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Implementing SPADE Protocol (Save Patient from Pain, Agitation and Delirium, Execution Protocol) to Decrease the Incidence of ICU Delirium

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1. Abstract

This is a proposal for a multidimensional, multidisciplinary protocol pathway model that was dubbed SPADE. Due to pain, agitation, delirium magnitude (PAD) and its effect in intensive care on mechanically ventilated patients, it is recommended that intensive care units should have a standardized approach for PAD for early identification, prevention, and management. The protocol SPADE is driven from evidence-based guidelines and recommendation.

The clinical pathway model needs to incorporate a clinical information management system and educational materials to increase and improve the medical service provided to patients.

The implementation should be scalable and with the potential for sustainability so that it can be adopted by other departments.

2. Background

Delirium is a disorder characterized by acute brain dysfunction that manifests as a disturbance in attention, awareness, cognition, and a difficulty in orientation with the surrounding environment [1]. The prevalence of delirium in critical care patients was reported to be overall 30% but in sedated ventilated patients it reached to 60-80%, after exclusion of postoperative cases that have undergone major elective surgeries [2-4]. It is also worth noting that patients present in critical care are subjected to numerous painful procedures where around 75% of patients reported severe pain, 30% reported pain at rest and 50% reported pain during nursing procedures [5]. Unfortunately, due to the difficulties in assessing and by so controlling pain, it is often overlooked [5]. In 2018, the American College of Critical care Medicine released guidelines for the management of PAD Immobility, and Sleep Disruption in adult patients in the ICU. [6] These guidelines have shown the importance of adopting standardized assessment tools, early intervention to maintain patient safety and well-being [6,7]. However, reports showed lack of adherence to previous protocols dealing with PAD with percentages as low as 60% of ICUs in the United States [8].

3. Rationale

The reason for adopting this protocol is that delirium is often associated with agitation that may lead to the risk of the patient pulling their endotracheal tubes, lines, etc. That may endanger their lives and might expose their healthcare providers to the risk of injury. Patients diagnosed with delirium impose a load on the health system as they usually need intensive monitoring, polypharmacy resources, increased length of ICU and hospital stays [7,8]. Although there is still no established direct relationship between delirium and mortality, critically ill patients who develop delirium are up to three times more likely to die within 6 months than those who do not [8-10]. Determining patients with risk factors to develop delirium is of paramount importance. Risk factors as old age, severe illness, dementia, vision or hearing impairments, physical frailty, alcohol consumption, and the effect of different drugs interaction should be noted. Accordingly, patients should be triaged [11,12].

Data about the interventions used in literature showed different approaches but none alone showed significant difference in outcome and that was the reason for combining different pharmacological and non-pharmacological interventions in this protocol [13].

4. Charter

Problem statement: PAD cause significant morbidity, mortality and increased LOS in hospitalized patients especially the mechanical ventilated ones which directly impacts their safety and quality of care. Aim Statement: The primary aim is to decrease the incidence of pain, agitation, and delirium by 20% in mechanically ventilated patients over one year by implementing the SPADE protocol. The secondary aim**:** is to develop a process that helps embedding the program in the ICU culture and to keep measuring and updating it through continuous Plan, Do, Study and Act (PDSA) cycles and using an integrated clinical decision system (CDS) Target population: critical care mechanically ventilated patients with exclusion of traumatic brain injury patients, patients with brain tumor and patients who already on antipsychotic medication. Decision support tools: Behavior pain scale for pain, Richmond Agitation-Sedation Scale, and the Confusion Assessment Method in the ICU scales for agitation and delirium will be used to help in guiding the degree of intervention and measuring the outcome.

4.1. Workflow Tools: SPADE Protocol

Clinical information management system: Electronic medical system, medication alert system, and dashboard for tracking metrics.

Outcome metrics: ICU, hospital length of stay, ventilator free days, and mortality measurements will be used as secondary outcomes to help monitoring the degree of progress or regress of the intervention.

