

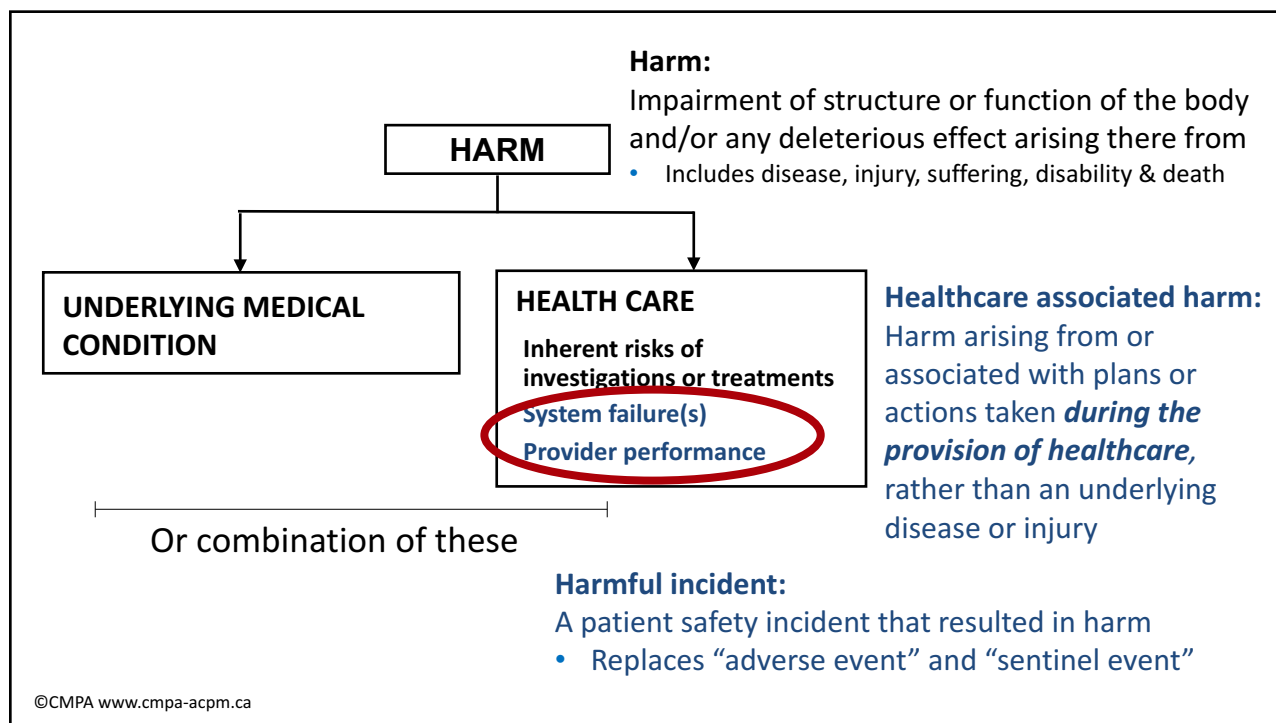
# Honest disclosure: after healthcare-related harm

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## Objectives:

- To discuss what constitutes disclosure and apology, using healthcare as an example
- To review factors which influence individuals' willingness to disclose
- To explore disclosure and apology, and how they relate to Just Culture
- Participants are encouraged to consider the roles of disclosure and apology in their own profession/industry/workplace.



## Patient safety incident =

An event or circumstance which could have resulted, or did result, in unnecessary harm

### Harmful incident:

A patient safety incident that resulted in harm

- Replaces “adverse event” and “sentinel event”

### Near miss:

A patient safety incident that did not reach the patient

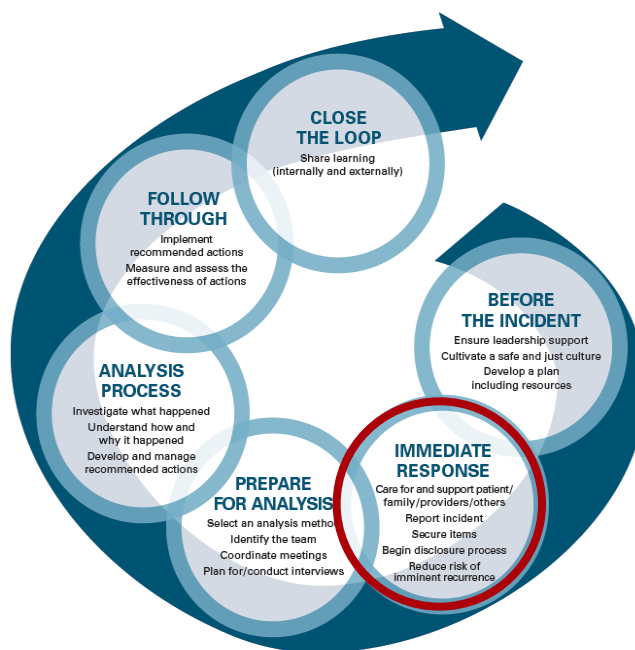
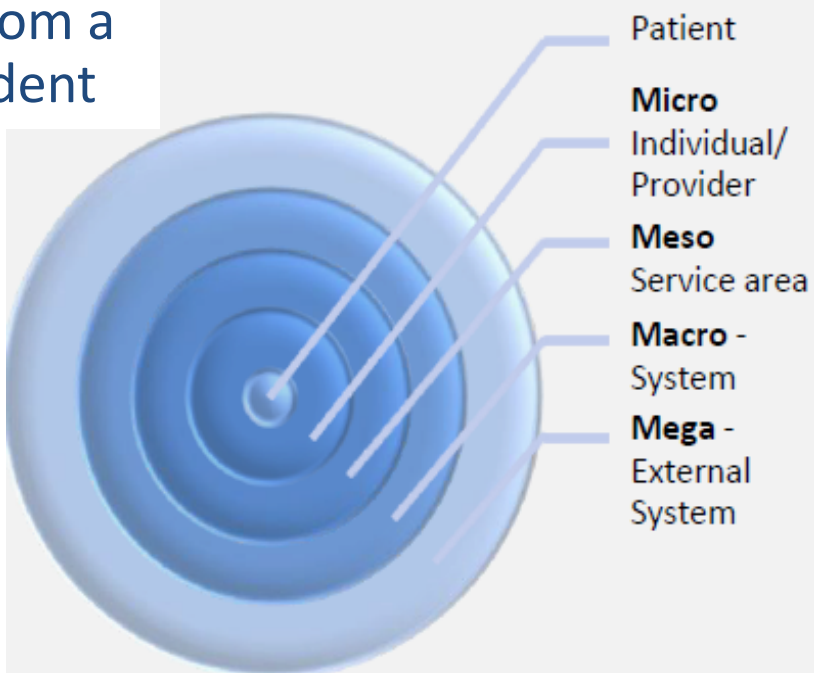
- Replaces “close call”

### No harm incident:

A patient safety incident which reached a patient but **no discernable harm** resulted

## Moving forward from a patient safety incident

- Patient care: priority
- Disclosure
- Incident reporting
- Investigation & analysis
- Sense-making:
  - Morbidity and Mortality conference
  - “protected” venue
  - Informal situations
- Commitment to change?
- Share learnings?





