

**A Collaborative
Failure Mode and Effects Analysis
Project with an Ontario Hospital:**

**Reducing the Risk of
Inadvertent Injection of
Concentrated Epinephrine
Intended for Topical Use**

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Failure Mode and Effects Analysis: Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use in an Ontario Hospital

Executive Summary and Priority Recommendations

A number of bulletins published by the Institute for Safe Medication Practices Canada (ISMP Canada), the US Institute for Safe Medication Practices (ISMP), and others have highlighted substitution errors involving the inadvertent injection of concentrated epinephrine 1 mg/mL intended for topical application during elective outpatient ear, nose, and throat (ENT) procedures.¹⁻⁷ Given the high risk of harm or death associated with this type of medication error, further study of the management of this medication was deemed necessary.

An Ontario hospital volunteered to assist ISMP Canada with a prospective analysis of processes related to the use of concentrated epinephrine intended for topical use in the operating room, using the *Canadian Failure Mode and Effects Analysis Framework*.⁸ The hospital had already implemented enhancements to its OR processes to reduce the potential for error with concentrated epinephrine intended for topical use and welcomed the opportunity to assess these enhancements and to share learning with others on completion of this analysis.

ISMP Canada gratefully acknowledges and thanks the Ontario hospital and all the FMEA team members who participated in this analysis process and the Ontario Ministry of Health and Long Term Care for the funding support for this project.

FMEA Process and Findings

ISMP Canada medication safety specialists and a human factors engineer worked with a multidisciplinary team that included OR practitioners (physicians and nurses), pharmacy staff, hospital managers, and quality improvement personnel to undertake an FMEA of the processes involved in performing functional endoscopic sinus surgery. Three on-site meetings were held in late fall 2009. Additional analysis and follow-up were conducted by the ISMP Canada team, and the hospital was given opportunity to review and comment on the report.

The analysis identified a number of potential failure modes. The FMEA framework includes a prioritization process to identify the most critical failure modes, and this process was applied here.

Recommended Actions

The hospital's FMEA team, supported by the ISMP Canada team (including the human factors engineer), used a hierarchy of effectiveness* describing higher and lower leverage strategies to develop system-based recommendations to enhance the safe use of concentrated epinephrine intended for topical use. Education of staff and physicians about the potential lethality of concentrated epinephrine was an important recommendation arising from this FMEA, but was recognized as a lower-leverage strategy for sustained change. Therefore, greater attention was given to other recommendations focusing on system-based (rather than person-based) strategies to reduce the potential for inadvertent selection of concentrated epinephrine, and to increase the likelihood that incorrect selection would be detected before such an error reaches the patient. The recommendations presented in this report are based on the analysis as it was completed; it is acknowledged that there may be additional latent failures or underlying conditions that were not considered by the team during this assessment. In addition, although automation and computerization may offer long-term safety enhancements, the focus of this FMEA was on short-term, readily achievable recommendations. ISMP Canada remains committed to working with the current Canadian manufacturer of epinephrine with a view to changing the packaging for concentrated epinephrine for topical application (for example, to facilitate opening and pouring of the product by OR practitioners, to enhance differentiation of these vials from vials used for injectable products, and to include a bar code for future automation†).

A key process change that had already been implemented at the hospital before the FMEA was conducted was involvement of the ENT surgeon in the checking process for both concentrated epinephrine intended for topical use and the local anesthetic with dilute epinephrine. This involvement is a departure from usual practice in many ORs, where it is more typical for nurses to pre-prepare all medications, so that everything to be used during the procedure, whether placed on a back table or in the sterile field, is ready when the surgeon arrives. Involving the surgeon in the medication-checking process represents a culture change for both nurses and surgeons. In addition, the FMEA team recognized the need to “uncouple” the handling of concentrated epinephrine from other medications used in the procedure. Administration of the correct product (local anesthetic with dilute epinephrine) during the injection step is perhaps the most critical aspect of the process, so involvement of the surgeon in checking the solution that is to be injected is an essential safeguard in separating, or uncoupling, the processes for preparing the various medications, as well as providing an additional check in the process. Thus, it is vital that the preparation

* Hierarchy of Effectiveness – refers to a hierarchy of strategies to eliminate or reduce the potential for error. Higher leverage strategies are those that rely on system design rather than individual performance. A further description is provided in the full report, pp 20, 21.

† Recognizing that automation and computerization represent higher-leverage strategies for medication use, ISMP Canada continues to co-lead the national bar-coding initiative to encourage and facilitate the use of bar codes on all drug products.

and checking of concentrated epinephrine intended for topical use be conducted separately (e.g., at a different time or different place) from the preparation and checking of the local anesthetic with dilute epinephrine.

In reviewing the following recommendations, readers should remember that, while many of the findings will be applicable to other hospitals, this FMEA was unique and specific to the hospital where it was conducted and to a particular ENT procedure (i.e., functional endoscopic sinus surgery [FESS]). Each recommendation must be carefully considered in the context of other existing processes before its implementation is attempted elsewhere.

