Chapter 9
Standard Solutions for Complex Settings: The Idiosyncrasies of a Weaning Protocol Use in Practice

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Healthcare Standardization

Patient safety efforts in health domain are oftentimes compared with other safety-critical and high-reliability domains including aviation, banking, and nuclear plants. In these industries, standardization of practices is seen as a viable strategy to mitigate error and improve safety [1]. Along similar lines, extensive efforts were made in medical domain to engineer high-safety processes by standardizing care delivery procedures and reducing practice variation. While standardization of procedures is based on the best scientific evidence available for a particular clinical problem at hand, it is also supposed to allow for practice of individual medicine to address patient-specific issues. Studies examining the impact of standardization reported improvements in quality of care – better clinical

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outcomes and reductions in infection transmissions. At the same time, standardization has also been shown to reduce healthcare expenditures [2].

Several hospital processes have been standardized using a variety of clinical decision support tools and techniques such as checklists, protocols, and Computerized Provider Order Entry (CPOE) systems [3–9]. These tools add structure and predictability to highly complex tasks in critical care, which has been proven effective in aviation. Such structured workflow removes unnecessary variation and improves the overall performance of the unit. A combination of these standardization techniques have been used to improve four important critical care processes- ventilator management, ventilator weaning, sedation and analgesia [10–12]. This chapter provides the assessment of a weaning protocol that aims to standardize the weaning process of critically-ill mechanically-ventilated patients. The objective of the assessment is to understand the socio-technical factors that affect the optimal use of the protocol. Detailed description of the weaning protocol is provided in section "Weaning protocol use in a medical intensive care unit" of this chapter. In section "Barriers to effective use of standardized clinical decision support", we examine the performance-related issues encountered with standardized decision support systems including weaning protocols reported in the existing literature. The remaining sections of the chapter focuses on three studies we conducted to evaluate the particular weaning protocol (described in section "Weaning protocol use in a medical intensive care unit") in a complex critical care setting. The central theme of the chapter is to provide a methodology that facilitates the consideration of complex systems' characteristics into the design, evaluation, and implementation phases of standardization tools in critical care.

Weaning Protocol Use in a Medical Intensive Care Unit

Mechanical Ventilation (MV) is a lifesaving procedure, however, prolonged ventilation carries numerous life threatening complications including increased mortality, ventilator-associated pneumonia, and airway trauma [13]. On the other hand, premature discontinuation of MV can result in unsuccessful extubation, requiring re-intubation [14]. Therefore, it is important to discontinue mechanical ventilation at the earliest possible and optimal time. Recent published literature suggests that daily screening of respiratory function in mechanically ventilated patients, followed by a sedation holiday and Spontaneous Breathing Trial (SBT) can result in a reduction of ventilator days, lower ICU costs and fewer related complications [10, 15]. The weaning protocol evaluated as part of the studies described in this chapter is currently used in a Medical Intensive Care Unit (MICU) and is primarily led by Respiratory Therapists (RTs). The objective of the weaning protocol is to provide adequate clinical decision support to clinicians and facilitate early, safe and evidence-based liberation from the ventilator. The decision support characteristics of the weaning protocol under study are discussed in detail in [16].

