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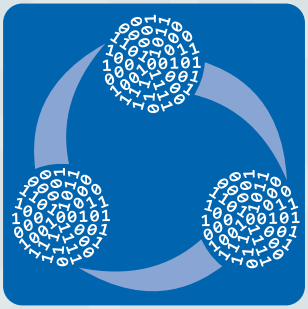

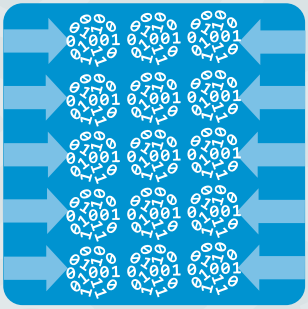

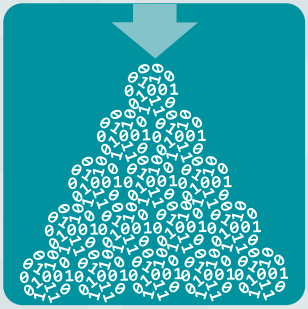

Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews

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Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews

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J.M. Davies

We are pleased to collaborate with the Health Quality Council of Alberta (HQCA) in making available the content of Systematic Systems Analysis: A Practical Approach to Patients Safety Reviews. Although soundly based on theory, this Guide was written to be exactly that – a guide – with the intention being to keep it simple and in the style of a 'how to' manual.

The methodology described in the Guide was developed specifically for healthcare reviews[1-4] and drawn from human factors and aviation investigation techniques.[5,6,1] The technique is both systematic and system-focused. It helps the user look beyond the contribution of individuals to consider how complex, interacting elements of the entire healthcare system influence care.

The methodology was first developed by Jan M Davies in the early 1980s and was modified over the next 15 years. First, the Structure, Process and Outcome[7] of an event were specifically embedded. Then, with the assistance of an aviation investigation expert, Human Factors and Professor James Reason's concepts[5] were integrated, including how events from the past influence current decision-making, as well as aspects of aviation accident investigation.[1]

Application of the methodology to a death in healthcare was first published in 1992.[2] The methodology's version was further expanded in 1996, for use in the Paediatric Cardiac Surgery Inquest,[8] to incorporate a model and revision of a working diagram of how accidents evolve, as well as the associated SAFER MATRIX (System Analysis and Factor Evaluation Review Matrix).[3]

Over the next decade, the methodology was frequently used in healthcare reviews, in cases from across Canada and internationally, as well as applied to case examples in aviation and the law. In 2005, Carmella Steinke helped to teach and embed the methodology as the former Calgary Health Region's analysis tool. Since then, Systematic Systems Analysis (SSA) has been taught and/or used in Alberta, B.C. and Manitoba.

Finally, we wish to acknowledge with thanks all the individuals at the HQCA who contributed to the development of Edition 1 and Edition 2. The authors would also like to recognize Dr. Ward Flemons and Edition 1's international expert review panel for their constructive feedback and support for the methodology. These individuals were Professor Sven Erik Gisvold, Norway; (the late) Dr. Rob Lee, Australia; Dr. David Musson, Canada; Professor Emeritus James Reason, England; and Ms. Bronwyn Shumack, Australia.

Jan M Davies and Carmella Steinke

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INTRODUCTION

What the Guide is
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Before getting started

In healthcare, many improvements come through the process of looking back at the care patients received. These reviews give healthcare providers, administrators and regulators the information necessary to show where and what changes are required to improve care, a core piece of a cycle of safety management[9] and part of a larger safety management framework or system.[10] The methodology described in this Guide was developed specifically for healthcare reviews and draws from aviation and human factors investigation techniques.[5-7]

This Guide was developed to assist you when conducting reviews of care and/or the healthcare system. You can use the methodology to analyze events in which:

- One or more patients suffered harm.
- One or more patients were nearly harmed in a close call.

What the Guide is

This Guide is designed to help you carry out your analysis at the system level, that is, you will view the system as though you were looking down from about 1,000 feet in the air. At that height, you should be able to see the whole system. This approach will help you to discover where the major flaws lie in the system.

The Guide is intended to encourage and assist you to conduct your review *systematically* and *systemically*. By *systematic*, we mean that you will be methodical and always perform the same basic activities. The benefit of being systematic is you will avoid leaving out things that could be important. The Guide outlines a three-phase methodology in a format that you can scale up or down and adapt as necessary. By *systemic*, we mean that you will keep in mind how all the parts of the healthcare system play a role, rather than look at only one particular factor in isolation. The benefit of being systemic is that, because you are considering the entire system in your analysis, then you are also considering the entire system when recommending and making improvements.

Three phases and their icons

There are three phases in a systematic systems analysis (SSA), each of which has an associated icon (Figure 1). These are:

- **Phase 1: Collect information**
  The Phase 1 icon has three parts, each representing one of the three parts of phase one (gather information, establish the chronology of events and focus). The icon also illustrates the cyclical and iterative nature of phase one.
- **Phase 2: Analyze information**
  The Phase 2 icon depicts the 15 pieces of the SAFER Matrix, the primary organizational, analytical and testing tool used in this phase.
- **Phase 3: Recommend improvements**
  The Phase 3 icon is pyramid-shaped, illustrating how starting from investigation of a single case, improvements are spread as widely as possible through the system. Recommendations can be made at each level of the system and are potentially more wide reaching at each level.

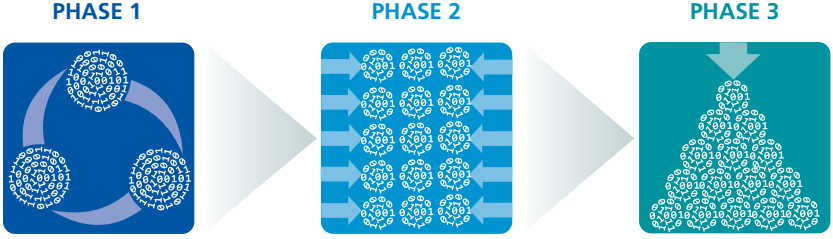


Figure 1: Icons representing the three phases of a systematic systems analysis

You should not view SSA strictly as a sequential process. Instead, think of it as dynamic, where you can revisit previous phases as you need to. For example, if during Phase 2: Analyze information, you recognize that you need additional information, then you should go back to Phase 1: Collect information, to fill in the missing pieces.

What the Guide is not

The Guide is not intended to help you find fault nor to apportion blame. Conducting a review using SSA will help your organization foster a just culture as part of its overall safety culture. With a focus on the system, the Guide is not intended to help you assess individuals. If necessary, your organization or regulatory authorities should use a separate and systematic process for assessing an individual's performance, including human error and non-compliance. In fact, some situations may require both an investigation of the system as well as assessment of one or more individuals.[11] Please remember, however, these are separate processes and should be undertaken by different individuals.

In addition, the aim of this approach is not to look for one or more 'causes', but to look for factors that likely contributed to what happened or nearly happened to the patient. When conducting an analysis, it is important to start with the end in mind. To do this, you will need to strive to gain an understanding of not only what happened to the patient, but also how and why 'it' happened, and then conclude with recommendations to make care safer for future patients.

At the same time, you may be asked to answer questions posed by the patient and/or family. Because SSA only looks for ways to improve the system for future patients, it cannot provide answers to many of these questions, in part because patients and families often wish to have answers about the decisions and actions of specific care providers. Also, conducting a systems analysis will take time and thus results may not be available for early disclosure conversations. While it is reasonable to share agreed upon facts from a systems analysis and any steps the organization has determined it will undertake, an independent process should be followed for disclosure and in reaching resolution with patients and families.[12]

Before getting started

The analysis of events that resulted in or could have led to patient harm is one part of a larger process of caring for the patient. Thus, the start of the process outlined in this Guide is not really the first action to be undertaken when a patient experiences a close call or suffers harm. The methodology described in this Guide starts at the point where a decision has been made to conduct a systems analysis. The preliminary steps of managing the event should have been carried out before any analysis is undertaken. The details of these preliminary steps are not included in this Guide because they are determined by organization-specific policies and procedures. In general, managing the event includes:

- Ensuring the immediate safety of all patients and staff involved.
- Securing any equipment and the environment where the event occurred.
- Documenting the event in the patient's healthcare record.
- Notifying individuals in authority about the event.
- Beginning initial disclosure of the event to the patient/family.
- Reporting what happened into the organization's safety reporting system.

