Shifting Paradigms in Healthcare

Event Review and Evaluation

The SPHERE Workshop

Applying Systemic Analysis and Review Frameworks to Better Understand Events and Assess Risks in a Non-linear World

Safety is not a commodity that can be measured but rather the sum of the accidents that do not occur. While accident research has focused on accidents that occurred and tried to understand why, safety research should focus on the accidents that do not occur and try to understand why.

— Erik Hollnagel

The world is made of Circles
And we think in Straight Lines

— Peter Senge

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Foreword

The SPHERE Workshop is part of a larger effort on the part of Healthcare System Safety and Accountability (HSSA) to apply systemic non-linear thinking to various aspects of healthcare system design, process implementation and service delivery. While the emphasis of SPHERE is on patient safety, the approach is broadly applicable in many domains within healthcare.

The SPHERE Workshop was developed during the winter of 2011-12 and was presented twice in 2012 (May and November) in conjunction with York University's Health Leadership and Learning Network (HLLN). The dates of future SPHERE Workshops (including four in 2013) can be found on the HSSA website.

The main faculty for the workshops will continue to be Dr. Rob Robson and Mr. Darrell Horn, both of whom have extensive experience in undertaking the review and investigation of healthcare events and critical incidents.

HSSA (Healthcare System Safety and Accountability) is creating a new workshop on the topic of Human Factors in System Safety, based largely on the work of Prof. Sidney Dekker and with his participation from Australia. The first offering will take place in the late spring of 2013.

HSSA also offers a wide range of advisory services, including the conduct of external and third party case reviews and distance mentoring of healthcare safety and quality staff across Canada. For more details, please visit the website www.hssa.ca

Overview of the SPHERE Workshop

Applying new perspectives to understand healthcare

The SPHERE Workshop integrates several new perspectives to the ways in which we review and learn from a range of healthcare situations. The impetus to adopt these new ways of thinking grew out of two main influences:

- The first of these was the recognition that a major shift in scientific inquiry about the world we live in was taking place in a wide range of fields and disciplines. These new ways of thinking are gradually being applied to healthcare. These new "lenses" for looking at the world include the concepts of systems thinking, complexity science and complex adaptive systems.
- The second influence was the realization that healthcare systems unintentionally and systemically generate many situations in which significant harm is experienced by the individuals receiving care. The conviction that the extent of patient harm was untenable and unacceptable created the conditions to consider new approaches to responding to unintentional patient harm.

While inviting you to become comfortable with and eventually adopt a new way of thinking about the work you undertake each day, it is necessary to outline the basic philosophic stance underlying the SPHERE Workshop. Healthcare is understood to be an example of an **open living system**[1] that is **complex and constantly adapting** to its external environment. However, there is significant confusion about system concepts and the implications of their application in specific circumstances[2]. It makes sense that particular kinds of systems require different investigative methods and tools in order to understand and influence them. The SPHERE Workshop offers a systemic non-linear perspective, coupled with methods and tools, on the investigation of healthcare critical incidents.

These investigative methods and tools also represent a paradigm shift in the way we undertake efforts to improve the quality and safety of our work. In healthcare, the philosophic stance outlined above leads us to use methods that are based on:

- a **non-linear view of causation** (moving away from a traditional mechanistic "cause-seeking" view),
- a **dialogic approach to gathering data** and discovering narratives (moving away from a typical Q+A "interviewing" approach),

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[1] *If we accept the standard definition of a system as a group of interacting, interrelated and interdependent components working together to accomplish defined objectives, it is important to distinguish what kind of system we are working within. The system may be living or nonliving, open or closed, and complex or non-complex (simple or complicated). Much more of this later in the workshop!*

[2] *For instance, it is quite possible to talk about "systems issues" without specifying the type of system in which the issues are "discovered". Or, it is quite common to see approaches that promote "system thinking" in a very mechanical rigid way or that discuss "complex systems" in a very static [non-dynamic] and linear way. These responses simply lead to more confusion, less understanding and less potential for improvement.*

- a **fluid approach to mapping** events (rather than a rigid linear chronological approach), and
- an **acceptance of the dynamic and sometimes unpredictable nature** of complex healthcare systems.

The SPHERE Workshop highlights the importance of the relationships between the semi-autonomous agents (this includes human participants—all the healthcare providers, managers, and planners), components and subsystems in complex social organizations. Traditional approaches to quality improvement and patient safety have assumed that problems can be "fixed" by searching for, finding, and repairing broken parts[3]. A more effective response, as outlined by SPHERE, to challenges such as providing safe care to patients will not be found by studying broken parts but rather by understanding the dynamic and changing nature of relationships and connections within the complex organizations and structures now providing care. SPHERE invites you to travel down a new and exciting pathway.

Rob Robson
Fall, 2012

Note: Any inaccuracies in the text of this manual or in footnotes or citations are entirely my responsibility. I welcome and will incorporate corrections as they arrive. Many of the ideas have emerged from reading and studying during the Master's program [Human Factors and System Safety] at Lund University in Sweden, as well as robust discussions with mentors (thank you Erik and Sidney) and colleagues and patient safety practitioners (Elaine Pelletier, Ryan Sidorchuk, Darrell Horn, Catheryn Martens, Sharon Erickson-Nesmith and Marilynne Dvorak) and the gentle unrelenting support from my wife Patricia Strachan.

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[3] *This concept is explored in exquisite detail by Sidney Dekker in his book* ***Drift into Failure*** *(2011).*

Module 1
The Context for patient safety efforts in Canada

The dialogue in Module 1 will focus on the following questions and issues:

- Is there a safety challenge in Canadian healthcare in 2012?
- How common is the challenge to the safety of patients receiving care in Canada in 2012?
- Is the healthcare system in Canada fundamentally safe?
- Is there a reasonable balance in healthcare risks and resources?
- Why are you interested in promoting safer quality of care for patients in Canada?

Why all the Fuss?

The fact that you are participating in the SPHERE Workshop indicates that you are curious about how we can best learn from events that unintentionally harm patients and formulate steps to decrease the recurrence of such events in the future. It also strongly suggests that you want to learn more about the characteristics of healthcare that lead to the emergence of unintentional harm and how to transform healthcare facilities into resilient organizations.

This workshop invites you to think in new ways and supports you in moving from passive curiosity to being actively willing to accept the challenges of leading a variety of struggles and initiatives to improve the patient safety reality in Canadian healthcare. In order to lead this change, you will need new tools and perspectives to understand the extent of the problem. This first module will provide background. We will rely on a number of sources (listed in the bibliography), including the **Canadian Adverse Event Study** (Baker et al, 2004). As providers, managers, and leaders in healthcare and as potential Patient Safety (PS) investigators you should read these reports (more than once!!) to be able to understand the details and explain the current reality in Canadian healthcare to others.

The present PS situation in Canada is, quite simply, unacceptable. In order to promote a change in thinking that could lead to safer quality care for patients we will need to transmit a sense of urgency about the potential for unintentional harm that patients face as they seek help from the healthcare system. You need to be able to discuss the risks[4] for patients compared to those for providers

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[4] *It is perhaps not fair to compare the risk of unintentional harm (in terms of morbidity or mortality) for patients, with the risk of litigation for providers or facilities. The risk of unintentional harm for providers is not routinely measured. On the other hand, the risk of*

and facilities—for instance **one in thirteen (1/13) patients hospitalized in an acute care setting in Canada will experience harm (including death) in association with an adverse event**, compared to the miniscule risk of an emergency physician being sued in Canada, which will occur once for every one hundred and sixty thousand (1/160,000) patients seen[5].

The resources available to help hospitals and physicians deal with lawsuits are one hundred (100) times greater than the resources available to promote PS initiatives; the risk of harm to a patient is approximately seven hundred (700) times greater than the risk of a lawsuit occurring. This comparison reflects a **mismatch of resources and risks in the range of 70,000:1**[6]. This seems to be a very strange ordering of priorities by our society.

By the end of this module, we hope that you will be moving away from the role of the "passively curious" observer to one of active engagement. This is not easy work. We welcome you in the search for solutions to make healthcare safer.

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litigation (which for patients is definitely approaching zero) is often cited as a reason to modify patient safety initiatives or approaches and is thus a valid issue to be examined. These "patient apples" and "provider oranges" may be considered comparable at least to the extent they are felt to be important to each of the parties.

