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Preface

This thesis is written as a completion of the MSc. program in Industrial Economics at the University of Stavanger, Faculty of Science and Technology, Department of Safety, Economics and Planning. The thesis was written during the spring semester 2018, and it accounts for 30 credits.

The thesis summarizes the research and work that I have done during this semester. This has been an interesting and challenging task, and I feel that I have learned a lot from this work, both about the topic of the thesis and about conducting and writing a scientific text.

I would like to use this opportunity to express my gratitude to my supervisor professor Eirik B. Abrahamsen for constructive discussions and guidance with writing this thesis. The guidance has been very valuable for my work with this report. I would also like to thank Chief physician Kristian Strand at Stavanger University Hospital for the expert assistance provided under the development of this report. Finally, a special thanks to my family for the patience and support during the time I have worked with this thesis.

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Summary

Economic evaluations comprise comparative analyses of different alternatives in terms of their costs and consequences, and is used as a basis for making prioritizations and decisions. When deciding on whether to provide a healthcare intervention, the primary concern is the extent to which it improves health outcomes, entailing quality of care and patient safety. The rapid development of information technology systems deployed in healthcare introduces changes; that will positively or negatively affect the work and clinical processes and the consequent patient, employee and organizational outcomes.

In general, economic evaluations performed for health technology assessments (HTAs) are conditional to the available information in the form of e.g. historical data, system performance and knowledge of the phenomena in question; defined as the background knowledge (K).

Economic analyses may oversimplify complex decisions in healthcare contexts, often ignoring important health and economic consequences, contextual elements, interactions or other relevant modifying factors. Hence, the importance of obtaining and identifying relevant knowledge elements that may influence the outcome of the economic evaluation. System interactions among people, tasks, tools and technologies, physical environment, and organization should be considered to understand the impact of introducing new health technology.

The objective of this thesis has been to contribute to the approaches that can be employed to inform decision-making in a healthcare context, more specifically to the proposed expanded approach by Sørskår et.al. for economic evaluation of new health technology. A discussion on the suggested framework has been performed using a real-world example, aiming to detect possible limitations and consider adjustments. In this way, the applicability of the framework in being a useful evaluation tool has been examined.

Health information technology systems serve, as a tool, medical personnel throughout the clinical and patient care work constituting a human-automation interaction. These systems are seen as significant means of improving healthcare quality and patient safety, as well as being beneficial for the general productivity and performance.

This study also explores a supplementary method to the socio-technical systems approach incorporated in Sørskår et.al. conceptual study; with the aim to conceive human-automation interaction in the context of system's adaptation and self-organization. The examined framework stresses the importance of system adaptability to cope with unanticipated situations and challenges posed by the environment in which HIT systems are set in use.

In summary, the structure of this report is as follows. Chapter 1 presents the background, problem formulation and objectives of this thesis. Chapter 2 presents economic evaluation approaches that may be applied for HTA, and further discuss challenges in the use of the analysis tools. In Chapter 3, the conceptual methodology to assess K proposed by Sørskår et.al is presented, followed by an example using part of the methodology. In Chapter 4, the applicability of the suggested framework is discussed. In Chapter 5, a similar systems approach to improve the methodology is explored. Finally, in Chapter 6 some conclusions are drawn.

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Chapter 1

1. Introduction

The objective of this chapter is to familiarize the reader with this thesis, its background and purposes. The introduction includes some background information, a problem formulation and purpose description.

1.1 Background

Health information technology (HIT) systems have become an essential part of healthcare delivery and are seen as significant means of improving healthcare quality and patient safety [1,2]. And, as indicated by recent research, health information technology benefits could also include hospital financial performance and productivity [3].

IT's associated abilities to improve productivity, quality of care and healthcare system efficiency has encouraged governments around the world to lay down long-term plans for development and implementation of HIT systems.

In Norway, for example, based on the Report no. 9 (2012-2013) [4] to the Norwegian Parliament, the government set clear goals and path for further IT development in the national healthcare sector; which has resulted in a race of large investments in information technology systems such as Electronic Patient Record (EPR) and Patient Administrative (PAS) systems, among others.

The government's goal is to modernize the whole IT platform and work for common and integrated health information technology systems that will improve the national healthcare services' quality, efficiency and resource utilization, as well as patient's safety.

According to the Report, the future common system shall provide healthcare professionals access to the most updated patient information such as referrals, epicrisis, drug use, test results and x-rays. Missing access to this essential information could lead to unintended consequences as giving patients an incorrect medical treatment.

However, one of the main challenges in the Norwegian healthcare sector is that it consists of five regional health authorities, including the large-scale university hospitals; each with duties of prioritization, acquisition and operation of their own HIT systems [5].

As a result, they have increasingly coordinated the acquisition of new systems through large-scale bid-for-tender processes. The larger-scale projects have not only had direct consequences for the close vendor/user relationship, previously found in smaller hospitals, but also added powerful stakeholders with contrasting interests [5].

Despite the efforts of software vendors to offer a complete and integrated solution based on common architecture, integrated modules, and APIs (Application Program Interface) to enable integration with third party systems; the fully integration of healthcare software systems has remained as one of the main issues in healthcare software development [5].

In large hospitals, there is in fact a high demand for specialized functionalities that IT systems should supply. This triggers the need for continuous development and acquisition of new or improved health IT systems that will hopefully better serve medical personnel throughout the clinical and patient care work. The introduction of new technology in clinical settings is however not without challenges, as expressed below.

1.2 Problem

The rapid pace of technological advances in medical records and information systems, introduces changes in the established hospital's internal work processes. Depending on how the change or improvement is designed and implemented, it will either positively or negatively affect the work and clinical processes and the consequent patient, employee, and organizational outcomes [6].

Regardless of the effort and will from health authorities to provide healthcare professionals with the necessary tools for their work, the introduction of health information technology does not necessarily ease the health personnel's day-to-day work. It may rather increase the complexity on the personnel's job that is, in most cases, already overloaded with patient and clinical work. Moreover, IT skills constitute a tiny part of healthcare professionals' education. Thus, motivation for constantly learning convoluted systems is rather little given that IT systems are only a tool to perform their primary job.

Healthcare workers could then end up utilizing only a minor percent of the available functionalities, using the system unsafely, and develop work-arounds. This can be seen as an inefficient use of resources and have potential impact on patient safety and quality of care [7].

Another issue is that existing health information systems are underutilised. Even if technology can meet the criteria set out at the start of the project yet fail to become part of everyday clinical routines [8] due to a lack of awareness of system interactions such as organizational and sociotechnical changes [6] in the design specification stage. According to SEIPS (System Engineering Initiative for Patient Safety) model research, when new

health IT is implemented, it transforms the work system structure, thus altering care processes and then influencing outcomes such as patient safety [7].

While HIT is pushed as a solution to healthcare's quality and efficiency problems, it is the regional health authorities, quality improvement professionals and the government who accrue most of the benefits of current HIT systems from direct patient care processes. In contrast, those who suffer the costs of poorly designed and inefficient HIT are front-line providers, and patients. Most HIT systems, has been designed to meet the needs of people who don't have to enter, interact with, or manage the primary data [9].

With large investments in HITs, questions related to financial and productive payoffs become increasingly important. Economic evaluations are used as a basis for assessing acquisition/investment and implementation of IT systems, and provide valuable information of the intended investment. However, they may not necessarily be performed entailing a systems approach that is associated with the sociotechnical aspects of healthcare delivery. Hence, the results of such economic analyses should be used with caution. Economic evaluations could unintendedly give green light for acquisition and implementation of IT systems with integration deficiency, poor interoperability, and usability issues; making a negative contribution to patient safety, healthcare quality, and ultimately hospital financial performance and productivity.

1.3 Purpose

In healthcare settings, technology and information processing challenges arise as a consequence of sociotechnical changes with, for instance, the introduction of a new electronic medical chart in a clinical unit. Hence, system interactions among people, tasks, tools and technologies, physical environment, and organization should be considered in order to understand the impact of implementing health information technology.

Economic evaluations applied in healthcare technology assessments constitute a collection of analysis methods for systemizing and comparing possible alternative courses of action in terms of both their costs and consequences [10]. Resources are limited, and choices must, and will, be made based on the performed assessments.

Good decision making depends on reliable economic assessments, but they are determined by the quality of the input data for estimating costs and consequences; i.e. the results depend on the background knowledge/evidence. Given the complexity of healthcare, it is necessary to have a clear understanding of the context in which information technologies are to be used. A poor understanding may affect the quality of the background knowledge (K), and in a worst-case scenario the outcome of the decision-making.