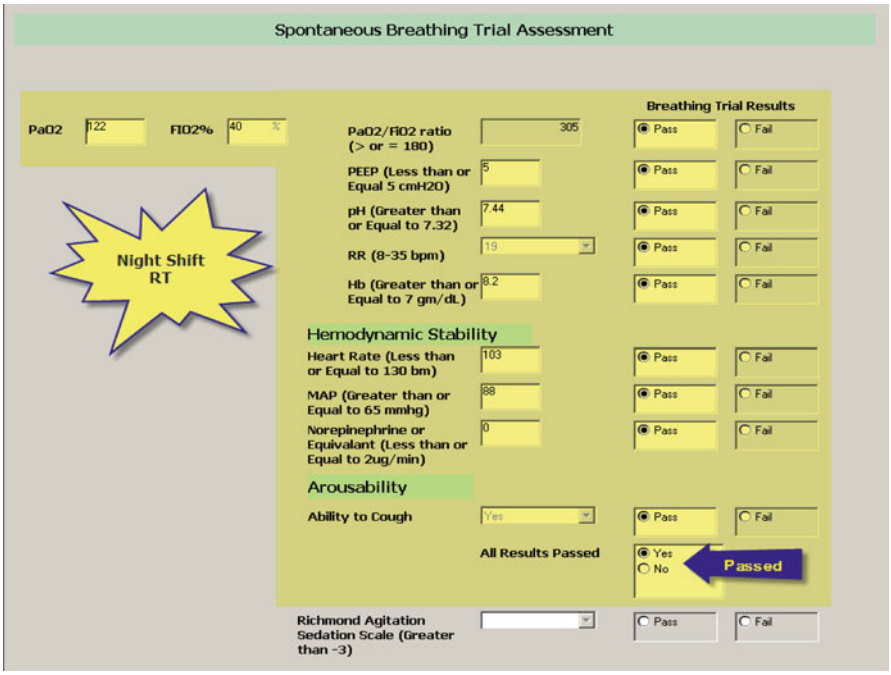

Fig. 9.1 Sample illustration of the Computerized Weaning Protocol (CWP) Form

The workflow of the Respiratory Therapist (RT) led weaning protocol is as follows. The protocol involves four major steps- (a) Data collection: Patient-related data collected by RTs (night shift and day shift) as part of the protocol's requirements were recorded in the Electronic Health Record (EHR), (b) Screening for SBT eligibility: All mechanically-ventilated patients were screened daily to determine their eligibility and readiness for a Spontaneous Breathing Trial (SBT) by the night shift RT starting at 4 am every day. Physiological data (e.g. hemodynamic stability, respiratory rate, positive end-expiratory pressure, fractional concentration of inspired oxygen) were collected at this point and fed into the EHR. The inbuilt Computerized Weaning Protocol (CWP) module uses these data to automatically assess the patient's eligibility for SBT and provides the clinicians with the results (Pass/Fail, see Fig. 9.1) provides an illustration of the protocol data entry. The RT manually entered the weaning mechanics data into the text boxes seen in the figure and the subsequent results (Pass/Fail) seen in Fig. 9.1 were generated by the system based on the values entered in the corresponding data fields. The CWP provided guidance to the RT in every step (cuff leak checks, ventilator mode selection) using checklists and simple data entry. All data related to weaning mechanics (e.g. tidal volume, rapid shallow breathing index) were collected using CWP module. If the patient failed any part of the SBT screen, then it was considered that the patient did not meet criteria required to proceed to the actual SBT. The patient will be re-screened again the next day.

Table 9.1 Richmond Agitation Sedation Scale (RASS) used for sedation assessment as part of weaning protocol in Medical Intensive Care Unit

RASS score	Description
+4	Combative, violent, danger to staff
+3	Pulls or removes tube(s) or catheters; aggressive
+2	Frequent nonpurposeful movement, fights ventilator
+1	Anxious, apprehensive, but not aggressive
0	Alert and calm
−1	Awakens to voice(eye opening/contact) >10 s
−2	Light sedation, briefly awakens to voice(eye opening/contact) <10 s
−3	Moderate sedation, movement or eye opening. No eye contact
−4	Deep sedation, no response to voice, but movement or eye opening to physical stimulation
−5	Unarousable, no response to voice or physical stimulation

For patients who passed the above screen, the nightshift RT informed the day shift RT when giving report. The dayshift RT would then inform the day shift nurse who would proceed with a "sedation holiday" at 7:30 am. During the "sedation holiday" the RT and bedside nurse would assess patient's arousability using the Richmond Agitation Sedation Scale (RASS). The day shift RT conducted sedation assessment using Richmond Agitation Sedation Scale (RASS) to determine if the patient's eligibility to be included in the SBT (see Table 9.1). If a patient had a RASS score > −3, the RT indicated that the patient passed the sedation assessment and proceeded with the trial by placing the patient on the appropriate trial ventilator settings. The RT would remain at the patient's bedside for the first 5 min of the trial to assess tolerance to the SBT settings, then remained in the unit for the duration of the trial and continued to monitor the patient. For patients who failed the sedation assessment, the protocol was deemed complete and these patients would be re-screened for SBT readiness the next day. The aggregated data were then presented to the attending physician and the clinical team for the final decision on ventilation during daily morning multi-disciplinary team rounds.

Barriers to Effective Use of Standardized Clinical Decision Support

A Clinical decision support system (CDSS), which encompasses a variety of interventions including computerized alerts, electronic clinical guidelines providing clinicians with just-in-time evidence-based support [17, 18], thereby enabling safe and efficient care delivery [19]. Often used in critical care units to mitigating life-threatening complications associated with mechanical ventilation is CWP, a form of decision support to ensure early and safe extubations. An overview of various weaning protocols (WPs) that are in use currently by various health institutions can be

found in [20–25]. With growing emphasis on digitizing health care, Health Information Technology (HIT) is a frequent component of these protocols and other standardization efforts. Automation and technology are seen as two major carriers of these policies. Introduction of new workflow procedures and/or modification of existing practices are often the primary consequences of these efforts.

Several studies identified problems with efficient implementation and safe use of CWP. Most of these problems are socio-technical found within the protocol (e.g. software errors, underlying logic errors) and distributed across the clinicians' understanding of the protocol [26–29]. Understanding complex interdependencies commonly observed in the critical care environment is essential in order to improvise the sub-optimal implementation practices of weaning protocols [30, 31]. Clinician adherence and compliance to the newly established guidelines is also cited as a major challenge that needs to be addressed in order for our health systems to fully benefit from any CDSS [32]. Therefore, detailed understanding of all the involved components (e.g. care setting, support algorithm, user impression) is incumbent to maximize the benefits and minimize the losses that may be caused by ineffective implementation and/or unintended consequences [33, 34]. It has been suggested that such assessments should take the context and complexity of CDS environment into account for high yield in quality improvement [35, 36], and that failure to assess the environment prior to implementation of an intervention can have harmful unintended consequences [37, 38]. Several studies have documented the rise of medical errors as a result of unintended consequences of the standardization tools [37, 39–44]. Failure to understand the dynamics of complex adaptive environments such as critical care can be one reason for the emergence of these unintended adverse consequences. Most protocols and checklists have been created with a high-level objective such as improving a clinical outcome or process. However, such a clinical process is a conglomeration of multiple low-level processes that in turn involves a multitude of actors, tools, and events. In other words, the patterns found in complex adaptive systems at higher levels emerge from localized interactions and selection processes acting at lower levels [45]. Therefore, it is essential to carefully understand the localized interactions of standardization strategies to successfully anticipate and address the emergence of high-level patterns. This chapter introduces a new method that analyzes localized interactions to explain high-level risks in a complex setting. We explain the findings derived from a set of evaluation studies of a CWP, which is under use in a MICU.