[5] *Based on figures provided by the Canadian Medical Protective Association for the year 2006.*

[6] *These are "soft" figures based on extrapolations (for instance, most provincial government agencies in the "healthcare self-insurance" arena do not publish figures) and while the final "mismatch' may be greater or smaller than 70,000:1, the extent of the imbalance is unquestionable.*

Module 2
Healthcare and complexity science

The dialogue in Module 2 will focus on the following questions and issues:

- Why is it important to understand the nature of the system in which we are working?
- What are the characteristics of healthcare systems?
- What is the difference between complicated and complex processes and systems?
- How can complexity science inform us about methods to learn about and initiatives to change healthcare?

Baking a cake, designing an aircraft carrier or providing healthcare: Which is the most complex system?

It may seem like a commonsense proposition that before starting on a journey one should have a map and some basic information about the factors that may make the trip easy or "less easy" (in other words, difficult). In the same vein, it makes sense that prior to trying to understand events or challenges within a particular industry or structure, one should have at least some understanding of the nature and internal processes of that system, as well as an inkling of the environment in which it functions and with which it interacts. This would seem to be extremely obvious or commonsense in industries that are "safety critical" (for instance nuclear, chemical, aviation, mining, and others, including healthcare).

Unfortunately, healthcare leaders, managers, administrators and providers are often so preoccupied with day-to-day challenges that they have little time to think about such questions. There is clearly an acute awareness of the challenges that face the healthcare system in Canada but relatively less understanding of the specific characteristics of that system and how they might influence initiatives and programs intended to improve services.

This module will touch briefly on these broad "systems" questions and introduce you to the concept of healthcare as a complex adaptive system (CAS). We will explore how viewing healthcare as a CAS can influence our understanding of events and situations, especially with respect to PS (patient safety) and quality of care.

Paul Plsek (Plsek, 2003) has written in more depth about this idea and has not only clearly identified healthcare as a CAS but has differentiated between complicated and complex situations or circumstances.[7] Most of the time, healthcare providers and managers understand that there are many parts to the healthcare system but have not made the distinction between it being complex as opposed to a complicated system. This distinction is quite important not only for managers and planners, but also for providers who wish to understand how best to improve quality and safety of care. Understanding the distinction between a complex and a complicated system is **crucial** for safety investigators.

The way in which events arise following the non-linear interaction of factors and through the often unpredictable influences of other events and decisions in distant parts of the healthcare system will become clearer when investigators have a different understanding of the nature of the system in which they are working.

The emphasis here will be on the **nature of complex adaptive systems** and other complex social organizations rather than on "systems thinking". Several references in the bibliography will help you explore that important area (for instance Cilliers, Capra, Bohm, Senge, Peat, to name only a few). The common characteristics of complex socio-technical systems (another name for CAS) will be explored, based on the understanding that has developed in the past three decades of studying diverse industries and organizations. Reference will be made to some of the principles in complexity science. Informative articles about how this has been applied in healthcare will also be found in the bibliography (for instance

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[7] *Plsek suggests that a project such as putting an astronaut on the moon is merely complicated while raising a child or improving quality and safety in healthcare are both examples of complex endeavours.*

the book by Letiche [2008], and articles by Lanham [2009], Jordan [2009] and others).

Finally an overview of tools and approaches that have been found useful in the domain of organizational development (OD) when working in CAS will be provided (Olson, 2001). This will help to make sense of the claim by several of the leading thinkers in this area (see Plsek and Letiche) that there is an urgent need in the PS domain to shift the paradigm applied to quality improvement efforts for several decades (structure-process-outcome) to one that is more appropriate to a CAS—(namely, structure-process-patterns).

This module will be an exciting taste of future directions and will give PS investigators a more solid theoretical and philosophical foundation for the important work of reviewing healthcare events, including the very common ones that have not produced any obvious harm.

Module 3
Approaches to Investigations: Making the "form fit the fuss"

The dialogue in Module 3 will focus on the following questions and issues:

- What are the main approaches to the review and investigation of healthcare events?
- What are the relative advantages and disadvantages of the different approaches?
- Does the type of system in which the event occurs influence the investigation approach to be adopted?
- What is the nature of non-linear causation and how does it differ from traditional Newtonian or Cartesian causation?
- What the heck is WYLFIWYF?
- Does "sense-making" lead to different understanding than looking for "root causes"?

Methods to make sense of events

Prior to looking at the approach proposed by the SPHERE Workshop, some background and context will be helpful. An overview of the development and characteristics of three broad groups of safety investigations[8] is provided in ***Barriers and Accident Prevention*** (Hollnagel, 2004). This is an important area to explore since the model we use in an investigation significantly influences the results we are likely to find. The acronym WYLFIWYF summarizes this well—"what you look for is what you find". (see Lundberg, Rollenhagen and Hollnagel, 2009)

These three types of safety investigations evolved more or less in parallel with the development of science and industry and reflected the urgent need for new ways to think about accidents as industrial processes changed and socio-technical systems became more complex. In ***Barriers and Accident Prevention***, Hollnagel distinguishes **three industrial ages** (technological, human factors, and safety culture/organizational ages). These corresponded roughly with the development of the **three categories of investigation** (sequential or simple linear, epidemiological or complex linear and systemic non-linear).

Underlying these categories we find major philosophic differences about how processes develop and about the question of **causation**. Most scientific thought

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[8] *There is a very clear distinction between a safety investigation and many other types of reviews or investigations that may occur following an event in a healthcare setting. Because patient safety investigations are a relatively new phenomenon in Canada it is not surprising that there may be significant confusion about the nature of such investigations and the important differences between safety investigations and other (completely legitimate) investigations that may be undertaken at the same time—these may include administrative reviews, disciplinary reviews, performance management reviews, investigations by a coroner or medical examiner, or police investigations about possible criminal negligence, to name a few.*

has subscribed to a classic understanding of causation ("cause and effect") that is **linear and direct**. You will hear terms to describe this way of understanding causation such as **Newtonian** (Sir Isaac Newton), **Cartesian** (Rene Descartes), **mechanical**, or even **binary** (referring to the binary system of mathematics in which the only numbers used are 1 and 0). This reflects a way of thinking which see the world as either black/white, or right/wrong. The safety investigation category that most closely corresponds to this way of thinking is the **sequential or simple linear method** (for instance, the work of Heinrichs who put forward the "Domino Theory" in his 1931 book *Industrial Accident Prevention*). The original **RCA** (**Root Cause Analysis)** method developed by the Veteran's Administration in the U.S. is another example of this approach.

A more complicated but related way of thinking about accident investigations also relies on a linear understanding of causation, but allows the possibility that several factors may need to combine before an event occurred (or was "caused"). This is referred to as the **epidemiological or complex linear method.** Common examples are the **Swiss Cheese Model** (Jim Reason), the **London Protocol** (Charles Vincent) and the Canadian Patient Safety Institute (CPSI)-sponsored **Canadian Root Cause Analysis (RCA) Framework**.[9]

A basic premise that underlies both the simple and complex linear approaches to accident investigation is that of a **cause-and-effect sequence** to explain or understand events. Implicit in this premise is the idea of a cause-consequence equivalence that is symmetrical. In other words, a big "effect" (a patient dying in association with a breakdown of care) is invariably linked to (must have been the result of) a big "cause". In most cases, the "usual suspects" to explain the event are easily located in the "rubble" that is present after the breakdown in care, at the

[9] *Presently (2012) undergoing a major revision—for details visit* www.patientsafetyinstitute.ca

so-called "sharp end"[10] of the system where an array of healthcare providers are in close or direct contact with the patient.

The process of focusing attention on the direct care providers flows directly from the traditional ideas about causation and diverts attention away from a myriad of other factors which almost always must be present in order for an event to occur. This creates the unusual situation where multiple factors that have contributed to an accident are largely ignored in exchange for a focus on the providers who are close at hand. In this way there is a virtual guarantee that learning will be severely limited and the possibility of implementing changes or improvements to reduce future harm is severely truncated; this dilemma is explored in greater detail in the book ***Behind Human Error*** (Woods et al, 2010).[11]

In the early 20th century, physicists began to discover that many phenomena could not be explained on the basis of Newtonian mechanics or Cartesian theorems. The concept of **uncertainty** emerged and was found to have applications in other fields of science, including biology. You will hear names such as Capra, Bohm, and Peat associated with these ideas. This led to the development of chaos/

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[10] *The distinction between "sharp end" and "blunt end" activities or decisions is an important one for PS investigators to make. Typically, activity at the sharp end involves those providers with direct contact with the patient [in the case of healthcare]—for instance the doctor holding the scalpel, the nurse with the syringe about to give an injection, the pharmacist dispensing medications. It is "easy" to find these operators when re-constructing events after harm. The "ease" with which the "sharp end" providers are identified often prepares the ground for blaming, without consideration of the context in which they were working. It is less obvious that those at the "blunt end" [typically involved in management or leadership of the facility] might have contributed to an event occurring, for instance through decisions about protocols or policies or the determination of financial priorities.*

[11] *Another way of looking at this dilemma is summarized in the observation "what may work very well for steam engines and other mechanical systems seems to work much less well in complex adaptive social systems".*

complexity theory and the gradual understanding that complex socio-technical systems often behave in unpredictable ways that reflect significant uncertainty. People began to realize that many events occur in a **non-linear** fashion and used this new understanding to apply complexity theory to organizations[12] and the processes they develop.