Introduction of health IT systems in a safe, effective and transparent manner is a complex process, involving many disciplines and players within and outside a healthcare

organization. Decision-making upon IT investments should be systematic and reflect on the context it will be implemented. To this, the expanded framework, suggested by Sørskår & Abrahamsen et.al [11], proposes the SEIPS model [6] of work system and patient safety as the preferred systems approach for identifying and assessing K as part of economic evaluation. The framework aims to contribute to the reduction of arbitrariness in economic evaluations, which in the case of healthcare systems could ultimately affect the overall care quality and patient safety with the implementation of new information technology.

One of the purposes of this paper is to highlight the need to obtain sufficient and good quality background knowledge for performing economic evaluations prior acquisition/investment and implementation of health IT systems.

This study also aims to contribute to improvements of the suggested framework in [11] by providing an analysis of the evaluation approach. The objective of the analysis is to detect potential limitations, and propose adjustments correspondingly. The analysis is to be carried out using the suggested expanded framework on an illustrative example. The selected example serves dual purposes: (1) to evaluate the factors of introducing new health information technology in the context of an intensive care unit of a medium-sized hospital; (2) examine the applicability of the framework in being a useful evaluation tool.

As systems evolve, it is necessary to further develop the methodologies applied for identification and evaluation of sociotechnical changes. Therefore, in the final chapter this paper explores additional concepts and related analysis framework that may complement the SEIPS model and ultimately better espouse the established sociotechnical systems approach.

Chapter 2

Theory

2. Economic evaluation in Health Technology Assessments

According to the World Health Organization (WHO), Health Technology Assessment (HTA) is defined as the systematic evaluation of properties, effects and/or impacts of health technology and interventions. It addresses the direct and intended consequences, as well as indirect and unintended consequences. The approach is used to inform policy and decision-making in healthcare, especially on how to best allocate limited funds to health interventions and technologies [12]. HTAs encompass a wide range of health technologies including medical devices, drugs, medical and surgical procedures, and the organizational and supportive systems for care provision [13].

As other sectors of society, healthcare sector faces the issue that there are limited resources—people, time, equipment, and knowledge—to fulfil unlimited wants, the unlimited needs of patients. Decisions upon adoption of new health technology, including information technology, are inevitably constrained by financial resources from the healthcare institution, programme, or other designated project.

Economic evaluation provides an organized review of the factors involved in a decision to commit resources to one use instead of another. It systematically identifies, measures, values, and compares the range of possible courses of action in terms of both their costs (what must be given up) and consequences (the overall benefits expected to be received) [10].

In general, economic evaluation is defined as the comparative analysis of alternative courses of actions in terms of both their costs and consequences, and is used as a basis for making prioritizations and decisions. Whilst results of such analysis do not provide a definitive answer to how resources should be allocated, they act as a tool for use in the decision-making process [10,14].

Spending choices or decisions that are made in healthcare delivery incur an opportunity cost. This concept is key to health economics, and refers to the idea that use of resources on one intervention means sacrificing others as a consequence [14]. Opportunity costs represent the value of benefits forgone by choosing one particular allocation of scarce resources over another.

The most important concern when deciding on whether to provide a healthcare intervention is the extent to which it improves health outcomes [14]. Economic evaluation in health technology assessments provides guideline in the decision-making process by comparing alternatives or no intervention with respect to resource utilization and expected outcome. The outcomes are usually valued in monetary units or in natural (clinical) units, such as quality-adjusted life years (QALYs) [15].

2.1 Analysis methods for HTAs

Economic evaluation provides information on the efficiency of decision alternatives by comparing the likely costs and consequences of at least two alternative options. Economic evaluation comprises decision analysis tools such as cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis, and some other approaches. In the following, a description of the most common methods used when performing economic evaluation in healthcare is given.

2.1.1 Cost-of-Illness Analysis (COI)

COI estimates the economic burden or total costs attributable to a particular disease to society. Although it was the first economic evaluation method used in health economics, the analysis does not fall into the category of economic evaluations since alternatives are not compared [10]. For this reason, the approach is considered inappropriate for the purpose of this study.

2.1.2 Cost-Benefit Analysis (CBA)

Traditional cost-benefit analysis is a method to measure benefits and costs of a project expressed in monetary terms. This means that all relevant attributes are assigned monetary values. The main rationale in transformation of attributes into money is to measure the change in economic welfare associated with all costs and all benefits generated by a project, or intervention [16,18].

After transformation of all attributes into one comparable unit of measure, the total performance is summarised by calculating the expected net present value (E[NPV]). The expected costs are subtracted from the expected benefits. When the E[NPV] is greater than zero, it means that the value of the outcomes is worth more than the value of resources used by the intervention, so from a societal perspective the intervention should be implemented [16,17].

CBA is in general seen as a tool for obtaining efficient allocation of resources, by identifying which potential actions are worth undertaking and in what fashion [19]. CBA's greatest appeal lies in the fact that it can be used to compare projects with a range of different outcomes. In practice, however, the monetary valuation of benefits in CBA is difficult. Placing e.g. value on human life and health can be extremely hard [16].

2.1.3 Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis is the most employed method of economic evaluation in the health sector. Under this analysis, the quantity of health gained is compared to the cost of the intervention to attain this effect. The improvement in health is described in natural units (e.g. life years saved). Unlike CBA, this analysis method does not explicitly put a value to the benefit [16, 19].

CEA is often expressed as a cost-effectiveness ratio (CER); expected costs over expected effects of an intervention, $E[C] / E[X]$. The CER of one intervention can then be compared with that of another. It is also expressed as incremental cost-effectiveness ratio (ICER). As such, ICER compares the differences between the costs and health outcomes of two alternative interventions that compete for the same resources, and is described as the additional cost per additional health outcome. [10]

To see whether an intervention is preferred to the status quo or not, the CER must be compared with the reference value, R . This value clarifies how much money the decision-maker is willing to pay to obtain one unit of effectiveness. The implementation of the intervention is preferred to the status quo if $R > CER$ [17].

CEA is generally used in situations where a decision-maker, operating with a given budget, is considering a limited range of options within a given field. However, CEA is to be used if the effects of the competing interventions are of the same nature but with different results in each of the compared alternatives. This restriction makes it difficult to assess the opportunity cost (i.e. benefits forgone) in other projects covered by the same budget; being the biggest limitation of this analysis [10,20].

2.1.4 Cost Minimization Analysis (CMA)

CMA has a general resemblance to CEA but it is typically used to measure and compare costs across alternatives where there is good evidence that there is no difference in effectiveness. In other words, assumed that the alternative interventions

are to produce equivalent outcomes, CMA is used to determine the least costly among them.

Hence, the types of intervention that can be evaluated with this method are rather limited. In addition, it has been shown that the adoption of CMA produces biased results as it ignores the correlation between magnitude of effect and cost [10,14,16].

2.1.5 Cost-Utility Analysis (CUA)

The CUA approach is considered as a special form of cost-effectiveness analysis. Cost-utility analysis differs from CEA in how outcomes are measured. In CUA, the effect of an intervention is measured as 'health years' and generally valued as quality-adjusted life years (QALYs). In this way, not only quantity of life but also quality of life gained due to an intervention is incorporated into the analysis.

Recognized as the reference standard utility measure in economic evaluations, QALY measures life expectancy adjusted for quality of life. It provides a common unit for comparing different types of health effects, as well as it allows cost-utility comparisons across different healthcare programmes [10,14,15].

Similar to CEA, CUA analysis examines the effects of at least two competing alternatives within a fixed budget. The results are expressed as the ratio of expected cost per expected QALY gained, $E[C] / E[QALY]$, such that the alternative that maximizes the health outcome for a given cost can be established [10].

2.1.6 Multiple Criteria Decision Analysis (MCDA)

The MCDA approach is described as a collection of formal approaches which seek to take account of multiple and often conflicting criteria. For each decision alternative, attention is given to several aspects or attributes of benefit in an explicit manner [10,22,23].

For some attributes it is common to adopt quantitative analysis, while for others, such as social aspects, qualitative analysis are usually adopted. The total of these analyses is referred to as MCDA. The main aspects of any MCDA are: to evaluate the alternatives; establish the criteria (or attributes) by which the alternatives are evaluated; determine the performance of the alternatives on each of the criteria, followed by scores that reflect the performance's value; and weight the different individual criteria for their impact as compared with others. The latest captures the

different preferences of individual decision makers (clinicians, administrators, etc) accounting for their views in an open and transparent way [11,22,23,24].

