# DEPARTMENT OF ANAESTHESIA AND CRITICAL CARE

# CRITICAL CARE AT UNIVERSITY TEACHING HOSPITAL, ZAMBIA: MORTALITY AND QUALITY OF LIFE OUTCOMES: CROSS SECTIONAL STUDY

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(BSc. Biological sciences, BSc. HB. MB.ChB.)
A dissertation submitted in partial fulfillment of the requirement for the award of the degree of Masters of Medicine in Anesthesia and Critical Care.
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**DECLARATION**


I hereby declare that this dissertation represents my own work and has not been presented either wholly or in part at the University of Zambia or any other university.



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## APPROVAL

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Examiner 03    :     . . . . . . . . . .

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**DEDICATION**

To my father who has always been a great pillar and encouraged me to pursue life. To my Siblings Lloyd, Brenda and Brian for being such great examples. To my friends, the family I have chosen to cheer me on.

ABBREVIATIONS
ADLs Activities of daily living
GCS Glasgow Coma Scale
HR Heart rate
HIV Human Immunodeficiency Virus
ICU Intensive care Unit
  ICM Intensive care Medicine
  IV Intravenous
LAMA Leaving Against Medical advise
MMed Masters of Medicine
MICU Main Intensive Care Unit
RR Respiratory rate
SCCM Society of Critical Care Medicine
TBI Traumatic Brain Injury
UTH University Teaching Hospital

ABSTRACT

**Background**:
The Traditional goal of intensive care has been to reduce short-term mortality. While worthwhile in terms of "saving lives", this goal fails to address the issue of what it means to survive intensive care (ICU). Key questions include whether ICU survivors have optimal long-term outcomes. This study provides updated mortality rates of ICU patients at UTH and compares this to historical data. Also, for the first time it will provide an insight into the mortality and functional recovery of patients discharged alive from ICU. This extremely important outcome data is essential if the ICU is to apply its limited resources in the most effective manner and plan its admission, treatment and discharge protocols accordingly in the future.
Outcome from critical care is related to patient selection. Criteria for admission for maximum utility and most beneficial outcomes include severity of admission illness (i.e. severity and number of organ/system failure), age and physiological reserve. Admission GCS is a particularly powerful indicator of outcome potential in brain injury. The underlying diagnosis must also be of a recoverable illness. Admission GCS and diagnosis or clinical category was recorded to try to identify areas of best and worst outcome to guide further admission policy development.

**Method:** This is an observational cross sectional study conducted at the University Teaching Hospital Lusaka Zambia. 559 Patients were sampled comprising both male and female. Five patients had missing data hence were omitted from analysis and one patients was lost to follow up. The age range was between 16 and 80years old. Patients were recruited on admission to ICU over a period of 3 months and were seen at discharge and interviewed two weeks post discharge from ICU using a structured questionnaire. Hospital records were looked at to get information on the 2015 ICU admissions. The data was analyzed using SPSS version 22 for Mac and logistical analysis done for the qualitative variables

**Results:** Findings of the study showed that patients who had GCS less than 6 had a mortality rate of 81.1%. Traumatic brain injury was the leading cause of admission, with patients admitted for postoperative stabilization having the most benefit with 6% mortality. Of patients discharged alive from ICU, 25% were fully functional at 2 weeks post discharge from intensive care, 45% could undertake ADLs but were not back to function in full capacity, 20% of the patients required assistance with ADLs and the remaining 10% had died by 2 weeks post discharge from ICU. ICU mortality was found to be at 37%.

**Conclusion:** There is a high overall mortality rate of patients admitted to ICU with a particularly high mortality and residual disability in those with admission GCS less than 8 compared to those admitted with a higher GCS. Mortality of particular groups warrant further investigation such as the HIV positive, pregnancy related and TBI admitted with GCS less than 6. Functional outcomes in the small sample studies achieved good return to function in a short period.

**Aknowledgements**

I would like to thank my supervisors for their guidance throughout the whole journey from proposal stage till the completion of the dissertation. Dr Dylan Bould for his help with the analysis of the data. My Brother Lloyd, for his support and encouragement. The MICU nurses for assisting in collection of data and Lastly, I would like to give thanks to all the participants of this study and their families, without whom this research would not have been possible.

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# 1    INTRODUCTION

Intensive care began in the early 1950s during the polio epidemic in Scandinavia (Berthelsen & Cronqvist 2003) where patients were for the first time kept alive with mechanical ventilation during the acute phase of polio, and many who would have died survived. The development of positive pressure ventilation and reduction in mortality led to the development of Intensive Care Units (ICUs). Intensive care (also known as Critical Care) has evolved greatly from its inception in 1953 to become a highly complex hospital specialty, which has the ability to support multiple failing organs or systems in those patients who have the capacity to recover and survive. This has mainly been brought about with improvements in organization of units, training of a wide range of healthcare professionals, technology and pharmacology - especially in the developed world.

 It was recognized that anesthetists have the necessary knowledge of the pathophysiology of reversible organ failure and the skills of organ and system support that can sustain life in for critically ill patients who have reversible system or organ failure. In general, doctors with primarily anesthetic training tend to manage intensive care units and critical care has become a recognized subspecialty of anesthesia worldwide. In Zambia intensive care is still a developing specialty of hospital medicine. From its inception in UTH, Intensive care was considered as a branch of surgery until 2012, when it became a separate unit nominally under the control of the department of anesthesia.

A key outcome measure for an ICU is hospital mortality. At UTH in 1988, hospital mortality of ICU was found to be 77% in a study published (Sinclair J.R 1988). A second study done at UTH in 2010 (Jochberger S. et al 2010) found an ICU mortality of 55.9%. These studies of mortality outcomes from the UTH ICU are the benchmarks for further evaluations, as there are no other studies done within Zambia to offer comparison with studies outside Zambia.    There is a great amount of data on mortality and outcomes of ICU admissions from developed countries but very little information from ICUs in developing economies. (Towey R.M. 2008). Assessing outcomes from critical care is extremely dependent on admission case mix. No two units will admit exactly the same profile of diagnoses, ages, chronic health status and other independent variable affecting outcome. However, in general terms in developed countries where the admission age profile is of much older patients than encountered at UTH, a unit mortality of 20% and a further post discharge hospital mortality of a further 10% would be regarded as reasonable. In the younger patient cohort as in UTH – this should be significantly lower. In UTH, which has 10 bed ICU serving the whole country, admission to the unit is dependent on capacity, and ages range from neonatal to geriatric, making it challenging to analyze and compare outcomes.

The long-term qualitative outcomes of patients admitted in ICU is not known as no study so far has looked at survival beyond ICU discharge in Zambia. Few outcome studies look at a survivor's functional status after ICU discharge and neither of the previous ICU from UTH studies looked at this. (Angus & Carlet 2003). Currently there is no data for the survivor's functional status after ICU admission at UTH. Functional status according to the American Thoracic Society, is the ability of a discharged patient to undertake daily physical activities of living or more advanced activities in relation to return to work or study (Leidy 1994), (Wilson & Cleary 1995). It may be considered that simple survival is an inadequate measure of the success of intensive care, and that critical care should rather aim to return survivors to an acceptable quality of life (Angus & Carlet 2003) (Wischmeyer & San-Millan 2015). This focus on quality of survival may be more important in a developing country because of inadequate support services for survivors with residual disability. (M. W. Dünser et al. 2006). Without patient follow up, hospital death is the only outcome which has been measured, and in this age such a crude measure does not suffice as a tool for assessing the effectiveness of critical care at UTH.

