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How to Make the Most of Actions and Outcome Measures

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The other day, one of my friends mentioned that back at her place of work (not VA), RCA stands for Root Canal Analysis. She said they were painful, often a dead-end, and that staff resist them.

Many things can become painful for RCA teams, such as: a lack of information; too big a focus (saving the world); too narrow a focus (saving one particular patient); and repeat events (before actions have been implemented or had a chance to have an effect). However, there are effective ways to work through the pain: get additional information (do more interviews, simulate the event); focus on the situation at hand (don't unduly dilute the effort by going outside your scope); look at tragedy without staring (don't get hypnotized by the event at hand, focus on what can be done to prevent a similar situation); and find out what others have done to address similar problems, such as selecting bite-sized root causes, actions and outcome measures.

How to Make the Most of Actions

After finding a root cause, an RCA team needs to come up with actions that will minimize or prevent the root cause from happening again. Ordinarily, it's best to avoid actions that place an extra burden on a person's memory (e.g., training, written policy). Sometimes, particularly if there hasn't been previous training or a policy hasn't been developed, such actions are necessary and important. Ideally, the team should go for actions that are physical rather than procedural (e.g., keypad lock versus a "do not enter" sign), and permanent rather then temporary. It's very useful for teams to ask all interviewees — especially process owners and managers responsible for implementing the actions — how they'd fix the problem, and what has or hasn't worked before.

Here's a partial listing of actions for teams to consider:

- Architectural or physical plant changes (e.g., extra handrails in the bathroom to prevent falls, break-away fixtures to prevent hanging)
- Human factors engineering consultation (e.g., to analyze, troubleshoot and streamline work areas and processes, to evaluate equipment use and conduct usability testing)
- Tangible involvement and action by leaders in support of patient safety (e.g., greeting and closing out with RCA teams; patient safety related individual or team rewards; constructive feedback; town meetings; newsletters)
- Forcing functions that design processes or equipment so that it is only possible to do the correct thing the first time and every time (e.g., only the correct dose and strength of medication in a patient's drawer; tubing connectors that only fit one way)
- Simplify and remove unnecessary steps from processes (e.g., document in one place, instead of two, to reduce transcription mistakes; establish 24/7 "point of contact" experts to provide assistance as soon as high risk problems arise)
- Standardize equipment (e.g., limit the types of IV pumps, defibrillators, code carts, etc., so that it is as easy as possible for staff to use them quickly and correctly under stressful conditions in any care setting)
- Standardize processes through the use of protocols, guidelines, standing orders (e.g., all departments and care settings use the same tools/form for fall risk assessment or suicide screening)
- Do "usability testing" with staff who will actually be using the equipment or supplies before purchasing any new equipment or supplies
- Develop cognitive aids for complex or high risk processes (e.g., Cognitive Aid for Anesthesiology laminated cards, surgery time-out posters)
- Reduce staff fatigue (e.g., set a cap on consecutive hours of work; reduce complexity of memory and vigilance tasks — like calculations — for staff doing a "double shift")
- Reduce staff's reliance on memory and vigilance (e.g., cognitive aids, automatic computerized alerts/flags/warnings)
- Increase staff effectiveness/decrease workload (e.g., enable/train non-clinical staff or volunteers to deliver lab specimens or provide other escort-related services)
- Use effective team communication skills (e.g., "read back," briefings, debriefings and other team-training skills)
- Eliminate "look-a-likes" and "sound-a-likes" (e.g., don't have two patients with the same name on the same ward, or differentiate them by using an additional identifier; store easily confused IV and irrigation solutions physically apart from each other)
- Eliminate or reduce distractions (e.g., prevent interruptions when passing meds, consider the area to be a "quiet zone")
- Enhance documentation in hardcopy or software (e.g., templates)
- Build in redundancy, double checks, and fail-safes (e.g., have a second person check chemotherapy orders; have a designated printer produce hardcopy medication records in case the computerized system goes down)
- Warnings and labels in hardcopy or software (e.g., brightly colored stickers on the correct IV line to use; automatic flags for "panic" lab values)
- New policy where one does not exist but it's needed (e.g., contraband searches)
- Training on any new policy/procedure/equipment

continued on back page

Unit Dose – It's the Gold Standard for a Reason

By Mary Burkhardt, MS, RPh, FASHP, program manager

Sue was a new graduate nurse who had worked at a university hospital before joining the VA. She was assigned to administer medications in the nursing home care unit one day. She carefully scanned a patient's wristband, and scanned the medication bottle, but got distracted during the process. When she returned to her task, she gave the patient 60 ml (2 ounces) of furosemide liquid. Upon finishing the medication pass, she noticed that the bottle containing the furosemide held 600 mg of the liquid, not the 40 mg she thought was in the bottle.