To sum up, in a MCDA there is no attempt to transform all the different attributes into a comparable unit. The decision-maker has to weight the different attributes, which means that the trade-offs are made implicit [16]. MCDA adds consistency and transparency through explicit scoring and weighting of criteria [22]. However, unless MCDA takes account of costs and benefits (effectiveness), it may not constitute an economic evaluation [11].

2.1.7 Cost-Consequence Analysis (CCA)

CCA is a form of cost-benefit analysis in which different units for costs and benefits are used. The analysis presents the information on costs and outcomes of the alternatives separately in a non-aggregated format. This allows decision-makers to see clearly what types of information are included and omitted, and where information is quantitative or qualitative. As such, this type of evaluation can be useful for obtaining a picture of the impact of the intervention. It does, however, place the burden of aggregating, weighing and valuing the components on decision-makers [20].

All these methods have in common that they are systematic approaches for organising and highlighting the advantages and disadvantages of alternative courses of action. Yet, they differ with respect to the extent the outcomes are made explicitly comparable, i.e. which outcome is to be measured per unit of cost [11, 17].

Traditional CBA-based economic analysis has not been widely accepted as the evaluative method of choice in the healthcare setting due to the practical problems of measuring and valuing benefits that result from an intervention [16, 25].

Recognized health technology assessment (HTA) agencies, such as NICE¹, consider CEA analyses appropriate to inform decision-making because they maintain health outcomes in their natural units rather than monetize the outcome. However, they are criticized by not including benefits and costs from a societal perspective [10].

MCDA approach has been proposed as a likely alternative to address the shortcomings of HTAs based on economic evaluation. The concepts of inclusion of a comprehensive list of value dimensions in an explicit manner, assignment of quantitative weights across the different evaluation criteria, and involvement of decision-maker's preferences advocates for the use of MCDA in HTA processes. By taking into consideration and measuring criteria

¹ National Institute for Health and Clinical Excellence (NICE) in England and Wales

other than cost-effectiveness MCDA ensures that innovation and social preferences are not neglected in the decision-making process. This results in a MCDA approach that fosters transparency, consistency, and flexibility in healthcare decision-making [22,23,26].

Nevertheless, the use of MCDA is not without challenges. Criteria selection and measurement (how much weight should be given to each criteria), as well as that of placing an increasing cognitive effort on the decision-makers are among some of the practical issues related to the use of MCDA in HTA [26].

To decide which analysis method is ought to be used when performing economic evaluations in Health Technology Assessments is not part of the scope of this study. However, one of the analysis tools will later be used in an example to illustrate the expanded framework proposed by Sørskår et.al.

2.2 Knowledge and uncertainties in economic evaluation

As presented in the chapter above, economic evaluation methods consist of determining costs and effects of various alternatives. However, they cannot be determined with certainty and consequently predictions are required. The most common practice for this is to express costs and benefits as expected values. The basis for using expected values is anchored in the “law of large numbers”, which states that the average of a large number of observations can be accurately approximated to its expected value [11,19,29]. The literature defines expected value as the “probability-weighted average of the payoffs associated with all possible outcomes”; i.e. the value that we would expect on average [28].

In general, cost-benefit, cost-effectiveness and similar analyses are just tools providing insights into trade-offs between outcomes and associated costs. Nevertheless, the expected values (estimated or assigned) could produce poor predictions of the real outcome. The results of the analyses are conditioned on a number of assumptions and suppositions, i.e. the knowledge on which the assessment is based on [19]. Also referred as the background knowledge (K), it is normally obtained from models, historical experience data and knowledge about the phenomena and system in question. Assumptions are important part of this knowledge [29,30]. For healthcare assessments, observational studies, randomized controlled trials (RCTs) (and other clinical studies), as well as expert opinions constitute among others a source for background knowledge [14].

For instance, when performing economic evaluation for HTA, CEA is usually undertaken alongside clinical trials which provide the opportunity to observe and collect resource use and health outcomes in a single study. There is to some extent advantages in doing so, but to answer questions relating to resource allocation that are usually beyond the scope of single clinical effectiveness evidence, analytical models within cost-effectiveness analyses are preferably used. These models are populated with K. In the case of CEA, the cost-effectiveness ratio (CER) is calculated as $E[C|K] / E[X|K]$ where the expected cost and expected effectiveness are conditional on the background knowledge K [11,14,31,32], and uncertainties could be hidden in K. Figure 1 presents a simplistic illustration of the association of K and U in economic evaluations for HTA.

In general, assessments of the additional health benefits and additional cost offered by an intervention are uncertain. The reason for this is e.g. missing data, as well as uncertainty in the estimates of inputs or model parameters used to estimate costs and effects. These results in poor quality of knowledge (K) which causes economic analyses to be inherently uncertain [10,30].

The ultimate purpose of any economic evaluation is to inform decision-making, it is thus necessary to understand the different sources of uncertainty in K that can impact upon the results of an economic evaluation. Consideration on whether the nature or the magnitude of the uncertainties is such that there is a substantial risk making the wrong decision using the available information, should not be kept outside economic evaluations [14].

Uncertainty (U) may be considered as the expected values' predictability of the real outcomes [32]. As such, sensitivity analysis provides an analytic response for assessing uncertainty in the results of economic analyses. The analysis is conducted repeated times deliberately varying different sets of background knowledge (inputs and key parameters) to examine the effect on the study results. Despite of setting focus on the changes in inputs and parameters, sensitivity analysis does not provide any conclusions on uncertainties. However, the analysis reflects the uncertainty underlying the assumptions made in the estimation of both costs and outcomes, by quantifying and evaluating the uncertainties [10,11,14,16,30].

The uncertainties around the estimates of costs and effects may cause the expected values to produce poor predictions [29,30]. It must also be acknowledged that the analysis methods in economic evaluations focusing on expected values has limitations. In the literature, it is argued that expected values, in general, do not adequately reflect

the uncertainties [17]. Hence, such economic evaluations should be interpreted with care. The way uncertainties are managed will depend on the context as different contexts call for different decision-making principles [17,19].

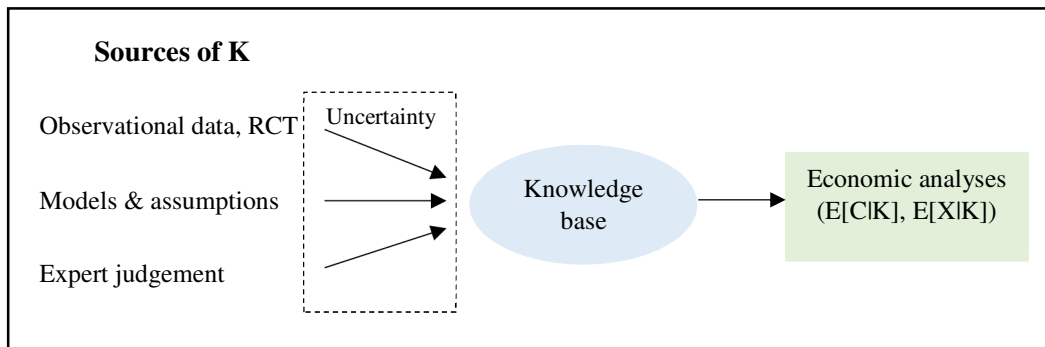


Figure 1 - Illustration of K and U in economic evaluations for HTA.

2.2.1 K and U in relation to the implementation of Health Information Technology

As economic evaluations, in this case for HTA, are conditional to the available knowledge K (which contains uncertainties U), it follows the challenge of obtaining sufficient and good quality knowledge. In a more specific context, towards implementation and use of health information technology (HIT) in hospital units, capturing relevant knowledge is rather demanding due to the intricateness of each clinical department. These can be described as a dynamic and complex sociotechnical system characterizing healthcare delivery [6,9,33].

HIT systems are inextricably linked to human factors ergonomics and user-centred design, and are intended to work with the norms, expectations, and mental models in existing healthcare practices; as well as other technological systems and the environment in which they are set in use [34]. The understanding of these sociotechnical elements and interactions, associated with HIT implementations, is critical to obtain good quality background knowledge and avoid potential flaws in the economic evaluations.

