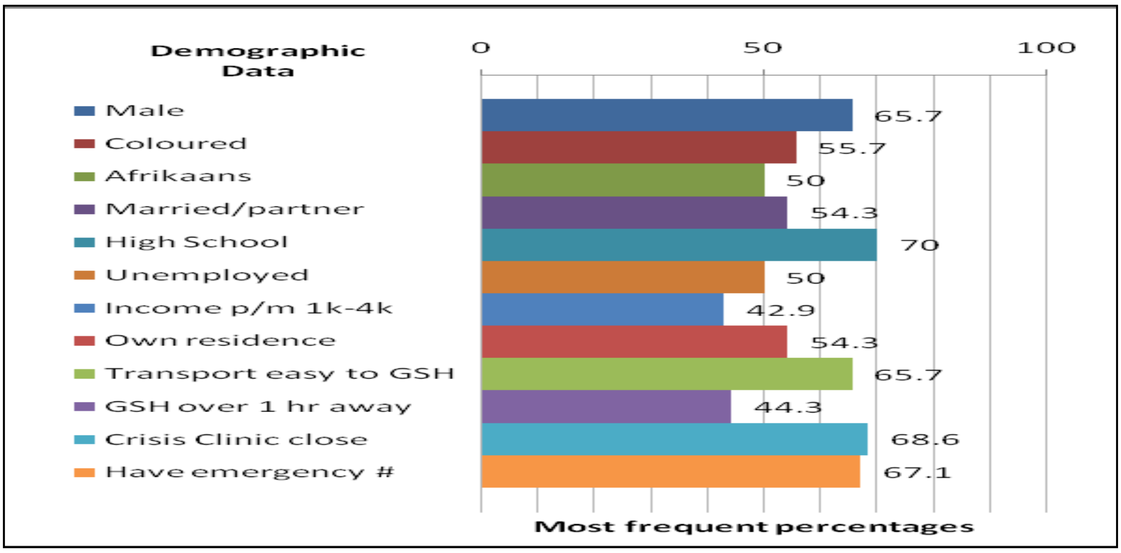
COMORBIDITY

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	42	60.0	60.0	60.0
	1	25	35.7	35.7	95.7
	99	3	4.3	4.3	100.0
	Total	70	100.0	100.0	

