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A New Framework To Idenitfy And Assess Hidden Assumptions In The Background Knowledge Of A Risk Assessment

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ABSTRACT

A risk assessment has a more or less subjective nature, as the analyst needs to make assumptions, analyse data, use models, and so on, to produce risk-related knowledge of the phenomena of interest. This background knowledge that forms the foundation of a risk assessment can be more or less strong, implying that it needs to be taken into consideration when describing and communicating risks. To meet this challenge, different methods have been developed to evaluate and inform the decision-maker about the strength of the background knowledge. For all these methods to be fully informative, the content of the background knowledge needs to be of good quality, covering, for example, all the relevant assumptions. To identify all the relevant assumptions, however, is not a trivial task, and the risk of missing assumptions increases with the complexity of the situation of interest. Hidden assumptions, which are not considered or identified, may induce false confidence in the risk assessment, its results and recommendations. This paper suggests a framework, using a systems approach, to identify and assess the background knowledge, as a means to reduce the risk of missing critical knowledge and obtain a more complete background knowledge, on which risk can be assessed.

1. Introduction

If we are to study risk of real-life systems and activities, such as offshore installations or emergency medical services, the assessments will inevitably be more or less conditional on our knowledge (justified beliefs), which is often formulated as assumptions [14], founded on data, models, information, and so on [39]. The fact is that a risk assessment is subjective by nature [16,47], which implies that the background knowledge, K, on which a risk assessment is based, needs to be taken into consideration when describing and communicating risk [8,46]. By simply addressing the conditional risk description, all the relevant uncertainties are not properly reflected [16], as the knowledge can be more or less strong [5] and uncertainties can be hidden within it, such as assumptions that turn out to be wrong [71]. To meet these challenges and inform the decision-maker of the foundation of the risk assessment, different approaches have been developed over recent decades to consider and reflect the strength of the background knowledge (e.g., [5,8,39,46,56,90]).

A prerequisite for all these methods to be fully informative is that the content of the background knowledge is of high quality, covering, for example, all the relevant assumptions. To identify all the relevant and critical assumptions, however, is not always straightforward, especially if the situation of interest is complex [53,87]. Take the case of evaluating the background knowledge associated with a risk assessment. Following common practice, the analyst identifies, inter alia, a list of assumptions and evaluates the extent to which they are reasonable. The more reasonable the assumptions are, the stronger is the judged strength of knowledge [39]. But what if this knowledge only includes a fraction of the relevant assumptions? The consequence is incomplete background knowledge, which hampers risk management and decision-making and potentially leads to false confidence in the produced risk description and level of safety [17]. The issue is that the analyst might be unaware that crucial assumptions are missing.

In other words, it is not always sufficient just to have a sound methodology to evaluate the strength of the knowledge. In many situations, there is also a need to assist the analyst in identifying the critical and relevant assumptions, to obtain more complete background knowledge. Here, assumptions are understood as fixed conditions/inputs that underlie the risk assessment but which are acknowledged to have the potential to deviate [20]. The hidden assumptions are then understood as the ones not identified (i.e. missed) by the analyst. Consequently, they are not included in the analysis and therefore not presented to the decision-makers. Multiple reasons can be seen as factors for not having identified the hidden assumptions. Amongst them,

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the paper particularly addresses the assumptions that are made implicitly by the analyst, in the sense that the analyst is not aware of them, or the ones missed as a result of lack of understanding of the phenomenon of interest, for example that relevant interactions are ignored. The assumptions are subjective beliefs, expectations or considerations about some unknown aspects (in a broad sense) related to the real system of interest. The challenge is therefore not to identify assumptions per se but to identify the unknown aspects of the real world that we want to make fixed in the assessment. We refer to these unknown aspects as knowledge elements, which have a role to play in the background knowledge.

Although there are a few methods that address how to identify assumptions in certain situations (e.g., [32,59]), there is, to the extent of our knowledge, no systematic framework for identifying and assessing the knowledge elements that contribute to obtaining good-quality background knowledge in a risk assessment context. Perfect knowledge is obviously unachievable in any practical setting, but it does not negate the goal of searching for more complete knowledge [59]. Another practical problem is that it is not feasible to consider all possible knowledge elements; thus, the analyst must limit the identification and assessment of knowledge, to some extent. However, a more or less arbitrary approach to these tasks does not appear to be the optimal solution [87].

In this paper, we suggest a framework that takes a systems approach to identify and assess relevant knowledge elements for a risk assessment, which assists the risk analyst in obtaining a good-quality background knowledge, reduces the arbitrariness of how the identification is carried out and reduces the risk of missing critical knowledge elements. In the safety and risk domains, there is a significant number of system approaches that could be applied, ranging from linear thinking of accidents as chains of events (e.g., [18,19,62,75]) to consideration of the dynamic interactions (e.g., [26,48,51,54,58,59,61,73]). But, as our goal is to develop a framework to identify and assess knowledge elements rather than accident scenarios and hazards, the systems engineering initiative for patient safety (SEIPS) by Carayon et al. [26] seems to be promising (see, [57]). The SEIPS model is relatively easy to use and suitable for most systems and activities, as it forms a general basis for identifying and describing system components and interactions. In addition, the model provides a starting point to evaluate how critical the identified knowledge elements are with respect to the risk assessment; thus, the framework is also a means to increase the trustworthiness of the risk assessment and inform the decision-maker about the quality and uncertainty of the background knowledge [87]. Although the suggested framework can inform the decision-makers about the knowledge, which is an important dimension of risk [16], it is also a means to provide information on which the other system models can be based, such as the Workgroup Occupational Risk Model (Papazoglou and Ale, 2007) or Storybuilder [18]. The key is to ensure a good knowledge base on which risk is assessed.

The remainder of the paper is organised as follows. In Section 2, we motivate the need for a systems approach to identify and assess background knowledge. Section 3 introduces the SEIPS model, which is the starting point for the framework presented in Section 4. Section 5 illustrates the framework with an example. A discussion of the framework is given in Section 6. Finally, in Section 7, we make some concluding remarks.

2. Motivativing the need to assist the risk analyst

To motivate the need for a framework that can assist the risk analyst in mapping and assessing knowledge elements, parts of a risk assessment performed by Eidesen et al. [36] will be used. The case of interest is a medical procedure called tracheotomy, which is used to secure the airway of critically ill patients that require ventilator support. In simple terms, the procedure consists of making an incision on the frontal aspect of the patient's neck, where a tube is inserted, allowing the patient to breathe without the use of mouth or nose. Traditionally, surgeons have performed this type of procedure, but an increasing number are now being performed at the bedside in the intensive care unit (ICU), using a special technique called percutaneous dilatational tracheotomy (PDT). The experience from the Norwegian ICUs, at least at the time when Eidesen and her colleagues conducted their study, indicated the potential for serious complications and negative patient outcomes related to PDT [86]. This resulted in a discussion among experts about whether PDT should be the preferred technique in cases where tracheotomy is deemed necessary [36]. One way to contribute to the discussion is by a risk assessment, which was carried out in Eidesen et al. [36], aiming to produce risk-related knowledge in respect of performing a PDT procedure in the ICU.

In light of the premises outlined in Section 1, proper treatment and communication of risk and uncertainties related to the PDT procedure is conditional on the background knowledge being taken into account. The risk assessment in Eidesen et al. [36] is in compliance with this understanding, as the background knowledge was assessed in an apparently comprehensive manner. For example, 12 years of data on tracheotomy practice at the Stavanger University Hospital's ICU were collected, analysed and evaluated. In addition, a series of interviews with attending physicians or managers at 30 Norwegian ICUs had been conducted (see, [86]), which provided both general and specific knowledge. All the available information was structured and evaluated to form the background knowledge, on which the risk was assessed. The identified background knowledge in Eidesen et al. [36] is presented in Figure 1.

