



Healthcare QUALITY & SAFETY Management

Sample Scenarios

A companion document to the
Healthcare Quality and Safety Management Framework.

July 2017

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Introduction

This is a companion document to the Healthcare Quality and Safety Management Framework (HQSMF). The HQSMF describes the rationale and reason for considering quality and safety management as distinct but interlinked constructs and provides details about the three components that make up the framework: the **System Design Model**, the **Harm Response Model**, and a set of six Enablers (Appendix I).

This document was designed to guide users of the HQSMF on the practical application of the System Design Model and the Harm Response Model elements. Three sample scenarios were created for this purpose; the scenarios are broken down into the different phases of the System Design Model and the Harm Response Model. Key functions of each phase are highlighted in **bold** type. In addition, shaded text boxes are used to emphasize important points and tips for the successful completion of the phases.

Scenario 1

Using the System Design Model In Continuing Care

For people who live in long-term care the international resident assessment instrument (interRAI 2.0) provides a standardized initial assessment of their needs and then a routine assessment of their function, health, social support, and service use every three months. The routine assessment of residents using the interRAI 2.0 creates longitudinal, valid, reliable data about residents in long-term care that can be monitored over time. The following scenario example of a hypothetical long-term care facility, Pine Pass Continuing Care Centre, shows how the System Design Model could be used in this sector of the healthcare system. Pine Pass provides long-term care through a contract relationship with the health authority.

PHASE 0: GOALS, VALUES AND GUIDING PRINCIPLES

Define and use to influence decision-making

The mission of the Pine Pass Continuing Care Centre is to enrich the lives of residents by providing person-centred care and continuous improvement of the quality of care. The Pine Pass vision is to be known as the home where residents want to live and the place where staff choose to work. Pine Pass Continuing Care's **values** are CARE: compassion, accessibility, respect, and excellence.

PHASE 1: HEALTHCARE ENCOUNTERS

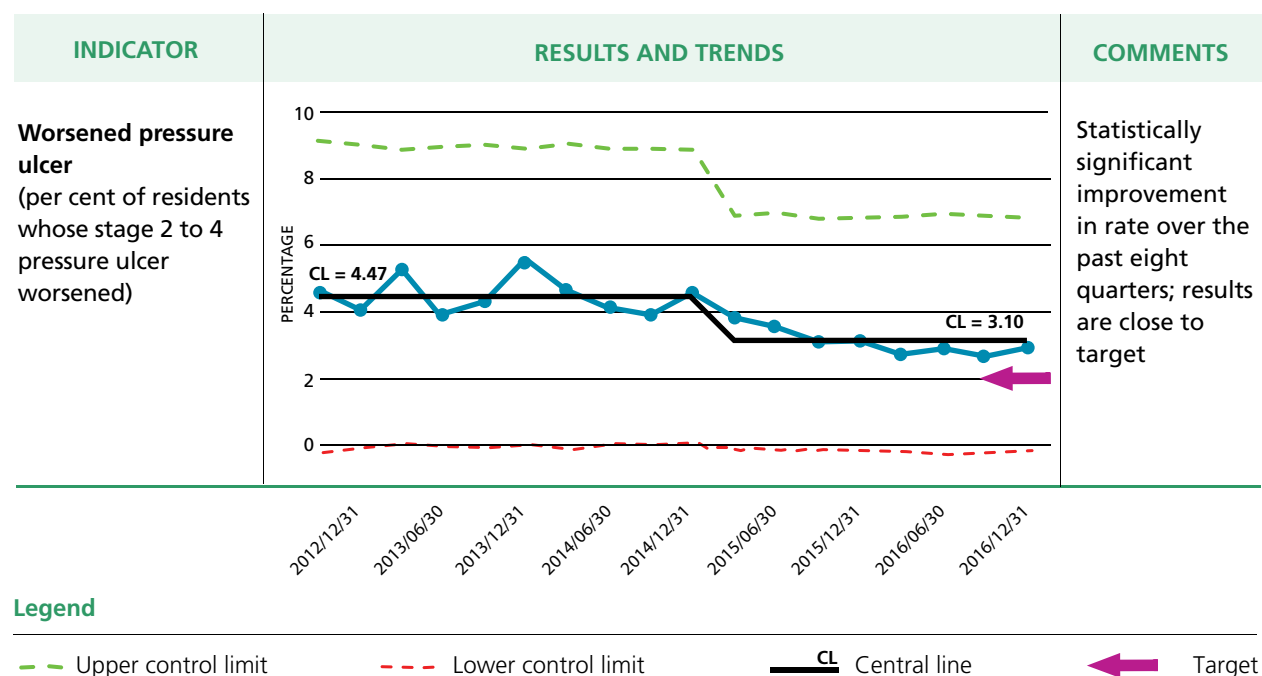
Measure, Monitor, Evaluate

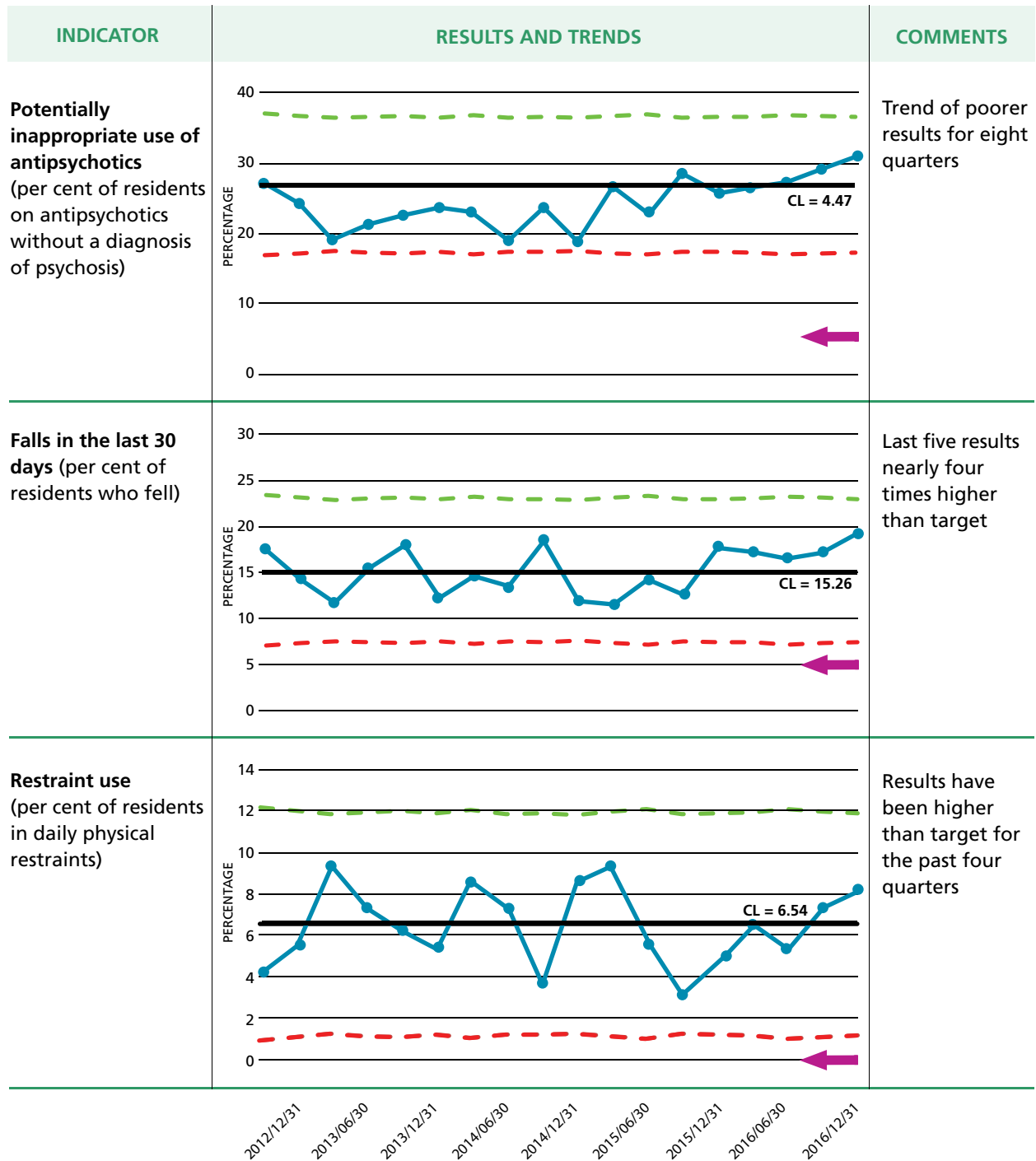
Pine Pass Continuing Care Centre uses a dashboard of quality measures that its Quality Committee regularly monitors (Table 1). Some of the indicators are from their interRAI data, some originate from data supplied from the health authority, while others are from a family experience survey. The dashboard includes organizational targets for performance (arrow). Pine Pass can benchmark to national results and best organizational performance in Canada by comparing their results to those published by the Canadian Institute for Health Information. The quality data acquired through the quarterly interRAI assessments and data acquired from the health authority has produced enough data points going back several years to report the results in a statistical process control (SPC) chart. This allows the Quality Committee members and others to see the degree of variability in results over time and determine if there is common cause variation or special cause variation. It also allows data trends to be seen, determine if they are statistically significant, and quickly understand how close or far away from the target the results are.