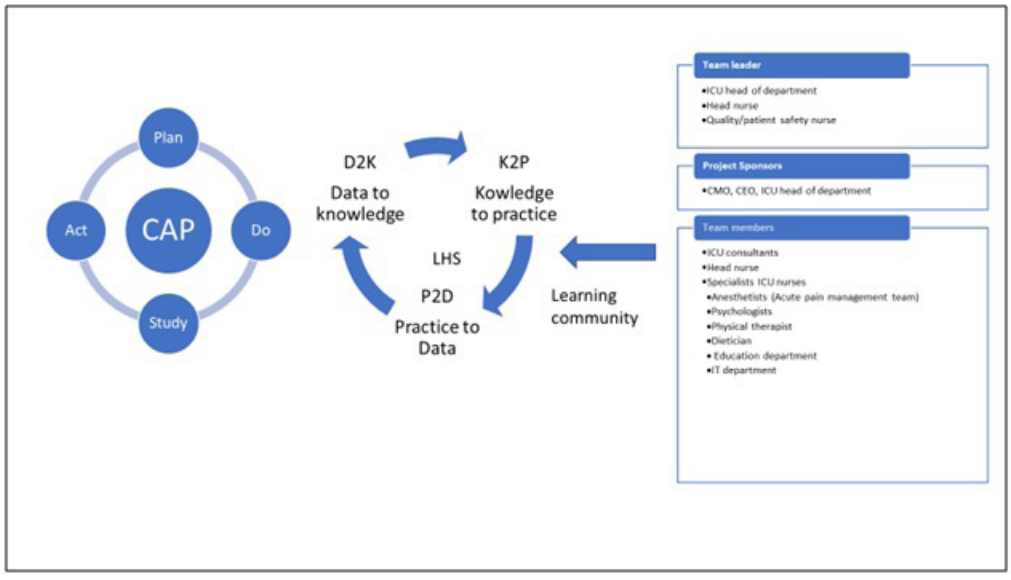
This project will focus on hardwiring and standardization of SPADE protocol, a multidimensional multidisciplinary protocol involving pharmacological and non- pharmacological interventions to prevent and decrease the incidence of pain, agitation, and delirium.

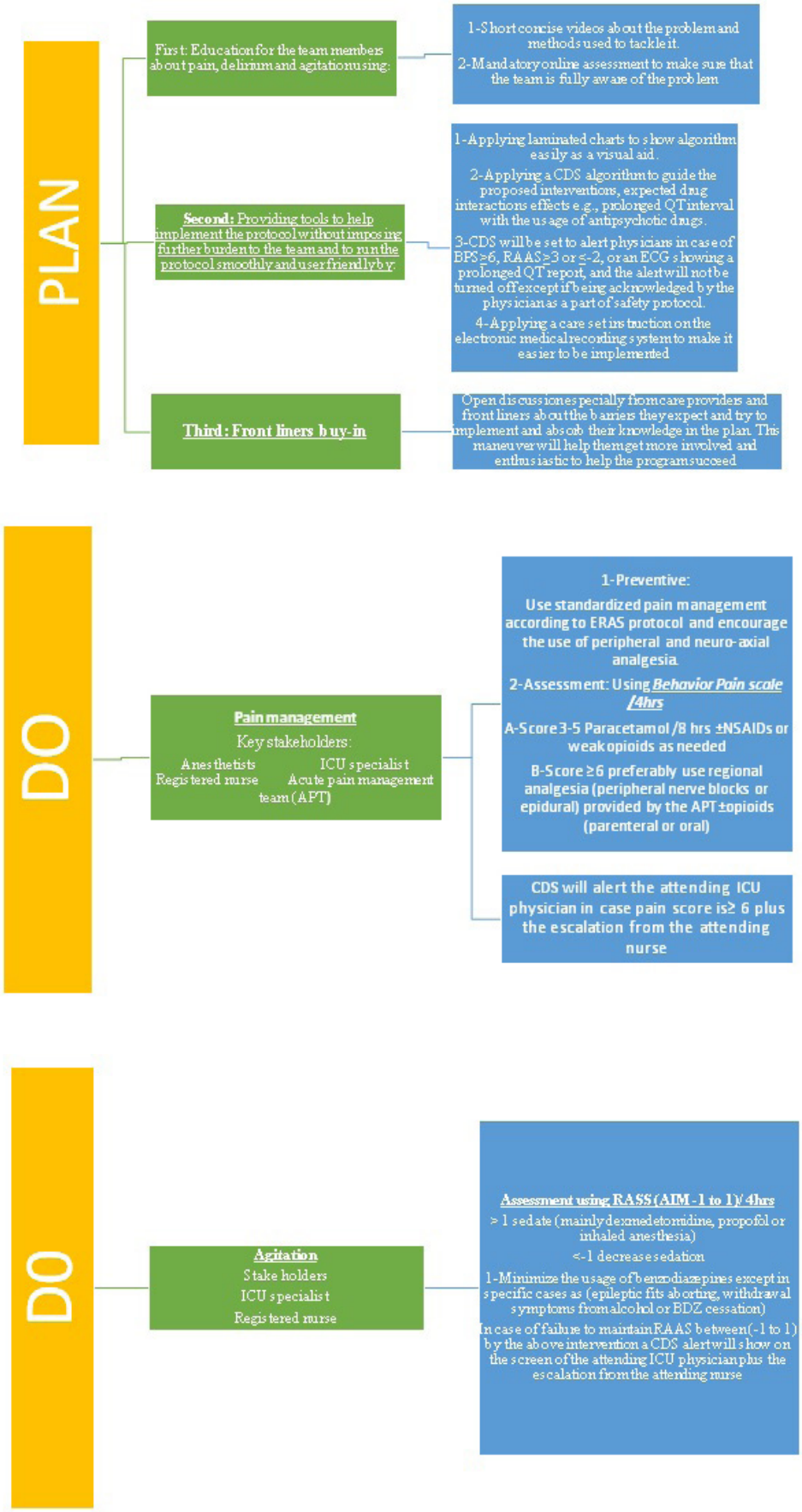
5. Learning Health System (LHS) And PDSA (Plan, DO, Study, Act) Cycles

