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What's inside

The Patient Safety Mandate

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The spotlight is increasingly on patient safety, quality assurance and risk management. How can you roll these three evolving mandates together into one meaningful portfolio? What are some key design features that you need to pinpoint?

Key Features of a Comprehensive Patient Safety, Quality & Risk Management System

Determining your goals is the first step to developing strategic direction and a functional framework. This is particularly the case now, as LHIN's are unfolding at the governance level. What do **you** need in order to make **your** system work for **you**? How will you decide? Who will approve the decisions? With your steering committee in place, you are ready to plan your system.

The major planning imperative is compliance with legal, medical, accreditation and professional requirements and standards. Legal requirements are found in statute and common law, and determining which ones apply and how they apply to you, are issues best determined in consultation with legal counsel. One element, for example, that forms part of a comprehensive patient safety system, is quality of care reviews. These may be conducted via the legally prescribed process under the *Quality of Care Information Protection Act (QCIPA)* when indicated. Medical considerations include a number of initiatives that impact patient safety. Canada's "Safer Healthcare Now" strategy is one that builds on the U.S. "100,000 Lives" campaign. CCHSA services, including their defined patient safety goals and organizational practices, along with professional licensing body standards and other standards (e.g., the OHA's Patient Safety Support Service, Hospital Scorecard, balanced scorecards) may be considered during the planning phase. Many elements of a comprehensive system, e.g. disclosure, draw from several of the above.

Planning is the time to consult with others, to benchmark, and to develop the indicators that are most meaningful in the circumstances. It is the time to build in accountability, and to ensure that the major challenge – change management – is addressed. A change management plan is crucial; some things will change as time goes on, and planning advance how to address them affords enhanced ability to control them when they occur.

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Designing the System

Many factors can impact on the design of a comprehensive system. Communication is key. While system components such as communication and rapidly changing technology come easily to mind, others, such as human and cultural factors, educational and systems features, may escape ready notice. Tools such as questionnaires and surveys may help bring these to the fore.

Some consideration may also be given, during the design phase, to the potential use of such strategies as root cause analysis, and failure modes and effects analysis. The former is usually considered a reactive technique employed retroactively following an adverse or sentinel event to learn "what happened" and is frequently associated with risk management. The latter is generally perceived as a proactive strategy used to learn "where a process might fail" and is more commonly associated with the quality side of the coin.

Once designed, the system needs to be rolled out strategically. An initial pilot is usually followed, after any challenges have been corrected, by implementation on a staged basis. Follow-up evaluation and continuous monitoring are critical to ensuring that a coherent system is sustained.

This necessarily very brief overview touches on only a few of the many elements to be considered in the design of a comprehensive and effective patient safety, quality and risk management system, and needs to be supplemented by the many resources available.

Taming the "Lockbox"

Barbara Watson, LLB, RN, BA, PhD (ABD)

The thought of having to develop a fully functional lockbox is creating a lot of angst for a lot of Ontario hospitals. The lockbox is law. Common law principles that address personal health information in Ontario are now codified to a large extent. The bulk of these now fall under the *Health Information Protection Act*, the statute that includes the *Personal Health Information Protection Act (PHIPA)* and the *Quality of Care Information Protection Act (QCIPA)*. Public hospitals were granted a one year "grace period" to comply with the lockbox provisions of the legislation. That grace period has expired.

The term "lockbox", not defined in *PHIPA*, refers to hospitals' attempts to give effect to patients' instructions not to use or disclose to specified persons their personal health information (PHI) for healthcare purposes without consent. Patients may withhold or withdraw this consent. Attempting to translate lockbox law into hospital policy and procedure presents many challenges, some to be discussed below.

