Strengthening Medication Safety in Long-term Care

Model Policy 9 (DRAFT)

To support LTC Homes in their review and updating of medication management policies

# Medication Incident Reporting, Learning, & Acting

**Purpose**

To ensure a timely, consistent, and standardized organizational process for reporting, learning, and acting after a medication incident in the home. The outcomes for this process are defined below.

**Table A: Report, Learn & Act After a Medication Incident Outcomes**

| Report | Learn | Act |
|---|---|---|
| • All residents, family, staff, and prescribers recognize and report when something related to a resident and medications may have gone wrong.<br><br>• Any significant changes to a resident's health status are reviewed to determine if an adverse drug reaction, error, or other related issue (e.g. hypoglycemia) may have occurred, then a report is completed as applicable.<br><br>• Residents, family, staff, and prescribers are engaged in developing and maintaining a Just Culture[1] in the home. An atmosphere of trust is maintained, including ensuring that blame and retribution are absent, and disciplinary action or other punitive steps are implemented only in appropriate and rare circumstances. | • Medication incident reports are reviewed by designated staff in the home as they are submitted in order to ensure:<br><br>a. appropriate initial steps have been taken to prevent or treat any harm to the resident and ensure that no other residents are also at risk of a similar incident;<br><br>b. sufficient facts are obtained and reviewed to ensure that no one intended to harm the resident;<br><br>c. the types of medication incidents, and their contributing factors, are identified in collaboration with a team of providers and a resident/family representative using a systems analysis approach[2]; and,<br><br>d. incident analysis findings are compiled and shared regularly with the designated committee at the home. | • The Director of Care (DOC) ensures that contributing factors causing medication incidents and harm to residents, or significant risk of harm, are prioritized and resolved by taking action.<br><br>• Quality Improvement (QI) tools and strategies are formalized and available to develop, implement, and evaluate medication safety improvements.<br><br>• Staff, prescribers, and pharmacy service providers are engaged in using the QI tools and strategies to take action.<br><br>• Reporting, learning, and acting at the home leads to the redesign of policies, processes of care, products, and procedures, and the working styles of individuals and teams. Such actions will usually lead to measurable, sustained reduction of risk for residents. |

**See Appendix A for a Glossary of Terms.**

**Scope**

This policy applies to all long-term care staff and prescribers involved in the delivery of care to residents and families.

**Overview of Process**

The process of medication incident reporting, learning and acting is interprofessional, interdependent, and reliant on a team approach that meaningfully engages the residents and families.

A standardized process that is reliably implemented supports safe medication management in the home and applicable Accreditation requirements.

Clear roles and responsibilities are an essential aspect of this process.

*Roles and Responsibilities*

1. Residents & Family
    a. Regularly engage in discussions with their Care Team (nursing staff, prescribers, and pharmacists) regarding the medications being provided (see 5 Questions to Ask[3] as a resource for these discussions).
    b. Share any questions or concerns if they believe something with the medications may have gone wrong.
    c. Share any recommendations for reducing the risk of a medication incident with the Director of Care (DOC) or their designate.
    d. At the request of the DOC or designate, participate in an incident analysis using a systems approach.[2]
    e. Collaborate with nursing staff, prescribers, pharmacists and others to use QI tools to develop, implement and evaluate actions to reduce the risk of medication incidents.

2. Nursing Staff
    a. Engage in discussions with residents and their family members/caregivers regarding the medications being provided.
    b. Monitor residents to evaluate the effect of medications and to identify if something may have gone wrong with them.
    c. Notify the applicable prescriber and DOC or designate if they believe a medication incident has occurred.
    d. Complete any treatment and/or additional assessments ordered by the prescriber as well as any actions specified by the DOC or designate.