5.1. The Process Starts by Building the LHS and That Starts by the Following Steps:

1-Learning community (sponsors, team leaders and team members) (Figure 1)

2-Practice to data P2D where data are collected showing the real process inside the ICU regarding the prevalence rate of PAD in the ICU, defining if there is a standardized assessment tool, LOS and ventilator free days. A survey questionnaire for the team involved in the project to detect their degree of recognition of the problem, how far they deal with the cases, and if there is a protocol to deal with the PAD problem. 3-Data to knowledge D2K will follow and that includes: Collecting data about the prevalence of delirium in other ICU departments, data from literature about the prevalence worldwide, data about different interventions to decrease the incidence of PAD, rate of success and outcome measures, and the resources needed will be collected and analyzed. 4-Knowledge to Practice: In this stage a series of PDSA cycles will be implemented to gauge the process progress and to allow the identification of challenges and barriers.




PLAN
First: Education for the team members about pain, delirium and agitation using:
1-Short concise videos about the problem and methods used to tackle it.
2-Mandatory online assessment to make sure that the team is fully aware of the problem
Second: Providing tools to help implement the protocol without imposing further burden to the team and to run the protocol smoothly and user friendly by:
1-Applying laminated charts to show algorithm easily as a visual aid.
2-Applying a CDS algorithm to guide the proposed interventions, expected drug interactions effects e.g., prolonged QT interval with the usage of antipsychotic drugs.
3-CDS will be set to alert physicians in case of BPS≥6, RAAS≥3 or ≤-2, or an ECG showing a prolonged QT report, and the alert will not be turned off except if being acknowledged by the physician as a part of safety protocol.
4-Applying a care set instruction on the electronic medical recording system to make it easier to be implemented
Third: Front liners buy-in
Open discussions pecially from care providers and front liners about the barriers they expect and try to implement and absorb their knowledge in the plan. This maneuver will help them get more involved and enthusiastic to help the program sucseed
DO
Pain management
Key stakeholders:
Anesthetists
ICU specialist
Registered nurse
Acute pain management team (APT)
1-Preventive:
Use standardized pain management according to ERAS protocol and encourage the use of peripheral and neuro-axial analgesia
2-Assessment: Using Behavior Pain scale /4hrs
A-Score 3-5 Paracetamol /8 hrs ±NSAIDs or weak opioids as needed
B-Score ≥6 preferably use regional analgesia (peripheral nerve blocks or epidural) provided by the APT ±opioids (parenteral or oral)
CDS will alert the attending ICU physician in case pain score is≥ 6 plus the escalation from the attending nurse
DO
Agitation
Stake holders
ICU specialist
Registered nurse
Assessment using RASS (AIM -1 to 1)/ 4hrs
> 1 sedate (mainly dexmedetomidine, propofol or inhaled anesthesia)
<-1 decrease sedation
1-Minimize the usage of benzodiazepines except in specific cases as (epileptic fits aborting, withdrawal symptoms from alcohol or BDZ cessation)
In case of failure to maintain RAAS between (-1 to 1) by the above intervention a CDS alert will show on the screen of the attending ICU physician plus the escalation from the attending nurse