More specifically, the knowledge assessment indicated three components of importance: the physician, the patient and the system. For each component, several associated aspects (i.e. knowledge elements) were identified, each with its own potential to affect the real procedure and, therefore, also the risk assessment. This knowledge, K, and its strength explicitly inform the decision-makers about the foundation of the risk assessment results and recommendations [16] and implicitly affect the decisions. But does the background knowledge, K, in Figure 1 include and express all the relevant knowledge elements for this particular case?

The ICU is a sociotechnical system of interdisciplinary character, with high stress, high values at stake, intense time pressure, a myriad of decisions and shifting clinical situations [37,64], indicating that it is unlikely that all the relevant background knowledge is revealed by the consideration of three single components in isolation. The interactions between the system components clearly have a role to play. For example, the physician performs a PDT procedure in a certain physical environment that is likely to cause fatigue or stress [84]. If the mental or physical condition of the physician turns out to be lower than normal, which we have interpret to be the state implicitly assumed in Eidesen et al. [36], the risk assessment does not fully reflect the situation of interest. Another example of missed knowledge in this case is that the work environment could lead to contemporary disorders or interruptions, possibly affecting the procedure if they occur. The knowledge aspects depicted in Figure 1, such as a physician's level of training and the available equipment, cannot be viewed solely in isolation, as the interactions are also relevant for the real case of interest and, therefore, the associated risk assessment.

We are concerned that important information has been overlooked as a result of hidden assumptions of which the analyst is unaware or difficulties in identifying the relevant knowledge. These concerns are not particularly related to the PDT case but to (almost) all risk assessments, especially those concerning sociotechnical systems. It is, however, difficult to capture all the relevant background knowledge in a risk assessment context, and there is often a veil of arbitrariness surrounding the mapping of background knowledge, which stems from the subjective nature of this process. By acknowledging this, it is reasonable to call for a more systematic approach to identify the knowledge elements, especially those generated more or less by subjective reasoning, such as assumptions [15].

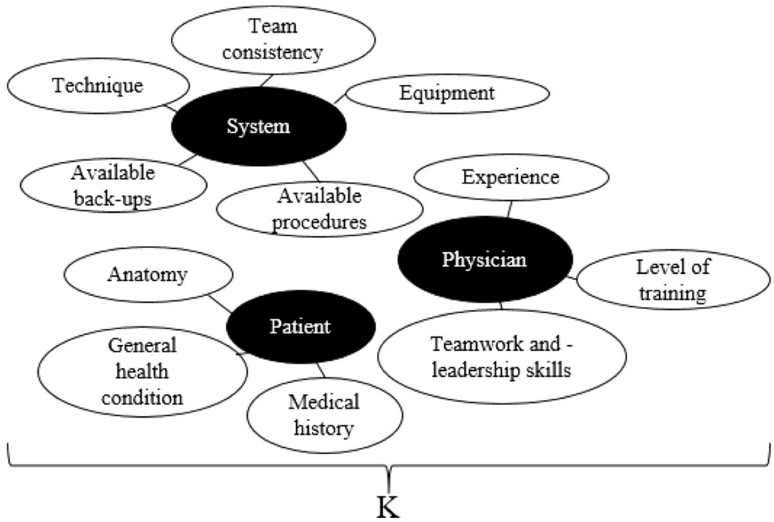

Figure 1. An overview of the knowledge on which the risk related to the PDT procedure was assessed. Based on: Eidesen et al. [36].

A general approach that guides the analyst in mapping the background knowledge appears to be useful and needed. Such an approach must take a holistic perspective on the system of interest, to capture both single components and interactions, given that many contemporary systems have sociotechnical features, which are characterised by their continuously interacting and influencing components [31,55]. In addition, the approach should explicitly assist the analyst, by pointing out where to look for knowledge, using simple generic components relevant for any system of interest. One issue, however, is that in theory an infinite number of knowledge elements can be embedded in a particular system, not all of which are critical for the real-life situation or risk assessment. It is therefore necessary to distinguish critical from non-critical knowledge elements, to inform the decision-makers about knowledge elements that might require further attention. Although a systematic approach to search for assumptions in the background knowledge is no guarantee that important knowledge will be missed, it is likely to reduce the risk of it happening.

3. The systems engineering initiative for patient safety

On these premises, an attractive tool for identifying the relevant knowledge elements of a system of interest is the systems engineering initiative for patient safety (SEIPS). The SEIPS model, developed by Carayon et al. [26], is custom-made to describe and understand the sociotechnical features of healthcare systems [27,50]. Despite the model's healthcare orientation, its components are general and suitable for most systems. The model, which is illustrated in Figure 2, builds on Donabedian's [33] structure-process-outcome model and consists of three dynamically influencing parts.

To illustrate, the SEIPS model components can be described in the case of, say, an air traffic control system. The *person*, who can be an individual or a group of individuals, such as a traffic controller or an organisational unit, respectively, is at the centre of the *work system*, performing certain *tasks*, which can be considered as actions, for example communicating with the aircraft crew. The tasks are performed within a *physical environment*, such as a control centre, supported by different *technologies and tools*, for example software simulators. All the tasks are subject to the *organisational* conditions such as rules and procedures. In addition, the *external environment* provides a boundary for the other five components, through resources, standards, legislation, and so on. The work system influences the *processes*, which are a series of steps [26], for example to direct the runway traffic, generating the *outcomes*, such as safe and effective flow of runway traffic. Finally, *feedback loops* are present in the model, to promote learning, knowledge sharing and improvement [27].

Although the SEIPS model requires all the relevant components within a work system to be described individually, it forms a framework which emphasises the interactions between the components, in order to provide a deeper and broader understanding of how they influence each other, the processes and outcomes [27]. If any changes occur within a work system, for example that a new technology is introduced, they have possible positive or negative effects on the other work system components, processes and outcomes (see, e.g., [87]). The SEIPS model can identify such implications, which is why the SEIPS model is attractive for the purpose of identifying and structuring relevant knowledge elements, on which a risk assessment can be based.

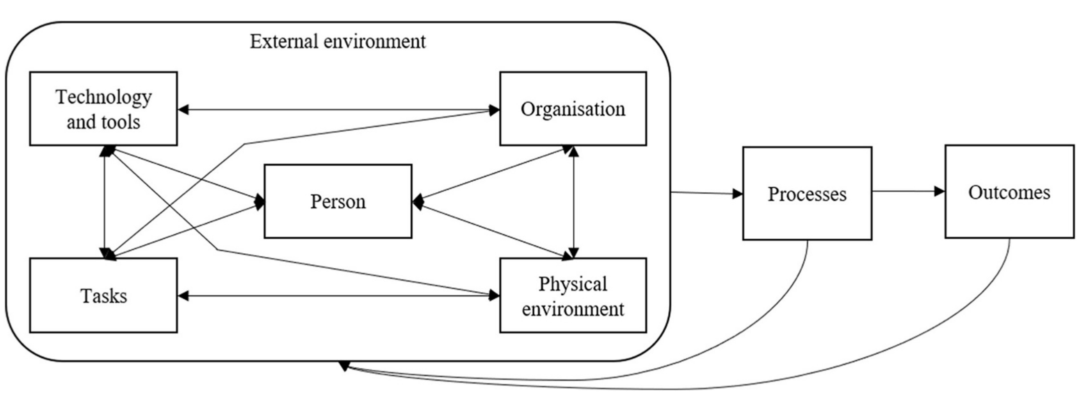

Figure 2. The SEIPS model. Based on: Carayon et al. [27].