Charles Perrow, in his book ***Normal Accidents***, categorized complex organizations according to certain characteristics such as **coupling** (tight versus loose) and **interactivity** (linear versus complex)[13]. These concepts validated the vision of healthcare as a complex socio-technical system. This framework facilitated the understanding of non-linearity and uncertainty in healthcare—that is, the emergence[14] of safety events from the unpredictable combination of multiple contributing factors, as frequently observed by healthcare safety investigators.

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[12] *This transition has not been an easy one. While the uncertainty that had been discovered by the experiments of quantum physicists (reflected very strongly in the 1930's in Heisenberg's Uncertainty Principle) has gradually been accepted with respect to the field of physics and mathematics, there has been significant resistance to thinking that such principles apply equally in the biological sciences. The subsequent leap to applying non-linearity and uncertainty principles to social organizations has required a major shift in thinking. Skepticism abounds.*

[13] *More recent work by sociologists such as Scott Snook suggests quite strongly that Perrow's grid (coupling versus interactivity) is overly simplistic. Snook proposed additional characteristics [specifically looking at the "logic-of-action" concept and contrasted activities and decisions that were "rule-based" compared to those that are "task-based"] that enrich the original framework proposed by Perrow.*

[14] *Emergence is one of the central concepts in complexity theory. Healthcare abounds with examples of emergence although we typically describe the events in other terms such as "misadventure" or more fatalistically "misfortune". These descriptors then easily become associated with blaming and the inappropriate assigning of responsibility rather than searching for understanding.*

This understanding led to the gradual development of the third broad category of accident investigation—**systemic non-linear analysis methodologies**. The SPHERE workshop builds on and expands the perspective of one local effort to apply these ideas in a Canadian healthcare context.[15]

An interesting issue concerning the three broad categories of accident investigation relates to the application of the methods and approach that each proposes for the investigation and analysis of various critical incidents. Each of the methods may be useful for a certain subset of events that harm patients. Some methods are simpler to apply (typically the sequential methods) and may be less resource intensive[16]. There is no simple way to know which method is most appropriate for a given critical incident, prior to completing the critical incident review[17]. In Module 5 we will explore other reasons why the systemic accident investigation and analysis method might be helpful in working towards more resilient healthcare organizations.

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[15] *The Winnipeg Regional Health Authority (WRHA) was the first large healthcare organization to attempt to apply a systemic non-linear approach to reviewing and learning from critical incidents. The initial one-day training workshop was called the New Lens Workshop, with the early versions presented at the end of 2005 and the early part of 2006. This evolved over time to a three-day intensive workshop known as the Patient Safety Investigator (PSI or NL-PSI) Workshop. The training method is currently (2009-2012) part of a multi-centre research project comparing the impact of patient safety investigation methods on the content of reports as well as the types of recommendations arising from those reports.*

[16] *This is pure speculation since the various methods have never been compared in a controlled manner.*

[17] *It is also fair to say that no one is able to say with certainty what percentage of healthcare critical incidents might "require" one method compared to another.*

Erik Hollnagel (Hollnagel, 2012) has actively explored the systemic (non-linear) accident analysis method through his work with FRAM[18]. In his recent book, ***The ETTO Principle***, he applies these ideas to both retrospective accident investigation and prospective risk assessment[19].

The overlap of work by Perrow, Hollnagel, Rasmussen, Dekker, Woods, Cook, and others and the development of the systemic non-linear accident analysis method is an example of "emergence" in the organizational domain. In this Module you will learn about the concepts related to Dekker's "New View" (Dekker, 2006). This has also been called the "Second Story" by Woods and Cook (Cook et al, 1998) and brings us back to thinking about why we are doing this PS work. We think you will find the New View helpful as you try to understand (**make sense of**) events that harm patients.

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[18] *FRAM refers to Functional Resonance Analysis Method and is being actively developed and applied to a wide variety of complex socio-technical system investigations under Hollnagel's leadership as Professor at the University of Southern Denmark (previously at Mines Paris-Tech where he functioned as the Chair of Industrial Safety.*

[19] *This is a fascinating read which will challenge many of the foundations of "modern" risk management practices by moving away from a rigid linear approach to risk assessment and demonstrating how a systemic approach might be applied.*

Module 4
Systemic (non-Linear) Analysis Method (SAM)

This method is based on several concepts drawn from complexity science; some of these have been highlighted in earlier modules. It is not necessary to become a student of complexity science to apply SAM.

The subsections in this Module will equip you with the ability to learn from an event by applying SAM. The approach is not formulaic or "menu-driven". Nevertheless, there are some broad categories of activities that will be discussed to help guide you in learning about SAM and in your applications of the method in specific instances.

The steps that should be considered in each case are the following:

- Identifying and engaging the participants
- Building a narrative understanding
- Mapping the event; developing a chronology
- Identifying relevant Human Factors issues
- Generating recommendations (or not)

In any given case the application of SAM will proceed in an iterative [back-and-forth] fashion—the progression of the investigation will not follow these steps in

a linear fashion. The process is one that is composed of inter-dependent “feed back” and “feed forward” learning loops. If you remember that your underlying purpose (remember WYLFIWYF) is to understand or make sense of an event it will be much easier and more meaningful to move backward and forward in the process.

Section (a): Identifying and Engaging Participants

Deciding on who should meet with the review committee; identifying the players to help make sense of events.

The dialogue in Module 4, Section (a) will focus on the following questions and issues:

- Why is it important to invite the participation of the patient who has been harmed and their family members?
- Are there any potential participants who should be excluded as sources of information?
- What are the sources of potential conflict of interest for members of the review committee?
- Are there any limits to what can and should be discussed in a review committee?
- Why is some form of legal privilege or "protection" important for the discussions and inquiries of a review committee?

Deciding on who should meet with the review committee

There are a number of reasons why the first individual to consider is the patient (and any close family members with some direct knowledge of the event). They are, almost invariably, a valuable source of information about the event—think of them as quality control officers who happen to be "on the job" 24 hours a day. They are in a position to notice things that are not always easily perceived by extremely busy healthcare providers. This is not to suggest that the providers will try to cover up any important questions—they are usually very busy and may not notice, or if they notice, not have the time to record, an event that seemed relatively unimportant at the time.

Involving the patient and family in the investigation process will also allow the facility to understand any misconceptions they may have and to provide relevant information to help them understand the process[20]. It is possible that there is a risk that their knowledge of the outcome will bias their comments or affect the accuracy of their observations[21] and this should be considered as you proceed.

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[20] *As Berlinger has noted in* ***After Harm*** *(2004), there are several kinds of harm experienced by the patient and family, over and above the initial obvious harm associated with the incident. Significant harm can arise as a result of the way in which the facility responds to questions and provides honest transparent answers to questions. From the outset, the patient and family should be provided with the name and contact information for a support person, who is not a member of the investigation team.*

[21] *This tendency to be influenced by knowledge of the outcome is called results bias or* **hindsight bias** *and applies equally to providers, investigators, experts—indeed to anyone involved in the investigations. This will be dealt with in more detail in a later section.*

Of course, there is an additional important reason (primarily an ethical consideration) to involve the patient and/or family members. They are the ones who have directly experienced the harm and who should be aware of efforts to discover what happened in a given situation. This is similar to the concept of "Whose Life is it Anyway?" explored in a movie of the same name. It is also recognized in Canadian courts that the legal duty to obtain the patient's informed consent also implies the legal duty to inform the patient when a complication or adverse event has occurred (Picard and Robertson, 2007; see page 204 *Stamos v. Davies* 1985).

