IS CRITICAL CARE SERVICE RELEVANT TO IRAN'S HOSPITAL CARE?

By

ALIREZA JEDDIAN M.D

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ABSTRACT

Delivering timely, safe, and optimal care to patients is an unalienable obligation of a health system and its workers; sub-optimal care, as a rule, ends up with deteriorating conditions for patients. This is certainly the case in general hospital wards, where an increasing number of acutely ill patients (AIP) are admitted, due to aging populations, advances in health technologies, and shortage of medical resources and beds in intensive care units (ICU), in particular. Failing to identify and manage AIPs may lead to catastrophic outcomes.

An exploratory study using qualitative content analysis of interviews data was carried out. Ten physicians and nurses participated in semi-structured interviews. This study aimed to define the current state of AIPs in Iranian hospitals. The qualitative study showed that flaws and shortcomings in the current services for identifying and managing AIPs. Implementing a Critical Care Service (CCS), aimed at timely identification and management of AIPs, was an approach to overcoming these shortcomings. An evaluation study was designed to explore the potential impact of CCS in an Iranian University Hospital. The study design was a Stepped-Wedge Cluster Randomized Controlled Trial (SW-CRCT).

I undertook SW-CRCT in a teaching general hospital with 800 adult beds. The CCS was introduced in sequence to 13 medical-surgical wards. The study included, for each ward, an unexposed to the intervention phase, a training phase, and an exposed to the intervention phase during which the ward went through a transition phase of adopting the intervention (CCS). All patients cared for during the unexposed; training

and exposed to the intervention phases were included as unexposed, training, and exposed respectively. The CCS team was nurse-led, and the CCS team members had responsibility for training and assisting the ward staff in caring for the AIPs. Patients admitted to study wards were categorised into three groups and their data was analyzed using three methods: all patients, matched randomized and before–after. The null-hypothesis was tested using the mixed effect logistic regression, linear mixed and the mixed effects models. Results show that during the 72-week period of the study, 21,042 admissions in 13 wards were included. The analysis included 7,802(37.1%) patients as unexposed, 10,880(51.7%) patients as exposed to the intervention and 2347(11.2%) patients as a training phase. The results showed a reduction in the primary outcomes (CPRs and mortality), but that this was not statistically significant: CPRs [Adjusted^ OR (95% CI=1.03 (0.71, 1.50)] and mortality [Adjusted^ OR (95% CI) = 0.84(0.50, 1.42)]. In addition, there are no significant differences in the secondary outcomes: length of stay [Adjusted^ OR (95% CI) = 0.83 (0.58, 1.17)] and ICU admission [Adjusted^ OR (95% CI) = 0.86 (0.22, 3.26)].

Implementation of a CCS failed to reduce a lower mortality rate of the acutely ill patients. A second qualitative study was conducted to find the views of staffs toward the CCS. Interviews and focus groups were carried out with 24 CCS team members, ward staff and collaborating physicians. The analysis of interviews and focus group discussions indicated that implementation of a CCS had had several favorable effects, including: (a) preparing the necessary supportive equipment and facilities; (b)

increasing the knowledge and experience of the hospital workforce; (c) adjusting the routine care activities and increasing sensitivity concerning AIPs; (d) caregiver-receiver satisfaction; and (e) disclosing medical errors and problems. In addition, the results of the qualitative study showed that overcoming structural and contextual problems in the hospital, prior to implementation of CCS, might facilitate its implementation.

To Acutely Ill Patients in Hospitals

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Acute Physiology And Chronic Health Evaluation	APACHE
Acute Physiology Score	APS
Acutely Ill Patients	AIP
Cardiopulmonary Resuscitation	CPR
Chronic Obstructive Pulmonary Disease	COPD
Cluster Randomised Clinical Trial	CRCT
Consolidated Standards Of Reporting Trials	CONSORT
Controlled Before-And-After Studies	CBAs
Controlled Clinical Trials	CCT
Critical Care Outreach Services	CCOS
Critical Care Outreach Team	CCOT
Critical Care Services	CCS
Do Not Resuscitation	DNR
Early Warning Scoring System	EWS
High Dependency Units	HDU
Institute For Healthcare Improvement	IHI
Intensive Care Unit	ICU
Length Of Stay	LOS
Medical Emergency Team	MET
Miastenia Gravis	MG
Ministry Of Health and Medical Education	MOHME
Multiple Logistic Regression Model	MLR
Not For- Resuscitation	NFR
Patient At Risk Team	PART
Randomised Clinical Trial	RCT
Rapid Response Team	RRT
Stepped Wedge - Cluster Randomized Clinical Trials	SW-CRCT
Stepped-Wedge	SW
Systematic Reviews	SR

Tehran University of Medical Siences	TUMS
Track and Trigger Warning Systems	TTS
Trinitroglycerin	TNG
World Health Organisation	WHO

CHAPTER 1

INTRODUCTION

Patients, upon admittance to hospitals assume that they are in a safe "haven" and will be provided with the best possible care, but in reality, that is not always the case. Evidence shows that sub-optimal care, in the form of unrecognized patient deterioration, delayed transfer to critical care areas and lack of critical care beds and expertise, exists and may result in acute worsening of the patient's condition. Critical Care Services (CCS) with different strategies such as the Medical Emergency Team (MET) in Australia, the Critical Care Outreach Team (CCOT) in the United Kingdom (UK) and the Rapid Response Team (RRT) in the US are followed for covering suboptimal care for acutely ill patients (AIP) in hospitals. The role of CCS is initially to ensure that patients at risk of becoming acutely ill receive appropriate and timely care in the non-critical units within the general wards of hospitals. Assessments indicate that the incidence of AIPs in Iranian hospitals is rising, and therefore sub-optimal care appears to be an important problem. Thus, the development of a strategy to combat this failing is essential.

This thesis, titled: *"Is Critical Care Service Relevant to Iran's Hospital Care?"* is about the implementation and evaluation of the effectiveness of CCS in a large teaching hospital in Tehran, Iran (Shariati Hospital). Shariati hospital is an adult general hospital affiliated with the Tehran University of Medical Science (TUMS).

This hospital is one of the most reliable teaching and referral centre in Iran, and was established in 1974. The hospital has 800 beds in 29 medical, surgical and critical care wards with 20,744 patients admitted and 20,732 discharged annually. These patients have an average length of stay (LOS) of 6.84 days and a gross mortality rate of 3.5% per year. Approximately 83.84% of the hospital beds are occupied at any given time.

The thesis is composed of 7 chapters. First, in chapters 2 and 3, the literature on the CCS and warning scoring systems will be reviewed. Then, in chapter 4, an exploratory study using qualitative methods aiming to define the current state of AIPs in Iranian hospitals will be presented. In chapter 5, the methodology, setting and analysis of cluster randomised controlled trials (CRCTs) in stepped-wedge (SW) design, used to explore the potential impact of CCS in the setting of an irannian University hospital, will be presented. After that, the carried out qualitative study as a focus group method to finding the views of staffs toward the CCS will be explained (chapter 6). Finally, the overall discussion will be presented in chapter 7.

1.1 HOSPITALS AND IMPROVING QUALITY OF CARE

Responsible health organizations always endeavor to enhance the quality of health services provided, by trying to optimize the quality of these services. Indeed, quality improvement in hospitals is a critical element of the provision of health services. On the other hand the complexities of hospital environments, rapid advances in medical technology, the increasing percentage of aged or elderly patients (1, 2), changes in

public demand and the growing rate of chronic diseases combine to make improving the quality of services a difficult task.

A large proportion of healthcare resources are assigned to hospitals, and so hospitals play a pivotal role in the provision of health services. Providing patients with health care is the primary responsibility of a hospital. It is essential that the care provided be of high quality, due to the fact that patients are continually being referred to hospitals, and in large numbers. Two indicators, which are assessed during quality control of a hospital, and are directly related to the quality of medical and nursing care, are mortality and LOS(3-5).

In the year 2000, the UK's Department of Health recommended that health care be categorised based on the level of care required by the patient, regardless of where this admittance has taken place. On this basis, in order to improve diagnosis and care patients were categorised as level 0 through 3. Level 0 consists of patients who are admitted to general wards and receive routine care. Level 1 represents patients with aggravated conditions who require more detailed observation and intervention. Level 2 consists of patients requiring further or more elaborate observation and interventions. And finally, Level 3 consists of patients requiring advanced respiratory support or those who require support and control of two or more organs (6, 7). Based on this categorisation, patients must be located in wards and provided with care in accordance to their level of requirements, to ensure that patients in levels 1, 2 and 3 receive appropriate care and CCS.

Nowadays, patients who require ICU and CCU are increasingly admitted to general wards. Admittance of AIPs to general wards is associated with higher rates of morbidity and mortality and researches have highlighted that the care of AIPs in general wards is suboptimal(8).

1.2 SUBOPTIMAL CARE AND ITS EFFECTS

Suboptimal care is frequently described as the failure to recognize abnormal vital signs, or the inappropriate treatment of AIPs by health professionals(9).Suboptimal care for AIPs is a worldwide problem, and so the World Health Organization (WHO) considers it as one of the priorities of research on patient safety (9, 10).

It is evident that many patients receive suboptimal care. In other words, diagnosis, treatment or referrals are delayed or the patients are not competently managed (8, 9). This may lead to adverse events and outcomes with catastrophic results, such as unexpected death, unplanned ICU admission or cardiac arrest (11-13). Adverse events and mortality following unorganized care for AIPs in general wards is a problem faced by hospitals worldwide(14), and NICE reports indicate that suboptimal care is responsible for one third of hospital mortality rates. This is based on the 2005 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report in the UKK(15).

Death registry in Iran is not as accurate as it should be, therefore reliable evidence for hospital mortality rates (either as a result of sub-optimal care, or otherwise) is lacking (16, 17).

Certain studies in Iran mention suboptimal care(18, 19), but few available studies have noted the detrimental impact of the shortage of nurses(19, 20), deficient professional knowledge of nursing staff, as well as inappropriate work management and work shifts(19) on the quality of care.

Studies conducted in other countries have mentioned lack of knowledge, failure to seek advice, failure to appreciate clinical urgency, complexities of patients' condition and lack of supervision as factors affecting the quality of care(8, 9, 11).

Suboptimal care also affects the patient's LOS(21). Few studies aiming to report LOS have been conducted in Iran. The mean LOS reported for burns is 8 days(22), 7.7 days for stroke(23), 6 days for cancer (24), and 48.5, 54.4, and 94.2 hours in obstetrics, surgery, and oncology units, respectively during the year 2011(25).

1.3 THE ICU BEDS DILEMMA

A large proportion of hospital costs (which dominate health expenditure in developed countries) arise from Intensive and Critical Care units(26).The results of a study conducted by Walsh et al (2008) indicate that no standard definition exists for the number of acute care hospital or ICU beds necessary in a hospital (even the hospitals within a country may differ in this respect).In addition, the ratio of the total number of hospital beds to population number varied almost three-fold, from 221/100,000 population in the United States to 593/100.000 in Germany. Also the number of Adult ICU beds varied seven fold from 3.3/100.000 population in the United Kingdom to 24.0/100,000 in Germany. The study indicates a strong, inverse

relationship between the number of ICU beds and the rate of in-hospital mortality for ICU patients (26). The ratio of hospital beds to population for Iran in the year 2009 was 185/100,000, and for adult ICU beds, this ratio changed to 5.2/100,000.

The total number of hospital beds in Iran (with a population of 70,000,000) in the year 2009 was 130,000, with 4,700 of these being ICU beds. Based on the strategic report of the Ministry of Health and Medical Education (MOHME), both groups of beds will be expanded to 141,000 and 7,400 beds respectively by the year 2014(27).

There are several reasons for the high need for ICU beds in Iran, these being the high rate of traffic accidents, the high incidence of natural disasters(28, 29), as well as the large number of cardiovascular patients(30).

This increased demand poses a challenge for the Iranian health care system and has been highlighted on numerous occasions by the mass media. For example the head of the Iranian Society of Critical Care has mentioned the shortage of at least 20,000 ICU beds nationwide(31).

ICUs are costly due to their particular type of personnel and services. The daily cost of routine care in ICU is 6 to 7 times higher than the cost of non-ICU care(32). According to the Department of Health (2006), level 3 care in ICU costs approximately £1,716 per day(15).

Although the policy of MOHME is to increase the number of ICU beds(27), the high cost of adding intensive care beds (as well as the cost of special equipment) is one of the main reasons for the shortage of these beds. According to a number of reports, the

cost of adding each intensive care bed is £ 100,000(33) in addition to the costs of staffing.

Besides the high costs of admission to the ICU, families of patients suffer a significant financial burden, most notably in private hospitals. The cost of intensive care beds in private hospitals is between 6 to 10 times higher than in public hospitals. Reports of patients unable to transfer to private hospitals due to monetary affairs exist, and as a result, these patients were forced to remain on the general wards of governmental hospitals and receive routine care. However, this has not been formally documented.

1.4 ADMISSION OF AIPS TO GENERAL WARDS

The rate of AIPs admitted onto general wards instead of ICU's is increasing worldwide (1, 34, 35). The frequency of such patients in Iran has risen for several reasons. The most notable of these is the high rate of traffic accidents (traffic accidents are the second cause of mortality in Iran)(28) and a steadily aging population(36). It is estimated that more than 10% of the Iranian population will be over 60 years old by the year 2021, and that this number will have surpassed 20% by 2050(37). This aging population brings about the increasing frequency of age-related and chronic diseases (38-41) rendering this group of patients more at risk of requiring critical care. Studies in other countries indicate that an aging population increases the number of critical patients. These studies have also identified other factors that influence the shifting of patients from ICUs to general wards. These include

technological advances, improvement in treatment options of known diseases, the growing expectations of society and limitations in resources and ICU beds (8, 42, 43), all of which are also true in Iran.

In the medical records of Shariati Hospital, one of the largest teaching hospitals in Iran and the main setting of this study, 520 patients were on the waiting list for ICU beds during the first 6 months of the year 2010. 112 of these died in general wards; 54 and 88 patients were transferred to critical care units in the study and other university affiliated hospitals respectively; 79 were discharged from hospital against medical advice (DAMA), and 88 requests were cancelled due to recovery. The range of LOS varied from 1 to 20 days, with a LOS of 1 day meaning that the patient died that same day. The average LOS was 8 days[1].

These patients would be notified by the Deputy of Health at Tehran University of Medical Sciences (TUMS) so that they may be immediately admitted to an ICU in one of the hospitals affiliated with the TUMS, as soon as a vacant place was found. Nevertheless, this procedure was difficult and time-consuming, as the majority of ICU beds were occupied. In addition, patient admission did not always adhere to the regulations of the province, and admittance was sometimes influenced by personal relationships between patients and staff members. According to the figures reported by the Deputy of Health at TUMS, over the afore-mentioned period of 6 months, over 4,000 Patients were on the ICU and CCU waiting lists for Shariati Hospital, which demonstrates the shortage of critical care beds in comparison with demand in Iran .

1. According to the AIPs booklet of the Shariati Hospital nursing office.

1.5 WORKLOAD IN WARDS

There is a significant inverse relationship between workload and quality of care (44), and as the workload increases due to admission of AIPs who need intensive care, the quality of care given to critical patients diminishes.

The severity of condition of the AIPs, discharged ICUs patients being transferred to general wards, the complexity of skills needed to manage and treat patients and the time taken to administer patient care, all add up to a considerable workload for nursing staff (45).

In 2009 the number of nurses in Iran was 90,029, showing a shortage of 240,000 nurses in comparison with recommended guidelines (20).

This added pressure and the shortage of nursing staff have resulted in a reduction in quality of care, as quality is directly related to the number of nursing staff (46).

In addition, patients discharged from ICUs are admitted to general wards, and studies have shown that the mortality rate of patients who have left the ICU directly correlates with the workload of the nursing staff(47).In addition, there is no support system for these patients, and they are cared for by staff, who may not have the necessary skills and expertise. Inexperienced clinicians and unsupervised trainees (who often deliver first-line care out-of-hours) have a higher error rate (48, 49).

1.6 AIMS AND OBJECTIVES

The overall aim of this study is to determine the efficacy of the critical care system in Shariati hospital. I specifically aim to determine the outcomes of implementation of CCS including: Mortality, LOS, cardiopulmonary resuscitation (CPR), and re-admission to ICU.

1.7 OUTLINE

Chapter 2 describes the literature review of CCS.

Chapter 3 describes the literature review of track and trigger warning systems and how the likelihood of patient mortality is determined.

Chapter 4 presents the current state of AIPs in Iranian hospitals with a qualitative study approach.

Chapter 5 presents the setting and methodology of the SW-CRCT to explore the potential impact of CCS in the setting of an Iranian University hospital.

Chapter 6 presents the views of staffs toward the CCS.

Chapter 7 presents the overall discussion for the thesis.

CHAPTER 2

CRITICAL CARE SERVICES

2.1 OVERVIEW OF THE CHAPTER

In this chapter, I will start by describing the different levels of care in hospitals, and will then continue by explaining the background of Critical Care Services (CCS). After this description of the different types of CCS has been provided, the history of their introduction will be presented. Finally, a literature review will be presented to present evidence of the effectiveness of the different types of CCS.

2.2 DIFFERENT LEVELS OF CARE FOR PATIENTS IN HOSPITALS

The Intensive Care Society in the UK defined four levels (0 through 3) of patient care in 2009. Level 0 patients require routine care, their needs can be met by general wards and observations are required less frequently than once every 4 hours. Patients who are at risk or those who have been transferred from higher care wards to routine wards are classified as Level 1, needing a minimum of 4 hourly observations. Criteria for this level are patients who have recently been discharged from a higher level of care, patients in need of additional monitoring/clinical interventions, clinical input, or advice, or patients requiring CCS support. Level 2 patients require more detailed observation and intervention. This level includes patients stepping down from higher levels of care, patients needing pre-operative optimization; patients needing extended

postoperative care; patients receiving single organ support; patients receiving Basic Respiratory Support; patients receiving Basic Cardiovascular Support; patients receiving Advanced Cardiovascular Support; patients receiving Renal Support; patients receiving Neurological Support and patients receiving Dermatological Support. Level 3 patients require advanced respiratory monitoring and support, or they require monitoring and support for two or more failing organs, one of which may be basic or advanced respiratory support. Criteria for this level are patients only receiving Advanced Respiratory Support or patients receiving support for a minimum of 2 organ systems(7).

Adam et al (2010), state that level 2 and 3 patients are cared for in ICU. However, level 1 patients are admitted to general wards and need the control, support and intervention of critical care teams(50). These are critical patients who cannot be admitted to ICU or high dependency units (HDU) and are cared for in general wards(51).Figure 2-1shows the relation between outreach and level of care.

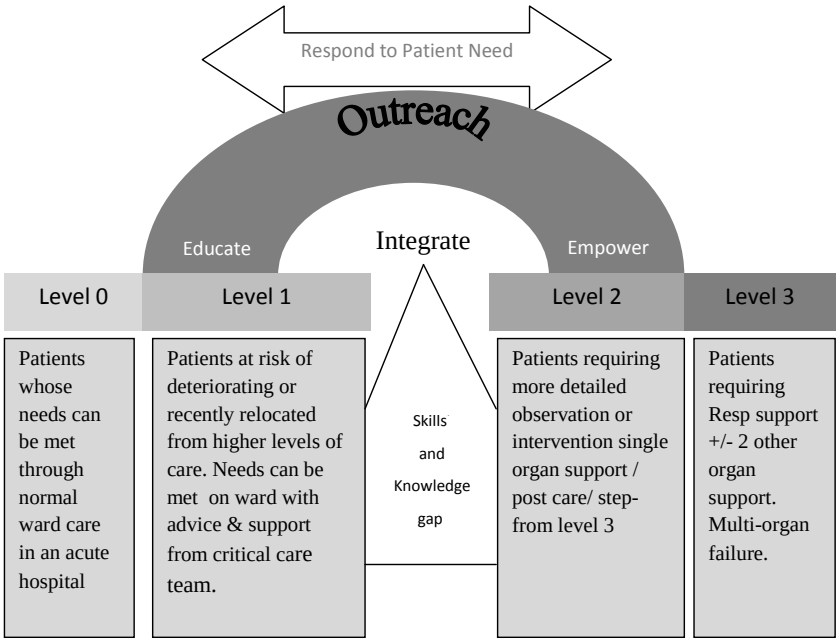


Figure 2-1: Model of critical outreach(the relation between outreach and level of care) (52)

2.3 DEFINITION OF CCS

AIPs are patients whose critical and unstable conditions are life threatening. They have deteriorated, physiologically or psychologically, to the point that they are at risk of serious harm. Timely care for these patients may attenuate the dangers they encounter. Numerous approaches and strategies have been implemented for the caring of these patients in Australian, British, and American hospitals (1) (defined as CCS). These are services which are able to respond to the needs of the patients regardless of whether they are in critical care units or general wards (53). They are composed of clinical personnel responsible for the support, management, and treatment of AIPs in general wards (54, 55). They have protocols and guidelines for patient management that will be described in the "protocols of CCS" section of this chapter.

2.4 ORIGINS OF CCS

There are several reasons for the implementation of CCS in different countries, as stated below:

1- The increasing number of AIPs in general hospital wards.

Currently, an ever-increasing number of AIPs are being admitted to medical and surgical wards in hospitals (34). This is the result of: the aging of populations worldwide (56) as well as in Iran (36); theinvention and development of more sophisticated therapy modalities, novel technologies; and emerging diseases (1).

2- Shortage of critical care beds

Since intensive care beds are not available in sufficient numbers, healthcare personnel encounter patients with unstable clinical conditions that require varying levels of critical care on a daily basis (34). Shortage of in-hospital beds, particularly intensive care beds, has hindered optimal care as it results in many patients being transferred to other hospitals (57).

3- Sub-optimal care of AIPs

Suboptimal care is defined as the misinterpretation or mismanagement of airway dysfunction, respiration and blood circulation. Many patients admitted to general wards receive suboptimal care, and this is especially important in the case of AIPs. Previous studies suggest that many cases of ICU admission are the result of insufficient care being provided in wards; in other words, if optimal care had been provided in wards, these patients would not have needed ICU admission (11, 13). The issue of suboptimal care leading to patient mortality is recognised in hospitals world-wide as a major problem requiring particular attention (58). Thus, AIPs in general wards are a major source of concern for hospitals. The following factors are identified as major factors that lead to suboptimal care:

1. Lack of knowledge
2. Poor organisation
3. Failure to recognise clinical urgency
4. Poor supervision
5. Failure to seek aid or support by personnel(11).

2.5 THE HISTORY AND MAIN TYPES OF CCS

CCSs were developed to address the problem of suboptimal care of AIPs in general wards. These systems originated in Australia, when the Trauma Teams were started in order to manage the victims of severe trauma, and afterwards the Medical Emergency Teams (MET) were established to care for AIPs on wards(54).Simultaneously in the UK, Patient-at-Risk Teams (PART) were developed (59) and followed by the implementation of the Critical Care Outreach Service (CCOT) as mandated by the NHS(6, 57, 60). Four years later, the United States of America (USA) the CCS, called the Rapid Response Team (RRT), was developed in the US healthcare system(61, 62).Table 2-1 shows the history of CCS in different countries on a timeline bases.

Table 2-1: Time line bases of CCS

Type of Team	Country	Year
Medical Emergency Team (MET)	Australian	1990
Patient - at -Risk Team (PART)	UK	1999
Critical Care Outreach Team (CCOT)	UK	2000
Rapid Response Team (RRT)	USA	2004

Subsequently, other countries such as Canada(63) and Sweden (64), started using CCS. Despite having different names and sometimes, different protocols, they all aimed to care for and prevent mortality of AIPs in general wards. In this section, I

will describe the systems in Table 2-1 in more detail, with the adopted protocols for each system being presented. Following this, I will review the studies addressing the efficacy of these services.

2.5.1 Medical Emergency Team

The first critical care team was created in 1990 at Liverpool Hospital, South Western Sydney, Australia(54). In order to improve their outcome and also to shift these patients towards a shorter length of hospital stay (LOS). Their objective was the timely identification and management of AIPs before cardiopulmonary arrest took place. The main concept of the system was that the pathology of the cardiopulmonary arrest is reversible and that timely management will improve patients' outcome(65).This system came to be known as the MET and replaced the regular cardiac arrest team. In addition, it offered a broader range of interventions than the cardiac arrest team system. It came to be accepted as a system with a proactive approach, as it defined a scoring system for identifying patients at risk of deterioration(35).

MET was based on the trauma team previously created in Australian hospitals, which was in charge of the initial assessment and management of severely injured patients(66). Trauma teams consisted of surgery, intensive care, anesthesiology, emergency, and trauma personnel, who were alerted via the hospital's dispatch system whenever a patient fulfilled previously determined criteria(67, 68). Trauma teams were initiated in Australia(67) and the UK(69, 70) with similar objectives.

The MET aimed at:

1. Identifying patients at risk of acute illness using simple criteria.
2. Replacing the traditional hospital cardiac arrest team
3. Training personnel in advanced resuscitation programmes
4. Reducing the rate of cardiac arrest and unexpected death
5. Reducing the rate of unplanned ICU admissions
6. Collecting outcome indicators in order to:

    - Assess quality of care in patients with critical illness
    - Assess what is potentially preventable
    - Assess end of life decisions
    - Feedback for quality improvement (58, 71).

The main objective of MET was early intervention under any circumstances in which the patient's clinical condition deteriorated, whereupon the MET team were notified in order to provide rapid response interventions to change the patient's condition(72). Another goal of the MET was to train staff to respond quickly to patient deterioration in wards in order to prevent adverse events such as multi-organ failure or cardiac arrest (58). In this way, MET allowed wards to benefit from the performance of the ICUs, improving the quality of care for AIPs in general wards, preventing unplanned ICU admission, cardiopulmonary arrest and death(58).

2.5.2 Patient-at-Risk Team

In the United Kingdom, Goldhill et al. (1999) started the Patients-At-Risk Team (PART) in 1997 to care for critically ill hospital patients. The objective of PART was to improve patient care by facilitating their ICU admission or preventing unnecessary ICU admissions. Improved patient care would be achieved by providing support, staff education, early ICU admission, preventing unnecessary ICU admissions, and leaving ICU beds available for patients who were in greater need (59).

2.5.3 The Critical Care Outreach Team

After MET implementation in Australia and the Goldhill study (1999), CCS was developed internationally to improve care for critically ill patients outside of ICUs. In 1999, a UK Department of Health expert group recommended that hospitals establish outreach teams to care for AIPs, and that this service should be organized at the level of hospital bed management to ensure that all patients receive outreach team support(35).

In the UK in 1999, a report by the Audit Commission (60) and another report in 2000 by the Department of Health review of critical care (6), recommended CCS for AIPs and also for patients at risk of deterioration. From that point onwards, critical care outreach services (CCOS) were developed in the UK to expedite identification of AIPs in wards as well as to facilitate medical interventions in order to reduce the need for ICU admission (57). The organizational approach aimed to ensure the equity of care for critical patients, regardless of their whereabouts(73).

The Intensive Care Society (2002) defined CCOS as a multidisciplinary approach for collaboration of the ICU and other wards in order to guarantee patient care, regardless of their location (ward) with the following objectives:

1. Identifying patients at risk
2. Aiding patients recovering from critical illness,
3. Enabling early interventions or transfer of the patient to an appropriate ward for better care(35)
4. Preventing unnecessary ICU admissions to ensure that ICU beds are available for critical patients who need them
5. Enabling discharge from intensive care(74).

So the basic principles of outreach are to identify patients with critical conditions or at risk of deterioration, followed by interventions for improving their management through basic physiological support(35).Moreover, a major component of the outreach team is staff support and the sharing of intensive care skills and knowledge with ward staff. However, this concept was already advocated by Coad & Haines in 1999, with demands that ICU nurses support ward staff in caring for critically ill patients outside the ICUs(74).

The form and processes of these services are based on regional priorities and resources. Regardless of the model selected, outreach must form part of an organized approach for supporting all patients who need critical care. For instance, outreach in University Hospital Birmingham works as part of the critical care service committed

to providing high quality care in a timely manner and in any location, improving staff education, and encouraging sharing and learning(73).

Although different models with different titles have been introduced in England since the introduction of outreach, the basic principles have remained the same as those described in “Comprehensive Critical Care”. Regardless of the model chosen, the team forms part of an approach to support all patients requiring critical care. In other words, outreach service is an approach functioning at hospital level with the objective of identifying patients at risk, educating and sharing critical care skills with ward staff, and providing advice for patient management and follow up. A survey revealed that up to the year 2005, 73% of UK hospitals had developed outreach services(75).

The CCOT and MET shared many similarities, most importantly early diagnosis and interventions for patients with deteriorating conditions. Although CCOT was developed to provide critical care, it may also have enabled other personnel to provide such care. CCOT is based on engendering confidence and providing affirmation for ward staff, which is not emphasized as much in MET systems(53). These systems differ from each other and the MET system in terms of structure and service provision. While all the teams have similar objectives, their formation and the responsibilities of the team members may differ based on the milieu where the team is active. Some teams may be more interventional, thus resembling MET. In any event, the model accepted by each hospital reflects the subject and type of service required therein (35). In other words, the selected model must be based on local needs. These needs are determined by the following factors:

1. Which patients are at risk of acute disease
2. Location of patients
3. Clinical governance and risk management: for instance, complaints, adverse events, mortality and morbidity(35).

2.5.4 The RRT

In 2004, the American Institute for Healthcare Improvement (IHI) initiated the development of services aimed at AIPs. These services, named the RRT, were one of six lifesaving strategies recommended by the IHI to improve patients' outcome, and they were implemented alongside increased attention to the improvement of hospital quality and outcomes. At the time, little evidence existed to indicate the effectiveness of RRT; nevertheless, hundreds of hospitals responded to the demand by investing considerable financial and human resources. The RRT is considered part of the hospital quality improvement programs.

Typically, an RRT encompasses a multidisciplinary team of physicians, nurses and respiratory therapists, who evaluate triage and treat patients with critical conditions and have not been admitted to the ICU. The team is allowed to order critical laboratory tests, imaging and medication, request higher levels of monitoring and care for patients, and discuss end-of-life options with patients, independently of the primary care-giving physicians (76).

In summary, a review of the history of CCS shows that it goes by different names in different countries. Nevertheless, all of them consist of a team that provides a higher

level of care for AIPs, outside of the critical care areas. All make use of a specialist team of personnel with protocols for managing patients, and criteria for ward staff to identify when a patient requires CCS input. Also, the criteria for alerting the CCS and their range of responsibilities vary.

2.6 THE AFFERENT AND EFFERENT LIMBS OF CCS

The CCS has afferent and efferent limbs (Figure 2-2). The afferent or crisis detection limb includes the monitoring of patients for to detect deterioration, use of Track and Trigger Systems (TTs) and response to triggers (77, 78).

A strong method of identifying urgent unmet patient needs- meaning the differences between patients' emergent needs and delivered care- is an essential part of any CCS. Patients with unmet urgent needs are identified using criteria called Track and Trigger Systems (TTs) or Early Warning Systems (EWS), which, will be described in detail in chapter 3 (79).Urgent unmet patient needs and deteriorating patients can be identified by hospital staff, patients themselves or relatives (79).

The efferent limb (crisis response or response team) responds to detected events and patient deterioration. Different efferent limb models exist and terms such as RRT, CCO and MET, describe the efferent side(80).

CCS teams should be capable of assessing patients, diagnosis, as a minimum some therapy and fast transfer of AIPs to a higher level of care.

From the view of leading services two main types of CCS have been formed: The first are physician-led teams known as high capability teams and second are nurse-led or intermediate capability teams. Nurse-led teams are also known as “ramp up” teams (79).In the following parts, I will describe the main types of CCS in detail.

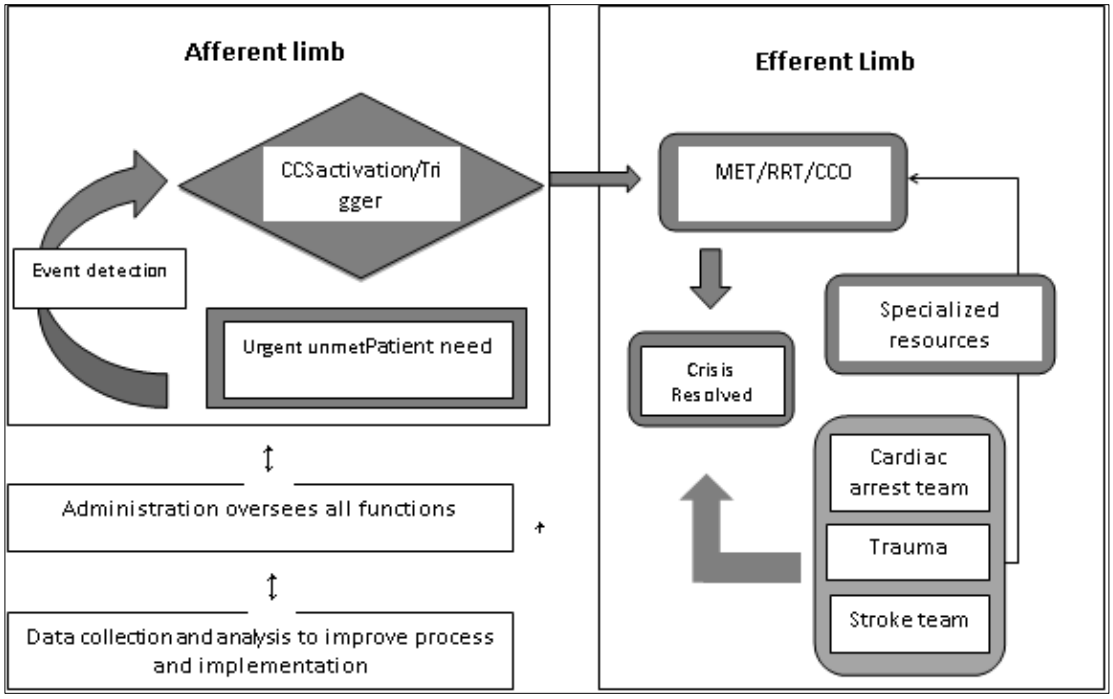


Figure 2-2: The afferent and efferent limb of critical care services(78, 81)

2.7 PROTOCOLS OF CCS

Although, the ultimate objective of all these CCS was common, they implemented different protocols for identification of patients and type of intervention, depending on the structure of the hospital or the country’s healthcare system. Table 2-2 summarizes the characteristics of these systems used in different studies.

Table 2-2: Summary of the characteristics of CCS in different studies

Authors	Year	Type of Team	Team Members	Availability	Identification of Patients	Type of Intervention
Lee et al,	1995	MET	Medical and nursing staff trained in the principles of resuscitation		Alerting Criteria: 1.Abnormal physiology 2.Abnormal pathology 3.Specific conditions (in the following sub-categories) • Cardiovascular shock • Poisoning/trauma • Neurological • Respiratory • Metabolic • Obstetrics • Surgical and any time urgent help is required	The team was modelled on the principals of the early recognition and rapid response used in managing severe trauma.
Goldhill et al,	1999	PART	An ICU consultant A senior ICU nurse A medical or surgical registrar if necessary		The senior ward nurse should contact the responsible doctor and inform them of a patient with: Any 3 or more of the following: Respiratory rate ≥25 breathes. min $^{-1}$(or<10) Arterial systolic pressure < 90 mmHg Heart rate≥ 110 beats.min^{-1} (or<55) Not FULLY alert and orientated Oxygen saturation< 90% Urine output< 100ml over last 4h OR a patient not FULLY alert and orientated AND with Respiratory rate ≥ 35 breaths min $^{-1}$OR heart rate≥140	The PART protocol was used to notify the physician directly responsible for the critical patient. The nurses would notify the physician in case of abnormal vital signs. If the physician needed support for the patient, or the nurses did not receive an acceptable response from the physician, PART would be alerted. In addition, the physicians were instructed to contact PART if they were concerned about their critically ill patients. Some patients would be transferred to ICU after evaluations. If the patient remained in the ward, PART would provide advice on

Authors	Year	Type of Team	Team Members	Availability	Identification of Patients	Type of Intervention
					beatsmin^{-1}	management. Also, it would be recorded if no intervention was indicated.
Pittard	2003	CCOT	Senior critical care nurses Medical staff	09.00–17.00, Monday–Friday		
DeVita et al,	2004	MET	ICU Physician (Team leader) ICU Nurse (Run medication/equipment cart) ICU Nurse (Recorder) Floor Nurse (Bedside nursing) Anaesthesia or critical care (Airway manager) Respiratory care(Airway assistant) Physician(Chest compression) Physician(Procedure physician)		Respiratory rate Heart rate Blood pressure Acute neurological change Other chest pain unresponsive to nitro glycerine or doctor unavailable colour change (of patient or extremity): pale, dusky, grey or blue unexplained agitation for more than 10 minutes suicide attempt uncontrolled bleeding	
Garcea et al,	2004	CCOT	Two senior grade nurses A consultant nurse specialist A consultant intensivist acts as lead clinician for the team.			Education Follow-up of patients
Priestley et al,	2004	CCOT	The CCOT was led by a nurse consultant with a team of experienced nurses	24-h cover	Patient at risk (PAR) score: Consciousness Level Respiratory rate per minute Heart rate per minute Systolic blood pressure Urine output over 4 hours	Nurse led Critical care medical support

Authors	Year	Type of Team	Team Members	Availability	Identification of Patients	Type of Intervention
Kenward	2004	CCOT				Intervention (changes in, or commencement of, oxygen therapy, ventilator support—with or without the administration of intravenous fluids or medications).
Jones et al,	2005	MET	An anaesthetic fellow A coronary care fellow and nurse An ICU fellow and nurse The Medical fellow of the receiving unit of the day		Acute changes in heart rate (<40 or >130 beats/minute) Systolic blood pressure (<90 mmHg) Respiratory rate (<8 or >30 breaths/minute) Oxygen saturation (<90% despite oxygen therapy) Conscious state	
Jones et al,	2007	MET	The deputy intensive care fellow A designated intensive care nurse The receiving medical fellow An ICU specialist available from 08:00 until 20:00.		Staff member is worried about the patient Acute change in heart rate to < 40 or > 130 beats/minute Acute change in systolic blood pressure to < 90 mmHg Acute change in respiratory rate to < 8 or > 30 breaths/minute Acute change in pulse oximetry saturation to < 90% despite oxygen administration Acute change in conscious state Acute change in urine output to < 50 ml in four hours.	

Authors	Year	Type of Team	Team Members	Availability	Identification of Patients	Type of Intervention
Dacey et al,	2007	RRT	A physician assistant (PA) (team leader) An intensivist A critical care nurse with _5 yrs of experience Respiratory therapists A hospitalist was continuously available in the house for emergency consultation, as was an anaesthesiologist			Members of the RRT were authorized to carry out discussions with patients or surrogate decision makers regarding wishes for specific interventions, including various forms of life support, if the clinical situation warranted it and especially if there was any delay in reaching the attending physician.
Baxter	2008	MET	A critical care nurse A respiratory therapist An intensivist ICU resident(s)	24 hr/day and seven days/week		Delegate responsibilities determine calling criteria Activation mechanism Equipment needs Educational needs
Chan et al,	2008	RRT	Two experienced ICU nurses A respiratory therapist An ICU attending or fellow		Acute changes in the patient's mental status, respiratory rate, heart rate, oxygenation, or blood pressure, and hypoxia, chest pain, or worry from clinical staff.	
Konrad et al,	2010	MET	ICU physician An ICU nurse	any time	One criterion was sufficient to in order to inform the MET	After calling MET, following assessment and initial treatment is made for each patient and a joint decision is made whether or not to transfer to a higher level of care.

The above table demonstrates the fact that different teams adopted different members, criteria, and protocols for management of AIPs.

As part of a large study of CCS in 239 hospitals, McDonnell et al (2007) conducted a study to describe, develop, introduce, implement, and evaluate the current critical care outreach service (CCOS) models. Initially, group discussions were planned for representatives of 56 hospitals who attended the CCOS conference. Subsequently, all 239 NHS acute care hospitals, which routinely provided care for level 1 patients were identified, and CCOS leads completed a questionnaire, in order to describe the level of outreach activity. 191 questionnaires were completed, and these revealed that these CCOSs were developing and evolving rapidly. The services varied in terms of team composition and size, the nature of activities, balance between providing direct care or assuming an advisory role, ratio of wards covered, and availability of services. In addition, the resources allocated to these services sometimes limited their development. Finally, it was concluded that although outreach and EWS constituted a major component of hospital strategies for improving identification and management of AIPs in general wards, their extensive implementation is not associated with strong practical evidence (82).

2.8 THE HUMAN FACTORS AND CCS IMPLEMENTATION

The efferent limb of CCS is a team that delivers care for AIPs in general wards of hospitals. As mentioned in CCS characteristic (Table 2-2), however, the nurses have central role, the combination of CCS team members are varied in different studies. They must have enough knowledge for being selected from seniors and

clinical experts, who could make decisions with enough knowledge to train ward staffs.

The cooperation of CCS team members with other health care workers can lead to successful CCS implementation. The level of integration of CCS directly depends on an eager leadership in the wards (83).

2.9 REVIEW OF EVIDENCE FOR CCS EFFECTIVENESS: A LITERATURE REVIEW

In this section I will review the evidence about patients seen, interventions and effectiveness of different CCS. As soon as MET, CCOT and RRT were initiated; numerous studies were conducted to assess the efficiency of the services, for example by measuring their impact on mortality and ICU admission.

The aims of the literature review were;

1. To identify studies those determine the effect of CCS on hospital mortality.
2. To identify studies those determine the effect of CCS on cardiac arrest.
3. To identify studies those determine the effect of CCS on ICU admission.
4. To identify studies those determine the effect of CCS on LOS.

I searched PubMed to find papers published up to 2011 and used sensitive search terms to minimize the risk of overlooking relevant studies. A combination of free text terms was used to identify studies. Search terms include: (Cardiac arrest OR Heart arrest OR “Length of stay” OR “Cardiopulmonary resuscitation” OR

Mortality [MeSH Terms] OR Mortality [MeSH Subheading] OR hospital mortality [MeSH Terms] OR hospital mortality) AND (Critical care outreach team OR CCOT OR Critical care outreach services OR Warning scoring system OR Trick and trigger warning system OR Rapid response team OR RRT OR Medical emergency team OR MET OR Patient at risk team or Critical care services OR CCS OR PART OR RRT).

Duplicate results were removed. The abstracts and titles were screened. Afterwards I eliminated those studies that were clearly irrelevant. Then the abstracts were reviewed. The full texts of potentially relevant studies were retrieved. I included the studies only if they evaluated the effects of CCS on patient outcomes including mortality, Cardiac Arrest, LOS, and ICU admission rate in hospitals.

Included studies' quality were assessed by using suggested risk of bias criteria developed by the Cochrane's Effective Practice and Organization of Care (EPOC) Review Group(81). The author's judgments and the reasons for supporting these judgments were recorded. Full details of these criteria are given below.

These nine standard criteria (Table 2-3) were used for assessing the included Randomized Controlled Trials (RCT), before after, prospective, retrospective, and observational studies.

Table 2-3:The standard criteria in assessing the included studies

	Criteria	Low Risk	High Risk	Unclear Risk
1	**Was the allocation sequence adequately generated?**	If a random component in the sequence generation process is described (eg Referring to a random number table)	When a non-random method is used (eg performed by date of admission). Non Randomized Controlled Trials (NRCTs) and Controlled Before-After (CBA) studies should be scored "High risk"	If not specified in the paper
2	**Was the allocation adequately concealed?**	If the unit of allocation was by institution, team or professional and allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care and there was some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used	CBA studies should be scored	If not specified in the paper
3	**Were baseline outcome measurements similar?**	If performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups. In RCTs, score "Low risk" if imbalanced but appropriate adjusted analysis was performed (e.g. Analysis of covariance). If "Unclear risk" or "High risk", but there is sufficient data in the paper to do an adjusted analysis (e.g. Baseline adjustment analysis or Intention to treat analysis) the criteria should be re scored as "Low risk"	If important differences were present and not adjusted for in analysis	If RCTs have no baseline measure of outcome
4	**Were baseline characteristics similar?**	If baseline characteristics of the study and control providers are reported and similar	If there is no report of characteristics in text or tables or if there are differences between control and intervention providers. Note that in some cases imbalance in patient characteristics may be due to recruitment bias	If it is not clear in the paper (e.g. characteristics are mentioned in text but no data were presented)

	Criteria	Low Risk	High Risk	Unclear Risk
			whereby the provider was responsible for recruiting patients into the trial	
5	**Were incomplete outcome data adequately addressed?**	If missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result)	If missing outcome data was likely to bias the results	If not specified in the paper (Do not assume 100% follow up unless stated explicitly)
6	**Was knowledge of the allocated interventions adequately prevented during the study?**	If the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors.	If the outcomes were not assessed blindly	If not specified in the paper
7	**Was the study adequately protected against contamination?**	If allocation was by community, institution or practice and it is unlikely that the control group received the intervention	If it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomised)	if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control)
8	**Was the study free from selective outcome reporting?**	If there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section)	If some important outcomes are subsequently omitted from the results	If not specified in the paper
9	**Was the study free from other risks of bias?**	If there is no evidence of other risk of biases. For the included Interrupted Time Series study, seven criteria were used		

Only two of included studies were RCT (84, 85) and allocation sequence was generated adequately in these studies while in one of them (85) it was not clear that allocation was concealed. In the other one (84) it was not clear that baseline characteristics of intervention and control groups are similar nor if there was missing data with an important effect on results.

The quality assessment process made clear that the prospective, retrospective, observational and before after studies had a high risk of bias. Overall result from quality assessment shows that except two RCT other included studies were at high risk of bias. Details of the quality assessment are given in Table 2-4, Table 2-5 and Table 2-6.