Family experience surveys are only completed annually so there are too few data points to produce an SPC chart. However, it is still useful to display the results in a run chart that shows variability and trends over time.



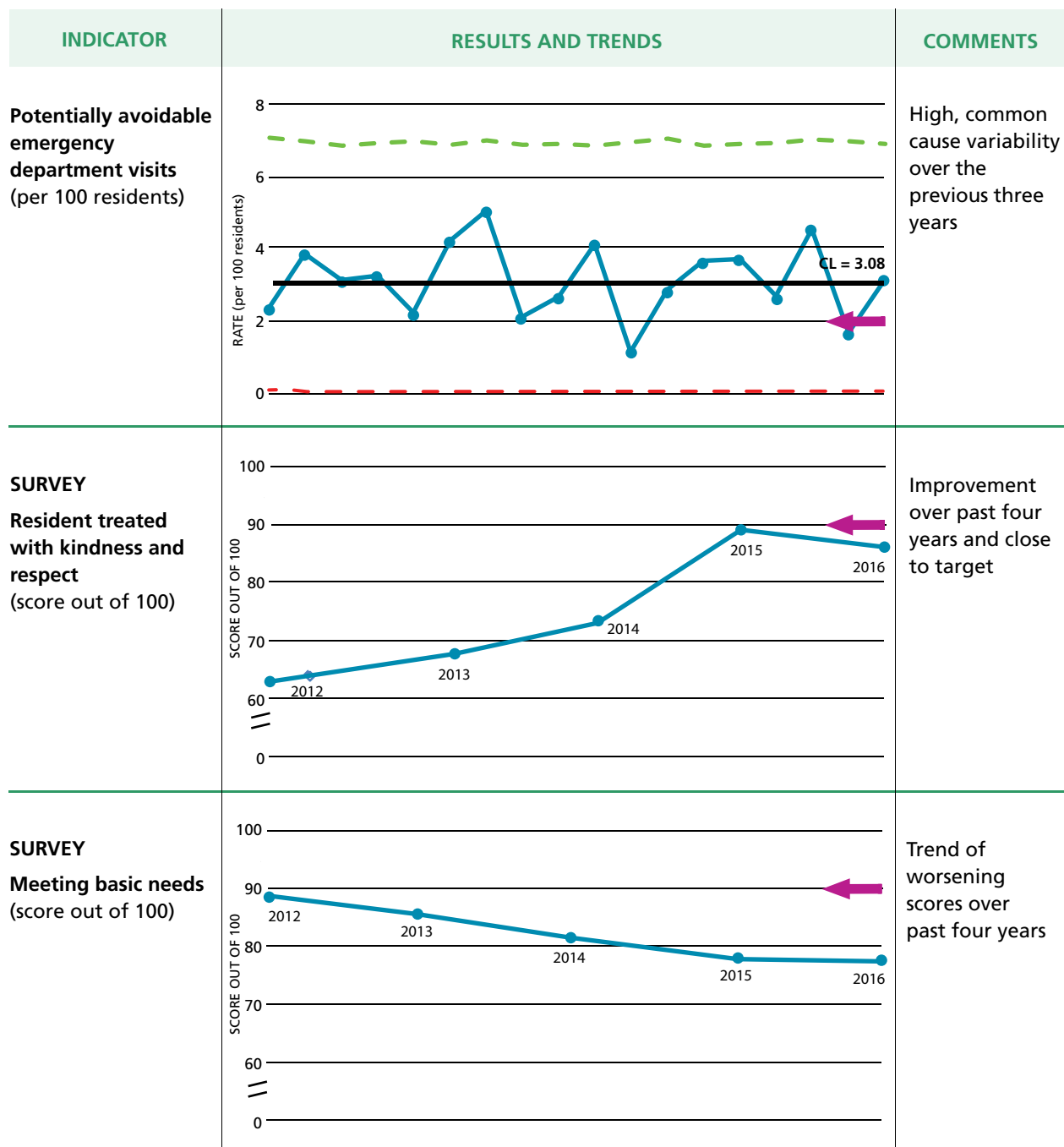
Table 1: PINE PASS CONTINUING CARE CENTRE KEY QUALITY INDICATORS





Legend

-- Upper control limit
 -- Lower control limit
 CL Central line
 → Target



Legend

-- Upper control limit
 -- Lower control limit
 CL Central line
 ← Target

Total number of residents during latest reporting period (denominator): 193

Number of respondents to last survey: 138

IMPORTANT POINTS AND TIPS

- Have clear unit and/or organization goals and values; this will help to guide decision-making about the most important opportunities for improvement.
- There are several 'internal inputs' that help to identify important issues or hazards that units or organizations can use, including key indicators that make up a quality and safety dashboard (Table 1).
- A quality and safety dashboard should have important outcome measures that answer the question 'What are we trying to accomplish?' as well as important process and structural indicators which are the major contributors to the outcomes.
- Outcomes can be clinical, functional or experience-based; cost can also be an important metric so that value of the services provided can be evaluated.

PHASE 2: ISSUES/HAZARDS → OPPORTUNITIES

Identify → Prioritize

The data in the dashboard highlights several improvement opportunities. The Pine Pass Quality Committee, which includes three people from the Resident and Family Council, **identified** indicators where the trend had been worsening or that were worse than the national average. These included potentially inappropriate antipsychotic use, falls, emergency department (ED) visits, rate of restraint use, and the *meeting basic needs* survey results. To **prioritize** these opportunities, the Quality Committee looked at the opportunities that would best enhance the safety and the experience of residents, by conducting the following exercise:



1. Committee members were asked to rate each identified issue or hazard using two five-point scales. The first scale was an estimate of how many residents were likely to be affected by the issue or hazard (*1 – very few to 5 – almost all*); the second scale was an estimate of how severely those residents who were affected would likely suffer (*1 – very little to 5 – very severely*).
2. Committee members were also asked to rate the likelihood that an issue or hazard could be substantively improved; another five-point scale was used (*1 – quite unlikely to 5 – very likely*).
3. Before the committee meeting where the prioritization rating would be completed, the resident and family members of the Quality Committee set up an online survey that asked respondents how important each issue was to them. Using a modification of the scales described above, they emailed each Pine Pass resident and/or a family member asking them to complete the survey. The information was used to help the committee members rate each of the issues.
4. At the Quality Committee meeting, each member rated each issue or hazard using the three scales described above. Scores for each of the three scales were averaged and then these average scores were multiplied together.

The results were sent to the Resident and Family Council and to the Pine Pass Executive Committee for review and approval. The two prioritized issues believed to represent the best opportunity for improving resident outcomes were resident falls and ED visits. The Quality Committee had also researched these issues using both external and internal sources. They were aware that fall-related injuries were a leading cause of injuries for seniors in Canada and the second-most frequent reason for the residents of Pine Pass to have to go to the ED. Resident falls was the top concern of the Resident and Family Council. The Quality Committee also learned that the procedure for managing any resident who fell was to call for an ambulance to transport that resident to the ED for a physician assessment, X-rays, and medical intervention, if required. Pine Pass had received seven complaints in the past 12 months from residents who had been taken to the ED after falling about how long they had to wait for the physician assessment and X-rays.

PHASE 3. PRIORITY OPPORTUNITIES

Analyze → Understand

In addition to the information provided from the quality dashboard, the Pine Pass Quality Committee reviewed information from their safety reporting system related to falls. Reading the narrative stories from the safety reports over the previous 12 months helped to identify that several residents had fallen when walking to the bathroom. In addition, they **analyzed** the data on the time of day that the residents were falling; 63 per cent of recorded falls occurred in the period from 6 a.m. to 8 a.m.

Further analysis involved reviewing, in more detail, the interRAI 2.0 data on the residents' self-performance related to toileting.



Table 2: INTERRAI DATA ON RESIDENTS' TOILETING NEEDS

Levels of self-performance toileting	Number of residents	Per cent	Cumulative per cent
Level 0. Independent	15	18.75	18.75
Level 1. Supervision	17	21.25	40.00
Level 2. Limited assistance	27	33.75	73.75
Level 3. Extensive assistance	13	16.25	90.00
Level 4. Total dependence	8	10.00	100.00
Total	80	100	

The Quality Committee found that more than 80 per cent of residents required some level of supervision or assistance with toileting (Table 2). The Quality Committee hypothesized that residents who required supervision or assistance may be attempting to go to the bathroom on their own, placing themselves at an increased risk of falling.

