Learn from what goes right: a demonstration of a new systematic method for identification of leading indicators in healthcare

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Highlights

- A new method for the identification of leading indicators in healthcare is proposed.
- The presented method was built on the concept of Functional Resonance Analysis Method.
- The method was demonstrated on the case of a complex healthcare process, the early detection of sepsis.
- The method consists of six overall steps to determine leading indicators of various healthcare processes.
Manuscript title: Learn from what goes right: a demonstration of a new systematic method for identification of leading indicators in healthcare

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Abstract

The work in patient safety is often centred on adverse events and errors. Typical methods to improve patient safety are reactive and focus on understanding past failures. This article presents the development of a proactive method towards improving patient safety and understanding why processes function as intended on a daily basis. The paper presents the steps of how the method was
developed and demonstrates it by using a former case study of early detection of sepsis. Emphasis is on understanding complex processes and identify aspects important for things going right and achieving intended outcomes. The study resulted in the development of 6 overall steps for identifying leading indicators in complex healthcare processes. These were (1) identification of relevant functions, (2) cluster of functions in sets, (3) identification of functions with variability, (4) identification of functions with upstream-downstream functions, (5) identification of leading indicators, and (6) confirmation of leading indicators through experts and adverse events.

The study outlined the development a new method on the topic of leading indicators in the context of patient safety.

**Keywords**

Complex systems, healthcare processes, FRAM, leading indicators, method development

1. Introduction

The aim of this study is to develop a systematic method for the identification of leading indicators for safety in healthcare based on a case study describing the early detection of sepsis in a Danish hospital ward. Based on these results and the literature on leading indicators, this study proposes a method to develop leading indicators in healthcare. The use of indicators in healthcare has been a priority for more than a decade in the Danish healthcare sector (1). Indicators are commonly used to document and measure quality, set priorities, support patient safety initiatives and describe historical trends (2). Another main aim of indicators is to support decision making with regard to when, where and how to take action (3). This paper argues that the current application of indicators is limited to taking actions. Studies of other industries suggest that indicators can be developed to prevent adverse events in healthcare.

1.1. Patient safety context

The field of patient safety has developed rapidly during the past 15 years, expanding from the focus of a few researchers to be placed on national agendas (4). Still, patient safety approaches primarily rely on methods that assume adverse events can be explained and avoided using linear models and applying reactive thinking, labelled Safety-I (5-10). This approach has played an important role in avoiding harm for patients and improving the safety of healthcare services (5, 7). However, adverse events still occur in up to 10% of acute admissions (4, 7, 11).
This paper presents an alternative method for patient safety and a new way to identify indicators to ensure that processes function as intended. These indicators are termed ‘leading indicators’ and are used as precursors of events. They contribute to a better understanding and management of processes in complex systems such as healthcare (12). In several high-risk industries, this approach has contributed to the viewpoint of safety (13).

1.2. Leading indicators

During the early 1980’s the use of measures of safety and major hazard risks emphasised direct or after-the-event indicators (2, 12). This perspective helped to establish sets of incidences for accidents or near-misses in the sector, but it did not provide the necessary information to avoid these unwanted events. To anticipate and create early warnings prior to accidents, one needs to understand the underlying relations and combinations of factors that enable the system to function on a daily basis (3, 5). This approach rapidly evolved in high-risk industries in the aftermath of major accidents such as the Piper Alpha oil platform accident, the Texas City Refinery explosion and the Deepwater Horizon blowout (3, 14, 15). Leading indicators can be used to actively monitor important components of a system to achieve desired safety outcomes and implement warnings prior to undesired outcomes (13). Industries apply different approaches to identify the relevant leading indicators for their own systems or organisations. Although these approaches are developed for a specific context, they have some common traits. First, leading indicators are identified based on modelling or understanding the investigated safety system. Second, the model of the system is used to identify potential factors that are relevant for safety by either reviewing previous incidences or collecting data from staff (16-20).

The healthcare industry has learned from and adopted approaches that have been developed in high-risk industries (21). However, the concept of and distinction between leading and lagging indicators has not yet been established in healthcare (22).

1.3. Aim

Inspired by the knowledge of leading indicators that have been developed and applied in fields such as aviation, nuclear power and offshore operations (23), this study aims to develop a generic method to identify leading indicators. Previous studies on the development of leading indicators have reported positive effects of using proactive methods to understand systems (13). This paper attempts to move the focus from the prevention of adverse events to achieving a higher number of
positive outcomes through a better understanding of the systems. This focus will provide a foundation for identifying factors that contribute to things going right, labelled Safety-II (6, 24, 25).

2. Background for the method

Indicators are typically extracted by first creating an understanding and model of the process; thus, this paper applies the results of a case study that describes the early detection of sepsis in a Danish hospital ward. Raben et al. conduct an in-depth analysis of this case. The case was used to test the development of a method for detecting leading indicators in healthcare. The process is described using a method for modelling complex socio-technical systems called the Functional Resonance Analysis Method (FRAM) (26).

The FRAM is used to produce a model of what is required to achieve the intended outcomes of processes performed on a regular basis (17). The model is constructed around functions; it describes the activities of a process and helps to illustrate how the performance of these functions can vary and how this variability can affect other functions later in the process (27).

