Disclosure of Medical Error and Root Cause Analysis

Facilitators Manual

Ethan Cumbler MD, FACP Dimitry Levin MD

Contact Information

Ethan Cumbler MD, FACP
Associate Professor of Medicine
University of Colorado School of Medicine

Ethan.Cumbler@ucdenver.edu
12401 E. 17th Ave.
Campus Box F-782
Aurora, CO
80045
Phone 720-848-4289
Fax 720-848-4293

Dimitry Levin MD
Assistant Professor of Medicine
University of Colorado School of Medicine
Dimitriy.Levin@ucdenver.edu
12401 E. 17th Ave.
Campus Box F-782
Aurora, CO
80045
Phone 720-848-4289
Fax 720-848-4293

Last Revised

2-28-2012

Resource Description

Preceptor-facilitated Small Group Workshop combining discussion of a major medical error, root cause analysis, and simulated disclosure and apology to the patient. Format is multimedia including Power-point didactic component, small group break-out session, and interactive group discussion with patient interaction simulation. This module begins with a dramatic case presentation of clinically significant medical error. The precipitating event in this sequence of medical errors is a simple slip error of a nature which will be familiar to any clinician. Participants are encouraged to think about the medical error in the context of errors of omission and commission, active and latent elements of error, and system structures which would reduce the chance of the slip error from causing patient-level harm. Small group break-out sessions divide up the root cause analysis into the elements of a fishbone diagram and the small groups will develop contributing factors for the adverse event. These are brought back for the larger group to discuss. The final element of the module includes a return to a short preceptor didactic covering the literature behind disclosure of medical error and discussion of when, and how, error and adverse events should be disclosed to patients (aspects of this portion were updated from Cumbler E, Glasheen J, Teaching Patient Safety via a Structured Review of Medical Errors: A Novel Approach to Educating Residents about Medical Error, Disclosure, and Malpractice. MedEdPORTAL; 2007). For the final component of the module volunteers from the audience will be used to simulate the disclosure and apology for the patient in the medical error case with structured feedback.

Purpose, Goals, and Objectives

Participants will be able to

1. Describe the multifactorial nature of medical error leading to patient harm with both active and latent contributors to error.
2. Utilize root cause analysis to systematically examine a medical error using fishbone methodology and the "five whys" technique to explore system-level contribution.
3. Perform disclosure to patients of medical error leading to adverse event.

Intended Audience and Prerequisites

This module is in use for second year Internal Medicine residents in a hospitalist training program. It could be expected to be applicable for house staff in Internal Medicine, Family Practice, medical students in the clinical years. Learners should be familiar with basic pathophysiology and pharmacology and most importantly in clinical operations of the hospital system. The complete module requires three hours to complete.

Instructor Qualifications and Responsibilities

The preceptor should be familiar with medical error, the hospital system, and have experience disclosing medical error to patients. Small group facilitation skills are needed and the willingness to share personal experience with medical errors and difficult disclosures will significantly enhance the module's performance.

Required Resources

Computer with projector. Flip charts, White/Black board or large surface to mount the flip chart results for fishbone diagram large group discussion.

Suggested Agenda

30 minutes	Didactic: Introduction to the Root Cause Analysis – Basics about using an RCA – Defines terminology
120 minutes	Small Group work: RCA Case – Presentation of RCA Case – Divide learners into small group work on Case and RCA thread (will need markers and paper) – Each group will work on one aspect of the fishbone; facilitators should be available – Report out to large group
40 minutes	Disclosure of Medical Errors – Each group will review their scenarios and present their findings
10 minutes	Debrief and eval

Suggested Preparation for Learners

Prior to the session, learners will need to read these articles:

- Gallagher, et al. Disclosing Harmful Medical Errors. *NEJM*, 2007; 356:2713-9.
- Wachter, RM. Patient Safety at Ten: Unmistakable Progress, Troubling Gaps. *Health Affairs*, 2010; 29(1):165-173.
- Complete IHI Open School Course: Root Cause and Systems Analysis and Communicating with Patients after Adverse Events (PS 104 and PS 105) http://www.ihi.org/lms/coursedetailview.aspx?CourseGUID=450435c3-f015-4541-9432-46eb235461bb&CatalogGUID=6cb1c614-884b-43ef-9abd-d90849f183d4

Procedures for Implementation

Notes section under each slide provides comments, references, and supplementary information for the facilitator.

Section I-Medical Error Case.

Slide 2 is a humorous reminder than the medical system has a history of inadequate response to medical error. The clinicians illustrate "hear no evil, see no evil, speak no evil" which in practice can translate into "physicians/hospitals bury their mistakes". This slide can be used to bring up the medical system's response to medical error which, at its worst, swings between ignoring or minimizing errors which are near misses or result in only minor adverse events and a punitive culture in which front line providers are blamed for errors leading to major adverse events without addressing the underlying systemic contributors to error.