What is  
Disclosure in  
healthcare?

The ***process*** by which a  
patient safety incident  
is communicated to  
the patient by  
healthcare providers.



## What should be/needs to be included in a “disclosure”?

- Acknowledgement
- Apology/expression of regret
- Factual explanation of what happened
- Explanation of what is being done to manage incident
- Explanation of how to avoid recurrence
- Commitment to prevent recurrence
- +/- Offer of compensation

## Reasons to disclose

- **Ethical imperative** to disclose adverse events:
  - Patients have a right to know what has happened to them
  - [Canadian Medical Association (CMA) Code of Ethics includes the following in their list of general responsibilities of physicians to their patients: “Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.”]
  - Disclosure is essential to allow informed consent for ongoing care
  - [Regulation & legislation]:
    - Public Hospitals Act, requires that the hospital have a system in place for disclosure of every critical incident (Government of Ontario, 2016).
    - Additionally, healthcare organizations need an explicit disclosure policy for accreditation purposes (Accreditation Canada, 2015).
- Good communication **strengthens physician–patient relationships**
  - Later discovery of an adverse event that has not been disclosed is damaging to the physician–patient relationship
- Disclosure can provide an **opportunity for forgiveness and reconciliation**
- Good disclosure practice makes effective reporting and learning more likely
- Disclosure allows for just compensation to be sought following an adverse event
- Disclosure may reduce the likelihood of litigation following an adverse event

O'Connor, E., Coates, H.M., Yardley, I.E. & Wu, A.W. (2010). Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care*, 22(5), 371-379.

## How do patient safety incidents impact patients and families?

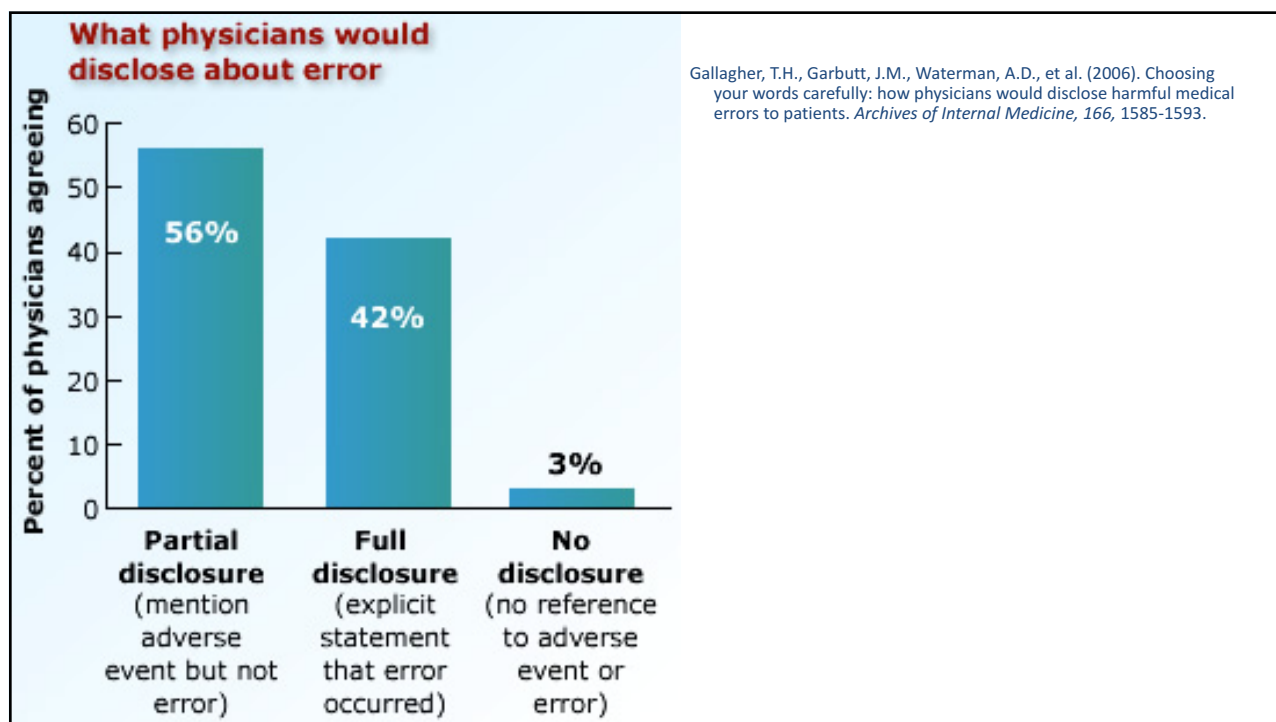
### Impact of patient safety incidents on patients

- Physical trauma
- Emotional trauma: patients and families
  - Sad
  - Anxious
  - Depressed
  - Traumatized
  - Angry
  - Guilt
  - Fear (further harm; retribution from providers)
- Financial trauma: additional costs; lost income; compensation

**Table 1.** Key findings on the frequency of and experiences with disclosure of patient safety incidents

	Medical professionals	The general public
Actual frequency or experience	There was considerable variation in the reported frequency of medical professionals' disclosure of patient safety incidents [13-16] Disclosure of patient safety incidents was conducted more often for minor errors than major errors [17,18] Physicians tended to disclose patient safety incidents more frequently than other medical professionals [19]	The general public reported less experience with the disclosure of patient safety incidents than the reported frequency of medical professionals' disclosure of patient safety incidents [33,34] Most of the general public had little experience with full disclosure, and medical professionals' disclosures were insufficient to meet the needs and expectations of the public [35,36]
Intentions or preferences in hypothetical cases	Contrary to the actual frequency of the disclosure of patient safety incidents, in hypothetical cases, the intention to disclose patient safety incidents generally increased with increased severity of the disability caused by the medical error [17,20] The intention to disclose patient safety incidents also increased with increased clarity of the medical error in hypothetical cases [21-23] Medical professionals were prone to conduct partial disclosure rather than full disclosure [24,25]	Most of the general public absolutely advocated for the disclosure of patient safety incidents in all types of hypothetical cases [25,37]
Simple intentions or preferences	Most medical professionals expressed a simple intention to conduct disclosure of patient safety incidents, and the numbers have gradually grown in recent years [23,26,27] Most medical professionals thought that disclosure of patient safety incidents was unnecessary in the case of near misses [17,22,28-32]	Most of the general public completely supported the disclosure of patient safety incidents regardless of the type of incident [38-43] Most of the general public thought that disclosure of patient safety incidents was necessary in the case of near misses [38,41-43]

Ock, M., Lim, S.Y., Jo, M-W., & Lee, S-I.(2017). Frequency, Expected Effects, Obstacles, and Facilitators of Disclosure of Patient Safety Incidents: a systematic review. *Journal of Preventive Medicine & Public Health*, 50, 68-82.



## Patients and families believe the patient has the right to:

- **Be informed** about the potential harm.
- A **comprehensive & timely investigation** of the facts.
- An **opportunity to provide input** into the investigation.
- **Empathy, understanding, and support** during what might be a very stressful time.
- **Honest, open and transparent disclosure** of the facts.