2.1. Combining perspectives to identify leading indicators

Leading indicators are elements or factors that can be used to indicate possible future states of a process; therefore, they can be used to manage desired processes (26). The method was developed based on the variability of the functions in the process, as well as the concept of upstream and downstream functions. Variability is described and used to point to indicators that are crucial for processes to succeed. Identifying these indicators involves a focus on two features of functions: variability and upstream–downstream couplings.

2.2. Variability

The FRAM comprises a number of functions that each describe an activity performed in the illustrated process. A key element of the FRAM is that it illustrates how different tasks are connected or coupled to each other and how earlier activities can affect later activities by delaying or affecting the quality of the activity. The visualisation of the FRAM illustrates that complex processes are difficult to describe in a linear way. Actions can vary or occur concurrently if the circumstances or surroundings change (27). Therefore, variability is investigated to provide an understanding of the couplings of functions.

Variability can occur for different reasons (27). First, functions can be affected by internal variability caused by psychological or physiological factors. These can include stress, fatigue, well-
being, decision-making ability, personal judgement and past experiences. Second, functions can vary due to the working environment in which they are carried out. This includes social factors such as group pressure, social norms, relations with and expectations of co-workers, and the overall organisational culture (27). Finally, variability can evolve from upstream–downstream couplings (27). Detecting such couplings is based on detecting potential variability and considering how it may spread through the system and affect functions later in the process (27). This view of processes and systems shows how variability emerges and how it is either amplified or dampened by actions later in the process. Analysis of variability and couplings can help highlight the emergence of unexpected outcomes; more importantly, it can describe how expected outcomes succeed despite variability in functions (27).

3. Results

3.1. Systematic method for identifying leading indicators

The systematic method outlined below was developed and applied using the case study of the early detection of sepsis in a Danish hospital ward.

Step 1 - Identifying relevant functions.

First, a very simple representation of early detection was developed. This included the main task of detecting sepsis. Functions such as referring the patient, examining the patient and calling the doctor were identified. Further variability of functions was considered to decide which functions should be described. If the function was likely to vary in relation to potential effects on the output, the researchers decided to describe it in detail. Using the FRAM to identify functions in a process provided an opportunity to create a very large and complex representation of reality. In this case, functions that were not related to early detection were not considered. Using this as a guideline, functions should be added by asking the question, ‘Can it in any way affect the intended outcome?’ until the answer to this question is ‘no’.

Step 2 - Clustering of functions in sets.

The second step was to cluster the functions into a number of sets. First, the model was used to examine the process and the chronological order of each function being performed. This provided an understanding of the process over time. Functions were then divided into sets, with each representing relevant tasks conducted with the aim of detecting sepsis. These tasks were the overall key tasks that staff listed when asked to explain the process of the early detection of sepsis. Figure 1
illustrates the sets. Clustering of functions was conducted based on the assumption that complex processes may contain many leading indicators. In this process, four sets of functions were included, but different numbers could occur in other cases depending on the size and complexity of the process. The FRAM model can be seen in Appendix A.

The four sets of functions identified in this process were: referring and obtaining information on the patient, transferring information to electronic systems, receiving and triaging the patient, and examining the patient and confirming or dismissing the diagnosis (6).

Each set included all activities that were conducted to fulfil the task. During the data collection process, informants mentioned the overall set as a single function (e.g., referral of the patient). The functions included in each set were identified as a result of observations and conversations with informants on smaller tasks performed to ‘refer the patient’. Using the first set as an example included having the sheet for referral in the pocket, receiving the call from the doctor, writing the information onto a sheet, asking additional questions and ticking blood samples to be ordered.

Examining each set separately provided an opportunity to focus on the factors in each set that influenced whether the process ended as intended.

Step 3 - Identification of the functions in each set with variability.

To find the leading indicators, a number of underlying assumptions were considered. Variability was not necessarily a criterion for considering a function. To be considered, variability should be important for the process and should affect the process later. Variability can affect functions in different ways related to either time or quality. To determine how variability affected the process, functions were analysed based on whether they varied internally, externally or due to couplings. Upstream–downstream couplings will be described in further detail in the next step.

In this case, internal variability was mainly considered in relation to human and organisational factors. An example of internal variability occurred in the second set in the function—‘to become aware of patients registered in electronic systems’ (see Figure 1). This variability was caused by the nurse’s experience, attention to electronic screens and high pressure on the ward. The nurse’s level of experience could affect whether he or she was able to keep track of electronic screens during high-pressure times in the ward, thereby affecting when the examination started, the speed of detecting of a possible sepsis diagnosis and how fast a doctor would arrive and conduct a further assessment of the patient.
The possibility and consequences of internal variability were considered for functions in all sets and in relation to how the variability affected the output of the functions.

Figure 1: Close-up of second set—‘transferring information into electronic systems’

Another example of internal variability was observed at the organisational level in the first set—‘referring and obtaining information on the patient’. The effectiveness of communication caused variability at the organisational level, and it arose from the general practitioner’s (GP’s) ability and willingness combined with the nurse’s ability to extract information from the GP. This variability affected the speed of detecting a possible sepsis diagnosis; therefore, it affected whether sepsis was diagnosed in a timely manner.