Slides 3-7 set up a case with medical error. This is based on an actual medical error in a transplant patient due to omission of a key immune suppressive agent during transfer from intensive care unit to general medical unit. All identifying PHI, has been removed from this case and non-essential but potentially identifying information, including the specific organ which was transplanted, has been changed to protect the identity of the patient involved. Facilitators are encouraged to substitute with a complex medical error case from their own system and experience. If this is done the facilitator should be aware of the details of the case and contributing factors such as by participation in a risk management investigation. Preferably a medical error case with contributors from multiple elements comprising the fishbone analysis should be selected. In this case the first key error was a "slip error" in which in the process of re-copying a long and complex list of medications in this recently transplanted patient one critical medication, mycophenolate, was inadvertently omitted from the transfer orders. The common experience of slip errors can be illustrated by asking the audience how often they write the wrong year on documents in January compared to December. The facilitator can point out that slip errors are difficult to guard against because they are not due to deficits in either knowledge or skill. At the same time point out that slip errors become more common in predictable circumstances such as in sleep deprivation, distraction, or excessive time pressure. The audience can be asked to reflect on the environment in which ICU transfer orders are commonly written and whether some of these factors are likely to be present.

Slide 8 illustrates the "Swiss cheese" conceptualization of medical error. This postulates that there are many latent predispositions to error ("holes") in a complex medical system. Most of the time the holes are not aligned and so the predisposition to error, or even errors themselves, do not manage to reach the patient (just as a when a few random slices of Swiss cheese are stacked together). However, when the circumstances are such that all of holes are in alignment, medical error can reach the patient and cause an adverse event. This slide is an opportunity to have the larger group actively participate in the session. They can brainstorm all of the latent factors which pre-dispose this situation to an error leading to an adverse event occurring. Examples can include: Upcoming transition of personnel. Medications with narrow therapeutic index. Closed ICU policy mandating a transfer of care. Policy which requires re-writing of orders at time of transfer between levels of care increasing risk for "slip errors". System designed for active orders for medications to be continued but lack of mechanism requiring medications being discontinued be explicitly stopped. Lack of pharmacy involvement in complex cases using high risk medications. Polypharmacy.

Slides 9-10 demonstrate the second error in the sequence of events which will lead to the patient's adverse event. The omission of the mycophenolate is now missed by all parties involved (facilitator can point out that more individuals are seeing this patient every day then the single house-officer whose note is being examined in this case discussion). The "failure to correct" errors are now being made by different clinicians than the one who made the initial mistake. In this case "selective perception" is at play. The physician in this case mistakenly believes mycophenolate is on the medication list because he or she knows that it should be there. While the clinician has underlined all of the important medications which appear on the medication list, they were unable to *perceive the absence* of an important medication.

Slide 11 illustrates that in many cases of medical error significant time can pass between the presence of the latent error or errors and the adverse event. Reading through this case can create the visceral reaction of watching a slow motion train crash.

Slide 12-18 show the daily propagation of the initial error. It may seem difficult to believe that such a significant omission could be missed by a large team of clinicians for days. This highlights the difficulty of active recognition of omission and the power of selective perception and human psychology in medical error. The identification of the original error is not made until 7 days after it is made even when the evidence of patient adverse event becomes obvious.

Section II- Root Cause Analysis

Slides 20-36 provide the session with a structure to conduct a root cause analysis on the case presented in the previous slides. It is helpful to transition the audience to the next activity which will involve some interaction

Slide 21-22 defines RCA as a technique that helps us answer the question of why a problem occurred in the first place. Participants are gathered to participate in this activity who are relevant stakeholders. This can include physicians, nurses, students, residents, staff – and sometimes even patients or their families can be involved. It is an exercise to help everyone understand and learn from an event that has occurred. Importantly, it is a process that uses a series of specific steps to identify the origin of a problem. The goal is to determine WHAT happened, WHY it happened, and REDUCE likelihood that it will happen again.

Slide 23 lays out five identifiable steps that are generally part of a root cause analysis.

Slide 24 is a time out to remind the audience some key definitions within patient safety. It is key here to emphasize the difference between an Error and an Adverse Event.

Slide 25-28 walk the audience through the 5 steps of a root cause analysis. Encourage the learners to drill down to exactly what was the adverse event. Defining the problem correctly is also vital to identifying causes, but also being able to propose changes down the road. Gathering information about the scope of the problem and it's impact is critical. Sources of information can

include both experts in content, but also from the front line providers who were involved in an incident. The medical record and also patient/family input can be important sources of information as well. There are several methods with which causal factors can be identified. In this course, we will be using the fishbone/cause and effect diagram (also known as ishikawa diagram) to help us work through the case. Consider that the problem that has arisen is really only what we see – "the Weed" in this case. They are the signs and symptoms of underlying issues. Importantly, even though we call it a root cause analysis, there is rarely only 1 single ROOT. In reality, as with real plants, roots are many.