Because prediction of outcome of critically ill patients is very difficult but very important in terms of admission policies and resource allocation, a number of predictive scoring systems have been developed in critical care such as APACHE II (Acute Physiology and Chronic Health), SOFA (Sequential Organ Failure Assessment) and SAPS II (Simplified Acute Physiology Score). These require detailed data from investigations that are not routinely done in the ICU in UTH and it is therefore not possible to undertake these currently at UTH. These scores are mainly research and audit tools and should not be used to plan treatment options for individual patients.

Of more relevance to practice at UTH is the outcome of various categories of ICU patients. It is important to find out whether patients admitted with trauma, cancer, sepsis or neurosurgery (including brain injury) are benefiting from critical care so as to design improvements in care in those areas of greatest benefit to patients.

This is a descriptive study, which provides updated mortality rates of ICU patients at UTH and compares this to historical data. Also, for the first time it provides an insight into the mortality and functional recovery of patients discharged alive from ICU. This data is essential if the ICU is to apply its limited resources in the most effective manner and plan its admission, treatment and discharge protocols accordingly in the future

## 2 LITERATURE REVIEW

Intensive care units cater to patients with severe and life-threatening illnesses and injuries, which require constant, close monitoring and support from specialist equipment and medications in order to ensure normal bodily functions. They are staffed by highly trained doctors and nurses who specialize in caring for critically ill patients. ICUs are also distinguished from normal hospital wards by a higher staff-to-patient ratio and access to advanced medical resources and equipment that is not routinely available elsewhere. ICUs can vary in terms of size, and also types of patients admitted as well the design of operation, i.e, whether it's an open or closed ICU. The university teaching hospital MICU is an open unit which is now norminally under the department of

anaesthesia. It's a 10 bed ICU which admitts for ventilation as well as close monitoring of high risk patients. Admission to ICU is dependant on availability of space and ventilators and is on first come basis. The nurse patient ratio ranges from 1:2 to 1:3 for most of the time due to lack of qualified manpower.

Intensive care patients are a heterogeneous group, presenting with a very wide variety of disease processes, co-morbidities, and severity. (Vincent & Singer 2010), all of which have an influence on outcomes. For example, patients admitted from the general wards have a worse outcomes than those admitted from emergency or theatre (Escarce & Kelley 1990). This may indicate that the deterioration or disease process has progressed more than those presenting acutely via emergency. Outcomes also depend on treatment before ICU admission and after ICU discharge (Vincent & Singer 2010). As pre-admission treatment has a significant impact on ICU outcomes, one emerging school of thought is "intensive care without walls" (Hillman, K. 2002). This is the application of simple critical care or resuscitation treatments to ill patients prior to admission to intensive care, directed by intensive care experts who are called to see at-risk patients on wards by nurses or doctors. Such a system requires a sophisticated early warning system of logging and tracking vital signs and the application of an "early warning" algorithm in order to identify at-risk patients before severe deteriorations occur. Functional status post ICU may be affected by the functional status on discharge from ICU (Rydingsward et al. 2016). For example, age and pre-sepsis functional status were found to be predictors of functional status after ICU discharge. (Arabi et al. 2015)

Measured outcomes from ICU could be short-term mortality (Keenan & Dodek 2003), longer-term mortality (Quartin et al. 1997) or morbidity and quality of life (Dowdy et al. 2005) (Angus & Carlet 2003). ICU survivors face physical (Herridge et al. 2003) and non-physical morbidity such as depression, anxiety, delirium and cognitive impairment (Davydow et al. 2008). Despite the recognition of these facts, there are no known measures to prevent post ICU morbidity while patients are still critically ill (Adhikari et al. 2010). Recently it has been suggested that high caloric nutrition from the onset of critical illness may indeed reduce mortality and increase functional status of patients post discharge(Wischmeyer & San-Millan 2015). The results of randomized trial (Schweickert et al. 2009) have suggested that a combination of daily interruption of sedation and early exercise and mobilization improved functional status outcomes at hospital discharge. It is not clear whether the effect is due to exercise or reduced sedation and whether it can be generalized or indeed feasible for all patients admitted in intensive care.

It is important for intensive care specialists to be aware which patients are at high risk of mortality and morbidity to reduce these risks (Desai et al. 2011). A study of elderly patients by Montuclard et al showed 41% ICU survival at 1 year with 23% having difficulties with bathing, 15% difficulty toileting, 26% had difficulty with mobility from chairs or beds, while 19% were incontinent (Montuclard et al. 2000). Clearly age is a significant factor in outcome from critical illness. The duration of stay of greater than 30 days is also indicative of severity the critical illness. The fact that patient's recovery from ICU is poor, poses a challenge to the patient, relatives and indeed the country. There is the personal cost of one's resources and personal frustration of not carrying out ADL without assistance. Which may explain some of the psychological problems patients who survive ICU are face with. There is also additional cost to

the relatives in terms of finances, psychologically and as well as time to care of the relative who is not able to achieve the ADL. A lot of the patient may need rehabilitation after ICU, such as being trained to walk, talk, control of body functions such as bladder control, which all involve a lot of resources to a community or indeed country.

ICU mortality rates in most developed countries such as North America, Australia and New Zealand is about 8-18% (Adhikari et al. 2010). This study was performed for development of scoring systems and incorporated at-risk patients admitted for routine monitoring. It may therefore conceal higher mortality of those who are acutely ill, such as patients with acute lung injury with a mortality rate of 35-45% (Phua et al. 2009) and septic shock 50-60% (Annane 2003)(Odden et al. 2013). In China, 10% of trauma patients in ICU had full recovery, 30% could self care for ADL but not able to return to work and more than 60% of these dying after follow up for one year (Rainer et al. 2014) In general, according to the Society of Critical Care Medicine (SCCM) ICU mortality rates in developed countries ranges between 10-29% (Mayr et al. 2006), (Joint Commission Resources 2004) (Wang et al. 2010).

In the developing world, patients are admitted to ICU mainly due to severe infection, perinatal complications and major trauma (Adhikari et al. 2010), while those in developed countries are mainly due to complications of chronic cardiac, vascular and pulmonary disease and may explain the disparity in statistics. Patients admitted in developing world ICUs also have high illness severity compared to developed countries (Adhikari et al. 2010), and consequently have a poorer outcome (M. W. Dünser et al. 2006).  The above data demonstrates that reported  ICU mortality rates are very variable and dependent on the cohort being studied. Direct comparisons are possible if cohorts are reasonablyclosely matched

A closer comparison with UTH may therefore be obtained from a recent study done in northern Uganda (Towey & Ojara 2008), where the overall ICU mortality was 27% and that of ventilated patients was 53%. However, the greatest proportions of admissions (41%) were for postoperative stabilization. General surgery patients had a 41% mortality and obstetrics 35%. There were no reported deaths from eclampsia. In this study the mortality for head injury of 32% was low  - possibly as patients were only admitted to ICU with GCS of ≥12 for close observation.  Tetanus had a mortality rate of 57% and other medical conditions 40%. A study on a surgical ICU in South Africa found an ICU mortality of 12% which is comparable to those found in developed countries (Hanekom et al. 2008). In a one year ICU audit done in Nigeria showed a mortality rate of 35% (Abubakar A,Ojo E, El-Nafaty A 2014)

The ICU outcome study done at UTH in 1988 showed mortality of ventilated patients was 74% with hospital mortality of 77% (Sinclair et al. 1988). This was much higher than seen elsewhere in the region. Head injury had the greatest number of patients admitted and those ventilated had a mortality of 85.1%.  This could be attributed to the fact that these patients were admitted with very low GCS, which probably indicates that severity of injury in the UTH ICU population was higher than that from Uganda (Towey 2008). Non-traumatic coma had a mortality of 76.4%, eclampsia 16.6%, tetanus 85.7% and surgical patients 64.2%. Pulmonary disease had a mortality of 63%, while cardiac and renal failure combined had a mortality of 100%. Obstetric

patients who mainly presented with puerperal sepsis had a mortality of 60%. Overall, these figures are much higher than those in related studies done in Uganda and South Africa.