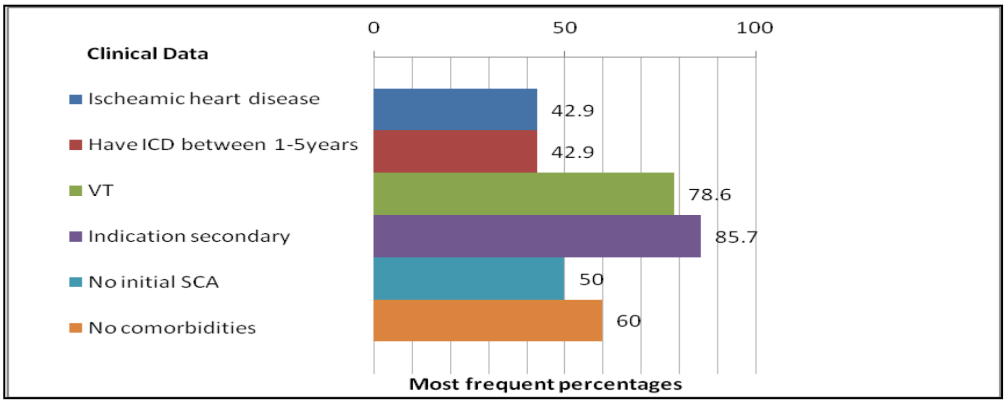
0No 1Yes 99Unknown



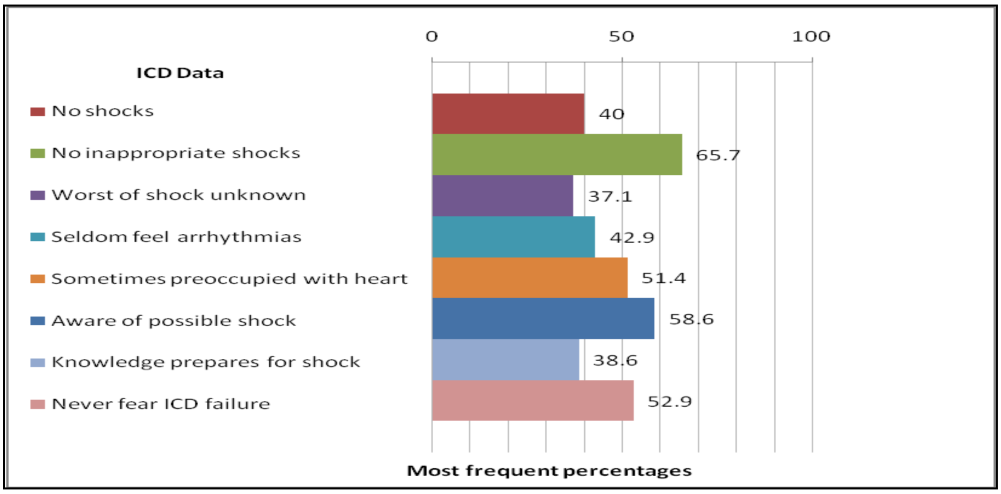
Bar Graph 1 Demographic Characteristics of total sample, n = 70



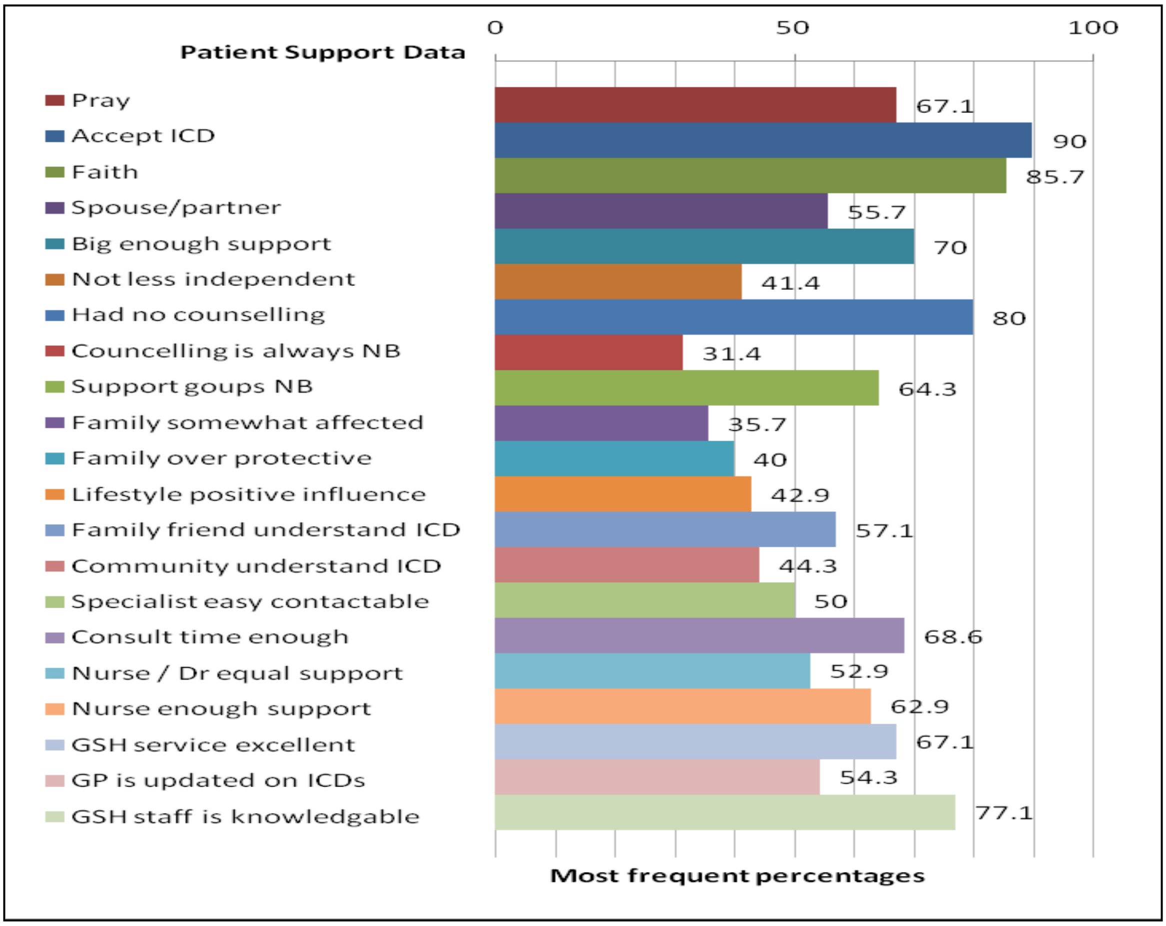
Bar Graph 2 Clinical Characteristics of total sample, n = 70