Slide 29 sets up the audience to conduct an analysis of factors that contributed to a problem using a fishbone diagram. Orient them to the structure of the "fish head" which points to the Identified Problem. Each of the larger "fishbones" then represent major domains of factors that contribute to that problem. On those domains, then, contributing factors are placed horizontally.

Slide 31-33 describe the process inputs for the domains of the fishbone diagram that are commonly used.

Slide 34 reminds us that the goal of conducting a root cause analysis is really to prevent future similar events from occurring.

Slide 35 directs the audience to conduct a root cause analysis on the case previously described. It should be paired with the RCA tool document to guide discussion and reflection about the event.

Section III-Disclosure of Medical Error

Slide 37 is three rhetorical questions to ask the audience (the session will return to these questions for this case in Section IV).

Slide 38 points out that traditionally clinicians are not transparent with medical error and frequently do not disclose them to patients.

Slide 39-41 should be paired with a story of a difficult disclosure of a medical error which did not cause significant harm from the facilitator's own experience. An example which Dr. Cumbler uses is an error in which an anxious patient transferred from an outside hospital with a diagnosis of PE had the heparin drip discontinued by nursing on arrival because of equipment incompatibility between the pump used by the transport paramedic service and the hospital. This was not communicated to the physician who believed the heparin drip was still running while he reviewed the records from the outside hospital and interviewed the patient. By the time this was recognized the heparin drip was no longer therapeutic. The heparin drip is restarted with a new bolus and the patient suffers no apparent harm. The case, or one similar, can be used to illustrate the difficulties that physicians have in disclosing medical error. They do not want to cause the patient to suffer anxiety if no significant harm is thought to be likely. Having to disclose error creates internal dissonance between the clinician's self-image as a competent healer and the disclosure that they did not live up to patient expectations. There may be concerns that

disclosure of an error which is not apparent to the patient or family could increase the risk of a law suit. One of the most dominant factors making physicians hesitant to disclose error is the desire to avoid conflict with patients as it can be profoundly uncomfortable having an angry patient. Finally, clinicians may be hesitant to disclose error when they do not understand what led to the error at the time it is recognized or if the error involves more than one individual. This slide can be used to point out that disclosure of medical error does not need to include a full explanation if the facts are not fully known at the time but that disclosure to the patient should not wait until the full investigation is complete. Disclosure of the error and that an investigation will follow may be appropriate as the initial step. At the same time as these inhibiting factors are mentioned they are counterbalanced by the recognition that a culture of secrecy and non-disclosure does long term damage to the physician-patient relationship, may increase the chance of litigation if the patient/family finds out about the error independently, and decreases the chance that the systems elements which contribute to error will be addressed.

Slide 26 outlines 3 innovative programs of disclosure-apology-compensation which have been demonstrated effective at reducing litigation while increasing transparency. For instance the COPIC insurance 3Rs program (Recognition, respond, and resolve) trains and supports clinicians to disclose and apologize for medical error which leads to adverse events. "Responding in a timely fashion to an unanticipated medical outcome, communicating with the patient in an empathetic manner, and arranging for additional care or services the patient might need as a result of the outcome". The program then offers compensation to the patient to cover medical expenses and lost work up to a cap of $25,000. Patients do not waive their ability to seek compensation through the legal system, and payments are not reportable to the National Practitioner Database, but the program found that fewer patients chose to do so when the 3Rs program was implemented. Information available at http://www.callcopic.com/home/what-we-offer/coverages/medical-professional-liability-insurance-co/physicians-medical-practices/special-programs/3rs-program/ Last accessed 2/28/2012. Features of the VA and Michigan systems are similar with a divulge-apology-compensate model. Important to point out is that these effective programs do not rely on apology alone but rather pair this with reasonable resolution of the financial harms resulting from the medical error.

Slide 42 points out that the legal protection for apologies vary by state and in preparation for this presentation it is prudent for the facilitator to familiarize him/herself with the relevant state law for the setting in which this is being presented. Most of the states which have legislated protection for apologies protect statements of sympathy or regret but statements admitting fault are still admissible. Colorado has the strongest legal language protecting apologies by clinicians and the wording is included in the presentation but this does NOT apply to all states. Some have argued that the Colorado statute could be excessively protective in that it allows physicians to apologize and admit fault to the patient but deny fault in court.

