Survival and health related quality of life of patients 12 months following discharge from an adult surgical intensive care unit

FARHANA KARACHI

BSc Physiotherapy (Cape Town)

Thesis presented in partial fulfillment of the requirements for the degree of Master of Physiotherapy at the University of Stellenbosch

STUDY LEADERS

Mrs Susan Hanekom

MSc Physiotherapy (Stellenbosch)

Mrs Mary Faure

NatDipPhysio (Cape Town) BA (Unisa) MPhil (UWC)

DECEMBER 2005

1

DECLARATION

"I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it for any degree or examination at any university. This study has been approved by the research Ethics Committee of the Faculty of Health Sciences, University of Stellenbosch, protocol number N04/05/092."

Signed by: _____ **Date:** _____

FARHANA KARACHI
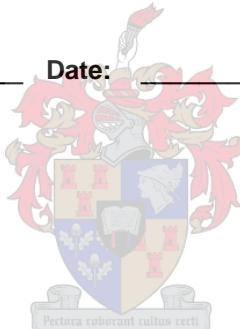
ABSTRACT

Objectives: This study forms part of a baseline study conducted on patients admitted to an adult surgical ICU between June and October 2003. The survival rate and health related quality of life (HRQoL) of patients 12months following ICU discharge was determined. The correlation of selected demographic and ICU variables to survival and HRQoL was determined. ***Design:*** Prospective observational cohort study. ***Setting:*** Ten-bed closed public tertiary adult surgical ICU. ***Patients:*** 180 subjects obtained from a previous baseline study. ***Measurements:*** The baseline study provided the demographic data and ICU variables. Survival rate was determined from a Kaplan Meier survival curve. A self-developed questionnaire was used to obtain other selected variables for comparison. A modified Short-Form 36 version 2 (SF-36v2) was use to measure HRQoL perceptions of patients. ***Results:*** The survival rate was 62% at 12 months following ICU admission. None of the selected variables were significantly correlated to the long-term survival outcome except for APACHE II which was negatively correlated to this outcome (p<0.01). Forty-six subjects took part in the HRQoL study. The mean HRQoL scores ranged between 43% and 53% for each of the SF-36 HRQoL domains. The physical functioning (43.5%), role play (44.5%) and role emotion (43.1%) domains had the lowest scores. APACHE II had a significantly negative correlation to the physical functioning domain of HRQoL (p=0.02). Age was positively correlated to social functioning (p<0.01) and role emotion (p=0.03). Patients employed after ICU had significantly higher scores for general health (p<0.01) than those who were not. Patients unsure of their TB status and HIV status had significantly lower scores in general health (p=0.02) and role emotion (p=0.05) respectively. ICU length of stay was negatively correlated to role play (p=0.05) and role emotion (p<0.01). Intubation period was negatively correlated to general health (p=0.04). ***Conclusion:*** APACHE II was the only variable significantly correlated to both long-term survival and the physical functioning domain of HRQoL. Although the long-term survival was comparable to that of international ICU populations the HRQoL outcomes were slightly lower. Similar to international studies and a South African study evaluating the HRQoL of aids sufferers and police, the current ICU population presented more limitation in the physical functioning, role play and role emotion domains of HRQoL.

ABSTRAK

Doelstellings: Hierdie studie vorm deel van 'n basislyn studie wat uitgevoer is op pasiënte wat toegelaat is tot 'n volwasse chirurgiese ISE tussen Junie en Oktober 2003. Die oorlewingskoers en gesondheidsverwante lewenskwaliteit [health related quality of life (HRQoL)] van pasiënte is bepaal 12 maande na ontslag uit die ISE. Die verband tussen geselekteerde demografiese en ISE veranderlikes met oorlewing en HRQoL is bepaal. ***Ontwerp:*** Prospektiewe observasie kohort studie ***Plek:*** Tien-bed geslote publieke tersiêre volwasse chirurgiese ISE ***Pasiënte:*** 180 deelnemers verkry vanuit 'n vorige basislyn studie

Metings: Die basislyn studie het die demografiese data en ISE veranderlikes voorsien. Die oorlewingskoers is bepaal met behulp van 'n Kaplan Meier oorlewingskurwe. 'n Self-ontwerpte vraelys is gebruik om ander geselekteerde veranderlikes vir vergelyking te verkry. 'n Aangepaste Short-Form 36 deel 2 (SF-36v2) is gebruik om die HRQoL persepsies van pasiënte te meet.

Resultate: Die oorlewingskoers was 62% 12 maande na opname in die ISE. Daar was geen beduidende verband tussen die geselekteerde veranderlikes en die oorlewings uitkoms, behalwe die APACHE II wat 'n negatief verband met die langtermyn oorlewings uitkoms (p<0.01) vertoon het. Ses-en-veertig deelnemers het deelgeneem aan die HRQoL studie. Die gemiddelde HRQoL tellings het gevarieer tussen 43% en 53% vir elk van die SF-36 HRQoL domeins. Die fisiese funksionering (43.5%), rolspel (44.5%) en rol emosie (43.1%) domeins het die laagste tellings getoon. APACHE II het 'n beduidende negatiewe verband getoon met die fisiese funksionering domein van die HRQoL (p=0.02). Ouderdom het 'n positiewe verband met sosiale funksionering (p<0.01) en rol emosie (p=0.03) vertoon. Pasiënte wat in diens geneem is na ISE ontslag het beduidend hoër tellings vir algemene gesondheid (p<0.01) behaal, teenoor dié wat nie in diens geneem is nie. Pasiënte wat onseker was oor hulle TB status en MIV status het beduidend laer tellings gehad ten opsigte van algemene gesondheid (p=0.02) en rol emosie (p=0.05) respektiewelik. Lengte van verblyf in die ISE het 'n negatiewe verband met rolspel (p=0.05) en rol emosie (p<0.01) vertoon. Intubasie periode het 'n negatiewe verband met algemene gesondheid (p=0.04) vertoon. ***Gevolgtrekking:*** APACHE II was die enigste veranderlike wat 'n beduidende verband met beide langtermyn oorlewing en die fisiese funksionering domein van HRQoL vertoon het. Alhoewel die langtermyn oorlewing vergelykbaar was met dié van internasionale ISE populasies, was die HRQoL uitkomste effens laer. Soortgelyk aan internasionale studies en 'n Suid-Afrikaanse studie wat die HRQoL van VIGS lyers en die polisie evalueer het, het die huidige ISE populasie meer beperking getoon in die fisiese funksionering, rolspel en rol emosie domeins van HRQoL.

ACKNOWLEDGEMENTS

The author would like to express her gratitude and sincere appreciation for and acknowledge the following people for their continuous support, encouragement, patience, sacrifice, guidance and advice during the completion and writing up of this research study:

STUDY LEADERS

Mrs S Hanekom: MSc Physiotherapy (Stellenbosch)

Mrs M Faure: NatDipPhysio (Cape Town) BA (Unisa) MPhil (UWC)

STATISTICIAN

Dr Martin Kidd: Statistician, Centre for Statistical Consultation, US

PHYSIOTHERAPY DEPARTMENT TYGERBERG HOSPITAL

The staff of the Physiotherapy Department Tygerberg Hospital

PHYSIOTHERAPY DEPARTMENT UNIVERSITY OF STELLENBOSCH

The staff of the Physiotherapy Department of the University of Stellenbosch

THE PATIENTS

For partaking in this study

MY FAMILY

My Parents (Abdul Hamid and Amina Karachi) and my sisters (Ayesha and Rubeena)

SPECIAL FRIENDS AND COLLEAGUES

Mr MS Soeker: MSc Occupational Therapy UWC

Ms M Bakardien: BSc Physiotherapy UCT

Dedicated to my family, friends, colleagues and patients

TABLE OF CONTENTS

CHAPTER 5: RESEARCH ARTICLE

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

CHAPTER 1

Introduction

The rapid development of the intensive care specialty during the past few decades has not been accompanied by adequate evaluation of outcome after such care (Eddleston et al 2000). While intensive care unit (ICU) survival rates are well documented, health care professionals must now begin to question whether services are having an impact on the long-term health and well being of individuals who consume these services. Importantly, advances in technology and medical therapies have resulted in more patients surviving ICU, many of who then require on going community and rehabilitative services (Chaboyer & Elliot 2000). It is therefore insufficient to evaluate patient outcome after intensive care by means of survival only as quality of life must be examined.

The measurement of quality of life (QoL) after intensive care is not common practice (Buckley et al 2001). In contrast to the amount of data relating to the effect of ICU care on survival, the evaluation of quality of life outcomes after ICU care has been scarce (Granja et al 2002). Few studies could be found relating to the long-term survival and quality of life outcomes following surgical intensive care treatment in South Africa, and specifically the Western Cape.

In the Western Cape, the Department of Health has produced a strategic plan for the re-shaping of public health services. This initiative, Healthcare 2010 Service Delivery Plan, maps a way forward with the aim of substantially improving the quality of care of the health service and simultaneously bringing expenditure to within budget (Househam 2003). Based on the primary health care approach, Healthcare 2010 proposes a shift of patients to more appropriate levels of care with commensurate cost savings (Househam 2003). Healthcare 2010 is built on the restructuring plans that were begun in 1994. Quality care at all levels, cost-effectiveness, accessibility of care, efficiency, primary healthcare approach, collaboration between all levels of care and de-institutionalization of chronic care are the underlying principles of Healthcare 2010. In the Healthcare 2010 Service Delivery Plan, the shape of the service platform that results from the application

of the conceptual model is that 90% of patient contacts should occur at primary level, 8% at secondary level and 2% at tertiary level (Househam 2003). Assessing the quality of life outcomes of surviving ICU patients may help in determining the rehabilitative and cost requirements in the secondary and primary levels of care that are needed by these patients following intensive care.

There is therefore increasing pressure for outcome evaluation of intensive care to incorporate assessment of long-term survival and the quality of life (QoL) in ICU survivors (Buckley et al 2001). According to Capuzzo et al (2000) there is a need for patients to know if and how critical care will change their quality of life. Doctors and nurses as well as allied health professionals, need to know what the long-term effects of their treatments in ICU are (Capuzzo et al 2000). This knowledge may aid in the implementation of appropriate post ICU follow-up that may assist in improving patient outcomes and quality of life as required. As evidence-based practice is becoming increasingly important (Mishoe & Maclean 2001), outcome-based questionnaires regarding quality of life especially post intensive care should be used in the intensive care setting. In this way appropriate rehabilitation programs may be developed and implemented and intensive care patients may be treated more holistically.

Assessment of patient outcome after intensive care will become essential if we are to justify the current level of financial investment in this specialty (Eddleston et al 2000). "…A better understanding of how this expensive service affects the health and well being of its survivors will allow nurses and other health care professionals to plan for and provide appropriate follow-up care…"] (Chaboyer & Elliot 2000:88).

The cost of intensive care and the limited resources available raises questions about the utilization of such resources. The rising cost of intensive care has also prompted questions concerning the benefit of intensive care and correspondingly, has motivated the evaluation of intensive care outcome (Granja et al 2002). Although ICU services are acknowledged as some of the largest consumers of hospital resources, little scrutiny of the effect of these services has taken place in the past. Bed allocation in ICU is often related to bed availability, a practice that has recently been challenged by health care

ethicists who suggest that patient outcomes beyond simple survival are important considerations in the utilization of these expensive services (Chaboyer & Elliot 2000).

In South Africa (SA), ICU resources are extremely limited in terms of medical equipment and the availability of beds, and yet the demands are potentially greater than in first world countries (Michell 2005). This is because of the high incidence of severe trauma and infectious diseases in SA (Michell 2005; http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf). This limitation in resources and the increasing costs and admission demands on these ICU's raises questions as to which patients should be admitted and whether the specialty is effective and efficient in terms of long-term outcomes. Thus in South Africa there is also a need for long-term survival and quality of life outcome evaluation of patients following treatment in these ICU's. This may contribute to the debate regarding the effect of ICU on long-term outcomes and may provide information which may be used to set up evidence-based guidelines for ICU admission in South Africa (Michell 2005).

The 2002 Brussels Roundtable consensus conference highlighted questions regarding whether intensive care survivors have optimal long-term outcome and whether ICU care decisions would change if more was known about these outcomes. They recommended that future clinical trials of ICU therapies should include long-term follow-up of survival, quality of life, morbidity, functional status and costs of care (Angus & Carlet 2003).

To ensure that health care professionals remain part of the decision-making process in relation to health care policy, accurate data on the burden of illness and injury and the impact of health care services are needed to develop position statements (Chaboyer & Elliot 2000). Michell (2005) stated that South Africa needs to make a start at developing written, accessible and evidence-based guidelines for ICU admission.

1.1 Quality of Life (QoL)

Illness and injury can have profound effects on a person's quality of life (Mishoe & Maclean 2001). In addition to relieving symptoms and prolonging survival, a primary objective of any health care intervention is the enhancement of quality of life and well-

15

being. For those individuals diagnosed with a chronic condition where cure is not attainable and therapy may be prolonged, quality of life is likely to be the essential outcome (Staquet et al 1998).

The World Health Organization (WHO) described health as a "…state of complete physical, mental and social well-being and not merely the absence of disease or infirmity…" (Mishoe & MacClean 2001:1237). For the purpose of clinical trial research health related quality of life (HRQoL) is more specific and appropriate. HRQoL refers to the patients' appraisals of their current level of functioning and their satisfaction with their HRQoL compared to what they perceive to be ideal. The concept therefore, can be considered synonymous with subjective health status assessment and points to those aspects of a person's life that are affected only by health care interventions (Staquet et al 1998). HRQoL results from the overlapping of health status with those non-medical aspects influencing well-being. According to this concept, QoL should describe the sum of persons' physiological and psychological functions, their capacity for meeting their social needs and their own perception of their situation. Thus, the instrument to measure QoL should include these aspects. In addition the QoL instrument has to be suitable for the purpose of the study to be performed, the population and the circumstance where it has to be used. In an ICU setting, the instrument should be generic, to be used in patients with different illnesses, sensitive to changes realized at an already restricted level and simple, that is not too long or difficult (Capuzzo et al 2000).

1.2 Health Related Quality of Life Outcome Measures

The purpose of a health related quality of life instrument is not merely to measure the presence and severity of symptoms of disease, but also to show how the manifestation of an illness or treatment are experienced by an individual. Health related quality of life can be assessed with health profile (descriptive) questionnaires that are either generic or specific. A health profile instrument is a health status questionnaire, which measures different aspects of health related quality of life and well-being defined across multiple health domains or areas that the patient has identified as being important. Each domain is represented by a separate scale and calculated data from each scale, produces a separate numerical value or score that is un-weighted (Staquet et al 1998).

16

The 2002 Brussels Roundtable consensus conference reported that the EuroQoL EQ-5D and the Short Form-36 (SF-36) are the best suited instruments for measuring quality of life in a critical or intensive care setting (Angus & Carlet 2003). The SF-36 is the most recently developed HRQoL measure (Ware 2004).

The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) was developed using factor analysis from the much longer batteries of items used in the RAND Corporation's health insurance study experiment (Ware 2004). It is one of the most widely used health related quality of life measures in medical outcome studies today and has been included in over 500 clinical trials (Staquet et al 1998). The SF-36 has been translated for use in more than 40 other countries. Numerous studies have shown that the SF-36 is psychometrically sound and applicable to a range of settings and has become an industry standard in the United States (Mishoe & Maclean 2001). The SF-36 is classified as a profile health related quality of life measure because it yields scores for multiple domains of health related quality of life. It is a 36-item instrument for measuring health status and outcomes from a patients' point of view. It is designed for use in surveys of general and specific populations, health policy evaluations, and clinical practice and research. The instrument takes less than 10 minutes to complete and can either be self-administered by people 14 years of age or older, or administered by trained interviewers either in person or by telephone (Ware 2004). Chrispin et al (1997) reported that the SF-36 is a valid and reliable instrument that may be used in the ICU setting.

1.3 Physiotherapy and HRQoL outcomes of ICU Patients
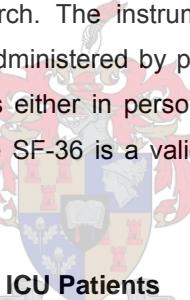
The precise role of the physiotherapist in the ICU varies in different units. This has led to a lack of standardization regarding the role and responsibilities of the physiotherapist in the ICU setting. However, the physiotherapist is still regarded as an integral part of the multidisciplinary team involved in the management of patients in the ICU (Stiller 2000). According to Nava & Ambrosino (2000) the only way for physiotherapists to convince administrators of the value of physiotherapy in ICU, is to report on patient-centered outcomes. HRQoL is one of these patient-centered outcomes. It is thus essential that physiotherapists determine the effect of their treatments in ICU on long-term quality of

17

life outcomes as this may help to determine whether physiotherapy is of more consequence in the ICU setting or at a later stage following intensive care treatment.

1.4 Available Evidence

The most common determinant of ICU outcome studies is survival however recently focus has been on the long-term survival outcomes of ICU patients. Many studies in South Africa have focused on survival outcomes in ICU and not looked at long-term survival and QoL outcomes following discharge (Michell 2005). Quality of life assessments have occurred infrequently in the ICU literature and are of limited methodologic quality (Heyland et al 1998). Therefore more studies using valid and reliable instruments are necessary to document long-term quality of life of critically ill patients especially those at risk of a poor outcome (Heyland et al 1998). No studies could be found regarding the long-term quality of life as measured by the SF-36 of adult surgical intensive care unit survivors in South Africa (refer to Chapter 2, pages 11-12). According to the 2002 Brussels Roundtable consensus conference quality of life outcomes need to be focused on (Angus & Carlet 2003). Dowdy et al (2005) state that with more patients surviving ICU, QoL outcomes have become a research priority. Thus the aim of this study was to determine the survival and health related quality of life after stay in an adult surgical intensive care unit at a tertiary academic hospital in the Western Cape, South Africa.

1.5 The setting
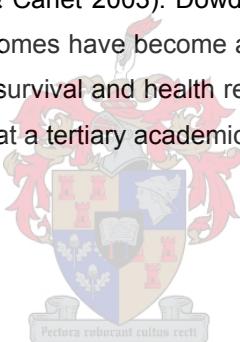
The Western Cape has a unique environment and a specific health profile which may impact on long-term survival and HRQoL outcomes.

According to the data from the Strategic and Service Delivery Improvement Plan (SSDIP) Provincial Government of the Western Cape Department of Health Draft Paper (2000), tuberculosis is the predominant communicable disease in the Western Cape. The province has the highest TB rates nationally and is amongst the highest in the world. The rising HIV epidemic is likely to augment the burden of TB, as evidence shows

that 15-20% of TB patients are HIV-infected. TB and HIV may have a significant effect on long-term survival and the physical and emotional domains of HRQoL outcome.

Besides these underlying pathologies, the most common causes of mortality in the Western Cape are intentional and unintentional injuries (Hanekom 2004). The injuries sustained, in this violent community are often times excessive and multifaceted. In the sample population obtained from the baseline study by Hanekom (2004) it was found that approximately 30% of the sample population admitted to this adult surgical ICU had sustained injuries due to violence. This may be a significant determinant long-term survival and HRQoL outcomes.

In addition, 52% of South African males and 17% of women over 18 years of age were reported to smoke in 1996. In the Western Cape 45% of women smoke compared to the national rate of 17% with the highest rates being amongst colored women, almost reaching 60% (Hanekom 2004). These factors may affect the general health, social and mental components of HRQoL outcome.

There is a 30% unemployment rate and 40% of South Africans live in poverty. Furthermore, 75% of the population live in rural areas where they are deprived of health services (http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf). This may also have an influence on long-term survival and HRQoL outcomes.

The surgical ICU is based in a tertiary academic hospital that is situated in the Western Cape. It has 1385 beds of which 10 make up the SICU (A1West). The hospital serves the Northern Suburbs of the City of Cape Town and the Winelands District (Stellenbosch, Paarl and Malmesbury). Surgical elective and surgical emergency patients as well as all trauma patients (except burns) requiring intensive support or monitoring are admitted to this ICU. Patients once stable in the unit, are discharged first to the appropriate wards and then home. As many of these patients may have economic, educational and social problems their HRQoL outcomes may be affected.

1.6 Significance

This study aims to provide information on the long-term survival rate and HRQoL of subjects 12 months following discharge from an adult surgical ICU in the Western Cape, South Africa. It will contribute to the discussion on the use of outcome evaluation after intensive care treatment and will provide information about the effectiveness of medical interventions by medical professionals in the ICU. Physiotherapy is seen as an integral part of the management of patients in an ICU (Stiller 2000). This study may add to the discussion in assisting to identify the physiotherapists' role in improving patient outcomes following ICU especially in the physical functioning aspect of HRQoL by improving rehabilitation programs offered.

1.7 Structure of Masters Thesis

The thesis is a follow up to a previous baseline study conducted by Hanekom (2004) in the same intensive care unit. It is presented in the form of six chapters, two of which will be in article format. This structure has the following implications:

- In order to demonstrate clarity and rigor to the complete thesis the articles are detailed. This has led to repetition in the introduction, methodology and discussions. This was also necessary so that the articles could be independent documents. Thus the articles are much longer than would be accepted for publication by any journal. However they will be revised before submission for publication.

- The methodologies described in Chapters 4 and 5 are only relevant to the data that is reported in the specific article. The entire methodology including all the data extraction sheets, questionnaires and approval or consent letters will therefore be described in Chapter 3.

- The bibliography of each of the two articles and the comprehensive bibliography included in this Master's Thesis are based on a modified Harvard system as prescribed by the Department of Physiotherapy, University of Stellenbosch. This

will be modified as necessary on submission of the articles to the various journals.

The structure of this Masters Thesis is as follows:

Chapter 2: Literature Review
This is represented as one chapter reviewing all the literature found.

Chapter 3: Methodology
This chapter contains a detailed account of the methodology used in this follow up study.

Results and Discussion
The results of the study and the discussion of the results are presented as two independent articles. Each of these articles is presented in a different chapter.

Chapter 4: Survival 12 months following adult surgical ICU admission

Chapter 5: Health Related Quality of Life 12 months following adult surgical ICU discharge

Chapter 6: Conclusions and Recommendations

CHAPTER 2

Literature Review

2.1 Introduction

The rapid development, increasing expense and demands of intensive unit care has initiated a growing concern regarding the effects and benefits of such care as the long-term outcomes have not been adequately evaluated (Lipsett et al 2000, Eddleston et al 2000, Dowdy et al 2005).

The initial goal of intensive care was to decrease short-term mortality. This goal however fails to address the issue of what it means to survive intensive care for patients and relatives. Whether surviving intensive care has optimal long-term outcomes and whether ICU care decisions would change if more was known about these outcomes are key questions being asked according to Angus & Carlet (2003) reporting on the 2002 Brussels Roundtable Consensus Conference. Angus and Carlet were the two co-chairs of this Roundtable.
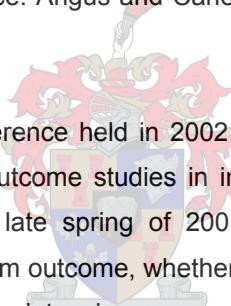
The Brussels Roundtable consensus conference held in 2002 has provided a base or foundation from which to conduct future outcome studies in intensive care. The 2002 Brussels Roundtable was chaired in the late spring of 2001. Key questions about whether ICU survivors have a good long-term outcome, whether these outcomes are the best results from intensive care and whether intensive care would change if more were known about these outcomes were outlined. A syllabus with a list of speakers was developed by the chair people of this Roundtable. The syllabus was divided into four sessions: the natural history of critical illness, the predictors and modifiers of long-term outcomes, future research issues and approaches to improve long-term outcomes. In the fall and summer of 2001 speakers were invited and given instructions and details regarding their proposed topic. Each speaker was asked to prepare a manuscript and a 20 minute oral summary. Speakers had to include a systematic review. The manuscripts were circulated to all participants before the Roundtable. In March 2002 the Roundtable

was held over two days in Brussels where each participant presented his/her topic followed by a 30 minute discussion. After the four sessions a further discussion took place discussing the key themes emerging from the session. At the end of the Roundtable presentation and resulting discussions of common themes the key points were presented at the Opening session of the 22nd International Symposium on Intensive care and Emergency Medicine. Following this the manuscripts were revised in accordance with the thoughts and comments raised during the Roundtable and resubmitted to the two chairs. The entire collection of manuscripts was published after any further feedback and critique and summarized in an article by Angus and Carlet (2003). The Brussels Rountable recommended that long-term outcomes following ICU need to be evaluated as research in this area is minimal (Angus & Carlet 2003).

2.2 Search for Available Evidence

A literature search was conducted in order to obtain evidence regarding long-term survival and health related quality of life outcomes and factors related to these outcomes in surgical ICU survivors' particularly in South Africa as well as in international countries.

Electronic databases were searched. These included PubMed/Medline, EBScho Host, CINAHL, SA ePublications, South African Studies, Science Direct and Cochrane Library.

The following limits were set for these data bases:
- 1 January 1995 – 30 September 2005
- Human.
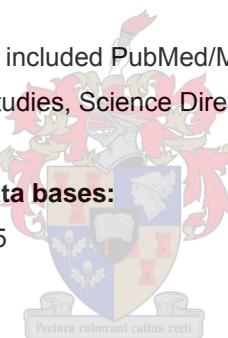
The following search words were used:
Quality of life, health status, health related quality of life, surgical intensive care, survival, predictors, admission criteria, outcomes, South Africa and short form-36.

Combinations of these words were used in order to refine the search in each electronic database. When searching PubMed/Medline specifically the following combinations of words were used and the following hits were found:

23

surgical intensive care + admission criteria	265 hits
predictors + surgical intensive care + survival	106 hits
health related quality of life + short form-36 + surgical intensive care	8 hits
predictors + surgical intensive care + health related quality of life	4 hits

Adding the words South Africa to the above searches resulted in 0 hits in this database as well as when used in searching the other electronic databases mentioned.

The references of retrieved articles were screened and the relevant articles were obtained.

Other relevant journals were hand-searched from 1990 – 2005 for relevant articles as follows:

Journal of public health medicine
SA Journal of Physiotherapy and the
Australian Journal of Physiotherapy

Internet websites were searched to obtain related information to the topic. These included the following:

http://www.sf-36.com.

http://www.csvr.org.za/papers/papstres.htm

http://www.atsqol.org/key.asp

http://www.outcomes-trust.org/instruments.htm

http://www.atsqol.org/nott.asp

http://www.qualitymetric.com/products/CompareSFSurveys.shtml

http://www.hqlo.com/content/1/1/2

http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf

http://www.sf-36.org/tools/SF-36.shtml

All were visited during the period of 2004 and 2005, for specific dates visited refer to comprehensive reference list.

2.3 Survival

With the improvement of medical technologies in intensive care units, intensive care has been able to prolong lives thereby increasing the survival rates of ICU populations (Eddleston et al 2000, Rubenfeld & Curtis 2003). Many studies have focused specifically on survival outcomes in ICU (Hariharan et al 2002, Parikh et al 1999, Beck et al 1997) and according to Eddleston et al (2000) this has been the most common determinant measured in ICU outcome studies. However, Angus & Carlet (2003) reported that ICU outcome studies should include prolonged follow-up for survival.

Long-term survival or cumulative survival rate are used interchangeably to report the percentage of patients alive over a given period of time for example 3, 6 or 12 months. Mortality refers to the number of patients who have died at a specific point in time (Rubenfeld et al 1999). Although at first glance survival seems fairly easy to measure, in practice it is well recognized that any cohort of ICU patients will exhibit a cumulative survival over time (Rubenfeld et al 1999). Survival curves are used to measure survival over a period of time. The survival curve for the general population plateaus at a specific period in time. Survival curves for intensive care populations also reaches this plateau however the time taken for these survival curves to reach this plateau or parallel the plateau reached by the survival curve of the general population is unclear (Eddleston et al 2000).
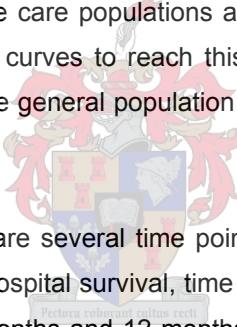
Although death is a clear endpoint, there are several time points from which it can be measured. It can be measured as ICU or hospital survival, time until death or death at a fixed end point for example 3 months, 6 months and 12 months. The end point chosen depends on the specific research question, the mechanisms and timing of the disease and/or treatment under study, and the study design. With each end point chosen for survival assessment, certain important general aspects need to be considered.

The interpretation of the survival endpoints may be changed by practice and referral patterns within a specific ICU. The transfer of ventilator-dependant patients directly from an ICU to a long-term care facility can reduce the hospital mortality. Although survival to a fixed point can avoid this problem, careful consideration of the selection of time points

is required. Depending on disease processes, the length of stay in an ICU may be longer than a month (30 days) and thus 30-day survival may not be as useful a measure. However one year survival may avoid this problem but may also only reflect the patient's underlying disease prognosis more than the effectiveness of ICU care. The Brussels Roundtable held in 2002 suggested a prolonged follow-up of ICU survival of at least 6 months and ideally longer (Angus & Carlet 2003).

Survival analysis techniques use the actual survival time as the endpoint. As survival time is a continuous variable, it is a more sensitive outcome measure than mortality. According to Rubenfeld et al (1999), although survival analysis is potentially useful for investigators in identifying promising treatments for further study, it is unlikely that these represent meaningful outcomes to patients as treatment that prolongs time to death without affecting morbidity could do more harm than good.

Survival outcomes whether in ICU or following discharge may depend on certain admission criteria followed by different units. For example in South African state hospitals where intensive care beds are extremely limited, ethical issues regarding who should receive life support in terms of mechanical ventilation are being discussed or questioned. Hospital administrators are calling for admission policies however it is difficult to develop these as few finite clinical criteria reliably predict death. Intensivists have been controlling decisions regarding ICU admissions and therefore have been able to reduce ICU mortality and improve cost-effectiveness in 'closed' intensive care units. However making these kinds of decisions are no longer that simple and recent concepts in bioethics now require end-of-life decisions to be based on clear guidelines, justified by evidence and open to scrutiny with some degree of public participation and an element of appeal and accountability to ensure that the decision making process is being applied fairly and consistently (Michell 2005).

Van der Merwe et al (2005) reported on outcome prediction of the APACHE II score in a South African tertiary public ICU. This provides some local data on ICU outcome. Although this paper represents the achievement of internationally acceptable mortality rates however the mortality in some patient categories are surprisingly high which may indicate a tendency to admit too many patients who cannot be salvaged by the ICU.

Another reason could be that tertiary hospitals in the Western Cape receive a high proportion of transfers from secondary level hospitals and ICU's. This category of patient has recently been reported to be the cause of higher than predicted mortality. This paper unfortunately does not report on the effect of ICU length of stay as it is the patient who dies after prolonged ICU stay that unnecessarily consumes a disproportionate amount of scarce resources (Michell 2005). Michell (2005) further states that a start needs to be made at developing written accessible and evidence-based guidelines for ICU admissions in South Africa. Thus before we can develop these we need to record baseline ICU data and determine which of these variables predict positive long-term outcomes. Besides this baseline data, information regarding whether patients are surviving in long-term also need to be known (Michell 2005).

2.4 Determinants and outcomes of long-term survival

Patient and intensive care unit factors determining long-term intensive care outcomes have presented investigators with unique challenges as there is little systematic guidance for measuring these outcomes and factors affecting these outcomes within the ICU setting (Needham et al 2005). Various studies have measured the effects or association of different patient and ICU variables on survival outcome.

Dowdy et al (2005) reported that the most commonly measured survival predictors besides patient demographics are severity of illness (APACHE II) (57 studies), admission diagnosis (54 studies) and length of stay (42 studies). Clinical management including physician interventions was considered in 35 studies and 14 studies measured laboratory data. None of the 70 cohort studies reviewed by Dowdy et al (2005) measured ICU organizational factors and ICU volume.

Studies by Rockwood et al (1993), Chelluri et al (1993), Fakhry et al (1996), Capuzzo et al (1996), Lipsett et al (2000), and Eddleston et al (2000) were among the most recent found that determined long-term survival of ICU patients following ICU discharge. These are all international studies as no study could be found evaluating the one-year survival outcome in a cohort of surgical ICU patients. Michell (2005) reported that in South Africa studies determining long-term survival outcomes 6 months to a year later are needed.

However to gather this kind of data is beyond the resources of most state ICU's in South Africa.

Rockwood et al (1993) reported on the one year survival outcome of intensive care patients over and under the age of 65 years old. A prospective study was undertaken and a sample of convenience (n=1040) was obtained of which 145 were lost to follow-up. Demographic, case-mix and severity data were collected. ICU length of stay was also recorded. The demographic and severity data for both age groups were similar. They reported a one year survival rate of 51% of patients more than 65 years old and 69% of patients less than 65 years old. It was concluded that although elderly patients had a significantly lower survival rate than younger patients, age was not a major contributor to the variance in outcome. Long-term survival is most strongly predicted by APACHE II, length of stay, prior ICU admission and respiratory failure (Rockwood et al 1993).

Chelluri et al (1993) evaluated the long-term mortality of critically ill elderly patients requiring intensive care. They conducted a prospective study comparing the outcome of critically ill patients aged 75 years and older with patients aged 65 – 74 years. Ninety-seven patients were included in the study of which 54 were aged 75 and over and 43 who were aged between 65 and 74 years of age. There was no significant difference between the length of stay, gender, APACHE II, Acute Physiology Score (APS), Therapeutic Intervention scoring system (TISS) and one year mortality between the two groups. They reported that age was not a reliable marker as an independent predictor of long-term survival outcome. However severity of illness as measured by the APACHE II score was reported to be a better predictor of long-term survival outcome than age. A 39% long-term survival rate was reported in this study.

Fakhry et al (1996) evaluated the effect of prolonged ICU length of stay of more than 14 days on long-term (18 months) survival outcome in an adult surgical ICU. They identified 83 patients who spent over 14 days in the ICU of which 62 survived ICU discharge and 52 survived hospital discharge. A mail and telephonic survey was conducted in order to collect detailed follow-up information. Follow-up time ranged from 4 – 30 months. A sample of 39 patients was obtained. Long-term survival was documented in 30 of the 39

patients. They also were able to determine the survival data but no other data for a further 8 patients of which 7 were alive at 13.3 months resulting in a 50.2% survival rate. Thus the resultant long-term survival rate was 44.5% (37 out of 83). No correlation was found between ICU length of stay and long-term survival. The surviving patients actually had a longer average length of stay than those who had died. Of the patients who died during the follow-up period, all were older than 53 years. The study also showed a significant decrease in long-term survival with an increased age of more than 65 years. According to Fakhry et al (1996) this finding was similar to that found ten years prior by Fedullo and Swinburne (1983).

Capuzzo et al (1996) evaluated the long-term survival outcome of all consecutively admitted ICU patients more than 18 years old who stayed in the ICU for more than 24 hours. A population of 328 patients was used. Determinants of survival recorded were demographics, type of ICU admission, simplified acute physiology score (SAPS II), APS and APACHE II Scores. They also identified underlying diseases grouped according to organ systems, as well as medications, complications during ICU course and ICU treatment procedures such as blood transfusions and mechanical ventilation of more than three days. They reported that 37 died in ICU and 31 died in hospital after ICU discharge. Therefore 260 patients were followed for a year after discharge. The cumulative survival rate at 12 months was 82.4%. The ICU admission type or diagnosis was significantly related to survival. No trauma patients died. Patients admitted to ICU after elective surgery for neo-plastic disease had a lower survival rate than patients with non-neoplastic disease. Those admitted to ICU after emergency surgery for neo-plastic disease also had a lower survival rate than non-neoplastic cases. Medical patients had an even lower survival rate than patients with neo-plastic disease. The one year survival rate was higher in patients without underlying diseases than those with one or more underlying diseases. Mechanical ventilation did not affect the one year survival rate.

Lipsett et al (2000) evaluated the long-term outcome of all patients in a surgical ICU with a continuous length of stay of greater than 6 days admitted to a 16-bed tertiary surgical ICU. Determinants of long-term survival such as demographics, diagnosis, APACHE II score on ICU admission and charge data were collected. A population of 128 patients was used. Fifty-three patients did not survive until hospital discharge with the majority

dying in the ICU and of the 75 patients alive after discharge 58 were still alive at one year. Thus during the period of one year, a further 17 had died due to prolonged surgical illness. In this population non-survivors had a significantly higher APACHE II score than survivors. Patients with an APACHE II score of 30 or more had a dismal one year survival rate. Diagnosis groups significantly affected one year survival outcome. However after multivariate regression analysis with age, sex, length of stay, APACHE II and diagnosis groups, only an elevated APACHE II score remained a significantly negative predictor of long-term survival.

Eddleston et al (2000) evaluated the one-year survival outcome of consecutive patients more than 17 years old discharged from a surgical ICU. A population of 370 patients was used. Determinants of survival such as age, gender, admitting specialty, APACHE II Score and ICU length of stay were collected. During ICU stay 107 patients died and a further 36 died within three months of discharge from ICU of which 30 occurred within hospital before discharge. Ten patients died within 3 and 6 months and five within 6 to 12 months. Therefore at 12 months following ICU discharge there was a cumulative survival rate of 57%. They did not report on the factors influencing long-term survival outcome.

The outcomes of these studies have shown that the determinants of long-term survival differ among ICU populations studied and therefore these determinants must be considered when evaluating long-term survival outcomes for different groups of ICU populations. Even though more patients are surviving at 12 months following discharge, we need to now question whether ICU services are having an impact on the long-term health and well-being of individuals' who consume these services (Chaboyer & Elliot 2000). In South Africa there is also a need to know whether patients surviving ICU are not just surviving but are going home and enjoying fulfilling lives six months or a year later (Michell 2005).

2.5 Moving beyond Survival

The increase in patients surviving ICU results in increased patients requiring ongoing community and rehabilitative services (Chaboyer & Elliot 2000). As health professionals

providing both acute and follow-up care, we need to consider how patients' changing health status impacts on their quality of life and on the types of problems and needs ICU survivors bring home with them (Chaboyer & Elliot 2000).

Dowdy et al (2005) state that despite the rapidly growing body of literature, previous reviews of HRQoL in ICU survivors have been descriptive or methodological, and have not broadly synthesized research findings. Specifically no systematic review of how HRQoL in ICU survivors compares with the general population, changes over time and is predicted by baseline characteristics has been done (Dowdy et al 2005).

2.6 What is QoL or HRQoL

In order to measure QoL and more specifically health related quality of life (HRQoL) it is important to understand these two concepts and how they may relate to each other. Gill and Feinstein (1994) reported that investigators defined quality of life in only 11 (15%) of the 75 articles they had reviewed. They reported that no article distinguished "overall" quality of life from health related quality of life.
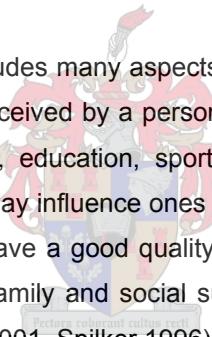
Quality of life is a broad concept which includes many aspects of a persons' life. These aspects may affect how quality of life is perceived by a person. Aspects such as health status, social responsibilities, work, family, education, sport or hobbies, financial or economic status, etc. are all factors which may influence ones perception of ones quality of life. For example one may perceive to have a good quality of life if one is educated and financially stable, or if one has good family and social support (Chaboyer & Elliot 2000, Eales et al 2000, Mishoe & Maclean 2001, Spilker 1996).

Health related quality of life refers to the effect of health status on ones perception of QoL. For example a person may have an amputation, diabetes or asthma, etc. but still be able to take part in sport, work or social activities and therefore perceive to lead a good quality of life. However another person may have a similar health condition and be content with not being able to play sport or take part in social activities and still perceive to have a good quality of life. Therefore measuring HRQoL differs from functional status measures as functional status has a more objective aspect to it than HRQoL which is

more subjective. However functional status may represent a part of a HRQoL measure. For example a physiotherapist can measure or observe limitations in functional status by measuring range of movement, determining distance walked or observing limitations in activities of daily living and objectively score the patient on a lower HRQoL score than what is perceived by the patient themselves (Rubenfeld et al 1999, Chaboyer & Elliot 2000).

HRQoL comprises different aspects of life such as physical, emotional, mental, social and psychological. Each of these aspects are broken down into smaller items for example the physical aspect can be itemized into activities of daily living, employment or worker role, hobbies and sport. These aspects have therefore been considered and used to develop a variety of questionnaires or instruments to measure HRQoL perceptions (Chaboyer & Elliot 2000).

"…The measurement of HRQoL is therefore a subjective assessment of one's well-being – a perception of the degree of contentment with and capability to perform and control all the facets of one's life…" (Möller & Smit 2004:32).

2.7 How to measure HRQoL

A HRQoL measure or instrument may be generic or disease-specific. In a population where a variety of factors play a role, a generic measure is best. As intensive care patients are affected by pre-morbid, intra and post-ICU factors and may have a variety of underlying diseases and pathology a few generic HRQoL measures have been recommended for use in patients following intensive care (Rubenfeld et al 1999, Angus & Carlet 2003).