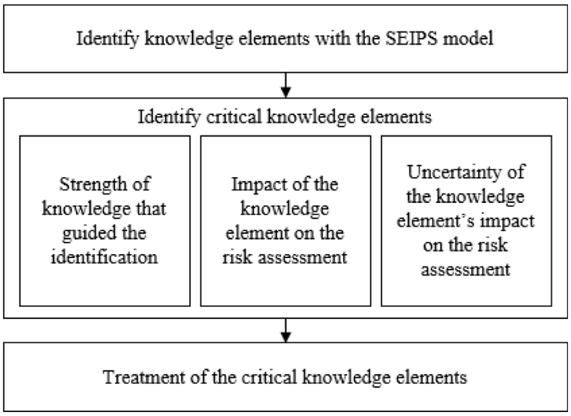

Figure 3. The workflow of the suggested framework.

The key is to remember that the work system components are networked, mutually interacting with and influencing each other. But, as the processes and outcomes are thought to be shaped by all the interactions in the work system at the same time, it is in theory possible that any number of work system components can interact with any other simultaneously [50]. The result is an unmanageable situation, in which there are too many interactions associated with a particular process of interest. To overcome this issue, Holden et al. [50] suggest applying the concept of configuration. The idea of configuration is to limit all the possible interactions which can occur in the work system to a subset of them, which includes only those relevant for the particular process of interest [50]. Building a configurative model is not straightforward, but, if performed correctly by qualified analysts with knowledge of the situation on interest, the SEIPS model can assist the analyst in scrutinising the system components and interactions, in order to identify knowledge elements that are not intuitively and easily discovered. One issue, which was highlighted by one reviewer of an earlier version of the paper, is that such simplifications can lead to missed assumptions. This is true and important to acknowledge. However, we believe that simplifications will always be more or less required when using the tools available in a risk assessment; for example, a model is a simplified representation of reality [6]. This fact is not an argument against the use of configurative models and the SEIPS, but rather a part of the motivation to develop a framework for identifying the relevant background knowledge, such that we foster increased understanding of what knowledge the risk analysis considers and what it does not take into account.

4. The framework

This section introduces the suggested framework, which intends to guide the analyst in identifying and assessing relevant background knowledge to support a risk assessment. The foundation of the framework stems from the SEIPS model and its ability to identify knowledge elements, which have a role to play in the background knowledge. In such matters, the framework aims to reduce the risk of missing critical assumptions (knowledge elements). Depending on the characteristics of the system in focus, the number of identified knowledge elements might be significant, resulting in an unmanageable situation, where the many identified knowledge elements provide limited practical decision support, possibly concealing those which need further treatment. It is therefore recommended to distinguish the critical knowledge elements from the non-critical.

Here, the meaning of criticality is influenced by the ones in the literature on critical infrastructure, in which it is commonly referred to as an incapacity or destruction which leads to significant consequences [21,94]. In light of this, we consider a critical knowledge element to be an element of the background knowledge related to the phenomena of interest, where its incapacity or destruction leads to significant consequences, for both the real case of interest and the risk assessment. To determine whether a knowledge element is critical, we evaluate its foundation (background knowledge), implication for the risk assessment and associated uncertainty. The background knowledge, on which the knowledge element is identified, is reasonable to consider in this context, as an element can be related to more or less strong knowledge. The impact of a knowledge element on the risk assessment should also be evaluated, as some elements are likely to be of greater importance for the risk assessment than others. Finally, we must take into account that the impact is uncertain, and it is informative to know whether the evaluated impact can be considered to give a good or poor prediction of the real impact. These three evaluations provide information about the uncertainties and quality of the knowledge elements, making the framework a means to increase the trustworthiness of the risk assessment. From the list of critical knowledge elements, the analyst can also study how to best treat and control them. The main parts of the framework are illustrated in Figure 3.

Before the framework can be applied, however, it is paramount that the analyst has a good understanding of the risk assessment context, which is established in a planning phase [7]. This involves, amongst other things, clarifying and specifying the decisions to be supported by the risk assessment and developing the objectives of the assessment [11]. Without a clear and unambiguous context, the analyst will struggle to understand which knowledge elements are relevant and critical for a particular case of interest. In the following, we discuss each step of the framework.

4.1. Identification of the Knowledge Elements

The first step in the framework is to identify relevant knowledge elements using the SEIPS model, which requires it to be customised to the risk assessment context. Only then can the analyst use its generic components as guidance for identifying those knowledge elements which are relevant to the real processes and the risk assessment. In theory, however, any number of work system components can interact with any other at the same time [50], resulting in a situation with too many (irrelevant) interactions. To overcome this issue, we apply the concept of configuration, which is similar to our idea of identifying the relevant knowledge elements. We consider the configuration to be a two-step procedure, in which we first focus on single components and then the interactions.

The single components are identified and described using the SEIPS model and its generic components as guidance, that is, to identify and describe the person, tasks, physical environment, technologies and tools, organisation, and external environment, associated with the specified processes and outcomes. Based on human factors principles (e.g., [34]), a natural starting point is the person component at the centre of the work system, followed by the other work system components, systematically. The components should be accompanied by descriptions of their characteristics (see, e.g., [26]).

Following the single component characterisations, the analyst has a basis to identify interactions among the components that are relevant for the processes. This is more challenging and time-consuming than the single component considerations, but it is also likely to be more rewarding, given that the risk of missing knowledge elements is greater among the interactions [87]. Different approaches are possible [50], but we recommend starting by pairing two and two components and their characteristics, for example the person's level of training and the tasks' complexity, then proceeding with person and physical environment, and so forth. Depending on the scope of the risk assessment, the analyst might also consider the interactions between three or more components.

The identified components and interactions (i.e. the configurative model) are the basis for identifying relevant knowledge elements, which are believed to influence the processes of interest and/or risk assessment. To illustrate, consider the case of applying the SEIPS model to identify knowledge elements for a risk assessment related to a medical procedure. First, the analyst directs his attention to the person component, leading to the physician performing the procedure being identified and described. Secondly, the analyst focuses on the task component, leading to an identification and description of multiple actions (e.g., communication, decision-making, teamwork). For simplicity, we limit this example to those two components. The physician is characterised, among others, by his experience and training. The levels of these two attributes have the potential to influence the process and, therefore, should be considered and explicitly listed as knowledge elements. The link between the person and tasks is obvious, but the key is to remember that this interaction is networked with the other components and must be evaluated from a systems perspective; how will the physician perform the tasks, given the presence of the other work system components? Depending on the system of interest, the physician can experience fatigue or stress, which will affect his performance. These are other examples of knowledge elements, potentially affecting the process, and, therefore, have a role to play in the background knowledge.

The SEIPS model assists the analyst in taking a systematic and holistic approach to identify knowledge elements, which is likely to reduce the risk of missing relevant knowledge [57,87]. We suggest that the identified knowledge elements are listed and presented along with descriptions of the elements, as well as a reflection of the source (i.e. expert judgments, assumptions, data, and models) that guided the identification.

4.2. Assessment of the Knowledge Elements

Despite the fact that all the identified knowledge elements are believed to have an effect on the processes of interest and the risk assessment, it is likely that some of them are more critical than others. Considerations of the criticality should be made to increase the trustworthiness of the risk assessment and to fully inform the decision-maker about the uncertainties in the background knowledge. In addition, highlighting the critical knowledge elements means that the decision-maker obtains a basis for understanding which knowledge elements require further treatment and how to efficiently respond to the threats ([13], p.136). The three aspects of criticality will be discussed in the following.

4.2.1. Evaluation of the Strength of Knowledge

Knowing whether it was expert judgments, data, models, assumptions or, most likely, a combination of the four, which resulted in a particular knowledge element being identified is informative for the decision-makers [6,46]. More important is knowing whether the knowledge elements constitute uncertainty, in the sense that they might be based on poor or insufficient knowledge. This relates to the purpose of this step in the framework: to reveal any weak or insufficient knowledge elements, which might demand further treatment, as they impose uncertainties on the risk assessment.

