ROOT CAUSE ANALYSIS (RCA)

Sylvia Hyland, BScPhm
Julie Greenall, BScPhm

Medication Error Response

"I should have read the label."
"This has not happened before."
"This is unlikely to happen again."

Physician who reported a medication error

Medication Error Response

"Thank you for helping me fulfill my moral obligation to the patient's family - my promise to the patient's wife to share the information with others so that steps can be taken to try to prevent the same error from happening again."

Physician who reported a medication error

The definition of an error is that it is unintended.

Need to Believe:

Each human error must have a preceding cause.

(The discovery that a human has erred does little to aid the prevention process)

It’s not the error that is the “treasure”.

It’s the underlying cause that is the “treasure”.

Example: Tb syringe

“Cause” implies no assignment of blame.

Refers to a relationship, or potential relationship between certain factors that enable a sentinel event to occur.

The outcome of the reporting and analysis process must generate a “win win win win” situation for the hospital, patient and health care professional and other hospitals, patients and professionals.

Root Cause Analysis

Case Example:

Solu-Medrol – Depo-Medrol

Why did this child receive the wrong drug?

- Incorrect medication dispensed by nursing supervisor.
- Look-alike/sound-alike drug names.
- Lack of staff familiarity with Solu-Medrol and Depo-Medrol due to infrequent use.
- Poor warning labelling on the product

Why was the incorrect medication dispensed?

- Lack of drug knowledge on the part of the nursing supervisor.
- Look-alike/sound-alike drug names.
- Products stored beside each other in Pharmacy but Depo-Medrol brand name product and Solu-Medrol generic product.
- Only size of Solu-Medrol available in hospital was 1 gram vials.
- Poor warning labelling on product.
- Lack of weekend/after hours pharmacy service.

Extra safety checks completed:

- Dose of medication double checked with children's hospital.
- Drug name double checked in CPS.

Additional Contributing Factors:

- ER department extremely busy.
- Supervisor had been tied up most of the day dealing with staffing issues. Supervisors have commented that they are often filling medications “on the run”.

What are the root causes (i.e. most responsible causes)?

- Lack of weekend/after hours pharmacy coverage.
- Poor warning labelling on product.

What actions were taken as a result of this error?

- Supplementary “IM use only” labels affixed to all vials & boxes of Depo-Medrol.
- Manufacturer notified of incident and requested to consider labelling changes.
- E-mail alert to all pharmacists in region.
- Error reported to ISMP Canada and published.
- Policy change was made to clearly require full disclosure of clinically significant errors to patients/families .
- Proposal submitted to provide weekend pharmacy service.

Additional complicating factors (small hospital issues):

- The nurse who administered the dose was a personal friend of the child's mother.
- One of the hospital pharmacy technicians was a relative of the child.

Some things that went well:

- Once the error was discovered, immediate steps were taken to assess the potential for harm by contacting the children's hospital and the drug manufacturer.
- The Chief of ER was also the family physician and a member of the hospital medication incident review committee.
- The error was disclosed to the family in a timely way.
- Hospital administration was supportive of publishing the error through ISMP Canada.

"We must never let "good enough" be good enough. We must be relentless in our pursuit of finding ways to improve our systems".

VA hospital website

What is Root Cause Analysis (RCA)?

Root Cause Analysis (RCA)

is a technique most commonly used after an incident has occurred in order to identify underlying causes.

Reference: Root Cause Analysis in Healthcare: Tools and Techniques, Joint Commission Resources

What is Root Cause Analysis (RCA)?

A systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.

Reference: The Canadian Patient Safety Dictionary October 2003.

What is a Root Cause?

A cause may be identified as a set of actions, circumstances or conditions.

Things to keep in mind:

"Action errors follow the principle of least effort".

Dr. John Senders

Need to Answer the Question:

What should we do to prevent this in the future?

NOT

What should we have done to prevent this from having occurred?

Things to keep in mind:

"There is an infinite number of equipotent causes. The absence of any one may preclude the error event".