High-Priority Recommendations for the Hospital and its Practitioners

- Do *not* place a medication such as concentrated epinephrine intended for topical use into a parenteral syringe.
- Conversely, do *not* use open containers to hold medications intended for injection (e.g., local anesthetic with dilute epinephrine).
- Separate processes for preparing concentrated epinephrine intended for topical use from processes for preparing any medications intended for injection, including independent double checks. It is important that all staff and physicians understand the need to “uncouple,” in space and/or time, the handling of concentrated epinephrine for topical use from the handling of other medications, such as local anesthetic with dilute epinephrine intended for injection.
- Keep local anesthetics for injection in their original vials, and withdraw each such medication into a syringe (and label the syringe) immediately before use.
- Use the pour-bottle format of concentrated epinephrine intended for topical use.
 - For situations where the pour-bottle format of concentrated epinephrine is not available (e.g., because it is on back order), have the pharmacy prepare concentrated epinephrine in pour bottles.
 - If the topical epinephrine product is unavailable (e.g., because it is on back order), do not provide or use the injectable format of concentrated epinephrine. If the injectable format is available, it may be withdrawn into a parenteral syringe, even though it is intended for topical use. Whenever a topical medication is placed into a parenteral syringe, there is a risk that it will be injected.
 - The current packaging of concentrated epinephrine 30 mL (for topical administration) is a pour-bottle type format (i.e., vial with pull-tab ferrule), but this has a similar appearance to the vial used for the injectable formulation. Therefore, consideration may be given to routine repackaging by the pharmacy into a more distinct pour-bottle format.^{‡,§}

[‡] ISMP Canada has been advised that some hospitals are routinely repackaging concentrated epinephrine intended for topical use in a distinct pour-bottle format as well as in oral syringes incompatible with parenteral systems. Any hospital taking this approach should consider the factors affecting the stability of epinephrine⁹ to determine the appropriate packaging and expiry date required.

- Consider conducting the surgical pause and completing the intraoperative portion of the surgical safety checklist immediately before injection of the local anesthetic with dilute epinephrine. As part of the surgical safety checklist, consider incorporating a review of the medications to be used during the procedure, whether available in the sterile field or on the back table.
- Continue with independent double checks for medications that have been removed from their original packaging before placement in the sterile field or on the back table.
- To make medication verification more independent, determine who is the best person to read out the manufacturer’s label. Ideally, this should not be the circulating nurse, since this is the person who has retrieved the medication.
- Continue to involve the surgeon in check processes for the local anesthetic with dilute epinephrine (i.e., the medication to be injected). This is a key process in which the ENT surgeons should be involved, since it relates to the medication that they will be injecting (local anesthetic with dilute epinephrine).
- Ensure that all syringes and containers holding medications and/or solutions are labelled at all times.
 - Prepare and label medications (and/or solutions) one at a time. Preprinted labels can facilitate labelling, so long as they are readily available; blank labels and sterile markers should also be readily available as back-up.
 - Ensure that the labelling process includes verification of the preprinted or handwritten label against the original manufacturer’s container.
 - Ensure that the word “TOPICAL” appears on the label of the container holding concentrated epinephrine intended for topical application. Auxiliary labels reading “for external use” may not fully convey the intended meaning for a medication that is applied to a surgical area.
- In the OR, keep concentrated epinephrine for topical use segregated from medications intended for injection (e.g., local anesthetic containing dilute epinephrine) at all times.
- Do not include any medications in the disposable surgical dressing tray. Use a separate labelled container to segregate absorbent products soaked with concentrated epinephrine intended for topical use.**
- Reassess the need for repeated injection of local anesthetic with dilute epinephrine during procedures. For example, at one facility where a mix-up occurred between the concentrated epinephrine for topical use and the local anesthetic with dilute epinephrine, the surgeons now infiltrate the site with local anesthetic before they scrub

[§] On Aug 12, 2010, the manufacturer released *Health Canada Endorsed Safety Information* regarding the risk of inadvertent injection of the topical formulation. For additional information, please refer to: 1) the letter *For Health Professionals*: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2010/adrenalin_hpc-cps-eng.php, and 2) the *Notice to Hospitals*: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2010/adrenalin_nth-aah-eng.php

** Noted by reviewers that alternatives to cotton balls found in disposable dressing trays include ribbon gauze and Neuro Patties absorbent products (which are radiopaque).

and gown for surgery. Subsequent infiltration is seldom required, which means that only one medication (the topical medication) is present in the sterile field.² If additional infiltration of the surgical site is required, the solution should be drawn directly into a syringe from the manufacturer's vial immediately before use. This obviates the need to use a container to hold the injectable solution and ensures that the solution remains in its original vial until required. This also serves to "uncouple" or separate the processes for preparing concentrated epinephrine for topical application and local anesthetic with dilute epinephrine.

