GETTING AHEAD OF HARM BEFORE IT HAPPENS:

A guide about proactive analysis for improving surgical care safety

Contents

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Forward

In its business plan for 2013-2018, the Canadian Patient Safety Institute made a commitment to advance a national action plan to accelerate patient safety improvement in Canada. The commitment focuses on accelerating safety improvements in four priority areas: medication safety, surgical care, infection prevention and control, and home care. These are not efforts the Canadian Patient Safety Institute can or should do on its own — safety is a collective responsibility, achievable only through collaboration and drawing on the expertise of many organizations and individuals. The Canadian Patient Safety Institute undertook to organize a series of meetings with national, provincial, territorial and local stakeholders in patient safety, with each day-long event dedicated to developing a specialized action plan for one of the priority areas.

The initial driver for this particular literature review and guide came from the Surgical Care Safety Summit which brought together over 30 individuals representing professional associations, quality councils, provincial ministries, health authorities and a patients' group. The subsequent Surgical Care Safety Action Plan identified a goal of preventing surgical harm through enhancing the use of both retrospective and proactive analyses. Action Teams were struck to develop the retrospective and proactive analyses resources. This guide is the culmination of the work of the Proactive Analysis for Surgical Care Safety Action Team. Surgical Safety in Canada: A 10-year review of CMPA and HIROC medico-legal data, the retrospective analysis, is also available.

In healthcare, when patients are harmed or nearly harmed, reactive investigations are conducted. While these are important, they usually focus only on one patient, although occasionally the care of a group of patients may be reviewed. In a way, these investigations are too late – some patients will have come to harm from hazards in the healthcare system. From a safety point of view, being able to find those hazards before patients are harmed is better for patients, their care providers and the entire healthcare system. This kind of investigation – proactive analysis – is rarely used in healthcare. This guide, although not a 'how to' document, will help you and your colleagues to learn more about proactive analyses and prepare to undertake them. This document may be useful for individuals, quality improvement teams and organizations that are committed to reducing harm.

Introduction

This vignette illustrates an opportunity to use proactive analyses in surgical care. In this guide, several questions are answered:

1. What are proactive analyses?
2. What are proactive analyses not?
3. When are proactive analyses used?
4. How are proactive analyses conducted?
   4.1 What models can be used to guide proactive analyses?
   4.2 What tools can be used for proactive analyses?
5. What should be considered while engaging in proactive analyses?
6. What might a proactive analysis look like in the ‘real world’?

This guide is derived from a longer literature review of the tools and models used for proactive analyses. The full literature review is included in the Appendix of this guide.

This guide will follow Nurse Jordan as he considers and undertakes a proactive analysis process.

Every day, Nurse Jordan notes that something goes wrong with the surgical counts. So far, they haven’t left a sponge in any patient – that he knows of. But still he worries and wonders how he and his team-mates could look at this – before there’s a big problem with a patient.

1. What are proactive analyses?

Proactive analysis, that is, ‘evaluative looking ahead’, has the goals of identifying and mitigating hazards before problems occur. This technique has its origins and a rich history in industry including: manufacturing, food safety, and aviation. Proactive analyses can also be useful in healthcare, improving both patient and healthcare provider safety. Indeed, in 2001 in the United States, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a new standard mandating that all accredited hospitals complete at least one proactive risk assessment every year[1]. In Canada, proactive analyses have been part of Accreditation Canada’s Required Organizational Practices (ROP) since at least 2008, with compliance rates rising steadily over the years[2,3].

Nurse Jordan, concerned about the surgical counts, consults with his team-mates. Together, they decide to use a proactive analysis to identify and minimize hazards in the OR. As we will discuss later, there a variety of models and tools they could use to help them identify previously unknown hazards before any problems occur.

2. What are proactive analyses NOT?

The terms ‘proactive’ and ‘prospective’ are often used in ways that conflict. Searches for ‘prospective analysis’ yield many publications focused on prospective studies in which specific patients or groups of patients were studied and monitored to see how certain patient and/or treatment factors related to patients’ health outcomes. In addition to focusing on outcomes and not looking for hazards, many ‘prospective’ publications actually represent ‘concurrent’ studies, that is, those monitoring and evaluating patients and their care - as the care was delivered. These are not proactive analyses.

If Nurse Jordan and his team-mates were tracking surgical counts, looking for errors, and identifying hazards as problems happened over the course of regular patient care, this would not be a proactive analysis. Again, proactive analysis requires looking ahead, and identifying potential hazards before problems occur.

3. When are proactive analyses used?

True proactive analyses should be used when looking ahead to anticipate and evaluate potential adverse events that could occur in the future. This entails seeking out structural hazards and resulting problematic processes, which could contribute to close calls or adverse outcomes.

Proactive analyses can be used at any time. While Nurse Jordan may have been concerned about patient safety in the OR for a long time, it is never ‘too late’ to undertake a proactive analysis. What is required is looking ahead to identify previously unknown hazards or existing hazards that have not been dealt with, perhaps, except through ‘work-arounds’.

4. How are proactive analyses conducted?

Proactive analyses require the use of models and tools to guide the analyses. A model (or framework) gives us a 'basic concept underlying a system' and should be used to understand the context, purpose and goal(s) of a proactive analysis. Tools or techniques then help with the analyses, like checklists or step-by-step processes. Specific tools or techniques will be most effective when they are used with an appropriate model or framework to guide the analysis.

Nurse Jordan and his team will be most effective at identifying hazards if they use both a model and tool to guide their analysis. We will discuss this further in the next sections.

4.1. Which models are used to guide proactive analyses?

Eight models or frameworks have been used to guide proactive analyses. The most useful of these have two characteristics: (1) they have clear categories of 'structure', 'process', and 'outcome' (SPO), as this ensures comprehensive coverage of the healthcare system in the analysis; and (2) they originate in healthcare (as opposed to industry), as they are better suited to analyzing problems in healthcare.

The eight models/frameworks are listed in Table 1 in chronological order of development, with the most useful models bolded.

Table 1. Proactive Analysis Models or Frameworks

Model/Framework	Origin	SPO Categories
Donabedian's Structure, Process, Outcome (SPO) Model	Healthcare	**Yes**
Reason's Swiss Cheese Model	Industry	No
Moray's Model	Industry	No
Davies' Winnipeg Model	Healthcare	**Yes**
Taylor-Adams & Vincent's Model	Healthcare	No
Human Factors Analysis and Classification System (HFACS)	Industry	No
Battles' Nested Model	Healthcare	**Yes**
Systems Engineering Initiative for Patient Safety (SEIPS)/SEIPS 2.0	Healthcare	**Yes**

The four models that originated in healthcare and have categories of 'structure', 'process' and 'outcome' are: Donabedian's SPO Model, Davies' Winnipeg Model, Battles' Nested Model, and the SEIPS model. For detailed information about each of these models, see the full white literature review included in the Appendix of this guide.

Donabedian's Structure, Process, Outcome

Dating from 1966, Donabedian's model of the healthcare system is the oldest and the simplest. The model defines the three basic components of the healthcare system:

- Structure
- Process
- Outcome

$$\text{Structure} \xrightarrow{p} \text{process} \xrightarrow{p} \text{outcome}$$

Figure I. Donabedian's SPO model.[4]

The triad provides a clear differentiation between patients' characteristics (Structure), what patients do or undergo (Process) and the results of those actions and activities (Outcome). The arrows and 'p' in the diagram illustrate how Structure influences Process, which influences Outcome. Of the three components, Structure is the least well understood and studied. Donabedian described the assessment of structure as including "administrative and related processes that support and direct the provision of care". Structure is "concerned with such things as the adequacy of facilities and equipment; the qualifications of medical staff and their organization; the administrative structure and operations of programs and institutions providing care; fiscal organization and the like".[5] Donabedian's triad also forms the basis of other models, such as Davies' Winnipeg Model[6] and SEIPS.[7]

Davies' Winnipeg Model

Davies developed the Winnipeg Model in 1995-1996, in part for the creation of a Quality Assurance database framework in Obstetrics and Gynecology, to be used proactively and reactively. The model was further refined, including the development of the associated SAFER Matrix tool (see below), to assist with review of evidence during the Pediatric Cardiac Surgery Inquest[8] in Winnipeg, Manitoba, between 1996 and 1998.

The five components of the Winnipeg Model (as used in healthcare) are:

- Patients
- Personnel
- Environment / Equipment
- Organization
- Regulatory Agencies.

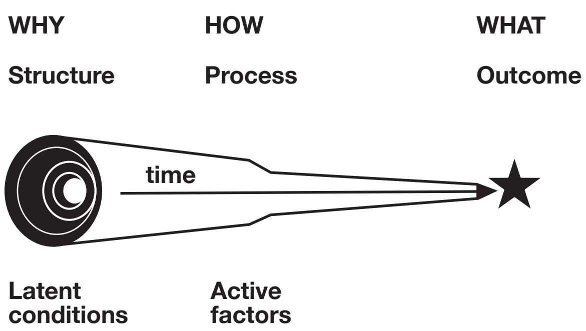

Figure 2. Winnipeg Model.[6] Reproduced with permission from the author.

Thus, any system is made up of specific people (Patients), who interact with Personnel, within one or more Environments and using various pieces of Equipment, within one or more Organizations and regulated by different Regulatory Agencies. In Figure 2 above, the five system components are shown (but not named in the Figure) as the concentric circles, which also represent where the Latent Conditions are found. Addition of the SAFER Matrix provided the model with both a framework and a tool. (See below.)

Nested Model (2003 & 2006)

In 2003, Battles and Lilford presented a model illustrating Reason's "active failures interacting with latent conditions", nested "within the framework of the Donabedian model".[9] Three years later, Battles presented an updated and "graphic representation of the nested model of the critical elements of structure and process required in a healthcare system".[10] In this version, the patient is at the core and surrounded by the other elements of the model. These elements include:

- Clinical Work Systems
- Tools & Devices
- Clinical Microsystems
- Education and Training
- Built Environment
- Macro Organization.

The purpose of Battle's model was to provide a framework for system design, with the "framework of structure and process" helping to determine "what to design for the healthcare system".

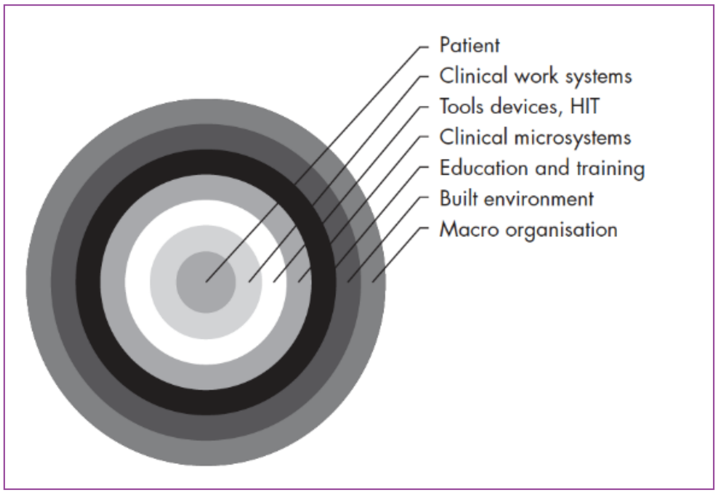

Figure 3. 2006 Nested Model. Reproduced from 'Quality and safety by design. J Battles, 15, i1-i3, 2006' with permission from BMJ Publishing Group Ltd.