Bar Graph 3 ICD Characteristics of total sample, n = 70



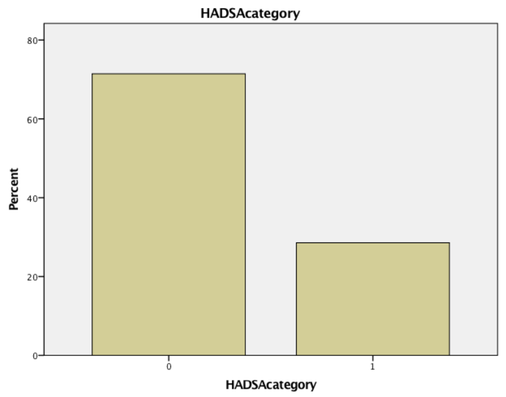
Bar Graph 4 Patient Support Characteristics of total sample, n = 70



Appendix – 1X HADS Results

Statistics HADS ANXIETY Category

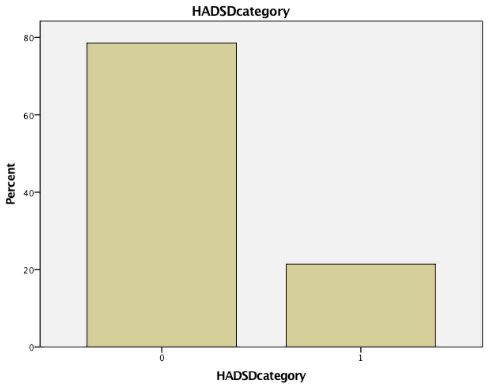
N	Valid	70
	Missing	0
Mean		.29
Std. Error of Mean		.054
Median		.00
Mode		0
Std. Deviation		.455
Variance		.207
Skewness		.970
Std. Error of Skewness		.287
Range		1
Minimum		0
Maximum		1
Sum		20
Percentiles	25	.00
	50	.00
	75	1.00



		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	50	71.4	71.4	71.4
	1	20	28.6	28.6	100.0
	Total	70	100.0	100.0	

Statistics HADS DEPRESSION Category

N	Valid	70
	Missing	0
Mean		.21
Std. Error of Mean		.049
Median		.00
Mode		0
Std. Deviation		.413
Variance		.171
Skewness		1.423
Std. Error of Skewness		.287
Range		1
Minimum		0
Maximum		1
Sum		15
Percentiles	25	.00
	50	.00
	75	.00



		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	55	78.6	78.6	78.6
	1	15	21.4	21.4	100.0
	Total	70	100.0	100.0	