 The Sinclair UTH study did not give any information on the functional status of the survivors even though there was apparently follow up of patients.  Even though this study only looked only at ventilated patients, it gives baseline data of mortality and survival rates 26 years ago and can be used as a benchmark to compare the current performance of the ICU at UTH. In this study there was a very small difference between brain-injured patients who died in ICU and those who died in hospital. This suggests that non-survivors were held in ICU until death and the overall mortality was extremely high at 74%. This paper also gives some insight into the organization of the ICU at UTH.  However this study did not include non-ventilated patients and consequently not clear on how well these patients performed. A subjective predictive outcome score was used, which seemed to have been more accurate with negative prediction than the positive, which may seem to suggest that, the mortality was high even for those expected to survive.

From many publications it seems clear that admission GCS has a well established relationship with outcome (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009)(Choi et al. 1988) (Choi et al. 1994)(Fearnside et al. 1993). This was also found in the 1989 study in Zambia on non-traumatic coma. (Sinclair et al. 1989).

A later paper published in UTH by Jochberger et al looking at anesthesia education etc. (Jochberger et al. 2010) provided limited data on ICU mortality. Overall ICU mortality was 55.9% and the highest proportion of admissions was for trauma (80%) with a mortality rate of over 50%. These data suggest that a very high ICU mortality rate at UTH persists.

There are many complex and sophisticated tools for assessing quality of life (QOL). Compared to the general population, ICU survivors in developed health systems have an overall lower QOL prior to ICU admission – suggesting a high rate of co-morbidities. After hospital discharge, QOL in ICU survivors remains lower than general population levels. Age and severity of illness are also predictors of physical functioning (Dowdy et al. 2005) and the best indicator for quality of life after intensive care proved to be the health status prior to the acute illness (Jacobs, van der Vliet, et al. 1988). In this study, the functional status will be assessed using a formulated tool as attached in appendix 1. Both subjective and objective measures of physical function are all informative in ICU survivors as shown by a study recently published (McNelly et al. 2016) as well as when a proxy is used (Ahasic et al. 2015)


## 3    STATEMENT OF THE PROBLEM

Intensive care medicine consumes a high level of resources in terms of manpower, laboratory investigations, radiology, drugs and a wide range of consumables on a daily basis. There is a need to make sure that such high cost of resources has a reciprocated output and particularly so,

when resources are limited such as in Zambia.  There is no current measure of overall mortality; mortality of diagnostic subgroups, and an evaluation of the functional status of ICU survivors in UTH have never been undertaken. There is also no data on quality of ICU survival in the region.

# 4    STUDY JUSTIFICATION

The traditional goal of intensive care has been to reduce short-term mortality. While worthy in terms of "saving lives", this goal fails to address the issue of what it means to survive intensive care. Key questions include whether intensive care survivors have optimal long-term outcomes and whether ICU care decisions would change if we knew more about these outcomes.

The study will provide updated mortality rates of ICU patients at UTH and compare this to historical data. Also, for the first time it will provide an insight into the mortality and functional recovery of patients discharged alive from ICU. This extremely important outcome data is essential if the ICU is to apply its limited resources in the most effective manner and plan its admission, treatment and discharge protocols accordingly in the future.

# 5    RESEARCH QUESTION

What is the current ICU mortality rate of patients at UTH in comparison to previous data?
What is the 14-day post ICU discharge mortality?
What is the functional status of ICU survivors at 2 weeks post discharge from ICU?
Do different diagnostic categories of patients show significantly differing outcomes in terms of mortality and functional recovery?

# 6    OBJECTIVES

## 6.1    General objective
To establish survival rates and associated factors of ICU patients and functional status up to 2 weeks after ICU discharge

## 6.2    Specific objectives
To establish the unit mortality rate of patients admitted to ICU for one year in 2015
To measure ward mortality rates of discharged ICU patients up to 14 days after ICU discharge.
To measure post hospital discharge mortality rates of ICU patients up to 14 days after ICU discharge.
To define this mortality profile, according to admission diagnostic category/specialty.
To explore functional recovery of survivors at approximately two weeks post discharge from ICU.
To examine if functional status is associated with the admission Glasgow coma scale in trauma and non-trauma patients.

# 7    RESEARCH METHOD

## 7.1    Setting
Main intensive care unit, at the University Teaching Hospital, Lusaka, Zambia.

## 7.2    Study population
Study population will include all patients admitted to main Intensive care unit (MICU).

## 7.3    Inclusion criteria
Patients admitted to ICU for over 4 hours.
Patients above 16 years of age. 16 years has been chosen, as this is the age at which adult medicine is instituted at UTH.

## 7.4    Exclusion criteria
Patients below the age of 16yrs
All whom consent is not obtained.
Patients who, would have stayed in ICU less than 4hour.
Patients that are discharged to other hospitals or have LAMA

## 7.5    STUDY DESIGN
Cross sectional study of patients admitted to the main intensive care unit that were 16 years and above. The study was in 2 parts. A retrospective audit of mortality for a full calendar year using the inclusion and exclusion criteria above and a prospective study of outcome and quality of life 2 weeks post ICU discharge.

## 7.6    VARIABLES
Primary outcome: Survival status- survived or died, recorded as 1 or 0 respectively and functional status

Independent Variables include, Age, Sex, Admission GCS, Discharge GCS, and Admission diagnosis. Ventilation, cardiac arrest prior to admission and whether patient had trauma or not. The dependent variables were mortality and functional status 14 days post discharge from ICU.

## 7.7    SAMPLE SIZE AND SAMPLING
Sampling methods: consecutive admissions and data collecting questionnaires were used to capture the study information. The retrospective arm of the study, used hospital records to get data on admission to ICU for one full calendar year, looking at patient's admission parameters as well as outcome. Admission parameters included admission GCS, age, comorbidities and admission diagnosis as these have implication on outcome of patients and help characterize the MICU in terms of patients being admitted and the disease profile and outcomes. For the prospective arm of the study, all patients meeting the inclusion criteria were captured at admission, and were seen at discharge and followed up 2 weeks post discharge from ICU to check on their functional status using the tool formulated. No sample size was predetermined; data was collected over a period of 3 months. The study looked at 559 patients of which 442

were from the retrospective data and 117 were enrolled for the prospective arm of the study. Of those enrolled for the prospective are of the study to look at outcome and quality of life, 51 of them died on the unit, while 6 were lost to follow-up. As is the expectation in such studies, loss to follow up may arise, especially if the follow up period in long. A total of 61 patients were assessed for functional status 2 weeks post discharge from ICU.