Literature reviewed recommended the Nottingham Health Profile (NHP) (Hurel et al 1997), Sickness Impact Profile (SIP) (Lipsett et al 2000), Euro-QoL 5D (EQ-5D) (Granja et al 2002) and the Short- Form 36 (SF-36) (Eddleston et al 2000) and will be discussed below. These measures have all been validated for use in ICU settings. However, it was noted that of these four measures, the SF-36 and EQ-5D were the most recently developed measures. The Brussels Roundtable held in 2002 recommended the EQ-5D

and SF-36 as they reported these to be the best-suited instruments for measuring QoL in multi-centre critical care trials (Angus & Carlet 2003). Dowdy et al (2005) reported that 13 of the 14 (93%) studies reviewed used the EQ-5D or SF-36 and were published in and after 2000 compared to one of seven (14%) using the SIP or NHP.

Table 2.1 gives a summary of and comparison between these four generic HRQoL measures which are discussed in more detail after the table.
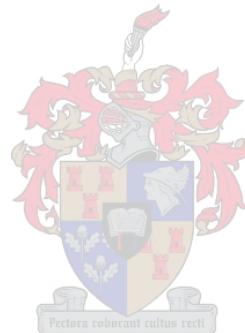
Table 2.1 Summary of and Comparison between four generic HRQoL measures (modified from Chaboyer & Elliot 2000).

Instrument	Purpose	Description	Concepts Measured
SF-36 (Ware et al 1993)	A survey of general health status	36 Items grouped into 8 domains scales and physical and mental summary scores	Physical functioning, role play, bodily pain, general health, mental health, role emotion, social functioning and vitality
EQ5D (EuroQol Group 1990)	To assess state of health and preferences for 14 hypothetical health states	5 items assessed at 3 levels	Mobility, personal care, usual activities, pain/discomfort, anxiety/depression
NHP (Hunt et al 1986)	To measure perceived physical, social and emotional health	First part: 38 items Second part: 7 items	Sleep, physical mobility, energy, pain, emotional reactions and social isolation Employment, looking after the home and social life, home life, sex life hobbies and holidays
SIP (Bergner et al 1981)	To measure health related dysfunction	136 items grouped into 12 categories	*Physical:* body movement, mobility, ambulation *Psychosocial:* intellectual, social interaction, emotional, behaviour, communication *Other:* Sleep and rest, daily work, household, leisure and recreation

2.7.1 Nottingham Health Profile (NHP)

This generic instrument was developed in Nottingham from factors considered by lay people to be relevant to quality of life. It is used to evaluate the perceived distress across populations. It is a self administered questionnaire that takes five to ten minutes to complete (http://www.atsqol.org/nott.asp). The NHP consists of 38 items categorized into six domains: energy, pain, emotional reactions, sleep, social isolation and physical mobility. It consists of dichotomous 'yes/no' answers to each item. Scores for the NHP are computed and weighted, giving rise to a range of scores from zero (best possible health) to 100 (worst possible health). This is opposite to the scoring of the SF-36. Local community norms for Nottingham are available. It has reported validity and reliability. However the NHP has recently been criticized for failing to detect lower but potentially important levels of morbidity (Brown et al 2000).

2.7.2 Sickness Impact Profile (SIP)

The Sickness Impact Profile (SIP) is a widely used quality of life measure and is a general measure applicable to any disease or disability group. It has been used successfully with a variety of different cultural subgroups. It includes 136 items divided into 12 categories that describe the effect of sickness on behavior and function, clustered into 3 groups: independent categories, physical and psychosocial (Staquet et al 1998). Everyday activities in 12 categories (sleep and rest, emotional behavior, body care and movement, home management, mobility, social interaction, ambulation, alertness behavior, communication, work, recreation and pastimes, and eating) are measured. It requires 20-30 minutes to complete the 136 items providing an overall score and 2 domain scores: physical and psychosocial. The instrument has reported reliability, validity, and responsiveness, as well as research use in a clinical trial. It has been compared to clinical indices of asthma and disease-specific quality of life measures. The SIP is a self- or interviewer-administered, behaviorally based, health status questionnaire. Respondents "endorse" items that describe themselves and are related to their health. The SIP is scored according to the number and type of items endorsed. Scoring can be done at the level of categories and dimensions as well as at the total SIP level (Bagner 2004).

2.7.3 Euro-QoL 5D (EQ-5D)

Sznajder et al (2001), Granja et al (2002), Badia et al (2001) and Garcia Lizana et al, (2000) used the EQ-5D to determine the HRQoL of patients after ICU discharge. The EQ-5D was developed in 1990 and comprises five domains of HRQoL and consists of three parts. The EQ-5D self-classifier which is a self reported description of health problems according to a five dimensional classification namely mobility, self-care, usual activities, pain/discomfort and anxiety/depression is the first part of the questionnaire. These are divided into three levels namely:

1. without problems
2. moderate problems and
3. very severe problems.

The second part consists of the self-rated EQ VAS (visual analogue scale) which is similar to a thermometer that records the perceptions of the participant's current overall health. This scale is graded from zero (the worst imaginable health state) to 100 (the best imaginable health state). In the third part, respondents are asked to value on a visual analogue scale from 0 to 100, each of 14 health states of varying degrees of impairment. At the end, respondents are to asked to mark on the same scale where "being dead" is scored.

The questionnaire is scored using an index scale of 0-100 and is calculated to describe the overall HRQoL of these patients. The measure has been validated in several European countries and has been used to measure health for both clinical economic appraisals (Jelsma et al 2000). At present there are many European language versions of the instrument as well as a Japanese version (Jelsma et al 2000). In a fairly recent study by Jelsma et al (2000) it has been translated to a Southern African language spoken in Zimbabwe, namely Shona. However the instrument has not been validated in terms of its pyschometric criteria of reliability, validity and responsiveness.

2.7.4 Short-Form 36 HRQoL

The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) was developed using factor analysis from the much longer batteries of items used in the RAND Corporation's health insurance study experiment (Ware 2004). It is one of the most widely used health related quality of life measures in medical outcome studies today and has been included in over 500 clinical trials (Staquet et al 1998). The SF-36 is one of the most recent HRQoL measures developed. It has been translated for use in more than 40 other countries including South Africa. Numerous studies have shown that the SF-36 is psychometrically sound and applicable to a range of settings and has become an industry standard in the United States (Mishoe & Maclean 2001). The SF-36 is classified as a profile health related quality of life measure because it yields scores for multiple domains of health related quality of life. It is a 36-item instrument for measuring health status and outcomes from a patients' point of view. It is designed for use in surveys of general and specific populations, health policy evaluations, and clinical practice and research. The instrument takes less than 10 minutes to complete and can either be self-administered by people 14 years of age or older, or administered by trained interviewers either in person or by telephone.

The instrument measures the following eight health domains, which are relevant across age, disease and treatment groups:

1. **Physical Functioning** - limitations in physical activities because of health problems (8 questions);
2. **Role Play** - limitations in usual role activities because of physical health problems (4 questions);
3. **Bodily Pain** (2 questions);
4. **General Health** perceptions (6 questions);
5. **Vitality** (energy and fatigue), (4 questions);
6. **Social Functioning** - limitations in social activities because of physical and emotional problems (2 questions);
7. **Role Emotion** - limitations in usual role because of emotional problems (3 questions); and
8. **Mental Health** (5 questions) (Mishoe & Maclean 2001).

The surveys' standardized scoring system yields a profile of eight health scores and two summary measures and a self-evaluated change in health status (Ware 2004).

The SF-36 is considerably shorter than the Sickness Impact Profile's 136-item questionnaire and therefore, easier to complete (Eddleston et al 2000). The major disadvantage is that it does not provide data that are easily used in cost-utility or cost-effectiveness analysis. The deficiency is that it is not scored by preference. It does not have age-specific questions and it is unclear whether it is equally appropriate at each level of the age continuum; nevertheless it is most commonly used in contemporary medicine (Staquet et al 1998).

The general nature of the SF-36 and its previous use both within the post-ICU population and outside, in conjunction with the availability of normal data, make it a useful tool for assessing outcome after critical illness (Eddleston et al 2000). Although this is true for countries such as the UK and USA, the SF-36 does not have normative data for the South African population thus presenting a problem when trying to relate disease specific population scores to the general South African population.

The SF-36 has been used in many ICU settings or populations in studies done by Chrispin et al (1997), Elliot and Leeder (1998), and Eddleston et al (2000).

Brazier et al (1992) tested the validity of the SF-36 using 1980 people aged 16-74 years randomly selected from two general practice lists in Sheffield, UK. A postal survey was conducted and reminder letters were sent to non-responders. To examine retest reliability 250 randomly selected respondents were sent the SF-36 again after two weeks. They found the internal consistency of the questionnaire to be acceptable. The questionnaire was found to be highly reliable. The test-re-test reliability was found to be excellent as there was an insignificant difference in scores. The evidence for the construct validity of the SF-36 was substantial. In comparing the NHP with the SF-36 Brazier et al (1992) found that the SF-36 was able to detect low levels of ill health in patients who had scored good health on the NHP. This result supported the criticisms that the NHP taps the extreme end of ill health and is unsuitable for examining improvements in health in a general population. The SF-36 is able to identify people with

perceived health problems in particularly the mental health and vitality domains who were missed by the NHP. Brown et al (2000) reported that the SF-36 appeared to be a more sensitive measure than the NHP in detecting the impact of symptoms such as breathlessness and other milder symptoms experienced by 4-year survivors of myocardial infarction. It also had the ability to distinguish the effect of differing degrees of angina severity and frequency on social functioning.

Chrispin et al (1997) reported on the validity, reliability and acceptability of the SF-36 in the ICU setting. They used 166 patients who were discharged from a general ICU in the Norfolk and Norwich Hospitals. The nurses were trained in using the SF-36 questionnaire and were responsible for explaining the purpose of the project. At discharge the patient was given the questionnaire to be self-completed and help was only given by the nurses where necessary. In terms of acceptability Chrispin et al (1997) reported that in this population the questionnaire took considerably longer to complete (15-20 minutes) unlike suggested by other studies (5-10 minutes). Patients frequently required nurses to read the questions that took a considerable amount of time therefore resulting in patients being excluded if urgent discharges were required. As emphasis was placed on the fact that the data was related to pre-existing health it was sometimes distressing for patients. Reliability was quantified by measuring the internal consistency of items in the different domains using correlation coefficients among the items. All items exceeded the recognized statistical standard of 0.4 apart from the General Health item. Cronbach's alpha for mental health was the only coefficient not to obtain statistical standard, missing by only a few percent. They also reported that the wide range of scores in six of the domains suggest that the content validity is good. In conclusion, they reported that the SF-36 is a robust tool and recommend its use following critical care to assess HRQoL.

Although much of the literature above supports the use of the SF-36 it must be questioned whether the questionnaire is able to evaluate the outcome of physiotherapy intervention. To measure the effects of intervention on physical functioning the physical functioning, role play and social functioning domains which relate to physical well-being must be validated (Mawson 1995). The SF-36 is based on a theoretical model that is a medical model of intervention and recovery that is illness - treatment - recovery therefore

39

assuming that after intervention patients will return to significantly full or advance functional and social levels. In the SF-36 the lowest level of function is to play golf however this outcome is not suitable to all subjects where the models of intervention may be different. The medical model is not necessarily the theoretical model underpinning physiotherapy intervention therefore using a questionnaire based on a medical model would not be a valid measure of physiotherapy intervention (Mawson 1995). Mawson (1995) identified three models of intervention that differ from the proposed medical model in order to establish whether the SF-36 can measure the predicted response to physiotherapy. These are as follows:

1. *Patients with chronic illnesses and irreversible pathologies*

   These are those patients who are not able to achieve any of the advanced functional skills included in the SF-36. Their functional status is improved by intervention but irreversible pathologies prevent achieving any high level of function. For example COPD patients who are able to dress without oxygen support and independently walk to the toilet, Parkinson patients who after intervention are able to rise from a chair and spinal injury patients who following intensive therapy are able to function independently. These activities which enable independent living are not recorded in the item on physical impact on the SF-36.
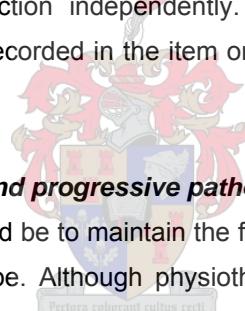
2. *Patients with terminal illnesses and progressive pathologies*

   The role of physiotherapy here would be to maintain the functional status of these patients at whatever level it may be. Although physiotherapy may bring about significantly clinical changes in function and maintain the patients' ability to cope with their disabilities for example in multiple sclerosis patients, the patient may not score anywhere near the predicted norms on which the SF-36 is based.

3. *Patients receiving health education*

   These refer to patients who are educated via classes and rehabilitation groups for example rheumatoid arthritis groups, ante-natal groups and cardiac rehabilitation groups where the outcome is an increase in knowledge levels and therefore affecting HRQoL outcomes which may not be measured by the SF-36.

In physiotherapy, the measure of pain is pertinent to the outcome after an intervention. For example a number of theoretical models of physiotherapy intervention specifically identify the effects of treatment on patients' perception of pain. The approaches of McKenzie, Maitland and Cyriax rely heavily on patients' interpretation of pain levels as a measure of their therapeutic outcomes. These are usually related to their functional skills which may be high levels of activities such as driving, typing, moving which are affected by pain. The time span or period for recording changes in pain levels is important. The measurement of the effect of pain over a four week period as is in the SF-36 may not be clinically significant as other factors may influence the patients' perception of pain. Four weeks may be an acceptable time period for the normal or healthy population but not necessarily for chronic pain sufferers. This shows some more of the limitations of the SF-36. This measure of pain for physiotherapists is not an acceptable measure of outcome as it would not record changes that would be very significant for the patient but rather produce no statistically significant changes in aggregated data (Mawson 1995).

Questions about other important issues regarding the reliability of the SF-36 such as whether patients' are able to fill in the form, what the patients perceptions of health are and what factors might alter their perception and attitudes of health are also being asked (Mawson 1995). The sensitivity is also questionable as the functional levels measured by the SF-36 are gross and will unlikely record changes that are clinically significant to patients receiving physiotherapy. In order to establish measures sensitive or responsive to changes induced by intervention both starting and end points need to be identified, together with levels of measurement and increments of change within a scale. The starting point for physical functioning of the SF-36 is the ability to play golf. A significant 'floor effect' would therefore occur for a large number of patients as although a change may be induced, their end points would fall below the levels measured. The measure of change in physical activity limitation is 'limited a lot', 'limited a little' or 'not limited'. This is a non-parametric ordinal scale. This raises concerns regarding its level of responsiveness to clinically significant change. This also then questions the analysis of this questionnaire as total scores to obtain aggregated data may result in canceling out the extremes. This method disregards the theory of measuring scales and the theory of appropriate statistics and error. Mawson (1995) states that if these theories are fulfilled then what the measure says it is measuring is being measured. These theories require

41

each point on a scale to be defined to provide a unique meaning and then also for these defined scales to be hierarchical if the scale is ordinal, interval or ratio. This is questionable in the SF-36 as the hierarchy among items is doubtful and as the ordinal scores are summed scales have lost their uniqueness. The resultant analysis therefore can be extremely inaccurate and misleading especially if the information is used to determine resource allocation (Mawson 1995).

It is also important to measure changes in health status over time and before and after intervention. However the SF-36 may not be appropriate to measure this as it does not give an idea of what specifically changes ones health status. For example in patients admitted to ICU after a laparotomy whether the surgical technique, sterility, nursing care interventions or the post-operative physiotherapy treatments improved health status is questionable (Mawson 1995). Bullock (1994) measured length of stay on an orthopedic ward which was used to assess the outcome of physiotherapy. However after using an alternative outcome measure to the SF-36 which measured clinically significant changes in time it became apparent that the length of stay was prolonged to achieve wound healing as indicated in the nursing protocol. Therefore careful selection of measures must be taken when trying to answer specific questions (Mawson 1995).

The SF-36 measures patients' perceptions of their quality of life and this therefore may give an idea as to where to focus medical and allied health therapies. However either other measures need to be used in conjunction with these in order to determine change over time with intervention or the SF-36 needs to be modified to fit the needs of the specific patients and fulfill the conceptual and theoretical models of physiotherapy intervention (Mawson 1995).

The scoring and interpretation of the SF-36 HRQoL measure is quite detailed and can be found in the manuals provided by the Medical Outcomes Trust. These manuals can be ordered and a license agreement obtained in order to use the measure. Due to the immense detail regarding the scoring and interpretation the most important points will be summarized in the next paragraph. For more detail and clarity please refer to Chapter 3, pages 39 to 41 and Addendum C.

The SF-36 version 2 is scored by means of a Likert-type scale. Each set of options per item is scored from between one and six depending on the number of options per item. These scores are pre-coded with a final item code which is used to score the questionnaire. All scores can be entered into an electronic database which can automatically score each domain and produce summary component scores. The scores can also be manually calculated using the instructions in the SF-36 scoring manual. The scores range between zero and 100%. Interpretation is aided by the SF-36 Health Survey Manual and Interpretation Guide (Ware et al 2000). Depending on sample sizes when comparing differences between domain scores in a population and domain scores between different populations or at different time points, either a 2, 5, 10 or 20 point difference may be clinically or socially relevant (Ware et al 2000).

Various methods of administration of HRQoL questionnaires have been used by various outcome studies following intensive care. Methods of administration used are telephonic interviews, face to face or self administration methods, proxy respondents or postal surveys (Angus & Carlet 2003, Chaboyer & Elliot 2000). Differences in SF-36 domains differ by means of administration. It has been reported that domain scores were significantly lower than scores obtained in telephonic interviews (Lyons et al 1999).

2.8 Determinants of health related quality of life

HRQoL is a measure of the subjective perceptions of ones feelings about how health status affects their QoL and there are many determinants which may influence these perceptions. Some of the most commonly researched determinants will be discussed in the following paragraph.

Age may influence HRQoL outcomes. Eddleston et al (2000), Wehler et al (2003), Graf et al (2003) and Pettilä et al (2000) found significantly lower physical functioning (SF-36), Granja et al (2003) found a decrease in usual activities (EQ-5D) and Tian & Miranda (1995) and Kleinpell et al (1991) found a decreased physical or total QoL (SIP) in older versus younger ICU survivors. No significant association between age and mental health (SF-36), anxiety/depression (EQ-5D) or psychosocial QoL (SIP) has been found by these authors.

Gender may also affect HRQoL outcomes. Dowdy et al (2005) reported in a review that nine studies investigated the association between HRQoL and gender. Only two of these studies by Wehler et al (2003) and Garcia et al (2003) reported a significant association of gender with any HRQoL domain.

The time it takes for patients to return to work or normal activity after surgical interventions is an outcome measure more frequently being used. The factors influencing time back to work or normal activities are complex and are largely unexplained. The type of occupation, the amount of sick pay received and the cultural norms with regards to leave after surgery all play a part in return to work. The extent of variation in the time back to work and its effect on health status is not clear (Lawrence et al 1996). Lawrence et al (1996) reported that the when evaluating the health status of patients who had inguinal hernia repairs using the SF-36 the two domains most affected were role play and role emotion. Therefore physical and emotional health problems can have an effect on work and regular daily activities in patients with surgery. Also whether patients are employed or not after intensive care may affect HRQoL outcomes.

Personal habits such as smoking and alcohol use may affect health related quality of life. Sitas et al (2004) reported that 58% of lung cancer deaths, 37% of COPD deaths, 20% of tuberculosis deaths, and 23% of vascular deaths is caused by smoking. About 8% of all adult deaths in South Africa (more than 20 000 deaths a year) were caused by smoking. Smoking therefore is known to have a negative effect on one's health. In South Africa 52% of males and 17% of women over 18 years of age were reported to smoke in 1996. In the Western Cape 45% of women smoke compared to the national rate of 17% with the highest rates being amongst 'coloured' women, almost reaching 60%. In Scotland cigarette smoking is believed to be the single most important contributor to ill-health. Tillman & Silcock (1997) evaluated the HRQoL among smokers and ex-smokers in Scotland using the SF-36 and found that smokers reported significantly poorer general health, less vitality and a poorer mental health status and thus affect HRQoL outcomes. Thus smoking in South African ICU populations may also affect HRQoL outcomes.

Alcohol misuse is a major cause of mortality and morbidity and an important health care burden. However the QoL of alcohol misusing subjects has been little studied to date (Foster et al 1999). Important factors in the QoL of alcohol dependant subjects are psychiatric co-morbidity, social environment and disturbed sleep. The QoL of alcohol-dependant subjects was found to be very poor but improved with abstinence, controlled or minimal drinking (Foster et al 1999). Therefore there may be a difference between patients who consume alcohol and those who do not.

Co-morbidities such as TB and HIV/AIDS may affect HRQoL outcomes. Möller & Smit (2004) measured and compared the HRQoL of two sample groups in South Africa namely members of the police on active duty (as example of the 'normal' population) and people living with AIDS. They used the SF-36 HRQoL measure to determine differences in HRQoL among the two groups. A difference in domain scores between the perceptions of HRQoL between the two groups was found. They reported that people living with AIDS had a lower perceived HRQoL than the police in all domains but specifically lower in the role emotion followed by the physical functioning and bodily pain domains. These differences were clinically and socially relevant on a 20 point scale for this particular sample size. As critical care patients may also experience the same emotional and/or physical stresses due to health problems, those patients with HIV/TB may present with an even further decrease in HRQoL domains due to the added burden of these co-morbidities.

Admitting diagnosis such as medical, surgical or traumatic health problems may affect HRQoL outcomes. In ICU survivors with medical versus surgical diagnosis, Hurel et al (1997) found a significant difference between these two diagnosis groups in more than one QoL domain. Badia et al (2001), Granja et al (2002) and Garcia et al (2003) demonstrated significantly worse pain/discomfort on EQ-5D in patients surviving trauma, compared with the other ICU survivors 6-18 months after ICU discharge. Thus admitting diagnosis should be taken into account when determining differences in HRQoL outcomes.

Elective or emergency surgical procedures may affect HRQoL outcomes. Sage et al (1986), Hurel et al (1997) and Short et al (1999) found no significant association

between surgical status and overall QoI at 6-18 months after ICU discharge. Vedio et al (2000) and Granja et al (2002) found that emergency surgical patients had significantly worse quality of life in a minority of domains.

The severity of illness score (APACHE II) was developed by Knaus et al (1985) to predict mortality in the ICU. However it may prove to be a more important determinant in determining long-term HRQoL outcomes. Kleinpell (2003), Wehler et al (2003), Vedio et al (2000) and Pettilä (2000) using the SF-36 found a significant association between APACHE II and lower physical functioning or general health perceptions. Granja et al (2002) and Garcia et al (2003) using the EQ-5D found a significant association between APACHE II and a decrease in usual activities and lower self rating score as measured by the EQ-VAS. Sage et al (1986), Kleinpell et al (1991) and Tian & Miranda (1995) did not find an association between APACHE II and the total SIP QoL score. However Short et al (1999) found a significant association between the two. Granja et al (2004) did not find a significant association between APACHE II and HRQoL using the NHP.

A prolonged period of stay in ICU is known to result in muscle wasting and weakness (Jones et al 2003). This may influence the physical functioning of patients in their activities of daily living. Pettilä et al (2000) found a significant negative correlation between ICU length of stay and bodily pain and vitality. Graf et al (2003) did not find length of stay to affect HRQoL.

Timing of HRQoL evaluations also may have an effect on HRQoL outcomes. Depending on the time at which HRQoL measures are administered for example immediately following ICU discharge or 3, 6 or 12 months following ICU discharge, the HRQoL outcome may differ. Two studies by Vedio et al (2000) and Badia (2001) evaluated changes in HRQoL over time. Vedio et al (2000) reported that 76% of elective versus 31% of emergency surgical patients reported an improved HRQoL from baseline after 6 months follow-up. Badia et al (2001) reported significant improvements from baseline to 12 months in four of five EQ-5D domains (mobility, usual activities, pain/discomfort and anxiety/depression) among scheduled but not unscheduled surgical patients.

2.9 HRQoL Outcomes

Studies that have evaluated HRQoL of ICU patients have evaluated outcomes prior to admission and 6 months to 2 years following ICU discharge. Although the following studies by Tian & Miranda (1995), Konopad et al (1995), Capuzzo et al (1996), Fakhry et al (1996), Vazquez Mata et al (1996), Brooks et al (1997) used different HRQoL outcome measures in their ICU populations they all reported limitations in the physical functioning or role physical domains of QoL more than other domains.

The SF-36 was used by Eddleston et al (2000) and Kvåle et al (2003) to determine HRQoL outcomes in patients 6 and 12 months following intensive care. Eddleston et al (2000) reported that young men less than 65 years old struggled in the role play, role emotion domains and social functioning domains whereas older women more than 65 years old struggled in the role emotional and physical functioning domains. Kvåle et al (2003) reported reductions in all domains of the SF-36 especially physical functioning, role play and role emotional scores.

Various studies used different methodologies when evaluating HRQoL in ICU survivors. While some studies only gave total scores others showed domain scores. Studies have used different time points for evaluation and have evaluated differences between pre and post-ICU scores or between ICU populations and the general population. Therefore trying to compare and draw conclusions can be difficult as many factors affect this outcome.

Quality of life assessments have occurred infrequently in the ICU literature and are of limited methodological quality. Therefore more studies using valid and reliable instruments are necessary to document long-term quality of life of critically ill patients especially those at risk of a poor outcome (Heyland et al 1998). In conclusion the literature provides support for the current study as there is a reported need (Dowdy et al 2005, Angus & Carlet 2003) for long-term survival and HRQoL outcome studies following ICU and especially in SA (Michell 2005).

CHAPTER 3

Methodology

This chapter describes the methodology of this study. It includes the research question, specific aims of the study, research design and population. This is then followed by a description of the sampling process, the instruments, the process of data collection and capturing, data analysis and finally the ethical considerations.

3.1 Research Question

What is the survival rate and health related quality of life (HRQoL) 12 months following discharge from an adult surgical intensive care unit (ICU) in a public sector tertiary academic hospital in the Western Cape, South Africa?

3.2 Objectives

The objectives of the study were to determine:

3.2.1 the survival rate of patients admitted to a tertiary public sector surgical ICU 12 months post ICU admission,

3.2.2 the HRQoL of patients admitted to a tertiary public sector surgical ICU 12 months post ICU discharge,

3.2.3 whether the following variables are associated with survival rate and HRQoL:
- age
- gender
- length of stay in the ICU
- the intubation period
- the admitting diagnosis (elective/emergency surgery/traumatic injury)

- the severity of illness/disease on ICU admission (APACHE II)
- treatment provided by student or graduate physiotherapists

3.2.4 and in addition whether the following variables are associated with HRQoL:
- employment status
- HIV/TB status
- Smoking/Alcohol habits and
- whether patients attended follow-up or not.

3.3 Research Design

A prospective cohort observational study was undertaken. A descriptive study by means of a telephone survey was done. Quantitative as well as qualitative and descriptive data were collected.

3.4 Population

A population of 182 admissions of 180 subjects to a tertiary public sector adult surgical ICU was obtained from the initial baseline study.

3.5 Sampling

Of the total population, two were re-admissions thus 180 subjects was obtained from the initial baseline study and used in this follow-up study. As the research question is composed of two parts, two sample sets were used from the same population. The sample sets were obtained as follows:

Sample Set One

The total population of 180 subjects was used in sample set one which was used to determine the survival rate of this population.

Sample Set Two

This sample was the sample used to determine the HRQoL of this population. All alive and contactable patients in sample set one were used as the population for this part of the study. This population included 66 patients. For this population a sample was obtained after taking into account the following **exclusion criteria**:

- Any subject younger than the 18 years of age was excluded. There were two subjects who fell into this exclusion category.

- Subjects with contact numbers who could not be contacted after four attempts were excluded from the study. There were a total of 10 subjects who were not contactable for participation.

- Subjects who did not consent to take part in the study were excluded. These included subjects refusing to consent at the beginning of the study and those who decided to withdraw during or after the interview. No subject withdrew during or after the interviews and only five refused to take part.

- Subjects who could not speak either English or Afrikaans were excluded. These were subjects not able to understand, speak and/or write either English and/or Afrikaans with ease, as only English and Afrikaans questionnaires were available for use. There were three Xhosa speaking subjects.
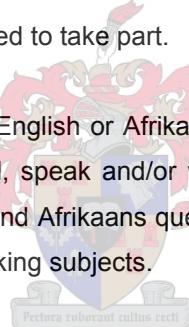
3.6 Instrumentation

In this study, two instruments were used and will be discussed under this heading.

3.6.1 UK Short Form 36 version 2 (UK SF-36v2) HRQoL Outcome Measure

- A copy of the UK SF-36v2 HRQoL questionnaire was obtained from the Medical Outcomes Trust (MOT) website, http//:www.sf-36.com (Addendum A). A license agreement was obtained from the MOT via email and completed and a license obtained to use the specific questionnaire, its' scoring and the UK SF-36v2 manuals. The license number is R1-061704-19248 (Addendum B).

- Due to the structure of the thesis literature regarding this HRQoL questionnaire has been discussed in the literature review section (cf pg 25-31) and therefore has not been repeated or discussed in the methodology. However it is important to note here that this generic HRQoL measure is a valid and reliable measure (Ware et al 2004, Brazier et al 1992, Chrispin et al 1997). It has been widely used in medical outcome studies today and has been included in over 500 clinical trials (Staquet et al 1998) including ICU settings (Chrispin et al 1997, Elliot & Leeder 1998, Eddleston et al 2000). It was also one of the HRQoL outcome measures recommended by the 2002 Brussels Roundtable critical care consensus conference (Angus & Carlet 2003). Thus it was the preferred choice for use in this study. The scoring of this questionnaire and the interpretation guidelines as mentioned in the literature is quite detailed. Therefore the most important details regarding the scoring and interpretation has been included in a comprehensive addendum (Addendum C).
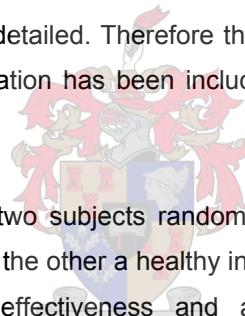
- The questionnaire was piloted on two subjects randomly chosen, one being a patient discharged from an ICU and the other a healthy individual. The purpose of this pilot was to examine the effectiveness and appropriateness of the questionnaire to the sample population in the Western Cape.

- The questionnaire presented the following problems:

  a) The wording of the questions and length of the wording of the options presented problems as questions and especially options needed frequent repetition in order for the respondent to grasp the question itself and also remember which option suited them. The respondent could not remember

51

the first option read to them by the time the interviewer read the last option. Although the length of the wording of the options was changed, the number of options per question was kept the same so as not to affect the scoring of the questionnaire and to maintain the validity and reliability of the questionnaire. For example most of the options in the original questionnaire read "all of the time, some of the time, most of the time, a little of the time and none of the time". This was too 'wordy' and resulted in the need for repetition, thus they were changed to "always, mostly, sometimes, a few times and never".

b) In South Africa, distance is measured in meters or kilometers and not yards or miles. Therefore, questions regarding mobility over distances in the physical functioning category had to be changed. However, as not everyone may understand the concept of meters or kilometers, everyday activities which could measure distance walked such as going to the toilet, outside in the garden or to the corner shop or end of the road or walking in a mall or hiking which was similar to the amount of distance used in the questionnaire was used to determine the extent of disability.

These small modifications in the questionnaire were made in collaboration with Dr Maria Burton, Senior Lecturer at Sheffield Hallam University, UK, who has had experience with this questionnaire that she used during her PhD study (Addendum D).

▪ Due to the differences in language of subjects in the sample population, an available validated Afrikaans translation of version one was also purchased from the MOT. This questionnaire however was not received after numerous attempts at contacting the supplier. Thus due to time constraints and no response from the MOT regarding the Afrikaans translation, the modified questionnaire was then sent to the Language Center of Stellenbosch University where it was translated from English to Afrikaans and back-translated to English (Addendum 3E&F). The

Afrikaans version of the questionnaire was finally received after the study due to delay from the supplier (Addendum G&H).

3.6.2 Self-developed questionnaire (Addendum I)

The SF-36 HRQoL questionnaire does not include specific aspects of the subjects' life such as hobbies, work, social habits, co-morbidities and follow up post ICU care. It was considered however that this information was important for evaluating subjects and relating it to their HRQoL as suggested by other authors (Angus & Carlet 2003). For this reason a separate questionnaire was developed which included questions about:

a) Hobbies and work before and after critical illness (as this gives an idea of their pre-morbid status in terms of the level of activity at which they were at pre-morbid level and how their illness has affected them),

b) Smoking and alcohol habits, TB&HIV testing and status
(Statistics from the Strategic and Service Delivery Plan (SSDP) show high rates for smoking, drinking, TB&HIV especially in the Western Cape and these may therefore have had an effect on the HRQoL [cf pg 6-7]).

c) Follow-up post ICU discharge as this information may give an indication as to whether increased medical input changed or had an effect on HRQoL.

d) Additional questions regarding physical functioning were added. In order to obtain a better understanding about the limitations in smaller components of physical functioning and to evaluate whether further rehabilitation may still be required, 4 extra components of functional activities were added under the physical functioning category (lying to sitting, sitting to standing, walking with support or without support).

e) A question regarding how subjects felt about the interview was also added to the end of the questionnaire. The researcher considered that this was important as it

may give an indication of whether the interview for the interviewee was a negative or a positive experience. It is also a debriefing to end off the interview.

The self-developed questionnaire preceded the modified UK SF-36v2 questionnaire in the interview as was suggested by the literature (Kvåle et al 2003, Angus & Carlet 2003) in order to maintain the validity and reliability of the questioning process and the internal consistency among items. This questionnaire was not scored according to the SF-36 scoring system but was separately analyzed and compared to the SF-36 HRQoL outcome scores.

- A second pilot was carried out using the first six subjects contactable and who gave consent. The purpose of this pilot was to evaluate the responsiveness of subjects to a telephonic interview, the ease of administration of the self-developed and modified UK SF-36v2 questionnaire and any problems or difficulties that could be eliminated. The following minor problems were experienced:

a) The length and wording of questions 4 and 5 as well as the similarity of the questions under question 4 and 5 presented a problem in that it had to be read out a few times to the patient. It was thus decided by the researcher that since the question could not be changed drastically without affecting the validity and reliability, the questions would be repeated three times to the respondent and that any response was noted, no response or use of another word to describe their answer would be calculated as missing data as specified by the instrument scoring manual (Addendum C).

b) At times patients could not apply question 4 and 5 to either work or home activity since they were either unemployed and had house help. It was decided by the researcher to ask the patient to use their hobby as an activity that they do regularly instead if they did not work or do housework.

The data collection for the rest of the sample proceeded. The subjects in the pilot formed part of the study sample.

3.7 Procedure

The procedure used during the study period is as follows:

3.7.1 Administration

- Permission was requested and received to obtain the sample used in the previous baseline study completed by Mrs S Hanekom (Addendum J&K).

- Missing contact details and language preferences of subjects was obtained from the hospital database system called Clinicom. Permission to obtain data not available on Clinicom but in the medical records, was requested and obtained from the head of medical records (Addendum L).

- A telephone call timetable was drawn up to use during the interviews which included all patient names, dates of discharge or whether deceased and contact numbers and a section for notes to be remembered by the researcher. The call list was used to keep track of the interviews (Addendum M).

- Patient letters were also written in English and Afrikaans which were posted approximately 1-2 weeks before the telephone interview in order to inform and forewarn patients about the study and being contacted for participation (Addendum N&O).

- During interviews the English and Afrikaans questionnaires and patient letter were used as scripts during the process of the interview and a diary was used to record interviews booked and interviews completed, dates and cause of death of patients and reasons for not being contactable.

- For the purpose of ease, subject names were used on the questionnaire and later replaced with the folder number.

- Each subject had a separate questionnaire answer sheet on which answers were marked and any other comments documented.

- On completion of interviews the questionnaires were dated and filed. The researcher stored the file until all data could be captured on a computerized database by the researcher.

3.7.3 Telephonic Interview

- Patients were contacted telephonically approximately 5 days prior to or after the day of discharge in the following year.

- The same interviewer (researcher) completed all the interviews. All interviews followed the same process (Addendum P).

3.8 Data Capturing

One data capture sheet was used to capture the relevant data after the data collection period:

3.8.1 Patient Information Data Capture Sheet: This was an Excel spreadsheet used in the previous study to which information obtained in the current study was added and information not needed from the baseline study removed. Thus it included the following categories:

   a. Patient Demographics (name, address, telephone number, age, gender, language, employment status),

b. Date of discharge from ICU, if deceased in ICU, the date of death and reason, and the date of death of further deceased patients collected during the study period,

c. ICU variables (admitting diagnosis, APACHE score, length of stay, intubation period, treatment by graduate/student physiotherapist),

d. Co-morbidities such as HIV/TB status, smoking (yes/no) and alcohol use (yes/no). These four co-morbidities have been specifically chosen because of their high prevalence in South Africa and especially in the Western Cape as reported earlier,

e. Work (yes/no and type), Hobbies, Follow-up(yes/no) and,

f. Health Related Quality of Life Scores for the 8 domains and 2 summary measures of the SF-36 Questionnaire.

Categories (d-f) were obtained and entered into the spreadsheet after the interviews (Addendum Q).

Information needed to determine long-term survival and HRQoL and the factors affecting each outcome were extracted for data analysis as required.

3.9 Data Analysis
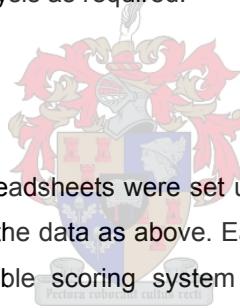
With the help of the Statistician, Excel spreadsheets were set up in order to capture all raw data. The researcher then entered all the data as above. Each SF-36 answer sheet was individually scored using the available scoring system on the SF-36 website (http://www.sf-36.com) and manually checked according to the scoring instructions in the SF-36 scoring manual (Addendum C). Each subjects' scores for each of the 8 scales as well as the two summary scales were printed and kept with the original subjects answer sheet and this data also entered into the above mentioned Excel spreadsheet (Addendum Q). The survival data was captured as above and analyzed to determine the survival rate and variables associated with survival rate. The statistician used various data analysis techniques or methods as follows:

3.9.1 Data analysis for Survival Statistics:

Survival data and selected demographic and ICU variables was extracted from the patient data capture sheet to determine outcomes. Statistica 7 was used to analyze the data in conjunction with the statistician. Data was analyzed as follows:

- Descriptive data was summarized,
- a histogram was used to plot the categorical data for survival
- Kaplan-Meier survival curves were used to determine survival over time and
  the effect of selected demographic and ICU variables on survival.
- Gehan's Wilcoxon tests, Mann-Whitney U tests and Spearman Correlations were used
  to determine associations between selected demographic and ICU variables.

3.9.2 Data analysis for HRQoL Statistics:

Data was analyzed in the following manner:

- The mean scores and standard deviations were calculated for each HRQoL domain and the two component summary scores. This descriptive data was plotted in a box whisker graph.
- Mann-Whitney U, Chi-square t-tests and Spearman Correlations were used to determine associations between the different selected variables and between selected variables and the HRQoL domain scores.
- Other descriptive data were summarized in tables for analysis.

Values were accepted as significant at the 5% level ($p<0.05$).
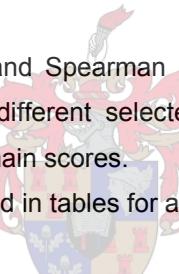
3.10 Ethical Considerations

The following ethical considerations were adhered to during the project:

3.10.1 Registration of project

- Registration with the Faculty of Health Sciences (Research Committee) Project number N04/05/092 (Addendum R)

3.10.2 Confidentiality and consent

- All subjects' details were held in strict confidence.

- Subjects were sent letters in both English and Afrikaans forewarning them of being contacted and thus they were not coerced into taking part in the study (Addendum N&O). The letters were mailed approximately 1-2 weeks before the telephone interview. The letter explained that the study was being conducted to determine the survival rate and health related quality of life of patients 12 months after discharge from the ICU. The aim and relevance of the study was explained. They were informed that participation was voluntary and that they were allowed to withdraw without explanation and that all information revealed would be held confidentially.

- Appointments were made with each subject so as to respect their time and carry out the interview when it was convenient for them and the researcher to do so.

- Subjects were re-informed telephonically about the purpose of the study and matters regarding confidentiality of all information received before participating.

- Subjects were asked to consent before taking part in the study.

- Subjects were asked to consent in revealing information such as TB or HIV/AIDS status.

- Subjects were asked to consent to answering questions in the SF-36 HRQoL questionnaire.
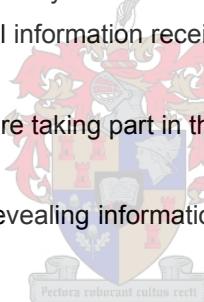
3.10.3 Permission was obtained from the following people

- Mrs S Hanekom Senior Respiratory Physiotherapy Lecturer at Stellenbosch University - to use sample gained her study (Addendum J&K)

- Dr JP Muller Senior Clinical Executive Member at TBH – to obtain access to patient medical records for the purpose of the study (Addendum L).
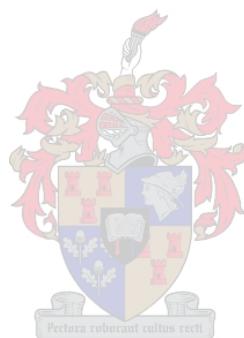
CHAPTER 4

RESEARCH ARTICLE

Long-term Survival following ICU admission

ABSTRACT

Objectives: To determine the survival rate and selected variables that may affect the long-term survival of patients 12 months following adult surgical ICU admission.