Complex healthcare environments like hospital units involve multiple agents (clinical staff, patients, decision-makers, among others) with different objectives, as well as numerous evolving technologies, processes, and external environment factors. Their interactions are dynamic, emergent, hard to understand, and bring often surprises [35,36]. These various elements that take part in a complex sociotechnical system are interconnected, so that changes on one parameter can also have effects on another parameter. Therefore, when a change in the system occurs, the effects on the entire system need to be considered, giving

economic (cost-effectiveness) models a challenge when it comes to identification of necessary background knowledge [37,14].

In regard to HIT systems, the introduction of information technology in healthcare have stumbled for a variety of reasons, including lack of sensitivity to user's needs and the significant changes induced and required by the technology. This means that the way new technology is implemented is also important for the result, and have a strong dependency on sufficient understanding of the context of use, including consideration of human and organizational factors [37].

Health information technology systems are often argued to lead to benefits such as improvements in healthcare quality (e.g., better communication), increases efficiency (e.g., quicker transfer of patient information) and safety (e.g. reducing the probability of human error) [38,39,40]. However, the implementation and use of new information technology does not come without challenges. Several reports on issues following the implementation of HIT are to be found [41,42,43,44,45]. For instance, new technology may create more or new work for physicians such as increased time on documentation, and consequently less time for patient care. Caring for critically ill patients demands communication and coordination of multiple healthcare team members, and changes in physician work routines could affect their ability to provide safe, high-quality care [42].

The above underlines the need for good understanding of the complexity of HIT implementation in healthcare system (clinical units) and the possible issues (e.g. impact on workflows and processes) succeeding the implementation of such technology; as these strengthen the risk of obtaining poor or missing knowledge when performing economic evaluation. Decision-making based on the resulting evaluation may have consequences as lower-than-intended effects or exceeding costs once technology is implemented, and consequently a potential negative impact on the overall healthcare quality and patient safety [11].

Chapter 3

3. Expanded framework for performing economic evaluations for new information technology in healthcare settings

Economic analyses may oversimplify complex decisions in healthcare contexts. These often ignore important health and economic consequences, contextual elements, interactions or other relevant modifying factors [20].

To deal with this, more focus should be given to the assessment of K when performing economic evaluations for new technology, such that the quality of the outcome of the economic evaluation (basis for decision-making) is improved. For a proper assessment of the background knowledge, it is necessary to have a way to first identify and structure it. This may be achieved by taking a systems approach and considering HIT as part of the healthcare complex sociotechnical system, and describing its implementation and use as such [11].

With a systems approach, relevant K may be identified and evaluated, including interactions between parameters. In this way, it is possible to address some of the challenges described previously (chapter 2.2), and enrich the models used in the economic analysis.

Sørskår et.al proposes an expanded framework for performing economic evaluations for new health technology, providing an approach for identification, structuring and properly consideration of relevant background knowledge (K) as a basis for both the economic evaluation and the decision-making.

The authors argue that a systems approach for assessment of K is crucial for quality of the outcome of the economic evaluation. Therefore, they suggest integrating to the economic analyses a model for describing sociotechnical systems. More specifically, one of the several models developed for this purpose, the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety [7,14,35]. SEIPS integrates human factors and healthcare quality models to propose a systems engineering model to understand the care process; allowing for an evaluation of healthcare work system and processes, and their impact on healthcare quality and patient safety.

The suggested framework intrinsically introduces different elements for identifying and describing relevant knowledge for new technology in a healthcare setting. In the first step of the framework, as depicted in Figure 2 in [11], the background knowledge is processed. To this end, the SEIPS model (described in next chapter) is employed; providing a basis for identifying relevant context knowledge elements and a scheme to structure and describe

them. This is accompanied by an assessment of the identified elements that includes a description of how elements have an impact on the economic evaluation, the elements' degree of impact relative to the overall results, the degree of uncertainty for the element, and a critically matrix between impact and uncertainty. This first step of the expanded framework makes the presentation and focus of processing the background knowledge simpler and more purposeful to the decision-making.

In the next step the assessed background knowledge is used as a basis for the economic evaluation which may be performed using one of the approaches described in chapter 2.1. Then, and finally, the decision-makers are presented with the compound outcome from the two first steps. To what this concerns, decision-makers are to be made aware of the properties and challenges associated with the applied approach, contributing to a transparent decision-making process [21].

In the following sections, a summarized description of the SEIPS model is presented, followed by an actual example of health IT implementation where the proposed methodology by Sørskår et. al is utilized. As expressed in chapter 1.3, through this example this study aims to analyse the suggested approach and try to detect potential limitations or weaknesses and suggest adjustments correspondingly.

3.1 SEIPS – a systems engineering approach for assessment of background knowledge

The SEIPS model provides a representation of the complexities of healthcare by describing the work system, the interactions between its components, and the interaction between different system levels [6,7]. These can be described as follows:

1. Six components and their interactions comprise the work system structure in the SEIPS model:
 - a. Person – the individual at the centre of the system can be a single individual (e.g. physician, nurse, patient), or a group of people (e.g. healthcare team, organizational unit) involved in the process.
 - b. Organization – includes characteristics such as the formal and informal organization and culture, rules and procedures, organizational structure, and management.
 - c. Technologies and tools, such as health information technology, medical devices and other tools used in the process. It includes human factors characteristics of technologies and tools.
 - d. Tasks – goal-oriented activities within the care process which are described and characterized by their variety, content and demands.

- e. Physical environment, including layout, workstation design, lightning, noise, and distractions.
 - f. External environment – comprised of extra- organizational rules, standards, legislation, that can influence all work system components.
2. The SEIPS model builds on the structure-process-outcome (SPO) model of healthcare quality [57] where the work system described above constitutes the structure. The process is embedded in the work system. Each step in the process is a task involving various people using various tools and technologies, occurring in a specific environment within an organization.
 3. Outcomes, include patient outcomes, including quality of care and patient safety, and employee/organizational outcomes such as job satisfaction and stress.
 4. Feedback loop between the processes and outcomes, to the work system for organizational learning and quality improvement in the work system.

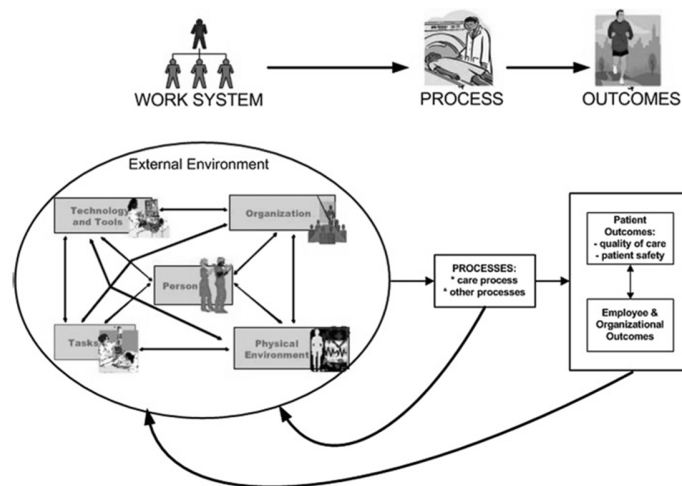


Figure 2 – The SEIPS model of work system and patient safety [6].

The different components and possible interactions in the SEIPS model provide a systems approach basis for identifying relevant K as basis for economic evaluation for new technology.

3.2 Example using the expanded framework

In the following an illustrative example using the suggested expanded framework for identifying and assessing K, as part of economic evaluations for new technology, is presented. But, in this example the framework is applied to a different healthcare area than the one covered by Sørskår et.al, namely for new Health Information Technology in the form of a computer system, planned to be used in an intensive care unit (ICU) of a medium-sized university hospital in Norway.

The system supplies an electronic medical chart (EMC) for the course of clinical treatment of each patient, to help keep track in complex situations and systematically document certain parameters; from patient admission to discharge, allowing for example for retrospective review after adverse events. The system in question presents an organized history of the different patient's measured parameters, drugs supplied, and changes in administered medication and remedies, among other information.

A typical course of clinical treatment may for example proceed as described below:

1. Critically ill patients, currently in a different lower level care unit, are appraised by a clinician from the intensive care unit and considered for transfer to the ICU.
2. Based on clinical features, lab results and vital parameters such as blood pressure, body core temperature, respiratory rate, oxygen saturation level, evaluation of the level of severity is performed, and decision is made as to what measures are required in order to stabilize and treat the patient. These parameters reveal whether the patient is stable or not, and are measured repetitively. The values are documented manually in the patient's chart, it being a computer system or paper-based. The latter has been common practice for years. It provides an overview over the patient's current status and immediate status history within the ICU.
3. Every morning and after each shift, a take-over meeting is held between at least the clinician and nurse responsible for a patient and the new staff, in order to communicate the necessary information on the current state of the patient, actions taken and the results of them, and the planned procedures.