Figure 1. Flow diagram of study population

559 patients

Retrospective

Prospective

442 2015 admissions

117 enrolled For Follow up

51 died on the unit
6 lost to follow up

60 analysed for functional status
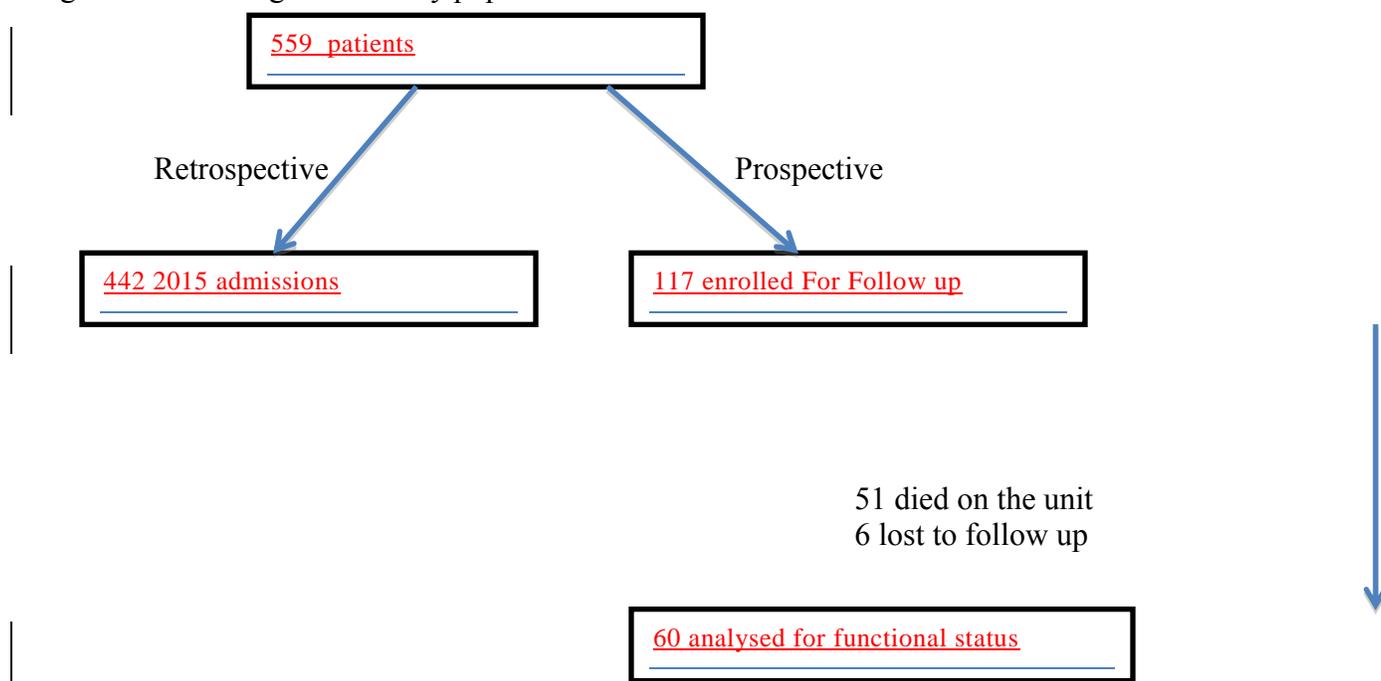
## 7.8    DATA COLLECTION

A Standardized data collection form (Appendix 1) was used to collect information from patients, next of Kin and medical charts. Consecutive patients admitted to ICU who meet the inclusion criteria were enrolled in the study. Data collection was done over a period of 3 months from 1st April to 30th June 2016. For both retrospective and prospective arms of the study, information collected was the same up to the discharge from ICU. Then those discharged from the prospective arm of the study were followed up for assessment of their functional status 2 weeks post discharge from ICU. The principle investigator with the help of two research assistants did data collection. Functional status was assessed two weeks post discharge from ICU. The follow-up intervals performed in previous studies of 2 weeks, I month, 6 months and 1 year were unachievable and unrealistic in this environment and in the setting of an MMed dissertation. An additional benefit of a two-week cut-off is that the numbers lost to follow-up in a setting such as Zambia, where long term follow up may prove to be difficult, was reduced.

Most of the functional status tools formulated in previous studies are complex and may not be appropriate for this study. This is the first ever study that will be looking at functional status post ICU discharge in Zambia. For easy and uniformity of data collection and analysis, a functional status tool has been formulated which is in appendix. A review of all patients' files and hospital records meeting the inclusion criteria was done for the year 2015 of all patients admitted to ICU.

## 7.9 DATA MANAGEMENT

Data was kept and recorded by the principle investigator in accordance with best practice research governance.  A second data set prior to analysis was created on SPSS. Version 22 The information was obtained from the questionnaires.

## 7.10 DATA ANALYSIS

Data analysis was done using SPSS version 22. Proportions were used for descriptive data. Mortality trends, survival status and associated factors were calculated. Mortality rate in hospital and out of hospital at 95% confidence interval and P value less than 0.05 was considered statistically significant. Multiple Logistic regression was used to establish associations and controlling for confounders

## 8 ETHICAL CONSIDERATIONS

Approval was sought from ERES Converge. A standardized questionnaire was used to recruit participants and considering that the study was observational there were no anticipated adverse events to the participants. The study was not introducing any new treatments or any intervention to the patient, it was the process of care being looked at and the outcomes from this process

Informed consent was obtained from all participants/ next of kin and they were informed that they could withdraw from the study at any time. The consent was explained in the language the patient was familiar with. All patients were treated with respect. The data findings were kept confidential for all patients and no name was used in the data set only numbers, which each patient was assigned.
Data collected on patients was kept confidential.
Permission to undertake the study was sought from the management of UTH.

## 9 RESULTS

A total of 559 patients were recruited for the study, 5 of which had missing data and were not included in the analysis another was lost to follow up. Giving a total of 553 patients. Of these 307 (55.6%) were male and 246 (44.4%)were female. The mean age was 36.8yrs with an average stay in ICU of 5.3 days. Of the 553 patients included in the study, 442 patients were for 2015,of which 161 had died on the unit giving a mortality of 36.5% for 2015. For the follow-up 111 patients were enrolled and only 60 of them could be followed up at 14 days post discharge from ICU as 51 of them had died on the unit.

Figure 2. Flow diagram of 2015 and 2016 admissions.