There are three points you should clarify before undertaking the analysis:

1. Governance and direction

Before starting, you need to clarify the governance with the individual from within your organization who requested the systems analysis. It must formally be determined if the analysis will be carried out under the protection of section 9 of the *Alberta Evidence Act*.[13] It is strongly recommended that you read and become familiar with this information. Acquiring protection under section 9 requires following a defined process that must be established in each organization.

Please note: A subsection within section 9 of the *Alberta Evidence Act* specifies that protection of documents "does not apply to original medical, and hospital records pertaining to a patient."[13]

You should also clarify what the deliverable will be. You will almost always need to provide a written report outlining the systemic findings and recommendations for improvements. Before starting, you should also clarify timelines, ownership of the report, as well as editorial control and distribution of the report. Remember that style and language used in the report should meet the needs of the intended recipients, as well as adhere to privacy legislation requirements. Many experienced investigators find it helpful to have a written and agreed upon plan for this purpose.

2. Scope and scale

You may need to vary your analysis both in scope and scale. Adjusting the scope of an investigation means you might choose to focus on only one specific event or time interval. Adjusting the scale of an investigation means you can make an analysis bigger or smaller. The decision to adjust scope and scale will be partly determined by the opportunity to learn and to make system-level changes as well as availability of individuals qualified to conduct an analysis, time constraints, and financial resources.

However, choosing a smaller scope and/or scale of an analysis does not mean that you will not be systematic and systemic; rather that you will:

- Allocate fewer resources.
- Gather and analyze smaller amounts of information.
- Take less time to complete the investigation.

For example, if an event appeared to be a repeat of a systemic issue that was recently investigated, then an organization might decide that an analysis of smaller scope and scale would be more appropriate than a duplication of previous efforts.

3. Resources

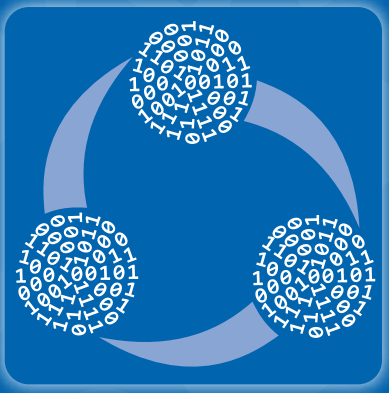
In some cases, having only one investigator may be appropriate, while in others a team may be more suitable. Success of the analysis will depend on individuals' knowledge and experience of the:

- systems analysis methodology.
- subject area(s) of the analysis.
- organization.

It is possible that you could possess knowledge of all three areas. However, including others and employing a team can be beneficial in that individuals bring differing knowledge and skill sets and can also share the workload. Of course, too large a team can be problematic because scheduling meetings is more difficult and managing group dynamics may be required.

Please note: There is no *right* composition of an analysis team.

If a team is required, you may find it helpful to have one or two individuals collect preliminary information and develop an initial ordering of events, in the form of a chronology, before having the larger group meet. You may also want to consider having a core group perform the majority of the activities and then bring in others with specialized knowledge as required. For example, seeking the advice of an individual with expertise in human factors can be helpful.



PHASE 1: COLLECT INFORMATION

1.1 Gather information
1.2 Establish a chronology
1.3 Focus on areas that need probing
1.4 Case example
1.5 Tools

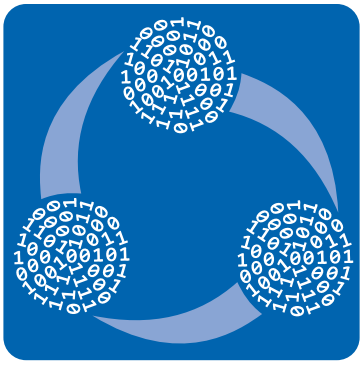


Figure 2: Phase 1 icon

There are three activities during this phase where the chronology of the event(s) is developed through an iterative process of gathering information, setting down the events in a chronological order, focusing, and then circling back to gather more information as necessary, as shown in Figure 2. This icon should also show you how important it is to be able to continue to circle back as often as you need to.

1.1 Gather information

Sources of information

There are many sources of information you can use when conducting a systems analysis. The number of sources you use and the amount of information you collect will depend on the scope and scale of the analysis.

Obviously, the more sources you use, the more information you will retrieve, the more detailed your chronology, the better your understanding of the event(s). However, accessing more sources and gathering more information means you will need more time and resources.

One way of thinking about sources of information is to classify them as to the five basic components of the healthcare system. These are the:

- patient
- personnel
- environment/equipment
- organization
- regulatory agencies

You can, and should, gather information about each of these components. Information about the *patient* typically comes first, and in some investigations, mainly from the healthcare record. Other documents and reports include dispatch records (of an ambulance or other transport), results of toxicology

testing and possibly an autopsy. In addition, you may also gain valuable knowledge from interviews with the patient (if possible and appropriate), family members and other supporters, and the individuals who provided direct and even indirect care to the patient.

Some investigations derive information about personnel solely from interviews, most often from those direct care providers at the 'sharp end' of the system (closest to the point of care). In addition, consider looking at job descriptions, shift schedules, timesheets and security logs.

You can obtain information about the environment, the location(s) where the event(s) occurred, from direct observation. You may find it useful to take photos or prepare a schematic layout for future reference and analysis. Gather information about equipment – its availability, use and maintenance. Again, photographs and sketches may be helpful. Equipment can include items such as infusion pumps and medication vials as well as their content. Other sources of information include maintenance and clinical engineering records, as well as quality control histories. Remember to consider such aspects as built-in lightning, ventilation, and gas pipelines.

Please note: It is important to secure any equipment that was part of the patient's care for two reasons. First, this helps ensure that other patients are not exposed to equipment that could be a factor contributing to harm. Second, tests should be run to determine if the equipment was functioning properly or not.[14] Additionally, some testing could need external expertise.

The influence of the *organization* on the event should not be discounted. Sources of information about the organization itself include vision/mission/values documents; organizational structure charts; funding, budgets, and other financial documents; briefing notes and minutes of relevant meetings. Other sources, more specific to how care is delivered include policies and procedures, manuals and other training/education materials, and documents that staff members consult as a resource. Sometimes you may find it helpful to obtain the opinion of experts or find information from the literature as to best practices. In addition, information from safety learning reports and

reports/recommendations from other similar safety analyses (internal and external) may be very useful; however, access to these may be restricted. You may also wish to interview individuals holding administrative and/or decision-making positions; that is, those individuals at the 'blunt end' of the system.

Similar to the role of the organization, *regulatory agencies* also have an influence on events leading to a close call or a patient being harmed. Sources of information about regulatory agencies include the agency's organizational structure charts; legislation/bylaws; standards and policies; and safety information such as recall notices and standards for medication labelling or equipment. Documents that describe the relationship or communication between the organization and the regulatory agency may also be valuable.

Important points about interviews

Depending on the scope and scale of the analysis, you may need to interview various individuals. The intent of these interviews is to gain an understanding of how the event unfolded and what factors may have contributed; it is not about the performance of these individuals. While interviews can be one of the most valuable sources of information in a systems analysis, to make the most of the information you gather, you will want to keep the following points in mind:

1. Establish a basic chronology before starting interviews. You will find this extremely helpful, especially with the initial interviews, as the chronology provides you with a synopsis of the event.
2. Conduct interviews as soon as possible after the event. Memories fade quickly and can be unintentionally influenced by other versions of the events. For example, discussions with colleagues can influence and shape how one remembers an event.
3. Carefully consider who from the team should conduct each interview. You will require someone with content knowledge as well as a sound understanding of the methodology. One-to-one interviewing is optimal, but two interviewers may be required to achieve the necessary level of expertise.

4. Interview only one person at a time so that you can capture an unbiased and uninfluenced interpretation of the event. Talking privately with an individual who was involved in an event will help a participant to feel that it is safe to speak openly and candidly.
5. The first interviews should be with the patient (where possible) and/or the patient's family. Interviewing the entire family in a single interview is the exception to the one-to-one rule mentioned above. Note, additional preparation for a patient or family interview may be necessary, including spending more time up front explaining the purpose of the interview so that there is a mutual understanding and to manage expectations.
6. Consider the need for support for those who have been interviewed.

1.2 Establish a chronology

What is a chronology?

A chronology is the setting down of information in the order in which the various pieces of information were thought to occur. Your goal in developing a chronology is to establish what you believe to be the sequence or chronological order of the event(s). This is one of the most useful and important activities in understanding what happened.