*Roles and Responsibilities (continued)*

2. Nursing Staff (continued)

    e. Ensure that the resident and family (if applicable) are notified of any errors or issues that occurred with the medications and the follow up actions that are being implemented.
    f. Complete and submit a medication incident report as per the home policy.
    g. Share any recommendations for reducing the risk of a medication incident with the DOC or their designate.
    h. At the request of the DOC or their designate, participate in an incident analysis using a systems approach.
    i. Collaborate with prescribers, pharmacists and others to use QI tools to develop, implement and evaluate actions to reduce the risk of medication incidents.

3. Prescribers
    a. Regularly engage in discussions with their residents and/or family members regarding the medications being provided.
    b. Monitor residents to evaluate the effect of medications and to identify if something may have gone wrong with them.
    c. Notify the nursing staff and DOC or designate if a medication incident has occurred.
    d. Order any treatment and/or additional assessments to be completed by the nursing staff or pharmacists.
    e. Ensure that a medication incident report has been completed as per the home policy.
    f. Share any recommendations for reducing the risk of a medication incident with the DOC or their designate.
    g. At the request of the DOC or their designate, participate in an incident analysis using a systems approach.
    h. Collaborate with nursing staff, pharmacists and others to use QI tools to develop, implement and evaluate actions to reduce the risk of medication incidents.

*Roles and Responsibilities (continued)*

4. Pharmacists at Pharmacy Service Providers
    a. Monitor residents to evaluate the effect of medications and to identify if something may have gone wrong with them.
    b. Notify the applicable nursing staff and DOC or designate if they believe a medication incident has occurred.
    c. Notify the applicable nursing staff and DOC or designate if a medication incident at the pharmacy has occurred related to medication provided for the resident(s).
    d. Ensure that a medication incident report has been completed.
    e. Share any recommendations for reducing the risk of a medication incident with the DOC or their designate.
    f. At the request of the DOC or their designate, participate in an incident analysis using a systems approach.
    g. Collaborate with nursing staff, prescribers, and others to use QI tools to develop, implement and evaluate actions to reduce the risk of medication incidents.

5. Director of Care or Designate
    a. Utilize the Incident Management Continuum[1] (See Appendix B) to develop and maintain a timely, consistent, and standardized organizational process for reporting, learning, and acting after a medication incident in the home.
    b. Collaborate with the Medical Director and nursing leadership at the home to ensure that all medication incidents are reviewed to determine if resident harm was intended.
    c. Collaborate with the Medical Director and nursing leadership at the home to ensure that a just culture is in place. This includes an atmosphere of trust where blame and retribution are absent, and disciplinary action or other punitive steps are implemented only in appropriate and rare circumstances.
    d. Ensure that all residents/family, nursing staff, prescribers and pharmacists can easily report a medication incident.
    e. Ensure that medication incidents are analyzed using a systems approach to identify contributing factors and that those causing harm to residents, or significant risk of harm, are prioritized and resolved by taking action.
    f. Ensure that QI tools are used to design, implement, and evaluate medication safety improvements.
    g. Ensure that the Medication Management Committee is engaged in this work, including regular updates on all aspects of the incident management continuum.

*Roles and Responsibilities (continued)*

6. Medication Management Committee
    a. Resident/Family rep(s), nursing staff, pharmacist, DOC, Medical Director, and any other participants meet quarterly.
    b. The Committee reviews any relevant information regarding medication management in the home, including the number and type of incident reports over the past quarter (as well as trending over the past few years) and discuss their contributing factors as identified following a systems analysis.
    c. Priorities for action are determined based on the actual and/or potential risks to residents.
    d. The Committee reviews the progress of quality improvement actions to reduce the risk of the same or similar incidents reoccurring. If applicable, changes to the actions are finalized and communicated.

**Compliance with Long-Term Care Provincial Reporting Requirements**

The Director of Care and Medical Director have a number of important medication incident reporting requirements that are formalized in regulations. These requirements are laid out in Ontario Regulation 246/22 in following the following sections.