Patients for Patient Safety Canada

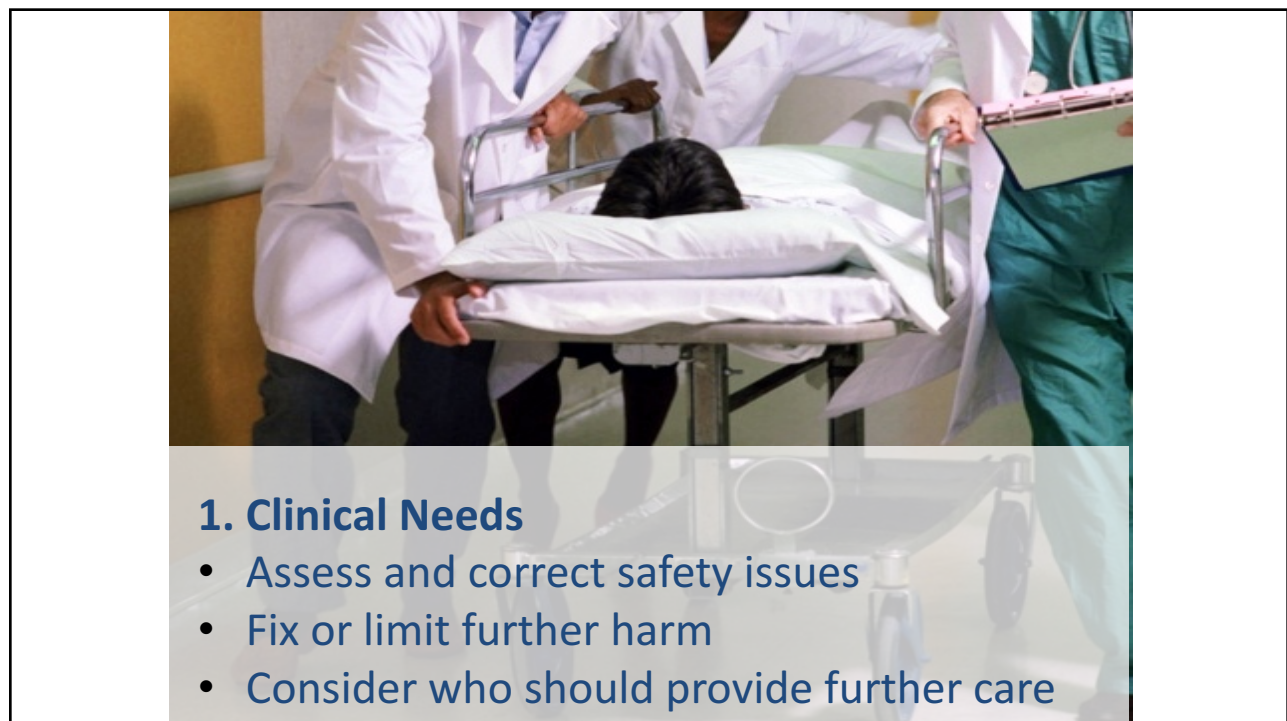


## When it has been found that harm has occurred, the patient expects:

- To be **fully informed** about the harm.
- **Apology** in a timely, respectful, and sincere manner.
- **Acknowledgment** of accountability and responsibility.
- To receive a **complete and comprehensive report** about the AE & to have them shared.
- Informed of how the **harm will be prevented**.
- (Opportunities to be part of the improvement process)
- (Fair and timely compensation)









## 2. Information Needs

- determine known facts
- plan what you will say

## 3. Emotional Needs

- Anticipate patient's reactions
- Consider the need for:
  - family or other support
  - nurse
  - social worker or spiritual advisor



## RESEARCH

**Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study**

Iedema, R., Allen, S., Britton, K., Piper, D., Baker, A., Grbich, C. et al. (2011). Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study. *British Medical Journal*, 343:d4423.

## What physicians don't do well:

- (a) Lack of (or inaccessibility of) timely open disclosure & inadequate preparation
- (b) inappropriate disclosure of unexpected outcomes; inadequate disclosure (lacking open dialogue, sincere apology, plan of care and for avoiding recurrence)
- (c) lack of follow-up support
- (d) lack of appropriate closure
- (e) insufficient integration of open disclosure with improvement of patient safety

## Why don't physicians do a good job disclosing: barriers

- Intrapersonal
- Interpersonal
- Institutional
- Societal

*International Journal for Quality in Health Care* 2010; Volume 22, Number 5: pp. 371–379  
Advance Access Publication: 13 August 2010

10.1093

## Disclosure of patient safety incidents: a comprehensive review

ELAINE O'CONNOR<sup>1</sup>, HILARY M. COATES<sup>2</sup>, IAIN E. YARDLEY<sup>3</sup> AND ALBERT W. WU<sup>4</sup>

**Results.** Both patients and healthcare professionals support the disclosure of adverse events to patients and their families. Patients have specific requirements including frank and timely disclosure, an apology where appropriate and assurances about their future care. However, research suggests that there is a gap between ideal disclosure practice and reality. Although healthcare is delivered by multidisciplinary teams, much of the research that has been conducted has focused on physicians' experiences. Research indicates that other healthcare professionals also have a role to play in the disclosure process and this should be reflected in disclosure policies.

**Conclusions.** This comprehensive review, which takes account of the perspectives of the patient and members of the care team across multiple jurisdictions, suggests that disclosure practice can be improved by strengthening policy and supporting healthcare professionals in disclosing adverse events. Increased openness and honesty following adverse events can improve provider–patient relationships.

## Understanding the Barriers to Physician Error Reporting and Disclosure: A Systemic Approach to a Systemic Problem

Bianca Perez, PhD,\* Stephen A. Knych, MD, MBA,† Sallie J. Weaver, PhD,‡ Aaron Liberman, PhD,\*  
Eileen M. Abel, PhD,§ Dawn Oetjen, PhD,\* and Thomas T. H. Wan, PhD||

**Results:** The current literature underscores that a complex Web of factors influence physician reluctance to engage in transparency. Specifically, 4 domains of barriers emerged from this analysis: intrapersonal, interpersonal, institutional, and societal.

**Conclusion:** Transparency initiatives will require vigorous, interdisciplinary efforts to address the systemic and pervasive nature of the problem. Several ethical and social-psychological barriers suggest that medical schools and hospitals should collaborate to establish continuity in education and ensure that knowledge acquired in early education is transferred into long-term learning. At the institutional level, practical and cultural barriers suggest the creation of supportive learning environments and private discussion forums where physicians can seek moral support in the aftermath of an error. To overcome resistance to culture transformation, incremental change should be considered, for example, replacing arcane transparency policies and complex reporting mechanisms with clear, user-friendly guidelines.

*Journal of Patient Safety, 10(1), 45-51*

## Facing Our Mistakes David Hilfiker

*"Medical school was also a very competitive place, discouraging any sharing of feelings. The favorite pastime...seemed to be sharing...the story of the patient who had been presented to one's team, and then describing in detail how the diagnosis had been reached...The storyteller, having spent the day researching every detail of the patient's disease, could, of course, dazzle everyone with the breadth and depth of his knowledge. Even though I knew what was going on, the game still left me feeling incompetent, as it must have many of my colleagues. I never knew for sure, though, since no one had the nerve to say so...**It almost seemed that one's peers were the worst possible persons with whom to share those feelings.**"*

Hilfiker, D. (1984). *New England Journal of Medicine*, 310(2), 118-22.