Please note: Because a chronology organizes information on the basis of time, this means that events have a relationship based on time. A timeline does not imply that events have any kind of cause-and-effect relationship. For example, if a patient is admitted to the hospital and dies, then the events in the chronology of *admission* and *death* are related in time only. The chronology does not imply that the death was caused by the hospital admission or by the care received.

What does a chronology look like?

The basic format for a chronology consists of a table of three columns, as shown in Table 1. In column one, you will list the date and time of the event or piece of information. In column two, you will list the event or piece of information. In column three, you will list the source of the information, remembering to include page numbers if the information was obtained from paper documentation.

Table 1: Example of a basic chronology

Date/Time	Event/Condition	Source
2010/03/04 15:00	Patient arrives in emergency department, complaining of feeling short of breath.	Triage nurse
2010/03/04 15:13	Patient appears in mild respiratory distress, diaphoretic. RR=28, HR=114	Nursing notes

How is a chronology developed?

At the start of your analysis, consider developing a very simple chronology. This initial chronology may be constructed from a single source, such as from a description provided by a staff member reporting the event or based on a quick review of the healthcare record. This initial chronology will be less detailed than subsequent versions. As you add more information, the chronology will become more detailed and the greater the detail, the more descriptive the

chronology. This process is analogous to creating a painting: initially you will make a sketch of a scene, but then you, as the 'investigative artist', will add more detail and bring in layers of colour, eventually creating your 'final masterpiece'. This final product, which could total anywhere from one to more than a dozen pages, will contain many separate pieces of information.

Please note: A chronology that only contains information from the patient's health record may be used for purposes other than a systems analysis, for example as part of the disclosure process.

An important part of conducting a chronology involves reviewing the chronology with each interview participant. This process has two benefits. First, the participant has an opportunity to see the chronology and to suggest changes. Second, you have the opportunity to confirm your understanding of how events unfolded. Confirming both points of view – the interviewee's and yours – is very useful. However, please note that there will often be differences of opinion. Participants will probably base their statements on memory only. In contrast, you, as the investigator, will have the benefit of accessing multiple sources of information.

What are the challenges in developing a chronology?

One major challenge you will face is deciding where to start and end a chronology. When did the problem actually begin and how far back into the system and into past actions and decisions should you delve? You will face the same challenge in determining when to end the chronology. Should you 'stop the clock' when the patient first suffered harm, after the healthcare providers recognized and responded to the harm, when the disclosure conversation occurred, or when you know the final outcome to the patient, the personnel, or the organization? There is no easy answer. While the decision is yours to make as the investigator, prudent advice would be to be clear about the times where you decided to start and end the chronology, and also why you chose those times.

Another challenge is that chronologies, to some extent, are subjective, and as such, there is no single *right* chronology of an event. In other words, you will not be able to establish the sequence of events. The information you include will depend on why you are carrying out the systems analysis. Also, you as the individual developing the chronology will have an effect on the chronology, since your professional background, training, experience, and personal preferences may all have an influence on the information sources, content and details that you choose. In addition, you will only be able to approximate the sequence and timing; it is impossible to reconstruct events as they actually occurred.

A third challenge comes from the usual problems associated with having to review paper-based, hand-written healthcare records. Parts of documents may often be illegible, pages may occasionally be missing, and even more rarely, documents may appear to have been altered in some way. How you as an investigator deal with these challenges will depend on the particular problem you encounter. You may find it helpful to have two individuals read a document that appears illegible. Finding lost pages may require a separate investigation, and discovering what appears to be some form of tampering may require notifying the appropriate individuals.

A fourth challenge concerns the review of electronic records. Special access may be required. In contrast, with paper-based records, you may be able to obtain permission to duplicate these records or access them remotely, which can free you as the investigator from having to read through the record in a health records department or on a patient care unit.

Are there different variants of the basic chronology?

Having developed a basic chronology, you might then wish to consider other ways of presenting the information to best understand how events unfolded. There are many ways to display certain details and in fact, within a single analysis, you can use several different tools. Examples include different styles of vertical and horizontal timelines, a sequence of events or flowchart, graphs, and combinations of these. Please see the tools at the end of this section for more information on and examples of these different types.

1.3 Focus on areas that need probing

Part of your analysis may involve focusing on certain events in the sequence of what happened to the patient. The decision to do so may have been made at the start of the analysis, for example, as part of the decision to limit the scope of the investigation. At other times, you might decide to focus as a result of what you learned during the course of your analysis, for example, about events before and after important changes in the patient's care and/or condition.

It is important to note that the purpose of focusing on certain aspects of the healthcare encounter is neither to determine fault nor to assess performance of individuals. Rather, your purpose will be to highlight areas where you need to seek more information. For example, a patient might have had a week-long stay in an acute care hospital. Your initial, high-level chronology would likely include major occurrences during the stay, such as admission, major treatments/interventions and transfers. However, your systems analysis might then concentrate on the parts of this healthcare encounter where the problem(s) arose and where you think there is potential to uncover system deficiencies, such as when the patient received the wrong dose of a medication on three separate days. You will gather additional information about these three particular events as you focus and refine your chronology.

1.4 Case Example

Imagine that you have received a phone call asking you to look into the case of a man who fell in a supportive living facility and then died postoperatively in hospital. Here is what you have since learned.

> *Mr. A., an 87-year-old man with a history of dizzy spells, slipped on a scatter rug in his room in a designated supportive living facility (DSL) and fell, fracturing his hip. He was taken by ambulance to hospital and after four days underwent an operation. He developed pneumonia and died one week later.*

From the preliminary information you have received, you can start an initial chronology. You choose to use a dark-blue font for chronology entries of information you gather from interviews.

Date/Time	Event/Condition	Source
2011/07/28 9:45	Mr. A is found by a patient care attendant on the floor in his room. He is slightly confused, but is able to say he slipped and fell earlier in the morning. He states his left leg and hip are very sore. The registered nurse is notified.	Interview: DSL facility's director
2011/07/28 10:00	The nurse assesses the patient. Mr. A states his leg is sore. He is unable to stand. An ambulance is called. Mr. A's family and doctor are notified.	Interview: DSL facility's director
2011/08/01 (no time given)	Mr. A undergoes surgery on his fractured hip.	Interview: DSL facility's director
2011/08/07	Mr. A dies while in the hospital.	Interview: DSL facility's director

As you gather additional information, you will add to this chronology. For example, in reviewing the chart from the emergency department, you will find additional information that is relevant to this chronology.

Date/Time	Event/Condition	Date/Time
2011/07/28 9:45	Mr. A is found by a patient care attendant on the floor in his room. He is slightly confused, but is able to say he slipped and fell earlier in the morning. He states his left leg and hip are very sore. The registered nurse is notified.	Interview: DSL facility's director
2011/07/28 10:00	The nurse assesses the patient. Mr. A states his leg is sore. He is unable to stand up. An ambulance is called. Mr. A's family and doctor are notified.	Interview: DSL facility's director
2011/07/28 10:23	On arrival, patient is on floor with nurse at side. Patient is awake and complaining of +++ pain to left hip and leg. Vital signs: HR=109 BP=118/89 RR=22. Patient placed on stretcher and transported to Regional Hospital. Stable throughout transport. Morphine 10 mg IM given for pain.	Transport Record
2011/07/28 11:17	Patient arrived with paramedics. Found this morning in his DSL facility after falling. Alert, complaining of pain to L leg and hip. L hip bruised and swollen. L leg shorter. L foot externally rotated. VS stable. R/O # L hip.	Emergency physician notes

Date/Time	Event/Condition	Source
2011/07/28 11:24	Orders: Morphine 5 mg IM Consult ortho X-ray	Physician orders
2011/07/28 14:30	Ortho consult by resident: Physician progress "OR booked. E-24. Fast. Clear IM"	Physician progress notes
2011/08/01 (no time given)	Mr. A undergoes surgery on his fractured hip.	Interview: DSL facility's director
2011/08/07	Mr. A dies while in the hospital.	Interview: DSL facility's director

In the above chronology, the orthopedic resident's assessment was put in quotation marks to show that the statements were taken verbatim from the chart.

1.5 Tools

Additional chronology tools

In addition to the basic timeline described in phase one, there are additional tools that can be used to organize information into chronological order.