Table 2-4: Risk of bias criteria in the Randomized Controlled Trials studies

Bias	Authors' judgment	Support for judgment
GEORGE PRIESTLEY 2004		
Was the allocation sequence adequately generated?	Low Risk	This is a study with a pragmatic (cluster) ward-randomized trial design.
Was the allocation adequately concealed?	Unclear	It is not specified in the paper if the allocation was concealed adequately.
Were baseline outcome measurements similar?	Low Risk	The length of the study, and consequently the sample size, was determined by the CCOT's prior decision about how to introduce outreach services across the hospital.
Were baseline characteristics similar?	Low Risk	Wards were paired, on the basis of professional judgment, according to patients and conditions usually treated, in an attempt to match for overall risk of death or other serious adverse outcomes.
Were incomplete outcome data adequately addressed?	Low Risk	It is mentioned in the discussion part that the SAPS II results were incomplete because the full range of physiological measures is not recorded for all patients and no tests were done specifically for the study. Since more tests were probably available for very ill patients, missing values for patients who would have had low SAPS II scores anyway may not be serious; nevertheless, this is a shortcoming.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	The main outcomes measures were objective in this study. Mortality and length of stay.
Was the study adequately protected against contamination?	High Risk	Blinding has not occurred. Intervention introduced to all wards in sequence thus it is possible that communication between intervention wards and control wards could have occurred.
Was the study free from selective outcome reporting?	Low Risk	All related outcomes results about mortality and length of stay were reported adequately.
Was the study free from other risks of bias?	Unclear	The study has some weaknesses: It would have required participation of a very large number of hospitals. There may have been "Hawthorne" effects: carrying out the study was a stimulating experience for all concerned, which may have encouraged dynamic delivery of the intervention, beyond what would be expected of effective implementation outside a research context. Those who delivered the intervention collected much of the data and this is another possible bias, even though someone else undertook data handling and analysis (A.R.). Also, there was only one study site, which limits generalisability.

Bias	Authors' judgment	Support for judgment
HILLMAN 2005		
Was the allocation sequence adequately generated?	Low Risk	It is a clustered randomized trial study. Randomization was done in the study by an independent statistician (who had no other involvement in the study).
Was the allocation adequately concealed?	Low Risk	Theindependent statistician randomly assigned hospitals to receive standardized MET implementation or to be controls. Randomization was concealed from the project investigators and participating hospitals.
Were baseline outcome measurements similar?	Low Risk	Outcomes and process measures were obtained in all hospitals for baseline period of 2 months.
Were baseline characteristics similar?	Unclear	It is not clearly mentioned that the baseline characteristics of MET and control hospitals were assessed and if there were similar.
Were incomplete outcome data adequately addressed?	Unclear	It is not clear enough if there was missing data with an important effect on results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	The primary outcomes were objective. The composite of cardiac arrest, unexpected death, or unplanned ICU admission during the 6- month study period after MET activation.
Was the study adequately protected against contamination?	Low Risk	However randomization was concealed from the project investigators and participating hospitals, the chance of contamination the control hospitals with the intervention hospitals during the study is still possible.
Was the study free from selective outcome reporting?	Low Risk	All related outcomes data were reported in the paper.
Was the study free from other risks of bias?	Unclear	The results may be influenced by the effects of confounding factors. The ability to show that the MET system improved outcome would have also depended on the quality of care provided by the participating hospitals, because if hospitals already had effective systems to manage deteriorating patients in general wards, the MET implementation might not improve outcome.

Table 2-5: Risk of bias criteria in the Before and After studies

Bias	Authors' judgment	Support for judgment
BUIST 2002		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no concurrent control group exists for comparison. the control was historical, the tertiary referral teaching hospital before implementation MET)
Were baseline characteristics similar?	Low Risk	Basic characteristics of patients before (1996) and after (1999) implementation of medical emergency team were measured. A significant difference was found in Types of admissions and men of Length of stay
Were incomplete outcome data adequately addressed?	Low Risk	As data on cardiac arrest calls and hospital population were collected differently in 1994 and 1995 from the rest of the data, these two years were not used in statistical comparisons with data collected from 1996 onwards.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Incidence and outcome of unexpected cardiac arrest were the objective main outcomes
Was the study adequately protected against contamination?	Unclear	As the control was historical, the tertiary referral teaching hospital before implementation MET, and it is not specified in the paper, it is not clear enough if the contamination was occurred.
Was the study free from selective outcome reporting?	Low Risk	All main outcomes about incidence and outcome of unexpected cardiac arrest were reported adequately.
Was the study free from other risks of bias?	Unclear	The study was based on data from only one tertiary teaching hospital, in which organizational structures may be different from other hospitals in other regions and countries. The use oftwo discontinuous time points could mean that the observed reduction in cardiac arrest calls could have resulted from a "natural regression" due to medical progress, or at worst, random fluctuation. The improvement in mortality could also be an indirect effect, unrelated to the medical emergency team—namely, the Hawthorne

Bias	Authors' judgment	Support for judgment
		effect.
BELLOMO 2003		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: Number of cardiac arrests, number of patients dying after cardiac arrest, number of post cardiac-arrest bed-days and overall number of in-hospital deaths.
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	All related data about main outcomes (cardiac arrests, number of patients dying after cardiac arrest, number of post cardiac-arrest bed-days and overall number of in-hospital deaths) were reported.
Was the study free from other risks of bias?	Unclear	The 4-month MET intervention period included by chance, 3 months immediately after the start of the working year for new interns (a possible seasonal bias against the MET)
DEVITA 2004		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group
Were baseline characteristics similar?	High Risk	There is no control group except the historical control. Thus no comparison of baseline characteristics occurred.
Were incomplete outcome data adequately addressed?	Unclear	It is not specified in the paper if there were missing data with an important effect on results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	It is not mentioned if the variables were assessed blindly. But the main outcomes were the cardiopulmonary arrests and objective.

Bias	Authors' judgment	Support for judgment
Was the study adequately protected against contamination?	Unclear	The study has before after design. The outcomes were measured following increased use of MET. thus there is no obvious evidence about protection against contamination in the paper before MET activation.
Was the study free from selective outcome reporting?	Low Risk	The incidence and outcomes of cardiac arrests were reported and no important outcomes are subsequently omitted from the results.
Was the study free from other risks of bias?	Unclear	The possibility that confounding factors may have influenced our results. In particular, changes in patient care contemporaneous to increased MET use may have contributed to the observed decrease in the incidence of cardiopulmonary arrest. It is possible that our MET responses could have resulted in more cardiopulmonary arrests occurring in ICU settings where their occurrence was less likely to be recorded.
GARCEA 2004		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No control group exists. Outcomes were measured 21 months prior to the introduction of outreach (July 1999 to March 2001) and a period of 30 months following introduction of the outreach team (April 2001 to September 2003) in Leicester General Hospital, UK.
Were baseline characteristics similar?	High Risk	Not met. The study has before after design with no concurrent control group. It is obvious that the characteristics of the hospital before and after intervention contain many changes.
Were incomplete outcome data adequately addressed?	Unclear	It is not specified in the paper if there was missing data during conducting study with an important influence on main results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Readmission rate, mortality Critical care mortality, in-hospital mortality and 30- day mortality were the outcomes which all were objective.
Was the study adequately protected against contamination?	High Risk	As the study has before after design, there is no concurrent control group for assessing the possible contamination. However with considering the before intervention period as the historical control group the contamination will be possible.

Bias	Authors' judgment	Support for judgment
Was the study free from selective outcome reporting?	Low Risk	It seems that all relevant outcomes in the methods section (Readmission rate, mortality Critical care mortality, in hospital mortality and 30- day mortality) are reported in the results section.
Was the study free from other risks of bias?	Unclear	Confounding factors effects are possible: Although the time of transfer to critical care was equal before and after the introduction of outreach, it is possible that the influence of outreach resulted in better immediate management of patients whilst on the ward awaiting transfer. Specifically, introduction of appropriate intravenous fluid resuscitation, intravenous antibiotics and oxygen therapy on the ward could well influence the subsequent outcome of readmitted patients.
KENWARD 2004		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before-and-after interventional trial with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	No evidence is available about missing data and incomplete data.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	However it is not mentioned if the data were assessed blindly, Main outcome measurement was cardiac arrest and objective.
Was the study adequately protected against contamination?	High Risk	As the study has before after design and before intervention period considered for comparison, the risk of contamination is highly possible.
Was the study free from selective outcome reporting?	Low Risk	All data about mentioned outcomes in method were adequately reported in results.
Was the study free from other risks of bias?	Unclear	Risk of other bias is high.
JONS 2005		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before-and-after interventional trial with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group

Bias	Authors' judgment	Support for judgment
Were baseline characteristics similar?	High Risk	There is no concurrent control group. The Austin Hospital was assessed as a historical control.
Were incomplete outcome data adequately addressed?	Unclear	There is no evidence about missing data and incomplete data.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Cardiac arrests and hospital admissions were the objective outcomes measured in pre and post MET implementation.
Was the study adequately protected against contamination?	High Risk	Due to the before after design of the study, there is no concurrent control group. However the historical control (Austin Hospital before the introduction of the MET) would not be free from contamination.
Was the study free from selective outcome reporting?	Low Risk	It seems that all relevant data of measured outcomes were reported.
Was the study free from other risks of bias?	Unclear	It is possible that the decrease in cardiac arrests was secondary to some other improvements in patient care during the period that separated the control from the intervention period. Seasonal bias is also possible.
JONES 2007		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with historical control, No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	Not met; There is no concurrent control group. It is a before after study; No baseline measurement
Were baseline characteristics similar?	High Risk	Not met; As the study has before after study and the same hospital (Austin Health is a teaching hospital of the University of Melbourne) were assessed before and after intervention, no control group were compared for baseline characteristics.
Were incomplete outcome data adequately addressed?	Unclear	It is not specified in the paper if there were incomplete data for any outcome affecting the results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	However it is not specified in the paper if the outcomes measured blindly, The primary outcome measure for the study was objective; the time to death (in days) from the date of admission.
Was the study adequately protected against contamination?	High Risk	The study does not contain concurrent control group. The period before MET implementation were assessed as a historical control period. Though by considering the before MET period as the control group, the risk of contamination is still in high level.

Bias	Authors' judgment	Support for judgment
Was the study free from selective outcome reporting?	Low Risk	There is no evidence that outcomes were selectively reported. All relevant data reported adequately in tables and results section.
Was the study free from other risks of bias?	Unclear	The study demonstrates findings in a single institution only in a particular country. Its findings might not apply to other hospitals or health care systems. Also seasonal bias is possible because of different seasons of control and MET period.
BRILLI 2007		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Low Risk	No incomplete data were likely to bias the results, However the lack of statistical mortality difference reason may be that 21 of the 36 code patients had only a respiratory arrest. Patients with respiratory arrest but without cardiac arrest are more likely to survive to hospital discharge, thus potentially diminishing our ability to discern a difference in mortality rates before and after MET implementation.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were incidence of codes, respiratory arrests or cardiopulmonary arrests, before and after MET implementation. So there were objective outcomes.
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	All main outcomes were reported in result part adequately.
Was the study free from other risks of bias?	Unclear	The MET activation criteria used in this hospital have not been validated across multiple centers. The effects of confounding factors were not mentioned.
DACEY 2007		
Was the allocation sequence adequately generated?	High Risk	This is a before after study; no sequence generation process is described.
Was the allocation adequately concealed?	High Risk	No allocation unit exists in the study.

Bias	Authors' judgment	Support for judgment
Were baseline outcome measurements similar?	Unclear	However the comparison is done with historical control group, it is not specified in the paper if the measurements were similar before and after the study.
Were baseline characteristics similar?	High Risk	As the study has historical control, the base line characteristics would have significant difference before and after intervention as a result of other changes during study periods
Were incomplete outcome data adequately addressed?	Unclear	It is not specified in the paper if there was missing data with an effect on results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	The main outcomes were objective, the incidence of cardiac arrests that occurred outside of the intensive care unit, total intensive care unit admissions, unplanned intensive care unit admissions, intensive care unit length of stay, and the total hospital mortality rate.
Was the study adequately protected against contamination?	Low Risk	No rapid response system were conducted in hospital of the study before implementation period (October 2005- October 2006)
Was the study free from selective outcome reporting?	Low Risk	All of the main outcomes were reported in paper. There is no sign of selective reporting.
Was the study free from other risks of bias?	Unclear	There are many factors that might influence the clinical outcomes of hospitalized patients in addition to the RRS (rapid response system). A type of Hawthorne effect is also possible.
BOXTER 2008		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	The comparison was done with a historical control, before the MET program implementation.
Were incomplete outcome data adequately addressed?	Unclear	Not specified in the paper if there is any missing data through the study periods.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	The primary outcomes variables were objective: number of; cardiac arrests (“Code Blue” calls and Health Records coding), in-patient ICU admissions and readmissions, and hospital mortality (overall and HSMR).
Was the study adequately protected against	Unclear	However this is not a CBA study, if we consider the before

Bias	Authors' judgment	Support for judgment
contamination?		intervention period as a historical control, protection against contamination is not clear enough.
Was the study free from selective outcome reporting?	Low Risk	Number of cardiac arrests, in-patient ICU admissions and readmissions, and hospital mortality as the main outcomes and major postoperative complications, mortality and unplanned, postoperative ICU admissions, post-cardiac arrest ICU admissions and outcomes, and hospital mortality of ICU survivors as the seconds outcomes were adequately reported.
Was the study free from other risks of bias?	Unclear	Using historical control may be confounded by other known or unknown variables that might potentially influence outcomes. Improving in other aspects of medical care during the study period could have influenced the results as confounding factors.
HUNT 2008		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before-and-after interventional trial with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group
Were baseline characteristics similar?	High Risk	The study conducted in pediatric medical emergency team (PMET) A tertiary care, academic children's hospital before and after intervention. No different groups were assessed.
Were incomplete outcome data adequately addressed?	Unclear	No evidence available for the possible missing data with a significant effect on results.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Combined rate of respiratory arrests and CPAs, rate of CPAs, and rate of respiratory arrests on the wards were assessed as main objective outcomes.
Was the study adequately protected against contamination?	Unclear	It is not a controlled before after study, however in comparison with historical control (hospital before intervention) the risk of contamination is highly possible.
Was the study free from selective outcome reporting?	Low Risk	All relevant data about Combined rate of respiratory arrests and CPAs, rate of CPAs, and rate of respiratory arrests on the wards were reported adequately in results.
Was the study free from other risks of bias?	Unclear	Small sample size and observational nature of the design with Hawthorne effect are some kinds of important limitation of this study.

Bias	Authors' judgment	Support for judgment
TIBBALLS and KINNEY 2009		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before-and-after study with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group
Were baseline characteristics similar?	High Risk	There is no concurrent control group. The Royal Children's Hospital, was assessed as a historical control.
Were incomplete outcome data adequately addressed?	Low Risk	All data were collected and reported clearly before and after intervention. No incomplete data were reported.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Cardiac arrests were assessed as primary objective outcome.
Was the study adequately protected against contamination?	High Risk	Due to the before after design of the study, there is no concurrent control group for comparison.
Was the study free from selective outcome reporting?	Low Risk	All data about mentioned outcomes in method were adequately reported in results.
Was the study free from other risks of bias?	Unclear	It is possible that factors other than the operation of MET have altered the incidence of hospital death and of unexpected cardiac arrest and death in the institution. Bias may have been introduced into the study by the definition of cardiac arrest as the application of external cardiac compression rather than a state of pulselessness. Also staff turnover during study periods may have been an important and unknown factor.
KONRAD 2010		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before-and-after study with No randomization)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no concurrent control group)
Were baseline outcome measurements similar?	High Risk	No baseline measurement occurred due to before after design and lack of concurrent control group
Were baseline characteristics similar?	High Risk	There is no concurrent control group. The Karolinska University Hospital was assessed as a historical control.
Were incomplete outcome data adequately addressed?	Unclear	There is no evidence about missing data and incomplete data.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	The primary outcome is objective. (Cardiac arrests per 1000 admissions)
Was the study adequately protected against	High Risk	Due to the before after design of the study, there is no concurrent

Bias	Authors' judgment	Support for judgment
contamination?		control group for comparison.
Was the study free from selective outcome reporting?	Low Risk	All relevant data of measured outcomes were reported.
Was the study free from other risks of bias?	Unclear	The historical control groups were fewer and identified during two randomly selected days which should be taken into consideration. Severity scores were not collected for MET patients on the wards.

Table 2-6: Risk of bias criteria in the prospective, retrospective observational studies

Bias	Authors' judgment	Support for judgment
LEE 1995		
Was the allocation sequence adequately generated?	High Risk	Not met (it is not a CBA study. the study assessed the outcomes after MET implementation in Liverpool hospital)
Was the allocation adequately concealed?	High Risk	Not met (it is after only study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not specified in paper if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Unclear	It is not clearly mentioned if the outcomes assessed blindly.
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	All relevant outcomes in the methods section are reported in the results section
Was the study free from other risks of bias?	Unclear	Other risk of bias is possible.
GOLDHILL 1999		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a observational study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a observational study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Unclear	It is not mentioned in paper if the outcomes were assessed blindly.
Was the study adequately protected against contamination?	High Risk	Not met (as the study does not have control group checking the contamination is not possible)
Was the study free from selective outcome reporting?	Low Risk	There is no evidence that outcomes were selectively reported
Was the study free from other risks of bias?	Unclear	Other risk of bias will be possible.

Bias	Authors' judgment	Support for judgment
BRISTOW 2000		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a cohort study so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a cohort so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (this is a cohort study)
Were baseline characteristics similar?	High Risk	This is a cohort study (no intervention). Three hospitals were compared while no matching was reported.
Were incomplete outcome data adequately addressed?	Unclear	Not specified in paper.
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: cardiac arrest, unanticipated admission to intensive care unit (ICU), death
Was the study adequately protected against contamination?	High Risk	This is cohort study not a CBA, MET hospitals were compared with others during study period but there is no data about protection against contamination.
Was the study free from selective outcome reporting?	Low Risk	All related data about main outcomes (cardiac arrests, death and…) were reported.
Was the study free from other risks of bias?	Unclear	Cannot answer definitively if the MET was the cause of the benefit they observed; it does show that the MET concept is worthy of further study
SALAMONSON 2001		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a 3-year review of with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a after only study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: in-hospital deathscalls for cardiopulmonary arrest
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	All related data about main outcomes were reported.
Was the study free from other risks of bias?	Unclear	The influence of other confounding factors were not assessed.

Bias	Authors' judgment	Support for judgment
PITARD 2003		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (it is not a CBA study, no concurrent control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned clearly if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: admission rates, mortality and so on.
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no concurrent control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	all relevant outcomes in the methods section are reported in the results section
Was the study free from other risks of bias?	Low Risk	Confounding factors may influence the results during study period.
SHAREK 2007		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a cohort study design with historical controls so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (there is no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison)
Were baseline characteristics similar?	High Risk	Not met (no control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: hospital-wide mortality rates (all deaths, irrespective of where they occurred in the hospital) and code rates outside of the ICU (per 1000 eligible patient days and per 1000 eligible admissions).
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no concurrent control group for checking the contamination with)
Was the study free from selective outcome	Low Risk	All related data about main outcomes were adequately reported.

Bias	Authors' judgment	Support for judgment
reporting?		
Was the study free from other risks of bias?	Unclear	It is possible that the reduced rates of mortality and codes outside of the ICU were simply the result of differences in the pre-intervention and post-intervention populations and are independent of the RRT intervention. Second, it is possible that there were 1 or more other interventions implementedcontemporaneously that might have decreased mortality rates and code rates outside of the ICU setting.
CHAN 2008		
Was the allocation sequence adequately generated?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Was the allocation adequately concealed?	High Risk	Not met (it is a before after study with no control group so that allocation was not occurred)
Were baseline outcome measurements similar?	High Risk	Not met (no control group exists for comparison, the main hospital campus of Saint Luke's Health Care System assessed before and after intervention)
Were baseline characteristics similar?	High Risk	Not met (no concurrent control group exists for comparison)
Were incomplete outcome data adequately addressed?	Unclear	It is not mentioned if there were missing data during conducting the study
Was knowledge of the allocated interventions adequately prevented during the study?	Low Risk	Main outcome measures were objective: hospital- wide cardiopulmonary arrest rates per 1000 admissions and mortality rates per 100 admissions.
Was the study adequately protected against contamination?	High Risk	Not met (as it is not a controlled before after study, there is no control group for checking the contamination with)
Was the study free from selective outcome reporting?	Low Risk	All related data about main outcomes were reported.
Was the study free from other risks of bias?	Unclear	Confounding factors such as quality-improvement may have influenced study outcomes.

The RCT studies were used to guide the design of the trial in this thesis, but due to low number of RCT studies in this field, to have enough evidence and a comprehensive understanding to implement a suitable form of CCS, I extracted the following data from each study included: authors, study type, duration, year, country, type of study, type of system, type of patients, study aims and outcomes including mortality, cardiac arrest, LOS and ICU Admission rate.

In the following section, I will present the characteristics and results of some of the more important interventional studies dealing with each system.

2.9.1 Characteristics of CCS studies

In this section the characteristics of different methods of studies are presented in tables, as listed below:

Table 2-7: Systematic reviews (SR)

Table 2-8: Randomized Clinical Trials (RCT)

Table 2-9: Before/after studies

Table 2-10: Prospective, Retrospective and Observational studies

Table 2-7: Characteristics of the SR for CCS studies, described in this chapter (arranged in chronological order)

Authors	Study Type	Year	Country	Type of Patients	Study Aims
Esmonde et al.	SR	2006	England	Adult patients	Assessing the impact of critical care outreach activity on patient and service outcomes and aiming to contribute to developing a typology of CCOS.
McGaughey et al.	SR	2009	England	Adult patients	Determining the impact of CCOS on hospital mortality rates, ICU, admission patterns, length of hospital stay.
Chan et al.	Meta-analysis	2010	United States	Adult and paediatric patients	Assessing the effect of RRTs on reducing cardiopulmonary arrest and hospital mortality rates

Table 2-8: Characteristics of the Randomized Controlled Trials of CCS described in this chapter (arranged in chronological order)

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
Priestley et al.	A step wedge, pragmatic, ward-randomized trial	32-week period	2004	England	CCOT	All admissions to the 16 surgical, medical and elderly care Wards	Investigating the effects of introducing a critical care outreach service on in-hospital mortality and LOS
Hillman et al.	Prospective cluster-randomized controlled trial	Collecting baseline data over 2 months. Twelve hospitals were allocated to MET and 11 hospitals to control.	2005	Australia	MET	All admitted patients in Twenty-three hospitals	Determining the effect of MET on incidence of cardiac arrests, unplanned admissions to ICU, and deaths.

Table 2-9: Characteristics of the before and after studies of CCS described in this chapter (arranged by the date of study)

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
Buist et al.	Non-randomized. Before and after introduction of the medical emergency team	two 12 month period	2002	Australia	MET	all patients admitted to hospital	Determining effect of MET in reducingthe incidence of and mortality from unexpected cardiac arrest in hospital. (Incidence and outcome of unexpected cardiac arrest)
Bellomo et al.	Prospective Before-and-after intervention trial	Before (4-month) preparation and education period to introducing the MET. After(4-month)	2003	Australia	MET	All patients admitted to the hospital were considered as participants	To determine the effect on cardiac arrests and overall hospital mortality of an intensive care-based medical emergency team.
DeVita et al.	Retrospective analysis Before-and-after	6.8 years Before(5 years) and after(1.8 years)	2004	America	MET	All admitted patients, except those in the emergency department, ICU and post-anaesthesia care	"Determining how the incidence and outcomes of cardiac arrests have changed following increased use of MET"
Garcea et al.	Retrospective observational study- before and after	Period of 21 months prior to the introduction of outreach and a period of 30months following introduction of the outreach team	2004	England	CCOT	All discharges from the intensive therapy unit (ITU) and the high dependency un it (HDU)	Determining the change in the critical care readmission rate, critical care mortality and in-hospital mortality

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
Kenward	Prospective and retrospectively	12-month period	2004	England	MET	All adult admissions receiving intervention by the MET	To evaluate the activity and impact of a MET one year after implementation
Jones et al.	Prospective before-and-after interventional trial	Four years in 3 periods. 1- Before (control) 2- Education 3- After (intervention)	2005	Australia	MET	All patients admitted to the hospital for at least one night were considered as participants	Analysing the incidence of cardiac arrests following the introduction of the MET service.
Jones et al.	Prospective, controlled, before-and-after trial	1500 days (4.1 years)	2007	Australia	MET	All patients who had undergone inpatient surgery during the study period and who remained in hospital for 48 hours or more after surgery	Assessing the effect of the MET and other variables on long-term mortality in patients with major surgery.
Brilli et al.	Retrospective chart review and program implementation		2007	United States	MET	Children	MET impact on the rate of CPR codes outside ICU
Dacey et al.	prospective, controlled, before and after trial	5 months before the RRT and 13 months after it.	2007	Rhode Island - United States	RRT	All adult patients (Exclusion criteria including any patient _15 yrs old and any patient already in the ICU. Patients in the emergency department but not yet admitted to the hospital as well as any patients who had comfort measures as the only goals of therapy were also excluded.)	To determine the effect of a rapid response system composed primarily of a RRT led by physician assistants on the rates of in-hospital cardiac arrests, Total and unplanned ICU admission, and hospital mortality.

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
Baxter	Prospectively collected data with historical comparators	Two years before (retrospective) and two years after (prospective) MET introduction	2008	Canada	MET	Adult medical and surgical patients	Effect of MET on cardiac arrests, postoperative complications, and hospital mortality
Hunt	A before-and-after interventional trial	12 months Pre intervention and 12 months post intervention	2008	United States	RRT	Admitted patients who subsequently had either the code team or paediatric medical emergency team (PMET) called or who had a respiratory arrest or CPA on the wards	To study the effects of an intervention on prevention of respiratory arrest and cardiopulmonary arrest (CPA) and to characterize ward CPAs by precedingsigns and symptoms and initial cardiac rhythm.
Tibballs and Kinney	Interventional Retrospective – prospective (before and after)	41-month period pre-MET and48 months post-MET	2009	Australia	MET	Paediatric	To determine the effect of MET on the incidence of unexpected cardiac arrest and death.
Konrad et al.	Prospective before-and-after trial	A control period of 5 years And	2010	Sweden	MET	All adult patients, apart from cardiothoracic, admitted to the hospital were regarded as participants	Evaluating the implementation of a RRT in the form of a MET with regard to cardiac arrests and hospital mortality

Table 2-10: Characteristics of the CCS studies (prospective, retrospective and observational) described in this chapter (arranged by the date of study)

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
Lee et al.	Interventional Prospective	12-month period	1995	Australia	MET	Patients hospitalized in: Emergency Department Hospital wards Critical care areas	Describing the utilization and outcome of MET interventions
Hourihan et al.	Prospective	6 months	1995	Australia	MET	Inpatients and outpatients	Describing the utilisation of an emergency team that employs standardized calling criteria to facilitate the early identification and resuscitation of patients who are at risk of cardio respiratory arrest.
Goldhill et al.	Prospective	6 months	1999	United Kingdom	PART	All patients admitted to ICU from the wards	To see whether the physiological criteria used to call the PART were appropriate and useful in determining the necessity for admission to ICU, and whether early review or intervention improved patient outcome.
Bristow et al.	Cohort comparison	6 months	2000	Australia	MET	All adult (≥ 14 years) patients admitted to three hospitals	To evaluate the effectiveness of a MET in reducing the rates of selected adverse events
Salamonson et al.	Retrospective	3-year review	2001	Australia	MET	Patients died in hospital and all unanticipated patients. And Patients transferred from the wards to the ICU	Examining the effects of the MET system on admission to ICU and on hospital mortality rate
Pittard	Observational	6-month	2003	England	CCOT	Surgical	Changes in unplanned admission rate on intensive

Authors	Study Type	Duration	Year	Country	Type of system	Type of Patients	Study Aims
							care, LOS, mortality rate and number of re-admissions following the introduction of outreach
Sharek et al.	Cohort with historical control		2007	United States	RRT	Paediatric inpatients	To determine the rate of hospital mortality and code alerts outside ICU, following RRT implementation
Chan et al.	Prospective cohort		2008	United States	RRT	Adult inpatients	To determine rates of hospital-wide codes and mortality, before and after implementation of a long-term RRT intervention.

2.9.1.1 Systematic Review (SR)

An SR by Esmonde et al. (2006) addressed the impact of CCOS on patients and service outcome. The researchers attempted to develop a typology of CCOS. They searched the relevant articles published from 1996 to 2004. Other information sources, such as papers and seminars were also considered. A further two studies published after the review date were also included. Among these, 17 studies and 6 brief reports were chosen, including two RCTs(84, 85), 16 uncontrolled before-and-after studies(85-100), three quasi-experimental studies(59, 101)and (S. Ingleby, unpublished),one controlled before-and-after study(102) and one post-only controlled before-and-after study(103).From these studies, 15 were published and the rest were brief and reports. The most frequent outcomes measured, were mortality, cardiac arrest, unplanned critical care admissions from wards, LOS, and critical care readmission. The patients in all studies were adults (> 18 years), but hospital setting varied between studies, and studies also varied in terms of hospital type and size, nature of the service offered, operational characteristics of the services, timing of service evaluation, and critical care discharge follow-up(104).

Mc Gaughey et al. (2007) conducted an SR to determine the impact of outreach on hospital mortality and the pattern of ICU admission, LOS, and adverse events. The study encompassed RCTs, controlled clinical trials (CCTs), controlled before-and-after studies (CBAs), and interrupted time series (from 1999 to 2005). These were dealing with hospital mortality, ICU admission, ICU readmission, LOS, and adverse events following outreach and TTs implementation in general wards and their comparison with hospitals or wards without these systems, in order to demonstrate the deteriorating conditions of adult patients. Two high-quality studies (RCTs) were found: one compared 12 hospitals with outreach to

11 hospitals without it(84); another compared 16 wards with outreach to those without (85). Another study indicated that the system reduces mortality, while the other showed no significant difference (105).

Chan et al. (2010) completed a SR followed by a meta-analysis of 17 studies (from 1950 to 2008) (84, 85, 90, 93, 98, 100, 103, 106-115). The articles made comparisons with a control group or after a control period, or they provided enough quantitative data for primary outcomes of hospital wide mortality or secondary outcomes of cardiopulmonary arrest outside ICU to be analyzed. All 17 studies were published from the year 2000 onwards, with 50% (9 articles) published after 2007. The sample volume of these studies was 1,271,864 patients, with 580,776 patients in the control period and 691,088 in the intervention period (76).

In summary, Chan et al. (2010) was an SR with meta- analysis, conducted in order to assess the effect of RRTs on reducing cardiopulmonary arrest and hospital mortality rate. Study patients were both adults and children. However, the McGaughey et al (2007) and Esmonde (2006) studies were SRs without meta-analysis.

2.9.1.2 RCT studies

Priestley et al. (2004) conducted a step wedge, pragmatic, ward-randomized trial to evaluate the impact of CCOS on hospital mortality and LOS. The study was completed in 16 wards of an 800-bed hospital in northern UK. All patients admitted to these 16 wards during the 32 weeks of the study were included. All admissions to the 16 wards of medicine, surgery, and geriatrics over 32 weeks were recorded. The intervention team consisted of nurses and physicians experienced in intensive care and a nurse led it. CCOT was available for 24 hours every day and provided education, support and practical help for the staff(85).

The Hillman et al. study (2005), known as the MERIT study, is a multi-centered, cluster-randomized trial carried out in 23 Australian hospitals to investigate the impact of MET on frequency of cardiac arrest, unplanned ICU admission and mortality. In this study, after two months of data collection, the 23 hospitals were randomly assigned as either control or intervention hospitals. According to the study protocol, the MET was, at the very least equal to the cardiac arrest team already in place, and consisted of at least one physician and one nurse from the emergency department or the ICU. 12 hospitals were assigned to intervention hospitals and 11 to control hospitals(84).

2.9.1.3 Before-and-After studies

Buist et al. (2002) conducted a non-randomized population study from 1996 to 1999. Its purpose was to determine the impact of earlier clinical interventions on reduction of cardiac arrest and its mortality before and after implementation of the MET system. The MET system consisted of two physicians and one senior nurse, who attended to clinically unstable patients with resuscitation medication, fluids, and equipment as soon as their condition worsened. Physicians and nurses

according to predefined criteria would summon the team. The researchers investigated the frequency and outcome of unexpected cardiac arrest(90).

Bellomo et al. (2003) conducted a prospective before-and-after study to assess the impact of intensive care-based medical emergency teams on cardiac arrest and overall hospital mortality. All patients admitted to the hospital four months prior to, and following, intervention were included in the study (100).

Although MET was initially started in Australia, its use in an American hospital and was reported by DeVita et al. (2004) in a study designed to evaluate the impact of MET on hospital mortality. The MET consisted of 8 members, including physicians, nurses, and a respiratory therapist. From 1996 onwards, with the initiation of the study, the system was expanded to cover all admitted patients, except those in the emergency department, ICU, and post-anesthesia care. In 2000, the hospital developed a protocol to define objective criteria for MET activities. Data related to cardiac arrest and ensuing death, and the number of calls made to MET before and after its extended use were collected and analyzed in order to check for significant differences(93).

Garcea et al. (2004) conducted a study in a large teaching hospital in England to assess the impact of CCOT on mortality and ICU readmission. An outreach program was started in the hospital in 2001, consisting of two senior nurses and a consulting intensive care nurse. The study spanned from 1999 to 2003, encompassing 21 months prior to outreach and 30 months after its implementation(96).

Kenward (2004) conducted a study in the UK to evaluate the activity and impact of MET one year after its implementation. The study population consisted of all adults admitted to the hospital who received MET interventions (98).

Jones et al. (2005) conducted an interventional trial to study the impact of MET on long-term incidence of cardiac arrests. Their study was planned over three different time periods: before intervention, during training and four years after intervention. The number of hospital admissions and MET reviews were recorded for each time period(109).

Jones et al. (2007) conducted a study to determine the impact of MET and other variables on long-term mortality in Australian patients. The study population consisted of patients admitted for major surgery requiring more than 48 hours of hospital stay. Over the 4 months of intervention, the MET consisted of an intensive care fellow, an intensive care nurse, and an internal medicine fellow. An ICU specialist was also available on demand(14).

Brilli et al. (2007) implemented MET in a pediatric hospital and investigated its impact on the rate of CPR codes outside ICU in a retrospective chart review (107). In order to assess RRT, Dacey et al. conducted a trial on all patients admitted to a 350-bed, non-teaching hospital in 2005-6 (108).

Boxter et al. (2008) conducted a study to investigate the impact of MET on cardiac arrest, post-surgical complications, and in-hospital mortality in two locations in a hospital in Ottawa. The hospital admitted both medical and surgical patients (106).

Hunt (2008) conducted a study to investigate the impact of MET on preventing cardiopulmonary arrest in a pediatric hospital(115). Tibballs and Kinney (2009) investigated the impact of MET on the frequency of cardiac arrest and unexpected death in a pediatric hospital(112).

Konrad (2010) investigated the effect of an RRT (in the form of an MET) on cardiac arrest and in-hospital mortality in a hospital in Stockholm, Sweden. All patients admitted to the hospital (except children and patients with heart diseases) were included in the study(64).

2.9.1.4 Prospective, retrospective and observational studies

Lee et al. (1995) conducted a study to assess MET application and the outcome for patients who required MET interventions. Data from all calls made to MET from March 1992 through February 1993 was collected (54).

Hourihan et al. (1995) described the utilization of an emergency team, which uses standardized calling criteria in order to facilitate the recognition and resuscitation of patients at risk of cardiac arrest. The study was conducted in a 460-bed teaching hospital in Sydney, Australia and measured the rate of unplanned ICU admission and mortality (116).

Goldhill et al. (1999) started the patients at risk team (PART) similar to MET in 1997 to care for critically ill patients in the United Kingdom. The objective of PART was to improve patient care for those admitted to wards, through facilitating their ICU admission or preventing unnecessary ICU admissions(59).

Bristow et al. (2000) conducted a cohort study to assess the efficiency of MET in reducing adverse events for all patients admitted to 3 Australian hospitals in 1996. Cardiac arrest, unplanned ICU admission, and mortality were recorded (103).

Salamonson et al. (2001) evaluated the impact of MET on the pattern of transfer of ICU patients to wards and improvement of patient survival in a retrospective study spanning 3 years. Data regarding unanticipated ICU transfer and MET calls was collected(101).

An observational study was conducted by Pittard (2003), following the introduction of an outreach service in three surgical wards and the surgical high dependency unit in a large teaching hospital in the UK during a 6-month study period. The outreach team comprised senior critical care nurses and medical staff. The service was available from 09.00–17.00, Monday–Friday(86).

A cohort study with historical control was conducted by Sharek et al. (2007) following RRT implementation in a 264-bed teaching pediatric hospital to determine the rate of hospital mortality and code alerts outside of ICU. The RRT consisted of an ICU trained fellow or attending physician, an ICU nurse, an ICU respiratory therapist, and a nursing supervisor(111).

In Chan's (2008) study, the RRT was led by a nurse and consisted of two ICU nurses and a respiratory therapist responsible for responding to all calls for critical patients 24 hours a day. An ICU attending physician and a fellow joined the team on demand. The team attended to the patient within 10 minutes and completed the evaluations within 30 minutes(114).

In summary, it is notable that the three SRs included all of the studies described in RCT, before-after, prospective, retrospective and observational studies, except for three studies (54, 64, 116).

2.9.2 Results, outcomes and limitations of different studies

In this section the results and outcomes of the above studies are described in three tables as follows:

Table 2-11: SR studies

Table 2-12: RCT studies

Table 2-13: Before & After studies

Table 2-14: Prospective & Retrospective studies.

Table 2-11: Outcomes and limitations of the CCS -SRs described in this chapter (arranged in chronological order)

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
Esmonde et al.	The results suggested an improvement in patient outcome, but failed to yield conclusive proof. Critical care outreach activity is ineffective				Insufficient robust research to assess the impact of critical care outreach activity on patient or service outcomes in the United Kingdom. No clear typology of outreach services emerges for analysis from review. Across all studies there is wide variation in terms of service membership, type of outreach activity and availability of the service.
McGaughey et al.	No effectiveness for outreach reducing patient mortality (inconclusive)	No effectiveness for outreach reducing cardiac arrest (inconclusive)	No effectiveness for outreach reducing patient mortality (inconclusive)	No effectiveness for outreach reducing patient mortality (inconclusive)	
Chan et al.	No reduction in hospital mortality. The paediatric studies indicated a significant reduction in hospital mortality	Significant reduction in adult cardiopulmonary arrest			

Table 2-12: Outcomes and limitations of Randomized Controlled Trials of CCS described in this chapter (arranged in chronological order)

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
Priestley et al.	Intervention reduces mortality compared to the control group		Intervention impact on LOS remained unclear		Single centre Hawthorne effects "carrying out the study was a stimulating experience for all concerned, which may have encouraged dynamic delivery of the intervention, beyond what would be expected of effective implementation outside a research context" "Members that delivered the intervention collected much of the data and this is another possible bias" "contamination of control wards with the practices being introduced in other nearby wards is a possible problem" "The SAPS II results were incomplete because the full range of physiological measures is not recorded for all patients and no tests were done specifically for the study"
Hillman	No significant difference between hospitals with MET and the control hospitals in incidence of, unexpected death	No significant difference between hospitals with MET and the control hospitals in incidence of cardiac arrest		No significant difference between hospitals with MET and the control hospitals in incidence of unplanned ICU admissions	Under powering the study Contamination of control hospitals because control hospitals may have been exposed to MET concepts through coverage in the literature.

Table 2-13: Outcomes and limitations of the CCS studies (Before –After) described in this chapter (arranged in chronological order)

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
Buist et al.	MET significantly reduces the incidence of, and mortality from unexpected cardiac arrest.				Single hospital Historical control. The research project had a high profile within the hospital and the authors'" concerns were well known. "Natural regression" due to medical progress or random fluctuation because of two discontinuous time points
Bellomo et al.	The incidence of death following cardiac arrest, and overall in-hospital mortality decreased	The incidence of in-hospital cardiac arrest decreased	The bed occupancy related to cardiac arrest decreased		Single centre This trial was not double-blind, or placebo-controlled or randomised.
DeVita et al.		Significant decrease in cardiopulmonary arrest			Single centre Changes in patient care contemporaneous to increased MET use may have contributed to the observed decrease in the incidence of cardiopulmonary arrest. The retrospective nature of these data makes it difficult to exclude hidden biases.
Garcea et al.	Hospital and intensive care mortality had decreased following outreach implementation, although the difference was not statistically significant				Small population sizes Better resource management secondary to the work by outreach may contribute to reduced pressure on critical care beds and prevent early discharge. The skills taught by outreach to nursing and junior clinical staff are transferable to the management of all ward-based patients, and as such may result in better management of

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
					critical care discharges and so improved mortality.
Kenward	A reduction in overall mortality was noted but this was not statistically significant	A reduction in cardiac arrest rate was noted but this was not statistically significant			Single centre
Jones et al.		MET in conjunction with a detailed education program intervention was associated with sustained and progressive reduction in cardiac arrests. Inverse correlation between the level of activation of the MET service and the incidence of cardiac arrests.			Single institution Not randomised, blinded or placebo-controlled. The inclusion of episodes of insufficient data. As the frequency of cardiac arrest was low during the training period. Thus, training and intervention were considered synergistically in reducing incidence of cardiac arrests.
Jones et al.	MET was associated with increased survival even after adjusting for other factors influencing mortality in patients undergoing surgery				Single centre Neither double blinded nor placebo controlled or randomised. Analysis revealed differences in characteristics of the patient cohorts admitted during the control and MET periods. Reduction in long-term mortalityof surgical

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
					patients. The effect on medical patients was not assessed.
Brilli et al.	Reduction in the risk of respiratory and cardiopulmonary arrest outside of the critical care areas				
Dacey et al.	Significant decreases in rates of in-hospital cardiac arrest	The ICU LOS not varied significantly	Significant decreases in rates of unplanned ICU admissions		Single centre There are many factors that might influence the clinical outcomes of hospitalized patients in addition to the RRS. The case mix index was constant for patients in the year before and the year after RRS, yet it does not justify the differences in acuity that might have existed. Although the nursing staffs were unchanged, generally, the study could not consider the daily variations which might have had some bearing on the diagnosis of critical patients. The performance of nursing staff might have improved due to the fact that they were aware of being observed, but this difference could not be quantified.
Baxter	Successful implementation of MET reduces patient morbidity and ICU resource utilisation.				Historical controls outcome data are collected and reported at arm's length from clinical patient management. Other factors may contribute to the observed outcome improvements concurrent. Structural, or organisational changes and preoperative improvements coincided with the implementation of MET
Hunt		Transition to a PMET was not associated with a			

Authors	Outcomes				Limitation
	Mortality	**Cardiac arrest**	**LOS**	**ICU Admission**	
		change in CPAs but was associated with a significant decrease in the incidence of ward respiratory arrests.			
Tibballs and Kinney	MET was associated with reduction of total hospital death and reduction of preventable death with increased survival in wards	MET was associated with reduction of preventable cardiac arrest			Single centre
Konrad et al.	Significant reductions in overall hospital mortality	Significant reductions in cardiac arrest rate			Single centre Historical controls Severity scores were not collected for MET patients on the wards

Table 2-14: Outcomes and limitations of the prospective, retrospective observational studies of CCS described in this chapter (arranged in chronological order)

Authors	Outcomes				Limitation
	Mortality	Cardiac arrest	LOS	ICU Admission	
Lee et al.	"mortality rate remained unchanged"				Single centre
Hourihan et al.	A standardised team approach may be potentially beneficial for reducing mortality				
Goldhill et al.	Of admissions seen by the team, 25% died on the ICU compared with 45% of those not seen (not significant) Among those not seen by the team, mortality was 40% for those who did not require Resuscitation and 57% for those who did (not significant).	cardiopulmonary resuscitation before ICU admission was 3.6% for patients visited by PART and 30.4% for those not visited, indicating a statistically significant difference			
Bristow et al.	Hospital with MET had no increase in overall hospital mortality. No significant difference in total deaths between the three hospitals.	Hospital with MET had no increase in the rate of cardiac arrest No significant difference in the rates of cardiac arrest		Hospital with MET had the lowest rate of unplanned ICU admission. a significantly reduced rate of unanticipated ICU/HDU admissions at the MET intervention hospital	
Salamonson	A slight decrease in the	MET reduced the		Number of	Single centre

Authors	Outcomes				Limitation
	Mortality	**Cardiac arrest**	**LOS**	**ICU Admission**	
et al.	percentage of in-hospital deaths.	proportion of cardiac arrest.		ICU transfers remained constant	Information relating to severity of the illness was not collected and study notable to demonstrate conclusively that reduction in hospital mortality was due to the introduction of the MET system.
Pittard	Reduced in mortality but not statistically significant		Reduced in LOS, but not statistically significant	Reduction in emergency admission in the ICU, but not statistically significant	Single centre
Sharek et al	Statistically significant reduction in code mortality outside PICU				
Chan et al	No significant decrease in mortality			No significant decrease in code rate	

2.9.2.1 Systematic Review studies

The results of the SR by Esmonde et al. (2006) suggested an improvement in outcomes, but the evidence was insufficient to demonstrate this conclusively. The authors concluded that the studies included in this SR were weak due to a number of important limitations in study design. The discrepancies between the different systems implemented made it impossible to define a service typology. Although no strong evidence was found to prove the impact of CCO on patient outcome, the review did not demonstrate its ineffectiveness, either. In conclusion, the authors stated that further comprehensive studies are required for these services, and there is no reason to suggest their discontinuation or to oppose their development(104).

The review study conducted by McGaughey et al. (2007) revealed the diversity and poor methodology of most studies that dealt with CCS. Because of the heterogeneity in terms of intervention, setting, outcomes, and study, design comparison across studies and meta-analysis was not possible(105).The strength of McGaughey et al. was the inclusion of two RCTs. In the study by Esmonde et al., these two studies as well as 21 other studies were included. The Mc Gaughey et al. (2007) and Esmonde (2006) studies highlight the poor quality of research and the lack of evidence to support the benefits of CCS.

In the Chan et al. (2010) study, overall, RRT implementation was associated with a 33.8% fall in untreated cardiopulmonary arrest outside ICU for adults. Studies labeled high quality (in adults) indicated a 21.1% reduction in cardiopulmonary arrest compared to 47.8% reduction in other studies. In 5 studies conducted on children, 4

studies reported significant reduction in cardiopulmonary arrest outside ICU. RRT implementation was associated with a 37.7% fall in non-ICU-treated cardiopulmonary arrest, with a strong subgroup analysis.

In general, 11 studies indicated that RRT implementation did not affect hospital-wide mortality. Moreover, studies of different qualities did not differ significantly in this regard. As for pediatric RRT, 2 studies out of 4 indicated a significant reduction in hospital mortality. However, the results were considerably heterogeneous in this respect. Furthermore, combination of adult and pediatric data did not indicate that RRT implementation reduced hospital mortality. This SR indicated that RRT implementation was associated with a significant (33.8%) reduction in adult cardiopulmonary arrest, but with no reduction in mortality rates. On the other hand, the pediatric studies indicated a significant reduction in hospital mortality(76).

2.9.2.2 RCT studies

The results of the Priestley et al. (2004) study indicate that intervention reduces mortality compared to the control group. Nevertheless, its impact on LOS remains unclear(85).

