

Development of ABCDEF Bundle for Improving Outcomes of ICU Patients

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Abstract

Introduction: The ICU liberation campaign helping improve quality of intensive care and reduces post-intensive care syndromes through the release of ABCDEF bundle, which utilizes an interprofessional approach. Evidence has shown barriers to proper bundle implementation (such as complexity and multiplicity of bundle interventions, limited bundle understanding by staff, poor interprofessional collaboration, shortage of staff) may play an important role. A multistage study was conducted to localize the ABCDEF bundle.

Methods: Firstly, the ABCDEF bundle was translated into Persian using the WHO protocol. The initial Persian translation was performed by both a nonmedical and medical individual. After combining and enhancing the translations, it was transformed into a checklist comprising 6 elements and 53 items, which were directed to experts to evaluate its face validity and qualitative content validity. After adjustment, the first expert panel validated the checklist, and a 5-point Likert rating system for assessment of importance, relevance, and feasibility were scored by them. Based on the results of descriptive analysis by SPSS, the experts' consensus led to elimination of one item and inclusion of other 52 items. Next, the second expert panel was held.

Results: The final ABCDEF bundle was prepared with 52 items and, the plan, the proper time and implement responsible, for its management is proposed.

Conclusions: Due to absence of the Iranian version of the ABCDEF bundle, our study provided a fluent and eloquent translation, to be both comprehensible and practical for the intensive care team members. The expert panel's opinion, adapted the bundle for implementation in the ICUs of Iran. We recommend that the localized ABCDEF bundle be implemented in specialized intensive fields (such as medical, surgical, trauma, etc). The contents of the bundle could not only be incorporated into ongoing training of staff, but also into the curriculum of undergraduates and medical residents.

Keywords: Post-Intensive Care Syndromes, Implementation, Barriers, Delirium, Pain, Early Mobilization, Family Engagement.

Introduction

Development of ICUs and intensive care medicine have improved the quality of intensive care in recent years. Despite this improvement, the mortality rate is 20-43% in critically ill patients,¹ and post-intensive care syndromes (PICS) are highly prevalent in ICU survivors as a real, developing and deteriorating issue.

² PICS consists of a neurologically heterogeneous complex of impairments observed in critically ill

patients after treatment in an ICU.³ The syndrome is characterized by new onset or increased impairments of physical cognitive, and/or psychological functions that outlast the stay in hospital. Some of these complications (PICS) including delirium, prolonged mechanical ventilation and ICU acquired weakness syndrome, can result in in poor quality of care, patient safety, and higher mortality.^{4,5} One of the key aspects of intensive

care is the rapid assessment of life threatening events and timely life-saving interventions, which are essential and best practices for critically ill patients.⁶ Also, due to the complexity of situation, single interventions are not very promising, so bundles of care are considered for improving the patient's outcomes as well as minimizing PICS.⁷

ICU liberation campaign as a fundamental component of the intensive care philosophy, suggests a systematic bundle with interprofessional approaches aimed to improve the quality of care.⁸ The ABCDEF bundle is designed based on existing care bundles and comprises of a set of six elements using an evidence-based approach.⁹⁻¹¹ This interprofessional, structured strategy helps improve the intensive care processes and patient outcomes, based on the recommendations of the PADIS (Pain, Agitation/Sedation, Delirium, Immobility, Sleep Disruption) guidelines.^{12,13} The ABCDEF bundle elements represent a small set of evidence-based assessments that lead to interventions.¹⁴⁻¹⁶ The elements of this bundle, include element A, assessing, preventing and managing pain, element B, both spontaneous awakening and breathing trial, element C, choose the most proper medication for analgesia and sedation, element D, assessing, preventing and managing delirium, element E, early mobilization, and finally element F, family engagement, which can have a role in preventing PICS.^{17,18}