Primary tools: timelines

1. Vertical timelines

a) **Basic timeline:** As described previously, the basic vertical timeline is a simple table that allows you to list events in chronological order. The format of the basic timeline consists of three columns for the date/time, the event/condition, and the source of the information. The number of rows will be set by the amount of information you gather – the more information, the longer the timeline. This style of timeline is very useful for creating the initial, intermediary and even final chronologies.

b) **Timeline with set time intervals:** This is a modification of the basic timeline. Rows are defined by specific time intervals, using a unit of time most appropriate for the situation, for example, seconds or minutes versus days. You may find this variant helpful when illustrating how much time specific events took and in identifying delays and gaps. You might consider using this variant for specific parts of the healthcare encounter that require more in-depth analysis, such as during a delivery of a baby or resuscitation, or for lengthy admissions, to determine the passage of days, weeks or months.

2. Horizontal timelines

a) **Detailed timeline:** In this variant, columns contain a specific date/time while the rows describe the processes that occurred, or actions undertaken. This version has the benefit of allowing you more easily to identify events/processes/changes in condition that were happening at the same time. As with a timeline with set time intervals, you would most likely use this variant for a detailed analysis of a small, specific part of the healthcare encounter. One way to use this type of timeline would

be to use the rows for a variety of events and findings, such as: actions/observations of a healthcare provider, vital signs, diagnostic and treatment interventions.

	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME
Vital signs									
LPN									
Aide									
Medications									

b) **Time person grid**: Similar to a swim lane process chart, this type of timeline is a version of a horizontal timeline in that the date/time elements are in the columns and each row contains descriptions of the actions and behaviours for a separate individual. For example, you could set different players (e.g., patient, family, staff members) in each row, which would allow you to appreciate what numerous individuals did at specific time intervals before, during, and after an event.[15]

	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME	DATE/ TIME
RN1									
RN2									
RT1									
RT2									
Resident									
Physician									

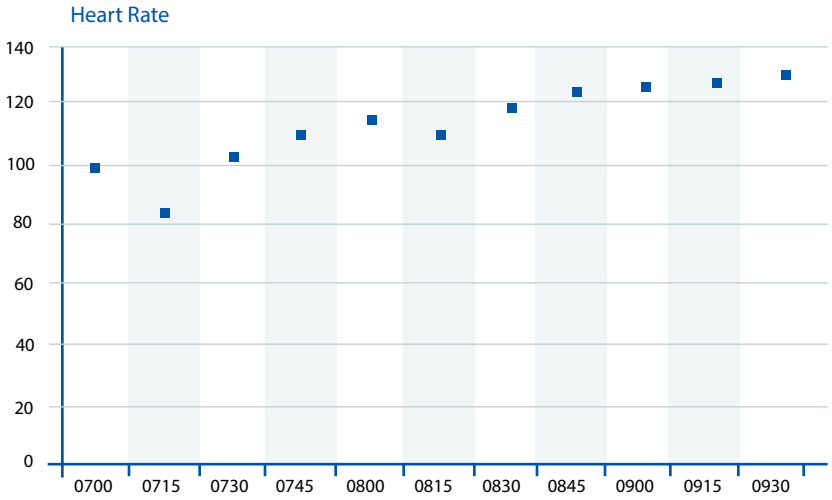
Secondary tools

3. Sequence of events chart

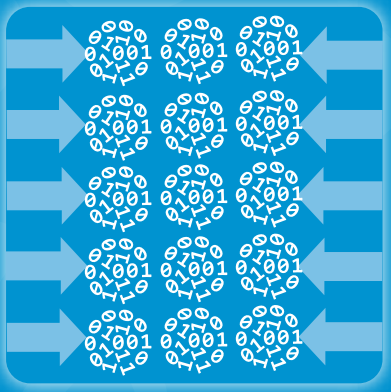
You may find a sequence of events chart or a flow diagram or flowchart useful to create "a picture of the movement of people, materials, documents, or information within a process."[15] You could use this type of chart during the early phases of a systems analysis to illustrate significant events, as in the case of an individual becoming unresponsive, being transferred to hospital, and remaining comatose. A sequence of events chart can also be helpful to diagram a specific process within a systems analysis, such as the steps followed when receiving, reviewing, following-up and filing diagnostic reports at a family physician's office.

4. Graphs

a) **Basic**: A graph may help you to visually display how a specific parameter changed over time, particularly if you include annotations on the graph to provide explanations. You would most likely use a graph as a secondary tool, having previously developed a timeline or sequence of events chart to detail the event. One commonly used application of graphs is the plotting of a patient's vital signs or laboratory results (e.g., electrolytes) against time.



b) **Combination of graph and sequence of events chart**: With this tool, a parameter is plotted over time with actions/process steps displayed below the graph. This variant will give you a visual representation of how the change in the parameter is related to the process. For example, a patient's heart rate could be plotted above the actions of the staff displayed in a flow diagram below. You would most likely use this variant in addition to another chronology tool.



PHASE 2: ANALYZE INFORMATION

2.1 Organize information

2.2 Analyze for system deficiencies

2.3 Test for system perspective

2.4 Case example

2.5 Tools

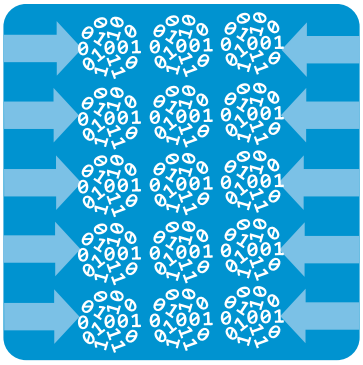


Figure 3: Phase 2 icon

You have now worked through the iterative process of gathering information and have established a chronology of the event. In Phase 2, you will organize all the information you have collected in Phase 1 and then analyze this information to identify system deficiencies. Once you have done this, you will then test your findings for system perspective. All three tasks (organizing, analyzing and testing) are carried out iteratively using the primary tool, the SAFER (Systems Analysis and Factor Evaluation Review) Matrix, depicted by the icon in Figure 3.

While the SAFER Matrix may initially look like a simple, 15 cell table, it is actually a powerful tool to help you organize, analyze and test not only the information you have gathered but also the problem you are investigating. The matrix can be thought of as a representation, picture or model of the system. Keeping a model or picture in mind will help you to arrange the multiple points or factors you have listed in the chronology into an orderly array that represents the entire healthcare system. Failing to use a model means you might miss entire components of the system and therefore could fail to understand where important problems lie in all of these interacting components. Using the SAFER Matrix will help you, as an investigator, ensure your analysis is systematic, is focused at the level of the system, and delves deep to understand the underlying structure of the system.

The SAFER Matrix is a 15-cell table made up of three columns and five rows.

Three columns

Each of the three columns is labeled according to the quality assurance triad of structure, process and outcome.[7]

1. *Structure* describes the basic starting point of any system.
2. *Process* represents all the activities and events within a system.
3. *Outcome* includes all the results of the system.

The structure of any system comes from the past and determines process, which in turn yields outcome. Simply put, structure drives process, which results in outcome. Thus, these three terms also present the main phases of any event, from the historical beginnings, to the activities, to the final result.

There are a few analogies to structure, process and outcome that you might find useful in understanding the terms.

- Structure, process and outcome correspond to the input, process and output (IPO) categories in a traditional engineering view of systems.[16]
- Subject, verb and object describe the three grammatical components of any sentence. If you compare these three terms to structure, process, and outcome, then the subject of a sentence aligns with structure, the verb with process and the object with outcome.
- Structure, process and outcome can be considered to represent one of three simple questions: what happened? (outcome); how did this happen? (process); and, why did this happen? (structure).[3]

Five rows

A complete SAFER Matrix also has five rows, each of which represents one component of the healthcare system. These are:

1. Patient
2. Personnel
3. Environment/equipment
4. Organization
5. Regulatory agencies

Based on a human factors model,[6] these five components were chosen because they represent the major and interacting parts of the system. Having only five components allows anyone to easily remember each part of the system.

The following table shows the SAFER Matrix with the three columns and the five rows labelled.

Table 3: The SAFER Matrix

	Structure Why did this happen? (Input or subject)	**Process** How did this happen? (Process or verb)	**Outcome** What happened? (Output or object)
Patient			
Personnel			
Environment/ equipment			
Organization			
Regulatory agencies			

2.1 Organize information

Initial use of the SAFER Matrix involves taking all the information you have gathered and entering it into the cells of the matrix. Some of the information will come from the chronology and some from other sources such as review of policies and other documents.