Systems Engineering Initiative for Patient Safety (SEIPS) and SEIPS 2.0

Carayon and colleagues developed the Systems Engineering Initiative for Patient Safety (SEIPS) model in the early 2000s[11] and published the concept of a "work design for patient safety" in 2006.[7] In this model, a work system has several elements:

- Environment
- Task
- Technology
- Organizational factors
- Individual
- Work system or Structure (Person, Organization, Technology and Tools, Tasks, Environment)
- Process (Care processes and other processes)
- Outcomes (Employee and organizational outcomes; Patient Outcomes).[7]

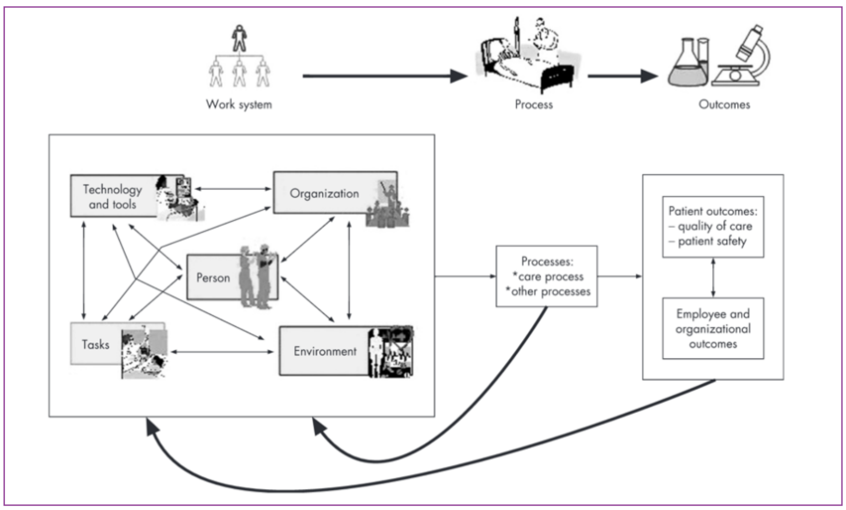

Figure 4. SEIPS model of work system and patient safety. Reproduced from 'Work system design for patient safety: the SEIPS model. P Carayon, A Schoods Hundt, B-T Karsh, A P Gurses, C J Alvarado, M Smith, P Flatley Brennan, 15, i50-i58, 2006' with permission from BMJ Publishing Group Ltd.

These components all interact with and influence each other. The outcomes of these interactions include "performance, safety and health, and quality of working life".

The goal of SEIPS was to "guide studies to empirically examine system design in relation to patient safety and medical errors".

In 2013, Holden, Carayon and colleagues updated the SEIPS model (which became SEIPS 2.0). In this latter version, the authors incorporated three new concepts: configuration, engagement and adaptation. "Configuration" relates to systems being dynamic and interactive, as well as hierarchical. "Engagement" denotes activities carried out by individuals either separately or collaboratively. "Adaptation" describes the evolution of dynamic systems, both intentionally and unintentionally.[12]

Currently, SEIPS is only a model, though Holden and colleagues described creating a practical toolkit to accompany the framework. Lacking a practical toolkit, SEIPS might be most useful when used with a tool for proactive analysis.

After looking at the above models, Nurse Jordan and his team-mates decide to use Donabedian's Structure-Process-Outcome model, due to its simplicity. They begin their proactive analysis by identifying these three components in the OR.

4.2. Which tools are used for proactive analyses?

Many tools have been developed specifically for proactive analysis, including the following:

• FMEA	Failure Mode and Effects Analysis
• HACCP	Hazard Analysis and Critical Control Points
• PRA	Probabilistic Risk Assessment
• SAFER Matrix	Systems Analysis & Factor Evaluation Review Matrix
• HFMEA	Healthcare Failure Mode and Effect Analysis
• SEABH - “SAVE”	Systems and Error Analysis Bundle for Healthcare
• SWIFT	Structured What-If Technique
• LOTICS	Leiden Operating Theatre Intensive Care Scale
• In-Situ	In-Situ Simulation

We have summarized the tools in Table 2, providing a brief description and history of each tool and examples of use in healthcare. We note that all tools will be more effective when used properly under the guidance of experts. Although these various tools are distinct, they share common features, for example, “having an interdisciplinary team focus” and “a preventive orientation” towards fixing quality problems or hazards.[31] For detailed information about each of these tools, see the full white literature review included in the Appendix of this guide.

In determining which tool to use for a proactive analysis, it is useful to consider four factors:

Personnel: All the tools and techniques require a multidisciplinary team, involving participants from all the related areas under study, and a facilitator or team leader. The facilitator should have specific training and experience with the chosen technique and also Human Factors expertise. For example, Rath (2008) explained that while FMEA can be daunting due to the need for resources, few additional resources are needed once organizations are trained in the use FMEA tools and have experienced facilitators to apply these tools.[32]

Time investment: SWIFT requires the least time to complete, with one paper reporting only two hours required for completion of an analysis. There is insufficient information published about SEABH to determine exactly how much time a SEABH analysis would take, though it was designed to take less time than HFMEA. FMEA, HACCP, HFMEA and *in-situ* simulation all can be time-consuming. Publications about HFMEA analyses described needing anywhere from 69 to 250 people-hours. Experience with the SAFER Matrix suggests that reviews can be tailored in scale and scope, depending on the problem, time allocation and resource availability.

Financial resources: While all tools require some financial investment, SWIFT and SAFER are the least demanding, largely because they do not require massive teams or significant time investment. FMEA, HACCP and HFMEA are all resource-intensive due to the significant time investment required to undertake them. In-situ simulation is potentially the most financially demanding, as it requires use of real work environments and equipment, and the participation of many personnel. We cannot comment on LOTICS or SEABH due to a lack of published information.

Ease of use: From the ease of use point of view, SWIFT could be undertaken tomorrow by a surgical team. SEABH was designed to be less complex than HFMEA, but more information is needed to accurately discuss its ease of use. Use of the SAFER Matrix, LOTICS, FMEA, HACCP, HFMEA and in-situ simulation can be complex and require familiarity with the techniques.

Based on these four characteristics, we were not able to find published evidence that one single tool or technique is best suited to proactive analyses in healthcare. Each has its strengths and weaknesses, and various factors will determine which tool or technique or combination of tools or techniques would be best for different processes.

Nurse Jordan and his teammates decide to use SWIFT as their tool, as this is their first experience with proactive analyses, and they want something that will be easy to use.

Table 2. Proactive Analysis Tools

Tool	Summary	Examples of Healthcare Applications	Time Investment	Financial Resources	Ease of Use
FMEA	• designed to help identify system failures, causes & effects of these failures, how critical failures would be, and potential fixes & safeguards to prevent future failures • described as "design procedure in its purest form", thus truly proactive[13]	• three different case studies in Ontario: endoscopy processes, narcotic administration & infection control practices: assessing existing processes, developing action plans & providing staff with knowledge[14]	• can be time-consuming	• resource-intensive	• can be complex and requires familiarity with technique
HACCP	• involves seven steps to guide participants through conducting hazard analysis: identify critical control points, establish critical limits, monitor requirements, develop & implement corrective actions, undertake verification procedures, & follow record-keeping practices	• to examine potential causes of surgical site infections in patients undergoing joint replacement[15] • to evaluate the preparation of anti-cancer drugs[16] and in infection prevention and control[17]	• can be time-consuming	• resource-intensive	• can be complex and requires familiarity with technique
PRA	• typically involves these steps 1. Definition of system under study 2. Identification of the event combinations that lead to failures; "What can go wrong?" 3. Estimation of the likelihood of the identified scenarios 4. Estimation of the severity of each scenario[18] • very quantitative approach to proactive analysis, relying on ability to estimate likelihood and severity of different scenarios	• to compute probability of failure of a hospital's ICU oxygen supply system[18] • to identify hazards for surgical site infections in ambulatory surgery centres[19]			• requires very specific knowledge

Continued

Tool	Summary	Examples of Healthcare Applications	Time Investment	Financial Resources	Ease of Use
SAFER Matrix	• essentially a tabular version of the Davies' Winnipeg Model, with three columns (Structure, Process and Outcome) and five rows (Patient, Personnel, Environment/Equipment. Organization(s) and Regulatory Agencies) • includes the perspective of the healthcare system that guides users as to the range of information needed when conducting an analysis and where to plot information in the Matrix[20]	• review of site location of obstetrical and neonatal services[21] • review of safety implications of the then-planned closure of an airport for patients requiring medevac services to and from the airport[22]	• reviews can be tailored in size and scope	• least financially demanding	• can be complex and requires familiarity with technique
HFMEA	• five steps: 1. Define HFMEA 2. Assemble team 3. Graphically describe process 4. Conduct hazard analysis 5. Actions and outcome measures[23] • goal is to identify 'failure modes' or possible ways the system could fail	• examined pediatric oncology ward for potential hazards related to prescription and administration of vincristine[24] • undertaken following death of two patients from inadvertent overdose of potassium chloride; used to improve policies for ordering and administration of potassium chloride and potassium phosphate[25]	• can be time-consuming; can need anywhere from 69 to 250 people-hours	• resource-intensive	• can be complex and requires familiarity with technique
SEABH –"SAVE"	• developed to address several weaknesses of HFMEA • best used for processes that can be modeled, and not for emergency or non-predictable situations[26]	• evaluation of a Low-Dose-Rate brachytherapy procedure[26]	• designed to take less time than HFMEA, but not enough published information to determine	• not enough published information to determine	• not enough published information to determine

Continued

Tool	Summary	Examples of Healthcare Applications	Time Investment	Financial Resources	Ease of Use
SWIFT	• aims to identify system-based risks through "structured brainstorming" • facilitator prepares set of guide words/headings associated with systems and processes being examined • participants then use prompts such as "What if…" or "How could…" that relate to guide words, to identifying risks/hazards[27]	• proactive risk identification of non-operative risks associated with adult elective surgery under general anaesthesia[28]	• least amount of time to complete	• least financially demanding	• easy to use; could be undertaken 'tomorrow'
LOTICS	• designed to identify underlying causes of errors by measuring latent risk factors (LRFs) through survey of indicator questions that map onto LRFs • teams are given survey, which questions participants' perceived incident rate of accidents, errors and near-misses, from scale of 1 (never) to 6 (very frequently)[29]	• study of if safety program intervention would lead to improvement on LRFs & increase in incident reporting[29]	• not enough published information to determine	• not enough published information to determine	• not enough published information to determine
In-Situ Simulation	• takes place in actual working environment, with people performing their usual tasks, with all equipment typically used	• before introducing new technique (high-dose-rate intraoperative radiation therapy, or HDR-IORT) to Johns Hopkins hospital • followed these steps: 1. Identify existing knowledge of hazards and defenses 2. Anticipate what can go wrong or any weaknesses 3. Simulate the process 4. Summarize hazards/defects (debriefing the process) 5. Design system to defend against hazards[30]	• can be time-consuming	• can be financially demanding	• can be complex to organize and execute • requires familiarity with technique

5. What should be considered before engaging in proactive analyses?

- *Is this an appropriate topic for proactive analysis? Is this application truly proactive?*
  - Ensure this is not a study looking solely at patient treatment and outcomes
  - Ensure that the analysis involves projecting ahead and looking for any hazards, as opposed to a concurrent study.
- *What model should I use?*
  - Choose a model that has clear categories of 'structure, 'process', 'outcome', for this ensures comprehensive coverage of the healthcare system in the analysis.
  - Consider the origin of the model, as those developed specifically for use in healthcare are likely better suited to a healthcare analysis.
- *What tools should I use?*
  - The appropriateness of different tools will depend on the proactive analysis and its context. Each tool has its strengths and weaknesses, and various factors will determine which one or combination would be best for different analyses. These questions might help when deciding which tool to use:
    - Personnel

      Do you need a multidisciplinary team? What specialized training might a facilitator need? How many team members are required? Is there a role for patients and/or patient advisors in this analysis?
    - Time investment

      How long will it take to use this tool? Does this analysis need to be completed in a certain time frame?
    - Financial resources

      How much will it cost to use this tool? This question is related to the first two, as larger teams undertaking longer analyses will require more financial resources.
    - Ease of use

      How complex is it to use this tool? Does this tool rely on familiarity and/or training, or could anyone carry out an analysis using it?

Nurse Jordan and his team-mates are confident that this is an appropriate application for a proactive analysis, and hope to identify and minimize previously unknown hazards. They have chosen to use Donabedian's SPO model and the SWIFT tool, as both are simple to understand and use. They set aside one day to conduct the analysis, and recruit a facilitator who is familiar with Human Factors and proactive analyses. They also engage two patients to participate on the analysis team.