The meeting itself is considered an essential step in optimizing quality and continuity of care, and patient safety. In these meetings computer systems are utilised to provide and present data while discussing and evaluating the patient.

4. Process steps 2 and 3 are repeated continuously until discharge.

In this case, the question on whether to invest and implement or not an electronic medical chart, and substitute the existing paper-based chart in the ICU of a mid-sized hospital constitutes the decision problem and decision-making context. Human and organizational factors, work process and outcomes will be influenced with the introduction of a new information technology, having a potential impact on patient safety and quality of care.

Considering an economic evaluation of electronic medical chart implementation in the ICU, the steps described in the expanded framework [11] can be applied. The first step (1) is to use SEIPS model's main components and identify relevant context elements to structure the background knowledge (K). Knowledge elements (K1,K2,...,Kn) with a potential impact on the economic evaluation (effect on costs and benefits) are further described and assessed. It follows an evaluation of impact on cost-effectiveness, uncertainty and criticality. This is presented in Table 1.

The presented K elements and corresponding description are derived from gathered literature on implementation of similar HIT systems and their impact on the work process. For the selected example, domain knowledge on intensive care units has been a crucial part of the process of identifying and studying the components and underlying elements within the SEIPS methodology. Valuable contributions to the information presented in this example has been provided and later validated by Kristian Strand, MD, PhD, Chief physician – Intensive Care Unit at Stavanger University Hospital.

Table 1 – SEIPS model for identifying relevant background knowledge in a HIT/ICU context

SEIPS components	K elements (K#)	Description of K elements	Impact	(U)	Criticality
Person	Training & knowledge (K1)	Due to limited knowledge of functions within the specific HIT system, ICU personnel must be trained in the EMC and its unique interface. IT is not a prioritized part of the general education of most healthcare personnel. Learning to know a new interface can be a substantial challenge especially for the more senior staff, where often times one introduction course is not sufficient. [46,48]	M	L	
	Motivation (K2)	Continuous introduction of new technology work tools, that poorly fit user-needs, potentially increases the workload of already overworked staff. This may affect the personnel's motivation to learn and use them. [40,42]	L	M	
Organization	Resource availability (K3)	Added workload to personnel due to HIT systems requirements causes personnel to spend more time on the computer and possibly less time with the patient, changing the main focus of the clinicians in the ICU. [7]	H	M	
	Communication patterns & practices (K4)	Team communication effectiveness have a direct impact on patient care and safety. EMC gives possibility for large screen display in take-over meetings, easing communication of current patient's state among the staff [41,47,49].	L	M	
Technology & tools	Interface (K5)	The interface between personnel and computer system is crucial for the overall effectiveness. Usability and functionality factors of an electronic system play a significant role in providing flexibility and reducing user-interface issues that can lead to time delays, reduced cognitive processing, confusion, frustration, and potentially errors which may increase risk for the patient. [34,40,49,51]	H	M	
	Interoperability (K6)	The new HIT system should be seamlessly integrated with other HIT systems such as EPR, PAS, and fit in with existing organizational processes. This may help to decrease duplicate documentation and information entries. Effective information exchange with other applications is essential to avoid time delays, potential for loss of information, and workarounds such as continued use of paper which can create documentation incongruities. [34,46]	H	M	
	Time-efficiency (K7)	The new system needs to be at least as quick as the system it replaces, i.e. not slowing down users in their everyday work. Required separate system logins, or not possible to access multiple applications simultaneously may cause delay in access to patient information. [42,46,49]	H	M	
Tasks	Workload (K8)	HIT may increase the workload for personnel, which may constitute an issue for team coordination. Lack of or poor system interoperability leads users to enter patient's data and search for different patient information in multiple HIT applications. EMC gives the possibility for automated data acquisition from clinical equipment, eliminating the need for staff to manually record patient's vital parameters. Issues during implementation phase may increase personnel's workload and require system adaptations to attempt to decrease the gap between actual versus ideal performance. [6,42,52]	L	M	
	Procedures (K9)	Workarounds employed by users to cope with perceived shortcomings in a technical system may arise. For instance, deviations from regular procedures when using the EMC, such as having to temporarily record some of the vital parameters on paper. [6]	L	M	
Physical environment	Accessibility (K10)	The electronic chart system provides greater portability and remote monitoring options. Physicians can access the EMC system from different locations within the hospital's intranet.	M	L	
	Reliability (K11)	HIT system downtime is unacceptable due to the criticality of care which may be rapidly changing, and immediate history is needed to decide further course of treatment.	H	M	
	Hardware (K12)	To maximize productivity of personnel, reliable PCs and peripherals designed to reduce operator fatigue and discomfort should be made available. [48]	L	L	

External environment	Alternative EMC systems (K13)	Currently in use and well-proven EMC systems can provide evidence of available solutions that can match the requirements of ICU's intended use. Introduction of HIT systems that not specialized in intensive care units may cause additional substantial costs in required development, and large implementation delays and ultimately jeopardize patient safety [48]	H	M	
Processes	Treatment process (K14)	EMC moves the overview of current patient's vitals from paper on to a computer system with login requirements, this may cause delay in the documentation and retrieval of information. On the other hand, the HIT system can enhance take-over meetings. [50,52]	L	M	
	Work process (K15)	Perceived or real inefficiencies and limitations with the HIT system resulting from poor integration of the system with work processes and expectations may encourage personnel to continue using paper-based alternatives, or supplement perceived deficiencies of an electronic system with paper-based cognitive aids. EMC may eliminate searching for paper charts and multiple entry of information. [34,40]	M	L	
Feedback loops	Organizational learning (K16)	Over time the personnel's learning curve flattens and the excess time consumed on the new HIT system reduces. EMC's possibility of retrospective analysis of adverse events provides great benefits for sharing of knowledge among personnel.	M	L	
Outcome	Health and safety benefits (K17)	When new health IT is implemented, it transforms the work system structure, thus altering care processes and then influencing outcomes such as patient safety [7]. EMC may increase patient safety through better traceability. It also contributes to a minimization of errors and adverse events. Other benefits: provides ICU personnel great accessibility to patient's information, possibly increases personnel satisfaction by reducing number of manual tasks. [34,35]	H	M	

Following the steps in the suggested expanded framework [11], an economic analysis is to be performed (2) using the information from Table 1. Considered the preferred economic analysis tool in HTAs [10,14], cost-effectiveness analysis (CEA) is carried out using the above K elements as a basis for $E[C|K]$ / $E[X|K]$.

In the third step (3), the results of the CEA are provided to the decision-makers for managerial review and judgement. This includes the background knowledge on which it is based, the impact and uncertainty related to the different K elements, and finally (4) a visualization of the criticality based on the element's impact and uncertainty. In the table above, the uncertainty ratings have been assigned based on Flage & Aven's classification scheme [53], while the shaded area for severe critically follows the generic critically matrix presented in [11].

It can be assumed that the performed CEA provides a positive outcome compared to the alternative, e.g. not replacing the existing paper-based EMC system. By only considering this result, the decision-maker should acquire and implement the electronic medical chart in the intensive care unit; substituting the paper-based solution.

Information provided by Strand, K. on how the decision process was carried out in the specific example above revealed that intensive care specialists were not at all part of the analysts' team when assessment of electronic medical charts were performed. Additionally, the assessment focused on EMC systems for surgical wards and not specifically for intensive care units. All this could have introduced high uncertainty in the estimation of both costs and effects (benefits) reflecting a lack of knowledge on the ICU context. In spite of not involving intensive care specialists, decision on acquiring a general EMC system with limited available functionalities for an intensive care unit was taken. As of today, the implementation of the system has not yet been completed. Extensive development has been required to attempt to meet ICU's needs and goals to enhance the quality of healthcare and patient safety with a new HIT system, the electronic medical chart.

An economic analysis based on the assumption that the EMC system would also serve the needs of an ICU as for the surgical wards constitutes a good example of how the overall cost-effectiveness of the intervention can be reduced due to deficient or missing background knowledge. The first implementation attempt revealed missing needed functionalities, specific for the course of treatment in an intensive care unit. This has resulted in costly and time-consuming development towards an adequate electronic medical chart for the clinical context of an intensive care unit.