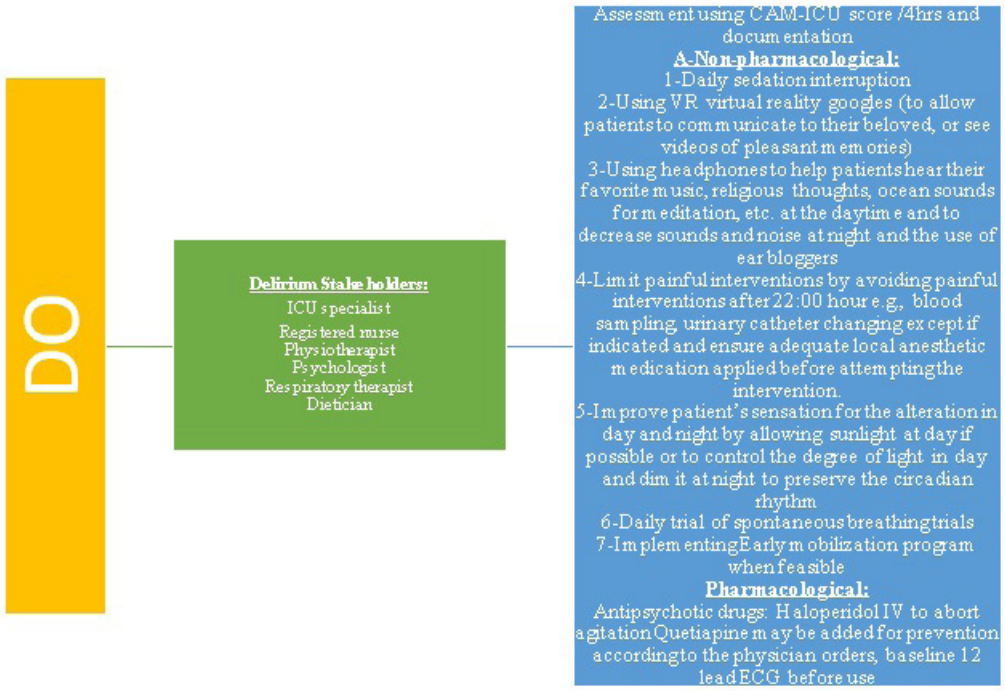


Figure 1: PDSA and learning community: starting from the left is the PDSA model (Plan, Do , Study and Act) for change acceleration process, the charter was defined , data collected of the actual process ,then the Do part came for gauging the process on a smaller scale then a study and analyzing of the progress followed by the Act process. Data driven will be the driving force for the next PDSA cycle. The right side represents the learning health community within the learning health system (LHS) and aid in moving practice -to-data(P2D) to data-to-Knowledge (D2K) to advance the new evidence-based best practices.

6. First A Cycle of PDSA will Start

6.1. Plan

It will start on parallel scales of introducing and standardizing sets of interventions while supporting a continuous medical education background to stakeholders.