Appendix - X SF-36v2 Results

SF-36 V2 Scale and Summary Measure Scores, Norm-Based Scoring

	Scales								Summaries	
	PF	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**	**PCS**	**MCS**
Mean	41.36	41.34	48.47	47.05	49.46	44.73	41.79	49.30	43.83	47.81
25th Percentile	34.57	34.70	38.21	38.92	43.69	37.29	35.28	43.02	38.08	39.90
50th Percentile (median)	42.23	39.19	49.10	48.43	49.63	47.31	38.76	50.87	44.37	48.23
75th Percentile	49.88	50.42	62.00	54.61	55.57	57.34	56.17	58.72	50.55	55.28
Standard Deviation	9.89	10.73	11.95	10.43	9.92	10.69	12.09	10.66	9.43	10.71
Min	19.26	21.23	21.68	26.08	28.83	17.23	14.39	24.71	18.46	23.51
Max	57.54	57.16	62.00	66.50	70.42	57.34	56.17	63.95	59.48	74.77
N	70	70	70	70	70	70	70	70	70	70

Table 2. SF-36 V2 Scale Scores, 0-100 Scoring (Transformed Scores)

	Scales							
	PF	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Mean	57.71	55.98	66.44	59.10	55.89	68.57	65.60	72.00
25th Percentile	40.00	37.50	41.00	42.00	43.75	50.00	50.00	60.00
50th Percentile (median)	60.00	50.00	68.00	62.00	56.25	75.00	58.33	75.00
75th Percentile	79.99	81.25	100.00	75.00	68.75	100.00	100.00	90.00
Standard Deviation	25.84	29.86	29.64	21.94	20.88	26.64	28.93	20.37
Min	0.00	0.00	0.00	15.00	12.50	0.00	0.00	25.00
Max	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
N	70	70	70	70	70	70	70	70

Item Descriptive Statistics - Raw Data

Scale = PF - Physical Functioning

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
PF01	1-3	0	0.0	47	19	4	0	0	0
PF02	1-3	0	0.0	21	25	24	0	0	0
PF03	1-3	0	0.0	20	26	24	0	0	0
PF04	1-3	0	0.0	27	28	15	0	0	0
PF05	1-3	0	0.0	7	32	31	0	0	0
PF06	1-3	0	0.0	12	31	27	0	0	0
PF07	1-3	0	0.0	19	26	25	0	0	0
PF08	1-3	0	0.0	10	23	37	0	0	0
PF09	1-3	0	0.0	8	21	41	0	0	0
PF10	1-3	0	0.0	3	13	54	0	0	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = RP - Role Physical

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
RP01	1-5	0	0.0	6	12	23	9	20	0
RP02	1-5	0	0.0	6	21	16	8	19	0
RP03	1-5	0	0.0	7	19	16	10	18	0
RP04	1-5	0	0.0	5	20	17	10	18	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = BP - Bodily Pain

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
BP01	1-6	0	0.0	25	12	13	11	8	1
BP02	1-5	0	0.0	28	12	17	8	5	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = GH - General Health

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
GH01	1-5	0	0.0	5	12	29	21	3	0
GH02	1-5	0	0.0	7	13	16	12	22	0
GH03	1-5	0	0.0	16	21	10	13	10	0
GH04	1-5	0	0.0	2	10	23	11	24	0
GH05	1-5	0	0.0	13	25	10	15	7	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = VT - Vitality

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
VT01	1-5	0	0.0	14	24	26	5	1	0
VT02	1-5	0	0.0	7	13	21	19	10	0
VT03	1-5	0	0.0	3	9	27	13	18	0
VT04	1-5	0	0.0	8	12	31	11	8	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = SF - Social Functioning

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
SF01	1-5	0	0.0	29	15	14	11	1	0
SF02	1-5	0	0.0	4	8	24	8	26	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = RE - Role Emotional

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
RE01	1-5	0	0.0	3	9	22	10	26	0
RE02	1-5	0	0.0	3	13	20	9	25	0
RE03	1-5	0	0.0	3	11	21	9	26	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Scale = MH - Mental Health