Evaluation of the Standardization Tools

For evaluation of risks posed by a given standardization strategy or protocol, a variety of retrospective and proactive safety engineering approaches have been used in health care. The Department of Veterans Affairs had adapted the classic failure mode and effect analysis (FMEA) approach for use in medical domain [46, 47], thus setting stage for a series of methodological adaptions of risk assessment frameworks. In addition to FMEA, a variety of risk management methods have been

tested- root cause analysis, fault tree analysis, cause and effect diagram, hazard operability study, probability tree method, man- machine systems analysis, and probabilistic risk assessment to name a few [48–50]. With the phenomenal growth of electronics and computer technologies in the past decade, the socio-technical underpinnings of the workflow and technical infrastructure have become quite complex in almost every safety-critical area including healthcare [41]. To keep up with growing complexity, risk analysis methods have also been transitioned from being linear approaches to non-linear models attempting to understand the local patterns to understand global effects. In this chapter, we present and demonstrate the use of a non-linear risk assessment methodology to analyze the safety issues concerning the use of the previously described protocol in the context of weaning mechanically-ventilated patients in a critical care unit. Functional Resonance Accident Method (FRAM) motivated by complex systems research was chosen given its proven applicability to intractable environments such as manufacturing plants and financial markets [51, 52]. FRAM is a systemic method originally developed for the analysis and prediction of adverse events in the aviation industry. Motivated by complex systems research, the method considers local variations within the protocol, related actors, and events, thus accounting for the complexity of MICU environment.

Functional Resonance Accident Method

Functional Resonance Accident Method provides a way to describe how multiple individual functions and conditions can combine to produce an adverse outcome accounting for the interactions and interdependencies within complex settings and offering us insights into the how and why of a particular event chain [53]. FRAM is based on the following four major principles [51]:

1. The principle of equivalence of successes and failures: FRAM adheres to the resilience engineering view that failures represent the flip side of the adaptations necessary to cope with real-world complexity [54]. Success depends on the ability of teams and individuals to anticipate risks and critical situations, to recognize them in time, and to take appropriate action.
2. The principle of approximate adjustments: Since the conditions of work never completely match what has been specified, individuals must adjust their performance so that they can succeed under the existing conditions.
3. The principle of emergence: The variability of normal performance is rarely large enough to be the cause of an ineffective activity in itself or even to constitute a risk. But the local variability from multiple functions may combine in unexpected ways, leading to consequences that are disproportionally large producing a non-linear effect at global scale.
4. The principle of functional resonance. The variability of a number of functions may resonate, i.e., reinforce each other and thereby cause the variability of one function to exceed normal limits. The consequences may spread through tight couplings rather than via identifiable and enumerable cause-effect links.

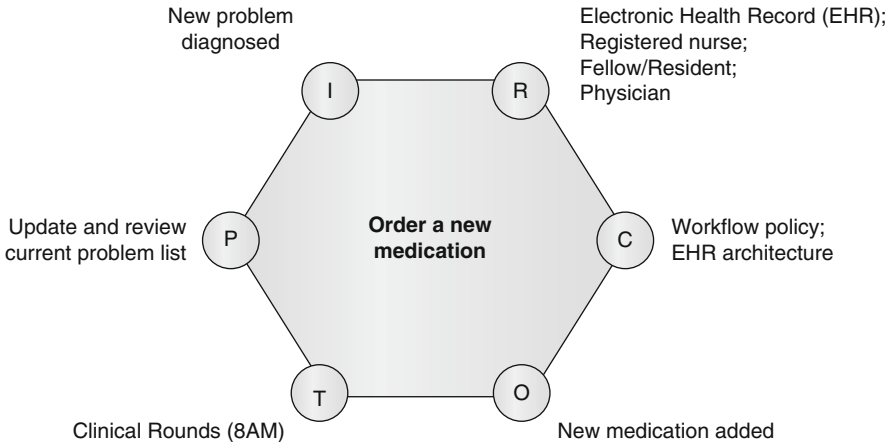

Fig. 9.2 A FRAM module describing a function (*I*-Input, *O*-Output, *T*-Time, *R*-Resource, *C*-Constraint, *P*-Precondition)

The steps to apply FRAM for evaluation of the effective use of standardized CDSS tools ((in this context, a CWP) are as follows. In step 1, we identify and characterize essential functions that are being accomplished using the standardized CDSS. All functions required to complete a decision support activity are specified in this step. Each function is separately identified, but not pre-arranged in any way. A function may, for instance, be to update the medication list of a patient. Each function is modeled using six parameters: Input, Output, Time, Resource, Precondition, and Control (see Fig. 9.2).