6. What might a proactive analysis look like in the 'real world'?

1. **Prepare the guide words:** The facilitator should select a set of guide words to be used in the SWIFT.
2. **Assemble the team:** Select participants for the SWIFT workshop based on their knowledge of the system/process being assessed and the degree to which they represent the full range of stakeholder groups.
3. **Background:** Describe the trigger for the SWIFT (e.g., a regulatory change, an adverse event, etc.).
4. **Articulate the purpose:** Clearly explain the purpose to be served by the SWIFT (e.g., to improve patient satisfaction scores).
5. **Define the requirements:** Articulate the criteria for success (e.g., no lost revenue over the next 5 years from reduced compensation as a result of low patient satisfaction scores).
6. **Describe the system:** Provide high-level textual and graphical descriptions of the system or process to be risk assessed. Do not get bogged down in detail.
7. **Identify the risks/hazards:** This is where the structured what-if technique is applied. Use the guide words/headings to each system, high-level subsystem, or process step in turn. Participants should use prompts starting with the phrases like "What if…" or "How could…" to elicit potential risks/hazards associated with the guide word. For instance, if the process is "Keep the patient informed about his or her condition," and the guide word is "time, timing or speed," prompts might include: "What if the patient is told about his or her condition while still sedated?" (wrong time) or "How could the patient be left waiting too long without an update on his or her condition?" (wrong timing).
8. **Assess the risks:** With the use of either a generic approach or a supporting risk analysis technique, estimate the risk associated with the identified hazards. In light of existing controls, assess the likelihood that they could lead to harm and the severity of harm they might cause. Evaluate the acceptability of these risk levels, and identify any aspects of the system that may require more detailed risk identification and analysis.
9. **Propose actions:** Propose risk control action plans to reduce the identified risks to an acceptable level.
10. **Review the process:** Determine whether the SWIFT met its objectives, or whether a more detailed risk assessment is required for some parts of the system.
11. **Overview:** Produce a brief overview document to communicate the results of the SWIFT.
12. **Additional risk assessment:** Conduct additional risk assessments using more detailed or quantitative techniques, if required.

Figure 5. Description of SWIFT process.[27]

• • •

On the day set aside for the analysis, Nurse Jordan and his team-mates gather in a conference room, along with the trained facilitator.

The facilitator is familiar with Card's (2012) description of the SWIFT process (Figure 5) and has prepared several guide words.

Nurse Jordan explains that the proactive analysis arose from his worry about errors with surgical counts. The purpose of the analysis is to identify hazards that could lead to misplaced objects in the OR, and then remove those hazards or try to mitigate their presence.

They start the analysis by describing the OR, the process of surgery, and what is currently being done (checklists for surgical counts, etc.). They use Donabedian's SPO model to make sure their description of their operating room system is comprehensive. The two patient members describe their personal and family's stories, and ask numerous questions. Although this increases the time that the process is taking, the facilitator, Nurse Jordan and the rest of the team soon realize that the patients' seemingly 'naïve' questions are very helpful in getting them all to talk about what actually goes on in the OR.

The facilitator then introduces a guide word: 'communication'. The team works through each component of Donabedian's model, asking "What if…" and "How could…" questions about Structure, Process and Outcome components in the OR, such as "What if the case is considered high risk for a retained sponge?" and "How could break relief of the nurses during the case impact communication?". They create a list of hazards as they work through these questions and repeat the process with other guide words.

The team then assess the probability of these hazards leading to a sponge or other piece of surgical equipment being left inadvertently in a patient. Next, they identify the hazards they think should be immediately addressed, such as poor documentation practices when items are added to the sterile field and lack of communication if there is a change of staff. They also propose ways in which these hazards could either be removed or mitigated, such as through new procedures for documenting counted items.

At the end of the day, Nurse Jordan and his team-mates determine they are satisfied with the process and believe that as they follow through on their actions to remove and/or mitigate hazards, the OR will become safer for patients. The prepare a brief document that outlines the process they went through and their recommendations for changes to be made, and distribute the document to key stakeholders.

After some changes are made in the OR, Nurse Jordan and his team-mates are happy to see increased accuracy in the surgical counts, and look for other opportunities to conduct proactive analyses. The patients are also pleased and volunteer to help with other safety activities.

Conclusion

Proactive analyses are an essential component of patient care. A proactive, rather than reactive, approach has the potential to improve patient care and provider safety, even saving lives. In healthcare, it is important to 'look ahead' and not only rely on learning from problems the past. Everyone in the healthcare system shares this duty — governments and health boards, hospital CEOs and administrators, and front-line providers.

We recommend that hospitals be provided with the resources to hire and train workers with the responsibility, protected time, knowledge and skills, and experience with models and tools to conduct proactive analyses. Although budgets in healthcare are overdrawn and time is always in short supply, the aviation industry has demonstrated that it is less costly, and more importantly, safer to be proactive than to be reactive. This is true for the safety of the healthcare system – when it comes to peoples' lives – as well as to the system's economics. The aviation adage, that it is cheaper to look for and fix the small problems than to investigate the crash, also applies to healthcare.

We also recommend that front-line providers, like Nurse Jordan, contribute by taking the leadership to solve problems they are confronted with daily. While busy with providing care 'in the moment', front-line workers should be vigilant about identifying potential hazards. Patients also have a unique vantage point from which they view the healthcare system. They should be included in proactive analyses whenever possible and could also assist in determining topics for proactive analyses.

We encourage all to become familiar with proactive analyses and the models and tools used to undertake them. This will help us all meet our moral requirement to look for harm before it happens, to mitigate the hazards we find, and to make care safer for patients.

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UNIVERSITY OF CALGARY |

PROSPECTIVE/PROACTIVE ANALYSIS: A REVIEW OF PUBLISHED FRAMEWORKS, MODELS, TOOLS & TECHNIQUES

Prepared for: The Canadian Patient Safety Institute

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1. Introduction

Prospective analysis, that is, 'evaluative looking ahead', has the goals of identifying and minimizing hazards before problems occur. This technique has its origins and a rich history in industry, including manufacturing and food-safety, and aviation. For example, in 1959, Pillsbury, a food manufacturer, worked with NASA to develop a prospective method to ensure that the food taken into space was safe for NASA's astronauts to eat (Baird, Henry, Liddell, Mitchell, & Sneddon, 2001).

Healthcare has also adopted prospective analysis. One of the earliest publications to describe using proactive analysis for healthcare is found in the 1992 issue of the Journal of Clinical Engineering. At that time Failure Modes and Effects Analysis (FMEA) was "becoming commonplace among manufacturing companies" but was considered little known outside manufacturing. Willis (1992) described a technique for site-specific FMEA that could be implemented in hospitals by "medical device end-users who could address design or functional concerns specific to their situation" (Willis, 1992).

More than two decades later, prospective analysis is increasingly used in healthcare. The Canadian Patient Safety Institute's Surgical Care Safety Action Plan seeks to "enhance learning and sharing through prospective analysis to avoid surgical harm" (Canadian Patient Safety Institute, 2014). In this report, we advance this goal by presenting a literature review of prospective analysis in surgery.

The objective of this research proposal is two-fold:

1. To identify the tools and frameworks used in prospective analysis in health care for harm reduction and improvement of patient safety, focusing on but not limited to surgical care.
2. To identify published research on the effectiveness of the tools and frameworks used in prospective analysis for harm reduction and improvement of patient safety, focusing on but not limited to surgical care.

To meet these objectives, we completed two steps: Definition of key terms and Completion of a review of the literature. We present the results of the literature search, summarizing each framework and each tool, and then commenting on the effectiveness of each.

2. Methods

2.1 Definitions of key terms

As the term 'prospective analysis' was used by the CPSI in the proposal for this project, we chose to use it as our initial search term. However, searching 'prospective analysis' yielded many publications focused on prospective studies in which specific patients or groups of patients were studied and monitored to see how certain patient and/or treatment factors related to patients' health outcomes. For example, one of the earliest publications about prospective analysis in healthcare was that by Prensky, Raff, Moore and Schwab (1967), in which the authors looked at the use of diazepam in patients with refractory epilepsy (Prensky, Raff, Moore, & Schwab, 1967). Another early publication was Swan's and Ganz' review of the first 100 uses of their eponymously-named Swan-Ganz catheter (Swan, et al., 1970) In addition to focusing on outcomes and not looking for hazards, many publications using the term "prospective" actually represented 'concurrent' studies, that is, studies monitoring and evaluating patients and their care as the care was delivered. We included a few papers of this type for illustration of the point. Other publications, describing but not evaluating a program, were also excluded, as were theses.

In an attempt to find publications searching for hazards in the surgical system, we therefore established a definition of the term 'system' because of its frequency of use, as in surgical system or healthcare system. Moray (1994) provided an excellent definition: a system is "any collection of components and the relations between them, whether the components are human or not, when the components have been brought together for a well-defined goal or purpose" (Moray, 1994). When some studies relating to system analyses did use 'prospective', the term was often paired with another descriptor, such as 'prospective risk analysis' or 'prospective hazard analysis'. We included articles when the terms were used in this way.

In contrast to 'prospective analysis', the term 'proactive analysis' more often is used to refer to system analyses, determining what can be done actively to minimize the possibility of bad outcomes. System analyses are often found in the domain of Human Factors, a field that examines the interaction between individuals and other people, tasks, equipment and environments (Wickens, Gordon, Liu, & Lee, 1998).

These differences in the use of 'prospective' and 'proactive' led us to look at the definition and etymology of both terms for clarification. The word 'prospective' comes from the Latin *prospectivus*, "affording a prospect; pertaining to a prospect". In the 17th century, prospective was also used as a noun for what we now call a spy glass or telescope. (http://www.etymonline.com/index.php?term=prospective) 'Proactive', a more modern term, first originated in 1921 in the field of psychology, as a word meaning the opposite of 'reactive'. This term is in turn derived from 'react' or "to exert, as a thing upon, an opposite action upon an agent. (http://www.etymonline.com/index.php?term=proactive) Proactive carries more of a sense of action, of doing something to make a change, rather than looking forward, as with 'prospective. Thus, the terms 'prospective' and 'proactive' are subtly different, although they are often used interchangeably. We therefore chose to search using both 'prospective' and 'proactive'.

In addition, we set the definition of a 'tool' as a "thing used to help perform a job" (http://www.oxforddictionaries.com/definition/english/tool) But before tool can be used, its context, purpose and goal(s) of use must be understood. This understanding can come from a framework or "basic concept underlying a system" (http://www.oxforddictionaries.com/definition/english/framework) A framework can either be free-standing or providing the outline of a model, which in turn is the 'representation of a thing'. (http://www.oxforddictionaries.com/definition/english/model) Additionally, instead of the term 'tool', the term 'technique' (a "way of carrying out a particular task" (http://www.oxforddictionaries.com/definition/english/technique) was also sometimes used in some publications we found.

We therefore grouped 'tools and techniques', and 'frameworks and models'. Based on these groupings, we chose to search for these four terms, using both 'prospective' and 'proactive'.

2.2 Completion of a review of the literature

The literature review was conducted using the following parameters:
- Published literature
- Past 15 years (2000 – 2016)
- English sources

Our review was exemplary (non-exhaustive) and focused on, but not limited to, surgical care.

We used Google Scholar as the primary search database, as it draws from the widest variety of journals. Many articles about proactive/prospective analyses are found in engineering and psychology journals, which are often not found in Medline or PubMed. For example, we include references from the journals *Ergonomics*, and the *Journal of Energy and Technology Management*, neither of which is found in PubMed.

We also searched medical databases, such as MedLine and PubMed, which yielded articles about frameworks focused on proactive patient care, such as POPS (Peri-Operative Care of Older People Undergoing Surgery) and PACE (Program of All-Inclusive Care for the Elderly). Both POPS and PACE are frameworks for comprehensive geriatric assessments. Although POPS is a screening tool for older patients undergoing surgery, it was not designed to look at overall surgical safety but was designed to be applied to individual patients (Harari, et al., 2007). We did not include articles like this on the basis that they focused entirely on individual patients and not on focus on other components of the surgical system (including hazards).

Boolean operators were used with the following key words and phrases:
- Prospective analysis
- Proactive analysis
- Proactive hazard analysis
- Healthcare/health care
- Patient safety
- Simulation
- Surgery
- Surgical safety
- Evaluation
- Model
- Framework
- Tool
- Healthcare system

This table gives examples of the search strategies we used and the number of resulting articles:

Example Search Terms (limited from 2000-present, not including citations or patents)	**Number of Results**
"prospective analysis" AND (healthcare OR "health care")	15,900
"prospective analysis" AND (healthcare OR "health care") AND "surgery" AND "framework"	2,990
"prospective analysis" AND (healthcare OR "health care") AND "surgery" AND "model"	10,500
"prospective analysis" AND (healthcare OR "health care") AND "surgery" AND "tool"	7,360
"prospective analysis" AND (healthcare OR "health care") AND "surgery" AND "technique"	8,730
"surgical safety"	11,300
"surgical safety" AND "prospective analysis"	240
"surgical safety" AND "proactive analysis"	5
"proactive analysis" AND (healthcare OR "health care")	256
"proactive analysis" AND (healthcare OR "health care") AND "surgery" AND "framework"	37
"proactive analysis" AND (healthcare OR "health care") AND "surgery" AND "model"	55
"proactive analysis" AND (healthcare OR "health care") AND "surgery" AND "tool"	46
"proactive analysis" AND (healthcare OR "health care") AND "surgery" AND "technique"	33
"prospective analysis" AND "surgery"	106,000
"prospective analysis" AND "surgery" AND "model"	31,400
"prospective analysis" AND "surgery" "AND "framework"	4830
"prospective analysis" AND "surgery" "AND "model"	17,600
"prospective analysis" AND "surgery" "AND "tool"	27,000
"prospective analysis" AND "surgery" AND "model" AND "framework"	3740
"prospective analysis" AND "surgery" AND "model" AND "tool"	10,600
"prospective analysis" AND "surgery" AND "model" AND "technique"	13,300
"proactive analysis" AND "surgery"	86
"model of the healthcare system"	60
"prospective analysis" AND "model of the healthcare system"	0
"proactive analysis" AND "model of the healthcare system"	0
"proactive analysis" AND "surgery" "AND "model"	63
"proactive analysis" AND "surgery" "AND "framework"	41

After scanning titles and abstracts, we found over 50 papers that we accessed and read the full text. We chose these papers on the basis of the following criteria: relevance to the terms of reference, comprehensiveness and most up-to-date. In this report, we also include selected references either already known to us or mentioned in references found during our formal review, for a total of 70 references discussed in this report.