## Role-Modeling and Medical Error Disclosure: A National Survey of Trainees

William Martinez, MD, MS, Gerald B. Hickson, MD, Bonnie M. Miller, MD, David J. Doukas, MD, John D. Buckley, MD, MPH, John Song, MD, MPH, MAT, Niraj L. Sehgal, MD, MPH, Jennifer Deitz, MA, Clarence H. Braddock, MD, MPH, and Lisa Soleymani Lehmann, MD, PhD, MSc

Academic Medicine, Vol. 89, No. 3 / March 2014

### Abstract

#### Purpose

To measure trainees' exposure to negative and positive role-modeling for responding to medical errors and to examine the association between that exposure and trainees' attitudes and behaviors regarding error disclosure.

#### Method

Between May 2011 and June 2012, 435 residents at two large academic medical centers and 1,187 medical students from seven U.S. medical schools received anonymous, electronic questionnaires. The questionnaire asked respondents about (1) experiences with errors, (2) training for responding to errors, (3) behaviors related to error disclosure,

(4) exposure to role-modeling for responding to errors, and (5) attitudes. Academic Medicine, Vol. 89, No. 3 / March 2014 regression, the authors analyzed whether frequency of exposure to negative and positive role-modeling independently predicted two primary outcomes: (1) attitudes regarding disclosure and (2) nontransparent behavior in response to a harmful error.

#### Results

The response rate was 55% (884/1,622). Training on how to respond to errors had the largest independent, positive effect on attitudes (standardized effect estimate, 0.32,  $P < .001$ ); negative role-modeling had the largest independent,

negative effect (standardized effect estimate,  $-0.26$ ,  $P < .001$ ). Positive role-modeling had a positive effect on attitudes (standardized effect estimate,  $0.26$ ,  $P < .001$ ). Exposure to negative role-modeling was independently associated with an increased likelihood of trainees' nontransparent behavior in response to an error (OR 1.37, 95% CI 1.15–1.64;  $P < .001$ ).

#### Conclusions

Exposure to role-modeling predicts trainees' attitudes and behavior regarding the disclosure of harmful errors. Negative role models may be a significant impediment to disclosure among trainees.

## Intrapersonal Barriers

**Knowledge gaps:** lack of knowledge of disclosure processes and protocols

- the disclosure policy of the institution
- the apology legislation for the region
- the stance of the liability carrier towards apology
- Lack of formal teaching on patient safety or disclosure/how to conduct a disclosure meeting in the context of legal and insurance risk

**Experiential gaps:**

- neither observed a staff physician conduct a disclosure meeting, nor participated in a disclosure meeting

**Emotionally challenging:**

Lack of insight among clinicians into what patients and family members regard as requiring disclosure

Concerns about how to disclose incident information to patients and family members

The challenge of communicating with colleagues about (their) incidents

Iedema, R., Allen, S., Sorensen, R., & Gallagher, T. H. (2011). What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety*, 37(9), 409–417.

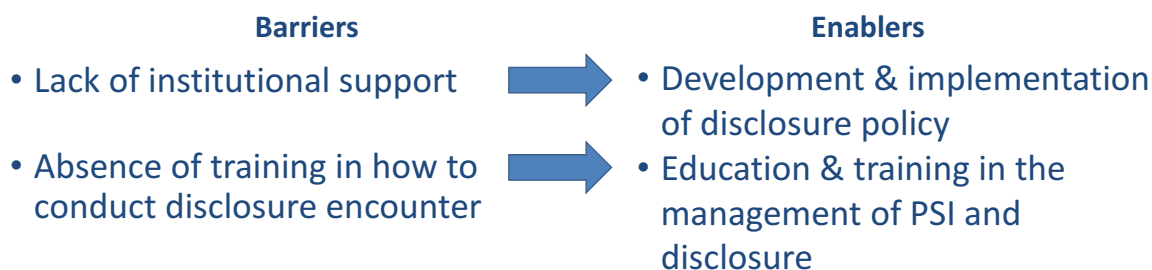


## Interpersonal barriers

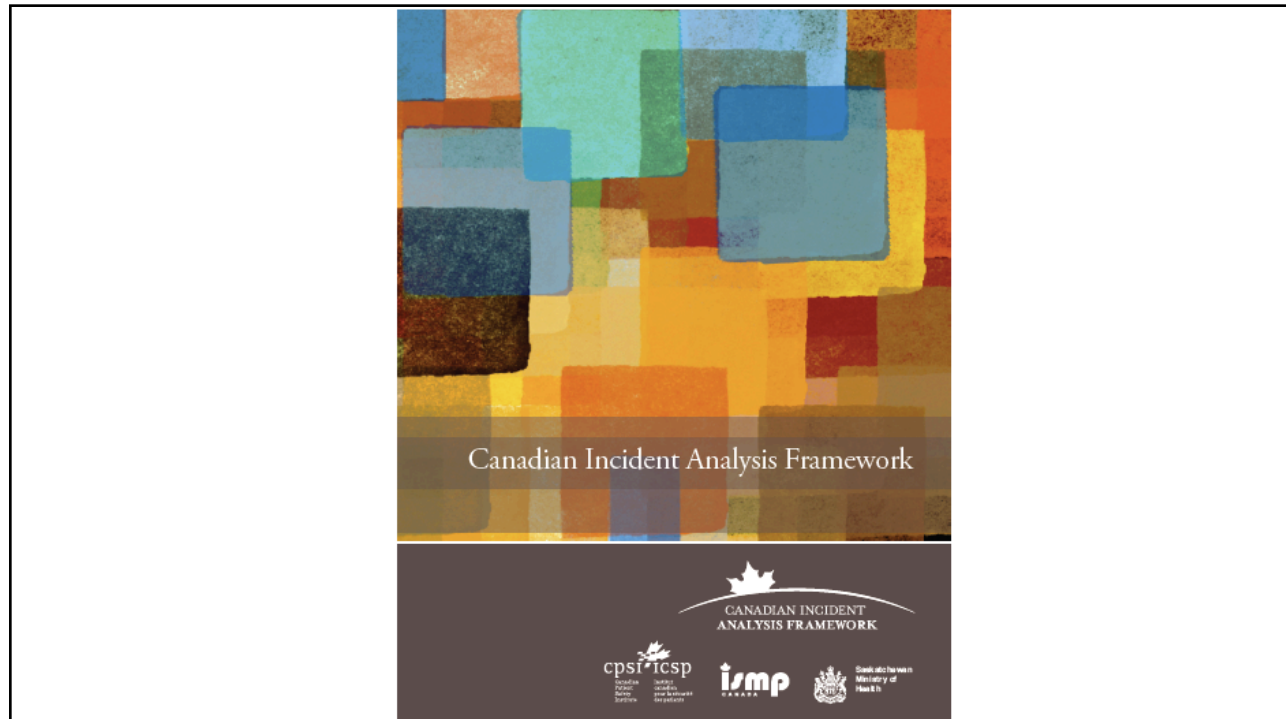
- Fear of loss of relationship with the patient
- Fear of loss of reputation or damage to career progression
- Fear of loss of colleagues' respect
- Patients may have broader definition of medical error:
  - Poor interpersonal skills
  - Quality issues (eg. wait times)
  - Studies indicate that patients understand medical errors to be inevitable; that an error could happen during their care was frightening to them

Gallagher, T.H., Waterman, A.D., Ebers, A.G., Fraser, V.J., & Levinson, W. (2003). Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association*, 289(8), 1001-1007.

