



INSTITUTE OF HEALTH SCIENCES

DEPARTMENT OF INTERNAL MEDICINE

**MAGNITUDE OF IN-HOSPITAL INTENSIVE CARE UNIT MORTALITY AND
ASSOCIATED FACTORS AMONG ADULT MEDICAL PATIENTS ADMITTED TO
THE INTENSIVE CARE UNIT AT WALLAGA UNIVERSITY COMPREHENSIVE
SPECIALIZED HOSPITAL, NEKEMTE, WESTERN ETHIOPIA: AN
INSTITUTION-BASED CROSS-SECTIONAL STUDY BETWEEN JANUARY 1, 2023
AND DECEMBER 31, 2025.**

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NEKEMTE, ETHIOPIA

WALLAGA UNIVERSITY
INSTITUTE OF HEALTH SCIENCES
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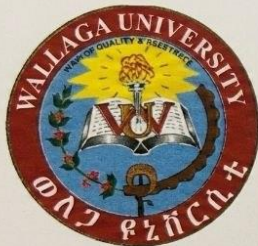
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APPROVAL SHEET FOR SUBMITTING THESIS PROPOSAL

As members of the examining the thesis proposal defense, we certify that we have read and evaluated the proposal prepared by **Dr. Abdissa Dula Habiba** the title: **Magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted to the intensive care unit at Wallaga University Comprehensive Specialized Hospital between January 1, 2023 and December 31, 2025.**

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List of Abbreviations and Acronyms

AKI: Acute Kidney Injury

AOR: Adjusted Odds Ratio

CHF: Congestive Heart Failure

CI: Confidence Interval

CKD: Chronic Kidney Disease

CLD: Chronic Liver Disease

COPD: Chronic Obstructive Pulmonary Disease

COR: Crude Odds Ratio

DVT: Deep Venous Thrombosis

ETB: Ethiopian Birr

HIV: Human Immune Deficiency Virus

LMICs: Low- and Middle-Income Countries

MICs: Middle-Income Countries

MODS: Multi Organ Dysfunction Syndrome

PE: pulmonary Embolism

VAP: Ventilator Associated Pneumonia

WHO: World Health Organization

WUCSH: Wallaga University Comprehensive Specialized Hospital

Table of Contents

Acknowledgement	iii
List of Abbreviations and Acronyms	iv
List of Tables.....	vii
List of Figures	viii
Summary	ix
1. Introduction.....	1
1.1. Background.....	1
1.2. Statement of the Problem.....	2
1.3. Significance of the Study	4
2. Literature Review.....	5
2.1. Magnitude of In-Hospital ICU Mortality.....	5
2.2. Associated factors of In-hospital ICU Mortality.....	6
2.2.1. Demographic associated factors	6
2.2.2. Neurological Status (Glasgow Coma Scale - GCS).....	7
2.2.3. Sepsis and Septic Shock.....	7
2.2.4. Mechanical Ventilation (MV)	8
2.2.5. Use of Vasopressors	8
2.2.6. Shock and Hemodynamic Instability	9
2.2.7. Organ Dysfunction (AKI, MODS)	9
2.2.8. Length of ICU Stay	9
2.2.9. Comorbidities.....	10
2.3. Conceptual frame work.....	11
2.4. Objectives	12
2.4.1. General Objective	12
2.4.2. Specific Objectives	12
3. Methods and materials	13
3.1. Study area and Period	13
3.2. Study design.....	13
3.3. Population	13
3.3.1. Source Population	13
3.3.2. Study population	13
3.3.3. Study unit.....	13

3.4. Inclusion and Exclusion Criteria.....	14
3.4.1. Inclusion Criteria	14
3.4.2 Exclusion Criteria	14
3.5. Variables.....	14
3.5.1. Dependent variables.....	14
3.5.2. Independent variable	14
3.6. Sample Size Determination and Technique	14
3.6.1. Sample size determination	14
3.6. 2. Sampling procedures.....	16
3. 7. Operational definitions.....	16
3.8. Data collection instruments and data collection procedures.....	17
3.9. Plan for Data processing and analysis procedures.....	18
3.10. Data quality assurance	19
3.11. Ethical consideration.....	19
3.12. Dissemination plan.....	20
4. Work plan.....	20
5. Budget.....	21
References.....	22
Annexes.....	27
Annex I: Data extraction sheet.....	27
Annex II: Investigator assurance form.....	29

List of Tables

Table 1 sample size calculation for second objective for associated factors of in-hospital ICU mortality among adult medical patients admitted to ICU at Wallaga University Comprehensive Specialized Hospital, 2026.	15
Table 2 Work Plan to Assess Magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted to ICU at Wallaga University Comprehensive Specialized Hospital, 2026.....	20
Table 3 Budget Breakdown for Undertaking a Research Study on magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted at Wallaga University Comprehensive Specialized Hospital, 2026.....	21

List of Figures

Figure 1: Conceptual framework Magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted at wallaga University Comprehensive Specialized Hospital,2026.....	11
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Summary

Background: Patients admitted to ICU often require and benefit from continuous observation, mechanical ventilation, hemodynamic support, and complex therapeutic interventions. ICU mortality is one of the major indicators used to assess ICU performance, quality of care, disease severity, and healthcare resource utilization. In resource-limited settings, the service provided to ICU patients is lagging far behind due to various reasons which resulted in high mortality of ICU patients. There is lack of evidence concerning the magnitude and associated factors of mortality among adult medical ICU patients in the study area.

Methods: An institution-based cross-sectional study will be conducted at the intensive care units of Wallaga University Comprehensive Specialized Hospital during January 1, 2023 to December 31, 2025. A total of 259 adult medical patients' charts will be selected. Data will be collected by using a structured, pretested data extraction sheets that assesses in-hospital mortality and associated factors as well as relevant sociodemographic and clinical variables. The collected data will be entered into Epi data version 4.6 and exported to SPSS version 27 for analysis. Descriptive statistics will be used to summarize patient characteristics. Frequencies and percentages will describe categorical variables, while means and standard deviations will be used for continuous variables. Bivariate logistic regression will be conducted to identify candidate variables ($p < 0.25$) for multivariable analysis. Multivariable logistic regression will then be employed to determine associated factors of ICU in- hospital mortality by Adjusted Odds Ratios (AOR) with 95% Confidence Intervals (CI) will be used to report the strength of associations, and statistical significance will be determined at a p -value < 0.05 . Results will be presented using texts, tables, and graphs.