The arguments for taking the strength of the knowledge, which guided the identification of knowledge elements, into account, follow those presented in Section 1. That is, the knowledge can be more or less strong, and uncertainties can be hidden within it. To evaluate the strength of knowledge (SoK) associated with the identified knowledge elements, we suggest using the qualitative categorisation by Flage and Aven [39], but other methods exist (e.g., [46,90]). The crude SoK categorisation is presented in Table 1. In a stringent form, the knowledge elements are said to be based on strong knowledge if all the aspects (whenever they are applicable) in the left column of Table 1 are met, and weak knowledge if at least one of the aspects in the right column is satisfied [6]. Cases in between strong and weak are said to be medium SoK [6,39]. The evaluation of SoK will be case-specific and subject to the analyst's judgments, where each of the four aspects related to weak and strong SoK can take on a weak, medium or strong score [41]. The SoK can be represented as an overall evaluation of the four aspects (see, [6]) or by separately highlighting the SoK for each of the four aspects (see, [46]).

4.2.2. Evaluation of the Impact

Although an assumption that is formulated on the basis of a weaker knowledge element is often considered a (strong) simplification, it can be justified if the knowledge element has a negligible impact on the risk assessment [42]. All the identified knowledge elements are assumedly affecting the risk assessment but most likely to varying degrees, in the sense that some knowledge elements are of greater importance for the risk assessment than others. The purpose of this step is to gain such understanding, emphasising that the analyst must address what effects the knowledge elements have on the risk assessment. Traditionally, sensitivity analysis is preferred in such cases, as it can be understood as the "study of the relationships between information flowing in and out of a model" [82]. However, given that many of the identified knowledge elements will have a qualitative nature without a mathematical relationship to the risk assessment, it is not straightforward to use sensitivity analysis as a standard tool [83]. Please note that sensitivity analysis is not the same as uncertainty analysis [10,82].

Whenever a knowledge element relates to an observable quantity or direct input to a mathematical model, its value and impact on risk can be expressed quantitatively. A common approach is to use predictors, for example expected values, to represent the quantities of interest [87], but such metrics have limitations [1]. An alternative is to represent the quantities by prediction intervals (credibility intervals for model parameters), reflecting that we are, say, 90% certain that the unknown quantity will be in the interval [a, b], i.e. $P(a \leq X \leq b) = 0.90$ [10]. For these knowledge elements, which are direct input to mathematical models, traditional sensitivity analysis is recommended to determine the impact on the risk assessment (see, e.g., [83]).

For other knowledge elements, which are neither observable nor direct input to models, it can be meaningless, but not impossible or undesirable, as it is not economical, to assign quantitative values and use them as input in a model. If quantification is desired, however, the analyst can build a mathematical model, which links the "qualitative" knowledge elements, expressed for example by a cardinal (0.5, 1.5, 2.3 …) or ordinal (low = 1, medium = 2 …) scale [24], to the risk assessment. However, there are two aspects which must be considered: is such treatment of knowledge elements in line with the context of the risk assessment, and does it, in comparison to, say, a qualitative scoring of the impact, produce additional decision support. It is outside the scope of the paper to study these questions in detail, but we strongly recommend making such considerations before evaluating the impact.

Although a qualitative evaluation of the knowledge elements' impact on risk assessment does not give the comprehensive and integrated level of quantitative insight of traditional sensitivity analysis, it offers practicality and manageability, providing a sufficient impression of the knowledge elements' impact on the risk assessment [5,42]. We suggest expressing the impact qualitatively (e.g. low, medium, and high), unless traditional sensitivity analysis is believed to significantly increase the decision support or strongly desired. Consequently, it is necessary to clarify what is meant by, for example, a scoring of low, medium and high impact. A qualitative categorisation, which is frequently used in the literature (e.g., [12,20,89]), is the crude sensitivity classification suggested by Flage and Aven [39], which we have modified to fit our context (based on [39]):

3- High impact: Relatively small changes in the knowledge elements needed to bring about different risk assessment results and recommendations.
3- Medium impact: Relatively large changes in the knowledge elements needed to bring about different risk assessment result and recommendations.
3- Low impact: Unrealistically large changes in the knowledge elements needed to bring about a different risk picture.

Table 1
The strength of knowledge (SoK) categorisation [6,39].

Strong SoK	Weak SoK
- The assumptions made are seen as very reasonable - Large amount of reliable and valid data - There is broad agreement among experts - The phenomena in focus are well understood; the models are known to give predictions with required accuracy.	- The assumptions made are seen as strong simplifications - None or highly unreliable data - There is strong disagreement among experts - The phenomena in focus are poorly understood; models are non-existent or believed to give poor predictions.

The intent of this section is not to propose a "correct" method to evaluate the impact but, rather, to highlight the importance of considering how each knowledge element can affect the risk assessment. We must emphasise that the impact evaluations and, therefore, the definitions of the qualitative categories, will be case-specific [39,89]. It is not our intention, or desire, that the framework should be a "black-box", with an explicit input-output relation, but a tool for guidance and assistance on how to manage the knowledge elements. In Table 2, we have provided an example of how the analyst can summarise the impact evaluation in a clear and informative matter, by a consideration of the knowledge element, "person's level of experience"; the impact is evaluated and represented qualitatively, complemented by informative descriptions.

4.2.3. Evaluation of the Stochastic Uncertainty

From the previous step, each knowledge element has been evaluated in terms of its impact on the risk assessment, but the evaluated impact could be a good or poor prediction of the real (unknown) impact. To be in line with fundamental principles of risk management, such as the cautionary principle, we need to be aware of these uncertainties. Over time, system components, both social and technological, will be replaced, fail, change, be repaired, age, adapt to their surroundings, and so on [95], indicating that the associated knowledge elements' impact can vary. In other words, the evaluated impact could turn out to be wrong. This is of especial importance working with sociotechnical systems, which involve (unpredictable) human actions and components that are adaptive and dynamic by nature [31,55]. Conditioned on the knowledge elements' SoK and impact on risk assessment, the quality of the knowledge elements' expected impact might be a trigger for taking precautionary actions.

To reflect the evaluated impact's quality in predicting the real impact, we suggest considering the stochastic uncertainties. A qualitative measure of the stochastic uncertainty in the knowledge element's impact (i.e., low, medium or high) is considered sufficient for the scope of the paper. We therefore suggest the following criteria for evaluating the quality of the impact (based on [3]):

3- High stochastic uncertainty: The uncertainty is classified as high if the expected impact is considered to give a poor prediction of the real impact.
3- Low stochastic uncertainty: The uncertainty is classified as low if the expected impact is considered to give a good prediction of the real impact.

Medium stochastic uncertainty is then given as cases in between high and low. All these evaluations must be seen in light of the available knowledge, for example referring to the SoK from Section 4.2.1. Through these definitions, stochastic uncertainty is understood as a reflection of variation, in the sense that high (low) stochastic uncertainty is used when the population of a certain knowledge element has high (low) variation. To inform the decision-makers about the variation in the expected impact, the uncertainty can be represented next to the impact evaluation, as in Table 2.

4.2.4. Summarising the Critical Knowledge Elements

After the three evaluations, the results should be communicated to the decision-maker in a clear and unambiguous way, which helps to classify critical knowledge elements. Here, the challenge is to decide on which combinations of SoK, impact and uncertainty make a knowledge element critical. Is a knowledge element with, say, weak SoK, low impact and medium stochastic uncertainty more critical than another with strong SoK, high impact and medium stochastic uncertainty? We consider this to be a managerial issue, which must be seen in light of the context of the risk assessment. Following general risk management principles, however, it is intuitive that the weaker the SoK is and the greater the impact and stochastic uncertainty are, the more critical is the knowledge element for the risk assessment.