- Continue to provide education and to enhance awareness among all OR staff and physicians that concentrated epinephrine is potentially lethal if injected inadvertently. Use this FMEA to illustrate the implications of process details on the potential for error.

ISMP Canada

- ISMP Canada remains committed to working with the manufacturer of concentrated topical epinephrine 30 mL format, with a view to enhancing product packaging and labelling.
- ISMP Canada will continue to share learning from medication incidents.

Additional recommendations are available in the report, on pages 23 to 25 inclusive.

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Failure Mode and Effects Analysis: Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use in an Ontario Hospital

1. Background and Understanding of Project

Organizations interested in minimizing the risk of adverse or unintended events often conduct what is known as failure mode and effects analysis (FMEA). FMEA is a proactive technique applied by a multidisciplinary team to identify potential process and product problems before they occur. It is a safety tool that helps in identifying not only what problems might occur, but also the severity of their effects, their anticipated frequency, and the likelihood that their impending occurrence would be detectable beforehand. In the context of healthcare, the aims of FMEA are first to eliminate potential failures before they occur and then, if elimination is not possible, to prevent failures from reaching the patient; if neither of these goals is achievable, the final goal of FMEA is to reduce the impact of any failure.

The use of a local anesthetic containing dilute epinephrine (0.01 mg/mL or 0.005 mg/mL, also known as 1:100,000 or 1:200,000) by injection (infiltration) is common during surgical procedures in otolaryngology and other specialties. The small dose of dilute epinephrine helps to ensure vasoconstriction of the blood vessels, which promotes hemostasis, as well as prolonging the duration of action of the local anesthetic.¹ However, inadvertent injection of the concentrated formulation of epinephrine (1 mg/mL or 1:1000) intended for topical use can lead to severe harm, or even death, from fatal cardiac arrhythmias.²⁻⁸ Both forms may be present in the operating room during certain procedures, because otolaryngologists sometimes inject a local anesthetic with dilute epinephrine and, at other times during the same surgical procedure, apply concentrated epinephrine topically to the surgical site. The use of both dilute and concentrated epinephrine in the same surgical setting increases the potential for mix-ups and misadministration of concentrated epinephrine.³

A number of bulletins published by the Institute for Safe Medication Practices Canada (ISMP Canada) and the US Institute for Safe Medication Practices (ISMP) have highlighted substitution errors involving the inadvertent injection of concentrated epinephrine 1 mg/mL intended for topical application during elective outpatient ear, nose, and throat (ENT) procedures.^{2,5-8} The most recent bulletin highlighting this issue, published in 2009, described a critical incident in which concentrated epinephrine, instead of the intended local anesthetic lidocaine 1% with dilute epinephrine 0.01 mg/mL, was inadvertently administered by injection during an elective ENT day surgery procedure.² As a result of the error, the patient experienced cardiac arrhythmia, which led to cardiac arrest. Despite full resuscitation measures, the patient died. ISMP Canada has since received reports of similar errors that have occurred in Canada.

With support from the Ontario Ministry of Health and Long-Term Care, through the Ontario Medication Safety Support Service, ISMP Canada has been working to enhance medication safety in acute care and other sectors. In particular, several resource kits have been developed to assist hospitals in better managing high-alert medications.⁹⁻¹¹ A current focus in Ontario is safety in the operating room (OR). The *Operating Room Medication Safety Checklist*¹² was developed in 2007-2008 by ISMP Canada, in collaboration with the Canadian Anesthesiologists' Society and the Operating Room Nurses Association of Canada (ORNAC), with feedback from several Ontario hospitals. Version 1 of the checklist was based on feedback from OR practitioners and the results of pilot testing in spring 2008 by 18 Ontario hospitals (4 of which were multisite organizations). The checklist was further updated, as Version 2, to share learning from the incident referenced earlier.² In early 2010, the Ontario Hospital Association led the province-wide implementation of the surgical safety checklist.¹³ ISMP Canada participated in this initiative to share medication safety strategies for the OR, specifically highlighting methods of preventing inadvertent injection of concentrated epinephrine intended for topical use.

Given the high risk of harm or death associated with this type of medication error, further study of the management of this medication was deemed necessary. An Ontario hospital volunteered to assist ISMP Canada with a prospective analysis of processes related to the use of concentrated epinephrine intended for topical use in the operating room, using the *Canadian Failure Mode and Effects Analysis Framework*.¹⁴ The hospital had already implemented enhancements to its OR processes to reduce the potential for error with concentrated epinephrine intended for topical use and welcomed the opportunity to assess these enhancements and to share learning with others on completion of this analysis.

2. Purpose and Scope

The purpose of the project was to work as a multidisciplinary team to conduct a failure mode and effects analysis (FMEA) on operating room processes for functional endoscopic sinus surgery (FESS) procedure involving the use of concentrated epinephrine 1 mg/mL intended for topical use to identify:

- Previously unrecognized opportunities for error;
- System-based strategies to address identified process gaps to reduce the potential for inadvertent injection of concentrated epinephrine intended for topical use.