The results of the Hillman et al. study (2005) indicated that MET use was associated with an increased number of emergency calls. Although the number of cardiac arrests and unexpected death decreased in control and intervention groups, no significant difference was observed between the two groups in terms of composite primary outcome. The study indicated that establishing an MET system considerably increases the number of calls for help, but has no impact on the number of cardiac

arrests, unplanned ICU admissions, or unexpected deaths. In other words, no significant difference was found between hospitals with MET and the control hospitals in terms of the composite outcome(84).

Chrysochoou and Gunn (2006) have criticized the study by Hillman et al., stating that other explanations may be found for the improvement of outcome; for instance, MET may have augmented Do Not Resuscitate (DNR) orders, thus reducing the number of pointless resuscitations(117).

2.9.2.3 Before-and-After studies

In the study by Buist et al., results indicated that MET considerably reduced the number of cardiac arrests as well as the mortality of unexpected cardiac arrests, lowering it from 77% before MET to 55% after its implementation(90).

The Results of the Bellomo et al. (2003) study revealed that the overall number of cardiac arrests decreased from 63 to 22 (RRR, 65%; $P<0.001$). Also, the overall number of cardiac arrests over the four months of intervention was lowered significantly compared to a similar period in the previous two years. Moreover, a significant reduction was observed in the overall mortality and LOS compared to the period before intervention, as well as a similar period in the previous two years. The researchers concluded that implementation of MET reduced the frequency of in-hospital cardiac arrest and death following cardiac arrest, and also admission rates related to in-hospital cardiac arrest and death(100).

In the DeVita et al. (2004) study, the results indicated that the frequency of MET calls rose from 13.7 to 25.8 per 1,000 admissions. Furthermore, cardiopulmonary arrest diminished from 6.5 to 5.4 per 1,000 admissions, which was statistically significant. The ratio of fatal arrest was similar before and after MET. In general, the results of the study suggested that extended MET use may result in a significant decrease in cardiopulmonary arrest(93).

The results of the Garcea et al. (2004) study revealed that hospital and intensive care mortality had decreased following outreach implementation, although the difference was not statistically significant. The researchers concluded that despite the large number of confounding variables, mortality rate was lowered among patients readmitted to ICU. Therefore, they stated that the service may improve mortality rate(96).

In the Kenward (2004) study, during the one-year of MET implementation, 40% were alive on discharge after MET interventions. Among those who had died, 22% had a DNR order. The mortality cases had 3 or more items of abnormal physiology and higher MET scores(98).

The Jones et al. (2005) study indicated that the intervention had a significant impact on the incidence of cardiac arrest compared to the period before intervention. Their results indicated that an ICU-based MET service with a training program is associated with a reduction in the number of cardiac arrests. The rate of cardiopulmonary arrest declined over the four years of MET implementation (109).

In the Jones et al. (2007) study, 1,369 procedures were performed for 1,116 patients during the control period, while in the MET period, 1,313 procedures were performed for 1,067 patients. The results showed that MET was associated with increased survival even after it had been adjusted for other factors influencing mortality in patients undergoing surgery. Patients in the MET period had better 1,500-day survival. Over this period of 1,500 days, 381 and 303 deaths occurred in patients of the control and MET periods, respectively, yielding 1,500-day survival rates of 71.6% for MET patients and 65.8% for control patients, which are significantly different(14).

In the Brilli et al. (2007) study, the frequency of code for respiratory and cardiopulmonary arrests was significantly lowered from 1.54 to 0.62 per 1,000 admissions. The frequency of cardiac arrest was not significantly different before and after the intervention. As for preventable codes, the rates indicated another significant difference (p = .04). The mortality rate declined from 0.12 per 1,000 patient days to 0.06 after MET. The difference, however, was not statistically significant. The study concluded that MET implementation is associated with a lower risk of cardiopulmonary arrest outside ICU (107).

Dacey et al. conducted a prospective study. During the 5 months preceding the study, cardiac arrests dropped from 7.6 to 3 cardiac arrests per 1,000 discharges per month. The mortality rate was 2.82% in the year before the RRT program, which had decreased to 2.35% by the end. Furthermore, unplanned admissions dropped from 45% to 29% during the study period. The results indicated an association between an

RRT led by an assistant physician with specialized skills and considerable decrease in rates of in-hospital heart arrest and unplanned ICU admissions (108).

The findings of Boxter et al. (2008) indicated that compared to the period before intervention, cardiac arrest was reduced from 2.53 ± 0.8 to 1.3 ± 0.4 /1,000 admissions ($P < 0.001$). ICU admission had occurred for 27% of MET patients, and the rate of ICU admissions from in-patient nursing units was lowered (42.3 ± 7.3 to 37.6 ± 5.1, $P = 0.05$). Also, readmissions after ICU discharge/month were reduced ($P = 0.01$). The results indicated that successful MET implementation improves most parameters and causes a significant decrease in unexpected cardiac arrest, post-surgical complications, and ICU admission and readmissions(106).

The results from a study by Hunt (2008) indicated that calls rates for the team were increased insignificantly. The combined rate of respiratory arrest and cardiopulmonary arrest was reduced, although the difference was not significant. The survival rate after respiratory or cardiopulmonary arrest decreased insignificantly after the intervention. Nevertheless, a significant decrease (73%) was observed in the rate of respiratory arrests requiring intubation (115).

The results of Tibballs and Kinney (2009) indicated that MET results in an overall decrease in hospital mortality, cardiac arrest, and preventable death in addition to an improvement in patient survival(112).

The results of the Konrad (2010) study indicated that MET implementation is associated with a significant improvement in adjusted hospital mortality and cardiac arrest rates (64).

2.9.2.4 Prospective, Retrospective and Observational studies

In the study by Lee et al. (1995), 522 MET calls from admission wards, emergency rooms, and regular wards of the hospital were recorded. Among these, 443 calls for resuscitation were made for the first time, and 35 patients required more than one resuscitation. The survival rate following cardiopulmonary arrest was less than 29% on discharge, compared to other critical illnesses (76%). Despite MET implementation, the mortality rate following cardiac arrest remained unchanged (54).

In studies by Hourihan et al. (1995), a total of 194 calls were made, with 53% of these occurring on wards and 31% in the emergency department. The researchers concluded from the results that MET perform favorably as a rapid intervention team. In addition, they suggested that a standardized team approach promoting early interventions for patients at risk may be potentially beneficial for reducing mortality (116).

In the Goldhill et al. (1999) study, the frequency of CPR before ICU admission was 3.6% for patients visited by PART, and 30.4% for those not visited by the team ($p<0.005$). However, the difference between numbers of patients who died in the ICU was not significant. The results indicated that the system reduces the need for CPR, and may therefore help reduce mortality on wards(59).

In the Bristow et al. (2000) study, the results did not indicate a significant difference among the three hospitals in terms of cardiac arrest or overall death; nevertheless, the rate of unplanned ICU admission was lower in the intervention hospital as compared to the other two. The hospital with MET had the lowest rate of unplanned ICU admission, with no increase in the rate of cardiac arrest or overall hospital mortality (103).

The results of the study by Salamonson et al. (2001) indicated that the number of MET calls was doubled during the second and third years, and the team's scope was broadened to cover more than simply patients who were extremely ill. Although the number of calls for cardiac arrest remained constant, implementation of MET reduced the proportion of cardiac arrest calls from 30% in the first year to 13% in the third year. In addition, despite the fact that the number of patients transferred to ICU did not change, the critically ill patients were transferred through MET. All these results could not demonstrate whether the slight improvement in hospital survival during the three years of the study could be attributed to MET. The researchers concluded that further studies were required to confirm the impact of MET on patient survival (101).

The Pittard (2003) study indicated that implementing the CCS on three surgical wards of a large hospital resulted in reductions in: emergency admission to the ICU from 58% to 43% ($p=0.05$), LOS from 7.4 to 4.8 days, mortality from 28.6% to 23.5% ($p=0.05$) and readmission from 5.1% to 3.3%(86).

In the study by Sharek et al. (2007), after RRT implementation, monthly mortality rate fell by 18%, and monthly code rate decreased by 71.2%. Moreover, RRT implementation was associated with a statistically significant reduction in code mortality outside ICU(111).

In Chan's (2008) study, from all 376 calls to RRT, the hospital code rate fell from 11.2 to 7.5 per 1,000 admissions following RRT implementation, but no difference in mortality rate was found. In summary, the study did not indicate a significant decrease in mortality or code rate (114).

2.9.3 Conclusion of review of evidence for CCS effectiveness

There are many studies that have investigated the CCS effects on mortality/ cardiac arrest / LOS / CPR/ ICU admission in different adult and pediatric patients. After looking at the results, it is clear that designs such as SRs (76, 104, 105) and RCTs (84) showed no effect. But studies with a high risk of bias such as before-after (14, 64, 90, 93, 96, 100, 106, 109, 112), prospective, retrospective(59) and observational studies(86) showed that CCS had been effective.

RCTs and SRs design studies have failed to yield any conclusive proof of these services for reducing cardiac arrest, expected death, or unplanned ICU admission. The studies suggested that further research be carried out to evaluate the effectiveness of CCS. Because of this evidence, I decided to undertake an RCT for evaluating the effectiveness of such systems. A further factor that I considered was that all studies

were carried out in developed countries, and no studies were found for middle income or developing countries such as Iran.

In addition, these services have affected other aspects of medical service, as summarized below:

1. Facilitating the evolution of hospital attitude
2. Leading hospitals to Patient-oriented polices
3. Enabling staff to demand help when necessary(58)
4. Unprecedented support and security for medical and nursing staff, since a supportive system reduces stress and helps learning
5. Providing a new channel for communication and discussions related to patient care
6. Sharing the experiences of team members(118)
7. Improving critical care through provision of advice, support and training
8. Improving access to CCS
9. Facilitating the development of critical care skills in clinical wards
10. Making better quality of end-of-life care for patients and their families
11. Establishing a pivotal point of contact between different types of healthcare teams (53)
12. Establishing a basis for clinical governance
13. Improving appropriatenot for- resuscitation(NFR) documentation in early stages, thus reducing the rate of unnecessary reports of cardiac arrest (58)

CHAPTER 3

TRACK & TRIGGER WARNING SYSTEMS AND DETERMINING THE LIKELIHOOD OF MORTALITY

3.1 OVERVIEW OF THE CHAPTER

In this chapter, I will address the Track and Trigger warning systems (TTs), which have been developed alongside critical care services for timely identification of AIPs. Then I will review the rationale for their development, their different types, and the studies dealing with them. Moreover, as I will need to define the mortality probability for two groups of patients that were admitted to wards (control and intervention groups of SW-CRCT), the systems for determining the likelihood of mortality for patients will be presented in the last part of the chapter. Thus, the chapter will contain two main sections, as follows:

- TTs
- Determining the likelihood of mortality

3.2 TTs

The first step in managing AIPs is timely diagnosis. If critical conditions are identified in a timely manner, the patient will have a higher chance of survival. Initially, diagnosis of AIPs depended on the clinical insight and experience of staff. However, with the evolution of clinical environments, the increasing number of AIPs, high workload and employment of inexperienced staff, timely diagnosis of these patients became a challenge(1). Given these circumstances and the introduction of care quality and safe care programs, as well as the implementation of critical care systems, criteria were needed for the diagnosis of AIPs and notification of critical care systems.

Previous studies indicate that deterioration of clinical conditions is reflected in early signs and symptoms such as variations in breathing and pulse rate. In addition, critical patients who undergo cardiac arrest or ICU admission often demonstrate signs of deterioration hours before the actual event(12, 13, 119, 120), and patients admitted to ICU often have abnormal findings as early as 24 hours prior to admission(55).Based on these findings, systems were created that used predefined criteria to diagnose AIPs, especially outside of the ICUs. These systems aided staff in notifying CCS teams(57) and preventing the deterioration of patients' state and their subsequent admission to ICU (105, 121).These systems, generally called TTs, were developed in countries such as Australia, the USA and the UK.TTs uses periodic observation of selected vital signs (tracking) with predefined criteria (trigger) to alert expert personnel. In the majority of cases, TTs is implemented through routine

observation of vital signs by ward staff, thus allowing a large number of patients to be monitored without imposing extra work load upon the staff (121). With the development of CCSs in different countries, diverse physiological scoring systems were created for identifying patients at risk of deterioration (121).All the previously mentioned (Chapter 2) systems of CCSs use these TTs (58, 76, 121).

In this section, I will describe the main categories of TTs; single, multiple, aggregate weighted scoring, and combination systems, as categorized by the Department of Health and the Modernization Agency, 2003(73), Gao et al., 2007(121) and NICE guidance 2007(15). Afterwards, evidence for the effectiveness and the advantages of each type will be provided. Table 3-1 shows brief characteristics of 4 TTs.

Table 3-1: Types of TTs

System	Characteristics
Single parameter system	Periodic observation of selected vital signs that are then compared with a simple set of criteria with predefined thresholds, with a response algorithm being activated whenever any criterion is met.
Multiple parameter system	The response algorithm requires more than one criterion to be met, or differs according to the number of criteria met.
Aggregate scoring system	Weighted scores are assigned to physiological values and compared with predefined trigger thresholds.
Combination system	Single or multiple parameter systems are used in combination with aggregate weighted scoring systems.

Centre for Clinical Practice at NICE 2007(15)

3.2.1 Single parameter systems

Single parameter systems were described for the first time in 1995 in a study by Lee et al. Any one of a set of certain criteria were used as a signal to alert the critical care system(122).Single parameter TTs combined some 4-11 physiological parameters, and often encompassed additional criteria based on specific events such as cardiac arrest or convulsion(121). Based on the recommendation of the NICE guidance on the Single Parameter System, when a patient fits any one or more of the criteria in Table 3-2, intervention is required. The system has the following characteristics:

Tracking: Periodic observation of selected vital signs.

Trigger: Changes in one or more observational values (73).

Table 3-2: Single parameter values

values	definition
Breathing	Respiratory rate of less than 8 or greater than 25/min Oxygen saturation of less than 90% despite use ofoxygen PaO2 of less than 8 k Pa on an arterial blood gas sample despiteuse of oxygen
Circulation	Pulse of less than 45 or greater than 125/min Systolic blood pressure of less than 90 or greater than 200 mmHg, or a sustained fall of greater than 40 mmHg from patient's normal value pH of less than 7.3 Base Excess of lower than –7 mmol/l
Renal	Urine output of less than 30 ml/hr for 3 consecutive hours Evidence of deteriorating renal function
Conscious Level	Patient not responding to voice Glasgow Coma Score of 8 or less
OR	Patient looks unwell or you feel worried about their clinical condition

DH and Modernisation Agency, 2003(73)

Single parameter systems which showed considerable variation in their physiological variables were also used in studies by Salamonson et al., 2001(101),Parr et al.,

2001（71），Bristow et al., 2000(103) ，Buist et al., 2002(90)and DeVita et al., 2004(93).

Smith et al. (2008) analyzed the Single Parameter weighted TTs in clinical settings by measuring the sensitivity and specificity of the system, and found that these systems have high specificity and very low sensitivity(122).

3.2.2 Multiple parameter

Multiple parameter systems were introduced in the UK for the PART study(59). They involved scoring the parameters in different ways and therefore had different trigger thresholds. The system characteristics are:

1. Tracking: Periodic observation of selected basic vital signs.
2. Trigger: Two or more extreme observational values(73).

Goldhill et al., described criteria for the multiple parameter systems(59).The senior ward nurse contacts the doctor in charge and informs them of a patient having 3 or more of the below criteria (Table 3-3) . Another example of the multiple parameter system is shown in Table 3-4.

Table 3-3: Criteria for multiple parameter system

respiratory rate ≥25 breaths.min (or < 10)
arterial systolic pressure < 90mmHg
heart rate ≥110 beats.min (or < 55)
not FULLY alert and orientated
oxygen saturation <90%
urine output < 100 ml over last 4 h
respiratory rate ≥35 breaths.min OR heart rate ≥140

Goldhill et al., 1999(59)

Table 3-4: Another example of the multiple parameter system

Systolic Blood Pressure <101 >200
Respiratory Rate <9 >20
Heart Rate <51 >110
Saturation (room air) <90%
Urine output <1ml/kg/2 hours
Conscious level Not fully alert
If a patient fulfils two or more of the above criteria OR you are worried about their condition call the Registrar from the admitting team and the Outreach Sister (899)

DH and Modernisation Agency, 2003(73)

3.2.3 Aggregate scoring system

The aggregate scoring system was introduced by Morgan et al. (1997) and is mostly used in UK hospitals. Most versions of this system include heart rate, respiratory rate, and systolic blood pressure, as well as level of consciousness [usually AVPU (alert/voice/pain/unresponsive)], urine output, and temperature. These systems use different thresholds for triggers, based on the hospital's resources, and have been used by Odell et al., 2002(118)， Subbe et al., 2001(123)， Pittard, 200380)（，Priestley et al.2004(85). The system has the following characteristics:

Tracking: Periodic observation of selected basic vital signs and the assignment of weighted scores to physiological values alongside calculation of a total score.

Trigger: The total score reaching a previously agreed trigger threshold(73).

Table 3-5 shows the aggregated scoring system applied by Morgan et al. (1997)

Table 3-5: The Aggregated scoring system

A score of 3 or more results in referral

Score	3	2	1	0	1	2	3
HR		<40	41-50	51-100	101-110	111-130	130
SBP	<70	71-80	81-100	101-199		>200	
RR		<8		9-14	15-20	21-29	>30
TEMP		<35	35.1-36.5	36.6-37.4	>37.5		
CNS				A	V	P	U

A= alert; P= response to pain; V= response to verbal stimulus; U= unconscious; HR= heart rate; SBP=systolic blood pressure; RR=respiratory rate; TEMP=temperature; CNS= central nervous system (50, 124).

3.2.4 Combination systems

An SR by Gao et al. (2007) described a combination system introduced by a paper in a UK hospital (Sharpley and Holden, 2004). This is basically an aggregate score system; however, a response is also triggered if any one of the parameters is found to be at maximum level (121, 125).

Figure 3-1shows an example of a combination system:

Score	8	4	2	1
Risk bands	*Normal*	*Observe*	*Warning*	*Emergency*
Coma score	Alert	responds to Voice	responds to Pain	Unresponsive
Respirations (min^{-1})	10-20	21-30	31-40	>40
		8-9	6-7	<6
SpO_2 on air (%)	>95	90-95	80-89	<80
Systolic BP (mm Hg)	100-180	90-99	80-89	<80
Pulse (min^{-1})	50-115	116-125	126-140	>140
		45-49	30-44	<30

The most abnormal finding places the patient in the associated risk band.

Always seek advice if you are concerned about a patient for any reason.

Note re. BP: systolic BP >200 mm Hg requires consideration – is it normal for patient?
Is pain a factor? A >25% drop from normal systolic BP places patient in 'Observe' risk band.

Risk band 'Normal'

Risk band 'Observe' – moderate deviation from normal.

Level I Action – PRHO/SHO from parent team (or any available doctor) should review in <60 mins. Consider level II action. Re-review in <4hours.

2–4 hourly respirations, SpO_2, pulse, BP, temp., urine; (DPS in notes).

Risk band 'Warning' – significant deviation from normal.

Level II Action – PRHO/SHO from parent team (or any available doctor) should review in <15 mins. Senior doctor must re-review in <30 mins. Consider outreach service.

Consider ICU (consultant to consultant); or if not, DNAR.

< hourly resps., SpO_2, pulse, BP, temp., urine; ABG, FBC, U&E; ECG; ? CVP; (DPS in notes).

Risk band 'Emergency' – dangerous deviation from normal.

Level III Action – Registrar or equivalent from parent team (or any available Doctor) should review immediately, and request the urgent help of more experienced Doctor. Consider outreach service.

Note high risk of cardio-pulmonary arrest. Consider ICU; if not, DNAR.

< hourly resps., SpO_2, pulse, BP, temp., urine; ABG, FBC, U&E; ECG; ? CVP; (DPS in notes).

For further details of this system (and associated vital signs observation chart). *Contact* John Welch, Consultant Nurse, Critical Care, Kingston Hospital, Surrey: John.Welch@kingstonhospital.nhs.uk.

Figure 3-1: An example of combination system (73)

3.2.5 Advantages and disadvantages of different systems

Different studies have described some of the advantages of these systems, as mentioned below:

Improving the nurses' ability to express their concern for their patient by using an objective language based on physiological parameters(118).

Timely identification of patients with established or potentially critical diseases, regardless of their location.

Facilitating timely attendance to critical patients by skilled staff(73).

DOH (2001) considers this as a helpful method for ward nurses(57).Table 3-6 shows some of the advantages and disadvantages of different TTs types:

Table 3-6: Advantages and disadvantages of different types of TTs

TTs	Advantages	Disadvantages
Single parameter	•Simple to use •ASimple system with better reproducibility	•Does not allow a patient's progress to be tracked •Dose not allow a graded response strategy •Current evidence suggests that the system has low sensitivity, a low positive predictive value but high specificity. This could potentially cause increased triggers that are not related to an adverse event •Not widely used in UK hospitals
Multiple parameter	•Allows monitoring of clinical progress •Allows for a graded response strategy •Widely used in UK hospitals	•May lack reproducibility and reliability because systems are prone to human calculation errors •These systems have high sensitivity but low specificity when one abnormal observation is present, but sensitivity decreases and specificity increases as the number of abnormal variables increase
Aggregate scoring system	•Allows monitoring of clinical progress •Allows for a graded response strategy •Widely used in UK hospitals	•May lack reproducibility and reliability because systems are prone to human calculation errors •A range of sensitivities and specificities exist depending on the cut-off score used, but it is possible to achieve high sensitivity and specificity at a defined cut-off point.

Centre for clinical practice at Nice 2007(15)

In summary, these systems have explicit protocols for alerting the team of concern over the patient's condition. All systems include blood pressure measurements and assessment of level of consciousness, and most consider heart rate and respiratory rate as well. Most of these physiological parameters are triggered at specific thresholds, which may vary, and which are defined by different systems (for example, tachycardia ranging from 110 to 160 beats per minute). However, evidence suggests

that breathing and circulation should be the main elements of any warning system. Combining these simple observations with measurements of fluid balance and neurological evaluations of the patient forms the basis of a simple system of early identification(57).

Gao et al. (2007) conducted an SR to describe TTs and its development and to determine the optimal TTs for timely identification of critical patients. The study assessed TTs' sensitivity (i.e. the proportion of patients with established critical disease who triggered the system) and positive predicting value (i.e. the proportion of triggered critical patients with established acute disease), specificity (i.e. the proportion of patients without established critical disease who did not trigger) and negative predicting factors value (i.e. the proportion of patients who did not trigger and did not have an established critical disease). They found 336 articles, dealing with 24 different TTs for review. Although 31 articles described the implementation of TTs, and 5 articles addressed its development or evaluation, none of these articles completely fulfilled the criteria for a standard methodology. In general, diverse TTs were found with little evidence existing of their validity, reliability, or utility. The authors found poor sensitivity, which they potentially attributed to the nature of monitoring physiological signs or the selection of trigger thresholds. The available data was deemed insufficient to define optimal TTs.

Despite the large body of research for TTs and the availability of important and helpful criteria, there is still need for further studies. In the study by Gao, none of the TTs were validated for use in an extensive range of settings, because it was not

assured that they would change clinical behavior and improve outcomes. Therefore, the role of scoring systems for identifying patient risk remains controversial and no system has yet gained overwhelming acceptance. In other words, there is still no evidence to favor one system over the others (121).

According to the study by Gao et al, there was a need to further studies to improve and also to assess the effectiveness of TTs (121). In 2010 Prytherch et al. based on the data from 198755 patients, proposed a new paper based, early warning scoring system and because VitalPACTM devices were used, they called it EWS-VitalPACTM or ViEWS (Table 3-7). ViEWS includes six recommended vital signs from the NICE list(15) in addition to SpO2. Therefore, for ViEWS, classic vital signs such as Blood pressure, Body temperature, Pulse rate, Respiratory rate, Mental statues, Oxygen saturation and use of supplemental oxygen, were used. In this study, prediction of ViEWS for some outcomes as mortality were compared with thirty three other Aggregate Weighted Track and Trigger system (AWTTs) and the result showed better performance for ViEWS with AUROC 0.888 (0.880-0.895) and for 33 AWTTSs from0.803 (0.792-0.815) to 0.850 (0.841-0.859)(126).

Table 3-7: EWS-VitalPACTM/ ViEWS

Physiological Parameters	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Pulse(bpm)		≤40	41-50	51-90	91-110	111-130	≥131
Respiratery rate(bpm)	≤8		9-11	12-20		21-24	≥25
Temperature(°C)	≤35.0		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic BP(mmHg)	≤90	91-100	101-110	111-249	≥250		
SpO_2(%)	≤91	92-93	94-95	≥96			
Inspired O_2				Air			Any o_2
CNS(use AVPU)				Alert(A)			Voice(V) Pain(P) Unresponsive(U)

(126)

Prytherch et al (2010) presented a new concept and usage for TTs, to predict mortality and for timely identification of AIPs. ViEWS includes classic vital signs that can be easily measured in busy hospitals.

ViEWS has been improved and validated in the UK, the USA(127) and sub-Saharan Africa(128). The results presented ViEWS as a good tool for predicting mortality not only at time of admission but also at any time during hospital stay(129).

In 2012 Kellet & Kim carried out an abbreviated version of ViEWS, without the mental status variable, in a Canadian regional hospital. They showed that the

abbreviated version was fit for most of patients with the exception of those needing critical units(130).

In the UK, the RCPL National Early Warning Score Design and Implementation Group (NEWSDIG), because of clinical requirements, made minor modifications to ViEWS and developed a National Early Warning System/NEWS (Table 3-8) (129).

Table 3-8: The National Early Warning Score (NEWS)

Physiological Parameters	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Respiration Rate(breaths per minute)	≤8		9-11	12-20		21-24	≥25
SpO_2(%)	≤91	92-93	94-95	≥96			
Any supplemental oxygen?		Yes		No			
Temperature(°C)	≤35.0		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic BP (mm Hg)	≤90	91-100	101-110	111-219			≥220
Heart/ Pulse rate(beats per minute)	≤40		41-50	51-90	91-110	111-130	≥131
Level of consciousness (using the AVPU system)				A			V, P or U

Level of consciousness: A = alert; V = responds to voice; P = responds to pain; U = unresponsive(131)

Comparing Table 3-7 and Table 3-8 shows variation between ViEWS and NEWS for giving score to some variables as Supplemental oxygen, Systolic blood pressure, and Heart rate. Smith et al analyzed 198755 observations to assess the performance of the national early warning system (NEWS) compared with 33 other EWS. The study showed acceptable performance of NEWS for discrimination and timely identifying

of patients with high risk of cardiac arrest, unanticipated ICU admission and mortality within 24 hours of a vital sign dataset(129).

The Royal College of Physicians recommended NEWS for the routine evaluation of adult patients. They also suggested NEWS as the indicator of professional judgment and AIPs identification in hospitals(129).

NEWS needs to progress and its development is not the end of other systems improvement and it should not be considered as the unique way out to identify deteriorating patients. It should be considered as the least necessity for monitoring patients and staff alerts for further evaluating of patients. It should be used alongside and not instead of other triggers such as signs and symptoms for chest pain, diaphoresis, GCS or nurses' concerns (129).

3.3 DETERMINING THE LIKELIHOOD OF MORTALITY

In this study I want to evaluate the impact of CCS on patient mortality and other outcomes on general wards. Since the risk of mortality and probability of death differs for the patients in control and intervention trial groups, and this diversity could act, as a confounding factor for the effect of CCS, a tool for assessing mortality risk and adjusting it for outcomes in different groups of patients was needed. For this purpose, it was necessary to utilize one of the previously developed tools for determining mortality risk.

In this section, the tools previously used to determine mortality risk will be explained, and their benefits and drawbacks shall be compared. The first of these systems is

APGAR score (**A**ppearance, **P**ulse, **G**rimace, **A**ctivity, and **R**espiration), introduced in 1953 for assessing neonatal vitality (132, 133). It was followed by other scoring systems aimed at assessing patients' vital status, such as the GCS, Acute Physiology and Chronic Health Evaluation (APACHE), Mortality Prediction Models (MPM) and Simplified Acute Physiology Score (SAPS). These systems are based on physiological abnormalities and have been used successfully for evaluating disease severity in AIPs (Table 3-9).

Table 3-9: Type of tools for assessing mortality risk

APACHE
APACHE II
APACHE III
APACHE IV
MPM
SAPS
SAPS II
SAPS III

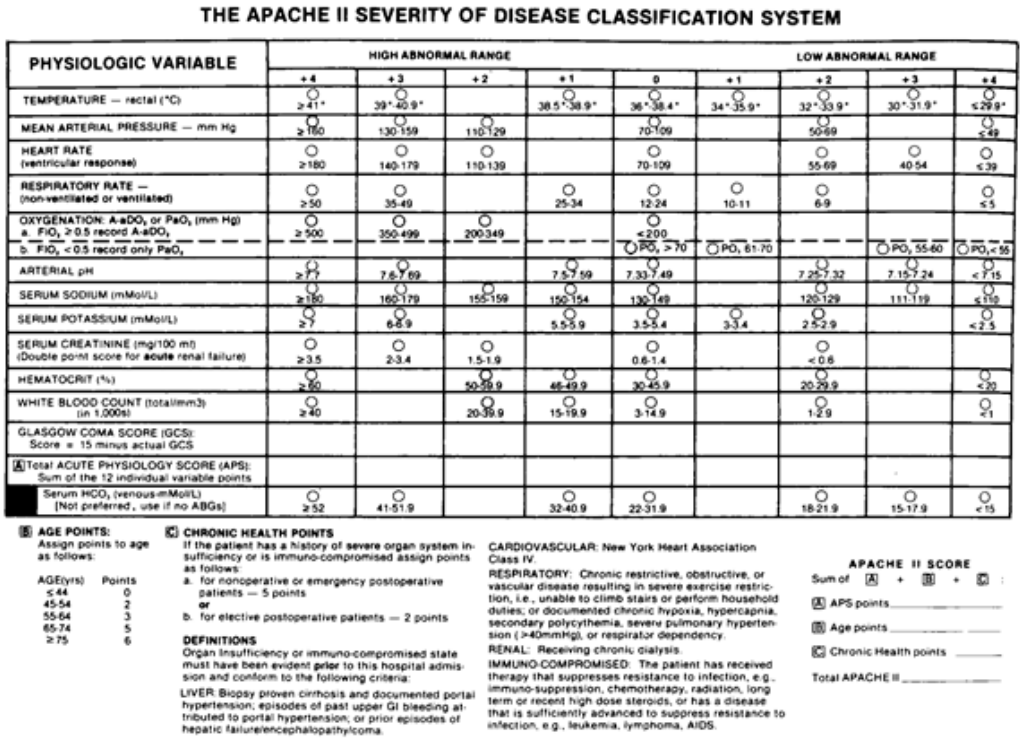
3.3.1 APACHE

APACHE, also known as Acute Physiology Score (APS), was first used in the US, based on the hypothesis that the severity of acute disease may be quantified through assigning scores to the abnormality of physiological parameters. The system considered 34 physiological variables that were collectively called APS. In addition, since chronic and severe diseases influence survival, these were also incorporated into APACHE scoring. The variables were given a score of 0 to 4 and a higher APS was associated with a greater risk of patient mortality (134).

According to Le Gall et al. (1984), APS was deemed a valid estimation of disease severity; however, since many of the unmeasured variables were considered normal, variation in patients' score created a systematic bias (135). Furthermore, APS and APACHE were complicated and required considerable time in order to be calculated.

3.3.2 APACHE II

Due to the complexity of APACHE, APACHE II was presented to simplify the system and render it more practical by using: clinical judgment; assigning new weights to physiological relations, which were established between selected variables; reducing the number of physiological parameters from 34 to 12; and also taking into account age and chronic health. These physiological variables were weighted based on the worst values recorded during the first 24 hours of ICU admission. The ability of APACHE II to categorize ICU admission was evaluated in a study by Knaus et al., which showed that in the 5,815 ICU admissions at 13 hospitals assessed, increased APACHE II scores (ranging from 0-71) were closely associated with the risk of in-hospital death (136). The variables of APACHE II are shown in Figure 3-2.



THE APACHE II SEVERITY OF DISEASE CLASSIFICATION SYSTEM

PHYSIOLOGIC VARIABLE	HIGH ABNORMAL RANGE					LOW ABNORMAL RANGE			
	+4	+3	+2	+1	0	+1	+2	+3	+4
TEMPERATURE — rectal (°C)	≥41°	39°-40.9°		38.5°-38.9°	36°-38.4°	34°-35.9°	32°-33.9°	30°-31.9°	≤29.9°
MEAN ARTERIAL PRESSURE — mm Hg	≥160	130-159	110-129		70-109		50-69		≤49
HEART RATE (ventricular response)	≥180	140-179	110-139		70-109		55-69	40-54	≤39
RESPIRATORY RATE — (non-ventilated or ventilated)	≥50	35-49		25-34	12-24	10-11	6-9		≤5
OXYGENATION: A-aDO$_2$ or PaO$_2$ (mm Hg) a. FiO$_2$ ≥ 0.5 record A-aDO$_2$	≥500	350-499	200-349		<200				
b. FiO$_2$ < 0.5 record only PaO$_2$					PO$_2$ > 70	PO$_2$ 61-70		PO$_2$ 55-60	PO$_2$ < 55
ARTERIAL pH	≥7.7	7.6-7.69		7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	< 7.15
SERUM SODIUM (mMol/L)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110
SERUM POTASSIUM (mMol/L)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		< 2.5
SERUM CREATININE (mg/100 ml) (Double point score for **acute** renal failure)	≥3.5	2-3.4	1.5-1.9		0.6-1.4		< 0.6		
HEMATOCRIT (%)	≥60		50-59.9	46-49.9	30-45.9		20-29.9		< 20
WHITE BLOOD COUNT (total/mm3) (in 1,000s)	≥40		20-39.9	15-19.9	3-14.9		1-2.9		< 1
GLASGOW COMA SCORE (GCS): Score = 15 minus actual GCS									
[A] Total ACUTE PHYSIOLOGY SCORE (APS): Sum of the 12 individual variable points									
Serum HCO$_3$ (venous-mMol/L) [Not preferred, use if no ABGs]	≥52	41-51.9		32-40.9	22-31.9		18-21.9	15-17.9	< 15

[B] AGE POINTS:
Assign points to age as follows:

AGE(yrs)	Points
≤44	0
45-54	2
55-64	3
65-74	5
≥75	6

[C] CHRONIC HEALTH POINTS
If the patient has a history of severe organ system insufficiency or is immuno-compromised assign points as follows:
a. for nonoperative or emergency postoperative patients — 5 points
or
b. for elective postoperative patients — 2 points

DEFINITIONS
Organ insufficiency or immuno-compromised state must have been evident prior to this hospital admission and conform to the following criteria:

LIVER: Biopsy proven cirrhosis and documented portal hypertension; episodes of past upper GI bleeding attributed to portal hypertension; or prior episodes of hepatic failure/encephalopathy/coma.

CARDIOVASCULAR: New York Heart Association Class IV.

RESPIRATORY: Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction, i.e., unable to climb stairs or perform household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40mmHg), or respirator dependency.

RENAL: Receiving chronic dialysis.

IMMUNO-COMPROMISED: The patient has received therapy that suppresses resistance to infection, e.g., immuno-suppression, chemotherapy, radiation, long term or recent high dose steroids, or has a disease that is sufficiently advanced to suppress resistance to infection, e.g., leukemia, lymphoma, AIDS.

APACHE II SCORE
Sum of [A] + [B] + [C] :
[A] APS points _____
[B] Age points _____
[C] Chronic Health points _____
Total APACHE II _____

Figure 3-2: The APACHE II Severity of Disease Classification System(136)

3.3.3 APACHE III

In order to refine the APACHE II scoring system, a study was conducted with the aim of defining a more accurate way of predicting hospital mortality risk for critically ill, hospitalized adults. Data was gathered from the first day of ICU admission to 40 American hospitals for 17,440 medical and surgical patients. Patients under 16 years of old, burn patients, and transplantation patients were excluded from the study. The relationship between patient survival after discharge from hospital and variables, such as medical illness or major surgery, physiological abnormalities, age, previous functional limitations, major co-morbidities and place of treatment immediately prior to ICU admission, were investigated. The tool used in the study was named APACHE III, and its score was calculated by measuring 17 physiological variables during the first 24 hours of ICU admission.

The risk of mortality was calculated by adding the APACHE III score to the logarithm of [Odds of death] as well as other values, based on the operative or non-operative nature of the treatment plan. Furthermore, in order to evaluate outcomes in patients with multiple diagnoses, the APACHE III score was calculated through a combination of APACHE III disease categorization and patient location immediately prior to ICU admission. The findings indicated that an increase in APACHE III score is associated with a significant increase in risk of in-hospital mortality(137).Although APACHE III demonstrated better discrimination compared to APACHE II, its calibration was not perfect, and due to complexity, time consuming calculations and

dependence upon the last diagnoses of the illness, it was not deemed suitable for current study.

3.3.4 APACHE IV

Zimmerman et al. (2006) conducted a study to improve the accuracy of APACHE in predicting hospital mortality of critical patients and evaluating the changes made in the original APACHE scoring system. This system was developed based on results obtained from 110,558 patients admitted to 104 intensive care or coronary care units (CCUs) in 45 hospitals in the United States. The system was made up of APS with age and admission circumstances that encompass a total of 142 variables, with 115 of them being related to diagnosis on admission. In this system, which is similar to the original APACHE, APS was based on abnormal values recorded during the first 24 hours of ICU admission. APACHE IV also had a separate scoring system for patients undergoing coronary bypass.

Although APACHE IV had good discrimination and calibration and was successful in predicting in-hospital mortality rate(138), I did not use it in this study due to the large number of variables and the lengthy procedure of completion. Some characteristics of APACHE scores are shown in Table 3-10.

Table 3-10: Some characteristics of APACHE scores

Risk-Prognostication Systems	Year Published	Origin of database	Age(year)	Collection of data
APACHE II	1985	USA	>16	First 24 h in ICU
APACHE III	1993	USA	>16	First 24 h in ICU
APACHE IV	2006	USA	>16	First 24 h in ICU

Strand and Flaatten, 2008(132)

3.3.5 MPM

Lemeshow et al. (1985) developed objective criteria for predicting mortality that were different from approaches followed in APACHE and SAPS. In APACHE, the weights of the variables used for evaluating hospital outcomes were determined by a panel of experts, who considered the outcomes' deviation from normal values. SAPS used the same variables as ASP. Thus, the Multiple Logistic Regression model (MLR) was devised for estimating in-hospital mortality for ICU patients. The most important difference between this approach and other approaches lies in the use of statistical techniques for assigning weights to variables (known as maximum likelihood) rather than a team of experts. In addition, the results express the probability, rather than the scores. For practical reasons, researchers used two models of MLR; one based on admission time data, and the other using data from the first 24 hours.

The study used data obtained from 755 patients upon ICU admission or during the first 24 hours of ICU admission. Table 3-11 shows these variables. The outcomes predicted by this model were closely related to the real outcomes(139).

Table 3-11: ICU admission and first 24 hours of ICU admission

ICU admission	The first 24 hours of ICU admission
Age	Age
Therapy variables(systolic blood pressure, heart rate, number of organs with failure)	Hours of coma
Admission service (internal/surgical)	Hours under mechanical ventilation
Infection on admission	Number of lines
CPR prior to admission	Hours of vasoactive drugs
Type of admission (elective/emergency)	Number of high-dose vasoactive drugs
PO2	Number of organs with failure on admission
Bicarbonate, Creatinine	Highest value of PEEP or CPAP
level of consciousness on ICU admission	Admission service
	Low urine output
	Swan-Ganz catheter
	Patient service during 24 hours
	Type of admission
	PO2, inspired oxygen fraction
	PH, creatinine, platelet, PTT, PT
	Infection
	Shock
	Anti arrhythmia drugs
	CPR
	Level of consciousness

Lemeshow et al., 1985(139)

Mortality Probability Model II (MPM II) includes two types of measurements (Table 3-12); one, titled MPM II0, records variables during the first hour of patient admission and the other, titled MPM II 24, records them during the first 24 hours of ICU admission. The MPM II does not generate scores; rather, it directly predicts mortality risk (140).

Table 3-12: MPM II (0, 24) variables

MPM II0 variables	MPM II24 variables
Age	Age
Cardiopulmonary resuscitation within 24 hrs	Medical or unscheduled surgical admission
Medical or unscheduled surgical admission	Mechanical ventilation
Mechanical ventilation	Coma or deep stupor
Coma or deep stupor not due to drug	Creatinine value >2 mg dL_1
Heart rate ≥ 150beats min	Confirmed infection
Systolic blood pressure ≤ 90 mm Hg	PaO2 _60 mm Hg
Three chronic diagnoses	Prothrombin time >3 secs above reference
Five acute diagnoses	Urine output <150 mL in 8 hrs
	Continuous intravenous vasoactive drug therapy
	Two chronic diagnoses

In 1993, Lemeshow et al. revised the MPMII to present a system based on an international cohort of ICU patients. The model was tested in surgical ICUs of 12 countries. In their study, 6,514 out of 12,610 patients were selected to verify model validity (patients aged below 18 years, cardiac and heart surgery patients were excluded from the study) and the patients' vital status on discharge was assessed. The admission model (MPM0) included 15 easily obtainable variables with acceptable validity and discrimination in two groups of samples (developmental and validation). The 24-hour model (MPM24) (which was developed on 10357 patients) included 5 on-admission variables and 8 additional variables, which were easily obtainable during the first 24 hours of admission. In conclusion, the researchers suggested that both MPMs are useful tools and may provide important clinical data when used alone or jointly (140).After MPM II, MPM III was also introduced in North America (in the IMPACT project) and used in later studies.

Although studies indicate the convenience of MPM in scoring and its use for sequential assessment of patient mortality risk during ICU admission, its validation has not been studied as extensively as that of SAPS or APACHE scores(132) and thus it was not used in this trial. Some Characteristics of MPM are shown in Table 3-13.

Table 3-13: Some characteristics of MPMs

Risk-Prognostication Systems	Year Published	Origin of database	Age(year)	Collection of data
MPM II 0	1993	Europe/North-America	>18	ICU Admission
MPM II 24	1993	Europe/North-America	>18	At24 h in ICU

Strand and Flaatten, 2008(132)

3.3.6 SAPS

In 1984, researchers used 14 clinical and biologic variables to develop a simple scoring system to reflect mortality risk in ICU patients. The idea was that since APS or APACHE aim at facilitating multi-center studies and comparing valid outcomes in groups of patients with similar pathologies, and also because some values are not measured, there is a risk of bias for APS scores. For this purpose, the researchers selected 13 variables, which were commonly measured in wards, and also included age. The values for each variable are expressed in Figure 3-3.

Variable SAPS Scale	4	3	2	1	0	1	2	3	4
Age (yr)					≤45	46–55	56–65	66–75	>75
Heart rate (beat/min)	≥180	140–179	110–139		70–109		55–69	40–54	<40
Systolic blood pressure (mm Hg)	≥190		150–189		80–149		55–79		<55
Body temperature (°C)	≥41	39.0–40.9		38.5–38.9	36.0–38.4	34.0–35.9	32.0–33.9	30.0–31.9	<30.0
Spontaneous respiratory rate (breath/min)	≥50	35–49		25–34	12–24	10–11	6–9		<6
or									
Ventilation or CPAP								Yes	
Urinary output (L/24 h)			>5.00	3.50–4.99	0.70–3.49		0.50–0.69	0.20–0.49	<0.20
Blood urea (mMol/L)	≥55.0	36.0–54.9	29.0–35.9	7.5–28.9	3.5–7.4	<3.5			
Hematocrit (%)	≥60.0		50.0–59.9	46.0–49.9	30.0–45.9		20.0–29.9		<20.0
White blood cell count (10^3/ mm^2)	≥40.0		20.0–39.9	15.0–19.9	3.0–14.9		1.0–2.9		<1.0
Serum glucose (mMol/L)	≥44.5	27.8–44.4		14.0–27.7	3.9–13.9		2.8–3.8	1.6–2.7	<1.6
Serum potassium (mEq/L)	≥7.0	6.0–6.9		5.5–5.9	3.5–5.4	3.0–3.4	2.5–2.9		<2.5
Serum sodium (mEq/L)	≥180	161–179	156–160	151–155	130–150		120–129	110–119	<110
Serum HCO_3 (mEq/L)		>40.0		30.0–39.9	20.0–29.9	10.0–19.9		5.0–9.9	<5.0
Glasgow coma score					13–15	10–12	7–9	4–6	3

Figure 3-3: Variables of SAPS(135)

The variables were given a score of 0 to 4. The SAPS was assessed in 679 patients admitted to 8 French ICUs. Data pertaining to the first 24 hours of ICU admission was collected. As a comparison, APS was also measured for these patients. The findings indicated a correlation between hospital mortality and SAPS. An SAPS requires fewer biological values, is less expensive and causes less discomfort for the patients. It also consumes less time. For those reasons, researchers chose SAPS as a simple method for comparative studies and management studies between different ICUs. In addition, SAPS provides an effective indicator of mortality over a wide range of pathologies(135).

3.3.7 SAPS II

SAPS stratified patients without predicting outcomes, and classified patients, so that increasing scores reflected increasing risk of death without taking into account

underlying systematic disease (135). Therefore, in the Le Gall study a system was developed to convert the SAPS score into in-hospital prediction of mortality risk. The 13,152 patients of 137 medical and surgical ICUs in 12 countries (10 European and 2 North American countries) were divided randomly into developmental (65%) and validation (35%) groups. Patients below 18 years of age, burn, cardiac surgery and cardiac patients were excluded from the study. The data consisted of demographic variables, all variables related to SAPS, a series of new variables, which might be added to SAPS II and also the patient's vital status on discharge from hospital. The physiological variables were recorded based on the patient's worst conditions during the first 24 hours of ICU admission, and the highest scores were assigned to the worst conditions. From the 37 assigned variables of the study, 17 were eventually selected for SAPSII (age, 12 physiological variables, type of admission and 3 variables for underlying disease) (Table 3-14).

Table 3-14: SAPS II variables

Age	
type of admission	Unscheduled and Scheduled surgical, or Medical
three systemic diseases	AIDS, metastatic cancer, and hematologic malignancies
physiological variables	heart rate, systolic blood pressure, temperature, oxygenation(PaO2/FIO2 only if ventilated),urine output, urea, white blood cell count, potassium, sodium, bicarbonate, bilirubin, GCS (including pre sedation GCS for sedated admissions)

The ranges assigned to each variable were different; for instance, temperature ranged from 0 to 3, while GCS ranged from 0 to 26. The basis for the scoring of the 12

physiological variables was the worst value recorded during the first 24 hours of admission. Patients who were not under ventilation did not require arterial blood sampling. Ultimately, with the logistic regression equation, the SAPS II score was converted into the probability of hospital mortality. The results of data quality analysis revealed good reliability for the SAPS II variables. Also, researchers concluded that SAPS II was capable of estimating the probability of mortality without needing the primary diagnosis of patients (141).