Input (I): that which the function transforms or that which starts the function, Output (O): that which is the result of the function, either an entity or a state change, Preconditions (P): conditions that must exist before a function can be executed, Resources (R): that which the function needs or consumes to produce the output, Time (T): temporal constraints affecting the function (with regard to starting time, finishing time, or duration) and Control (C): how the function is monitored or controlled

In Step 2, we describe the potential variability of the functions. For this purpose we adopted previously established practices to assess the common performance conditions (CPCs) outlined in (1) Hollnagel's cognitive reliability and error analysis method (CREAM) [55], and (2) Ten Commandments for effective use of CDSS [56]. A list of CPCs from both the above sources was presented to an expert physician, who chose the final list with 12 CPCs (Table 9.2) that captures the working conditions in MICU. Then, in Step 3 we identify functional resonance and potential variability. The functions identified in Step 1 may be coupled via their parameters. For example, the pre-condition of a function may be the output of another function, which in turn may be an input a third function. Similarly same functional parameter can serve an input to another function, or provide a resource, fulfill a pre-condition, or enforce a control. Couplings between functions can be identified by analyzing commonly related parameters. These couplings may then be combined with the results of Step 2, the characterization of variability, to specify how

Table 9.2 Variability checklist for context-dependent evaluation of clinical decision support

Conditions for effective clinical decision support	Rating scale
On-time support delivery	*Adequate*
Fit into user's workflow	*Inadequate*
Usability	*Unpredictable*
Positive perception of clinicians	
Collaboration quality	
Communication quality	
Training and experience	
Monitoring impact and feedback	
Time needed/available	
Knowledge management and update	
Quality and support of organization	
Operational support	

the variability of one function may have an impact on the variability of another by categorizing them into (1) Human, (2) Technology, and (3) Organization. In order to gain deeper understanding of this functional classification, please refer to [57]. Functional dependencies can spread variability across the activity beyond the normal boundaries, pushing the outcome into a danger/suboptimal zone and result in an adverse or unfavorable event. Finally in Step 3, we propose variability monitoring and attenuating interventions. Understanding the nature, cause, effect, and propagation of variability in CDSS is essential to contain the inefficiencies and improve performance.

Now, let us demonstrate the way this method can be used to evaluate standardization tools. The next sections of this chapter attempts to dissect and present how FRAM has been used to evaluate the weaning protocol previously described in section "Weaning protocol use in a medical intensive care unit".

Study 1 – Application of FRAM to Evaluate the Use of the Weaning Protocol

The clinical version of FRAM was adopted to identify the risk factors creating barriers to effective use of the CWP in the MICU. A FRAM-based normative model of the CWP was created following a sequence of steps . The first step in FRAM was to identify essential functions of an activity. Five essential steps in the CWP were identified using multiple methods (observations, review of hospital manuals, semi-structured interviews) as follows: (1) patient inclusion, (2) SBT screening assessment, (3) sedation assessment using RASS score (see Table 9.1), (4) SBT, and (5) decision making: extubation. As shown in Table 9.3, each of these functions was modeled using six parameters -input (I), output (O), resource (R), time (T), precondition (P), and control (C).

Table 9.3 Essential functions of the computerized weaning protocol

Function	Input	Output	Resource	Time	Control	Pre-condition
Function 1: *patient inclusion*	Ventilator settings; protocol order	SBT screening assessment order	EHR; day RT; fellow		MICU weaning policy	Patient exclusion criteria
Function 2: *SBT screening assessment*	SBT screening assessment order	Eligible/ineligible for SBT; respiratory mechanics	EHR; night RT	4 AM	MICU weaning policy	Patient exclusion criteria; Protocol order
Function 3: *sedation assessment* (*RASS Score*)		Arousability score	EHR; day RT; RN	7:30 AM	MICU weaning policy; RASS	Sedation holiday; eligible for SBT
Function 4: *spontaneous breathing trial* (*SBT*)	Ventilator settings	Pass/Fail SBT	day RT; EHR		MICU weaning policy	Eligible/ineligible for SBT; arousability score > −2
Function 5: *decision making*: *extubation*	Ventilator settings	Patient extubation	RN; day RT; Physician; Fellow; Residents; EHR	8 AM	Clinical objectives; MICU weaning policy	Pass/Fail SBT; arousability > −2

Table 9.4 FRAM based variability checklist for weaning protocol

Conditions for effective clinical decision support	Rating
On-time delivery of decision support	Unpredictable
Fit into user's workflow	Adequate
Usability and understanding	*Inadequate*
Positive perception of clinicians	*Inadequate*
Collaboration quality	Unpredictable
Communication quality	Unpredictable
Training and experience	*Inadequate*
Monitoring impact and feedback	*Inadequate*
Time needed/available	Unpredictable
Knowledge management and update	*Inadequate*
Quality and support of organization	Adequate
Operational support	Adequate

In Step 2, using the CPC-based checklist, the variability of the CWP functions was assessed (see Table 9.4). Different factors were considered to assess the variability of the protocol and it was found that on-time support delivery, collaboration and communication quality, and the time needed to complete the CWP in order to standardize the weaning process in the MICU were unpredictable. The factors were rated by domain experts- physician and RT. Cohen's Kappa measure was used to determine inter-rater reliability. The raters had a reliability of 0.855 ($p<0.001$) with only one disagreement in "positive perception of clinicians" category. The disagreement has been resolved by asking two additional raters to assign a rating for that particular condition, and the final rating was the one that has most agreement. It was clear from Table 9.4 that multiple factors were given inadequate and unpredictable rating. This highlights the possibility that the CWP under evaluation may be subjected to variability by several sources, which are possibly inter-dependent.