3. Methodology

The FMEA was conducted by a local multidisciplinary team, that included an ear, nose and throat surgeon, the Chief of Anesthesia, the OR manager, two OR charge nurses, two OR clinical practice leaders, the Director of Pharmacy and a staff pharmacist, two pharmacy technicians and the Manager of Quality and Risk Management. The FMEA was facilitated by three medication safety specialists from ISMP Canada (two registered nurses and a pharmacist) with the assistance of a human factors engineer. The FMEA was conducted using the methodology described in the *Canadian Failure Mode and Effects Analysis Framework*.¹⁴

3.1 Off-site preparation

Prior to the site visit, the ISMP Canada team worked with the Manager of Quality and Risk to develop a detailed schedule for the project, including the on-site visit. An off-site review of background material pertaining to the project was completed. The ISMP Canada team examined information provided by the hospital to develop a preliminary understanding of the FESS process and locally identified areas of concern. Information provided by the hospital was used to develop a preliminary process map of the FESS process.

3.2 On-site Information Gathering and Analysis

First Meeting:

- Project orientation:
 - Overview of the project
 - Orientation to FMEA, introduction to human factors engineering principles
- Simulation/walk-through of the FESS procedure in the OR

Second Meeting:

- FMEA process initiated
 - Failure modes identified
 - Failure modes prioritized
 - Actions prioritized
 - Incidental findings identified

Third Meeting:

- FMEA process continued
 - Edit process map
 - Determine criticality score cut-off
 - Solution development

3.3 Off-site Analysis

After completion of the site visits, the process maps and spreadsheet were further refined to reflect the on-site discussions and a project report was created.

3.4 Report Preparation

Hospital staff and physicians who participated in the FMEA were asked to provide comments on the draft report, and their feedback has been incorporated. Additional expert review was provided by experts in human factors, anesthesiology and OR nursing.

4. Overview of the FMEA

FMEA is a proactive safety technique that helps to identify process and product problems before they occur. It is one of several types of proactive risk assessment that can be used in healthcare settings. It is also widely used as an integral aspect of improving quality and safety in other industries, e.g., automotive, aviation, and nuclear power.

Failure Mode and Effects Analysis (FMEA) is conducted by a multi-disciplinary team in order to identify:

- *ways that a system or process might fail;*
- *why it might fail;*
- *the effects of the failure; and*
- *how the process can be made safer.*

FMEA focuses on *how and when* a system or process will fail, not *IF* it will fail.

A typical FMEA consists of 8 steps:

Step 1	Select the process to be analyzed and assemble the team.	Step 5	Prioritize the failure modes.
Step 2	Diagram the process and perform a cognitive walkthrough.	Step 6	Redesign the process to address the potential failure modes.
Step 3	Brainstorm potential failure modes for the process and determine their effects.	Step 7	Analyze and test the changes.
Step 4	Identify the causes of potential failure modes.	Step 8	Implement and monitor the redesigned process.

Step 1: Select the process to be analyzed and assemble the Team

The OR procedures in which concentrated epinephrine intended for topical use was utilized were identified by the hospital. This led to the decision to use the FESS procedure as the model for the FMEA.

To maximize the effectiveness of FMEA, a multidisciplinary team of process experts that includes front-line staff and physicians is required. The hospital, with the assistance of ISMP Canada, identified the key positions and individuals who would be invited to participate.

Step 2: Diagram the process to be analyzed

A number of steps were undertaken in order to create a process map of the FESS procedure.

The Manager of Quality and Risk met with staff from the OR to develop preliminary process maps for the FESS procedure. At the first team session, an overview of the FMEA process was provided and the team reviewed the preliminary process maps. A simulation walk-through of the FESS procedure was conducted and photographs were taken to support the analysis process. Information obtained from the multi-disciplinary process review was used to create a new process map, which identified six high-level process steps, plus pre-steps in the FESS procedure. These are listed below and illustrated in Figure 1:

Pre-Steps:

1. Pharmacy provides stock three times a week based on nurse requisition
2. Medication stock is put away by non-registered staff
3. Supplies are picked for case carts.

High-level Process Steps:

1. OR is prepared for case
2. Patient arrives at OR
3. Patient is prepared for surgery
4. Team prepares for surgery
5. Surgery proceeds
6. Case is completed

The FMEA focused on the pre-steps and the high level process steps 1 and 5, as illustrated in the process map (Figure 1) on the following page. These steps were selected for analysis, because they were thought to include the most significant opportunities for error.