The Quality Committee reviewed data on the last 20 residents who had fallen and were taken to the ED for an assessment by a physician and X-rays. One resident had suffered a non-displaced hip fracture and was admitted to hospital for management. One resident had a non-displaced wrist fracture requiring a cast, but did not require hospital admission. One other resident had suffered a cracked rib and was discharged from the ED. The other 17 residents required no medical intervention and were able to return to Pine Pass after the physician assessment and X-rays were completed.

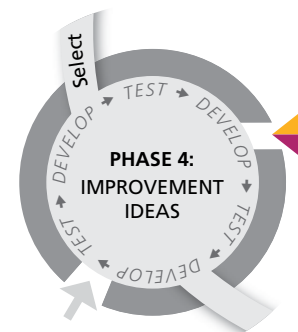
IMPORTANT POINTS AND TIPS

- Creating clear and defensible criteria that can be used to judge the relative merit of one quality issue or safety hazard to others is useful to accomplish the important task of prioritization.
- It is appropriate to ask in Phase 2, “How do we know this issue or hazard is high priority?” Assessment of the magnitude of the issue or hazard for residents is an important criterion when deciding what to prioritize.
- Often additional information is required to further understand the factors that most contribute to the identified quality issue or safety hazard that was identified in Phase 2.
- This in-depth understanding will often identify strategies to improve the quality issue or to mitigate the risk from an identified quality issue or safety hazard – these can then be tested in Phase 4.

PHASE 4: IMPROVEMENT IDEAS

Develop → Test → Select

While the Pine Pass Quality Committee recognized there are numerous strategies to consider in planning improvement in fall risk, the committee chose to also study the role of medication, to take advantage of the improvement work already taking place on their dementia unit. Here they hypothesized there could be a correlation between the use of antipsychotic medications and falls. In their dementia unit, which had the highest rate of falls during the study period, a new training program on how to manage resident behaviours using a non-pharmacological approach had been introduced after initial **testing** showed promising results. The initial test resulted in a 20 per cent reduction in antipsychotic medication use on that unit over three months, and the number of residents reported to have fallen decreased slightly. However, the time frame had not been long enough to draw definitive conclusions from the results.



A **search** of published and grey literature highlighted several other potential improvement ideas: (1) healthcare aides proactively check in with residents in the morning about getting up to the bathroom, (2) remind residents in the evening to call for assistance when needing to get to the bathroom, (3) develop a schedule for bathroom assistance and share this with healthcare aides and residents, (4) get residents to use walkers to assist them in ambulating to the bathroom in the morning, and (5) use a motion detector-activated light in the residents' rooms and in bathrooms to improve visibility.

With the goal of reducing their fall rate, the staff from a non-dementia unit decided to **test** ideas specifically targeted to residents falling when they arose in the morning and were walking to the bathroom. A plan-do-study-act (PDSA) cycle was designed to **test** the idea of verbally reminding residents in the evening to call for assistance in getting to the bathroom in the morning. One evening they reminded 10 residents who were at a toileting level of 2 and 3 to call for assistance the following morning. They predicted that nine of the 10 would follow through. The next morning only three residents called the staff. The Quality Committee's analysis was that this idea by itself was not successful; therefore, they tested additional ideas.

Another test of change was to have a healthcare aide offer assistance to residents in the morning with their walk to the bathroom. All five residents who were part of this PDSA cycle positively responded to this offer. However, one of the barriers identified was that many residents wanted to get up at the same time as staff shift change. Therefore, in another PDSA cycle, healthcare aides' shift times were changed by half an hour, to ensure that more aides would be available when residents were getting up to go to the bathroom. The initial test worked, so additional testing was done on different days (weekends, for example). After many PDSA cycles and testing multiple ideas under different conditions, the Quality Committee elected to **implement** two of the improvement ideas: (1) reduce antipsychotic use to manage resident behaviour, and (2) increase the availability of healthcare aides in the morning to help residents to the bathroom.

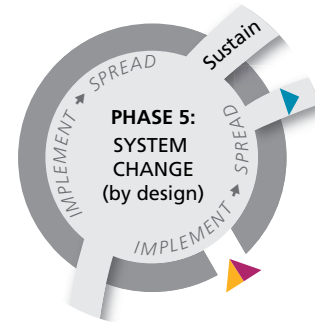
Pine Pass also contacted the health authority to discuss another improvement idea. From their experience and information learned by analyzing the 20 falls, they knew not all residents who experience a fall need care from the emergency department. The health authority had recently launched a community paramedicine program. The two organizations decided to **test** a process where a paramedic would respond at the continuing care centre if a resident fell, to avoid unnecessary transfers and diagnostic testing. Criteria were developed for nurses to assess residents who fell. If residents fell and met the criteria for a paramedic assessment, the community paramedic would be contacted to determine if the resident required an X-ray to rule out a fracture. Residents who required an X-ray would be taken directly to an urgent care facility by an inter-facility transport (IFT) team for diagnostic imaging and physician assessment, rather than be taken to an ED. It was hypothesized that having the resident undergo the X-ray before the physician assessment would reduce the total time the resident was away from Pine Pass. This process would also likely reduce the number of residents transported for X-rays, the number of ED visits, the amount of time a resident spent being assessed by a physician after they had fallen, and demand on the ED. Testing these hypotheses involved completing a PDSA cycle on three Pine Pass residents who experienced a fall. Data was also collected and matched to information from the emergency department's information system. This analysis showed two of the three residents who were brought by the IFT team to urgent care for imaging received care more quickly and were returned to the long-term centre sooner than residents who historically were transported by EMS to the emergency department. None of the three residents required admission to hospital.

PHASE 5: SYSTEM CHANGE

Implement → Spread → Sustain

The Quality Committee reviewed the results of the improvement opportunities that were tested.

The Quality Committee decided, with the health authority, to continue **testing** the community paramedicine idea and gather more data before making a decision to permanently **implement** this procedure. As part of this decision-making they planned to have a meeting with residents and their family members to discuss the approach and their early results, and to determine if there was support to continue toward implementation. The Quality Committee also planned to engage with other stakeholders such as physicians, nurses and healthcare aides to gain their perspective.



The Quality Committee decided to **spread** two of the initiatives where PDSA cycles had shown consistently positive results: (1) provide training to staff on managing behaviours with non-pharmaceutical approaches, (2) change the healthcare aide shift start/end times and incorporate 'toileting rounds' at 7 a.m. Part of the change management plan was to obtain agreement from the healthcare aides and the organization's human resources department that the shift change would take place 30 minutes earlier. This was felt to be a better solution than waking residents up early or delaying the toileting rounds. A 'spread strategy' was developed to support this, by ensuring behaviour management training sessions were included for staff in all units in the facility. In addition, discussions were held with each unit to determine how to implement the toileting rounds and manage the change in healthcare aide start time.

Finally, the Quality Committee continued to **monitor** progress of spreading the initiatives, including regular monitoring of fall rates and rates of antipsychotic medication use, through information on their dashboard. They also devised a method of obtaining resident experience information to determine what percentage of residents were being offered assistance in the morning to get up and walk to the bathroom. A six-month data gathering exercise was planned to **monitor** the **implementation** and **spread** of these change initiatives and to **monitor** whether the improvements would be **sustained** over time.

IMPORTANT POINTS AND TIPS

- Think of planning Phase 5 before or as you get started on Phase 4 – in other words, 'begin with the end in mind'.
- During Phase 4 it is appropriate to ask the question, "What changes can we make that will result in improvement?"
- Test as many ideas as possible during Phase 4 with well-defined PDSA cycles, or other improvement methods like Lean or Six-sigma; also consider simulated usability testing.
- During Phase 4 and Phase 5, planning around measurement is important both for testing ideas and for the implementation/spread of the selected solutions – ask: "How will we know that a change is an improvement?"

Scenario 2

Using the Harm Response Model to Manage a Patient with an Anticoagulant Overdose

A patient (Mrs. A) with a history of atrial fibrillation contacted her physician for a refill of warfarin (8 mg once daily). A refill prescription was faxed to the community pharmacy that same day for: warfarin 5 mg x 1 tab daily and warfarin 1 mg x 3 tabs daily. The prescription was filled by the pharmacy, and the patient continued on therapy as directed. One week later, the patient developed abdominal cramping, bloody stools and light-headedness and presented to the local emergency department where she was diagnosed with a life-threatening, lower gastro-intestinal (GI) bleed. Her INRⁱ was 7.8 (more than three times higher than the upper limit of expected). She was transferred to a medical unit in a tertiary hospital 100 kilometres away so she could be assessed by a gastroenterologist and to determine if she required surgical intervention.

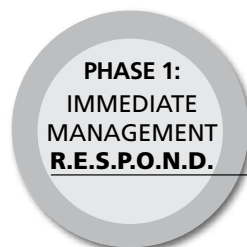
PHASE 0: WAS A PATIENT HARMED?

