



**The Effect of an integrated Mobile Health Platform on early detection
of clinical outcomes of Critical ill patients
Protocol**

Submitted for Partial Fulfillment of the Requirements For doctoral degree
in Critical Care and Emergency Nursing

Submitted by

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Introduction:

The intensive care unit (ICU) functions as a highly specialized, patient-centered component within the broader healthcare framework, designed to manage critical physiological instability with precision and responsiveness. At its core, it integrates complex technological infrastructures with the coordinated efforts of a multidisciplinary workforce trained to navigate acute, rapidly evolving clinical scenarios. **(Vernic et al.,2025)**

Critical care nurses are essential members of the intensive care team who must continuously and accurately monitor, analysis and record physiological parameters to spot early changes in patients' states, ascertain their prognosis, and inform the appropriate doctors of the patient's condition, as well as recognition of any subtle changes and outcomes of care 24 hours. **(Jones et al., 2021)**

Critically ill patient is one who needs intensive care and is at high risk for real or future life-threatening health issues. A patient is typically admitted to the ICU for the following reason: either the patient is physiologically unstable, risk for catastrophic complications, will require frequent assessments or required cardiopulmonary support **(Jackson, & Cairns, 2021).**

Clinical deterioration in critically ill patients is a common phenomenon that can occur several hours before an adverse outcome. Early detection of subtle changes in vital signs, such as alterations in pulse and blood pressure, is crucial in preventing adverse events. However, these are not often recognized early enough to prompt quick intervention. This increases the chances of adverse events occurring. **(Davwar et al.,2023).**

Monitoring of critical care patients depends on direct observation and physical examination and is intermittent, with the frequency depending on the patient's illness. Other monitoring is ongoing and continuous, provided by complex devices that require special training and experience to operate. Most such devices generate an alarm if certain physiologic parameters are exceeded. Every intensive care unit (ICU) should strictly follow protocols for investigating alarms **(Sundrani et al., 2023)**

There are measures that can improve the recognition of acute deterioration and reduce the likelihood of major adverse events such as all-cause mortality. These measures include the implementation of Early Warning Scores (EWS) such as the National and Modified Early Warning Scores (NEWS and MEWS) which generate aggregate scores based on single point in time observations and have also been implemented in automated computerized systems. **(Bassin et al., 2023)**

Despite the widespread adoption of EWS algorithms and associated escalation protocols, patient outcomes have not improved significantly. It is possible that errors in the calculation of the EWS are partially to blame. Studies have shown that errors in the calculation of EWS are common and failure to calculate the correct EWS may result in failure to take the correct action. Other barriers to escalation include delays in documentation, lack of familiarity with the protocol, failure to follow the protocol escalation, and poor communication. **(Subbe & Bramley , 2022).**

The digital revolution is transforming ICU care by enhancing efficiency, precision, and responsiveness across critical domains, from patient outcomes to safety. In patient outcomes, real-time monitoring and predictive analytics help detect health changes early, improving survival

and recovery rates. Recent advances in ICU digitalization, particularly the use of Machine learning (ML) and electronic health records (EHRs), have shown promising potential to improve patient outcomes by enhancing mortality prediction and optimizing care delivery. **(Vernic et al.,2025)**

Significance of the Study:

Patient deterioration is the physiological decompensation that occurs when a patient experiences worsening conditions or acute onset of a serious physiological disturbance that increases their risk of serious adverse health events (**Bamgboje-Ayodele et al., 2025**) Delayed recognition of hemodynamic and respiratory deterioration during hospitalization may increase morbidity and mortality rates. **(Bassin et al., 2023)** **Melaku, et al., (2024)** reported that ICU mortality rate was 46.8% in there study of Determinants of mortality of patients admitted to the intensive care unit at Debre Berhan comprehensive specialized hospital.

According to current records in intensive care unit at Sohag University Hospital in the year of (2025) revealed that the number of patients admitted to intensive care unit were approximately 700 patients the mortality rate of theme was (43.3 %) **(Hospital records of Sohag University 2025).**

The transition from paper-based to digital and mobile-integrated early warning systems is essential for achieving timely rescue interventions **(Subbe & Bramley2022).**

Therefore, an integrated mobile health platform will be carried out in these study as it enables analyzing total rather than isolated values as improving the accuracy of deterioration prediction and therefore improve the outcomes of the patients.