Further, external variability can be caused by factors in the working environment. In this case, external variability affected the function of ‘calling the doctor for examination’ (see Figure 2). The output of this function was affected by the nurse’s relationship with the doctor. If the nurse knew the doctor, the conversation could be straightforward and the nurse could inform the doctor of symptoms and vital signs and use his or her observations of the patient to ask the doctor to examine the patient shortly thereafter. Conversely, nurses who did not have a relationship with the doctor
sometimes found it difficult to voice their assessment of the patient, thereby making it difficult for the doctor to assess how fast the patient should be examined.

Internal and external variability were considered for all functions in the model to provide a thorough understanding of how each function could cause different outputs and to determine which functions were likely to be subject to variability. Appendix B includes information for all functions and their variability.
Step 4 - Identification of functions in each set with upstream-downstream couplings.

In addition to variations caused by internal and external factors, functions can vary because of upstream–downstream couplings. When attempting to understand a representation of reality, it is not only necessary to know how variability may occur for each function, but also how variability may be combined. Examining the model and considering upstream–downstream relations provided an understanding of the consequences of combinations of variability. Two characteristics were considered when examining how variability affected functions later in the process: timing and precision. This section presents examples for each aspect and discusses how variability caused changes in downstream functions later in the process. Examples are presented in Figure 3 and the function of ‘to triage patients based on vital signs and evaluation’.

*Figure 3: Close-up of third set—‘Receiving and triaging the patient’*
First, preconditions for triaging the patient were considered. The data showed that a delay in the evaluation could cause a delay in the diagnosis. Variability also occurred if the evaluation was not conducted precisely. Nurses improvised or relied on false assumptions, thereby causing the output of the function to be vague and creating a possibility of misunderstanding and misinterpreting the symptoms, eventually delaying the diagnosis.

Resources that are necessary to perform functions represent elements that are needed or consumed by a function or that must be present while a function is being carried out (27)—for example, using a referral sheet to write down information from the doctor. In some cases, the sheet was not available for the nurse during referral, so the variability delaying the function and quality of the output was reduced. This led to imprecise and limited knowledge of the referred patient and a possible delay in blood sample results, thereby delaying the diagnosis. The findings further showed that precise referral of patients enabled nurses to be aware of sepsis at an early point, which saved time later in the process and reduced variability and delays caused by other functions.

Control is used to describe aspects within an activity that regulate how processes are conducted (17). Based on the theoretical background, control can cause variability if performed functions are imprecise, incomplete or incorrect. In this case, a sepsis checklist was used as a control aspect. If the sheet was not filled out correctly or in a timely manner, the staff were not aware of a possible sepsis condition and therefore would not react. This caused a delay in which the condition worsened. Further, given that the condition of patients with sepsis changes quickly, if the checklist was filled out too early, it would not consider symptoms that occurred later, thereby reducing its effect.

Time can relate to the time it takes to perform tasks or the time at which the tasks are performed. Time played a significant role in several functions in this case (see Figure 3). For example, to detect sepsis in a timely manner, the checklist had to be filled out within an hour of admission. This time constraint was set based on evidence that shows that the one-hour mark is critical in detecting sepsis. A delay in detection resonated throughout the system and affected the outcome.

Input represents the start of a function, and functions often ‘look’ for a signal to begin. Input can therefore affect the performance of a function if it is started by a wrong signal or if the signal is too weak, which may lead to a lack of response (27). This aspect was important because admission started when the function of ‘to become aware of the patient’s arrival on
the electronical system screen’ was completed. If the input was not performed in a timely manner, it resulted in a delay in the admission process and thus the rest of the process.

The process of considering the possible consequences of functions and aspects was conducted for the entire model of the selected process. Each function in the model was systematically considered and all aspects were investigated to detect possible variability and investigate how this variability affected the outcome of the model - in this case, the timely detection of sepsis.

Step 5 - Identification of leading indicators for each set in the process
This step summarises the two previous steps in the method and identifies the leading indicators for the process. All functions were systematically examined for variability and were considered based on the couplings this variability entailed. Both aspects were equally important, as some functions could be subject to variability, but it was not before involved staff associated the variability with future scenarios, that they are applied as leading indicators. This meant that staff were especially aware and attentive of variability if they had experienced previously that the variability lead to specific results (28). For this reason, the FRAM was a suitable tool for identifying leading indicators, as the method assisted in identifying variability and the connections and results of this variability (27, 28). Therefore, if a function with variability did not have consequences later in the model, it was not considered a potential leading indicator. Conversely, if a function with variability affected the timely detection of sepsis, it was considered a leading indicator. This work concluded with the selection of four functions that were considered precursors or leading indicators for positive and successful outcomes in this case:

- Receiving and obtaining the necessary and sufficient information on the patient from the referring doctor.
- Remaining alert and becoming aware of when a patient had been received at the ward and was ready for admission.
- Using former experience and clinical judgement to evaluate the symptoms of the patient to supplement vital signs.
- Calling the doctor to conduct the examination and explaining the overall state of the patient to the doctor, including both vital signs and other observed symptoms.

Step 6 – Supporting the leading indicators through experts and adverse events
Next, it was important to support the findings of the first five steps of the model. To be meaningful and relevant for the organisation, it was crucial that they were relevant for the setting they were
developed in and that the identified factors played a role in managing the process and securing positive outcomes. Two approaches were applied in this confirmation.

First, relevant staff or experts in the field were consulted and presented with the work. This provided an opportunity to assess whether the indicators resonated with the staff. Second, a review was conducted of adverse events previously reported in the field to investigate whether it was possible to recognise the functions deemed to be leading indicators in any reported adverse events.