While the patient and family should, in all instances, be offered an opportunity to meet and share information and questions with the review committee, it is important to recognize that not all patients will be ready to participate actively in the early stages after a critical incident. The offer should always be made in a sincere and sensitive manner.[22] It is important to state clearly that involving the patient and/or family in the investigation is much more than the simple but important matter of disclosing the facts of what happened[23]. Indeed, the disclosure discussion is best undertaken by the involved clinicians rather than the investigation team.

While a patient safety investigation is not necessarily designed as a therapeutic process, it may, when conducted in a deliberate manner, conscious of the traumatic effects experienced by the various participants in an adverse event,

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[22] *The response to harm can cover the gamut of reactions and in some cases prolonged grieving may make direct patient or family participation unrealistic. In a small number of cases patients may respond in a manner that is analogous to post-traumatic stress disorder (PTSD) reactions and their involvement in the investigation may ultimately be negative, resulting at times in flash-back experiences.*

[23] *The question of* **disclosure** *is discussed in detail in a separate workshop "Disclosing Unanticipated Medical Outcomes" developed by the Institute for Healthcare Communication. Disclosure is a legal and professional requirement in most provinces of Canada.*

have a profound therapeutic effect. It is important to recognize, in a small number of cases, the potential for negative therapeutic effects as a result of the investigation stimulating or renewing unpleasant and painful memories of the experience. Investigators should be aware of the potential for such a negative reaction and respect the occasional refusal of patients/families who have been invited to participate in the investigation process.

We may acknowledge and deal with the first harms (related directly to the adverse event), by processes of apology and disclosure, which are useful in mitigating secondary harm. We cannot undervalue the meaning of an opportunity for those patients/families to tell their own stories in a safe way, and the further succor achieved by the sense of a meaningful participation in a process that seeks to understand and prevent future harms.

The second harm is often a result of what an organization does or does not do to help the patient/family move towards a more normal cycle of grief and thus recover from the initial harm. Patients/families experiencing second harm, talk openly about feeling isolated after the harm. They speak about being shut out of meetings and discussions with those who were directly involved and whom they believe have vital information that can help them understand what happened and why. They talk of questions the organization's leaders and providers will not answer. Many are quite frank about situations that they experienced as disrespectful; where no apologies were offered, where they see no consideration of their loss or the impact that the situation has had on their life. This type of response by the healthcare organization is understood to cause further harm to the patient and family and could move the patient/family into *complicated grief* (Trew, M. et al 2012).

These processes are of equal importance and value for the care providers themselves, who are observed from time to time, in a manner similar to patients/families, exhibiting the same grief and occasional symptoms of post trauma stress related to adverse events. A skillfully conducted dialogic conversation, with careful associated processes, will guide both patient/families and care providers alike, on a safe and meaningful journey through recounting and hopefully better understanding the events related to what may be often one of the most traumatic episodes experienced in their personal and/or professional life. Regardless of the success of an investigation in any empirical sense [in terms of its findings and recommendations], the exercise of the process itself will often have profound and lasting effects on the relative well being of all involved, through the cycles of grief and/or the course of careers. It will also provide excellent opportunities for investigators to refer participants to a wide array of supportive resources, in terms of counseling and otherwise.[24]

Other potential participants in the investigation process include the direct care providers (physicians[25], nurses, technologists, pharmacists) as well as any support staff who may have relevant observations or useful information. It is also important in many cases to invite similar direct care providers from a different unit or facility to provide some comments about what normally happens in a similar situation to the one that led to harm in the particular critical incident. The process of

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[24] *It is important to note that the SPHERE workshop is not suggesting that patient safety investigators become therapists or post-traumatic stress counselors. Rather they should appreciate the impact that the process of the investigation can have on all participants, in both positive and potentially negative ways.*

[25] *To a great extent this will depend on the extension of legal privilege to the activities of the review process team. Physicians are encouraged to participate in safety reviews by their medical defense organization (Canadian Medical Protective Association) and at the same time are cautioned about their responses if the activities of the review process are not accorded legal privilege.*

"making sense" of an event associated with unintentional patient harm starts with the assumption that healthcare providers come to work to provide care, not to produce injuries or harm. Colleagues from a similar background or unit can often provide insight into why a certain decision "made sense" given the information available at the time.[26]

It is extremely difficult for those providers directly involved in a critical incident to assess their own actions in a balanced and neutral way (indeed, there is a strong tendency for physicians and nurses to be very self-critical after an event associated with significant harm[27]). It is important to be aware of this tendency when meeting with involved direct care providers, and this is another reason why it is crucial for investigators to gather information from non-involved providers who can provide sense-making context.

Managers and administrative staff (who may be located more upstream at the so-called "blunt end" of the care provision process) will also be a useful source of information about policies, procedures, approaches, and traditions within a facility. When managers have a reporting relationship with the involved direct care providers they can certainly provide useful information but **should not be members of a safety review team** because of the potential conflict of interest[28].

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[26] *This is often referred to as the "local rationality" principle and is explored further in a later section. Dekker in his* ***Field Guide*** *(2004) describes this process of sense-making as "crawling inside the tunnel" to understand how the situation appeared to the providers at the time of and preceding the event.*

[27] *This is related to the concept of the "second victim", a term coined by Dr. Albert Wu.*

[28] *The obvious conflict of interest (COI) arises when an individual has a personal connection with any of the staff directly involved in the adverse event, or a personal interest in a certain element of the event. The less obvious COI arises when a direct care provider's supervisor is a member of the team—regardless of how confidential and privileged the discussions are, it is highly unlikely that a staff member will be comfortable providing information about an event,*

It is also important to think of the many sources of written and electronic[29] data, other than the obvious record of treatment and records from other facilities. Records from private pharmacies may be invaluable as will be alternative information sources (such as the Kardex[30] which often is destroyed after a patient's discharge and is not routinely considered part of the medical record). Other useful sources of information may come from websites of medical supply or pharmaceutical companies; the positions of licensing bodies and professional associations may provide important information about the expected way to perform certain procedures.

In some unusual cases it may be useful to consult an external consultant or to discuss with the safety review teams of an entirely different jurisdiction about their experience in similar situations. Systemic non-linear investigations are iterative processes and there are many useful sources of data that will become apparent and emerge as the investigation evolves.

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if that information then may be part of the performance evaluation. This manifestation of COI is **not well understood in healthcare**.

[29] *The development and expanded use of the electronic medical or health record [EMR/EHR] will be explored in greater detail during the workshop. Not only is the EMR/EHR a great source of information to providers it may also be a significant source of confusion and surprises (this phenomenon is sometimes referred to as "unruly technology"). At the same time, there will be some challenges for investigators as they learn about the way in which different software programs operate and interact.*

[30] *This is an extremely common situation in acute care facilities all across Canada. If a review team is named soon after a critical incident it may be possible to retrieve this source of data.*

Section (b): Building a Narrative Understanding

Gathering Data to Populate the Healthcare Landscape

The dialogue in Module 4, Section (b) will focus on the following questions and issues:

- What are the main differences in a dialogic versus traditional "interviewing" approach to gathering data from participants in a critical incident?
- How does the search for the underlying narratives lead to a richer understanding of the event?
- How are relational and emotional elements of the story allowed to emerge?
- Is "sense-making" a useful way to balance the risks of hindsight balance?

Allowing the story to emerge

This section will focus on the question of how to gather data through conversations with a wide range of participants (including the patient and family) involved in the particular event that led to patient harm.

But first, two comments. Typically, initial reports about occurrences and critical incidents are paper-based and involve selecting from a number of choices ("tick boxes") to describe elements of the event. It has become clear that a much richer[31] understanding comes from asking participants to "tell their story"[32]. This explains the emphasis, in SPHERE, on "narrative". The second point refers to the concept of "populating the landscape" around a particular event as a result of your curiosity and skills as an investigator. This process illustrates the concept of "emergence" introduced briefly in Module 3—your understanding will eventually emerge from the often non-linear combination of factors and elements.