3. Results

3.1 Frameworks and Models

Although we have defined frameworks and models as related but slightly different entities, we discuss them here together. We start with those developed before 2000, followed with those from 2000 and after, some of which were found through searching the literature.

3.1.1 Pre-2000 Frameworks and Models

We identified five models/frameworks developed before 2000. These include Donabedian's Structure, Process and Outcome model (Donabedian, 1966); Reason's "human contributions to accidents and the various elements of production" (Reason, 1990) (later renamed the "Swiss Cheese Model" (Reason, Hollnagel, & Paries, 2005)); Moray's "complex hierarchical human-machine system" model (Moray, 1994); Davies' Winnipeg Model; (Davies, 1998; Davies, 2000) and Taylor-Adams' & Vincent's Adapted Organisational Accident Causation Model and framework (Vincent, Taylor-Adams, & Stanhope, 1998).

Donabedian's Structure, Process, Outcome

Of all the models, Donabedian's model of the healthcare system is the oldest (dating from 1966) and the simplest. The model defines the three basic components of the healthcare system:

- Structure
- Process
- Outcome.

The triad also provides a clear differentiation between, for example, patients' characteristics (Structure), what the patients undergo (Process) and the results of those undertakings (Outcome). Of the three components, Structure is perhaps the least well understood and studied. Donabedian described the assessment of structure as including "administrative and related processes that support and direct the provision of care". Structure is "concerned with such things as the adequacy of facilities and equipment; the qualifications of medical staff and their organization; the administrative structure and operations of programs and institutions providing care; fiscal organization and the like" (Donabedian, 1966). Donabedian's triad also forms the basis of other models, such as Winnipeg (Davies, 2000) and SEIPS (Carayon, et al., 2006). In addition, Donabedian's model has provided the outline for prospective/proactive reviews of the healthcare system, such as the Australian and New Zealand Guidelines for Surgical Audit, (Watters, Green, & Van Rij, 2006) as well as for other retrospective/reactive studies, for example, review of factors contributing to 30-day readmission after pancreaticoduodenectomy (Hyder, et al., 2013).

Reason's Model

Reason's model was initially described as "human contributions to accidents and the various elements of production" (Reason, 1990) but later named the "Swiss Cheese Model" (Reason, Hollnagel, & Paries, 2005). The components of the model include:

- Decision makers
- Line management
- Preconditions
- Productive activities
- Defences.

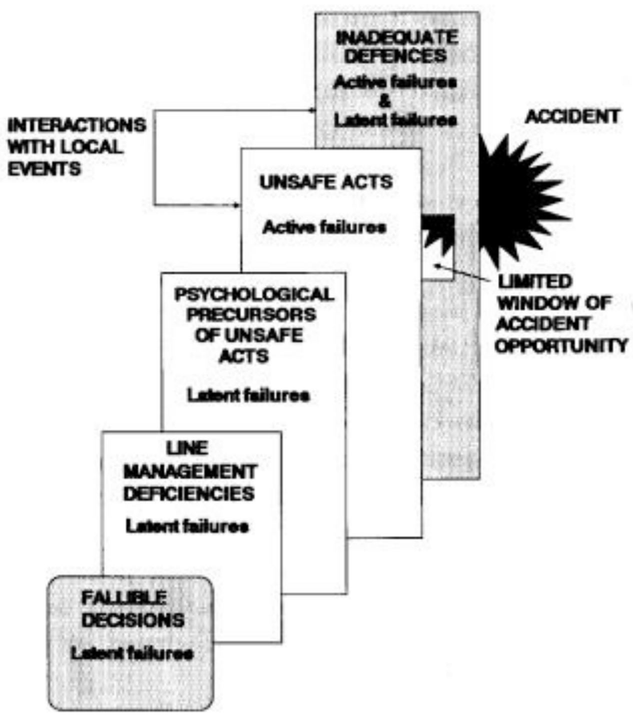

Figure 1. Reason's Model (1990).

The model was developed to help present a "general framework for understanding the dynamics of accident causation" in industrial systems, such as Bhopal and Chernobyl. Reason described the two ways in which humans contributed: through "active failures" (such as errors and violations) and "latent failures" (or "resident pathogens"). The latter were considered to lie dormant in the system until a time when they "combine with local triggering factors" and "breach the system's defences".

The model was further developed (Reason, 1997) and as a result of the slightly different design, unofficially renamed as the "Swiss Cheese Model" (Reason, Hollnagel, & Paries, 2005). In this version, Reason envisaged failures resulting when 'holes' in the defensive layers of a system lined up, like holes in slices of Swiss cheese. Defenses include people, the built environment, procedures and administrative controls. Latent conditions, such as organizational processes, interact with error-producing conditions to produce active failures, which become accidents if adequate defenses are not in place.

Reason's model has been most often used to investigate and/or explain how industrial and aviation accidents evolved. Probably the best and most common example of use of the Reason model for proactive studies has been in aviation, where the model has helped shape Safety Management Systems (SMS). The definition of an SMS is a "systematic approach to managing safety, including the necessary organizational structures, accountabilities, policies and procedures" (International Civil Aviation Organization, 2013). Reason's model effectively underpins the architecture of many SMS, in which safety is now approached from the point of view of 'organizational accidents', rather than from the technical or human factors approaches of previous eras. The organizational approach uses the "routine collection and analysis of data using proactive as well as reactive methodologies to monitor known safety risks and detect emerging safety issues". Proactive analysis involves the evaluation of current situations through different methods, including audits and employee reporting (International Civil Aviation Organization, 2013).

The first application to healthcare was by Eagle and colleagues in 1992, when they used the Reason model to investigate an anesthetic complication (Eagle, Davies, & Reason, 1992). We could not find any proactive application of the Reason model relating to surgical care.

Moray's Complex Hierarchical Human-Machine System

Moray's model of a "complex hierarchical human-machine system" model was developed to provide an approach to design analysis. The "human-machine" component was described as "something where there is a piece of equipment that the operator controls directly or through use of an automatic control". The model has seven major components:

- Societal and Cultural Pressure
- Legal and Regulatory Rules
- Organizational and Management Behavior
- Team and Group Behavior
- Individual Behavior
- Physical Ergonomics
- Physical Device.

Moray described the components of a healthcare system as including the "human components" (*e.g.,* doctors, nurses, managers); "hardware components" (*e.g.,* computers, telephones, records, drugs, operating theaters, scalpels, beds); "management policies; and "financial mechanisms". All components of the system must be considered. Moray's model has been applied proactively to the design of a pre-hospital care computing system (Mentler & Herczeg, 2014).

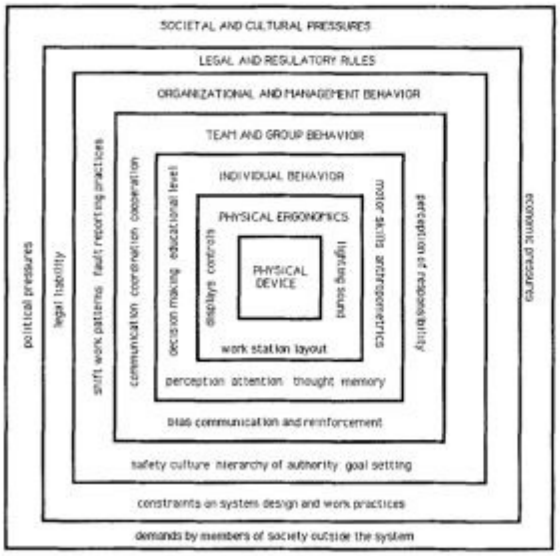

Figure 2. Moray's Model (1994).

Davies' Winnipeg Model

Davies developed the Winnipeg Model in 1995-1996, in part for the creation of a Quality Assurance database framework in Obstetrics and Gynecology, to be used both proactively and reactively. The model was further refined, including the development of the associated SAFER Matrix tool (see below), to assist with review of evidence during the Pediatric Cardiac Surgery Inquest (Sinclair, 2000) in Winnipeg, Manitoba, between 1996 and 1998.

The model was based on Donabedian's Structure, Process and Outcome, arranged according to their chronological sequence. This was not meant to imply linearity but to recognize that everything occurs in time and has a time stamp, although sometimes this time stamp cannot be determined. Components of Reason's model are also included, in the form of both Latent Conditions, that is, the structural elements of the system, and Active Factors or the process elements. In addition, the model includes four factors defined by Helmreich, in his aviation model of "Flightcrew Environment: Factors Influencing Behaviour" (Helmreich, 1992). These four factors, Crew, Physical Environment, Organizational Environment and Regulatory Environment, were modified and expanded to include Passengers (applying the model in the aviation system). In a second revision for use in the healthcare system, Patients were substituted for Passengers, occupying the innermost concentric circle. The five components of the Winnipeg Model (as used in healthcare) are therefore:

- Patients
- Personnel
- Environment / Equipment
- Organization
- Regulatory Agencies.

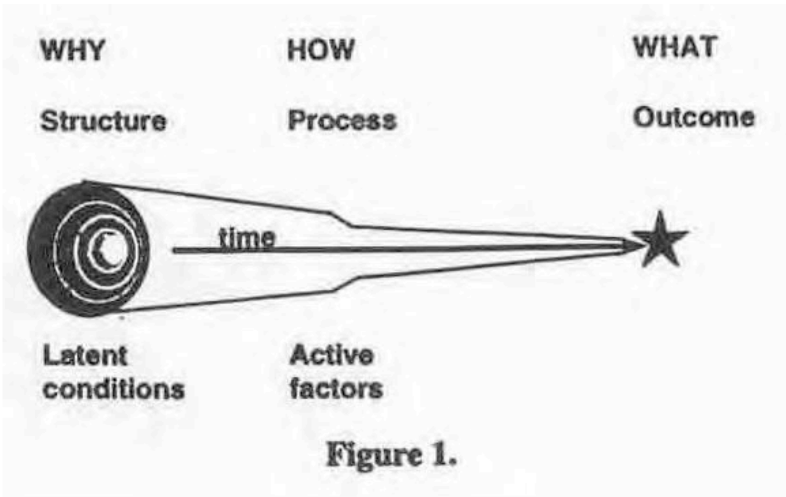

Figure 3. Winnipeg Model (Davies, 2000).

Thus, the any system is made up of specific people (patients or passengers), who interact with Personnel, within one or more environments and using various pieces of equipment, within one or more organizations and regulated by different regulatory agencies. In the Figure above, the five system components are shown (but not named in the Figure) as the concentric circles representing the Latent Conditions.

Addition of the SAFER Matrix provided the model with both a framework and a tool (see below). As a framework, the SAFER Matrix (Duchscherer & Davies, 2012) facilitated application of the model in many retrospective reviews and investigations, as well as proactively. Two examples of proactive application are the review of site location of obstetrical and neonatal services in the north-west sector of Calgary (Davies & Duchscherer, 2006), and the review of safety implications of the then-planned closure of the Edmonton Municipal Airport for patients requiring medevac services to and from the Edmonton International Airport (Health Quality Council of Alberta, 2011).