Design: Prospective observational cohort

Setting: Ten-bed closed public tertiary adult surgical ICU

Patients: 180 subjects obtained from a previous baseline study.

Measurements: Demographic data (age and gender) and ICU variables (admission for emergency or elective surgery or traumatic injury, severity of illness (APACHE II), length of stay (LOS) and length of intubation (LOI) obtained from the baseline study.

Methods: The recorded survival status of patients was determined from baseline data, hospital medical records or electronic database. Patients alive at ICU discharge were sent letters informing them of this follow up study. As part of a telephonic quality of life interview, survival status of discharged patients was also determined, where necessary, from their families.

Results: All 180 subjects were included in the survival analysis. The cumulative survival rate was 62%. APACHE II was the only variable significantly associated to long-term survival ($p<0.01$). No other variables were significantly associated to long-term survival.

Conclusion: APACHE II may be a useful determinant of long-term survival. It is possible that APACHE II might contribute to decision-making regarding appropriate ICU admission. In addition the long-term survival of this ICU population suggests that the standard of care provided by this third world ICU setting is similar to that of first world ICU settings despite limited resources and the increased demand due to the high incidence of traumatic injury and infectious diseases in South Africa.
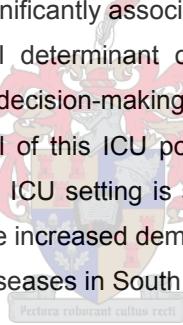
INTRODUCTION

Intensive care is a fairly new specialty in South Africa. A number of units were set up in the late 1960's and early 1970's. However, it was only in the early 1980's that a formal approach to this specialty was undertaken by the establishment of the Critical Care Society in South Africa. The guidelines setup by this society was based on units found in first world countries such as Australia, USA and Europe (Mathivha 2002).

The practice of critical care medicine which involves sustaining and prolonging the lives of critically ill patients has evolved with development of new technologies. This practice of prolonging lives extends to all ages of life and disease processes. Thus patients, who otherwise would have died, now have a longer lifespan (Lipsett et al 2000).

The cost of management of patients in intensive care is very high and the long-term value of this care is being questioned (Eddleston et al 2000, Mathivha 2002, Stiller 2000). In the South African context the provision of this expensive speciality is also increasingly being re-evaluated (Mathivha 2002, Potgieter et al 1995). Michell (2005) stated in his editorial that in South Africa there is not only a need to know whether patients are surviving the ICU but whether they are going home and surviving and enjoying a fulfilling life six months or a year later. Objective outcome evaluation after intensive care is therefore required as there is limited research done in this area (Angus & Carlet 2003). Angus & Carlet (2003) reported that the Brussels Roundtable held in 2002 recommended that all ICU outcome studies include survival follow-up for at least 6 months and preferably or ideally longer.

Survival Outcomes

Assessing outcome is notoriously difficult and survival is the determinant most commonly quoted in outcome studies (Eddleston et al 2000). Survival rate can be defined as deaths over a period of time whereas mortality is the number of deaths at a given time or point (Rubenfeld et al 1999). Although at first glance survival seems fairly easy to measure, in practice it is well recognized that any cohort of ICU patients' will

exhibit a cumulative mortality with time and that the time required for survival curves to return to normal (that of the general population) is unclear (Eddleston et al 2000).

According to Rubenfeld et al (1999), death is an unequivocal endpoint. However there are several time points from which this outcome can be measured. These points include ICU or hospital survival, time until death or death at a fixed end point for example 3 months, 6 months, 12 months after ICU discharge. The time or endpoints used depends on the specific research question, the mechanisms and timing of the disease and/or treatment under study, and the study design.

With each type of mortality assessment certain important general aspects need to be considered. These aspects include the various practice patterns that can change the interpretation of the mortality endpoints and the transfer of ventilator-dependant patients directly from an ICU to a long-term care facility that can reduce the hospital mortality. Although survival up to a fixed point can avoid the latter problem, careful consideration of the selection of time points is required (Rubenfeld et al 1999). Depending on disease processes or trauma, the length of stay in an ICU may be longer than a month (30 days) and thus 30-day survival may not be as useful a measure for example in the fibroproliferative phase in patients with acute respiratory distress (ARDS). Although one-year survival may avoid this problem, it may also only reflect the patient's underlying disease prognosis more than the effectiveness of intensive care (Rubenfeld et al 1999).

Long-term survival has been determined in many studies (Zaren & Bergstrom 1988, Dragsted et al 1990, Ridley & Plenderleith 1994, Niskanen et al 1996) however the duration of follow-up is not standardized and varies among populations. A variety of optimum periods of follow-up from intensive care have been suggested. Zaren & Bergstrom (1988) suggested that after six months, the survival of patients discharged from an ICU paralleled that of the general population. Much earlier LeGalle et al (1982) also confirmed that short follow-up times were needed for the survival curves to reach a parallel. In contrast, Ridley & Plenderleith (1994) and Dragsted et al (1990) found that long-term follow-up as long as four and five years respectively was necessary. Both studies found a higher mortality risk rate in intensive care survivors compared to the

normal population and that the survival curves for intensive care survivors and the normal population only paralleled at these points in time.

Ridley & Plenderleith (1994), state that intensive care provides life-saving interventions rather than specific therapy aimed at curing an underlying disease. Therefore the best duration of survival of patients without chronic or malignant disease is normal life expectancy that is the life expectancy of an age and gender matched cohort of healthy individuals. In order to estimate the effectiveness of ICU and to overcome the variability of ICU therapy, Ridley & Plenderleith (1994) attempted to relate the numbers of survivors with normal life expectancy to the cost of critical illness. These authors aimed to compare the long-term survival of ICU patients with an age and gender-matched population and also apply long-term survival as a measure of ICU effectiveness. They concluded that the proportion of ICU patients who survive with normal life expectancy offers a definite endpoint and could be linked to cost as a measure of ICU effectiveness.

Survival analysis techniques use the actual survival time as the endpoint. Survival time is a continuous variable and it is therefore a more sensitive outcome measure than mortality. Survival analysis is potentially useful for investigators in identifying promising treatments for further study. However it is unlikely that the analysis of survival represents meaningful outcomes to patients. The reason for this may be that treatment that prolongs the time to death without affecting one's morbidity could be more harmful than is good for the patient (Rubenfeld et al 1999).

Outcomes related to survival
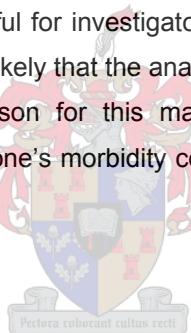
Mortality and long-term survival following ICU admission may be affected by a variety of demographic and ICU variables. These include age and gender, APACHE II, length of stay, length of intubation or ventilation period and admitting diagnosis. The relationships between the demographic and ICU variables and survival have been determined in several studies (Zaren & Bergstrom 1988, Ridley & Plenderleith 1994, Lam & Ridley 1999, Eddleston et al 2000 and Lipsett et al 2000). The main predictor of long-term survival reported by Eddleston et al (2000), Lipsett et al (2000), Rockwood et al (1993)

and Capuzzo et al (1996) is the APACHE II score. As the above variables may be associated to long-term survival outcomes, they are potential confounding factors and need to be taken into account when analyzing the survival outcomes (Rubenfeld et al 1999). According to Rubenfeld et al (1999), techniques such as matching, stratification, multivariate adjustment, propensity scores and instrumental variables can be used to adjust for confounding.

Significance of this study

There is a shortage of intensive care beds in South African state hospitals however the demand is potentially greater than first world countries (Michell 2005). This demand stems from the high incidence of severe trauma and infectious diseases in South Africa (Michell 2005). Due to this demand, doctors in intensive care units in South Africa and internationally are faced with the same decision making problem of which patients will benefit from ICU admission. This places tremendous pressure on them and other ICU staff. Without knowing which outcomes ultimately affect survival, limited resources may be wasted on patients who receive long-term care and eventually die (Michell 2005).

According to the editorial by Michell (2005), hospital administrators require written ICU admission policies. Few finite clinical criteria reliably predict ICU death therefore developing these policies is a daunting task. Michell (2005) states that we need to begin to develop written, accessible and evidence-based guidelines for ICU admission in South Africa. He also points out that all units should record APACHE II scores and outcome data and use these to refine and justify their admission policies.

Long-term survival outcomes studies in SA surgical ICU's are few and few finite demographic and clinical criteria are known to affect long-term survival outcomes (Michell 2005). This study hopes to provide some insight regarding these aspects in this SA ICU population.

Setting

The setting is tertiary public hospital based in the northern suburbs of the Western Cape in South Africa. There are 1385 beds and the adult surgical ICU is a closed 10-bed unit that is in this public university-affiliated tertiary hospital. There is a full multi-disciplinary team on staff. The hospital serves the Northern Suburbs of the City of Cape Town and the Winelands District (Stellenbosch, Paarl and Malmesbury). Surgical elective and surgical emergency patients as well as all trauma patients (except burns) requiring intensive support or monitoring are admitted to this ICU. Patients once stable in the unit, are discharged first to the appropriate wards and then home or to appropriate care facilities.

The Western Cape has a unique environment and a specific health profile which may impact on long-term survival outcomes. The province has the highest TB rates nationally and is amongst the highest in the world. The rising HIV epidemic is likely to augment the burden of TB, as evidence shows that 15-20% of TB patients are HIV-infected (Strategic and Service Delivery Improvement Plan (SSDIP) Provincial Government of the Western Cape Department of Health Draft Paper 2000). Besides these underlying pathologies, the most common cause of mortality in the Western Cape is intentional and unintentional injuries (Hanekom 2004). The injuries sustained, in this violent community is often times excessive and multifaceted. In the sample population obtained from the previous baseline study by Hanekom (2004), it was found that approximately 30% of the sample population admitted to the adult surgical ICU had sustained injuries due to violence. In addition, to these problems faced in SA 52% of South African males and 17% of women over 18 years of age were reported to smoke in 1996. In the Western Cape 45% of women smoke compared to the national rate of 17% with the highest rates being amongst coloured women, almost reaching 60% (Strategic and Service Delivery Improvement Plan (SSDIP) Provincial Government of the Western Cape Department of Health Draft Paper 2000). The social dynamics encountered in the South African population is diverse. There is a 30% unemployment rate and 40% of South Africans live in poverty. Furthermore, 75% of the population live in rural areas where they are deprived of health services (http://www.capegateway.gov.za/text/2003/mobilising-

against-tb.pdf). All of the above may significantly determine the long-term survival outcome of this ICU population.

METHODOLOGY

A prospective observational cohort study was undertaken and approved by the Research Ethics Committee of the University of Stellenbosch (Project number N04/05/092).

Aim

The aim of the current study was to determine both the long-term survival outcome and the factors associated with this survival outcome in a cohort of patients admitted to the adult surgical ICU at a public tertiary academic hospital based in the Western Cape in South Africa.

Population and Sample

A population of 180 subjects obtained from the original baseline study, which evaluated the profile of a surgical intensive care unit by describing the baseline data of this adult surgical ICU at a public tertiary academic hospital based in the Western Cape in South Africa. This population was used in order to determine the survival rate of this population 12 months following surgical ICU admission.
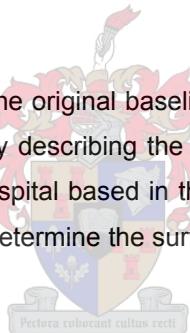
PROCEDURE

Demographic and ICU variable data collection

Selected variables were obtained from the baseline study data or from patient hospital folders where necessary and analyzed to determine their association to the survival rate for this population. This included the following:

1. Age
2. Gender
3. Length of stay (LOS) in ICU
4. Length of Intubation (LOI)
5. Admitting Diagnosis (elective, emergency surgery, traumatic injury)
6. Severity of Illness/Disease on admission (APACHE II)

In order to contact the subjects, their telephone numbers and addresses were obtained from the baseline data sheets, the hospitals electronic database or directly from patient folders.

Contacting Subjects

The subjects were posted letters 2 weeks in advance informing them of the study and its purpose. They were thus forewarned of being contacted to partake in the study.

The recorded survival status of patients was determined from baseline data, hospital medical records or electronic database. Patients alive at ICU discharge were sent letters informing them of this follow up study. As part of a telephonic quality of life interview, survival status of discharged patients was also determined, where necessary, from their families. The appropriate date of death or the date of the telephone call was recorded if the subject was alive. For those subjects not contactable after four attempts, the date of discharge from ICU was recorded as the last day the subject was known to be alive. These subjects were grouped in the lost to follow-up group when analyzing the survival outcome of this population.

Data Capturing and Analysis

Survival data and selected demographic and ICU variables was extracted from the patient data capture sheet to determine outcomes. Statistica 7 was used to analyze the data in conjunction with the statistician. Data was analyzed as follows:
- Descriptive data was summarized,
- a histogram was used to plot the categorical data for survival

- Kaplan-Meier survival curves were used to determine survival over time and the effect of selected demographic and ICU variables on survival.
- Gehan's Wilcoxon tests, Mann-Whitney U tests and Spearman Correlations were used to determine associations between selected demographic and ICU variables.

Values were accepted as significant at the 5% level ($p < 0.05$).

RESULTS

There were 180 subjects admitted to the unit between June 2003 and October 2003, with two subjects being readmitted in this same period. The first ICU admission date was used to calculate survival.

In this population there were more males than females. The females were older and had a shorter ICU length of stay and intubation period than the males however this observed difference was not significant. Significantly more males than females suffered traumatic injury ($p=0.03$) (refer to Table 4.1).
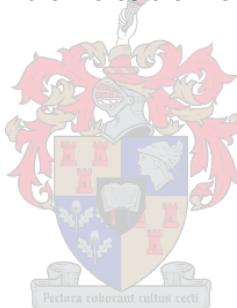
Table 4.1. Demographic & clinical characteristics of subjects admitted from June to October 2003 (n = 180) – (mean +/-SD), (* – significant p-value)

Selected Variable	Male (n=103)	Female (n=77)	Total Population (n=180)	p-value
Age (Range: 12yrs – 87yrs)	46.3 years (SD+/-20.1)	51.3 years (SD+/-18.7)	48.4 years (SD+/-19.6)	p=0.07
Length of Stay (LOS) (Range: 0.48d – 33.2d)	6.3days (n=88) (SD+/-6.7)	5.4days (n=67) (SD+/-6.4)	5.9days (SD+/-6.21) (n=155)	p=0.19
Length of Intubation (LOI) (Range: 0.23 – 56.5d)	6.01days (n=33) (SD+/-10.5)	4.96days (n=21) (SD+/-4.6)	5.6days (SD+/-8.15) (n=54)	p=0.68
Admitting Diagnosis: 1. Elective Surgery 2. Emergency Surgery 3. Traumatic Injury	(n=29) (n=52) (n=34)	(n=30) (n=32) (n=14)	(n=59/159) (n=84/159) (n=48/159)	p=0.07 p=0.35 p=0.03*
APACHE II Score (Range: 0-38)	12.3 (n=88) (SD+/-7)	12.4 (n=67) (SD+/-7.5)	12.3 (SD+/-7.2) (n=155)	p=0.90

71

The Survival Rate

Of the 49 (27%) patients that died the majority of patients (n=40) were never discharged from the hospital, with 38.8% (n=19) dying in the ICU and 42.8% (n=21) patients dying in hospital. Only 18.4% (n=9) patients died during the 12 month period after ICU discharge (refer to Graph 4.1).
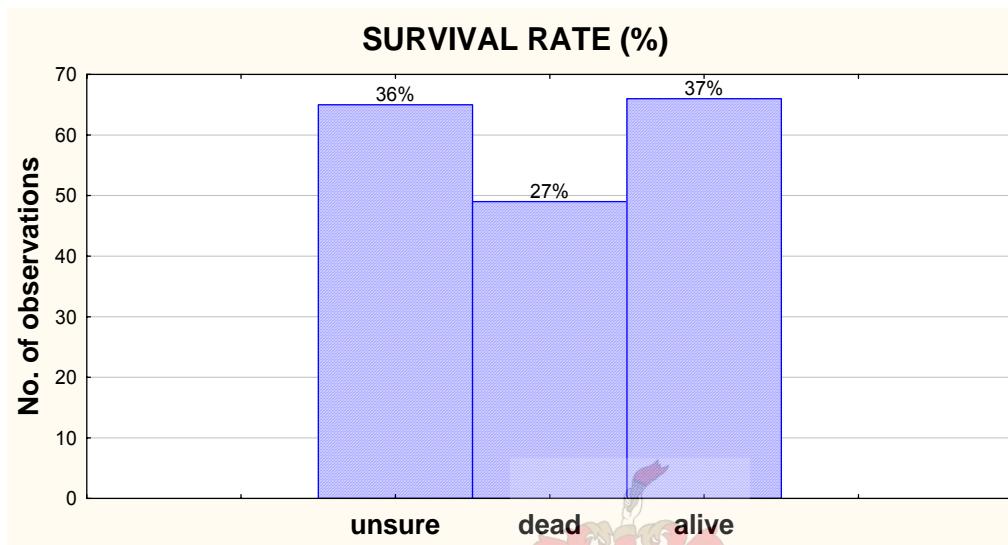
SURVIVAL RATE (%)

Graph 4.1 – Survival rates

Long-term Survival Outcome

The Kaplan-Meier Survival curve (Graph 4.2) displays the cumulative proportion of subjects surviving over a period of 12 months (365 days) and is representative of the whole population of 180 subjects. Each dot is representative of one subject and this is shown as complete data. The censored data is of those individuals that were alive at ICU discharge and were grouped as lost to follow-up as they could not be contacted. At 12 months following ICU discharge the cumulative proportion of surviving subjects was 62%. Thus the cumulative mortality rate was 38%. It can be seen that most deaths (22.2% [n=40]) occurred within the first 60 days and plateaus at approximately 150 days. The cumulative proportion surviving at 3 and 6 months were 67% and 64 % respectively.

Survival Curve 12months following ICU admission
○ **Complete**   + **Censored**
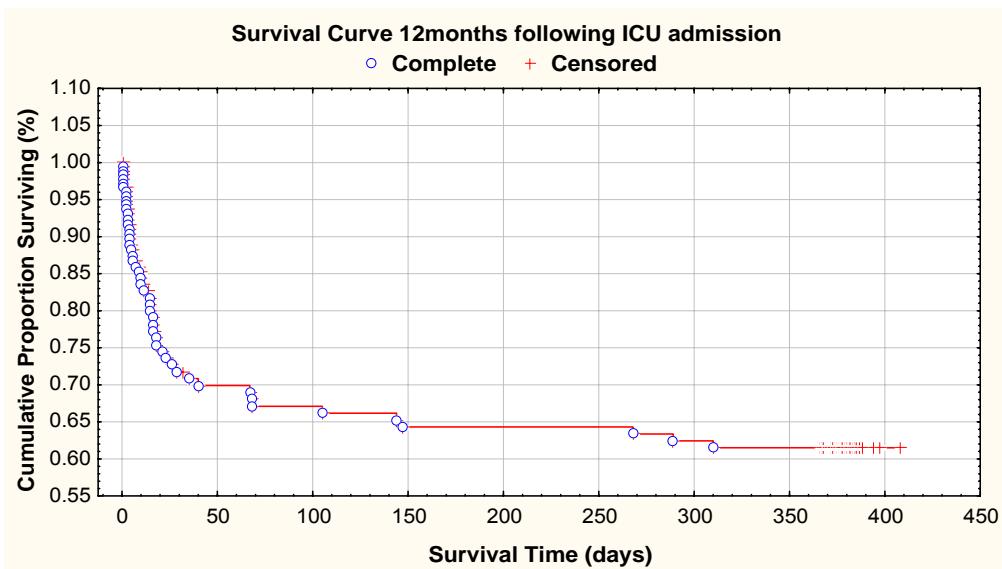
Graph 4.2 – Cumulative survival rates

The Effect of Demographic Variables on Long-term Survival

Gender did not affect the long-term survival outcome of this population (p=0.56).

The population was divided into three age groups for comparative purposes. These were subjects less than 45 years, those between 45 and 65 years and those above 65 years of age. This was done in order to compare this cohort with other patient populations. Severely ill patients were older (p<0.01) however age was not significantly associated with the long-term survival outcome (p= 0.83) (refer to Graph 4.3)

73
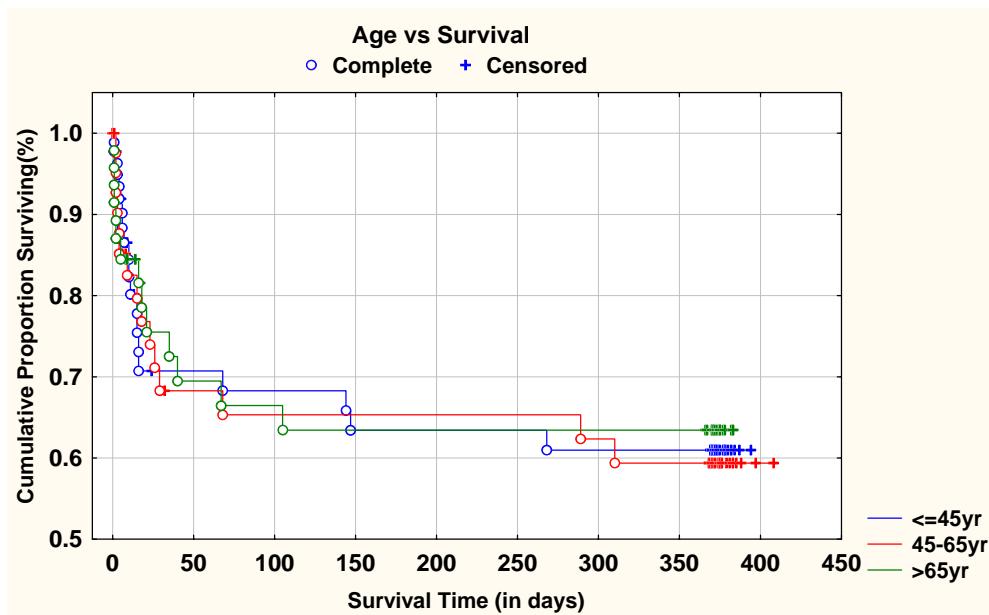
Graph 4.3 – Correlation between age and long-term survival
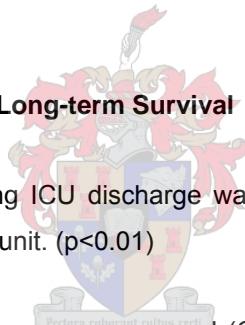
The Effect of Selected ICU Variables on Long-term Survival

The long-term survival of patients following ICU discharge was strongly correlated to their severity of illness on admission to the unit. ($p < 0.01$)

For analysis purposes, the APACHE II scores were grouped (Graph 4.4). The survival curves for this population decreased with increasing APACHE II scores. It is evident from graph that the long-term survival outcome of patients specifically in the 19-24 and >24 APACHE II categories was poor (refer to Graph4.4)

74
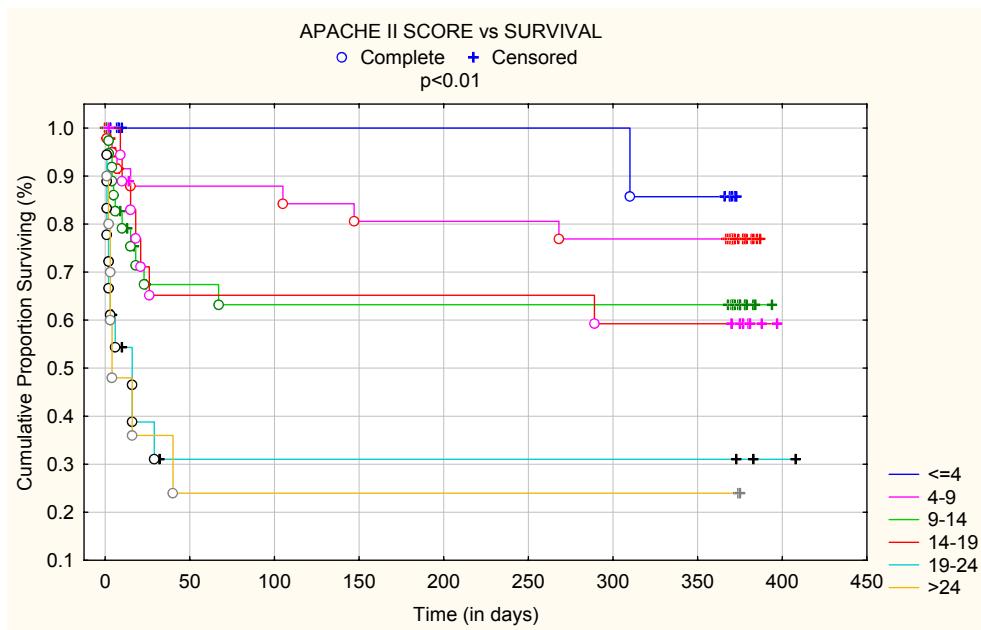
Graph 4.4 - Correlation between APACHE II and long-term survival

None of the other selected variables were significantly associated with survival.

It is interesting to note that even though patients with higher APACHE II scores stayed in the unit for longer (p<0.01) the length of stay in ICU did not have a significant influence on their long-term survival (p=0.4). Patients who had elective surgery were not as severely ill as those who had not (p=0.02) (refer to Table 4.2).

Table 4.2. Correlation between selected ICU variables and survival and APACHE II (*– significant p-value).

Selected ICU Variables vs :	Survival (p-value)	APACHE II (p-value)
ICU Length of Stay	P=0.40	p<0.01*
Length of Intubation	P=0.43	p=0.12
Admission Diagnosis :		
1. Elective surgery	p=0.82	p=0.01*
2. Emergency surgery	p=0.38	p=0.11
3. Traumatic Injury	p=0.07	p=0.56

DISCUSSION

The long-term survival outcome of the current study population is comparable to ICU populations investigated in a variety of international studies (refer to Table 4.3). All these studies were completed in first world countries. The researcher failed to identify long-term survival data from other third world countries. The cost involved in conducting these long-term observational studies could be reason for this as Michell (2005) pointed out that it is currently beyond the resources of most state ICU's to gather this kind of data.

A comparison between ICU populations can be seen in Table 4.3. These are recent studies which used the same long-term survival outcome of 12 months following ICU discharge.

Table 4.3. Comparison of survival outcomes and outcome associated variables of different ICU populations.

Author/s and Country	ICU	Population	(n=)	Period Months/yr	APACHE II	ICU LOS	Survival
Karachi et al 2005 (current study), SA	Surgical	180	180	12 months	12.3+/-7.2	Mean 5.9d +/-6.21 Median = 3.6d Range (0.48-33.2)	62%
Lipsett et al 2000, USA	Surgical	128	127	12 months	23.4+/-6.6	Median = 11d Range(7-77)	45.3%
Eddleston et al 2000, UK	University Hospital	370	370	12 months	15+/-7	Median = 3.7d Range (1.1-11.3)	57%
Rockwood et al 1993, Canada	Two Adult multi-disciplinary closed unit	1040	884	12 months	17+/-9 (<65yr) 21+/-9 (>65yr)	4.1d+/-5.8 (<65yr) 4.2d+/-6.2 (>65yr)	65%

This population has a comparably higher survival rate at 12 months than those of Lipsett et al (2000) and Eddleston et al (2000) but is comparably lower than that of Rockwood et al (1993). This difference however can be attributed to the variance in associated ICU variables such as APACHE II scores. However although Rockwood et al (1993) had a slightly higher survival rate than this cohort the mean APACHE II score for their population was higher.
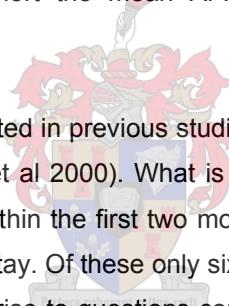
The same decline in cumulative survival noted in previous studies, was also observed in this cohort (Eddleston et al 2000, Lipsett et al 2000). What is quite alarming though is that of the 49 patients who died 40 died within the first two months following admission and only 9 patients survived their hospital stay. Of these only six survived for longer than 50 days after going home. This does give rise to questions concerning for example the cost associated with this specialized care and the worth of ICU treatment (refer to Graph 4.2).

In this cohort the only variable that was associated with long-term survival was the APACHE II. Patients who had APACHE II scores of more than 24 only had a 25% chance of survival (refer to Graph 4.4). This raises questions about decisions regarding admission of patients to ICU. Even though severely ill patients with high APACHE II scores have a small chance of survival they do have a chance. Therefore this presents

an ethical dilemma when deciding which of these patients would benefit more and what would benefit intensive care units in reducing ICU mortality rates and improve cost-effectiveness. The APACHE II scoring system was developed by Knaus et al (1985) to predict ICU mortality and was not originally intended to predict long-term survival. This outcome presents an important clinical finding that may be useful or have a role in determining whether ICU admission will be beneficial in terms of long-term survival outcomes. This finding is supported by Lipsett et al (2000) who state that after multivariate regression analysis of age, gender, surgical ICU LOS, hospital LOS, APACHE II and diagnosis as predictors of survival, only an elevated APACHE II remained a significantly negative predictor of survival. Earlier Rockwood et al (1993) also stated that the long-term outcome from critical illness is most strongly predicted by the severity of illness as scored by the APACHE II system.

In this cohort no association could be found between long-term survival and length of stay. A possible reason for this is that patients with higher APACHE II scores were more likely to die in the first three days (Hanekom 2004). Long-term stays in ICU result in various complications that in turn may affect outcome (Barie et al 1996). It could be postulated that length of stay in ICU would negatively influence survival outcomes due to these complications that can developed from prolonged stay. This was not seen in this study. This could be because of the very few patients (n=17) who stayed in the unit for more than 14 days. Fourteen days has been described by Fakhry et al (1996) as prolonged ICU stay. Fakhry et al (1996) found that despite significant economic investment, their population had a relatively high survival rate even after prolonged ICU stays. They therefore did not support withdrawal of therapy or triage decisions solely or primarily based on ICU length of stay. This supports the finding of this study that ICU length of stay is not significantly associated with the long-term survival in this South African based ICU population.

Age was not significantly related to the long-term survival outcome of this population. This outcome is supported by Fakhry et al (1996) and Rockwood et al (1993). Rockwood et al (1993) reported that although survival rates differed between age groups it did not have an important impact on long-term survival prediction.

Chelluri et al (1993) studied the long-term outcome of critically ill elderly patients requiring intensive care. The study included 54 patients who were aged 75 and older and 43 patients aged between 65 and 74 years. They reported a survival rate of 39% at 12 months but concluded that age alone was not an adequate predictor of long-term survival in elderly critically ill patients. As age is one variable used to determine APACHE II scores on ICU admission, it is not surprising that a significant positive correlation was found between these two variables in this population.

The length of intubation in this cohort had no significant association to long-term survival. Douglas et al (2002) evaluated the effect of short term (>24 - ≤96 hours) and long-term (≥96 hours) intubation on long-term survival outcomes in ICU patients. They reported that there was no significant difference in the survival outcome for the two groups. This is in agreement with the outcomes of the current study. However Combes et al (2003) reported poorer long-term survival outcomes after prolonged intubation. Montuclard et al (2000) reported that elderly patients with prolonged mechanical ventilation and ICU length of stay showed a 3 month survival outcome. This again raises questions regarding cost and effectiveness of ICU as 3 months increased survival is not necessarily beneficial as the costs may be far greater to maintain the quality of life for this short period. Again this results in an ethical dilemma regarding the cost of saving lives at the expense of wasting already limited resources.

Even though no association could be identified between the admission diagnosis (elective, emergency surgery and/or traumatic injury) and long-term survival, it was interesting to note the trend in a poor survival outcome in patients admitted after a traumatic injury. This could be attributed to the severity of traumatic injuries that patients in SA are faced with such as injuries due to violence (Hanekom 2004). APACHE II was significantly related to elective surgery as those who had elective surgery had lower APACHE II scores.

The factors affecting long-term survival outcome differed among studies. The reasons for this could be due to sample size, period of follow-up, differing demographic and ICU variables, differences in ICU standards and practices. Therefore it is not always known which factors to take into consideration when making decisions regarding ICU

admission. However it is clear that the common factor affecting outcomes and associated to other factors is the APACHE II score which has shown to be useful not only as an outcome predictor within ICU as intended but also of long-term outcome.

CONCLUSION

The long-term survival outcome of the current study is comparable to that of international ICU populations. This outcome may suggest that the standard of care in this third world ICU setting is on par with that of first world ICU settings despite the limited resources and increased demands due to the high incidence of infectious disease and trauma in South Africa (Michell 2005).

APACHE II was intended for use in predicting ICU mortality however this study has shown that it is also able to predict long-term survival outcomes in these populations. This variable may aid in making decisions regarding who will benefit from ICU in the long-term which may assist in decreasing cost by utilizing limited resources more effectively.

The fact that a set population was used many patients were not contactable as they had moved homes or no longer had telephones could be considered as a limitation of this study.
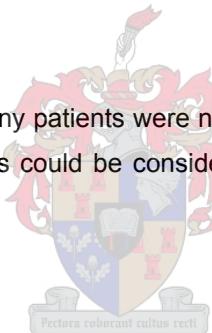
RECOMMENDATIONS

Further studies in the Western Cape and South Africa need to be done in order to make closer comparisons between SA ICU's and their outcomes in order to determine the value of this specialty. Although survival studies give us an idea of how well ICU's fare in prolonging life and producing a good survival outcome it can be seen that it does not give us a full picture of the effect of ICU on patients. Therefore it is recommended that further study in this field include health related quality of life outcomes in ICU survivors in order to determine how intensive care affects the patient on the whole.

REFERENCES

Angus DC, Carlet J 2003 Surviving Intensive Care: a report from the 2002 Brussels Roundtable. Intensive Care Medicine 29:368-377

Barie PS, Hydo LJ, Fischer E 1996 Utility of illness severity scoring prediction of prolonged surgical critical care. Journal of Trauma 40(4):513-519

Capuzzo M, Bianconi M, Contu P, Pavoni V, Gritti G 1996 Survival and quality of life after intensive care. Intensive Care Medicne 22:947-953

Chelluri L, Pinsky MR, Donahoe MP, Grenvik A 1993 Long-term Outcome of Critically Ill Elderly Patients Requiring Intensive Care. JAMA 269(24):3119-3123

Combes A, Costa MA, Trouillet JL, Baudot J, Mokhtari M, Gibert C, Chastre J 2003 Morbidity, mortality, and quality-of-life outcomes of patients requiring ≥14 days of mechanical ventilation. Critical Care Medicine 31(5):1373-1381

Douglas SL, Daly BJ, Gordon N, Brennan PF 2002 Survival and quality of life: Short-term versus long-term ventilator patients. Critical Care Medicine 30(12):2655-2662

Dragsted L, Qvist J, Madsen M 1990 Outcome from intensive care IV A five year study of 1308 patients: long-term outcome.European Journal of Anaesthesiology 7:51-62

Eddleston JM, White P, Guthrie E 2000 Survival, morbidity, and quality of life after discharge from intensive care. Critical Care Medicine 28(7):2293-2299

Fakhry SM, Kercher KW, Rutledge R 1996 Survival, Quality of Life, and Charges in critically ill surgical patients requiring prolonged ICU stays. The Journal of Trauma: Injury, Infection and Critical Care 41(6):999-1007

81

Hanekom 2004 The profile of a surgical ICU in a public sector tertiary hospital in South Africa. (unpublished)

Knaus WA, Draper EA, Wagner DP, Zimmerman JE 1985 APACHE II. Severity of disease classification system. Critical Care Medicine 13:818-829

Lam S, Ridley S 1999 Critically ill medical patients, their demographics and outcome. Anaesthesia 54:845-852

LeGalle J-R, Brun-Buisson C, Trunet P, et al 1982: Influence of age, previous health status and severity of acute illness on outcome of intensive care. Critical Care Medicine 10:575-577

Lipsett PA, Swoboda SM, Dickerson J, Ylitalo M, Gordon T, Breslow M, Campbell K, Dorman T, Pronovost P, Rosenfeld B 2000 Survival and Functional Outcome After Prolonged Intensive Care Unit Stay. Annals of Surgery 231(2):262-268

Niskanen M, Kari A, Halonen P 1996 Five year survival after intensive care – comparison of 12180 patients with the general population - Finnish ICU Study Group. Critical Care Medicine 24:1962-1967

Mathivha LR 2002 ICU's worldwide: An overview of critical care medicine in South Africa. Critical Care 6(1):22-23

Michell WL 2005 Editorial: Who is too sick for the ICU? South African Journal of Critical Care 21(1):8

Mobilising against TB: South African Plan for TB control for 2002-2005: http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf (visited 18/11/05)

Montuclard L, Garrouste-Orgeas M, Timsit JF, Misset B, De Jonghe B, Carlet J 2000 Outcome, functional autonomy, and quality of life of elderly patients with long-term intensive care unit stay. Critical Care Medicine 28(10):3389-3395

Potgieter P, Hammill L, Gough, Hamond J 1995 Cost of Critical care in South Africa. South African Medical Journal 85(5):425-430

Ridley S, Plenderleith L 1994 Survival after intensive care: Comparison with a matched normal population as an indicator of effectiveness. Anaesthesia 49:933-935

Rockwood K, Noseworthy TW, Gibney RT, Konopad E, Shustack A, Stollery D, Johnston R, Grace M 1993 One-year outcome of elderly and young patients admitted to intensive care units. Critical Care Medicine 21(5):687-691

Rubenfeld GD, Angus DC, Pinsky MR, Curtis JR, Connors AF, Bernard GR and The Members of the Outcomes Research Workshop 1999 Outcomes Research in Critical Care – Results of the American Thoracic Society Critical Care Assembly Workshop on Outcomes Research. American Journal of Respiratory and Critical Care Medicine 160:358-367

Stiller K 2000 Physiotherapy in Intensive Care. Towards and Evidence-based Practice. Chest 118(6):1801-1813

Strategic and Service Delivery Improvement Plan (SSDIP) Provincial Government of the Western Cape Department of Health Draft Paper 2000: http://www.westerncape.gov.za/health-social-services/policy planning (visited 15 April 2004)

Zaren B, Bergstrom R 1988 Survival of intensive care patients I: prognostic factors from the patient's medical history. Acta Anaesthesiology Scandinavia 32:93-100

CHAPTER 5

RESEARCH ARTICLE

Health Related Quality of Life following surgical ICU discharge
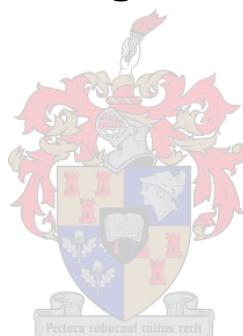
ABSTRACT

Objectives: To determine the HRQoL and the selected variables that affect the HRQoL of patients 12 months following adult surgical ICU discharge.

Design: Prospective observational cohort

Setting: Ten-bed closed tertiary adult surgical ICU at TBH

Patients: A population of 66 subjects.

Measurements: Demographic data (age and gender) and ICU variables (admission for emergency or elective surgery or traumatic injury, severity of illness (APACHE II), length of stay (LOS), length of intubation (LOI) and treatment by student or graduate physiotherapist). This was obtained from the baseline study. Employment status, smoking/alcohol use, TB/HIV status and follow-up status was obtained from the self-developed questionnaire.

Methods: Telephonic interviews were conducted on consent. A self-developed questionnaire was used to obtain selected variables. A modified SF-36 version 2 questionnaire was used to determine HRQoL.

Results: Forty-six subjects took part in this study. The mean SF-36 HRQoL domain scores ranged between 43% and 53%. Age and APACHE II were significantly associated with the social functioning (p=0.01) and physical functioning (p=0.02) domains respectively. None of the other variables were significantly associated with any of the HRQoL domains.

Conclusion: APACHE II may be a useful contributor in predicting long-term physical functioning outcomes. The HRQoL outcomes are slightly lower than international ICU populations however the domains affected are comparable to them. Low scores in the physical functioning, role play and role emotion domains indicate a need for further physical and emotional rehabilitation.

INTRODUCTION

As an increasing number of patients are surviving critical care, quality of life assessment among ICU survivors has become a research priority (Dowdy et al 2005). The cost of intensive care is huge (Eddleston et al 2000, Stiller 2000). However with increasing numbers of patients surviving, the long-term outcome of these survivors needs further evaluation in order to determine the further health care costs involved for follow-up and rehabilitation that may be required to improve a poor quality of life outcome after ICU discharge (Buckley et al 2001). Health researchers are moving away from the emphasis on mortality and are focusing more on the causes and consequences of disability (Eales et al 2000). These authors maintain that a greater understanding of the impact and treatment of illness is provided by the evaluation of quality of life than traditional outcome measures such as mortality.