Various policies can be used to determine criticality. For example, a simplified scoring system (see, e.g., [88]) with a predetermined criterion might be sufficient, but this could also lead to a mechanistic classification of criticality, which hampers risk-informed decision-making. We, therefore, recommend summarising the evaluations from the previous steps, as in Table 3, in which criticality can be determined by an overall evaluation of the SoK, impact and uncertainty. In terms of being precautious, however, cases in which the SoK is evaluated to be weak might require special treatment, as the implication is that the impact and uncertainty evaluations are founded on weak knowledge. The summary informs the decision-makers on what knowledge the decision support is based, which elements that are deemed critical and how they could affect the risks. From this, the decision-makers has a basis to evaluate if the system is safe enough and to consider different types of treatment of the critical elements. This can be achieved by considering one knowledge element of the time, or by an overall impression of all the knowledge elements (e.g. a majority of critical knowledge elements might need precautionary measures such as not carrying out the activity).

4.3. Treatment of the Critical Knowledge Elements

A critical knowledge element is one which calls for further attention, as it brings about uncertainty and/or a possible adverse effect on the system of interest, potentially weakening the credibility of the risk

Table 2
Example of impact and uncertainty evaluation.

Knowledge element	Impact	Stochastic uncertainty	Comments
The level of experience	Medium/high	Medium	The values of the element can be medium or high. Given the complexity of the tasks, level of experience is likely to be important for the outcome. The knowledge element contributes more to uncertainty than to the consequences.

Table 3
Example of a summary of the identified knowledge elements.

Knowledge element	SoK	Impact	Stochastic uncertainty	Critical	Risk-reducing measure	Effects and costs
#1	Strong	High	Medium	Yes	Physical safety measure.	Reduces consequences. Medium costs.
#2	Weak	Medium	Medium	Yes	Increase the knowledge base.	No direct impact on system. Low costs.
#3	Medium	Low	Low	No	–	–

Table 4
A non-exhaustive list and description of the relevant SEIPS components for the example case. Based on: Langdalen et al. [57].

System components	Descriptions and characteristics
Person	Physician who performs the tasks, with the following characteristics: - Education, specialty (e.g., intensive, anaesthesiology, neurology), experience. - Level and type of training and post-assessment of the training. - Level of non-technical skills (i.e., decision-making, leadership, communication, situation awareness, teamwork, managing stress, coping with fatigue). Patient, not relevant/performing any tasks in our case, but his/her characteristics are important for the outcome: Medical history, general health condition, anatomy, medication, etc.
Tasks	Performing the tracheotomy; different steps and techniques: - Communication, care coordination, decision-making, leadership, teamwork, stress, high work demand, etc.
Technology and tools	Perform tracheotomy with the PDT technique, requiring the following tools: - Equipment (endotracheal tube, monitors, headlights/source of natural light, mechanical ventilator, bronchoscope and video screen, checklists, anaesthetics, sedatives, etc.), supplies (haemostats, dilators, surgical sutures, etc.) and back-ups.
Physical environment	Intensive care unit, characterised by, e.g.: - Noise, lighting, air quality, room hygiene, space (large enough), etc. - Physical layout of the room (location of the bed, monitors, ventilator, etc.), unit (e.g., sleeping/resting facilities for on-call staff, waiting area for family) and team (e.g., physician on the right side of the bed).
Organisation	Department/hospital level - Interaction with managers, organisational support, information flow, safety culture and climate, procedures, best practice guidelines, rules, teamwork, team composition, experience, etc.
External environment	Resources, legislation, standards, new technology, duty regulations, etc.
Processes	The PDT procedure, which is affected by all the components in the work system.
Outcomes	Patient safety and quality of care.

assessment results and recommendations. The final step in the framework is to provide decision support on how to best manage the knowledge elements of potential risk-reducing measures and the implication of those measures for the system. One way to present the findings to the decision-makers is to include them in the summary of the knowledge elements, for example as in the two right-most columns of Table 3.

Which risk-reducing measures are required can be seen in light of the criticality evaluations, where the measures should, at least, aim to reduce the uncertainty and consequence of incapacity or destruction of a knowledge element, by strengthening the factors that contributed the most to its criticality. For example, the first knowledge element in Table 3 has a high impact on the risk assessment, indicating that it should be treated, for example, by implementing a physical measure to reduce the associated vulnerabilities in the system. Other risk-reducing measures could be to increase the knowledge base and understanding, as is relevant for the second knowledge element in Table 3. The critical elements are those which mostly require treatment, but we also suggest going through the non-critical elements in terms of potential surprises, unexpected or unwanted events.

An evaluation of the effects of the identified measures is recommended, since the measures might have lower than intended or unexpected negative effects on the system. Implementation of risk-reducing measures also raises concerns about costs and benefits which should be taken into consideration. It is outside the scope of this paper to say how this should be done, but alternative methods could be cost-benefit analyses or the ALARP principle (see, e.g., [9]). The final task for the analyst is to ensure that all the information is presented in a clear and unambiguous way to the decision-maker for review and judgments, as it enhances the risk management and decision-making process [6]. The results can, for example, be presented by the summary in Table 3 with references to Table 2 and a list of the identified knowledge elements. See also Sørskår et al. [87] for inspiration on how to represent the findings.

5. An example: applying the framework to support the pdt risk assessment

In this section, we revisit the PDT case of Eidesen et al. [36], introduced in Section 2, to illustrate how the suggested framework can support the risk analyst in revealing and reducing the risk of missing critical knowledge elements. We therefore focus on the first two steps of the framework: the identification of knowledge elements (Section 4.1) and the assessment of criticality (Section 4.2). The identification step of the example is a revised version of the example presented in Langdalen et al. [57], improved by the experience of creating the initial study. Prior to operationalising the framework, however, we need to align the SEIPS model to the risk assessment context. Given that the objective of the risk assessment introduced in Section 2 is to provide risk-related knowledge of performing PDT procedures in the ICU, it is reasonable to specify the processes of interest as the PDT procedure, while limiting the outcomes to patient safety and quality of care. The SEIPS model and its components can then be used to identify knowledge elements to support the risk assessment.

5.1. Identification of the Knowledge Elements

The first steps of the framework are to identify and describe the components and interactions within the work system, which are relevant for the specified process and outcomes. According to the workflow described in Section 4.1, we start by identifying and describing the person component and systematically mapping all the other components. The characteristics of the components of interest are presented in Table 4. Although the framework suggests that the single component descriptions should be followed by identification and description of the relevant interactions, such as the fact that the level of experience affects the way the different tasks are performed, we have, for the sake of simplicity, not reported the list of interactions. But, based on all the characterised single components and (non-reported) interactions, we

Table 5
A list of ten critical knowledge elements with associated criticality assessments.

No.	System component or interaction	Knowledge elements influencing the risk assessment and/or outcomes	Knowledge source	SoK	Impact	Uncertainty	Critical	Reference	Comment
1	Person	Experience	Data, expert judgments	Weak	Medium	Medium	Yes	Brass et al. [23]; Melloni et al. [66].	No clear evidence of a difference in outcome. PDT more beneficial for trainees, in terms of complications, than for ICU staff. Great heterogeneity (disagreement) in outcomes/populations.
2	Tasks	Teamwork and leadership	Data, expert judgements	Strong	High	Low	Yes	Manser [63]	Well documented. Consensus among experts that teamwork is critical for the outcome of any medical procedure.
3	Technology and tools	The reliability of the equipment (monitors, bronchoscope, etc.)	Data, model	Medium	High	Low	Yes	Weerakkody et al. [91]	High reliability of the equipment, given standards, etc. But critical, as, if an error occurs, it will most likely lead to error.
4	Physical environment	Familiar team members	Data, expert judgments, assumption	Medium	Medium	Medium	Yes	McElroy et al. [65]	Ref. teamwork (no. 2)
5	External environment	Limited resources	Assumption	Weak	High	Medium	Yes		Limited resources might affect other activities or planned activities.
6	Person-Tasks	Interruptions/disturbances during the PDT procedure	Expert judgments, assumption	Medium	High	High	Yes	Rivera-Rodriguez and Karsh [81]	
7	Person-Tasks	Callings/paging during the PDT procedure	Expert judgments, assumption	Medium	High	High	Yes		
8	Person-Tasks	Physical condition of the physician (fatigue, etc.)	Data, expert judgments, assumption	Weak	High	Medium	Yes		
9	Person-Tasks	Mental condition of the physician (fatigue, stress, etc.)	Data, expert judgments, assumption	Weak	High	Medium	Yes		
10	Person-Technology and tools	Relevant training in the available equipment	Data, expert judgments, assumption	Strong	High	Low	Yes	Sollid et al. [86]	Important to have training in the available equipment (e.g. bronchoscope). If not, should not carry out the activity.

have identified numerous knowledge elements that are relevant for this particular case, which are summarised in Tables 5 and A1.