After admission to the medical unit and questioning Mrs. A about her warfarin prescription, it was suspected that Mrs. A's warfarin dose may be incorrect. A close friend was contacted and asked to go to Mrs. A's apartment and take her medication back to the pharmacy. Once that was done the pharmacy confirmed that Mrs. A's bottles contained the incorrect strength of warfarin. The bottle labeled warfarin 1 mg tablets (instructions: take 3 tabs daily) contained 5 mg tablets; the bottle labeled warfarin 5 mg tablets (instructions: take 1 tab daily) contained 1 mg tablets. Therefore, it was very likely that Mrs. A was taking 16 mg of warfarin daily for the past week, instead of the intended 8 mg. Based on this information it was concluded that Mrs. A had suffered harm. Because the resulting GI bleed was life-threatening the harm was classified as severe. The physician looking after Mrs. A contacted the pharmacy manager and together they developed a plan for the immediate management of Mrs. A's situation.



PHASE 1: IMMEDIATE MANAGEMENT

The emergency department had addressed Mrs. A's immediate medical needs (**resuscitation**). She was mildly hypotensive and her hemoglobin was 62 g/L (normal > 110 g/L). She was initially given one litre of normal saline and then two units of packed red blood cells. Cardiac investigations were completed to ensure she had not suffered a myocardial infarction.



Resuscitate patient(s)
Ensure environment is safe
Secure equipment
Protect other patients
Offer support to patient/family/
healthcare providers
Notify chain of command
Disclose (acknowledge event)

ⁱ INR: international normalized ratio – a blood test result that calculates the extent of anticoagulation. The goal is an INR of 2 to 2.5.

The medical team assumed responsibility for monitoring Mrs. A's condition and **ensuring** her ongoing safety. Her high INR was treated with fresh frozen plasma. An order was written for her not to receive any form of anticoagulation (the mislabeled warfarin bottles had been **secured** by Mrs. A's close friend who took them to the pharmacy).

To **protect** other patients, the pharmacy manager checked the pharmacy's warfarin stock supply to ensure the labelling was correct. He also reviewed the pharmacy's records to determine if any other patients had had warfarin prescriptions filled on the same day that Mrs. A received her prescription. He determined five other patients had received prescriptions for warfarin on the same day, seven patients had received one the day prior, and two patients had filled a prescription for warfarin the day after Mrs. A. All 14 patients were contacted and asked to bring their warfarin medication back to the pharmacy to be checked; it was determined that they had all received the correct dosage.

The medical team **offered** initial support to Mrs. A by asking one of the hospital social workers to meet with her. Mrs. A expressed a desire to have her minister notified; this was done and her minister called her later that day. Spiritual services within the hospital was also contacted and a minister arranged to meet regularly with Mrs. A to offer ongoing support.

The pharmacy manager **notified** the regional director of pharmacy operations, who worked in the city where Mrs. A had been admitted to hospital, and reviewed the details of Mrs. A's case with her, as they were currently known. The regional director in turn **notified** the company's vice-president in charge of pharmacy operations. The physician made a **note** in the patient's hospital chart about what happened that led to Mrs. A receiving an overdose of warfarin; similarly, the pharmacy manager entered a note on Mrs. A's file in the community pharmacy about the mislabelled warfarin bottles and what happened to Mrs. A.

After Mrs. A's physician had confirmed with the pharmacy manager that her two warfarin bottles had been mislabelled, which resulted in her taking 16 mg rather than her prescribed 8 mg, he met with Mrs. A and her daughter and **disclosed** this information to them. He told them he had spoken with the pharmacy manager, who was conducting an investigation in the community pharmacy to understand how this had happened.

The regional pharmacy director came to the hospital that evening to speak with Mrs. A. After apologizing for what had happened and confirming with Mrs. A what the physician had told her, she committed to a full investigation to understand what factors had contributed to Mrs. A receiving the incorrect warfarin dose. The pharmacy director told Mrs. A that she expected to have additional information to share with her within two or three days, but that the full investigation would likely take several weeks to complete. She offered to arrange a time to meet with her and any family members she wanted to include, to continue the disclosure conversation when more information was available.

IMPORTANT POINTS AND TIPS

- When it is recognized by a healthcare team that they may be involved with a patient who has suffered harm, it is helpful to have a checklist to remind them of the things that need to be thought of to manage this type of situation effectively.
- The RESPOND acronym can be used to remind team members of seven issues that may need to be addressed:
 - Resuscitate the patient(s)
 - Ensure environment is safe
 - Secure equipment
 - Protect other patients
 - Offer support to patient/family/healthcare providers
 - Notify chain of command/note in chart
 - Disclose (initial acknowledgement of the event)
- Someone with decision-making authority must determine what else is required to effectively manage the situation when it has been determined that a patient or client has been harmed.

PHASE 2: SITUATION ASSESSMENT

The regional director of pharmacy operations assumed leadership for the additional considerations about how the company would continue to manage Mrs. A's case. The director asked for a chronology of events, starting from the time the pharmacy first received a faxed prescription request from Mrs. A's doctor for the warfarin until she entered the hospital's emergency department, so she could **assess** the facts. She also asked for any information that was available about Mrs. A's current status. The director **decided** to proceed with implementing all three remaining phases of the Harm Response model for the continuing management of an event where a patient suffered serious harm: patient(s) and family, healthcare providers, and healthcare system.

PHASE 2:
SITUATION
• Assess
• Decide

PHASE 3: PATIENT AND FAMILY

The pharmacy director met with Mrs. A again the following day. After offering another apology for what had happened, the director asked Mrs. A what the company could do to **support** her recovery. The director learned that Mrs. A's son lived 1,500 km away and he wanted to be with his mother. The director offered to pay for Mrs. A's son to travel by plane later that day to be with her. As well, the director offered to pay for all expenses incurred by her son for his stay in the city until Mrs. A was discharged, which was

PHASE 3:
**PATIENT &
FAMILY**
• Support
• Disclose

expected to be in four or five days. The director had discussed these arrangements with the company's legal department and asked Mrs. A to sign a document stating the company's offer to pay for these expenses would not legally prejudice any case that Mrs. A might choose to bring against the pharmacy in the future.

As part of an ongoing **disclosure** process, the director asked and listened to Mrs. A about her experience from the time Mrs. A first began feeling unwell. She expressed empathy for how Mrs. A had been suffering and then offered to explain what the pharmacy had learned about what had happened. She offered to meet with Mrs. A and her son in a few more days when she had additional information to share.

The director then asked Mrs. A to think about where she would like to receive her pharmacy care in the future. She told Mrs. A that she could transfer her care to the company's other store in her town or if she decided to choose a different company, the director would understand that decision. Regardless of Mrs. A's decision, the director offered to make the transition happen seamlessly.

IMPORTANT POINTS AND TIPS

- An important part of disclosure is offering an apology by people in positions of authority and also if possible, by the people directly involved in providing the care that contributed to a patient's harm.
- Support for patients and their family may involve spiritual care, counselling support, and arranging for a family member to travel and stay near a patient.
- Offers to pay for out-of-pocket expenses can be done without affecting the possibility or outcome of future legal settlements. Senior management, and often the organization's lawyers, will be involved with these decisions.
- Patients and their family members need to understand what happened and why it occurred, in addition to being told how future healthcare needs will be met.

PHASE 4: HEALTHCARE PROVIDERS

The day following the discovery that Mrs. A had received the wrong dose of warfarin, the pharmacy manager met individually with the pharmacist and the two pharmacy technicians who had been involved with filling Mrs. A's prescription. He informed them what had happened to Mrs. A and about the mix-up of the 5 mg and the 1 mg warfarin tablets, resulting in an overdose of medication leading to a high INR and a severe GI bleed. He offered each of them the opportunity to contact the company's employee assistance program for counselling **support**, if needed. He also offered to connect them with a new **peer support** program that the company had started recently to help staff deal with stressful workplace events such as this. Finally, he offered them the opportunity to take some time off, if needed, to ensure they were emotionally and psychologically safe to continue working.

**PHASE 4:
HEALTHCARE
PROVIDERS**

- *Support*
- *Assess fairly*

The manager then reminded the three employees that consistent with the company's just culture process, he would be conducting a **fair assessment** of their actions in as unbiased a way as possible. First, he would evaluate the actions taken and if they were judged to be errors rather than non-compliance with standard operating procedures, there would be no discipline.ⁱⁱ Second, if it was believed that standard procedures for filling the warfarin prescription had not been followed, then these actions would be assessed in the context of system factorsⁱⁱⁱ that are known to contribute to unanticipated outcomes for patients. Third, that although the severity of harm the patient had suffered was very important for how he and the company responded to the patient and her family, it would not be taken into consideration as part of the assessment of the employees' decisions and actions. Finally, based on his preliminary assessment, he shared that he believed that there had not been any willful intent to harm the patient. He stressed to the workers that according to company policy, discipline would only be considered if, after his analysis of the system factors that influenced the workers' actions, he concluded the worker's actions demonstrated they were the result of considering their own interests over the best interest of the patient.