Work Plan and Budget: The study will require a total estimated budget of 31,809.8 Ethiopian Birr and will be carried out between January 1, 2023 to December 31, 2025. The source of funding will be Wallaga University.

1. Introduction

1.1. Background

An ICU is an organized system for the provision of care to critically ill patients that provides intensive and specialized medical and nursing care, an enhanced capacity for monitoring, and multiple modalities of physiologic organ support to sustain life during a period of life-threatening organ system insufficiency. These patients often require continuous observation, mechanical ventilation, hemodynamic support, and complex therapeutic interventions(1).

ICU mortality refers to death occurring during ICU admission before discharge from the intensive care unit. It is one of the major indicators used to assess ICU performance, quality of care, disease severity, and healthcare resource utilization(2). Common causes of ICU admission include sepsis, acute respiratory failure, stroke, trauma, congestive heart failure, and acute respiratory distress syndrome (ARDS)(3).

Globally, ICU mortality rates have improved over the past decades due to advancements in early diagnosis, antimicrobial therapy, and organ support technologies. As stated in large international cohort studies, ICU mortality in high-income countries ranges between 9% and 18%, with lower mortality attributed to improved healthcare infrastructure and trained personnel(4).

In contrast, low- and middle-income countries (LMICs) experience significantly higher ICU mortality rates. As stated in systematic reviews, ICU mortality in LMICs ranges from 20% to 40%, often exceeding this range in resource-limited settings(5). This disparity is largely attributed to limited ICU capacity, shortage of trained healthcare professionals, delayed patient presentation, and inadequate access to essential life-saving equipment(6).

The burden is even more pronounced in Africa, where ICU mortality rates are among the highest globally. As stated in a systematic review of African ICUs, mortality rates range between 32.9% and 54%, with infectious diseases, sepsis, and organ failure being the leading causes of death(7). Similarly, studies conducted in East Africa demonstrate that ICU mortality frequently exceeds 35%, reflecting persistent challenges in healthcare delivery systems(8).

Ethiopia, as part of sub-Saharan Africa, faces similar challenges. A national systematic review and meta-analysis reported that the pooled ICU mortality rate in Ethiopia is approximately 39.7%, which is significantly higher than global averages(9). Furthermore,

regional analysis indicates that mortality in Oromia is approximately 41%, suggesting a substantial burden in areas similar to the current study setting(10).

Several primary studies conducted in Ethiopia have reported variable ICU mortality rates. For instance, studies from Jimma and Addis Ababa reported mortality rates of 50.4% and 60.7%, respectively, while studies from Gondar and Debre Berhan reported relatively lower rates of 38.7% and 30%. These variations highlight the influence of institutional capacity, patient characteristics, and availability of resources(11–13).

In addition to the magnitude of mortality, identifying predictors of ICU mortality is essential for improving patient outcomes. As stated in multiple studies, predictors such as low Glasgow Coma Scale (GCS), sepsis, mechanical ventilation, use of vasopressors, shock, and organ failure are strongly associated with increased mortality. These predictors reflect both disease severity and limitations in critical care delivery(14,15).

1.2. Statement of the Problem

In-hospital mortality among ICU patients remains a significant global health challenge, with disproportionately higher rates in low- and middle-income countries. While ICU mortality in high-income countries ranges between 9% and 18%, it increases to 20–40% in LMICs and exceeds 30–50% in African settings(4,6,7)

Ethiopia is among the countries with a high burden of ICU mortality, with a pooled estimate of approximately 39.7%, indicating that nearly two out of five ICU patients do not survive hospitalization (9). Some institutional studies report even higher mortality rates, reaching up to 60.7% among mechanically ventilated patients, which reflects severe illness and limited critical care resources(13).

High ICU mortality has multiple consequences on patients, families, healthcare institutions, and the national health system. For patients, it results in preventable deaths and loss of productive life years. Families experience psychological distress, social disruption, and significant financial burden related to prolonged hospitalization and treatment costs. High mortality also contributes to reduced public confidence in healthcare services and increased emotional stress among healthcare workers. At the institutional level, ICU mortality is associated with prolonged length of stay, increased healthcare expenditure, resource depletion, and overcrowding of critical care services. In resource-limited settings, these effects further strain already limited healthcare infrastructure and workforce capacity(16,17).

The high mortality rate is influenced by multiple factors, including delayed presentation, limited ICU infrastructure, shortage of trained personnel, and high burden of infectious diseases such as sepsis (5)(6). Furthermore, clinical predictors such as low GCS, mechanical ventilation, vasopressor use, shock, and organ failure significantly increase the risk of death(14,15).

Recognizing the growing burden of critical illness, the government of Ethiopia and other stakeholders has initiated several interventions aimed at improving ICU care and reducing mortality. The Federal Ministry of Health Ethiopia has expanded ICU services in tertiary and regional hospitals, developed national guidelines for emergency and critical care management, and strengthened training programs for physicians, anesthetists, nurses, and emergency care professionals. During and after the COVID-19 pandemic, substantial investments were made to increase oxygen infrastructure, ventilator availability, and intensive care capacity across the country. International organizations such as the World Health Organization, non-governmental organizations, universities, and professional associations have also supported capacity building, workforce training, infection prevention programs, and procurement of critical care equipment (18–21).

Although several studies have been conducted in Ethiopia, there are important gaps in the existing literature. First, most studies are concentrated in central and northern parts of the country, such as Addis Ababa, Gondar, and Jimma, leaving western Ethiopia underrepresented. Second, many studies include mixed ICU populations (medical, surgical, trauma), limiting the ability to identify associated factors specific to medical ICU patients. Third, there is variability in reported associated factors across studies, suggesting the need for context-specific evidence.