5.2. Assessment of the Knowledge Elements

To fully inform the decision-maker about the uncertainties and quality of the knowledge element, we proceed by evaluating the associated criticality, according to Section 4.2. For the purpose of this example, it is sufficient to qualitatively evaluate the three aspects of criticality. The knowledge that guided the identification is classified using the crude SoK classification by Flage and Aven [39], as explained in Section 4.2.1. For the impact evaluations, we follow the criteria listed in Section 4.2.2, whereas the uncertainty related to the impact is determined according to the qualitative criteria presented in Section 4.2.3. Based on the three aspects, we have made an overall judgment about each knowledge element's criticality for the risk assessment. If this had been a real-life project, we would have continued the assessment by identifying risk-reducing measures for the knowledge elements and evaluated the associated effects on the system (as discussed in Section 4.3). However, the purpose of this example is to illustrate how the suggested framework provides additional information, compared to the case of not taking a systematic and holistic approach to the knowledge identification. We therefore proceed by comparing the findings in Tables 5 and A1 with the information provided in Section 2.

5.3. Comparing the Different Knowledge Bases

After we have applied the SEIPS model to identify knowledge elements, it is reasonable to say that the identified knowledge in Eidesen et al. [36] was incomplete. By comparing the knowledge elements in Figure 1 and Tables 5 and A1, it is clear that the systematic and holistic approach is capable of providing a more complete and informative knowledge base. More specifically, the systems approach is able to identify interactions between the single components, identify more knowledge elements for each single component, and highlight the quality and uncertainty associated with the identified elements.

It is the ability to take the interactions into consideration that really makes the framework and SEIPS model attractive in terms of obtaining a more complete background knowledge. As an example, in Figure 1, the relevant components (physician, patient, system) are considered in isolation, such as the physician's level of training and the type of equipment that is available, but what is important for the real PDT procedure is whether the physician has training in using the available equipment (no. 10 in Table 5). The systematic and holistic approach has identified other apparently critical knowledge elements that should have been considered in the risk assessment (see Table 5). The physician's mental and physical conditions, for example, are implicitly assumed to be good in Eidesen et al. [36], implying that any physician performing a PDT procedure will neither be, nor has been during his time on-call, subject to fatigue or stress at the time of the procedure, if the risk assessment results and recommendation can be considered representative for the real case of interest. These assumptions, however, can easily be violated, given the characteristics of working in the ICU (see, [84]). As the SEIPS model assists the analyst in taking a system perspective, the risk of missing such assumptions is reduced (nos. 8 and 9, Table 5). Other critical interactions, which were ignored by the somewhat atomistic and arbitrary identification in Eidesen et al. [36], are listed in Table 5.

Although it is the ability to identify and consider interactions that really promotes the use of the SEIPS model to map knowledge elements, the systematic and structured approach of the framework also enables the risk analyst to identify more knowledge elements related to each single component than is the case if a non-systematic approach is taken. For example, the external environment's impact on a system of interest (no. 5 in Table 5 and nos. 37 and 38 in Table A.1), is easily forgotten when working with sociotechnical systems [93]. The framework, on the other hand, will explicitly direct the analyst's focus towards the relevant system components, demanding that each component is fully understood and described; it reduces the risk of missing critical knowledge elements.

The assessment of criticality is clearly informative and ensures that the uncertainties and quality of the background knowledge are properly understood, reflected and communicated. In such matters, the framework assists the risk analyst in proper treatment of the background knowledge (e.g., [16]). The SoK, impact and uncertainty evaluations inform the decision-makers about the quality of what the risk assessment considers and represents, what the outcome expresses and the knowledge that guided the analyst. Therefore, the framework is also a means to increase the trustworthiness of the risk assessment. Finally, we must emphasise that our aim is not to criticise the work of Eidesen et al. [36] but, rather, to highlight the advantage of and need for a systematic and holistic approach to identify, structure and evaluate the background knowledge.

6. DISCUSSION

The fundamental idea of the paper is that, in order to map and obtain good-quality background knowledge, a systems or holistic approach, which captures both single components and system interactions, is often needed. Risk assessments will always be more or less conditional on the available background knowledge (data, information, assumptions, etc.) and it is important that this knowledge contains all the relevant elements. Making sure that the background knowledge contains all the relevant information is a challenging task. The current practice of identifying background knowledge does not appear to be the ideal solution, as it is usually a more or less arbitrary approach. The suggested framework, provides a methodological approach that contributes to this end and can be applied to assist the risk analyst in the search of relevant knowledge, on which the risk assessment can be based. This is an important issue as the quality of the background knowledge influences the risk management. The suggested framework can be used to assist the risk analysts to increase the quality of the risk analysis by improving the quality of the background knowledge and reducing the risk of missing assumptions. By presenting the results to the decision-makers, the framework can also increase the trustworthiness and understanding of the produced decision support.

We have suggested a framework which can assist the risk analyst. Firstly, the framework reduces the risk of missing critical knowledge, as it guides the analyst in the search for knowledge elements which have a role to play in the background knowledge. However, a reasonable question that needs further elaboration is why the SEIPS model, and not one of the many other system models reported in the literature, should be applied. Secondly, the framework increases the trustworthiness of the risk assessment, which is achieved by evaluating the SoK, impact and stochastic uncertainty related to the identified knowledge elements. The suggested framework, however, does not need to be applied in this depth of detail. Its application and implementation should be seen in light of the scope of the risk assessment and the uncertainty, complexity and ambiguity of the risk-related problem. We therefore also need to discuss the practical application of the suggested framework.

6.1. Why the SEIPS model?

The SEIPS model is, as stated in the introduction, one of many candidates with promising features for identifying knowledge elements. The reader may therefore wonder why the SEIPS model was selected over the other system models reported in the literature (e.g., [18,19,48,51,54,58,59,61,62,69,73,75]). First of all, we are not claiming that the SEIPS model is the only model which is applicable for mapping knowledge elements, but it is, to the extent of our knowledge and understanding, one of the most suitable models for this task with respect to certain aspects which we consider essential for obtaining good-quality background knowledge: (1) the model takes a systems approach and perspective, (2) the model captures both social and technological aspects, and (3) the model also captures external factors, such as economic concerns.

In many contemporary real-life systems, the complexity is high and increasing, as a result of globalisation, digitalisation and so on [34,55]. The increased complexity gives rise to previously rare and non-existent forms of risk [49,73], such as unforeseen interactions between the system components [25,30]. Therefore, most of the traditional approaches to systems design and safety that were considered adequate in the past are now seen as less useful [60]. It is, for example, acknowledged that, to capture the complexity of many contemporary systems, traditional root-cause analysis is unsuitable [31,59]. Consequently, a model which is based on linear thinking is generally not suitable to map all the relevant knowledge elements to support a risk assessment, as such models are likely to miss knowledge elements whenever interactions within a system are present (see, e.g., [87]). The SEIPS model supports this way of thinking, as it captures the interactions and interdependencies among the system components. This is what we mean when speaking of taking a systems approach, which is similar to the understanding of a systems approach within the disciplines of ergonomics and human factors (see, e.g., [34]).