The traditional way[33] to gather information from participants (healthcare providers, the patient, family, friends, content experts and other staff not directly involved) is

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[31] *You will hear about "thin" and "thick" explanations. Weightwatchers is definitely to be avoided when seeking to understand or make sense of an event ("thick" explanations are preferred!). This footnote as well as the one that follows reflect one of the important differences between quantitative and qualitative research methods. It is interesting to note that complexity science validates the value of developing a "rich" or robust understanding (such as a thick explanation) of an event in order to fully appreciate the context or environment within which the work was being done (i.e., care provided to the patient).*

[32] *This is the main reason that the only way to report a critical incident within WRHA (footnote 15) involves speaking directly to a 24/7 live operator phone line with a transcription of the "story" being the key element.*

[33] *I wish to acknowledge the insights and contributions of Catheryn Martens in the preparation of this section—her long career in healthcare including many years as a patient representative*

through interviews. In an interview we tend to fire out questions (that are often pre-arranged or part of a "routine" approach to a given situation) to the person being interviewed. You may already think you know the answer[34] and are confirming your first thoughts about a situation that needs some clarification. Even if you keep an open mind about the answers, using standardized questions tends to limit and narrow the way in which information is gathered and thus understood; this is very similar to the way that tick boxes function on paper-based reporting forms.[35]

A skilled safety investigator will learn to use open-ended questions and to wait patiently for answers and comments to promote an understanding of what was happening from the perspective of a particular participant.[36] This method is

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in a large tertiary care hospital provided profound understanding of the processes described.

[34] This reflects the important phenomenon of **hindsight bias***—a very common human tendency. Knowledge about the outcome of an event has an important impact on the way we think about the event as well as the types of questions we ask (remember WYLFIWYF). Linear methods of accident investigation, based as they are on a sequential chain of events foundation, have great difficulty mitigating the effect of hindsight bias.*

[35] It will seem paradoxical that an approach which seems to provide many options to gather information (for instance many questions in a structured interview or many tick boxes in a paper-based questionnaire) can have the contrary effect of narrowing the scope of information provided by a participant. This is similar to the Sherlock Holmes mystery that was solved by reflecting on what didn't happen ("the case of the dog that didn't bark in the night"). In the safety realm what didn't happen may be more important than what did happen and since the investigator was not present at the time it is rare that a preconceived list of questions will be able to anticipate and therefore uncover such factors.

[36] This is part of what Dekker describes as "getting inside the tunnel" with the operator or participant. This is also similar to the idea of the Second Story as developed by Woods and Cook. It is impossible to get a full understanding of what the direct care providers in a healthcare event that has harmed a patient were thinking without effectively creating space for the participant to recollect and reflect what they were experiencing at the time.

closer to the approach used in critical incident stress de-briefing and is useful in "surfacing" emotional cognitive elements that traditional interviewing techniques and approaches will miss.

In order to successfully gather "thick" data from participants we are suggesting that you enter into a **mini-dialogue**[37] with the participant; helping them re- construct their experience as you seek to understand the event. You may find places in the process where you reflect (hopefully silently!) "that shouldn't have happened" or "they should have done that test instead". These are examples of counterfactual reasoning[38] that reflect (again!) **hindsight bias** and limit the information that can be gathered. Instead, as the leader in this dialogue process, you may ask "How did that make sense at the time?" We can explore with participants what they were seeing and hearing, what information was being fed to them, what they saw as the most important information, and why.

As the safety investigator you may discover that the bits of data that could have helped transform the situation from harm to safety were present in the working environment of the operator[39] prior to the event. If it was available but not used you will likely be curious about whether the data was readily observable? You may also ask what would have made it more observable or, how might additional information have been more effectively made available to the front-line operators[40]?

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[37] *Isaacs and Senge (see bibliography) have written about this approach and the core components of dialogue—***listening, respecting, suspending,** *and* **voicing**.

[38] *See Dekker's* ***Field Guide*** *(2006) for a more in-depth discussion of this phenomenon which inadvertently builds judgment into what seems to be a simple information gathering process.*

[39] *Operator is a generic term used in most industries other than healthcare to describe an individual directly or indirectly involved in providing a service.*

[40] *The concepts of* **data availability** *and* **data observability** *are derived from a human factors analysis that is expanded in more detail in the human factors module. See also Dekker*

A useful mini-dialogue will be one where the participants can **make sense** of the event (see the classic ***Sensemaking in Organizations*****,** Weick [1995]). This may involve finding meaning in possibly banal details as the story begins to focus on a particular understanding. Just as a good diagnostician develops a differential list of possible explanations, a safety investigator will remain open to many options while looking for data and other evidence to support or enhance a particular understanding. If this understanding is revealed as being unsustainable then the exploration must continue.

For true dialogue to be possible, both parties must view themselves as colleagues, and colleagues without a power differential in the context of the conversation. This will ensure that you, as the facilitator, can move the dialogue along and keep the work going until there is some new understanding. This is not always an easy task and the workshop will use examples while exploring ways to reach this goal. Gary Klein's work (***Sources of Power*** [2002], and ***Streetlights and Shadows*** [2011]) is particularly useful and informative on this subject**.**[41]

In order to effectively gather data from participants, investigators must also be capable of recognizing the feelings of the front-line operators involved in the event; it may be equally challenging to acknowledge our own feelings which may limit our ability to hear and even accept the narrative that is unfolding (emerging)

(2006) and Woods et al (2010).

[41] Klein has done broad investigation of decision-making "in the field" as opposed to the more artificial laboratory setting which is the basis of many traditional "logic-based"decision-making theories proposed by cognitive psychologists. Klein refers to his approach as "naturalistic decision-making" and sometimes as "recognition-primed decision-making". This approach recognizes the importance of the broader context in which the frontline operator is actually making decisions (or not making decisions which may be even more important at times!). This could be considered "contextual decision-making" and is entirely consistent with complexity science concepts.

before us. The skills of a good listener are essential; to listen and to hear is to see the world from a place that is not your own. Your experience as an investigator may include some personal and professional challenges. Learning to ask the right questions and create the possibility of dialogue is not easy.

In this section of Module 4 you will have an opportunity to practice the dialogue process. You will likely discover that entering into a conversation or dialogue that is non-judgmental and curious in an open-ended way is harder than it seems. These skills are central to successful investigations and to mitigating some of the influence of hindsight bias.

Section (c): Mapping the event and developing a chronology

Creating Pathways to make sense of the data

The dialogue in Module 4 Section (c) will focus on the following questions and issues:

- Does the way in which data or information is displayed affect how it is understood?
- Does a linear chronology of events accurately reflect the narrative of that event?
- How can an event "map" capture some of the non-linearity and self-organization of a complex system?
- Can a multi-layered map of an event facilitate "capturing" the emergence of patterns?
- Why is it useful to use "time-equivalent units" for the mapping of events in complex adaptive systems?

Making the narrative visible and visual

Building a chronology of events is something that most healthcare professionals are comfortable doing; this has been part of a traditional history and physical exam that is recorded in the patient record. Indeed, the record of treatment is itself a chronology. So why should we focus more intently on this? There are a few reasons to think about this question.

The traditional clinical record of treatment presents data in a linear chronological way. The patient's record of treatment is completed, typically from top to bottom and from left to right, whether it is done manually or electronically. It is read in a similar fashion. This tends to encourage us to think about events in a linear fashion and inevitably we begin to make links about causation based on such a linear presentation.

Patient safety practitioners appreciate that multiple factors need to be considered in order to understand a particular event; thus the importance of contextual factors which can rarely be represented in a linear fashion. Elements such as social, organizational, environmental and human factors contribute to a broader contextual picture of an event. In spite of the growing knowledge that these elements often come together in unpredictable and non-linear ways we have continued to record them in a fairly traditional linear fashion. Unfortunately this method of data display[42] means that we sometimes miss out on the potential

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[42] *The concept of the "Mythical Iceberg Model" [which essentially supposes that critical incidents arise from the subset of serious incidents which arise from the subset of incidents, which arise from the subset of low harm occurrences which arise from the subset of near misses which ultimately arise from the category of "unsafe acts"] is discussed in some detail (Dekker et al, 2008) and the experience of "ultra-safe" systems (Amalberti, 2001) seems to indicate minimal connection or correlation between different categories of events.*

to make sense of how the many factors may have combined or interacted to contribute to the event.

A number of observers have pointed out that the way in which we display data influences the way we think about the events the data is drawn from—Davies [2003] and Dekker et al [2008] have made some interesting points about this. During this section of Module 4 we will suggest to you that the way in which you create your "event map" or chronology will significantly assist or limit you in gaining a more comprehensive understanding of the event leading to patient harm. In addition, the way that you choose to display data will influence your understanding of the non-linear relationships in the data collected.

We are proposing that you become comfortable using a multiple layer "scaffolding" that has the interesting property of letting you "bend" time to facilitate the display of data and as well as making sense of it. You are doing this, of course, to increase the relevance of your findings and associated recommendations in each case.