## Institutional Barriers & Enablers



Ock, M., Lim, S.Y., Jo, M-W., & Lee, S-I.(2017). Frequency, Expected Effects, Obstacles, and Facilitators of Disclosure of Patient Safety Incidents: a systematic review. *Journal of Preventive Medicine & Public Health*, 50, 68-82.







**Individual  
Accountability**

**Systems  
Issues**

[http://upload.wikimedia.org/wikipedia/commons/9/90/Embl%C3%A8me\\_de\\_la\\_Justice.jpg](http://upload.wikimedia.org/wikipedia/commons/9/90/Embl%C3%A8me_de_la_Justice.jpg)

## Disclosure & Just Culture:

How can JC be enacted in the disclosure process?

What about your:

- Industry?
- Organization?

## How & why things go wrong



## TRUST: the 5 Rights for the Second Victim

Denham, C.R. (2007). TRUST: the 5 rights of the second victim. *Journal of Patient Safety*, 3(2), 107-119.

1. Treatment that is just:
  - Avoid stigmatizing
2. Respect
  - Avoid blaming-shaming
3. Understanding and Compassion:
  - Don't abandon the healthcare provider
4. Supportive Care:
  - Access to appropriate support services
5. Transparency and the Opportunity to Contribute:
  - Culture of learning

Waterman, A.D., Garbutt, J., Hazel, E., Dunagan, W.C., Levinson, W., Fraser, V.J., & Gallagher, T.H. (2007). The emotional impact of medical errors on practicing physicians in the United States and Canada. *Joint Commission Journal of Quality and Patient Safety*, 33:467-476.

## The Emotional Impact of Medical Errors on Practicing Physicians in the United States and Canada

Amy D. Waterman, Ph.D.  
Jane Garbutt, M.B., Ch.B.  
Enik Hazel, Ph.D.  
William Claiborne Dunagan, M.D.  
Wendy Levinson, M.D.  
Victoria J. Fraser, M.D.  
Thomas H. Gallagher, M.D.

- 90% physicians surveyed disagreed that hospitals and healthcare organizations adequately support them in coping with stress associated with safety incidents
- 82% somewhat or very interested in counseling
- Barriers:
  - Taking time off work
  - Did not believe counseling would be helpful
  - Confidentiality concerns
  - Negative impact on record of employment
  - Negative impact in malpractice insurance costs
- 89% ever disclosed serious patient safety incident
- **18% received education or training**
- **86% somewhat or very interested in receiving education/training**

## Review

## Teaching Medical Error Disclosure to Physicians-in-Training: A Scoping Review

Lynfa Stroud, MD, MEd, Brian M. Wong, MD, Elisa Hollenberg, MSW, and Wendy Levinson, MD

Academic Medicine, Vol. 88, No. 6 / June 2013

### Abstract

#### Purpose

This scoping review identified published studies of error disclosure curricula targeting physicians-in-training (residents or medical students).

#### Method

In 2011, the authors searched electronic databases (e.g., MEDLINE, EMBASE, ERIC) for eligible studies published between 1960 and July 2011. From the studies that met their inclusion criteria, they extracted and summarized key aspects of each curriculum (e.g., level of learner, program discipline) and educational features (e.g., curriculum design, teaching and assessment methods, and learner outcomes).

#### Results

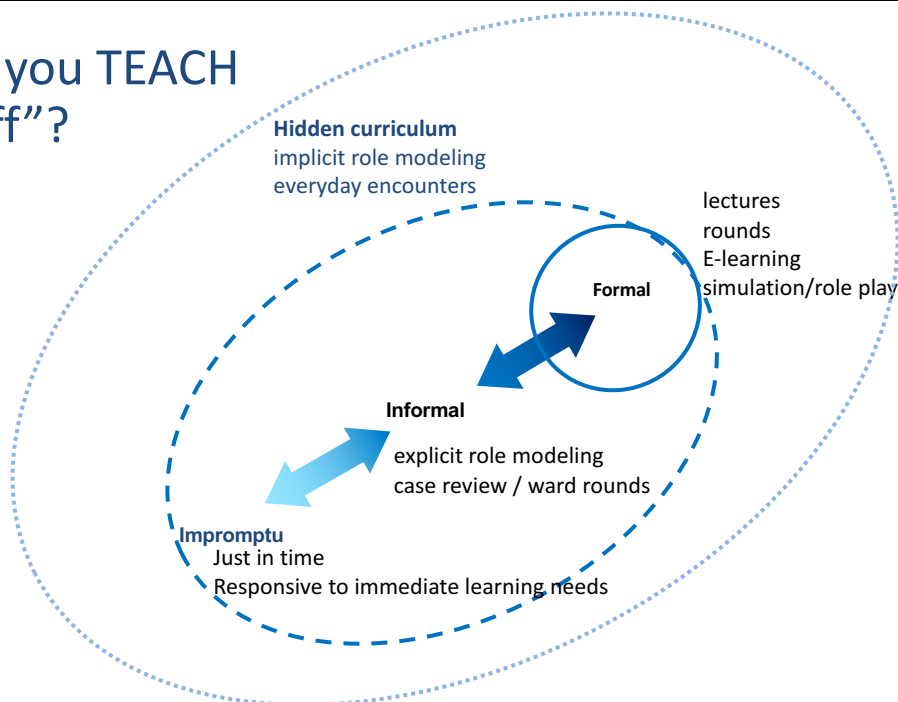
The authors identified 21 studies that met their inclusion criteria. These studies described 19 error disclosure curricula, which were either a stand-alone educational activity, part of a larger curriculum in patient safety or communication skills, or part of simulation training. Most curricula consisted of a brief, single encounter, combining didactic lectures or small-group discussions with role-play. Fourteen studies described learners' self-reported improvements in knowledge, skills, and attitudes. Five studies used a structured assessment and reported that learners' error disclosure skills improved after completing the curriculum;

however, these studies were limited by their small to medium sample size and lack of assessment of skills retention. Attempts to assess the change in learners' error disclosure behavior in the clinical context were limited.

#### Conclusions

Studies of existing error disclosure curricula demonstrate improvements in learners' knowledge, skills, and attitudes. A greater emphasis is needed on the more rigorous assessment of skills acquisition and behavior change to determine whether formal training leads to long-term effects on learner outcomes that translate into real-world clinical practice.