We suggest that you organize this information in a systematic way. Here's how. You will probably know the outcome for the patient, so first enter this into the top right-hand cell of the matrix, that is, in the cell for the outcome for the patient. Those of you who enjoy reading maps will quickly see the analogy to a map referencing system, as in *patient:outcome*.

You will then be able to fill the *patient:process* cell with an abbreviated list of what the patient did or underwent. This cell may also include information such as results of diagnostic or therapeutic procedures.

Tip: You may first find it helpful to go through the chronology and highlight any of the decisions, actions and events relating to what the patient did or underwent. You can then easily search the chronology for this highlighted material and then transfer it to the appropriate cell of the matrix.

Also, you will probably know a few details about the patient, such as sex, age, co-morbidities, medications and allergies. You should enter these details into the top left-hand cell, *patient:structure*. You can then work down the structure column, entering some basic information about the structure of each of the other four components of the system (personnel, environment/equipment, organization and regulatory agencies). For example, in *personnel:structure* you should list each of the individual healthcare providers and their attributes.

After entering information into the structure column, continue putting information in the process column. For example, fill the *personnel:process* cell with an abbreviated list of the decisions made and actions undertaken by each of the healthcare providers.

Tip: You can use the same technique as you did for identifying *patient:process* decisions, actions and events in the chronology by using a different color to highlight those undertaken by individual personnel.

Next, populate the matrix with information from sources other than the chronology. For example, information about policy and procedures should be entered into the *organization* row of the matrix.

Tip: As you gain familiarity with the SAFER Matrix you will find yourself entering information into the matrix early on in your analysis, perhaps as soon as you receive the request asking you to undertake a systems analysis.

As you arrange each piece of information into its respective position in the matrix, you will start to see if you have missed anything because one or more cells of the matrix will remain empty. This is where you may find the matrix ontology (Table 4) to be of help. An ontology is a rule-based framework of relationships which helps organize information. The matrix ontology is based on a model of the healthcare system and is simply an explicit description of the healthcare system, the components of the system, and their relationship to each other and to the system as a whole. Table 4 shows the matrix ontology with some of the highest level terms in most of the cells. Also, note that the matrix ontology does not contain the option 'other' because every factor will fit within one of the cells of the SAFER Matrix.

Table 4: The SAFER Matrix ontology

Components	Structure	Process	Outcome
Patient	Characteristics/ attributes Numbers Tasks & methods to be undertaken	Decisions & actions Events Mechanism of injury	Death Dysfunction Dissatisfaction
Personnel	Characteristics/ attributes Numbers Diagnostic/treatment Tasks & methods to be undertaken	Decisions & actions	
Environment/ equipment	Design, construction manufacture Supply Maintenance/ housekeeping Planned use	Environment – context of care Equipment – present, working, – adequate numbers	

Table 4: The SAFER Matrix ontology – continued

Components	Structure	Process	Outcome
Organization	Administration Funding/budget & goals/priorities Human resources Communication channels Policies, procedures and manuals Culture	Effect on decisions & actions	
Regulatory agencies	Administration Funding/budget & goals/priorities Human resources Communication channels Policies, procedures and manuals Culture	Effect on decisions & actions	

2.2 Analyze for system deficiencies

In providing a 'postcard view' of the system, the SAFER Matrix not only contains the various components of the system but also shows you how each of the components interact and the relationship of one to another. Having organized all the multiple factors as to their position in the matrix, you will start to see these relationships, in part because the matrix reminds you to think about all five components of the healthcare system: patient, personnel, environment/equipment, organization and regulatory agencies. As you do so, you will consider each of the factors according to the phase of the evolution of the problem. Was the factor something new, which arose during the course of a patient's hospitalization? In other words, was it a process-related issue? Or was the factor an environmental one, which had been present for many years, that is, was it a structural issue? You will find that the SAFER Matrix is a powerful analysis tool because it will require you to think beyond process – the activities and events, the decisions and actions – in order to identify the driving components for any process that exist in structure.

Thus, the second use of the SAFER Matrix as an analytical tool requires you to identify the structure (or structural components) of the system and determine how it (or the components) influenced the decisions and actions (or process) of all the individuals, including the patient. As you complete the matrix, you will start to see a picture of the relationship between the five system components and between structure, process, and outcome. For example, the cell representing an organization's structure (*organization:structure*) may list a specific policy. The corresponding cell for *organization:process* will describe the effect this policy might have had on the decisions and actions of the personnel.

In effect, through populating the SAFER Matrix you are developing a picture of the system at the time of the event in the same way that completing a jigsaw puzzle will show the picture made from the component puzzle pieces. Of course, no investigation can ever be so extensive as to give a true and complete picture of what actually occurred; it is simply not possible to reconstruct the past with complete accuracy. What the matrix does give you is a somewhat blurry 'snapshot'. Like each piece of a puzzle or each pixel of a digital photograph, each detail or factor in the matrix will have contributed in some way to the event. Thus, all details or factors can be said to be contributory.

But usually the aim of any investigation is not simply to develop the snapshot of what happened. Rather, the aim of the review is to identify the system deficiencies, develop recommendations and then make changes where possible to improve the system. The key is to determine where the system deficiencies lie. Like 'resident pathogens',[5] most system deficiencies lurk in the structure of the system and may not be obvious until a patient is harmed or nearly harmed.

2.3 Test for system perspective

Even after organizing and analyzing all the information, you may still have some cells in the SAFER Matrix that are empty. These cells will most likely be those in the outcome column for personnel, environment/equipment, organization and regulatory agencies. This is quite acceptable, particularly when an analysis is completed within a short time after an event. In that case, it would be unlikely for there to be any major outcomes for any of those components of the system. However, you might still have a few empty cells in addition to those in the outcome column. If so, then you should review the matrix ontology to make sure you did not overlook any factors and that you have a system perspective of the problem.

In addition, you will want to test that you have captured enough detail in your investigation. To do so, you will ask yourself questions about each of the components of the system for each of the three phases. These factor review questions (FRQs) are derived from the matrix ontology and are related to each of the major components of the SAFER Matrix, thus reflecting different parts of the system. Like the matrix ontology, the FRQs do not include the option 'other'. The FRQs – posed in a systematic and system-oriented way – will prompt you to think about what you have put into the matrix and into which cell the piece of information was inserted. The FRQs will also help you to ensure you have identified as many of the system deficiencies as possible for your investigation. Refer to the tools at the end of this section for a starting list of FRQs.

2.4 Case example

Let's return to the summary of our case as given in phase one.

> *Mr. A., an 87-year-old man with a history of dizzy spells, slipped on a scatter rug in his room in a designated supportive living (DSL) facility and fell, fracturing his hip. He was taken by ambulance to hospital and after four days underwent an operation. He developed pneumonia and died one week later.*

First, think about what happened to Mr. A. What was his final outcome? The answer to this question is that Mr. A died or suffered death. You would therefore insert the word death into the *patient:outcome* cell of the SAFER Matrix.

	Structure Why did this happen? (Input or subject)	**Process** How did this happen? (Process or verb)	**Outcome** What happened? (Output or object)
Patient			death
Personnel			
Environment/ equipment			
Organization			
Regulatory agencies			

Next, insert the two statements about Mr. A into the first two columns of the matrix. To decide how to choose into which cell you should insert these statements, think about Mr. A as being the subject of the sentence. You will therefore put "an 87-year-old man" into the patient:structure cell. Because Mr. A had a history of dizzy spells and lived in a DSL facility, these are considered descriptors of Mr. A and his life and you should therefore insert these descriptors into the same cell. The rest of the sentence about Mr. A describes everything that he underwent – he slipped, he fell, he fractured his hip.

Essentially you will summarize Mr. A's activities, such as slipping and falling, as well as the care he received, such as being transported to hospital and undergoing surgery. These details belong in the *patient:process* cell. Even though other individuals may have carried out some of the activities, such as an ambulance crew, the details in this cell are those which provide Mr. A's point of view.

	Structure Why did this happen? (Input or subject)	**Process** How did this happen? (Process or verb)	**Outcome** What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel			
Environment/ equipment			
Organization			
Regulatory agencies			

As you insert information into the matrix, arrange each piece of information (factor) as a separate line in bullet format.

Now think about where Mr. A's story began – in a DSL facility. You should then list 'DSL in the *environment:structure* cell. Similarly, the scatter rug is a piece of 'equipment' found in his room in the DSL facility. The ambulance that was used to transport Mr. A to the hospital represents a second environment, which for the purposes of this case, is considered non-contributory.