IMPORTANT POINTS AND TIPS

- Healthcare providers can be supported through this stressful time in their lives by receiving counselling and by being connected with a peer or peers who have been trained how to support a co-worker who has been involved in a situation where a patient has suffered serious harm.
- The procedure and the criteria used by organizations to assess the decisions and actions of healthcare providers should be proactively defined and conducted without hindsight bias; this includes not considering the severity of the patient's harm in the assessment process.
- Treating healthcare providers in a just way, especially during the aftermath of a situation where a patient suffered serious harm, supports a culture of reporting; this in turn supports a learning culture which makes it possible for improvement to occur.

PHASE 5: HEALTHCARE SYSTEM

When the pharmacy manager learned about what had happened to Mrs. A, he submitted a safety learning **report** electronically to the company's safety reporting and learning (SRL) system to ensure the company had a record of the event. The company's safety officer reviewed the report and gathered additional information from the pharmacy manager about factors that possibly contributed to the event. This information was then entered into the SRL system. Other contributing factors, discovered as part of a system-based **analysis** of the event were also entered and the factors were then categorized using the Winnipeg Model approach.^{2,5 (iii)}



**PHASE 5:
HEALTHCARE
SYSTEM**
• Report
• Inform
• Analyze

ⁱⁱ By definition errors are unintended. Progressive health systems who are striving to support a just culture that will make it possible for a reporting and learning culture to develop, recognize that punishing people for making an error does not change behaviour long-term and does nothing to improve the safety of healthcare delivery.

ⁱⁱⁱ Patient factors, personnel factors, environment and equipment factors, organizational factors, and regulatory factors.

The system-based **analysis** was conducted by the company's safety team. One of the two members of this team was a human factors-trained psychologist, and the other member was an experienced pharmacist. Through their investigation they discovered the following system factors:

Patient: Elderly, suffered from macular degeneration, unaware of the colour difference between 1 mg and 5 mg warfarin tablets; she was taking Ginkgo biloba, which she had not reported to the pharmacy; she was unaware of the interaction between Ginkgo biloba and warfarin.

Personnel: *Pharmacist* – Three and one-half years experience with only three months as a community pharmacist; new child at home and sleeping poorly – very fatigued during shifts; could not recall if the warfarin dose on Mrs. A's prescription had been double-checked. *Pharmacy technician* (day shift) – 15 years community pharmacy experience; was on sixth shift in a row and working late (covering for the evening pharmacy technician, who was late); was interrupted frequently throughout the day due to multiple customers and concurrent phone calls. *Pharmacy technician* (evening shift) – six years community pharmacy experience; arrived to work 45 minutes late (car failed to start); briefed by day technician and completed filling Mrs. A's prescription.

Environment and Equipment: Prescription drop off and pick up in the same small area; lighting is dim in this area; drug preparation area not isolated from the customer prescription drop off/pick up; phone and fax machine are close to the drug preparation area and can create distractions for employees when dispensing drugs. Warfarin 1 mg and 5 mg tablets are peach and pink respectively – some people with poor vision cannot distinguish the difference. The stock containers are indistinguishable other than their label. Warfarin is stocked with all other medications.

Organization: Policies exist about identifying high-alert medications but there is no specific policy about dispensing two different dosages of the same drug at the same time. Policy does state that all high-alert medications will be double-checked for accuracy before securing the bottles and giving them to a patient. There is no fatigue management policy or procedure. There is no policy or procedure for the pharmacy to direct staff on how to collect information from patients about any over-the-counter medications or herbal products that a client might be using and that could potentially interfere with a prescription medication. Capital budgets for upgrading pharmacies had been frozen for three years; a previous recommendation by the pharmacy manager to upgrade the dispensing area was not given high priority status, and therefore, it was not acted upon.

Regulatory: The Institute for Safe Medication Practices (ISMP) Canada lists warfarin as a high-alert medication. There are no provincial regulatory standards about dispensing different doses of the same high-alert medication at the same time or a need for double-checking high-alert drugs' dosage and labelling.

The pharmacy *informed* all other pharmacies in the corporation about this adverse event, and specifically key learnings from their system-based analysis. ISMP Canada was also informed to facilitate information sharing with other pharmacies. All possible identifying information, including the specific pharmacy, the pharmacist and pharmacy technicians, as well as the patient, was anonymized.

IMPORTANT POINTS AND TIPS

- Have a reporting system that is easy to use, is routinely analyzed for trends and cases that need analysis, is effective (leads to improvement), and is safe (no negative repercussions to the reporter for reporting).
- Proactively informing others can be important for protecting other patients/citizens from hazards, for managing an organization's reputation, and for supporting a culture of transparency.
- Conduct an analysis of the system that includes not only what healthcare providers did, but also considers other contributing factors including patient, personnel, environment and equipment, organizational, and regulatory.

Scenario 3

Using the System Design Model to Make Care Safer

This scenario builds on Scenario 2. The company that owns the pharmacy where Mrs. A received the wrong dose of warfarin completed a full system-based analysis of the events leading to the harm that Mrs. A suffered.

PHASE 0: GOALS, VALUES AND GUIDING PRINCIPLES

Define and use to influence decision-making

The goals of the pharmacy's parent company where Mrs. A received her prescription are to consistently increase the number of people they serve while providing exceptional experiences, and to provide the safest care possible. Their stated values include personalized service, dedication to employee wellness, and a culture of caring. They use the six principles of the Healthcare Quality and Safety Management Framework (HQSMF): patient engagement or co-production; respectful and transparent relationships; healthcare is complex; just culture; responsibility and accountability; and continuous learning and improvement to help guide their decision-making.^{1,4}

PHASE 1: HEALTHCARE ENCOUNTERS

Measure, Monitor, Evaluate

The system-based analysis that was conducted by the company's safety team as part of Phase 5 of the **Harm Response Model** represents Phase 1 of the **System Design Model** because it is an **evaluation** of a healthcare encounter. This evaluation alone could provide an internal input into the next phase of the System Design Model because it identified several hazards that represented improvement opportunities. The company did a search of their safety reporting and learning (SRL) system to determine if they had other reports of clients receiving the wrong dose of warfarin. They found that in the past five years, seven reports had been submitted where clients had received a higher warfarin dose than had been prescribed; and there were four reports of clients receiving an inappropriately lower dose than prescribed. There was no mention in any of these reports of a client other than Mrs. A having experienced serious harm.

While searching their company's SRL system the safety team also found reports of clients who had received prescriptions for the wrong dose or wrong drug when being prescribed other high-alert medications, including insulin, narcotics (morphine and hydromorphone), novel oral anticoagulants and chemotherapy agents (methotrexate and cyclophosphamide) prescribed for non-cancer conditions.



PHASE 2: ISSUES/HAZARDS → OPPORTUNITIES

Identify → Prioritize

The safety team **identified** the following hazards based on their analysis of Mrs. A's case: (1) warfarin; and (2) vision impairment that prevented clients from being able to read medication information sheets or prescription labels. From their review of the SRL system they added several other hazards to their list for consideration of a more in-depth analysis: (3) novel oral anticoagulants; (4) chemotherapy agents; (5) insulin; and (6) narcotics. They constructed a high-level BowTie model^{5,6} for each hazard that allowed them to estimate, using a safety risk assessment matrix (Table 3), which of the hazards represented the most important risk to clients' safety. In addition, they evaluated which hazards were lacking important risk mitigation strategies. Anticoagulants had the highest safety risk index (Table 4).



Table 3: SAFETY RISK ASSESSMENT MATRIX (ADAPTED FROM ICAO⁷)

Probability of Occurrence		Severity				
		Catastrophic A	Major B	Moderate C	Minor D	Negligible E
Frequent	5	5A	5B	5C	5D	5E
Occasional	4	4A	4B	4C	4D	4E
Remote	3	3A	3B	3C	3D	3E
Improbable	2	2A	2B	2C	2D	2E
Extremely Improbable	1	1A	1B	1C	1D	1E

LEVEL OF RISK ASSESSMENT ● Unacceptable ● Acceptable ● Tolerable

Table 4: SAFETY RISK INDEX CALCULATION

Hazard	Safety risk probability	Safety risk severity	Safety risk index
Warfarin	4	1A	4A
Client vision impairment	4	D	4D
Novel oral anticoagulants	3	B	3A
Chemotherapy (methotrexate, cyclophosphamide)	3	C	3C
Insulin	2	B	2B
Narcotics	3	C	3C

Because warfarin and novel oral anticoagulants had the highest safety risk index (4A and 3A), they were prioritized for further analysis and development of risk mitigation strategies (improvements). Warfarin was 10 to 12 times more likely to be prescribed than other anticoagulants so it was decided to focus Phase 3 on this one drug. The safety team believed that their analysis and improvements in risk mitigation approaches for warfarin would be applicable to other high-alert drugs, especially other anticoagulants.