It can then be argued that the analyses performed would have benefited from an involvement of intensive care specialists providing relevant knowledge. By obtaining and presenting relevant information regarding the work process in an intensive care unit, the consequent decision-making may have been truly affected. For a hospital facing resource rationing, other interventions would probably have to bear with particular "unexpected" allocation of resources, ultimately reducing the overall patient care.

Chapter 4

4. Analysis and adjustments to the suggested expanded framework

Sørskår et.al's expanded framework is mostly valuable in identifying and examining relevant background knowledge as a basis for the economic evaluation for new health technology. It opens for consideration of different aspects of a healthcare setting when new technology is introduced and its possible effects on the sociotechnical system. It is though limited in its recognition and consideration of interactions and interdependencies among work system components.

It could be argued that by only describing the potential impact of the different work system components on the economic evaluation in an individual manner, the relevance of the interactions with other components is not acknowledged. The importance and impact of the described individual K element might differ when combined with other elements. The interaction creates a sort of a “new compound K element”, possibly with a modification of how it has an impact on the economic evaluation.

In the context of economic evaluations for new health information technology systems this acknowledgement is rather necessary due to the nature of these systems and their application in complex healthcare settings. By excluding the identification of the components' and underlying elements' interactions, there might be a risk for insufficient understanding about the complexity of implementing a new HIT system. Overlaps between K elements might e.g. not be easily foreseen, but they could be revealed in the process of considering relevant interactions.

To address this limitation, it is suggested to incorporate the concept of *configuration* as presented in the new human factors/ergonomics framework for studying and improving health and healthcare, SEIPS 2.0 [35]. Under the *configuration* perspective, the performance of a process is seen as the emergent property of the whole interacting system, and not of its separate elements. According to the framework, “any number of work system components can interact simultaneously, at ‘a moment in time’, to shape performance processes and outcomes”. It assumes that all components and their elements are interconnected, that each can interact with any other, and that often several components are interacting at the same time.

The *configuration* concept is based on the idea that only a subset of all possible interactions is in fact relevant in a particular work process or situation; making it possible to distinguish a configuration of a finite number of relevant components that interact to strongly or weakly influence the performance of the given process. This can be an important contribution for

the purpose of the expanded framework as the different configurations may reveal background knowledge that is crucial for the outcome of the economic evaluation and decision-making preceding the implementation of a new health information technology.

This speaks for an adjustment in the evaluation steps suggested by Sørskår et.al. The author of this paper suggests including an inventory of relevant component interactions, and providing a description that considers both the economic evaluation and the influence on the structure-process-outcome (process performance) and quality outcomes; emphasizing on systematic impact of organizational and sociotechnical changes.

This adjustment seems appropriate for the purpose of identifying and systemizing relevant background knowledge in the context of implementing a HIT system into the work process of an intensive care unit, that can ultimately have implications on healthcare quality and patient safety. This is in accordance to the SEIPS healthcare human factor principle that performance, safety and health results from the interaction of a sociotechnical system.

Another adjustment suggestion is related to the adequacy of collected information. There are (opportunity) costs of making the wrong decision and introducing a new technology when the knowledge base is not sufficiently certain [14,55]. An importance task in decision-making is to determine whether the decision basis is adequate or if further information should be collected. Hence, a qualitative uncertainty assessment should be performed [56]. In the following, a sketch how this assessment can be carried out.

1. Identify some main components or subset of components worth assessing, referred as uncertainty factors. Components assigned Medium and High degree of uncertainty with Medium and High impact are the most relevant for consideration. However, components and underlying elements with assigned Low impact could be also relevant if uncertainty is Medium or High.
2. An importance ranking of the identified uncertainty factors is introduced to highlight which of them should be considered for further treatment (research), if time and resources allows.

The suggested adjustments to the expanded framework are applied and presented in Table 2. For the sake of simplicity, only a couple of configurations are presented in the table below. These are based on the information from Table 1, and on the clinical work process information provided by intensive care clinician Strand, K.

Table 2 – Adjusted SEIPS model for identifying relevant background knowledge

Components / subset of components	K elements (K#)	Description of the impact on the SPO and economic evaluation	Impact	(U)	Criticality	Importance ranking
Person – Technology (C1)	K1, K2, K5	Ease of learning how to use the system depends on the effectiveness of user interface (e.g simple, easy to navigate, information presented in line with importance, flexible, customizable).	M	M		3
Organization – Technology – Tasks – P. environment (C2)	K3, K7, K8, K9, K11	Extra time spent on computer may represent a barrier to personnel to provide good quality of patient care. Potential negative effects on patient quality of care and safety due to personnel’s response to perceived barriers.	H	M		1
Technology – Tasks (C3)	K6, K8	Built-in capabilities for integration with existing systems and processes possibly alleviates implementation issues, reduce workload for personnel, and may reduce additional development time and costs.	H	M		2

Configuration (C1) examines the interaction between K elements from Person and Technology components. It sets the focus on how the personnel’s training on the HIT system could be eased from a well-designed interface that fits user needs, possibly avoiding an increase on personnel’s workload.

Configuration (C2) looks at the efficiency of the new technology in comparison to the existing solution (paper-based). It focuses on the potential negative effects due to technological barriers (e.g. lack of automated data acquisition). Additional tasks, such as temporary manual record of patient’s information, may result in loss of crucial information, possibly impairing patient’s safety under the course of treatment.

Configuration (C3) describes the importance of considering the interoperability with other HIT systems. Through an integrated system that provides additional information required for patient treatment, this may positively contribute to a better quality of care and ensure high levels of patient safety.

The configurations are then ranked based on the degree of importance, which is defined as qualitative measure for highlighting which interdependent K elements are worth collecting additional information on. The assigned level of impact and uncertainty are used as a basis to rank the subset of components

The suggested adjustments treat the information, first provided in Table 1, in a way that it is condensed on an interacting work system perspective. The contribution to the expanded framework [11] is the additional understanding of how the work system components interact and influence the outcomes of a new health technology implementation, as well as pointing which interactions should be considered for further treatment.

It can be concluded that the use of the SEIPS model and the rest of the evaluation steps suggested in [11] should not be considered as a straight-forward process. Accurate comprehension and analysis of complex sociotechnical systems such as healthcare is a daunting task. In turn, identifying and describing relevant K elements is a challenge as it requires the analysts to have knowledge of three different areas: information technology, healthcare and economics. Nevertheless, SEIPS provides a framework on how to think about the different aspects of a work system, their interactions, and possible outcomes – promoting socio-technical systems thinking. It could be seen as a checklist providing a view of the whole system instead of focusing on only one aspect of the work system.

Another aspect of the Sørskår et.al research paper is that it does not include a guideline on how to assign the degree of impact relative to total cost-effectiveness. This can represent a challenge. In the absence of a proper guideline or criteria to be considered, a tendency of assigning most of K elements to Medium impact was observed. Hence, this should be considered and included in future versions of the research approach.

4.1 Reflections on the expanded framework

Sørskår et.al conceptual study, in its first version [11], presents a solution to improve the basis for decision-making through an expanded framework for performing economic evaluations. The applicability of the framework is examined in Chapter 3.2, and later a general analysis of the framework is performed in Chapter 4. In this analysis, two main contributions aiming to improve the proposed framework are posed: (1) to include a list of relevant component interactions and corresponding contextual description, (2) to perform a quality uncertainty assessment through identification, classification and ranking of uncertainty factors.

The above adjustments, suggested by the author of this report, resemble parts of the proposed methodology for knowledge assessment presented in the latest version of Sørskår et.al conceptual study [58] - just recently accepted for publication. It is then important to remark that the author of this report did not have access to the second version of Sørskår et.al paper at the time the presented adjustments were formulated.

Nevertheless, it seems appropriate to make some reflections on the expanded framework from the former paper [11] and the proposed adjustments taking in consideration the improvements made on the latter paper [58]:

- Figure 2 in the former paper depicts the expanded framework in a way that the identification and evaluation of K using SEIPS model seems to belong to a separate stage, aside the economic evaluation. To this, the decision-making process with

focus on knowledge assessment is better represented in Figure 1 in the latest version of the research paper. The evaluation of human factors and economic evaluation is outlined as one interactive, parallel process. Evaluation of the impact on the outcome of the economic analysis is also incorporated in the second phase of the knowledge assessment process as depicted in Figure 3 - [58].