Sweeny and colleagues suggested the possibility of delirium reduction through adherence to the ABCDEF bundle. They also acknowledged that successful implementation of the bundle requires strong organizational support from managers and leaders.¹⁹ Study of Chai and colleagues indicated that there was a lower incidence of delirium and a shorter ICU length of stay (LOS) associated with the ABCDEF bundle implementation compared to the control group.¹³ Further, intensive care costs are reduced due to the reduction of ICU LOS and long-term PICS.^{20,21} Despite some evidence supporting the safety and effectiveness of ABCDEF bundle implementation, limited understanding of the bundle and its components by intensive care members (ICTMs)^{8,22,23} as well as poor interprofessional coordination appear to be obstacles to the proper implementation of the bundle.²⁴

The other barriers for implementation of the ABCDEF bundle are getting stuck in daily routine care, inappropriate organizational culture (general, critical

care, and patient safety), lack of interprofessional education and coordination, shortage and excessive Interdepartmental transfer of staff, long work shifts, over-documentation, inappropriate physical environment, and lack of proper medical equipment.^{4,8,12,25-27} Additionally, it is important to highlight the complexity and diversity of the bundle interventions, as well as the limited understanding of its components by the ICTMs.¹⁷ The intricate and multifaceted nature of the bundle elements, as well as the numerous references to the PADIS bundle, seem to indicate the absence of a concise and clear clinical guideline for ICTMs that is in line with the Iranian intensive care culture. As such, strategies should be considered for timely publishing, updating, and implementing clinical guidelines (such as care bundles) in order to reduce the complexity and ambiguities for implementers based on clinical conditions.²⁸ Hence, the present study aimed to generate the Iranian ABCDEF bundle to enhance ICU patient's outcomes.

Methods

The present study was conducted from November 2022 to March 2023 at the Baqiyatallah Hospital in Tehran, Iran, in a multi-stage manner involving bundle translation, assessment of face and content validity, and finally localization and generating the implementing bundle. In the first stage, after signing up on the website of the Society of Critical Care Medicine (SCCM), the updated ABCDEF bundle was downloaded from this website and translated into Persian based on the World Health Organization protocol. The initial translation into Persian was done by both a non-medical (master's degree in music) and a medical person (Master of Nursing). After combining two Persian translations together and editing it, the revised Persian translation was forwarded to the experts that (include ICTMs). In the next step, revised Persian translation was converted into a checklist containing 6 elements and 53 items.

Element A (assessment, prevention and management of pain) contained 11 items, Element B (both spontaneous awakening and spontaneous breathing trial) had 7 items, Element C (choosing appropriate analgesics and sedatives) had 1 item, D element (assessment, prevention and management of delirium) consisted of 17 items, element E (early mobilization) had 12 items, and finally the element F (family engagement) had 5 items,

which in terms of feasibility, importance and relevance, were columned from 0 to 4 in the form of a 5-part Likert scale.

Along this phase, the experts were asked to provide their corrective perspectives after studying the checklist, in order to establish the face validity of the checklist. In this regard, the level of difficulty (recognition of items, expressions or words that are difficult to understand) and the degree of appropriateness (accuracy in the appropriateness and relationship of the items) as well as ambiguity (checking the existence of wrong perceptions of the expressions of the items or the existence of insufficiency in the meanings of words) were evaluated. Furthermore, the qualitative content validity was examined by assessing the level of grammar compliance, using relevant words, placing items in their proper place.

Subsequently, during this phase, an expert panel was convened with the participation of 18 members of intensive care team, as follow:

Table 1: Characteristics of the participants (expert panel)

Gender n (%)	
Male	16 (88.9%)
Female	2 (11.2%)
Position n (%)	
Nursing PhD	6 (33.4%)
Nursing Bachelor	2 (11.2%)
Physiotherapist	1 (5.6%)
Intensivist	4 (22.3%)
Pain Fellowship	1 (5.6%)
Toxicologist	1 (5.6%)
Pharmacotherapist	2 (11.2%)
Psychiatrist	1 (5.6%)