Dr. John Senders

Picture a Tree

Proximate Causes

- Superficial
- Obvious (apparent)
- Immediately precede

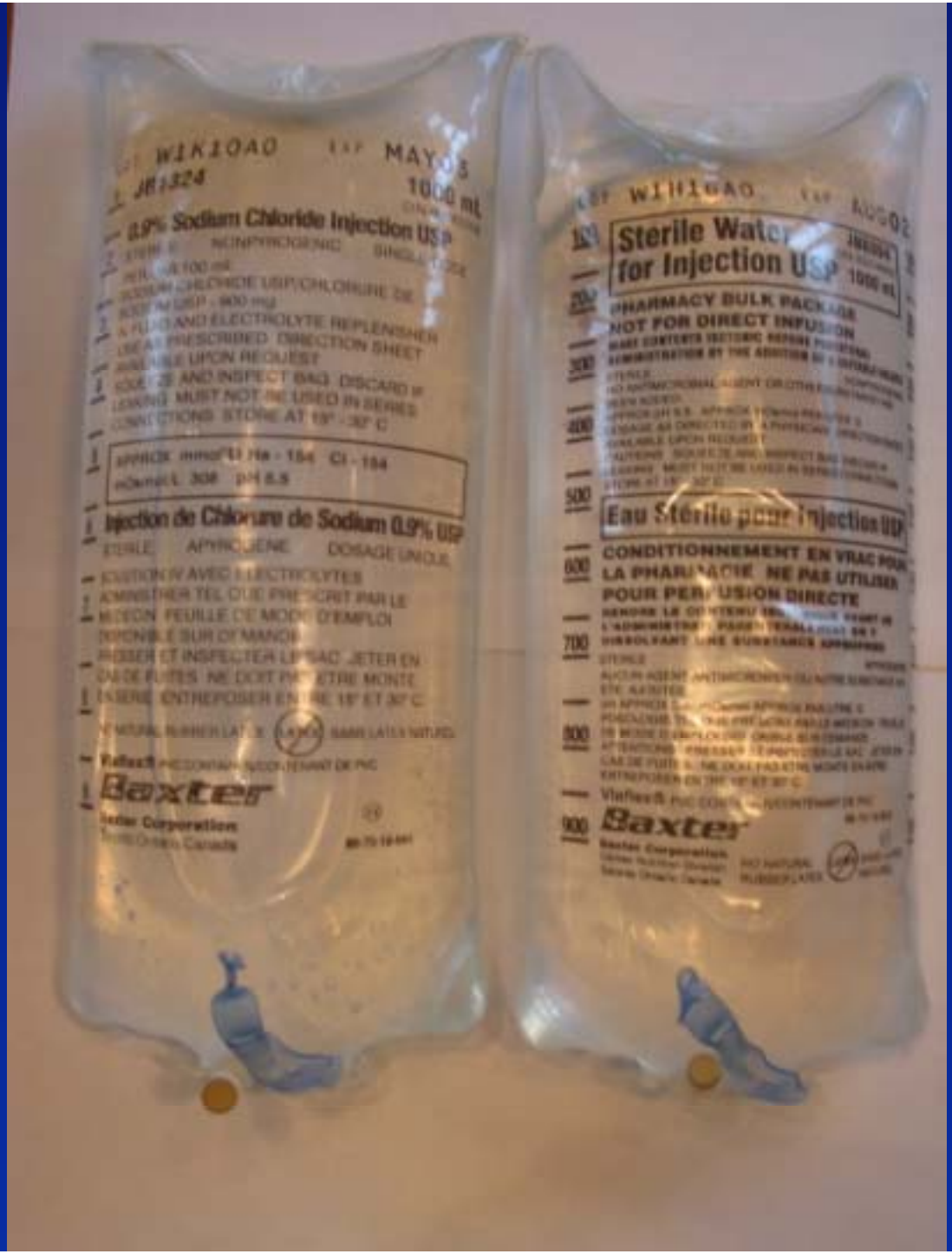
Underlying Causes

- Causes that lead to the proximate causes
- Remote
- Predisposing factor

“FMEA and RCA are mirror images”.

Canada:
3 reports
2 hosp
1 ambulance

US
1 death



Worksheet

Proximate Causes	Underlying Causes
• Water for inj. /water for irrig.	- backorder - same product - less expensive/ one item
• In Central Supply: storage with IV solutions	- catalogue categorized as IV - label on shelf incorrect
• Placed in wrong area in patient room and then administered without detection.	- similar packaging/labelling