The success in the prolongation of life of ICU patients may result in a health outcome that is considered to be worse than death (Lipsett et al 2000). A patient may survive ICU but may be severely disabled and may therefore need continuous care as they are unable to live independently. Thus in critically ill patients establishing a good quality of life outcome is important (Lipsett et al 2000).

Eales et al (2000) stated that as long ago as 1908 J Royce stated that a human person is a life lived according to a human plan. These authors also state that even though diseases are not always fatal the patients comfort and happiness is affected by them. As a result the patient is unable to lead a life according to his or her plan and therefore the quality of life of the patient is affected. The objective of rehabilitation teams should therefore be to assist patients in reformulating their life-plan in order to lead a life with some quality. In the final outcome the quality of life of the patient may be affected and therefore it is important to assess the patients' judgment of the medical treatment and the resultant outcome (Eales et al 2000).

Gill and Feinstein (1994) state that in order to determine the outcome that is being measured, the outcome needs to be defined. However quality of life is an outcome that has not been accurately defined. No consensus regarding the definition of health related

quality of life and quality of life has been reached as authors' use these terms interchangeably (Gill & Feinstein 1994). They evaluated how well quality of life was measured in the medical literature. In a review of 75 eligible articles where one or more quality of life instruments were used only 11 of the 75 articles had defined quality of life. No article distinguished "overall" quality of life from health related quality of life. Quality of life is a uniquely personal perception denoting the way that individual patients feel about their health status and/or non-medical aspects of their lives. Overall quality of life consists of health related factors such as physical or functional status, emotional and mental well-being as well as non-medical factors such as family, jobs, friends and other life circumstances that affect patients (Gill & Feinstein 1994). Therefore it is important to note that health related quality of life refers to how health status or health related factors impacts on a patients' quality of life. Therefore one of the major problems with quality of life research is that there is no universal definition of quality of life and therefore failure to define quality of life has been identified as a major weakness in many studies (Eales et al 2000).

"…HRQoL is a subjective measurement of one's well-being - a perception of the degree of contentment with and capability to perform and control all the facets of one's life…" (Möller & Smit 2004:32).

HRQoL is a patient centered outcome and can be affected by a variety of factors. These factors could be:
- patient-based which would include factors like age, gender, employment, severity of illness (APACHE II) ICU admission diagnosis, and co-morbidities,
- clinical management exposures such as mechanical ventilation time, ICU length of stay, physiotherapy treatment and/or
- ICU organizational factors such as ICU physician staffing, nurse to patient ratio, ICU and hospital volume, available technology and hospital teaching status (Needham et al 2005).

In order to measure HRQoL outcomes in ICU survivors valid and reliable instruments are needed that are generic, as ICU survivors may have a variety of underlying diseases

(Rubenfeld et al 1999). Four of these most frequently cited in the literature are the Sickness Impact Profile (SIP), Nottingham Health Profile (NHP), Euro-QoL 5D (EQ-5D) and the Short Form 36 (SF-36). At a consensus conference, the Brussles Roundtable held in 2002 the EQ-5D and the SF-36 were however recommended as the most appropriate instruments for research in ICU populations (Needham et al 2005).

The SF-36 was developed using factor analysis from the much longer batteries of items in the RAND Corporation's health insurance study experiment. The advantage of the SF-36 is that it has been more widely used and that it may be administered telephonically taking approximately 5-10 minutes to complete (Mishoe & Maclean 2001). It measures eight domains of HRQoL, namely physical functioning (PF), role play (RP), role emotion (RE), bodily pain (BP), social functioning (SF), vitality (VT), general health perception (GH) and mental health (MH). Each domain measures the extent to which physical and/or emotional health problems affect physical, social, emotional, psychological and psychosocial aspects of HRQoL. There is also a self reported health transition item that asks patients' how they feel their health is compared to a year ago. This item is not used to score any of the eight multi-item scales mentioned above (Ware 2004; Möller & Smit 2004).

.

Scoring may be done manually by using the scoring guidelines provided by the SF-36 Medical Outcomes Trust or by using the electronic database scoring system (refer to Addendum C). Each domain has a set of items and options or scales. The options/scales are measured using a Likert-type scale which is then calculated to a percentage which can range from zero [worst possible health status] to 100 [best possible health status] (Eddleston et al 2000). There are two summary component scores namely the physical (PCS) and mental component score (MCS). Figure 5.1 below shows which of the eight domains contribute to each of the summary component scores.
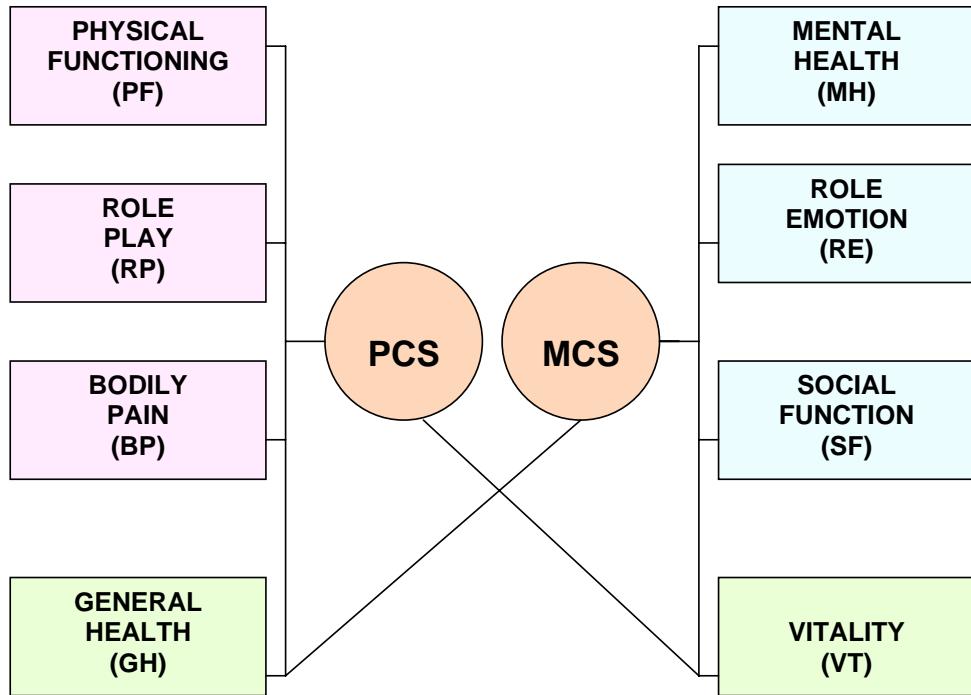
Figure 5.1 SF-36 Scales Measure Physical and Mental Components of Health (Ware 2004).

The SF-36 HRQoL measure has reported validity and reliability for use within the ICU setting (Chrispin et al 1997). It has not been used in a South African ICU population nor in the general South African population and therefore no normative data is available for either for comparisons.

Quality of life assessments have occurred infrequently in the ICU literature and are of limited methodological quality. Therefore more studies using valid and reliable instruments are necessary to document long-term quality of life of critically ill patients especially those at risk of a poor outcome (Heyland et al 1998). The shift of focus of outcome research in intensive care to quality of life evaluation and the lack of quality of life outcome studies in South African ICU populations has therefore led to the following question: "What is the HRQoL of adult surgical ICU survivors 12 months following discharge from a public tertiary hospital intensive care in the Western Cape, South Africa?"

METHODOLOGY

This study is a follow-up to a baseline study conducted in the adult surgical ICU of a public sector tertiary hospital in South Africa between June and October 2003. The purpose of the baseline study was to evaluate the profile of this ICU by describing the baseline data of a surgical ICU in South Africa. This prospective observational cohort study was undertaken to determine the HRQoL outcome of patients' 12 months after discharge from a surgical ICU. Approval was obtained from the Research Ethics Committee of the University of Stellenbosch (Project number N04/05/092).

Patients who were younger than 18 years of age, who could not be contacted, who refused to participate and who could not speak English or Afrikaans were excluded. This resulted in 66 subjects from the original cohort of 180 subjects forming the population to determine the HRQoL of this population 12 months following surgical ICU discharge.

Selected variables were obtained from the baseline data or from patient hospital folders and included the following:

- Age
- Gender
- Length of stay in ICU
- Intubation Period
- Admitting Diagnosis (elective, emergency surgery, traumatic injury)
- Severity of Illness/Disease on admission (APACHE)
- Treatment received by student or graduate Physiotherapists

A self-developed questionnaire was designed which consisted 3 sections with a total of 15 questions which provided information on:
- employment status before and after critical illness,
- TB status,
- HIV status,

- smoking,

- alcohol consumption and

- whether patients attended follow-up or not.

These were used to determine their association with HRQoL.

A license agreement (number: R1-061704-19248) was obtained to use the UK SF-36 version 2 questionnaire. This questionnaire was modified in conjunction with Dr Maria Burton who has had experience with this questionnaire in her PhD study. It was done in order to suit the population being studied and was translated to Afrikaans as this besides English was a common language spoken and understood in this population.

Subjects were sent letters two weeks in advance to inform them of the study and the telephonic interview. They were contacted telephonically in order to make an appointment to carry out the interview which was done on consent.

The data and the results from the questionnaires were captured in an Excel spreadsheet. The self-developed questionnaire was descriptively analyzed. The SF-36 was scored using the electronic internet SF-36 scoring system and scores were checked manually using the SF-36 scoring manuals for accuracy by the researcher.   In conjunction with the statistician, the data was then analyzed and comparisons were made.

Data was analyzed in the following manner:
- The mean scores and standard deviations were calculated for each HRQoL domain and the two component summary scores. This descriptive data was plotted in a box whisker graph.
- Mann-Whitney U, Chi-square t-tests and Spearman Correlations were used to determine associations between the different selected variables and between selected variables and the HRQoL domain scores.

Values were accepted as significant at the 5% level ($p < 0.05$).

RESULTS

A description of the demographic and ICU variables of this sample population and HRQOL outcomes will be reported.

Descriptive Data

A total of 46 subjects qualified to complete the SF-36 questionnaire. Twenty subjects were excluded according to the exclusion criteria. The demographic and clinical characteristics of this sample are shown in Table 5.1. Important differences noted in the table are that although females were older, they had a shorter ICU length of stay, and intubation period had a slightly lower APACHE II score, none suffered traumatic injury, fewer females smoked or consumed alcohol and more attended follow-up after ICU discharge compared to the males. However, none of these noted differences were significant.
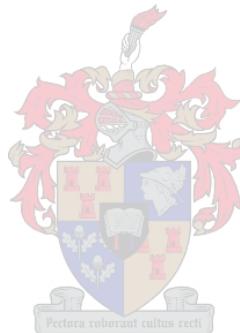
Table 5.1 Demographic and clinical characteristics of subjects who completed the SF-36 (n=46)

Selected Variable (Average)	Male (n=22)	Female (n=24)	Total Population (n=46)
Age (Range: 30yrs – 81yrs)	52.3yrs (SD+/-20)	56.3yrs (SD+/- 19.5)	54.3yrs (SD+/-19.8)
Length of Stay (LOS)	6.4d (SD+/-7.8)	3.5d (SD+/-7.5)	4.91d (SD+/-5.52)
Length of Intubation (LOI)	7d (n=7) (SD+/-7.8)	2.65d (n=6) (SD+/-7.5)	3d (n=13) (SD+/-7.3)
Admitting Diagnosis: 4. Elective Surgery 5. Emergency Surgery 6. Traumatic Injury	n=6 n=12 n=6	n=12 n=12 n=0	n=18 n=24 n=6
APACHE Score (Range: 0-38)	12.9 (SD+/-6.21)	11.2 (SD+/-6.2)	12 (SD+/-6.1)
Physiotherapy: 1. Treatment by student 2. Treatment by graduate	n=5 n=17	n=9 n=15	n=14 n=32
Employment: 1. before ICU 2. after ICU	n=12 n=5	n=12 n=5	n=24 n=10
TB Status: 1. Yes 2. No 3. Unsure	n=1 n=10 n=11	n=1 n=11 n=12	n=2 n=21 n=23
HIV Status: 1. Yes 2. No 3. Unsure	n=0 n=10 n=12	n=0 n=11 n=13	n=0 n=21 n=25
Smoking: 1. Yes 2. No	n=11 n=11	n=2 n=22	n=13 n=33
Alcohol: 1. Yes 2. No	n=11 n=11	n=5 n=19	n=16 n=30
Follow-up: 1. Yes 2. No	n=17 n=5	n=22 n=2	n=39 n=7

Of the 46 subjects interviewed all reported taking part in at least one hobby.

It will be seen from Table 5.2 that lying to sitting and sitting to standing were the only components where subjects reported some limitation.

Table 5.2 Limitations in physical activity

Physical activity	Yes, limited a lot	Yes, limited a little	No, not limited at all
Lying – sitting	n=2	n=10	n=34
Sitting – standing	n=2	n=15	n=29
Walking with support	n=3	n=0	n=43
Walking without support	n=5	n=6	n=35

HRQOL Data

The average HRQoL for this sample ranges between 43% and 53% (SD +/-9.4 -12.5) (refer to Graph 5.1). The subjects scored the highest percentage for the vitality domain (52.5%) and the lowest percentage on the physical functioning domain (43.5%). The mental component score was higher (49.1%) than the physical component score (45.8%). In the self-reported transition question the majority of patients (n=23) reported their health to be much better than a year ago following ICU discharge, 5 were slightly better, 10 were the same, 5 were slightly worse, and 3 were much worse than a year ago.
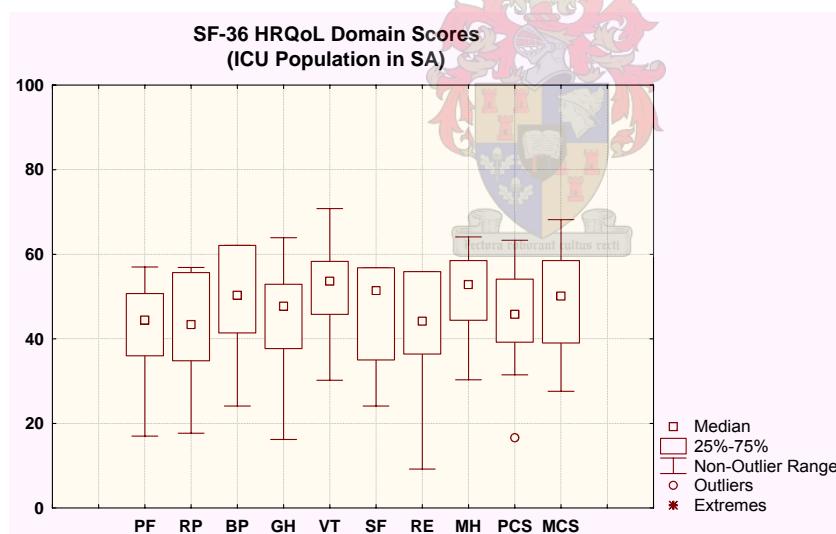
Graph 5.1 - HRQoL Domain Percentage Scores

Determinants associated to the HRQoL outcomes

Significantly more males sustained traumatic injury than females (p=0.03). The patients treated by student therapists presented with significantly lower APACHE II scores (p=0.03). Patients admitted to the unit following emergency surgery presented with significantly higher APACHE II scores (p=0.03). While all patients with higher APACHE II scores stayed in the unit significantly longer (p<0.01)

The more severely ill patients scored significantly lower in the physical functioning domain (p<0.01), while increasing scores in the social functioning domain and role emotion domains were significantly influenced by increasing age (p=0.03).

Patients who were employed after ICU had a significantly better general health score than those who were not (p<0.01).

Patients who were unsure of their TB status reported to have a poorer general health outcome (p=0.02). However patients unsure of their HIV status had more problems in the role emotion domain (p=0.05). Patients requiring mechanical ventilation for a prolonged period and therefore would have had a longer ICU length of stay reported a poorer general health outcome (p=0.04). However, an increased length of stay in ICU resulted in those patients reporting significant limitations in the role play (p=0.05) and role emotion (p<0.01) domains.
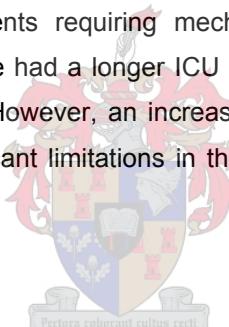
Table5.3 Association of selected variables with SF-36 HRQoL domains (*- significant p-values)

Selected Variable	PF	BP	VT	SF	MH	RP	RE	GH
Age	0.06	0.44	0.97	<0.01*	0.07	0.58	0.03*	0.28
Gender	0.41	0.13	0.11	0.22	0.57	0.79	0.58	0.49
APACHE II	0.02*	0.83	0.28	0.73	0.54	0.58	0.7	0.09
Employed after ICU	0.12	0.74	0.43	0.99	0.65	0.39	0.96	<0.01*
TB status	0.17	0.10	0.36	0.72	0.80	0.06	0.07	0.02*
HIV status	0.15	0.15	0.54	0.33	0.98	0.1	0.05*	0.06
Alcohol	0.96	0.23	0.54	0.12	0.18	0.3	0.08	0.11
Smoking	0.6	0.48	0.62	0.83	0.71	0.97	0.98	0.67
Treatment by student Physiotherapist	0.63	0.38	0.81	0.61	0.45	0.76	0.64	0.23
Elective	0.26	0.97	0.33	0.41	0.21	0.51	0.33	0.74
Emergency	0.15	0.80	0.37	0.61	0.57	0.52	0.33	1.0
Traumatic	0.67	0.90	0.97	0.30	0.45	0.09	0.43	0.88
ICU LOS	0.06	0.9	0.69	0.89	0.86	0.05*	<0.01*	0.16
Intubation period	0.34	0.95	0.07	0.43	0.98	0.25	0.55	0.04*
Follow-up	0.67	0.51	0.10	0.86	0.53	0.7	0.7	0.43

DISCUSSION
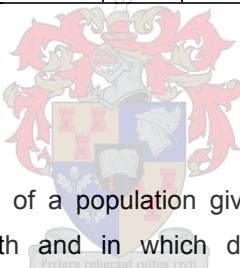
The health related quality of life outcome of a population gives an idea of how the particular population perceive their health and in which domains the population experiences the most problems. However it is helpful to compare the values to those of other populations when interpreting the outcomes. This may provide a context in which to interpret the HRQoL perceptions of a specific cohort. The general population of SA may not necessarily perceive their QoL to be 100% and therefore comparisons will give an idea of how specific cohorts of patients fair against each other and the general population. A difference of 20 points in a dimension is considered clinically and socially relevant depending on the sample size when comparing the SF-36 domain scores (Ware, 2000).

The ICU population struggled mostly in the physical functioning, role play and role emotion domains where they scored the lowest percentages.

The HRQoL perceptions of two South African population subgroups namely active police and AIDS sufferers examined by Möller & Smit (2004) were compared to the outcome of the ICU population in the current study. The reason for this comparison instead of a comparison between the ICU population and the general SA population is that SF-36 normative data for the general South African population is not available.

The ICU population was more limited in the physical functioning, role play, role emotion, social functioning and bodily pain domains compared to the police. However when compared to the AIDS sufferers they struggled more than the AIDS sufferers in the physical functioning and role play domains. These differences among the subgroups were clinically and socially relevant (refer to Graph 5.2).
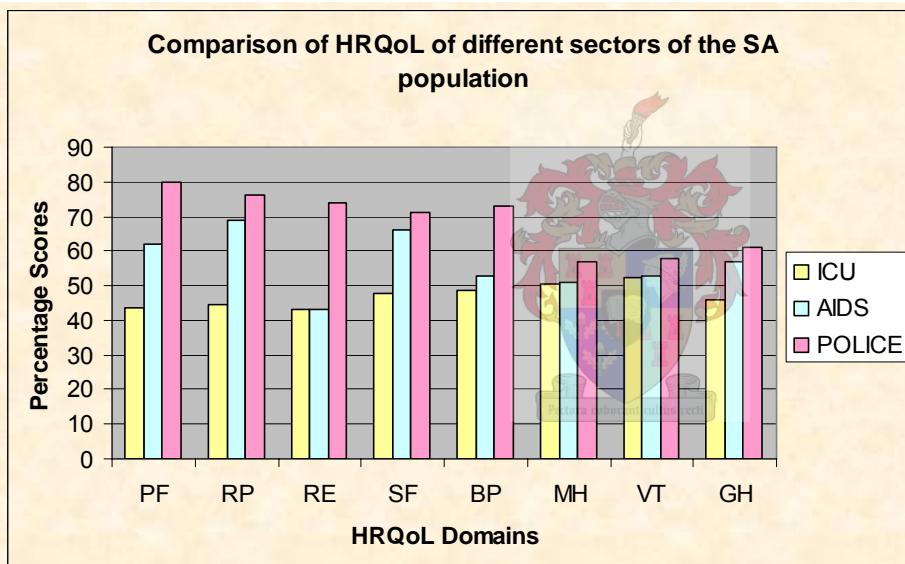
Graph 5.2 Comparison between HRQoL perceptions of active police, AIDS sufferers and critically ill surgical intensive care unit survivors.

In comparison to international ICU populations the HRQoL outcomes of the ICU survivors were in general comparably lower.

Physical Functioning

The physical functioning domain represents any limitations in activities of daily living such as vigorous activities like running, moderate activities like vacuuming or bowling, lifting or carrying groceries, climbing one/several flights of stairs and walking over various distances and bathing and dressing. The scores indicate the extent to which the patients' perceptions of their quality of life are affected by their physical health problems. The slow physical recovery of ICU survivors occurs due to muscle wasting and weakness which is a result of limited mobility in ICU (Jones et al 2003). ICU survivors in the current study who were severely ill in ICU stayed longer in ICU and also reported greater limitations in physical functioning. The scores were comparably lower than that of AIDS sufferers and police in South Africa. This difference was clinically and socially relevant. The physical functioning scores were also lower at 12 months compared to that found internationally by Eddleston et al (2000) at 3 months, Kvåle et al (2003) at 6 months and Pettilä et al (2000) at 12 months. These studies used the SF-36 questionnaire and had larger sample sizes than the current study. Compared to studies using other HRQoL measures in ICU survivors such as Capuzzo et al (1996) (researcher devised questionnaire), Tian & Miranda (1995) (SIP), Konopad et al (1995) (Spitzer Quality of Life Index) and Granja et al (2002) (EQ-5D) physical functioning also presented limitations.
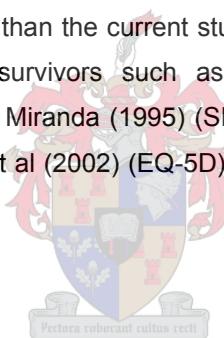
Role Play

Role play measures the extent to which physical health problems affect performance at work or other regular daily activities at home respectively such as cutting down on time spent on these activities or accomplishing less in these activities. The outcomes in this domain show that the ICU survivor feels that his/her role is limited due to physical health problems and may lead to the need to change the previous role that the patient may have had. It also suggests that these patients are unable to endure physical activities such as work in and out of the home as they need to cut down the amount of work or accomplish less at work. Patients who had a longer ICU length of stay had more

limitations in their work role or regular activities of daily living. Again muscle wasting and weakness may result in slow recovery and therefore limit the endurance in higher functional activities like working (Jones et al 2003). These ICU survivors scored lower in this domain than the AIDS sufferers and police in South Africa. This difference was also clinically and socially relevant. The ICU survivors in the current study had less limitation in role play than the population studied by Kvåle et al (2003) at 6 months and Pettilä et al (2000) at 12 months but more limitation than Eddleston et al (2000) at 3 months. Fakhry et al (1996), Vazquez Mata et al (1996) and Capuzzo et al (1996) found similar outcomes in this domain using different HRQoL outcome measures.

Role Emotion

Role emotion measures the extent to which emotional health problems affect performance at work or other regular daily activities respectively such as cutting down on time spent on these activities or accomplishing less in these activities. The ICU survivors experienced a limitation in this domain similar to that of the AIDS sufferers. The limitation however was greater than that experienced by the police group but less than that found by some international studies (Eddleston et al 2000, Pettilä et al 2000, Kvåle et al 2003). The effect of emotional trauma due to high levels of psychological distress including post-traumatic disorder in these patients supports the limitation in role due to emotional health problems reported by this sample of ICU survivors (Jones et al 2003). ICU survivors who reported to be unsure of their HIV status scored significantly lower in this domain than those who reported a negative HIV status. The result of some patients not knowing their HIV status may have a negative effect on the emotional status of these patients therefore resulting in a poorer outcome in this domain. Patients who stayed for a longer period in ICU experienced more problems in their activity roles due to emotional health problems than those with a shorter stay. The effect of ICU stay may result in delirium, hallucination and problems with short term memory due to the stress of illness, drugs, sleep deprivation, etc. which may result in emotional health problems therefore affecting functional roles (Kvåle et al 2003). Elderly ICU survivors also reported less limitation in role emotion than younger individuals. It may be that as elderly survivors had more support as they stayed with their families, did not have to work and belonged to social groups the support base may be greater than with younger survivors

who have to continue with work and support their family and who may not have as much free time to speak to friends and family for support.

Social Functioning

Social functioning refers the extent to which physical and emotional health problems have interfered with the patients' social interaction with family, friends and social groups or clubs. It also measures how often the patients' physical and emotional health problems have interfered with their social interactions. The ICU population had greater limitations in social functioning than the AIDS sufferers and police in South Africa and the international ICU populations studied by Pettilä et al (2000) and Kvåle et al (2003). Elderly ICU survivors in the current study had a better perception of their social functioning than younger survivors. Elderly survivors in this population either stayed with their families or in care facilities where they were taken care of. They therefore had more time to have social interactions by attending social groups or clubs or spend time with their family and friends.

Bodily Pain

Bodily pain refers to how much pain the patient experiences and how often the amount of pain interferes with their work or regular daily activities. A low score in this domain means that the patient experienced more than very mild pain which results in limitations in work and activities of daily living. There is a greater limitation in the physical role of these ICU survivors due to bodily pain. A possible reason for this could be that surgical ICU patients experience more painful procedures in ICU such as putting in A-lines for blood pressure measurements, surgical procedures (laparotomies), insertion of intravenous lines, naso-gastric tubes, catheters and suctioning than AIDS sufferers or police and this perception of pain may linger for months after discharge and therefore affect their function. The ICU survivors in the current study had lower scores than international populations (Eddleston et al 2000, Pettilä et al 2000 and Kvåle et al 2003) but the difference in scores was clinically and socially relevant when compared to Eddleston et al (2000). Granja et al (2002) found moderate to extreme problems in the pain/discomfort domain using the EQ-5D.

General Health

General health perception measures how good or bad patients feel their health is, how they feel their health compares to other people they know and whether they expect their health to get worse or deteriorate. ICU survivors who require prolonged mechanical ventilation and who reported to be unsure of their TB status perceived to have a poorer general health. TB has an effect on the respiratory system and critically ill patients with TB admitted to ICU may need prolonged ventilation due to poor respiratory function. However prolonged mechanical ventilation also affects respiratory function. Survivors who went back to work after their ICU stay perceived to have good general health as they felt their health was good, was similar to that of other people they knew and that their health would not deteriorate. This outcome is similar to those found by Lawrence et al (1996).

Mental Health

Mental health measures how often a patient has experienced a certain positive or negative feeling such as being happy, down in the dumps, calm or peaceful, nervous or down hearted and blue. Lower scores correspond to more negative feelings than higher scores. The SA ICU population had more problems with mental health than Eddleston et al (2000), Pettilä et al (2000) and Kvåle et al (2003) but the difference in scores was clinically and socially relevant when compared to Eddleston et al (2000) and Kvåle et al (2003). Granja et al (2002) found moderate to extreme problems in this domain as well using the EQ-5D.
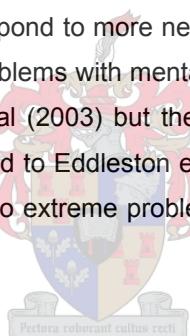
Vitality

Vitality measures how often a patient feels full of life, has a lot of energy, feels tired or worn out. Lower scores relate to a lesser feeling of vitality. The outcome of the current study was similar to that found by Pettilä et al (2000) at 12 months and was slightly higher than the score found by Kvåle et al (2003). Hurel et al (1997) reported decreased vitality with sleep disturbance and decreased energy using the NHP.

It can be seen in graph 5.2 that the ICU survivors, AIDS sufferers and police had similar scores in the mental health, vitality and general health domains. These scores are lower

than international ICU populations. This outcome is plausible for the ICU and AIDS populations as it is expected that disease or chronic illness and possible traumatic experiences in ICU may impact negatively on these HRQoL domains (Schelling et al 1998). The outcome in the current study suggests that ICU survivors perceive to be more nervous, down and depressed than calm, peaceful and happy (mental health), have less energy and life, are more tired and worn out (vitality) and perceive that they are generally sicker than other people they know, that their health will become worse and that they have poor health status (general health).

Being a police officer in SA in the past and currently is probably the most stressful area of work in this country. The South African police force has also undergone changes due to the movement towards a more democratic dispensation. Police are expected to uphold a good standard and image in communities. Their work is often exhausting, dangerous and even traumatic and they are at the receiving end of all community problems. In the townships police are exposed to violent crimes, poverty and hardships on a daily basis. These may result in post-traumatic stress syndromes and feelings of anger, depression, distress and pain. Yet, they are poorly acknowledged and receive poorly paid salaries. They generally also do not receive any positive feedback and encouragement from their superiors. Police officers often feel they cannot speak to family and friends about their experiences while on duty and therefore may feel isolated. They may often feel misunderstood and experience further stress due to domestic responsibility. There is a high rate of divorce in South African police officers and feelings of isolation and despair can lead to suicide as in 1994 when a total of 180 South African police committed suicide (http://www.csvr.org.za/papers/papstres.htm). These factors may explain the poor perception of mental health, vitality and general health status in the police group. The ICU population and AIDS sufferers had the same mean score for the role emotion domain which was lower than that of the police. This suggests that disease or chronic illness may have a more negative impact on function (work and regular daily activities) due to emotional health problems. Police are faced with stressful situations daily and may not perceive to experience limitations in function due to emotional health problems as they may have developed coping mechanisms to deal with their functional roles as police officers.

102

Traumatic injuries are more prevalent in men (http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf) and this supports the findings in this study. Patients who were admitted to the unit after emergency surgery, were more severely ill and patients who were more severely ill had longer ICU stays and also experienced a poorer outcome in physical functioning. Severity of illness (APACHEII) may be a significant predictor of long-term physical functioning outcomes following ICU discharge as increased APACHE II scores resulted in a poorer physical functioning. This is supported by Kleinpell (2003), Granja et al (2002) and Garcia et al (2003).

In the self reported health transition item patients' are asked how they feel their health is compared to a year ago. The majority of patients felt their health was much better compared to a year after ICU discharge. They therefore perceive that admission to ICU has helped improve their health. This is an important finding as it gives some support regarding the benefit and value of intensive care despite the high costs and limited resources seen in South Africa.

CONCLUSION AND RECOMMENDATIONS

It can be concluded that the study achieved its intended aim in terms of determining the HRQoL perceptions of patients 12 months following ICU by using the SF-36 HRQoL patient-centered outcome measure. Age, APACHE II, employment status, HIV/TB status, ICU LOS and intubation period are variables shown to significantly affect certain domains of HRQoL and are therefore important factors that may be taken into consideration when predicting long-term HRQoL outcomes following ICU intervention. Half of the population felt that their health was better now (12 months after ICU discharge) than before ICU admission which suggests that ICU interventions may have helped to improve health status. It was observed that similar HRQoL domains were affected in the current study compared to other studies. The ICU population in the current study showed clinically and socially relevant lower scores in the physical functioning, role play and role emotion than those of international ICU populations studied using the SF-36 as well as that of the two SA subgroups studied by Möller &

103

Smit (2004). Therefore there does seem to be a need for improvement in HRQoL in this SA ICU population.

The limitations faced in this study were as follows:

- small sample size due to set population size obtained from previous baseline study,
- no SF-36 normative data available for the SA general population therefore comparisons could not be made to determine whether the ICU population had a similar or poorer outcome,
- studies available in the literature used different time periods in the measurement of HRQoL outcomes and used different HRQoL outcome measures therefore making it difficult to compare outcomes across studies.

Physical functioning, role play and role emotion are domains in which patients reported to struggle the most. These are areas of HRQoL that may be improved with appropriate early intervention in ICU and out in the community settings by physiotherapists and other rehabilitation therapists. It is therefore recommended that further research focus on the HRQoL outcomes of ICU patients after specific intervention programs in order to determine which interventions will assist in improved HRQoL outcomes from the patients perception. Although we are able to determine HRQoL outcomes based on the patients perception it is recommended that physiotherapists develop further appropriate assessment tools to determine what specifically affects the HRQoL perceptions of patients for each domain. It is also suggested that SF-36 normative data for the general South African population or population subgroups be determined in order to make comparisons among critically ill disease groups and the general population. Further research in this area in different ICU settings in SA is needed in order to determine whether there are differences in outcomes so that set standards of practice can be developed and benchmarking of units can occur. It is also recommended that studies be done determining pre and post ICU HRQoL as well as HRQoL studies in this population over time which may assist in determining whether SA ICU populations with prolonged surgical illness like those internationally are recovering over time. This will aid in determining whether the long-term cost implications are worthwhile in a setting with

already limited resources and also the need for appropriate medical, social and psychological support.

Therefore research on long-term HRQoL of SA ICU survivors may assist in the debate regarding the effectiveness of intensive care and the huge amount of resources spent on this area of health care especially in South Africa.
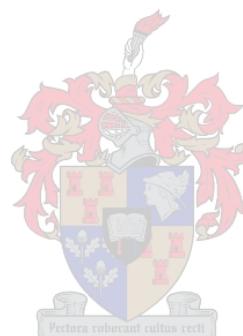
REFERENCES

Buckley TA, Cheng AYC, Gomersall CD 2001 Quality of life in long-term survivors of intensive care. Annals Academy of Medicine Singapore 30(3):287-292

Capuzzo M, Bianconi M, Contu P, Pavoni V, Gritti G 1996 Survival and quality of life after intensive care. Intensive Care Medicne 22:947-953

Chrispin PS, Scotton H, Rogers J, Lloyd D, Ridley SA 1997 Short Form 36 in the intensive care unit: assessment of acceptability, reliability and validity of the questionnaire. Anaesthesia 52:15-23

Dowdy DW, Eid MP, Sedrakyan A, Mendez-Tellez PA, Pronovost PJ, Herridge MS, Needham DM 2005 Quality of life in adult survivors of critical illness: A systematic review of the literature. Intensive Care Medicine 31:611-620

Eales CJ, Stewart AV, Noakes TD 2000 Chronic Illness and Quality of Life. South African Journal of Physiotherapy 56(4):10-16

Eddleston JM, White P, Guthrie E 2000 Survival, morbidity, and quality of life after discharge from intensive care. Critical Care Medicine 28(7):2293-2299

Fakhry SM, Kercher KW, Rutledge R 1996 Survival, Quality of Life, and Charges in critically ill surgical patients requiring prolonged ICU stays. The Journal of Trauma: Injury, Infection and Critical Care 41(6):999-1007

Garcia Lizana F, Peres Bota D, De Cubber M, Vincent JL 2003 Long-term outcome in ICU patients: what about quality of life? Intensive Care Medicine 29:1286-1293

Gill TM, Feinstein AR 1994 A Critical Appraisal of the Quality of Quality-of-Life Measurements. JAMA 272(8):619-626

Granja C, Teixeira-Pinto A, Costa-Pereira A 2002 Quality of life after intensive care – evaluation with EQ-5D questionnaire. Intensive Care Medicine 28:898-907

Heyland DK, Guyatt G, Cook DJ, Meade M, Juniper E, Cronin L, Gafni A 1998 Frequency and methodologic rigor of quality-of-life assessments in the critical care literature. Critical Care Medicine 26(3):591-598

Hurel D, Loirat P, Saulnier F, Nicolas R, Brivet 1997 Quality of life 6months after intensive care: results of a multicentre study using a generic health status scale and a satisfaction scale. Intensive Care Medicine 23:331-337

Jones C, Skirrow P, Griffiths RD, Humphris GH, Ingleby S, Eddleston J, Waldman C 2003 Rehabilitation after critical illness: A randomized, controlled trial. Critical Care Medicine 31(10):2456-2461

Kleinpell RM 2003 Exploring outcomes after critical illness in the elderly. Outcomes Management 7:159-169

Konopad E, Noseworthy TW, Johnstone R, Shustack A, Grace M 1995 Quality of life measures before and one year after admission to an intensive care unit. Critical Care Medicine 23: 1653-1659

Kvåle R, Ulvik A, Flaatten H 2003 Follow-up after intensive care: a single center study. Intensive Care Medicine 29:2149-2156
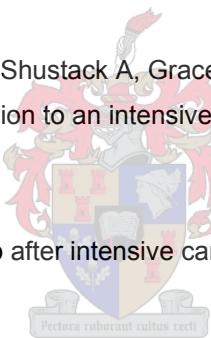
Lawrence K, Doll H, McWhinnie D 1996 Relationship between health status and post-operative return to work. Journal of Public Health Medicine 18(1):49-53

Lipsett PA, Swoboda SM, Dickerson J, Ylitalo M, Gordon T, Breslow M, Campbell K, Dorman T, Pronovost P, Rosenfeld B 2000 Survival and Functional Outcome After Prolonged Intensive Care Unit Stay. Annals of Surgery 231(2):262-268

Marks M- Stresses in the South African Police Service-
http://www.csvr.org.za/papers/papstres.htm (visited 18/11/05)

Mishoe SC, MacClean JR 2001 Assessment of Health Related Quality of Life. Respiratory Care 46(1):1236-1255

Mobilising against TB: South African Plan for TB control for 2002-2005: http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf (visited 18/11/05)

Möller PH, Smit R 2004 Measuring health-related quality of life: A comparison between people living with Aids and police on active duty. Health SA Gesondheid 9(2):31-42

Needham DM, Dowdy DW, Mendez-Tellez PA, Herridge MS, Pronovost PJ 2005 Studying outcomes of intensive care unit survivors: measuring exposures and outcomes. Intensive Care Medicine 31:1153-1160

Petillä V, Kaarlola A, Makelainen A 2000 Health related quality of life of multiple organ dysfunction patients one-year after intensive care. Intensive Care Medicine 26:1473-1479

Rubenfeld GD, Angus DC, Pinsky MR, Curtis JR, Connors AF, Bernard GR and The Members of the Outcomes Research Workshop 1999 Outcomes Research in Critical Care – Results of the American Thoracic Society Critical Care Assembly Workshop on Outcomes Research. American Journal of Respiratory and Critical Care Medicine 160:358-367
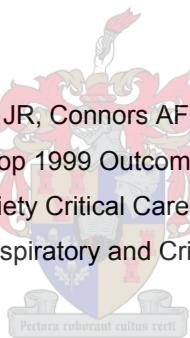
Schelling G, Stoll C, Haller M, Briegel J, Manert W, Hummel T, Lenhart A, Heyduck M, Polasek J, Meier M, Preuss U, Bullinger M, Schuffel W, Peter K 1998 Health-related quality of life and post-traumatic stress disorder in survivors of the acute respiratory distress syndrome. Critical Care Medicine 26(4):651-659

Stiller K 2000 Physiotherapy in Intensive Care. Towards and Evidence-based Practice. Chest 118(6):1801-1813

Tian ZM, Miranda DR 1995 Quality of life after intensive care with the sickness impact profile. Intensive Care Medicine21:422-428

Vazquez Mata G, Rivera Fernandez R, Perez Aragon A, Gonzales Carmona A, Fernandez Mondejar E, Navarrete Navaroo P 1996 Analysis of quality of life in polytraumatized patients two years after discharge from an intensive care unit. The Journal of Trauma, Injury, Infection, and Critical Care 41:326-332

Ware JE 2004 The SF-36 Community - SF-36 Health Survey Update http://www.sf-36.org/tools/SF-36.shtml (visited 17/02/2004)

Ware JE, Kosinski M, Gandek B 2000 SF-36 ® Health Survey: Manual & Interpretation Guide. Lincoln, RI: QualityMetric Incorporated
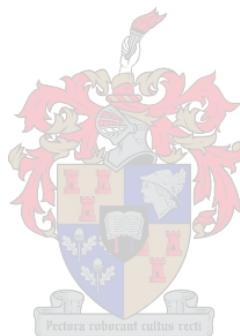
Chapter 6

Conclusion and Recommendations

In an attempt to contribute to the debate on long-term survival and HRQoL of ICU patients, the intended aims of this study has provided some evidence regarding these outcomes. In addition it has described the factors predicting these outcomes in a South African ICU population.

The survival rate of this population at 12 months following ICU discharge is comparable to that of other ICU populations studied (Eddleston et al 2000, Lipsett et al 2000, Rockwood et al 1993). These results suggest that the standard of care provided by this third world ICU setting is similar to that of first world ICU settings despite limited resources.