During the panel, the ABCDEF bundle elements were presented through a PowerPoint presentation, followed by discussions regarding each element of the bundle

and its associated items. The research team recorded the opinions of the experts, and at the same time, the comments were taken with the bundle checklist scored. The bundle checklists were also taken from them after recording the comments and scoring. The research team reviewed and applied the corrections written in the checklists with the view of further enhancing item fluency and facilitate the perception by participants and implementers. Ultimately, the checklists' data were entered into SPSS software (v. 24.0), and a descriptive statistics analysis of weighting items was conducted. The items with mean scores of importance, relevance, and feasibility of at least 3 were retained and considered to be important, relevant, and feasible. Then after one month, the second expert panel was held to determine the steps, time and responsible of implementations for each element as well as compiled in the final format of the implementation steps table.

Results

After weighing the various elements of the bundle and evaluating their significance by the experts, the 16th item in element D, namely the recommendation against utilizing light therapy to reduce delirium in critically ill patients, received an average score of 2.98. The experts' consensus led to the removal of an item and the inclusion of other 52 items, which were considered important, relevant and feasible. Based on the results of descriptive analysis by SPSS (v. 24.0), the localized ABCDEF bundle was formed.

Table 2: Implementation Steps of the ABCDEF bundle.

Row	Implementation Steps	Implement time	Implement responsible
Element A			
1	Measuring the pain intensity with CPOT/VAS 3 times a day for 3 days and record it in the patient data collection form.	8-16-24	Physician/ Nurse
2	Relaxation and distraction techniques, informing (about place and time) and education, massage and touch therapy, and music therapy could be implemented.		
3	For adult intubated adult patients in the ICU, the first line of pain treatment is intravenous infusion of fentanyl at a dose of 0.7-10 mcg/kg/hr or morphine at a dose of 2-30mg/hr.		
4	Acetaminophen can be taken orally, intravenously, or rectal (up to 4 grams per 24 hours) along with opioids.		
5	Ketamine should be given as an infusion at a dose of 1-2 mcg/kg/min with opiates		
6	Gabapentin or carbamazepine should be prescribed in addition to intravenous narcotics in neuropathic pain.		
7	A thoracic epidural block should be performed in patients who have had thoracic surgery or a chest trauma.		
Element B			
1	The patient should be assessed using Richmond Agitation Sedation Scale (RASS)	8-16-24	Nurse
2	If the patient received sedation and had a score lower than the range of 0 and -1, the dose of sedatives should be adjusted so that the patient is more awake and the RASS score reaches the range between 0 and -1.		Physician
3	If the patient meets the SAT (spontaneous awakening trial) inclusion criteria, such as: no seizures, alcohol deprivation, agitation, myocardial ischemia, Not taking muscle relaxant drugs, or normal ICP, SAT should be tried once a day.	9	Physician/ Nurse
4	Stopping the sedative infusion for two hours.	9	
5	If there is no evidence of anxiety, agitation, pain, RR>35, Spo2<88%, Fio2>50%, Peep>7.5cmH2o, cardiac dysrhythmia, or respiratory distress, one may proceed to the SBT (spontaneous breathing trials) stage by employing one of the following strategies: 1) T Piece Trial: Oxygen flow is established through T Piece connected to the tracheal tube or trachostomy tube for half to two hours. 2) CPAP Trial: CPAP adjustment equal to PEEP should be done for half to two hours. 3) Pressure Support: Adjust Pressure Support equal to 5 to 8 cmH20 along with invasive ventilation for half to two hours.	11	
6	If SBT is successful, the patient can be considered for extubation in absence of anxiety, agitation, pain, RR>35, Spo2<88%, Fio2>50%, Peep>7.5cmH2o and cardiac dysrhythmia and respiratory distress.		
7	In the event of failure of SBT (anxiety, restlessness, pain, RR>35, Spo2<88%, Fio2>50%, Peep>7.5cmH2o, and cardiac dysrhythmia and respiratory distress), sedative infusion may be administered for a duration of up to 24 hours, with a half of the previous dose and with full mechanical ventilation support.		
Element C			
1	According to the PADIS guidelines, a safe and effective drug regimen for the management of pain and agitation in critically ill adults should be prescribed.		Physician/ Pharmacist
Element D			
1	These items should be considered by physicians to help them better manage delirium: 1. Some modifiable risk factors of delirium include transfusion of blood products, administration of benzodiazepines. 2. Old age, dementia, history of previous coma, recent trauma or emergent surgery, high Apache score and electrolyte imbalances are some of the non-modifiable factors. 3. Not using haloperidol and atypical antipsychotics, dexmedetomidine, statins, and ketamine to prevent and treat delirium in critically ill ICU patients. 4. It preferred to prescribe dexmedetomidine instead of benzodiazepines for patients who were agitated.		Physician/ Pharmacist
2	Three times a day, check the patient with cam-icu for delirium.	8-16-24	Nurse