- n=442 • 2015 admissions
- n=161 • in Unit mortality(36.5%)
- n=281 • Discharged from ICU (63.5%

- n=111 • 2016 follow up cohort
- n= 51 • in ICU mortality (45.9%)
- n=60 • discharged from ICU(54.1%)
- n=6 • Died by day 14 (10%)
- n=54 • functional status assesed
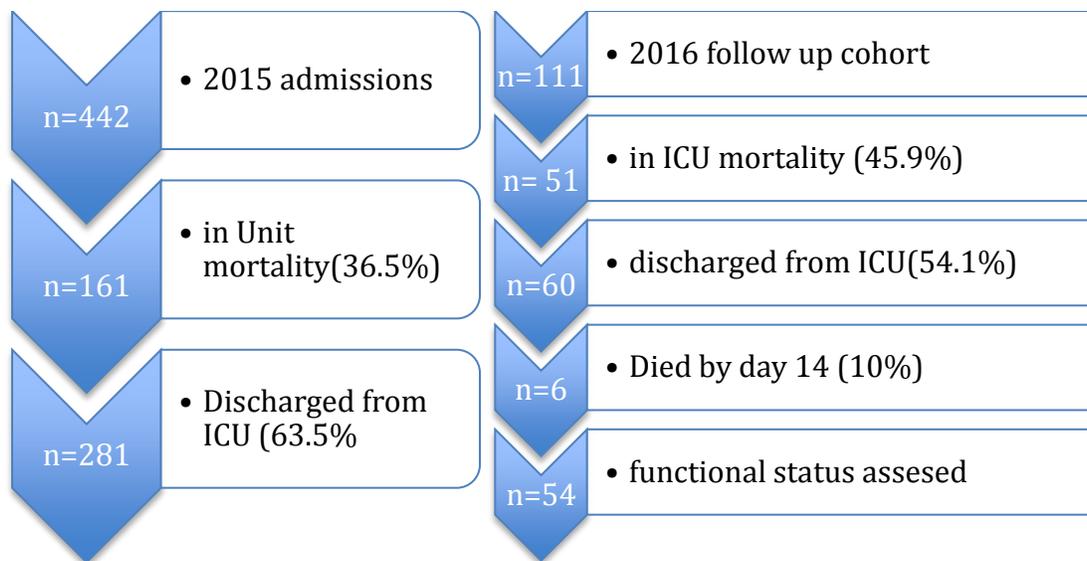
Table 1. Demographics and basic cohort data.

| Variable | |
|---|---|
| Age | 16-83  (mean = 36.8) |
| Male: Female | 307(55.5%): 246 (44.5%) |
| Pregnancy Related | 51 (9.2%) |
| Ventilated | 404  (73%) |
| Length of ICU stay | 0-61 days (mean = 5.3) |
| HIV Positive | 83 (15%) |

The mean age of 36.8yrs suggests that patients admitted to the intensive care are a particularly young cohort in comparison to most published series and hence should have had better outcomes as younger patients have a greater functional reserve compared to older patients.  There was a relatively high proportion of pregnancy related admissions (patients who are pregnant or are immediately post partum) may be unusual. The incidence of HIV in the unit is at 15%, which reflects local circumstances. The average length of ICU stay of 5.3 days may be due to severity of illness but could also be significantly influenced by the discharge practice of the unit of the patients admitted required ventilation. Almost three quarters of patients required ventilation, which is a powerful marker of the severity of illness of ICU patients at UTH.

Table 2: Incidence of co-morbidities

| Co-morbidity | Numbers | % |
|---|---|---|
| Hypertension | 47 | 8.5 |
| Asthma | 2 | 0.4 |
| Cardiac | 30 | 5.4 |
| Diabetes | 21 | 3.8 |
| Epilepsy | 7 | 1.3 |
| Total | 107 | 19.3% |

Overall, the proportion of patients with significant co-morbidities was surprisingly low, at only 19.3%. This contrasts with ICU data from developed healthcare systems where most

ICU patients have significant co-morbidities. The low incidence at UTH is probably related to the extremely low mean age of patients in this cohort.

Table 3. 2015 ICU admission and mortality (Retrospective cohort)

| | | |
|---|---|---|
| **Patient admitted 2015** | 442 | |
| **In unit mortality** | 161 | 36.5% |
| **Discharged from ICU** | 281 | 63.5% |

The overall ICU mortality rate found in this study was 36.5% This is lower than the 55.9% found at UTH in 2010 (Jochberger et al. 2008), and higher than that found in Uganda at 27% (Towey & Ojara 2007) while much higher than South Africa mortality of 19% (Hanekom et al. 2008).

Table 4 14-day post ICU discharge mortality

| Variable | Number | Percentage (%) |
|---|---|---|
| Patients enrolled | 111 | |
| Discharged from ICU | 60 | 54.1 |
| In unit mortality | 51 | 45.9 |
| 2 weeks post ICU mortality | 6 | 10 |

The 14-day mortality post ICU discharge was 10%, which is comparable to those, found in developed world and will be further discussed below. This is the first that we are obtaining this data in Zambia.

Figure 3: Function status 14 days post ICU discharge
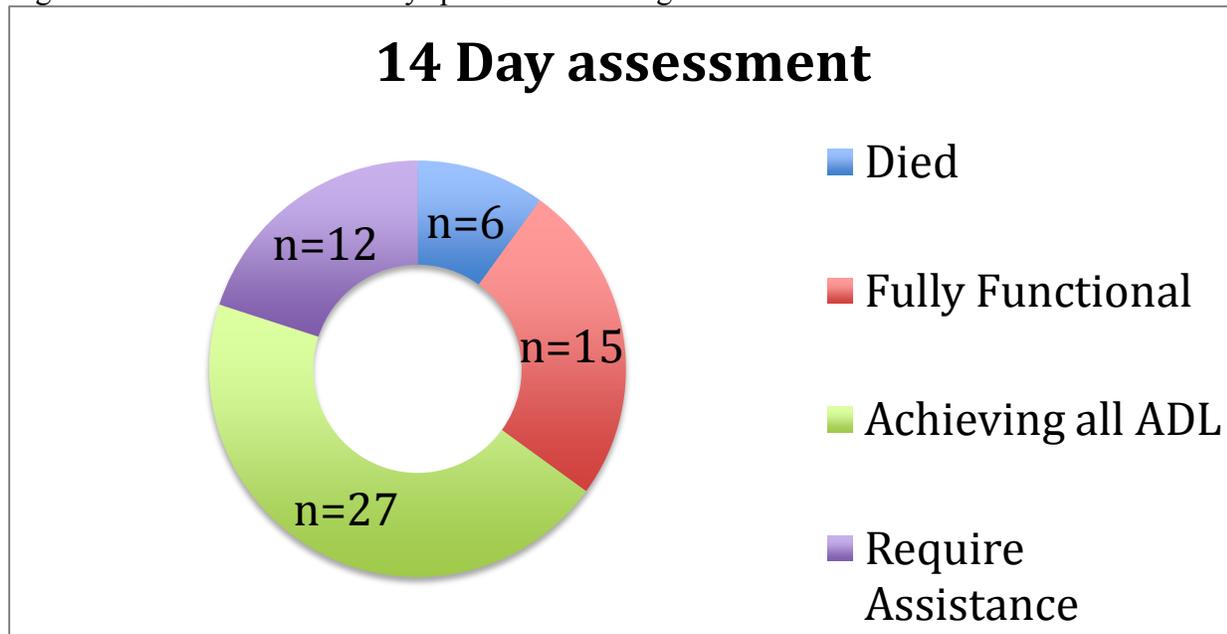
Of all patients assessed for functional status, 42 of them (70%), could achieve ADL, of which 15(25%) of the patients were fully functional and had returned to work by day 14 after ICU discharge, while 27 (45%) of them could attain activities of daily living but not yet gone back to work. A further 12 (20%) required assistance with ADL. The mortality at 14 days post ICU discharge was 10% which is similar to that found in most data on ICU outcomes and is unexceptional.