Aim of the Study:

This study will aim to examine the Effect of integrated Mobile Health Platform on early detection of clinical outcomes of Critical ill patients.

Operational definitions

Mobile health (mHealth) platform: is a digital ecosystem using mobile devices—smartphones, tablets tools track the patients’ data (respiratory rate, oxygen saturation, blood pressure, heart rate, conscious level, body temperature and urine output) to support clinical decision. With notification when there any abnormality.

Outcomes: length of stay, mortality rate, respiratory complication (pulmonary edema, pulmonary embolism, pneumothorax, Pneumonia, ARDS and difficult weaning), cardiac complications (cardiac arrest, myocardial dysfunction, shock and arrhythmia), renal complication (acute renal failure)

Hypothesis

H1: Implementing Mobile Health Platform will decrease length of stay of patients in ICU.

H2: Implementing Mobile Health Platform will decrease mortality rate of patients in ICU.

H3: Implementing Mobile Health Platform will decrease respiratory complications of patients in ICU.

H4: Implementing Mobile Health Platform will decrease cardiac complications of patients in ICU.

H5: Implementing Mobile Health Platform will decrease renal complication of patients in ICU.

Research design:

Quasi experimental research design will be used to achieve the aim of the study.

quasi-experimental design is the most frequently used quantitative research design. With this approach, the independent variable is still manipulated and there is a control group, but there is no randomization. **(Carol Boswell, Sharon Cannon 2018)**

Setting:

This study will be carried out in the **General Intensive Care Unit (ICU)** at **Sohag University Hospital**, which located in Sohag governorate, Egypt. The **General ICU** consists of **twenty beds** distributed across **four separated rooms**, with each room containing five beds. This setting will be chosen due to its high volume of critically ill patients who need close monitoring.

Sample:

The study sample size was calculated by power analysis using (Epi-Info program) applying the following information:

- ☐ Expected frequency =50%
- ☐ Acceptance error =5%
- ☐ Confidence coefficient =95%
- ☐ design effect=1
- ☐ Power=80%.

So that A convenient sample of 250 adult patient (age 18-60 years) and recently admitted to ICU.

Patients will be assigned into two equal groups; **group “A”** (control group) will be subjected to the usual care, while **group “B”** (study group) will be subjected to Mobile Health Platform.

Study tools:

Tool (I): A The smart phone based patient assessment tool The researcher developed this tool after examining related literature (Cui, et al 2021; Münzel et al 2019; (Brekke et al., 2019; Rivera-Fernández et al., 2012 ; Considine et al., 2016). that was divided into two parts.

This tool included two parts:

- **Part (1) demographic data** consists of five items code, age, gender, level of education, occupation, marital status, and smoking.
- **Part (2) clinical data** consists of four items (past medical and surgical history, current diagnosis, obesity index and type of ventilation)

Tool (II): The smart phone based National Early Warning Score 2 and predictive dashboard:

This tool was adapted by researchers based on the related literature (Royal collage of Physician, 2017; Alias & Ludin, 2021) An updated version that better accommodates patients with chronic hypoxia (e.g., COPD) and includes delirium in the consciousness chart, becoming the default for the NHS. It is used to improve acute disease evaluation, detect clinical deterioration, and initiate a competent clinical response in a timely manner (Eckart et al., 2019). It depends on seven easily obtained clinical parameters and produces a total score between 0 and 20. is adapted by researcher by adding urine output as it taken on 0, 3 and 7 days of admission

Scoring System (Color-Coded Risk Levels):

- o Level 1 (Green/Low): Score 0–3 (Stable).
- o Level 2 (Yellow/Moderate): Score 4–6 (Pre-symptomatic trend triggers urgent response).
- o Level 3 (Red/High): Score > 7 (Critical risk; triggers immediate action) or if the urine output less than 0.5 ml / kg / hr for 6 hours.