- Section 108-112: reporting of complaints and investigations
- Section 115: Reports related to Critical Incidents
- Section 147: Reports related to medication incidents and adverse drug reactions
- Section 168: Annual Continuous Quality Improvement initiative report
- Section 284: Annual Report
- Section 285: Key Personnel Report

Section 115 relates specifically to Critical incident reporting and outlines the different timelines for reporting critical incidents that take into account the urgency or severity of the incident.

Critical incidents that must be reported **immediately** include:

- emergencies (fire, unplanned evacuations),
- an unexpected or sudden death,
- a missing resident for three hours or more,
- a missing resident who returned to the home with an injury or any adverse change in condition (regardless of the length of time the resident was missing),
- an outbreak of a disease of public health significance or communicable disease, or
- Contamination of the drinking water supply

Critical incidents that must be reported **within one business day** include:

- A resident who is missing for less than three hours and who returns to the home with no injury or adverse change in condition,
- An environmental hazard that affects the provision of care or the safety, security or well-being of one or more residents for a period greater than six hours (breakdown security system, major equipment, flooding),
- A missing or unaccounted for controlled substance,
- An incident that causes an injury to a resident for which the resident is taken to a hospital and that results in a significant change in the resident's health condition,
- A medication incident or adverse drug reaction in respect of which a resident is taken to hospital,
- The use of glucagon that results in a resident being taken to hospital, or
- An incident of severe hypoglycemia or unresponsive hypoglycemia in respect of which a resident is taken to hospital.

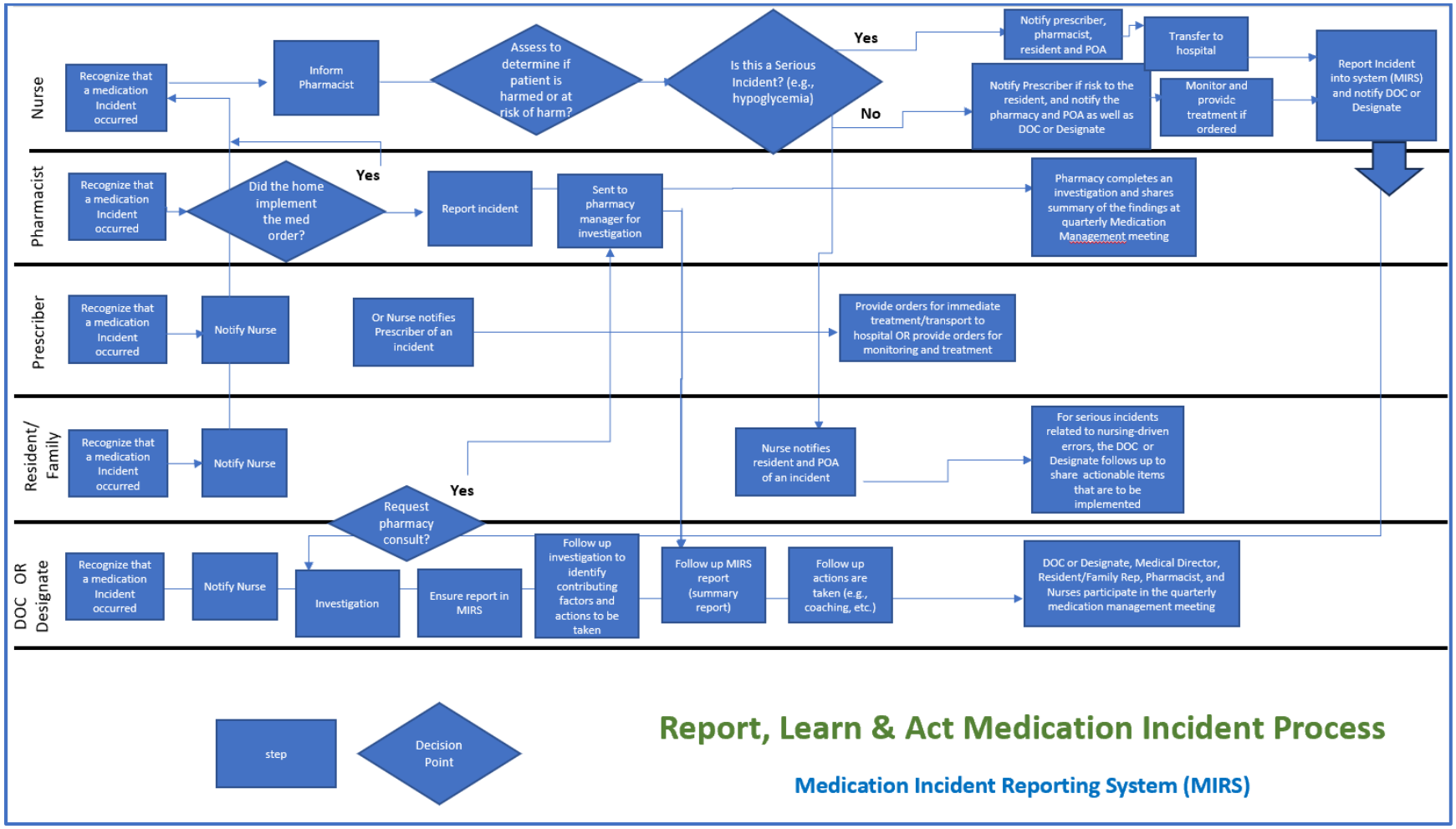
The Regulation also prescribes (in Section 115(5)) what information is to be included when making a report to the Ministry and who must be notified (e.g., when a resident's substitute decision maker is notified).