We should emphasise that this does not imply that SEIPS is only applicable if the system involves non-linear and non-foreseen scenarios or that other system models that does not see non-linearity as an essential factor of complexity can be used in the framework. Tools such as Workgroup Occupational Risk Model [69] or Storybuilder [18], are examples of promising tools for identifying relevant knowledge elements. However, they are based on a different way thinking compared to the one in the suggested framework. In the suggested framework, we are concerned about the background knowledge, which is used as input data in the other tools when focusing on scenarios and accidents. The challenge with those models, is that they imply a reliance on having the input data. The SEIPS model, when applied as described in Section 4, can contribute to this end by providing relevant knowledge about the situation. Although the analysts use should use their own and other experts' experience, available literature and logic to identify scenarios [18], we believe that a more systematic approach is needed to reduce the risk of missing relevant knowledge. In addition, the framework can complement risk assessments and accident investigations when there is insufficient data about the situation of interest. For example, Bellamy et al. [18] states that determining if a centre event in a bow-tie model occurs implies a reliance on having knowledge about the barriers. It is this knowledge the suggested framework aims to identify and reveal to the decision-maker.

Which interactions we are able to identify in a system, however, is also conditional on which single components we include in the system model, as the system as an integrated whole is understood as the set of interactions between the single components [34]. A framework which is supposed to reduce the risk of missing knowledge needs to take the relevant single components into account. The number of possible system components that can be relevant for any risk assessments is almost infinite, and we need to generalise it to a manageable number. In the human factors discipline, for example, system components are commonly divided into humans and their environment, understood as other humans and so-called human-made artefacts, such as workplaces, tools, technologies, tasks, products, organisational procedures, and so on [34,92]. This is similar to the common understanding of sociotechnical systems, which can be defined as the influencing combination of "humans, machines, environments, work activities and organizational structures and processes impacting an organization and its performance" [25], in which the system components are related to either social or technological aspects [68]. Therefore, the system model applied to identify knowledge elements in the suggested framework should be capable of considering both social and technological components, which the SEIPS model does.

Although it is essential to focus on the individual components and interactions within a work system, to map the relevant background knowledge, the external environment (pressure, factors) could also have a role to play [27,74,93]. If the decision to be supported by a risk assessment is, say, formulated as a go or no-go decision about a certain process, it is essential that, for example, the economic (budget) constraints are taken into account. Resources spent on one activity might lead to fewer resources spent on other activities or planned activities [2]. Then, from a portfolio perspective, assuming that a company is involved in several projects (activities, systems), the effect of an activity might be less than intended if economic concerns are not taken into consideration. This is often forgotten when working with sociotechnical systems [93], which is why we find it important to explicitly have the external environment as an element in the system model, in order to obtain good-quality background knowledge, on which risk can be assessed. In the initial SEIPS model [26], the external environment was not separated from the physical environment. But, as a result of increased understanding [50], the external environment is now considered a separate component in the SEIPS model [27], which increases the likelihood of identifying knowledge elements related to external aspects, such as scarce resources or new technology, as well as the potential implications and effects of the external environment on the work system and its components.

The SEIPS model and the use of configurative models to identify knowledge elements have some weaknesses which we must acknowledge. As one of the reviewers of an earlier version of the paper highlighted, knowledge elements that are not considered critical toady may become critical in the future. Using configurative models implies that we are taking snapshots of the system as it is today, which might be different in the future (see e.g. [87]). The time dimension could be an addition to the three aspects of criticality that we mentioned in Section 4. One possible method that appears to be useful is the concept of assumption deviation risk (see, e.g., [5]). The three aspects of criticality (SoK, impact and stochastic uncertainty) provide relevant information to assess the deviation risk of the knowledge elements. This is potentially a topic for further development and improvement of the suggested framework.

To summarise, any model that is applied to identify relevant knowledge to support a risk assessment should take a systems approach, cover single components related to both social and technological aspects, and motivate considerations of external factors such as economic concerns. This does not imply that the SEIPS model is the only option, although it is clearly an attractive alternative. In addition, the SEIPS model does not rely on any initial assumptions about the system of interest before it is applied. It has a given structure with a few generic components, which can be used directly to assist the risk analyst in identifying the relevant knowledge elements.

6.2. Using the Framework in Practice

Independent of which system model is used as the search engine of the framework (e.g. SEIPS or SADT), it is, as presented in Section 4, somewhat detailed and comprehensive. Consequently, it might not

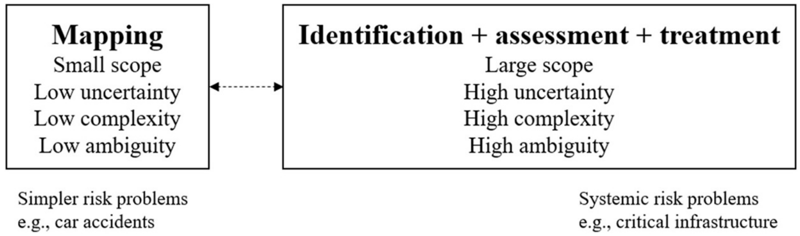

Figure 4. A dynamic interpretation of the suggested framework allows it to be more resource-effective, as its use should be seen in light of the risk assessment context.

always be resource-effective nor in line with the risk assessment context to apply the full framework (i.e. identification, assessment and treatment of knowledge elements). This does not mean that the framework has limited applicability, as the fundamental idea of taking a systems approach to map the background knowledge will always be relevant. The key is to understand when to perform a crude mapping of knowledge elements versus a full identification and assessment.

In the planning phase of the risk analysis process, we therefore recommend considering the scope (e.g., aim and resources) of the risk assessment and the uncertainty, complexity and ambiguity of the risk-related phenomena of interest. Then the analyst can decide how detailed and rich in information the background knowledge should be, to fully support the risk assessment. We have presented the two boundaries of the framework's applications in Figure 4. In general, a risk assessment that is characterised by a small scope and low degrees of uncertainty, complexity and ambiguity is likely to be sufficiently supported by a crude mapping of the background knowledge, by using, for example, the first step of the suggested framework (see Section 4.1). Whenever the scope is large and the uncertainty, complexity and ambiguity are high, it is reasonable to call for a more detailed approach to handle the background knowledge.

There are various types of risk problems that require different types of risk assessment and management strategies, which the suggested framework acknowledges when being interpreted as a dynamic framework that ranges from a crude mapping to a more detailed assessment of knowledge elements (Figure 4). For the simpler risk problems, in which the phenomena of interest are well understood, the consequences are obvious, the uncertainty and ambiguity are low [80], it would not necessarily be resource-effective to perform a full assessment of the knowledge elements in terms of SoK, impact, uncertainty and risk-reducing measures. On the other hand, a risk problem that is, say, emerging (e.g., [40]) or systemic (e.g., [79]) would require a more detailed and holistic approach to risk assessment. Then, the value of the background knowledge is likely to increase with its quality of information, implying that a more detailed and comprehensive treatment of its uncertainties and quality can be justified and should be taken, for example as described in Section 4.

The key, however, is to focus on the interactions and interdependencies among the system components, and their potential ripple- and spill-over effects on the other components and the risk-related problem of interest. The framework is therefore an appropriate tool for obtaining better background knowledge, independent of the risk problem, but the extent to which it is applied should always be seen in relation to the risk assessment context.