6.2. Design of the Intervention

After collecting data and the survey to get an idea about the baseline knowledge

The intervention will start on multiple parallel levels:

6.3. The DO Phase

After collecting data:

Standardizing a scale for measuring the degree of pain by Behavior pain scale (BPS), agitation by the help of Richmond Agitation-Sedation Scale (RASS), and Delirium by the Confusion Assessment Method in the ICU (CAM-ICU).

Intervention for pain, agitation and delirium will be pharmacological, and non-pharmacological.

6.4. For Pain

A stepwise escalation for pain management will be adopted with encouraging regional anesthesia techniques (e.g., epidural, peripheral nerve blocks, etc.) to decrease opioid requirements.

Standardizing the practice for daily follow-up rounds by the clinical pharmacist and ICU Consultant about drugs that may precipitate delirium and the alternative proposed drugs.

- Huddle in the beginning of every shift will include the degree of patient pain, agitation, and delirium scores.
- Monitoring the practice through a weekly feedback by the front liners, defining barriers and knowing the weak and strong sides.
- Monthly online refresher course (short video) and online assessment will be held.
- Implementing the orders as a care set along the electronic medical system.
- Implementing CDS to help and propose the best evidence- based practice and as an alert system to the attending nurse and ICU physician.
- Identifying non-compliance by continuous auditing and develop ways to tackle the problem e.g., by making the care set more user friendly.

6.5. Study & ACT

Necessary changes will be made based on the drills done, audit made, feedback from front liners as well as other stakeholders.

To ensure the sustainability of the program and with the aim of embedding it in the culture different approaches were suggested:

- An online resource guide will be provided with links to make it easier to navigate for each specialty and at the same time an auxiliary link will be addressed for further

resources if needed.

- Simple algorithm will be provided supported by pictures and mnemonics to make it easier to remember.
- Mandatory monthly on-line assessment will be held.
- Sustaining staff engagement by acknowledging and celebrating champion of the month.
- Getting the feedback from patients and families and if possible, arrange for live or zoom meetings between the staff involved and families to see how much they (the staff) helped in rescuing lives and how much they are appreciated for their role.
- Care steps will be incorporated into the workflow to make them routine and a part of the staff culture.
- Performance data will be shared between stakeholders and the staff to sustain their enthusiasm and focus. Long term performance will be followed up with continuous cycles of PDSA to improve the progress.

7. Metrics

7.1. The aim is to address three types of measurements outcome, process and balancing measurements.

First the outcome measurements regarding incidence of PAD in the first year, ICU and hospital length of stay, number of free days from the ventilator, total doses of sedation drugs used, adverse effects from drugs e.g., prolonged QTc with haloperidol, complications of regional anesthesia as IV injections, organ injury, neurological injury, rate of catheter related infection, and failure will be collected.

Secondly will be the process metrics with the aim to increase early mobility program by 60% and achieving 100% targets in daily spontaneous breathing trial (SBT) and PAD assessment documentation.

Thirdly will be the balancing measurements for bed turnover rate (BTR)and the financial revenue.

Ongoing data will be conducted by the Quality officer, Quality RN, ICU manager with immediate feedback shared with the team members on monthly basis. All data will be shared by the multidisciplinary work group on the first Sunday of each month, trends and the effectiveness of the interventions will be analyzed, and necessary interventions will be implemented.

A 3,6,9 and 12 months analysis meeting will be held on a higher managerial level to identify challenges and percentage of goals achieved.

7. Discussion

The clinical pathway is unique and in line with movement of designing patient care centered approach.

The pathway is multidisciplinary and multidimensional to help patients on ventilators suffering from PAD from one side and provide a way to ensure the continuity of care and education to the health care team on the other side.

An early success in the pathway's rollout will support the implementation across other intensive care units, also may extend to different set of patients who are not on mechanical ventilation. The program provides an evidence based, electronically supported infrastructure that can accelerate and accommodate further intervention. As for any new protocol, challenges and barriers are expected and that will be the driving force for the next PDSA cycles for improvement. The use of the clinical information system, medication alert system and the clinical decision system will help alert, track, and even adjust the provided clinical service. We believe that investment in extending and upgrading the usage of CDS for decision making and alerting systems will be the cornerstone to ensure the delivery of high quality and safe practice.

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