Translating Lockbox Law into Hospital System: Factors to Consider:

How can you ensure legislative compliance and minimal risk as you comply with lockbox provisions? Developing your system involves several steps that can be envisioned as follows: planning, initiating, implementing and controlling the design of the system. In planning, you consult best practice guidelines to ascertain clearly defined goals and to plan your approach, including the scope

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Taming the "Lockbox"

and timeframes you wish to adhere to and the risk you will accept. Planning allows for control; any feature not planned for becomes either a scope creep or a risk event. During your initiation phase, various tools (incident reports, accreditation results, etc.) can be employed to help you assess your current PHI-related documents and practice, as you conduct a gap analysis to identify inconsistencies and the legal risks they present. Tools, such as a risk rating matrix, may be used to design the plan. The plan should include: legally compliant and professionally workable strategy and process that can live into the future (e.g., in the event of legislative change); and policy documents and associated templates that incorporate your strategy and process. The next phase is implementation, in which you pilot your plan in what is essentially its first test, and then roll it out strategically on a staged basis, revising as necessary. Controlling involves ongoing monitoring and evaluation to ensure that your goals, initial and changed, are met. There are many decision points throughout this process.

The major challenge is translating lockbox law into policy and procedure is to design a process with the requisite capabilities. Putting the lockbox process in place involves implementing a number of measures that can be broken down roughly into three areas: physical, organizational and technological. Physical methods involve a range of items from locking drawers to managing remote access. Organizational measures may range from establishing security clearances to providing information on a "need to know" basis. Technologically, hospitals are looking at measures such as passwords and database linkage with its ability to transfer PHI. These types of measures are increasingly important in this era of hospital amalgamations and LHINs.

Many questions need to be considered, among them: Who should have access to PHI? To what extent? How do they obtain access? Where do agents and recipients fit in? Who decides? What happens when staff change jobs to work in other programs or sites? What about ensuring that PHI is not visible to those who do not need it to provide care? Do patients realize that locking their chart may cause treatment delays (though not always)? Do they understand that locks must be overridden in some circumstances? What method will you use to inform them? How do you manage breach? Who is accountable, and what are the lines of response? In sum, what are the best practices to follow?

While I have considered some of the fundamental elements required to tame the lockbox, many others are necessarily beyond the scope of this brief essay. Let me finish with some further very critical elements: to develop an effective comprehensive lockbox system requires commitment from senior executives and the Board, buy-in from the staff, built-in accountability and clear lines of communication.

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Incident Reporting – Too Important to Ignore!

An incident reporting system (IRS) is a fundamental component of any risk management program. An IRS helps an organization capture event data that is necessary to analyze trends, prevent similar circumstances from reoccurring and provide notice to the insurer of an event that may lead to a claim.

What is an Incident?

An incident can be defined an any condition, occurrence or happening that deviates from normal operational routine. It is an unplanned event that is inconsistent with the routine and the safe operation of the business/institution.

What information should be captured?

- Identification/contact information – name, address, telephone number, E-mail address, witnesses.
- Personal details – age, gender, marital status, employment status
- Location of loss – should include weather, housekeeping details at the time of the loss\
- Description of incident – a concise description of what happened

Who should be responsible for completing an incident report?

Incident reporting must be understood to be part of the job responsibility of all staff including management; full-time or otherwise.

When should an incident report be completed?

As soon as possible after an accident has occurred.

When should an incident be reported to the insurer?

The Conditions section of the Hospital Medical Malpractice Liability Policy reads:

> ### Notice of Occurrence or Accident:
> When an occurrence or incident on which a **claim** may be founded takes place, notice shall be given by or on behalf of the **Insured** to the Insurer or to Frank Cowan Company Limited or any or its authorized agents as soon as practicable. Such notice shall contain particulars, sufficient to identify the **Insured**, and also reasonably obtainable information respecting the time, place and circumstances of the occurrence or incident, the names and addresses of the injured, and particulars of the injuries, and the names and addresses of all witnesses.

An effective IRS is not only fundamental to an effective risk management system, it is also important to meet the insured's obligation under the insurance policy. By meeting this obligation, their Insurers can give prompt and efficient service to the client.

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