The case description also mentions the health authority in which Mr. A received care. You should insert this term into the matrix, working down the structure column to *structure:organization*.

Similarly, from reading the health record you will acquire a list of the personnel involved, which you will include in the personnel:structure cell. In looking at the chronology from Phase 1, you will also know many of the decisions made and actions undertaken by the various personnel. For example, two paramedics transported Mr. A from the DSL facility to the

Please note: Do not include names of individuals in the SAFER Matrix. In this example, 'Paramedic 1' and 'Dr. Emergency' are used. Another way to do this would be use the designators EMT-P #1, MD #1, etc.

hospital. A doctor in the emergency department assessed him and then consulted orthopedics. Put this information in the *personnel:process* cell.

From further interviews, you determine that the health authority had a falls prevention initiative, which included a policy that scatter rugs should not be used in designated supportive living facilities. In probing deeper, you also determine that having a falls prevention strategy was an Accreditation Canada Required Organizational Practice (ROP). You should now enter this additional information into the matrix.

	Structure Why did this happen? (Input or subject)	Process How did this happen? (Process or verb)	Outcome What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Paramedic 1&2 Dr. Emergency	– transported patient to hospital – assessed patient in ED – consulted orthopedics	
Environment/ equipment	Environment #1: DSL – scatter rug Environment #2: ambulance (non-contributory)		
Organization	Health authority – falls prevention initiative – policy stating no scatter rugs in a DSL		
Regulatory agencies	Accreditation Canada – ROP for falls prevention strategy		

You can also complete the *process* column by looking at what the effect each structural component had on the situation. For example, the edge of the scatter rug that was in Mr. A's room protruded into the hallway, creating a tripping hazard.

	Structure Why did this happen? (Input or subject)	Process How did this happen? (Process or verb)	Outcome What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Paramedic 1&2 Dr. Emergency	– transported patient to hospital – assessed patient in ED – consulted orthopedics	
Environment/ equipment	Environment #1: DSL – scatter rug Environment #2: ambulance (non-contributory)	edge of rug protruded into hallway of patient's room	
Organization	Health authority – falls prevention initiative – policy stating no scatter rugs in a DSL	– policy only enforced in common areas of the DSL facility, while Executive Director seeking legal opinion about rugs in patients' rooms	
Regulatory agencies	Accreditation Canada – ROP for falls prevention strategy	– falls prevention initiative immediately before last accreditation cycle	

Changing the focus of the investigation

In this case example, the focus of the investigation was to look at why Mr. A fell and how the results of this investigation could be used to help make system changes to minimize the numbers of individuals falling in a DSL. Thus, the SAFER Matrix completed for this case example was used to

organize information and perform a systems analysis about the patient's fall and his initial hospital assessment. However, you could also focus on another aspect of Mr. A's healthcare and use a new matrix to analyze that problem. For example, you might be asked to conduct an analysis into why Mr. A waited four days to have surgery.

The information about Mr. A, including that contained in the *patient:structure*, *patient:process* and *patient:outcome* cells is still important for this new matrix. Some of the information in the personnel row, such as the staff and the care provided once Mr. A arrived in the emergency department, is also still relevant and can be included. You should also include the health authority in the *organization:structure* cell. However, you will need to gather additional information about the personnel, environment/equipment, organization, and regulatory agencies levels as well.

	Structure Why did this happen? (Input or subject)	**Process** How did this happen? (Process or verb)	**Outcome** What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Dr. Emergency	– assessed patient in ED – consulted orthopedics	
Environment/ equipment			
Organization	Health authority		
Regulatory agencies			

After further review of Mr. A's chart, you determine that the orthopedic resident assessed Mr. A, determined that he required surgery, and then consulted the general internal medicine (GIM) physician so Mr. A could be cleared for surgery. Mr. A was transferred to an inpatient nursing unit, where he was assessed by the GIM consult service the following day. As part of the consult, the GIM physician ordered blood work. You can now add this information to the new matrix.

	Structure Why did this happen? (Input or subject)	**Process** How did this happen? (Process or verb)	**Outcome** What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Dr. Emergency Dr. Orthopedic Dr. GIM	– assessed patient in ED – consulted orthopedics – assessed patient and determined surgery required – assessed patient – ordered blood work	
Environment/ equipment	Environment #3: inpatient unit		
Organization	Health authority		
Regulatory agencies			

More information is available from the chart, including the fact that blood work revealed Mr. A's INR was elevated. He was taking anticoagulants (warfarin) at home for atrial fibrillation. The GIM physician ordered vitamin K, fresh frozen plasma, and repeat blood work, and also requested that Mr. A's next dose of warfarin be held. Because of his elevated INR, Mr. A could not have his operation within 24 hours of admission to hospital.

You conduct interviews to gather additional information about Mr. A's care. You learn that Mr. A received another dose of warfarin, despite the GIM's order not to give any. The nurse assigned to Mr. A stated she went into the room and gave the medication to the patient in bed #1. She then realized an hour or so later that the medication was ordered for the patient in bed #2.

This is an example of where using the SAFER Matrix can help you determine how part of the structure of the system drove a process. You also interviewed the charge nurse, who stated that the bed numbering on this particular nursing unit was different from the previous unit on which she had worked. In this unit, bed #1 was closest to the window while on the other unit bed #1 was closest to the door. The nurse who gave the medication said she did not check the patient's identification (ID) band because she was in a hurry to finish the task before the end of her shift. The nurses on the unit had been told the previous week that they had been encouraged to not work overtime (OT) for the next three months due to budget shortfall. You can now add this information to the matrix and start to look through the communication book for comments about overtime.

	Structure Why did this happen? (Input or subject)	Process How did this happen? (Process or verb)	Outcome What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Dr. Emergency Dr. Orthopedic Dr. GIM RN-1	– assessed patient in ED – consulted orthopedics – assessed patient and determined surgery required – assessed patient – ordered blood work – did not check Mr. A's ID band – gave Mr. A the dose of warfarin intended for patient in next bed – was in a hurry to complete tasks before end of shift, avoiding OT	
Environment/ equipment	Environment #3: inpatient unit – labelling of bed numbers	– not standardized in the hospital	
Organization	Health authority – budget (priority & goals)	– note in communication book re: encouraging staff to not work OT	
Regulatory agencies			

From further interviews you determine that once Mr. A's INR was in the acceptable range, there was a further delay in getting Mr. A to the OR. Despite Mr. A being classified as an emergency case, his scheduled OR time was taken by a trauma patient who was considered more urgent. You can now insert this additional information about the delay into the *patient:process* cell.

The matrix, or the FRQs derived from the matrix ontology, will help prompt you to think about *all* of the components of the system and which factors could have contributed to the event. For example, at the organizational level, you discover the health authority has a protocol for determining the emergency status of patients requiring surgery and within which time limits each class of emergency patient should undergo surgery. You can now insert this protocol into the *organization:structure* cell. However, you also learn that patients were not always undergoing surgery within accepted time limits. You should now insert into the matrix your finding that implementation of the protocol has been ineffective. Whereas the actual protocol represents part of the structure of the organization, the apparently ineffective implementation represents a process.

You now consider the *regulatory agencies* level of the matrix. You learn from interviewing the orthopedic surgeon that although additional operating rooms (ORs) were recently built and equipped, there was no funding from the government for additional operating and recovery room nurses. The new ORs were therefore not actually opened and sat unused.

	Structure Why did this happen? (Input or subject)	Process How did this happen? (Process or verb)	Outcome What happened? (Output or object)
Patient	Mr. A – 87-year-old man – history of dizzy spells – lived in a DSL facility	slipped in his room – on a scatter rug fell – fracturing his hip taken to hospital – by ambulance 4 days later – underwent operation 2 days post-op – developed pneumonia	death
Personnel	Dr. Emergency Dr. Orthopedic Dr. GIM RN-1	– assessed patient in ED – consulted orthopedics – assessed patient and determined surgery required – assessed patient – ordered blood work – held warfarin – ordered vit K & FFP – did not check Mr. A's ID band –gave Mr. A the dose of warfarin intended for patient In next bed – was in a hurry to complete tasks before end of shift, avoiding OT	

	Structure Why did this happen? (Input or subject)	Process How did this happen? (Process or verb)	Outcome What happened? (Output or object)
Environment/ equipment	Environment #3: inpatient unit – labelling of bed numbers	– not standardized in the hospital	
Organization	Health authority – budget (priority & goals) – OR protocol for determining emergency status of patient	– note in communication book re: encouraging staff to not work OT – protocol implementation ineffective	
Regulatory agencies	Health ministry – no funding for staffing (by nurses) of new OR suites	– insufficient # of OR suites for # patients requiring emergency operations	

2.5 Tools

Factor Review Questions (FRQs)

The following list of questions was developed to help you, the reviewer, with Phase 2. While the questions are arrayed systematically in each of the five separate rows of the matrix , they do not represent all the systemic issues that might exist.