## HOW do you TEACH "this stuff"?



## Societal barriers/enablers: Apology Legislation

- Many physicians are concerned that by offering a patient an apology for an adverse event they will expose themselves to liability.
- One of the objectives of apology legislation is to reduce the concerns about the legal implications of making an apology. The protection afforded by the apology legislation is substantially similar from province to province. It typically provides that an apology:
  - does not constitute an admission of fault or liability
  - must not be taken into consideration in determining fault or liability
  - is not admissible as evidence of fault or liability
- The protection extends both to legal proceedings before courts and proceedings before tribunals or quasi-judicial bodies, such as regulatory authority (College) disciplinary committees or coroners' inquests.
- An apology is generally defined in the statutes as encompassing an expression of sympathy and regret and a statement that one is sorry, or any other words or actions indicating contrition or commiseration, **whether or not the words or actions admit or imply an admission of fault.**

<https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2008/apology-legislation-in-canada-what-it-means-for-physicians>

## What are the implications of apology legislation? The view of the liability carrier, CMPA:

- Physicians practising in a jurisdiction in which apology legislation has been enacted, have statutory protection that any apology they make to a patient cannot be used against them in subsequent court proceedings as evidence to establish fault or liability.
- For physicians practising in a jurisdiction in which apology legislation is **not** in place:
  - an apology was made and any admission of fault that might have been made during an apology could be admissible in legal or College proceedings.
- Expressions of regret will be appreciated by all patients:
  - At the post-analysis disclosure stage, after the analysis of the adverse event is complete and it is clear that a healthcare provider or healthcare organization is responsible for, or has contributed to, the harm from an adverse event, it is appropriate to acknowledge that responsibility and to apologize.
- Avoid the use of words that express or imply legal responsibility, such as negligence, liable, fault or failed to meet the standard of care.

## Alberta Evidence Act, Chapter A-18: **Apology**

### **Effect of apology on liability**

**26.1(1)** In this section, “apology” means an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate.

**(2)** An apology made by or on behalf of a person in connection with any matter

- (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter
- (b) does not constitute a confirmation or acknowledgment of a claim in relation to that matter for the purposes of the *Limitations Act*,
- (c) does not, notwithstanding any wording to the contrary in any contract of insurance and notwithstanding any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available, to the person in connection with that matter, and
- (d) shall not be taken into account in any determination of fault or liability in connection with that matter.

**(3)** Notwithstanding any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter.

**(4)** This section does not apply to the prosecution of an offence.

## Why do patient sue?

## Unmet need for disclosure increases litigation

### Why patients sue doctors:

- **To obtain access to medical records:**
  - **Fulfill unmet information need for an explanation** of what happened
- Concern for **standards of care**
- **Compensation for additional/ongoing healthcare costs**
- **Compensation for pain, suffering**
- **Accountability**

## Liability Claims and Costs

- **University of Michigan Health System has fully disclosed and offered compensation** to patients for medical errors since 2001.
- **Retrospective before-after analysis** from 1995 to 2007.
- UMHS implemented this program **without increasing** its total claims and liability costs.
  - New claims/month/100 000 patient encounters: 7.03 → 4.52
  - Lawsuits/month/100 000 patient encounters: 2.13 → 0.75
  - Interval to claim resolution: 1.36 → 0.95 year
  - Average cost lawsuit: \$405 921 → \$228 308

Kachalia, A., Kaufman, M.A., Boothman, R., Anderson, S., Welch, K., Saint, S., Rogers, M. (2010). Liability claims and costs before and after implementation of a medical error disclosure program. *Annals of Internal Medicine*, 153, 213-221.

## The UMHS program

- Institution-wide comprehensive program that starts before a medical error occurs, focussing on process improvement along with the risk management aspects of a patient safety incident.
- Aiming to create realistic expectations for the patient
- May prevent some of the surprise or disappointment that the patient and his/her family would otherwise experience when an adverse outcome occurs.
- Department of Risk Management is charged with assisting healthcare providers to identify patient injuries before they become claims.
- Online reporting system

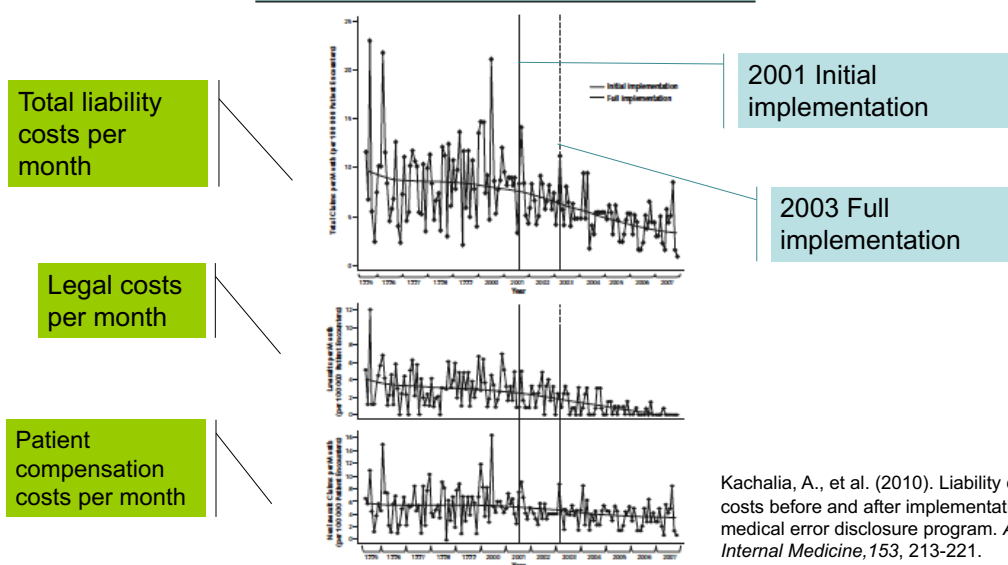
American Medical Association. (2015). Early disclosure and compensation programs.

## The UMHS program

- The UMHS claims management model follows three basic principles:
  - Compensate quickly and fairly when unreasonable medical care causes injury;
  - Defend medically reasonable care vigorously; and
  - Reduce patient injuries (and therefore claims) by learning from patients' experiences.

## Liability Claims and Costs and Costs Before and After Implementation of a Disclosure Program

Figure 1. Monthly rates of new claims before and after implementation of the University of Michigan Health System disclosure-with-error program.



## BUT...

- Computer modelling:
  - Dependent on which data sources; including experts
  - EDC programs may encourage patients and families to undertake a claim
- System of complaints and compensation
  - Canada: anecdotally, increased complaints but fewer claims



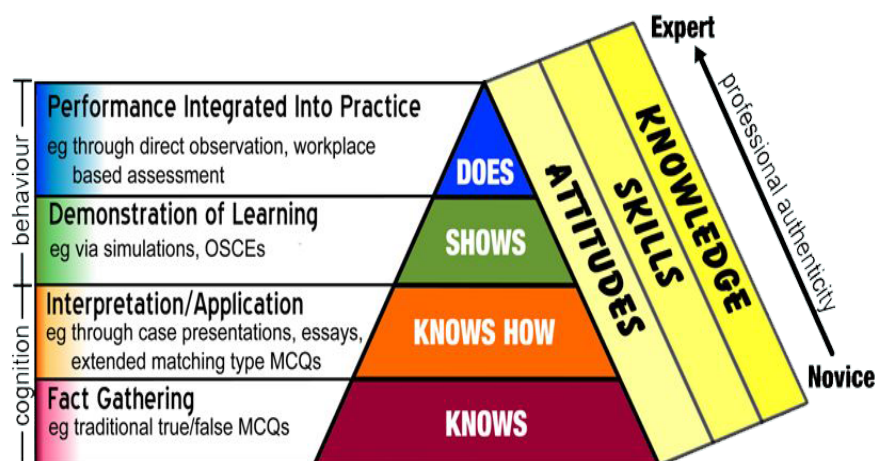
## If physicians did disclose, what then?