The local dependencies and global networks of the CWP components were also analyzed. We identified and analyzed possible ways in which these variability sources might resonate and affect the performance of the protocol [16]. Next, we describe the functional dependencies of one of the CWP functions- the "Sedation assessment (RASS Score)".

Sedation assessment (RASS Score) is function 3 of the CWP. The control for this function is the use of RASS to determine the arousability of a patient (see Fig. 9.3). The output of function 3 is a precondition for functions 4 and 5. Once the functional dependencies such as this were all identified, the functions were reexamined using the list of previously determined CPCs by mapping the functions to three categories into human, technology, and organization. From this analysis, it was found that the sedation assessment is primarily dependent on the human resource applying RASS to assess the sedation level of a patient and the immediate variability sources were traced to usability and understanding, training and experience, both of which are rated inadequate by domain experts. For instance, consider a hypothetical case where a clinician assigns a wrong score to a patient because of inadequate understanding of the sedation assessment scale. At that point, the patient would be ineligible to

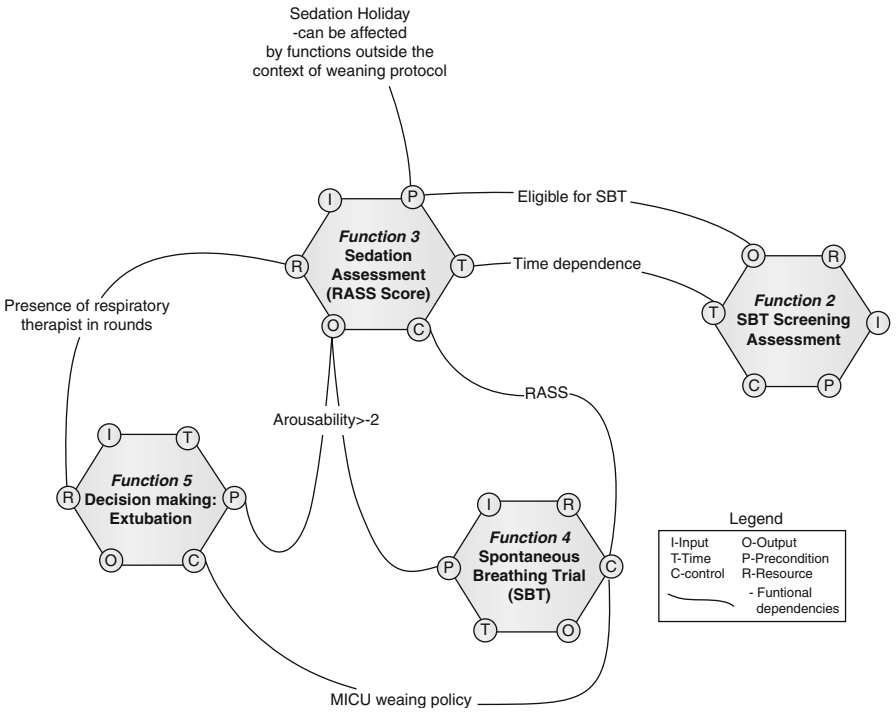

Fig. 9.3 Functional dependencies of Function 3- Sedation Assessment (RASS Score)

proceed to function 4, and therefore cannot be timely extubated. From this example, it was evident that inadequate understanding of protocol mechanisms (such as RASS) might pose risks to the effective use of CWP. However, such discrepancies in score assignment could be resolved during case discussions. Given the expert rating that the communication among clinicians is unreliable, this safety net might not be trustworthy enough. Other variability sources affecting optimal use of the CWP were identified to be: a) misinterpretation of the sedation scale, b) lack of RTs presence in the daily rounds, c) communication breakdown among clinicians, d) problems of on-time support delivery, e) clinicians' negative perception of the protocol.

Finally in Step 4 we propose variability monitoring interventions to mitigate the risks posed by the standardization of the weaning process in MICU. Reinforced clinician education on the new policies and guidelines, facilitating improved communication, and disseminating the impact of the newly introduced workflow practices can help minimize the unintended variability in the CWP functions. Examples of immediate short-term and long-term intervention strategies include-

Training and Education: Design a training module for clinicians to fill existing knowledge gaps and conceptual misunderstandings. Such a refresher module should be developed based on multi-disciplinary input from clinicians involved in the daily use of the CWP. Efforts need to be channeled to identify and address confusing aspects in the protocol's procedures.