In another study, in Italy Bertolini et al. (1998) compared SAPS II with the previous version and concluded that SAPS II was superior in determining hospital probability of mortality (142).

A cohort study by Apolone et al. (1996) assessed the validity of SAPS II in a large sample (1393 patients) of patients admitted to Italian ICUs. The findings validated SAPS II for predicting hospital mortality (143).

Since cardiac patients were excluded from the Gall et al. (1993) study, Schuster et al. (1997) conducted a study with a prospective cohort design, using 1,587 patients to assess SAPSII over 18 months. The findings indicated a similar mortality risk for ICU and CCU patients. It was also found that SAPS II was appropriate for describing disease severity and prognosis in cardiac patients(144).

Another prospective study was conducted on 433 patients to assess the impact of SAPS II in intermediate care units in France. The majority of these patients had just been released from emergency wards. The findings validated SAPS II (145).

Another study was conducted on 310 patients to evaluate the ability of SAPS II to predict disease severity in surgical ICUs in Germany. The mean SAPS II score for all patients was 29.9 ± 12.7; in surviving patients the mean was 27.7 ± 11.4 and among deceased patients it was 45.7 ± 11.2. The study demonstrated that SAPS II has an acceptable predictive ability and is particularly helpful for accurate mortality risk estimations (146). Again SAPS II was evaluated in a retrospective cohort study on 148 patients with subarachnoid hemorrhage in the Netherlands. The findings indicated that SAPS II is a valid and helpful predictor of outcomes (147).

Another retrospective review study was conducted to analyze SAPS II in obstetric patients who needed intensive care in India. A total of 57 patients were studied. Analysis of data revealed that SAPS II is able to predict mortality accurately in obstetric patients(148).

An observational prospective study was conducted in 2009 to evaluate SAPS II in patients admitted to the emergency department of an Italian teaching hospital. It was used to assess mortality risk, and data was collected during the first 24 hours of ICU admission. In the 1993 SAPS II study, the 15 variables were considered and three systemic diseases -metastatic cancer, hematologic malignancy, and AIDS- were all considered as one variable. Clinical and laboratory findings were collected for each patient and SAPS II scores and probability of mortality were calculated according to the method described by Gall et al. (1993). The results showed that SAPS II is a useful tool for predicting mortality in an emergency department (149).

3.3.8 SAPS III

The SAPS III project was devised by the European Society of Intensive Care Medicine in 2002 (150). The objective was to develop a new model for modifying risk in critical patients, a new model that would be freely available for the scientific community. Data pertaining to risk factors and outcomes of an international multi-center cohort study was collected to develop a model for assessing disease severity and predicting vital status on discharge, based on data collected on ICU admission (151). The total population consisted of 16784 patients admitted to 303 ICUs and 20 variables were selected for SAPS III, as shown in Table 3-15.

Table 3-15: SAPS III variables

Part 1	Part 2	Part 3
Age	planned/unplanned ICU	Estimated Glasgow coma
co-morbidities	Reason for ICU admission	Total bilirubine (highest)
Use of major therapeutic	Surgical status at ICU	Body temperature(highest)
intra hospital location before	Anatomical site of surgery	Creatinine (highest)
length of hospital stay before	Acute infection at ICU	heart rate (highest)
		Leukocytes(highest)
		pH (lowest)
		Platelet (lowest)
		systolic blood pressure (lowest)
		Oxygenation

The SAPS III score ranges from 0 to 217, and may be used to predict the patient's vital status on discharge from hospital (150).

3.4 COMPARISON OF SYSTEMS

Numerous studies have addressed SAPS III since its development. Those findings are summarized below:

One study assessed SAPS III in a general ICU with a small sample size. The findings of this study, which also aimed at comparing SAPS III and II, indicated that SAPS III is accurate for predicting hospital mortality, while SAPS II overestimates the risk (152).

A cohort study evaluated the predictive ability of SAPS III for hospital mortality in 28357 patients from 147 Italian ICUs. The findings suggested that SAPS III score does not calibrate adequately in a large sample size and cannot be used for benchmarking (153).

Another comparison between SAPS II and SAPS III in ICUs of two different Norwegian hospitals indicated that the performance of SAPS III was acceptable but not better than SAPS II (154). Characteristics of SAPSs are shown in Table 3-16.

Table 3-16: Characteristics of SAPSs

Risk-prognostication Systems	**Year Published**	**Origin of database**	**Age(year)**	Collection of data
SAPS II	1993	Europe/North-America	>18	First24 h in ICU
SAPS III	2005	All Continents	>16	ICU admission ± 1h

Strand and Flaatten, 2008(132)

Table 3-17and Table 3-18 show the Characteristics of systems:

Table 3-17: Characteristics of general risk-prognostication systems 1

Risk-Prognostication Systems	Simplicity of scoring	a ROC*	GOF H-L C- test (P)**	External Validation
APACHE II	++	0.86	-	+++
APACHE III	+	0.90	-	++
APACHE IV	+	0.88	16.8(0.08)	-
SAPS II	+++	0.86	-	+++
SAPS III	++	0.85	14.3(0.16)	-
MPM II 0	+++	0.82	(0.327)	++
MPM II 24	+++	0.84	(0.231)	++

*Discrimination (a ROC area under curve of receiver operating characteristic) in original publication
**Calibration (goodness-of-fit Hosmer–Lewenshow C-statistic) in original publication
APACHE(Acute Physiology and Chronic Health Evaluation), SAPS(Simplified Acute Physiology Score), MPM (Mortality prediction model), ROC (receiver operating curves)(132).

Table 3-18: Characteristics of general risk-prognostication systems 2

Risk-Prognostication Systems	Characteristics				
	Number of parameters measured	Time-consuming	Complexity	disadvantages	Advantages
APACHE(134)	34	✓	✓	Built by subjective method, using a panel of experts to select variables and weights(141)	
APACHE II(136)	15 including APS points, chronic health points, age points			Built by subjective method, using a panel of experts to select variables and weights(141)	
APACHE III(137)	17 including APS, age, chronic health Plus categorization of disorders based on being operated or not	✓	✓		
APACHE IV(138)	142	✓	✓		
MPM II 0(139)		✓	✓	Need for data collection on admission as well as 24 hours after admission	
MPM II 24(140)		✓	✓		
SAPS(135)	13			Built by subjective method, using a panel of experts to select variables and weights(141)	
SAPS II(141)	17				Easy and rapid data collection Estimation of mortality risk without an initial diagnosis
SAPS III(150, 151)	20				

The above tables indicate better simplicity for SAPSII as compare to other items. Furthermore, it provides an estimation of mortality risk without needing an initial diagnosis. Therefore it is suitable for current study, which is conducted on medical and surgical wards of the hospital within the initial 24 hours of admission, since establishing a diagnosis sometimes requires up to several days.

CHAPTER 4

THE CURRENT STATE OF CARE FOR ACUTELY ILL PATIENTS IN IRANIAN HOSPITALS: A QUALITATIVE STUDY

In previous chapters I discussed the challenges faced by hospitals regarding caring for AIPs, and the consequences of these, such as the presence of AIPs in general wards and the effect this has on mortality and LOS. Worldwide strategies for the improvement of AIP care and those identifying with TTs were also defined. The present study aims to evaluate the effectiveness of CCS. In order to achieve that aim, a good understanding of these patients and their state in the Iranian context is necessary. In Iran, shortcomings such as the scarcity of intensive care beds, an aging population and an increase in the diseases that come with this lead to AIPs being hospitalized in general wards instead of ICUs. Receiving inappropriate care, and a subsequent increased mortality rate among AIPs, may lead to deterioration of their condition. However, since no studies have been conducted concerning the care of AIPs in Iran, I carried out an exploratory qualitative study, to define the current state of AIPs in Iranian hospitals.

This chapter presents a qualitative study of AIPs state and the quality of care they receive in hospitals. It reflects the physicians' and nurses' experiences regarding these patients.

4.1 INTRODUCTION

Increased life expectancy, more advanced and complex therapeutic methods, economical changes in the health system and diverse therapeutic choices have all led to an increase in the number of AIPs(8, 42).

This trend has increased demand for intensive care beds in hospitals. On the other hand, the emphasis placed by health policy makers upon decreasing the LOS, alongside the high cost of ICU beds, as well as the limited number of available ICU beds have all resulted in more and more patients being hospitalized in general wards instead of ICUs (8). Consequently, due to discrepancy in the quality of care provided in general wards and ICUs, which occur even in the most suitable care systems, some deterioration in the condition of AIPs can be expected. Also in some instances the management and care process for these patients is delayed (42).

Today this trend is a critical issue in Iranian hospitals, and improving the quality of care for these patients has become a key objective. For example, in Shariati general teaching hospital, the number of ill patients admitted to general wards has increased due to the shortage of ICU beds. During the first 6 months of the year 2010, 520 patients who needed ICU admissions were hospitalized in general wards instead.

4.1.1 Why qualitative studies?

This chapter focuses on the state of care provided for AIPs and to define the current state of AIPs in Iranian hospitals. Since no studies exist that focus on the condition of these patients in Iran, carrying out an exploratory study with a qualitative method seemed appropriate. The reason for this is that qualitative studies are particularly useful whenever knowledge of a phenomenon is limited and is insufficient for shedding light on doubts and uncertainties(155). I tried to study the condition of these patients in a particular setting, in order to achieve a holistic understanding of the subject from the viewpoint of research participants. As described by Wood and Huber (2010), qualitative studies have a descriptive and explanatory nature. These studies cause the world to be seen from different perspectives. It is assumed that a good understanding of a phenomenon is only achieved by studying it in its own context. Corbin and Strauss (2008) state that the qualitative approach, unlike the quantitative, has a fluid, evolving, and dynamic nature and allows the researcher to get at the inner experience of participants, to determine how meaning is formed and to discover, rather than test, the variables involved(156).

Qualitative research places an emphasis on understanding participants' experiences. This approach studies the phenomenon comprehensively and in depth, and gives an accurate picture of emotions, feelings and thought processes(157).

In this qualitative study, I want to understand the AIPs condition from the individual viewpoints of participants; viewpoints that are subjective and context related. So, in effect, this is a qualitative study using a naturalistic approach, which is in contrast to a positivistic approach or positivism. Positivism is the traditional scientific method

that considers the reality of a constant and external existence, irrespective of the observations and perceptions of the human mind. In this paradigm, the researcher can observe these phenomena by using regular and predesigned procedures, and also by measuring and examining these phenomena, in order to prove a cause and effect relationship using a deductive approach. In the naturalistic paradigm approach, sometimes called constructivism, there is no absolute and constant reality, and a relativism based on perception is present. Therefore, for each mind the "reality" is different, and this reality is also related to the context(157, 158). In this method, exploration is based on an inductive approach used for gaining insights through the exploration of meanings.

4.1.2 Objective

In order to determine the condition of AIPs and the quality of care given them beyond the policies and methods for this group of patients, an exploratory study in the form of this qualitative research was carried out in Tehran University of Medical Science (TUMS) and two related general teaching hospitals.

4.2 METHODS

4.2.1 Design

A qualitative study with a conventional qualitative content analysis method was used to define the current state of AIPs. The design is appropriate for this study since it allows participants to describe their experiences concerning the state of AIPs in their own words. The content analysis method is a method to analyze oral, visual, and

written data, and it is applied in order to identify categories, which explain this phenomenon. The aim of this method is to achieve a comprehensive definition of the phenomenon (159, 160). A conventional qualitative content analysis was employed wherein coding categories were derived directly and inductively from the data(160).

4.2.2 Setting

Qualitative studies are carried out in the field where the participants are, and where their experiences are formed. The research could be carried out at home, in class or anywhere else chosen by the participants. The purpose of this is to keep the situation in which the phenomenon occurs natural(157).

The aim is to study the actions, behaviors, beliefs, and understandings of a person or a group as they really happen in their real lives. The qualitative research environment is the real setting of phenomena (meaning where the subject of study lives and gains experience)(158). The setting of the present study was TUMS and its two affiliated teaching hospitals, Shariati and Imam Khomeini, which are Iran's two most important hospitals. Both these hospitals are general teaching hospitals with a high inflow of patients. They have several ICUs.

4.2.3 Sampling and participants

Sampling procedures in qualitative research are not so rigidly prescribed as in quantitative studies(161). The aim of a qualitative study is to achieve a holistic understanding of the subject under investigation, not to generalize findings to a sample population as in quantitative studies. Quantitative studies aim to measure,

evaluate, and determine the relationships in a population; therefore the sample size is critical. However, most qualitative studies aim to study the deep meaning of a phenomenon; therefore generalization is not a very important aspect of these studies. In qualitative research there is no way of determining the number of participants that will be needed prior to commencement.

The qualitative researcher mentally follows questions related to sampling. For example, “Who has rich information on the phenomena under study?”, “Who should I interview?” or “What should I observe in order to understand the phenomena?” As the study progresses, new questions will evolve; for example, “Who can confirm and modify my perception of the study phenomenon?” or “Who can enrich the data?”(158).

In this study, the participants were initially selected based on the objective of the study and their experiences. This type of sampling is called purposeful sampling. This sampling focuses on selecting information-rich participants for in-depth study, who are willing to provide information and therefore reflect the subjects properly (158, 161, 162). The participants in this study were selected based on criteria as shown in Table 4-1.

Table 4-1: The participants' criteria

Agreeing to enter the study
Working as either a physician or a nurse
Being knowledgeable about the condition of AIPs and able to provide deep and rich information concerning them
Having at least 5 years work experience

The participants of the present study consisted of 4 physicians and 6 nurses involved in caring for AIPs. The specifications of participants in this study are shown in Table 4-3. They were selected by purposive and snow ball sampling as follows:

Study participants were selected from amongst policy makers and service providers (physicians and nurses). I chose this group of professionals to ensure that they would be able to speak about the subject well and have enough knowledge to discuss the details. Snowball sampling was also used, based on the findings gained from the analysis of the previous interviewee. Sampling was continued until information saturation was achieved. Saturation means that information gathering yields recurring data and previously collected data is only confirmed, and not added to(157, 163), and no new themes or essences emerge (157). In the two final interviews, the data was repeated and no new information generated.

Interviewing the AIPs themselves confronted me with some moral issues due to their difficult conditions such as: low blood pressure, high temperature, low level of consciousness, being attached to devices, among other situations, and therefore interviewing them was impossible.

4.2.4 Data collection

Data was collected through interview. Interviews are the best and simplest way to gather data(35), in order to understand something from the participants' point of

view, to uncover the meaning behind participants' experiences, and to convey to others a situation from a participants' perspective and in their own words(164).

Semi-structured face-to-face interviews were carried out with participants during the year 2010. All interviews consisted of a combination of open questions. This method of interview provides the participant with the chance to elaborate on certain cases and points (165). The questions were arranged with flexibility beforehand, as were the time and location of the interviews. The participants consented to take part, and the interviews were only recorded if the interviewer was given express permission to do so. Otherwise, written notes were taken. A short time was allocated to each participant in order to familiarize him or her with the main idea of the study, and the aim and method of interview. In addition, a suitable environment was prepared, in order for them to be able to talk about their experiences comfortably. Three interviews were performed in Imam Khomeini hospital, 2 in the health deputy office of the university and 5 in Shariati hospital. All interviews were conducted and recorded in Persian. None of interviewees asked for the interview not to be recorded.

Due to my familiarity with the research area (I have been a clinical manager for several years); I defined my understanding about the state of the AIPs in general wards and my conception of its meaning. For example, I noted that it is usual for many AIPs to be admitted to general wards instead of ICU, that there is insufficient care for AIPs in general wards and a shortage of ICU beds in hospitals. Predefining my subjectivity in AIPs in general wards prevented me from selectively searching for evidence of the current state of AIPs emerging from the views of participants.

Therefore, I was fully aware of my own opinions and tried to prevent them influencing the participants' views. Table 4-2 shows the questions were designed to assist the interviewer in leading the interview with the participants.

Table 4-2: The main interviews questions

How do you define AIPs?
Do you have any special grading system for selecting those AIPs, who should be admitted to general wards?
How do you evaluate the condition of AIPs in your hospital?
How is the condition of the AIPs in wards?
Do you have any protocol or guideline for admitting AIPs in ICU?
Do you have any plan for AIPs' follow up?
What is the patient's state on discharge from ICU and when transferred to a general ward?
Is there a person or office responsible for following AIPs in the hospital's chart of organisation? Do you have any record of AIPs readmissions to ICU?
Do you have any plans for controlling the rate of mortality or the LOS?

To direct the interviewees in answering the questions, more explanation was asked for by adding phrases like: "How?" , "Please explain more." and "What else?"

4.2.5 Data analysis

The interviews were transcribed verbatim immediately after each interview and re-read several times to obtain a comprehensive view of the data. Then, each interview text was imported to the MAXQDA software for analysis and coding. The analysis and coding were concurrent with data collection. This began with the first interview, and continued until the last.

In MAXQDA, the interview texts were coded line by line, and a name was given to every event, idea, or point. In this freely generated coding system, meaningful

statements and paragraphs were identified, marked as the units of analysis and had codes assigned to them. In the next stage, by comparing similarities and differences, reflection, and using interpretation techniques, codes with similar meanings were grouped together to form categories and subcategories, and a label was assigned to each. The analysis was finalized by identifying several categories that emerged during description of the current state of AIPs in Iranian hospitals. The analysis process was performed in Persian and the results were translated into English.

4.2.6 Rigor

In quantitative research, validity and reliability are used to measure data accuracy. But in qualitative studies, rigor and trustworthiness are used instead. The aim of a qualitative study in analyzing the rigor and trustworthiness of a study is to ensure that the study truly represents the participants' experiences(157). The accuracy of a qualitative study is judged using measures that are appropriate for this approach. Four criteria for measuring accuracy of qualitative data are described below; credibility, conformability, dependability and transferability(166).

4.2.6.1 Credibility: ensuring that researcher have not misinterpreted the participants' words. To achieve this I considered these points:

Member checking: in order to ascertain that the codes were accurate, all of the transcript texts and data were given to the participants for confirmation.

Peer debriefing, interview texts, sub-categories and categories were given to other researchers to be evaluated.

Triangulation: interviews with physicians, nurses and matrons were carried out to increase the validity of the data.

4.2.6.2 Confirmability: the results of this study were not a result of the concepts and knowledge of the researcher, and all of the stages of analysis were clearly designed in order to make an unbiased judgment.

Due to the fact that I have 20 years' experience working in clinical areas of hospitals, a fear was that my background and thoughts regarding AIPs would affect the manner of data analysis. Therefore, I put my own clinical experiences aside during data gathering and analysis, to prevent them in any way impacting on the results obtained by the study. I tried to listen to and explore the views of participants without prejudice and judgment. This is titled "reflexivity" in qualitative studies. The purpose of reflexivity is to expand researcher's understanding of how his/her subjectivity affects the research process. Reflexivity enhances the quality of research because it extends researcher's understanding of how position and interest could affect all stages of the research process(167).

4.2.6.3 Dependability: "seeks means for taking into account both factors of instability and factors of phenomenal or design induced change, that is, the degree to which data changes over time and alterations made in the researcher's decisions during the analysis process"(166). In a qualitative study, all data must be agreeable and logical. To achieve this goal, other investigators and experts reviewed the data for verification.

4.2.6.4 Transferability: that the result of a study be valid for use in other circumstances. Transferability of findings depends on whether readers recognize the findings in general ward settings. Selecting participants from different hospitals and departments of the university and different professions, along with contextual features of the sample and setting of this study could help readers decide on the transferability of the findings. This indicates that the findings of this study can be transferred to other settings facing similar situations, especially in Iran. The readers can refer to the participants' quotations and descriptions on the context and field of research for generalization to other fields.

4.2.7 Ethical considerations

The ethical committee of the Tehran University of Medical Sciences approved this study. Participation was not obligatory and participants were provided with information about the research, aims, and methods. All interviews were carried out at a time and location agreed upon by participants, and the participants could exclude themselves from the study at any time. I promised that all interviews are kept confidential and data be used only for research purposes. In addition, the names of the participants were protected. Participants had access to the interviewer's cell phone number and e-mail address to call or email their points of view about the study at any time.

4.3 FINDINGS

Four physicians and six nurses participated. All physicians were male and all nurses were female. The mean work experience of participants was 15.9 years (ranging from 5-27 years). The participants varied from hospital staff to deputy of the university （Table 4-3）.

Table 4-3: Characteristics of participants

ID	Profession	Sex	Experience/Years	Capacity
1	Physician	male	5	Head of the emergency ward
2	Physician	male	18	Health deputy of the TUMS
3	Physician	male	20	Head of the hospital
4	Nurse	female	27	Matron of a hospital
5	Nurse	female	12	Nursing supervisor
6	Nurse	female	27	Matron of a hospital
7	Nurse	female	17	Head of the nursing office of the university
8	Nurse	female	12	Staff
9	Nurse	female	15	Staff
10	Physician	male	6	Staff

The data analysis led to the formation of categories that illustrated the condition of AIPs in general wards. The main extracted categories were: “Problems in identifying AIPs”, “Problems in handling AIPs”, “Inappropriate use of ICU beds” and “Poor structure for mortality control”. Four categories and 18 sub-categories were identified, as shown in Table 4-4.

Table 4-4: Categories and sub- categories

Category	Sub-category
Problems in identifying AIPs	Lack of protocol Individual Judgment Overlooking the AIPs and deterioration of their condition Poor Nurse-physician relationships
Problems in handling AIPs	Usual care for AIPs Overcrowding of AIPs in general wards Knowledge and experience deficit among staff Staff and equipment shortage Inability to educate and train all staff Problems with CPR team
Inappropriate use of ICU beds	Lack of guidelines for ICU admission Inappropriate patients' prioritisation Emotional decision making in ICU admission Favouritism
Poor structure for mortality control	Poor quality management at the hospital level Lack of programs for reducing mortality Lack of a functional mortality committee Lack of mortality analysis

4.3.1 Problems in identifying AIPs

Identifying the AIPs in general wards was problematic and not conducted correctly. This problem was caused by lack of protocol, individual judgment, overlooking AIPs and deterioration of their condition, and poor nurse-physician relationships.

4.3.1.1 Lack of protocol

Although, variety of patients' grading systems are described in nursing and medical textbooks, but none of them has been implemented in practice. In addition, in the settings of the study, no guideline or protocol existed for identifying AIPs in general wards. One participating nurse said:

"Nurses should pay attention to ill patients and allocate more time to special patients. But in general, no program or protocol for patient grading exists."(Participant 4)

Another participating nurse indicated:

"We have a grading system based on nursing references and our general books. But putting into effect those grading systems? No! It is not done."(Participant 8)

Another nurse said:

"In nursing, we have patient grading systems, but nobody actually works with them." (Participant 5)

4.3.1.2 Individual judgment

According to some participants' opinion, AIPs were identified based on individual judgment. One of the participating physicians cited in this regard as follows:

"I can tell which patient is ill. For example systemic lupus erythematosus (SLE) patients who have thrombocytopenia and kidney involvement, need more care." (Participant 3)

One of the physicians stated that:

"In some instances, we have scientific criteria which are mentioned in our references, and different people use them in various fields with different methods. However, some use them more, and some not at all. In general, we have no grading system for identifying AIPs, and it depends on the ward staff, or our scientific board memberstationed in every ward to decide."(Participant 1)

4.3.1.3 Overlooking the AIPs and deterioration of their condition

Because AIPs were identified based on individual judgment, a number of these types of patients were overlooked, and their condition would deteriorate due to inappropriate care. One member of the nursing staff indicated that deterioration might be due to the patient being overlooked:

> *"We had a patient, who was admitted with peritonitis tothe emergency ward, but unfortunately his admission process to the emergency ward took too long. When his condition and health worsened, he was transferred to the operating room and from there to ICU. In ICU, he had a myocardial infarction and after that, he was transferred to the surgery ward again and came back to the operative room for laparotomy. Eventually, he was returned to the ICU and became unconscious. His GCS was3, I don't know if he survived" (Participant 5)*

One of the nurse participants stated about repeated transfers from general wards to ICU:

> *"Unfortunately because of the shortage of ICU beds, a patient who really needed post ICU service was transferred to a general ward. Finally, he acquired so many problems that he was at risk of death. Last week, we had another case who was admitted to neurosurgery ICU more than 4 times due to changes in his condition."(Participant 4)*

4.3.1.4 Poor nurse-physician relationships

Problems in nurse-physician relationships were another point that was mentioned by participants. The interviewees believed that physicians and nurses didn't have professional relationship for exchange of patients 'information. Quite often, physician visits to patients have been done without nurses. In these cases the information about

patient's condition and history was taken from the medical document and records. The study participants added that this poor communication could affect the care for AIPs. One nurse said:

> *"Doctors and nurses are not sincere with one another. Our sole aim is to carefor the patient, but unfortunately, no professional relationship exists between doctors and nurses, and this probably affects the diagnosis of AIPs and their treatment."*

Not only the nurses, but also the physicians mentioned the poor communication among staff. One physician participant added:

> *"Even when we go to a patient's bedside to evaluate them, no nursing staff are present. Also in some wards, when the physicians attend to give consultation concerning the patient's condition, the nurses refer them to the patient's records without offering any clarification of the patient's condition."(Participant 3)*

Based on participant views, this category shows that no protocols or guidelines exist for identifying AIPs and any action taken in this field is based on individual experience and the professional judgment of physicians and nurses. The condition of these patients may worsen due to lack of protocol and timely identification. Poor communication between nurses and physicians seriously affects this as well.

4.3.2 Problems in handling AIPs

Usual care for AIPs, overcrowding of AIPs in general wards, knowledge and experience deficit among staff, shortage of equipment and staff, lack of staff

education and training and problems with CPR teams were all problems in handling AIPs.

4.3.2.1 Usual care for AIPs

According to the interviews, most AIPs were admitted to general wards, instead of ICUs. When these patients were discharged from ICUs and were admitted to general wards, in some instances they did not receive appropriate care.

A participating nurse commented:

> *"Some patients, on discharge from ICU, require further care. Patients, who are admitted to ICU and receive ICU services, receive "usual" care on transfer to general wards."(Participant 7)*

A physician describe that the caring for patients after discharge from ICU is inappropriate and lead to deterioration:

> *"When a patient requires continual care, even if he has been discharged from ICU, his care must be continued, no matter which ward he is in. Unfortunately ¸critical care for these patients does not continue out of ICU. We have seen patients who showed no evidence of bedsore in ICU, or getting bed sore or respiratory problems out of ICU. For example, one patient had had airway and tracheal suction performed on him in ICU, but his breathing problems were exacerbated out of ICU."(Participant 2)*

4.3.2.2 Overcrowding of AIPs in general wards

Another point was mentioned in interviews was overcrowding of AIPs in general wards. Interviewees commented that usually the ICU beds were full and patients

needing critical care had to stay in general wards and this led to overcrowding of AIPs in general wards. One of the physicians said:

> *"We have extreme shortage of ICU beds in our hospital and university too. Usually, all beds in ICU are full, and we have no extra beds for new patients." (Participant 3)*

In the study setting, as participants described, most of the time, there are some AIPs in general wards that need ICU bed. One of the nurses stated:

> *"When the number of beds in the ICU is low, we cannot transfer our ICU candidate patients to ICU. We always have a long list of patients that need to be transferred to ICU." (Participant 5)*

4.3.2.3 Knowledge and experience deficit among staff

Interviewees frequently mentioned the low level of knowledge and experience on AIPs among nursing staff, especially during evening and night shifts. A participant commented:

> *"Many nurses don't have enough knowledge and experience in critical care. Most of them have worked in general wards for years."(Participant 5)*

Another nurse participants stated:

> *"In the evening or during the night, most of the temporary nurses on duty don't have enough experience."(Participant 6)*

A nurse commented:

> *"Sometimes when a patient with internal bleeding comes to the emergency ward at night, our nurse fails to diagnose the patient's problem, and*

unfortunately this leads to increased mortality and morbidity in our system."(Participant 5)

4.3.2.4 Staff and equipment shortages

Staff and equipment shortage was particularly evident in participants' statements. The participants believed that staff and equipment shortage were effective factors in patients' continual care and, this serious shortage caused inappropriate care. A surgeon, who worked as head of the emergency ward said:

"We need permanent nursing care to stay by the bed and evaluate the patient´s health 24 hours a day, and we also need a fixed doctor to know about the health and condition of the AIPs 24 hours a day too."(Participant 1)

He commented:

"Some wards, like the surgery ward, have4 or 5 complicated operations a day, and some of these patients have to be transferred to the surgery ward after the operation But when this ward lacks the sufficient number of nurses, how can they provide suitable care for these ill patients? For example, one nurse, I think, covers 3 or 4 post-operational patients. We have limited equipment and staff. These two shortages face us with this awful situation."(Participant 1)

Some of the participants mentioned nursing and medical equipment shortage on caring the AIPs. It is notable that ward staff had to get help from patients' family to handle this situation:

"At present, the emergency ward informed me that they have 7 ICU patients, which 5 patients have been intubated, and 3 of 5 have been connected to a

ventilator. And the other two need two nurses to carry out ventilationwith ambo bags for them, but that unfortunately this procedure are being done by their family members."(Participant 6)

Sometimes the shortage in nursing staff causes blocking of beds:

"For example our Emergency ICU has 16 beds with equipment, but due to the lack of staff, only 10 beds are active."(Participant 4)

4.3.2.5 Inability to educate and train all staff

Another factor mentioned by participants was difficulty providing critical care training for all ward staff. A severe nursing shortage has caused newly graduated nurses immediately to start to work in wards without any training about critical care and AIPs. Also the shortage leads to nurses' rotating between wards. Therefore, training of nurses in the field of critical care was problematic. One of the nurse participants said:

"Due to the shortage of staff, new nurses start working in the wards, evenon the critical ward, immediately upon graduation from universities, and without enough experience or training, and without even receiving an induction to the hospital or ward."(Participant 5)

Another nurse participant said:

"We cannot train all nurses to care for very ill patients, and staff rotation in the wards is common."(Participant 7)

The nurse managers tried to distribute the senior nurses among the different shifts for decreasing this problem. As one of the participants (hospital matron) said:

"We tried to distribute the nurses among the wards; in a way theywould ensure that at least one nurse had sufficient ability and knowledge concerning CPR, but we couldn't manage it."(Participant 6)

4.3.2.6 Problems with CPR teams

The interviewees commented that CPR teams attend by the beds of patients, just after cardiopulmonary arrest to do intubation and resuscitation. One nurse participant said:

"When does the CPR group arrive? Too late! Unfortunately, in the final stages of a long illness, they only attend for resuscitation or intubation."(Participant 9)

Some participants believed that reasons such as long distance between wards and multiple duties of CPR team members led to delayed attendance of CPR teams by the beds of AIPs in general wards. A supervising nurse added:

"We had a patient who was transferred to another building for a CT scan, and his condition worsened. He needed CPR, but it took a long time to announce the CPR Code and even longer for the anaesthesiologist to arrive, due to the long distance. The patient died after the CPR."(Participant 5)

The participants added that beside the above mentioned reasons, lack of familiarity of CPR team members of the patients' medical history, and treatment could result in unsuccessful CPR. Even if the CPR teams arrive in time, they are usually not aware of the patients' previous medical history:

"When our CPR group arrives, they don't know what the illness is, or the patient's condition prior to CPR, and we need to explain our patients' history to the cardiologist or anaesthesiologist. During intubation, we have

to explain the patient's illnesses and history, for example, bleeding, cirrhosis or encephalopathy". (Participant 8)

The same participant continued:

"Most of our CPRs (approximately all of them) are not successful and sometimes two or three CPRs have been done without any positive results and eventually the patient dies".

Personnel of the CPR team also had other responsibilities beside CPR during their working shifts. This contributed to their delayed presence in some instances:

"One of the ICU nurses along with residents of cardiology and anaesthesiology form our CPR team members. They have lots of tasks to do and responsibilities in the ward and other parts of the hospital, as well as being in the CPR group." Participant 5)

This category introduced the idea that the care given to AIPs in general wards is the 'usual care' given to other patients. Same as the problem in AIPs identification, the AIPs handling was problematic because of some shortcomings in the general wards. The shortcoming were in the broad spectrum as the high number of AIPs in general wards, shortage of staff, lack of equipment, and low knowledge and experience of nurses. In addition, the CPR team is responsible for attending to patients only at the time of arrest, so this team is not responsible for AIP identification, or preventing AIPs health from deteriorating. Consequently, the management of AIPs in general wards could lead to deterioration of the patient.

4.3.3 Inappropriate use of ICU beds

Lack of guidelines for ICU admission, inappropriate patient prioritization, emotional decision making in ICU admission and favoritism were the sub-categories of this category.

4.3.3.1 Lack of guideline for ICU admission

Participants commented that there were no defined policies or protocols for admitting patients to ICU, also a protocol for when ICU admission was not needed. One of the participants pointed out that:

> *"We have no guidelines for transferring our patients to ICU. There are many reasons for ICU admission, of course, but the final decision belongs to the physician. It also sometimes depends on the views of the consultant and head of the ICU ward."(Participant 10)*

When a patient was categorized as an ICU-needing patient, based on the diagnosis of a physician, the name of the patient was inserted into a long ICU admission waiting list. Even if a patient's condition had improved, his name would stay on the list, due to a lack of guidelines and a good control system:

> *"We have a waiting list for ICU admission, and sometimes you can easily find that 20% of the patients on the list are in good condition and their state has changed during the past few days, but they are still on the list. We have no guidelines or plans for ICU admission for patients, and we have problems in these cases. Patients on the waiting list are not visited by consultants to verify whether they should stay on the list." (Participant 5)*

4.3.3.2 Inappropriate patient prioritization

Following on to the lack of guidelines for ICU admission, there is no systematic prioritization for ICU admission. Almost all of the participants mentioned inappropriate patient prioritization during ICU admission. The ICU admissions depend on physicians' views. A nurse participant said:

> *"We had a patient with cancer for whom all the necessary care and efforts were done. Unfortunately he was ill, intubated, with difficulty breathing, and was transferred to ICU instead of another patient with miastenia gravis (MG). The doctor preferred to transfer this patient to ICU, instead of the patient who really needed ICU care."(Participant 5)*

Preferring younger patients with a better prognosis for transfer to ICU was another case of prioritization that was mentioned by one of participants:

> *"We have ICUs, internal ICU, general ICU, and surgical ICU, which are managed by different groups of physicians with different policies for prioritisation of patients. For example, some ICUs prefer young patients and those with a good prognosis."(Participant 7)*

4.3.3.3 Emotional decision making in ICU admission

Some participants believed that making decisions emotionally, as opposed to logically plays a critical role in ICU admission. Some times AIPs admitted to ICU in order to satisfying family. One of the nurse participants said:

> *"In some cases we admit the patient to ICU simply to satisfy his parents or family, sometimes even end-stage patients with poor prognosis." (Participant 7)*

One of the physician participants said:

"We have controversial criteria in choosing candidate patients for ICU. For example, when the patient is in a terminal stage, and chances of survival are extremely low, the patient is admitted to ICU, due to moral distress. Now, I want you to know something important about this decision making process, and that is that some of these patients don't have the indications necessary for staying in ICU." (Participant 2)

4.3.3.4 Favouritism

Some interviewees believed that, another important aspect of patient selection for ICU admission was choosing the patient based on personal preference and, in this atmosphere, favoritism emerged. One of the participants stated that:

"I know that some patients are not selected correctly. It is due to preferring some patients against the scientific indications necessary for transfer to ICU. What I mean is, in our system, sometimes the ill patients that really needed it could not be transferred to ICU, because of personal "preference" in choosing patients."(Participant 7)

The same participant continued:

"In addition, when somebody is well-connected or related to staff members, they can get their patients transferred to ICU more easily."

Sometimes, patients admitted to ICU after a call or recommendation of an influential person. One of the physicians said:

"Recommendation is an important factor that can be seen in our hospital. For example, we had a case 2 days ago, I don't know who recommended him, but we were informed that the patient was on his way to the hospital. After we prepared the bed, we were faced with a 91 year-old man who was admitted to ICU immediately after being operated." (Participant 1)

The relationship between the patients or their relatives with health care workers was another important factor for ICU admission. One of the nurse participants said:

> *"It depends on the patients' relations with our staff. Sometimes these patients have priority for admission toICU; even though the patient does not really need ICU care."(Participant 4)*

This category shows inappropriate use and allocation of ICU beds. Based on participants' views, there is no systematic approach to defining the protocol or guideline for ICU admission. The responses suggest that such a climates contributes to favoritism and emotional admissions, where the influence and power of some hospital or university staff can interfere with logical admission of patients for ICUs.

4.3.4 Poor structure for mortality control

This category consisted of poor quality management at the hospital level, lack of programs for reducing mortality, Lack of a functional mortality committee, and lack of a mortality analysis.

4.3.4.1 Poor quality management at the hospital level

Some participants stated that evidence of quality management in their hospitals was lacking and the programs such as clinical governance need to develop. One of the participants said:

> *"We don't have a quality management committee in our hospital, and no quality indexes to control them. Some efforts were made, like a clinical governance system, but its efficiency and performance require consideration, and more time to develop." (Participant 2)*

4.3.4.2 Lack of programs for reducing mortality

According to participants' views, no defined policy exists for decreasing the rate of mortality in hospitals:

> *"I do not recall any mortality or morbidity reports being given that moved our authorities and made them reconsider and think about designing a mortality reduction plan." (Participant 2)*

Another participant had similar views regarding this subject:

> *"We have no plans for controlling mortality and morbidity, apart from the physicians sometimes mentioning it in their morning reports." (Participant 10)*

4.3.4.3 Lack of a functional mortality committee

Some of participants stated that a mortality committee was either missing or mostly non-functional, and there was no single person or entity responsible for controlling it's functioning. On the other hand, no systematic effort was carried out, and only sporadic cases were reviewed by some mortality committees (if the hospital had one). A physician participant mentioned:

> *"Some mortality committees are founded in hospitals, but they are merely formalities. There is no one responsible for contacting the doctors or nurses in order to uncover the causes of mortality in a ward. You know, we need to have an office or a person responsible for following up the mortality cases in the hospital. But we don't have one." (Participant 2)*

A matron of a hospital said:

"In some cases, the committee gave verbal notification to the ward or nurse or physician, but they did not have a systematic problem solving approach." (Participant 6)

4.3.4.4 Lack of a mortality analysis

Interviewees stated that mortality rates for hospitals were recorded and collected, but no analysis was performed or reported. One of the participants said:

"You see, we have a mortality rate index, but no system to analyse it."(Participant 1)

This category, based on interviewees' declaration, indicated that not enough attention was paid to mortality analysis, and also that a sufficient and effective system for providing the staff with follow-up or feedback was lacking. This is worthy of notice, since feedback is one of the most important quality indicators of hospital care.

4.4 DISCUSSION

This research shows that problems in identifying AIPs, problems in handling AIPs, inappropriate use of ICU beds and, poor structure for mortality control were main findings in relation to the current state of AIPs in Iranian hospitals. Respondents' accounts indicated that there is no systematic program or strategy for management of AIPs in the general wards.

Findings indicated an absence of protocols in governing the diagnosis of AIPs, and over-reliance on personal judgment. Some studies in1990 cited that the identification of AIPs in general wards was not done in a timely manner, and therefore led to adverse events(11, 168). As mentioned in chapter 3, in some developed countries TTs

were formed for solving the problem of timely diagnosis and care of AIPs(59, 121, 169). Such systems were used in countries such as the UK, Australia, and the USA in order to optimize the quality of care for AIPs(121). This qualitative study showed that in Iran, such a system is lacking, and identification of AIPs is generally based on the professional judgment of clinical staff. Lack of protocols for identifying AIPs led to overlooked patients, inappropriate care being delivered, and deterioration of patient health in general wards, as has been mentioned in other studies(11, 42, 103).

The existence of a professional relationship between health care staff is critical for improving the care given to patients(170, 171). But study findings show that lack of such a relationship led to deterioration of AIPs' health. Communication between nurses and physicians in the process of identifying these patients was deficient, and of poor quality.

Studies have shown that nurses and physicians hold different views in relation to collaboration and communication, and therefore the problem of professional relationships still remains. In this case, the underlying cultural factors that facilitate or hinder communication between professionals is of note(172). If nurses and physicians gain proper understanding of each other's attitudes, the best possible connection, based on mutual trust will be established(170, 172, 173).

In Iran, the nurse-physician relationship leans towards a system that puts the nurses completely under the control of the physician and does not give them enough opportunity to actually enter the decision making process(20). This has caused a sub-

optimal interpersonal reliance between these two groups of health care providers and consequently influences patients' diagnosis and care.

Even if a patient is diagnosed as an AIP, problems in handling them still remain. Participants described how sometimes the number of AIPs in general wards was very high, and therefore ward staff were unable to handle them. For example, in Shariati hospital, the nursing office usually keeps a list of these patients. The nursing officer then informs the university's deputy of health office of those patients requiring ICU beds, and a search is conducted among university-affiliated hospitals, to see if there are any free spaces. Most of the time, such free spaces do not exist, which makes transfer of AIPs to other hospitals impossible. During the first 6 months of 2010, 520 patients in Shariati hospital needed ICU care, and most of them never left the waiting list. In a bilateral manner, high numbers of AIPs in a general ward might lead to increased workload of ward staff, which consequently leads to all patients receiving low-quality care (44). According to the perspective of the participants, when AIPs stay in general wards, they received the care usual for ward patients, which is simply not enough. The fact that provision of inappropriate or suboptimal care to AIPs' in general wards is a trend has also been indicated by other studies (11-13, 42).

The findings show that the knowledge and work experience among some nursing staff in general wards on AIPs is low and there are no ability and time for education and training all nurses. This had a considerable effect on AIPs' care, which has also been mentioned by other researchers(11). Although no studies assessed the knowledge of general ward nurses on the care of AIPs in Iran, studies evaluating the

knowledge of nurses about triage of emergency ward patients(174), or CPR guidelines(175), indicated the need for nurses to be better educated.

Obviously, education alongside training and skills-upgrading is more effective in increasing the knowledge ability of nurses and the quality of care they provide. Also, the importance of related training courses has been emphasized by the WHO(176). Training courses for clinical nurses in Iran are mostly theoretical, rather than practical. Through my experience as a clinical manager in Iranian hospitals, I witnessed that sometimes nurses are trained theoretically for CPR, rather than practically. During the past 5 years, most training courses for nurses in hospitals consisted of providing training materials and exams via the Internet. In addition, at the hospitals in which the study took place, and also at other hospitals, only one supervisor in each nursing office was actively involved with the nurses' training. It is evident that education and training of the nurses was not done properly considering the variety of subjects, especially in general hospitals. It is notable that it was found that nurses in general wards have between 2 and 25 years of work experience, with an average of 8.7 years, and that 55 nurses had less than two years' experience. These are the nurses that have to work in public hospital settings for the first 1–2 years after graduation, according to governmental law (20).

Shortage of nursing staff and equipment were other problems in handling AIPs. According to studies, having a standard and adequate number of nurses will result in better care outcomes, and the quality of care will improve (2, 177). However, the nurse-to-population ratio varies in different countries, from less than 10/100,000 to

more than 1,000/100,000. In Iran; this proportion is 12/10,000. Zarea, 2009 stated that the standard proportion of nurses to beds is 1.5-2, and in Iran, this proportion is 0.8. This is at least half the standard ratio. There are 110,000 active hospital beds in Iran, and based on the upper rate, Iran needs 220,000 nurses, but the number of nurses is under 100,000 (2, 20). According to the information taken from medical documents and from the nurses' office of Shariati Hospital, in the 13 wards that were studied there were a total of 375 beds, but the number of nurses present was 187. Furthermore, the nurse to bed ratio was 0.5. Adib Hajbaghery and Salsali (2005) stated that the impact of this shortage led nurses to work more than their required shift hours per month, with potentially 150 hours of overtime in some parts of the country(178). This is evident in field research; for example the mean hours of overtime is more than 110 hours per month. This consequently affects the quality of care provided for AIPs and other patients.

Studies, which were carried out in Iran, demonstrate job dissatisfaction among Iranian nurses. Many left their jobs, or requested early retirement for such reasons as: low level of respect, heavy workload, and limited clinical autonomy (179, 180). For example, in an unpublished study carried out in the year2010 in Shariati hospital, 14 nurses with work experience ranging from 5 to 15 years left Shariati hospital, and 4 nurses requested early retirement (UN published).

Beyond the consistent nurse shortage, lack of medical equipment was another factor that contributed to suboptimal care of AIPs. McQuillan et al. (1998) stated that lack of equipment is one of the most important contributively factors to suboptimal care in

hospitals(11). This study has shown that there is a lack of medical equipment necessary for care of AIPs in general wards, such as ventilators, perfusors, and digital monitors. Overcrowded wards, alongside hospitalizing AIPs with critical care needs in general wards, and accompanying financial problems of governmental hospitals (as has been my experience) are the most prominent reasons for medical equipment shortage in Iran. Some studies also indicated that the expenses of the health care system have risen due to the high cost of new technology and expensive medical equipment, and hospitals have to take measures to control these costs (181, 182).

CPR was one other important part of AIP handling in general wards. The participants of the study believed that the CPR team is insufficient. Findings also pointed to other shortcomings in the CPR process, namely group members being responsible for multiple tasks, having to cover all wards. For example in Shariati hospital, during each shift (morning, evening and night), the CPR team consisted of a physician and nurses that have lots of other tasks to do. Although, the studies state that on-time attendance of the CPR team is an important indicator of a successful CPR(183).

CPR in the field of study was performed with suboptimal results. According to a survey in Shariati hospital in 2009, 95% of CPRs were not successful (unpublished data). Some studies in teaching hospitals in Iran have reported a success rate for CPRs of only 10%(183-185). In another study, from among the 7.5% of patients discharged after CPR, only 2.8% had adequate cerebral function (183).

Inappropriate use of ICU beds was another problem for care of AIPs in Iran. The study showed that there are no guidelines or protocols for ICU admission, and admission takes place solely based on physicians' orders. Many patients were named as patients needing ICU without fitting any protocol or criteria. In addition, emotional decision-making and favoritism were affecting patients' ICU admission. A probable cause for favoritism maybe rooted in Iranian culture, which leans toward the eastern attitude of collectivism and puts a high priority on interpersonal connections in daily life(186, 187). The same culture may also influence the decision making process, making it a more emotional, rather than scientific, matter. This may not be the case in western countries. As a result, inappropriate use of ICU beds is carried out. However, there are many efforts being made by the Iranian MOHME to increase the number of ICU care beds(27), which is a time consuming and expensive process(32, 188).