3	Stopping or reducing medications that increase the likelihood of delirium (for example, benzodiazepines) if possible.		Physician/ Pharmacist
4	As soon as possible, start and take the patients out of the bed at least once a day.	10-11	Physiotherapist
5	Every three hours, change the patient's position.		Nurse
6	Patients with sensory deprivation should have assistive devices, such as glasses and hearing aids, during the day.		
7	It is imperative to regulate ambient noise, including but not limited to the noise of personnel and ICU devices.		
8	During bedtime, ambient light should be reduced by turning off extra lamps.	23 to 6	
9	In order to improve the patient's sleep, It's important to schedule the painful care, medication, blood sampling, and visits.	23 to 6	
10	Patients should have face-to-face and physical contact with their families, and if necessary, family participation in patient care.	16	
11	All caregivers focus to increase the level of knowledge and awareness of patients about the time, date, and place where they are present.		All ICTMs
12	As much as possible, the patient's favorite music or the sound of the Qur'an should be played during the ICU stay.		Nurse
Element E			
1	Step 1: The inclusion criteria for early mobilization are: 1) The hemodynamic stability without the need for high doses of vasopressors. 2) Breathing spontaneously without the need for mechanical ventilation (Fio2> 80% or PEEP> 12 mmHg or severe respiratory failure) 3) No recent acute neurological event (eg, CVA, SAH, ICH) has occurred. 4) The patient is responsive to verbal stimuli and, and does not have fractured and unstable spine and extremities. 5) Not a patient who is dying. 6) An open abdomen patient or at risk of evisceration is not a candidate.	10	Physician
2	Step 2: involves the assessment of the patients' activity history. How has the patients' activity been over the past two hours, two days, two weeks, two months, and two years?		Physiotherapist
3	Step 3: Assessing the patients' strength. The ability to lift the legs from the bed and bear weight on the legs is important		
4	Step 4: Evaluating the patient's capacity to participate and adhere to instructions.		
5	According to the condition of the patient and the strength of the ward, once a day at 10 o'clock, move out of bed according to the steps below. Step 1: Remove the patient's physical restraint and secure the monitor cables, patient tubes, and connections. Step 2: Commence physical activity in bed concurrently with the monitoring. Step 3: Place the patient on the edge of the bed and assess their pain and orthostatic blood pressure. Step 4: Getting the patient to stand up. Step 5: Begin walking by keeping the chair close and asking for help from other team members to move the chair and keep the veins open. Step 6: Sit down and rest the patient if needed.	10-11	
6	If the patient is unresponsive, tired, pale, tachypneic, muscular atonic, imbalanced, cannot bear weight, or sweats, stop and rest the patient.		
7	If the patient is unable to out of bed, it is recommended that active or passive movements in the range of motion of the joints be performed within the confines of the bed.		
Element F			
1	Patient-centered care is provided with utmost respect and consideration for the patient's preferences, needs, and individual values, ensuring that all clinical decisions are guided by the patient's values.		All ICTMs
2	Family presence in the ICU should be scheduled with open and flexible meeting hours.	16	Nurse
3	Establishing daily sessions with the family to provide an explanation of the condition and its progression during the hours of face-to-face meetings.	15	Physician
4	Engaging with family members by involving them in the decision-making.	15	Physician/ Nurse
5	Following intensive care, the empowerment of family members to continue the patients' care first in the medical ward and then at home.	15	Physician/ Nurse

