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Tool Tutorial

A Practical Tool to Learn From Defects in Patient Care

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Introduction

In September 2004, a team of quality and safety researchers at the Johns Hopkins Medical Institutions, Baltimore, developed a practical tool to investigate defects in patient care. The impetus for creating this tool came after the Institute of Medicine targeted incident reporting systems as a method to collect defect information and improve safety.[1–3] To translate data into safety improvements, incidents must be investigated and hazards mitigated. The Learning From Defects (LFD) tool provides a structured approach to help caregivers and administrators identify systems that contribute to defects and includes a follow-up mechanism to ensure safety improvements are achieved. It supports the staff's ability to investigate more incidents closer to the time of the incident and to identify and mitigate a larger number of contributory factors.

Tool Description

The LFD tool has a one-page user's guide. The tool is divided into three sections. Section I asks the investigator to explain "what happened." In section II, investigators are directed to review and check all factors that caused or increased risk of patient harm (negatively contributed) and all factors that reduced or eliminated harm (positively contributed). Section III asks the investigator to list specific actions to reduce the likelihood of this defect from happening again, to assign a project leader and follow-up date, and to consider how to evaluate if risk is reduced. Measuring risk reduction could be qualitative (for example, talk to the users and see if effort mitigates or prevents defect), or quantitative, such as point prevalence (that is, periodic audit).

Tool Application to Quality and/or Safety

LFD is a "lighter" version of a root cause analysis (RCA); the contributing factors in the framework are informed by safety expert Charles Vincent's model of systems.[4,5] LFD enables unit/department-based real-time incident analysis and action planning to enhance safety. An unusual and value-added aspect of the tool is its ability to focus users on positive factors that prevented or mitigated harm as well as those factors that contributed to the process or system failure. These positive findings can then be considered to enhance safety across a variety of systems and processes.

We currently use this framework in the Intensive Care Unit Safety Reporting System[6,7] and recently reported aggregate data on common event types, contributing factors and harm.[6,8] How best to use aggregate data to improve safety is yet unknown. LFD allows for quick yet thorough investigation of defects reported and provides a mechanism to manage improvement activities and measure results.

Tool Application Settings

This tool can be applied in any patient care area (for example, intensive care unit [ICU], general medical), whether inpatient or outpatient, adult or pediatric. In addition, this tool has been used during morbidity and mortality (M&M) conferences to more thoroughly investigate defects. Application to other peer review processes is being explored.

"Best" Application

This tool is best applied within the context of the Comprehensive Unit-Based Safety Program (CUSP) to investigate individual incidents, including near misses.[9,10] CUSP is a six-step safety program; one step asks staff in patient care areas to use the investigative tool to learn from one defect per month. All staff involved in the delivery of care related to this defect attend when an evaluation of the incident is presented. At a minimum, this includes the physician, nurse, and administrator and other professions as appropriate (for example, medication defects include pharmacy).

How To

Table 1 (page 103) is the user's guide for applying this tool to a defect investigation.

Output

Table 2 (104) represents an example of a completed defect investigation that is filled out at local meetings to evaluate the defect and is then given to the department chairman and administrator in the clinical area(s) affected by the incident. In section II of the example provided (Table 2), "a protocol to guide therapy" was a negative contributor because a weaning protocol was not available for difficult airway cases. As a result, the patient was extubated prematurely, could not breathe, and required emergency intubation. In addition, "communication during a crisis" was checked as a positive contributor because the anesthesia team was provided with the appropriate information needed to make an informed decision regarding the best method of reintubation. To evaluate if risk was reduced in the example, periodic audits could be done on all difficult airway cases to see if a cuff leak test was done prior to extubation (quantitative).

Table 1. Learning from Defects (User's Guide)

Problem Statement: Health care organizations could increase the extent to which they learn from defects.

What is a Defect? A defect is any clinical or operational event or situation that you would not want to happen again. These could include incidents that you believe caused patient harm or put patients at risk for significant harm.