The review showed that several reported adverse events occurred during the admission process, where the first assessment of the patient was made. These were often caused by not measuring vital signs and not considering other symptoms besides the vital signs. Next, the review showed that adverse events were caused by a lack of communication between the staff referring the patient to wards and the staff receiving the referral. This resulted in wards not being prepared for the severity of the patient’s condition, or they lacked information on the patient, identified as the first leading indicator for successful outcomes. In these cases, this led to, or could have led to, a delayed diagnosis. Finally, the examination was also mentioned in adverse events. Either the staff found it difficult to get the doctor to respond fast, or the assessment was not conducted with an emphasis on sepsis. This lack of response could be caused by relations between doctors and nurses, or nurses’ ability to voice suspicion or concern that was not necessarily based on clinical symptoms. This variability could be caused by the doctor’s workload or miscommunication between the doctor and nurse, thereby causing the examination to be delayed. In some cases, there was a delay in receiving, or a lack of, blood sample results, which prevented the confirmation of sepsis. Either the blood samples were delayed or they were not ordered early in the admission process.

The review of adverse events helped support the findings from the first steps. We cannot conclude that the indicators were confirmed. However, it was important to investigate whether some of the factors identified as important for success were actually contained in previously registered adverse events. They gave an indication of whether the description of the process was recognisable in adverse events.

3.2. Summary of the method for identifying leading indicators (MILI)

Extracting the developed method from the illustration provided by a specific case study is an important step in the development of a useful method. The six steps of the systematic method are extracted and summarised below.
1) Identifying relevant functions
It is important to identify and describe all relevant functions of the process in a systematic manner. Equally important is the explicit consideration of when to stop the description of the process. The FRAM is a proven tool for this, as it includes clear criteria for when the functional model is complete.

2) Clustering of functions into sets
Processes in healthcare and other fields typically comprise a number of smaller activities referred to as sets. To assess the number of leading indicators that are relevant to the process, the process should be clustered into sets, which can then be analysed separately.

3) Identifying the variability of functions in each set
The description of how each function might be subject to variability helps with the initial identification of important functions in the process. The functions that are most likely to vary under different conditions should be further analysed in the next step.

4) Identifying upstream-downstream couplings of functions in each set
This step deals with all functions and emphasises the functions previously identified as being likely to vary. Upstream–downstream couplings are those in which the variability of the function early in the process affects functions later in the process.

5) Identifying the leading indicators for each set of the process
The aim of this step is to propose and recognise observable characteristics of functions that may be variable and that can affect one or more of the functions that follow. Observable characteristics are candidates for leading indicators. This step serves to identify the leading indicators more precisely and to describe how they can be observed or measured. Measuring indicators as identified in this process, containing elements like communication, awareness, relationships or experience can be challenging to measure quantitatively, and therefore we recommend considering the inclusion of qualitative measurements.

6) Confirming the developed leading indicators through adverse events and experts
Finally, the method includes confirmation of the developed leading indicators. This confirmation may contain two elements. First, if available and possible, the leading indicators can be compared to previous adverse events to detect whether the indicators are recognisable in adverse events. Second,
the indicators should be presented to expert practitioners who can confirm the relevance of the proposed indicators.

4. Discussion

This paper presents an alternative method to indicators (1). Most research and progress in patient safety has tended to focus on reactive methods towards safety management (7). Indicators developed in a patient safety context have primarily been outcome indicators (1). However, these methods do not offer indicators and do not indicate which factors in a process are important to achieve success.

Typically, patient safety is defined as avoiding, preventing and ameliorating adverse outcomes or injuries stemming from the process of healthcare (29). This definition is widely used within the field of patient safety as a basis for developing patient safety initiatives. Thus, measurements should seek indications of a lack of safety, such as the unwanted events mentioned previously (30).

This work feeds into a discussion of how to improve work in healthcare. Understanding incidences using root cause analysis does not prevent the same mistakes from repeatedly occurring (7, 10, 31).

This study makes a contribution to the field of patient safety by trying to improve processes based on the identification of functions that are vital for success (30).

This study applies an alternative approach to the understanding of safety in healthcare. It argues that safety should not only be characterised by the lack of presence of accidents, but also by how often intended outcomes are achieved (5, 9, 30). Considering this alternative understanding of safety and applying it to the identification of indicators, the method helps to identify important aspects of a given process (10). The developed indicators are signs for ‘what to focus on in the process in order to assure that things go right’ (6). This different perspective can be illustrated by comparing it to measures previously applied in sepsis, such as the ‘number of patients transferred to intensive care with severe sepsis or septic shock’ and the ‘number of sepsis patients in intensive care who die’ (32). These indicators represent actual measures used to track the safety of the hospital where this study was conducted. They are also a useful example of describing how this developed approach towards indicators is different from the reactive approach (30). The indicators are not performance-shaping and do not indicate which factors in the process of sepsis treatment are important to achieve success (32). The indicators measure unwanted events with a focus on death and worsened conditions. This fits with the perspective of Safety-I and reactive safety management, which focus on what has gone wrong (6).
Identifying leading indicators of safety is typically a task for high-risk organisations (16). Studies show that industries such as oil and gas, nuclear, aviation, production and transport apply the concept of leading indicators to a variety of critical safety processes (19, 33-36). When investigating previously applied methods for identifying leading indicators, no consensus was reached. Each study had its own approach or method towards identification that was specially fitted to the relevant setting (26). The lack of a consistent method was both a challenge and an advantage. For example, it was not necessary to follow already-set guidelines and face the challenge of adapting it to a different context (21). Conversely, there was a higher risk of developing a method that did not fit the context, and for which shortcomings might be discovered later in the process.