At Wallaga University Comprehensive Specialized Hospital (WUCSH), there is limited documented evidence regarding the magnitude of in-hospital mortality and its associated factors among adult medical ICU patients. Without such data, it is difficult to design targeted interventions, allocate resources efficiently, and improve patient outcomes.

Therefore, this study aims to assess the magnitude of in-hospital mortality and identify its predictors among adult medical patients admitted to WUCSH ICU, thereby filling an important knowledge gap and contributing to evidence-based critical care practice in the region.

1.3. Significance of the Study

This study will make important contributions to clinical practice, hospital management, Research and health policy by providing evidence on the magnitude and associated factors of in-hospital mortality among adult medical patients admitted to the Intensive Care Unit (ICU) of Wollega University Comprehensive Specialized Hospital (WUCSH). First determining the magnitude of mortality will help quantify the extent of the problem at WUCSH and establish a baseline against which future improvements in critical care services and patient outcomes can be measured.

Second, identifying associated factors of in-hospital ICU mortality will assist physicians, intensivists, internists, residents, nurses, and other healthcare professionals in early recognition of patients at high risk of death. Such information may support timely clinical decision-making, prioritization of interventions, closer monitoring, and implementation of preventive strategies aimed at reducing avoidable mortality.

Third, Understanding which patient characteristics and clinical conditions are associated with increased mortality can help healthcare providers and hospital administrators allocate available resources more efficiently and prioritize patients who may benefit most from intensive monitoring and treatment. Fourth, Health administrators, hospital managers and policymakers require reliable local data to guide decision-making. Evidence generated from this study may help inform strategies aimed at strengthening critical care services, improving workforce training, enhancing resource mobilization, and ultimately reducing mortality among critically ill patients.

Fifth, the identified associated factors of mortality may generate new research questions and guide prospective, multicenter, or interventional studies. Researchers may use the findings to explore causal pathways, validate risk factors, develop predictive models, and evaluate interventions aimed at improving survival among critically ill patients.

Finally, the ultimate significance of this study lies in its potential contribution to improving patient outcomes. Through identification of modifiable and non-modifiable associated factors of mortality, the study may facilitate earlier recognition of high-risk patients, promote evidence-based clinical practice, improve quality of care, and contribute to reducing in-hospital ICU mortality among adult medical ICU patients at WUCSH.

2. Literature Review

2.1. Magnitude of In-Hospital ICU Mortality

A study conducted at Gazi Yaşargil Training and Research Hospital in Turkey reported a medical ICU mortality rate of 23.8%(22). Similarly, a study conducted within the Unified Health System in Sergipe, northeastern Brazil, found an in-hospital ICU mortality rate of 21%(23). In Jordan, a study conducted at Jordan University Hospital reported an ICU mortality rate of 34%(24).

Study done in South Africa among medical patients admitted to ICU showed that ICU and hospital mortality rates were 11.1% and 21.5% respectively(25). Another study done in Cameroon showed that overall in-ICU mortality rate was 59.4% out of 662 ICU admissions(26). Study done in Tanzania showed that Mortality during HDU- and hospital stay was 30% and 37% respectively(27). One study from Uganda showed that the 28 day ICU mortality was 25.6%(28). Another Study done in south western Kenya showed the overall ICU mortality was 26.1%(29). Similarly one study showed that mortality in critically ill patients at a private tertiary hospital ICU in Kenya was 31.7%, most of whom were male (61.4%) with a median age of 53.4 years(30). Another study from Rwanda showed that Among 427 consecutive adults ICU mortality was 48.7%(31). When compared to LMIC averages, African ICU mortality is higher, likely due to resource limitations, high burden of infectious diseases, and delayed healthcare access(8).

Ethiopia has a high ICU mortality burden compared to global standards. As stated in a national systematic review and meta-analysis, the pooled ICU mortality rate in Ethiopia is approximately 39.7%(9). Similarly, subgroup analysis revealed that mortality in Oromia region is around 41%, which is comparable to the setting of the current study(10). Several primary studies in Ethiopia have reported varying ICU mortality rates. A study conducted in Jimma University Specialized Hospital reported ICU mortality of 50.4%, which is among the highest in the country(10). In contrast, a study from Gondar University Hospital reported mortality of 38.7%, indicating regional variation(11).

Similarly, a study conducted in Addis Ababa among mechanically ventilated patients found mortality of 60.7%, highlighting the impact of disease severity(12). Another study from Debre Berhan reported a lower mortality rate of approximately 30%, possibly due to differences in case mix and ICU capacity(13). One study done at Hawassa University

Comprehensive Specialized Hospital ICU showed that In-patient mortality rate was 45.8%(32). When compared across these studies, ICU mortality in Ethiopia shows significant variability, emphasizing the importance of hospital-specific research.

2.2. Associated factors of In-hospital ICU Mortality

Predictors of in-hospital ICU mortality can be broadly categorized into demographic, clinical condition and severity, and treatment-related factors. As stated in multiple studies, these predictors reflect both severity of illness at admission and quality of care provided in the ICU (4,5).

2.2.1. Demographic associated factors

Age is one of the most consistently reported predictors of ICU mortality. As stated in a global cohort study, advanced age is associated with increased ICU mortality, largely due to decreased physiological reserve and higher prevalence of comorbidities. Similarly, a large systematic review reported that patients aged ≥ 65 years have significantly higher mortality compared to younger patients. When compared to high-income countries, LMIC studies demonstrate a similar trend, although the age threshold may vary due to differences in population structure (6).

Study done in Nigeria showed that overall ICU mortality among elderly was 58.1%(33). Another study done in morocco among elderly patients admitted to medical ICU showed that the overall ICU mortality was 44.7%, and 64% of deaths occurred within 5 days of admission and the median age was 70 years (interquartile range 67 - 75 years)(34).