Vincent and colleagues' Framework for Analyzing Risk and Safety in Clinical Medicine

Vincent and colleagues initially derived their framework from Reason's 1997 version of his model of organizational accidents (Reason, 1997). In this model, organizational processes and management decisions can lead to latent failures in the workplace, resulting in conditions conducive to errors and violations, or active failures. People 'inherit' the conditions that lead to these errors and violations, rather than causing, for example, 'through their own volition' the errors. If the system's barriers and defences are unable to mitigate these active failures, then the result will be an 'accident' (Vincent, Taylor-Adams, & Stanhope, 1998).

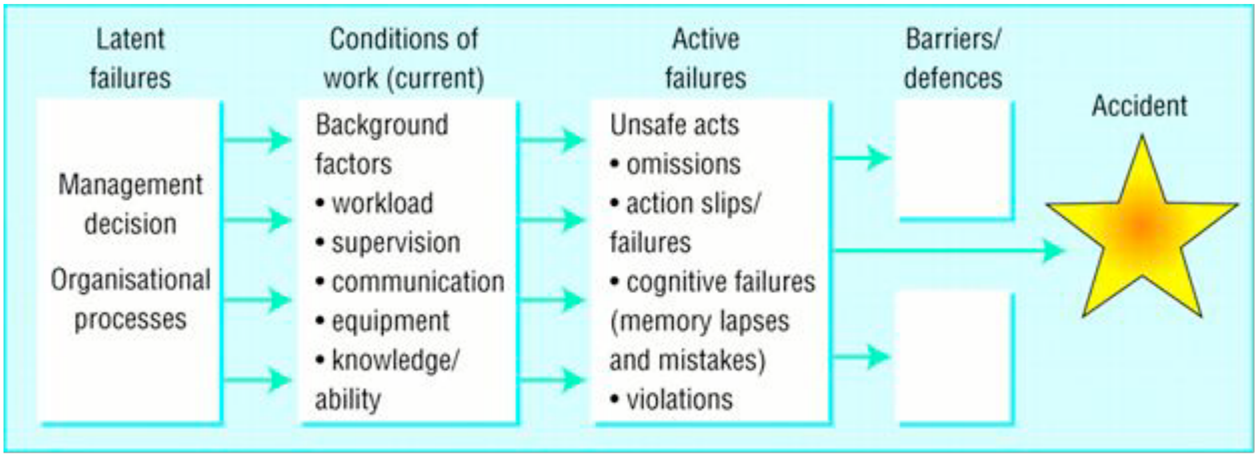

Figure 4. Framework for Analyzing Risk and Safety in Clinical Medicine (Vincent, Taylor-Adams & Stanhope, 1998)

Vincent and colleagues used the major components of Reason's model and then added "factors of potential relevance to medicine". The "components for the major factors" were "primarily derived from medical publications on error, adverse outcomes and risk management". These major components include:

- Institutional Context
- Organisational and Management Factors
- Work Environment
- Team Factors
- Individual (Staff) Factors
- Task Factors
- Patient Characteristics.

The framework was presented as having a number of uses:

- for the analysis of specific clinical events
- for the design of studies relating factors to care and its outcomes
- for the "design and validation of risk assessment instruments".

This latter use describes a proactive intent. However, we were unable to find any publications describing this forward-looking use, except for one chapter by Vincent & Moorthy (2010). This chapter provides a general review of studies of surgical adverse outcomes, a summary of "approaches to human error and system safety" and examples of interventions and directions to improve surgical safety (Vincent & Moorthy, 2010)

3.1.2 Post-2000 Frameworks and Models

Human Factors Analysis and Classification System

In 2000, Shappell and Wiegmann presented their Human Factors Analysis and Classification System or HFACS. They described the impetus for the development of HFACS as "how best to identify and mitigate the causal sequence of events" in an aviation accident. In particular, they

were concerned with what they described as the 70-80% of accidents that could be attributed to human error". The authors wanted to develop a framework that would form the basis of a "needs-based, data-driven safety program". The authors had previously developed a "Taxonomy of Unsafe Operations", based on analysis of more than 300 naval aviation accidents
The outline for this taxonomy was very focused on the individual with three categories: Unsafe supervisory practices; Unsafe conditions of operators; and the Unsafe acts committed by operators (Shappell & Wiegmann, 1997)

Analysis of additional accident data contributed to the development of HFACS, the framework of which was then influenced by Reason's model. Shappell and Wiegmann (2000) similarly described "four levels of failure", which form the four basic components of HFACS:

- Unsafe Acts (errors & violations)
- Preconditions for Unsafe Acts (substandard conditions or practices of operators)
- Unsafe Supervision (from inadequate to violated supervision)
- Organizational Influences.

HFACS still has a strong orientation toward dissecting the behaviour of the operator, especially when considering the first three components. Unsafe Acts include errors and violations; preconditions for unsafe acts represent substandard conditions or practices of operators; and Unsafe Supervision ranges from inadequate to violated supervision. It is only when one considers the factors underlying organizational influences that a more systemic point of view is visible. The factors here include resources (human, financial and environmental); the structure, policies and culture of the "organizational climate"; and the operations, procedures and oversight of "organizational process" (Shappell & Wiegmann, 2000)

We found one example that described use of HFACS in a prospective way. In 2015, Thiels and colleagues published their report on the "first prospective analysis of human factors elements contributing to invasive procedural never events by using a validated Human Factors Analysis and Classification System". They applied the HFACS classification to 69 never events which were collected from approximately 1.5 million procedures performed between 2009 and 2014. The authors stated that "systematic causation analysis" was carried out "promptly after the event". They categorized the contributing human factors "using the four levels of error causation described by Reason", as well as the "161 HFACS subcategories or nanocodes". Thus, this was not a true example of a prospective or proactive analysis but a concurrent one. Furthermore, the authors described their results as showing that "in addition to the system, individual human factors play a substantial and relevant role in determining whether and when never events occur". Organizational influences, reflecting system problems, were coded the least often (Thiels, et al., 2015).

Nested Model (2003 & 2006)

In 2003, Battles and Lilford presented a model illustrating Reason's "active failures interacting with latent conditions", nested "within the framework of the Donabedian model". That is, structure 'surrounds' process, with the core being composed of human behaviours. There are three sets of links: behaviours with active failures, process of care with organizational failures, and structure with technical failures. The purpose of developing this model was to describe the “conceptual framework for patient safety research”, with the aim of “identifying risks and hazards in patient safety” (Battles & Lilford, 2003)

Figure 5. 2003 Nested Model (Battles & Lilford 2003).

Three years later, Battles presented an updated and “graphic representation of the nested model of the critical elements of structure and process required in a healthcare system” (Battles, 2006) . In this version, the patient is at the core and surrounded by the other elements of the model. These elements include:

- Patient
- Clinical Work Systems
- Tools & Devices
- Clinical Microsystems
- Education and Training
- Built Environment
- Macro Organization.

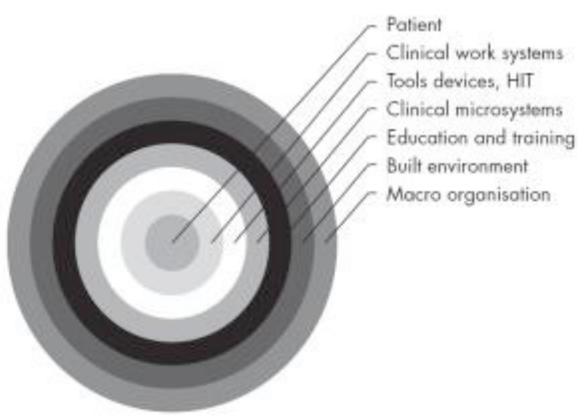

Figure 6. 2006 Nested Model (Battles 2006).

Battles stated that the model shared characteristics with Moray’s “onion” model (Moray, 1994) and with another “model of the healthcare system” by Ferlie & Shortell (2001), although “four-level framework” is perhaps a better description of the latter (Ferlie & Shortell, 2001). The purpose of Battle’s model was to provide a framework for system design, with the “framework of structure and process” helping to determine “what to design for the healthcare system”.

However, we were not able to find any publications describing the application of this model in proactive approaches to surgical safety.

Systems Engineering Initiative for Patient Safety (SEIPS) and SEIPS 2.0

Carayon and colleagues developed the Systems Engineering Initiative for Patient Safety (SEIPS) model in the early 2000s (Carayon & Smith, 2000) and published the concept of a "work design for patient safety" in 2006 (Carayon, et al., 2006). The authors took some inspiration from Brasel and colleagues' interpretation and adaptation of the Haddon's "logical framework for categorizing highway safety phenomena and activity" (Haddon, 1972; Brasel, Layde, & Hargarten, 2000) (and not directly from Haddon's model as stated in Carayon et al, 2006). They also used the "work system model". In this model, according to their "Balance Theory of Job Design", a work system has five elements:

- Environment
- Task
- Technology
- Organizational factors
- Individual (Smith & Carayon-Sainfort, 1989; Carayon & Smith, 2000).

These five components all interact with and influence each other. The outcomes of these interactions include "performance, safety and health, and quality of working life". In revising the "work system design model" for healthcare, Carayon and colleagues integrated Donabedian's model of Structure, Process and Outcome, (Donabedian, 1966) and renaming it the SEIPS model of work system and patient safety. This resulted in an expanded set of components:

- Work system or Structure (Person, Organization, Technology and Tools, Tasks, Environment)
- Process (Care processes and other processes)
- Outcomes (Employee and organizational outcomes; Patient Outcomes) (Carayon, et al., 2006)

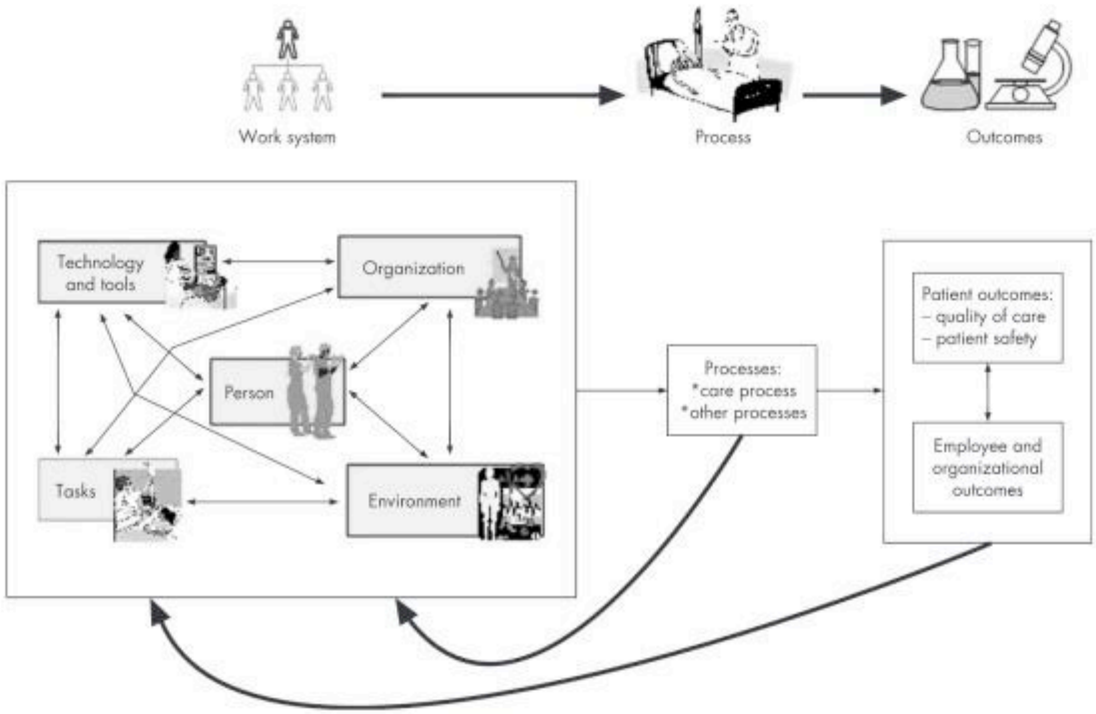

Figure 7. SEIPS model of work system and patient safety (Carayon, et al. 2006).

One point that should be clarified about the model is that with respect to the patient. In the SEIPS model, there are two versions of where the patient fits. In one version, the term "individual" refers to "healthcare provider" and not to the patient, who is the object of tasks the healthcare provider performs. The patient is also the "'recipient' of good or bad outcomes of the care process". In another version, the patient is the "individual", undertaking such tasks as seeing the doctor and collecting medications.

The goal of SEIPS was to "guide studies to empirically examine system design in relation to patient safety and medical errors". The model was tested as a "guide for safety assessment and intervention" by reviewing five outpatient surgical centres, through the use of questionnaires for quality and safety concerns, shadowing patients to review flow of information, review of floor plans, and clarification of roles. Issues identified included lack of patient related information leading to the procedures being cancelled on the day booked and high noise levels.