**Process Map**

With the number and variety of roles and responsibilities involved in reporting, learning, and acting after a medication incident, it is important to develop a process map that simply describes the key steps and who is accountable for them. See Graphic 1 for an example of a process map.

The process map is an important quick reference for nursing staff, pharmacists, and physicians in the home.

**Graphic 1. Summary of Medication Incident Report, Learn, and Act Roles and Responsibilities**




Model Policy for review and adaptation by LTC Home
Note: each Home is unique therefore review and modification where applicable is required.

**Attachments:**

**Appendix A – Glossary of Terms**

**Appendix B - Incident Management Continuum**

**Appendix C – Incident Analysis Timeline Template**

**Appendix D – Incident Analysis Constellation Diagram Template**

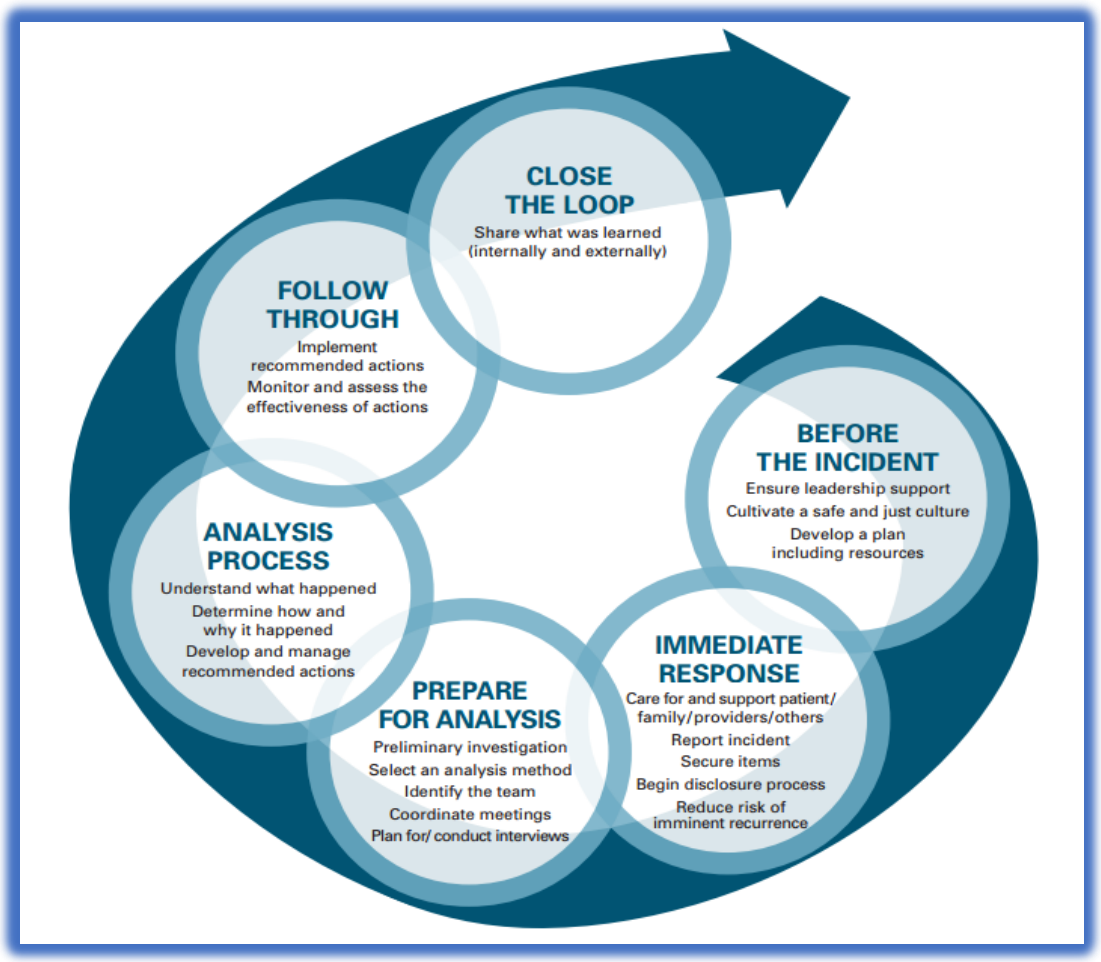
**Appendix E – Hierarchy of Intervention Effectiveness**

**Appendix F – Incident Analysis Summary Statement and Action Plan Template**

**Appendix A: Glossary of Key Terms**

| Term | Definition |
|---|---|
| Hierarchy of Intervention Effectiveness | A risk management theory that rates interventions related to human behaviour (e.g., education and training) at the lower end of its scale, and technological interventions (e.g., forcing functions and automation) as higher leverage actions and more reliable. |
| Human Factors Engineering | Human factors engineering is the discipline concerned with understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology, and cognitive science, to define the parameters and restraints that influence human performance. This knowledge can be used to design systems so that they are compatible with human characteristics. Conversely, if systems are not compatible with human characteristics, performance can be adversely affected. |
| Just Culture | Culture is a set of shared attitudes, values, goals, and practices that characterize an organization. A just culture is a small part of a larger healthcare organizational culture – 'the way we do things around here' – that strives to make care as safe as it can be.[4] |
| Medication Incident | Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. |
| Systems Analysis Approach | A structured process that aims to identify what happened; how and why it happened; and, what can be done to reduce the risk of recurrence and make care safer. |
| Quality Improvement | Using evidence-informed methods to improve policies, processes of care, products, and procedures, and the working styles of individuals and teams. Such actions would usually lead to measurable, sustained reduction of risk for residents.<br><br>The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change — by planning it, trying it, observing the results, and acting on what is learned. Several PDSA cycles are needed to effectively test the proposed changes before widespread implementation at a home. |

***Appendix B: Incident Management Continuum***




Source: Canadian Incident Analysis Framework[2]

Before the Incident

A structured plan for how to recognize, respond and report medication incidents is essential. Establishing and maintaining a Just Culture[1] in the home is fundamental to everyone feeling safe to report and engage in the learning.