Similarly, Ethiopian studies confirm that advanced age is associated with increased mortality, although some studies report weaker associations due to younger ICU populations(16). One study from Debreberhan showed age greater than or equal to 60years strongly associated with high ICU mortality(35).

The relationship between sex and ICU mortality remains inconsistent. As stated in some studies, male sex is associated with higher ICU mortality, possibly due to higher burden of comorbidities and risk behaviors. In contrast, other studies found no significant association between sex and ICU outcomes(7).

Similarly, Ethiopian studies report inconsistent findings, with some showing no statistically significant association(16). When compared across regions, sex appears to be a less consistent predictor compared to clinical variables.

2.2.2. Neurological Status (Glasgow Coma Scale - GCS)

Neurological status at admission is one of the strongest predictors of ICU mortality. As stated in the APACHE and other severity scoring systems, low GCS is strongly associated with increased mortality(36). A global study found that patients with GCS < 9 have significantly higher mortality rates, often exceeding 50%(37).

Low GCS is frequently associated with delayed presentation and limited access to early intervention. In African settings, studies consistently identify GCS < 8–9 as a major predictor of death, particularly in patients with sepsis, trauma, or central nervous system infections(7). Similarly, Ethiopian studies report that altered mental status increases mortality risk significantly, with one study showing more than a 10-fold increase in risk(8). Study done at university of Gondar teaching and referral hospital showed that low GCS is strongly associated with increased Medical ICU mortality(11). Another study done at Hawassa comprehensive specialized hospital showed that GCS<13 is significantly associated with increased ICU mortality(32). When compared across all predictors, GCS remains one of the most reliable and consistent indicators of ICU outcome.

2.2.3. Sepsis and Septic Shock

Sepsis is a leading cause of ICU admission and mortality worldwide. As stated in the Sepsis-3 definition, sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection(15). Globally, sepsis accounts for a large proportion of ICU deaths, with mortality rates ranging from 25% to 40%, are increasing to over 50% in septic shock. (38)

A systematic review done in sub-Saharan Africa showed the ICUs pooled prevalence and mortality of sepsis was 31% and 46% respectively. Based on the sub-group analysis, the pooled prevalence in the ICU was 14% and 13% for East and Southern Africa, respectively. The hospital-wide and ICU-based sepsis prevalence and mortality are high in sub-Saharan Africa(39). Study done at eastern cape tertiary hospital in south Africa showed that sepsis is strongly associated with medical ICU mortality(25). Another study done in Democratic Republic of the Congo (DRC) among septic patients ICU mortality was 78%, with most deaths occurring within the first five days of admission(40).

Similarly, Ethiopian studies identify sepsis and septic shock as major predictors of ICU mortality, often associated with multi-organ failure. When compared to non-septic patients, septic patients have significantly higher mortality due to systemic inflammation, circulatory collapse, and organ dysfunction(37).

Study done in North West Ethiopia among five teaching hospitals showed that the overall ICU mortality among septic shock patients was 58.29%(41).Recent studies confirm that lactate levels, SOFA score, and comorbidities remain strong predictors of mortality(38,42,43).

2.2.4. Mechanical Ventilation (MV)

Mechanical ventilation is a critical life-saving intervention but is also strongly associated with increased mortality. As stated in global studies, patients requiring mechanical ventilation have significantly higher mortality due to underlying disease severity(36).

Similarly, a large cohort study reported that mortality among ventilated patients ranges from 30% to 50%, depending on the indication. In LMICs, mortality among ventilated patients is even higher due to limited ventilator availability and lack of expertise(44).

In African ICUs, mechanical ventilation is consistently associated with poor outcomes, with mortality rates often exceeding 50%. One study from Uganda showed that the necessity of mechanical ventilation was significantly associated with high ICU mortality. (28) Another study from Zambia showed that requirement of mechanical ventilation is strongly associated with high ICU mortality rate(45).

Similarly, a study from Ethiopia reported mortality of 60.7% among ventilated patients, highlighting the severity of illness and resource limitations. When compared to non-ventilated patients, the increased mortality reflects both disease severity and complications such as ventilator-associated pneumonia (VAP) (7,12).

One study done at Addis Abeba governmental hospital showed mechanical ventilation requirement strongly associated with high ICU mortality(46). Another study from debreberhan also relieved that mechanical ventilation requirement was strongly associated with high ICU mortality(35).

2.2.5. Use of Vasopressors

The requirement for vasopressors is an important indicator of hemodynamic instability and shock. As stated in global studies, use of vasopressors is independently associated with increased ICU mortality, particularly in septic shock(47).Similarly, patients requiring vasopressors have higher mortality due to persistent hypotension and impaired tissue perfusion. In LMICs, vasopressor use is often associated with worse outcomes due to delayed initiation and limited monitoring(48,49).

In African settings, studies show that patients requiring vasopressors have significantly higher mortality, particularly in septic and cardiogenic shock. Similarly, Ethiopian studies confirm that vasopressor use is a strong predictor of mortality, reflecting severe illness at admission(37). When compared to other predictors, vasopressor requirement is a marker of advanced disease and circulatory failure.

2.2.6. Shock and Hemodynamic Instability

Shock is a major determinant of ICU mortality. As stated in global studies, hypotension and shock significantly increase the risk of death, particularly when associated with organ dysfunction(37).

Similarly, septic, cardiogenic, and hypovolemic shock are all associated with high mortality rates. In LMICs and African settings, delayed recognition and treatment of shock contribute to poor outcomes. Ethiopian studies also identify shock as a significant predictor of ICU mortality(7,12,13).

2.2.7. Organ Dysfunction (AKI, MODS)

Organ failure is a critical predictor of ICU mortality. As stated in global studies, multi-organ dysfunction syndrome (MODS) is associated with very high mortality rates(15). Similarly, acute kidney injury (AKI) is a strong predictor of death in ICU patients(16). In LMICs, lack of dialysis and supportive care worsens outcomes in patients with organ failure. One study from South Africa showed that acute renal failure is strongly associated with high ICU mortality(50). Ethiopian studies also confirm that AKI and MODS significantly increase mortality risk(37). Study done at Hawassa comprehensive specialized hospital showed that development of AKI is associated with increased ICU mortality(32).