Purpose of Tool: The purpose of this tool is to provide a structured approach to help care givers and administrators identify the types of systems that contributed to the defect and follow-up to ensure safety improvements are achieved.

Who Should Use this Tool

- Clinical departmental designee at Morbidity and Mortality Rounds
- Patient care areas as part of the Comprehensive Unit Based Safety Program (CUSP)

All staff involved in the delivery of care related to this defect *should be present when this defect is evaluated.* At a minimum, this should include the physician, nurse, and administrator and other selected professions as appropriate (e.g. medication defect should include pharmacy, equipment defect should include clinical engineering).

How to Use this Tool

Complete this tool on *at least one defect per month.* In addition, departments should investigate all of the following defects: liability claims, sentinel events, events for which risk management is notified, case presented at Morbidity and Mortality Rounds, and health care–acquired infections.

Investigation Process

I. Provide a clear, thorough, and objective explanation of *what happened.*

II. Review the list of factors that contributed to the incident and check off those that negatively contributed and positively contributed to the impact of the incident. *Negative contributing factors* are those that harmed or increased risk of harm for the patient; *positive contributing factors* limited the impact of harm.

III. Describe how you will reduce the likelihood of this defect happening again by completing the table. List *what* you will do, *who* will lead the intervention, *when* you will follow up on the intervention's progress, and *how* you will know risk reduction has been achieved.

Table 2. Investigation Process*

I. What happened? (Reconstruct the timeline and explain what happened. For this investigation, put yourself in the place of those involved, in the middle of the event as it was unfolding, to understand what they were thinking and the reasoning behind their actions/decisions. Try to view the world as they did when the event occurred.)

A 65-year-old man was admitted to a cardiac ICU postoperatively. Intraoperative course was notable for the patient being a difficult mask and difficult intubation, requiring multiple direct laryngoscopies. The operating room anesthesia team transferred this information to the ICU care team during the course of the standard sign-out. The patient was weaned and extubated at 4 A.M.. On extubation he was unable to move any air and was desaturating. The emergency anesthesia team was mobilized and intubated the patient fiberoptically without difficulty.

II. Why did it happen? Below is a framework to help you review and evaluate your case. Please read each contributing factor and evaluate whether it was involved and if so, did it negatively contribute (increase harm) or positively contribute (reduce impact of harm) to the incident.

Contributing Factors *(Example)*	Negatively Contributed	Positively Contributed
Patient Factors:		
Patient was acutely ill or agitated *(Elderly patient in renal failure, secondary to congestive heart failure.)*	Patient was status post-cardiac surgery.	
There was a language barrier *(Patient did not speak English).*		
There were personal or social issues *(Patient declined therapy).*		
Task Factors:		
Was there a protocol available to guide therapy? *(Protocol for mixing medication concentrations is posted above the medication bin.)*	A standard weaning and extubation protocol is in place. There are no parameters to guide extubation on patients with a difficult airway.	
Were test results available to help make care decision? *(Stat blood glucose results were sent in 20 minutes.)*	Standard parameters were available. A cuff-leak test was not performed.	
Were test results accurate? *(Four diagnostic tests done; only MRI results needed quickly—results faxed.)*		The results of the tests performed were accurate and available.
Caregiver Factors:		
Was the caregiver fatigued? *(Tired at the end of a double shift, nurse forgot to take a blood pressure reading.)*		
Did the caregiver's outlook/perception of own professional role impact on this event? *(Doctor followed up to make sure cardiac consult was done quickly.)*	The junior team member did not recognize his or her inexperience in evaluating patients with difficult airways.	
Was the physical or mental health of the provider a factor? (*Provider having personal issues and missed hearing a verbal order.)*		
Team Factors:		
Was verbal or written communication during hand offs clear, accurate, clinically relevant, and goal directed? *(Oncoming care team was debriefed by outgoing staff regarding patient's condition.)*	Transferring team relayed the facts.	