Discussion

This study was conducted with the aim of localizing the ABCDEF bundle within Iran's health system. The bundle converted into Persian, to provide a fluent and eloquent translation of the bundle, to be both comprehensible and practical for the ICTMs as well as the implementation steps presented with the time and responsible staff for implementation.

This is despite the fact that the implementation of the ABCDEF bundle not only reduces the likelihood of hospital mortality within 7 days by 68%, shortens delirium days and coma by 25-50%, the utilization of physical restraint by more than 60%, and the ICU readmission by half, but there is also evidence that incomplete implementation of the bundle elements can reduce PICS.^{17, 29}

Acute pain in association with the other PICS, such as anxiety, sleep disorders, post-traumatic stress and chronic pain, can disrupt and complicate the healing process of acute diseases. Researchers found that 33% of ICU patients experienced pain while resting and 56% during routine procedures.³⁰ In element A, which pertains to pain assessment and management, two implementation steps are enacted, which entail measuring pain intensity with CPOT/VAS, three times a day, employing relaxation or distraction techniques, informing the patients (about place and time) and education, and utilizing massage, touch, and music therapy could be implemented. Considering the detrimental effects of deep sedation on patient outcomes, providing adequate sedation, maintaining comfort, reducing pain, and minimizing agitation and delirium are the main priorities of ICTMs.³¹ Hence, with regard to element C, which adult pertains to the prescription of a safe and effective drug regimen for the management of pain and delirium, in accordance with the PADIS, there is an overlap of pain and delirium management (A and D elements), which is attributed to the significance of managing these two adverse consequences of intensive care in the deterioration of the patient's condition. It is therefore understandable to emphasize their importance.

Element B implementation steps are particularly complicated due to the difficulty of SBT in medical ICU patients. Evidence suggests that many patients who successfully complete the SAT and SBT steps are not

extubated at the same day.³² Because of this complexity, SAT starts from the assessment of sedation with RASS. If the patient received sedation and had a score below the range of 0 and -1, the dose of sedatives should be adjusted so that the patient is more awake, and the RASS reaches the range between 0 and -1. The patient should meet the criteria for SAT (Table 2). Sedative infusion should be interrupted for two hours. As long as the SBT criteria are met, one of the standard strategies should be used to try to SBT. If the patient is able to tolerate one of the standard SBT strategies for a duration of 30 to 120 minutes, SBT is deemed successful and extubation will be considered. Nevertheless, in medical ICU patients, the decision to extubate after a successful SBT is complicated, and probably there will be no other consequence than re-intubation after hasty extubation. In the event of unsuccessful SBT, sedative infusion may be continued for a duration of up to 24 hours, with a half of the previous dose and complete ventilator support.

There are a variety of medical conditions responsible for delirium, including neuroinflammatory processes, cerebrovascular dysfunction, brain metabolism changes, neurotransmitter imbalances, and even intestinal microbiota imbalance. Unfortunately, delirium is largely invisible to medical professionals and is overlooked 75% of the time.³³ The delirium measurement is performed three times a day, by a trained intensive nurse using a valid and reliable CAM-ICU scale on a daily basis. It is imperative that the patient is promptly woken up and ambulated from their bed at least once a day. The steps for delirium assessment, prevention and management are outlined in Table 2 in a clear and comprehensible manner. Considering the extensive evidence on the impact of delirium management on reducing mortality and ICU stay in various clinical conditions,^{34,35} it is hoped that through the implementation of these steps, and in conjunction with the reduction of delirium, the duration of ICU stay and mortality will also decrease.