2.2.8. Length of ICU Stay

Length of ICU stay has a complex relationship with mortality. As stated in several studies, short ICU stay (<5 days) is often associated with early death due to severe illness. In contrast, prolonged ICU stay may reflect either survival or complications such as infections (44).

As reported in study done in university of Gondar length of ICU < 4 days is associated with increased ICU mortality(11). Similarly study done in Hawassa comprehensive specialized hospital also showed that ICU stay less than 3 days was associated with high ICU mortality rate(32).

2.2.9. Comorbidities

Comorbid conditions such as diabetes, hypertension, and chronic organ disease significantly affect ICU outcomes. As stated in global studies, patients with comorbidities have higher mortality due to reduced physiological reserve.

One study from Turkey showed that hypertension, coronary artery disease and chronic renal failure were strongly associated with high ICU mortality rate(51). One study from Zambia showed that ICU mortality among AKI patients strongly associated DM with 2.82 times more likely to die in ICU compared to those without it. Compared to patients without respiratory disease, those with respiratory disease were 2.57 times more likely to die in ICU(45). Similarly, Ethiopian studies report increased mortality among patients with underlying chronic diseases(16).

2.3. Conceptual frame work

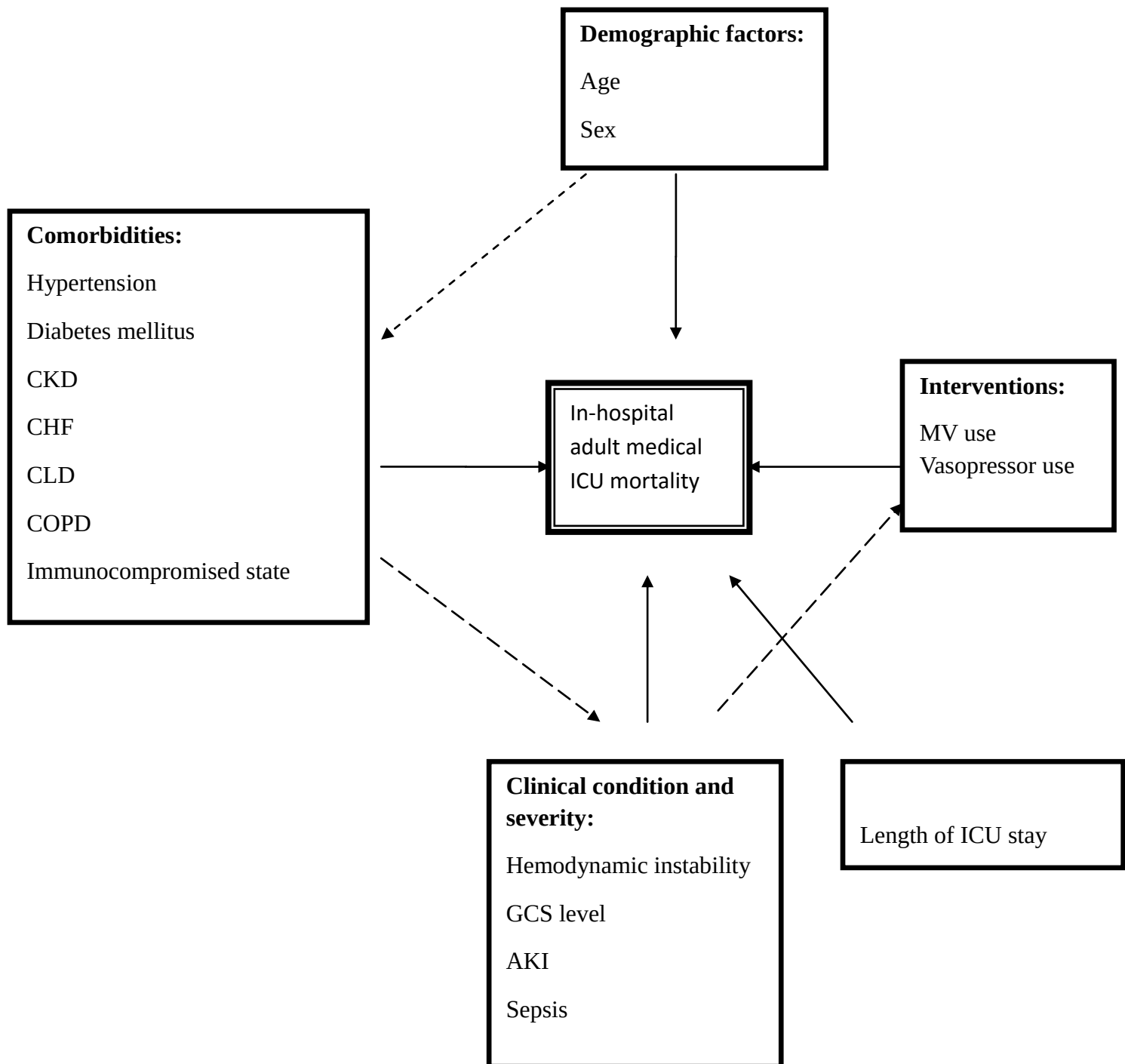


Figure 1: Conceptual framework Magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted at wallaga University Comprehensive Specialized Hospital,2026 (7,8,12,15,33,51).