- Legal actions:
  - does not appear to increase likelihood
  - May reduce rates of lawsuits
- Patient-physician relationship:
  - Improved patient satisfaction, improved credibility
  - Improves evaluation of quality of care
- Provider:
  - Reduces sense of guilt
  - Reduces likelihood of similar safety incident
  - Promotes professional behaviour, collaboration, respect, positive role modelling to trainees

Ock, M., Lim, S.Y., Jo, M-W., & Lee, S-I.(2017). Frequency, Expected Effects, Obstacles, and Facilitators of Disclosure of Patient Safety Incidents: a systematic review. Journal of Preventive Medicine & Public Health, 50, 68-82.

### MILLER'S PRISM OF CLINICAL COMPETENCE (aka Miller's Pyramid)

it is only in the "does" triangle that the doctor truly performs



Based on work by Miller GE, The Assessment of Clinical Skills/Competence/Performance; Acad. Med. 1990; 65(9): 63-67  
Adapted by Drs. R. Mehay & R. Burns, UK (Jan 2009)

## Empathy = “emotional process with substantial implications for moral behaviour”

“Empathic responsiveness requires:

- (a) the cognitive ability to take another person’s perspective
- (b) the cognitive ability to accurately recognize and discriminate another person’s affective experience
- (c) the affective ability to personally experience a range of emotions (since empathy involves sharing another person’s emotional experience).”

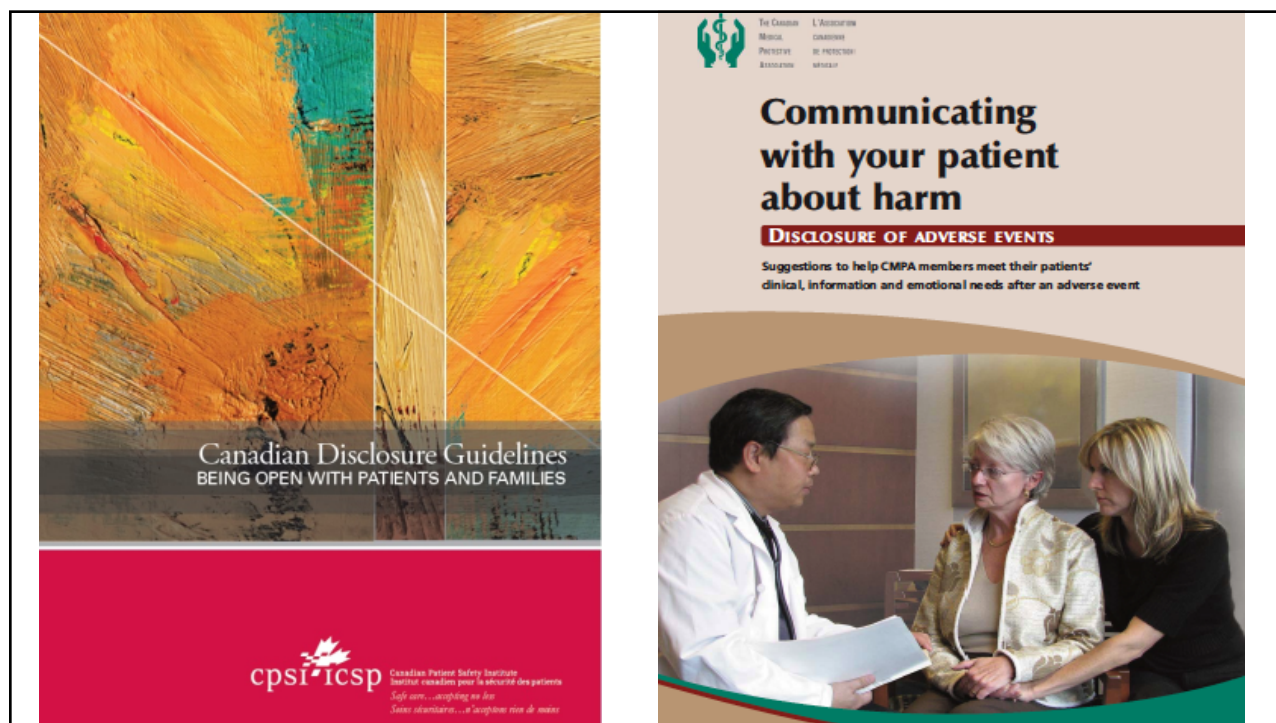
Consequences:

1. Generates concern for the affected other
2. Prompts helping behaviour
3. Inhibits aggressive behaviours

Tangney, J.P., Stuewig, J., & Mashek, D. J. (2007). Moral emotions and moral behaviour. *Annual Review of Psychology*, 58, 345–372.

## How would you assess empathy?

- As an observer?
- As a family member?
- As a colleague?
  
- Video: anesthesiology



## Initial Disclosure Meeting Checklist:

### Elements of disclosure:

1. Introduction - setting the stage
2. Posture and positioning
3. Content
4. Manner
5. Listening
6. Ending the meeting—wrapping up

The Canadian Medical Protective Agency. Communicating with your patient about harm: disclosure of adverse events. 2008.

## Introduction: Setting the Stage

1. **Introduce** those present as required.
2. Introduce the **topic** for discussion
3. Ask if there is **someone else** whom he or she would like present.

## Posture and Positioning

1. **Avoid barriers** such as a desk.
2. **Sit at eye level** or a little lower whenever possible.
3. **Appropriate eye contact** and a **forward sitting posture** will reflect concern.

## Content

1. **Express regret** as appropriate.
2. Find out **what the patient already knows** and is experiencing.
3. **Describe the clinical condition** as it now exists.
4. Present the existing **facts**.
5. **Do not speculate or blame** others.
6. **Emphasize how seriously you are taking** the situation.
7. **Allow patient time** to express feelings.

## Manner

1. **Be professional** in appearance and demeanor.
2. Use plain language, **avoid jargon**.
3. Speak at a comfortably **slow rate**.
4. **Focus on patient's needs**.
5. ? Touch ?