7. Conclusion

In this paper, we have suggested a framework that takes a systems approach to identify and assess the background knowledge, on which risk can be assessed. We conclude that to ensure a good quality background knowledge a systems approach is required. The framework serves the purposes of reducing the risk of missing critical knowledge elements, which might have a role to play in the background knowledge, and increasing the trustworthiness of the risk assessment, its results and recommendations. In addition, the identification and assessment of knowledge elements highlight the background knowledge that might require further attention and treatment to obtain the desired outcome of an activity/system. The core message of the paper, however, is that, to obtain good-quality background knowledge, it is often essential to take a systems approach, which captures social and technical components, interactions and interdependencies and their potential effects on the system of interest and risk assessment. In such matters, the framework presents a new approach, which explicitly assists the risk analyst in the challenging task of obtaining good-quality background knowledge. An example was included in the paper, which builds on a shorter version that was presented at the ESREL 2019 conference in Hannover, Germany [57], to illustrate the framework.

CRediT authorship contribution statement

Henrik Langdalen: Conceptualization, Methodology, Writing - original draft, Visualization. **Eirik Bjorheim Abrahamsen:** Conceptualization, Methodology, Validation, Writing - review & editing, Supervision. **Håkon Bjorheim Abrahamsen:** Conceptualization, Methodology, Validation, Writing - review & editing, Supervision.

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Appendix A

Table A1

Table A.1
A non-exhaustive list of identified knowledge elements with associated criticality assessments for the example case.

No.	System component or interaction	Knowledge elements influencing the risk assessment and/or outcomes	Knowledge source	SoK	Impact	Uncertainty	Critical	References	Comments
11	Tasks	Situation awareness	Data, expert judgments, assumption	Medium	Medium	Medium	Yes	Reid and Bromiley [77]	
12	Tasks	Unanticipated events/complications/ bleedings	Data, Assumption	Medium	High	High	Yes	Brass et al. [23]	Uncertain about the estimated effect, as further research is very likely to have an impact on the knowledge base.
13	Technology and tools	Back-ups	Assumption	Medium	Medium	High	Yes		Most likely available but, if not, high impact.
14	Technology and tools	Best available technology	Data, expert judgments, assumption	Medium	High	Low	Yes	Sollid et al. [86]; Powell-Cope et al. [72]	Identified as very important for the perceived safety of the operator. Need the support from all the best tools, to minimise the risk of complications.
15	Physical environment	Familiar equipment	Data, expert judgments, assumption	Medium	Medium	Medium	Yes	McElroy et al. [65]	
16	Organisation	The safety culture and climate in the ICU	Data, expert judgments, assumption, model	Medium	High	Medium	Yes	Huang et al. [52]	Moderate association between culture/climate and outcomes.
17	Organisation	Work schedules, with clear roles and working hours	Expert judgments, assumption	Medium	Medium	Medium	Yes	Parshuram et al. [70]	Shorter schedules – positive for fatigue/stress but involve more transitions.
18	Organisation	Leadership	Assumption	Weak	Medium	High	Yes	Botwinick et al. [22]	Leadership is the critical element in a successful patient safety programme and is non-delegable.
19	External environment	New technology	Assumption	Weak	Medium	Low	Yes		
20	Tasks-technology and tools	Increased workload	Data, assumption	Medium	High	Medium	Yes	Simpson et al. [85]	Increased number of tracheostomies performed with PDT.
21	Person-tasks-organisation	Contemporary disorders	Assumption	Weak	Medium	High	Yes		
22	Organisation-tasks-physical environment	The number of staff present in the ICU at any time	Expert judgments, assumption	Weak	Medium	High	Yes	Reason [76]	Meeting peak demand periods, whenever they occur.
23	Person	Specialty (e.g., anaesthesiology, intensive)	Expert judgments, assumption	Medium	Medium	Low	No	Brass et al. [23]; Sollid et al. [86]; Simpson et al. [85]	Given that all operators, independent of specialty, have experience in using the PDT technique.
24	Person	Level of training (and assessment)	Data, expert judgments	Medium	Medium	Low	No	Gardiner et al. [45]	Should not perform PDT without proper training.
25	Person	Level of non-technical skills	Expert judgments, assumption	Medium	Medium	Medium	No	Flin and Maran [43]	Critical for safety and patient outcome. Data from other medical procedures/domains.
26	Tasks	Performance	Assumption	Medium	High	Low	No		No evidence, but what and how the operator performs the tasks is of interest, but most likely to a satisfying level.
27	Tasks	Communication/Coordination	Data, expert judgments, assumption	Medium	Medium	Medium	No	Coiera et al. [29]	
28	Tasks	Decision-making	Assumption	Medium	Low	Medium	No		
29	Tasks	Duration	Data, expert judgments	Strong	Low	Low	No	Friedman et al. [44]	More rapid procedure, beneficial for the outcome.
30	Tasks	Complexity	Assumption	Strong	High	Low	No		Many potential sources for errors or unwanted outcome.
31	Technology and tools	Position	Assumption	Medium	Low	Low	No		Location of technology and equipment might be crucial to avoid adverse events.
32	Physical environment	The physical layout of the room	Expert judgments, assumption	Strong	High	Medium	No	Reiling et al. [78]	
33	Physical environment	The quality of the lighting	Assumption	Medium	Low	Low	No		Poor lighting leads could complicate the procedure, but likely that the quality is sufficient in the ICU.
34	Physical environment	Sleeping/resting area	Expert, judgments Assumption	Weak	Low	High	No	Ferri et al. [38]	Assumption that, without such facilities, it is likely that the operator is not properly rested.
35	Organisation	The information flow system	Data, assumption	Medium	Low	Medium	No	Ehteshami et al. [35]	No clear evidence, but likely to be important.
36	Organisation	Experience with PDT procedures	Assumption	Strong	Medium	High	No		Reasonable assumption; the more experience in ICU and PDT procedures, the better.
37	External environment	Relevant rules and regulations	Data, assumption	Strong	Medium	Medium	No	Clark et al. [28]	
38	External environment	Opportunity cost of PDT procedures	Assumption	Medium	Low	Low	No		
39	Tasks-technology and tools	Reduced experience/skills in other types of surgeries	Data, assumption	Weak	High	Medium	No	Simpson et al. [85]	Reduced opportunities to perform open surgical tracheotomy. Especially for trainees. Implications for surgical training.

(*continued on next page*)

Table A.1 (*continued*)

No.	System component or interaction	Knowledge elements influencing the risk assessment and/or outcomes	Knowledge source	SoK	Impact	Uncertainty	Critical	References	Comments
40	Technology and tools-external environment	Medical device design/development	Expert judgments, assumption	Medium	Low	Low	No	Money et al. [67]	Encourage to involve in the design/development.
41	Technology and tools-physical environment	The position of the monitors in the room (e.g., can all team members see the monitors?)	Assumption	Medium	Low	Medium	No		
42	Technology and tools-physical environment	Damage to equipment	Expert judgments, assumption	Weak	Medium	Low	No	Amoore [4]	Physical environment can cause damage to equipment (humidity, etc.).
43	Technology and tools-organisation	Equipment and supplies in place	Expert judgments, assumption	High	High	Low	No	Reason [76]	If equipment is not in place, the procedure will not be carried out.
44	Technology and tools-external environment	Power supply	Assumption	Medium	High	Low	No		Critical if loss of power, but unlikely to occur.
45	Organisation-tasks	Guidelines/procedures for how to perform PDT procedures	Data, assumption	Medium	Medium	Low	No	Clark et al. [28]	See no. 37.
46	Organisation-physical environment	Changing work environment	Expert judgments, assumption	High	Moderate	Low	No	Reason [76]	
47	Organisation-person-tasks	Fatigue risk management programme	Expert judgments, assumption	Medium	Medium	Medium	No		In place, likely to be positive, but no evidence of direct negative impact.

Supplementary materials

Supplementary data associated with this article can be found, in the online version, at 10.1016/j.ress.2020.106909.

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