IMPORTANT POINTS AND TIPS

- Use reports of several cases or an in-depth analysis of a single important case as an internal input into Phase 2 of the System Design Model – identifying hazards.
- Prioritizing hazards can be done by combining safety probability and safety severity tables using a safety risk assessment matrix table to create a safety risk index.
- The alphanumeric score from the safety matrix table can be used to classify hazards as: (1) acceptable risk (nothing else needs to be done at this time), (2) tolerable risk (may require some risk mitigation strategies), and (3) unacceptable risk (requires urgent strategies to reduce the risk).

PHASE 3: PRIORITY OPPORTUNITIES

Analyze → Understand

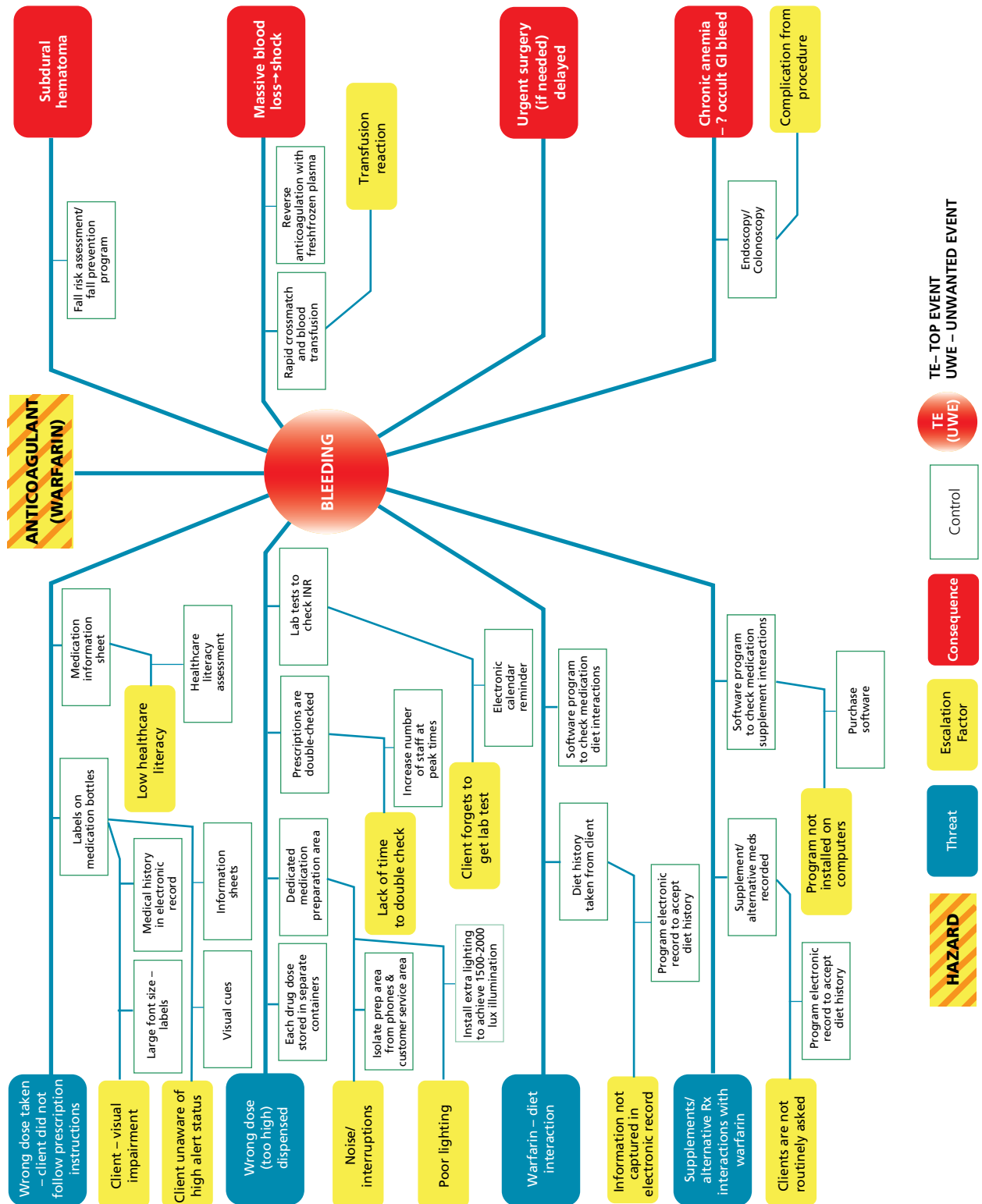
An in-depth **analysis** of warfarin was performed first by conducting a human factors study of how high-alert medications were dispensed by the pharmacy and then second, by constructing a detailed BowTie model^{5,6} (Figure 1). The human factors study **identified** several threats, prevention controls and escalation factors associated with warfarin, and by extension with other high-alert medications. The BowTie model helped the safety team visualize these relationships and **understand** what prevention controls were lacking and what escalation factor controls required attention. This helped the safety team focus on **opportunities** for improving client safety by reducing the probability of harm (see Healthcare Quality and Safety Management Framework – Appendix III).¹



The top-event for warfarin was bleeding. A total of four threats and four consequences were highlighted using the warfarin BowTie model. A total of 10 prevention controls and four recovery controls were identified. In this BowTie model, impaired vision was treated as an escalation factor because it was felt to affect clients' ability to properly read labels and therefore contribute to the possibility of clients not following the prescription instructions and taking the wrong dose (a threat). One of the controls they had for this escalation factor was their electronic information system which had a data field where pharmacists could record client's medical conditions. However, a review of a sample of client's records found that this data was often missing and there were no examples found where it had been documented that a client had a vision impairment. The lack of important medical information in the electronic record was viewed as an escalation factor; that is, it interfered with the potential benefit that such information could have for alerting pharmacy staff about this important handicap. The pharmacy also had no policy or procedures for how medications were reviewed with clients who had impaired vision.

Another escalation factor related to the threat of the wrong dose of warfarin being dispensed was the problem with noise in the medication dispensing area and interruptions of the pharmacy staff when they were preparing prescriptions. Both issues contributed to the interference with pharmacists and pharmacy technicians' ability to concentrate while dispensing medications.

Figure 1: WARFARIN BOWTIE MODEL



The human factors study of the pharmacy medication dispensing area revealed additional details and understanding of the critical steps involved with getting the correct medication and dose prepared for the right client. They are featured in the BowTie model and are expanded on below:

1. High-alert medications were stored with other medications, generally in alphabetical order. In several cases, high-alert medications were stored on the same shelf or within the same bin as regular medications. There were no warnings to visually identify a medication as high-alert.
2. There was nothing unique about the labelling of high-alert medications. The labels used were identical to those used for all other types of medication.
3. Although there was supposed to be an independent double check of all prescriptions for high-alert medications, this was sometimes missed when the pharmacy was busy.
4. Medications were not physically separated by type or dosage.
5. When workload was high, medication labels for multiple medications, and sometimes for multiple clients, were printed simultaneously.

IMPORTANT POINTS AND TIPS

- A deeper understanding of how identified hazards can translate into harm for patients is often required before developing ideas that could mitigate the risk.
- Studying how humans function in simulated or actual environments can be used to gain this understanding (Phase 3) as well as to develop and test risk mitigation ideas (Phase 4).
- Risk mitigation/improvement ideas can also be generated from the experience of others; these external inputs can come from peer-reviewed publications or the grey literature.
- Avoid the temptation to jump straight to solutions and begin implementing without going through an adequate phase of testing the ideas first to gather evidence of effectiveness.

PHASE 4: IMPROVEMENT IDEAS

Develop → Test → Select

The human factors study, in addition to providing understanding about the hazards, threats, escalation factors and controls identified and prioritized in Phases 2 and 3, resulted in several ideas for improvement. Some ideas targeted structural improvements and others focused on process improvements. The following recommendations (ideas) for reducing the risk of bleeding (harm) are listed as a square ■ to indicate a change to structure and an arrow head ► to indicate a change to process for six areas of concern:

1. Medication dispensing area – distracting environment for staff
 - Move the phone and fax machine to the front of the pharmacy where customers pick up prescriptions, so pharmacists and pharmacy technicians are not answering it while dispensing medication.