- The third step of the expanded framework in the former paper regards presenting the outcome from the first two steps to the decision-makers, however it does not specifically contemplate the judgement and review process resulting in a decision. A common approach in decision-making process is to perform a managerial review and judgement of the economic evaluation before making a decision (Figure 1.3 - [30]). This is specified in Figure 1 [58].
- For the assessment of K as basis for economic evaluations, Sørskår et.al (in the latter paper) suggests a methodology similar to the main steps of a risk analysis process [30], where knowledge assessment is divided in three phases: a planning phase, an analysis phase, and a treatment phase.

The analysis phase consists of three parts; the application of the SEIPS model to identify K elements with a potential impact on the economic evaluation, an evaluation on the identified knowledge to determine strength of knowledge (SoK), and evaluation of K elements with relatively weak SoK for their potential impact on the outcome of the economic analysis.

The proposed adjustment (1) to identify and consider system components' interaction within the SEIPS model is equivalently introduced and described in the first part of the analysis phase. In addition, Sørskår et.al considers the identification of K elements and interactions as an iterative process given that different subsets of work system interactions constitute different processes and/or outcomes. This is a step forward in the overall assessment involving a dynamic system such as healthcare.

The second part of the analysis phase treats the identified knowledge in a similar way as the adjustment (2) proposed above. While Sørskår et.al employs the principles and methods to assess the strength of background knowledge [17], this author basis the adjustment (2) on the value of information (VOI) analysis method [55,56]. This latter can be seen as a more general approach than the one presented by Sørskår et.al. However, the objective appears to be the same; to qualitatively assess the quality of K when performing economic evaluation, and determine whether further examination is necessary.

Chapter 5

5. Future directions for the SEIPS model systems approach

Human factors and ergonomics (HFE) principles are normally applied to healthcare work systems and processes to improve quality and safety of care. To this end, healthcare practitioners and researchers make use of the person-centred model of sociotechnical system, the SEIPS model. This system engineering model anchored within HFE highlights how work system design (structure) is linked to patient safety (outcome) through care processes (see fig. 2) [7,35].

Cognitive, physical and organizational ergonomics, domains of HFE, are integrated and combined in SEIPS. The model allows for an understanding of the healthcare sociotechnical system and the impact of complexity on patient care by addressing patient safety and other quality of care problems. It looks at e.g. cognitive HFE issues which include limited information for clinical decision-making (e.g. care transition with incomplete patient records), clinical tasks resulting in high cognitive workload, health IT and medical devices designed without considering cognitive abilities of healthcare professionals [59].

Lack of attention to HFE in the design and implementation of healthcare technologies, processes, workflows, jobs, teams and sociotechnical systems can result in poor quality of care and patient safety incidents, as well as undesirable employee and organisational outcomes [59].

The original SEIPS model has certainly been successfully applied in healthcare research and practice - table 1 [35]. Though, it has to be recognized that the HFE discipline as well as its models and methods must evolve to keep at being useful and relevant for an evolving healthcare domain whose core issues and values change with time. To achieve this, SEIPS 2.0 [35] incorporates contemporary thinking in human factors science and practice, ensuring that the model is attentive to emerging issues and priorities in the healthcare domain. It introduces the concept of *adaptation* as a feedback mechanism that explains how dynamic systems evolve in planned and unplanned manners.

The novel concept of adaptation, introduced in the SEIPS 2.0 conceptual model, opens for research on approaches that support the adaptive capacity of a system as well as individuals' adaptation to enable them to cope with unanticipated situations; which are situations that pose the greatest threat to system performance and safety. This particular focus is drawn by the need to extend the systems thinking orientation and look for means to jointly analyse and optimise the sociotechnical system.

5.1 Designing sociotechnical systems for adaptation

Complex sociotechnical systems such as healthcare are characterized by changing or dynamic conditions. This instability may result from frequent perturbations either within the system or in the external environment [60], and which transforms the system. The introduction of new technology, improvement programmes such as lean thinking, and planned redesign efforts in general constitute these perturbations. In a dynamic system as healthcare, processes and their outcomes are evaluated; then, adaptations are made to accommodate the inevitable flux that arises in the system, with the ultimate goal of decreasing the gap between actual versus ideal performance [35,60].

By including *adaptations* to human factors studies, multiple outcomes are taken into account: from safety and worker well-being to productivity, efficiency and organisational performance. In this way, it is possible to identify how work systems are being adjusted in planned and unplanned ways. This is important as some of the adaptations may constitute violations of protocol or even take healthcare works into areas of unfamiliar performance and may therefore have safety consequences [35].

Recently, methods such as *Cognitive Work Analysis* (CWA; [61]) are being applied to analyse overall systems, interactions and their resulting emergent behaviours. Designing for *adaptation* requires special approaches for work analysis, as the work demands of a system are tightly integrated with how those work demands are supported through design. Healthcare workers operate under continually shifting conditions. Therefore, design methods for system's features as interfaces, teams, and automation (through new technology) must be able to support the unstable and uncertain conditions under which workers must perform.

To this end, CWA provides a framework of methods for the analysis, design, and evaluation of complex sociotechnical systems. It defines the work demands of sociotechnical systems in terms of the constraints, or boundaries, on actors which must be upheld by their actions irrespective of the particular conditions they are faced with, if a system is to perform effectively.

Within these constraints, workers still have many degrees of freedom for action and can form or generate a variety of work patterns including novel behaviours to deal with unanticipated events. By basing designs on these constraints, actors can be given the flexibility to adopt a wide variety of work practices without violating the boundaries of effective performance and safety. [60,62,63,64,65]

CWA consists of five dimensions of analysis for identifying the different kinds of constraints (both social and technical) on worker's behaviour. These are depicted in the table below.

Table 3 – CWA dimensions, constraints. Adapted from [60].

Dimensions	Constraints
Work domain analysis	Work domain—constraints placed on actors by the physical, social, and cultural environment, including the system’s purposes, values and priorities, functions, and physical resources
Activity analysis	Activity—constraints placed on actors by the activities necessary in the system to achieve the system’s purposes, values and priorities, and functions with the available resources
Strategies analysis	Strategies—constraints placed on actors by the cognitive strategies that can be utilized for achieving the activities necessary in the system
Social organization and cooperation analysis	Work organization—constraints placed on actors by the ways in which work can be allocated, distributed, and coordinated in the system
Worker competencies analysis	Workers—constraints placed on actors by the ways in which the work demands of the system can be met given human cognitive capabilities and limitations

These dimensions of cognitive work analysis collectively define a constraint-based space within which actors have many possibilities for behaviour within complex systems. By focusing on constraints, CWA promotes designing for *adaptation*.

The aim is to create work system designs that support e.g. healthcare workers in adapting their behaviour as they see fit without violating the system’s constraints; instead of developing design which have been prescribed or described by analysts a priori, as this could lead or contribute to unsafe or unproductive outcomes [60,63]. Healthcare professionals must, in general, contend with dynamic operating conditions, in which the problems, demands, and pressures they are faced with change or evolve constantly. They must contend with events that have not been (and cannot be) foreseen or specified entirely by analysts or designers.

Cognitive work analysis does not only concern with adaptations in sociotechnical systems at the level of behaviours of individual actors but also their structure, or organization, in line with the evolving situation. These are examined closely in the first and fourth dimension of CWA.

Whereas the term *adaptation* is generally used to encompass changes in actor’s structures or behaviours, the literature refers also to the term *self-organization* which is concerned with changes in organisational structure. This concept provides an explanation of how behavioural and structural adaptations in sociotechnical systems can appear spontaneously as a respond of the system itself to challenges posed by its environment. New organizational structures may be observed in sociotechnical systems without being planned, centrally coordinated, or imposed by external agents.

The *self-organization* concept indicates that a system’s structure may limit its response in manners that are unsuitable or ineffective when specific conditions are encountered.

However, structure and behaviour are closely interrelated. Novel structures emerge from the spontaneous behaviour of individual, interacting elements responding to the local conditions, enabling the system to respond appropriately to the circumstances. A new structure constrains and enables behaviours to adapt to the situation, until it changes, then the spontaneous actions of individual, interacting actors result in further structural changes. This interplay evolves continuously to deal with the challenges posed by the environment. Figure 3 below depicts this relationship with respect to social systems. [65,66]

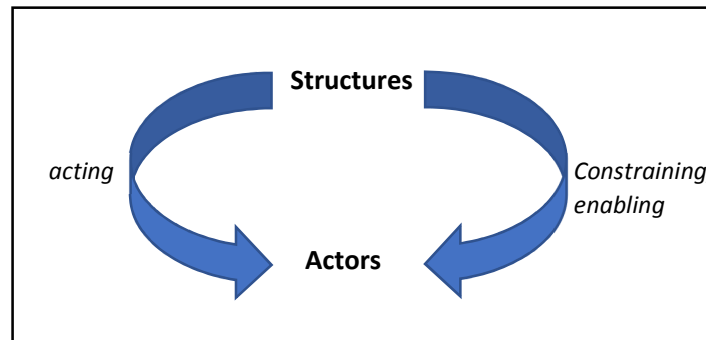


Figure 3 – Social self-organisation [65,66].