The process of confirming or validating the method is time-consuming when there is no available method to start with. Issues concerning whether the identified leading indicators were dependent on the researcher were considered. The results were reviewed by informants and employees in the ward and by experts in the studied field. These procedures showed that the results of this study align with those of relevant peers. However, it is not certain whether other individuals would have arrived at the same result. In relation to this statement, we considered the consequences of having limited knowledge of the investigated processes (37). A lack of clinical training, and therefore a lack of clinical knowledge of the process, enabled the researcher to focus on the entire process and all aspects, as the researcher was not looking for specific issues that were known beforehand. Many actions performed during the daily work were based on tacit knowledge. By being an outsider, one may be more likely to ask questions to uncover such aspects of work. An insider might not consider the importance of this and might not be able to extract it from the situation (38). As the objective of the study was to develop an applicable method, limited knowledge of the process enabled the researcher to focus on the method’s development rather than expose specific aspects of sepsis that are deemed important in the field. However, limited knowledge of the investigated process can also be a limitation, as there is a risk of not focusing on the aspects that are important in the case. The researcher may not have the ability to uncover all important factors because the relevant questions may not be asked.

One of the main challenges relates to further development of this method and to make it more reliable. It has been developed based on the data collection of one case, as well as the observations, considerations and analysis of one researcher. This is a major consideration for the refinement of the method and will be addressed in a future study, which will focus on testing the methods in other settings and using different cases, as well as allowing other researchers to apply the method to
investigate its usefulness and application. This approach will help test the reliability of the method and reveal aspects that need to be described more thoroughly.

A final consideration relates to whether the proposed indicators are effectively leading. To determine this, the proposed indicators must be implemented and measured in the wards. Indicators for the early detection of sepsis cases could be used to investigate whether there is a correlation between not achieving the indicators and the occurrence of unwanted outcomes. However, it is important to consider the possibility of making the developed indicators measurable. The extracted indicators primarily describe implicit factors within a process, which can be difficult to measure on a daily basis, as they can be part of the intuitive actions of staff. This does not eliminate the possibility of measuring, but it might require the consideration of qualitative measures (12, 39). As the identified indicators consider importance of aspects like communication and relation, heightened awareness and strengthening of ability to detect none clinical symptoms the collection of quantitative data can be limited. Instead, additional observations or interviews could be conducted to inform and support how these factors influence the success of the process and how they can be measured. Using the example of the first indicator ‘receiving and obtaining the necessary and sufficient information on the patient from the referring doctor’, could be assessed through focus group interviews with experienced staff-members in order to extract what questions they typically ask the referring doctor. This knowledge could be extracted and converted to the referring form that nurses already use during referral. Similar initiatives could also be pursued for the other indicators. In addition the analysis of this collected information could be interesting to examine for variability. As we present indicators through the perspective of FRAM, we are interested in measuring and understanding variability because a heightened degree of variability may mean that the process is developing in an unintended direction.

If further development results in a strengthening of the application of the method, it should still be considered that different researchers might obtain different results, as qualitative research is usually affected by the individual undertaking it (37).

5. Conclusion

This study used the FRAM and observational studies to understand and map a complex process that served as a framework to develop a systematic method to define leading indicators for the process using a proactive safety management view.
This paper aimed to develop a number of systematic steps to identify the leading indicators of a given healthcare process using a systematic description of the process. This work suggests that these guidelines can help identify and manage important aspects of the process.

To successfully identify the leading indicators, six steps were applied in a systematic manner: (1) identify relevant functions, (2) cluster functions into sets, (3) identify the variability of functions in each set, (4) identify upstream–downstream couplings of functions in each set, (5) identify the leading indicators for each set of the process and (6) confirm the developed leading indicators through adverse events and experts.

This paper demonstrates how this method can be applied as a framework for studying and defining leading indicators. Further studies are necessary to validate the method developed in this study. Therefore, the systematic method is currently being applied to already established descriptions of complex processes in healthcare to assess its usability in a different context.

The results of this study will contribute to the discussion of whether safety in healthcare can be developed further than current methods and approaches allow. This study suggests that new perspectives of healthcare processes can be explored by focusing on positive outcomes. The proposed method offers a different way of investigating a process that may reveal aspects that have not been considered with methods such as the often-applied root cause analysis, which is driven by analysing near-misses, incidents and accidents.

**Competing interests**

The authors declare that they have no competing interests.

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**Authors’ contributions**

DCR carried out the data collection and analysed the data. DCR drafted the manuscript and developed the method. EH contributed significantly to the conception and design of the study, and revised the manuscript critically. BV, KLM and SBB contributed in revising the manuscript. All authors read and approved the final manuscript.