2.4. Objectives

2.4.1. General Objective

To determine the magnitude and associated factors of in-hospital intensive care unit mortality among adult medical patients admitted to intensive care units at Wallaga University Specialized Hospital between January 1, 2023 and December 31, 2025

2.4.2. Specific Objectives

- I. To determine the magnitude of in-hospital intensive care unit mortality among adult medical patients admitted to intensive care units at Wallaga University Specialized Hospital between January 1, 2023 and December 31, 2025.
- II. To determine associated factors of in- hospital intensive care unit mortality among adult medical patients admitted to intensive care units at Wallaga University Specialized Hospital between January 1, 2023 and December 31, 2025

3. Methods and materials

3.1. Study area and Period

The study will be conducted at Wallaga University Comprehensive Specialized hospital. It is located in Nekemte town, Oromia Regional state, which is 331 km west of Addis Ababa, the capital city of country. The Hospital started to give service in 2017 and it has been giving service for the past 8 years with some renovations and expansions. It has got its current name Comprehensive specialized hospital in 2024 by Federal ministry of health and oromia health bureau. More over the Hospital is providing service for about 3.5 million people. It has greater than 250 bed capacity distributed among clinical department of Internal medicine, Surgery, Gynecology/Obstetrics, Pediatrics, Intensive care unit and Oncology units.

WUCSH ICU has a total of 6 beds with 3MV. 1:1 nurse-to-patient ratio, physician –to-patient ratio varies each month depending on the attaching residents.

The study will be conducted among adult medical patients admitted to the intensive care unit at WUCSH between January 1, 2023 and December 31, 2025.

3.2. Study design

An institution-based cross-sectional study will be conducted.

3.3. Population

3.3.1. Source Population

The source population will be adult medical patients admitted to the ICUs of Wallaga university comprehensive specialized hospital.

3.3.2. Study population

The study population will be adult medical patients admitted to the ICUs of Wallaga university comprehensive specialized hospital between January1, 2023 and December 31, 2025.

3.3.3. Study unit

Study units will be selected adult medical patients admitted to ICU of WUCSH who full fill inclusion criteria from study population.

3.4. Inclusion and Exclusion Criteria

3.4.1. Inclusion Criteria

Medical Patients aged 18 years and above who were admitted to ICU of WUCSH during the study period.

3.4.2 Exclusion Criteria

Patients whose medical records are incomplete or lack clinical information required for the study will be excluded.

3.5. Variables

3.5.1. Dependent variables

In-hospital ICU mortality

3.5.2. Independent variable

Sociodemographic characteristic: Age, Sex

Comorbidities: Hypertension, DM, CKD, CLD, CHF, Immune compromised state

Clinical condition and severity: Admission blood pressure, Respiratory rate, Pulse rate, Oxygen Saturation, Glasgow coma scale, AKI, Sepsis

Length of ICU study

Interventions: MV use, Vasopressor use

3.6. Sample Size Determination and Technique

3.6.1. Sample size determination

The sample size for the first objective will be determined using the single population proportion formula because the objective aims to estimate the magnitude of in-hospital mortality. So, using single population proportion formula with the following assumption given that the mortality rate at medical intensive care unit was 38.7% as reported in retrospective study conducted in University of Gondar comprehensive specialized hospital(11).

$$\text{Sample size } n = \frac{\left[(z_{\alpha/2})^2 \times p(1 - p) \right]}{d^2}$$

Z= Standard normal distribution value at 95% CI= (1.96)²

p= MICU mortality rate (0.387).

d= margin of error (0.05)

Therefore, $n = [(1.96)^2 (0.387 \times (1-0.387))] / (0.05)^2 = 364$

So, by adding 10 % contingency for incomplete records, the final sample size for first objective will be 400.

The sample size for the second objective will be determined by using the EPI info 7 as follows:

Table 1 sample size calculation for second objective for associated factors of in-hospital ICU mortality among adult medical patients admitted to ICU at Wallaga University Comprehensive Specialized Hospital, 2026.

Factor	%exposed	%unexposed	Ratio	CI (%)	Power (%)	OR	RR	final sample size	REFERENCE
MV	103	103	1	95	80	4.3	3.7	206	(11)
Low GCS	230	230	1	95	80	2.8	2.6	460	(11)
Length of ICU stay	70	70	1	95	80	5.6	4.5	140	(11)

Sample size will be calculated separately for each specific objective, and the largest sample size obtained will be selected. The highest sample size was 460 patient charts, calculated for the second specific objective. After adding a 10% contingency for incomplete or missing data, the sample size increased to 506. Since the source population was less than 10,000, a finite population correction will be applied to obtain the final adjusted sample size using the following formula:

$$nf = \frac{n_o}{1 + \frac{n_o}{N}}, \text{ where } nf = \text{final sample size}$$

n_o = initial sample size

N = Total adult medical ICU admission during study period

$$nf = \frac{506}{1 + \frac{506}{530}}$$

$$nf = 259$$

Therefore, the final sample size for this study will be 259.

3.6. 2. Sampling procedures

During the study period, 530 adult medical ICU patients were admitted to WUCSH and constituted the sampling frame. The required sample size will be 259 patient charts. A systematic random sampling technique will be employed. The sampling interval (K) was determined by dividing the total number of eligible patient charts by the required sample size: $K = N/n = 530/259 = 2.04$ which are approximately 2. The first chart will be selected by lottery method from the first two charts. Subsequently every second chart will be selected.

3. 7. Operational definitions

In-hospital ICU mortality: Death of a patient occurring during ICU stay or before discharge from the hospital after ICU admission(2).

Incomplete medical record: A patient chart in which the primary outcome variable (survival status at hospital discharge) or 10% independent variables required for the analysis cannot be obtained from the medical record despite review of all available documentation.

Medical ICU patient: A patient admitted to the ICU for non-surgical, non- obstetric and non-trauma-related medical conditions, such as sepsis, respiratory failure, cardiovascular diseases, or metabolic disorders.

Glasgow Coma Scale (GCS): A neurological scoring system used to assess level of consciousness, ranging from 3 to 15, categorized as: Severe: ≤ 8 Moderate: 9–12 Mild: 13–15(15).

Hemodynamic instability: Documentation of systolic blood pressure <90 mmHg, mean arterial pressure <65 mmHg.

Sepsis: Life-threatening organ dysfunction caused by a dysregulated host response to infection, identified clinically or documented in patient records(52).

Septic shock: A subset of sepsis characterized by persistent hypotension requiring vasopressors and elevated lactate levels despite adequate fluid resuscitation(52).