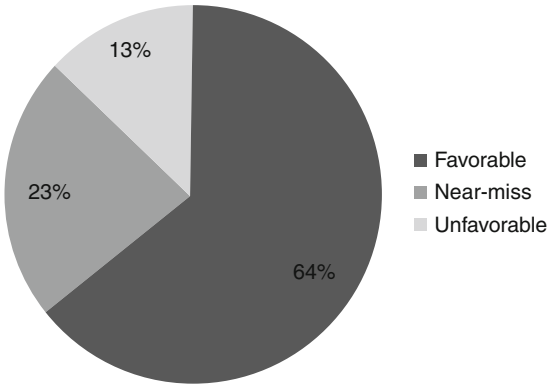

Fig. 9.4 Classification of the outcomes from 65 weaning sessions

Feedback and Impact Monitoring System: Research and development of a virtual platform that establishes a communication channel among clinicians soliciting feedback on CWP operations, disseminating quality metrics relevant to the CWP to all the involved clinicans such that they stay motivated to adhere to new workflow practices that make a positive impact on the care setting and culture.

Before we can set out and implement the above stated interventions, it is important for us to validate the finding derived using FRAM. To our knowledge, the use of FRAM as a risk assessment method in critical care medicine is the first attempt of its kind, and we are not aware of any published work that employed FRAM to evaluate the standardization tools such as the weaning protocol. Henceforth, we carried out a second study to validate our findings.

Study 2: Validation of the FRAM Method for Use in Critical Care

The objective of this study was to validate that the use of FRAM as an evaluation method to identify the risks posed by the standardization tools such as the computerized weaning protocol. As part of the study, a trained researcher conducted ethnographic study by unobtrusively observing clinicians as they conducted weaning sessions using the CWP. A total of 65 weaning sessions were observed and these data were coded into three categories- favorable, unfavorable, and near-miss. As shown in Fig. 9.4, 45 (69 %) of the 65 sessions were favorable, 16(25 %) fell under near-miss category, while the remaining four (6 %) were unfavorable [58]. A weaning session was classified as *favorable* if a mechanically-ventilated (MV) patient passes night-RT assessment AND sedation assessment AND spontaneous breathing trial, and then he/she is extubated (OR) if a MV patient fails night RT assessment OR sedation assessment OR spontaneous breathing trial), and then he/she is not extubated. (OR) if a MV patient passes night RT assessment AND sedation assessment AND spontaneous breathing trial, and then he/she is not extubated because of

airway management issues or other clinical objectives. A weaning session was classified as *unfavorable* if a MV patient passes night RT assessment AND sedation assessment AND spontaneous breathing trial, and then he/she is not extubated (OR) if a MV patient fails night RT assessment OR sedation assessment OR spontaneous breathing trial, and then the patient is extubated and is again re-intubate (OR) a physician makes a decision on extubation with no or erroneous data from the protocol. Unfavorable sessions can be a result of functional coupling among locally variable components. A weaning session was coded as a *near-miss* event if the variations of the individual components at local level did not couple with one another causing an unfavorable outcome.

Major problems identified with the CWP in the shadowing sessions were related to misinterpretation of sedation scores, issues with on-time delivery support, inadequate communication and collaboration among clinicians, and insufficient feedback of protocol's impact on quality of care delivery in MICU. Detailed explanations of some important observations made in this study with respect to CWP use in the critical care unit are described below.

Misinterpretation of sedation scale was observed in seven of these sessions. The sedation scale was misinterpreted, which subsequently led to erroneous extubation and re-intubated, and therefore placing the patient at unnecessary risk and preventable harm from inadequate respiratory support. Reason for the wrongly assigned sedation scores is that the RTs misinterpreted the word "sedation" in the RASS scale as referring to the prescription sedative, instead of an assessment of the physical arousable state of the patient, there by indicating that knowledge issues with the protocol mechanisms posed problems to the effective use of the CWP. There were five instances during which the SBT was prolonged for more than 150 min, where the protocol-based time limit was 30–120 min. The RTs placed the patients on minimal ventilator support subjecting patients to higher levels of discomfort. Such practice was potentially life-threatening for patients with airway management issues. Problems with on-time data delivery were also observed which limited the just-in-time application of the weaning protocol. During two sessions, the physician had to make a decision without considering the CWP data because of data collection delay caused by ICU crowding and resource allocation to another critically ill patient. Lack of compliance by clinicians to the protocol procedure was also found to be a risk factor. Adherence issues were as a result of some physicians who did not trust the protocol, although the protocol is evidence-based, and henceforth, disregarded RT's data.