100
200
300
400
500
600
700
800
900
Sterile Water for Injection USP
JB0304
DIN 02014882
1000 mL
PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION
MAKE CONTENTS ISOTONIC BEFORE PARENTERAL ADMINISTRATION BY THE ADDITION OF A SUITABLE SOLUTE
STERILE
NONPYROGENIC
NO ANTIMICROBIAL AGENT OR OTHER SUBSTANCE HAS BEEN ADDED
APPROX pH 5.5 APPROX mOsmol PER LITER 0
DOSAGE AS DIRECTED BY A PHYSICIAN DIRECTION SHEET AVAILABLE UPON REQUEST
CAUTIONS SQUEEZE AND INSPECT BAG DISCARD IF LEAKING MUST NOT BE USED IN SERIES CONNECTIONS
STORE AT 15° - 30° C
Eau Stérile pour Injection USP
CONDITIONNEMENT EN VRAC POUR LA PHARMACIE NE PAS UTILISER POUR PERFUSION DIRECTE
RENDRE LE CONTENU ISOTONIQUE AVANT DE L'ADMINISTRER PARENTERALEMENT EN Y DISSOLVANT UNE SUBSTANCE APPROPRIEE
STERILE
APYROGENE
AUCUN AGENT ANTIMICROBIEN OU AUTRE SUBSTANCE N'A ETE AJOUTEE
pH APPROX 5.5 mOsmol APPROX PAR LITRE 0
POSOLOGIE TEL QUE PRESCRIT PAR LE MEDECIN FEUILLE DE MODE D'EMPLOI DISPONIBLE SUR DEMANDE
ATTENTIONS PRESSER ET INSPECTER LE SAC JETER EN CAS DE FUITES NE DOIT PAS ETRE MONTE EN SERIE
ENTREPOSER ENTRE 15° ET 30° C
Viaflex® PVC CONTAINER/CONTENANT DE PVC
88-70-19-603
Baxter
Baxter Corporation
Clintec Nutrition Division
Toronto Ontario Canada
NO NATURAL RUBBER LATEX
SANS LATEX NATUREL


JB0304
1000 mL
DIN 02014882
Sterile WATER for Injection USP
H2O
NOT FOR DIRECT INFUSION
PHARMACY BULK PACKAGE
STERILE
NONPYROGENIC
NO ANTIMICROBIAL AGENT OR OTHER SUBSTANCE HAS BEEN ADDED APPROX pH 5.5 APPROX mOsmol PER LITER 0
DOSAGE AS DIRECTED BY A PHYSICIAN DIRECTION SHEET AVAILABLE UPON REQUEST MAKE CONTENTS ISOTONIC BEFORE PARENTERAL ADMINISTRATION BY THE ADDITION OF A SUITABLE SOLUTE
CAUTIONS SQUEEZE AND INSPECT BAG DISCARD IF LEAKING MUST NOT BE USED IN SERIES CONNECTIONS STORE AT 15° - 30° C
EAU Stérile pour Injection USP
H2O
NE PAS UTILISER POUR PERFUSION DIRECTE
CONDITIONNEMENT EN VRAC POUR LA PHARMACIE
STERILE
APYROGENE
AUCUN AGENT ANTIMICROBIEN OU AUTRE SUBSTANCE N'A ETE AJOUTEE pH APPROX 5.5 mOsmol APPROX PAR LITRE 0
POSOLOGIE TEL QUE PRESCRIT PAR LE MEDECIN FEUILLE DE MODE D'EMPLOI DISPONIBLE SUR DEMANDE RENDRE LE CONTENU ISOTONIQUE AVANT DE L'ADMINISTRER PARENTERALEMENT EN Y DISSOLVANT UNE SUBSTANCE APPROPRIEE
ATTENTIONS PRESSER ET INSPECTER LE SAC JETER EN CAS DE FUITES NE DOIT PAS ETRE MONTE EN SERIE ENTREPOSER ENTRE 15° ET 30° C
VIAFLEX PVC CONTAINER/CONTENANT DE PVC VIAFLEX IS A TRADEMARK OF BAXTER INTERNATIONAL INC/VIAFLEX EST UNE MARQUE DE COMMERCE DE BAXTER INTERNATIONAL INC
88-70-19-914
Baxter
Baxter Corporation
Clintec Nutrition Division
Toronto Ontario Canada
NO NATURAL RUBBER LATEX
SANS LATEX NATUREL