The early mobilization of patients in intensive care is important as it facilitates physical recovery and minimizes the emergence of immobility-related PICS, such as ICU-acquired weakness.³⁶ It can be defined as: "the application of traditional modes of physiotherapy at an earlier stage than and delivered more regularly than conventional practice".³⁷ Further,

improving physical mobility is widely considered the most challenging part of intensive care transformation, as it involves the most dramatic change in culture and daily processes. Note that the enhancement of physical mobility is accompanied by a decline in sedation in a natural progression: heightened patient activity necessitates patient vigilance and interaction, rather than sedation. Also significant reduction in the exposure to sedatives and analgesics results in diminished mechanical ventilation, hospital and ICU LOS, as well as mortality rate.⁴

Since the implementation of element E requires a sufficient number of staff, so the ideal time for assessment and interventions were considered to be in the morning. As we should contemplate the inclusion and exclusion criteria and the implementing steps outlined in Table 2, it is imperative to remember, if the patient is unable to get out of bed, it is recommended that active or passive movements in the joint's range of motion must be performed within the confines of the bed. As Lang and colleagues emphasized, protocolized approach as a significant prerequisite of ICU patient's early mobilization, should be implemented in a developmental process. Furthermore, one of the facilitating factors in this process can be patient's and family engagement.³⁸

Family engagement in ICU is defined as a proactive collaboration between ICTMs and families purposed to enhancing patient outcomes, safety and quality of intensive care. It can involve the implementation of procedures to maintain communication, values, and enhance the respect and dignity of patients and family.^{39,40} Based on the experts recommendations and in accordance with the meeting schedule of the hospital, the implementation timeframe for element F steps was determined to be in the evening as table 2.

Participation in clinical decisions, scheduling open and flexible meetings to explain the patients' condition and disease progress, and empowering the significant family members to continue the patients' care are emphasized by some evidence.^{10,14,36,39-41} One of the challenging dimensions of family engagement in ICU is patient's family presence during CPR, which is less experienced by ICTMs compared to other specialized fields such as the emergency department. In this regards, colleagues indicated ICTMs may feel a threat from the patient's family presence during CPR, which is likely to diminish this feeling if they increase their contact with the

patient's family during CPR 42.

Conclusion

Studies have been conducted to improve the outcomes of ICU patients using the ABCDEF bundle, the results show complexity and multiplicity of bundle elements as the most significant barriers in implementation. Some of the other obstacles are mentioned for instance, Inopportune organizational culture, lack of interprofessional education and coordination, improper comprehension of the bundle elements by implementers, few and novice staff, long work shifts, inappropriate physical environment and medical equipment.

Due to the lack of an Iranian version of ABCDEF bundle, we tried to provide a fluent and expressive Persian translation of this bundle in the first step, which was easy to understand and use by the ICTMs. After obtaining the opinions of experts, this bundle was adapted for implementation in the ICUs of Iran. Ultimately, the executive steps including the times of interventions and the staff responsible for implementing each element were presented.

A recommendation for further studies can be implementation of the Persian version of ABCDEF bundle in the specialized fields of medical ICU, trauma, surgical ICU, etc., assessing the implementation barriers and, if necessary, implementing novel management and leadership strategies to encourage staff participation and enhance interprofessional coordination as well as multidisciplinary rounds. This bundle could be included in the ongoing staff training, including physicians, nurses, and rehabilitation specialists, and even as a part of the course plans of undergraduate students and medical residents.

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Conflict of Interest Disclosures

There is no conflict of interests among the contributing authors of the current study.

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Authors' Contributions

STM, AE, and JMN were responsible for study design, supervising study implementation, and providing methodological support. RJ and STM wrote the manuscript. STM, JMN, RJ, and ABF participated in the coordination and organizing the expert sessions. All authors have thoroughly reviewed and given their approval to this final manuscript.

Ethical Statement

This study licensed by the Research Ethics Committee of Baqiyatallah University of Medical Sciences with IR number. BMSU. BAQ. REC.1401.051 was performed, and informed written consent was obtained from the study participants.

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