Table 5:Distribution of Mortality by clinical category

| Clinical Category | Number of patients | % Mortality |
|---|---|---|
| TBI | 90 | 66 |
| Sepsis | 63 | 56 |
| Pulmonary Disease | 11 | 55 |
| Tetanus | 6 | 50 |
| Non TBI trauma | 39 | 44 |
| Malaria | 20 | 40 |
| Miscellaneous | 73 | 37 |
| Pregnancy related | 53 | 30 |
| Post Op stabilization | 82 | 6 |

As anticipated, the mortality rates of those admitted with severe acute life-threatening illnesses was much higher than those admitted electively after elective surgery. However, the mortality rates overall were very high and this finding will be discussed below

Table 6 HIV infection and ventilation with associated mortality

| Variable | Number of patients | % Mortality |
|---|---|---|
| **HIV infection** | 83 | 54.2 |
| **Ventilated** | 404 | 49.5 |

The incidence of HIV infection on the unit was found to be 15% and a mortality of 54.1%, which may call for closer evaluation of these patients. The mortality of those ventilated was 49.5%, which may indicate severity of illness or indeed inappropriate care during ventilation.

**Table 7. Traumatic Brain Injury Patients: Admission GCS and associated mortality**

| Admission GCS | Number of Patients | Mortality (%) |
|---|---|---|
| 3-6 | 69 | 81.1 |
| 7-10 | 19 | 26.3 |
| 11-15 | 2 | 0 |

This data clearly demonstrated the extremely high mortality of TBI patients with admission GCS 3-6. Patients admitted to the ICU having already been intubated were deemed to be GCS 3.

**Table 8: Multiple logistic regression at 14-day mortality controlling for age, sex, ventilation, cardiac arrest prior to admission Trauma**

| Variable | P value | Odds ratio | 95% CI | |
|---|---|---|---|---|
| Sex | 0.194 | 0.728 | 0.451 | 1.176 |
| Age | 0.846 | 1.002 | 0.985 | 1.019 |
| Trauma | 0.169 | 1.732 | 0.792 | 3.786 |
| HIV | 0.000 | 0.322 | 0.186 | 0.558 |
| Admission GCS | 0.142 | 0.954 | 0.896 | 1.016 |
| Ventilated | 0.000 | 7.139 | 2.882 | 17.684 |
| Cardiac Arrest | 0.823 | 1.090 | 0.511 | 2.328 |

This analysis shows that ventilation and HIV +ve status were found to be independent predictors of mortality.

**Table 9: Multiple logistic regression for 14-day Functional status controlling for age, sex, admission GCS, ventilation, cardiac arrest, HIV status and trauma**

| Variable | P value | Odds | 95% C I | |
|---|---|---|---|---|
| | | | Lower | Upper |
| Age | 0.455 | 1.016 | 0.975 | 1.059 |
| Admission GCS | 0.299 | 1.095 | 0.923 | 1.299 |
| Ventilation | 0.009 | 13.112 | 1.876 | 91.667 |
| Cardiac Arrest | 0.402 | 2.845 | 0.246 | 32.863 |
| HIV Status | 0.006 | 0.123 | 0.027 | 0.554 |
| Trauma | 0.174 | 2.778 | 0.636 | 12.125 |
| SEX | 0.672 | 0.801 | 0.286 | 2.238 |

This analysis shows that ventilation and HIV status are statistically significant predictors of poor functional status at 2 weeks post ICU discharge. Respiratory support by mechanical ventilation is required mainly for acute severe disease and therefore may be expected to be

associated with poorer outcomes. However, the finding that HIV status was an independent indicator of poor functional outcome was not anticipated. Surprisingly admission low GCS was not an independent predictor although this is strongly suggested by other data.

## 10 DISCUSSION

The mean age of patients admitted was 36.8yrs, which indicates that patients admitted to our intensive care are a particularly young cohort in comparison to most published series (Towey 2008) and very much lower than that found in the developed world healthcare systems at 65yrs (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009) 2010). Younger patients have much greater physiological reserve and and invariably have better outcomes compared to older patients.

The finding of almost 10% of the cohort (and therefore almost 20% of female patients) that were admitted due to pregnancy related complications was most unexpected and warrants further investigation in conjunction with the Obstetricians. This may reflect the high-risk nature of obstetric practice at UTH due to high incidence and/or late presentation of patients with complications of pregnancy, inadequate antenatal care or other factors to be identified. "Pregnancy related" in this study meant, patients who were pregnant and had other medical complications such as Malaria, heart failure, and sickle cell disease, or patients immediately post partum but had complications of pregnancy such as eclampsia, postpartum hemorrhage or sepsis.

Interpretation of ICU mortality requires recognition that no two ICUs admit identical cohorts of patients, and that case mix varies between units and within units over time. Many units in developed systems do not admit children who are cared for in specialist ICUs as are neurosurgery and cardiac surgery patients, and these will have very different outcome profiles. Without scoring systems such as APACHE scoring system being applied, it is not possible to provide detailed analysis of subgroup mortality.

The overall ICU mortality rate found in this study was 36.5% as shown in Table 3. This is lower than the 55.9% found at UTH in 2010 (Jochberger et al. 2008), and higher than that found in Uganda at 27% (Towey & Ojara 2007) while much higher than South Africa mortality of 19% (Hanekom et al. 2008).

The ICU mortality rate is still higher than that found in developed world ICU which ranges from 10-26% (Mayr et al. 2006) (Joint Commission Resources 2004) (Wang et al. 2010). It is much higher than that found in a recent study looking at ICU mortality and predictors of mortality (Braber & van Zanten 2010) which found ICU mortality at 16.3% . A UK study of a group of ICUs in 1998 (Goldhill & Sumner 1998) found mortality rate at 32.5% which may be more camparable to that currently found at UTH. The case mix audit program in the UK(www.icnarc.org) compares similar units outcomes and this consistently yields an overall mortality of around 20% for current UK practice, admission profile and resources.

All of these studies suggest that for 2015-16, the mortality in the ICU at UTH is still very high.

As shown in table 4, the14-day mortality post ICU discharge was 10%, which is comparable to those found, in developed world. This is the first that we are obtaining this data in Zambia. Despite a very high in unit mortality rate, it appears that the quality of survival of discharged UTH ICU patients at 14 days seems to be acceptable. Reasons for this could be the very young age group and the high mortality itself selecting out particularly resilient or fit patients who survived. Another reason could be that patients with low severity of illness survived, but this would not be demostrable without meticulous severity scoring on admission which is currently beyond the scope of the ICU. However the fact that 10% of the patients discharged alive from ICU die, warrants further investigation to look at whether these patients were appropraite discharges or whether the wards they were discharged to were appropriate or gave appropriate care as currently there is no high dependancy unit at UTH for patients discharged fro ICU.

In our study of quality of function in survivors refer to figure 3, it was found that 70% of the patient could undertake activities of life without assistance 14 days post discharge from ICU. Of these 25% were fully functional and back to work or school, while the remaining 45% could attain activities of daily living but had not yet returned to full functionality. 20% of all patients followed up required assistance for activities of daily living 2 weeks post discharge from ICU. , which is comparable to data from earlier study(Montuclard et al. 2000)(Desai et al. 2011). There is no data in the region to compare this with and no wordwide data of units with similar mortality who have studied functional status on discharge. A poor functional status was said to be any patient who did not attain ADL.