An example of proactive hazard analysis was also given – that of a medication administration system in a nursing home. The director of the home was described as referring to the SEIPS model for advice on what information to collect. This was listed as "all the people involved in the medication administration process, as well as the technology, tasks and procedures, organizational policies and culture, and environment". The description of this list, "far more data than she would have otherwise thought to collect", shows the benefits (more systematic approach when using the model) and drawbacks (not as simple as one would think) of such an approach.

In 2013, Holden, Carayon and colleagues updated the SEIPS model, SEIPS 2.0. In this version, the authors incorporated three new concepts: configuration, engagement and adaptation.

"Configuration" relates to the fact that systems are dynamic and interactive, as well as being hierarchical. "Engagement" denotes activities being carried out by individuals either separately or collaboratively. "Adaptation" describes the evolution of dynamic systems, both intentionally and unintentionally (Holden, et al., 2013).

Holden and colleagues describe SEIPS as "one of the most widely used healthcare human factors systems models". We reviewed their cited examples of applications in surgery. The earliest of these was the initial testing of the model in outpatient surgical centres (Holden, et al., 2013).

Three studies have since been carried out in cardiovascular surgery. In 2010, Wiegmann and colleagues presented a review of specific work system factors in the OR, using the five components of the SEIPS model as the framework. They considered factors that could have a direct effect on surgical care and also considered recommendations to improve the safety of surgical patients (Wiegmann, Eggman, Elbardissi, Parker, & Sundt, 2010). This was not a proactive analysis of hazards but a few of the topics discussed could serve as triggers for such a (focused) analysis. We have reformatted these topics as questions:

- OR environment
    - OR layout (standardized, cluttered?)
    - policies and procedures to reduce noise in the OR (present, effective?)
- Tools and technology
    - review of usable and acceptable technology (present, effective?)
    - review of unintended consequences of new technology (present, effective?)
- Task and workload factors
    - standardized procedures and checklists for critical tasks (present?)
    - breaks incorporated into the work to reduce fatigue (present?)

In 2011, Martinez and colleagues carried out a focused review of the literature "as part of the FOCUS initiative (Flawless Operative Cardiovascular Unified Systems), a multifaceted effort supported by the Society of Cardiovascular Anesthesiologists Foundation to identify hazards and develop evidence-based protocols to improve cardiac surgery safety". Hazards were defined as "anything that posed a potential or real risk to the patient, including errors, near misses, and adverse events". This definition is problematic because a hazard – a source of potential damage – should not be the equated with the damage. Articles were reviewed for contributing (latent) factors, which were classified using "adopted components" of the SEIPS model: Tasks, Tools and technology, Team characteristics, Patient characteristics, Provider characteristics, Organizational characteristics and Physical environment. The authors stated that misclassification was a possibility and they therefore used only one category although others might also have been appropriate. In addition, Martinez and colleagues used the "work system" part of the model, reasoning that "most, if not all, of the hazards also reflect elements of the latter two components (processes of care and outcomes)" (Martinez, et al., 2011). Again, this is a problematic statement with respect to the definition and hazards, leaving their results to be potentially confusing.

In 2013, Gurses and colleagues looked for hazards related to cardiac surgery, from the period immediately before the patient entered the OR to handover to the ICU. The authors used what they term "prospective methods". However, as the data were collected while patients underwent cardiac surgery, the term "concurrent" is more correct. Methods included "direct observations, contextual inquiry and photographs". The SEIPS model was used to categorize the top level of a three-level classification. The authors' list of hazards ranged from structural problems, such as lack of standardisation of workspace designs in different operating rooms to procedural issues, for example, demonstration of lack of respect for others and noncompliance with practices (Gurses, et al., 2012) While we would agree that the structural problems represent hazards that need to be addressed, the procedural issues are more problematic. Although the examples given can interfere with and influence the quality and safety of care delivered, they are dynamic and not amenable to the same type of mitigation as are the structural issues. Thus, listing them all as hazards could contribute to less effective improvements.

Currently, SEIPS is only a conceptual framework, though Holden and colleagues described creating a practical toolkit to accompany the framework. To date, no studies have been published using SEIPS for true proactive analysis or evaluating its effectiveness. Without a practical toolkit, SEIPS might be most useful when used with a tool for proactive analysis.

3.2 Tools and Techniques

Many tools have been developed specifically for proactive analysis, including the following:

- FMEA — Failure Mode and Effect
- HACCP — Hazard Analysis and Critical Control Points
- PRA — Probabilistic Risk Assessment
- SAFER Matrix — Systems Analysis & Factor Evaluation Review Matrix
- HFMEA — Healthcare Failure Mode and Effect Analysis
- SEABH - "SAVE" — Systems and Error Analysis Bundle for Healthcare
- SWIFT — Structured What-If Technique
- LOTICS — Leiden Operating Theatre Intensive Care Scale
- In-Situ — *In-Situ* Simulation

McDonough (2004) describes many of these tools as having "a common ancestry in the application of the scientific method to process analysis pioneered by Shewhart and Deming". Although these various tools are distinct, they share common features, for example, "having an interdisciplinary team focus" and "a preventive orientation" towards fixing quality problems or hazards (McDonough, 2004).

We first give a brief history of four tools which were developed before 2000: FMEA, HACCP, PRA and the SAFER Matrix. We then discuss in detail the five tools found from the literature search that have been applied in healthcare and published after 2000.

3.2.1 Pre-2000 Tools and Techniques

Failure Mode and Effect Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), Probabilistic Risk Assessment (PRA) and the SAFER Matrix

Failure Mode and Effect Analysis (FMEA) was developed in 1949 by the U.S. military to look at problems with military equipment, and later used by NASA and the automobile industry. FMEA is a tool designed to help identify system failures, the causes and effects of these failures, how critical the failures would be, and potential fixes and safeguards to prevent future failures. The tool was described by Willis (1992) as a "design procedure in its purest form", thus truly proactive. FMEA has been extended to include an analysis of the criticality of each failure; when thus used, it is known as Failure Mode Effects and Criticality Analysis (FMECA).

FMEA has been applied in healthcare, for example, in Ontario. In 2009, Tezak and colleagues presented their experience at Lakeridge using FMEA for three different case studies of endoscopy processes, narcotic administration and infection control practices. The authors described assessing existing processes, developing action plans and providing staff with knowledge through communication and education. In addition, although not specifically stated, their FMEA studies also evaluated the structural elements associated with the processes, such as reorganizing medication storage (Tezak, et al., 2009).

Recently, Guida et al. (2015) used FMECA to assess its application in surgery and to compare laparoscopic versus open appendectomy. They reviewed 177 appendectomies performed in 2009 for adverse events. They conducted an FMECA on each phase of the procedure and on the data from the complications. Results were assessed according to (1) process analysis and failure detection, (2) risk identification, and (3) recommendation or action plan. For example, the procedure was divided into five phases: Preoperative assessment; Skin incision and access to the peritoneum; Management of the vascular pedicle; Appendectomy; and Postoperative assessment. In the second year of the study the authors proactively looked for the problems they had previously found. Again, this is a concurrent study. In addition, Guida and colleagues termed postoperative infections as a "failure mode", whereas in actuality these represent a "failure effect" (Guida, et al., 2015).

Hazard Analysis and Critical Control Points (HACCP) was developed in the food sector in 1959, to ensure the safety of food taken into space for astronauts. A HACCP analysis involves seven steps that guide participants through conducting a hazard analysis, identifying critical control points, and establishing critical limits, monitoring requirements, developing and implementing corrective actions, undertaking verification procedures and following record-keeping practices (McDonough, 2004).

HACCP has been used in surgical settings, for example, to look at potential causes of surgical site infections in patients undergoing joint replacement (Quattrin, et al., 2008). The tool has also been used in healthcare more generally, for instance, in evaluating the preparation of anti-cancer drugs (Bonan, et al., 2008) and in infection prevention and control (Baird, Henry, Liddell, Mitchell, & Sneddon, 2001). The latter publication described use of HACCP in tackling the problem of postoperative endophthalmitis, which threated to close the ophthalmology unit. Five processes were examined: pre-operative assessment; pre-operative eye drops administration; provision of local anesthesia; provision of general anesthesia, surgery, postoperative eye examination, and postoperative topical medication administration. For each process, four critical control points were identified: Patient, Procedures, Equipment; Environment. A number of infection control issues were found, which the authors described as not having been "identified by the earlier conventional approach" used over the previous year. (Baird, Henry, Liddell, Mitchell, & Sneddon, 2001)

Probabilistic Risk Assessment (PRA) was developed in the nuclear industry. Keller and Modarres (2005) discuss the origins of PRA and give a history of the nuclear industry, explaining that during the Manhattan Project during World War II, safety was "defined as the ability of the nuclear reactor to withstand a fixed set of prescribed accident scenarios". As the need for consistent assessment of safety arose, PRA was developed, with a key study, the 'Reactor Safety Study', completed in 1975. This study shifted safety design and regulations in the nuclear industry (Keller & Modarres, 2005).

Deleris, Yeo, Seiver & Pate-Cornell (2006) explained that PRA typically involves these steps:

1. Definition of the system under study
2. Identification of the event combinations (classes of scenarios) that lead to partial or total failures. This steps seeks an answer to the question, "What can go wrong?"
3. Estimation of the likelihood of the identified scenarios
4. Estimation of the severity of each scenario (Deleris, Yeo, Seiver, & Pate-Cornell, 2006).

This is a very quantitative approach to proactive analysis and relies on the ability to estimate the likelihood and severity of different scenarios. The tool has been used in healthcare on occasion. Deleris, Yeo, Seiver & Pate-Cornell (2006) described using it to compute the probability of failure of a hospital's ICU oxygen supply system. They calculated for their hospital with 20,000 admissions each year, that during a 30-year period they would expect to see 44 failures. The analysis led to identification of such organizational issues as an inadequate supply of back-up oxygen cylinders in case of failure of the oxygen supply (Deleris, Yeo, Seiver, & Pate-Cornell, 2006).

More recently, Bish, Azadeh-Fard, Steighner, Hall, & Slonim (2014) used what they called Socio-Technical PRA to identify hazards for surgical site infections in ambulatory surgery centres. They sought factors leading to a surgical site infection in a patient undergoing outpatient knee arthroscopy. The authors built a "fault-tree model", which is a (complicated) engineering technique using Boolean logic to analyse a system from the top down and demonstrate how the system can fail (Roland, 1970). A number of factors were identified, including "failure to prepare the skin appropriately" and "preoperatively antibiotic-related failures related to timing or administration", which were the top two influencers. Interventions aimed at these factors were developed (Bish, Azadeh-Fard, Steighner, Hall, & Slonim, 2014).

The SAFER Matrix or Systems Analysis & Factor Review Evaluation

The SAFER Matrix was initially developed by Davies as a way to analyze large amounts of information from the evidence tendered at the Pediatric Cardiac Surgery Inquest (Sinclair, 2000). The Matrix is essentially a tabular version of the Winnipeg Model, with three columns (Structure, Process and Outcome) and five rows (Patient, Personnel, Environment/Equipment. Organization(s) and Regulatory Agencies). In addition to the tabular format, Davies developed an ontology of the healthcare system, that guides users of the tool as to the range of information needed when conducting a systems analysis and also where to plot the information in the Matrix

(Duchscherer & Davies, 2012). The Matrix can be used when investigating reactively (Health Quality Council of Alberta, 2012) or analyzing proactively (Davies & Duschscerer, 2006; Health Quality Council of Alberta, 2011), for both large and small scale problems.

The method of proactive analysis using the SAFER Matrix involves having one or more subject matter experts (SMEs) analyse the particular area for structural defects, problematic processes and untoward outcomes for both patients and personnel, as well as the other system components. Ideally the SMEs include a patient (representative) and personnel from all necessary roles. The team members use the ontology as a basis to review all the structural components, present and lacking. They consider the existing processes, using process mapping where necessary. The SMEs then review known adverse outcomes, with examples drawn from the literature, local databases, and the SMEs' personal experience. The aim of the analysis is to identify any hazards in the current Structure that require mitigation. Once the hazards have been identified, a plan for their mitigation is developed and this plan must include how the Processes will be affected and modified. Like any other set of recommendations, there must be follow-up to ensure that previously recognized adverse outcomes are reduced in frequency and/or severity and that no new adverse outcomes have been introduced.