In summary, our findings from this evaluation study were in agreement with the results from Study 1. The FRAM based analysis positively predicted 81 % of the variability sources that resonated to cause near-misses and unfavorable outcomes observed as part of Study 2. The two studies described so far enabled us to identify the risk sources proactively and retrospectively. While the findings were intuitive enough to develop remedial solutions, the sources of the risks were not quite clear. These risks might have stemmed because of multiple reasons- (a) knowledge-related deficiencies, (b) lack of cognitive support such as reminders, and (c) ignorance or workarounds. In the next section of the chapter, we describe the findings of a study that attempted to look at knowledge structures of individual clinicians

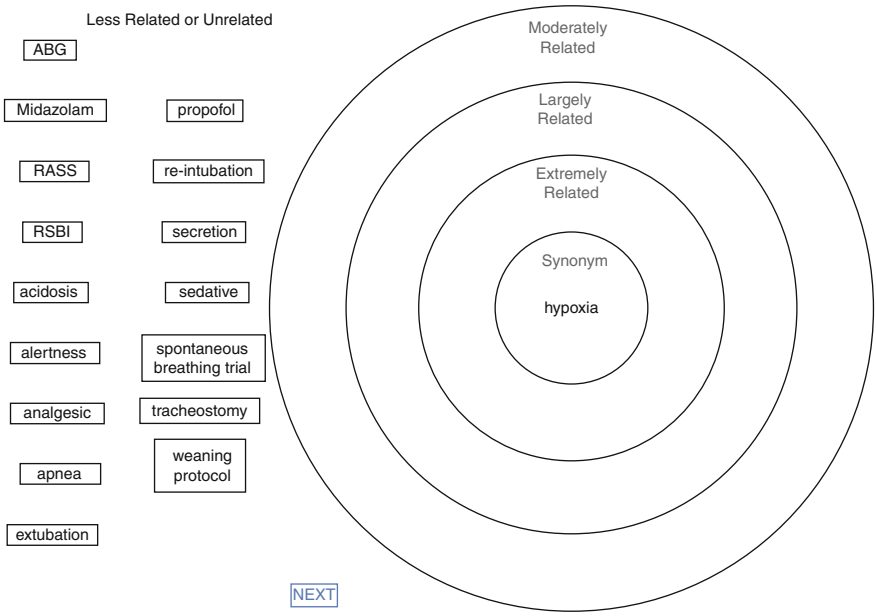

Fig. 9.5 Target – a concept-mapping tool to assess knowledge structures

to identify knowledge-related risk sources, which in turn can be addressed by deploying effective training interventions.

Study 3: Tracing the Knowledge Gaps to Improve Standardization Tools

In the previous sections, we have learned that conceptual knowledge gaps can sometimes lead to underutilization of the standardization tools. Such knowledge-related shortcomings can be remedied by having a strong training regimen in place to bolster important clinical concepts so as to enhance patient safety. In this study, we used a concept-mapping methodology to analyze knowledge-structures of the clinicians. Cognitive psychologists have long used memory organization and inference patterns to understand the specialized knowledge structures of an individual. One way to gain insight into memory organization is by using conceptual proximity data, often derived from pairwise estimates of conceptual relatedness provided by participants. Concepts related to one another are nearer, and those that are not related are farther. To elicit these data, we used a concept-mapping tool called "Target", which gives us an estimate of how subjects relate several concepts related to specialized content, thereby letting us explore their knowledge structures. Target (shown in Fig. 9.5) is based on Pathfinder network scaling [59, 60] which can be used to assess learning of an individual by examine their knowledge structures. A Pathfinder

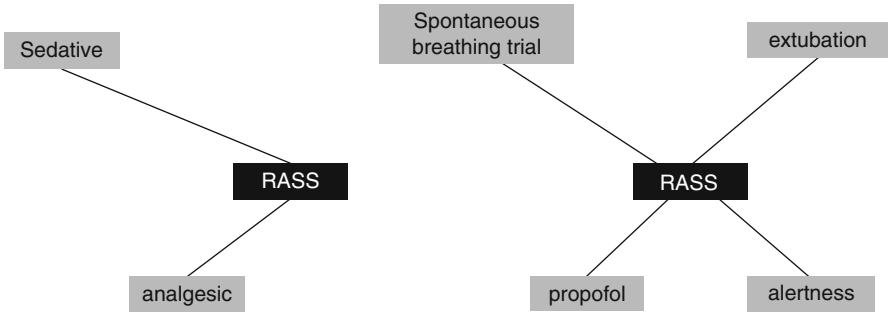

Fig. 9.6 Conceptual gaps- In the image on the left, RASS is not connected to alertness or SBT- (the RT contributing the proximity ratings that underlie the image on the left also assigned an incorrect RASS score during an observed clinical encounter)

network is derived from proximities for pairs of concepts with a pattern of relationships [59]. In the Pathfinder network, the concepts correspond to the nodes of the generated network, and the links in the network are determined by the patterns of proximities. Pathfinder eliminates links in the network where a shorter path between the nodes concerned can be found through some other node, thereby revealing the most significant links in the network based on local patterns of proximity.

We asked eight MICU clinicians (RTs and physicians) to use Target to rate the distance between concepts related to the CWP. A total of 17 concepts are used for the purpose of this study. Each clinician was required to drag concepts related to the concept in the center of the target from a location on the left. Each concentric circle represents a degree of relatedness, ranging from moderate to extremely related, to the concept in the center. Each concept is at the center of the target once before the completion of the task.

Based on the proximity data captured using Target, knowledge structures of the clinicians (with respect to the CWP) were created using Pathfinder. Based on these structures, we were able to trace the risk sources and conclude if they originated because of knowledge deficiencies. For instance, see Fig. 9.6, it shows the knowledge structure of two RTs for RASS concept alone. As you can see, one of the RTs related RASS to sedative and analgesic alone (see structure on left in Fig. 9.6), while the correct representation of RASS should include alertness as well (see structure on right in Fig. 9.6).