The distribution of mortality by clinical category yields some important data refer to Table 5. Even though no APACHE scoring was applied to the different subgroups, descriptive information on mortality could still be useful as baseline for further evaluation. Death from TBI and sepsis are very high but may be expected for these categories. Patients with TBI are often admitted after significant logistical delays and neuroprotective regimens in critical care are only designed to limit further injury and provide physiological conditions to maximize recovery – rather than address the existing injury. Likewise, severe sepsis and septic shock are extremely dangerous conditions with significant associated mortality unless patients receive sophisticated care by a dedicated well-resourced critical care team. However, tetanus is a highly treatable condition, which should be associated with good outcomes. The mortality in pregnant related patients is also concerning as this is by definition a very young fit population.

The high proportion of ventilated patients is indicative of the overall severity of life-threatening illness of this cohort. As UTH is the principle critical care facility in Zambia, it is not surprising that predominantly very ill patients present for admission. So this finding was anticipated. Patients who were ventilated had a case fatality of 49.5% as shown in table 6,which is comparable to data from Uganda 50% (Towey R.M 2007) but much lower than

found in an earlier study done at UTH 74% (Sinclair et al. 1988). This may indicate an improvement in standards in the unit. The case fatality for ventilated patients still higher than that in developed countries 25.1%(Kahn et al. 2006). Ventilation was associated with poor functional status 2 weeks post discharge which is comparable to the study by Schaaf (Schaaf et al 2008.)

The incidence of HIV infection in our study population was 15%, which reflects local circumstances. Not every patient was HIV tested and therefore the overall high mortality rates may have been affected by undiagnosed HIV positive status as the analysis of data revealed that HIV positive status was an independent predictor of poor outcome. A specific audit of HIV testing, status and mortality using the data of this study as baseline would address this important question.

The mortality rate for HIV +ve patients was 54.2% and this seems to be in agreement with earlier studies done in Uganda suggesting that being HIV positive reduces survival (M. Dünser et al. 2006). However its not clear if these patients were on ARVs or what the CD4 count was. At the same time, administration of ARVs does not seem to alter the course of critical illness as according to Meyback.(Meybeck et al. 2012).

As HIV patients are prone to opportunistic infections that may not immediately manifest due to the immunosuppression, they may have had infections which may not have been apparent on admission. However because of the apparent association between HIV postive and subsequent mortality, care givers in the intensive care will have to be more vigilant when such patients are addmitted to the intensive care. In a study done in France, ICU mortality was unchanged whether patients were on HAART or not (Vincent et al. 2004), However 3 month mortality increased upon HAART therapy, which may be due to the immune response that infected patients have after initiation of antiretroviral therapy. However another study found survival improved though not associated with antitretroviral therapy during admission but rather increase in CD4 counts.(Powell et al. 2009). This may reflect that ARVs reduce the incidence of AIDS related events.(Meybeck et al. 2012)

Only 19.3% of the patients had documented co-morbidities as indicated in table 2. This was probably related to the extremely low mean age of patients in this cohort. Health status prior to ICU admission is a major influence on the long-term health outcome of ICU patients (Jacobs, Vliet, et al. 1988)(Granja et al. 2002)(M. W. Dünser et al. 2006). Functional status of survivors has been found to be reduced in patients who had chronic disease compared to those without in a recent study done by McNelly et al(McNelly et al. 2016). The data on co-morbidities in this cohort shows that the incidence of of co-morbidity was low and this correlates with the low age of the patients. Co-morbidity is therefore very unlikely to be a factor causing the high overall mortality.

Tetanus is a preventable and treatable diseases. In this study tetanus had a mortality of 50%. In Uganda this was was 57% (Towey 2008), and in Ghana at 50% mortality (Hesse et al. 2005)(Hesse et al. 2003). Tetanus is common in developing countries ranging from 40-60

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mortality(Hesse et al. 2005). In Uganda the high case mortality was attributed to inappropriate treatment where adequate wound debridement, antibiotics administration and Human Tetanus Immunoglobulin were not admistered. Similar factors may be present at UTH as immunoglobulin are not readily available and this may be a very cost-effective and successful treatment given that ,tetaus patients tend to have long ICU stays at great expense.

An important finding of this study relates to the GCS of patients admitted with traumatic brain injury (TBI) and their outcomes. Patients with TBI and admission GCS less than 6 had a mortality of 81.1% which is higher than data found in earlier studies (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009). It is also higher than the mortality of about 60% found in a multicenter study done in China (Rainer et al. 2014). It is also higher than a recent study which found mortality of traumatic head injury at 10.4% (BrattstrÖm et al. 2010) .

In this study, GCS was assigned at admission regardless of whether the patient was intubated or sedative and muscle relaxants were administered. This may underestimate the true GCS, but only patients with severely depressed level of consciousness and/or multitrauma requiring intubation for stabilization would have been intubated, so scoring GCS of 3 in these patients is probably clinically appropriate.

The accurancy of admission GCS in predicting outcomes is dependant on when it was assessed and whether all 3 parameters were assessed. The predictive value for low GCS in poor outcomes is 78% according to Gale et al (Gale et al. 1983). This problem of assessment has been noted in earlier studies (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009) (Gale et al. 1983). However it is still the case that when a low GCS is recorded, poor outcomes have been seen in 88% of cases regardless of whether all parameters were taken or patient was intubated (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009) especially for GCS 3-6.

Outcomes from severe TBI depends on immediate intervention to maintain oxygenation and perfusion of the brain (neuroprotective measures) as well as management of all other injuries and maintenance of normal physiology such as adequate hydration and temperature. In all settings polytrauma with TBI has a very poor prognosis. Therefore the level  of ICU intervention for these patients needs to be carefully managed as as to limit inappropriate and excessive intervention in cases with very poor predicted outcomes. This approach is particularly relevant in settings of limited resources where an element of triage to maximise outcomes is necessary.

In all healthcare systems, consideration must be given to the benefit obtained from the resources allocated. Intensive care is an expensive venture (Graf et al. 2008) (d'Empaire & Amaral 2012) and the goals of treatment should not only be simple survival but also a consideration on the

quality of life after intensive care admission.(Mayr et al. 2006)(Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009)(Angus 2014).

Other studies have shown that age and admission GCS play a significant role in predicting outcome (Randall M. Chesnut, M.D.Jamshid Ghajar, M.D.Andrew I.R. Maas, M.D.Donald W. Marion, M.D.Franco Servadei, M.D.Graham M. Teasdale, M.D.Andreas Unterberg, M.D.Hans von Holst, M.D.Beverly C. Walters 2009) (Braber & van Zanten 2010). This maybe due to the fact that the mean age of the previous studies was 65-70yrs while for our study the mean age was 36.8 yrs.  It is reasonable to expect that a much younger cohort will do better due to having a better functional reserve.

In all healthcare systems, resources are directed to where they can provide most benefit; in public health, primary care, secondary care or a tertiary center such as UTH. It follows therefore that admission to ICU should be targeted to those patients that are likely to benefit from ICU care. If ICU outcomes are to be improved, one of the essential developments is to identify patients for whom ICU admission and treatment are very unlikely to alter outcome risk of death. Resources and initiatives can then be targeted to those patients most likely to benefit.