The initial time sequence will look very traditional with discrete events listed one after another across the top of the scaffolding. The events may simply be listed or may be identified with specific dates or times. As the underlying narratives emerge from dialogic conversations you will begin to identify specific episodes (for instance "initial clinical assessment", or "induction of anesthesia in the OR"). These episodes will be assigned the appropriate "time equivalent units" (TEU's)

for the events within a given episode. Some episodes can be fully understood on the basis of day-by-day TEU's, others will be more readily understood on the basis of an hour-by-hour TEU basis. In some circumstances the units may be even shorter (minute-by-minute). During the workshop you will look at examples of cases using different data display methods. You will start to map out various layers—at a minimum these may involve items such as the patient experience, the physical findings, the diagnostic investigations undertaken, and the treatment interventions.

You may also have layers in the investigation that identify unanswered questions or unexplained gaps that require further investigation, human factors issues and broader contextual issues that may change and evolve over time (environment, social, and organizational factors). Of particular importance in your investigation will be a clear identification of organizational **goal conflicts**[43] and these may merit a separate and distinct layer. These layers will provide a much richer "landscape" from which will emerge your understanding of the event you are investigating. Please refer to the two samples of a layered horizontal chronology that follow and modify according to your circumstances.

A final layer may reveal potential recommendations that are linked to the findings and broad context of the event that harmed the patient.

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[43] *The issue of* **organizational or social goal conflicts** *is an important one and reflects the age-old struggle in many complex socio-technical systems and industries between "protection" and "production". You will likely hear comments to the effect that "safety is never the only priority" which initially, in the healthcare context, may sound cynical but is in fact a reflection of reality. Surfacing these goal conflicts and understanding how they provide a broad social and organizational context within which an operator works and makes decisions is an important function of a safety investigation.*

Displaying the data on this kind of "scaffolding" may require special "props"—we are strong advocates of the use of large white boards during these SPHERE training workshops; there will undoubtedly be flexible electronic solutions as well.

Section (d): Identifying relevant Human Factors Issues

Finding gaps and building bridges

The dialogue in Module 4, Section (d) will focus on the following questions and issues:

- How does the field of human factors apply to critical incident reviews?
- What is the range of human factors categories that apply to healthcare events?
- How will investigators identify human factors issues relevant to a given event?
- Should a critical incident investigator expect to become a human factors specialist?

The scope of human factors in healthcare

There has been increasing interest in the field of human factors as it relates to healthcare safety and quality efforts over the past 15-20 years. This is due in large part to the initial work of Jens Rasmussen [Rasmussen, 1997] in the 1980's and then, somewhat later, James Reason in the 1990's [Reason, 2008]. In other industries, (aviation is the prime example but the comment also applies to the chemical and nuclear complex socio-technical systems) there has been sustained interest in human factors analysis for well over 50 years.

This interest and enthusiasm was stimulated by impressive (and very cost-effective) improvements in safety in certain complex systems. In general these improvements were identified by examining the working environment in which operators were expected to perform tasks and then delineating the extent to which those environments often demanded more from the operators than they were humanly capable of performing in a consistent manner[44]. This phenomenon was highlighted by the apocryphal Far Side cartoon showing a pilot in a cockpit in which the switch for "Landing gear goes down" is right next to the switch for "Wings Fall Off".

The interest in human factors roughly parallels the three industrial ages of safety identified by Hollnagel [2004]. We should perhaps not be totally surprised that healthcare is just starting to learn about the application of techniques developed in the second "age" (namely the human factors age) when attention in the study

[44] *The important human factors study by Fitts (1947) dramatically reduced the number of airplane crashes (and pilot deaths) observed in a certain type of airplane during the war (WWII) simply by differentiating the shape and position of the switches for raising the wing flaps and lowering the landing gear—confusion over the placement of the switches led to many instances of planes "landing" forcefully without the landing gear in place.*

of accident prevention in other complex socio-technical systems is shifting to an examination of the social and organizational contributing factors to major harm events.

We will explore during this section the three large domains that have historically been of interest to human factors specialists—the **individual**, the **social and organizational**, and the **environmental** areas. Depending on whether a human factors specialist has been trained in an engineering program (compared to a social or industrial psychology program) there will be more emphasis on the individual and environmental domains of human factors analysis and less on the social/organizational area. Generally speaking the reverse can be said for those trained in social psychology programs. At the present time in Canadian healthcare significant influence comes from human factors specialists with engineering backgrounds[45].

A large JCAHO[46] study on sentinel events (the definition is similar to that for critical incidents in Canada) in the US revealed that the most common identifiable contributing factors leading to unintentional patient harm relate to breakdowns in communication and collaborative team work within facilities and units. These breakdowns are clear examples of social/organizational human factors conditions identified above.

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[45] *The University of Toronto Faculty of Engineering has been a pioneer in this regard, stimulated in no small part by the leadership of Professor Kim Vicente.*

[46] *JCAHO = Joint Commission on Accreditation of Healthcare Organizations. Now simply JC And for more information go to* www.jointcommission.org

Another extremely important issue in the social and organizational domain of human factors analysis is the presence of **goal conflicts**[47] and the need for the investigator to understand how they are experienced by the operators and how they may influence decision-making.

The question of "environmental" human factors is an important one, especially when thinking of healthcare as an example of a complex adaptive system. Open living systems are constantly interacting and exchanging information with multiple broader environments. Most patient safety investigations have tended to ignore this area of human factors analysis, in part because it is very challenging to formulate recommendations relating to such factors. As will be seen in section (v) of this module, identifying human factors issues in the broad contextually sensitive "environmental" domain may provide some of the most useful understanding that emerges from an investigation.

A new and vital area for the investigator's concern is the Electronic Health Record (EHR) and its various associated electronic archives of data related to patient care (such as radiology images/interpretations or medication records). Just as an investigation required information from the bound paper chart and the skillful interpretation of its contents, we require now all manner of electronic history, and skillful interpretations not just of the data itself, but also detailed understanding of just how and when this information was available to or used by clinicians and indeed, how its use was integrated with non-electronic data (particularly during periods of transition when dual track systems are often in place).

Technology has changed the workplaces of modern medicine more than any other factor, and while it has reduced many types of failure, it has introduced new ones.

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[47] *These goal conflicts may be present at the individual, sub-unit, unit or facility level as well as at the broad system level.*

The EHR has introduced several direct and indirect[48] human factors challenges that may contribute to breakdowns in the provision of safe care. Dekker [2011] writes about this phenomenon, as he describes "The Substitution Myth":

> *The original idea behind many technological interventions is that technology can do a task better, faster, or cheaper than human beings. Technology is seen as one way out of the "human error problem". If technology does the work, then humans cannot make errors in doing that work. Or if there is technology that checks the human, then errors can be caught before they have any effects. This is the idea of substitution. Technology substitutes for human work. But the idea of substitution is a myth. The problem is that the introduction of new technology creates new human work. And by creating new human work, technology introduces new opportunities to do that work well or less well. With new technology, people will have to spend time remembering input modes or understanding display readings, for example. This creates new opportunities for error and new pathways to failure.*

Of course these concerns relate not only to the EHR but also to every element of technology used in healthcare and our ever-evolving relationship with these technologies will present ongoing challenges for investigators. The human factors "mismatches" which will be present for front-line providers adapting to new technologies may frequently be present for investigators as well. Knowing where to find advice that reflects familiarity with the new technology as well as the software that animates it will more and more become a necessity for investigators.

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[48] *The direct challenges concern the cognitive capacity to learn how to use and navigate through the EHR, as well as how to integrate its use into daily clinical practice; the indirect challenges relate to the ability to recognize the software designer/programmer's mindset in setting up multiple page views that may not logically reflect the way a clinicians have learned to organize data and to prioritize questions about the care of specific patients.*

As a patient safety investigator it is important for you to recognize that the field of human factors analysis is concerned with gaps or mismatches between the capabilities (perceptual, physical, or cognitive) of normal operators who are asked to perform tasks in various (usually under-specified)[49] social/organizational and environmental contexts. Your job as a PS investigator is not to become a human factors specialist but rather to become expert at recognizing the gaps and mismatches that are revealed (or emerge) during your safety investigation.

Identifying these human factors gaps and mismatches will assist you in formulating recommendations which will address the specific findings revealed by your investigation. You will be surprised at how practical and useful the recommendations may become when approached through a human factors lens of gaps and mismatches.