Findings also indicated the poor structure of mortality control measures in studied hospitals. Based on the Iranian MOHME guidelines, one of the most important quality control indicators of any hospital is the proportion of deaths to admitted cases. This proportion is divided into 3 parts: desirable, moderate, and undesirable. Although these indexes are measured in hospitals, there is no evidence of any study comparing the results with developed countries (189). The lack of an efficient structure for controlling the rate of mortality and morbidity affects the AIPs' state. In summary, findings described that in Iranian hospital the AIPs considered as other general wards patients and no specific pay attention to them. The high number of AIPs in general wards, along with lack of guidelines for AIPs' identification and

handling, as well as the limited number of ICU beds lead to many shortcomings in caring for and managing these patients. These problems and shortcomings highlight the need for changes in the current state of AIPs in Iran. The findings can help Iranian healthcare policy makers and managers devise plans for improving the quality of care for Iranian AIPs. Therefore, policy makers and managers are required to bring sensible changes through legislating suitable rules for AIPs' management.

4.5 STRENGTHS AND LIMITATIONS

The strength of this qualitative study is that I was able to interview a wide range of staff. My role as a manager in the hospital where the participants were interviewed might have affected their responses. To reduce this effect, I described the aim of the study with details and assured the participants that their responses would be kept confidential.

4.6 CONCLUSION

Findings show that many shortcomings exist in the care of AIPs in Iran, which range from identifying to handling them, as well as there being structural and contextual problems. Bearing in mind the ever-increasing number of AIPs, it is important to consider quality of care and support for these patients. An immediate plan, to circumvent the challenges and to improve the care for AIPs is necessary. Considering policies and programs to improve the capacity of general wards in identifying and managing AIPs has been recommended, as well as enhancing the competencies of staff through improving their knowledge, skills, and attitude towards AIPs.

Establishment of support systems or counseling centers in hospitals, educating and training staff (especially nurses) about AIPs could possibly help prepare them for the care of AIPs. As mentioned in chapter 2, based on international experience, incorporating critical care services into hospitals can make health care workers more familiar with caring for AIPs.

CHAPTER 5

A Stepped Wedge Cluster Randomized Controlled Trial (SW-CRCT) to Assess the E ffectiveness of CCS in A Teaching Hospital in Iran

5.1 INTRODUCTION

Chan et al. (2010) completed an SR of the effectiveness of CCS. This review showed that the number of actual RCTs was low, the effects on mortality in adult hospitals were heterogeneous and suggested that further research is necessary in order to evaluate the effectiveness of critical care systems(76).

My literature review of CCS (Chapter 2), found no studies on the implementation or evaluation of Critical Care Systems in Iran or other developing countries. Since the qualitative study in chapter 4 showed that Iranian hospitals are in need of CCS strategies, this study was conducted in order to assess the effectiveness of CCS in Iran.

This study was a Stepped Wedge Cluster Randomized Controlled Trial (SW-CRCT) aiming to assess the effectiveness of CCS in the general wards of one

teaching hospital in Iran, by comparing mortality and CPR between the two groups of study. The study was funded by TUMS and was based at the Shariati teaching Hospital. A full description of the intervention and wards will be given later.

The trial compared wards exposed to the intervention (intervention) and wards unexposed to the intervention (control). The trial followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct and reporting of RCTs and the extension to Cluster Randomized Controlled Trials (CRCTs) (190-192).

5.1.1 Why a Cluster Randomized Controlled Trial?

Randomized Controlled Trials are accepted as "the gold standard" for assessment of health care interventions(193). A RCT is the most scientifically sound method for assessing effectiveness, as long as it has been designed in such a way as to minimize bias. Since the mid 1990s, CRCTs have been applied more frequently in clinical trials, as individual randomization is not possible for some studies(194). This method evaluates the impact of intervention on a group of individuals (for example, in this study, it was patients in hospital wards); while in a traditional randomized trial patients are assigned to exposed and unexposed to the intervention and evaluated individually.

The CRCTs have two key characteristics that differentiate them from individual randomized trials:

1. The units of randomization is the cluster,

2. The observations within the cluster are not independent of each other and this must be allowed for both in the power calculation and analysis.

The CRCTs is used when individual randomization may lead to contamination, and /or when it is not possible or desirable because of logistic, financial or ethical reasons (195, 196).

In the current study, the intervention was a complex intervention that whilst although it did not necessarily have to be delivered at the level of the ward, if the trial had used individual randomization would have probably led to contamination with patients not randomized to the intervention in avertedly being treated by the CCS team, or their skills being passed on in other ways and so becoming partially exposed.

5.1.1.1 Rationale for a Stepped Wedge CRCT

Conducting a CRCT is possible using several different methods, such as parallel, cross- over, and stepped wedge (SW) design. The stepped wedge design is a one way crossover trial, in which an intervention is rolled-out consecutively to the trial clusters over several time periods (197), and by the end of the random allocation, all clusters (wards for clusters) will have received the intervention (198).In this method, the clusters move unidirectional from being unexposed to the intervention to being exposed to the intervention. At each time point, intervention may be initiated in more than one cluster (197).

Figure 5-1 demonstrates an example of a stepped wedge trial with five steps. As shown in the figure, no intervention is implemented at the first time period, and

the first cluster randomly crosses to become exposed to the intervention at the second time period, while all the other clusters remain being unexposed to the intervention. The second cluster then becomes exposed to the intervention randomly at the third time point, and so on; as a result, all clusters will be exposed to the intervention by the sixth time period.

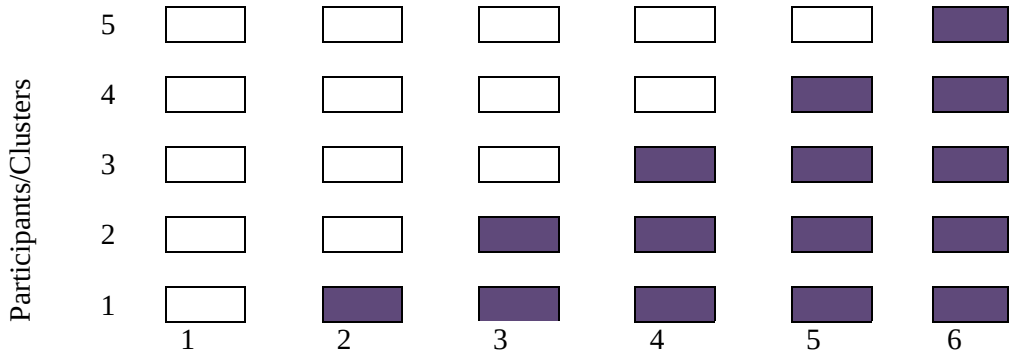


Figure 5-1: Example of a stepped-wedge study design with five steps(198)

For studies having a larger number of clusters, conducted in the stepped wedge design, several clusters can be randomly selected at each time point(194), and data is collected whenever a new cluster becomes exposed to the intervention (198).

This method has the potential to be a more efficient study design than the parallel (but this depends on the cluster size (199) and the intracluster correlation (ICC) (200)):

1. In the parallel design, the intervention is initiated in half of the clusters simultaneously, while in the stepped wedge method it is possible to initiate the intervention in a smaller fraction of the clusters at each time period (197), and this makes the method suitable for evaluating the effect of an intervention that needs to be implemented during routin implementation (194, 197).

2. Since the SW design is unidirectional, eventually all the clusters become exposed to the intervention. This makes the design valuable in evaluating interventions for which there is strong supporting evidence of effectiveness, perhaps from other similar settings; or where there is a need to carry out a pragmatic evaluation perhaps because of stakeholders desire for complete implementation irrspective of evidence; or if there is a prior belief that the intervention will do more good than harm (194, 197, 198).
3. The SW design was preferred when the intervention involved training of professionals, becouse the learning effects may occure in the trainers or the staff that apply the intervention. The trainers or appliers at the first step may become more experienced than later steps, that affect the estimated treatment effect(195).

5.1.1.2 Why has the stepped wedge design been chosen for this study?

A SW- CRCT was selected for this study for several ethical, financial and logistical reasons, listed below:

1. Randomization at the patient level was not practical, because some patients in a ward would receive the CCS intervention and simultaneously other patients in the same ward would not.
2. The SW- CRCT allowed staggered roll out of the intervention(it was infeasible to train all wards simultaneously).
3. There was evidence that the CCS worked in other settings(85) (chapter 2) and this coupled with the need to obtain robust randomized evidence(76) whilst reconciling the desire by

stakeholders to implement what they believed to be an effective intervention.

4. The CCS involved training of staffs.

5.1.2 Objectives and primary outcomes

As described in chapter 3, CCS has been introduced in developed countries for managing AIPs on general wards. The primary outcomes for evaluation of CCS would be its effect on mortality, and the frequency of CPR outside of ICU. The study also aimed to investigate a number of secondary outcomes, namely changes in LOS and admission to ICU.

5.2 THE SETTING FOR THE SW-CRCT

The study was carried out in Shariati hospital, TUMS, Iran from 17th July 2010 to 13th January 2012. The hospital, as described in chapter 1, is an adult hospital with 31 hospitalization wards (Table 5-1); six research centers (rheumatology, nuclear medicine, digestive disease, endocrinology, hematology, oncology and the stem cell center); 38 clinics and Para-clinics. Staffs include 142 faculty members, 435 residents and fellowships, as well as 468 nurses.

Table 5-1: Wards in Shariati Hospital

General wards in CRCT	Other wards
Cardiology	Neurosurgery ICU
Pulmonary	CCU
Urology & Nephrology	Open heart surgery ICU
General	surgical ICU
Medical2(including gastrointestinal and endocrine)	Medical ICU
Medical 1(including neurology and rheumatology)	Infertility and IVF
Maxillofacial	Kidney transplantation
Orthopaedic	Dialysis
General Surgery	Endoscopy and ERCP
Neurosurgery	Hematopoietic Stem Cell Transplantation (HSCT) 1(adult)
Obstetrics and Gynaecology	HSCT2(adult)
Haematology& Oncology B	HSCT3 (paediatrics)
Haematology& Oncology A	HSCT4(adult)
	Neonatal
	Neonatal Intensive Care Unit(NICU)
	Interventional cardiology
	Emergency
	Nuclear medicine

5.2.1 Eligibility criteria for wards as clusters

The role of CCS is to deliver care in the non-critical care units of general hospital wards (53). Therefore, Neurosurgery ICU, CCU, Open heart surgery ICU, surgical ICU, Medical ICU, Infertility and IVF, Kidney transplantation, Dialysis, Endoscopy and ERCP, HSCT wards (HSCT1, HSCT2, HSCT3, HSCT4), Neonatal, NICU, Interventional cardiology, Emergency and Nuclear medicine were excluded (as shown other wards column in Table 5-1)[1], and only general wards were included in the study. There were no other exclusion or inclusion criteria, and all patients admitted to these wards were included in the trial.

[1] These were either the critical care units or the outpatients visited there.

5.3 ETHICAL CONSIDRATIONS

This research was approved by the Institutional Review Board of TUMS and Digestive Diseases Research Institute (DDRI) in accordance with the Helsinki Declaration and guideline of the Iranian Ministry of Health and Medical Education (Appendix 1) with grant number 10612.

The institutional review board permitted randomization at the level of cluster without obtaining the individual consent of patients. The study was initiated after obtaining approval of the ethical permissions. The aims of the study were explained in detail to the wards' staff before their involvement in the study.

5.4 INTERVENTION

The intervention in this study was the implementation of a CCS in eligible general wards. In order to clarify the intervention, I will first describe how the CCS team was created; how the CCS team members were selected and trained, and how the training of ward nurses was carried out. After that, I will mention the protocol and process of AIP identification by the CCS team and, finally, the management and follow up of CCS patients.

5.4.1 Creating the CCS team in Shariati Hospital for intervention

As mentioned in chapter 3, CCS was implemented in different countries (with different names in each), but all have three main objectives: to avoid admissions (or ensure timely admission) to ICU, to enable discharge from ICU and to share skills with ward staff.

To familiarize myself with CCS, I personally visited Birmingham and York Hospitals. Following this, a committee was formed in Shariati hospital to form the CCS team and protocols. The committee included representatives of the management, nursing and medical teams (Table 5-2), and it was responsible for running the CCS team in the hospital, facilitating and defining training needs, medical equipment, financial aspects and any necessary coordination in the hospital.

Table 5-2: Member of CCS implementation committee in hospital

Committee Members
Manager of Shariati Hospital
Consultant Nurse
Nursing Matron
Head nurse of CCS
Project manager
Nursing Educational Supervisor
Director of Anaesthesiology Group
CPR team director
One Assistant Professor of Pulmonology
One Assistant Professor of Cardiology

5.4.2 Selecting and training of CCS team

Six nurses were selected for the CCS team. Selection of nurses was based on NICE recommendations(15). The CCS implementation committee identified five criteria for selection of CCS team nurses:

1. A Bachelor degree (or higher) in nursing
2. At least 10 years' experience in hospital,5 of which should be in ICU
3. Having a certificate for an additional course in critical care
4. Being a formal full time member of staff and having a permanent contract with the hospital.
5. Being interested in working in this field

Additional training courses related to critical care in ICU &CCU, patient's health status recognition and CCS team duties based on NICE Guidance were provided for CCS team members during the 3 months prior to the start of the trial (Table 5-3).

Table 5-3: Outline of training courses provided for CCS team members

Outline of training courses
Anatomy and physiology of Respiratory System
Oxygen therapy
Acid . base balance
Arterial Blood Gas Interpretation
Mechanical ventilation
Ventilator types & ventilation modes
Cardiopulmonary resuscitation
ACLS
ABCD
Signs of cardiac arrest
Defibrillation
Basic Life Support (BLS)
Advanced Cardiac Life Support
Common complications of CPR
Anatomy and Physiology of Heart
Heart Health Assessment
Vascular Health Assessment

Coronary artery disease (CAD)
Myocardial infarction (MI)
Pacemaker
Electrocardiography
Arrhythmia & Dysrhythmia
ECG interpretation

5.4.3 Training of ward nurses

Because ward nurses are the first step in the CCS process, an additional 8-week period of training was also provided for them before starting the intervention on each ward. Training was based on the NICE recommendations: (Table 5-4). The CCS team members were introduced to nursing staff, physicians and heads of wards during meetings and training sessions.

Table 5-4: Training provided to ward nurses before introducing CCS to wards

Training provided to ward nurses
Warning scoring system
Accurate evaluation of vital signs
Importance of post operation fever
Respiratory status
GCS
Accurate intake and output chart
Airway management
Appropriate airway suction
CVP measurement
Chest tube control and bottle replacement
NG tube insertion and control
Wound care
Mechanical ventilators application

Posters describing the single parameter scoring system in Persian (Appendix 2), including the process of CCS in Shariati hospital, were put up in each nursing station during the training period and explained to ward staff. In Appendix 3, the English version of the single parameter warning scoring system is shown.

5.4.4 Protocol and process of AIP identification

Timely identification of AIPs is one of the most important aims of the CCS, and, as mentioned in chapter 3, the TTs or early warning scoring system (EWS) has been introduced for this matter. In a study carried out by Gao et al. (2007), it is shown that there is still no single best or high quality TTs for identifying AIPs. The reason for this is inability to compare TTs applied in different studies due to the presence of wide variations in the characteristics of patients, response algorithms and data collection(121).

In this study, the committee, for medical staff of wards, applied single parameter criteria (Appendix 3) to detect AIPs, and an aggregated scoring system(Appendix 4) was used for assessment of candidate patients by CCS team members.

Patients' vital signs in Iran are documented routinely based on four main findings: pulse rate, temperature, blood pressure, and respiratory rate. The hospital committee suggested the single parameter method for ward nurses considering the routine duties of nurses. Listed below are the features of the single parameter method that made it a suitable choice for the study:

- Simplicity and ease of use
- Acceptable sensitivity and specificity
- Small number of items that need to be measured
- It does not require too much time investment or skill

Variables and values of single parameter criteria (Table 5-5) applied in present study were carried out based on NICE recommendations and committee opinion, as stated below:

Table 5-5: Variables of single parameters' warning scoring system used by ward staff to identify patients

Single Parameter Criteria
8< Respiratory Rate >15bpm
Oxygen Saturation< 90% on O2
50/min<Pulse Rate > 100/min
80mmHg<Systolic Blood Pressure >160 mmHg
36ºC< Body Temperature >38ºC
UrineCatheter Drainage < 160mls in 6hrs
Unexplained Decrease in Consciousness
General Concerns about Patient

As mentioned above, most of these variables were measured in all wards as a part of routine examination. For example, systolic blood pressure, respiratory rate, heart rate and body temperature are measured three to four times within 24 hours for each patient. In post-operative or special patients, vital signs are evaluated every two to four hours. Furthermore, urine output, levels of consciousness and oxygen saturation were assessed based on physicians' orders and were recorded in daily reports by doctors and nurses.

5.4.5 Admitting AIPs under the care of CCS

Patients could come under the care of the CCS in one of three ways:

1. Patients who met the single parameter criteria were referred by the ward staff to the CCS team
2. Patients discharged from ICU
3. The CCS team could actively identify patients in the wards

It is notable that there were two forms of identification: referral by ward staff (the decision is that of the ward staff), and also active identification by the CCS team (the decision is that of the CCS team). The CCS team members visited the patient and completed an aggregated scoring system form (

Appendix 4) before performing initial interventions in three different ways. After visiting patients, the CCS team allocated an aggregated score to the patient. Scores were categorized as below:

A: Low score: An aggregated score<3 for those who were receiving routine medical care. These patients were not referred to the CCS team.

B: Medium score: Scores of 3 to 5 were taken under the care of the CCS team, as long as the CCS team agreed that this was necessary.

C: High score: Patients scoring >5 were taken under the care of the CCS. (SeeAppendix 5)

The values mentioned are based on articles published in this field (15, 57, 93, 125, 201) and the committee opinions. The three ways of AIP identification will be described below:

5.4.5.1 Protocol for referral by ward nurses

Ward nurses identified patients requiring intervention by the CCS based on a single parameter warning scoring system described in chapter 3. This is summarized in Table 5-5.

The ward nursing staff reported any changes in systolic blood pressure, respiratory rate, heart rate, urinary output, body temperature, level of consciousness and any other general concerns about the patient's condition to the shift's head nurse. They continued to observe the patients for 30 minutes, and if there was no improvement; they informed the CCS team (by calling 2222). Then the CCS team attended the

patient's bedside and completed the aggregated score. The patient's care was taken over by the CCS team if the patient had a high score. Also patients with a medium score were taken over if the CCS team agreed, based on clinical judgment and consultation with ward staff. If the patient was assessed and found not to need CCS (those with low scores or those with a medium score, who the CCS team decided did not need CCS), they were given the same treatments as other patients in wards.

5.4.5.2 Protocol for follow up of patients discharged from ICU

A list of patients, who were transferred from ICUs to general wards, was taken from supervisors in each shift and passed to the CCS team. Following these patients were visited by CCS team members and placed in CCS team service after completion of an aggregated form.

5.4.5.3 Protocol for identification of patients by CCS team members

During ward visits, CCS team members opportunistically visited and reviewed patients' charts. And if they found patients who fulfilled the criteria, they admitted the patient under CCS team care. This included the patients that ward nurses had neglected to introduce to the CCS team. Afterwards, the patients were visited by CCS team members and placed in CCS team service after completing an aggregated form.

5.4.6 Management and follow up of CCS patients

After admitting patients to CCS, immediate evaluations were carried out and decisions were made for their management. Methods for patients' management based on NICE guidelines(15)were applied to CCS patients, as described below:

5.4.6.1 Active intervention

In these situations, team members were responsible for patients' critical care, such as airway suction, changes in patients' position, oxygen therapy, and consultation with physicians about patient care.

5.4.6.2 Training of ward staff

Medical staffs, particularly wards nurses, were trained in patient care. This included appropriate airway management, suction, oxygen therapy, changing the patient's position, endotracheal tube care, working with a ventilator and regulating its settings based on the patient's needs. The team members gave practical tutoring to the staff on the correct performance of these procedures. Furthermore, they were trained to recognize AIPs. The staffs were supposed to notify the CCS team if any abnormality in the patient's breathing, pulse rate, blood pressure, temperature, urine output, level of consciousness, or any concerns about the patient's health status arose. In case of high workload, CCS patient overload, or time shortage, the team members provided ward staff with telephone guidance.

5.4.6.3 Training and active intervention

This method is a combination of previous methods and is applied in most circumstances. To summarize, nursing staff provide support and supervision in caring for AIPs. They also offer negotiation about the patient's condition and nursing care, and are present at the patient's bedside whenever necessary taking into account the patient's condition. Coordination and facilitation of patient admission in ICU were other important duties of CCS team members

After intervention, haemodynamically stable patients were observed for 72hours and then discharged from CCS if they had recovered. If not, another intervention was decided upon. Patients who remained ill and unstable, or whose conditions caused concern, were transferred to ICU if there were any empty beds available. If not, the intervention was continued on general wards.

In addition to training and active intervention, the CCS team nurses covered a number of other activities (Appendix 6).

5.5 OUTCOMES

There were two primary outcomes;

1. Mortality during hospital stay
2. The number of CPRs.

However, as not all deaths (or CPRs) occurred within study wards, I subdivided deaths according to their location (study ward or transferred ward). The primary analysis was carried out with an intention to treat basis and so included all deaths or CPRs irrespective of their location. However, the other two analyses subdivided the deaths (and CPRs) into those that occurred in the admittance ward (i.e. a study ward), and those which occurred in a transferred ward.

I also studied two secondary outcomes:

1. LOS
2. Admissions to ICU

The mortality data came from hospital information systems. I also reviewed the reports that CCS team members documented after visiting the CCS patients (Appendix 12 and Appendix 13); and medical documents of patients that will be explained further in the data gathering section.

5.6 SAMPLE SIZE

This was a pragmatic study and the sample size was determined by the time taken to roll out the intervention to the included wards. Nonetheless a power calculation was carried out post hoc to inform on the change in mortality rate that this study would be able to detect. The calculation of the power of the study (or more accurately, the calculation of a detectable difference) will depend on the event rate of the primary outcome (mortality) and the magnitude of correlation [intra-class correlation coefficient (ICC)] of mortality rates between wards. It is estimated that the in-hospital mortality is about 3.5%. I used a range of ICCs, from 0.01 to 0.05. Over the duration of the study (72 weeks) there were 23,000 patients admitted to the wards, which gives an average of 319 admissions per ward per 4-week period. This design would have 80% power (at 5% significance) to detect a decrease in mortality to about 2.65%, for values of ICC between 0.01 and 0.05 (the impact of ICC was negligible). This therefore means that the study was powered to detect a 25% relative risk reduction (equating to a 20% RRR when including training period of wards but assuming exposure to the intervention).

5.7 MATCHING AND RANDOMISATION

The thirteen general wards of Shariati Hospital selected for the study were different in terms of characteristics such as mortality rate, number of beds, admission, discharge, number of AIPs, LOS, workload for nurses and bed occupancy rate (Appendix 7). Therefore, random allocation of the 13 wards between the exposed and unexposed to the intervention groups without considering these differences could introduce allocation bias into the study. There was a need to match the characteristics of the selected wards to ensure that exposed and unexposed interventional clusters were as similar as possible (193).

The method used for matching wards was as follows. A multiple linear regression model was derived to predict the risk of mortality or CPR for each ward, using known characteristics of the ward patients. The results of the logistic regression model were used to rank the 13 study wards according to their risk of mortality rates (Table 5-6). To confirm the validity of this ranking, an expert group of two nurses and two anesthesiologists also undertook to rank the wards. The two rankings were very similar, and therefore predict the risk of mortality based on linear regression, was chosen for matching of wards. This is explained in more detail in Appendix 8.

Thirteen wards were included in the study, but two small wards (neurosurgery and cardiology) were combined. The remaining 12 wards were matched into pairs based on their predicted risk of mortality. This gave us six pairs of wards (one was a trio) so that in each pair there were two wards with similar risk estimates (Table 5-7).

Then I randomly selected two wards from the list, so that they did not belong to the same pair. I allocated the intervention to these two wards so that these wards were the first to expose the intervention (i.e. wards B and F) in Period 1. This meant that the other wards in each pair were assigned to expose the intervention at the start of the second half of the intervention implementation (i.e. Period 4). This also meant that the intervention was carried out in one ward from the first subgroup and one ward from the second subgroup, and allocated to randomly selected wards. In each eight-week period, a new pair of randomly selected wards exposed to the intervention as depicted in the graph. I allocated the wards, which were to expose the intervention in Period 2 (and Period 5) using a similar process, by random selection from the remaining wards. For allocating the remaining wards to Periods 3 (and Period 6), the wards were randomly selected from each of the remaining pairs (Table 5-8).

Allocation concealment: the whole process of randomization, and the logic of allocating wards from each pair to different periods, was conducted by an experienced researcher who was not based at the Shariati Hospital and was involved in the implementation of intervention. The team members at Shariati Hospital were informed of the list of wards to receive the intervention, 2-3 days before the start of each period.

Table 5-6: Wards matching based on predict – mortality in regression method

		Ward Name	Ward Type	predict mortality
1	A	General	Med - Surge	6.3
2	B	Medical 2	Medical	4.5
3	C	Medical 1	Medical	3.5
4	D	Pulmonary	Med - Surge	2.5
5	E	Urology & nephrology	Med - Surge	2.3
6	F	General Surgery	Surgical	1.5
7	G	Haematology& Oncology A	Medical	1.3
8	H	Haematology& Oncology B	Medical	1.3
9	I	Orthopaedics	Surgical	0.25
10	J	Maxillofacial	Surgical	0.25
11	K	Obstetrics and Gynaecology	Med - Surge	0.15
12	L	Neurosurgery	Surgical	0.06
13	L	Cardiology	Med - Surge	0.06

Table 5-7: Pair wards

Pairs	symbol	Ward	symbol	Ward
1	A	General	B	Medical 2
2	C	Medical 1	D	Pulmonary
3	E	Urology & nephrology	F	General Surgery
4	G	Haematology & Oncology A	H	Haematology& Oncology B
5	I	Orthopaedics	J	Maxillofacial
6	K	Obstetrics and Gynaecology	L	Neurosurgery / Cardiology

Table 5-8: Randomization tables

Period 1		Period 2		Period 3		Period 4		Period 5		Period 6	
9 October- 3 December		4 December - 28 January		29 January- 25 March		9 April - 3 June ✳		4 June - 28 July		29 July - 24 September	
General Surgery											
Medical 2											
		Obes & Gyn									
		Pulmonary									
				Haemat&Onco B							
				Orthopaedic							
						Urology & Nephrology					
						General					
								Neurosurgery / Cardiology			
								Medical 1			
										Haemat&Onco A	
										Maxillofacial	

5.7.1 Stepped wedge table implementation

There are always pre and post periods in any SW study, the current study differs slightly to a conventional SW study as it has an extra post period. This was because whilst the sample size was pragmatic, excluding all observations in the training phases would quite dramatically reduce the sample size (but is desirable as the wards are either exposed or unexposed during these periods). The study design was therefore extended to include 12 weeks prior to the first phase of the training course (as unexposed to the intervention) and 12 weeks after the last training course (as exposed to the intervention). With 8 weeks in every cluster excluded to allow implementation of the training in each ward.

The starting day for every phase or time period was Saturday, and each cell of the Table 5-9 represents four weeks.

During the Iranian New year (Norouz[3] 21st March) and its related holidays, which last for over 13 days, there is a decrease of more than 30 percent in bed occupancy rate, which could affect expected sample size. Therefore, the period of Norouz had to be located in the middle of the table in such a way as to be before, or after, a training course (9th April -6th May). Therefore, the best time to start the project was 17th July 2010, lasting until 13th January 2012 (Table 5-9).

[3] The name of the Iranian New Year in the Solar Hijri calendar .

Table 5-9: Research Steped Wedge Design

	17 July 2010	14 August 2010	11 September 2010	9 October 2010	6 November 2010	4 December2010	1 January 2011	29 January 2011	19 March 2011	9 April 2011	7 May 2011	4 June 2011	2 July 2011	30 July 2011	27 August 2011	24 September 2011	22 October2011	17 December 2011
4-week periods	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Paired wards	**Pre**															**Post**		
Medical II	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Surgical	Unexposed	Unexposed	Unexposed	Train	Train	ccst	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Pulmonary	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Obstetrics &Gynecology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology& Oncology B	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Orthopedics	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
General	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Urology & Nephrology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Medical I	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Neurosurgery-Cardiology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology& Oncology A	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed
Maxillofacial	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed

There are 13 wards matched into 6 pairs. The intervention was sequentially rolled out, two wards at a time, every 8 weeks, within a transition/implementation period of 8 week periods. There was a 12 week period of observation, and the study lasted a total duration of 18*4 weeks.

5.8 DATA COLLECTION

The data for this study was collected using 4 information sheets, as listed below:

1. Main SAPS II sheet (Appendix 9)
2. Aggregated form (sheet) (Appendix 4)
3. Adverse events sheet (Appendix 11)
4. Follow up sheets (Appendix 12 and Appendix 13)

5.8.1 Main SAPS II sheet

As mentioned in chapter 3 and Table 3-18, the SAPS II is easy to use, without necessity an initial diagnosis, which makes it suitable in medical and surgical wards of setting that the diagnosis take time. Data collection by SAPS II is rapid and it is proper due to the staff shortage in the study setting. Therefore, the table of SAPS II (141)(Appendix 9)was translated into Persian. Professionals determined the accuracy of the translation. Afterwards, a summary sheet was prepared (Appendix 10).

The SAPS team members visited admitted patients at 13 study wards during the first day (24 hours) of hospitalization, and they completed the SAPS II sheet based on information in the patients' records. It is notable that every day, the team secretary prepared a list of patients admitted in the last 24 hours by comparing data from the Hospital Information System (HIS) and wards' records to prevent any patients being overlooked. Then, a SAPS team was formed, and in order to prevent contamination, the members were different from those on the CCS team. SAPS team members completed the forms using the list placed by the bedside of the patient. In case of transfer of patients between wards, the sheet was filled in

based on the first admitted ward information. The team secretary, under my supervision, carried out entry of data into the Microsoft Excel program.

5.8.2 Aggregated form

The aggregated form (Appendix 4) was completed by CCS team members during the first visit of the patients admitted to the CCS follow up list.

5.8.3 Adverse events sheet (Mortality and CPR)

This form was filled in for death and CPR for all patients in study wards (Appendix 11). The adverse events sheet was filled in by CCS team members in exposed to the intervention wards, and by SAPS team members in unexposed to the intervention wards.

Listed below are the criteria considered for approved CPR and death:

A. Criteria for CPR:

1. A CPR call was made for the patient(was called code 145 in study setting)
2. Completed CPR form being attached to the medical records of the patient.

B. Criteria for Death: Physician's certification of death being attached to the medical records of the patient.

5.8.4 Follow up sheet

Upon under care of CCS, this form was filled in for all patients. Team members visited patients at least once in each shift and recorded patients' information, the

date and time of the visit, procedures, and comments, to follow up for the next shifts (Appendix 12 and Appendix 13). The forms were filled out on each shift (morning, evening, night) and included information on date and time of admission; patient's first and last name, file number, first diagnosis, staff whom the patient has been referred to (for example, nurse, intern, resident), score and primary interventions and other consequences, as listed below:

1. False call
2. Patients with no specific problem
3. Patients needing ICU admission
4. Patients admitted to CCS
5. Death

5.9 STATISTICAL METHODS AND ANALYSIS

Patients admitted to study wards were categorized into three clusters; those admitted during the unexposed to the intervention phase, training phase or exposed to the intervention phase. The characteristics of patients in these three clusters were summarized using appropriate summary statistics. These characteristics include patients' age, gender, type of admission (scheduled surgery, medical or unscheduled surgery), chronic disease (AIDS, hematological cancer or metastatic cancer), and physiological variables (Patients SAPS II Score).

The primary aim of the study is to evaluate whether there is a difference in the proportion of patients dying before and after exposure to the intervention. The null-hypothesis (no difference) was tested using a mixed effect logistic regression model, with the outcome being death. Important independent variables to consider

were the clustering effect (i.e. ward) and fixed effect for calendar time measured in four-week periods (since the intervention is sequentially rolled-out), and an indicator of intervention for each ward at each time point in addition to adjusting for other patient characteristics. The patient characteristics to be included in the adjustment were pre-specified and included age, sex, and SAPS II score. I report both adjusted and unadjusted odds ratios. Null hypotheses for secondary outcomes take a similar form to that for the primary outcome. Analysis of binary secondary outcomes takes a similar form to that described for the primary outcome. For the continuous outcome (LOS), I first transferred the data onto the natural log scale and then fitted it to a linear mixed model. Reported coefficients are exponentiated and can be interpreted as the ratio in geometric means between the exposed and unexposed to intervention wards. These models were fitted using the mixed effects models STATA.

The study included, an implementation period for each ward, during which the ward went through a transition phase of adopting the intervention. During these periods of time, the ward was neither in a pre or post exposure status. Therefore, these data were excluded from the multivariate analysis. However, to allow for use of data from all periods of time, these periods were also included in a sensitivity analysis assuming them to be exposed to the intervention.

Three methods have been anticipated for data set as below:

5.9.1 Method 1(All patients)

In this method of analysis all patients in both unexposed and exposed to interventional were included (Table 5-10).

Table 5-10: All patients

4-week periods	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Paired wards																		
Medical II	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Surgical	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Pulmonary	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Obstetrics &Gynecology	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology & Oncology B	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Orthopedics	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
General	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Urology & Nephrology	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Medical I	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Neurosurgery	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Cardiology	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology& Oncology A	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed
Maxillofacial	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	unexposed	Train	Train	Exposed	Exposed	Exposed

5.9.2 Method 2 (Matched Randomised)

As mentioned earlier in this chapter, I used matching for creating 6 pairs (one is a trio) of wards that were as similar as possible. In order to prevent time bias in this type of randomization, the random pairs of matched wards were compared with each other during a similar time period **(**Table 5-11**).**

Table 5-11: Matched randomised

4-week periods	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Paired wards																		
Medical II	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Surgical	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Pulmonary	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Obstetrics &Gynaecology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology & Oncology B	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Orthopaedics	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
General	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Urology & Nephrology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Medical I	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Neurosurgery	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Cardiology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology& Oncology A	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed
Maxillofacial	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed

5.9.3 Method 3 (Before-After)

As mentioned before, in this randomization method, I tried to match pairs of wards with a mortality risk. In this type of confirmatory analysis, to prevent bias caused by differences in the wards' characteristics, the results for each ward were compared in a before–after analysis method (Table 5-12).

Table 5-12: Method 3

4-week periods	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Paired wards	**Pre**															**Post**		
Medical II	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Surgical	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Pulmonary	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Obstetrics &Gynaecology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology & Oncology B	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Orthopaedics	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
General	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Urology & Nephrology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed	Exposed
Medical I	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Neurosurgery	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Cardiology	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed	Exposed	Exposed
Haematology& Oncology A	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed
Maxillofacial	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexposed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Unexpos ed	Train	Train	Exposed	Exposed	Exposed

5.10 RESULTS

The participant flow, as well as the prevalence (percent), mean (standard deviation), and baseline characteristics (based on what was discussed in the analysis section) will be presented in this section.

5.10.1 Flow diagram of trial

Figure 5-2 shows the diagram of the progress through the phases of a SW randomized trial (enrolment, intervention allocation, follow-up, and data analysis).

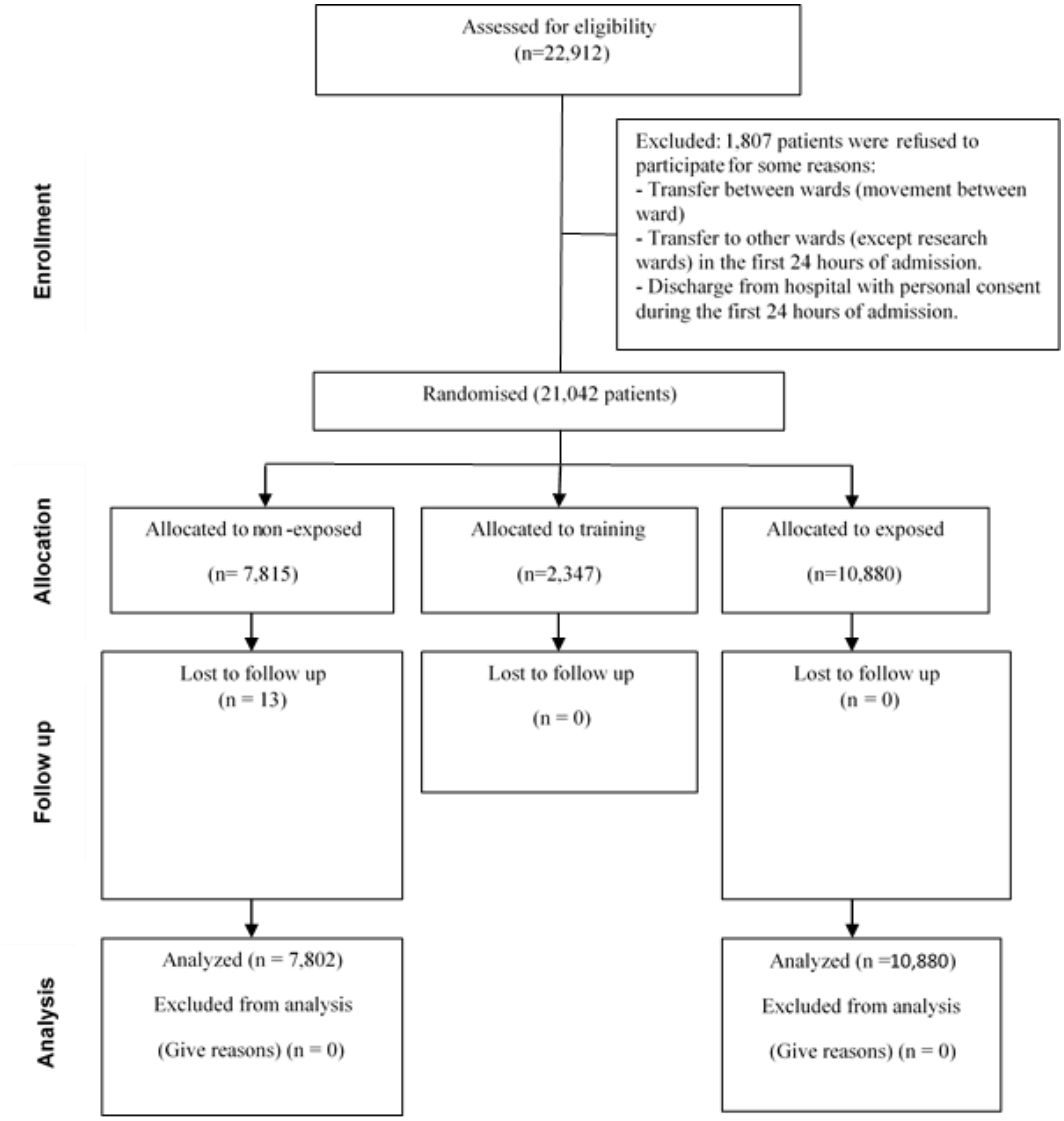


Figure 5-2: Flow diagram of the progress through the phases of a SW randomized trial (enrolment, intervention allocation, follow-up, and data analysis)

5.10.2 Describing patient characteristics based on method type

During the 72 weeks of study duration, 21,042 patients were included in the study. These patients were admitted to hospital for different reasons. Of these patients, 7,815 were admitted to the unexposed wards (clusters) and 2,347 to the training wards. Finally 10,880 were put in the exposed to the intervention wards (clusters). Thirteen patients in the unexposed wards were excluded from the study because those did not meet inclusion criteria. The demographic findings of included patients are presented in Table 5-13.

The mean age and its standard deviation for the clusters unexposed, in training and exposed to the intervention were 44(20), 43(19), and 43(19) respectively. The male patients were fewer than female patients in all three types of clusters. The percentage of male patients was 48%, 42%, and 39%in the unexposed, training, and clusters exposed to the intervention respectively. The average of SAPS II score in the unexposed clusters was 13 with a standard deviation of 9.8. This average was 12.3 with a standard deviation of 9.3 in the training clusters, and 12.2 with a standard deviation of 9.4 in the clusters exposed to the intervention. In other words, the mean SAPS score was higher in the unexposed cluster in comparison with the other two clusters. The percentage of SAPSII score was 3.01 with a SD of 5.6; 2.62 with a SD of 4.8; and 2.69 with a SD of 5.37 in the clusters unexposed, in training, and exposed to the intervention.

Table 5-13 also shows that 2% of patients in the unexposed period, 1% in the training period, and 2% in the exposed to the intervention period were transferred between wards.

Table 5-13: Baseline and clinical characteristics of participants (primary analysis including all observations)

	Unexposed	Training	Exposed
Number of patients	7,802	2,347	10,880
Age, years *	44 (20)	43 (19)	43 (19)
Male	3,732 (48)	983 (42)	4,266 (39)
SAPS II score*	13.0 (9.8)	12.3 (9.3)	12.2 (9.4)
Type of admission			
Scheduled surgery	2,113 (27)	739 (31)	3,849 (35)
Medical	3,689 (47)	969 (41)	4,124 (38)
Unscheduled surgery	1,684 (22)	621 (26)	2,855 (26)
Not known	316 (4)	18 (<1)	52 (<1)
Transferred between wards	170 (2)	29 (1)	170 (2)
Chronic Diseases			
AIDS	0 (0)	0 (0)	2 (0.02)
Haematological	107 (1.37)	59 (2.51)	235 (2.16)
Metastatic cancer	35 (0.45)	3 (0.13)	36 (0.33)
Month			
July 2010	578 (7)	0	0
August 2010	1,155 (15)	0	0
September 2010	1,145 (15)	0	0
October 2010	1,002 (13)	185 (8)	0
November 2010	1,012 (13)	220 (9)	0
December 2010	751 (10)	362 (15)	217 (2)
January 2011	716 (9)	372 (16)	297 (3)
February 2011	538 (7)	105 (4)	586 (5)
March 2011	276 (4)	74 (3)	309 (3)
April 2011	218 (3)	196 (8)	599 (6)
May 2011	275 (4)	286 (12)	833 (8)
June 2011	75 (1)	226 (10)	973 (9)
July 2011	60 (1)	196 (8)	1,134 (10)
August 2011	0	70 (3)	1,350 (12)
September 2011	0	54 (2)	1,277 (12)
October 2011	0	0	1,354 (13)
November 2011	1 (<0.5)	0	1,303 (12)
December 2011	0	1 (<0.5)	648 (6)

Values are numbers and percentages, except for * where mean (SD) is provided.
Notes: Thirteen patients with admission dates in January 2010 (before the study started) were excluded.

Table 5-14 shows the baseline characteristics of patients in regard to the second set of data/matched randomized (sensitivity analysis including only those wards matched by time). This set included 4,540 patients with 1,927 patients in the unexposed and 2,613 in the clusters exposed to the intervention. The mean age for

patients in the unexposed clusters was 46 years (standard deviation 20). These values for the clusters exposed to the intervention were 40 and 18, respectively. There were some differences in the age of patients in the exposed and unexposed to the intervention wards (clusters), and the mean age of the unexposed clusters was higher than the exposed to the intervention.

Fifty six percent of the unexposed clusters and 32% of the clusters exposed to the intervention were males. There were some differences in the percentage of gender in the exposed and unexposed clusters due to the location of the gynecology ward in the stepped wedge table. The mean and standard deviation of SAPS II score for the unexposed clusters was 15.4. These values in the clusters exposed to the intervention were 10 and 8.4 respectively. 3.5% of patients in the unexposed clusters and 1.1% in the clusters exposed to the intervention were transferred between wards.

There were also some differences in unscheduled surgery, with 301 patients (16%) being in the unexposed cluster and 786 (30%) in the exposed to the intervention cluster.

Table 5-14: Baseline and clinical characteristics of participants (sensitivity analysis including only those wards matched by time) (matched randomized).

	Unexposed	Training	Exposed
Number of patients	1,927		2,613
Age (years)*	46 (20)		40 (18)
Male	1,075 (56)		825 (32)
SAPS II score *	15.4 (10.0)		10.0 (8.4)
Type of admission			
Scheduled surgery	352 (18)		1,249 (48)
Medical	1,268 (66)		564 (22)
Unscheduled surgery	301 (16)		786 (30)
Unknown	6 (0.3)		14 (0.5)
Transferred between wards	68 (3.5)		28 (1.1)
Chronic Diseases			
AIDS	0 (0)		0 (0)

Haematological	82 (4)	15 (0.6)
Metastatic cancer	3 (0.2)	5 (0.2)
Month		
December 2010	279 (14)	217 (8)
January 2011	309 (16)	297 (11)
February 2011	466 (24)	586 (22)
March 2011	244 (13)	308 (12)
April 2011	218 (11)	388 (15)
May 2011	275 (14)	577 (22)
June 2011	75 (4)	131 (5)
July 2011	60 (3)	108 (4)

Values are numbers and percentages, except for * where mean (SD) is provided.

Table 5-15 shows the characteristics of patients, with equal time periods before and after the training. In this set of data, 11,658 patients were studied. Of these patients, 5,516 patients were in the unexposed clusters and 6,142 in the clusters exposed to the intervention. The mean age and its standard deviation for the unexposed clusters were 44 and 19, and for the clusters exposed to the intervention these values were 43 and 19 respectively. 45% of patients in the unexposed clusters and 44% of the patients in the clusters exposed to the intervention were males. The mean and standard deviation of the SAPS II score in the unexposed clusters were 13.1 and 9.7. These values were 13.0 and 10.0 in the clusters exposed to the intervention. 2% of patients in the unexposed clusters and 2% in the clusters exposed to the intervention were transferred between wards.

Table 5-15: Baseline and clinical characteristics of participants (sensitivity analysis including only those wards with equal time duration before and after the training period) (before and after the study).