In spite of the comparably good long-term survival rate it is evident that the patients are experiencing difficulty in the physical functioning, role play and role emotion domains of HRQoL due to illness as in other populations (Möller & Smit 2004, Kvåle et al 2003). The physical functioning domain represents any limitations in activities of daily living such as vigorous activities like running, moderate activities like vacuuming or bowling, lifting or carrying groceries, climbing one/several flights of stairs and walking over various distances and bathing and dressing. In contrast to this role play and role emotion measures the extent to which physical and emotional health problems affect performance at work or other regular daily activities respectively. These domains were significantly affected by ICU variables such as ICU length of stay and APACHE II. These areas of difficulty and the factors affecting them can be positively addressed in rehabilitative efforts.

Severity of illness (APACHE II) proved to be an important factor affecting outcome after ICU discharge. It was the only significant predictor of both long-term survival and the physical functioning domain of HRQoL in the current ICU population. Higher APACHE II scores significantly lowered the survival

rate and physical functioning scores in this ICU population. APACHE II was developed to predict mortality in intensive care however it has shown to have an even further function in determining long-term survival and HRQoL outcomes. This has implications for ICU admission criteria.

Limitations of this observational cohort study

- With a set population size obtained from the previous baseline study and the high percentage of subjects lost to follow-up only a small sample was obtained at 12 months after discharge to determine the HRQoL of this cohort. The large amount of people who were lost to follow up might, in part, have been due to the diversity in social population dynamics encountered in South Africa. There is a 30% unemployment rate and 40% of South Africans live in poverty. Furthermore, 75% of the population, live in rural areas where they are deprived of health services (http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf). Due to illness, subjects may be unable to maintain their jobs and therefore cannot maintain their homes and telephone bills. In the case of the elderly, subjects may have been transferred to other frail care facilities and therefore no longer live at home. Some patients may live in rural areas and might have come to the city for surgery returning to their rural homes later and were therefore not contactable. Although patients lost to follow up had similar demographic and ICU variables compared to the sample obtained they may have ended in poorer home situations and therefore the extent of selection bias is not known.

- No other studies were found regarding HRQoL of ICU survivors 12 months following discharge from a South African ICU. Thus it was impossible to make any comparisons with the HRQoL outcomes that may have been found in other South African ICU settings.

- The aim of the study was achieved and the patient reported HRQoL perception was achieved by using the SF-36. However using this

measure does not give a clear understanding of what specific physical and emotional health problems has affected the patients' perceptions of their HRQoL. For example a patient may report to have to cut down on the amount of time spent on work or accomplish less in his/her work due to physical or emotional health problems according to the SF-36. However what specifically in their physical and emotional health is affecting their work does not come through in the SF-36 questionnaire.

The way forward - suggestions for further research:

▪ For future studies on long-term follow-up of ICU survivors a much larger population size is recommended especially in SA given the particularly mobile lower socio-economic people staying in rural or outlying communities.

▪ Further long-term survival outcome studies in South African ICU settings and the evaluation of factors affecting long-term survival are recommended so that cross comparisons can be made between units in order to find criteria by which to measure the standards of practice and outcomes of ICU settings (i.e. benchmarking of units).

▪ SF-36 normative data for the general South African population is needed. As there is no SF-36 normative data for the South African population no comparisons could be made between this ICU population and the general population. Thus it is not known whether the HRQoL outcome for this population is similar to or poorer than that of the general population. Population norms will provide a base for comparison between critically ill subjects and the 'normal' healthy population and give an idea of the improvements in HRQoL that may be needed.

▪ The SF-36 measures the perception of how health status affects various aspects of the patients' quality of life. This measure is therefore a patient-centered outcome. The current study observed lower scores

in the physical functioning, role play and role emotion domains of HRQoL. Therefore physiotherapists need to focus more on the functional needs of the ICU patients as these were the areas patients reported to have more limitations in. This patient-therapist goal directed rehabilitation may eliminate inappropriate treatments and minimize wastage of limited resources.

- The SF-36 is not a reliable and sensitive enough measure to determine changes in health status after physiotherapy interventions (Mawson 1995). Physiotherapists therefore need to develop other more appropriate measures in order to determine what specifically limits intensive care patients' in their physical functioning. These measures should be measures that can be used independently and in conjunction with other existing HRQoL measures. Similarly other health care therapists need to develop appropriate measures to determine what specifically limits the emotional, mental and social functioning of these patients. These will aid in therapists focusing their treatments on specific problems and assist in more effective and efficient care in an area of limited resources.

- In South Africa, ICU resources and the availability of ICU beds are extremely limited yet the demand is potentially greater than in First-World countries because of the high incidence of severe trauma and infectious disease (Michell 2005). It is therefore suggested that further research should focus on the factors that affect HRQoL outcomes and the HRQoL outcomes in ICU patients' pre-ICU admission where possible, immediately at discharge and then later over time. This may assist in making appropriate comparisons over time and determining the main problems that ICU survivors in South Africa are faced with. It may also help determine whether South African ICU populations are also experiencing improvements over time as in international ICU populations. This may also provide information that will assist in appropriate decisions regarding admissions of patients to ICU and may

assist in preventing re-admissions thereby reducing costs and wastage of limited resources.

- It is also suggested that an intervention programme be developed and implemented in ICU which must be followed by a HRQoL evaluation to determine the effect of the intervention on the HRQoL outcome. This evaluation of interventions implemented may aid in determining what role physiotherapists have in the ICU setting, what techniques are appropriate for improving outcome and where the most difference can be made in HRQoL outcomes following intensive care. This may also ultimately assist in preventing wastage of limited resources due to re-admissions and result in more effective resource utilization.

In conclusion the current study has provided information on an area of research not well studied in SA. It also supports part of the recommendations made in the previous baseline study regarding the development of an evidence-based physiotherapy protocol for ICU management, its implementation and the measurement of its effect. This may ultimately provide information useful to health professionals in determining where their efforts should be focused in the management of ICU patients.

117
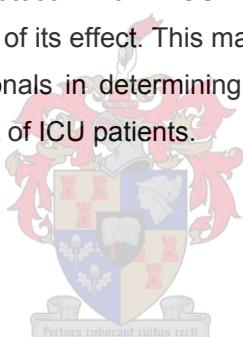
REFERENCES

Comprehensive List

American Thoracic Society – Quality of Life: Specific Diseases – The Nottingham Profile: http://www.atsqol.org/nott.asp (visited 08/11/2005)

Angus DC, Carlet J 2003 Surviving Intensive Care: a report from the 2002 Brussels Roundtable. Intensive Care Medicine 29:368-377

Barie PS, Hydo LJ, Fischer E 1996 Utility of illness severity scoring prediction of prolonged surgical critical care. Journal of Trauma 40(4):513-519

Badia X, Diaz-Prieto A, Gorriz MT, Herdman M, Torrado H, Farrero E, Cavanilles JM 2001 Using the Euro-Qol-5D to measure changes in quality of life 12 months after discharge from an intensive care unit. Intensive Care Medicine 27:1901-1907

Bagner M 2004 Sickness Impact Profile – http://www.outcomes-trust.org/instruments.htm (visited 19/03/2004)

Beck DH, Taylor BL, Millar B, 1997 Prediction of outcome from intensive care: a prospective cohort study comparing acute physiology and chronic health evaluation II and III prognostic scores in a United Kingdom intensive care unit. Critical Care Medicine 25:9-15

Bergner M, Bobbit RA, Carter WB, Gilson BS 1981 The Sickness Impact Profile: development and final revision of a health status measure. Medical Care Journal 19:199-208

Brazier JE, Harper R, Jones NMB, O'Cathain A, Thomas KJ, Usherwood T, Westlake L 1992 Validating the SF-36 health survey questionnaire: new outcome measure for primary care. British Medical Journal 305:160-164

Brooks R, Kerridge R, Hillman K, Bauman A, Daffurn K 1997 Quality of life outcomes after intensive care. Comparison with a community group. Intensive Care Medicine 23:581-586

Brown N, Melville M, Gray D, Young T, Skene AM, Hampton JR 2000 Comparison of the Sf-36 health survey questionnaire with the Nottingham Health Profile in long-term survivors of a myocardial infarction. Journal of Public Health Medicine 22(2):167-175

Buckley TA, Cheng AYC, Gomersall CD 2001 Quality of life in long-term survivors of intensive care. Annals Academy of Medicine Singapore 30(3):287-292

Bullock E 1994. Personal communication to Mawson S 1995 What is the SF-36 and Can It Measure the Outcome of Physiotherapy? Physiotherapy 81(4):208-212

Capuzzo M, Bianconi M, Contu P, Pavoni V, Gritti G 1996 Survival and quality of life after intensive care. Intensive Care Medicne 22:947-953

Capuzzo M, Grasselli C, Carrer S, Gritti G, Alvisi R 2000 Validation of two quality of life questionnaires suitable for intensive care patients. Intensive Care Medicine 26:1296-1303

Chaboyer W, Elliot D 2000 Health-related quality of life of ICU survivors: review of the literature. Intensive Critical Care Nursing 16(2):88-97

Chelluri L, Pinsky MR, Donahoe MP, Grenvik A 1993 Long-term Outcome of Critically Ill Elderly Patients Requiring Intensive Care. JAMA 269(24):3119-3123

119

Chrispin PS, Scotton H, Rogers J, Lloyd D, Ridley SA 1997 Short Form 36 in the intensive care unit: assessment of acceptability, reliability and validity of the questionnaire. Anaesthesia 52:15-23

Combes A, Costa MA, Trouillet JL, Baudot J, Mokhtari M, Gibert C, Chastre J 2003 Morbidity, mortality, and quality-of-life outcomes of patients requiring ≥14 days of mechanical ventilation. Critical Care Medicine 31(5):1373-1381

Douglas SL, Daly BJ, Gordon N, Brennan PF 2002 Survival and quality of life: Short-term versus long-term ventilator patients. Critical Care Medicine 30(12):2655-2662

Dowdy DW, Eid MP, Sedrakyan A, Mendez-Tellez PA, Pronovost PJ, Herridge MS, Needham DM 2005 Quality of life in adult survivors of critical illness: A systematic review of the literature. Intensive Care Medicine 31:611-620

Dragsted L, Qvist J, Madsen M 1990 Outcome from intensive care IV A five year study of 1308 patients: long-term outcome. European Journal of Anaesthesiology 7:51-62

Eales CJ, Stewart AV, Noakes TD 2000 Chronic Illness and Quality of Life. South African Journal of Physiotherapy 56(4):10-16

Eddleston JM, White P, Guthrie E 2000 Survival, morbidity, and quality of life after discharge from intensive care. Critical Care Medicine 28(7):2293-2299

Elliot D, Leeder SR 1998 Patient outcomes from general ICU: the use of proxy respondents and two health status instruments -15D and SF-36. 23rd Australian and New Zealand Annual Scientific Meeting on Intensive Care, 1-11 October, Adelaide, Australia

Euroqol Group 1990 Euroqol: a new facility for the treatment of health-related quality of life. Health Policy 16:199-208

Fakhry SM, Kercher KW, Rutledge R 1996 Survival, Quality of Life, and Charges in critically ill surgical patients requiring prolonged ICU stays. The Journal of Trauma: Injury, Infection and Critical Care 41(6):999-1007

Fedullo AJ, Swinburne AJ 1983 Relationship of patient age to cost and survival in a medical ICU. Critical Care Medicine 11:155

Foster JH, Powell JE, Marshall EJ, Peters TJ 1999 Quality of Life in alcohol-dependant subjects – a review. Quality of Life Journal 8(3):255-261

Garcia Lizana F, Manzano Alonso JL, Gonzalez Santana B, Feuntes Esteban J, Saavedra 2000 Survival and quality of life with multiple organ failure one year after leaving an intensive care unit. Medicina Clinica Journal 114 Suppl 3:99-103
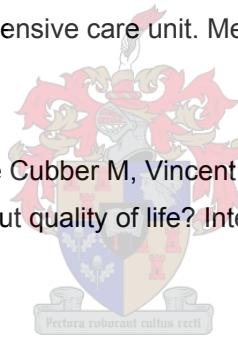
Garcia Lizana F, Peres Bota D, De Cubber M, Vincent JL 2003 Long-term outcome in ICU patients: what about quality of life? Intensive Care Medicine 29:1286-1293

Gill TM, Feinstein AR 1994 A Critical Appraisal of the Quality of Quality-of-Life Measurements. JAMA 272(8):619-626

Graf J, Koch M, Dujardin R, Kersten A, Janssens U 2003 Health-related quality of life before, 1 month after, and 9 months after intensive care in medical and cardiovascular and pulmonary patients.cost. Critical Care Medicine 31:2163-2169

Granja C, Dias C, Costa-Pereira A, Sarmento A 2004, Quality of Life of survivors from severe sepsis and septic shock may be similar to that of others who survive critical illness. Critical Care Journal 8:R91-98

Granja C, Morujao E, Costa-Pereira A 2003 Quality of life in acute respiratory distress syndrome survivors may be no worse than in other ICU survivors. Intensive Care Medicine 29(10):1744-1750

Granja C, Teixeira-Pinto A, Costa-Pereira A 2002 Quality of life after intensive care – evaluation with EQ-5D questionnaire. Intensive Care Medicine 28:898-907

Hanekom 2004 The profile of a surgical ICU in a public sector tertiary hospital in South Africa. (unpublished)

Hariharan S, Moseley HSL, Kumar AY 2002 Outcome evaluation in a surgical intensive care unit in Barbados. Anaesthesia 57:434-441

Heyland DK, Guyatt G, Cook DJ, Meade M, Juniper E, Cronin L, Gafni A 1998 Frequency and methodologic rigor of quality-of-life assessments in the critical care literature. Critical Care Medicine 26(3):591-598

Househam 2003 – 2010 Healthcare Service Delivery Plan: http://www.capegateway.gov.za/text/2004/2/healthcare 2010.pdf (visited 15 April 2004).

Hunt SM, McKenna SP, McEwen J, Williams J, Rapp E 1986 The Nottingham Health Profile:subjective health status and medical consultations. Social Science Medicine 15A:221-229

Hurel D, Loirat P, Saulnier F, Nicolas R, Brivet 1997 Quality of life 6 months after intensive care: results of a multicentre study using a generic health status scale and a satisfaction scale. Intensive Care Medicine 23:331-337

Jelsma J, Chivaura V, De Weerdt W, De Cock P 2000 A Bridge Between Cultures: A Report On The Process Of Translating The EQ-5D Instrument into Shona. Physiotherapy 56(4):3-9

Jones C, Skirrow P, Griffiths RD, Humphris GH, Ingleby S, Eddleston J, Waldman C 2003 Rehabilitation after critical illness: A randomized, controlled trial. Critical Care Medicine 31(10):2456-2461

Kleinpell RM 2003 Exploring outcomes after critical illness in the elderly. Outcomes Management 7:159-169

Kleinpell RM 1991 Needs of families of critically patients: a literature review. Critical Care Nursing 11(8):34, 38-40

Knaus WA, Draper EA, Wagner DP, Zimmerman JE 1985 APACHE II. Severity of disease classification system. Critical Care Medicine 13:818-829

Konopad E, Noseworthy TW, Johnstone R, Shustack A, Grace M 1995 Quality of life measures before and one year after admission to an intensive care unit. Critical Care Medicine 23: 1653-1659

Kvåle R, Ulvik A, Flaatten H 2003 Follow-up after intensive care: a single center study. Intensive Care Medicine 29:2149-2156

Lam S, Ridley S 1999 Critically ill medical patients, their demographics and outcome. Anaesthesia 54:845-852

Lawrence K, Doll H, McWhinnie D 1996 Relationship between health status and post-operative return to work. Journal of Public Health Medicine 18(1):49-53

LeGalle J-R, Brun-Buisson C, Trunet P, et al 1982: Influence of age, previous health status and severity of acute illness on outcome of intensive care. Critical Care Medicine 10:575-577

Lipsett PA, Swoboda SM, Dickerson J, Ylitalo M, Gordon T, Breslow M, Campbell K, Dorman T, Pronovost P, Rosenfeld B 2000 Survival and Functional Outcome After Prolonged Intensive Care Unit Stay. Annals of Surgery 231(2):262-268

Lyons RA, Wareham K, Lucas M, Price D, Williams J, Hutchings HA 1999 SF-36 scores vary by method of administration: implications for study design. Journal of Public Health Medicine 21(1):41-45

Marks M - Stresses in the South African Police Service
http://www.csvr.org.za/papers/papstres.htm (visited 18/11/05)

Mathivha LR 2002 ICU's worldwide: An overview of critical care medicine in South Africa. Critical Care 6(1):22-23

Mawson S 1995 What is the SF-36 and Can It Measure the Outcome of Physiotherapy? Physiotherapy 81(4):208-212

Medical Outcomes Trust - http://www.sf-36.org (last visited 1 November 2005)

Michell WL 2005 Editorial: Who is too sick for the ICU? South African Journal of Critical Care 21(1):8

Mishoe SC, Maclean JR 2001 Assessment of Health Related Quality of Life. Respiratory Care 46(1):1236-1255

Mobilising against TB: South African Plan for TB control for 2002-2005:
http://www.capegateway.gov.za/text/2003/mobilising-against-tb.pdf (visited 18/11/05)

Möller PH, Smit R 2004 Measuring health-related quality of life: A comparison between people living with Aids and police on active duty. Health SA Gesondheid 9(2):31-42

Montuclard L, Garrouste-Orgeas M, Timsit JF, Misset B, De Jonghe B, Carlet J 2000 Outcome, functional autonomy, and quality of life of elderly patients with long-term intensive care unit stay. Critical Care Medicine 28(10):3389-3395

Nava S, Ambrosino N 2000 Rehabilitation in the ICU: the European phoenix. Intensive Care Medicine 26(7):841-844

Needham DM, Dowdy DW, Mendez-Tellez PA, Herridge MS, Pronovost PJ 2005 Studying outcomes of intensive care unit survivors: measuring exposures and outcomes. Intensive Care Medicine 31:1153-1160

Niskanen M, Kari A, Halonen P 1996 Five year survival after intensive care – comparison of 12180 patients with the general population - Finnish ICU Study Group. Critical Care Medicine 24:1962-1967

Parikh CR, Karnad DR 1999 Quality, cost, and outcome of intensive care in a public hospital in Bombay, India. Critical Care Medicine 27(9):1754-1759

Petillä V, Kaarlola A, Makelainen A 2000 Health related quality of life of multiple organ dysfunction patients one-year after intensive care. Intensive Care Medicine 26:1473-1479

Potgieter P, Hammill L, Gough, Hamond J 1995 Cost of Critical care in South Africa. South African Medical Journal 85(5):425-430 profile. Intensive Care Medicine21:422-428

Ridley S, Plenderleith L 1994 Survival after intensive care: Comparison with a matched normal population as an indicator of effectiveness. Anaesthesia 49:933-935

Rockwood K, Noseworthy TW, Gibney RT, Konopad E, Shustack A, Stollery D, Johnston R, Grace M 1993 One-year outcome of elderly and young patients admitted to intensive care units. Critical Care Medicine 21(5):687-691

Rubenfeld GD, Angus DC, Pinsky MR, Curtis JR, Connors AF, Bernard GR and The Members of the Outcomes Research Workshop 1999 Outcomes Research in Critical Care – Results of the American Thoracic Society Critical Care Assembly Workshop on Outcomes Research. American Journal of Respiratory and Critical Care Medicine 160:358-367

Rubenfeld GD, Curtis JR 2003 Health status after critical illness: beyond descriptive studies. Intensive Care Medicine 29:1626-1628

Sage WM, Rosenthal MH, Silverman JF 1986 Is intensive care worth it? An assessment of input and outcome for the critically ill. Critical Care Medicine 14:777-782

Schelling G, Stoll C, Haller M, Briegel J, Manert W, Hummel T, Lenhart A, Heyduck M, Polasek J, Meier M, Preuss U, Bullinger M, Schuffel W, Peter K 1998 Health-related quality of life and post-traumatic stress disorder in survivors of the acute respiratory distress syndrome. Critical Care Medicine 26(4):651-659

Short TG, Buckley TA, Rowbottom MY, Wong E, Oh TE 1999 Long-term outcome and functional health status following intensive care in Hong Kong. Critical Care Medicine27:51-57

Sitas F, Urban M, Bradshaw D, Kielkowski D, Bah S, Peto R 2004 Tobacco attributable deaths in South Africa. Tobacco Control Journal 13(4):396-399

Spilker B 1996 Quality of Life and Pharmoeconomics in Clinical Trials, 2nd edition. Philadelphia: Lippincott-Raven.

Staquet MJ, Hays RD, Fayers PM, editors 1998 Quality of life assessment in clinical trials: methods and practice. New York, Oxford University Press

Stiller K 2000 Physiotherapy in Intensive Care. Towards and Evidence-based Practice. Chest 118(6):1801-1813

Strategic and Service Delivery Improvement Plan (SSDIP) Provincial Government of the Western Cape Department of Health Draft Paper 2000: http://www.westerncape.gov.za/health-social-services/policy planning (visited 15 April 2004)

Sznajder M, Aegerter P, Launois R, Merliere Y, Guidet B, Cub Rea 2001 A cost-effectiveness analysis of stays in intensive care units. Intensive Care Medicine 27:146-153

Tian ZM, Miranda DR 1995 Quality of life after intensive care with the sickness impact
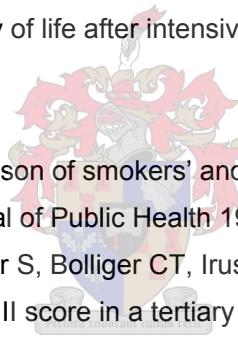
Tillman M, Silcock 1997 A comparison of smokers' and ex-smokers' health-related quality of life. Journal of Public Health 19(3)268-273

Van Der Merwe E, Kidd M, Metzker S, Bolliger CT, Irusen EM 2005 Validating the use of the APACHE II score in a tertiary South African ICU. South African Journal of Critical Care 21(1):46-54

Vazquez Mata G, Rivera Fernandez R, Perez Aragon A, Gonzales Carmona A, Fernandez Mondejar E, Navarrete Navaroo P 1996 Analysis of quality of life in polytraumatized patients two years after discharge from an intensive care unit. The Journal of Trauma, Injury, Infection, and Critical Care 41:326-332

Vedio AB, Chinn S, Warburton FG, Griffiths MP, Leach RM, Treacher DF 2000 Assessment of survival and quality of life after discharge from a

127

teaching hospital general intensive care unit. Clinical Intensive Care 11:39-46

Ware JE 2004 The SF-36 Community - SF-36 Health Survey Update
http://www.sf-36.org/tools/SF-36.shtml (visited 17/02/2004)

Ware JE, Kosinski M, Gandek B 2000 SF-36 ® Health Survey: Manual & Interpretation Guide. Lincoln, RI: QualityMetric Incorporated

Wehler M, Giese A, Hadzionerovic D, Aljukic E, Reulbach U, Hahn EG 2003 Health- related quality–of-life of patients with multiple organ dysfunction: individual changes and comparison with normative population. Critical Care Medicine 31:1094-1101

Zaren B, Bergstrom R 1988 Survival of intensive care patients I: prognostic factors from the patient's medical history. Acta Anaesthesiology Scandinavia 32:93-100
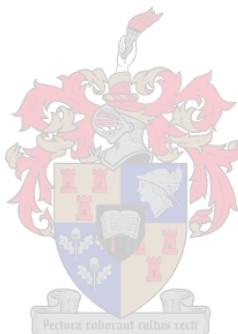
ADDENDUM A

UK Short Form – 36 version 2 HRQoL Outcome Measure

A.   Standard Self Report for Your Health and Well Being (FOUR WEEK RECALL)

Your Health in General

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully, and mark an ⊠ in the one box that best describes your answer. *Thank you for completing this survey!*

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 than one year ago	Much worse now than one year ago
▼	▼	▼	▼	▼
☐₁	☐₂	☐₃	☐₄	☐₅

130

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

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐₁	☐₂	☐₃
b <u>Moderate activities</u>, 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 <u>several</u> flights of stairs	☐₁	☐₂	☐₃
e Climbing <u>one</u> flight of stairs	☐₁	☐₂	☐₃
f Bending, kneeling, or stooping	☐₁	☐₂	☐₃
g Walking <u>more than a mile</u>	☐₁	☐₂	☐₃
h Walking <u>several hundred yards</u>	☐₁	☐₂	☐₃
i Walking <u>one hundred yards</u>	☐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
ᵦ Accomplished less than you would like	☐₁	☐₂	☐₃	☐₄	☐₅
ᵪ Were limited in the kind of work or other activities	☐₁	☐₂	☐₃	☐₄	☐₅
ₔ 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
ᵦ Accomplished less than you would like	☐₁	☐₂	☐₃	☐₄	☐₅
ᵪ 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, neighbors, 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 during the past 4 weeks. 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 past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel 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. Did you have a lot of energy?	☐₁	☐₂	☐₃	☐₄	☐₅
f. Have you felt downhearted and depressed?	☐₁	☐₂	☐₃	☐₄	☐₅
g. Did you feel worn out?	☐₁	☐₂	☐₃	☐₄	☐₅
h. Have you been happy?	☐₁	☐₂	☐₃	☐₄	☐₅
i. Did you feel tired?	☐₁	☐₂	☐₃	☐₄	☐₅

10. During the past 4 weeks, how much of the time has your physical health or emotional problems 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

THANK YOU FOR COMPLETING THESE QUESTIONS!
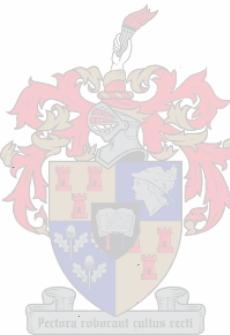
135

ADDENDUM B

**UK Short Form-36 version 2
License Agreement**

LICENSE AGREEMENT

License Number: R1-061704-19248

This License Agreement is entered into, by, and between QualityMetric Incorporated (the "Licensor"), 640 George Washington Highway, Lincoln, RI 02865 and University of Stellenbosch (the "Licensee"), Physiotherapy Department, PO Box 19063, Western Cape, 7505 South Africa.

Licensor owns or has the exclusive commercial rights to the survey(s) named below. The Licensor is engaged in the business of licensing the rights to use the survey(s), including survey items and responses, scoring algorithms, and normative data (the "Intellectual Property") to organizations wishing to use the Intellectual Property either in conjunction with projects or studies or as part of a product or service offering.

Upon payment of the fees described in the sections below captioned "License Fee" and "Payment Term", this agreement will authorize Licensee to reproduce the survey(s) in the languages indicated below, perform data collection, perform data entry, use the scoring algorithm and normative data published in the manuals, in connection with the study indicated below. Licensor understands Licensee may publish the results for the study indicated below.

Licensee is the only licensed user under this License Agreement, of the survey(s) indicated below (the "Licensed Survey(s)") in the language(s) indicated below. Licensee may administer an unlimited amount of survey administrations from August 10, 2004 through August 10, 2005 using any language combination of the survey(s) listed below.

- SF-36® and/or SF-36v2™ Health Surveys

    Afrikaans

This license cannot be assigned or transferred, nor can it be used by the Licensee to obtain data to be used in studies other than "HRQL and survival rate of patients 12 months after discharge from a Surgical ICU."

This agreement, including the attachment(s), contains the entire understanding of the parties with respect to the subject matter contained herein, and supersedes all prior written or oral communications. This agreement may not be modified or amended except by an instrument in writing signed by both parties.

Trademark and Copyright Reproduction

Licensee agrees to reproduce the appropriate copyright and trademark symbols on all written or displayed versions of the Licensed Survey(s) and/or the results attributed to the Licensed Survey(s), as indicated in the footer of the licensed surveys distributed by QualityMetric Incorporated.

Proprietary Rights

The Intellectual Property and any and all copyrights or rights under the trade secret laws of any jurisdiction shall be and remain at all times the property of the Licensor. The Licensee shall have no rights, title, or interest in the Intellectual Property except as expressly provided in this Agreement.

Confidentiality

The Licensee acknowledges that the Intellectual Property is a valued asset of the Licensor, that the Intellectual Property is of great commercial value to the Licensor, and that the value of the Intellectual Property would be significantly impaired by the unauthorized distribution or use of the Intellectual Property. The Licensee shall protect the Intellectual Property from unauthorized use by its employees, agents and customers and shall limit the use to the permission granted to Licensee by this Agreement.

August 9, 2004   Customer Initials: _LH_   Date Signed: 16/09/2004   Page 1 of 3

137

QM QualityMetric INCORPORATED   MEDICAL OUTCOMES TRUST   **H.L**

LICENSE AGREEMENT

License Number: R1-061704-19248

Disclaimer of Warranty

The Licensee understands and acknowledges that a complex and sophisticated product such as the Intellectual Property is inherently subject to undiscovered defects. The Licensor cannot and does not represent or warrant to the Licensee that the Intellectual Property is free from such defects, that operation of the Intellectual Property will be uninterrupted or error-free, or that its results will be effective or suitable with respect to any particular application. Furthermore, the Licensor does not represent or warrant that the Intellectual Property is capable of industrial realization or commercial exploitation, the risks of which are being assumed solely by the Licensee. THE INTELLECTUAL PROPERTY IS LICENSED AS-IS, AND THE LICENSOR DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, RESPECTING ANY OF THE INTELLECTUAL PROPERTY OR ANY OTHER MATTER RELATED TO THIS AGREEMENT.

Term and Termination

This License Agreement shall be effective from August 10, 2004, the date the Licensee will start reproducing the Licensed Survey. This License Agreement shall terminate on August 10, 2005, the date the Licensee will score the last Licensed Survey.

Licensor may terminate this Agreement in the event of a material breach of its terms by Licensee or any of its agents by written notice delivered at least fifteen (15) days prior to the effective date of the termination.

Project Registration Fee

The project registration fee for the licensed surveys ("the License") is $200.00.

This License is limited to the languages indicated on the first page of this License.

Payment Terms

Licensee shall pay $200.00 upon execution of this License Agreement, per the enclosed invoice.

Scoring Manuals

Licensee is required to have purchased or purchase the manuals indicated below for the Licensed Survey(s) indicated on the first page of this License

- SF-36® Health Survey Manual & Interpretation Guide
- The SF-36® Physical and Mental Health Summary Scales: A Manual for User's of Version 1, Second Edition
- How to Score Version 2 of SF-36® Health Survey

August 9, 2004   Customer Initials: _H_   Date Signed: _16/09/2004_   Page 2 of 3

138

QM QUALITYMETRIC INCORPORATED

MEDICAL OUTCOMES TRUST

H.L Health Assessment Lab

LICENSE AGREEMENT

License Number: R1-061704-19248

Other Services

In addition to the rights described above, Licensee may access Licensor's Online Scoring Service for an additional fee.

EXECUTED, as of the date set forth in the paragraph captioned Terms and Termination, by the duly authorized representatives as set forth below. By Executing this License Agreement, the undersigned Licensee represents that it is an organization that will only use the Licensed Survey(s) in the languages indicated on the first page and according to the terms of this License to obtain data in connection with a clinical trial or other project that is supported by grant from a government foundation or other non-profit organization.

University of Stellenbosch
Physiotherapy Department

PO Box 19063

Western Cape, 7505 South Africa

Signature: _A Hanekom_
Name: _Susan Hanekom_
Title: _Mrs_
Date: _16/09/2004_
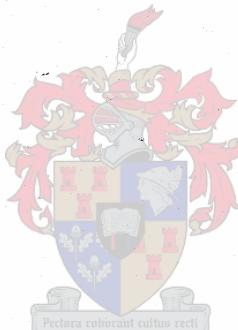
August 9, 2004   **Customer Initials:** _AH_   **Date Signed:** _16/09/2004_   Page 3 of 3

139

ADDENDUM C

Short Form-36 Scoring and Interpretation
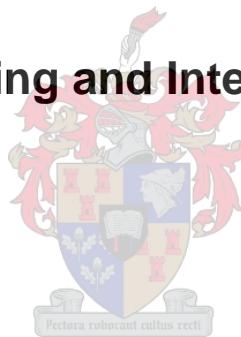
This chapter provides scoring instructions for the eight multi-item scales and for the reported health transition item included in the SF-36 Health Survey. Chapter 3 describes the SF-36 scales and items. General scoring information and steps for data entry and scoring that are common to all items are discussed first (see Figure 6.1). Next, formulas for item aggregation and transformation of scale scores are presented. Finally, formal checks for errors in scoring are explained.

Importance of standardization

As with all standardized tests, standardization of content and scoring is what makes interpretation of the SF-36 scales possible. The content of the SF-36 form and the scoring algorithms were selected and standardized following careful study of many options. The algorithms described in this chapter were chosen to be as simple as possible while still satisfying the assumptions of the methods used to construct SF-36 scales.

Changes in the content of the survey or in scoring algorithms may compromise the reliability and validity of scores. Changes are also likely to bias scores sufficiently to invalidate normative comparisons and to prevent comparisons of results across studies.

There are at least two good reasons to adhere to the standards of content and scoring described in this manual. First, they are most likely to produce scores with the same reliability and validity as those reported here and in other Medical Outcomes Study (MOS) publications. Second, comparisons of results across studies are made possible to the benefit of all who use these content and scoring standards.

Prior to using the SF-36 scoring rules, it is essential to verify that the questionnaires being scored, including the questions asked (item stems), response choices, and numbers assigned to response choices at the time of data entry, have been reproduced exactly. The scoring rules described in this chapter are

FIGURE 6.1
FLOW CHART FOR
SCORING THE SF-36
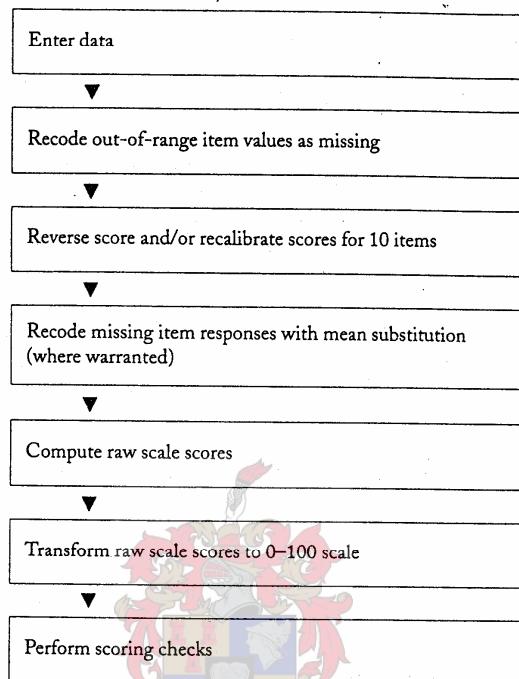
Enter data

▼

Recode out-of-range item values as missing

▼

Reverse score and/or recalibrate scores for 10 items

▼

Recode missing item responses with mean substitution (where warranted)

▼

Compute raw scale scores

▼

Transform raw scale scores to 0–100 scale

▼

Perform scoring checks

appropriate for the standard SF-36 survey questions, response choices, and numbers assigned to response choices as reproduced in Appendix B. The chapter ends with algorithms that help to equate scores for the Developmental version and the Standard version of the SF-36.

General scoring information

SF-36 items and scales are scored so that a higher score indicates a better health state. For example, functioning scales are scored so that a high score indicates better functioning and the pain scale is scored so that a high score indicates freedom from pain. After data entry, items and scales are scored in three steps:

(1) item recoding, for the 10 items that require recoding;

(2) computing scale scores by summing across items in the same scale (raw scale scores); and

(3) transforming raw scale scores to a 0 - 100 scale (transformed scale scores).

We recommend that both item recoding and scale scoring be performed by computer, using the scoring algorithms documented here or computer software available elsewhere (THI, 1992).

Data Entry

The SF-36 item responses should be keypunched as coded in the questionnaire. It is important to note that, although the numbers printed along with the response choices should be keypunched, they may not be the numbers ultimately assigned to those responses when SF-36 scales are scored.

In most cases, this means that the precoded number that is circled or marked by the respondent should be entered. However, sometimes it is not clear what number should be entered. Suggested rules for handling some of the more common coding problems are:

- If a respondent marks two responses which are adjacent to each other, randomly pick one and enter that number.

- If a respondent marks two responses for an item and they are not adjacent to each other, code that item "missing."

- If a respondent marks three or more responses for an item, code that item "missing."

- If a respondent answers the "yes/no" items by writing in "yes" or "no," code the answer as though "yes" or "no" had been marked.

Response Technologies Inc. and other companies have developed scanning forms for use with the SF-36, in both standard and acute formats. Sample forms appear in Appendix B. Optical scanning generally reduces the time required to process questionnaires, but may involve greater initial investment in form design. Some scanning forms may require special processing equipment; however, this method may be cost-effective, especially if the SF-36 is being administered frequently or to a large sample (see Chapter 12).

Tables 6.1 through 6.9 present scoring information for the items used in each of the eight SF-36 health scales and the reported health transition item. Each table presents the verbatim content of each question, response choices, and both the precoded values printed in the questionnaire and final values for scoring each item. Item numbers in Tables 6.1 through 6.9 correspond to those on the Standard SF-36 form (reproduced in Appendix B).

Item Recoding

The next stage after data entry is the recoding of response choices as shown in Tables 6.1 through 6.9. Item recoding is the process of deriving the item values that will be used to calculate the scale scores. Several steps are included in this process: (1) change out-of-range values to missing, (2) recode values for 10 items, and (3) substitute person-specific estimates for missing items.

Out-of-Range Values

All 36 items should be checked for out-of-range values prior to assigning the final item values. Out-of-range values are those that are lower than an item's precoded minimum value or higher than an item's precoded maximum value (see Tables 6.1 through 6.9). Out-of-range values are usually caused by data-entry errors and, if possible, should be changed to the correct response through verification with the original questionnaire. If the questionnaire is not available, all out-of-range values should be recoded as missing data.

144

**TABLE 6.1   PHYSICAL FUNCTIONING: VERBATIM ITEMS AND SCORING
INFORMATION**

Verbatim Items

3a.   Vigorous activities, such as running, lifting heavy objects, participating in strenuous
      sports

3b.   Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or
      playing golf

3c.   Lifting or carrying groceries

3d.   Climbing several flights of stairs

3e.   Climbing one flight of stairs

3f.   Bending, kneeling, or stooping

3g.   Walking more than a mile

3h.   Walking several blocks

3i.   Walking one block

3j.   Bathing or dressing yourself

Precoded and Final Values for Items 3a - 3j

Response Choices	Precoded Item Value	Final Item Value
Yes, limited a lot	1	1
Yes, limited a little	2	2
No, not limited at all	3	3

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text
for handling of missing item responses. This scale is scored so that a high score indicates
better physical functioning.

Note.   Precoded values are as shown on the appended form. This scale does not require recoding of items
         prior to computation of the scale score.

145

TABLE 6.2 ROLE–PHYSICAL: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

4a. Cut down the amount of time you spent on work or other activities

4b. Accomplished less than you would like

4c. Were limited in the kind of work or other activities

4d. Had difficulty performing the work or other activities (for example, it took extra effort)

Precoded and Final Values for Items 4a - 4d

Response Choices	Precoded Item Value	Final Item Value
Yes	1	1
No	2	2

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better Role–Physical functioning.

Note. Precoded values are as shown on the appended form. This scale does not require recoding of items prior to computation of the scale score.

146

TABLE 6.3   BODILY PAIN: VERBATIM ITEMS AND SCORING
INFORMATION

Verbatim Items

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

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

Precoded and Final Values for Item 7

Response Choices	Precoded Item Value	Final Item Value
None	1	6.0
Very mild	2	5.4
Mild	3	4.2
Moderate	4	3.1
Severe	5	2.2
Very severe	6	1.0

Scoring for Item 8 — if both Items 7 and 8 are answered

Response Choices	If Item 8 Precoded Item Value	and	Item 7 Precoded Item Value	then	Item 8 Final Item Value
Not at all	1		1		6
Not at all	1		2 through 6		5
A little bit	2		1 through 6		4
Moderately	3		1 through 6		3
Quite a bit	4		1 through 6		2
Extremely	5		1 through 6		1

Scoring for Item 8 — if Item 7 is not answered

Response Choices	Precoded Item Value	Final Item Value
Not at all	1	6.0
A little bit	2	4.75
Moderately	3	3.5
Quite a bit	4	2.25
Extremely	5	1.0

Scale Scoring

Compute the simple algebraic sum of final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored positively so that a high score indicates lack of bodily pain.

Note. Precoded values are as shown on the appended form. This scale requires recoding of both items prior to computation of the scale score.

TABLE 6.4 GENERAL HEALTH: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

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

11a. I seem to get sick a little easier than other people

11b. I am as healthy as anybody I know

11c. I expect my health to get worse

11d. My health is excellent

Precoded and Final Values for Items 1 & 11a-11d

Item 1	Response Choices	Precoded Item Value	Final Item Value
	Excellent	1	5.0
	Very good	2	4.4
	Good	3	3.4
	Fair	4	2.0
	Poor	5	1.0

Items 11a & 11c	Response Choices	Precoded Item Value	Final Item Value
	Definitely True	1	1
	Mostly True	2	2
	Don't Know	3	3
	Mostly False	4	4
	Definitely False	5	5

Items 11b & 11d	Response Choices	Precoded Item Value	Final Item Value
	Definitely True	1	5
	Mostly True	2	4
	Don't Know	3	3
	Mostly False	4	2
	Definitely False	5	1

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better general health perceptions.