Immediate Response to an Incident

The most important immediate action is to care for the resident and care providers involved in the incident. Ensure the care needs of the resident involved in the incident are met to reduce further harm and ensure optimal recovery. Notify the resident's family if harm has occurred and ensure they have an ongoing contact for further information. It is also important to ensure that other residents at the home are not at risk for the same or similar type of incident.

Immediate Response to an Incident (continued)

Additionally, the care providers in the home may need support following an incident. An assessment of their ability to continue to work should be completed and also determine the need for other supports.

Any items involved in the incident are obtained and secured for the upcoming analysis. Items may include the medication vial(s), medication packaging, syringes, health record documentation, devices, etc. that were accessed/involved during medication administration.

Preparation for Analysis

A preliminary investigation, including review of the incident report and health record information as well as interviews with involved care providers and resident/family members, is completed. A decision to conduct a concise or comprehensive analysis is informed by the severity of resident harm related to the incident and the likelihood that a similar incident will reoccur.

Concise Analysis – a facilitator is identified, and they work over several hours or days to complete.

Comprehensive Analysis – a facilitator is identified, and they meet with a formalized analysis team over one or two meetings to complete.

Analysis Process

The primary goal of the incident analysis process is to understand what happened and why so that recommended actions to address the gaps or issues in the process may be developed and implemented.

There are several tools and templates that can help support this goal.

- A timeline document *(see Appendix C)* is used to record the events leading up to, during and after the incident. It incorporates the information gathered from the health record and interviews with the parties involved in the incident from their perspective. The facts are documented in order with the date (and time where available) recorded and the source of the information noted on the timeline document.

- The constellation diagram (*see Appendix D*) is used to document contributing factors under several contributing factor categories – Task, Equipment, Work Environment, Resident, Care Team and Organization. Contributing factors that do not align with these six contributing factor categories are documented under the "other" category.

  With each contributing factor the team asks the question "Why" several times to develop causal chains for the incident. The team keeps asking "Why" until they arrive at a finding that reflects most clearly what in the system contributed to the incident and if it were addressed, it would meaningfully reduce the risk to residents.

- Summary statements are developed based on the findings from the constellation diagram. They describe the relationships between contributing factors and the incident/outcome. The following format is used when developing summary statements.

> *"The contributing factor(s), within the context of the incident, increased/ decreased the likelihood that this outcome would occur."*

- The Hierarchy of Effectiveness[5,6] (*see Appendix E*) can be used to help design improvement actions that are informed by human factors principles and will therefore be more effective in addressing the contributing factors.
- The Action Plan (*see Appendix F*) provides a structured approach to listing the summary statements and the actions that will be taken to address them. Each action should be associated with a goal that is **S**pecific, **M**easurable, **A**chievable, **R**elevant and **T**imely (SMART goal).

Follow-through

The implementation of the action plan involves the pilot and usability testing of the recommended changes. The Plan, Do, Study Act model of iterative cycles of improvement is useful in assessing the effectiveness of the change.

- Plan what you will do,
- Do it,
- Study it for effectiveness and
- Act to improve the process further.

Starting with a small area of the home and spreading to the entire home is an approach to change management that can be effective. When implementing a change, ensure a method of measurement and monitoring the effectiveness of the change as the rollout proceeds.

Close the Loop

Share the learnings from the incident analysis and quality improvement efforts in the home. This can be done both internally within the home and externally for the benefit of other homes. De-identified incident details may be submitted to ISMP Canada via this link: https://ismpcanada.ca/report/