	Unexposed	Training	Exposed
Number of patients	5,516		6,142
Age (years)*	44 (19)		43 (19)
Male	2,504 (45)		2,720 (44)
SAPS II score*	13.1 (9.7)		13.0 (10.0)
Type of admission			
Scheduled surgery	1,458 (26)		1,850 (30)
Medical	2,596 (47)		2,703 (44)
Unscheduled surgery	1,215 (22)		1,563 (25)
Not known	247 (5)		26 (<0.5)
transferred between wards	118 (2)		121 (2)
Chronic Diseases			
AIDS	0 (0)		1 (<0.5)

Haematological	97 (1.8)	227 (3.7)
Metastatic cancer	23 (0.4)	26 (0.4)
Month		
July 2010	312 (6)	0 (0)
August 2010	597 (11)	0 (0)
September 2010	777 (14)	0 (0)
October 2010	718 (13)	0 (0)
November 2010	738 (13)	0 (0)
December 2010	451 (8)	217 (4)
January 2011	652 (12)	297 (5)
February 2011	466 (8)	575 (9)
March 2011	244 (4)	207 (3)
April 2011	163 (3)	388 (6)
May 2011	263 (5)	577 (9)
June 2011	75 (1)	725 (12)
July 2011	60 (1)	455 (7)
August 2011	0 (0)	643 (10)
September 2011	0 (0)	604 (10)
October 2011	0 (0)	675 (11)
November 2011	0 (0)	539 (9)
December 2011	0 (0)	240 (4)

Values are numbers and percentages, except for * where mean (SD) is provided.

5.10.3 The raw data-items used to generate SAPS

As mentioned in chapter 3, SAPS II consists of 17 variables including; age, heart rate, systolic blood pressure, body temperature, respiratory rate, Pao2/Fio2, urinary output, serum urea level, WBC count, serum potassium, serum sodium level, serum bicarbonate level, bilirubin level, Glasgow coma score, type of admission and chronic diseases.

In this study, the data required for the calculation of SAPS was collected using Appendix 9 and Appendix 10. The SAPS scores were calculated based on the routine ward observations or physicians' orders and no special examinations were carried out for the purposes of the study.

Table 5-16 shows the raw data-items used to generate SAPS in the current study and presents the number of patients with recorded data and the number with

missing data. It is possible that some data were measured but have not been recorded. The table's information can be categorized as listed below:

1. The variables that have been recorded in the majority of patients. Variables such as age, heart rate, systolic blood pressure, body temperature, respiratory rate, type of admission were recorded in more than 97.79% and GCS in 94.23% individuals. It is notable that heart rate, systolic blood pressure, body temperature and respiratory rate are routinely measured in wards, but 299 records of heart rate, 333 of systolic blood pressure, 406 of body temperature and 466 of respiratory rate were missing. The missing information was related to intra-ward transfer, early discharge during an evening or night shifts and subsequent, unavailability of the bedside vital sign charts. Also some variables such as type of admission were missing in 384 patients because of defects in the patients' medical documents during the first 24h of admission.
2. The variables that were recorded in between 80-90% of patients: Variables in this category include serum urea, sodium, potassium levels and WBC count. Data were missing in at least 17.2% of individuals. Obviously, from a medical point of view, there was no need to measure these groups of variables for all the patients admitted to the general wards.
3. The variables that have not been recorded in most of the patients: Variables in this group include Pao2/Fio2, bilirubin level, the

presence of chronic diseases, urinary output and serum bicarbonate level.

This study was carried out in the general wards of the hospital. It is obvious that most of the patients in the general wards did not require intubation, hence, there was no ethical and/or medical justification to measure the Pao2/Fio2. In addition, not necessarily all the patients had chronic disease such AIDs, Metastatic cancer or malignancy. Also, bilirubin level, serum bicarbonate level and urinary output measurement, were not done routinely in general wards unless recommended by the guidelines and/or medical texts.

Table 5-16: Information on the completeness of the data items used to generatr SAPS

	Data Recorded		Missing			
Variable	N	(%)	N	(%)	Mean	(SD)
Age	20977	(99.69)	65	(0.31)	43.27	(19.11)
Heart rate	20743	(98.58)	299	(1.42)	83.56	(9.44)
Systolic blood pressure	20709	(98.42)	333	(1.58)	113.59	(18.56)
Body Temperature	20636	(98.07)	406	(1.93)	37.01	(0.62)
Respiratory rate	20576	(97.79)	466	(2.21)	18.8	(2.88)
PaO2/ FIO2 (only if ventilated)	16	(0.08)	21026	(99.92)	165.1438	(84.09)
urinary output	1581	(7.51)	19461	(92.49)	2023.78	(1113.53)
serum urea level	17422	(82.80)	3620	(17.20)	19.11	(16.68)
WBC count	18711	(88.92)	2331	(11.08)	10928.09	(19839.87)
serum potassium level	17552	(83.41)	3490	(16.59)	4.36	(0.47)
serum sodium level	17827	(84.72)	3215	(15.28)	140.59	(3.59)
serum bicarbonate level	3415	(16.23)	17627	(83.77)	23.17	(5.34)
bilirubin level	5378	(25.56)	15664	(74.44)	1.73	(4.03)
Glasgow coma score	19827	(94.23)	1215	(5.77)	14.9	(0.78)
type of admission	20656	(98.17)	386	(1.83)	----	----
chronic diseases*	482	(2.29)	20560	(97.71)	-----	----

*Chronic diseases include (list types of chronic diseases)

In general, for patients with missing data in categories 2 and 3, the assumption was that the data would have been recorded if the physicians suspected that these values could have been abnormal. Hence, logically, normal scores were assumed

in case of missing values. Table 5-17 describes the missing data according to the phase of research. The missing data were similar in both periods (exposed and unexposed to the intervention), meaning that bias is less likely.

Table 5-17: The missing SAPS data according to the phase of research

SAPS Variables	missing data according to the phase of research					
	Unexposed		Training		Exposed	
	N	(%)	N	(%)	N	(%)
Age	16	0.21	11	0.47	38	0.35
Heart rate	160	2.05	41	1.75	98	0.90
Systolic blood pressure	181	2.32	37	1.58	115	1.06
Body Temperature	192	2.46	48	2.05	166	1.53
Respiratory rate	260	3.33	49	2.09	157	1.44
Urinary output	7526	96.46	2122	90.41	9813	90.19
Serum urea level	1690	21.66	369	15.72	1561	14.35
WBC count	812	10.41	252	10.74	1267	11.65
Serum potassium level	1417	18.16	309	13.17	1764	16.21
Serum sodium level	1360	17.43	288	12.27	1567	14.40
Serum bicarbonate level	6716	86.08	1930	82.23	8981	82.55
Bilirubin level	5910	75.75	1642	69.96	8112	74.56
Glasgow coma score	852	10.92	275	11.72	88	0.81
Type of admission	316	4.05	18	0.77	52	0.48
Chronic diseases*	7668	98.28	2285	97.36	10607	97.49

* Chronic diseases include (list types of chronic diseases)

5.10.4 Describing the outcomes for each analysis

There were two primary outcomes; mortality during hospital stay, and the number of CPRs. However, as not all deaths (or CPRs) occurred within study wards, I subdivided deaths according to their location (study ward or transferred ward). The primary analysis was carried out on an intention to treat basis, and so included all deaths or CPRs irrespective of their location. However, the other two analyses subdivided the deaths (and CPRs) into those that occurred within the admittance ward (i.e. a study ward), and those which occurred on a transferred ward. I also studied two secondary outcomes, the LOS and admission to ICU. However, it was not possible to subdivide these outcomes based on the place

where death had occurred. Figure 5-3 shows the patient flow chart of outcomes for each analysis.

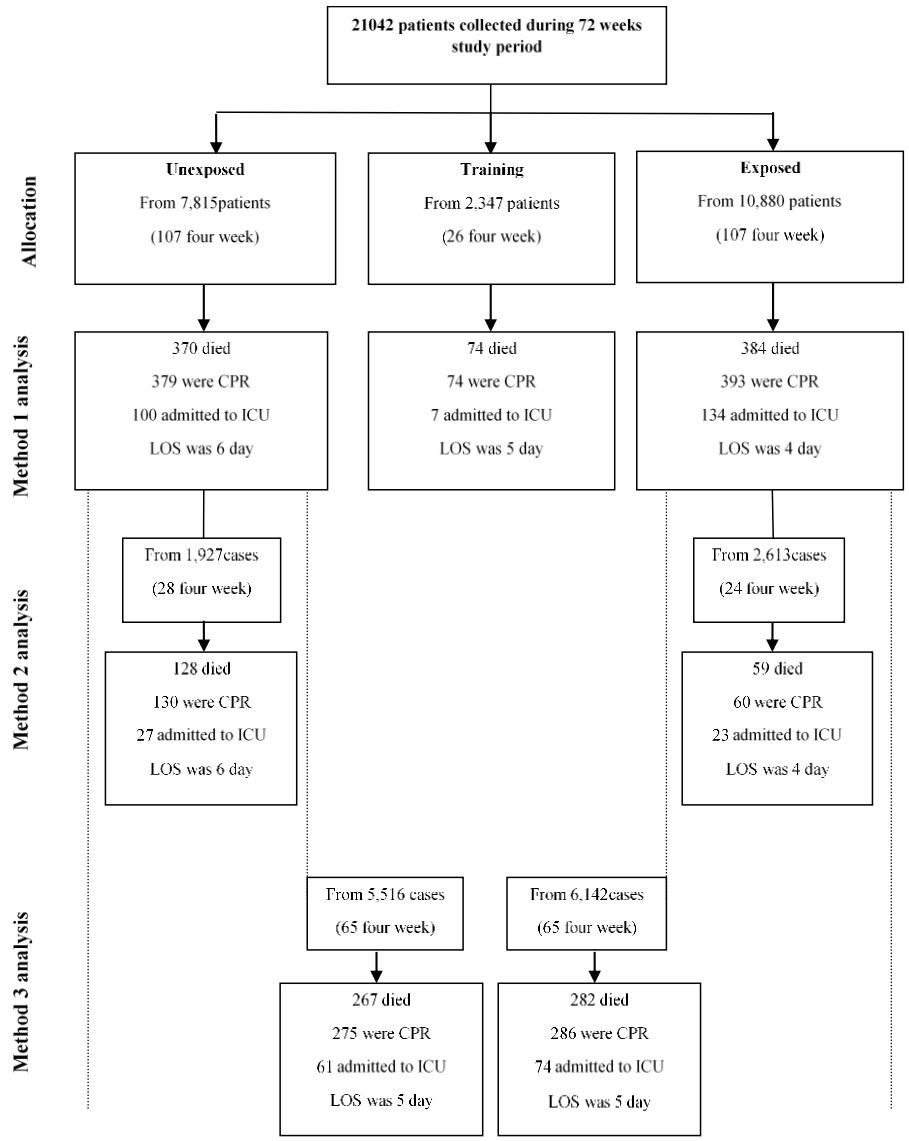


Figure 5-3: Patient flow chart. mortality, CPR, ICU admission and LOS

5.10.5 Outcomes in Method 1 analysis

The data analysis of the first set of data is shown in Table 5-18. As the table shows, 7,802 patients were admitted to the unexposed to the intervention wards,

370 of which died, 379 had CPR and 100 were admitted to ICU. The mean LOS was 6.0 days. For exposed to the intervention wards, 10,880 patients were admitted, 384 of which died, 393 had CPR, 134 were admitted to ICU, and their mean LOS was 4.0 days.

5.10.5.1 Primary outcomes

The results indicated that 4.74% (370/7802) of patients in the unexposed clusters, 3.15% (74/2,347) of patients in the training clusters and 3.53% (384/10,880) of patients in the clusters exposed to the intervention died. The crude mortality rate was adjusted with patient characteristics (age, sex and SAPS II score) and independent variables, such as the clustering effect (i.e. ward), fixed effect for calendar time (measured in four week periods) and an indicator of intervention for each ward at each time point. Although the percentage of mortality in the clusters exposed to the intervention was lower than the unexposed clusters, this difference was not statistically significant [Adjusted^ OR (95% CI) = 0.84 (0.50, 1.42)].

2.09% of deaths occurred (159/7,802) in the unexposed clusters, and the other 1.55% (165/10,880) occurred in other wards because the patient was transferred to another ward, ICU, or surgery room. Also, 2.12% (161/7,802) of CPRs were in the unexposed clusters, and the 1.42% (151/10,880) in the clusters exposed to the intervention occurred on other wards. Differences in mortality occurring in the primary ward [OR (95% CI) =0.28 (0.04, 1.49)] and the other wards [Adjusted^ OR (95% CI) =0.85 (0.50, 1.49)], and between the unexposed, and clusters exposed to the intervention, were not statistically significant.

The crude CPR rate was adjusted, similar to the mortality rate [Adjusted^ OR (95% CI=1.03 (0.71, 1.50)]. The comparison of CPR outcomes showed that a total of 18 patients stayed alive after performing CPR, with 9 being in the unexposed clusters and 9 in the clusters exposed to the intervention. Considering the rate of CPR the outcomes were similar to mortality rate, and there was no statistically significant difference between clusters exposed and unexposed to the intervention.

5.10.5.2 Secondary outcomes

The LOS in the hospital and admission to ICU were two secondary outcomes in this study. The mean and interquartile range (IQR) for the LOS were 6[3, 10] days for the unexposed clusters, 5 [2, 9] days for the training clusters and 4[2, 8] days for the clusters exposed to the intervention. Although there was a difference in the LOS between the clusters exposed and unexposed to the intervention, this difference was not statistically significant [Ratio in geometric LOS means (95% CI) = 0.99 (0.93, 1.01)]. 1.28% of patients (100/7,802) in the unexposed clusters, and 1.23% (134/10,880) in the clusters exposed to the intervention were admitted to ICU, this difference was not statistically significant [Adjusted^ OR (95% CI) = 1.10 (0.60, 2.04)].

Table 5-18: Effect of exposure to intervention on mortality, number of CPRs, the LOS in the hospital and admission to ICU within 72 weeks: primary analysis including all observations

	Unexposed	Training	Exposed	OR* (95% CI) Exposed to the intervention vs. Unexposed	Adjusted^ OR* (95% CI)
Number of Patients	7,802**	2,347	10,880		
Primary Outcomes					
Mortality					
All deaths	370 (4.74)	74 (3.15)	384 (3.53)	0.73 (0.64, 0.85)	0.84 (0.50, 1.42) P=0.517
Deaths in ward	211 (2.76)	46 (1.98)	219 (2.04)	0.78 (0.64, 0.94)	0.28 (0.04, 2.01) P=0.206$
Deaths in transferred ward	159 (2.09)	28 (1.22)	165 (1.55)	0.68 (0.54, 0.85)	0.86 (0.50, 1.49) P=0.590
CPR					
All CPR	379 (4.86)	74 (3.15)	393 (3.61)	0.73 (0.64, 0.82)	1.03 (0.71, 1.50) P=0.883
CPR in ward	218 (2.85)	47 (2.03)	242 (2.26)	0.79 (0.65, 0.95)	1.04 (0.63, 1.72) P=0.885
CPR in transferred ward	161 (2.12)	27 (1.17)	151 (1.42)	0.66 (0.53, 0.83)	1.12 (0.66, 1.93) P=0.671
Secondary Outcomes					
LOS***	6 [3,10]	5 [2, 9]	4 [2, 8]	0.84 (0.82, 0.86)	0.99 (0.93, 1.01) P=0.606
Admission to ICU	100 (1.28)	7 (0.30)	134 (1.23)	0.96 (0.74, 1.25)	1.10 (0.60, 2.04) P=0.749

* Exponentiated coefficients (interpreted as ratio in geometric LOS means between exposed and unexposed clusterss); $ convergence failed; ^ Analysis is adjusted for age, sex, SAPS II score, date of admission and ward (random effect).
** Thirteen patients in the unexposed clusters were excluded from the study (the reason for exclusion was that they were admitted to the ward before the unexposed started).
Values are numbers and percentages, except for *** where mean [IQR] is provided.

5.10.6 Outcomes of Method 2 analysis

Table 5-19 shows the results of analysis of method 2.

5.10.6.1 Primary outcomes

Data analysis using this method did not show a statistically significant difference between the unexposed and exposed clusters. The rate of mortality was 6.64% (128/1,927) in the unexposed clusters, and 2.26% (59/2,613) in the clusters exposed to the intervention. Although the percentage of mortality was lower in the clusters exposed to the intervention, the difference was not statistically significant [Adjusted^ OR (95% CI) = 2.05 (0.72, 5.83)]. The confidence interval is wide because of the increased uncertainty introduced by the including the random effect and the effects of time on mortality rates. It was the same for CPRs, and despite a reduction in percentage of CPRs from 6.75% (130/1,927) to 2.30% (60/2,613), the difference was not statistically significant.

5.10.6.2 Secondary outcomes

The mean and IQR of the LOS in this method were 6[3, 11] days for the unexposed clusters and 4[2, 7] days for the clusters exposed to the intervention, again showing no statistically significant difference [Ratio in geometric LOS means (95% CI) = 0.83 (0.58, 1.17)]. Considering the number of ICU admissions, 1.4% (27/1,927) of patients in the unexposed clusters, and 0.88% (23/2,613) of patients in the clusters exposed to the intervention were admitted to ICU, with no statistically significant difference being observed between the exposed and unexposed clusters [Adjusted^ OR (95% CI) = 0.86 (0.22, 3.26)].

Table 5-19: Sensitivity analysis of mortality, number of CPRs, the LOS in the hospital and admission to ICU in only those wards matched by time: including matched cohorts only

	Unexposed to the intervention	Exposed to the intervention	OR* (95% CI) Outreach vs. conventional care	Adjusted^ OR* (95% CI)
Matched on time[$]				
Number of Patients	1,927	2,613		
Death	128 (6.64)	59 (2.26)	0.32 (0.24, 0.44)	2.05 (0.72, 5.83) P=0.176
CPR	130 (6.75)	60 (2.30)	0.32 (0.24, 0.44)	0.54 (0.20, 1.44) P=0.218
LOS**	6 [3,11]	4 [2,7]	0.65 (0.61, 0.69)	0.83 (0.58, 1.17) P=0.279
Admission to ICU	27 (1.40)	23 (0.88)	0.62 (0.36, 1.09)	0.86 (0.22, 3.26) P=0.820

* Exponentiated coefficients (interpreted as ratio in geometric LOS means between exposed and unexposed clusters); $ this analysis was also adjusted for time (results were not found to be sensitive to this adjustment). Values are numbers and percentages, except for ** where mean [IQR] is provided.

5.10.7 Outcomes in Method 3 analysis

Table 5-20 shows the results of analysis of method 3.

5.10.7.1 Primary outcomes

The mortality rate was 4.84% (267/5,516) in the unexposed clusters and 4.59% (282/6,142) in the clusters exposed to the intervention, and there was no statistically significant difference between the clusters exposed and unexposed to the intervention [Adjusted^ OR (95% CI) =0.75 (0.36, 1.57)]. The same was true for the percentage of CPRs: 4.99% (275/5,516) in the unexposed clusters and 4.66% (286/6,142) in the clusters exposed to the intervention. The difference was not statistically significant [Adjusted^ OR (95% CI) =1.32 (0.76, 2.27)].

5.10.7.2 Secondary outcomes

The mean and IQR of the LOS were 5 [2, 9] in the clusters exposed to the intervention and 5 [2, 9] in the unexposed clusters with no statistically significant

difference [Ratio in geometric LOS means (95% CI) =0.97 (0.90, 1.05)]. It was the same for ICU admissions [Adjusted^ OR (95% CI) =1.96 (0.85, 4.52)].

Table 5-20: Sensitivity analysisof mortality, number of CPRs, the LOS in the hospital and admission to ICUin only those wards with equal time duration before and after the training period/before and after the study: including cohorts only

	Unexposed to the intervention	Exposed to the Intervention	OR* (95% CI) Exposed to the Intervention vs. Unexposed	Adjusted^ OR* (95% CI)
Matched on Number of Patients	5,516	6,142		
Death	267 (4.84)	282 (4.59)	0.95 (0.80, 1.22)	0.75 (0.36, 1.57) P=0.450
CPR	275 (4.99)	286 (4.66)	0.93 (0.79, 1.10)	1.32 (0.76, 2.27) P=0.321
LOS**	5 [2, 9]	5 [2, 9]	0.96 (0.93, 0.99)	0.97 (0.90, 1.05) P=0.526
ICU	61 (1.11)	74 (1.20)	1.09 (0.78, 1.53)	1.96 (0.85, 4.52) P=0.116

* Exponentiated coefficients (interpreted as ratio in geometric LOS means between exposed and unexposed clusters); $ this analysis was also adjusted for time (results were not found to be sensitive to this adjustment). Values are numbers and percentages, except for ** where mean [IQR] is provided.

5.10.8 The afferent side of the implemented system

The CCS team identified the eligible patients in three ways:

1. The CCS team identified the patient themselves
2. The existence of an AIP was reported by the ward nurses to the CCS team
3. The CCS team was informed by code 145 that such a patient was there.

Table 5-21 shows that out of a total 1,517 patients who had been cared for by the CCS team, 800 (52.7%) were identified directly by the CCS team members, 706 (46.5%) were diagnosed as AIPs by ward staff and duly reported to the CCS team

and only 11 patients (0.7%) were identified by announcing code 145. These results show that the majority of AIPs were actively identified by the CCS team (Figure 5-4).

Table 5-21: The ways that CCS memeber informed

Time of the CCS intervention	CCS Admission	Post ICU	How the CCS team was informed Frequency (percentage)		
			code 145	CCS Team member	ward nurse
First	1517	879	11(0.7)	800(52.7)	706(46.5)
Second	142		0	80 (56.3)	62 (43.7)
Third †	18		0	10(55.6)	8(44.4)
Fourth†	3		0	3(100)	0
Fifth†	2		0	1(50)	1(50)
Total			11(0.7)	894(53.2)	777(46.2)

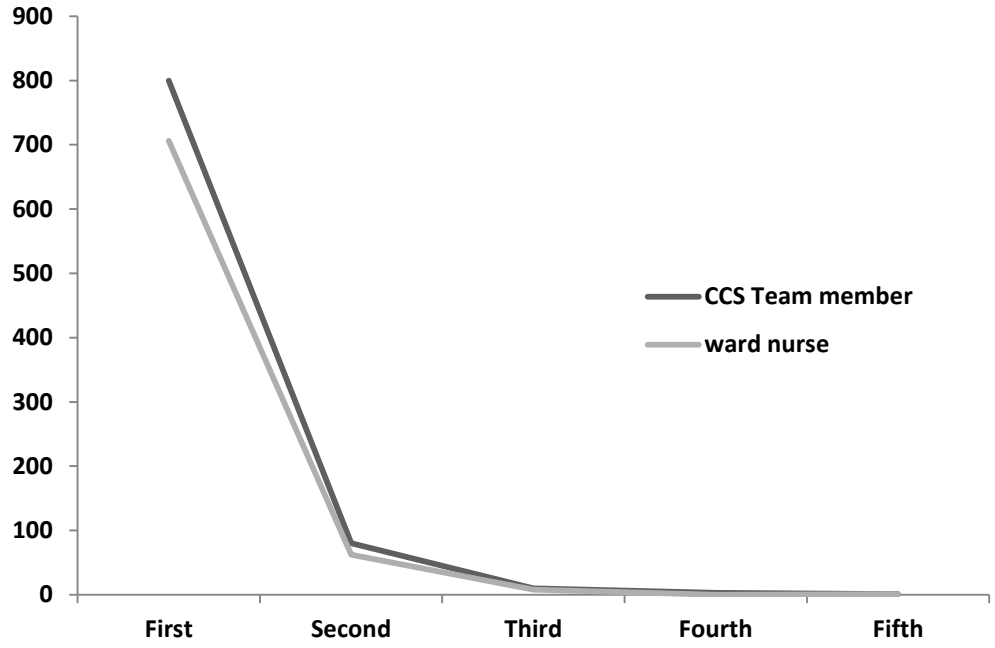


Figure 5-4 : Frequency of AIPs identification by CCS team members and ward nurses

The CCS activated by TTs that described in Appendix 2, Appendix 3 and Table 5-5. From 1517 admitted patients, 879 patients were post ICU and 638 patients were identified by CCS team members or ward nurses. Table 5-22 demonstrates the frequency and percentage of the single parameter variables used for identifying AIPs. It is notable that 34% of the patients were identified by 2 or more criteria using the single parameter system.

Table 5-22: The CCS activated by TTs

The Single Parameter	n	percentage
Number of AIPs = 638		
8<Respiratory rate>15	240	24
Oxygen Sats <90% on o2	168	16.8
50/min<Pulse Rate> 100/min	166	16.6
80mm Hg<Systolic Blood Pressure>160 mm Hg	70	7
36c<Body temperature>38c	97	9.7
Urine catheter drainage<160mls in 6hrs	14	1.4
Unexplained decrease in consciousness	178	17.8
General Concerns about Patients	68	6.8
2 or more than 2 variable	216	34.3

5.10.9 The efferent side of the implemented system

The CCS team was composed of 6 intensive care nurses. All were female, their average age and work experience were 41.5 (range 35-45) and 14 (range 9-17) years, respectively. In this section, I describe the dose of care delivered by them and also the characteristic of patients cared for.

5.10.9.1 The dose of care delivered by CCS team members

To measure the dose of care delivered for the AIPs, I analyzed the content of the care records of the CCS team members, and critical care sheets (Appendix 12 and Appendix 13). The number of interventions and activities of CCS team members were quantified and categorized. Table 5-23 and Table 5-24 show the detail of the dose of care delivered by the CCS for AIPs.

The most commonly used bedside intervention were starting oxygen therapy or modifying oxygen therapy (30.06%), continuous patient monitoring (Cardiac monitoring/ Pulse oximetry) (27.69%), changes in patients' position/Limb elevation (26.90%), vital sign monitoring adjustment (Frequency/ duration) (22.28%). The analysis revealed that alongside the intervention, the CCS team members' advised/ supported and trained the ward staff.

Table 5-23: Active bedside intervention provided by CCS for AIPs

Type of intervention*	Patients recived intervention	
	N	%
Vital sign adjustment(Frequency/ duration)	338	(22.28)
Starting oxygen therapy or modifying oxygen therapy	456	(30.06)
Continuous Patient monitoring (Cardiac monitoring/ Pulse oxymetry)	420	(27.69)
airway suction	160	(10.55)
changes in patients' position/Limb elevation	408	(26.90)
Insertion of an intravenous line	41	(2.70)
Insertion/ change an nasogastric tube (NGT)	11	(0.73)
Urinary catheterization	30	(1.98)
Adjustment of Medications:		
Analgesic for pain control	162	(10.68)
Acetaminophen Suppository for fever control	153	(10.09)

Other drugs (diuretics; BP drugs, e.g. TNG, Dopamine)	72	(4.75)
Changes in fluid management	160	(10.55)
Endotracheal tube care	110	(7.25)
Respiratory Physiotherapy	129	(8.50)
Care of pressure sores	42	(2.77)
Bleeding control	50	(3.30)

* Alongside the intervention, the CCS team members advised/ supported and trained the ward staff

Table 5-24: Other activites of CCS in order to better management of AIPs

Other Clinical activites	N(%)	
Consultation with physicians about patient care	466	(30.72)
Support/ advice to ward staff (bed side/ telephone guidance)	844	(55.7)
Patients / Family support and education	378	(24.92)
Coordination for patient intubation without CPR announcement	141	(9.29)
Preparing the equipment for ward staff to provide patient care, e.g. ventilator, infusion pump, tubes.	380	(25.05)
Following-up of AIPs paraclinic tests (MRI, CT scan, ..)	80	(5.27)
Delivery of rehabilitation programs for patients after a period of critical illness	89	(5.87)
Regulating ventilator settings/weaning based on the patient's needs	101	(6.66)
Referral to physiotherapist	176	(11.60)
Coordination and facilitating of patient admission to ICUs	150	(9.89)
Coordination and facilitating transfer of patients to other wards in hospital	15	(0.99)

The most common activity of CCS team members were giving support/ advice to ward staff (bed side/ telephone guidance) (55.7%), consulting with physicians about patient care (30.72%), preparing facilities e.g. ventilator, infusion pump, tubes...(25.05%) and, support and education to patients/family (24.92%). Other CCS activities included better management of AIPs such as referral to physiotherapist, coordination and facilitation of patient admission to ICUs, coordination of patient intubation without CPR announcement, regulation of settings of ventilators or weaning off ventilators based on the patient's needs, delivering rehabilitation programs for patients after a period of critical illness, follow-up of AIPs tests (MRI, CT scan), and coordination and facilitation of transfer to other wards in the hospital.

5.10.9.2 Patients cared for by the CCS team

In this section, I will review the performance of the CCS team, focusing on the number of patients cared for by the CCS team, times the AIPs were admitted by the team, the ways in which the patients were labeled and treated as AIPs, and the outcomes of interventions by the CCS team.

Table 5-25 shows that during the intervention, 1,517 in-patients came under the care of the CCS team, 879 (58%) of which were patients discharged from ICU and treated directly under the CCS team's supervision. Of 1517 cared for by CCS 51.48% were male and 54.53% were female with a mean (SD) age of 54.53 (19.65). Mean (SD) SAPSII score was 18.85(11.86). Also, the characteristics of patients cared for by the CCS for the second, third, fourth, and fifth times were presented.

Table 5-25: Characteristic of CCS performances

Time of the CCS intervention	CCS Admission	Sex (%male)	Age (mean(SD))	SAPS II (mean (SD))	Post ICU	Outcomes						
						Death	Discharged from hospital	discharged from CCS team's interventions	Discharged Against Medical Advise	Admission in ICU	Final of CCS	transfer to unexposed phase
First	1517	51.48	54.53(19.56)	18.85(11.86)	879	241(15.9)	120(7.9)	1029(67.8)	1(0.07)	121(8.0)	1(0.1)	4(0.3)
Second	142	57.75	57.28(19.12)	21.5(10.01)		22(15.5)	18(12.7)	80(56.3)		22(15.5)		
Third †	18	55.56	48.61(18.01)	16.77(9.93)		4(22.2)	2(11.1)	6(33.3)		6(33.3)		
Fourth†	3	66.67	50.66(12.01)	19.33(7.09)				2(66.7)		1(33.3)		
Fifth†	2	100	51(16.97)	15.5(3.53)		1(50)	1(50)					
Total						268(15.9)	141(8.4)	1117(66.4)	1(0.1)	150(8.9)	1(0.1)	4(0.2)

The outcomes of the AIPs after they were referred to the CCS team can be classified as followed:

1. Deceased
2. Discharged from hospital - they were discharged from the hospital on physicians' orders, and thus, the CCS team were not able to intercept them further
3. Discharged from CCS - the CCS team discharged them, since their critical conditions had improved
4. Admitted to ICU - they were admitted to the ICU, on the recommendation of the CCS team
5. Discharged Against Medical Advice - they discharged themselves from the hospital, against medical advice
6. Not followed up – because the study had ended.
7. Were transferred from wards in the exposed to the intervention to wards in the unexposed to the intervention, and then they were no longer seen by the CCS

The overall data reveal that 268(15.9%) AIPs passed away despite the CCS team's intervention, and 150(8.9%) were transferred to the ICU.

At first, a total number of 1,517 patients came under the CCS team's supervision (see Figure 5-5). The breakdown of the outcomes of the CCS team's intervention is as follows:

1. 241 (15.9%) patients died, despite the CCS team's interventions,
2. 121 (8%) patients were admitted to the ICU,

3. 120 (7.9%) patients were discharged from the hospital,
4. 1,029 (67.8%) patients were discharged from CCS team's interventions,
5. 4 (0.3%) patients were transferred from wards in the exposed to the intervention to wards in the unexposed.
6. 1(0.1%) patient discharged against medical advice(DAMA),
7. 1 (0.1%) patient was not followed upas the study ended.

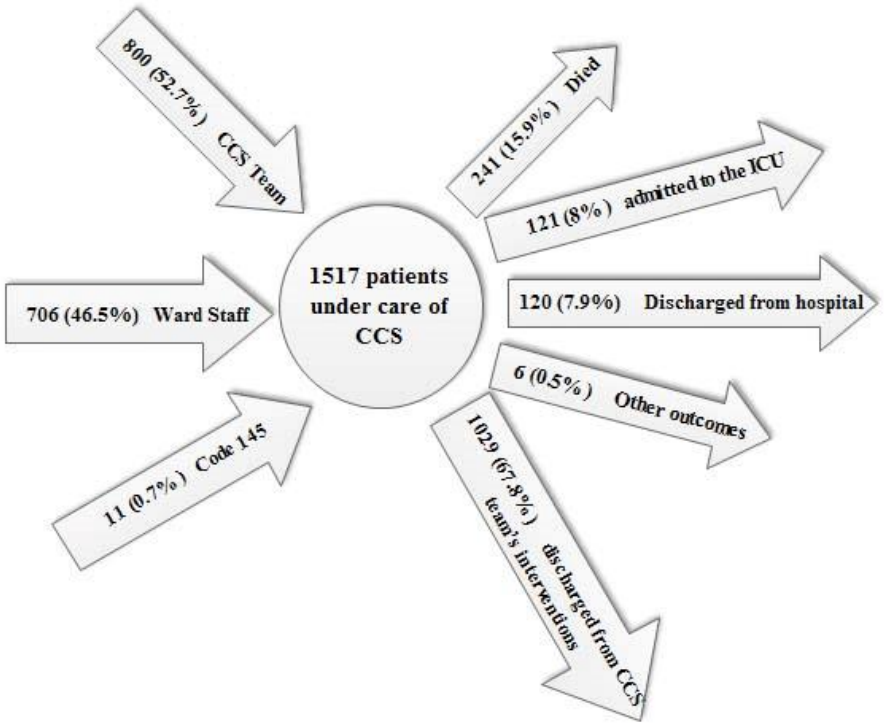


Figure 5-5: The flow chart of CCS performances at first time

Out of 1,029(67.8%) patients who were discharged from CCS team's interventions, 142 patients with deteriorating conditions were re-admitted by the CCS team; 22(15.5%) of the re-admitted patients died; 22(15.5%) patients were admitted to ICU; 80(56.3%) patients were re-discharged by the CCS team; and 18(12.7%) patients were discharged from hospital by the physicians.

Out of 80 patients who were re-discharged by the CCS team, 18 patients were admitted by the team for the third time. 4(22.2%) patients out of these 18 died; 6(33.3%) patients were admitted to ICU; 6(33.3%) patients were discharged by the CCS team; and 2(11.1%) patients were discharged from hospital by physicians. Out of these latter, the CCS team discharged 6 patients, 3 patients were admitted by the team for the fourth time, one patient was transferred to ICU and two were discharged by the CCS team. These two, however, came under the supervision of the CCS team again: one of them died and the other was discharged from the hospital.

Briefly, these results indicated that some of the patients admitted and then discharged by the CCS team, were admitted and taken care of by the CCS team for a second, third, fourth or even a fifth time.

5.11 DISCUSSION

5.11.1 Summary of the findings

In current study, three methods of data analysis were applied. First, all patients in the clusters exposed and unexposed to the intervention were compared head-to-head. Secondly, the data were analyzed using the matched randomized method, and lastly, the before-after comparison was conducted on clusters exposed and unexposed to the intervention. None of the results of the analyses showed a statistically significant difference between clusters exposed and unexposed to the intervention, with regard to mortality rates, CPR, LOS, and ICU admission.

Although a statistically significant difference was not observed in mortality rates between the exposed and unexposed clusters, when the data were analyzed using the first method, the results did show a lower mortality rate in the clusters exposed to the intervention (0.035=384/10,880) than in the unexposed clusters (0.048=370/7,802). Interestingly, CPR showed a similar pattern: the ratio of CPR to the number of admitted patients was higher in the unexposed clusters (0.049=379/7,802), compared to the clusters exposed to the intervention (0.036=393/10,880). Again, the difference was not statistically significant.

Results also showed that the mean of LOS had been 4 and 6 days in the exposed and the unexposed clusters, respectively. This difference was also not statistically significant. There was also no statistically significant difference regarding the ICU admission rates, between the exposed and unexposed clusters. ICU admission rate was 0.012=134/10880 in the exposed clusters and 0.013=100/7802 in the unexposed clusters.

When the data were analyzed by the matched randomized method and the third method, the same patterns were observed. There were lower mortality rates; rates of CPR and LOS in the clusters exposed to the intervention, but these differences were not statistically significant.

5.11.2 Strengths of the study

The design and conduct of this study had some strength, which are now discussed below:

5.11.2.1 Strong study design (SW-CRCT)

This study was designed as a CRCT. As mentioned earlier in this chapter, CRCT is a form of clinical trials, and since it has the potential to minimize the statistical bias of clinical studies, it is being increasingly used in healthcare settings. Stepped-wedge CRT is a specific type of CRTS, which is widely accepted in clinical studies for its ethical, logistical, financial, and methodological advantages. One of these advantages is the capacity to be applied to evaluate an intervention during routine implementation; particularly for interventions that have been shown to be effective in more controlled research settings. This may also be the case where there is lack of evidence of effectiveness, but when there is a strong belief that they will do more good than harm(194). More importantly, CRTs belong to the group of study design which provide the researchers with first level, hard-core and high quality evidence(15).

5.11.2.2 Long study duration and sufficiently large sample size

Two other strong points of this study were its duration (72 weeks = 18 months and considering an extra post period), as well as its sample size (n = 21,042). This

large number of patients, cared for over a long time, provided us with a considerable number of deaths and CPRs (two main outcomes of the study) and assisted us in carrying out sound statistical analysis on the results. The number of patients cared for by the CCS team in current study was larger than those of similar studies(85). However, Woertman (2013) believes that for CRTs, the stepped-wedge design is far more efficient than the parallel group and Analysis of Covariance (ANCOVA) design in terms of sample size(195).

5.11.2.3 Implementation in a general hospital

The fact that this study had been conducted in a general, teaching hospital was another strong point of the study. A very wide spectrum of patients, requiring medical and/or surgical interventions were admitted to the hospital, and since treatment of hematologic and oncologic cases were amongst the hospital's routine services, the results have been more generalizable.

5.11.2.4 Direct identification by CCS team members

Although ward staff duly reported the identified AIPs to the CCS team, a sizeable number of AIPs (869) were proactively identified by the CCS team member themselves (Table 5-25). This gave the CCS team the chance to start the necessary interventions faster.

5.11.3 Weaknesses of the study

5.11.3.1 Adjustment for many potential confounders

Patient characteristics, time effect, and clustering effect were used for adjusting, but some potential confounders, such as manpower shortage in the wards or cooperation/non-cooperation of the staff were not quantifiable. As shown in Table

5-25, more than half of the AIPs were identified by the CCS team members. Any other confounder was not detected. Although I used the randomization trials (CRCT), confounders should be equally distributed between clusters exposed and unexposed to the intervention. However, in practice, only a small number of wards were randomized, so there is the possibility that confounders were distributed unequally.

5.11.4 Comparison to other findings researches

Many studies investigated the CCS efficacy in developed countries such as Australia(103, 109, 116), the UK (59, 85, 96), the USA(93, 114), Canada(106), Sweden(64) and also in the Netherlands(202). However, few studies related to CCS were found in developing countries(203).

The results of this study demonstrated no statistically significant effect on hospital mortality/ CPR/LOS/ICU admission. Stronger study designs in the first level of evidence did not always find a reduction in mortality. An SR by Esmonde et al. (2006) revealed that although improvements in patient outcomes were found following to CCS implementation, the evidence is insufficient to demonstrate this conclusively(104). An SR by Winters et al. (2007) and Ranji et al. (2007) demonstrated weak evidence concerning reduction of hospital mortality and cardiac arrest rates following CCS implementation(204, 205). Results from the study by Chan et al. (2010) indicated that implementation of a CCS was not associated with a reduction in hospital mortality rate (pooled RR, 0.92; 95% CI, 0.82-1.04), but is associated with 33.8% reduction in rates of cardiopulmonary arrest in adults(76).

The results of another SR by Winters et al. in 2013 support the previous SRs(206).A CRCT by Hillman et al. (2005) did not demonstrate significant differences in mortality(84).Also, some prospective and retrospective studies have revealed the same result (103, 114, 207). However, many studies revealed that CCS implementation was associated with lower cardio-respiratory arrest and total hospital mortality. Results of an RCT by Priestley et al. demonstrated that CCS (outreach) intervention reduced in-hospital mortality (two-level odds ratio: 0.52 (95% CI0.32–0.85). However, results from this study did not fully support reduction in LOS following CCS implementation (85). Some studies with low level of evidence, such as before and after studies(59, 64, 90, 93, 100, 108, 112, 203, 208-210)and prospective or retrospective studies (211, 212), reported the efficacy of CCS on mortality, cardiac arrest and admission to ICU.

The findings of this study are therefore consistent with the findings of stronger studies (76, 84, 104, 204-206). These findings suggest that CCS may not decrease mortality rates, CPR, LOS, and ICU admission.

Priestly and colleagues (2004) used the ward (cluster) randomized, stepped-wedge method to conduct their study in 16 hospital wards and found a statistically significant difference in mortality rates between the clusters exposed and unexposed to the intervention (85). This study was done over a shorter period of time (32 weeks = 8 months) on 7,450 patients. 3,391 patients were enrolled in the clusters exposed to the intervention. This study did not establish a determinate casual relation between CCS interventions and patients' LOS.

My study was executed over a period of 72 weeks (18 months), and a total number of 21,042 patients were enrolled, with 10,880 on the intervention arm of

the trial. Although the results of the study did not show a statistically significant difference in mortality rates between the exposed and unexposed clusters, overall fall in mortality rate in the exposed clusters, CPR, and LOS were some of the outcomes of the CCS intervention. The results of current study are consistent with those of Hillman and colleagues (2005), which were conducted in 23 hospitals in Australia, using the prospective cluster randomized method over duration of 10 months. Hillman et al. (2005) were also unable to establish a statistically significant difference in mortality rates between the exposed and unexposed clusters (84).

Chan et al. (2010) and Winters et al. (2013), in their systematic reviews came to a similar conclusion: there is no evidence that CCS implementation leads to a statistically significant fall in mortality rates of AIPs (76, 206). The systematic review conducted by Winters et al. explored the studies between January 2000 and October 2012. They have appraised the studies included in Chan et al (2010), as well as 26 studies done after Chan et al., from November 2008 to October 2012.

In brief, current study (in line with several international experiences) did not establish a decrease in mortality rates, CPRs, LOSs, and ICU admissions of AIPs, subsequent to the implementation of CCS. However, it should be noted that CCS implementation did reveal a desired change in identifying the AIPs, in current study, as shown in Table 5-25; 1,517 patients with deteriorating conditions were identified and managed by the CCS team, and this phenomenon might have led to a decrease in preventable deaths. As such, implementing CCS must be regarded as one of the best existing options for managing AIPs(206).

5.11.5 Comparison with other research related to method of implementation

CCS was implemented in different structures of human resources and members composition and styles or methods of AIP identification. It was also implemented in general wards. In this study CCS was implemented based on nursing capacity.

5.11.5.1 CCS members composition

In the relevant literature, different compositions for a CCS team have been reported:

According to studies done in Australia(54, 84, 90, 100, 109) and other countries (Konrad et al., 2010, DeVita et al., 2004, Baxter et al., 2008), MET includes both nurses and physicians. In the UK, some studies report that CCOT members are solely nurses (59, 96), while other studies suggest that CCOT is a nurse-led team. However, its members include both nurses and physicians experienced in critical care (85, 86).

McDonnell et al. (2007) have remarked in their study that: "We found variation in the composition and size of the outreach team, the nature of the activities undertaken by the service, the balance between provision of direct care or acting in an advisory role, the proportion of wards covered, and the availability of the service. However, the reasons for this variation are not clear"(82).

The reports indicate that RRT members are exclusively nurses in most of the cases, and doctors are added to them only if demanded by the nurses in order to evaluate the patients. Ina few instances, doctors were the usual members of RRTs (114, 203, 209). Respiratory therapists are members of some of these teams (93, 106-108, 114, 213).

Finally, it is noteworthy that other than composition of the team members, the numbers of team members are reported to be highly variable, and there is not a single standard to set the number of team members to number of hospital beds.

5.11.5.2 CCS implementation

There are also variations in methods of implementing interventions. Resource availability and regional priorities determine how the interventions are executed (35, 206). Implementation of MET in Australia is medically-led(212), while in the UK, other methods of implementation, such as nurse-led or multi-professional teams have been practiced (57).

In the UK, a large proportion of hospitals provide critical care education for ward based staff, and also use audit to determine important issues.

Different forms of outreach service have evolved depending on local priorities and resources (57).

In many instances, the CCS team acted based on the nurses' request, while in other cases the CCS team actively and independently examined the patients discharged from ICUs (96, 203, 206).

In some cases, implementation included a package of educational and practical support aimed at sharing the team's skills and knowledge with ward nurses (85, 96). Educational programs continued throughout the intervention period. As circumstances required, the CCOT might support and advice ward staff, remain with the patient, and provide individual nursing care on the ward during a crisis period, or facilitate admission to ICU. There was emphasis on sharing skills, on

collaboration with the admittance of the team and on provision of practical “hands on” help to ward staff.

In other settings, education was the only support given to ward staff (64, 90, 106).

Winters et al. emphasize the plurality of interventions and attribute the positive effect of CCS on mortality, to the maturation of interventions, as well as improvement of CCS procedures (206).

In current study, the CCS intervention included training the wards staff, as well as providing them with practical support. CCS team members were present in the hospital constantly, and the services of an on-call physiotherapist were made available to the wards. In addition to the wards staff using the calling criteria in order to report identification of AIPs, the CCS team proactively screened the wards to identify such patients.

5.11.5.3 CCS availability

There is no single pattern of CCS availability reported in the published studies. Some studies report around the clock, easy access to CCS (64, 85, 106, 207), while others indicate that access to the CCS team members was limited to certain hours (86). In some instances, access to some members of the CCS team (e.g. ICU specialists) had been restricted (106).

5.11.5.4 CCS calling criteria

As mentioned in chapter 4, calling criteria for the CCS team members varies across different settings. In some settings, single parameter criteria is used (64, 85, 93, 103, 106, 107, 207)); in others, multiple parameter criteria(59) or aggregated

parameters criteria (85) were in place. Also, the measured criteria varied in terms of the number of parameters measured and their frequency (121).

5.11.5.5 CCS implementation context

The contexts where the interventions are to be implemented are significantly heterogeneous. Various types of CCS have been implemented in very different settings in terms of wards specialty (internal, surgical, geriatric)(85, 203), type of hospital, including teaching (100, 115, 207) or non-teaching (108), and the size of hospitals. CCS has been implemented in adults' hospitals(64, 98, 103, 106, 108, 114, 207), as well as children's (107, 111, 112, 115).

Such vast variability in context of CCS implementation makes comparison of this study to other samples of CCS implementation very difficult. However, it is worth noting that while in many countries CCS team's support of the ward staff is merely educational, in current study, CCS team members assisted the ward nurses, as well as training them.

Belknap (2010) following the footsteps of Chan (2010) (76), referring to the Priestly et al.'s (2004) study in the UK (85), and to that of Hillman et al. (2005) in Australia (84), recommends implementation of CCS systems, in which education, support, and practical assistance are integrated (214).