The occurrence of self-organisation has important implication for the design of human-automation interaction in sociotechnical systems, which are necessarily self-organising. Design based on normative or descriptive or models of “who should do what” may compromise performance by limiting the capacity of a system for self-organisation, and consequently its capacity for dealing with instability or uncertainty.

Finally, human-automation interaction must be conceived in the context of both structure and behaviour, i.e. in the context of adaptation and self-organisation. The framework used for the analysis and evaluation should recognize how to support the interaction required between human and technologies, if the capabilities of the automation (e.g. electronic medical chart) are to be exploited. To this end, CWA framework with its strong systems thinking orientation stresses the importance of system adaptability to develop highly effective systems. [63, 65, 66]

The CWA framework implicitly incorporates the design principles of sociotechnical systems theory, and provides a consistent approach to analyse and optimise the social and technical system [64]. Similar to the basis of SEIPS model, it sets the actors (people, or group of people) in the centre of the work system, recognise that performance results from the interaction of a sociotechnical system and embraces design of work structures and processes grounded in sound human factors and practice. Table 1 in [64] gives a comprehensive summary on the alignment of sociotechnical systems principles and the CWA framework.

Being an established analysis framework CWA has been widely used to analyse complex systems including healthcare, military and air traffic control. With respect to SEIPS, remaining future work would include to develop a toolkit to accompany the SEIPS model utilizing the CWA framework. By combining these two system approaches, a powerful tool could enhance the identification, systematization and analysis of knowledge concerning introduction of new technologies within organisations such as healthcare. However, over comprehensive assessment tools should be avoided as it is time consuming, which might compromise rigorous evaluation.

Different arrangements to introduce CWA and combine it with the SEIPS model (and its underlying sociotechnical systems principles) may be proposed. CWA could, for instance, be incorporated to the first part of the analysis phase in the knowledge assessment process depicted in [58]. The SEIPS components and underlying K elements may serve as input to the CWA framework, and vice versa.

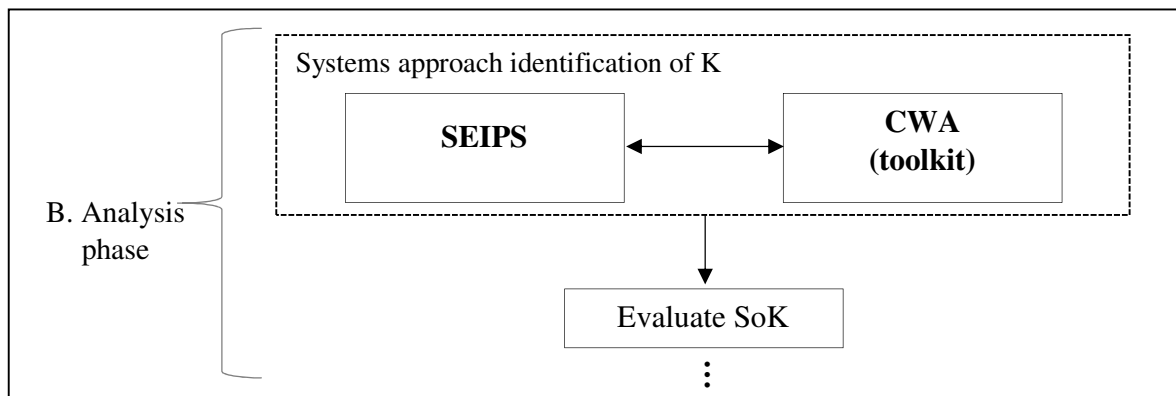


Figure 4 – Alignment of SEIPS and the CWA framework

For the development of a toolkit to accompany the SEIPS model, two tools may be considered as relevant: the abstraction hierarchy (AH) tool from the work domain analysis phase of the CWA framework [63] and the diagram of work organization possibilities (WOP) [60,66] from the social organization and cooperation analysis phase. The specific intent of these tools is briefly described below.

- The abstraction hierarchy captures the objectives and the affordances of the examined system at a number of levels of abstraction such as functional purposes, values and priority measures, purpose-related functions, and object-related processes [63]. In general, the tool is used to represent the constraints implicit on the domain in which the activity of a system is conducted [64].
- The WOP diagram models the structural possibilities of multiple actors and the behavioural opportunities of individual actors within a single representation that is consistent with the concept of self-organisation. Boundaries or limits on action (“who can do what”) are established by analysing the organizational constraints, or

the relationships between the action possibilities afforded by the work context, and the actors themselves. In practice, the diagram facilitates the description of the emergence of novel temporal, spatial, or functional structures from the flexible behaviours of individual, interacting actors, such that an analysis on the system's capacity for adapting to a constantly evolving work environment is performed [66].

Several application examples of AH and WOP tool are mentioned in the literature [63,64,66]. However, it is necessary to perform additional research on how these tools can seamlessly be implemented, and to what extent they may assist SEIPS in the process of identifying and analysing relevant work system knowledge in a healthcare context; considering technology, safety and quality of care factors. The arrangement presented above using AH and WOP is intended as a starting point for further development.

For the future work, it is essential to keep in mind that the basis of combining SEIPS and CWA tools is to increase the overall quality of knowledge when performing economic evaluations, by employing the systems adaptation concept and considering the self-organisation phenomena that arises in complex sociotechnical systems.

Chapter 6

6. Conclusion

Different analysis methods and techniques utilized in health technology assessments have the purpose to provide a comprehensive toolkit for considering the important clinical, organizational, technological, and economic aspects to the different healthcare stakeholders. As available resources become more scarce, economic evaluation of health technology has a crucial value in decision-making for acquisitions and informed decisions in general. This makes costs and effects analysis an important part of the health technology assessment process. Economic analyses guide the decision-making by comparing possible alternatives courses of action with respect to resource utilization and expected outcomes [15]. Although the analysis tools within economic evaluations are comprehensive, the result is still highly dependent on the extent and quality of the background knowledge that forms the basis for the evaluation.

In the process of identifying and obtaining relevant knowledge, healthcare organisations need to recognise the importance of human factors and sociotechnical system aspects to quality of care and patient safety. Implementation of new health information technology in clinical units exert challenges to the whole system. Thus, an emphasis on the understanding of systemic impact of organizational and sociotechnical changes is required to produce better knowledge basis for performing economic evaluations.

In this paper, the systems approach proposed by Sørskår et.al is applied for the retrospective evaluation of an ongoing health information technology implementation in a clinical unit, and identified, in a systematic manner, possible factors that could have influenced the background knowledge to the economic evaluation used in decision-making towards acquisition and implementation of the HIT system. Information provided by the chief physician of the intensive care unit of a medium-sized hospital revealed that the decision-making was based on a lack of knowledge or poor understanding of the context and its emergent properties that result from the interaction of the dynamic system components.

It is then argued that the suggested expanded framework's focus on the knowledge assessment as part of the economic evaluation do not acknowledge the components' interactions in sufficient extent. It is thus proposed an extension to better capture how the work system components interact and what impact they potentially have on the overall evaluation. Additionally, an importance ranking is set forth to express which configurations should be considered for further examination or improvement in knowledge base.

The analysis on the extended framework has aimed to test the applicability of the systems approach and look into possible adjustments that contribute with better background knowledge to the interactive process of human factors and economic evaluation.

Moreover, this study considers the Cognitive Work Analysis framework as a mean to espouse the SEIPS sociotechnical systems approach integrated in the expanded framework. CWA gives the possibility to analyse both emergent individual's behaviours and structural changes of the work system due to the introduction of new technology. This with the final goal to ensure consideration of the system's capacity to deal with instability and uncertainty circumstances that could have unwanted effects on the entire system, negatively affecting the overall healthcare quality and patient safety. Attention to these system features may accommodate healthcare domain-specific concerns and needs and consequently increase the quality of the background knowledge that form the basis for economic evaluations, and in turn support the decision-making.

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