Note. Precoded values are as shown on the appended form. This scale requires recoding of three items prior to computation of the scale score.

TABLE 6.5 VITALITY: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

9a.   Did you feel full of pep?

9e.   Did you have a lot of energy?

9g.   Did you feel worn out?

9i.   Did you feel tired?

Precoded and Final Values for Items 9a, 9e, 9g, & 9i

Items 9a & 9e	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	6
	Most of the time	2	5
	A good bit of the time	3	4
	Some of the time	4	3
	A little of the time	5	2
	None of the time	6	1

Items 9g & 9i	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1
	Most of the time	2	2
	A good bit of the time	3	3
	Some of the time	4	4
	A little of the time	5	5
	None of the time	6	6

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates more vitality.

Note. Precoded values are as shown on the appended form. This scale requires recoding of two items prior to computation of the scale score.

149

TABLE 6.6 SOCIAL FUNCTIONING: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

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, neighbors, or groups?

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

Precoded and Final Values for Items 6 & 10

Item 6	Response Choices	Precoded Item Value	Final Item Value
	Not at all	1	5
	Slightly	2	4
	Moderately	3	3
	Quite a bit	4	2
	Extremely	5	1

Item 10	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1
	Most of the time	2	2
	Some of the time	3	3
	A little of the time	4	4
	None of the time	5	5

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better social functioning.

Note. Precoded values are as shown on the appended form. This scale requires recoding of one item prior to computation of the scale score.

TABLE 6.7 ROLE–EMOTIONAL: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

5a. Cut down the amount of time you spent on work or other activities

5b. Accomplished less than you would like

5c. Didn't do work or other activities as carefully as usual

Precoded and Final Values for Items 5a - 5c

Response Choices	Precoded Item Value	Final Item Value
Yes	1	1
No	2	2

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better Role–Emotional functioning.

Note. Precoded values are as shown on the appended form. This scale does not require recoding of items prior to computation of the scale score.

151
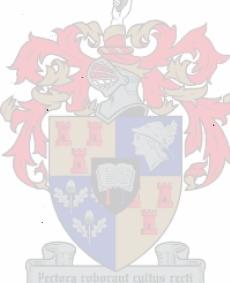
TABLE 6.8   MENTAL HEALTH: VERBATIM ITEMS AND SCORING INFORMATION

Verbatim Items

9b.   Have you been a very nervous person?

9c.   Have you felt so down in the dumps that nothing could cheer you up?

9d.   Have you felt calm and peaceful?

9f.   Have you felt downhearted and blue?

9h.   Have you been a happy person?

Precoded and Final Values for Items 9b, 9c, 9d, 9f, & 9h

Items 9b, 9c, & 9f	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1
	Most of the time	2	2
	A good bit of the time	3	3
	Some of the time	4	4
	A little of the time	5	5
	None of the time	6	6

Items 9d & 9h	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	6
	Most of the time	2	5
	A good bit of the time	3	4
	Some of the time	4	3
	A little of the time	5	2
	None of the time	6	1

Scale Scoring

Compute the simple algebraic sum of the final item values as shown in Table 6.11. See the text for handling of missing item responses. This scale is scored so that a high score indicates better mental health.

Note.   Precoded values are as shown on the appended form. This scale requires recoding of two items prior to computation of the scale score.

TABLE 6.9   REPORTED HEALTH TRANSITION: VERBATIM ITEM AND
SCORING INFORMATION

Verbatim Item

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

Precoded and Final Values for Item 2

Response Choices	Precoded Item Value
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

Note. Precoded item values are as shown on the appended form. The average measured change in health for respondents selecting each response choice is presented in Chapter 9.
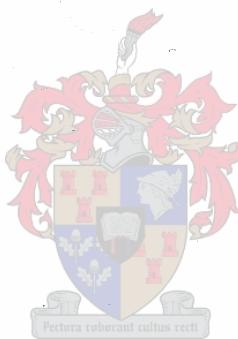
Recode Values for 10 Items

Seven items are reverse scored. Reverse scoring of items is done to ensure that a higher item value indicates better health on all SF-36 items and scales. SF-36 items that need to be reverse scored are worded so that a higher precoded item value indicates a poorer health state.

Item Recalibration

For 34 of the SF-36 items, research to date offers good support for the assumption of a linear relationship between item scores and the underlying health concept defined by their scales. However, empirical work has shown that two items require recalibration to satisfy this important scaling assumption. These items are in two different SF-36 scales: the General Health (GH) scale and the Bodily Pain (BP) scale.

General Health Rating Item. The "Very Good" and "Good" responses to Item 1 are recalibrated to achieve a better linear fit with the general health evaluation concept measured by the GH scale. Empirical studies during the Health Insurance Experiment (HIE) were among the first to document that the intervals between response choices for this item are not equal (Davies & Ware, 1981). Subsequent studies of Item 1, using both the Thurstone Method of Equal-Appearing Intervals (Thurstone & Chave, 1929) and other empirical methods, have also consistently shown that the interval between "Excellent" and "Very Good" is about half the size of the interval between "Fair" and "Good" (Ware, Nelson et al., 1992). These results have been confirmed in studies of SF-36 translations from 10 countries participating in the International Quality of Life Assessment (IQOLA) Project. Finally, in all studies we are aware of to date, mean values for a criterion general health scale for respondents who choose each of the five levels defined by Item 1 depart significantly from linearity.

Results from two MOS studies that served as the basis for the recommended recalibration of Item 1 are summarized in Table 6.10. As shown in Table 6.10 and discussed elsewhere (Ware, Nelson, et al., 1992), the mean criterion scores were remarkably similar for those who chose the same category of Item 1 across the screening (N=18,573) and longitudinal (N=3,054) samples. Intervals between adjacent response categories were unequal, as observed in the HIE (Davies & Ware, 1981). For these reasons, item scale values are transformed as shown in Table 6.10 using specific results from the

154

TABLE 6.10 MEAN CURRENT HEALTH SCORES FOR RESPONDENTS
CHOOSING EACH LEVEL OF SF-36 ITEM 1

| Response to Item 1 | Mean Current Health | | Recommended Scoring | |
	Screening Sample (N=18,573)	Baseline Sample (N=3,054)	1–5 Scale	0–100 Scale
Excellent	87.9	86.9	5.0	100
Very good	75.5	75.4	4.4	84
Good	57.6	55.9	3.4	61
Fair	30.0	30.6	2.0	25
Poor	10.8	10.8	1.0	0

Note. Adapted from "Preliminary tests of a 6-item general health survey: A patient application"
by J.E. Ware, E.C. Nelson et al., 1992, in A.L. Stewart & J.E. Ware (Eds.), *Measuring func-
tioning and well-being: The Medical Outcomes Study approach* (p. 299). Durham, NC: Duke
University Press.

screening sample. The result is a very high 0.70 correlation with the sum of
the other four items in the GH scale.

Bodily Pain Items. The scoring rules recommended for the Bodily Pain
(BP) scale were based on three considerations: (1) the items offer both differ-
ent numbers and different content of response choices, (2) administration
of Item 8 depended on the response to an item like Item 7 in the MOS, and
(3) empirical studies indicate that recalibration of Item 7 is necessary to
achieve a linear fit with the scale score and with other measures of bodily
pain.

As shown in Table 6.3, the two bodily pain items offer an unequal number
of response choices (six for Item 7 and five for Item 8). As a result, their vari-
ances are not equal, as required for a summated rating scale. Further, in all
MOS studies published to date, Item 8 was administered (following a skip
pattern) only to those respondents reporting at least some pain. Although
the MOS skip pattern has been dropped to make the SF-36 easier to admin-
ister, the dependence between responses must be taken into account to
compare results from new studies with published studies.

The recommended recoding of the first response choice for Item 8 on the
basis of the response to Item 7 solves two problems. First, it converts Item

155

8 to a six-level item of roughly equal variance to Item 7. This is done by splitting those free of role interference due to pain into two different groups: (1) free of interference and free of pain (the best level), and (2) free of interference but with at least some pain (the next best level). Second, it approximates the dependence between the two items in MOS studies of reliability and validity to date (McHorney et al., 1992, 1993, in press).

Davies and Ware (1981) reported that recalibration of the bodily pain severity rating was necessary to satisfy the equal interval assumption in studies during the HIE. MOS studies have confirmed that the relationship between Item 7 and criterion measures of pain departs significantly from a linear association. Criterion pain measures used in these tests include visual analogue scales measuring pain severity and categorical ratings of pain frequency and duration. Final response values for Item 7 were derived from the mean values of a summary MOS criterion pain measure computed for respondents who chose each of the six levels defined by Item 7, using methods much like those illustrated in Table 6.10 for Item 1.

How to Treat Missing Data

Sometimes respondents leave one or more questionnaire items in a scale blank, although this happens infrequently (1 to 2% or less) in most surveys. One important advantage of multi-item scales is that a scale score can be estimated even though responses to some items are missing. Using a scoring algorithm that estimates missing values, it is usually possible to derive scale scores for nearly all respondents across the eight SF-36 scales.

We recommend that a scale score be calculated if a respondent answered at least half of the items in a multi-item scale (or half plus one in the case of scales with an odd number of items).

The recommended algorithm substitutes a person-specific estimate for any missing item when the respondent answered at least 50 percent of the items in a scale. A psychometrically sound estimate is the average score, across completed items in the same scale, for that respondent (Ware, Davies-Avery, & Brook, 1980). For example, if a respondent leaves one item in the 5-item Mental Health scale blank, substitute the respondent's average score (across the four completed mental health items) for that one item. When estimating the respondent's average score, use the respondent's final item values, as

defined in Tables 6.1 through 6.9. This step is easy to program using standard software packages (e.g., SPSS, SAS). Examples of program code and scoring software are available elsewhere (THI, 1992).

Computing Raw Scale Scores

After item recoding, including handling of missing data, a raw score is computed for each scale. This score is the simple algebraic sum of responses for all items in that scale, as shown in Table 6.11. For example, the raw scale score for the Role–Physical scale is the sum of the scores for Items 4a, 4b, 4c, and 4d. Use recoded items values and imputed values where applicable. Generally, we recommend that if the respondent answers at least 50% of the items in a multi-items scale, the score should be calculated. If the respondent did not answer at least 50% of the items, the score for that scale should be set to missing. Some prefer a more conservative approach for the scales with only two items and set those scales to missing unless both items are completed.

This simple scoring method is possible because items in the same scale have roughly equivalent relationships to the underlying health concept being measured, and no item is used in more than one scale. Thus, it is not necessary to standardize or weight items. These assumptions have been extensively tested and verified across 24 patient groups (McHorney et al., in press).

Transformation of Scale Scores

The next step involves transforming each raw scale score to a 0 to 100 scale using the formula shown below. Table 6.11 provides the information necessary to apply this formula to each scale.

$$\text{Transformed Scale} = \left[\frac{(\text{Actual raw score} - \text{lowest } \textit{possible} \text{ raw score})}{\textit{Possible} \text{ raw score range}} \right] \times 100$$

This transformation converts the lowest and highest possible scores to zero and 100, respectively. Scores between these values represent the percentage of the total possible score achieved. While this final step is optional, it is strongly recommended because transformed scale scores can be compared with norms derived from the MOS (McHorney et al., 1992, 1993, in press),

157

TABLE 6.II FORMULAS FOR SCORING AND TRANSFORMING SCALES

Scale	Sum Final Item Values *(after recoding items as in Tables 6.1–6.8)*	Lowest and highest possible raw scores	Possible raw score range
Physical Functioning	3a+3b+3c+3d+3e+3f+3g+3h+3i+3j	10, 30	20
Role–Physical	4a+4b+4c+4d	4, 8	4
Bodily Pain	7+8	2, 12	10
General Health	1+11a+11b+11c+11d	5, 25	20
Vitality	9a+9e+9g+9i	4, 24	20
Social Functioning	6+10	2, 10	8
Role–Emotional	5a+5b+5c	3, 6	3
Mental Health	9b+9c+9d+9f+9h	5, 30	25

Formula and example for transformation of raw scale scores

$$\text{Transformed Scale} = \left[\frac{(\text{Actual raw score} - \text{lowest } \textit{possible} \text{ raw score})}{\textit{Possible} \text{ raw score range}} \right] \times 100$$

Example: A Physical Functioning raw score of 21 would be transformed as follows:

$$\left[\frac{(21-10)}{20} \right] \times 100 = 55$$

Where lowest possible score = 10 and possible raw score range = 20

158
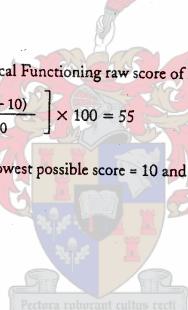
1990 National Survey of Functional Health Status, and other published and forthcoming results based on these scoring rules.

Raw and transformed scale scores are not calculated for the Reported Health Transition item. We recommend treating responses to this item as ordinal level data and analyzing the percentage of respondents who select each response choice or using the estimates of measured change reported for each response category in Chapter 9.

Scoring Checks

Because errors can occur while reproducing a form, entering data, programming or processing, which could lead to inaccurate scale scores, we strongly recommend formal scoring checks prior to using the scales. Any discrepancies observed during the following checks should be investigated for scoring errors:

(1) Calculate SF-36 scale scores by hand for several respondents and compare the results to those produced by your scale-scoring computer software.

(2) After items have been coded into their final item values, inspect the frequency distributions for the items to verify that only the final item values shown in Tables 6.1 through 6.9 are observed. Discrepancies should be limited to respondents with values estimated for missing data.

(3) After items have been recoded and scale scores have been computed, inspect the correlation between each scale and its component items to verify that all correlations are positive in direction and substantial in magnitude (0.30 or *higher*).

(4) Check correlations between the General Health scale and the other seven scales to verify that all are positive; with rare exceptions they should also be substantial in magnitude (0.30 or higher).

(5) For those familiar with principal factor or components analysis, inspect correlations between the eight scales and the first unrotated factor or component extracted from the correlations among those scales. Regardless of extraction method, these correlations should be positive and substantial in magnitude (0.30 or higher).

159

Scoring of the SF-36 Developmental version

Some studies have been based on the Developmental version of the SF-36 made available in December 1988 (Ware, 1988). This section explains how to score the Developmental version to be more comparable with the Standard version. Thirty-five items across seven scales in the Developmental version can be scored identically to items in the Standard version.

One Social Functioning (SF) item differs in both item content and response choice format in the two versions (Item 9j in the Developmental version and Item 10 in the Standard version). The item content in the Standard version asks specifically if "physical health or emotional problems interfered with your social activities," while the Developmental version asks if "health limited your social activities." Further, only five response choices are provided in the Standard version to equate the variance of the two SF items without recalibration; thus, its scoring is simpler. The Developmental version had six response choices for this item.

To make scores for the SF scale in the Developmental version (Items 6 and 9j) more comparable to the Standard version: (1) reverse the scoring of the first item (Item 6); (2) recalibrate the second item (Item 9j) so it ranges from "1" to "5" rather than from "1" to "6"; and (3) compute the scale by summing the two items. Table 6.12 details these scoring steps.

Scoring alternatives

Scoring algorithms made available to users of the SF-36 Developmental version in 1988 are identical to those for the SF-36 Standard version for six of the eight scales (Ware, 1988). Both Developmental and Standard scoring algorithms include the recalibration of Item 1 of the GH scale, as documented and explained earlier in this chapter. We are not aware of any published studies in the United States, United Kingdom, or elsewhere that do not use the SF-36 scoring algorithm for the GH scale.

Those using the Developmental version of the SF-36 have a choice between Developmental (old) and Standard (new) scoring algorithms for the SF scale. The Developmental version of the second SF item (Item 9j) offered six

TABLE 6.12 SCORING THE SF-36 DEVELOPMENTAL VERSION SOCIAL FUNCTIONING SCALE

Verbatim Items

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, neighbors, or groups?

9j.   How much of the time during the past month has your health limited your social activities like visiting with friends or close relatives?

Precoded and Final Values for Items 6 & 9j

Item 6	Response Choices	Precoded Item Value	Final Item Value
	Not at all	1	5
	Slightly	2	4
	Moderately	3	3
	Quite a bit	4	2
	Extremely	5	1

Item 9j	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1.0
	Most of the time	2	1.8
	A good bit of the time	3	2.6
	Some of the time	4	3.4
	A little of the time	5	4.2
	None of the time	6	5.0

Scale Scoring

Compute the simple algebraic sum of the final item values by summing Items 6 and 9j as described in the text. See text for handling of missing item responses. This scale is scored so that a high score indicates better social functioning.

Note. Precoded values are as shown on the appended form. This scale requires recoding of two items prior to computation of the scale score.

response choices, while the Standard version of this item (Item 10) has five response choices. The recalibration of this item, as recommended above (see "Scoring of the SF-36 Developmental version"), has no effect on the interpretation of SF scale scores. Instead, it adjusts the scale mean to be comparable to those in the normative data presented in Chapter 10.

Finally, we have published two options for scoring the Bodily Pain (BP) scale, which has identical item content across the Developmental and Standard versions. Advances in scoring for the Standard SF-36 are listed and explained above (see "Item Recalibration"). Early users of the Developmental version used the older (Developmental) scoring method (Ware, 1988). Thus, BP scales scored the old way will have means that are two to four points higher, on average, than BP scales scored the new (Standard) way. Scores for more than a third of respondents in the general population are shifted upward (i.e., towards better health) by five points or more when using the old scoring relative to the Standard scoring. The extent of this shift and implications for the precision and interpretation of BP scale scores, scored the old way, may vary depending on the proportion of respondents with chronic conditions and on their specific diagnoses. Therefore, we recommend routine use of the Standard scoring algorithms (as presented in this chapter). We encourage thorough documentation of any departures from this scoring system so that readers will know when they can and cannot compare results with other published studies.

Scoring Advances

We are presently evaluating several potential improvements in the scoring of the SF-36 including: (1) improvements in the enumeration of scale levels, (2) construction of aggregate (summary) indexes, and (3) norm-based scoring of scales and summary indexes. These and other SF-36 scoring issues that are likely to influence progress in the health assessment field are discussed in Chapter 12.

Chapter 6 SCORING SF-36 SCALES

This chapter provides scoring instructions for the eight multi-item scales and for the reported health transition item included in the SF-36 Health Survey, Version 2.0. General scoring information and steps for data entry and scoring that are common to all items are discussed first (see Figure 6.1). Next, formulas for item aggregation and transformation of scores to a 0-100 scale are presented. Following the 0-100 transformation is the norm-based scoring of each scale to have a mean of 50 and a standard deviation of 10 in the 1998 general U.S. population. Norm-based scoring methods of scales from standard (4-week recall) and acute (1 week recall) forms are presented separately. Finally, formal checks for errors in scoring are explained. A test dataset is available upon request (Info@QualityMetric.com) to confirm successful reproduction of the scoring methods outlined in this chapter.

Importance of Standardization

As with all standardized tests, standardization of content and scoring is what makes interpretation of SF-36 scales possible. The content of the SF-36 form and the scoring algorithms were selected and standardized following careful study of many options. The algorithms described in this chapter were chosen to: be as simple as possible. satisfy the assumptions of the methods used to construct SF-36 scales, and to achieve the nearly perfect linear association with the original SF-36 scores, necessary to preserve their original interpretations.

Figure 6.1   Flow Chart for Scoring SF-36 Scales

Enter data

↓

Recode out-of-range item values as missing

↓

Reverse score and/or recalibrate scores for 10 items

↓

Recode missing item responses with mean substitution (where warranted)

↓

Compute Raw Scale Scores

↓

Transform raw scale scores to 0-100 scale

↓

Transform 0-100 score to norm-based scores

↓

Perform scoring checks

163
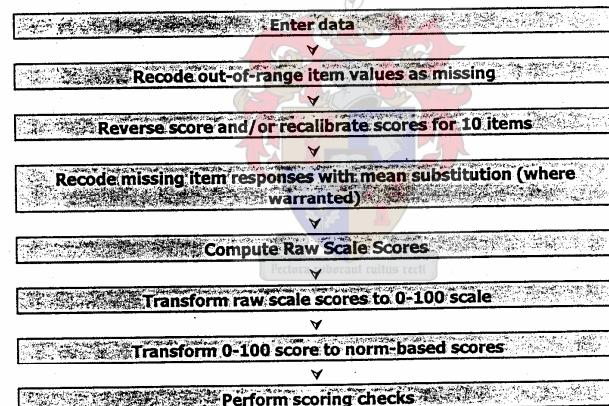
Changes in the content of the survey or in the scoring method may compromise the reliability and validity of scores. Changes are also likely to bias scores sufficiently to invalidate normative comparisons and to prevent comparisons of results across studies.

There are at least two good reasons to adhere to the standards of content and scoring described in this manual. First, they are most likely to produce scores with the same reliability and validity as those previously reported for SF-36v2™ scales. Second, comparisons of results across studies are made possible to the benefit of all who use these content and scoring standards. Third, differences in scores will have the same interpretations.

Prior to using the SF-36v2 scoring rules, it is essential to verify that the questionnaires being scored, including the questions asked (item stems), response choices and numbers assigned to response choices at the time of data entry, have been reproduced exactly. The scoring rules in this chapter are appropriate for the standard SF-36 survey questions, response choices, and numbers assigned to response choices as reproduced in the *Appendices A-D.*

General Scoring Information

SF-36v2 items and scales are scored so that a higher score indicates a better health state. For example, functioning scales are scored so that a high score indicates better functioning and the pain scale is scored so that a high score indicates freedom from pain. After data entry, items and scales are scored in four steps:

1.   Item recoding for the 10 items that require recoding
2.   Computing raw scale scores by summing across items in the same scale (raw scale scores)
3.   Transforming raw scale scores to a 0 - 100 scale (transformed scale scores)
4.   Transforming 0-100 scale scores to have a mean of 50 and standard deviation of 10 in the general U.S. population (norm-based scale scores).

Note that for both standard and acute SF-36v2 forms, steps 1, 2 and 3 are the same for scoring the scales. However, step 4 differs for standard and acute forms. The transformation of 0-100 scales to norm-based scores requires a different set of means and standard deviations to standardize the scales from standard and acute forms.

164

Scoring & Data Quality Analysis Service

QualityMetric Incorporated offers a scoring and data quality analysis service for both Version 1 and Version 2 of the SF-36 and SF-12. Information on this service can be found on the Internet at www.QualityMetric.com, or by sending an email to scoring@QualityMetric.com or by calling 401-334-8800.

Data Entry

The SF-36v2 item responses should be data entered as coded in the questionnaire. It is important to note that although the numbers printed along with the response choices should be data entered, they may not be the numbers ultimately assigned to those responses when SF-36 scales are scored.

In most cases, this means that the precoded number that is circled or marked by the respondent should be entered. However, sometimes it is not clear what number should be data-entered. Suggested rules for handling some of the more common coding problems are:

1. If a respondent marks two responses that are adjacent to each other, randomly pick one and enter that number.
2. If a respondent marks two responses for an item and they are not adjacent to each other, code that item "missing".
3. If a respondent marks three or more responses for an item, code that item "missing".

Several licensed vendors have developed scanning forms for use with the SF-36v2 in both standard and acute formats. Optical scanning generally reduces the time required to process questionnaires, but may involve greater initial investment in form design. Some scanning forms may require special processing equipment; however, this method may be cost-effective, especially if the SF-36 is being administered frequently or to a large sample. Other mechanisms for capturing data include interactive-voice response (IVR) systems, computer touch screen administration, and Internet based systems. For a listing of licensed vendors, please visit the QualityMetric Incorporated Web site (www.QualityMetric.com).

Tables 6.1 through 6.9 present scoring information for the items used in each of the eight SF-36 health scales and the self-reported health transition item. Each table presents the verbatim content of each question, response choices, and both the precoded values printed in the questionnaire and final values for scoring each item. Item numbers in Tables 6.1 through 6.9 correspond to those on the Standard and Acute SF-36 forms (reproduced in the Appendix).

Table 6.1 Physical Functioning: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
3a.	PF01	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
3b.	PF02	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
3c.	PF03	Lifting or carrying groceries
3d.	PF04	Climbing several flights of stairs
3e.	PF05	Climbing one flight of stairs
3f.	PF06	Bending, kneeling, or stooping
3g.	PF07	Walking more than a mile
3h.	PF08	Walking several hundred yards
3i.	PF09	Walking one hundred yards
3j.	PF10	Bathing or dressing yourself

PRECODED AND FINAL VALUES FOR ITEMS 3A – 3J		
Response Choices	Precoded Item Value	Final Item Value
Yes, limited a lot	1	1
Yes, limited a little	2	2
No, not limited at all	3	3

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better physical functioning.

Note: Precoded values are as shown on the appended form.
This scale does not require recoding of items prior to computation of the scale score.

166

Table 6.2 Role-Physical: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
4a.	RP01	Cut down the **amount of time** you spent on work or other activities
4b.	RP02	**Accomplished less** than you would like
4c.	RP03	Were limited in the **kind** of work or other activities
4d.	RP04	Had **difficulty** performing the work or other activities (for example, it took extra effort)

PRECODED AND FINAL VALUES FOR ITEMS 4A - 4D		
Response Choices	Precoded Item Value	Final Item Value
All of the time	1	1
Most of the time	2	2
Some of the time	3	3
A little of the time	4	4
None of the time	5	5

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better Role-Physical functioning.

Note: Precoded values are as shown on the appended form.
This scale does not require recoding of items prior to computation of the scale score.

167

Table 6.3 Bodily Pain: verbatim Items and Scoring Information   Bodily Pain: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
7.	BP01	How much bodily pain have you had during the past 4 weeks?
8.	BP02	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

PRECODED AND FINAL VALUES FOR ITEM 7		
Response Choices	**Precoded Item Value**	**Final Item Value**
None	1	6.0
Very mild	2	5.4
Mild	3	4.2
Moderate	4	3.1
Severe	5	2.2
Very severe	6	1.0

SCORING FOR ITEM 8 IF BOTH ITEMS 7 AND 8 ARE ANSWERED			
Response Choices	If Item 8 Precoded Item Value	&Item 7 Precoded Item Value	Then Final Item Value
Not at all	1	1	6
Not at all	1	2 through 6	5
A little bit	2	1 through 6	4
Moderately	3	1 through 6	3
Quite a bit	4	1 through 6	2
Extremely	5	1 through 6	1

SCORING FOR ITEM 8 IF ITEM 7 IS NOT ANSWERED		
Response Choices	**Precoded Item Value**	**Then Final Item Value**
Not at all	1	6.0
A little bit	2	4.75
Moderately	3	3.5
Quite a bit	4	2.25
Extremely	5	1.0

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates lack of bodily pain.

Note: Precoded values are as shown on the appended form.
This scale requires recoding of both items prior to computation of the scale score.

168

Table 6.4 General Health: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
1.	GH01	In general, would you say your health is:
11a.	GH02	I seem to get sick a little easier than other people
11b	GH03	I am as healthy as anybody I know
11c.	GH04	I expect my health to get worse
11d.	GH05	My health is excellent

PRECODED AND FINAL VALUES FOR ITEMS 1 & 11A - 11D

Item 1	Response Choices	Precoded Item Value	Final Item Value
	Excellent	1	5.0
	Very good	2	4.4
	Good	3	3.4
	Fair	4	2.0
	Poor	5	1.0
Items 11a & 11c	Response Choices	Precoded Item Value	Final Item Value
	Definitely True	1	1
	Mostly True	2	2
	Don't Know	3	3
	Mostly False	4	4
	Definitely False	5	5
Items 11b & 11d	Response Choices	Precoded Item Value	Final Item Value
	Definitely True	1	5
	Mostly True	2	4
	Don't Know	3	3
	Mostly False	4	2
	Definitely False	5	1

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better general health perceptions.

Note: Precoded values are as shown on the appended form.
This scale requires recoding of three items prior to computation of the scale score.

169

Table 6.5 Vitality: Verbatim Items and Scoring Information Vitality: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
9a.	VT01	Did you feel full of life?
9e.	VT02	Did you have a lot of energy?
9g.	VT03	Did you feel worn out?
9i.	VT04	Did you feel tired?

PRECODED AND FINAL VALUES FOR ITEMS 9A, 9E, 9G, & 9I			
Item 9a & 9e	**Response Choices**	**Precoded Item Value**	**Final Item Value**
	All of the time	1	5
	Most of the time	2	4
	Some of the time	3	3
	A little of the time	4	2
	None of the time	5	1
Items 9g & 9i	**Response Choices**	**Precoded Item Value**	**Final Item Value**
	All of the time	1	1
	Most of the time	2	2
	Some of the time	3	3
	A little of the time	4	4
	None of the time	5	5

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates more vitality.

Note: Precoded values are as shown on the appended form.
This scale requires recoding of two items prior to computation of the scale score.

170

Table 6.6   Social Functioning: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
6.	SF01	During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
10.	SF02	During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

PRECODED AND FINAL VALUES FOR ITEMS 6 & 10			
Item 6	Response Choices	Precoded Item Value	Final Item Value
	Not at all	1	5
	Slightly	2	4
	Moderately	3	3
	Quite a bit	4	2
	Extremely	5	1
Items 10	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1
	Most of the time	2	2
	Some of the time	3	3
	A little of the time	4	4
	None of the time	5	5

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better social functioning.

Note: Precoded values are as shown on the appended form.
This scale requires recoding of one item prior to computation of the scale score.

171

Table 6.7 Role-Emotional: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
5a.	RE01	Cut down the **amount of time** you spent on work or other activities
5b.	RE02	**Accomplished less** than you would like
5c.	RE03	Did work or other activities less **carefully** than usual

PRECODED AND FINAL VALUES FOR ITEMS 5A - 5C			
Items 5a – 5c	Response Choices	Precoded Item Value	Final Item Value
	All of the time	1	1
	Most of the time	2	2
	Some of the time	3	3
	A little of the time	4	4
	None of the time	5	5

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better Role-Emotional functioning.

Note: Precoded values are as shown on the appended form.
This scale does not require recoding of items prior to computation of the scale score.

172

Table 6.8 Mental Health: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
9b.	MH01	Have you been very nervous?
9c.	MH02	Have you felt so down in the dumps that nothing could cheer you up?
9d.	MH03	Have you felt calm and peaceful?
9f.	MH04	Have you felt downhearted and depressed?
9h	MH05	Have you been happy?

PRECODED AND FINAL VALUES FOR ITEMS 9B, 9C, 9D, 9F, & 9H			
Items 9b, 9c & 9f	**Response Choices**	**Precoded Item Value**	**Final Item Value**
	All of the time	1	1
	Most of the time	2	2
	Some of the time	3	3
	A little of the time	4	4
	None of the time	5	5
Items 9d & 9h	**Response Choices**	**Precoded Item Value**	**Final Item Value**
	All of the time	1	5
	Most of the time	2	4
	Some of the time	3	3
	A little of the time	4	2
	None of the time	5	1

Scale Scoring

Compute the simple algebraic sum of the final item scores as shown in Table 6.11. See text for handling of missing item responses. This scale is scored so that a high score indicates better mental health.

Note: Precoded values are as shown on the appended form.
This scale requires recoding of two items prior to computation of the scale score.
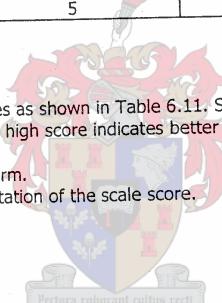
Table 6.9 Reported Health Transition: Verbatim Items and Scoring Information

Question No.	Variable Label	VERBATIM ITEMS
2.	HT	Compared to one year ago, how would you rate your health in general now?

PRECODED AND FINAL VALUES FOR ITEM 2			
Item 2	**Response Choices**	**Precoded Item Value**	**Final Item Value**
	Much better now than one year ago	1	1
	Somewhat better now than one year ago	2	2
	About the same as one year ago	3	3
	Somewhat worse now than one year ago	4	4
	Much worse now that one year ago	5	5

Note: *Precoded values are as shown on the appended form.*

Item Recoding

The next stage after data entry is the recoding of response choices as shown in Tables 6.1 through 6.9. Item recoding is the process of deriving the item values that will be used to calculate the scale scores. Several steps are included in this process: (1) change out-of-range values to missing, (2) recode values for 10 items, and (3) substitute person-specific estimates for missing items.

Out of Range Values

All 36 items should be checked for out-of-range values prior to assigning the final item values. Out-of-range values are those that are lower than an item's precoded minimum value, or higher than an item's precoded maximum value (see Tables 6.1 through 6.9). Out-of-range values are usually caused by data-entry errors and, if possible, should be changed to the correct response through verification with the original questionnaire. If the questionnaire is not available, all out-of-range values should be recoded as missing data.

Recode Values for Ten Items

Ten items are reverse scored. Reverse scoring of items is done to ensure that a higher item value indicates better health on all SF-36v2 items scales. SF-36 items that need to be reverse scored are worded so that a higher precoded item value indicates a poorer health state.

174

Item Recalibration

For 34 of the SF-36v2 items, research to date offers good support for the assumption of a linear relationship between item scores and the underlying health concept defined by their scales. However, empirical work has shown that two items require recalibration to satisfy this important scaling assumption. These items are in two different SF-36 scales: the General Health (GH) scale and the Bodily Pain (BP) scale.

General Health Rating Item

The "Very Good" and "Good" responses to Item 1 (GH1) are recalibrated to achieve a better linear fit with the general health evaluation concept measured by the GH scale. Empirical studies during the Health Insurance Experiment (HIE) were among the first to document that the intervals between response choices for this item are not equal (Davies & Ware, 1981). Subsequent studies of Item 1 (GH1), using both the Thurstone Method of Equal-Appearing Intervals (Thurstone & Chave, 1929) and other empirical methods, have also consistently shown that the interval between "Excellent" and "Very Good" is about half the size of the interval between "Fair" and "Good" (Ware, Nelson et al., 1992). These results have been confirmed in studies of SF-36 translations from 10 countries participating in the International Quality of Life Assessment (IQOLA) project. Finally, in all studies we are aware of to date, mean values for a criterion general health scale for respondents who choose each of the five levels defined by Item 1 (GH1) depart significantly from linearity.

Results from the Medical Outcome Study (MOS) that served as the basis for the recommended recalibration of Item 1 (GH1) are summarized in Table 6.10. As shown in Table 6.10 and discussed elsewhere (Ware, Nelson, et al., 1992), the mean criterion scores were remarkably similar for those who chose the same category of Item 1 across the screening (N=18,573) and longitudinal (N=3,054) samples. Intervals between adjacent response categories were unequal, as observed in the HIE (Davies & Ware, 1981). For these reasons, item scale values are transformed as shown in Table 6.10 using specific results from the screening sample. The result is a very high 0.70 correlation with the sum of the other four items in the GH scale.

Table 6.10 Mean Current Health Scores for Respondents Choosing Each Level of SF-36 Item 1 (GH1)

Response to Item 1	Mean Current Health		Recommended Scoring	
	Screening Sample (N=18,573)	Baseline Sample (N=3,054)	1-5 Scale	0-100 Scale
Excellent	87.9	86.9	5.0	100
Very good	75.5	75.4	4.4	84
Good	57.6	55.9	3.4	61
Fair	30.0	30.6	2.0	25
Poor	10.8	10.8	1.0	0

Note. Adapted from: Ware, Nelson et al. (1992). Preliminary tests of a 6-item general health survey: A patient application. In A.L. Stewart & J.E. Ware (Eds.), Measuring functioning and well-being: The Medical Outcomes Study approach (p. 299). Durham, NC: Duke University Press.

Bodily Pain Items

The scoring rules recommended for the Bodily Pain (BP) scale were based on three considerations: (1) the items offer both different numbers and different content of response choices, (2) administration of Item 8 (BP2) depended on the response to an item like Item 7 (BP1) in the MOS, and (3) empirical studies indicate that recalibration of Item 7 (BP1) is necessary to achieve a linear fit with the scale score and with other measures of bodily pain.

As shown in Table 6.3, the two bodily pain items offer an unequal number of response choices (six for Item 7 and five for Item 8). As a result, their variances are not equal, as required for a summated rating scale. Further, in all MOS studies published to date, Item 8 was administered (following a skip pattern) only to those respondents reporting at least some pain. Although the MOS skip pattern has been dropped to make the SF-36v2 easier to administer, the dependence between responses must be taken into account to compare results from new studies with published studies.

The recommended recoding of the first response choice for Item 8 (BP2) on the basis of the response to Item 7 (BP1) solves two problems. First, it converts Item 8 to a six-level item of roughly equal variance to Item 7. This is done by splitting those free of role interference due to pain into two different groups: (1) free of interference and free of pain (the best level); and (2) free of interference but with at least some pain (the next best level). Second, it approximates the dependence between the two items in MOS studies of reliability and validity to date (McHorney et al., 1992, 1993).

176

Davies and Ware (1981) reported that recalibration of the bodily pain severity rating was necessary to satisfy the equal interval assumption in studies during the HIE. MOS studies have confirmed that the relationship between Item 7 (BP1) and criterion measures of pain departs significantly from a linear association. Criterion pain measures used in these tests include visual analogue scales measuring pain severity and categorical ratings of pain frequency and duration. Final response values for Item 7 were derived from the mean values of a summary MOS criterion pain measure computed for respondents who chose each of the six levels defined by Item 7, using methods much like those illustrated in Table 6.10 for Item 1 (GH1).

How to Treat Missing Data

Sometimes respondents leave one or more questionnaire items in a scale blank, although this happens infrequently (1 to 2% or less) in most surveys. One important advantage of multi-item scales is that a scale score can be estimated even though responses to some items are missing. Using a scoring algorithm that estimates missing values, it is usually possible to derive scale scores for nearly all respondents across the eight SF-36v2 scales.

We recommend that a scale score be calculated if a respondent answered at least half of the items in a multi-item scale (or half plus one in the case of scales with an odd number of items).

The recommended algorithm substitutes a person-specific estimate for any missing item when the respondent answered at least 50 percent of the items in a scale. A psychometrically sound estimate is the average score, across completed items in the same scale, for that respondent (Ware, Davies-Avery, & Brook, 1980). For example, if a respondent leaves one item in the 5-item Mental Health scale blank, substitute the respondent's average score (across the four completed mental health items) for that one item. When estimating the respondent's average score, use the respondent's final item values, as defined in Tables 6.1 through 6.9. This step is easy to program using standard statistical software packages (e.g., SPSS, SAS). An example of SAS statistical software program code is available at QualityMetric Incorporated (info@QualityMetric.com).

At the time of this publication, new software was being evaluated for use in removing bias in estimates of scores for those having one or more missing SF-36 responses and to enable score estimation for virtually all respondents, regardless of the amount of missing data (see Kosinski, Bayliss, Bjorner and Ware 2000). For example, this software has made it possible to estimate summary scores for 88% of elderly respondents with missing data in the Medicare Managed Care Health Outcomes Survey (HOS). Scoring services using this software will be offered on the Internet at www.sf-36.com.

177

Computing Raw Scale Scores

After item recoding, including handling of missing data, a raw score is computed for each scale. This score is the simple algebraic sum of responses for all items in that scale, as shown in Table 6.11. For example, the raw scale score for the Role-Physical Scale is the sum of the scores for Items 4a, 4b, 4c, and 4d. Use recoded item values and imputed values where applicable. Generally, we recommend that if the respondent answers at least 50% of the items in a multi-item scale, the score should be calculated. If the respondent did not answer at least 50% of the items, the score for that scale should be set to missing. Some prefer a more conservative approach for the scales with only two items, and set those scales to missing unless both items are completed.

This simple scoring method is possible because items in the same scale have roughly equivalent relationships to the underlying health concept being measured and no item is used in more than one scale. Thus, it is not necessary to standardize or weight items. These assumptions have been extensively tested and verified for both Versions 1.0 and 2.0 (McHorney et al., 1994; Ware 1993; see chapter 4).

Transformation of Scale Scores

The next step involves transforming each raw scale score to a 0 - 100 scale using the formula shown below. Table 6.11 provides the information necessary to apply this formula to each scale.

$$\text{Transformed Scale} = \frac{(\text{Actual raw score} - \text{lowest } possible \text{ raw score})}{Possible \text{ raw score range}} * 100$$

This transformation converts the lowest and highest possible scores to 0 and 100, respectively. Scores between these values represent the percentage of the total possible score achieved. Raw and transformed scale scores are not calculated for the Reported Health Transition item. We recommend treating responses to this item as ordinal level data and analyzing the percentage of respondents who select each response choice or using the estimates of measured change (observed changes in SF-36v2 scale scores) reported for each response category.