To address these issues all ICUs in developed settings have admission policies, which state clearly the goals and limitations of critical care, and these agreed statements guide admission policies as well as treatment escalation decisions. Dedicated intensivists who have the authority to manage the resources as directed by the policies invariably manage this process.

## 11  CONCLUSIONS

This observational study addresses two key questions relating to ICU outcomes at UTH Lusaka. Firstly, it provides updated mortality rates, both in ICU and post-discharge, of ICU patients and compares this to historical data with ICU mortality at 36% and post discharge mortality at 2 weeks to be 10%. Secondly, it provides an insight into the functional recovery of patients discharged alive from ICU. This important outcome data is essential if the ICU is to apply its limited resources in the most effective manner and plan its admission, treatment and discharge protocols accordingly in the future.

Admission GCS and diagnosis or clinical category was recorded to try to identify areas of best and worst outcome to guide further admission policy development. Risk factors for increased mortality were ventilation, and HIV infection.Ventilation and HIV infection are predictors or poor functional status. Admission GCS, age or having cardiac arrest prior to admission was not predictive of poor outcome.

 Mortality of particular groups such as traumatic brain injury with admission GCS <6, HIV +ve and pregnancy related admissions, warrant further investigation.Due to the high mortality among tetanus patients who would most likely have better outcomes if appropriate and timely

treatment is instituted,consideration should be given to treating patients with tetanus with immunoglobulin to improve on mortality. This  may be easy and economical way to improve this subgroup of patiets admitted to ICU.

Functional outcomes in the small sample studied achieved good return of function in a short period. With 70% of the patient having good  functional status 2 weeks post discharge from ICU. Overall, the data raises many questions and and suggests areas for improvement.

## 12   RECOMMENDATIONS

Further work needs to be done on specific groups of patients to determine the reasons for poor outcomes and develop protocols for improvements that would work best in our environment.
Careful patient selection for admission to ICU may be required if the most benefit is to be achieved. This applies particularly to TBI with low admission GCS.
Further audit and research to be done on HIV positive patients to develop protocols for their appropriate management.
Special training in intensive care for both nurses and doctors is likely to have a positive impact on outcomes.
Developing processes of management and control of admission, treatment and discharge decisions may have a beneficial impact on performance on the intensive care unit.
Strengthening of support elements of the ICU such as laboratory and biomedical equipment for continued improvement in service delivery
Development of an HDU for the management of low risk postoperative patients may free the ICU resources for use on the sicker patients.

## 13   LIMITATION OF THE STUDY

Time frame: two weeks has been shown to give a limited impression of the patient's longer-term functional recovery.  Potential for deterioration after two-week follow-up and the impact this may have on long-term functional status.
Surrogate opinion of functional recovery is inevitably subjective. Admission GCS assessment of TBI was undertaken regardless of whether patient intubated, sedated or not. The functional status tool used was formulated and has since not been validated.
This study was unable to identify specific causes of poor outcomes in clinical categories, but has pointed the way to further investigation of causes.

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## 15 APPENDIX

### 15.1 APPENDIX 1

**MORTALITY AND QUALITY OF LIFE OUTCOMES: PROSPECTIVE COHORT STUDY**

**Data Collection Proforma**

| Social Demographics | | | |
|---|---|---|---|
| Patient ID | | File Number | |
| Date | ___/___/___ | Phone Number | |
| Age | Sex M ☐ F ☐ | | |
| Marital status | MARRIED ☐ SINGLE ☐ DIVORCED ☐ | | |

| Employment and Life Style demographics | |
|---|---|
| Employment status | Formal ☐ Self employed ☐ None ☐ Student ☐ |

| Admission Parameters | | | | | |
|---|---|---|---|---|---|
| Specialty | Obgy ☐ | Gynae ☐ | Med ☐ | Paeds ☐ | Surg ☐ |
| Admission place | Ward ☐ | Theatre ☐ | Casualty ☐ | Emergency ☐ | |
| Admission Diagnosis | | | | | |
| Admission GCS | | | | | |
| Ventilated? | Yes ☐ | | No ☐ | | |
| Pre-admission cardiac arrest | Yes ☐ | | No ☐ | | |

| Outcome or Survival parameters | | |
|---|---|---|
| Duration of stay in ICU | | |
| Died | Yes ☐ | No ☐ |
| Discharged | Yes ☐ | No ☐ |
| Died on Ward | Yes ☐ | No ☐ |
| Readmitted | Yes ☐ | No ☐ |

| FUNCTIONAL STATUS AT 2 WEEKS POST DISCHARGE FROM ICU | | |
|---|---|---|
| 1 | Fully functional and back to work / education / normal activities. | |
| 2 | Limited function. Not achieving (1) but self-caring in all activities of daily living. (ADLs) | |
| 3 | Needs assistance for ADLs | |
| 4 | Severely disabled, Bed bound, significant reduced LOC | |
| 0 | Patient died | |

## 15.2  APPENDIX 2

INFORMATION SHEET FOR PATIENT/NEXT OF KIN

I am Dr Naomi Shamambo, a specialist trainee in the school of medicine at the University of Zambia. I am pursuing a Master's degree in Anesthesia and Critical care. This study is in partial fulfillment for the award of a Master of Medicine in Anesthesiology and Critical Care. Before you make up your mind whether to take part in the study or not, I would like to explain to you the purpose of the study and what is expected of you. If you agree to take part in this study, you will be asked to sign this consent form in the presence of a witness.

Nature and purpose of the study

The study is being conducted to determine the outcome of patients admitted to the main intensive care unit.

Procedure of the study

If you agree to participate in this research, we will obtain information about you or your relative using a data entry sheet, follow you up 2 weeks after discharge from ICU to check on what you or your relative will be able to do at the time. You are however allowed to refuse follow up if you wish to do so.

Possible risks and discomforts

You/your relative will not be exposed to any additional risks by enrolling into this study. You/your relative will receive the standard care by the attending doctor. This study will not influence the type of management that you/your relative will receive and no extra procedures will be performed on you or your relative due to the study.

Possible benefits

The information obtained in this study could help in your care or relatives care and influence the care of other patients who are admitted to intensive care in the future.

Confidentiality

All the data collected is strictly confidential. Data that will be collected, analyzed, and reported on will not include your/your relative's name and therefore cannot be traced to you or your relative.

Your/Your relative's participation is strictly voluntary. You will not suffer any consequences if you decide not to participate in this study. You/your relative may also withdraw from the study at any time for any reason without consequences to you/your relative.

Thank you for considering participation in this study. If you have any questions, concerns, and clarifications, please contact Dr Naomi Shamambo or ERES Committee on the following addresses:

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## 15.3 APPENDIX 3
## CONSENT FORM

I, _____ hereby confirm that the nature of this clinical study has been sufficiently explained to me. I am aware that my personal details or relative's detail will be kept confidential and I understand that I may voluntarily, at any point, withdraw my/my relative's participation without suffering any consequences. I have been given sufficient time to ask questions and seek clarifications, and of my own free will do hereby declare my/ my relatives participation in this research.

I have received a signed copy of this agreement

_____     _____     _____
Name of Participant (Print)    Participant (Signature or thumbprint) Date

_____     _____     _____
Witness (Print Name)         Witness (Signature)              Date

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