Mechanical ventilation (MV): Use of a mechanical ventilator to provide respiratory support, including invasive ventilation via endotracheal tube.

Vasopressor use: Administration of medications such as norepinephrine, dopamine, or epinephrine to maintain adequate blood pressure in patients with shock(52).

Shock: A clinical state of inadequate tissue perfusion, evidenced by hypotension and signs organ dysfunction(52).

Acute Kidney Injury (AKI): Sudden decline in renal function identified by increased serum creatinine or reduced urine output(52).

Length of ICU stay: Number of days from ICU admission to ICU discharge or death.

Comorbidity: Presence of one or more chronic diseases (e.g., diabetes, hypertension, chronic kidney disease, HIV) documented in the patient's medical record.

Immunocompromised state: presence of one or more of the following:-HIV infection, malignancy, immunosuppressive therapy, or post-transplant status.

3.8. Data collection instruments and data collection procedures

Data will be collected using a structured and pretested data extraction sheet developed based on the objectives of the study and relevant literature(11,12,22–24,32–35). The tool will be designed to capture all necessary variables, including socio-demographic characteristics, clinical features, laboratory findings, treatment interventions, and patient outcomes. The data extraction checklist will be prepared in English and organized in a logical sequence to ensure consistency and completeness during data collection.

The data will be obtained from ICU admission and discharge logbooks. Each selected patient's medical record number will be used to retrieve the corresponding chart from the medical record department. Data collectors will review each chart thoroughly to extract relevant information according to the predefined variables.

The data collection will be conducted by two well-oriented BSc nurses working in ICU who will be supervised by one internal medicine resident not involved as the principal investigator. Prior to data collection, comprehensive orientation will be provided to ensure a clear understanding of the study objectives, variables, data extraction tool, and ethical considerations, including confidentiality and data handling procedures. The orientation will

also emphasize uniform interpretation of clinical variables to minimize inter-observer variability.

3.9. Plan for Data processing and analysis procedures

Data collection forms will be reviewed daily for completeness, consistency, and accuracy before data entry. All collected data will be coded and entered into EpiData version 4.6, which will be used for data management, validation, and data cleaning. During the data entry process, range checks, consistency checks, and verification procedures will be performed to minimize entry errors and ensure data quality. Following data cleaning in EpiData, the dataset will be exported to Statistical Package for the Social Sciences (SPSS) version 27 for further analysis. Prior to conducting statistical analyses, the dataset will be thoroughly examined for completeness, accuracy, missing values, outliers, and internal consistency. Any identified discrepancies or inconsistencies will be cross-checked against the original data collection forms and corrected accordingly.

Descriptive statistics will be employed to summarize the sociodemographic characteristics of the study participants, including variables such as age and sex. Clinical profiles—such as admission diagnosis, blood pressure on admission, level of GCS, length of hospital stay, use of mechanical ventilation, vasopressor use and the presence of comorbidities—will also be described. Frequencies and percentages will be used for categorical variables, while means and standard deviations (SDs) will be calculated for continuous variables. Furthermore, in-hospital ICU mortality rate will be assessed and reported using descriptive measures. Factors potentially associated with in-hospital ICU mortality—including age, GCS level, use vasopressor and use of MV—will be described using similar statistical methods.

For bivariate analysis, the association between each independent variable and in-hospital ICU mortality will be assessed using binary logistic regression. Categorical variables such as sex and presence of comorbidities will be summarized using frequencies and percentages, while continuous variables such as blood pressure) will be presented as means $\pm$ standard deviation (SD). Variables with a p-value < 0.25 in the bivariate analysis will be considered as candidates for multivariable analysis.

Subsequently, multivariable logistic regression analysis will be performed to identify independent factors associated with in-hospital ICU mortality, while controlling for potential confounders.

The fitness of the model will be assessed using the hosmer-lemeshow test, and multicollinearity will be checked using variance inflation factor adjusted odds ratio (AOR) with 95% confidence interval will be reported, and statistical significance will be declared at $p < 0.05$.

The model will be constructed using the forward likelihood ratio method. Adjusted Odds Ratios (AOR) with 95% Confidence Intervals (CI) will be used to report the strength of associations, and statistical significance will be determined at a $p\text{-value} < 0.05$.

3.10. Data quality assurance

To ensure data quality, several quality assurance measures will be implemented throughout the data collection and processing phases. A pre-test of the data extraction tool will be conducted on 5% of the calculated sample size two weeks prior to the actual data collection. This pilot test will take place at the study area, ICU of WUCSH to assess the clarity, consistency, and appropriateness of the tool. Based on the findings from the pre-test, necessary modifications will be made to improve the data extraction tool.

During the data collection period, the completeness and consistency of each filled questionnaire will be checked daily in the field by the supervisor and the principal investigator. In cases of incomplete or incorrect data, the chart will be reviewed on the same day if possible. To reduce data entry errors, a double data entry method will be used in Epi data Version 4.6. During the data cleaning phase, proper categorization, coding, and validation of responses will be performed to ensure the integrity of the dataset before analysis.

3.11. Ethical consideration

Prior to the commencement of the study, ethical clearance and approval will be obtained from the Institute of Health Science Research Ethics Committee (IHSREC) of Wallaga University. The ethically approved protocol will be submitted to the Medical Director's Office at Wallaga University Comprehensive Specialized Hospital (WUCSH).

In addition, formal permission will be sought from the Department of Internal Medicine, the head physician of the ICU director and the ICU nursing staff. The purpose, relevance, and potential benefits of the study will be clearly explained to all relevant stakeholders.

Confidentiality and privacy will be strictly maintained throughout the study. Identifiable personal information such as names and addresses will not be recorded on the questionnaire; instead, unique codes will be assigned to each participant to ensure anonymity. All collected data will be securely stored and accessible only to the principal investigator.

This study does not pose any environmental risk or promote gender-based discrimination. All individuals meeting the inclusion criteria will have an equal opportunity to participate, regardless of gender or background.