178

Table 6.11   Formulas for Scoring and Transforming Scales

Scale	Sum Final Item Values (after recoding items as in Table 1.2-1.9)	Lowest and highest possible raw scores	Possible raw score range
Physical Functioning	3a+3b+3c+3d+3e+3f+3g+3h+3i+3j	10, 30	20
Role-Physical	4a+4b+4c+4d	4, 20	16
Bodily Pain	7+8	2, 12	10
General Health	1+11a+11b+11c+11d	5, 25	20
Vitality	9a+9e+9g+9I	4, 20	16
Social Functioning	6+10	2, 10	8
Role-Emotional	5a+5b+5c	3, 15	12
Mental Health	9b+9c+9d+9f+9h	5, 25	20

Formula and example for transformation of raw scale scores to 0-100 scale scores

$$\text{Transformed Scale} = \left[\frac{(\text{Actual raw score - lowest } \textit{possible } \text{raw score})}{\textit{Possible } \text{raw score range}} \right] * 100$$

Example: A Physical Functioning raw score of 21 would be transformed as follows:

$$\left[\frac{(21 - 10)}{20} \right] * 100 = 55$$

Where lowest possible score = 10 and possible raw score range = 20

179

Norm-Based Scoring of Scale Scores, Standard Form (4-Week Recall)

The next step involves the norm-based scoring of each 0 - 100 scale score using the formulas shown below. Table 6.12 provides the information necessary to apply these formulas to each SF-36v2 scale from the standard form (4 week recall). The means and standard deviations (Table 6.12) used in norm-based scoring come from the 1998 general U.S. population. A linear z-score transformation is used so that all eight SF-36 scales have a mean of 50 and a standard deviation of 10 in the 1998 general U.S. population.

The advantage of the standardization and norm-based scoring of the 8 SF-36v2 scales is that results for one scale can be meaningfully compared with the other scales and their scores have a direct interpretation in relation to the distribution of scores in the 1998 general U.S. population. Specifically, all scores above or below 50 are above or below the average, respectively, in the 1998 general U.S. population. Because the standard deviation is 10 for all 8 scales, each one point difference or change in scores also has a direct interpretation. A one point difference or change is one-tenth of a standard deviation unit or an effect size of 0.10. Lastly, norm-based scoring provides the basis for comparing scale scores across Version 1.0 and Version 2.0 standard forms.

The first step in norm-based scoring consists of standardizing each SF-36v2 scale using a z-score transformation. A z-score for each scale is computed by subtracting the 1998 general U.S. population mean (Table 6.12) for each SF-36 scale and dividing the difference by the corresponding scale standard deviation (Table 6.12) from the 1998 general U.S. population. Formulas are listed below.

Step 1. Formulas for z-score standardization of SF-36v2 scales (Standard Form)

$$PF\_Z = (PF - 83.29094) / 23.75883$$
$$RP\_Z = (RP - 82.50964) / 25.52028$$
$$BP\_Z = (BP - 71.32527) / 23.66224$$
$$GH\_Z = (GH - 70.84570) / 20.97821$$
$$VT\_Z = (VT - 58.31411) / 20.01923$$
$$SF\_Z = (SF - 84.30250) / 22.91921$$
$$RE\_Z = (RE - 87.39733) / 21.43778$$
$$MH\_Z = (MH - 74.98685) / 17.75604$$

Means and standard deviations are from Table 6.12.

180

Table 6.12 1998 General U.S. Population Means and Standard
            Deviations Used to Derive SF-36v2 z-scores
            (Standard form)

SF-36 Scale	Mean	Standard Deviation
PF	83.29094	23.75883
RP	82.50964	25.52028
BP	71.32527	23.66224
GH	70.84570	20.97821
VT	58.31411	20.01923
SF	84.30250	22.91921
RE	87.39733	21.43778
MH	74.98685	17.75604

Step 2. Norm-based Transformation of SF-36v2 Z-Scores

The second step involves transforming each SF-36v2 z-score to the norm-based (50, 10) scoring. This is accomplished by multiplying each z-score from Step 1 by 10 and adding the resulting product to 50. Formulas are listed below.

Step 2.   Norm-based transformation of SF-36v2 z-scores (Standard Form):

Norm-Based PF: $PF = 50 + (PF\_Z * 10)$
Norm-Based RP: $RP = 50 + (RP\_Z * 10)$
Norm-Based BP: $BP = 50 + (BP\_Z * 10)$
Norm-Based GH: $GH = 50 + (GH\_Z * 10)$
Norm-Based VT: $VT = 50 + (VT\_Z * 10)$
Norm-Based SF: $SF = 50 + (SF\_Z * 10)$
Norm-Based RE: $RE = 50 + (RE\_Z * 10)$
Norm-Based MH: $MH = 50 + (MH\_Z * 10)$

Scoring Checks

Because of errors in reproducing a form, entering data, programming or processing, which can lead to inaccurate scale scores, we strongly recommend formal scoring checks prior to using the scales. Any discrepancies observed during the following checks should be investigated for scoring errors:

1. Calculate SF-36v2 scale scores by hand for several respondents and compare the results to those produced by your scale scoring computer software.
2. After items have been coded into their final item values, inspect the frequency distributions for the items to verify that only the final item values shown in Tables 6.1 through 6.9 are observed. Discrepancies should be limited to respondents with values estimated for missing data as described above.

181

3. After items have been recoded and scale scores have been computed, inspect the correlation between each scale and its component items to verify that all correlations are positive in direction and substantial in magnitude (0.30 or higher).

4. Check correlation's between the General Health scale and the other seven scales to verify that all are positive; with rare exceptions they should also be substantial in magnitude (0.30 or higher).

5. For those familiar with principal factor or components analysis, inspect correlations between the eight scales and the first unrotated factor or component extracted from the correlation's among those scales. Regardless of extraction method, these correlations should be positive and substantial in magnitude (0.30 or higher).

Norm-Based Scoring of Scale Scores, Acute Form (1-week Recall)

After scoring the acute version SF-36v2 scales on a 0-100 scale, the next step involves the norm-based scoring (50/10) using the formulas shown below. Table 6.13 provides the information necessary to apply these formulas to each SF-36 scale from the Acute form (1 week recall). The means and standard deviations (Table 6.13) used in norm-based scoring come from the 1998 general U.S. population. A linear z-score transformation is used so that all eight SF-36 scales have a mean of 50 and a standard deviation of 10 in the 1998 general U.S. population.

The advantages of the norm-based scoring of the standard recall form above also apply to the acute version. The methods for transforming 0-100 scores on the acute scales to norm-based scores are also similar to those used for the standard form. The first step in norm-based scoring consists of standardizing each SF-36v2 scale using a z-score transformation. A z-score for each scale is computed by subtracting the 1998 general U.S. population mean (Table 6.13) for each acute form SF-36 scale and dividing the difference by the corresponding scale standard deviation (Table 6.13) from the 1998 general U.S. population. Formulas are listed below.

Step 1. **Formulas for z-score standardization of SF-36v2 scales (Acute Form)**

$PF\_Z = (PF - 82.62455) / 24.43176$

$RP\_Z = (RP - 82.65109) / 26.19282$

$BP\_Z = (BP - 73.86999) / 24.00884$

$GH\_Z = (GH - 70.78372) / 21.28902$

$VT\_Z = (VT - 58.41968) / 20.87823$

$SF\_Z = (SF - 85.11568) / 23.24464$

$RE\_Z = (RE - 87.50009) / 22.01216$

$MH\_Z = (MH - 75.76034) / 18.04746$

Means and standard deviations are from Table 6.13.

182

Table 6.13   1998 General U.S. Population Means and Standard
Deviations Used to Derive SF-36 Z-Scores (Acute
Form)

SF-36 Scale	Mean	SD
PF	82.62455	24.43176
RP	82.65109	26.19282
BP	73.86999	24.00884
GH	70.78372	21.28902
VT	58.41968	20.87823
SF	85.11568	23.24464
RE	87.50009	22.01216
MH	75.76034	18.04746

Step 2. Norm-based Transformation of SF-36v2 Z-Scores (Acute Form)

The second step involves transforming each SF-36v2 z-score from Step 1 to the norm-based (50, 10) scoring. This is accomplished by multiplying each z-score by 10 and adding the resulting product to 50. Formulas are listed below.

Step 2.   Norm-based transformation of SF-36v2 z-scores (Acute Form):

Norm-Based PF: PF = 50 + (PF_Z * 10)
Norm-Based RP: RP = 50 + (RP_Z * 10)
Norm-Based BP: BP = 50 + (BP_Z * 10)
Norm-Based GH: GH = 50 + (GH_Z * 10)
Norm-Based VT: VT = 50 + (VT_Z * 10)
Norm-Based SF: SF = 50 + (SF_Z * 10)
Norm-Based RE: RE = 50 + (RE_Z * 10)
Norm-Based MH: MH = 50 + (MH_Z * 10)

Scoring Checks

Because of errors in reproducing a form, entering data, programming or processing, which can lead to inaccurate scale scores, we strongly recommend formal scoring checks prior to using the scales. Any discrepancies observed during the following checks should be investigated for scoring errors:

1. Calculate SF-36v2 scale scores by hand for several respondents and compare the results to those produced by your scale scoring computer software.
2. After items have been coded into their final item values, inspect the frequency distributions for the items to verify that only the final item values shown in Tables 6.1 through 6.9 are observed. Discrepancies should be limited to respondents with values estimated for missing data as described above.
3. After items have been recoded and scale scores have been computed, inspect the correlation between each scale and its component items to verify that all correlations are positive in direction and substantial in magnitude (0.30 or higher).
4. Check correlation's between the General Health scale and the other

183

seven scales to verify that all are positive; with rare exceptions they should also be substantial in magnitude (0.30 or higher).

5. For those familiar with principal factor or components analysis, inspect correlations between the eight scales and the first unrotated factor or component extracted from the correlations among those scales. Regardless of extraction method, these correlations should be positive and substantial in magnitude (0.30 or higher).

Chapter 7   Scoring SF-36v2 Physical and Mental Summary Measures

This chapter provides scoring instructions for the SF-36v2 physical (PCS) and mental (MCS) component summary measures. Scoring of the SF-36v2 PCS and MCS summary measures involves three steps. First, the eight SF-36 scales are standardized using means and standard deviations from the 1998 general U.S. population. Second, they are aggregated using weights (factor score coefficients) from the 1990 general U.S. population. These are the same weights as those used to score PCS and MCS from the SF-36 Version 1.0 (Ware et al., 1994). Finally aggregate PCS and MCS scores are standardized using a linear T-score transformation to have a mean of 50 and a standard deviation of 10, in the 1998 general U.S. population. Norm-based scoring of the standard (4-week recall) and acute (1 week recall) forms is presented separately.

General U.S. population statistics used in the standardization and in the aggregation of SF-36v2 scale scores are presented in Table 7.1 for the standard form and in Table 7.2 for the acute form. Note that for both standard and acute forms the same factor score coefficients are used to score PCS and MCS. To make sure that the original coefficients used in this scoring "recipe" have the same affect in 1998, as in 1990, 1998 variances are utilized. Detailed Information including formulas for scale aggregation and transformation of scores are presented below. Formal checks using a test dataset available upon request (info@QualityMetric.com) can be performed to confirm the successful reproduction of PCS and MCS scales, as discussed later in the chapter. We strongly recommend these tests.

Importance of Standardization

As with the 1998 NBS scoring of SF-36v2 scales, which are aggregated to score the summary measures, standardization of the scoring of the PCS and MCS scales is vital to their interpretation. Any changes in scoring of the SF-36 scales or the algorithms for the summary measures may compromise their reliability and validity. Changes in scoring may also invalidate normative comparisons, based on the 1998 norms documented here.

The methods documented here achieve 1998 scores that are a nearly perfect transformation of the 1990 scores. For scales and summary measures, NBS based on 1998 norms only shifts the score distribution to better reflect the health of the US population in 1998. Otherwise, 1998 scores have the same interpretations as 1990 scores.

Norm-Based Scoring of PCS and MCS, Standard Form (4 Week Recall)

Standard form PCS and MCS scales are scored using norm-based methods. The means and standard deviations used in scoring come from the 1998 general U.S. population and the factor score coefficients come from the 1990 general U.S. population (Ware et al. 1994). A linear T-score transformation method is used so that both the PCS and MCS have a mean of 50 and a standard deviation of 10 in the 1998 general U.S. population.

185

The advantage of the standardization and norm-based scoring of the PCS and MCS is that results for one can be meaningfully compared with the other and their scores have a direct interpretation in relation to the distribution of scores in the general U.S. population. Specifically, all scores above and below 50 are above and below the average, respectively, in the 1998 general U.S. population. Because the standard deviation is 10 for both PCS and MCS measures, each one point difference in scores also has a direct interpretation. A one point difference is one-tenth of a standard deviation. (See Chapter 5 for an example of these advantages.)

Table 7.1   1998 General U.S. Population Means, Standard Deviations and 1990 Factor Score Coefficients used to Derive PCS and MCS Scale Scores, Standard Form

SF-36 Scale	Mean*	Standard Deviation	Factor Score Coefficients	
			PCS	MCS
PF	83.29094	23.75883	0.42402	-0.22999
RP	82.50964	25.52028	0.35119	-0.12329
BP	71.32527	23.66224	0.31754	-0.09731
GH	70.84570	20.97821	0.24954	-0.01571
VT	58.31411	20.01923	0.02877	0.23534
SF	84.30250	22.91921	-0.00753	0.26876
RE	87.39733	21.43778	-0.19206	0.43407
MH	74.98685	17.75604	-0.22069	0.48581

*Note: The means and standard deviations for each SF-36v2 are based on the 0-100 scoring.

It should be noted that mean scores for most of the scales vary substantially form those from the 1990 norms used to score Version 1. For those scales (PF, BP and GH) that have not been changed in any way from Version 1 to 2, several explanations are being explored (e.g., sampling bias in the 1990 study, downward temporal trends in physical health). Regardless of the explanations, these differences underscore the importance of using up-to-date norms and also the importance of using the same normative data when equating Versions 1 and 2 of the SF-36. 1998 norms for both make these comparisons possible.

Steps in Scoring

Following the scoring of the eight scales according to the standard SF-36v2 scoring algorithms (0-100 scale) explained earlier in chapter 6, PCS and MCS are scored in three steps as explained below:

Standardization of Scales (Z-Scores), Standard Form

The first step in computing PCS and MCS consists of standardizing each of the 8 SF-36 scales using a z-score transformation. This is the same as Step 1 used in the norm-based scoring of the 8 SF-36 scales explained in Chapter 6. A z-score for each scale is computed by subtracting the mean 0-100 general US population score (see Table 7.1) for each SF-36 scale and dividing the difference by the corresponding scale standard deviation. Note that the SF-36 scales scored on the 0-100 scale are used in step 1. Norm-based SF-36 scale scores are not used in this step. Formulas are listed below.

186

Step 1. Formulas for z-score standardization of SF-36v2 scales, (Standard Form)

$$PF\_Z = (PF - 83.29094) / 23.75883$$
$$RP\_Z = (RP - 82.50964) / 25.52028$$
$$BP\_Z = (BP - 71.32527) / 23.66224$$
$$GH\_Z = (GH - 70.84570) / 20.97821$$
$$VT\_Z = (VT - 58.31411) / 20.01923$$
$$SF\_Z = (SF - 84.30250) / 22.91921$$
$$RE\_Z = (RE - 87.39733) / 21.43778$$
$$MH\_Z = (MH - 74.98685) / 17.75604$$

Means and standard deviations are from Table 7.1.

Aggregation of Scale Scores (Standard Form)

After a z-score has been computed for each SF-36v2 scale, the second step involves computation of aggregate scores for the physical and mental components using the physical and mental factor score coefficients from the 1990 general U.S. population as given in Table 7.1.

Computation of an aggregate physical component score consists of multiplying each SF-36v2 scale z-score by its respective physical factor score coefficient and summing the eight products, as shown below. Similarly, an aggregate mental component score is obtained by multiplying each SF-36 scale z-score by its respective mental factor score coefficient and summing the eight products.

Step 2. Formulas for aggregating scales in estimating aggregate physical and mental component scores (Standard Form)

$$AGG\_PHYS = (PF\_Z * .42402) + (RP\_Z * .35119) + (BP\_Z * .31754) + (GH\_Z * .24954) + (VT\_Z * .02877) + (SF\_Z * -.00753) + (RE\_Z * -.19206) + (MH\_Z * -.22069)$$

$$AGG\_MENT = (PF\_Z * -.22999) + (RP\_Z * -.12329) + (BP\_Z * -.09731) + (GH\_Z * -.01571) + (VT\_Z * .23534) + (SF\_Z * .26876) + (RE\_Z * .43407) + (MH\_Z * .48581)$$

Transformation of Summary Scores

The third step involves transforming each component score to the norm-based (50, 10) scoring. This is accomplished by multiplying each aggregate component scale score by 10 and adding the resulting product to 50. Formulas are shown in step 3.

187

Step 3. Formulas for T-score transformation of component scores (Standard Form)

Transformed Physical (PCS) = 50 + (AGG_PHYS * 10)
Transformed Mental (MCS) = 50 + (AGG_MENT * 10)

Norm-Based Scoring of PCS and MCS, Acute Form

Acute form PCS and MCS scales are scored using norm-based methods. The means and standard deviations used in scoring come from the 1998 general U.S. population and the factor score coefficients come from the 1990 general U.S. population (Ware et al. 1994). A linear T-score transformation method is used so that both the PCS and MCS have a mean of 50 and a standard deviation of 10 in the 1998 general U.S. population.

The advantage of the standardization and norm-based scoring of the PCS and MCS is that results for one can be meaningfully compared with the other and their scores have a direct interpretation in relation to the distribution of scores in the general U.S. population. Specifically, all scores above and below 50 are above and below the average, respectively, in the 1998 general U.S. population. Because the standard deviation is 10 for both PCS and MCS measures, each one point difference in scores also has a direct interpretation. A one point difference is one-tenth of a standard deviation.

Table 7.2   1998 General U.S. Population Means, Standard Deviations and 1990 Factor Score Coefficients Used to Derive PCS and MCS Scale Scores, Acute Form

SF-36 Scale	Mean*	Standard Deviation*	Factor Score Coefficients	
			PCS	MCS
PF	82.62455	24.43176	0.42402	-0.22999
RP	82.65109	26.19282	0.35119	-0.12329
BP	73.86999	24.00884	0.31754	-0.09731
GH	70.78372	21.28902	0.24954	-0.01571
VT	58.41968	20.87823	0.02877	0.23534
SF	85.11568	23.24464	-0.00753	0.26876
RE	87.50009	22.01216	-0.19206	0.43407
MH	75.76034	18.04746	-0.22069	0.48581

*Note: The means and standard deviations for each SF-36v2 are based on the 0-100 scoring.

Steps in Scoring

Following the scoring of the eight scales according to the standard SF-36v2 scoring algorithms (0-100 scale) explained earlier in chapter 6, PCS and MCS are scored in three steps as explained below:

Standardization of Scales (Z-Scores), Acute Form

The first step in computing PCS and MCS consists of standardizing each of the 8 SF-36 scales using a z-score transformation. This is the same as Step 1 used in the norm-based scoring of the 8 SF-36 scales explained in Chapter 6. A z-score for each scale is computed by subtracting the mean 0-100 general US population score (see Table 7.2) for each SF-36 scale and dividing the difference by the corresponding scale standard deviation. Note that the SF-36 scales scored on the 0-100 scale are used in step 1. Norm-based SF-36 scale scores are not used in this step. Formulas are listed below.

Step 1. Formulas for z-score standardization of SF-36v2 scales (Acute version)

$$PF\_Z = (PF - 82.62455) / 24.43176$$
$$RP\_Z = (RP - 82.65109) / 26.19282$$
$$BP\_Z = (BP - 73.86999) / 24.00884$$
$$GH\_Z = (GH - 70.78372) / 21.28902$$
$$VT\_Z = (VT - 58.41968) / 20.87823$$
$$SF\_Z = (SF - 85.11568) / 23.24464$$
$$RE\_Z = (RE - 87.50009) / 22.01216$$
$$MH\_Z = (MH - 75.76034) / 18.04746$$

Means and standard deviations are from Table 7.2

Aggregation of Scale Scores (Acute Form)

After a z-score has been computed for each SF-36v2 scale, the second step involves computation of aggregate scores for the physical and mental components using the physical and mental factor score coefficients from the 1990 general U.S. population as given in Table 7.2.

Computation of an aggregate physical component score consists of multiplying each SF-36v2 scale z-score by its respective physical factor score coefficient and summing the eight products, as shown in step 2. Similarly, an aggregate mental component score is obtained by multiplying each SF-36 scale z-score by its respective mental factor score coefficient and summing the eight products.

Step 2. Formulas for aggregating standardized scales in estimating aggregate physical and mental component scores (Acute Form)

AGG_PHYS = (PF_Z * .42402) + (RP_Z * .35119) + (BP_Z * .31754) + (GH_Z * .24954) + (VT_Z * .02877) + (SF_Z * -.00753) + (RE_Z * -.19206) + (MH_Z * -.22069)

AGG_MENT = (PF_Z * -.22999) + (RP_Z * -.12329) + (BP_Z * -.09731) + (GH_Z * -.01571) + (VT_Z * .23534) + (SF_Z * .26876) + (RE_Z * .43407) + (MH_Z * .48581)

Transformation of Summary Scores

The third step involves transforming each component score to the norm-based (50, 10) scoring. This is accomplished by multiplying each aggregate component scale score by 10 and adding the resulting product to 50. Formulas are shown in step 3.

Step 3. Formulas for T-score transformation of component scores

Transformed Physical (PCS) = 50 + (AGG_PHYS * 10)
Transformed Mental (MCS) = 50 + (AGG_MENT * 10)

Missing Data Estimation

Results from ongoing evaluations of options to score PCS and MCS when a respondent is missing any one of the eight SF-36v2 scales has shown considerable promise. Evaluation of missing data rates across general and clinical populations has shown that 50% of those who have missing PCS and MCS scores are missing PCS and MCS because of missing data on one SF-36 scale. QualityMetric Incorporated's Missing Data Estimator (MDE) will enable you to score PCS and MCS with data for 7 of the 8 SF-36 scales. PCS and MCS scores from MDE have proven to be reliable and valid (Ware et al., forthcoming). Further efforts are underway to evaluate options for scoring PCS and MCS when more than 1 SF-36 scale score is missing. More information will be available at these websites www.sf-36.com and www.QualityMetric.com.

Until QualityMetric Incorporated's MDE is made available, it is recommended that component scale scores be set to missing if the respondent is missing any one of the eight SF-36v2 scales. To minimize the number of component scores missing, we recommend estimating each of the eight scale scores if half or more of the items are complete, as documented earlier.

190

Features of PCS and MCS Scores

The PCS and MCS were constructed and scored to achieve a number of advantages, in addition to reducing the SF-36v2 from an eight-scale profile to two summary measures without substantial loss of information. Features of the PCS and MCS scores, including their reliability, confidence intervals (CI), skewness (percent ceiling and floor), and number of levels observed in the general U.S. population, are summarized in Table 7.3. These results confirm some of the theoretical advantages of the two summary measures as compared to the eight SF-36 scales, including a very large increase in the number of levels defined, smaller confidence intervals relative to each of the eight scales, as well as the elimination of both floor and ceiling effects.

Table 7.3   Comparison of Features of SF-36v2 Scales and Summary Measures, 1998 General U.S. Population

	SF-36v2 Scales[b]	Summary Measures	
		PCS	MCS
Reliability	.84 - .95	.95	.93
95% CI (±)	12 – 17	4.5	5.2
% Floor	0.0 – 2.1	0	0
% Ceiling	2.1 – 60.2	0	0
# of Levels[a]	8 - 20	486	494

[a] Scores rounded to first decimal place
[b] Statistics are presented as the range of results found across the eight SF-36v2 scales (standard and acute forms) in the 1998 general U.S. population.

Scoring Checks

Because errors can lead to inaccurate scale scores, we strongly recommend formal scoring checks of SF-36v2 scales prior to computing the SF-36 component summary scales. These formal scoring checks are explained in full detail in chapter 6: scoring SF-36 scales.

The following scoring checks are also strongly recommended for the SF-36v2 component summary scales. Any discrepancies should be investigated for scoring errors:

Check correlation's between the eight SF-36v2 scales and the PCS and MCS scales. The PF, RP, and BP scales should correlate highest with the PCS and lowest with the MCS. The MH, RE, and SF scales should correlate highest with the MCS and lowest with the PCS. The GH and VT scales should correlate moderately with both physical and mental component scales.

191

Check the correlation between the physical and mental component summary scales. The correlation should be very low.

Scoring Exercise

QualityMetric Incorporated offers a Scoring & Data Quality Analysis service (information available at www.QualityMetric.com).

Table 7.4 presents descriptive statistics for the eight SF-36v2 scales (0-100 and norm-based) and the physical and mental component summary measures from the test dataset for the standard form. Table 7.5 presents descriptive statistics for the eight SF-36v2 scales (0-100 and norm-based) and the physical and mental component summary measures from the test dataset for the acute form.

After scoring the test dataset, you should observe the same means, standard deviations, and minimum and maximum observed values as those presented in Table 7.4 for the standard form and in Table 7.5 for the acute form.

Table 7.4   Test Dataset Descriptive Statistics*: SF-36v2 Scales and Summary Measures (N = 100), Standard Form**

	Number of Cases	0-100 Scores				Norm-Based Scores			
		Mean	Standard Deviation	Min. Value	Max. Value	Mean	Standard Deviation	Min. Value	Max. Value
Physical Functioning	100	82.16	22.00	15	100	49.52	9.26	21.25	57.03
Role Physical	100	82.95	23.29	0	100	50.17	9.12	17.66	56.85
Bodily Pain	100	71.53	20.18	22	100	50.08	8.53	29.15	62.11
General Health	100	71.39	17.89	10	100	50.25	8.53	20.99	63.89
Vitality	100	60.35	18.13	7	94	51.01	9.06	23.99	67.70
Social Functioning	100	91.00	16.95	25	100	52.92	7.39	24.12	56.84
Role Emotional	100	89.50	18.93	0	100	50.98	8.83	9.23	55.87
Mental Health	100	78.86	14.85	40	100	52.18	8.36	30.29	64.08
Physical Component Summary (PCS)	100	N/a	-	-	-	49.29	8.66	23.93	61.58
Mental Component Summary (MCS)	100	N/a	-	-	-	52.58	7.71	30.06	64.18

*All descriptive statistics are rounded to the second decimal point.

Table 7.5   Test Dataset Descriptive Statistics*: SF-36v2 Scales and Summary Measures (N = 100), Acute Form

	Number of Cases	0-100 Scores				Norm-Based Scores			
		Mean	Standard Deviation	Min. Value	Max. Value	Mean	Standard Deviation	Min. Value	Max. Value
Physical Functioning	100	82.44	24.19	0	100	49.92	9.90	16.18	57.11
Role Physical	100	82.91	26.66	0	100	50.10	10.18	18.44	56.62
Bodily Pain	100	71.8	24.56	12	100	49.13	10.23	24.23	60.88
General Health	100	70.97	19.89	5	100	50.08	9.34	19.09	63.72
Vitality	100	58.35	19.93	7	100	49.96	9.54	25.01	69.91
Social Functioning	100	85.87	23.68	0	100	50.32	10.18	13.38	56.40
Role Emotional	100	90.16	19.76	0	100	51.21	8.97	10.24	55.67
Mental Health	100	77.55	15.52	20	100	50.99	8.60	19.10	63.43
Physical Component Summary (PCS)	100	n/a	-	-	-	49.29	9.33	19.34	65.35
Mental Component Summary (MCS)	100	n/a	-	-	-	51.17	8.73	16.38	70.66

*All descriptive statistics are rounded to the second decimal point.

SF-36v2 algorithms have been made available to computer software vendors and other organizations providing scoring and analysis services for the SF-36. Look for the symbol to the right.

This symbol is your assurance that computer software products and data processing services produce results that are comparable with this Manual and with other normative data and interpretation guidelines for the SF-36v2 Health Survey.

193
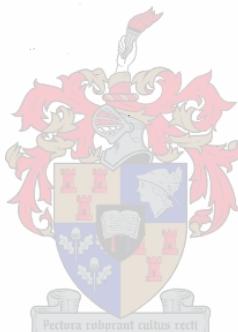
How to interpret the SF-36

Table 8.2 summarizes information presented in Chapters 9 and 10 that may be most useful for interpreting scores for SF-36 scales. Table 8.2 orders scales according to their validity, from the scale known to be the most valid measure of the physical component of health status, Physical Functioning (PF), to the last scale in the table, Mental Health (MH), which is the most valid measure of the mental component of health status. Interestingly, MH is the poorest measure of the physical component, and PF is the poorest measure of the mental component. Scales in between PF and MH are ordered according to their validity in measuring physical and mental components. Scales in the middle have substantial or moderate validity for both components of health status and should be interpreted accordingly.

The number of items and the number of levels defined by each scale is presented. The most precise (least coarse) scales are those with 20 or more levels (PF, GH, VT, and MH). The relatively coarse role disability scales (RP and RE) each measure only four or five levels.

Means and standard deviations for each of the eight scales in the general U.S. adult population are also presented. These can be used to determine whether a group or individual in question scores above or below the U.S. average. Reliability estimates and confidence intervals for individual scores are also presented.

The remaining information in Table 8.2 under the headings "Validity," "Range," and "Definitions of Lowest and Highest Scores" is presented to facilitate interpretation. The summaries and graphics in Table 8.2 are based on all available evidence described in Chapters 8 through 10. The following section discusses three distinct interpretation issues: (1) the extent to which each scale measures the physical or mental component of health ("Validity"), (2) whether both limitations and well-being are measured by each scale ("Range"), and (3) the description of the health states that are assigned at the lowest and highest possible score on each scale. These summaries will help determine what results mean.

Three of the scales (PF, RP, and BP) have substantial validity as measures of physical health status. Each scale, however, addresses a different aspect of physical health. PF measures limitations in behavioral performance of

TABLE 8.2 SUMMARY OF INFORMATION ABOUT SF-36 SCALES

Scale	Label	Items	Levels	Mean[a]	SD[a]	Reliability[a]	CI[b]	Validity[c] P	Validity[c] M	Range[d]	Lowest Possible (Floor)	Highest Possible (Ceiling)
Physical Functioning	PF	10	21	84.2	23.3	.93	±10	●	O	▬▬	Limited a lot in performing all physical activities including bathing or dressing due to health	Performs all types of physical activities including the most vigorous without limitations due to health
Role–Physical	RP	4	5	81.0	34.0	.89	±19	●	O	▬▬	Problems with work or other daily activities as a result of physical health	No problems with work or other daily activities as a result of physical health
Bodily Pain	BP	2	11	75.2	23.7	.90	±12	●	O	▬▬	Very severe and extremely limiting pain	No pain or limitations due to pain
General Health	GH	5	21	72.0	20.3	.81	±15	◐	◐	▬▬	Evaluates personal health as poor and believes it is likely to get worse	Evaluates personal health as excellent
Vitality	VT	4	21	60.9	21.0	.86	±13	◐	◐	▬▬	Feels tired and worn out all of the time	Feels full of pep and energy all of the time
Social Functioning	SF	2	9	83.3	22.7	.68	±21	◐	●	▬▬	Extreme and frequent interference with normal social activities due to physical or emotional problems	Performs normal social activities without interference due to physical or emotional problems
Role–Emotional	RE	3	4	81.3	33.0	.82	±23	O	●	▬▬	Problems with work or other daily activities as a result of emotional problems	No problems with work or other daily activities as a result of emotional problems
Mental Health	MH	5	26	74.7	18.0	.84	±12	O	●	▬▬	Feelings of nervousness and depression all of the time	Feels peaceful, happy, and calm all of the time

a Mean, standard deviation, and reliability for the general U.S. population (total sample).

b CI = 90% confidence interval around the score for an individual, general U.S. population.

c P = physical health, M = mental health, ● = substantial, ◐ = moderate, and O = weak validity.

d ▬▬ = limitations/disability range; ▬▬ = well-being range.

everyday physical activities, RP measures the extent of disability in every-day activities due to physical problems, and BP focuses specifically on the severity of bodily pain and resulting limitations in activities.

The three best measures of the mental component of health status are the MH, RE, and SF scales. All have substantial validity for measuring mental health. They differ in the range of mental health measured, with perfect SF and RE scores earned by those reporting no limitations or disability due to personal or emotional problems. In contrast, the MH scale is a bipolar scale with a mid-range score earned by those reporting no symptoms of psychological distress. A score of 100 on this scale requires reports of frequently feeling happy, calm, and peaceful.

The SF-36 scales most sensitive to both physical *and* mental health outcomes are the VT and GH scales, which have moderate empirical validity for these two components. They are relatively precise scales, with 21 scale levels. A mid-range score on the VT scale is achieved by those who do not report feeling tired or worn out; a score of 100, in addition to indicating an absence of these symptoms, is only earned by those who report feeling full of pep and energy all of the time. A mid-range score is obtained on the bipolar GH scale by reporting no unfavorable evaluations of health in general.

As indicated in the "Range" column of Table 8.2, the highest possible score on all but three scales indicates the absence of a negative state (limitation, disability, pain).

Content-referenced interpretation, criterion studies of validity, and norm-referenced scoring all support the summary of guidelines for scale interpretation presented in Table 8.2. Chapters 9 and 10 presents detailed evidence of each of the three types.

Although a great deal of information has accumulated about SF-36 score interpretation, a great deal remains to be learned. Users of this manual are encouraged to use the information presented here with a healthy degree of caution and to publish their own findings and interpretation guidelines whenever possible.

ADDENDUM D

# Modifications to the UK Short Form-36 version 2

Dear Maria Burton

Thank you for taking the time to look at the Quality of Life (QoL) questionnaire I have developed to use in my study. I am doing a study to determine the health related quality of life and survival rate of patients 12 months post intensive care treatment. My population is a group of 180 patients discharged from a surgical intensive care unit at a public tertiary academic hospital based in the Northern suburbs of the Western Cape in South Africa. Due to the differences in our population compared to populations of first world countries, it was required of me to change and/or adapt the questionnaire I intend to use.

I have decided to use the Short Form 36 QoL questionnaire. However, it has presented some problems as it is not as easily understood by our population as some of the wording was not understood and the response options too similar and offered too many alternatives at one time. This makes it difficult for patients to remember the options and respond appropriately. For this reason, I have made specific changes.

I also know that the SF-36 has been translated into other languages of many countries including South Africa. I would like to know which of the 18 indigenous South African languages has it been translated and whether Afrikaans is one of them as my population is predominantly Afrikaans literate. If not then I will have to translate it for my study.

Please use this page and the original SF-36 Standard Form as well as my modified questionnaire to follow the changes made. I have made the changes in Italics.

Thank you so much for your help. I greatly appreciate it.

Farhana Karachi

Changes:

Page Four: This is a separate page that consists of the patients' demographic data and specific ICU variables required. This information will be extracted from my population database. If a patient is reported dead at the time of follow-up questioning, the QoL questionnaire will then not obviously be required.

Page5-10: This consists of the QoL which has been modified.

The opening statement has been changed to make the language easier to understand.

1. option (d) has been changed from "fair " to "quite good"- for better understanding.

2. options (b) and (d) have been changed to "a bit better now" and " a bit worse now" respectively – for better understanding.

A-B: This is the highlighted and italic text. This line of questioning has been added to incorporate the patients' normal work and/or home activities of daily living. It precedes question 3 on the questionnaire. This question will aid the researcher in understanding the participants' situation and aid the participant in understanding the line of questioning in question 3 making it easier for the participant to follow. This is nominal data and will not be scored. However, if these questions interfere with the validity and reliability of the questionnaire, I will then remove them and add them to page one under the patients' demographic data.

Some of the following questions have had their response options reduced. Please note as I do not know how the SF-36 Standard Form is scored I am uncertain as to whether I may change the number of options given per

question. Would it be better to stick to the same number as in the original form?

3. The wording of this question and the options has been changed to make it easier to understand. I have kept some of the original activities and added extra ones. I have separated them accordingly to make it clearer to understand and respond to. As I have not seen how the SF-36 standard form is scored I would like to know if changing this question like this will impact on the scoring system or whether it won't matter so long as the scores are re-calculated to conform to the standardised scoring system.

4-6. The italics are words and options that have been changed to make it easier to understand. I have changed the options from 5options to 4 options and changed the words of the options to make it easier for my population to understand and respond to. I have however kept the options in descending format as in the original questionnaire. I am however also concerned here about the impact on the scoring system.

7. Again here, the number of options has been changed from 6 to 4 options. Would this impact on the scoring system? The wording of the options has been changed for better understanding.

8. The number of options here has been changed from 5 to 4 options. Would this impact on the scoring system? The wording of the options has been changed for better understanding.

NB! Questions (4-8) 7-11 the question has changed from "During the past 4 weeks" to "In the last month" for purposes of better understanding by the population.

9. The italics are where words have been changed to make it easier to understand. The sub-questions (a.-i.) have been kept the same however the words of the options given have changed but kept in descending order like the

original form. The options have also been changed from 5 to 4 options. Would this impact on the scoring system?

10. The italics are where words have been changed to make it easier to understand. The options given have changed but kept in descending order like the original form. The options have also been changed from 5 to 4 options. Would this impact on the scoring system?

11. The question has been changed slightly and the options have been changed from 5 to 3 options as the original options were to fine/small to distinguish making the response more difficult. Would this impact on the scoring system?

The last section has been added as one of my research aims is also to obtain information regarding follow-up consultations and other health conditions for this population group.

Thank You for your time it is greatly appreciated!

YAHOO! Mail ✉️

Comments on proposed changes to SF-36

- I think you should add past medical history & concomitant disease / disability. This will give greater understanding to your analysis.

- The other demographics you ask for need to be separate from the SF36 i.e. the info on pg 5 / 6 A, B, C, & pg10. It will make life easier for the you when you come to analyse and you will lose nothing. It also makes the form less cluttered for the patient.

- My main concern is the reduced responses in any of the questions. Given the extensive testing of this questionnaire and the recent additions to the responses in version 2 I feel you would be better to stick with at least the number of responses if not the exact wording. One of the problems with version 1 of the SF-36 was the lack of sensitivity to change and the strong floor and ceiling effects therefore the authors increased the number of responses to some items.

- Question 3 – You have added a number of items, I presume you feel you need more detail? Can I suggest that you try to stick to the originals – in a language your population understand but that any extra items are not scored or scored separately. As physios we tend to dwell on detail when it comes to physical things and it's not necessary in a QoL measure. Have you considered supplementing this with a validated functional / clinical measure? In this way you could stick with the standard

SF36 but increase the detail. It also allows you to make an evaluation of how the 2 measures work in your population. The authors have always suggested that this questionnaire was not intended as a stand-alone measure.

- It is always a problem getting the wording right for different populations / countries. If you wanted to justify your reasons for changing the wording a small pilot looking at the effect of changing words on the sensitivity of responses would be good. This is not essential but would add weight to the validity of your changes – maybe that's for your doctorate!

- Changing the wording to a month would I feel eventually lead to more confusion. Some patients may interpret that as the last calendar month and ignore the present month. 4 weeks identifies the time more precisely.

- Your question 10 – I would definitely stick to the original number and wording of this item.

In summary I would say that the more changes you make the less sensitive your study will be to change and less comparable it will.

Can I suggest that you and a few friends complete the standard SF36 and that you score it. This will give you a lot of insight into the problems of completion and scoring.

Do you know there is a SF36 website? It's SF36.com – and it's quite a good site.

Hope this has been of use to you. If you feel I can be any further

please contact me.

Good luck
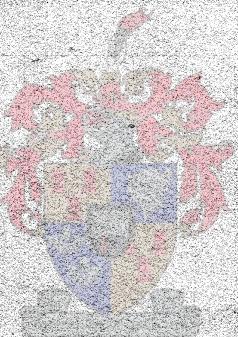
ADDENDUMS E & F

English and Afrikaans Translations of the Self-developed and Modified SF-36 Questionnaires
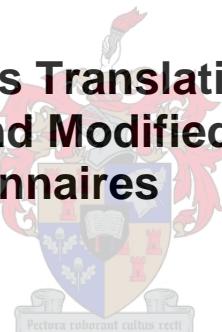
MODIFIED SELF-DEVELOPED QUESTIONNAIRE

Name of patient: Age:

Have you received the letter informing you that this study is being conducted?

YES   ☐
NO   ☐

All information will be kept strictly confidential! Do you agree to participate in this study?

YES   ☐
NO   ☐

Cause of death:

Date of death:

(If patient deceased do not continue with rest of questions)

WORK AND OTHER ACTIVITIES:

A. Do you have any of the following hobbies?
- ☐ Knitting
- ☐ Reading
- ☐ Watching television
- ☐ Sport:

           Walking/Hiking   ☐
           Swimming   ☐
           Cycling   ☐
           Running/Jogging   ☐
           Netball   ☐
           Soccer   ☐
           Cricket   ☐
           Other   ☐
           _____

- ☐ Other _____
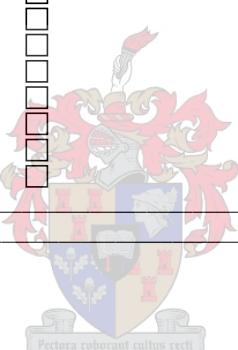
B. Were you employed before you fell ill?
- ☐ YES
     What work did you do?
     _____

- ☐ NO
     Are you:

         ○ Unemployed

         ○ A pensioner

         ○ A housewife

         ○ Retired

         ○ Recipient of a disability allowance

         ○ A student?