Appendix A: FRAM model of early detection of sepsis
Appendix B: All functions of ’Early detection of sepsis’, brief description, contribution to the model and possible variations

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<th>Nr.</th>
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<td>1</td>
<td>The General Practitioner (GP) or Emergency room (ER) contacts the acute visitation ward (AVW)</td>
<td>If the GP has a patient they suspect have an infection based on clinical signs, they will refer the patient to the medical ward, in order to be investigated and treated. The same is relevant for patients admitted to the ER. If they show signs of infections, doctors from the ER will also call the AVW.</td>
<td>Activating the function where the ward receives the call from either GP or ER.</td>
<td>The doctor has to be availability for calling and have a phone.</td>
</tr>
<tr>
<td>2</td>
<td>The nurse, responsible for the telephone in AVW, will receive the call.</td>
<td>One of the nurses on shift will always be responsible for carrying the telephone were patients are called in. The nurse with the telephone may have one of several other functions in the ward, including admission, care of admitted patients etc.</td>
<td>Activating the function where the ER doctor or GP refers the patient to AVW.</td>
<td>Variations occur if the nurse is occupied with something else, or does not carry the phone.</td>
</tr>
<tr>
<td>3</td>
<td>The nurse with the telephone has to be available, in order to receive the call (Background function)</td>
<td>The nurse is responsible of several activities besides attending the telephone. Therefore, in order to be able to answer the telephone, she has to be available.</td>
<td>Precondition for the nurse to be able to receive the call from the GP or ER and handle the referral.</td>
<td>Variations occur if the nurse is not free and if the telephone is not at hand it will delay the process.</td>
</tr>
<tr>
<td>4</td>
<td>The doctor refers the patient</td>
<td>During the telephone conversation</td>
<td>This activates the function, where the nurse will</td>
<td>Depending on time available variations can</td>
</tr>
<tr>
<td></td>
<td></td>
<td>between the ER doctor or GP, the nurse will receive information regarding the patient’s condition. This may vary in detail and severity.</td>
<td>document the information she received from GP or ER doctor.</td>
<td>occur when transferring the information and can stretch the time of the call.</td>
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<tr>
<td>5</td>
<td>The nurse documents the information received from the doctor.</td>
<td>The nurse with the telephone is obligated, besides the telephone to carry a sheet, which includes a number of aspects of the referral she needs to record. She will at this point also note if it will be necessary to order specific blood samples based on the knowledge from the doctor.</td>
<td>This activates the function where the nurse will pass the sheet on to the secretary.</td>
<td>Variations can occur if the nurse does not have paper to register the information, without paper the quality can be compromised of the referral information. Further variations occur if the doctor is vague it will take longer to withdraw information. This function affects variations in when the blood sample are request.</td>
</tr>
<tr>
<td>6</td>
<td>The nurse has the right experience to foresee potential sepsis. (Background function)</td>
<td>This includes the nurses past experience with detecting sepsis and knowing what the typical symptoms are or what to ask for when talking with the doctor.</td>
<td>This function is a resource for the nurse in functions prior to the patients arrival.</td>
<td>Variations occur based on the experience and clinical practice of the nurse and will improve the speed of the process, if the nurse is senior. This can cause variation in the time of when sepsis is detected.</td>
</tr>
<tr>
<td>7</td>
<td>The nurse with the telephone has to have the sheet in her pocket in</td>
<td>When the nurse is in charge of the</td>
<td>Precondition for the nurse to be able</td>
<td>If the sheet is printed or not</td>
</tr>
</tbody>
</table>

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23
order to record onto it. (Background function)  
telephone, she has to go to the secretary’s office, and collect a stack of sheets, she will carry in her pocket and use when a referral is made.
to record the information necessary to receive the patient properly.
and can cause variations in the process.