Patient

Identification

Did the patient have a single, unique identifier?
Could the patient's name be confused with another's?

Special characteristics

Did the patient have any special ***personal*** characteristics?

- physical characteristics (i.e., sex, age, height, weight, ethnic origin)
- co-morbidities (pre-existing medical and/or mental health conditions)
- medications (prescription, non-prescription, herbals) and allergies
- past healthcare encounters

Did the patient have any special ***psychosocial*** characteristics?

- family, friends
- culture, religion, employment

Personnel

Individual

What were the requirements for the personal and/or professional ***characteristics/attributes*** of the individual healthcare provider?

a) Personal

- physical characteristics (sex, age, height, weight, sleep/nutritional requirements)
- psychosocial characteristics (life situation, life changes)

b) Professional
- training (knowledge, skills, experience, currency)
- position
- call and scheduling/rostering

What were the ***tasks*** the individual was required to undertake/complete?

What were the ***requirements*** for these tasks?
a) training
b) guidelines/protocols/procedures
c) generally accepted standards of practice

Team

What are the requirements for ***characteristics/attributes*** of the team of providers?
- composition
- team members/numbers
- competencies
- ratio of experienced/inexperienced personnel
- degree and availability of supervision
- formation
- orientation/simulation
- apprenticeship period

What were the ***tasks*** the team was required to undertake/complete?

What were the ***requirements*** for these tasks?
a) training
b) guidelines/protocols/procedures
c) generally accepted standards of practice

Environment/equipment

Environment

What was the ***design/construction*** of the environment? Consider:
a) space
b) physical lay-out

c) lighting
d) ventilation
e) temperature
f) noise
g) vibration

What was the scheduled ***housekeeping/maintenance***?

What was the ***purpose/planned use*** of the environment?

Equipment

What was the ***design/manufacture*** of the equipment? Consider compatibility with existing systems.

What was the ***planned introduction*** of the equipment?

What was the ***planned use*** of the equipment?

What was the ***planned supply*** of equipment?

What was the ***maintenance*** of equipment?

Organization

What was the ***administration*** of the organization?
a) vision/mission/goals
b) organizational structure
c) reporting relationships

What were the organization's ***funding, budget, goals and priorities***?
a) safety versus productivity
b) short-term versus long-term goals

What was the organization's ***human resources*** management?
a) training
- understanding the requirements
- matching of training relative to operations
- assessment of training results

b) performance management
- proactive
- reactive

What were the ***communication channels*** for sharing information within the organization?

What were the organization's ***policies and procedures*** and ***manuals***?
a) available
b) understandable/usable
c) relevant
d) accurate
e) updated
f) cross-checked not to be in conflict with other policies

What was the ***culture*** of the organization?
a) Lowest level of safety culture – one where there is no systemic or systematic approach to safety problems and 'fixes' are only instituted locally.
b) Middle level of safety culture – one where there is a reactive approach to safety and 'fixes' from such reviews are instituted.
c) Highest level of safety culture – one where there is both a proactive and reactive approach to safety, carried out systemically and systematically, and 'fixes' are instituted throughout the system, as well as being shared with other systems.

Regulatory agencies

What was the ***administration*** of the regulatory agency?
a) vision/mission/goals
b) organizational structure
c) reporting relationships

What were the regulatory agency's ***funding, budget, goals*** and ***priorities***?
a) safety versus productivity
b) short-term versus long-term goals

What was the regulatory agency's ***human resources*** management?

a) training
- understanding the requirements
- matching of training relative to operations
- assessment of training results

b) performance management
- proactive
- reactive

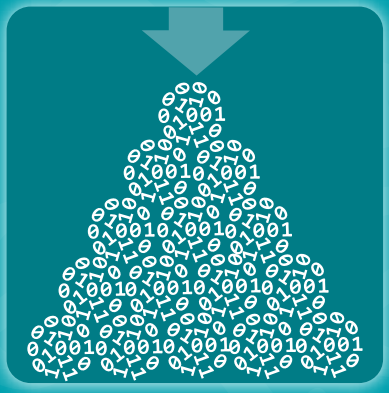
What were the ***communication channels*** for sharing information within the regulatory agency?

What were the regulatory agency's ***policies and procedures*** and ***manuals***?

a) available
b) understandable/usable
c) relevant
d) accurate
e) updated
f) cross-checked not to be in conflict with other policies

What was the ***culture*** of the regulatory agency?

a) Lowest level of safety culture – one where there is no systemic or systematic approach to safety problems and 'fixes' are only instituted locally.
b) Middle level of safety culture – one where there is a reactive approach to safety and 'fixes' from such reviews are instituted.
c) Highest level of safety culture – one where there is both a proactive and reactive approach to safety, carried out systemically and systemically, and 'fixes' are instituted throughout the system, as well as being shared with other systems.



PHASE 3: RECOMMEND IMPROVEMENTS

3.1 Devise recommendations
3.2 Write recommendations
3.3 Produce a report
3.4 Case example
3.5 Tools
3.6 After Phase 3

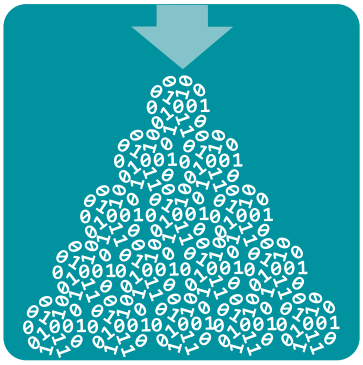


Figure 4: Phase 3 icon

Phase 2 focused on identifying system deficiencies through a systematic analysis. In Phase 3, you will recommend improvements aimed at these identified system problems by taking the findings from a single case and applying them as widely as possible throughout the system.

Specifically, you need to:

- Identify problematic processes.
- Focus on each system deficiency or deficiencies associated with the specific process.
- In your mind, re-run the situation to check that the (or each) system deficiency could have contributed to the problematic process.
  – Link the process and deficiency in a recommendation.

However, this might require asking more questions before devising the recommendation.

3.1 Devise recommendations

When formulating recommendations, you should ensure they:

- Deal with the identified system deficiencies and not individual practitioners.
- Are aimed at as wide a patient population as possible, so that care can be safer for the largest number of future patients. To do this you will need to determine if the system deficiency exists in a unit, a department, or a site, or even at the macro-system level.

Sources for recommendations

When something goes wrong, those involved will often have very good suggestions as to how to improve the system. These individuals include the patients, families, and the direct and indirect care providers. Try to get ideas

from those at the sharp end (the patient/family and direct care providers) and those at the blunt end (the decision makers who are in leadership roles). Involving individuals from both these groups is important when developing good recommendations that will be accepted for implementation by the organization. Options for doing this include:

- Ask for suggestions for recommendations at the end of each interview.
- Meet informally with direct care providers, management, and those responsible for staff education and policy development and ask them to help develop recommendations.
- Review draft recommendations with decision makers and those involved in the event in order to get feedback and refine the recommendations.

Sometimes you may need to seek additional information to formulate recommendations. Examples of sources include:

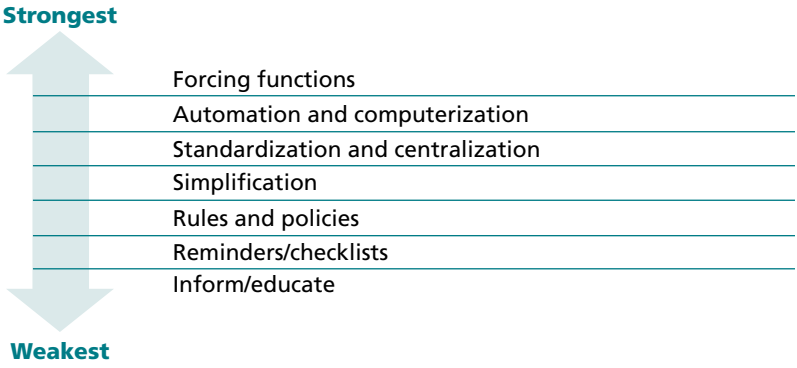
- Publications in specialty journals and even those from the non-healthcare literature.
- Other similar organizations as to their policies, practices, and equipment.
- Experts who can provide information about best practices or standards of practice.
- A human factors analysis.