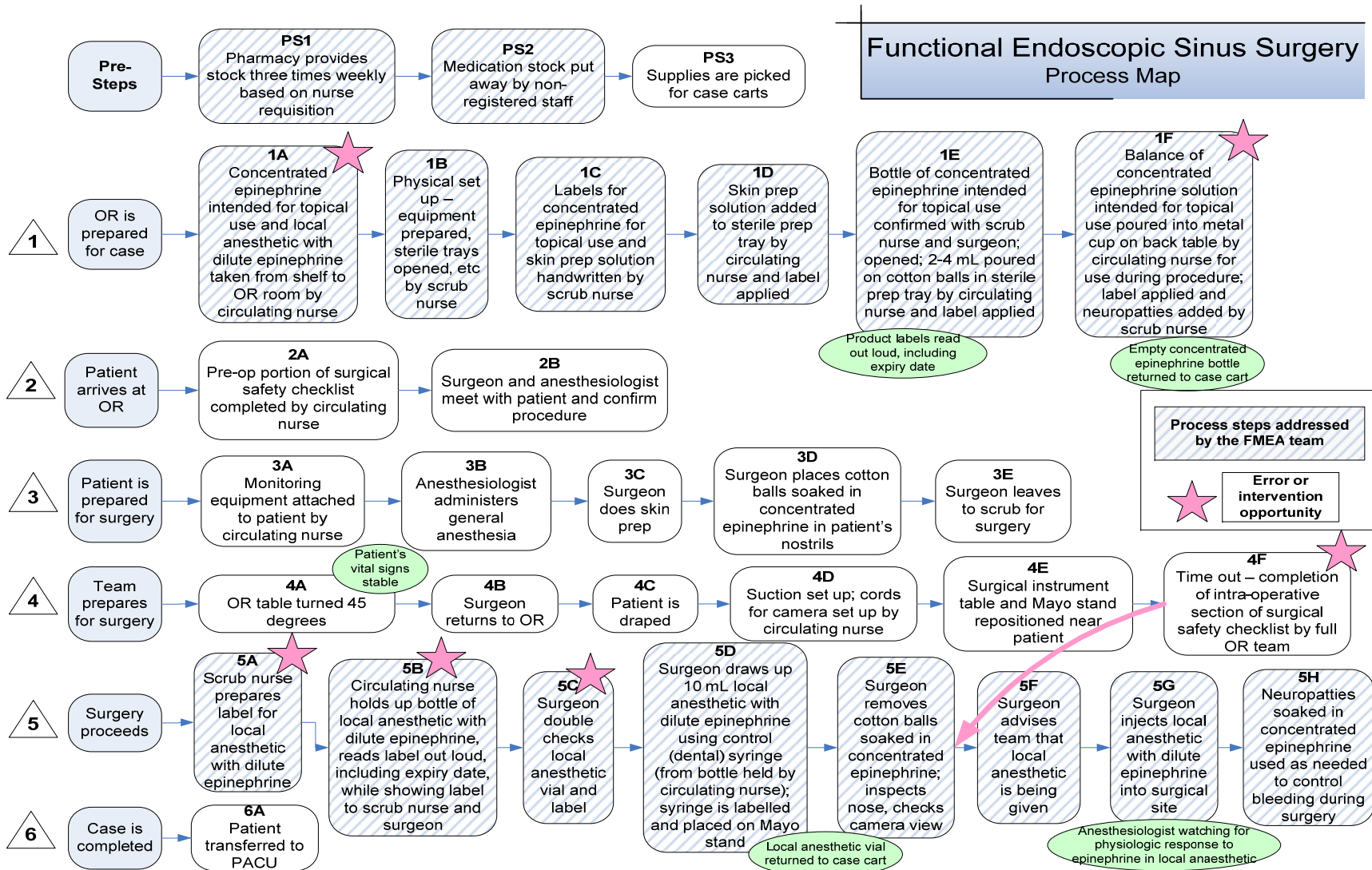


Figure 1: Process Map for Functional Endoscopic Sinus Surgery

Step 3: Brainstorm potential failure modes for the process and determine their effects

Step 4: Identify the causes of potential failure modes

At the second meeting, the team reviewed the updated process map and identified Pre-Step 1A (*Pharmacy provides stock three times weekly based on nurse requisition*), Pre-Step 1B (*Medication stock put away by non-registered staff*), Process Step 1 (*Operating room is prepared for case*) and, Process Step 5 (*Surgery commences*) as the critical steps for analysis.

The multidisciplinary team was divided into two sub-teams to increase the efficiency of the analysis and provide an internal “vetting” process.

To maximize efficiency of documentation, an Excel® spreadsheet was created and a laptop computer and projector were used to by each sub-team to track identified failure modes, effects, causes and recommended actions to reduce risk. (An example of a blank spreadsheet is provided in Appendix 1.)

Step 5: Prioritize the failure modes

In order to maximize the use of available resources, FMEA includes a prioritization process to identify the most critical failure modes. A criticality score is calculated for each failure mode based on the team’s assessment of the *severity of the effect*, the *frequency of occurrence*^{††} of the failure mode and the *detectability* of the failure mode prior to the effect being known. Assessment scales for severity, frequency and detectability used for this FMEA are provided in Table 1.