Item	Allowed Range	Missing		Response Value Frequency					
		Freq.	%	1	2	3	4	5	6
MH01	1-5	0	0.0	2	6	19	14	29	0
MH02	1-5	0	0.0	2	4	17	13	34	0
MH03	1-5	0	0.0	16	29	16	7	2	0
MH04	1-5	0	0.0	2	4	22	17	25	0
MH05	1-5	0	0.0	20	30	14	6	0	0
	Missing	0	0.0						
	Out-of-Range	0	0.0						

Notes:
1. Scale Percent Missing = Number Missing / Total Possible
2. Scale Percent Out-of-Range = Number Outside Allowed Range / Total Possible

Table 2. Multitrait/ Multi-Item Correlation Matrix

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = PF - Physical Functioning								
PF01	0.44*	0.16	0.24	0.22	0.22	0.10	0.12	0.01
PF02	0.58*	0.55	0.38	0.19	0.32	0.27	0.34	0.15
PF03	0.65*	0.42	0.27	0.28	0.17	0.13	0.22	0.07
PF04	0.68*	0.43	0.44	0.52	0.51	0.44	0.41	0.17
PF05	0.73*	0.54	0.42	0.48	0.46	0.35	0.36	0.25
PF06	0.55*	0.34	0.32	0.16	0.30	0.24	0.24	0.24
PF07	0.64*	0.32	0.46	0.37	0.42	0.33	0.23	0.12
PF08	0.83*	0.34	0.29	0.35	0.30	0.17	0.19	0.09
PF09	0.82*	0.27	0.29	0.31	0.30	0.20	0.12	0.06
PF10	0.59*	0.39	0.27	0.37	0.21	0.14	0.30	0.19

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = RP - Role Physical								
RP01	0.54	0.78*	0.50	0.54	0.50	0.41	0.69	0.37
RP02	0.36	0.81*	0.52	0.55	0.58	0.45	0.74	0.45
RP03	0.54	0.86*	0.49	0.41	0.46	0.31	0.66	0.31
RP04	0.44	0.82*	0.43	0.46	0.57	0.39	0.66	0.32

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = BP - Bodily Pain								
BP01	0.45	0.48	0.83*	0.48	0.61	0.57	0.39	0.46
BP02	0.45	0.55	0.83*	0.47	0.66	0.64	0.51	0.50

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = GH - General Health								
GH01	0.30	0.36	0.34	0.58*	0.41	0.31	0.41	0.38
GH02	0.29	0.48	0.55	0.40*	0.54	0.59	0.59	0.43
GH03	0.28	0.32	0.27	0.53*	0.33	0.23	0.38	0.26
GH04	0.27	0.29	0.14	0.36*	0.18	0.25	0.31	0.21
GH05	0.42	0.43	0.42	0.64*	0.48	0.34	0.36	0.31

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = VT - Vitality								
VT01	0.31	0.26	0.30	0.29	0.53*	0.44	0.37	0.36
VT02	0.26	0.32	0.44	0.38	0.50*	0.36	0.25	0.26
VT03	0.43	0.58	0.71	0.50	0.68*	0.48	0.48	0.52
VT04	0.37	0.61	0.55	0.52	0.51*	0.43	0.51	0.39

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = SF - Social Functioning								
SF01	0.28	0.37	0.51	0.44	0.46	0.55*	0.52	0.52
SF02	0.30	0.39	0.60	0.43	0.52	0.55*	0.49	0.49

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = RE - Role Emotional								
RE01	0.28	0.67	0.44	0.58	0.42	0.62	0.85*	0.66
RE02	0.36	0.74	0.48	0.58	0.56	0.50	0.84*	0.47
RE03	0.34	0.71	0.40	0.48	0.48	0.46	0.82*	0.46

Items	PF	RP	BP	GH	VT	SF	RE	MH
Scale = MH - Mental Health								
MH01	0.14	0.32	0.38	0.33	0.33	0.45	0.47	0.59*
MH02	0.16	0.27	0.34	0.34	0.36	0.39	0.42	0.64*
MH03	0.13	0.27	0.38	0.35	0.48	0.49	0.36	0.55*
MH04	0.12	0.31	0.38	0.33	0.38	0.46	0.45	0.74*
MH05	0.18	0.39	0.48	0.44	0.42	0.43	0.51	0.64*

Notes:
* Item-scale correlation corrected for overlap (relevant item removed from its scale for the correlation). Starred correlations are hypothesized to be highest in the row of correlations.