- ▶ Develop and implement a procedure that notifies other staff when pharmacists are dispensing medication so they are not interrupted.
 - Erect a barrier between the dispensing area and the customer service area of the pharmacy so there is reduced likelihood of distractions.
 - ▶ Implement a procedure for periods of high workload where the pharmacy changes to a prescription pick-up by appointment only, to reduce line-ups and reduce the pressure on pharmacy staff to fill prescriptions quickly.
2. High-alert medication – storage
 - Create a separate storage area for these medications to reduce the likelihood of substitution errors.
 - Store each high-alert medication in a separate area using shelf dividers or separate bins with highly visible lettering, to reduce the likelihood that pharmacy staff confuse or mix-up different products, strengths and formulations.
 3. High-alert medication – dispensed supply dosage strengths
 - Create unique bottles and/or labels for these medications.
 - Create different shape and/or different size bottles for different dosage strengths.
 - Standardize the unique characteristics of a bottle and the unique dose it represents for each high-alert medication.
 4. High-alert medication – labelling
 - Create red, high-alert stickers to be placed on each container given to a client, indicating that it is a high-alert medication.
 - Increase the font size for the name of the medication.
 - Increase the font size for the dose of the medication.
 5. High-alert medication – special procedures
 - ▶ Implement a system of independent verification of client identification against prescription and dispensed medication.
 - Create a unique client information sheet for these medications that reinforces to the client the importance of reading the directions for how to take it.
 - ▶ Implement a procedure where pharmacy staff document that they have verified with a client that they are taking a high-alert medication, and that they have reviewed the guidelines the client should follow to reduce the likelihood of a medication error.
 - ▶ Explore with all clients whether they have any problems with visual impairment, and document this in the pharmacy's electronic customer information system.
 - ▶ Develop a procedure for reviewing all medications with clients who have a visual impairment who are filling a prescription for a high-alert medication and/or who are taking multiple medications.

The pharmacy's parent company assigned a safety and quality project manager to oversee the testing of the improvement ideas. Searches of PubMed, other electronic databases of healthcare research, and the grey literature generated additional ideas for improvement. A multi-vote process was organized using experienced pharmacists and pharmacy technicians and a safety expert to select the 10 most promising improvement ideas to test.

For the recommended changes to the design of the pharmacy, a medication dispensing area was mocked up in a company-owned warehouse. Pharmacists and pharmacy technicians were observed working in the

test environment under different simulated scenarios. Design modifications were made to further optimize workflow and ergonomics. Usability testing was also performed within the mock-up to evaluate proposed changes to storage bins, stock bottle containers, and labels. As part of the usability testing, pharmacy staff were asked their opinions about how they thought this would change their workflow and their task performance when working with high-alert medications.

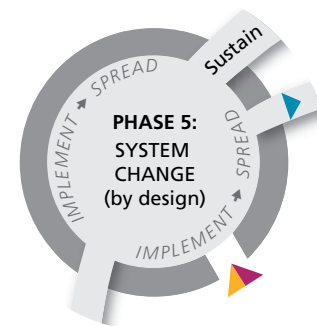
For proposed changes to procedures, a quality improvement project was designed to run multiple PDSA cycles of improvement that allowed for iterative changes to be made. The procedures were tested under different scenarios, for example when it was relatively quiet midday, when it was busy during evening shifts, and during times when there was reduced staffing.

The parent company convened a panel consisting of two pharmacists, two pharmacy technicians, three executives and four clients, to review the results from the simulation-based testing, the opinions about proposed changes to storage and labelling of stock supplies of high-alert medications, the proposed implementation of new medication bottles and information sheets provided to clients, and the PDSA cycles. The panel developed criteria for selecting the tested improvement ideas to invest in and implement in the pharmacy where Mrs. A received the wrong warfarin prescription, and developed a plan to make these changes in each of the company's pharmacies across the country. In addition to setting criteria such as likely effectiveness of the idea to mitigate harm, cost, and feasibility, the panel judged each idea against the company's goals and stated values, and the principles of quality and safety management.

PHASE 5: SYSTEM CHANGE

Implement → Spread → Sustain

The corporate operations team selected six changes to **implement**. They designed the 'implement and spread' approach around a corporate desire to live its values by fostering a culture of caring. They referred to this series of changes as the high-alert medication safety (HAMS) initiative. With Mrs. A's permission they created a sense of urgency, in part by relating the initiative to her story. Three experienced pharmacists, two pharmacy technicians, and three clients who were taking high-alert medications agreed to become the spokespeople and the 'face' of the initiative. The corporation's chief operating officer assumed the lead for the HAMS initiative.



Some of the structural changes involved adjusting policies (e.g., independent double checks for all high-alert medications) to indicate the organization's recognition and support for continually improving medication safety practices. A training package consisting of written material and an online teaching video were made available to all staff, so they could learn about the new policies and understand how it would affect the procedures they followed for handling and dispensing high-alert medications. Adjustments to the physical layout of the pharmacy, including moving the dispensing area towards the back of the pharmacy, erecting a Plexiglas barrier between the dispensing area and the customer service area, and relocating the phone/fax machine, were to be implemented in a staged fashion. Similarly, structural changes to the storage area, the bins, and the labelling of high-alert medications would take place after changes to the dispensing area. As part of the project management plan for **spreading** the changes, it was decided to start **implementation** in the pharmacy where Mrs. A had received her incorrect warfarin prescription. An evaluation was planned to identify what had gone well with the implementation and any problems that had not been foreseen but were

felt important to address, before introducing the changes to other pharmacies. A timetable for implementation was developed that guided the **spread** of these changes across the country. Local champions, including experienced staff and clients in each city and town, were contacted and asked to help lead the changes in the local pharmacies. Each pharmacy was allowed to review the proposed plans and provide feedback before implementing any changes. PDSA cycles were conducted if there were concerns about any of the new procedures being introduced, so local adaptations could be made. After each pharmacy made the changes an evaluation of the changes was conducted, so there was an ongoing assessment that could be incorporated into the next pharmacy implementation.

The company decided to **monitor** three metrics on an ongoing basis to keep executives and all employees up to date on the effect of the changes. The company had a well-functioning electronic safety reporting and learning (SRL) system where each pharmacy could report high-alert medication safety issues, so they elected to use monthly reports of these problems. They further categorized these reports into those where clients had received the wrong dose. For each of those reports they investigated whether the client had been harmed, and used that as another metric. The company also systematically captured client concerns electronically, which provided another source for discovering safety issues related to high-alert medications. It is well understood that reporting systems do not capture all cases of interest. Therefore, the company also elected to perform a survey each month on a random sample of clients who had been provided a high-alert medication. The survey probed if the client had experienced any issues related to their medication, and specifically if there had been any problems with the dose of the medication and/or side effects. The survey also included a question about any recent admissions to hospital or unscheduled visits to the emergency department or their physician that was possibly/likely related to the high-alert medication. Graphs of these data were created, updated monthly and shared with all employees, executives and the Board of Directors. As part of its communication about the HAMS initiative with the clients they served, the company also shared the results publicly on their website. Results were aggregated by province and by region, not by individual town or city and not by individual pharmacy. The company's website hosted a forum where employees could tell stories of the positive changes that had been seen related to the HAMS initiative. Client comments were also posted, as were ideas for additional improvements.