Severity	Frequency	Detectability
1 = no effect	1 = yearly	1 = always
2 = slight	2 = monthly	2 = likely
3 = moderate	3 = weekly	3 = unlikely
4 = major	4 = daily	4 = unlikely
5 = severe	5 = hourly	

Table 1: Assessment scales for calculation of criticality score

Criticality Score = Severity x Frequency x Detectability

^{††} The frequency scale must consider the likelihood of failure as well as the opportunity. For some FMEAs, consideration may also need to be given to adjusting the sensitivity of the time-scale.

The maximum criticality score that can be obtained is 100. Calculation of criticality scores in an FMEA will typically generate a range of results. Because teams performing FMEAs are typically unable to take action on all failure modes identified, the FMEA framework includes a prioritization process to identify the most critical failure modes, and this process was applied here. FMEA teams should generally be prepared to take action on 60-75% of identified failure modes. Calculation of criticality scores assists the team to identify the highest priority items for attention. Once criticality scores have been calculated, it is common for teams to identify a “cut-off” point for action. Often addressing failure modes with higher criticality scores will also assist with addressing failure modes with lower criticality scores.

Criticality scores calculated for this FMEA ranged from 1-60. The team initially decided to use a “cut-off” score of 20 to prioritize failure modes for action; this was later lowered to a score of 10. Additionally, any failure mode with a severity score of 5 is also automatically considered high priority, regardless of the total criticality score. (Note that criticality scores are relevant only in their relationship to each other within a single FMEA; criticality scores cannot be compared across FMEAs.)

Step 6: Redesign the process to address the potential failure Modes

During the third and final on-site meeting, the FMEA team focused on redesigning the FESS process to eliminate or control the identified failure modes.

Impact of Human Factors Engineering Principles on Error Potential and Solution Development

In planning to address identified failure modes and gaps in the process, it is important to understand the impact of human factors engineering principles in healthcare environments. Human factors engineering is a discipline concerned with how humans interact with the world around them and includes consideration of biomechanics, kinesiology, physiology and cognitive science. Human factors engineering principles can be used to design systems for optimal human performance. Conversely, performance may be impacted negatively when system design does not consider human factors (human abilities and limitations). Analysis of critical incidents often identifies human factors as underlying causes to errors.

When redesigning systems and processes, consideration must be given to whether there is an opportunity to eliminate the hazard, or develop a control mechanism, or safeguard. When considering possible process changes to address identified failure modes, the goal is to reduce the potential for harm by:

1. Decreasing the severity of the effect;
2. Decreasing the frequency of occurrence; and/or
3. Increasing the detectability of the failure, prior to the effect being known.

It is very important to consider the likelihood of sustained success of potential actions. Commonly in healthcare environments, remedial actions have focused on policy development, combined with training and education. The following hierarchy of effectiveness illustrates that these, while necessary, are not high leverage strategies for sustained change.

1. Forcing functions and constraints
2. Automation and computerization
3. Simplification and standardization
4. Reminders, checklists, double checks
5. Rules and policies
6. Education and information



Wherever possible, steps should be taken to eliminate identified hazards. If a problem cannot be eliminated, a control measure, or safeguard, is needed.

A summary of recommended actions follows in Section 5.

5. Recommended Actions from the FMEA

High Priority Recommendations

- Do *not* place a medication such as concentrated epinephrine intended for topical use into a parenteral syringe.
- Conversely, do *not* use open containers to hold medications intended for injection (e.g., local anesthetic with dilute epinephrine).
- Separate processes for the preparing concentrated epinephrine intended for topical from processes for preparing any medications intended for injection, including independent double checks. It is important that all staff and physicians understand the need to “uncouple”, in space and/or time, the handling of concentrated epinephrine for topical use from the handling of other medications, such as the local anesthetic with dilute epinephrine intended for injection.
- Keep local anesthetics for injection in their original vials, and withdraw such medications into a syringe (and label the syringe) immediately before use.
- Use the pour-bottle format for concentrated epinephrine intended for topical use.