The Matrix and associated methodology of Systematic Systems Analysis or SSA (Duchscherer & Davies, 2012) has been used for multiple reactive reviews and some proactive ones. The methodology was endorsed in 2012 by the Health Quality Council of Alberta when it published the guide to conducting patient safety reviews (http://hqca.ca/health-care-provider-resources/systematic-systems-analysis/). In addition, the methodology is now the subject of a University of Calgary certificate course, Patient Safety Event Management (http://www.patientsafetymanagement.ca/home). SSA and its associated SAFER Matrix has yet to be compared to other system-oriented investigative methods and tools.

3.2.2 Post-2000 Tools and Techniques

Healthcare Failure Mode and Effect Analysis (HFMEA)

Summary of HFMEA

In 2001, the Veterans Affairs National Center for Patient Safety (NCPS) formally adapted FMEA from the engineering community to healthcare, calling the new method Healthcare Failure Mode and Effect Analysis (HFMEA) (DeRosier, Stalhandske, & Bagian, 2002). HFMEA also uses concepts from HACCP and Root Cause Analysis (RCA). HFMEA involves five steps:

1. Define the HFMEA
2. Assemble the Team
3. Graphically Describe the Process
4. Conduct a Hazard Analysis
5. Actions and Outcome Measures (DeRosier, Stalhandske, & Bagian, 2002)

HFMEA is designed to be undertaken by a multidisciplinary team, using process flow diagramming, a specifically designed Hazard Scoring Matrix, the HFMEA Decision Tree and an HFMEA worksheet. These materials are all publicly available online, at http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp. The goal of HFMEA is to identify 'failure modes', or possible ways the system could fail.

HFMEA has been used in healthcare many times, with examples of case studies including the publication by Tilburg, Leistikow, Rademaker, Bierings & Dijk (2006). In that study, the authors examined a pediatric oncology ward for potential hazards related to the prescription and administration of vincristine, to determine if HFMEA was a "valid proactive method to evaluate circumscribed health care processes". They also described the implementation and evaluation of their recommendations. They found application of the HFMEA tool to a limited process to be helpful in not overloading the team. As circumscribed as the problem was, the study involved a multidisciplinary team (including a team leader self-taught in the FMECA technique and a patient's parent) of 11, meeting seven times and working for 140 man-hours (Tilburg, Leistikow, Rademaker, Bierings, & Dijk, 2006).

In 2005, Esmail and colleagues published the FMECA they undertook following the death of two patients from an inadvertent overdose of potassium chloride. The results of the FMECA were used by Alberta Health Services to improve policies with respect to the ordering and administration of potassium chloride and potassium phosphate (Esmail, et al., 2005).

Effectiveness of HFMEA

HFMEA is one of the most commonly reported tools used for proactive analysis, and many case studies report using it successfully, including for surgical processes. Linkin, et al. (2005) used HFMEA to investigate surgical instrument sterilization. Eight team members, including methodological advisors, were involved in the HFMEA. They met 19 times over 7 months, and between meetings and other tasks, spent over 250 collective hours on the analysis. While the group concluded they could not prove that the HFMEA improved safety or evaluate its cost-benefit, the HFMEA did reveal system errors with the potential for adverse outcomes. As well, despite the resource-intensive, "tedious" process, the group found the analysis useful. They suggest that HFMEA be used only for "the most clinically significant problems", where system errors are suspected and potential adverse events are serious (Linkin, et al., 2005).

A Dutch healthcare group sought to more systematically evaluate the use of HFMEA by conducting multiple HFMEA analyses and soliciting user feedback. They conducted 13 different analyses, each with a different team. On average, teams were composed of 7 people, including a facilitator, who met 6 times, for a total of 69 person-hours. After concluding their HFMEA, each team member was asked to fill out an evaluation form. The researchers found that about 90% of those involved found the HFMEA meaningful, with 87% expecting the analysis to improve safety. Team members made both positive and negative comments about HFMEA. Positive comments focused on the multidisciplinary nature and systematic approach of HFMEA. Negative comments pointed out the time-intensive process and the difficulty of the risk assessment aspect, which requires participants to determine the hazard score and use the HFMEA decision tree. Facilitators also recognized the need for more guidelines about how to use HFMEA. They emphasized that, in identifying failure mode causes, a system approach should be used, rather than a person approach. HFMEA could also be improved by providing guidelines for appropriate, effective countermeasures (Habraken, Van der Schaaf, Leistikow, &

Reijnders-Thijssen, 2009).

Systems and Error Analysis Bundle for Healthcare (SEABH) – (SAVE)

Summary of SEABH

In 2012, the Systems and Error Analysis Bundle for Healthcare (SEABH, pronounced 'SAVE') was developed to address several weaknesses of HFMEA. These weaknesses include difficulty using the flowchart, identifying failure modes, determining corrective measures, using the hazard scoring system and the time taken to complete studies. SEABH draws from several previously developed tools, including IDEFØ (a function modeling method), FMEA, Cognitive Reliability and Error Analysis Method (CREAM), HFMEA and the Irish HSE Risk Assessment Tool. SEABH is best used for processes that can be modeled, and not for emergency or non-predictable situations (Chadwick, Fallon, & van der Putten, 2012).

Effectiveness of SEABH

The authors report evaluating SEABH using the Validation Square, which is a prescriptive tool used to validate new methods. Its framework is based on a relativist, holistic, social view of scientific knowledge, and thus is appropriate for evaluating design and analysis methods, where no single, 'true' answer exists. The Validation Square requires case studies to support its evaluation. Chadwick (2012) applied SEABH in radiation therapy to examine a treatment process, and found that SEABH described potential hazards with better quality than other analysis methods and linked problems to potential causes. However, the paper does not describe how this comparison was made between SEABH and other methods.

Few conclusions can be drawn on the effectiveness of SEABH, as to date, only one conference proceeding has been published describing this method. While the original 2012 paper mentioned two case studies, the second case study has yet to be published, nor have the authors produced any further work (Chadwick, Fallon, & van der Putten, 2012).

Structured What-If Technique (SWIFT)

Summary of SWIFT

SWIFT was developed in the chemical process industry as an alternative method to Hazard and Operability (HAZOP) methods. Developed in the chemical industry in 1963, HAZOP studies aim to determine where and how processes may deviate from their original design intent. The technique HAZOP relies on process flow diagrams and guide words to identify possible hazards.

The first paper describing SWIFT in healthcare was published in 2008. This technique aims to identify system-based risks through "structured brainstorming". A facilitator prepares a set of guide words/headings associated with the systems and processes being examined. Participants then use prompts such as "What if…" or "How could…" that relate to the guide words, with the goal of identifying risks and hazards.

SWIFT seems to be used predominantly in the UK, possibly because the UK Department of Health's prospective hazard analysis tool kit includes SWIFT (Card, Ward, & Clarkson, 2012).

Effectiveness of SWIFT

SWIFT is much less time-consuming and resource-intensive than HFMEA. In 2014, a UK group conducted a study comparing HFMEA and SWIFT. An analysis using each method was conducted in an anticoagulation clinic, using the same facilitators for each analysis. From these analyses, SWIFT identified 61 risks and HFMEA identified 72 risks, but for each method, over half the risks were unique from those identified by the other method. Participants were also queried about their perceptions of SWIFT. They found it to be easy to use and useful in identifying hazards (Potts, et al., 2014).

Leiden Operating Theatre Intensive Care Scale (LOTICS)

Summary of LOTICS:

The Leiden Operating Theatre Intensive Care Scale (LOTICS) was developed by van Beuzekom, Akerboom and Boer in 2007 for the Leiden Operating Theatre Safety project (van Beuzekom, Akerboom, & Boer, 2007). This project aims to reduce incidents in the operating room through determining system failures, rather than individual issues. The LOTICS tool is designed to identify the underlying causes of errors by measuring latent risk factors (LRFs). The model of LRFs is based on the TRIPOD model of General Failure Types (GFTs). TRIPOD was originally developed by Shell International and is based on Reason's Swiss Cheese Model. TRIPOD-Delta, a questionnaire, was later developed to proactively identify GFTs. LOTICS is a questionnaire that works similarly to TRIPOD-Delta, but is focused on a medical setting (van Beuzekom, Boer, Akerboom, & Hudson, 2010).

LOTICS measures LRFs through a survey of indicator questions that map onto LRFs. The survey was developed by a team of two anesthesiologists and two surgeons who identified possible process failures in the ICU and operating room. Their list was reviewed by a larger team to ensure completeness and to identify possible underlying causes of these failures. The underlying causes were then categorized as LRFs and questions were developed to assess them. In 2007, LOTICS had 74 questions that mapped onto 10 LRFs: Training, Staffing Resources, Planning and Coordination, Communication, Material Resources, Maintenance, Design, Quality of Procedures, Teamwork, and Situational Awareness. The most recently published version of LOTICS has 51 questions and adds Team Instruction as an LRF (van Beuzekom, Boer, Akerboom, & Hudson, 2012). Each indicator question presents a statement, such as "There is sufficient information exchange during the surgery" or "In my departments, there are enough experienced staff", and then asks the respondent to indicate their agreement on a 4-point scale (1 = strongly disagree, 4 = strongly agree) (van Beuzekom, Boer, Akerboom, & Hudson, 2012). Scores from LOTICS point to strengths and weakness of an organization (van Beuzekom, Boer, Akerboom, & Hudson, 2010).

Multidisciplinary teams are given the survey, which also includes questions about participants' perceived incident rate of accidents, errors and near-misses, from a scale of 1 (never) to 6 (very frequently). In 2007, LOTICS also included sections on safety culture and safety goals. However, in the 2012 version, participants were asked about organizational and environmental conditions that affect patient safety and possible interventions for addressing these conditions. It is unclear which version of the survey is the 'official' version and there is no published information about why these changes were made.

Effectiveness of LOTICS:

LOTICS has demonstrated its effectiveness in practice in at least one instance. In 2012, van Beuzekom, Boer, Akerboom and Hudson published a study looking at whether a safety program intervention would lead to improvement on LRFs and an increase in incident reporting. LOTICS was used to identify LRFs that most needed improvement and an intervention was designed that focused on Material Resources, Staffing Resources and Training. This intervention led to improvements for Material Resources and Staffing Resources, though Training was not significantly affected (van Beuzekom, Boer, Akerboom, & Hudson, 2012).

***In-situ* Simulation**

Summary of In-situ Simulation:

There are many other techniques that, while not specifically designed as such, can be used for proactive analysis. One example is *in-situ* simulation. *In-situ* simulation takes place in an actual working environment, with people performing their usual tasks, using all the equipment they typically use.

A group at the Johns Hopkins Hospital developed a new (unnamed) tool for proactive risk assessment using *in-situ* simulation (Rodriguez-Paz, et al., 2009). They developed this approach to mitigate unforeseen hazards before introducing a new technique (high-dose-rate intraoperative radiation therapy, or HDR-IORT) to the hospital. Their process was systematic and multidisciplinary, involving five steps:

1. Identify existing knowledge of hazards and defenses
2. Anticipate what can go wrong/weaknesses
3. Simulate the process
4. Summarize hazards/defects (debriefing the process)
5. Design system to defend against hazards: creation of a multidisciplinary safety checklist and protocol (Rodriguez-Paz, et al., 2009)

For the third step, 'Simulate the process', the group conducted two simulations which tested three distinct scenarios. These simulations were run *in-situ* using a high-fidelity mannequin patient simulator, and even used real radiation.

We also participated in an *in-situ* simulation for a proactive analysis of donning and doffing preparation for a highly contagious infectious disease. With a group from W21C at the University of Calgary, we collaborated with Alberta Health Services (AHS) to evaluate the Calgary Zone hospitals' Ebola preparedness (Hallihan, et al., 2015). Part of AHS' Ebola preparations involved simulating the transport, triage and treatment of Ebola patients. We conducted six simulations at five hospitals, including starting one simulation at a patient's home. These simulations were conducted *in-situ*, that is, at acute care sites in real-time amidst ongoing patient care. Instead of simply conducting donning and doffing observational studies in the laboratory, we observed simulations in the environments in which HCWs normally work, with real and simulated components. This allowed us to look for real-life factors influencing HCWs and their actions and behaviours as they performed tasks and provided care. *In-situ* simulation provided the context of care that was necessary to identify these factors. The full report can be accessed at http://www.albertahealthservices.ca/assets/info/hp/ipc/if-hp-ipc-ebola-human-factors-evaluation.pdf.