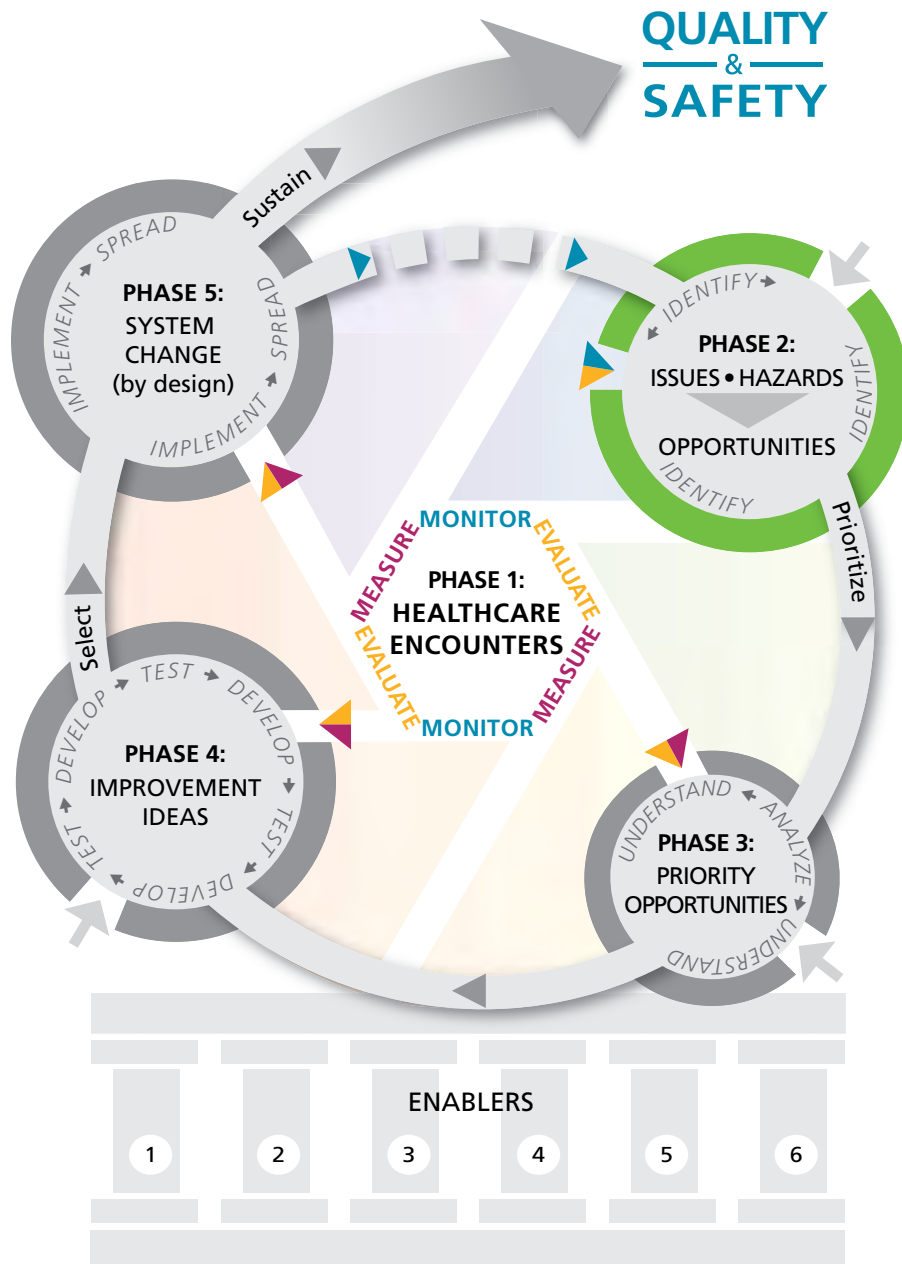
IMPORTANT POINTS AND TIPS

- Developing the plan for Phase 5 should start at about the same time as Phase 3 because of the amount of planning required to implement, spread and sustain change.
- Improvement ideas can fail at this stage without three components in place: (1) a project management plan, (2) a change management plan, and (3) a plan for ongoing measurement with feedback loops that allow for further iteration.
- Commitment to make the “new way the new normal” is needed – this requires change leadership.
- Use a structured change approach, for example Kotter's 8-step change model.⁸
- Measurement and evaluation that evolves into ongoing monitoring is important to build into the sustainability plan.

Appendix I

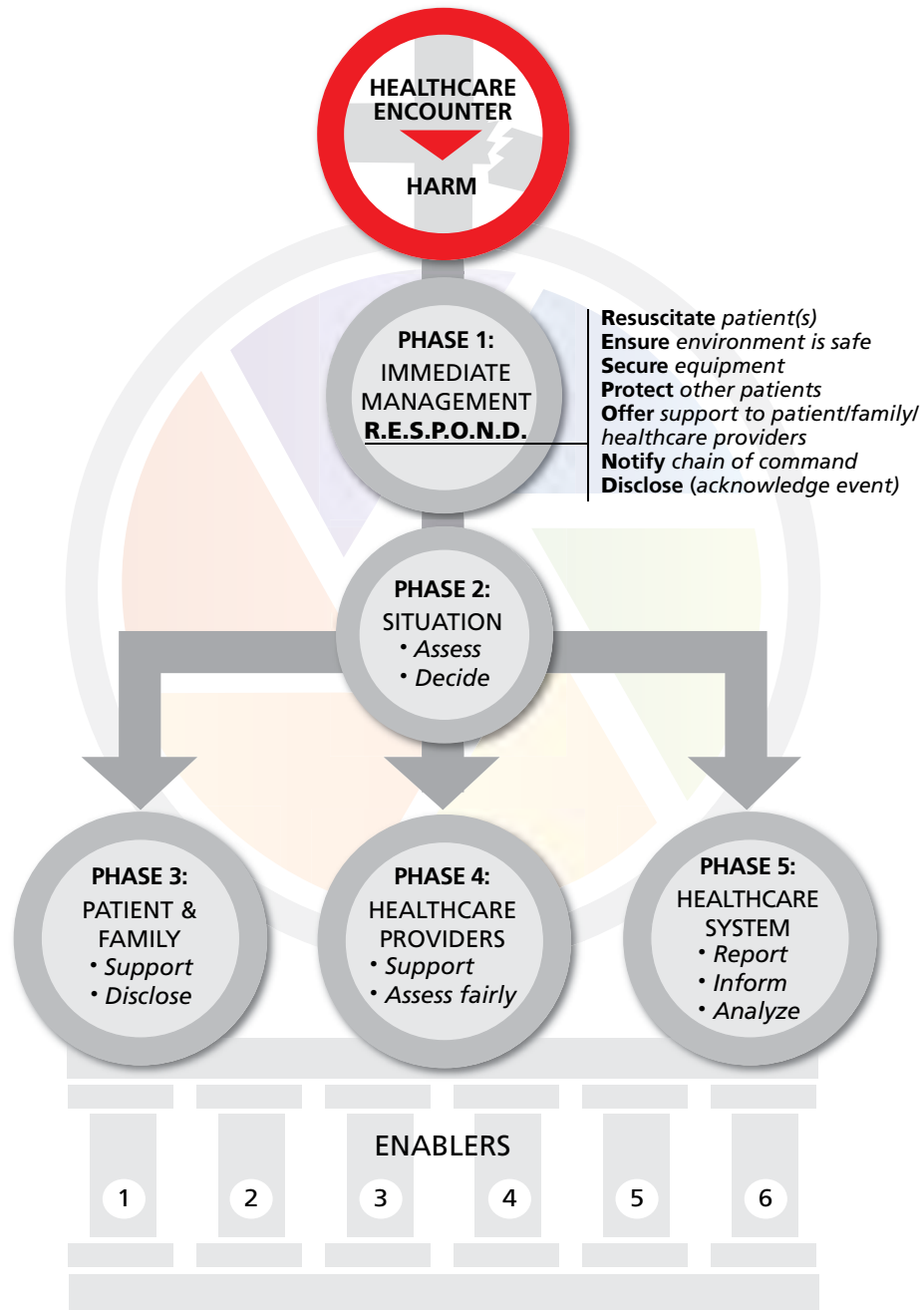
Healthcare Quality and Safety Management Models

Figure 2: SYSTEM DESIGN MODEL



1. Leadership 2. Followership 3. Governance and accountability structure 4. Capacity and capability 5. Supportive information systems 6. Values and guiding principles

Figure 3: HARM RESPONSE MODEL



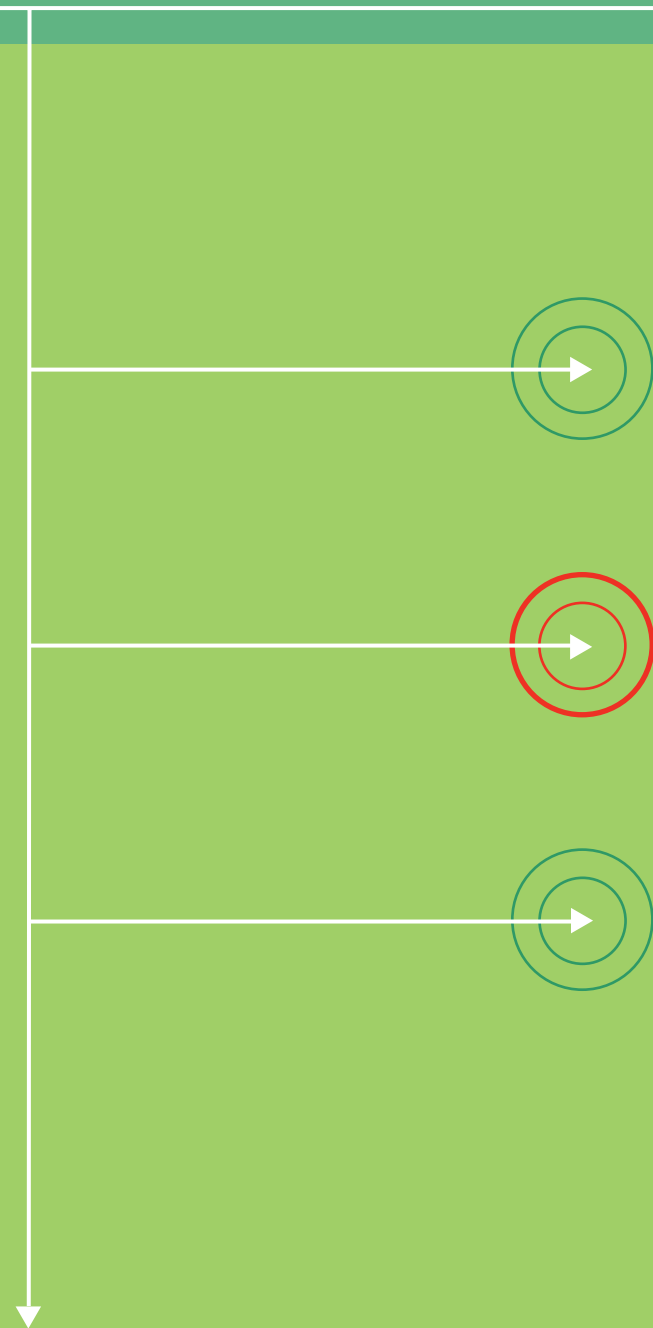
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