- For situations when the pour-bottle format of concentrated epinephrine is not available (e.g., because it is on backorder), have pharmacy prepare concentrated epinephrine in pour bottles.
- If the topical epinephrine product is unavailable (e.g., because it is on back order), do not provide or use the injectable format of concentrated epinephrine. If the injectable format is available, it may be withdrawn into a parenteral syringe, even though it is intended for topical use. Whenever a topical medication is placed into a parenteral syringe, there is a risk that it will be injected.
- The current packaging of the concentrated epinephrine 30 mL (for topical administration) format is in a pour-bottle type format (i.e., vial with pull-tab ferrule), but this has a similar appearance to the vial used for the injectable formulation. Therefore, consideration may be given to routine repackaging by pharmacy into a more distinct pour-bottle format.^{††,§§,15,16,17}
- Consider conducting the surgical pause and completing the intraoperative portion of the surgical safety checklist immediately prior to injection of local anesthetic with dilute epinephrine (in this particular FMEA, this change would be a move from 4F to 5F in the process map.) As part of the surgical safety checklist, consider incorporating a review of the medications to be used during the procedure, whether available in the sterile field or on the back table.
- Continue with independent double checks for medications that have been removed from their original packaging before placement in the sterile field or on and the back table.
- To make the medication double check more independent, determine who is the best person to read out the manufacturer’s label. Ideally, this should not be the circulating nurse, since this is the person who has retrieved the medication.
- Continue to involve the surgeon in the check processes for the local anesthetic with dilute epinephrine (i.e., the medication to be injected). This is a key process for the ENT surgeons to be involved in, since it relates to the medication that they will be injecting (local anesthetic with dilute epinephrine).
- Ensure that all syringes and containers holding medications and/or solutions are labelled at all times.

^{††} ISMP Canada has been advised that some hospitals are routinely repackaging concentrated epinephrine intended for topical use in a distinct pour-bottle format. If a decision is made to move forward with this, consider the stability of epinephrine to determine the new expiry date and the frequency required for repackaging.

^{§§} On Aug 12, 2010, the manufacturer released *Health Canada Endorsed Safety Information* regarding the risk of inadvertent injection of the topical formulation. For additional information, please refer to: 1) the letter *For Health Professionals*: http://www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/prof/2010/adrenalin_hpc-cps-eng.php, and 2) the *Notice to Hospitals*: http://www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/prof/2010/adrenalin_nth-aah-eng.php

- Prepare and label medications (and/or solutions) one at a time. Preprinted labels can facilitate labelling, so long as these are readily available; blank labels and sterile markers should also be readily available as back-up.
- Ensure that the labelling process includes verification of the preprinted or handwritten label against the original manufacturer’s container.
- Ensure that the word “TOPICAL” appears on the label of the container holding concentrated epinephrine intended for topical application. Auxiliary labels reading “for external use” may not fully convey the intended meaning for a medication that is applied to a surgical area.
- In the OR, keep concentrated epinephrine for topical use segregated from medications intended for injection (e.g., local anesthetic containing dilute epinephrine) at all times.
- Do not include any medications in the disposable surgical dressing tray. Use a separate labelled container to segregate absorbent products soaked with concentrated epinephrine intended for topical use.***
- Reassess the need for repeated injection of local anesthetic with dilute epinephrine in procedures. For example, at one facility where a mix-up occurred between the concentrated epinephrine for topical use and the local anesthetic with dilute epinephrine, the surgeons now infiltrate the site with local anesthetic before they scrub and gown for surgery. Subsequent infiltration is seldom required, which means that only one medication (the topical medication) is present on the sterile field.⁵ If additional infiltration of the surgical site is required, the solution should be drawn directly into a syringe from the manufacturer’s vial immediately before use. This obviates the need to use a container to hold the injectable solution and ensures that the solution remains in the original vial until required. This also serves to “uncouple” or separate the processes for preparing concentrated epinephrine for topical application and the local anesthetic with the dilute epinephrine.
- Continue to provide education and to enhance awareness among all OR staff including physicians that concentrated epinephrine is potentially lethal if injected inadvertently. Use this FMEA to illustrate the implications of process details on error potential.

ISMP Canada:

- ISMP Canada remains committed to working with the manufacturer of concentrated topical epinephrine 30 mL format, with a view to enhancing product packaging and labelling.
- ISMP Canada will continue to share learning from medication incidents.

*** Noted by reviewers that alternatives to cotton balls found in disposable dressing trays include ribbon gauze and Neuro Patties absorbent products (which are radiopaque).

Additional Recommendations

Operating Room and Pharmacy

- Keep concentrated epinephrine segregated from the local anesthetic containing dilute epinephrine for injection at all times. Consider enhancing the current storage of medications in the OR as medications for topical use and those intended for injection are currently stored together.
- Purchase and use preprinted sterile labels for concentrated epinephrine intended for topical use and ensure that the word “TOPICAL” is included.
- Always have blank sterile labels and sterile markers readily available as back-up in a designated storage area in each OR. Most custom packs of sterile labels include some blank labels; sheets of blank sterile labels can also be purchased separately.
- Consider carefully any changes to topical solutions that are used in the OR. For example, some of the skin prep solutions are tinted or coloured (e.g., providone) and this difference may be relied upon by practitioners to enhance differentiation from concentrated epinephrine intended for topical use. Changes in any solution used during a procedure from tinted to colourless and vice versa can precipitate new failure modes that need to be taken into account.
- Create an audit checklist that includes medication labelling and conduct audits at regular intervals.
- The current use of a control syringe (sometimes referred to by practitioners as a dental syringe) to inject local anesthetic with epinephrine to may assist with differentiation for the surgeon during FESS procedures; however the applicability of this for other procedures needs to be carefully assessed (e.g., in vascular procedures, some surgeons use the control syringe to inject heparin). It is critical that the processes leading up to the withdrawal of the local anesthetic with dilute epinephrine are *not* coupled (e.g., time, people, location of preparation, location of medication and supplies required) with the preparation of the concentrated epinephrine for topical application, otherwise a mix-up could occur. (This is similar to concerns for potential failures that can occur when practitioners add dye to the concentrated epinephrine for topical use during preparation to help differentiate the concentrated epinephrine from the local anesthetic with dilute epinephrine. Mix ups can occur between the two medications at the time the dye is added if the processes are tightly coupled.⁺⁺⁺