3.12. Dissemination plan

The final results of this study will be formally presented to the Department of Internal Medicine, Institute of Health Sciences, and Wallaga University. In addition, the findings will be shared with relevant stakeholders, including WUCSH medical director office and ICU director.

Efforts will also be made to disseminate the findings through presentations at academic and professional conferences. Furthermore, the study will be submitted for publication in peer-reviewed international journals to ensure broader visibility and to contribute to the global body of knowledge on in-hospital mortality and predictors.

4. Work plan

Table 2 Work Plan to Assess Magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted to ICU at Wallaga University Comprehensive Specialized Hospital, 2026.

S. N	Activities	Responsible Body									
			March 2026	April 2026	July 2026	Aug 2026	Sept 2026	Oct 2026	Mar 2027	Apr 2027	

1	Prepare proposal and submit to Advisors	I								
2	Proposal defending	I								
3	Obtaining ethical clearance	I								
4	Training of data collectors & pretest	I and DC								
5	Conduct Data collocation	I and DC								
6	Data entry and Cleaning	I and DC								
7	Data Analysis and write up	I								
8	Research defense	I								
9	Submission of final completed research paper	I								

KEY

I Investigator

DC Data collectors

5. Budget

Table 3. Budget Breakdown for Undertaking a Research Study on magnitude of in-hospital ICU mortality and associated factors among adult medical patients admitted at Wallaga University Comprehensive Specialized Hospital, 2026.

S. no	Budget category	Unit cost in birr	Multiplying factor		Total cost (ETB)
	Personnel	Fee per chart	Number of staff	No. charts	

1	Medical record officers	7	5	259	1,813
	Data collectors	50	2	259	12,950
	Advisors	2500	2	5000	
	Sub-total 1 = 19,763ETB				
2	Supplies	Cost per item	Number		
	Photocopy	2.50 birr	1200 page		6000
	Pen	15.00birr	10		150
	Pencil	10.00birr	10		100
	Eraser	15.00birr	5		75
	Sharper	15.00birr	2		30
	Printing	5.00 birr	50 pages *10 = 500 pages		2500
	Binding	30.00 birr	30*10copies		300
	Subtotal 2 = 9,155				
	Total	1+2= 28,918ETB			
3	Contingency (10%) = 4037.5				
4	Grand total	1+2+3= 31,809.8ETB			

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Annexes

Annex I: Data extraction sheet

Date of Data Collection: _____

Data Collector: _____

SECTION I: SOCIO-DEMOGRAPHIC CHARACTERISTICS

1. Medical Record Number: _____
2. Age (years): _____
3. Sex 1.Male 2. Female
4. Residence 1.Urban 2. Rural

SECTION II: ADMISSION CHARACTERISTICS

5. Source of Admission 1. Emergency Department 2. Medical Ward
6. Primary Diagnosis at ICU Admission _____
7. Presence of Comorbidity 1. Yes 2. No
8. Type of Comorbidity (multiple responses possible) 1. Hypertension 2. Diabetes Mellitus 3. Chronic Kidney Disease 4. Heart Failure 5. Chronic Liver Disease 6. HIV/AIDS 7. COPD 8. Immunocompromised state 9 Other (specify) _____

SECTION III: CLINICAL CHARACTERISTICS

11. Glasgow Coma Scale at Admission ____ /15
12. Systolic Blood Pressure (mmHg) _____
13. Diastolic Blood Pressure (mmHg) _____
14. Mean Arterial Pressure (mmHg) _____
15. Heart Rate (beats/minute) _____
16. Respiratory Rate (breaths/minute) _____
17. Oxygen Saturation (%) _____
18. Temperature (°C) _____
19. Hemodynamic Instability at Admission 1. Yes 2. No
20. Shock Present 1. Yes 2. No
21. Type of Shock 1. Septic 2. Cardiogenic 3. Hypovolemic 4. Obstructive 5. undifferentiated

SECTION IV: LABORATORY PARAMETERS

22. Hemoglobin (g/dL) _____
23. White Blood Cell Count (cells/mm³) _____
24. Platelet Count (cells/mm³) _____
25. Serum Creatinine (mg/dL) _____
26. Blood Urea Nitrogen (mg/dL) _____
27. Random Blood Sugar (mg/dL) _____
28. Serum Sodium (mEq/L) _____
29. Serum Potassium (mEq/L) _____

SECTION V: ICU MANAGEMENT CHARACTERISTICS

30. Mechanical Ventilation 1. Yes

2. No

31. Duration of Mechanical Ventilation (days) _____

32. Vasopressor Use 2. No

33. Type of Vasopressor 1. Norepinephrine/noradrenalin 2. Dopamin 3. Epinephrine/adrenalin 4. Dobutamine 5. Other (specify) _____

34. Oxygen Therapy 1. Yes 2. No

35. Blood Transfusion 1. Yes 2. No

SECTION VI: ICU COURSE

38. Length of ICU Stay (days) _____

39. ICU-Acquired Infection 1. Yes 2. No

40. Cardiac Arrest During ICU Stay 1. Yes 2. No

41. Complications Developed During ICU Stay 1. Yes 2. No

42. Type of Complication 1. Hospital-acquired infection 2. Sepsis/Septic shock 3. Acute kidney 4. Cardiac arrest 5. Arrhythmia 6. Pressure ulcer 7. DVT/PE 8. Acute respiratory failure 9. Major bleeding 10. Other (specify) _____

SECTION VII: OUTCOME VARIABLES

43. Outcome at ICU Discharge 1. Alive

2. Dead

44. If dead, Immediate Cause of Death _____

Annex II: Investigator assurance form

I the undersigned resident agree to accept all responsibilities for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as per the terms and conditions of the Research and Publication Committee and /or Department of Internal Medicine, of Wallaga University. I also assert that this proposal is my original work and that all sources of materials used for the proposal have been accordingly acknowledged.

Name of Resident

Signature.....

Date.....

Approval of Advisors

1. Name of Advisor.....

Signature:

Date

2. Name of co-Advisor.....

Signature:

Date