## Listening

1. **Be attentive, genuine and convey concern.**
2. **Be sensitive** to:
  - any language barriers.
  - the patient's cultural background / values
3. **Check for understanding** frequently.
4. Patient's **non-verbal communication**.
5. **Gently seek clarification** if you sense an unspoken concern.
6. **Welcome questions.**

## Ending the Meeting: Wrapping Up

1. **Do not put a time limit** on the meeting.
2. **Questions?**
3. Confirm the **clinical next steps**.
4. **Summarize** discussion of the facts.
5. **Ensure the patient's understanding**.
6. **Define nature and timelines** of any analysis to answer how/why the event occurred.
7. Provide **contact information**.
8. Arrange a **follow-up** meeting.
9. Informing patient's **family physician?**

## Documentation

- **Date, time, and location**
- **Name/roles** of those present
- **Facts** of what occurred
- **Reactions and responses**
- **Questions** raised, answers given
- Agreed upon **next steps**
  - Care plan
  - Analysis of the event
  - Follow-up meetings
- Share documents with patients/families

## What NOT to do!



- **Don't be evasive**
- **Don't use jargon**
- **Don't be defensive**
- **Don't speculate**
- **Don't blame others**
- **Don't rush**
- **Don't script**
- **Don't alter documentation**

## Maple Leaf Foods – Listeria, 2008

- Largest food processing company in Canada
- August 4: a series of 11 food samples tested positive for *Listeria monocytogenes*.
- August 7: Canadian Food & Inspection Agency (CFIA) initiated a food safety investigation.
- August 17: the CFIA issued successive 'Health Hazard Alerts' warning the public not to consume or serve certain Maple Leaf cold meat products; voluntary recall of 2 products
- August 20 : MLF voluntarily expanded the scope of its recall and announced that the Barton Road plant in Toronto (97B), would be temporarily closed.
- Aug 20 - September 6, the source of the outbreak was confirmed to be plant 97B, a hold and test protocol for the plant was implemented, and daily public health press conferences were held.
- August 23: MLF expanded voluntary recall to cover all 191 products manufactured at 97B.
- August 24: Mr. McCain reiterated that MLF's actions [were] guided by putting the public health first.

## How effective was this disclosure?

- [https://www.youtube.com/watch?v=r9sw\\_SU7Wpg](https://www.youtube.com/watch?v=r9sw_SU7Wpg)



## Michael McCain, CEO of Maple Leaf Foods, Public apology - August 23, 2008:

"My name is Michael McCain. As you may know *Listeria* was found in some of our products. Even though *Listeria* is a bacteria commonly found in many foods and in the environment, we work diligently to eliminate it. When *Listeria* was discovered in the product we launched immediate recalls to get it off the shelf. Then we shut the plant down. Tragically our products have been linked to illnesses and loss of life. To Canadians who are ill and to the families who have lost loved ones I offer my deepest sympathies. Words cannot begin to express our sadness for your pain. Maple Leaf Foods is 23,000 people who live in a culture of food safety. We have an unwavering commitment to keeping your food safe with standards well beyond regulatory requirements. But this week our best efforts failed and we are deeply sorry. This is the toughest situation we've faced in 100 years as a company. We know this has shaken our confidence in us. I commit to you that our actions are guided by putting your interest first."

[https://www.youtube.com/watch?v=r9sw\\_SU7Wpg](https://www.youtube.com/watch?v=r9sw_SU7Wpg)

## Michael McCain, CEO of Maple Leaf Foods, Public statement - August 25 & 27, 2008:

- 'Going through the crisis there are two advisers I've paid no attention to. The first are the lawyers, and the second are the accountants. It's not about the money or the legal liability, this is about being accountable for providing consumers with safe food.'
- 'I absolutely do not believe this is a failure of the Canadian food safety system or the regulators. Certainly knowing there is a desire to assign blame, I want to reiterate that the buck stops here. We have an unwavering commitment to keep food safe, and we have excellent systems and processes in place but this week it's our best efforts that failed not the regulators or Canadian food safety system.'

## Aftermath

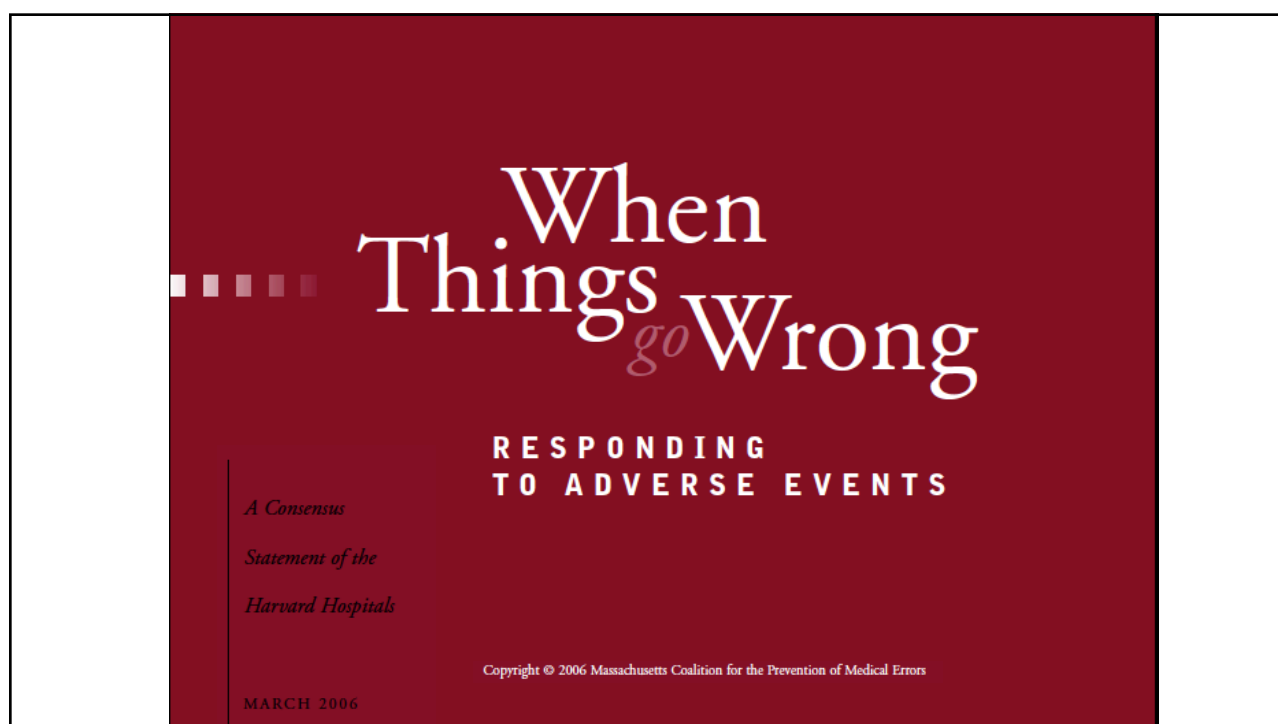
- 23 deaths; 57 confirmed cases
- Class action lawsuits: CA \$100 million compensation claimed
- December 2008: settled, CA \$ 27 million

## How effective was his strategy?

- Business
- Shareholder
- Reputation
- Sales fell significantly
- Share prices fell
- October 2009: returned to profitability

## Please discuss in your small groups:

- What is disclosure in your industry?
- How does it differ from disclosure in healthcare?
  - Discuss in your small groups: 5 min
  - Share in large group: 10 min





**Innovation Series 2010**

## Respectful Management of Serious Clinical Adverse Events



Conway J, Federico F, Stewart K, Campbell M. Respectful Management of Serious Clinical Adverse Events. IHI Innovation Series white paper. Cambridge, Massachusetts: IHI; 2010.

Many thanks for participating!

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