<table>
<thead>
<tr>
<th></th>
<th>The Sheet will have to be developed to be used (Background function)</th>
<th>In advance someone has developed and decided which categories go onto the sheet.</th>
<th>Control mechanism for writing down the necessary information.</th>
<th>The sheet helps control the information withdrew. If the sheet was not developed the quality of information would be subject of variability.</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>The secretary receives the sheet from nurse, containing the information from the GP or ER doctor.</td>
<td>The nurse will have to leave the activity she is performing or wait until she is finished, and walk to the secretary and hand over the sheet containing information on the referred patient.</td>
<td>This activates the function were the secretary takes the sheet, and transfers the information onto the computer system. It also activates the function were the secretary will order blood samples for the patient, if this is noted on the sheet.</td>
<td>Variations occur when the secretary is delayed with receiving the sheet or has a hard time understanding notes from the nurse.</td>
</tr>
<tr>
<td>9</td>
<td>The secretary must be available at the office in order to receive the sheet. (Background function)</td>
<td>The secretary has to be at her desk in order to directly accept the sheet containing the information.</td>
<td>This is a function affecting the preparedness for receiving the patient.</td>
<td>If the secretary is working somewhere else variations can occur.</td>
</tr>
<tr>
<td>10</td>
<td>The secretary will transfer the information from the sheet into the computer system.</td>
<td>The secretary is responsible for transferring the knowledge, which the nurse notes, on the sheet, into the computer system.</td>
<td>This activates the function were the nurses on the ward, are informed that a patient has been referred and can be expected at the ward and the function where the secretary prepares paperwork for the unavailable secretaries can cause variations if the transfer of observations is not completed, and the nurses in the ward have a harder time planning their work.</td>
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<td>11</td>
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<tr>
<td>Step</td>
<td>Activity Description</td>
<td>Details</td>
<td>Notes</td>
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<tr>
<td>12</td>
<td>The secretary will order specific blood samples. (background function)</td>
<td>If the information the nurse receives from the doctors indicates that specific conditions are likely she will note on the sheet that specific blood samples need to be ordered at the laboratory technician (LT).</td>
<td>This is an output from when the secretary transfers the additional information into the computer system. This function is subject of variability if the nurse receiving the call was not trained in being aware of sepsis symptoms.</td>
<td></td>
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<tr>
<td>13</td>
<td>The secretary will collect all necessary paperwork.</td>
<td>The nurse needs to fill out a number of paper during the admission of patients (Sepsis checklist, PatientSafe admission, etc.) and the secretary will put these in a folder for the receiving nurse to collect.</td>
<td>This is a precondition necessary in order to correctly admitting patients to the ward. Variability can occur if the secretary is occupied elsewhere, and unable to collect paperwork and this may cause variation in the process, for when the assessment of the patient can start and can affect the nurses awareness of possible sepsis.</td>
<td></td>
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<tr>
<td>14</td>
<td>The paperwork has to be developed</td>
<td>All the sheets necessary for admission must be developed in order to be used.</td>
<td>This function is a precondition for preparing the folder for admission. The design of the paperwork may cause either heightened or dampened variation in the process.</td>
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<tr>
<td>15</td>
<td>The patient arrives at the ward.</td>
<td>The patient will contact the secretary at the reception desk.</td>
<td>This activates the function where the secretary will show the patient into an admission room. Variations can be caused and delay the process if the patient is not registered immediately at arrival.</td>
<td></td>
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<tr>
<td>16</td>
<td>The secretary follows the patient into the admission room</td>
<td>After the patient has announced their</td>
<td>This activates the function were the</td>
<td>This can cause delay in the</td>
</tr>
<tr>
<td>17</td>
<td>The secretary updates the computer system with information on the patient.</td>
<td>After following the patient to the admission room, the secretary will update the computer system, with a number of the room the patient is in.</td>
<td>This activates the function where the nurse is becoming aware of the patients arrival.</td>
<td>Variations can occur if the secretary is busy after following the patient to the admission room, and cause delay later in the assessment.</td>
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<tr>
<td>18</td>
<td>The Nurse is aware of the patient’s arrival.</td>
<td>The nurse needs to keep updated with the computer system in order to get aware of when the patient has arrived, and in which room the secretary has put the patient.</td>
<td>This activates the function where the nurse starts the admission of the patient.</td>
<td>Variations can occur if the nurses are busy with other tasks, and not alert towards the computer system, the admission process can be prolonged. Further the amount of information on the computer screen can alert the nurse, of possible sepsis and cause variation in the initial treatment of the patient.</td>
</tr>
<tr>
<td>19</td>
<td>The admission process begins.</td>
<td>The patient is admitted and the nurse notes the patient in the electronic patient journal, updates all relevant information and symptoms.</td>
<td>This activates the function where the vital signs are measured.</td>
<td>Variation can occur if the necessary data is not available or not functioning. Variation can also occur based on nurses experience in specific symptoms.</td>
</tr>
<tr>
<td>Step</td>
<td>Action/Function</td>
<td>Description</td>
<td>Variations</td>
<td></td>
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<tr>
<td>20</td>
<td>Computer systems are available and functioning. (Background function)</td>
<td>Several of the functions in the model are dependent on the fact that computer or electronical systems are functioning. This is a resource function for several functions. This can cause delays and lack of specific treatment or awareness of symptoms, since computer systems contain important information of the patient.</td>
<td></td>
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</tr>
<tr>
<td>21</td>
<td>Measuring vital signs.</td>
<td>As soon as the nurse starts admitting the patient, the vital signs will be measured (Temperature, Blood pressure, respiratory frequency and pulse). These signs will be leading for how fast the patient will be seen by a doctor, when in the line of patients the patient will be admitted etc. This function activates the function were other symptoms in the patient are evaluated and the patient is triaged. It also starts the function were the patient is registered in the Electronic Patient Journal. Variation can occur if the necessary equipment is not available or not functioning.</td>
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<tr>
<td>22</td>
<td>Clinical Judgement is used as a tool when evaluating the patient. (background function)</td>
<td>Besides using vital signs and symptoms to evaluate the patient, staff will use their clinical judgement to look at the patient combined with past experience. Variations occur based upon each nurses experience and can affect the time before specific symptoms are linked towards a possible sepsis condition.</td>
<td></td>
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</tr>
<tr>
<td>23</td>
<td>Registration of the patient in the Electronic Patient Journal (EPJ)</td>
<td>In order to admit the patient, document vital signs and call a doctor later on the patient must be registered in the EPJ. This is a precondition for the doctor to be able to document treatment for the patient. Variation can occur if the data systems are not functioning properly and can cause lack of information or delay.</td>
<td></td>
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</tr>
<tr>
<td>24</td>
<td>The LT takes and analyses blood samples.</td>
<td>After the secretary informs the LT This is a precondition for Variation can occur based on</td>
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</tr>
</tbody>
</table>
about the patients, they will arrive at the admission room and take all necessary blood samples. They are then sent to the lab for analysis.

25 | The patient is evaluated based on other symptoms. | After measuring the vital signs, the nurse will also look at other symptoms in the patient. This is a precondition for diagnosing and for how the patient is triaged. | This is a precondition for triaging the patient. | This function may vary based on previously mentioned experience or clinical judgement and may be delayed or less thoroughly conducted.