C. Are you currently employed?
- ☐ YES
     What kind of work do you do now? _____

❑ NO

Are you:

- ○ Unemployed
- ○ A pensioner
- ○ A housewife
- ○ Retired
- ○ Recipient of a disability allowance
- ○ A student?

INFORMATION REGARDING GENERAL HEALTH AND FOLLOW-UP:

|	YES	NO
D. Do you smoke cigarettes?	☐	☐
How many?		
E. Do you use/drink alcohol?	☐	☐
How much?		

> **Comment [IT1]:** The fields for the 'How many/ much' answers do not appear in the printed document.

The following questions are of a personal and confidential nature, and deal with illnesses such as TB and/or HIV. May I read the questions to you so that you can decide whether you wish to answer them or not? The information will be kept strictly confidential (this means that no one will know what you have told me)!

	YES	NO
F. Have you been tested for HIV?	☐	☐
G. Have you been tested for TB?	☐	☐
H. Do you know your status?	☐	☐
I. Are you prepared to share this information?	☐	☐
	-	**+**
J. TB status	☐	☐
K. HIV status	☐	☐

L. Apart from your original illness, have you returned to the hospital and why?

_____
_____
_____
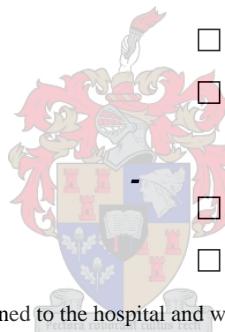
Modified SF 36 Standard Questionnaire

Your Health and Wellbeing

This questionnaire asks how you feel about your health and how well you are able to do your usual activities. For each question please choose the option that you think best describes you and your health.

1. Would you say that in general your health is:
   - ❑ Excellent
   - ❑ Very good
   - ❑ Good
   - ❑ Quite good
   - ❑ Poor

2. <u>Compared to a year ago</u>, how would you describe your general health at present?
   - ❑ Much better now
   - ❑ A bit better now
   - ❑ About the same as a year ago
   - ❑ A bit worse now
   - ❑ Much worse now

3. The following questions deal with activities you do during a normal day. <u>Does your health at the moment limit you</u> in any of these activities and, if so, to what extent?

	Very limited	*Slightly limited*	*Not limited at all*
a. <u>Energetic activities</u>			
i. Running	☐	☐	☐
ii. Participation in your sport/hobby	☐	☐	☐
iii. Picking up heavy object (e.g. child/boxes)	☐	☐	☐
iv. Driving	☐	☐	☐
b. <u>Moderate activities</u>			
i. Vacuuming/sweeping	☐	☐	☐
ii. Doing laundry/hanging clothes	☐	☐	☐
iii. Making the bed	☐	☐	☐
iv. Shifting table/chair	☐	☐	☐
c. Picking up/carrying the shopping	☐	☐	☐
d. Climbing ten or more steps	☐	☐	☐
e. Climbing one or more steps	☐	☐	☐
f. Bending or kneeling	☐	☐	☐

208

g.	Changing from a lying position to a sitting position	☐	☐	☐
h.	Standing up from a sitting position	☐	☐	☐
i.	Walking with support	☐	☐	☐
j.	Walking without support	☐	☐	☐
k.	Walking in the house or to the toilet	☐	☐	☐
l.	Walking outside or to the shop	☐	☐	☐
m.	Walking long distances (hiking)	☐	☐	☐
n.	Bathing or dressing yourself	☐	☐	☐

4. In the past four weeks, how has your work or your daily activities been limited as a result of physical health problems?

a. Have you reduced the amount of time that you devote to work or other activities?
- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*
- ☐ *Occasionally*
- ☐ *Never*

b. Did you manage to do less than you wanted to do in your work and other activities?
- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*
- ☐ *Occasionally*
- ☐ *Never*

c. Are you limited in the TYPE of work or other daily activities you do?
- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*
- ☐ *Occasionally*
- ☐ *Never*

d. Did you struggle to do the work or other activities (extra effort)?
- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*
- ☐ *Occasionally*
- ☐ *Never*

5. In what way has your work or other daily activities over the past four weeks been limited as a result of any emotional problems (such as feeling depressed or anxious)?

a. Did you reduce the amount of time you devoted to your work or other activities?
- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*

❑ *Occasionally*
❑ *Never*

b. Did you <u>do less</u> than you wanted to do in your work or other activities?
   ❑ *Always*
   ❑ *Usually*
   ❑ *Sometimes*
   ❑ *Occasionally*
   ❑ *Never*

c. Did you do your work or other activities <u>less carefully</u> than usual?
   ❑ *Always*
   ❑ *Usually*
   ❑ *Sometimes*
   ❑ *Occasionally*
   ❑ *Never*

6. In the <u>past four weeks,</u> how did your physical health or emotional problems interfere with your normal social activities with family, friends, neighbours or groups?
   ❑ *Not at all*
   ❑ *Slightly*
   ❑ *Moderately*
   ❑ *Quite a lot*
   ❑ *Extremely*

7. How much pain did you experience in your <u>body</u> during the <u>past four weeks</u>?
   ❑ *None*
   ❑ *Very mild*
   ❑ *Mild*
   ❑ *Moderate*
   ❑ *Severe*
   ❑ *Very severe*

8. During the <u>past four weeks</u>, how much did **pain** interfere with your normal work (with chores at home as well as work outside of the home)?
   ❑ *Not at all*
   ❑ *A little bit*
   ❑ *Moderately*
   ❑ *Quite a lot*
   ❑ *A great deal*

9. The following questions deal with the way you felt over the <u>past four weeks</u>. For each question give only one answer for how regularly you felt each feeling.

		Always	Usually	Sometimes	A few times	Never
a.	Did you feel full of life?	❑	❑	❑	❑	❑
b.	Did you feel very nervous?	❑	❑	❑	❑	❑
c.	Did you feel so depressed that nothing could cheer you up?	❑	❑	❑	❑	❑

| | d. | Did you feel calm and peaceful? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | e. | Did you have a lot of energy? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | f. | Did you feel downcast and depressed? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | g. | Did you feel exhausted? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | h. | Were you happy? | ☐ | ☐ | ☐ | ☐ | ☐ |

| | i. | Did you feel tired? | ☐ | ☐ | ☐ | ☐ | ☐ |

10. During the past four weeks, how regularly did your physical health and emotional problems interfere with your social activities (for example, visiting family, friends, relatives/group)?

- ☐ *Always*
- ☐ *Usually*
- ☐ *Sometimes*
- ☐ *A few times*
- ☐ *Never*

11. How **TRUE** or **FALSE** is each of the following:

	True	**Mostly** *true*	**Don't know**	**Mostly** *false*	**False**
a. It seems as if I become ill slightly more easily than other people.	☐	☐	☐	☐	☐
b. I am as healthy as any other person I know.	☐	☐	☐	☐	☐
c. I expect that my health will get worse.	☐	☐	☐	☐	☐
d. My health is very good.	☐	☐	☐	☐	☐

How did you feel about this interview?

Thank you for completing or answering these questions!

211

GEWYSIGDE SELFONTWIKKELDE VRAELYS

Naam van pasiënt: Ouderdom:

Het u die brief ontvang wat u in kennis stel dat die studie uitgevoer word?

JA   ☐
NEE   ☐

Alle inligting sal streng vertroulik gehou word! Stem u in om aan die studie deel te neem?

JA   ☐
NEE   ☐

Rede vir dood:

Datum van dood:

(Moet nie aan gaan na die ander vra as die pasiënt oorlede is)

WERK EN ANDER AKTIWITEITE:

A. Het u enige van die volgende stokperdjies?
- ☐ Brei
- ☐ Lees
- ☐ Televisiekyk
- ☐ Sport:
  - Stap/Voetslaan   ☐
  - Swem   ☐
  - Fietsry   ☐
  - Hardloop/Draf   ☐
  - Netbal   ☐
  - Sokker   ☐
  - Krieket   ☐
  - Ander   ☐
  - _____
- ☐ Ander _____
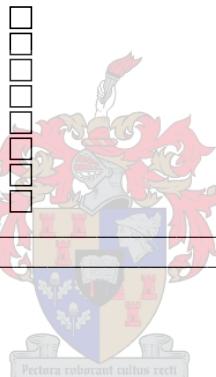
B. Het u voor u siekte gewerk?
- ☐ Ja
  Watter werk het u gedoen?
  _____

- ☐ Nee
  Is u:

  - ○ Werkloos

  - ○ 'n Pensioenaris

  - ○ 'n Huisvrou

  - ○ 'n Afgetrede persoon

  - ○ 'n Ontvanger van 'n ongeskiktheidstoelae

  - ○ 'n Student

C. Werk u tans?
- ☐ Ja
  Watter tipe werk doen u nou? _____

212

☐ Nee
Is u:

- ○ Werkloos
- ○ 'n Pensioenaris
- ○ 'n Huisvrou
- ○ 'n Afgetrede persoon
- ○ 'n Ontvanger van 'n ongeskiktheidstoelae
- ○ 'n Student

INLIGTING RAKENDE ALGEMENE GESONDHEID EN OPVOLG:

	Ja	Nee
D. Rook u sigarette?	☐	☐
Hoeveel?		

Comment [IT2]: The fields for the 'How much' answers do not appear in the printed document.

	Ja	Nee
E. Gebruik/drink u alkohol?	☐	☐
Hoeveel?		

Die volgende vrae is persoonlik en vertroulik van aard en handel oor siektes soos TB en/of MIV. Kan ek die vrae aan u lees sodat u kan besluit of u dit wil beantwoord of nie? Die inligting sal streng vertroulik gehou word (dit beteken dat niemand sal weet wat u my vertel het nie)!

F. Is u vir MIV getoets?	☐	☐
G. Is u vir TB getoets?	☐	☐
H. Weet u wat u status is?	☐	☐
I. Is u bereid om hierdie inligting te deel?	☐	☐
	-	**+**
J. TB-status	☐	☐
K. MIV-status	☐	☐
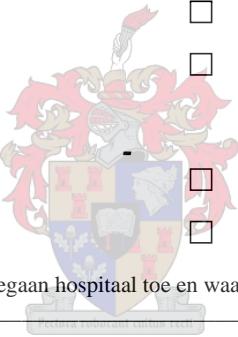
L. Behalwe vir u oorspronklike siekte, het u teruggegaan hospitaal toe en waarom?
_____
_____
_____

Gewysigde SF 36 Standaardvraelys

U Gesondheid en Welsyn

Hierdie vraelys vra wat u van u gesondheid dink en hoe goed u in staat is om u gewone aktiwiteite te doen. Kies asseblief vir elke vraag die opsie wat u en u gesondheid die beste beskryf.

1. Sal u sê u gesondheid is oor die algemeen:
- ❑ Uitstekend
- ❑ Baie goed
- ❑ Goed
- ❑ Redelik goed
- ❑ Sleg

2. <u>In vergelyking met 'n jaar gelede</u>, hoe sal u u algemene gesondheid nou beskryf?
- ❑ Baie beter nou
- ❑ 'n Bietjie beter nou
- ❑ Ongeveer dieselfde as 'n jaar gelede
- ❑ 'n Bietjie slegter nou
- ❑ Baie slegter nou

3. Die volgende vrae handel oor aktiwiteite wat u tydens 'n normale dag doen. <u>Beperk u gesondheid u tans</u> in enige van hierdie aktiwiteite en, indien wel, in watter mate?

	Baie beperk	*Effens beperk*	*Glad nie beperk nie*
a. <u>Energieke aktiwiteite</u>			
i. Hardloop	☐	☐	☐
ii. Deelname aan u sport/stokperdjie	☐	☐	☐
iii. Optel van swaar voorwerpe (bv. kinders/bokse)	☐	☐	☐
iv. Bestuur	☐	☐	☐
b. <u>Matige aktiwiteite</u>			
i. Stofsuig/vee	☐	☐	☐
ii. Wasgoed was/klere ophang	☐	☐	☐
iii. Bed opmaak	☐	☐	☐
iv. 'n Stoel/tafel skuif	☐	☐	☐
o. Inkopies optel/dra	☐	☐	☐
p. Tien of meer trappe klim	☐	☐	☐
q. Een of meer trappe klim	☐	☐	☐
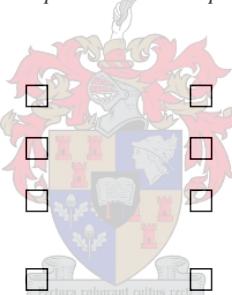
r.	Buk of kniel	☐ ☐ ☐
s.	Van 'n lê-posisie na 'n sit-posisie verander	☐ ☐ ☐
t.	Vanuit 'n sit-posisie opstaan	☐ ☐ ☐
u.	Met ondersteuning loop	☐ ☐ ☐
v.	Sonder ondersteuning loop	☐ ☐ ☐
w.	In die huis of na die toilet loop	☐ ☐ ☐
x.	Buite of winkel toe loop	☐ ☐ ☐
y.	Lang afstande loop (voetslaan)	☐ ☐ ☐
z.	Uself bad of aantrek	☐ ☐ ☐

4. In die <u>afgelope vier weke</u>, hoe is u werk of daaglikse aktiwiteite <u>as gevolg van fisieke gesondheidsprobleme</u> beperk?

  e. Het u die <u>hoeveelheid tyd</u> verminder wat u aan werk of ander aktiwiteite bestee het?
  - ❑ *Altyd*
  - ❑ *Meestal*
  - ❑ *Soms*
  - ❑ *'n Paar keer*
  - ❑ *Nooit*

  f. Het u <u>minder reggekry</u> as wat u in u werk of ander aktiwiteite wou doen?
  - ❑ *Altyd*
  - ❑ *Meestal*
  - ❑ *Soms*
  - ❑ *'n Paar keer*
  - ❑ *Nooit*

  g. Is u beperk in die <u>TIPE</u> werk of ander daaglikse aktiwiteite wat u doen?
  - ❑ *Altyd*
  - ❑ *Meestal*
  - ❑ *Soms*
  - ❑ *'n Paar keer*
  - ❑ *Nooit*

  h. Het u <u>gesukkel</u> om die werk of ander aktiwiteite te doen (ekstra inspanning)?
  - ❑ *Altyd*
  - ❑ *Meestal*
  - ❑ *Soms*
  - ❑ *'n Paar keer*
  - ❑ *Nooit*

5. Hoe is u werk of daaglikse aktiwiteite in die afgelope vier weke beperk <u>as gevolg van enige emosionele probleme</u> (soos
    om depressief of angstig te voel)?

  b. Het u die <u>hoeveelheid tyd</u> verminder wat u aan werk of ander aktiwiteite bestee het?
  - ❑ *Altyd*

215

- ❑ *Meestal*
- ❑ *Soms*
- ❑ *'n Paar keer*
- ❑ *Nooit*

c. Het u <u>minder reggekry</u> as wat u in u werk of ander aktiwiteite wou doen?
- ❑ *Altyd*
- ❑ *Meestal*
- ❑ *Soms*
- ❑ *'n Paar keer*
- ❑ *Nooit*

c. Het u u werk of ander aktiwiteite <u>minder sorgvuldig</u> as gewoonlik gedoen?
- ❑ *Altyd*
- ❑ *Meestal*
- ❑ *Soms*
- ❑ *'n Paar keer*
- ❑ *Nooit*

6. In die <u>afgelope vier weke</u>, hoe het u fisieke gesondheid of emosionele probleme met u normale sosiale aktiwiteite met familie, vriende, bure of groepe ingemeng?
- ❑ *Nooit*
- ❑ *Effens*
- ❑ *Matig*
- ❑ *Redelik baie*
- ❑ *Uitermate baie*

7. Hoeveel pyn het u die <u>afgelope vier weke</u> in u <u>liggaam</u> ervaar?
- ❑ *Geen*
- ❑ *Baie lig*
- ❑ *Lig*
- ❑ *Matig*
- ❑ *Erg*
- ❑ *Baie erg*

8. Hoeveel het **pyn** in die <u>afgelope vier weke</u> met u normale werk ingemeng (sowel werk buite die huis as huistake)?
- ❑ *Glad nie*
- ❑ *'n Klein bietjie*
- ❑ *Matig*
- ❑ *Redelik baie*
- ❑ *Uitermate baie*

9. Die volgende vrae handel oor hoe u die <u>afgelope vier weke</u> gevoel het. Vir elke vraag, gee slegs een antwoord van hoe gereeld u elke gevoel ervaar het.

		Altyd	*Meestal*	*Soms*	*'n Paar keer*	*Nooit*
j.	Het u lewenslustig gevoel?	☐	☐	☐	☐	☐
k.	Het u baie senuweeagtig gevoel?	☐	☐	☐	☐	☐
l.	Het u so terneergedruk gevoel	☐	☐	☐	☐	☐

dat niks u kon opbeur nie?

m. Het u kalm en rustig gevoel? ☐ ☐ ☐ ☐ ☐

n. Het u baie energie gehad? ☐ ☐ ☐ ☐ ☐

o. Het u neerslagtig en depressief ☐ ☐ ☐ ☐ ☐
gevoel?

p. Het u gedaan gevoel? ☐ ☐ ☐ ☐ ☐

q. Was u gelukkig? ☐ ☐ ☐ ☐ ☐

r. Het u moeg gevoel? ☐ ☐ ☐ ☐ ☐

10. <u>In die afgelope vier weke</u>, hoe gereeld het u <u>fisieke gesondheid en emosionele probleme</u> met u sosiale
aktiwiteite ingemeng (byvoorbeeld kuier by gesin, vriende, familielede/groep)?

❑ *Altyd*
❑ *Meestal*
❑ *Soms*
❑ *'n Paar keer*
❑ *Nooit*

11. Hoe **WAAR** of **ONWAAR** is <u>elk</u> van die volgende:

Waar   Grotendeels

Weet nie   Grotendeels   Onwaar

waar   *onwaar*

a. Dit lyk asof ek 'n bietjie makliker siek   ☐   ☐
☐
word as ander mense.   ☐   ☐

b. Ek is so gesond soos enige ander persoon
wat ek ken.   ☐   ☐   ☐
☐
☐

c. Ek verwag dat my gesondheid sal
versleg.   ☐   ☐   ☐   ☐   ☐

d. My gesondheid is baie goed.   ☐   ☐   ☐   ☐   ☐

Hoe het u oor die onderhoud gevoel?

Baie dankie vir die voltooiing of beantwoording van hierdie vrae!

ADDENDUM G & H

**Letter of Response from SF-36 Company
and
Afrikaans Short Form-36 version 1**

African Population specifically as I would like to do a comparison of my results. I do know about the US and UK norms however I do not have any information on South Africa.

If you know anything about norms for the SA population and can tell me where or how I can get it I would greatly appreciate it.

Thank you

Lynda LaPlante <llaplante@qualitymetric.com> wrote:

Dear Farhana,

Thank you for your email. I apologize for the oversight in our not sending your survey forms to you. Attached please find the appropriate word and pdf documents for the SF-36v1 Health Survey Forms which you purchased.

Kind Regards,

Lynda LaPlante
Sales Administrative Assistant
Phone (401) 334-8800 ext. 249
Fax (401) 334-8770
llaplante@qualitymetric.com

From: Farhana Karachi [mailto:thornmed@yahoo.com]
Sent: Monday, June 20, 2005 4:44 AM
To: Lynda LaPlante
Subject: RE: Faxed License Agreement #R1-061704-19248 (Univ of Stellenbosch)

DEAR LYNDA

I would just like to query about the SF36v1 Afrikaans version that we have purchased. As you will see below you emailed me last in September 2004 and were waiting for our payment to be processed before you sent me the SF36v1 Afrikaans version. I have not received anything from you since and since I have been extremely busy with my study I did not have a chance to check on this.

I would appreciate it if you can check on this and send me the Afrikaans version we have purchased as soon as is possible.

The invoice number is R1-061704-19248 and invoice date is 8/09/2004.

Thank You for your assistance and hope to hear from you soon.

Lynda LaPlante <llaplante@qualitymetric.com> wrote:

219

GESONDHEIDSOPNAME DEUR DIE VERKORTE "MOS-36 ITEM VORM"

Doel Van Vorm: Hierdie vraelys handel oor u gesondheid, hoe u voel en hoe effektief u u daaglikse take kan verrig.

Beantwoord alle vrae deur die antwoord te merk soos aangedui. As u onseker is oor 'n vraag, gee nogtans elke keer die aantwoord wat u gesondheid volgens u mening die beste beskrywe.

1.   In die algemeen sou u sê u gesondheid is:

(omring slegs een nommer)

Uitstekend 1

Baie Goed 2

Goed 3

Redelik 4

Swak 5

2.   <u>In vergelyking met een jaar gelede</u>, hoe sou u <u>nou</u> u algemene gesondheid beskrywe:

(omring slegs een nommer)

Baie beter as 'n jaar gelede 1

Ietwat beter as 'n jaar gelede 2

Omtrent dieselfde as 'n jaar gelede 3

Ietwat swakker as 'n jaar gelede 4

Baie swakker as 'n jaar gelede 5

3. Die volgende vrae hou verband met aktiwiteite wat u gedurende 'n gewone dag mag doen. In watter mate beperk <u>u gesondheid u nou</u> in die aktiwiteite?

<div style="text-align: right">(omring een nommer op elke reël)</div>

	AKTIWITEITE	**Ja, Baie beperk**	**Ja, Bietjie beperk**	**Nee, Geen beperking**
a.	**Inspanningsaktiwiteite** soos hardloop, swaar voorwerpe optel, strawwe oefening soos sokker, rugby, hokkie	1	2	3
b.	**Matige aktiwiteite** soos die skuif van 'n tafel, stoot van 'n stofsuier, vee met 'n besem, rolbal, gholf	1	2	3
c.	Optel of dra van kruideniersware pakkies	1	2	3
d.	Die klim van **'n paar** stelle trappe	1	2	3
e.	Die klim van **een** stel trappe	1	2	3
f.	Buk, kniel of hurk	1	2	3
g.	Stap **meer as een kilometer**	1	2	3
h.	Stap **'n halwe kilometer**	1	2	3
i.	Stap **eenhonderd meters**	1	2	3
j.	U self bad of aantrek	1	2	3

4. Gedurende die <u>afgelope 4 weke</u> het u enige van die volgende probleme in u werk of ander gereelde daaglikse aktiwiteite ondervind <u>as gevolg van u fisiese gesondheid</u>?

<div style="text-align: right">(omring een nommer op elke reël)</div>

		Ja	**Nee**
a.	Afname in die **hoeveelheid tyd** wat aan werk of ander aktiwiteite gespandeer word	1	2
b.	**Minder uitgerig** as wat u wou	1	2
c.	Beperk in die **tipe** werk of ander aktiwiteite	1	2
d.	Met **moeite** werk of ander aktiwiteite gedoen (bv. dit het meer inspanning geneem)	1	2

5. Gedurende die <u>afgelope 4 weke</u> het u enige van die volgende probleme in u werk of ander aktiwiteite ondervind <u>as gevolg van enige emosionele probleme</u> (soos terneergedruktheid of angstigheid)?

(omring een nommer op elke reël)

		Ja	Nee
a.	Afname in die **hoeveelheid tyd** wat aan werk of ander aktiwiteite gespandeer is	1	2
b.	**Minder uitgerig** as wat u wou	1	2
c.	Werk of ander aktiwiteite is nie **noukeurig** uitgevoer nie	1	2

6. Gedurende die <u>afgelope 4 weke</u> in watter mate het fisiese of emosionele probleme u gehinder in normale sosiale aktiwiteite met familie, vriende, bure of ander groepe?

(omring slegs een nommer)

Geen 1

Bietjie 2

Redelik 3

Heelwat 4
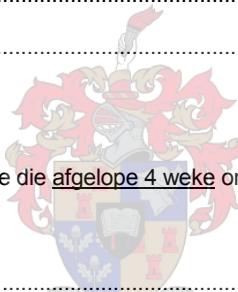
Uitermatig... 5

7. Hoeveel <u>liggaamlike</u> pyn het u, gedurende die <u>afgelope 4 weke</u> ondervind?

(omring slegs een nommer)

Geen liggaamlike pyn 1

Baie effens 2

Effens... 3

Matige 4

Erg.. 5

Baie erg.. 6

222

8. Gedurende die <u>afgelope 4 weke</u>, in watter mate het <u>pyn</u> u gehinder in u normale werk (insluitend werk buite sowel as binne in die huis)?

<div align="right">(omring slegs een nommer)</div>

Geen 1

Bietjie 2

Redelik 3

Heelwat 4

Uitermatig... 5

9. Die onderstaande vrae handel oor hoe u in die <u>afgelope 4 weke</u> gevoel het en hoe dit met u gegaan het. Vir elke vraag gee net een antwoord wat naastenby die tydperk van u besondere gevoelens aandui. Hoeveel van u tyd in die <u>afgelope 4 weke</u> -

<div align="right">(omring een nommer op elke reël)</div>

		Al die tyd	Meeste van die tyd	Redelike deel van die tyd	Somtyds	Min van die tyd	Nooit
a.	Het u vol lewenslus gevoel?	1	2	3	4	5	6
b.	Was u baie senuweeagtig gewees?	1	2	3	4	5	6
c.	Het u so teneergedruk gevoel dat niks u kon opbeur nie?	1	2	3	4	5	6
d.	Was u kalm en rustig gewees?	1	2	3	4	5	6
e.	Het u baie energie gehad?	1	2	3	4	5	6
f.	Het u neerslagtig gevoel?	1	2	3	4	5	6
g.	Het u afgemat gevoel?	1	2	3	4	5	6
h.	Het u gelukkig gevoel?	1	2	3	4	5	6
i.	Het u moeg gevoel?	1	2	3	4	5	6

223

10. Hoeveel van u tyd wat aan sosiale aktiwiteite (bv. kuier by familie, vriende) bestee word, is die <u>afgelope 4 weke</u> bederf deur <u>fisiese of emosionele gesondheidsprobleme</u>?

(omring slegs een nommer)

Al die tyd 1

Meeste van die tyd.. 2

Somtyds 3

Min van die tyd.. 4

Nooit.. 5

11. In watter mate is <u>elk</u> van die volgende stellings vir u waar of onwaar?

(omring een nommer op elke reël)

		Defnitief waar	Meestal waar	Weet nie	Meestal onwaar	Defnitief onwaar
a.	Ek word gouer siek as ander mense	1	2	3	4	5
b.	Ek is so gesond soos ander mense wat ek ken	1	2	3	4	5
c.	Ek verwag dat my gesondheid gaan verswak	1	2	3	4	5
d.	My gesondheid is uitstekend	1	2	3	4	5

SOUTH AFRICA (AFRIKAANS)

SF-36

ADDENDUM I

Self-Developed Questionnaire

<div align="center">

SELF-DEVELOPED QUESTIONNAIRE

</div>

Patient Name: Age:

Have you received the letter informing you that this study is being conducted?

YES   ☐
NO   ☐

All information will be kept strictly confidential! Do you agree to participate in this study?

YES   ☐
NO   ☐

Cause of Death:

Date of Death:

(If patient deceased do not continue with rest of questions)

1. WORK AND OTHER ACTIVITIES:

A. Do you have any of the following hobbies?:
   ❑ Knitting
   ❑ Reading
   ❑ Watching Television
   ❑ Sport:

Walking/Hiking	☐
Swimming	☐
Cycling	☐
Running/Jogging	☐
Netball	☐
Soccer	☐
Cricket	☐
Other	☐

_____
_____

❑ Other_____
_____

B. Did you work before your illness?
   ❑ Yes
     What work did you do?
     _____

   ❑ No
     Are you:
       ○ Unemployed
       ○ A Pensioner
       ○ A Housewife
       ○ A Retired Person
       ○ A Disability Grant Holder
       ○ A Student

C. Do you work now?
   ❑ Yes
   What kind of work do you do now?
     _____

   ❑ No
     Are you :
       ○ Unemployed
       ○ A Pensioner
       ○ A Housewife
       ○ A Retired Person
       ○ A Disability Grant Holder
       ○ A Student
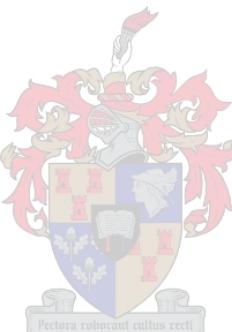
2. PHYSICAL FUNCTIONING:

	Limited a lot	Limited a little	No not Limited
A. Get up from lying to sitting	☐	☐	☐
B. Get up from sitting to standing	☐	☐	☐
C. Walk with support	☐	☐	☐
D. Walk without support	☐	☐	☐

3. INFORMATION REGARDING GENERAL HEALTH AND FOLLOW-UP

	Yes	**No**
Do you smoke cigarettes? How much?	☐	☐
Do you use/drink alcohol? How much?	☐	☐

The following question is of a personal and confidential nature regarding illnesses such as TB and/or HIV? Do you wish to be questioned regarding this? Would you like me to read the questions to you and you can decide whether you wish to answer or not? The information will be held strictly confidential!

	Yes	**No**
Have you been tested for HIV?	☐	☐
Have you been tested for TB?	☐	☐
Do you know your status?	☐	☐
Are you prepared to share this information?	☐	☐

	+ve	**-ve**
TB status	☐	☐
HIV status	☐	☐

4. Apart from your original illness, have you returned to the hospital and why?

ADDENDUM J & K

**Permission and Thank-you Letters for
obtaining baseline data**

Ms Farhana Karachi
Physiotherapy Department
Tygerberg Hospital
Tygerberg
7505
06 January 2004

Ms S Hanekom
Physiotherapy Department
University of Stellenbosch
Tygerberg
7505

Dear Madam

Request for Permission for use of data collected in your thesis study.

I am a Senior Physiotherapist, at Tygerberg Hospital and request permission to obtain access to the data collected on patients used in your study. The data is required in order to obtain a sample population for a research project to be conducted for a MSc in Physiotherapy.

The aims of the study are to determine the survival and health related quality of life of patients' at 12months following discharge from the adult surgical ICU at Tygerberg Hospital. Analyses of ICU variables and patient background data are required in order to gain the information required for the research. For this purpose, I would appreciate access.

All information regarding patient information will be kept confidential and reported.

I ask for your assistance in this regard and hope that you grant me permission so that I can conduct the study successfully.

Thank you for your co-operation.

Yours Sincerely
Ms F Karachi

Ms Farhana Karachi
Physiotherapy Department
Tygerberg Hospital
Tygerberg
7505
15 January 2004

Ms S Hanekom
Physiotherapy Department
University of Stellenbosch
Tygerberg
7505

Dear Madam

I would just like to thank you for your support and for giving me permission to use your data in order to complete my study. The data will be kept strictly confidential.

Thank you kindly.

Yours Sincerely
Ms F Karachi
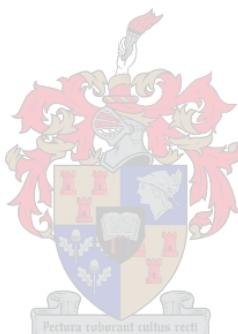
ADDENDUM L

Permission Letter to Medical Records

Ms. Farhana Karachi
Physiotherapy Department
Tygerberg Hospital
Tygerberg
7505

Medical Records
Tygerberg Hospital
Tygerberg
7505

Dear Sir/Madam

I, Ms F Karachi, Senior Physiotherapist in the Department of Physiotherapy, am conducting a research project for an MSc in Physiotherapy. My sample population is a group of patients admitted to the surgical intensive care unit at Tygerberg Hospital during the period of the 15th June to the 30th September 2003.

Data for the study will be collected telephonically. As not all patients' telephone numbers are present I will require such information from your department. It is for this specific reason that I request permission to gain access to your records for those particular patients.

All information will be held strictly confidential. I hope that you can assist me in this regard so that I may conduct the study successfully.

Thank you for your co-operation.

Yours Sincerely
Ms F Karachi
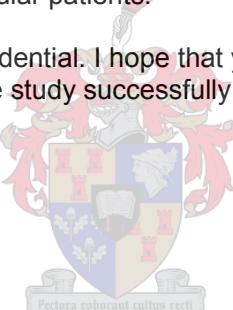
ADDENDUM M

Telephone Call Timetable

Telephone Call Timetable

Folder Number	Patient Name	Date of Discharge	Telephone/ Cellular Number	Comments

ADDENDUM N & O

**English and Afrikaans
Patient Information and Consent Letters**

Miss Farhana Karachi
Physiotherapy Department
Tygerberg Hospital
Parow Valley
7505

Dear Patient

I am a Physiotherapist working at Tygerberg Hospital. I am doing a study on the quality of life and the survival of patients 12months post discharge from the Adult Surgical Intensive Care Unit at Tygerberg Hospital.

I need to determine what the quality of life is for a patient who has been treated in an intensive care unit after 12months. This information is vital for the study and the results will assist both the medical professionals and the patients by making improvements in the health care facility for improved outcomes.

I will require an interview with you in order to gain the information. You will be contacted telephonically approximately 1week after you receive this letter and will be required to answer a questionnaire regarding your health. All the information will be kept strictly confidential!

In order for the study to be completed successfully I hope that you will consent to take part in it.

If you have any questions or queries, contact me at 938-5152.

Thank You for your co-operation.

Yours Sincerely
Ms F Karachi

Mej Farhana Karachi
Departement Fisioterapie
Tygerberg Hospitaal
Parowvallei
7505

Geagte Pasiënt

Ek werk as n Fisioterapeut by Tygerberg Hospitaal. Ek doen n narvorsingsstudie in verband met die lewenskwaliteit van pasiënte wat van die Volwasse Chirurgiese Eenheid in Tygerberg Hospitaal ontslaan is. Hierdie studie is deel van n opvolg studie wat verleede jaar in die Volwasse Chirurgiese Eenheid gedoen is.

Om hierdie inligting te kry, sal ek u oor 2 weke bel nadat u hierdie brief ontvang het. Ek sal u oor u persoonlike gesondheid uitvra. Die onderhoud sal omtrent 15-20 minute oor die telefoon duur.

Wanneer ek u bel, sal ek u toestemming vra om deel te neem aan die studie en om vra te beantwoord. Alle inligting wat u aan my gee, sal konfidensiël gehou word. U naam sal op geen vraelyste geskryf word nie en dus sal geen inligting na u spesifiek verwys nie. Inligting van die studie sal gepubliseer word met geen direkte verwysing na u nie.

U sal geen betaling ontvang om aan die studie deel te neem nie. Indien u deel neem aan die studie is dit vrywillig. U het die reg om te weier om deel te neem en mag op enige stadium onttrek.

Die inligting wat ek van u benodig, is belangrik omdat dit ons sal help om pasiënte wat in die toekoms in die Volwasse Chirurgiese Eenheid toegelaat word meer effektief te behandel of te hanteer. Ek hoop dat u sal deelneem aan hierdie studie sodat ek dit suksesvol en volledig sal kan voltooi.

Indien u enige vra het, kontak my by 938-5152.

Dankie vir u samewerking.

Die Uwe

Mej F Karachi

ADDENDUM P

Telephonic Interview Process
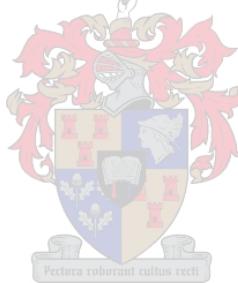
The inteviewer introduced herself to the subject (interviewee). The interviewee was asked whether the letter had been received. A brief explanation of the study, its purpose and relevance, voluntary consent and withdrawal and confidentiality of information obtained was given to the interviewee. The interviewee was also given a choice of whether they wanted to do the interview immediately or at another time or day that suited them and the interviewer. On consent, the interviewer then conducted the interview.

The interview began by asking the subject to give their full name and age. They were asked if they would consent to answer the questions that followed. If subjects refused,it was noted and reason for refusal was noted if given voluntarily, and the researcher apologized for any inconvenience.

Questions 1 and 2 from the self-developed questionnaire was read to the subject.

For question 3 of this questionnaire regarding general health the subject was asked to consent as these questions were more personal as they were about HIV and TB testing and status. Questioning proceeded if subjects consented. According to the structured questionnaire however, if subjects did not consent then this question was left blank.
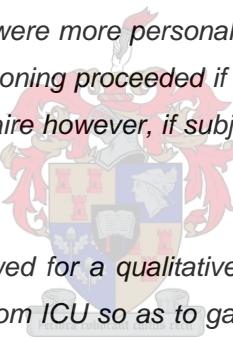
Question 4 of this questionnaire allowed for a qualitative response and was related to follow-up since discharge from ICU so as to gain depth and insight into the follow-up process and its relation to HRQoL responses.

The modified UK SF-36v2 followed the above self-developed questionnaire. The aim of this questionnaire was explained to the subject and the subject who was asked to respond to each question by choosing the one option that best described their function. Time was given to the subject to grasp, think and answer the question. The question was repeated if they did not hear or understand the question completely. Questions were repeated only three times as decided by the researcher and if no response was gained as in the patient could not describe themselves or used their word/s, the question was

omitted and the interview continued. It was noted next to the omitted question what the specific problem had been When subjects responded with another word that was not one of the listed options, they were asked to listen to the question and options again and choose one of the given options. Options were repeated three times as decided by the researcher. If the subject still responded in their words then the word used was recorded and the options left blank.

The Interviewer refrained from prompting the subject or choosing an option for the subject by leading the subject to an option. However, where patients responded by saying that they did not perform certain activities at all they were probed whether it was due to their health as this was the only form of probing used by the researcher/interviewer as suggested in the script in the SF-36 manual. Questions and options were only repeated three times if necessary for clarity as decided by the researcher. The option chosen by the subject, was repeated for clarity and to ensure that the option was heard correctly by the interviewer if a problem of noise or interference occurred during the call. The option was then ticked.

As the Researcher did not know any of the subjects, their specific diagnosis or severity of illness, the researcher could remain unbiased during the interview and only obtain the true perception of the patient regarding their health status and function.
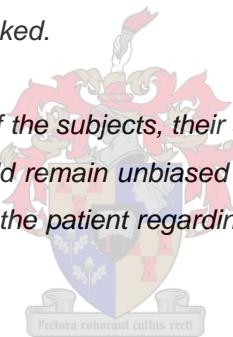
After the modified UK SF-36v2 questionnaire had been completed, the subjects were asked a final question about how they felt regarding the interview. They were thanked for their time and participation in the study and told that they would be informed of the results in a follow-up letter. Any questions subjects asked regarding their condition

were answered within the boundaries of the researchers' knowledge and where necessary subjects were referred appropriately if further assistance in terms of their health was required.

ADDENDUM Q

Patient Information Data Capture Sheet
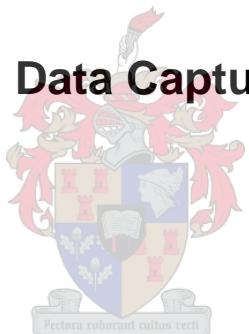
Name	Folder No.	Age	Addr	Tel No.	Date of D/C	Date Died	Date Alive	Apache II	LOS	LOI	GRAD Physio	STUD Physio	Elective Surgery	Emergency Surgery	Trauma Injury

PF	RP	RE	VT	GH	MH	BP	SF	PCS	MCS	TB status	HIV status	Smoking	Alcohol	Employed Before ICU	Employed After ICU

ADDENDUM R

Project Registration

30 July 2004

Ms F Karachi
Dept of Physiotherapy

Dear Ms Karachi

RESEARCH PROJECT: "SURVIVAL AND HEALTH RELATED QUALITY OF LIFE AT 12 MONTHS FOLLOWING DISCHARGE FROM AN ADULT SURGICAL INTENSIVE CARE UNIT AT TYGERBERG TERTIARY HOSPITAL"

PROJECT NUMBER   :   N04/05/092

At a meeting of the Committee for Human Research that was held on 14 June 2004 the above project was approved on condition that further information that was required, be submitted.

This information was supplied and the project was finally approved on 30 July 2004. This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in all further correspondence.

Patients participating in a research project in Tygerberg Hospital will not be treated free of charge as the Provincial Government of the Western Cape does not support research financially.

Due to heavy workload the nursing corps of the Tygerberg Hospital cannot offer comprehensive nursing care in research projects. It may therefore be expected of a research worker to arrange for private nursing care.

Yours faithfully

CJ VAN TONDER
RESEARCH DEVELOPMENT AND SUPPORT (TYGERBERG)
Tel: +27 21 938 9207 / E-mail: cjvt@sun.ac.za

CJVT/ev

C:\DOCUMENTS AND SETTINGS\EVISAGIE.000\MY DOCUMENTS\KMM\PROJEKTE\2004\N04-05-092-001.DOC

Fakulteit Gesondheidswetenskappe · Faculty of Health Sciences

Verbind tot Optimale Gesondheid · Committed to Optimal Health
Afdeling Navorsingsontwikkeling en -steun · Research Development and Support Division
Posbus/PO Box 19063 · Tygerberg 7505 · Suid-Afrika/South Africa
Tel: +27 21 938 9677 · Faks/Fax: +27 21 931 3352
E-pos/E-mail: rdsdinfo@sun.ac.za

247