When mapped to shadowing data collected as part of Study 2 (described in section "Study 2: Validation of the FRAM Method for Use in Critical Care" of the chapter), this RT also gave wrong RASS score to the patient thus leading to failed extubation. Similar pattern was observed in case of the two other RTs who assigned faulty RASS scores. Using this knowledge elicitation methodology, we conclusively determined that incorrect RASS scoring occurred on account of knowledge deficiencies. The aforementioned technique can be used for the formulation of new training strategies by identifying and remedying the knowledge deficiencies, and therefore improving the effectiveness of the existing standardized solutions such as the CWP.

Summary and Discussion

Standardization solutions including clinical decision support aids such as computerized weaning protocols (CWPs) aim to reduce medical errors by standardizing care process. Health Information Technology (HIT) plays a major role in these efforts. However, the dynamic nature of critical care environments demands context-specific and complexity -inclusive assessment of these support tools for optimal results. In this chapter, we describe three studies that focus on the safety assessment of a Computerized Weaning Protocol (CWP) which has been used to standardize the weaning process of mechanically-ventilated critically-ill patients. The factors posing risk to effective use of CWP included misinterpretation of CWP's sedation assessment scale, communication and collaboration breakdowns, problems with on-time support delivery, and negative perception of the protocol among clinicians. The identified risk factors are socio-technical in nature: inherent to the protocol and externalized in the environment, in addition to trust and understanding. These factors have led to sub-optimal protocol outcomes that are classified into near-misses and adverse events, which constituted almost 34 % of protocol outcomes. Some of the potential risks, such as clinicians' negative perception, protocol misinterpretation, and inadequate collaborative practices identified using FRAM are consistent with the results from previous research [15, 21, 26, 28]. These risks might have stemmed because of multiple reasons- a) knowledge- related deficiencies, b) lack of cognitive support such as reminders, and c) ignorance or workarounds. Variability monitoring interventions to mitigate the risks posed by the standardization of the weaning process in MICU can range from clinician education, improved communication, and impact demonstration. Multi-disciplinary collaborative input from clinicians involved in the daily use of the CWP needs to be considered in view to identify and address confusing aspects in the protocol's procedures. Tools that provide unique, unambiguous, and multifaceted perspective of clinical processes to all the involved stakeholders in a health institution is essential to optimally exploit the advantages of standardization with minimal disruptions. Methods such as FRAM show strong potential for assessment of critical care safety and standardization interventions by providing a holistic view of complex processes. Adoption of a non-linear risk assessment methodology based on resilience engineering concepts is a valuable approach to address dynamic, non-deterministic nature of critical care environment. FRAM when complemented with common performance conditions representing critical care context can help us determine local variability risk sources leading to sub-optimal use of standardization tools at global scale [16]. However, it is important to note that not all variability of a system is risky in nature. Deviations from normal working conditions might sometimes be an act of resilience and positive adaption to an unanticipated or emerging event [54]. Once the individual risk sources are identified, it is essential to understand their triggers to develop remedies. Such deeper understanding of the risk factors related to the effective use of the decision support can enable us to optimize the standardization solutions by minimizing unintended consequences and maximizing end user acceptance.

Implications for Biomedical Informatics

Health Information Technology (HIT) solutions form the basis for standardization efforts in this era of digital medicine. Without proactive safety improvement approaches, the same interventions designed to improve patient safety can in fact lead to medical errors. The growing complexity of health care environment mandates methods that can tend to intractability of the system. This chapter provides an account of three studies that focus on the safety assessment of a computerized weaning protocol. The first two studies describe the application and validation of a novel risk assessment method that accounts for complexity in critical care. Lastly, the third study provides the readers with an objective method that enables researchers and applied health professionals to devise a refinement plan to enhance the effectiveness of the existing HIT interventions such as the weaning protocol. While HIT systems such as the weaning protocol discussed in this chapter are essential for improvement of patient safety and to reduce medical errors, these "safety nets" require continuous assessment and refinement in order for them to reach optimal working conditions in a complex environment like critical care. Ways to improve the performance of such standardization tools are context-specific and can range from education and motivation to workflow re-engineering. In addition, it is also essential to consider the aspects of cognitive risk management employed by clinicians during error detection and recovery during intervention design [61]. This understanding can inform the design of HIT systems that support the workflow in critical care. This chapter provides a methodological foundation for biomedical informaticians in terms of design, evaluation, and improvisation of HIT-based standardization tools in complex critical care settings. The method also facilitates health professions to predict and mitigate the unintended consequences of these omnipresent HIT based standardization strategies in the real- world health care environment.

Discussion Questions

1. Consider you are appointed to design a new HIT-based standardization solution for an intensive care unit. How do you approach your job assignment? Provide a brief overview of your standardization strategy and evaluate it. Describe its pros and cons bearing in mind that your new improvements can also lead to unintended consequences.
2. Describe a real-life standardization practice or event that you think has made a major positive or negative impact on health care delivery. If the impact is positive, what do you think the benefits might have been in terms of efficiency, quality improvement, and patient safety? If the impact of the standardization effort is negative, what would you do to improve?

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