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[49] *The concept of* **under-specification** *is an important one and is explored in greater depth in Hollnagel's recent book* ***The ETTO Principle****. Under-specification is a very common characteristic of healthcare scenarios and events and is reflective of the nonlinearity and emergent properties of complex socio-technical systems. Unfortunately this feature is rarely recognized and we end up applying solutions that worked in highly specified situations, often with negative results. The concept of under-specification is a logical extension of the unpredictability and intractability of complex adaptive systems.*

Section (e): Generating Recommendations (or not)

Addressing gaps in the narrative and reducing the risk of recurrence

The dialogue in Module 4, Section (e) will focus on the following questions and issues:

- Does the formulation of one or more recommendations following an investigation reflect learning?
- How do you differentiate SMART recommendations from those that are not so SMART?
- Why bother making a recommendation that is unlikely to be implemented for practical or logistical reasons?
- What different types of recommendations might be useful in healthcare?
- Is it possible for a robust investigation to produce no recommendations at all?
- What do recommendations tell us (if anything) about the resilience of the organization where the critical incident took place?

From learning to change

When you have worked hard to make sense of a critical incident and have developed a set of "findings" to reflect your understanding of the event, you naturally want to propose solutions to the "problem(s)" which your investigation has identified. You may feel pressure from others in your facility or organization to propose one or more recommendations. Indeed, the investigation of a critical incident may seem to present a perfect opportunity for a unit or department to obtain some new technology, even if there is virtually no direct link between the technology and the findings of the review. Resisting such pressures are a particular challenge for PS investigators. Similar pressures may come from the political sphere, the media, and certainly from the affected patient and family. But finding changes that will make a difference is not easy and sometimes it may even seem as if there are no recommendations to be made[50].

There are a number of ways to look at recommendations. You will not be surprised to learn that most traditional linear investigation methods favour recommendations that fit well with the linear approach (see Dekker **2006**). These are often called **SMART** recommendations (SMART referring to specific, measureable, agreed, realistic, and time-bound). Unfortunately the SMART recommendations, in practice,

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[50] *At the risk of discouraging you, there is a strong debate within the system safety community about the value of recommendations that flow from retrospective accident investigations. There is an argument that the likelihood that the conditions that may have combined to result in a particular event would occur again is extremely low. There is still a good reason to conduct a robust systemic analysis—it may reveal some of the underlying characteristics of a particular complex system that makes it more resilient than others. As well, from a social justice perspective, we have a responsibility to undertake investigations about events which harmed patients even if we are not sure that the issues addressed by the recommendations are likely to recur.*

tend to focus most attention on short-term sharp end issues that typically involve the work of individuals. As a result, there is a tendency to move away from a systemic understanding of the event[51].

A systemic nonlinear analysis method encourages you to think about recommendations in a way that "fits" with that approach. These can be thought of as recommendations that make **SENSE** (or are perhaps "not-so-SMART"). Of course there is significant overlap as will be seen below. It is important to note that recommendations that make SENSE are not necessarily time-bound, and tend to shift the focus of attention from sharp end to blunt end factors. At the same time, the systemic nonlinear approach will explore organizational goal conflicts as important factors contributing to specific critical incidents.

At a very concrete level, it may be helpful to ask "what finding of the investigation is the recommendation trying to address?" To put it another way, you might ask "if the recommendation had been in place at the time of the incident would it have prevented the harm?" In other words, is the recommendation **specific** or **relevant** to the findings and understanding that emerged from your investigation? This is one area in which the different approaches to recommendations overlap—both linear and nonlinear approaches support the idea that recommendations should be **specific** to what has been revealed during the investigation of a particular case.

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[51] *The focus on SMART recommendations tends to have another confounding negative impact. There is a fairly broad consensus in the patient safety community that it is important to gradually shift the culture away from blaming individuals towards learning from events. This is not equivalent to having a "blame-free" culture, which is not appropriate and also not achievable. To the extent that SMART recommendations tend to shift the focus on sharp end individual findings and issues, there is a tendency to slide into a blaming perspective.*

Another way to think about this is to ask whether or not the recommendations are **shifting the focus from individual to systemic** issues, and from "sharp end" to "blunt end" issues. Are you addressing the behavior of individual operators (healthcare providers) or perhaps searching for a way to reduce the gap between the tasks or functions as designed (usually at the blunt end of the organization) vs. the work as actually done (usually occurring at the sharp end).

Another important aspect concerns the known **effectiveness** of the proposed recommendations. Some recommendations are known to be quite effective and there is a fairly clear spectrum ranging from **forcing functions** (most effective and therefore often the hardest to create) through **constraints** to calls for greater vigilance and alertness (known to be virtually useless). It will be helpful to make use of the evidence that has been accumulated in many complex socio-technical systems concerning what works and what doesn't.

You might also ask to what extent the recommendations **address underlying goal conflicts** (these could be at the organizational, unit, or sub-unit levels). In other words, did you get to a new understanding of the working environment by asking participants questions about the competing pressures they work under every day? Do you better understand how for some operators their focus does not change and safety is not compromised while for other providers the pressures were not even recognized and the effect only seen once harm was the result? Of course, goal conflicts are often not easily resolved and for this reason may not be easily identified when using a linear approach. By contrast, the systemic nonlinear approach actively encourages the exploration of goal conflicts, with respect to understanding events in complex adaptive systems.

One area in which there is overlap between the approaches concerns the value of establishing consensus about the proposed recommendations. You will find it

useful to do some active "reality testing" with both those colleagues who may be in a position to implement the recommendation(s) as well as those who routinely work in the same environment that produced the event you have investigated.

As you work through this section of Module 4 you will see that we are proposing **three levels** of recommendations, some of which probably don't even feel like recommendations!! In a sense, the systemic nonlinear approach will encourage you to explore the boundaries of recommendations in order to reflect the range of factors that are influencing complex systems in particular cases. We believe that distinguishing these different levels more fully reflects a systemic understanding of safety issues and the events that lead to patient harm.

The **first level** concerns those recommendations that can be directly linked to one or more of the findings of the safety review. The fact that these are linked to specific findings does not mean you will necessarily find it easy to identify or formulate the specific initiative that will address the gaps revealed by your review. We are suggesting that these be called "**Locally Actionable Initiatives** – LAIs"[52]. These tend to approximate the traditional understanding of what a recommendation should do—for instance the SMART recommendations.

The second and third levels are more challenging. The **second level** involves those proposals which make good sense, are connected to the contributing factors identified during the investigation, and would likely have made a difference if in place at the time of the event AND which will take a long time to put in place, usually for resource reasons.

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[52] *Special thanks to Wrae Hill from the Interior Health Authority in British Columbia for this suggestion.*

For instance, a recommendation that suggests re-instituting a training process for pathology technologists may not see the light of day for years. However, if we honestly believe that the identified lack of such technologists contributed in an important way to the patient harm event, then surely we must raise the issues. We might call these second level recommendations "**Long term proposals**". Getting to this kind of proposal is analogous to asking yourself "can I make a recommendation that may not be implemented for some time and that asks those decision makers in positions of power, who may be exerting pressure, to understand that sometimes change requires long-term vision?"

These second-level recommendations offer an opportunity to gain insight into the relationships and patterns of responses that emerge as overlapping complex systems interact with one another and with the environment within which they operate. Often the boundaries between systems and around systems are mobile, flexible, and permeable. In other words, one reason that these recommendations may not be simple to implement (aside from obvious concerns related to resources) is that they involve the often unpredictable and sometimes unknowable elements of a complex adaptive system.

The **third level** (almost at the 50,000 foot level—get the oxygen out!!) we can think of as "good questions" for which there are no immediate answers or "quick fixes". These may be related to ethical questions or even broader issues related to societal priorities. It may seem silly (as in, not very SMART) to even think of them as recommendations, and yet these often arise from the work you have undertaken in trying to make sense of the choices made by frontline operators and direct care providers who simply want to keep patients safe. An example of such a recommendation would be the formation of a multi-sectoral inquiry

to evaluate the impact of the teaching hospital setting on PS issues. The label proposed for these recommendations is "**Reflective consideration**"[53].

These third-level reflective consideration "recommendations" offer an opportunity to begin to understand how a complex system is less resilient than desired (at the organizational level). As you will see in Module 5, this is an important bridge from the circumstances of individual or particular events that have led to unintentional harm to the broader system(s) within which this has occurred. That kind of bridge and the understanding that comes from walking across it will provide significant possibilities to influence the healthcare system in ways that will benefit patients, providers, and the broader community.

What if you have finished an investigation and cannot find anything worthwhile to recommend? It may happen and you may take solace that at least you were not asking people to focus on changes that may, in fact, not make the experience safer for the next patient. Sometimes this arises from the uncertainty and unpredictability of nonlinear relationships within complex socio-technical systems; in spite of your best efforts you may not have identified an understanding of "what happened" that would lead to recommendations.