The context in which the interventions were implemented had characteristics of its own. It was a teaching hospital, medical students[1]rotated in different wards regularly, shortage of nurses was an established fact, and some of the staff working during late hour shifts did not have sufficient experience. As mentioned

[1]Medical students consisted of Intern, Resident and fellow ship. Intern is equivalentto a house officer, resident is equivalent to registrar and fellow is equivalent to senior registrar in the UK.

above, we implemented CCS as a nurse-led system, and 6 trained nurses were available 24/7 throughout the trial. During each working shift (morning, afternoon, night), at least one CCS nurses were working at the hospital. However, shortage of experienced nurses, as well as prevalence of less experienced nurses, during afternoon and night shifts could potentially skew the results of the study.

In Shariati hospital, the nurse-to-patient ratio was 1:20 at the time of study; in one study where CCS implementation was followed by lower mortality rate, this ratio has been reported to be as high as 1:4(203, 215).

5.11.6 Trial limitations

This study did not find a statistically significant reduction in mortality during the period in which CCS was implemented in the wards. There was also no reduction in CPR, LOS, and ICU concerning admission. In this section, I will present some limitations about these findings.

The first limitation is that I do not know if the CCS was implemented correctly. Did ward nurses refer patients correctly? Were the right actions taken?

In the qualitative study in the next chapter, this subject will be discussed with ward nurses and CCS team members. As presented in the performance of CCS section sometimes, the ward nurses did not inform CCS team members, or informed them with delay, about certain factors. Also, some contextual, structural, and organizational factors affect correct CCS implementation, and I will describe in detail in the next chapter.

In study wards heart rate, respiratory rate, and body temperature were measured routinely. But, other factors of single parameter TTs, such as SPO2 and urine output, were measured only if instructed by doctors. Also, due to the large number of patients and overloading of the wards, along with some measurements of vital signs being taken by hand, it is likely that there were errors in measurements. These could have affected the criteria for informing the CCS team members as used by ward staff. As a result, it could be consider that the identification of AIPs was not carried out perfectly during the intervention phase of the study. So, informing CCS team members based on single parameter TTs might have affected the implementation.

As I will mention in the next chapter, CCS team members followed and supervised the care of end stage patients, No code patients and patients with pressure sores and pain. As the interventions of the CCS team were extensive and varied in length over the duration of the study (18 months), this made a heavy workload for the CCS team, and insufficient time to care for AIPs. This could be considered as a risk of bias for effective implementation.

Another limitation was about blinding. It was impossible to blind staff to the CCS intervention. The design meant that there was a possibility of contamination with unexposed wards exposed to CCS concepts through contact with the intervention wards staff, sharing of training materials and learned skills. This could affect those outcomes such as mortality and CPR on the unexposed ward.

Outcome data collection should be blind to exposure. So, I should have asked a team or person to identify deaths, CPRs, ICU admissions, and LOS without

knowing whether the patient was in an exposed or unexposed ward. The person or team doing this should have been the same for exposed and unexposed wards. But in the current study it is not possible to do this. Also, I asked two teams to identify deaths and CPR in exposed and unexposed ward. Two separate teams assessed and they were not blind to the exposure. Therefore, in the current study, the outcomes were not blind outcome assessment. This is a limitation of this study.

The third limitation is that, the scores of SAPS were calculated based on the routine or physicians' orders of the wards, and no special exam was carried out solely for the purposes of the study. For example when patients arterial blood gases, GCS and urine output were not measured, normal scores was considered for these variables. I assumed that if the doctors suspected that these values could be abnormal, they would have asked for measuring. Since the SAPS score was not measured correctly based on the valid variables, this could be a cause of biases in the calculating of SAPS for all patients in the unexposed, training and exposed to the intervention phases.

The fourth limitation concerned the fact that some AIPs or end stage patients died a short time after changing the research situation of the ward from a training period to an intervention period. These deaths were calculated as the mortality of the intervention wards without CCS having had a chance to take effect.

Although the nursing office of the hospital prevented displacement of nursing staff among unexposed and exposed wards during the project implementation, there were some small daily changes for the relief nurses among the wards that could have caused contamination (there was the possibility of contamination

through nurses moving from one ward to another). Unfortunately, due to shortage of the staff, these small temporary displacements were not preventable. Also, it is compulsory for newly graduated nurses to work in government hospitals for the duration of two years, and in any hospital, a proportion of nurses belong to this inexperienced group. When a newly graduated nurse completes this duration, they will be replaced with others who are just starting this period. It was possible that at the time of their entry into wards, the training phase was finished, and in that case, those nurses would not have received the appropriate amount of training according to the procedures of the project. This should be considered as a fifth limitation.

5.11.7 Generalisability

Validity is the best approximation to the truth or falsity of the trial results and was defined by two types, namely internal and external(216). Internal validity refers to the results, or the experimental treatments validity, for the population of the study and external validity provides the bases for generalizability to other populations and settings.

Internal validity is concerned with the rigor and the degree of the control of study design (217)and is a perquisite for external validity(218). Obviously, if the results of a study were not accurate enough for the population of the study, a researcher could not speak about the validity of the results for other populations. Internal validity refers to the setting, implementation and analyses of the study(216, 217).

In this study, matching of wards was used for preventing the bias of potentially confounding variables among clusters of wards unexposed and exposed to the

intervention. Also, with randomization of the wards in the stepped-wedge table, the distribution of the confounding variables was tried to be as similar as possible in clusters unexposed and exposed to the intervention. The logistic regressions were used for analysis in order to control the confounding bias.

There is an inverse relationship between external and internal validity, as the researchers try to control confounding variables by increasing the internal validity, the external validity and generalizability (216). In contrast to internal validity, external validity is the degree to which, other than the original populations, results can be applied to a setting and samples with different aspects such as age, economic status, or variety in the severity of disease (217, 218).

Because external validity depends on the target population, the inclusion and exclusion criteria and a detailed description of the study population in terms of demographic data and other information were provided in this chapter. This trial was carried out in an adult, general, and teaching hospital's medical and surgical wards. Transplantation, critical care, neonatal, emergency and pediatric wards were excluded from the study, therefore, the study results cannot be generalized to patients of these wards and to other types of hospitals.

5.12 OTHER INFORMATION

This research was completed by the financial support of the Tehran University of Medical Sciences (TUMS), Ministry of Health of the Islamic Republic of Iran, and Digestive Diseases Research Institute (DDRI) of Shariati Hospital.

5.13 CONCLUSIONS

The results of the study indicate that implementation of CCS in Shariati hospital led to no statistically significant changes in the rates of mortality, CPR, and ICU admission, as well as a fall in LOS. However, none of the changes in those outcomes, before and after the implementation, was statistically significant. It is possible that CCS reduces mortality, CPR, and ICU admission, but this study failed to demonstrate this. Since current study was the first to explore the implementation of CCS in Iran, and also considering the necessity of managing AIPs in wards (chapter 4) and the need to improve the quality of care for inpatients in Iran, assessment of the effectiveness of multicenter implementation of CCS in the country is recommended.

As mentioned in chapter 2, SRs of literature have pinpointed the lack of sufficient evidence to support efficiency of CCS and have found it necessary to conduct in-depth studies to explore the subject. More CRTs can help to verify claims on the efficiency of CCS and assist decision makers in making evidence based decisions.

Certain conditions of the hospital under the study may also have affected the implementation of CCS. Since this hospital is a teaching hospital with rotating clinical staff, clarifying the specific circumstances and obstacles to implementation of CCS is a must. In the next chapter, the issue of how CCS was implemented will be discussed by using qualitative methods.

CHAPTER 6

OBTAINING FEEDBACK FROM STAFF FOLLOWING THE IMPLEMENTATION OF CCS: A QUALITATIVE STUDY

6.1 INTRODUCTION

Timely access to care facilities is crucial in order to achieve effective management of AIPs and improve the quality of care. To this end, CCS was designed in order to cover both the identification of and interventions with such patients, as a service in general wards with educational link between the wards and critical care units (6, 88).

As mentioned in chapter 2, the strategy of CCS has been followed in different countries with a variety of names such as MET, PART, CCS and RRTs to enhance the quality of care for AIPs. Alongside the implementation of these services, several studies have been carried out to evaluate the effectiveness of each system, by measuring outcomes such as mortality, LOS, admission and re-admission to ICUs, and CPRs(76, 84, 85, 104, 105). However, systematic review of CCS conducted by Chan et al. in 2010, failed to report any strong evidence

supporting the effectiveness of these services, suggested that without robust evidence to support their use, health quality organizations may need to reconsider their promotion of RRTs(76).

In order to assess the effectiveness of CCS in Iran, as a developing country, and analyze whether local hospitals would benefit from the use of a similar strategy, this system was implemented in Shariati Hospital, Tehran. As mentioned in chapter one, Shariati Hospital is a teaching hospital and one of the most important referral hospitals in Iran, for a variety of subspecialist services. Normally, specialist and subspecialist academic staff attend the hospital from between 7.00 to 14.00. During evening and night rounds, the lion's share of medical care is delivered by medical students, under the supervision of on-call1 specialist and subspecialist academic staff.

In the nursing care system of Shariati hospital every nurse is assigned to a finite number of patients, and s/he is responsible for providing all aspects of nursing care for those patients in each work shift2. The mean nurse /bed ratio, as shown in Appendix 7, is 0.5. This means that there is 1 nurse per every two hospital beds. In other words, there is 1 nurse for every 20 beds in each work shift. Nursing care in this hospital, and all other hospitals in Iran, is based on medical orders, given by physicians.

1In the setting study on- call means that if it is necessary, the residents, fellows and interns ask for the presence of academic staff or demand consultation of them via phone when they are not in hospital. They will attend at the hospital whenever necessary.

[2] Work shift means morning (from7:00^{am} till 2:00^{pm}), evening (from 2^{pm} till 7^{pm}) and night (from 7^{pm} till7^{am}).

CCS in Shariati hospital was designed in accordance with the defined goals for CCS, as a supplementary service running alongside the usual care and ordinary practices, such as the CPR team. Timely identification of AIPs and training the ward nurses about the necessary clinical cares and procedures were priorities of CCS implementation. As explained in chapter 5, analyses of a SW-CRCT showed no significant effects of CCS on decreasing mortality, CPR, and re-admission to ICUs.

In chapter 2, studies that assessed the effectiveness of CCS in different countries were presented. The present thesis, in conducting a CRCT, aimed to assess quantitative outcomes such as mortality, LOS, and re-admission to ICUs. Naturally, these systems have different effects on patient care and other care-related fields of hospital activities. Identifying these effects could potentially help policy-makers understand and make use of the trial results.

Different studies have been carried out using qualitative methods for assessing staff experiences and their views regarding CCS. Following a study assessing the state of patients who were at risk of deterioration in UK hospitals, Ryan et al. (2004), designed a framework that would identify these types of patients, and they found that ward nurses felt more confident when given guidelines and priorities that would help them identify AIPs. Also, physiotherapists, nurses and junior medical staff reported that communications between professionals on the diagnosis and treatment of these patients, had improved after the implementation of CCS (219).

Chellel et al. (2006) conducted a qualitative study, including interviews with 20 outreach nurses and 54 other members of teams that were involved with AIPs.

They reported action (getting things done, getting decisions made and following through), focus and vision (concentrating on one patient and having a vision of what action was needed to meet their care needs), orchestration (a communication and coordinating role) and expertise (bringing critical care skills and experience to the bedside), to be the four emerging themes of their study (220).

Baker-McClearn and Carmel (2008), in a qualitative study conducted in the UK, interviewed 100 staff in 8 acute care hospitals, with the goal of assessing the impact of CCS on the delivery and organization of care in hospitals. They reported that introducing CCS had two main impacts. Firstly, the organization of patient care was affected, reflected by less referring to and facilitated discharge from ICUs, and secondly, it was seen that educational aims affected the skills and confidence of ward nurses. The authors also perceived that links between junior doctors and nursing staff were improved due to the increased contact resulting from sharing clinical skills(221).

In Australia, Athifa et al. conducted a study to investigate the perceptions of nursing staff about managing AIPs, before and after the introduction of a CCS in 3 adult teaching hospitals. Results from their study showed that CCS had had several positive effects, such as improved educational support of inexperienced nurses and better communication among staff. The inexperienced nurses stated that the senior nurses educated them about complex procedures that were not regular in general wards (222).

These studies contribute to a better understanding of consequences resulting from introducing CCS. But exploring and clarifying the different problems, issues, and

challenges in the initial implementation of these systems can lead to better implementation of the system in the future. In particular, the context and culture of each country's health care system is different, and culture has a crucial effect on care(223). As such, the problems and resulting consequences can vary. Implementation of CCS, alongside taking into account the conditions of AIPs (see Chapter4) is a priority, as well as a necessity in Iranian hospitals. Therefore, a clear understanding of the challenges that may be faced, in implications and other outcomes, subsequent to CCS implementation, could facilitate the introduction of similar strategies in other hospitals in Iran. Qualitative studies are useful for extricating important information on CCS (222). Therefore, the present qualitative study was carried out in Shariati hospital, applying a focus group method, in order to find the views of staffs toward the CCS.

6.2 METHOD

The tradition of science is uniquely quantitative. The quantitative method was grounded in an objective reality, a position that supported the idea that cause and effect could explain all things. But the inability of quantitative methods in responding to some questions and challenges regarding human phenomena and clinical settings, especially where human subjectivity and interpretation are involved, led to an acceptance of qualitative research approaches as another way of gaining knowledge . The tradition of using qualitative methods to study human phenomena is grounded in the social sciences. These were applied in a clinical setting since some aspects of human values, cultures and relationships could not be fully described using quantitative research methods (157). Qualitative research

provides us with opportunities to answer questions about social experiences, their origins, and the way they affect human life (157, 158). Also, qualitative studies are used to contribute new knowledge and to provide new perspectives in health care (224) .

The CCS was implemented through a direct relationship between health care providers (nurses, physicians), patients and policy makers. Therefore, in order to explore the challenges, problems and possible outcomes of implementing CCS, the present study was carried out using a qualitative method.

6.2.1 Participants and setting

The present qualitative study was carried out in Shariati hospital, the setting for this thesis. Participants included 6 CCS team members, 11 research ward head nurses, 2 physicians, and 5 ward staffs. All of the nurses were female, with relevant university degrees, and their ages ranged from 25 to 52 years, with a mean of 42 years. They had varying degrees of work experience in nursing, between 2 and 30 years, with a mean of 16.8years. Two physicians were male; one of them was an internist and the other a general surgeon. Table 6-1 shows the participants' characteristics.

Table 6-1: Participants' characteristics

	CCS team members		Head nurses		Ward nurses		Physicians	
Participants' ID	Age	Work experie	Age	Work experie	Age	Work experie	Age	Work experien
1	43	14	45	21	27	4	50	18
2	45	12	48	23	30	8	38	5
3	35	9	45	16	25	2		
4	43	17	46	20	40	17		
5	41	15	49	25	35	11		
6	42	17	42	18				
7			47	21				
8			52	30				
9			52	29				
10			50	24				
11			42	18				

6.2.2 Data collection

The data for this study was collected in two phases, focus group discussion, and follow-up with individual interviews. A focus group is a form of group interview used to collect qualitative data (225, 226). It provides information about the range of ideas and the variety of feelings that individuals have about certain issues (157, 227). Focus groups enable the investigators to understand issues in depth(228). Assessment of program effectiveness and satisfaction among consumers and providers of services are both appropriate topics for focus groups (228).

In a focus group, it is possible to generate large amounts of data in a relatively short time span(227). This method is inexpensive (228), and it is a quick and convenient way to collect data from several individuals simultaneously(225).

In the present study, I initially collected the data through two focus groups. In order to pinpoint problems, challenges and outcomes in the CCS intervention, I formed two separate groups, one for CCS team members, and the other for ward

nurses. I aimed to use homogenous groups, because the use of a homogenous group is advocated for generating rich data, since individuals in these groups are more prepared to engage fully in discussion(229).

Prior to the focus group discussion session, I provided participants with comprehensive information about the purpose of interviews. Permission for recording group members' voices was acquired. The participants were assured their anonymity and informed that they could leave the group at any time; furthermore, I emphasized that they could refuse to answer any unpleasant questions.

The interview in each focus group started with broad questions in order to encourage participants to speak freely about CCS intervention. Some of the initial focus group questions included: "How was CCS implementation? What are your opinions on CCS? How were your feelings regarding CCS implementation?"

As the focus groups progressed, the questions became more specific, followed by probing questions, which allowed me to explore the issues that had been raised up by the participants in earlier questions. For example, when one CCS team member stated that ward staff were used to working routinely, I asked her: "What do you mean by routine? How did you deal with this?"

In each focus group, I gave the participants the opportunity to commit their opinions about CCS team to paper if they were not willing to talk about their opinions openly in a focus group. The participants of both focus groups were willing to speak and discuss the interview questions. They participated actively and dynamically, and this means that the participants influenced each other by responding to ideas and comments during group discussion.

After focus group sessions and subsequent data analysis, the follow-up with individual interviews was conducted in order to clarify some ambiguities, which emerged during the analyses.

For example, in focus group analysis, when the theme of “Shortcomings in Care” was coded, some questions were raised for me: "What were the shortcomings?” "Who made mistakes that caused these shortcomings?" Then, I conducted follow-up interviews with CCS members. Similarly, when the issue of "resistance caused by the notion of intervention in ward's activities" was brought up in the focus group analysis, I followed up individual interviews with both CCS team members and ward nurse. This was to answer these questions of "How and why did the ward staff resist the implementation?” In another example, in focus group analysis when the theme of “Not Taking the CCS Team Seriously” emerged, I interviewed physicians to find those experienced in this matter.

As described above for the focus groups, the consent procedure was considered for follow-up interviews. I interviewed 7 participants after conducting the focus groups. These participants were 2 physicians, 3 ward nurses, and 2 CCS team members.

The focus groups and individual interviews were recorded using digital recorders. I also took notes during interviews. Duration of the focus group sessions was 2 hours and 15 minutes for CCS team members, and 2 hours and 5 minutes for research ward head nurses. The length of each individual interview was between 30 and 60 minutes. All meetings and interviews were conducted in a comfortable environment in the clinical governance office of Shariati hospital, where

participants agreed to meet. Participants were seated in a circle. Data collection ended when there was no new information to collect, and the data became repetitive in each focus group as well as in the follow-up interviews. In the final two individual interviews, all data were repetitive and data saturation was reached.

6.2.3 Data analysis

The inductive content analysis (i.e. conventional content analysis) was used in the present study (see Chapter4) and coding categories were derived directly and inductively from raw data (230). All focus group discussions and interviews were voice-recorded, and the records were transcribed into texts. In many aspects, analysis of focus group data is similar to analysis of other qualitative data, such as one-to-one interviews (228, 231).

The transcribed interviews were read and re-read several times in order to obtain a comprehensive view of the data. Then, they were classified and coded, using MAXQDA software. The texts were coded line-by-line and key concepts and units of analysis (words and sentences) were identified. A code was assigned to each meaningful statement and paragraph. In the next step, codes with similar meanings were grouped together. Then, these codes were compared based on their similarities and differences. Finally, the categories were formed and a label was assigned to each category. The focus group discussions and interviews, as well as the analysis, were conducted in Persian language, and were subsequently translated to English by me and controlled by one English translator.

It is notable that I aimed to separate areas of agreement and controversy into two focus groups. For example, in the CCS team focus group, the participants agreed

that resistance was caused due to the perceived interference in ward's activities and not taking the CCS team seriously. But in the ward nurses group, the participants agreed on issues related to preparing the necessary supportive equipment and facilities. Two groups agreed about nursing shortage, and caregiver-receiver's level of satisfaction, but their views were different about the imposition of extra workload by CCS members. In each focus group, opinions of agreement were summarized and feedback was given to participants' for verification.

To maintain rigor, the findings were presented to the participants for verifying and validating the congruity of the findings with their experiences. I was constantly present in the setting, along with the CCS implementation team, who helped me to obtain more in-depth data. The codes and findings were discussed between my supervisors and me, in order to reach a consensus.

6.3 FINDINGS

In this section, the findings of interviews with CCS team members, physicians, ward nurses and head nurses, regarding the implementation challenges and outcomes, are presented.

6.3.1 Implementation challenges

Implementation of CCS involved a variety of challenges. These challenges included resistance caused by perceived interference in ward activities, imposition of extra workload, encountering ward staff routines, not taking the CCS team seriously, and structural and background dilemmas.

6.3.1.1 Resistance caused by perceived interference in ward activities

At the beginning the implementation was faced with resistance from both the ward nurses and ward physicians. They would resist in different ways and would defend their own previous way of doing things. A CCS team member said this about the initial resistance:

> *"Our first interventions were faced with resistance." [CCS team member No 2]*

The same person continued:

> *"We were probably a source of annoyance for them at first. They thought we would make them do heavier and more complicated work. Since our follow-up was more intensive and accurate, this would make seeing us around a nuisance." [CCS team member No 1]*

Some Physicians thought that the CCS interfered with those responsibilities of patient management. One physician said in this regard:

> *"Suddenly, we were faced with a group of nurses that not only exaggerated the illness but also recommended that we follow them. I thought this might interfere with the process of treatment, and this is difficult for a physician to accept."[Physician No1]*

Some ward nurses felt that there was no need to inform the CCS members for some patients against protocol. A ward nurse said that:

> *"We did not alert them about ill patients, but sometimes they found them during walk rounds. In my view, some of the patients were not critical, and the team was oversensitive. Why should I alert them about a patient with 38.5 body temperature when I myself know what I need to be done?"[Ward nurse No 1]*

Some ward nurses believed that had had ample experience in care of AIPs and identifying and managing them and thought that CCS team members delivered some unnecessary care for AIPs. One of the participants said:

> *"I have worked in this ward for many years, and I can identify ill patients from those in good condition. But this team identified the patients with poor prognoses and asked us to spend all our time and energy on these patients. After a few days, the patient stayed alive, they themselves were tired of the situation, and they reached the same conclusion we had reached in the first place". [Ward nurse No 4]*

According to some ward nurses opinion, CCS wasted their time, because of asking a lot about the patients. One of the ward nurses said:

> *"Most of the time, we preferred not to alert the CCS team, because they wasted our time by asking general questions about the patients, and we had to answer, why did I do this or why did I not do that?"[Ward nurse No1]*

Another participant (a ward head nurse) confirmed the above state and continued that the CCS team members demanded duties from the staff when they (the staff) had other tasks to do was widespread and this issue caused of ward nurses irritation:

> *"They demanded a lot from staff. They asked a lot of things from personnel. For example, a CCS nurse attended a patient's bedside and ordered bladder catheterisation, exactly when the ward nurse was busy giving other patients' drugs. The CCS nurse could wait for several minutes, but they would say: "Do what I tell you". My staff would complain about them ordering too much. This was annoying for the staff. Some of my nurses are very experienced in their work and know what to do and what not to do…and these demands irritated them. This was hard." [Head nurse No 7]*

The head nurses are responsible for nursing care in wards and some of them considered CCS as interference in ward activities, and CCS highlighted some problems. One of the head nurses said:

> *"Once we had a problem. I came to the ward in the morning. We had a shortage of staff the night before. I could not do anything about this shortage since we were under-staffed, but I was told that the CCS team had complained about, say, and a patient's condition. I knew that it was due to theshortage of nursing staff, and I did not want them to make my staff aware of this shortage. If the staff became aware, they would not obey what I asked them to do. For example, if I asked why the patient's vital signs were not taken as scheduled, they would say we hadn't enough nurses, so we did not take it." [Head nurse No 1]*

Opinions and co-operation of head nurses were instrumental in executing CCS. Some of the head nurses showed resistance to implementing CCS even up to the last days of the trial. One of the CCS team members said:

> *"In some wards,the head nurse did not cooperate with the team, even up to the last day. The personnel did not learn and did not accept the CCS. The personnel were reluctant to give the information required by the team members and refused to do so until the very last day." [CCS team member No 1]*

Some ward nurses believed that the CCS was useful for some wards and more useful for post operation patients. During the follow-up interview, exploring this issue, one of the ward nurses commented:

> *"In the general surgery ward, where post–op care is the responsibility of the ward nurses, this team could be useful. But in medical wards, particularly in the mornings, when all patients are to be visited by the*

residents, fellows and consultants, we really don't need to follow the orders of the CCS team."[Ward nurse No 4]

Findings revealed resistance of nurses and physicians of the wards were against the execution of CCS. The ward staffs considered the CCS as an implementation that interfered with their works and duties. The ward nurses thought that they have enough work skills and capabilities in managing the critical patients; reluctance to be interrogated by the CCS team and interference of head nurses' supervisory functions and those of CCS. In some cases, the nurses failed to inform the CCS team members of the existence of critical patients in the ward, or did not fully comply with CCS's proposed advisory guidelines.

6.3.1.2 Imposition of extra workload

From the very beginning and throughout the implementation process, the medical staff had the impression that the CCS imposes an extra workload on them. A nurse from CCS reflected on ward staff opposing the change during the early days of implementation:

"When we started our work, their attitude was not very favourable. Physicians, and nurses alike, thought that somebody with new orders and an extra workload had come along. Somebody has come to ask us to do something that will waste our time. For example, if I tell them to change a patient from spontaneous mode to T piece mode, they would consider this as extra work." [CCS team member No 2]

The engaged nurses emphasized their heavy workload. The ward nurses believed that hospital wards were crowded, and doing what the CCS team demanded of the nurses apparently added to their already heavy workload. A ward nurse said:

"Because of the overcrowded wards, it really added to the pressure on staff."[Ward nurse No 2]

Furthermore, in the ward nurses' opinion the CCS team members made them perform duties which were irrelevant to a patient's critical condition. In their view, the CCS team put an extra and unnecessary load on nurses. A ward nurse described the extra workload as follows:

"The CCS team members burdened us with extra tasks. For example, changing patients' clothes, transferring patients' beds, and some others tasks, had nothing to do with managing AIPs. Unfortunately, their orders were redundant and meant extra work for our staff". [Ward nurse No2]

According to the wards' nurses participants the CCS team members asked them to do tasks irrelevant to the care of AIPs. The same nurse added:

"Most of the time, CCS team members asked us to do ordinary tasks; tasks that in no way had anything to do with AIPs' care. For example, their orders were general things, such as cleanliness of the ward, transferring patients' beds, changing patients' clothes, etc. This didn't have anything to do with AIPs. I think some of those caused minor objections."[Ward nurse No 2]

The data regarding this sub-category showed that, after the implementation of CCS, extra workload really was imposed on ward nurses. Implementation of CCS led to more workload at the ward level and in regard to AIP patients. Furthermore, some of the ward nurses perceived the added tasks on them as redundant and believed that these new tasks imposed extra workload on them.

6.3.1.3 Encountering ward staff routines

Data showed that the CCS team faced with well-established routines in all wards of hospital as receiving patients from previous working shifts, preparing medicines, making arrangements for radiological exams, giving medicines to patients, writing the patients' records and reporting the latest condition of patients from one nursing shift to the next. The CCS team was faced with this environment during the project. One of the CCS team members said this about the routines:

> *"As soon as nursing staff come to start their daily works…for example, if they are on morning or night shifts…they first check and arrange the medicines. They haven't met the patients yet…they do not know if a patient needs something…they just stick to their routines. They might be anxious about not being able to do all their work, or give all the patients' drugs during their shift. But they have not learned that if they care for a critically ill patient on time this might reduce their work load later on."[CCS team member No 5]*

However, nursing staff on the wards believed that CCS team members were more acquainted with critical care wards and are less aware of what is to be done on routinely in general wards:

> *"Most CCT members are from ICUs, and they don't have enough insight on general wards, overloaded patients and concomitants. So team members were not familiar with the routines of general wards. The team members' approach to the patients was different, and we were not allowed to give priority to our own duties."[Ward nurse No 4]*

It seemed that any attempt to escape the routine approach led to challenges in the wards. One of the ward nurses described a situation that CCS demanded a specific task despite the fact that the routines had not been done:

"Some tasks demanded by the team brought challenges on the wards, and sometimes led to further complications. For example, when a patient was very ill and the family was agitated, and we were doing our best to take care of the patient, a member of the team would appear suddenly and ask us why some specific task had not been done. If the patient's relative heard that yet another member of staff had to explain the incident to them."[Ward nurse no 4]

The data was indicative of deeply established routines in general wards. However, implementing CCS called for activities beyond the scope of everyday and routine tasks.

6.3.1.4 Not taking the CCS team seriously

The CCS team members stated that, in some instances, the staff did not take the CCS team's comments seriously, or, simply, the AIPs were ignored. Occasionally, the managers did not pay due attention to the lack of co-operation with CCS team members. A CCS team member insisted on the importance of this issue:

"If I asked for something to be done, and the nurse or head nurse did not comply, they were not held accountable for not doing the right thing. The fact is our work was not taken seriously by the management, and they were thinking of it as another research project that would soon be forgotten. They believed that whether or not they co-operated, nothing would change."[CCS team member No 2]

The staff considered the CCS as a temporary change. A physician said:

"This one, like the others, has been carried out, temporarily implemented, and it has been stopped since. We always used to think it was carried out temporarily and would then finish. When the job or work is carried out temporarily, it cannot be taken seriously. This sort of work

has to be ordered from above and has to be explained carefully."[Physician No2]

This finding means that CCS protocols were under estimated by the managers and staff, because they felt the process was a temporary one.

6.3.1.5 Structural and background dilemmas

Shortage of staff, variation in the supportive needs of patients and lack of other teams that could help with this, absence of a No-Code system, and instability of the physicians' positions in some wards, formed the structural and background dilemma.

6.3.1.5.1 Shortage of staff

Shortage of staff was mentioned again and again in interviews with CCS team members and ward nurses. A head nurse cited the shortage of staff, and their time limitations, as the reason for not identifying and reporting the condition of AIPs in a timely fashion:

"We have a shortage of staff. When we have a shortage of staff, we cannot know enough about the patient's condition. My personnel did not have enough time to cooperate with CCS team members. For example, I asked a nurse why she had not told the CCS team members about the high temperature of a patient, and she replied that she had measured the temperature, but could not report it, because she didn't have enough time. After my notice, she said: I am going to tell them." [Head nurse No 11]

On this issue, a ward nurse reflected that in general wards, because of a low nurse –patient ratio, they couldn't carry out extra tasks:

"Most of the time, the basic and inevitable tasks that had to be done, took far longer, taking into account general wards conditions, it was almost impossible. When two nurses have to look after 40 patients, they won't have enough time to perform even their basic duties, how can you expect them to do extra tasks?"[Ward nurse No3]

A CCS team member said this about shortage of staff:

"The number of staff on wards is not sufficient for this kind of work. For example, we went to a patient's bedside and asked for something to be done, but when there was a load of other tasks to be done, and there were only one or two nurses on the ward, we had to do some of the necessary work ourselves." [CCS team member No 6]

The participant physicians described the shortage of nurses in the care of patients as below:

"We really have a shortage of nurses on our wards, and on general wards that had admitted AIPs, this was really something that many nurses could not cope with."[Physician No 2]

Based on findings, participants believed that shortage of nursing staff was one of the paramount obstacles in the way of implementation of CCS, which prevented appropriate interventions being carried out. Sometimes, the nurses used this shortage as an excuse for not following up the critical patients.

6.3.1.5.2 Variation in the supportive needs of patients and lack of complementary teams to fill the gap

One of the problems reported by some CCS team members was variation in the therapeutic and support needs of patients. A group of patients were end-stage but were brought to CCS team members' attention due to their serious condition. One

of the CCS team members said this about her experience of dealing with end stage patients and negative feedback from ward staff:

> *"We encountered many end stage patients during our interventions. There is a pattern in the internal medicine ward that the nurse would delay the report of a patient who has encephalitis and is gasping. We did tell the nursing team several times that a particular patient needs to be intubated, and she would ask the residents to come and intubate the patient. Next day the nursing staff told us that we had just postponed the patient's death by intubation, and that the patient would surely be dead the next week. They said: "Why did you bring the patient back? They are going to died anyway. You just made our work a little harder and made it harder for the patient's family." [CCS team member No 1]*

The same nurse then pointed to the lack of guidelines in identifying end-stage patients and said:

> *"We have no way of identifying which patients is end-stage. Even the physicians never commit anything about this to paper. So, for us, these patients are patients in need of intensive care."*

From the view of some head nurses, CCS interventions, and caring for end-stage patients diverted their attention from the patients who would actually benefit from their services. One of the head nurses mentioned:

> *"Conceptually, it's a good idea to take care of end-stage patients, right to the last minute, but this is not going to work in our country. I mean it would be so humane if we did not leave end-stage patients alone and took care of them. Under current circumstances, however, with the serious shortage of nursing staff and the high number of inexperienced and under-educated nurses, and considering our shortage of facilities, the CCS team cared for these patients…." [head nurses No 2]*

One CCS nurse told us about her experience, observing the ward nurses, taking care of end stage patients:

> *“When I told her to do something for an end-stage patient, she said: “I am busy giving medicine to a hypertensive patient. Why do you ask me to come and take care of an end-stage patient?” [CCS team member No 3]*

But one ward nurse noted the better care given to end-stage patients after CCS implementation:

> *"The presence of the team resulted in better cared-for end-stage patients; the staff care more about those patients now."[Ward nurse No 2]*

There was no pain control team in the hospital; therefore, the CCS group had to deliver pain control for the entitled patients. Also, there was no specialized team assigned to the task of taking care of patients’ wounds or caring for end stage patients. One of the CCS team members said:

> *“We don’t have a pain control team in our hospital. Some patients were in pain and we could not ignore this. If a patient was end-stage and there was no hope of survival, we still thought this patient should be kept clean, kept in an orderly condition and that the pain must be managed.” [CCS team member No 2]*

The same nurse continued:

> *“Taking care of patients’ wounds was one of our concerns during implementation of CCS. We did not have a specialised team for wound management, and in many instances we realised that our patients’ wounds needed attention.”*

Findings of this sub- category indicated that the CCS team had been involved in the treatment of end-stage patients, management of pain and wounds at the ward

level. This could be one of the main challenges that CCS members faced, and CCS members allocated a part of their time to managing this class of patients.

6.3.1.5.3 Lack of No Code system

Some CCS team members and ward nurses mentioned that for all patients with advanced metastatic cancer and even for brain dead patients a Code is called and the CPR team comes to the patient's bedside, on the other word, the No Code system (Do Not Resuscitate) for end-stage patients does not exist. This phenomenon caused the CCS team to label these groups of patients as AIPs and care for them. Reflecting on this situation, one of the CCS nurses said:

> *"We do not have a No Code in our hospital and, because of this; we have to cope with a lot of extra work load." [CCS member No 2]*

Another CCS nurse pointed resulting from following up these patients and added:

> *"We had some terminal patients in the ward, living on the ventilators for days. Well, we took care of them, too. Though we knew for sure they were about to die. Simplybecause we didn't have a 'no codesystem'". (CCS team member No 5)*

6.3.1.5.4 Instability of physicians' positions in some wards

In order to deliver sound treatment and care to AIPs in a hospital setting, well-established co-ordination with physicians and seeking their guidance is a must. Participants mentioned that in surgical wards in Shariati hospital, the process of diagnosis and treatment of patients were facilitated due to the permanent presence of a medical student in the ward.

In contrast, on other wards that lacked on-site physicians (e.g. medical wards), medical students had to manage all patients of medical wards for evening and night shifts. The physician not being constantly available added to the high number of patients under one physician's supervision, which led to him not being able to become thoroughly familiar with a high percentage of patients' conditions. A CCS team member said:

> *"I think physicians should become more involved. On the surgery ward, a resident stays in the same ward for four years and is not changed every other month. But on internal medicine wards, a resident is here today and will be transferred to another hospital tomorrow. This means they are never completely aware of patients' conditions. When they came to visit the patients, they would say: "I do not know this patient". They would start to read the patient's chart just to see what's going on! This whole process takes time, and, in the meantime, patients get worse. But the CCS team members would push the ward nurse to do this and to do that for the patients. How can this be done?" [CCS team member No 4]*

Based on the data, this category was indicative of the problems and complexities that the CCS team faced. Ward nurses reckoned implementation of CCS was unpaid overwork, and that was one of the reasons they resisted the process. Meanwhile, staff relying on established routines and believing that CCS was a passing fad caused problems for the CCS. Furthermore, background and structural problems, such as nursing shortage, different needs of patients, lack of pain and wound management groups, plus the lack of residing physicians in the wards brought more challenges for the CCS team.

6.3.2 Implementation outcomes

The participants believed that the care and follow-ups by CCS team members had some outcomes for nurses, physicians, patients, families, the health care system, and the hospital. Preparing the necessary supportive care, equipment and facilities, increasing the knowledge and experience among workforce, adjusting the routine care activities and making the staff more sensitive about AIPs, satisfying caregivers/receivers, and discovering medical errors and problems, were some of the main positive outcomes of the CCS team. The CCS team's dependency and the irresponsibility of individuals and conflicts between groups were some of the negative outcome categories.

6.3.2.1 Preparing the necessary supportive equipment and facilities

Implementing CCS required providing the wards with some medical equipment. The interviewees cited that CCS unveiled the shortcomings in ward equipment and facilities. The CCS teams did their best to relieve these shortcomings. One CCS team member said:

> *"We identified the equipment shortcomings on wards and took the necessary measures to supply this equipment. Before we started our work, on some wards there was no monitoring, but when the CCS team started, ventilators and also portable monitors were bought, and their presence became a norm in wards." [CCS team member No 1]*

As mentioned in Chapter 5, The CCS team provided 24/7 services. So, if there was a shortage of equipment, such as ventilators or monitors, the nurses would tell the CCS team members, and they would supply the required equipment. This, of course, pleased the wards nurses. A head nurse said:

"Our access to equipment became very good after the CCS. The CCS team would find the needed equipment promptly and the tasks were done as fast as possible. It was enough for a nurse to tell a CCS team member what they needed for care of AIPs, and it was ready for them…monitors, ventilators…and this was so good, it was a great help." [Head nurse No 7]

Another nurse commented:

"Most of the time the team did not manage to improve the condition of these patients and only facilitated the provision of medical instruments."[Ward nurses No 5].

6.3.2.2 Increasing the knowledge and experience of the hospital workforce

Findings showed that instructions given to nurses during the implementation resulted in an increase in their awareness about patient care. A CCS team member said:

"The CCS team trained them in monitoring, about perfusors, and a lot of other things. They learned how to care for patients more efficiently. They learned these things very well. The CCS team talked and discussed it with them and they learned a lot." [CCS team member No 1]

Interviewees cited that the most effective part of the staff training by CCS was improving the skills of low-experienced and recently graduated nurses that mostly worked in the evening and night shifts. One of the nurses said in this regard that:

"The presence of the CCS team had a good effect on new nurses, who work mostly on evening and night shifts."[Ward nurse No4].

This finding highlighted the influence of the presence of the CCS team and guidelines provided by them on the wards nurses, and, as a result, an increase in the staff's knowledge in the domain of caring for critical patients.

6.3.2.3 Adjusting the routine care activities and increasing sensitivity about AIPs

The implementation of CCS gradually changed the routine nature of care in wards. Nurses became more sensitive to patients' conditions, and their attitude towards patients changed. One CCS team member said:

> *"Before the start of CCS, whenever a patient was intubated, the nurses would think the patient would soon die, so they would leave the patient alone……but now, when a patient becomes ill they start monitoring the patient…they pay attention to ill patients…it's so much better now. They understand that when a patient becomes ill, there should be good ventilation, good monitoring…they now pay attention to these things. Their attitude toward patients has changed." [CCS team member No 4]*

Following the CCS, ward staff became more sensitive in finding and managing AIPs. A head nurse said:

> *"It was so good that my nurses learned to be careful and became able to identify ill patients and followed the patient, especially in evening and night shifts." [Head nurse No 9]*

The interviewees cited that prior to and at the start of intervention; nurses were not sensitive about alarms and the problems that caused the alarms. Subsequent to the implementation of CCS, the nurses' sensitivity to alarms, ill patients, and reporting their condition gradually increased:

> *"At the start of our work, it was interesting that when a monitor's alarm rang, the nurse would come and simply turn it off! Now, they know which alarm means that there is a problem with the patient, and that they should take care of that patient. Sometimes they would call me at home and say: "The perfusor is making this alarm or that alarm…what we should do?"This shows their increased sensitivity to the alarm. Now, I see them monitoring a patient, and when I ask them why the patient is*

being monitored, they reply that the patient is getting TNG[1], and that is why we are monitoring him. When the project was finished, I was on a ward, and I saw a nurse challenge a resident. It was something important about a patient's parameters…I remember well that this was a thing that we'd taught them. This was a positive point, which I saw myself." [CCS team member No 1]

This finding indicated that implementation of CCS has a notable effect on nurses' behavior at the ward level. The nurses had learned the care points from the CCS team and had become more sensitive in regard to critical patients.

6.3.2.4 Caregiver-receiver satisfaction

The findings highlighted that before starting the implementation, all AIPs were taken care of based on ward routines, but participants believed that CSS has changed the mode of care these patients receive, upgrading care to something more than just routine work. The ill patients were under the CCS teams' supervision, and therefore, care was immensely improved. This satisfied the patients, as well as their families:

"An important matter that I should talk about is the satisfaction of patients' families. Families, perhaps from past experiences, perceived that if their faced up one's condition deteriorated, it was the families who had to face the real challenge of finding an ICU bed anywhere. But when they realized that their patient was taken care of right up to the last minute…when they saw that the CCS team is doing all the things that should be done in ICU….when they saw the monitoring…the heart specialist coming to visit their patient…the surgeon coming to visit their patient…everybody coming…if their patient died, they did not complain that our patient would be alive if there was an ICU bed. They thanked me

[1]trinitroglycerin

several times for doing whatever could be done." [CCS team member No 5]

Patients would be visited several times by CCS team members, and this would translate into satisfaction among patients. Another CCS team member said:

"The CCS team nurse went to the patient's bedside several times, and this was pleasant for the patients. This would make them happy that they are getting monitored all the time. They were so satisfied, thinking they are getting more care." [CCS team member No 6]

A short while after CCS implementation had been started; the physicians were also happy to see the CCS team members being present at the patients' bedside and accepted their recommendation:

"Although there was some resistance at the beginning, the physicians accepted us very fast. I think their resistance broke very soon. I mean, when they saw what we did was really helping, like when a first year resident saw that we can tell him what to do with an intubated patient, or saw that we carried out interventions that changed the patient's condition for the better…then, they accepted what we told them. For example, we had said: "The patient has this condition…the patient can't eat anything…don't you want to start TPN? Or don't you want to ask for physiotherapy?" I remember after stopping the CCS they looked for us, asking several times: "Why are they not here? Why did it stop?" [CCS team member No 1]

When the implementation finished, some of the ward nurses and physicians asked about CCS and their absence reason. One of the head nurses said:

"[During implementation] there was always somebody who attended full-time every day and constantly checked the patient. Now that the CCS does not come to the ward anymore, the nurses and physicians ask:

"What happened to the CCS team? Why don't they come anymore?" [Head nurse No 1]

The satisfaction spectrum following the implementation of CCS was broad. At one end of the spectrum lay the satisfaction of service receivers (i.e. patients and their caregivers). Patients and their caregivers were satisfied that there was a system in place that cared for them. At the other end of the spectrum, were the physicians and nurses, who felt that the presence of the CCS team relieved their concerns in treating the patients.

6.3.2.5 Disclosing medical errors and problems

During the intervention, many shortcomings in care of patients surfaced. One of the CCS team members hinted at this subject and said:

"When we were working, we found that sometimes a reliable medical history is not taken. Many times in our work not only the nursing staff, but also the interns did not know anything about positioning a patient correctly. Many times, they did not know how to do a good ambulation." [CCS team member No 1]

Sometimes the shortcomings or mistakes led to major problems for some patients. The same person continued:

"There was a month when we saw that several patients started needing dialysis just because they did not get enough fluid after surgery. Or, we saw patients getting renal failure just because of a bad PO. Then we saw that they were reducing the patient's fluid intake since the patient was getting dialysis, and this would make the patient worse."

The mistakes took place not only at the physicians' level, but also at the nursing level. Sometimes, neither the physicians nor the nurses cared for the nutrition of

the patients. Another CCS member said this in confirmation of what her colleague had said:

> *"I remember well that in one ward, I saw a surgery patient …it was 15 to 20 days since he had last eaten. He had only got serum therapy, and his diet was PO every day, but the patient was so ill that he had not eaten anything. His food was put by his beside, and nobody was looking to see if he was really eating anything or not." [CCS team member No 2]*

These errors were also seen in patients who had received injections. The same person continued:

> *"A patient got TNG through a micro set, and his companion thought that this drug should go fast and therefore opened it…they did not know that this should be done gradually. Then, the patient's blood pressure would drop on a ward that checked the BP every 12 hours…they didn't have enough sense to break the routine and check a patient's pressure that is getting TNG out of turn…"*

This finding showed that implementation of CCS and following up the CCS team resulted in unveiling the physicians' and nurses' mistakes and shortcomings in different aspects of medical care.

6.3.2.6 Conflicts between groups

The CCS team nurses had some conflicts with the nursing staff and physicians. One of the head nurses said:

> *"There was some friction between the CCS team nurses and the physicians. The CCS team said this should be done, and the physician said no, there is no need for this."[Head nurse No 11]*

Another head nurse thought the conflicts, when they took place in front of the patients, was a weakness for the whole care process:

> *"There were some conflicts between CCS team nurses with physicians and other ward nurses in front of patients. For example, in one case, the anaesthesiologists thought the team nurse ordered them what to do and what not to do…" [Head nurse No 2]*

6.3.2.7 CCS team dependency and irresponsibility of individuals

As a consequent of CCS implementation, the ward staff depended to CCS for AIPs caring. One of the head nurses said:

> *"Nursing staff had become dependent on the CCS. I mean, they thought that AIPs are for the CCS team to take care of. If the CCS team came that's good…if they did not come then that's it." [Head nurse No 10]*

Another head nurse said this about the dependency of personnel on the CCS team and relying on them to take care of ill patients:

> *"Our nurses felt if a patient is intubated, a CCS team member should always come and do the suction for the patient. They were so relaxed that finally the CCS team nurse would come to check the patient and do whatever is needed. They had become too dependent on the CCS." [Head nurse No 3]*

Also CCS team nurses thought that ward staff were gradually feeling that taking care of AIPs is the responsibility of the CCS team members, and ward nurses were beginning to neglect their own responsibilities.

> *"The problem was, that after a while nurses felt that the CCS team should do all the work. If a patient is ill, then it's their responsibility to find a ventilator, to check on the patient. I felt that in my own ward, other nurses had begun to forget about their responsibilities and put it all on*

us. I mean, even the residents (physicians) started to do the same, and when there was a problem would say: "So, where is the CCS team nurse?" [CCS team member No 2]

Not accepting responsibility for the critical patients by nurses and even physicians was one of the negative outcomes following the implementation of CCS. In some cases, it was felt that managing the critical patients was transferred to the CCS team.