Gathering information for recommendations from sources other than interviewees will take additional time. Therefore, you will need to determine when this additional information is necessary and if this search is best done as part of the systems analysis or by making a recommendation for further study. The benefit of the latter is that you will be able to complete the analysis sooner.

Strength of recommendations

Usually there are a few different ways to address an identified system problem; however, not all fixes are equally effective in improving safety. One classification offers seven levels of fixes (Figure 5).[17] These fixes range from forcing functions as the strongest to information/education as the weakest with respect to their effectiveness.

Figure 5: ISMP levels of fixes



Recommendations that are the least effective (inform/educate; reminders/checklists) rely on our abilities as humans to remain vigilant at all times and not to forget anything. These types of recommendations can be easily worked around. The strongest recommendations (forcing functions) actually force individuals to do things differently. The most effective recommendation, but not shown in Figure 5, results in removal of a hazard from the system. Unfortunately in healthcare, removal is rarely possible because things that are hazards, for example concentrated potassium chloride, are also helpful in that they are needed to treat patients.

Inevitably there is a trade-off with all recommendations. While recommendations at the highest level are the most effective, they are also often the most difficult to implement because of their complexity. They are also likely to be more costly, more resource intensive, and take longer to implement. In contrast, lower-level recommendations can usually be implemented relatively quickly and easily, often with minimal impact on resources, but are less effective in contributing to long term improvements to patient safety. Thus, you will be faced with the challenge of developing recommendations that will have the greatest impact on safety and that will also be acceptable to operational leaders.

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3.2 Write recommendations

One approach to writing effective recommendations uses SMART criteria, with SMART standing for[18]:

- **Specific** — Be clear on what action is to be undertaken, writing in clear simple English and avoiding jargon.
- **Measurable** —Write the recommendation in a way that the organization can easily determine how and when implementation has occurred.
- **Assignable** — Ensure implementation can be assigned to an individual.
- **Realistic** — Take into consideration the current financial and other organizational realities.
- **Timely** — Consider what improvements can be implemented within a reasonable time.[14]

In healthcare we find it all too easy to focus on what went wrong. However, we also know that it is important to consider what went right, especially when developing recommendations. Consider which factors might have contributed to the outcome not being worse or which factors actually 'saved the day.'

In addition, you should remember that any of or all your recommendations could be released to the public. You should ensure that your recommendations do not include any clues that would allow identification of one or more specific patients or providers.

3.3 Produce a report

Because the contents of your report will depend on both the organization for which you are investigating and the purpose of the investigation, details about what to include are beyond the scope of this Guide. However, future consumers of your report will find it helpful to have three components:

- chronology
- short narrative summary describing the event
- recommendations.

The summary should be a factual description of what happened (the outcome) and how and why it occurred through the contribution of the problems within the structure and process of the system (system deficiencies). The summary should also be systemic, that is, describe the deficiencies across the system, and should not be provider-focused. The simplest way to do this is to derive the narrative summary from the SAFER Matrix and one option is to summarize the findings for each system component in a single sentence or a short paragraph.

The concept of multiple contributory factors means that no one single factor is more important than any other. There is no 'root cause'. This means that in your summary you should not try to list factors according to their priority or perceived magnitude of contribution to the event. "When we try to pick out anything by itself, we find it hitched to everything else in the universe."[19]

In addition, sometimes during the course of a systems analysis you may identify safety problems that you believe not to have been a factor in the event under review but could harm future patients. These issues should be viewed as a free lesson since you were able to identify them before they contributed to a patient being harmed. In other words, they represent a deficiency in the system – but in another context and not the context under investigation. Should you find one or more, then you should capture them in the analysis, with recognition in the written summary that you believe they did not contribute to the patient's outcome. Ignoring these factors could very likely mean that a patient will be harmed in the future, while identifying and providing recommendations aimed at these free lessons could help ensure safer care for one or more future patients.

Finally, clearly describing what you determined and what system improvements should be made is also important for organizational learning, informing and disclosing, which will all contribute to making the system safer for future patients.

3.4 Case example

Let us return to the first case example and the matrix you completed in Phase 2, describing the system with its system deficiencies that contributed to Mr. A. falling. You now need to develop recommendations that target these system deficiencies. From the first matrix, the main patient safety issue you identified was the existence of a scatter rug in a patient's room in a designated supportive living facility, despite there being an organizational policy prohibiting them. This is what you construct as a recommendation.

> ***Recommendation:*** *Fully implement the falls prevention initiative policy and conduct regular audits to ensure there are no loose rugs anywhere in the facility, including patients' rooms.*

In the second matrix, you were able to describe a number of different system deficiencies. You determined that one of the problems that contributed to Mr. A.'s surgery being delayed was the fact that he was given another patient's anticoagulant. In your interview, the charge nurse stated that the way beds were labelled in multi-bed rooms was different throughout the hospital.

> ***Recommendation:*** *Conduct a human factors assessment to determine the best (least error-prone) way to number beds in multi-patient rooms.*

You also spoke with the manager of pharmacy about the medication error. She agreed there is a problem with how the beds are labelled, but also thought the way in which medications are stored and dispensed on the unit could make the system safer. Although not identified as a system deficiency in the matrix, you are able to produce two further recommendations at the system level based on this additional information. The first recommendation can be implemented quickly. The second would take several weeks.

> ***Recommendation:*** *Conduct a four-week trial in which there is a dedicated nurse for medication administration for day and night shifts, with input into developing this trial from both nursing and pharmacy.*

> ***Recommendation:*** *Replace the current system of having open-stock medications on the nursing unit with a patient-specific system.*

Two significant system issues at the organization and regulatory levels were also identified as contributing to Mr. A.'s delay in undergoing surgery. The OR protocol for determining the emergency status of patients was recognized as being ineffective because Mr. A. had not undergone surgery within the recommended time. Also, the number of ORs was insufficient to cope with surges of patients requiring emergency operations. During the interviews you conducted in Phase 2, you received suggestions as to how to potentially address these system issues. Dr. Orthopedic Surgeon suggested having an OR dedicated to emergency cases from 8 a.m. to 5 p.m. Monday to Friday. He stated that this strategy had worked well in other hospitals.

> ***Recommendation:*** *If feasible, consider dedicating an operating room for emergency cases Monday to Friday to better support the OR protocol.*

You also interviewed the department head for surgery. He commented, "We never know from year to year about OR availability. This is madness. I would like to see a meeting with appropriate people set-up so we can work this out for the next three-to-five-year cycle." You also consulted the chief financial officer (CFO) about how she thought the issue should best be addressed. Based on the department head and the CFO's input, you added a recommendation to establish a working group to develop a consistent approach to plan for OR capacity across the province. This is an example of an action that will take some time to be completed and therefore is not undertaken as part of the investigation.

> ***Recommendation:*** *Establish a working group with key stakeholders, including the Ministry and patients/families, to develop a consistent approach to planning for OR capacity across the province based on standard metrics.*

3.5 Tools

Checklist for developing recommendations

Is the recommendation:

- ☐ about the identified system deficiency?
- ☐ directed at as wide a range of patients as possible?
- ☐ as strong as possible?
- ☐ SMART?
- ☐ written in plain English (not jargon) and suitable for public dissemination?

3.6 After Phase 3

A systems analysis is just one part of the patient safety conundrum: how can healthcare be made safer? Just as there are activities you will have undertaken before starting a systems analysis, so there are activities that should occur after your analysis has been completed.

Your goal of any system-level analysis will have been to identify the multiple factors that contributed to the patient experiencing a close call or suffering harm. Some of these contributing factors will represent deficiencies in the system for which you have devised recommendations. But simply developing recommendations will not make care safer for future patients. Remember that recommendations must be translated into action (i.e., be implemented) for there to be any potential for improvements in patient care.

Many organizations have found that a formal process is needed for leadership to review and then accept or reject recommendations. This leadership review and accept/reject process also ensures that there is agreement and allocation of resources by operational leaders to support implementation.

Furthermore, because healthcare is a complex system, making changes can have inadvertent and sometimes negative effects on other parts of the system. Organizations should regularly review and monitor those recommendations they have committed to implementing. They need to evaluate effectiveness to determine if any unintended negative consequences have occurred as a result of the change, and to ensure care has been improved.

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