Table 2. Investigation Process *(continued)*

Contributing Factors *(Example)*	Negatively Contributed	Positively Contributed
Team Factors *(continued)*:		
Was verbal or written communication during care clear, accurate, clinically relevant and goal directed? (*Staff was comfortable expressing his or her concern regarding high medication dose.)*	No discussion took place alerting that this patient may deviate from the standard protocol.	
Was verbal or written communication during crisis clear, accurate, clinically relevant, and goal directed? *(Team leader quickly explained and directed his/her team regarding the plan of action.)*		Immediately on arrival, the anesthesia team was informed that the patient was a difficult airway and went directly to obtaining an airway fiberoptically with the aid of the most senior staff member (attending) present.
Was there a cohesive team structure with an identified and communicative leader? *(Attending physician gave clear instructions to the team.)*		Attending physician gave clear direction on how to obtain an airway.
Training and Education Factors:		
Was provider knowledgeable, skilled, and competent? *(Nurse knew dose ordered was not standard for that medication.)*	Junior physician did not appreciate importance of multiple laryngoscopies and potential airway edema.	
Did provider follow the established protocol? *(Provider pulled protocol to ensure steps were followed.)*		
Did the provider seek supervision or help? *(New nurse asked preceptor to help her/him mix medication concentration.)*	Resident did not ask for assistance in evaluation of patient for extubation.	Resident immediately recognized that senior assistance was required for reintubation.
Information Technology/CPOE Factors:		
Did the computer/software program generate an error? *(Heparin was chosen, but Digoxin printed on the order sheet.)*		
Did the computer/software malfunction? *(Computer shut down in the middle of provider's order entry.)*		
Did the user check what he/she entered to make sure it was correct? *(Provider initially chose .25 mg, but caught his/her error and changed it to .025 mg.)*		
Local Environment:		
Was there adequate equipment available and was the equipment working properly? *(There were 2 extra ventilators stocked and recently serviced by clinical engineering.)*		Emergency airway equipment, including a fiberoptic scope, was available.
Was there adequate operational (administrative and managerial) support? *(Unit clerk out sick, but extra clerk sent to cover from another unit.)*		
Was the physical environment conducive to enhancing patient care? *(All beds were visible from the nurse's station.)*		

Table 2. Investigation Process *(continued)*

Contributing Factors *(Example)*	Negatively Contributed	Positively Contributed
Local Environment *(continued)*:		
Was the physical environment conducive to enhancing patient care? *(All beds were visible from the nurse's station.)*		
Was there a good mix of skilled with new staff? *(There was a nurse orientee shadowing a senior nurse and an extra nurse on to cover senior nurse's responsibilities.)*		
Was there enough staff on the unit to care for patient volume? *(Nurse ratio was 1:1.)*		
Did workload impact the provision of good care? *(Nurse caring for 3 patients because nurse went home sick.)*		
Institutional Environment:		
Were adequate financial resources available? *(Unit requested experienced patient transport team for critically ill patients and one was made available the next day.)*		
Were laboratory technicians adequately in-serviced/educated? *(Lab technician was fully aware of complications related to thallium injection.)*		
Was there adequate staffing in the laboratory to run results? *(There were 3 dedicated laboratory technicians to run stat results.)*		
Were pharmacists adequately in-service/educated? *(Pharmacists knew and followed the protocol for stat medication orders.)*		
Did pharmacy have a good infrastructure (policy, procedures)? *(It was standard policy to have a second pharmacist do an independent check before dispensing medications.)*		
Was there adequate pharmacy staffing? *(There was a pharmacist dedicated to the ICU.)*		
Does hospital administration work with the units regarding what and how to support their needs? (Guidelines established to hold new ICU admissions in the ER when beds not available in the ICU.)	Local pressures to rapidly wean and extubate patients due to patient complaints of being intubated and to be able to do the next day's cases	

III. How will you reduce the likelihood of this defect happening again?

Specific things you will do to reduce the risk of the defect?	Who will lead this effort	Follow-up date	How will you know risk is reduced
Educate OR and ICU staff to highlight intraoperative complications and makes certain these are "read back" to confirm understanding.	ICU and OR Attending		Implement readback system, ask OR and ICU teams if working (qualitative)
Develop curriculum for residents and staff to recognize complications in patients with difficult airways	ICU Attending		Airway lecture sign-up at start of each resident rotation (quantitative)
Develop weaning and extubation protocol for patients identified as a difficult airway	ICU Attending and Respiratory therapist		Audit difficult airway cases for cuff leak test (quantitative)

* ICU, intensive care unit; MRI, magnetic resonance imaging; CPOE, computer physician order entry; OR, operation room.