1. Poor convergent validity is indicated when items do not correlate .40 or higher with their hypothesized scale score.

2. Poor discriminant validity is indicated when items correlate significantly higher with competing scales than with their hypothesized scale.

Table 3. Item-Level Discriminant Validity Tests

	Scales							
Items	PF	RP	BP	GH	VT	SF	RE	MH
Scale = PF - Physical Functioning								
PF01	**	2	1	1	1	2	2	2
PF02	**	1	1	2	2	2	1	2
PF03	**	1	2	2	2	2	2	2
PF04	**	2	2	1	1	2	2	2
PF05	**	1	2	2	2	2	2	2
PF06	**	1	1	2	2	2	2	2
PF07	**	2	1	2	1	2	2	2
PF08	**	2	2	2	2	2	2	2
PF09	**	2	2	2	2	2	2	2
PF10	**	1	2	1	2	2	2	2

	Scales							
Items	PF	RP	BP	GH	VT	SF	RE	MH
Scale = RP - Role Physical								
RP01	1	**	2	2	2	2	1	2
RP02	2	**	2	2	1	2	1	2
RP03	2	**	2	2	2	2	1	2
RP04	2	**	2	2	2	2	1	2

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = BP - Bodily Pain								
BP01	2	2	**	2	1	2	2	2
BP02	2	2	**	2	1	1	2	2

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = GH - General Health								
GH01	2	1	1	**	1	2	1	1
GH02	1	-1	-2	**	-2	-2	-2	-1
GH03	2	1	2	**	1	2	1	2
GH04	1	1	1	**	1	1	1	1
GH05	1	1	1	**	1	2	2	2

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = VT - Vitality								
VT01	1	2	1	2	**	1	1	1
VT02	2	1	1	1	**	1	2	2
VT03	2	1	-1	1	**	1	1	1
VT04	1	-1	-1	-1	**	1	1	1

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = SF - Social Functioning								
SF01	2	1	1	1	1	**	1	1
SF02	2	1	-1	1	1	**	1	1

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = RE - Role Emotional								
RE01	2	1	2	2	2	1	**	1
RE02	2	1	2	2	2	2	**	2
RE03	2	1	2	2	2	2	**	2

	Scales							
Items	**PF**	**RP**	**BP**	**GH**	**VT**	**SF**	**RE**	**MH**
Scale = MH - Mental Health								
MH01	2	2	1	2	2	1	1	**
MH02	2	2	2	2	2	2	1	**
MH03	2	2	1	1	1	1	1	**
MH04	2	2	2	2	2	2	2	**
MH05	2	2	1	1	1	1	1	**

Notes:
Levels of Scaling Success Presented in the Table

2 = Item-scale correlation is significantly higher (2 standard errors or more) for hypothesized scale than for competing scale.

1 = Item-scale correlation is higher for hypothesized scale than for competing scale, but not significantly.

-1 = Item-scale correlation is lower for hypothesized scale than for competing scale, but not significantly.

-2 = Item-scale correlation is significantly lower (2 standard errors or more) for hypothesized scale than for competing scale.

Table 4. Scale Reliability and Homogeneity Estimates

Scale	k	Rtt	Rii
PF - Physical Functioning	10	0.899	0.471
RP - Role Physical	4	0.921	0.743
BP - Bodily Pain	2	0.892	0.805
GH - General Health	5	0.733	0.354
VT - Vitality	4	0.754	0.434
SF - Social Functioning	2	0.705	0.545
RE - Role Emotional	3	0.918	0.788
MH - Mental Health	5	0.832	0.497

Notes:
k = Number of Items
Rtt = Cronbach's Alpha.
Rii = Average inter-item correlation

THE END