6.4 DISCUSSION

The findings presented in this chapter describe challenges and outcomes of CCS implementation in Shariati hospital, Tehran, Iran. The first main category of implementation challenges consist of five subcategories, namely: resistance caused by perceived interference in ward activities; imposing of extra workload on hospital staff; encountering ward staff routines; not taking the CCS team seriously; and structural and background dilemmas. Shortage of staff, variation in supportive needs of patients and lack of other teams to address these needs, lack of a No Code system and instability of physicians' positions in some wards formed the structural and background dilemmas subcategory.

The second main category consisted of seven subcategories: preparing the necessary supportive equipment and facilities; increasing knowledge and experience among the workforce; adjusting the routine care activities and institutionalizing sensitivity about AIPs; caregiver-receiver satisfaction; disclosing Medical errors and problems; conflicts between groups and dependency on the CCS team; and irresponsibility of individuals.

I will discuss these findings in two main categories of implantation challenges and outcomes as follows:

6.4.1 Implementation challenges

As mentioned above, this main category consisted of five sub-categories. I begin by discussing the first four categories, and then, the final sub-category, namely, structural and background dilemmas will be presented.

6.4.1.1 First four categories

The resistance caused by perceived interference in ward activities, imposing of extra workload on hospital staff, encountering ward staff routines, and not taking the CCS team seriously were the first four sub-categories.

Nurses showed resistance to the CCS implementation. Their first impression was interference in the ward's affairs and being under the control of the CCS nurses. Watson (2006) has mentioned the same concern of staff about outreach services, and in order to prevent this type of judgment, she has proposed a detailed presentation of the goals of CCS and open participative discussion between CCS team members and ward staff(232).

Ward nurses in this study believed that CCS imposes additional workload on them. In Chellel et al.'s (2006) study, the interviewees also pointed out an increase in workload after CCS implementation, due to the complexity of care and demands of AIPs(220).

In Shariati Hospital, before CCS implementation, ward nurses provided usual care for AIPs according to physicians' instructions, and they did not pay enough

attention to the details of these patients' care and needs. After CCS, however, needs and problems of these types of patients, were being identified and referred by the CCS team, and this meant better and more comprehensive care for AIPs on one hand, and extra workload for the ward, on the other.

Another issue was CCS nurses' round-the-clock involvement in their well-established routine tasks. The ward nurses were merely in charge of doing pre-determined activities, such as giving medicine to patients, checking vital signs, sending medical tests and writing reports. These tasks left no room for the caring duties of the nursing staff. Studies conducted regarding this issue in Iran indicate that this phenomenon is not exclusive to Shariati Hospital, and that it is dominant everywhere in the country. In Iran, the nurses think that nursing is synonymous with caring, believing that both are just a series of formal and clear-cut activities. Following routines is an axiom for every Iranian nurse. It means doing the routine and repetitive work based on physicians' prescription, giving the top priority to the routines (and not the actual needs of patients), following whatever the ward and head nurse or the supervisor expect or demand, and doing things that the ward determines for them. Every nurse knows how to start a shift on the ward, how the responsibilities are shared, how to hand the shift to the next nurse, and what the head of the ward expects them to do (233, 234).

In fact, following the routines of the ward is considered to be the ultimate sign of a nurse's competency and qualifications. As a result, a "disease–centered" approach replaces a "patient-centered" approach. Also, exclusive following of the routines may result in negligence or habit formation, because it creates a sense of indifference about the surrounding events. Under these circumstances, the signs or

symptoms which are considered alarming in normal states will be ignored by the nurses(235).

Undermining and ignoring the CCS by some employees, due to considering it a transit research project, was another issue impeding efficient implementation. CCS was only being executed at Shariati Hospital, and no other hospital in Iran had been instructed to do so. Since in Iran hospitals nationwide are informed of protocols and instructions by MOHME, interpreting the CCS implementation in Shariati hospital as a passing fad was partly justifiable.

6.4.1.2 Structural and background dilemmas

Shortage of staff, variation in supportive needs of patients, lack of other teams to address these needs, lack of a No Code system and instability of physicians' positions were structural and background dilemmas.

The implementation of CCS started while the hospital was faced with the problem of the nursing shortage. According to the information taken from medical documents and nursing offices, at the time of study, Shariati Hospital had a total number of 375 beds in 13 wards of study, but the number of nurses in 13 wards was only 187. In addition, as shown in Appendix 7, the ratio of nurse to bed was 0.5. According to recent studies in Iran, the nurse to bed ratio is 0.8 at the national level, despite the international norm which is 1.5-2 nurses per bed (20). It is clear that nursing shortage in Shariati Hospital, with a ratio of 0.5, is below the national mean (0.8). This shortage is one of the challenges faced by the health system in Iran(179).

Although in the beginning of the intervention, identification and management of AIPs were the main objectives of the study end-stage patients were not been

clearly defined in the research context. Consequently, these patients were also considered AIPs, and thus caring and observing these groups of patients imposed additional work on the CCST and even on nurses on these wards.

The absence of an established system of palliative care in Iran was another major issue. There was no set of instructions or guidelines about managing end stage patients available in Shariati Hospital, or in other hospitals in Iran. Sepulveda et al. (2002) indicated that despite the emphasis and efforts of WHO to develop palliative care worldwide, there are still countries which fail to consider this care as a problem and have not put it on their health reform agenda(236). Unfortunately, there is no effective plan for performing palliative care in Iran, the issue has not been put onto the health agenda and few studies have been carried out in this field(237).

The findings of interviews also showed that in some cases, the CCS team was responsible for pain management and giving analgesics. There are no studies and documents available regarding pain team control in Iranian hospitals, and suffering patients, as well as post operational patients, receive analgesic, if necessary. In the study setting, work is done according to a physician's orders, and this should be handled under the supervision of the surgeons or anesthetists. Regarding the high number of patients under operation at the Shariati hospital, it is evident that pain control and management of these patients has not been done properly. However, in countries like the US(238, 239), the UK(240, 241) and Canada(242, 243) there are formal structures for pain management, and there are programs and teams throughout the hospitals to control and manage pain.

Moreover, findings revealed that there is no "Do Not Resuscitate" (DNR) or "Do-Not Attempt Resuscitation" (DNAR) system within the hospital; the CCS team followed patients who were under ventilation, desperate or hopeless, and those for whom no treatment is possible due to various reasons, such as metastatic cancer, COPD[1] and progressing diseases. However, routine CPR was still done for these patients. The absence of formal DNR orders has led to ineffective intervention for hopeless patients by staff and CCS team members. This issue and the question of how to deal with these patients were considered a problem for the CCS team, and decisions about continuation of treatment of these patients were among the challenges encountered by the team members.

DNR is now accepted in different countries and has become a general rule. In the US, according to the Joint Commission on Accreditation of Healthcare Organizations, it is compulsory for all type of hospitals to have a clear policy for DNR. This also applies to Europe and the UK (244, 245).

Iran is a Muslim country and its rules and legislations are based on Sharia (Islamic rules). The patient does not have the right to voluntary death in Islam, therefore human life cannot be terminated either by suicide or with the assistance of any physician(246). In Islam, it is necessary to save lives and health workers should not withhold any attempt to prevent premature or early death, even for end stage patients. So, there are ethical and religious challenges in this area that make decision making more difficult, and for this reason, there are no ethical or clinical guidelines for DNR (247). It is notable that in Saudi Arabia, which is also a Muslim country, there is a protocol for DNR in some hospitals(248).

[1]Chronic obstructive pulmonary disease

6.4.2 Implementation outcomes

Although CCS faced some difficulties and challenges, it had some impact on the system, both positive and negative. Positive implementation outcomes were: increasing the knowledge and experience among workforce; adjusting the routine care activities and institutionalizing sensitivity about AIPs; increasing caregiver-receiver satisfaction; preparing the necessary supportive equipment and facilities; and disclosing medical errors and problems. Conflicts between groups, dependency upon the CCS team and irresponsibility of individuals formed the negative implementation outcomes.

6.4.2.1 Positive implementation outcomes

Studies conducted on the efficiency of CCS have pointed out its impacts. Valentine and Skirton (2006), in a study reporting on the efficiency assessment and audit of CCS in acute hospitals, elicited the attitudes and opinions of clinical staff concerning CCS through a questionnaire. They concluded that the clinical staff believed that the CCS team enhanced medical care by: providing assistance and advice to clinical staff, facilitating access to ICUs, training and supporting nursing and medical personnel(53). Also, Plowright et al. (2005) reported that following CCS implementation, nurses have gained confidence in their own competencies on patients' assessments and decision-making ability. Some participants had achieved higher confidence in their abilities to communicate effectively with physicians in order to receive assistance for patients. Furthermore, practice on the wards had improved, and some factors such as pulse, respiration rate and liquid balance had become significant subjects for

nurses(249). In another study, inexperienced nurses gained positive points on CCS, since they had been trained on complicated procedures (222).

6.4.2.2 Negative implementation outcomes

Moreover, CCS implementation was accompanied by challenges between the medical and nursing groups. As mentioned before, in Shariati hospital, and generally in Iran, the medical system has a biomedical approach. Therefore, actions and caring for the patients are done according to the physicians' instructions; that is, the physicians give orders, and the nurses perform those orders. In Iran's hospitals, although all the nurses are educated and trained, they are always regarded as obedient assistants of physicians. Therefore, physicians have a higher and better position than nurses(233).

In this study, all CCS team members were experienced and trained in the field of intensive care. However, uncertainty and lack of understanding of physicians, regarding nurses and their view toward the nurses, as well as the said attitude, could have effects on the physician's resistance to the CCS team activities or the management of AIPs. However, the participants declared that after some time had passed from the start of CCS implementation, the existing resistances and challenges became less.

6.4.3 Summary

Findings show that the CCS was resisted and had a lot of problems. The ward staff did not like having their routines changed; they saw it as extra work, and they did not like taking orders from CCS staff. They resisted by not telling the CCS staff about AIPs; they knew they could ignore CCS staff orders; and they

knew CCS would be temporary (so they just had to wait and it would stop). So, without proper authority for the CCS, and the support and agreement of the ward staff, the CCS would not work well.

It could be claimed that although the results of the SW- CRCT reveal that CCS has no significant change on mortality and LOS, the findings of the qualitative research showed that CCS implementation, even with these problems, had some positive effects and good outcomes. The ward staff changed their behavior (started to challenge residents, began to pay attention to vital signs), and the physicians accepted the CCS was right when they identified patients as acutely ill. Therefore, CCS in hospitals could be considered as an essential service, because it can shift the care from routine focused to patient-based, and therefore increase the quality of care. CCS might work, but it has to be implemented in a different way. In order for sufficient CCS practice to be carried out in Iranian hospitals, it seems that considering the structural problems is essential.

Further research aiming to clarify attitudes of the ward staff, and to analyzing organizational needs for the implementation of CCS and delivery of high quality care, is essential. There is a need to describe the expectations and experiences of patients and their relatives in order to define other aspects of challenges and outcomes that may occur.

6.5 LIMITATIONS

This study was limited to descriptions and experiences provided by nurses and physicians. CCS was designed for increasing the quality of care for AIPs on general wards. Clearly, obtaining the views of patients and their relatives

(particularly those who accompanied patients during hospitalization) might help identify different perspectives regarding CCS or experiences of CCS implementation.

6.6 CONCLUSION

Findings show that CCS had some positive impacts. Implementation of CCS is recommended in Iranian hospitals, but before large-scale implementation is rolled out, full attention should be paid to the structural and contextual elements present in those hospitals. Introducing teams for pain control, palliative care, and wound care are necessary pre-requisites for successful CCS implementation in hospitals. Furthermore, practice guidelines will need to be developed in order to guide ward nurses. More specifically, topics of these guidelines should be introduced in the nursing curriculum. Also, preparing a guideline about No Code patients, with due attention to social, religion, and cultural related issues, may facilitate the CCS implementation. It is necessary that the MOHME prepare guidelines about CCS and notify the hospitals before their implementation.

Overcoming the problem of the shortage in nursing staff, and appropriately valuing this category of health workers, will lead to more efficient implementation of CCS and better care of critical patients. It is of the utmost importance that implementing any sort of change in Iran's hospitals be backed by the support of political of political, social and health authorities.

CHAPTER 7

Final Conclusion

I explored the literature and found that there was a lack of evidence supporting the use of CCS in developing countries. As mentioned in chapter 2, three SRs (76, 104, 105) have shown that CCS has no statistically significant impact on mortality rates, ICU admissions, or LOS on general wards. Also, a multi-center RCT indicated that CCS did not change hospital mortality rates (84).Another RCT, however, was unable to demonstrate a causal relationship between CCS and in-patients' LOS, but showed a significant decrease in hospitals' mortality rate(85).All relevant studies investigating the effects of CCS implementation in hospitals have been done in developed countries (such as the UK, the USA, Australia, Canada, and Sweden), and the results of these studies do not support CCS implementation in hospitals. However, despite this, CCS was recommended as a necessary service for hospitals in the UK.

Iran, a developing country, has not yet implemented a service to care for AIPs in general wards, and therefore, CCS or other similar services do not exist in the country. Although the number of AIP has raised in general wards due to aging, more advanced and complicated therapeutic methods, economical changes in the health system, various therapeutic choices, and shortage of ICUs. This may lead to adverse events and outcomes with catastrophic results.

As reported in chapter4, a qualitative study was conducted to explore the current situation of AIPs admitted to general hospital wards in Iran. The findings of this

qualitative research indicated that there were indeed several serious shortcomings in managing AIPs in Iran. These shortcomings include: problems in identifying AIPs; problems in handling AIPs; non appropriate use of ICU beds; and poor structure for mortality control in managing AIPs in general wards. As a result of these existing flaws, deteriorating signs and the responsible staff frequently missed symptoms of AIPs. There were also issues regarding the management of AIPs, even if these patients were identified as AIPs and in need of special attention on general wards. Also, lack of clinical guidelines to streamline ICU admission, plus poor mortality control, affected the state of AIPs on general wards. These issues highlight two important facts: firstly, there is a real need for a strategy for making changes in the way AIPs are managed currently; and secondly, there is a need to establish an appropriate system to support those changes.

According to international experiences, incorporating critical care services into the routine care of hospitals can make health care workers more familiar with caring for AIPs. So, a CCS including a trigger system was designed, and a team was formed. This system was supervised by an expert committee to monitor the changes and to define the guidelines. It was adopted from the UK model and NICE guidelines, but was made relevant to local needs(15).

As mentioned in chapter 3, there are several TTs to identify AIPs in hospitals. CCS implementation committee, in the current study, for three reasons, chose the single parameter system. Firstly, there was a shortage in number of nurses on the wards, and it might have been difficult for nurses to calculate the parameters needed in aggregated systems. This issue, besides the high probability of error,

could have led to delays in assessment of AIPs and reporting their situation to the CCS team. Secondary, vital signs, such as blood pressure, pulse and respiration rates, and body temperature, were routinely checked in the target hospital, and urine output and SPo2 were controlled at the request of physicians. Thirdly, the single parameter system has a high specificity and a low sensitivity(15). It means that the single parameter system could minimize false alerts but might result in missing AIPs(121). Subsequent to selecting the single parameter system to identify AIPs, the CCS team was formed.

Shariati hospital is representative of teaching and university hospitals in Iran, where residents and fellows rotate through one ward (for 3 or 6 months) and then to another ward for 3 or 6 months. Here, the attending physicians (the university's academic members) are present in hospitals from early morning to early afternoons, five working days a week. This ruled out the possibility of using residing physicians as the permanent, core members of the team. Therefore, the only remaining option was to form a nurse-led CCS team (the UK type of CCS), whose members had the NICE-needed qualifications, mentioned in Chapter 5. This nurse-led CCS team was able to perform their functions and duties around the clock.

Needless to say, having the support of the hospital's top management was a prerequisite for implementing the CCS. Fortunately, the main objectives of this project (i.e. lowering the mortality rates and LOS in the hospital) were aligned with the hospital's and the university's goals. So, even from the early days of the project, the CCS team enjoyed the support of the hospital's senior management.

Shariati Hospital is a general hospital with several medical and surgical wards. In addition, the hospital was overcrowded with patients, and there was a serious shortage of nursing staff in place. As there was limited capacity due to the small numbers in the CCS team, the CCS was implemented using a stepped-wedge method. The stepped-wedge method provided the CCS team with the opportunity to identify the obstacles and shortcomings in implementing the changes in one ward, and then overcome these issues when the team moved to other wards. In other words, using the stepped-wedge method was an action research method. For example, when the work had begun in the first ward and the CCS team appraised the issues around ward staff cooperation, it was decided that before starting the CCS implementation process on other wards the ward chief, and its physicians and nurses, should be thoroughly briefed about CCS.

The analysis of SW-CRCT, showed that implementing CCS did not result in a statistically significance decrease in CPR mortality, ICU admissions, and LOS between the clusters exposed and unexposed to the intervention. I believe that this could be due to some of the reasons below:

1. **Slow changes in culture**: Findings of qualitative research in chapter 6 showed that initially the staffs first resisted changes in routines and gradually after a while they accepted the CCS. In my opinion if the CCS was implemented without any resistance, it would be more effective.
2. **Unsuccessful CCS implementation**: In order to explore if the CCS had been successfully implemented, the process of implementation is assessed in the second qualitative study (chapter 6). Interviews with

focus groups showed that several factors interfered with the successful implementation of CCS. There was resistance to implementation from ward staff (resistance caused by perceived interference in the ward's activities); imposition of extra workload on the staff; encountering confronting ward staff routines; ward staff not taking the CCS team seriously; and some ward staff did not cooperate even until the last day. Also there are structural and organisational problems in the hospital staff such as shortage, physician's instability, the absence of a No Code system, and lack of complementary teams.

3. **Human factors**: It is obvious that different factors influence the effectiveness of CCS and the human factor is one of the important factors (chapter 2). As mentioned in chapter 6 some wards head nurses did not cooperate with the CCS, even up to the last day.
4. **Possible alarm fatigue**: Even though, the single parameter system depending on trigger thresholds(15), has high specificity and low sensitivity, theoretically, the single parameter system could cause to elevated triggers and call-out rates (CCS calls) with no relation to an adverse event and absolutely without any side effect to patients. Also, I reduced the trigger threshold of single parameter system for improving sensitivity. Increased triggers and alarm overload may cause to potentially alarm fatigue. Therefore alarms are neglected and will be missed by nurses (80, 250, 251). Breznit (1984) described that false alarms could generate a "cry wolf" phenomen,

where nurses might ignore or have a relaxed response to alarms (252). Alarms not only allocate most of nurses' time, but also can obstruct their efficiently arrangement of responsibilities(250). In this situation the alarm fatigue could affect patients' safety (77, 251). The two last reasons (human factors and alarm fatigue) could be lead to unsuccessfully CCS implementation.

Despite the fact that in the current study the CCS showed no significant improvement in mortality, CPR, LOS, and ICU admission, I believe that the CCS might still be useful in Iranian hospitals if these following challenges could be overcome:

1. CCS may not work if the conditions in the hospital are not appropriate for its correct implementation (e.g. policies for palliative care). Moving towards team work and forming clinical teams to provide patient-centred care are strongly recommended. These teams, which can potentially increase the quality of care, may include pain control, wound care, and palliative care teams.
2. The nursing shortage is an important hospital problem that affects delivery of the CCS. The nurse-to-beds ratio/ nurse-to-patient ratio is lower than the recommended ratio (253). Considering the mandatory nurse- to- patients ratios and supplying nurses could lead to better CCS implementation.
3. Timely identification of AIPs and notification of CCS are very crucial. Considering the shortage of nurses in Iran's hospitals and alarm fatigue in using single parameter systems; the use of tools such

as ViEWS (chapter 3) may be more practical since, blood pressure, body temperature, pulse rate and respiratory rate are routinely measured in Iranian hospitals. Other variables of ViEWS such as the use of supplementary oxygen, GCS and O_2 saturation level, could easily be added on request. The domain of parameters could be changed by experts' priorities and local conditions. These changes could definitely affect the sensitivity and specificity of the TTs and workload of the CCS team.

It is obvious that the education and training received by wards' staffs, and their memories of observing CCS in action, can be transferred verbally to other nurses and hospital staff. This collective memory of high standard care might lead into better care for the AIPs. I should mention the factors that helped me to better implement CCS, taking into account the local settings of Iran:

1. Since the staff shortage is more prevalent during the night shifts, and less experienced nurses usually work on those shifts, delivering care to AIPs during night shifts is a more difficult task. As such, it is recommended that, in order to have a more efficient CCS, specialized teams work all day in target wards and hospitals. This matter was emphasised by other researchers (232). Obviously, it needs human resources and funding.
2. Since the nurses carry out the majority of the care of patients on wards, it is recommended that if such a team is formed, it should be nurse-led, comprising the following members:

(i) Nurses well-trained and experienced in critical care, management and training. These nurses must work exclusively in CCS teams

(ii) A specialist physician with an executive position in the hospital, to facilitate necessary co-ordinations among relevant staff (CCS team members, ward heads, nutritionists, physicians and physiotherapists, etc).

(iii) A physiotherapist, for early respiratory interventions

(iv) It is preferablethat the team members work specifically for the team and are not involved with other responsibilities or activities in other parts of hospital.

3. The salary of the critical care team members was paid by TUMS, although, the CCS was not part of Ianian standard care. In the current study an economic evaluation was not carried out, implementing CCS needs allocation of financial resources and medical equipment to hospitals. CCS staff should be provided with some specific facilities and equipment:

    (i) A separate working area should be allocated to the CCS team, and the team be provided with appropriate facilities to receive reports on AIPs.

    (ii) Preferably, the team's work place should be inside the hospital and as close as possible to thenursing offices, to facilitate team members' connection with nursing supervisors.

    (iii) Medical equipment required for the proper working of the CCS team (such as ventilators, infusion pumps, monitors, etc) should

be installed on the wards, in proportion to the number of AIPs admitted.

4. Prior to implementation, the CCS members must be trained in fields such as the objectives, protocols and process of CCS implementation, and effective communication skills with other medical staff.
5. Due to nursing shortage and consequently the lack of adequate time for formal education and training, it is recommended that the ward nurses should be trained by the CCS team members in an informal situation by the bedside of patients.
6. Briefing the top management and the ward staff, and having open discussions with them, prior to the implementation, could decrease obstacles to implementation.

Finally, the results of the current study can led to future research:

1. This study is the first study of CCS implementation and evaluation in Iran. Other research could be conducted after solving the CCS implementation pre-requisites as mentioned in chapter 6.
2. The alarm fatigue should be considered when introducing TTs in Iranian hospitals. In future work other alert tools such as ViEWS can be used. Also, after discussion with staff, an appropriate alert tool could be introduced after evaluation.
3. Adding to the number of hospital beds devoted to intensive care is a priority for Iran's health system and needs funding. However,

implementing CCS may provide the AIPs with better care and lower the costs in ICU.

4. Other investigations are recommended in order to evaluate the cost of CCS implementation. Comparing the cost of ICU-bed establishment and CCS implementation may lead to better decision making for introducing the CCS in Iranian hospitals.
5. This is a need to research in other CCS implementation outcomes i.e. the potential impact of CCS on ICU readmission, recording of patients observations and adverse events (it is notable that finding of chapter 6 demonstrated that during the CCS implementation some medical errors were disclosed).
6. As the implementation of CCS needs changes in routines and behaviours, studies with a longer duration and larger population are recommended.
7. The current study was a single center. To reduce the risk of contamination and biases, multi-center studies are recommended, if CCS are introduced to Iranian hospitals.

APPENDICES

Appendix 1: Ethical clearance approval

Vice Chancellor for Research,
Tehran University of Medical Sciences,
Ghods St., Keshavarz Blvd,
Tehran, 1417653761,
I. R. Iran
Phone: 0098 21 88987381-2
Fax: 0098 21 88987382
Email: resdeputy@tums.ac.ir
Web: www.tums.ac.ir

TUMS

Tehran University of Medical Sciences
Vice Chancellor for Research

In the name of God, the Beneficent, the Merciful

Ethical Clearance Approval

Principal Investigator: Dr Alireza Jeddian

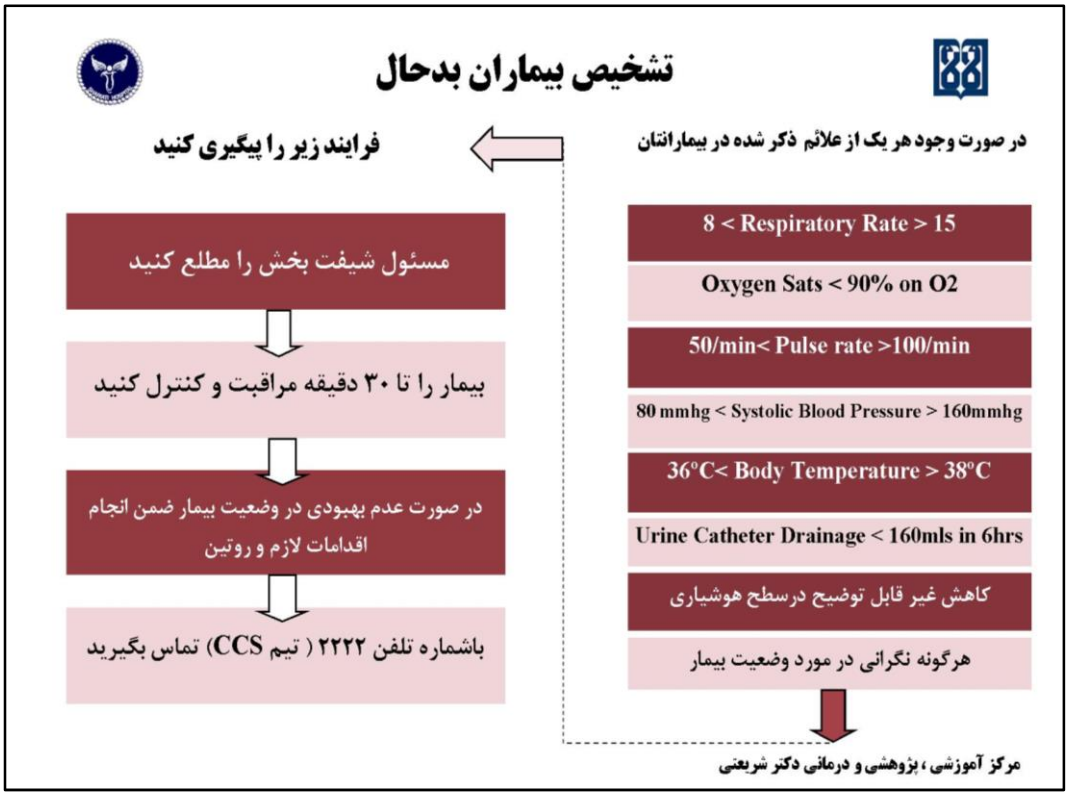
Title of Project: Assessment of effectiveness of Critical Care Outreach System (CCOS)by using Warning Scoring System

Has been approved by the Ethics Committee of Tehran University of Medical Sciences in accordance with Helsinki Declaration and guideline of Iranian Ministry of Health and Medical Education. The project is attached to this certificate.

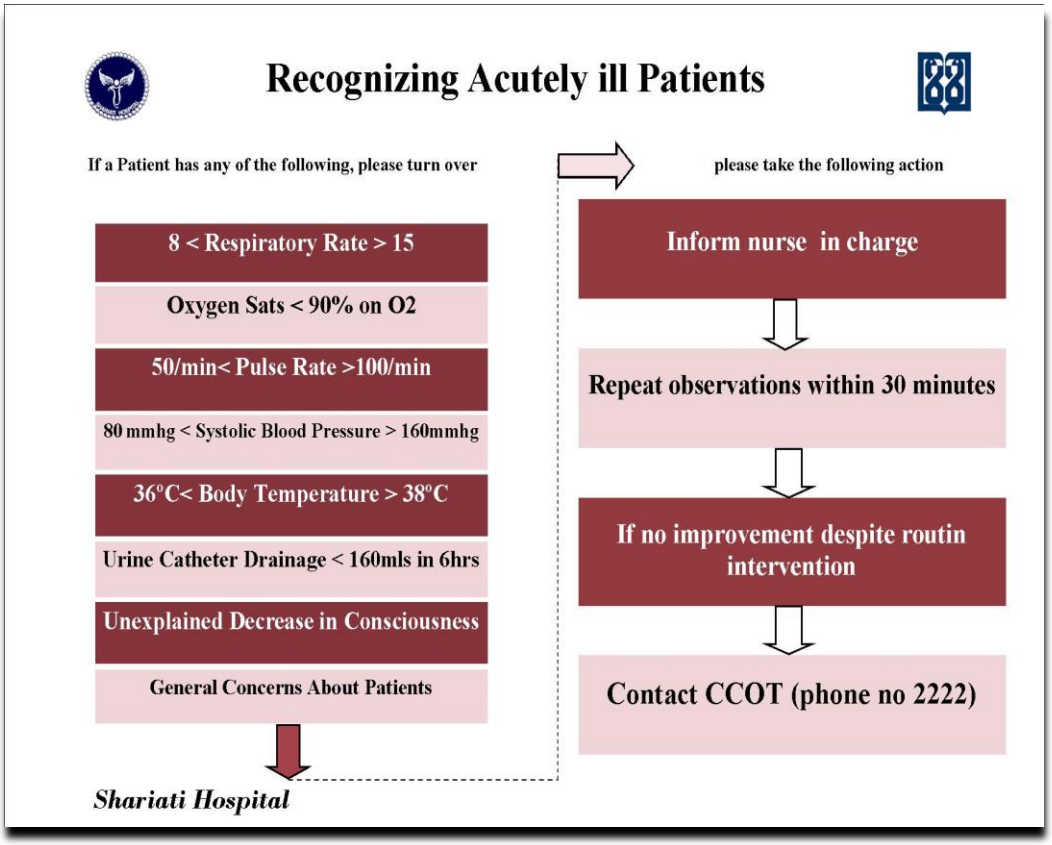
Akbar Fotouhi, MD PhD

General Secretory, Ethics Committee
and Vice Chancellor for Research
Tehran University of Medical Sciences

Appendix 2 : Single parameter system (Persian version)



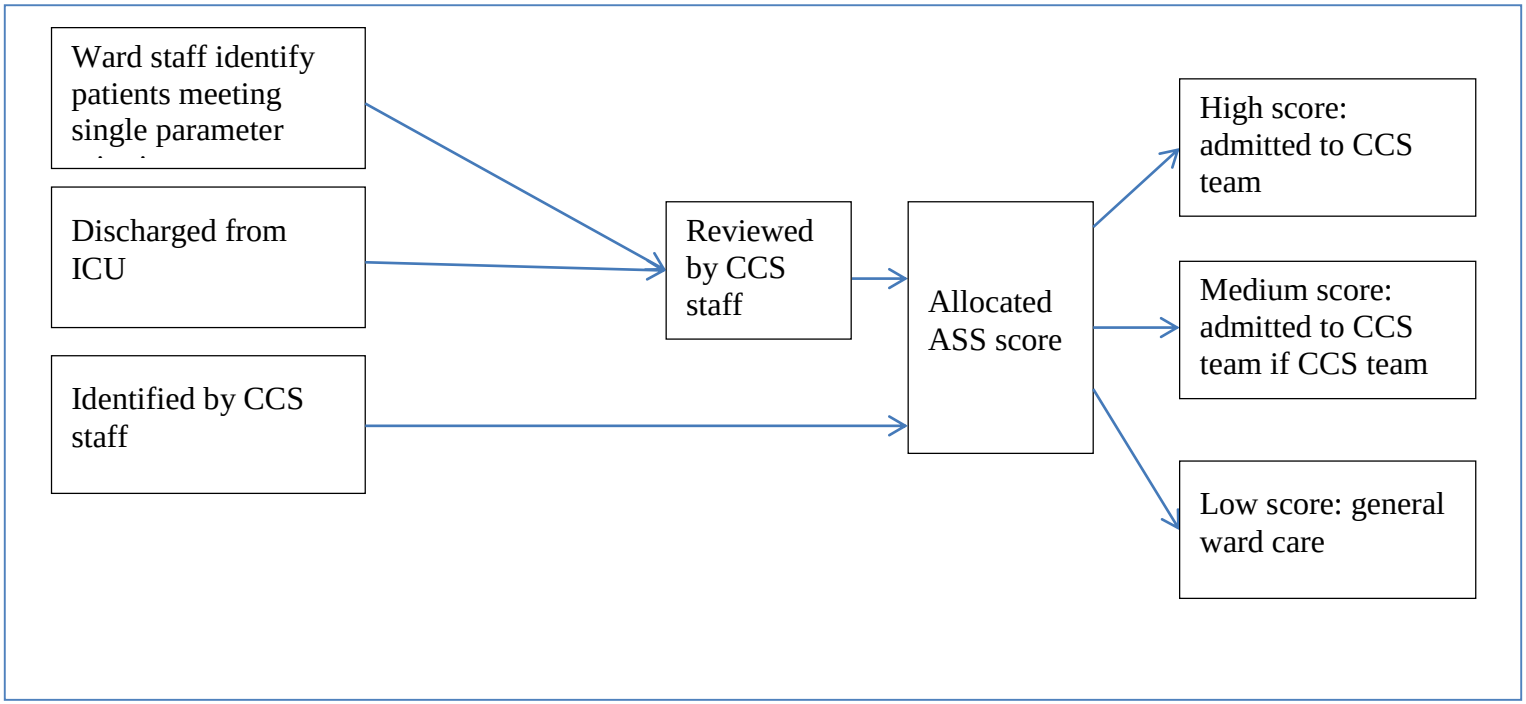
Appendix 3: Single parameter system (English version)



Appendix 4: Aggregated scoring system form

	3	2	1	0	1	2	3	Score
Level of Consciousness				Alert	Responds Only to Voice	Responds Only to Pain	Unresponsive	
Respiratory Rate; Breaths per min		Less than 8		9-14	15-20	21-29	Greater than 30	
Heart Rate; Beats per min		Less than 40	41-50	51-100	101-110	111-129	Greater than 130	
Systolic Blood Pressure(mm hg)	Less than 70	71-80	81-100	101-160	161-199	Greater than 200		
SpO2%	<85%	85-89%	90-94%	≥95%				
Urine Output over 6hours	Less than 120	120-180		Greater than 180				
Temperature °c		35.0<	35.0-35.9	36.0-37.4	37.5-38.4	38.5≥		
Total Score								

Appendix 5: Patient identification



Appendix 6: Key functions of CCS team

Key functions of CCS team:

1. Training being provided on the recognition of AIPs for general wards staff
2. The introduction of and response to physiological TTs in general wards
3. Telephone 'hotline' advice for ward staff
4. Follow-up of patients in general wards after discharge from critical care units and wards
5. Direct bedside clinical support in general wards
6. Audit and evaluation of critical care service activity
7. Delivery of rehabilitation programs for patients after a period of critical illness(15).

In summary, delivering shifts and list of the AIPs, consultations, supervision and direct care, coordination, preparing reports, and running rounds constituted the key functions of CCS team.

Appendix 7: Shariati hospital indicators

WARD		Nurse Number	Inpatient Bed Count	Nurse/Bed Ratio	Admission (Average)	Discharge(Average)	Mortality (Average)		Bed Occupancy Day	Total length of stay	Percentage of bed occupancy (Average)	Average length of hospital	Admission Per Bed	CPR (Total number in 6 months)	Patients in waiting List for Critical care units (Total number in 6 months)	Patients in waiting List who were transferred to our hospital Critical care units (Total Number in 6 months)	Patients in waiting List who were transferred to other hospital Critical care units(Total number in 6 months)	Net Death Rate
Type of Ward	Label						Before 24 hours	After 24hours										
Surgical	Orthopaedics	13	36	0.36	149	128	0	0.8	685	665	61.40%	5.2	4.1	3	4	1	1	0.6
Med - Surge	Pulmonary	16	32	0.5	130	127	0	2	727	727	75.55%	5.6	4.2	27	13	2	0	1.6
Surgical	General Surgery	17	40	0.43	179	175	0	2.8	950	949	76.60%	5.3	4.5	17	4	1	0	1.6
Surgical	Cardiology	15	24	0.63	86	85	0	0.8	617	617	82.90%	7.2	3.6	1	1	1	0	0.9
Surgical	Maxillofacial	10	19	0.53	78	76	0	0	461	461	78.30%	6.2	4.1	3	0	0	0	0
Medical	Medical I	18	36	0.5	136	130	0.4	5.6	1067	1068	95.31%	8.2	4.4	38	35	3	5	4.3
Med - Surge	urology & Nephrology	16	34	0.47	115	104	0	2.4	915	908	87.40%	8.7	3.3	25	18	3	5	2.3
Med - Surge	Obstetrics and Gynaecology	11	22	0.5	174	172	0	0.2	594	593	87.20%	3.5	7.9	2	8	2	1	0.1
Medical	Medical II	15	31	0.45	105	99	0	2	755	752	78.60%	7.4	3.4	49	17	9	2	2.0
Surgical	Neurosurgery	19	44	0.42	376	371	0	0.2	1184	1180	87.30%	3.2	8.6	1	2	0	0	0.1
Med - Surge	General	17	33	0.52	281	269	3.4	9.8	857	858	83.80%	3	8.5	69	75	9	6	3.6
Medical	Haematology& Oncology A	10	12	0.83	23	17	0	3.2	358	355	96.10%	17.4	1.9	14	2	0	0	18.8
Medical	Haematology& Oncology B	10	12	0.83	20	16	0	2.2	338	330	90.80%	19.1	1.7	14	4	0	0	13.8

Appendix 8: More detail predicted risk (of mortality or CPR) based on professional judgment and linear regression

In order to match each ward to a similar ward, and prepare a sorted list of hospital wards to create pairs of study clusters (wards), I followed different methods such as Professional Judgment and analysis of factors associated with risk of main outcomes (predictd risk of mortality & CPR) by linear regression. For professional Judgment, I organized an expert group that was comprised of two nurses and two anaesthesiologists, who were involved with actually ill patients in whole wards and also had sufficient insight into care throughout the hospital. Then the (Appendix 7) was presented to the group and the group was asked to rank the general wards from high risk to low risk based on their opinions and experience. Also, the predicted risk of mortality and CPR were analysed with regression.

Comparison of the two lists of wards, which were sorted with linear regression, showed that the list of predicted risk of mortality is more logical and real, being very similar to the result of professional judgment, unlike the list of predicted risk of CPR. So, thanks to expert team views and my belief in using reasonable statistical methods as a positive point for the survey, the analysis of factors associated with risk of mortality (Predicted risk of mortality) based on linear regression was chosen for matching of wards.

The purpose was to have pairs which were as similar as possible, based on different factors affecting main outcome of interest (mortality). This ensures that at any given point in time, wards with low and high expected risk of mortality have been under the intervention of interest for equal periods of time. A factor analysis was followed based on the variables influencing the evaluated outcome (mortality). The variables in linear regression included:

Variables for Linear Regression

Variables for Linear Regression
Bed Occupancy Rate
Average Length of Stay
Patients in Waiting List for Critical
Discharge and Admission Rates
Number of Beds
Nurse to bed ratio
Mortality
CPR

Appendix 9: Main SAPS II sheet

SAPS II Scoring Sheet (C)

Date: **Time :** **Ward Name:** **Gender:** **Marital State:** **Date of Birth:** **Hospital Document Number:**

Admission Type: (Emergency/Elective) **Primary Diagnosis:** **Final Diagnosis:** **Hospital Service:** **Address:** **Insurance State:**

	26	13	12	11	9	7	6	5	4	3	2	0	1	2	3	4	6	7	8	9	10	12	15	16	17	18
Age , y												<40						40-59				60-69	70-74	75-79		≥ 80
Heart rate , beats/min				<40							40-69	70-119				120-159		≥160								
Systolic BP , mmHg		<70						70-99				100-199		≥200												
Body temperature °C												<39 °			≥ 39°											
Only if ventilated or continuous pulmonary artery pressure Pao2 mm Hg/Fio2[1]				<100	100-199		≥200																			
Pao2 KPa/Fio2				<13.3	13.3-26.5		≥26.6																			
Urinary output L/d				< 0.500					0.500 - 0.999			≥1.000														
Serum urea level, mmol/L (g/L) or Serum urea nitrogen level , mg/dL												<10 (< 0.6) <28					10.0-29.9 (6.0-1.79) 28-83				≥ 30 (≥1.8.0) ≥84					
WBC count (10³/cu mm)			<1.0									1.0-19.9			≥20											
Serum potassium , mmol/d										<3.0		3.0-4.9			≥5.0											
Serum sodium level , mmol/l								<125				125-144	≥ 145													
Serum bicarbonate level ,mEq/l							<15			15-19		≥20														
Bilirubin level , µmol/L (mg/dL)												<68.4 (<4.0)				68.4- 102.5 (4.0-5.9)				≥102.6 (≥6.0)						
Glasgow Coma Score	<6	6-8				9-10		11-13				14-15														
Chronic diseases																				Metastatic cancer	Hematologic malignancy				AIDS [2]	
Type of admission												Scheduled surgical[3]					Medical[4]		Unscheduled surgical[5]							
Sum of points																										
																				Total SAPA II Score		=			**Points**	
																				Risk of Hospital Death		=			**%**	

Definitions for SAPS II

Age: Use the patient's ags (in years) at last birthday

Heart rate: Use the worst value in 24 hours, either low or high heart rate; if it varied from cardiac arrest (11 points) to extreme tachycardia (7 points),assign 11 points.
Systolic blood pressure: Use the same method as for heart rate .e.g., if it varied from 60 mm Hg to 205 mm Hg, assign 13 points.

Body temperature: Use the highest temperature in degrees centigrade or Fahrenheit.

Pao2/Fio2 ratio: if ventilated or continues pulmonary artery pressure, use the lowest value of the ratio.

Urinary output: if the patient is in the intensive care unit for less than 24 hours, make the calculation for 24 hours: e.g., 1 L in 8 hours = 3L in 24 hours.
Serum urea or Serum urea nitrogen level: Use the highest value in mmol/L or g/dL for serum urea, in mg/dL for serum urea nitrogen.

WBC count: Use the worst (high or Low) WBC count according to the scoring sheet.

Serum potassium level: Use the worst (High or Low) value in mmol/L, according to the Scoring sheet.
Serum sodium level: Use the worst (High or Low) value in mmol/L, according to the Scoring sheet.

Serum bicarbonate level: Use the lowest value in mEq/L.

Bilirubin Level: Use the highest value in µmol/L or mg/dL.

Glasgow Coma Score: Use the lowest value; if the patient is sedated, regard the estimated Glasgow Coma Score before sedation.

Type of admission: Unscheduled surgical, Scheduled Surgical, or medical.

AIDS: Yes, if HIV- positive with clinical complications such as Pneumocystic carinii pneumonia, Kaposi's sarcoma, Lymphoma, tuberculosis, or toxoplasma infection.

Hematologic malignancy: yes, if lymphoma, acute Leukemia, or multiple myeloma.

Metastatic cancer: Yes, if proven metastasis by surgery, computed tomographic scan, or any other method.

CCOT Member:
Signature:

Data Entry Code:

[1] Fraction of inspired oxygen
[2] Acquired immunodeficiency syndrome
[3] Patients added to operating room schedule within 24 hours of the operation.
[4] Patients whose surgery was scheduled at least 24 hours in advance.
[5] Patients having no surgery within 1 week of admission to intensive care unit.

Appendix 10: Brief SAPS II sheet

Sheet (A)

Date: **Time:** **Ward Name:** **Gender:** **Marital State:**
Date of Birth: **Hospital Document Number:** **Admission Type: (Emergency/Elective)**
Primary Diagnosis: **Final Diagnosis:** **Hospital Service:**
Address: **Insurance State:**

	Variable	point			
1	Age , y				
2	Heart rate , beats/min				
3	Systolic BP , mmHg				
4	Body temperature °C				
5	Breath rate				
6	Only if ventilated or continuous pulmonary artery pressure Pao2 mm Hg/Fio2[1]				
7	Urinary output L/d				
8	Serum urea level, mmol/L (g/L) or Serum urea nitrogen level , mg/dL				
9	WBC count (10^3/cu mm)				
10	Serum potassium , mmol/d				
11	Serum sodium level , mmol/l				
12	Serum bicarbonate level ,mEq/l				
13	Bilirubin level , µmol/L (mg/dL)				
14	Glasgow Coma Score				
15	Type of admission	Medical		Surgical	
		Emergency	Elective	Emergency	Elective
16	Chronic diseases: □DM □Asthema □COPD □MI □CVA □ CCU Admission □ AIDS □Metastatic cancer □Hematologic malignancy				

CCOT Member: **Data Entry Code:**

Signature:

[1] Fraction of inspired oxygen

Appendix 11: Adverse event sheet

Sheet (B)

Adverse Event

Date:	**Time:**
Ward:	
Gender:	**Date of Birth:**
Hospital Document Number:	**Admission Service:**
Primary Diagnosis:	**Final Diagnosis:**

Adverse Event:

- ☐ **MI**
- ☐ **CVA**
- ☐ **CPR related to :**
  - ○**Cardiac Arrest** ○**Respiratory Arrest**
- ☐ **D.C**

Notes:

- ☐ **Admission to Intensive Care**
- ☐ **Readmission to Intensive Care**

CCOT Nurse: **Signature:**

Appendix 12 : Critical care outreach sheet A

CRITICAL CARE OUTREACH SHEET

تاریخ : ساعت:

نام و نام خانوادگی : شماره پرونده :

تشخیص : تعداد دفعات تماس تلفنی با CCOT:

فرد ارجاع دهنده :

- پرستار بخش□
- پرستارCCOT □
- سایرین : اینترن□ رزیدنت□ استاد□ همراه بیمار□ خدمات□

Score :

مداخلات اولیه :

پیامدهای مداخله تیم CCOT :

□False call

□بیمار مشکل خاصی ندارد، با پرستار در رابطه با بیمار صحبت شد.

□نکات مراقبتی به پرستاران توضیح داده شد و قرار شد نحوه care تغییر کند.

□بیمار نیازمند به انتقال به ICU می‌باشد.

□بیمار در سرویس CCOT قرا گرفت.

□فوت

تاریخ مرور امضاء یا مهر CCOT

Appendix 13 : Critical care outreach sheet B

CRITICAL CARE OUTREACH SHEET

تاریخ	ساعت	علت اطلاع به CCOT	زمان حضور بر بالین بیمار	زمان ترک بالین بیمار	وضعیت بیمار	مداخلات	گزارشات (نتایج بعد از مداخلات)	موارد قابل پیگیری	نام و نام خانوادگی عضو CCOT- امضاء

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