## Appendix C – Incident Analysis Timeline Template[2]

**Timeline**

| Time | Information Item | Information Source |
|---|---|---|
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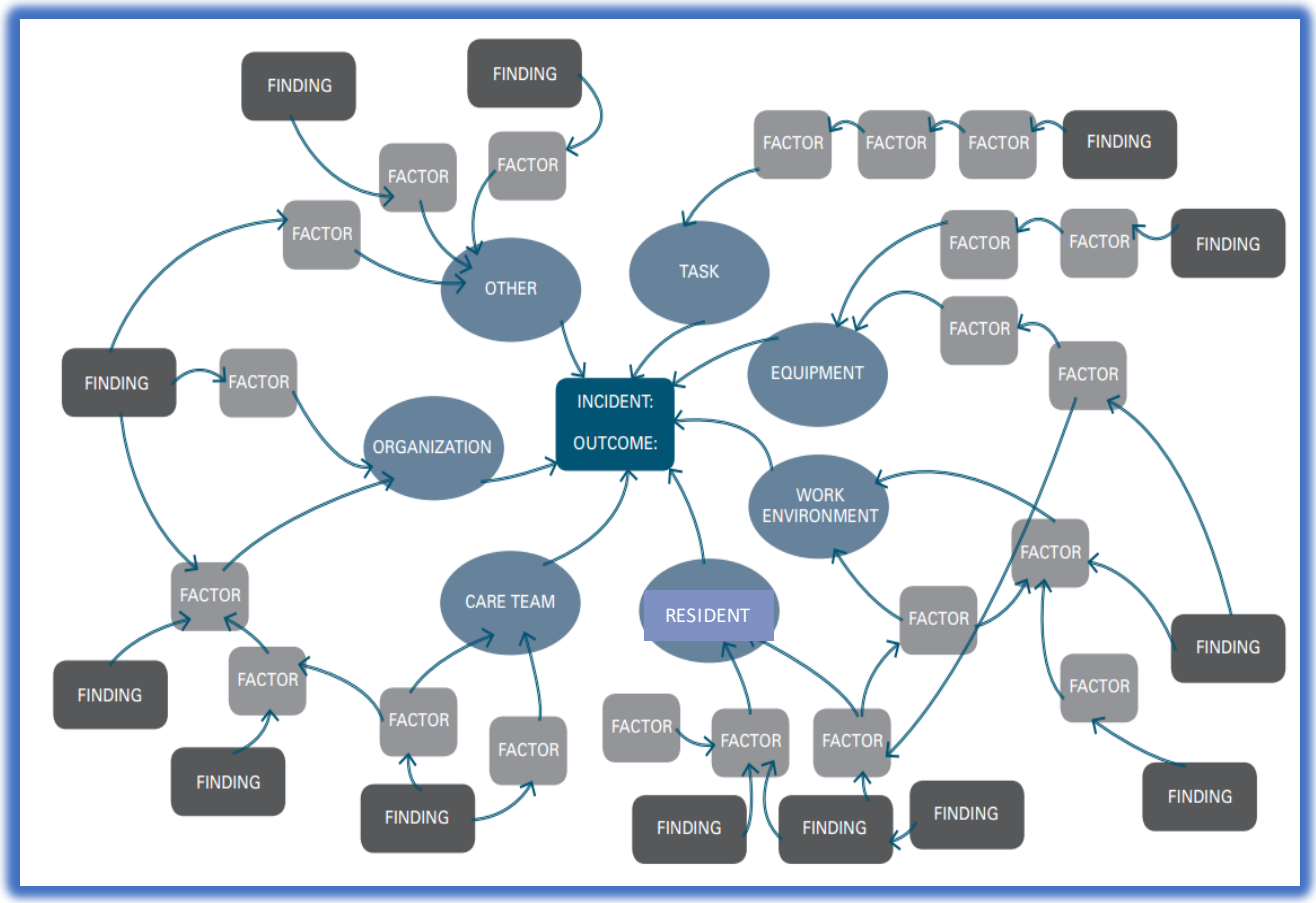
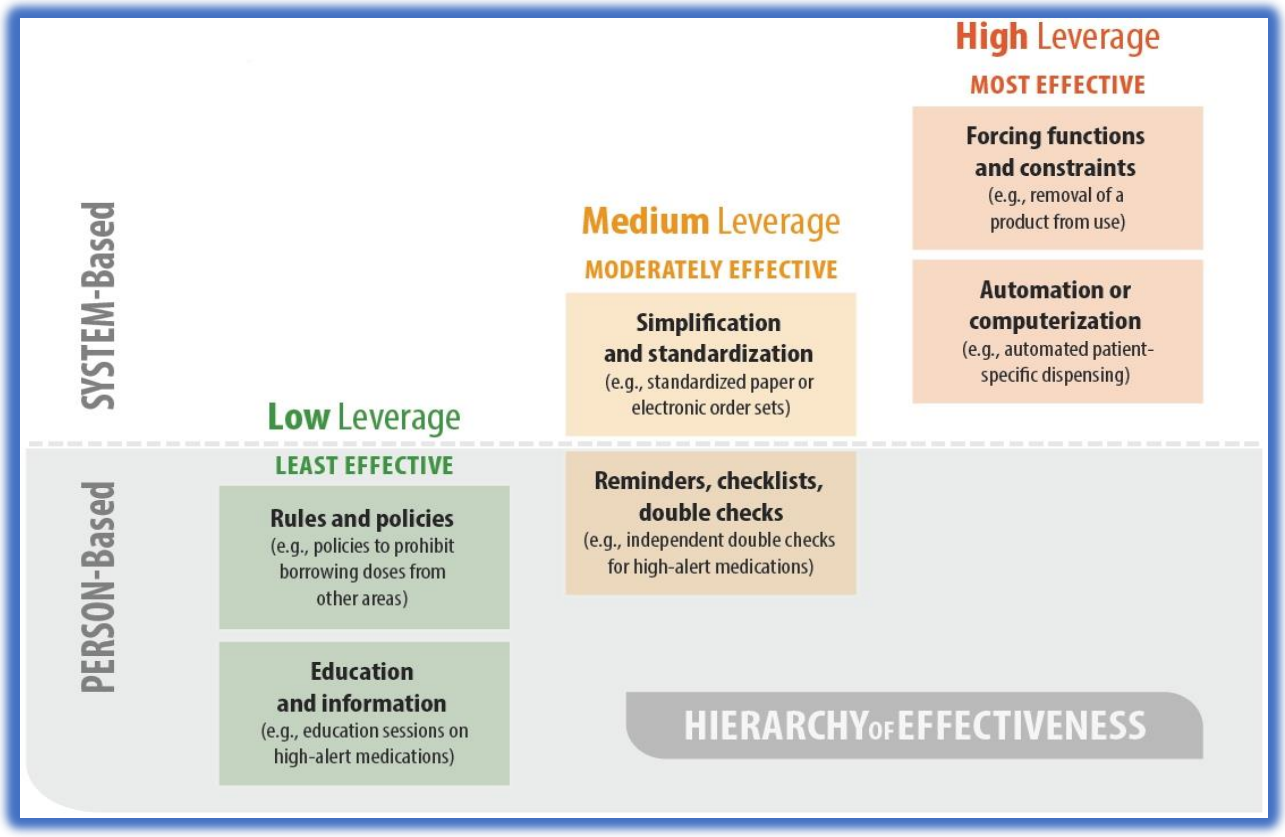
## Appendix D – Incident Analysis Constellation Diagram Template[2]



## Appendix E – The Hierarchy of Effectiveness [5,6]



## Appendix F – Action Plan[2]

**Action Plan**

| **Summary Statement:** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Recommendations/ Actions** *(What are you planning to do?)* | **Specific** *(Is the action clear and precise?)* | **Measurable** *(How will it be confirmed that the action was implemented? How will it be determined if it was effective?)* | **Achievable** *(Is the action attainable with resources and support by a defined date? What more is needed to achieve the goal?)* | **Relevant** *(Does the action actually address the issue? Will the incident be less likely to occur if the action is implemented?)* | **Time-bound** *(What is the timeframe for implementation?)* | **Rank Hierarchy of Effectiveness** *(high, medium, low)* | **Priority** | **Accountability** *(Who, or what department is accountable for the implementation?)* |
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