Using our experience with Ebola, we adapted the process used by John Hopkins, to describe the necessary steps for proactive analysis using *in-situ* simulation:

1. Identify existing and potential hazards
2. Anticipate what can go wrong and if there are any existing or potential defenses
3. Conduct *in-situ* simulation
4. Analyze for system defects and hazards
5. Fix the defects, remove the hazards or mitigate against the harm that the defects/hazards could present

It should be noted that all simulations are not *in-situ*. For example, Moorthy et al. (2005) used simulation to assess technical and team skills of surgical trainees. They created a simulated operating theatre designed to replicate a real operating room as closely as possible, with a simulated patient designed to follow a number of scenarios, such as hypoxia and laryngospasm. The simulated room was adjacent to a control room where audio and video data from the simulation was transmitted and recorded. Moorthy et al. used this simulation to assess surgical trainees along measures such as technical skills, communication, vigilance and leadership, but this technique could also be used to assess system factors. However, this is not *in-situ* simulation and, while useful in some respects, does not capture the same types of hazards that *in-situ* simulation could.

Effectiveness of In-situ Simulation:

At the time of publication (2008), the John Hopkins group reported that following their proactive analysis, eight real patients had undergone HDR-IORT with no adverse events (Rodriguez-Paz, et al., 2009). This study had a small sample size, however, and while *in-situ* simulation is known to be successful in education, there is less published about its effectiveness for proactive analyses.

In-situ simulation can be a difficult technique to use, as it is highly resource-intensive. Real environments, people and equipment must be used, and the simulation can and may need to be interrupted by the need to provide actual patient care. However, *in-situ* simulation does provide unique opportunities for proactive analyses. The technique was effective in allowing the John Hopkins group to test a new clinical practice before applying it to actual care. The group also found simulation effective in detecting otherwise unpredicted hazards. The risks and hazards anticipated in Step Two of their process, 'Anticipate what can go wrong/weaknesses', were very broad and general compared to the hazards identified through the simulations. Our experience with the proactive analysis of Ebola preparation demonstrated that hazards could be identified and recommendations developed and implemented. Fortunately, we have not had to test the resulting improved preparedness.

4. Discussion

The concept of proactive analysis has been very useful in industries such as aviation, aerospace, manufacturing and food safety, from where these techniques originate. Likewise, proactive analyses can be useful in healthcare, improving both patient and healthcare provider safety. Indeed, in 2001 in the United States, the Joint Commission on Accreditation of Healthcare Organizations (JCHAO) issued a new standard mandating that all accredited hospitals complete at least one proactive risk assessment every year (McDonough, 2002). In Canada, prospective analyses have been part of Accreditation Canada's Required Organizational Practices (ROP) since at least 2008, with compliance rates rising steadily over the years, from 55% compliance in 2008 to 87% in 2014 (Accreditation Canada, 2015; Accreditation Canada, 2011).

However, there appears to be some misunderstanding of what the term 'prospective' or 'proactive' analysis implies. We found many articles describing studies that were not truly proactive; that is, the authors looked at care as it was being delivered. We believe this is better described as 'concurrent' study. For example, Anderson, Brodie, Vincent & Hanna (2012) describe using HFMEA for a 'systematic proactive risk assessment' in a surgical ward. However, their analysis was based on seventy hours of observations where they recorded all the activities in a surgical ward (Anderson, Brodie, Vincent, & Hanna, 2012). Vries and colleagues (2010) studied the effects of a checklist on patient outcomes in what they described as a prospective study comparing outcomes before and after implementation of the SURPASS checklist (Surgical Patient Safety System). This checklist could provide an outline for proactive analysis, but because their analysis was based on review of care of actual patients, it was not truly proactive. True proactive analyses require looking ahead and anticipating and evaluating what potential events could occur in the future and what structural defects/issues and resulting problematic processes could contribute to those close calls or adverse outcomes.

4.1 Models/Frameworks

Our review, as well as our knowledge of previous publications, provided us with eight models/frameworks that have been or could be used for proactive analyses. In looking at these models/frameworks, we considered two characteristics that help differentiate each framework/model from the others.

First of all, the frameworks/models also have different origins. Three models originated in industry: Reason's Swiss Cheese model, Moray's model, and HFACS. The other five models came from healthcare: Donabedian, Winnipeg, Vincent, Battles, and SEIPS. In our opinion, the more useful models are those from healthcare.

Secondly, half of the frameworks and models have clear categories of 'structure', 'process' and 'outcome' or a version thereof; for example, SEIPS which uses the term 'work system' instead of structure. We think that the most useful models are those which identify these three parts of the healthcare system.

4.2 Tools and Techniques

When we reviewed the tools and techniques, we found nine tools and techniques suitable for proactive analyses. In looking at these tools and techniques, we considered four important characteristics:

Personnel: All the tools and techniques require a multidisciplinary team, involving participants from all the related areas under study, and a facilitator or team leader. The facilitator should have specific training and experience with the techniques. It would also be useful if facilitators had Human Factors expertise. For example, Rath (2008) explained that while FMEA can be daunting due to the need for resources, few additional resources are needed once organizations are trained in the use FMEA tools and have experienced facilitators to apply these tools (Rath, 2008). Similarly, all the tools in this report are more effective when they are properly used under the guidance of experts.

Time investment: SWIFT requires the least time to complete, with one paper reporting only two hours required for completion of an analysis. There is insufficient information published about SEABH to determine exactly how much time a SEABH analysis would take, though it was designed to take less time than HFMEA. FMEA, HACCP, HFMEA and *in-situ* simulation all can be time-consuming. Publications about HFMEA analyses described needing anywhere from 69 to 250 people-hours. Experience with the SAFER Matrix suggests that reviews can be tailored in scale and scope, depending on the problem, time allocation and resource availability.

Financial resources: While all tools will require some financial investment, SWIFT and SAFER are the least demanding, largely because they do not require massive teams or significant time investment. FMEA, HACCP and HFMEA are all resource-intensive due to the significant time investment required to undertake them. *In-situ* simulation is potentially the most financially demanding, as it requires the use of real work environments and equipment and the participation of many personnel. We cannot comment on LOTICS or SEABH due to a lack of published information.

Ease of use: From the ease of use point of view, SWIFT could be undertaken tomorrow by a surgical team. SEABH was designed to be less complex than HFMEA, but more information is needed to accurately discuss its ease of use. Use of the SAFER Matrix, LOTICS, FMEA, HACCP, HFMEA and *in-situ* simulation can be complex and require familiarity with the techniques.

Based on these four characteristics, we were not able to find published evidence that one single tool/technique is best suited to proactive analyses in healthcare. Each has its strengths and weaknesses, and various factors will determine which tool/technique or combination of tools/techniques would be best for different processes. For example, many tools/techniques are resource-intensive in terms of time, money and personnel.

4.3 Using Models/Frameworks and Tools/Techniques Together

We included both frameworks/models and tools/techniques in this report because we think it is important that the two be used together. The SAFER Matrix and LOTICS are the only tools that are combined with a framework/model. With LOTICS, van Beuzekom strongly emphasizes taking a system approach, rather than a person approach, and often referred to Reason's Swiss Cheese Model. The SAFER Matrix is tied to Davies' Winnipeg Model, and an underlying ontology of the system. The other tools do not direct participants to take a system approach to the analysis, nor do the tools then provide guidelines for hazards once they are found. For example, one concern with HFMEA is that participants may not take a systemic approach to the analysis. If SEIPS were to be used with HFMEA to guide participants in looking at the system, then the method would take less of a person and process-oriented approach, and the results would focus more on the system. In addition, we believe that using a system-based framework or model illustrates the point that 'what you look for is what you find' (WYLFIWYF). If one uses a narrower model, than the results of the proactive analysis are more likely to be limited in scope. For example, when Thiels and colleagues (2015) did their prospective analysis, they categorized human factors "using the four levels of error causation described by Reason", as well as the "161 HFACS subcategories or nanocodes". Organizational influences, reflecting system problems, were coded the least often. Thus, this study could be interpreted to show that 'what you look for is what you find (WYLFIWYF)'.

It is possible, however, to conduct a form of proactive analysis without the use of a model/framework or a tool/technique, and without specifically searching for "named hazards". For example, in 2013, Wortman published a paper describing his approach to establishing an office-based surgery program for gynecological procedures. Although he did not acknowledge basing his thinking on a specific model or framework, the concepts he presented form an outline that could be used by others to look for hazards. This publication is the only example of a proactive approach to setting up an office or a clinic that we found and which includes many aspects of care, from the regulatory requirements to patient selection, all of which Wortman described as "basic considerations" (Wortman, 2010). These basic considerations include:

- American College of Obstetricians and Gynecologists Guidelines for establishing an office-based surgery programme
- Gynecologic procedures that can be done in an office-based surgical setting
- Considerations in implementing an office-based surgery programme
  - Financial
  - Leadership, training & competence
  - Anesthesia
  - Emergency transfer plan
  - Mechanism of continuous quality improvement
  - Staff
  - Patient selection
  - State & local zoning requirements
  - Liability (Wortman, 2010)

While this list not complete, it does offer the start of an outline or framework for proactive analysis of hazards in an office-based surgical practice.

As well, Mort (2007) presented his approach to reviewing airway management by anesthesiologists in the emergency department. He described a “detailed action plan” for a proactive approach to emergency airway management. These tables included a table of “clinical topics for interdepartmental collaboration” such as “equipment acquisition, monitoring standards” (a structural issue) and “sharing medication information” (a Process). Another table listed examples of hazards at the organizational level; for example, “capital budget committee does not approve purchase of a difficult airway cart” and “restocking of difficult airway cart is not organized and timely”. While this paper did not demonstrate the use of a model/framework or tool/technique, the tables offer suggestions for development into a more systematic and system-oriented outline for use in proactive analyses.

Despite these two publications, we believe that proactive analyses require the use of frameworks/models and tools/techniques. These should not be used separately, but together. Tools for proactive analysis will be most effective when they are used with an appropriate framework/model to guide the analysis.

5. General Recommendations and Conclusion

Objective 1:

We identified the frameworks and tools used in prospective analysis in health care for harm reduction and improvement of patient safety, focusing on but not limited to surgical care.

Many of the proactive studies we found described frameworks/models and tools/techniques in isolation. Frameworks provide the context which tools operate within, and tools provide a concrete and practical way of looking at a system. We suggest that the most effective proactive analyses require the use of both a framework/model and a tool/technique.

In our opinion, the best proactive analysis of any surgical system will be one in which there is a thorough review of all the structural components from the types of patients through to the regulations that drive the system. This review of all the structural components provides what Donabedian called “fairly concrete and accessible information”. This review of the structural components will allow a team then to start to look at all the actions and behaviours in that particular system. Looking for and identifying hazards in all parts of the system will facilitate development of a wider range of recommendations than an analysis that is focused only on the patient, personnel, environments and equipment.

Objective 2:

We found published research only on the self-reported effectiveness of using these frameworks and tools for proactive analysis.

Many of the techniques used for proactive analyses are industrial ones that have been adopted but not validated in healthcare. To date, case studies are the only means by which the effectiveness of these tools have been evaluated. Future research needs to be carried out in healthcare to validate all the tools reviewed in this report.

In addition, we believe that healthcare could benefit from the development of new and refinement of existing frameworks and tools. Healthcare is a much more complex system than other industries and aviation, to which healthcare is often compared. The general approach in industry when identifying a hazard is to 'remove' it. However, in healthcare, many hazards, such as potassium chloride, are also therapeutic and necessary. Removal is not possible.

Finally, it is not enough to simply request or require that hospitals and healthcare providers engage in proactive analyses. This approach requires individuals who have the responsibility, knowledge and skills, protected time, and experience with models/frameworks and tools/techniques. We appreciate that budgets in healthcare are overdrawn. However, we know from aviation that it is less costly, and more importantly, safer to be proactive than to be reactive. This is true for the safety of the system - when it comes to peoples' lives – as well as to the system's economics. The aviation adage, that it is cheaper to look for and fix the small problems than to investigate the crash also applies to healthcare.

We close with Moray's (1994) message:

> "Only when the entire system is designed correctly will error be minimized. The components of the system must not be merely correctly designed and chosen, but the relations between the components must also be part of the design, as must the rules for its operation. If, for example, standard operating procedures are written without reference to the particular choice and layout of equipment, without reference to the training or social organization of the users, and without reference to maintenance practices and manning levels, then the system will be accident prone… These aspects of system design must be integrated. Error will even then not be eliminated. It will, however, be reduced, and the effects of errors rendered more manageable" (Moray, 1994).

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