Sometimes however, if you can't identify a gap and see a direct connection from that gap to a potential recommendation then perhaps you have to keep asking questions and trying to find why the choices that were made seemed like the best option at the time. In other words, keep trying to make sense of the event.

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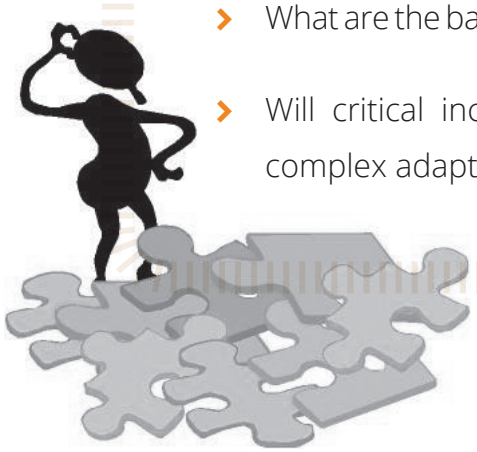
[53] *Special thanks to Ryan Sidorchuk for this suggestion.*

Module 5
Evaluating Patient Safety Efforts

Which pathway should we follow to create a more resilient (and safer) healthcare system?

The dialogue in Module 5 will focus on the following questions and issues:

- First, remind yourself why you are doing this kind of review of healthcare events (remember WYLFIWYF?).
- How can you evaluate whether your findings and recommendations were appropriate in a given case?
- What is the connection between individual healthcare events and the resilience of the system itself?
- What are the basic organizational elements of a resilient system?
- Will critical incident reviews and investigations help make complex adaptive systems more resilient?



Valuing the work of healthcare event reviewers

Reviewing healthcare events (especially those leading to significant unintentional patient harm) is among the most important and challenging work you can undertake. These events are frequently very difficult to investigate because of the profound human dimension—the obvious impact for the patient, the family, the providers and their colleagues and the system as a whole which may often be seen in a less trusting manner by others. It seems entirely reasonable to ask the question then "Are we making a difference?"[54]

Perhaps the first question to ask is "What would a difference look like?" After all, the harm has occurred, the patient has been injured (and sometimes has died), the family has often been traumatized, the healthcare providers have also been significantly affected and the system as a whole has been called into question. The various harms cannot be undone. To the extent that the critical incident investigation can provide answers and explanations about what happened AND can demonstrate that the learning has been shared with other units, facilities, and regions, then something positive will have occurred[55]. This can be measured through appropriate qualitative assessments and research.

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[54] *An interesting review article (Landrigan et al, 2009) asks this question more globally, ten years after the publication of the IOM report* ***To Err is Human*** *in the U.S. The conclusions may be interpreted as suggesting that ample challenges remain for PS practitioners well into the next generation!*

[55] Depending on the legislation in different regions, as well as the cultural "comfort level" of the organizations, it is important that the results of an investigation be shared as fully as possible with the patient, family, and providers. A commitment about sharing the findings and recommendations of an investigation should be made by the senior leaders of a given region or

It is possible that the impact of critical incident investigations can be reflected in changes in the rate of reported events in a given facility or region. This is significantly problematic in North America at this time given the abysmally low level of reporting that is common in most jurisdictions[56]. While this kind of quantitative measurement of the impact of critical incident investigations on reporting rates should be pursued, there remains significant doubt in the system safety community about the overall utility of such reviews and investigations.

There is an excellent reason to think that sharing the stories and narratives associated with healthcare events will provide important impetus for change. The narratives not only provide a powerful voice for patients and families but also provide a window into the patterns of interaction and the relationships that exist within a complex system. This knowledge, and the understanding that it stimulates will provide examples of how better to influence the system so that in the future, patterns will emerge that create fewer opportunities for unintentional harm for patients. This knowledge will provide insights into the level of resilience of the broader organization and will suggest ways to modify activities, policies, and values to strengthen that resilience.

The field of resilience engineering has grown in the past decade[57] and based on experience gained in many fields and industries has developed an understanding

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facility. Mechanisms should be found that will also allow broad sharing of de-identified summaries of events with other healthcare regions.

[56] *The general consensus seems to settle on a figure of 2-8% reporting of the projected/expected number of critical incidents in healthcare facilities in North America. At one point, the acute care sector of the Winnipeg Regional Health Authority reached the level of approximately 30% of the expected number of cases, based on the earlier cited Canadian Adverse Event Study.*

[57] *See multiple references (Hollnagel et al [2006], [2008], [2011] and Nemeth et al [2009])*

of the main elements that allow for the assessment of organizational resilience[58] in a given instance. The four main elements include **responding** to an event, **monitoring** the ongoing status of the system, **anticipating** future potential disturbances to the system and **learning** from particular disturbances or events that have led to harm.[59] Elaboration of these concepts and how they might be usefully applied to healthcare are extremely important tasks facing healthcare in Canada in the new millennium. That, of course, will have to be the subject of much research and dialogue and will also form the subject of a future HSSA workshop, on the topic of organizational resilience in healthcare.

One of the leaders in the field of Resilience Engineering, Erik Hollnagel, has asked a question that is very relevant to PS investigators and in particular to those who are applying a systemic non-linear approach to their investigations. The question goes something like this: "Why should we restrict ourselves to studying only those things that go wrong? We can and should learn from all of those situations when things go right." Front-line operators in complex adaptive systems like healthcare face the same circumstances in their work regardless of the outcome. These include inadequate time, resources, pre-conditions, and controls all in frequently under-specified environments. In spite of these limitations front-line operators create safety ("things that go right") far more often than not.

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[58] *A generally accepted definition of resilience refers to the* ***ability of an organization to respond to significant disturbances or disruptions in a way that allows the return to a required level of functioning in a timely manner with mitigation of the impact of the disturbance on the system and its components.***

[59] *Internationally there is good reason to be optimistic—a Resilient Health Care Net was formed in late 2011 and a first international symposium on Resilience in Healthcare was held in Denmark in June 2012 with 35 participants from more than a dozen countries.*

The main value in applying systemic non-linear approaches to the review of critical incidents may very well lie in what we are able to learn about the broader context in which the work is being done—in other words may help us to understand the extent to which the elements that promote organizational resilience are more or less present in a given complex system. Imagine then the advantage of applying systemic non-linear approaches to the vastly more frequent "things that go right" in terms of improving our understanding of organizational resilience!

Many questions have been asked about the extent of accomplishments in the PS domain, in a much broader sense. The present module addresses the general question of evaluating the impact of critical incident reviews and it is encouraging that there is a link between that work and the potential of strengthening the resilience of healthcare organizations. After more than a decade and the deployment of significant efforts and the investment of resources can we see progress in the field of patient safety? Initial reports (Landrigan et al, 2009) have been very tentative in drawing conclusions. Some feel this is because the changes required will be generational in scope and will not happen in a mere decade. Others feel quite strongly that evidence of progress will be hard to find and "measure" if we continue to look at the systems in which we work in a linear fashion and use methods of inquiry that are limited to quantitative techniques.

And possibly, as Hollnagel has suggested, we are quite simply asking the wrong questions and should be focusing our efforts on coming to a greater understanding of the resilient characteristics of complex social organizations like healthcare. Instead of asking "Are our reviews and their recommendations making a difference to patient safety?" or even asking "What woud a difference look like?" we should instead be asking "how can we influence healthcare to become more resilient, thereby promoting the delivery of safe and quality services to patients?" The SPHERE workshop is one part of moving in that direction.

Afterword

The SPHERE Workshop is part of a larger effort on the part of Healthcare System Safety and Accountability to apply systemic non-linear thinking to other aspects of healthcare system design and implementation. While the emphasis is on patient safety, the approach can be applied to other domains within healthcare.

The initial SPHERE Workshop is supplemented by several others:

- Disclosure of Unanticipated Medical Outcomes (created by the Institute for Healthcare Communication)
- Human Factors in Patient Safety
- Systemic non-linear Approach to Risk Assessment
- Organizational Resilience in Canadian Healthcare

These workshops will be offered periodically in different locations (please refer to our website www.hssa.ca) and can also be customized and presented locally to respond to the needs of particular facilities.

The Associates of Healthcare System Safety and Accountability have many combined years of experience in reviewing and evaluating healthcare events as well as situations from other safety critical organizations and systems. We are ready to assist in leading specific investigations that may be particularly complex, challenging or sensitive for local investigators. We are also prepared to provide distance mentoring for local investigations and reviews.

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