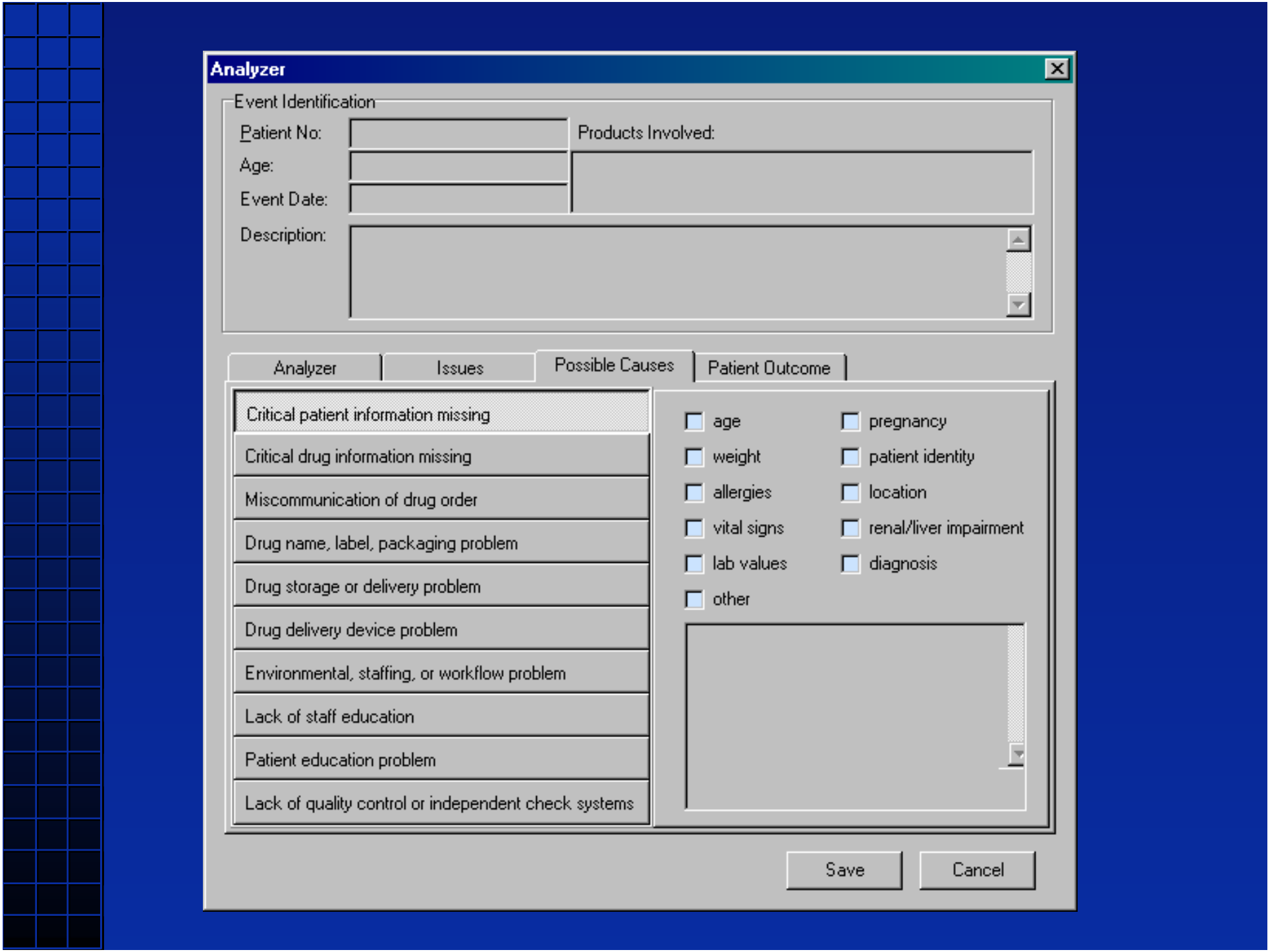

W1K10AO
JB1324
1000 mL
0.9% Sodium Chloride Injection USP
Injection de Chlorure de Sodium 0.9% USP
Baxter
Baxter Corporation
W3H07AO
JB0304
Sterile WATER
for Injection USP
NOT FOR DIRECT INFUSION
PHARMACY BULK PACKAGE
EAU Stérile
pour Injection USP
Baxter

A Root Cause Analysis needs:

- To involve the “right people”
  - Leadership representatives, and
  - Individuals closely involved in process and system under review.
  - Consultants/experts (e.g. purchasing)
  - Interdisciplinary
- To continually dig deeper – ask “why” at each level of cause and effect
- To include consideration of relevant literature
- To be thorough
- Time

A Thorough and Credible RCA Should Be:

- Clear
- Accurate
- Precise
- **Relevant**
- Complete
- Systematic
- Possess depth
- **Possess breadth of scope**


Analyzer
Event Identification
Patient No:
Products Involved:
Age:
Event Date:
Description:
Analyzer
Issues
Possible Causes
Patient Outcome
Critical patient information missing
Critical drug information missing
Miscommunication of drug order
Drug name, label, packaging problem
Drug storage or delivery problem
Drug delivery device problem
Environmental, staffing, or workflow problem
Lack of staff education
Patient education problem
Lack of quality control or independent check systems
age
pregnancy
weight
patient identity
allergies
location
vital signs
renal/liver impairment
lab values
diagnosis
other
Save
Cancel