Tool (III): - The smart phone based patients' outcomes assessment tool

: this tool developed by researcher after examining related literature(Yoon et al., 2019; Sundrani, et al. 2023; (Younes, et al., 2017); Tajarernmuang et al. 2022). Will examine the patient for outcomes length of stay, mortality rate, respiratory complication (pulmonary edema, pulmonary embolism, pneumothorax, Pneumonia, ARDS and difficult weaning), cardiac complications (cardiac arrest, myocardial dysfunction, shock and arrhythmia), renal complication (acute renal failure).

Methods: The study will be conducted throughout three main phases, which are preparatory, implementation and evaluation phase.

Preparatory phase: -

- 1- Approval from the ethical committee, faculty of nursing, Assiut University will be obtained.
- 2- Permission to conduct the study will be obtained from the administrative authorities of the previously mentioned settings after explanation of the aim of the study and coordination between the researcher and responsible physician .
- 3- Development of the tools after reviewing the related literature.
- 4- The tools will be reviewed by a jury to assess the clarity, feasibility, applicability, and the content validity
- 5- The reliability of the adapted tools will be done after reviewing literature, using appropriate tests.
- 6- Before the implementation of the main study, a pilot study will be conducted in 10% of the total sample (25 patients) to evaluate the objectivity, feasibility and clarity of the data collection tools if there is a modification a sample of pilot study will be excluded from the study.

Ethical Considerations:

- 1- Research proposal will be approved from ethical committee in the faculty of nursing.
- 2- There is no risk for study subject during application of the research.
- 3- The study will follow common ethical principles in the clinical research.

- 4- Informed consent will be obtained from participants. It included the aim of the study, potential benefits, risks and discomforts from participation and the right to refuse to participate in the study. participants' privacy, anonymity and confidentiality of the collected data were maintained during the implementation of the study.
- 5- Anonymity will be assured.
- 6- Study participants will be assured that they have the right to refuse to participate and/or withdraw from the study without any rational at any time.
- 7- Study subject privacy will be considered during collection of data

Implementing phase:

- 1- NEWS 2 will performed on admission and if total score is (o) measures every 12 hours, (1-4) Minimum 4–6-hourly Score of 3 in a single parameter Minimum 1-hourly, Total score = 5 or more
- 2- Urgent response threshold Minimum 1-hourly, Total score = 7 or more: Emergency response threshold Continuous monitoring of vital signs
- 3- The alarm will be informed to the physician and the Clinical decision will be taken and recorded in the sheet.
- 4- Compare between patients' data is recorded using paper observation charts. And a Mobile Health Platform is used.

Evaluation phase:

- 1- Both groups will be evaluated to test the effectiveness of using (**tool II**)
- 2- the study and control groups were compared according to their outcomes using (**tool III**)

3- The collected data will be analyzed and compared using the appropriate statistical tests

Statistical Analysis Plan:

Data will be extracted, coded, and analyzed using the Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics will be utilized to summarize demographic and baseline clinical characteristics; continuous variables will be presented as means with standard deviations (SD) or medians with interquartile ranges (IQR) based on normality testing, while categorical variables will be expressed as frequencies and percentages.

Baseline comparability between the mHealth intervention group and the control group will be assessed using the Independent Student's t-test (or Mann-Whitney U test for non-normal data) for continuous variables, and the Chi-square test (or Fisher's exact test) for categorical variables. To evaluate the primary outcome, the ICU mortality rate between the two groups will be compared using the Chi-square test, and relative risk (RR) with a 95% confidence interval (CI) will be calculated.

For the secondary outcomes, the difference in the ICU length of stay (LOS) will be analyzed using the Independent t-test or Mann-Whitney U test. The incidence rates of organ-specific clinical complications (respiratory, cardiac, and renal) will be compared using the Chi-square test. A p-value of less than 0.05 ($p < 0.05$) will be considered statistically significant for all tests to determine the effectiveness of the

Discussion:

Discussion of the obtained finding will be done based on related literature.

Conclusion and recommendation:

Conclusion and recommendation will be obtained from the study

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