Figure 1 (below) represents an example of the case summary learning tool that is disseminated broadly to caregivers in the specific clinical area, and elsewhere as appropriate, to encourage a community of learning.

Results and Lessons to Date

The LFD tool is currently being used in several care areas at the Johns Hopkins Hospital and by several clinical departments during M&M conferences. One of our system-level measures of safety is the percent of months where each patient care area learned from at least one defect. In addition, 123 ICUs in Michigan and 25 in New Jersey, which are working in statewide collaboratives with the Quality and Safety Research Group at Johns Hopkins to improve ICU care, are using the tool. Nevertheless, further research is needed to determine the tool's validity for improving patient safety locally and on a broader scale.

Case Summary Learning Tool

Safety Tips:

- **Develop training and education tools for airway management.**
- **Develop protocol to identify individuals at risk and how to identify these individuals during transfer of care.**
- **Rule: Always use a cuff leak test on high risk patients.**

Case in Point: A 65-year-old man was admitted to the CICU postoperatively. Intraoperative course was notable for him being both a difficult mask and intubation, requiring multiple direct laryngoscopies. The OR anesthesia team transferred this information to the ICU care team, during the course of the standard sign-out. The patient was weaned and extubated at 4 am. Upon extubation, he was unable to move adequate air and was desaturating. The emergency anesthesia team was mobilized and intubated him fiberoptically without difficulty.

System Failures:	Opportunities for Improvement:
Knowledge, skills & competence. Care providers lacked the knowledge needed to identify potential sequelae of multiple laryngoscopies.	Regular **training and education** on how to evaluate individuals with difficult airways for extubation, including use of cuff leak test.
Task factors. The patient's condition was inappropriate for standard protocol.	**Develop protocol** to identify those patients who are not appropriate for standard protocols.
Team factors. There was a breakdown in information transfer between care teams.	Develop care transfer criteria that includes a **readback** of complications or deviations from the expected.

ACTIONS TAKEN TO PREVENT HARM

The ICU team caregivers will have an airway lecture at the beginning of each rotation of residents. The OR and ICU team will implement a readback system. Patients with identified difficult intubation will have a cuff leak test performed prior to extubation.

Figure 1. *An example of the Case Summary Learning Tool is shown. CICU, cardiac intensive care unit; OR, operating room.*

We recognize a number of barriers in using the LFD tool. First, background training on the science of improving patient safety is required to ensure caregivers understand systems analysis. Nevertheless, the factor framework includes examples to guide staff in acquiring this knowledge. Second, use of the tool requires a culture that places less emphasis on personal performance and more emphasis on how work is organized. Third, it also requires that people use this form. Our experience with any tool is that the benefits caregivers derive from it must outweigh the burden of completing the tool. As such, we pilot tested the tool for feasibility and use as part of CUSP and M&M conferences. We revised the form to minimize the burden and enhance the benefits. Fourth, it requires that staff and, more importantly, administrators and hospital leaders be amenable to implementing system changes.

To improve safety we must investigate the defects that we see and report and we must implement improvement efforts. LFD may provide an efficient vehicle to identify a more diverse array of factors that pose threats to patient safety and provide a standard approach to mitigate those risks. In addition, the lessons we learn from the positive factors identified as preventing or lessening harm will be invaluable in shaping future improvement efforts. We look forward to broader application of this tool including use in the peer review process.

Other Applications

Beyond using the LFD tool as part of CUSP in clinical areas and in M&M conferences, it could be used in the investigation of sentinel events, liability claims, and adverse events reported to incident reporting systems.

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