Conducting a RCA and Developing an Action Plan

- Define the team (small groups and individuals for consultation)
- **Define the problem exactly**
- Study the problem
- **Determine what exactly happened**
- **Identify proximate and underlying causes**
- Confirm the causes through consultation
- Explore and **identify risk reduction strategies**
- Formulate recommendations/actions
- **Consider Human Factors and FMEA before changes**

Report to Senior Management

- Event description
- Scope of analysis (team members and consultants / methods)
- Proximate causes
- Underlying (root) causes
- Improvement actions and follow-up plan

A product of a RCA is an ‘Action Plan’

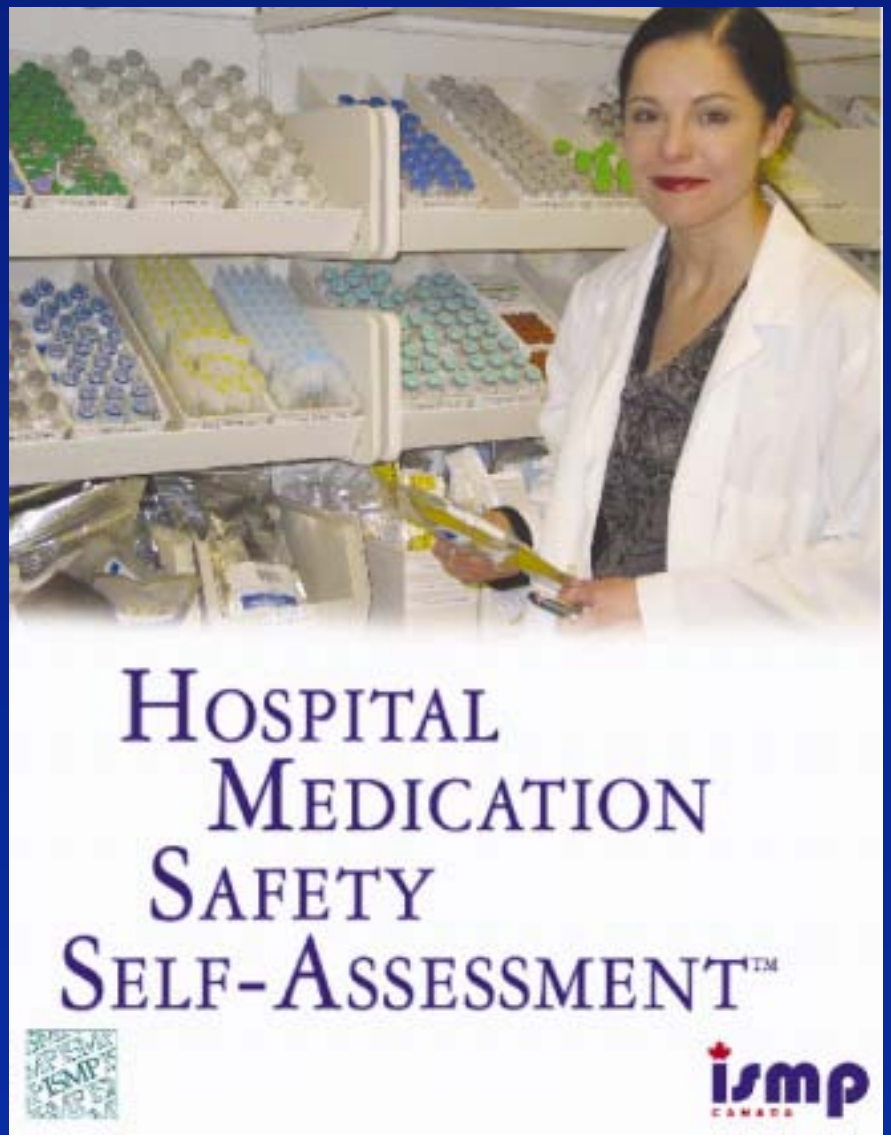
Should include:

- Responsibility for implementation,
- Oversight,
- Pilot testing if needed,
- Time lines,
- Effectiveness measurement.

The causative factor may be beyond an organization's control, however,

in most cases, protection of patients from the effects of the 'uncontrollable factor' can be addressed as a risk reduction strategy.

MSSA - Publication



Medication Safety Self-Assessment™

- Supported by the Ontario Ministry of Health and Long Term Care for all Ontario hospitals
- Added to the CCHSA guideline for Standard 14.0

Questions?