Slide 44-45 poses questions to the audience for discussion in which a patient is accidentally ordered an antibiotic to which they had previously had a life-threatening reaction (assume for this question that the practice of the clinician is to avoid cephalosporins in patients with history of anaphylactic shock to penicillin). "Say you ordered ceftriaxone to a patient with a documented history of anaphylaxis to penicillin. Would you disclose if the patient went into anaphylactic shock and died, how about required intubation for angioedema, how about just

hives, what if they did not have any reaction at all, what if the pharmacist caught your error before filling the order." The answer is ethically clear, consistent with the American Medical Association's code of ethics, that the patient who suffers harm as a result should have disclosure. For patients in whom the error is corrected by a properly functioning system before it reaches the patient a strong argument could be made that disclosure is not necessary as the error did not reach, much less harm, the patient. For cases in which the patient was administered the drug but suffered no harm debate and lack of agreement is appropriate. Use this slide to bring up the question of HOW you would tell the patient about the drug ordering error. For the patient who received the drug (an event which implies error on the part of the administering nurse in addition to the ordering clinician) ask how they would deal with the issue of responsibility in the disclosure. The main points are that harms as a result of medical error should all be disclosed but errors which are caught before reaching the patient do not mandate disclosure and that finger-pointing or assigning blame is not an appropriate component of a disclosure.

Slide 46 is a humorous example of how medical error apologies are frequently "pseudo-disclosure" in which the adverse event is disclosed but not the medical error that led to the event. This can be tied back into the discussion of the antibiotic ordering error case example from the prior slides.

Slide 47-53 offer a step by step outline on how to perform effective disclosure and apology with attention to all of the elements including preparation, setting, participants, body language, and content. Reiterate that it is appropriate to do a muti-stage disclosure in which the adverse event is disclosed immediately with promise of investigation and a follow-up conversation after the facts have been determined then a second meeting for explanation and apology if this is merited by the findings of the investigation. Analogize the setting necessary for a major medical error disclosure to that of an end-of-life discussion with family. Offer tips in setting the stage for a calm and uninterrupted conversation such as all participants sitting down and handing off your pager for the duration of the discussion. For the slide on participants refer back to the case of the error involving the antibiotic in the patient with an allergy to the class. Discuss whether it would be helpful or harmful to have the nurse, risk management, patient care advocate, or pharmacist in the room during the disclosure. Point out the importance of having all participants on the same page and agreement to avoid finger pointing prior to inviting in extra individuals to an emotional disclosure. For the slide on body language the facilitator should demonstrate the closed posture and psychomotor agitation in the body language of a defensive and upset clinician and contrast it to the calm, open, leaning forward, posture of a clinician who is conveying empathic concern. Point out the importance of a pause and gauging your own emotional tone prior to going in to an apology. Body language is often unconscious but can be intentionally modified to make sure the message the body is sending is not different than the words if it is attended to. For content this points out the essential elements of an apology from the Australian Open Disclosure Initiative:
Patients' desire to be informed of patient safety issues that have affected them
A simple and factual explanation of what occurred
Recognition of the distress they have experienced
A sincere and compassionate expression of regret
An explanation of what can be done to redress the harm done

Emphasize how patients often want to know how the harm they have experienced from a medical error will change your practice in particular, and the system in general, to assure that a similar harm does not happen again.

Slide 54 is some of the reasons that apologies fail offered as cautions.

Section IV-Simulated Disclosure
For this final section return to the case of medical error used in the root cause analysis. Select four volunteers. One will be the patient. You should counsel the patient to not take the news that there was a medical error underlying their major adverse event easily. The second volunteer should play the role of the attending physician who is going to disclose. For this role playing exercise this individual is not the one who made the original error but did fail to catch the error for a number of days. Prepare the participants that the fact that the adverse event occurred is known to the patient but not that a medical error caused the adverse event. The disclosing individual is aware of the results of the investigation. Two additional volunteers should be selected to provide constructive feedback. One will only note the aspects of the disclosure that were done well (setting, participants, body language, content) and the other will offer concrete things that could have been better. Experience demonstrates that even the simulation of a heated medical error disclosure and apology can be an emotionally stressful experience for the volunteer who plays the role of the clinician and thus make sure to acknowledge this and thank all of the volunteers at the conclusion of the simulation.

Evaluation
Post-session evaluations were distributed to the learners to gauge achievement of learning objectives.

Suggested Reading for Facilitators
Slides 41-43 are references. Butterfield S. Apologize like a Pro.ACP Hospitalist Jan 2008:14-16 is good preparation for the simulated disclosure/apology (Available at: http://www.acphospitalist.org/archives/2008/01/apologize.htm)

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Conflict of Interest
Dr. Cumbler has no conflicts of interest relevant to this educational product.