26 | Triaging patients based on vital signs and other symptoms | The patient are triaged using a form, were the triage is decided based on vital signs and other symptoms. | This activates the function were the doctor is called for examination. It also decides how fast the doctor needs to arrive. | This function can vary based on the experience of nurses and the ability to rely on evaluation of patients rather than vital signs.

27 | Triage tool is developed (Background function). | The form must be accessible and developed. | This function controls the triage function. | No affecting variation.

28 | The doctor is called for examination. | The doctor will be called to examine the patient. If the triage is orange or red, the timeframe for examination is within 1 hour, if the triage is yellow or green it is 4 hours. | This activates the function were the doctor examines the patient. | This can cause variation based on how busy the doctor and the ward is, and the experience of the nurse and ability to inform the doctor of the central aspects causing delay in the process.

29 | Using experience when talking to the nurse and evaluating the patient (background function) | The doctor will often depend on past experience and clinical judgement to evaluate how fast | This function serves as a resource and time element in the function of the | The experience can either cause variation in time of the examination,
<table>
<thead>
<tr>
<th>Step</th>
<th>Task Description</th>
<th>Details</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>The patient should be assessed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Looking into the patient's record before assessment</td>
<td>The doctor will look into the record to be informed of former hospital stays, diagnosis, blood sample results etc.</td>
<td>This is both a function to activate the 30 minute assessment or the treatment plan.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>This function may cause variations in how fast the doctor will assess the patient afterwards, and whether the doctor will conduct a 30 minute assessment or go straight into the full assessment with diagnosis assessment and preparation of a treatment plan.</td>
</tr>
<tr>
<td>31</td>
<td>Conducting the 30 minute assessment</td>
<td>The doctor will initially examine the patient to review the patient's general state and evaluate how fast treatment plans should be conducted</td>
<td>This function is the activating function for the examination of the patient and preparation of treatment plans.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>This function can vary based on how busy the doctor is but also based on the severity of the patient's condition. In some cases this function is not performed, if the doctor goes directly on to the full assessment of the patient.</td>
</tr>
<tr>
<td>32</td>
<td>Examining the patient for sepsis or other conditions and prepare treatment plan</td>
<td>The doctor will examine the patient and look for diagnosing sepsis.</td>
<td>This activates the function were the diagnosis is either dismissed or confirmed.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>This function may vary based on pressure on ward and doctor and duration may vary based on information transferred from</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Action</td>
<td>Notes</td>
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</tr>
<tr>
<td>33</td>
<td>The doctor must be available to examine the patient. (background function)</td>
<td>To examine the doctor must be available and present in the ward.</td>
<td>This is a precondition for examining the patient. No affecting variation other than pressure on the ward.</td>
</tr>
<tr>
<td>34</td>
<td>The sepsis diagnosis will be dismissed or confirmed</td>
<td>The doctor will use blood sample results, vital signs measured and overall symptoms to confirm or dismiss diagnosis. The doctor will further warrant the treatment.</td>
<td>This activates the treatment with sepsis bundle if confirmed and dismissed other treatment will be started. This also starts the function were the diagnosis is registered. Variations can occur based on the information accessible at the time, incl. blood sample report, information from nurses, and access to sepsis checklist.</td>
</tr>
<tr>
<td>35</td>
<td>Treating with sepsis bundle</td>
<td>After the diagnosis is confirmed, the patient will be treated with all elements in the sepsis bundle.</td>
<td>No output in this model. Time variations based on previous functions.</td>
</tr>
<tr>
<td>36</td>
<td>Registering signs in the sepsis sheet</td>
<td>The checklist for sepsis must applied with all patients with reasonable suspicion of sepsis and completed with all patients with at least two of four criteria for sepsis.</td>
<td>No output in this model. Variations can occur if the sheet is not available, symptoms in the patient change quickly, if tools to measure signs are not available or lack of experience in the nurse.</td>
</tr>
<tr>
<td>37</td>
<td>Developing the sepsis checklist (background function)</td>
<td>In order to be used the checklist must be developed and printed.</td>
<td>This is a control function for the diagnosis of sepsis and a precondition for completing the checklist. No affecting variations.</td>
</tr>
<tr>
<td>38</td>
<td>Conducting the diagnosis within an hour (Background function)</td>
<td>According to instructions and the checklist, patient with suspicion of sepsis, must be diagnosed within 1 hour of admission.</td>
<td>This is a time control, for the function of diagnosing the sepsis. All previous mentioned functions which may have variations connected to time, may have the ability to affect this</td>
</tr>
<tr>
<td>Function</td>
<td>Description</td>
<td>Output</td>
<td>Variations</td>
</tr>
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</tr>
<tr>
<td>39</td>
<td>Continuing other treatment of patients (background function)</td>
<td>If the sepsis diagnosis is dismissed the patient will continue in other examinations and treatments</td>
<td>No output in this model</td>
</tr>
<tr>
<td>40</td>
<td>Writing primary records and recording findings.</td>
<td>After assessing the patient and starting the treatment, findings and treatments will be recorded in the patients file.</td>
<td>This function is part of the assessment of confirming or dismissing the sepsis diagnosis as a control element.</td>
</tr>
</tbody>
</table>