⁺⁺⁺ During the discussions it was recognized that the addition of dye would be best done at the manufacturing level. However, because uses of the concentrated epinephrine (topical) product may also be utilized in other ways, the addition of dye could lead to unintended consequences elsewhere. For example, those utilizing this product for inhalation therapy would likely switch to using the injectable (colourless) solution which would require the use of a parenteral syringe to withdraw the medication—creating a significant and potential failure.

- Similarly, if such practices are to be discontinued, the benefits and risks of the change must be carefully considered by the team(s) involved.)
- Continue to work to create and maintain a "culture of safety" based on ORNAC and Accreditation Canada standards (e.g., expectation that everything is labelled, incorporation of independent double checks).
 - Provide ongoing support (e.g., education) for OR staff and physicians on the following:
 - How to conduct independent checks, including the value of oral and visual confirmation. An illustrative tool developed by the National Patient Safety Agency (UK) may be a helpful example.^{†††}
 - The importance of labelling all medications used in the OR in accordance with ORNAC standards and ISMP Canada's Operating Room Medication Safety Checklist.¹²
 - The importance of keeping conversations focused on the procedure at hand, particularly during critical parts of the procedure, i.e., "sterile cockpit"
 - Continue to use interdisciplinary meetings to assist with team building and support a culture of respect and safety.
 - Continue to monitor best practice research into possible safer alternatives for concentrated epinephrine 1 mg/mL for the FESS procedure. (During the FMEA, it was noted by the team that there have been no clinical trials to identify the ideal concentration of epinephrine to be applied topically to promote hemostasis.)
 - As part of a long-term patient safety plan, consider including the implementation of point of care bar code verification in the OR in the hospital's strategic plan. ISMP Canada is working with manufacturers to include bar coding on their labels. Recognizing that computerization and automation is a higher leverage strategy to enhance safety of medication use, ISMP Canada continues to co-lead the national bar coding initiative with the Canadian Patient Safety Institute to facilitate inclusion of bar codes on all drug products.

Pharmacy:

- Increase pharmacy support to provide pharmacy-based wardstock for the OR (i.e., pharmacy technicians check and replenish medications on a defined schedule).
- Ensure that the medication receiving process in pharmacy includes verification that the correct product has been received (e.g., by checking product numbers).
- Consider enhancing the current storage of medications for the OR to separate storage of medications for topical use and those intended for injection.

^{†††} Double-checking injected anaesthetic drugs. National Patient Safety Agency (UK) [Cited 2010July20]
Available from: <http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/anaesthesia/?entryid45=59845&q=0%C2%ACdouble+checking%C2%AC>

- If auxiliary labels are to be applied to the manufacturer's topical format of concentrated epinephrine, consider using a label that includes the word "TOPICAL". Currently pharmacy-applied auxiliary labels read "for external use" and the word "external" may not fully convey the intended meaning for a medication that is applied to a surgical area.
- Continue to ensure there is a formalized internal alert process in pharmacy regarding the unavailability of high-alert medications such as during backorders (e.g., a checklist that includes notification of the unit pharmacist, remedial steps to be taken, and written notification of the affected unit[s]).
- Work with contract buying group(s) to establish consistent communication processes between the manufacturer, the buying group and member hospitals specifically related to timely notification of unavailability, such as backorders.
- Develop a standard process to ensure that old and new stock is segregated when a labelling change occurs, to reduce the potential for incorrect product selection during the transition period. In addition, use shelf labelling showing the old and new packaging to provide an immediate visual cue to practitioners.

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6. Appendices

Appendix 1: Blank Spreadsheet

Appendix 2: Report References

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Appendix 1: Blank Spreadsheet

Failure Mode and Effects Analysis (FMEA) Worksheet

FMEA Subject:

Failure Mode Number	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Severity	Frequency	Detectability	Criticality Score	Proceed (Y/N)	Actions to Reduce Risk & Outcome Measures
Process Step 1:									
Sub-process step 1A:									
							0		
							0		
							0		
							0		
							0		
Sub-process step 1B:									
							0		
							0		
							0		
							0		
							0		
Sub-process Step 1C:									
							0		
							0		
							0		
							0		
							0		
Sub-process Step 1D:									
							0		
							0		
							0		

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Appendix 2: Report References

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