The above example was modeled from an actual RCA.

How could anyone give a WHOLE bottle of furosemide liquid like that, you ask? Well, it's not inconceivable. The university hospital where Sue trained had followed the "practice standard" in their medication use system. This means that her hospital provided patient care staff with unit dose products, not bulk bottles intended for pharmacy-level dispensing or outpatient use. She was more familiar with the "safe practice" of matching the product dispensed with the product prescribed.

But how could she give 60 ml of an oral liquid? Some drugs are dosed at that volume, so it wouldn't seem unusual. Slips like this can occur, especially due to frequent interruptions faced by staff in patient care areas. Although there was no intent to harm the patient, the dispensing process included a latent failure (a hazardous condition), which increased the likelihood that the label or volume could be misinterpreted.

In essence, if the product had been packaged in a liquid unit dose cup (40 mg/4ml), the nurse would have scanned the container and given the correct dose. In this case, the amount dispensed would match the amount prescribed, leaving little room for error.

Designed to improve medication safety, unit dose drug distribution has been the practice standard in health systems for decades. Conceived in the 1960s at the University of Kentucky, it was modeled after the individual packaging of condiments used in the food service industry.

The American Society of Health-System Pharmacists, the Joint Commission on Accreditation of Healthcare Organizations and many other credentialing organizations recognize unit dose drug distribution as the standard of practice for inpatient settings. This created a considerable amount of work in the 1960s, as pharmaceuticals were not packaged in unit doses. Pharmacies had to individually package each dose; further, there were no medication carts or cassettes.

Gradually, the pharmaceutical industry began to provide drugs in unit dose packages; but even today, a substantial number of drugs arrive at pharmacies in bulk or without a manufacturer-supplied individual bar code.

Having the necessary resources for both unit dose packaging and bar code labeling are key components of the medication system infrastructure required to gain maximum benefit from BCMA.

Challenging areas for implementation of unit dose systems include pediatric dosage forms, controlled substances, and oral liquids and injectable drugs that are only available in multi-dose vials. Fortunately, there are innovative methods to package and distribute these items within pharmacies. These methods can reduce the nursing time spent in non-value-added tasks and enable patients to receive the safest pharmaceutical care possible.

For further information please see:
Best Practices for Health-System Pharmacy (www.ashp.org)
Joint Commission on Accreditation of Healthcare Organizations — Medication Management standards (www.jcaho.org)

Unit dose systems provide the following benefit to patient care:	
Benefit	**Human Factors Principle**
Labeling to the point of administration, to include drug name, lot number, and expiration dating, etc.	Improved communication
Reducing the likelihood of a dosing error by providing drugs in doses prescribed for the patient	Standardization
Preparation in more centralized and controlled areas that are removed from the patient care area reduces the likelihood of contamination, packaging mix-ups and mislabeling	Centralization
Reduction of the need to do complicated mathematical calculations at the bedside, as the dose provided matches the dose prescribed	Simplification
Reduction in nursing time related to drug preparation	Centralization, simplification and standardization
Overall reduction in drug waste and increase in the ability to recycle unused drugs	Standardization and limited selections

Table for Actions and Outcome Measures

	Root Cause	Action	Outcome Measure
Definitions/Template	***Root Cause Statement:*** *Something caused or contributed to something else happening.*	***Actions:*** *Designated individual will develop a new process, procedure or clinical change using small cycles of change. The new process/procedure or clinical change will be implemented.*	***Outcome Measures:*** *- Initial draft of new process/procedure or clinical change will be developed by XX date. - Designated areas will pilot test ease of use and utility of new process and make necessary changes from XX date to XX date. If needed, several cycles of PDSA will be implemented to improve the process and pilot test on additional clinics/units. - Modified version will be implemented facility-wide by XX date. - Use and utility (staff feedback) of new process will be monitored on all units on XX date using monthly sampling. (Use: N = number of patients with new process used and outcome, D = number of patients at risk, Threshold = __%; Utility: N = number of staff who report using the new process, D = number of staff interviewed, Threshold = __%). - Rate of events before and after the change. - Results for all measures will be distributed to each/all units and shared at XX date with designated leadership, for further action/evaluation.*
Examples	Lack of timely warning about previous inpatient suicide attempts increased the likelihood of another inpatient attempt.	1. CPRS Problem List will be modified to include chronological posting of both the date and method of any/all known prior suicide attempts (e.g., "Inpatient Suicide Attempt: 1/1/04, antidepressant overdose," "Outpatient Suicide Attempt: 11/11/03, alcohol and street drug overdose," etc.).	A. Initial draft of Flag (prompt/advisory) will be jointly developed by designees of the chiefs of medicine, surgery, psychiatry and information technology by 4/2/04. B. Units 1, 2 and 3 will pilot test ease of data entry and utility of flag and make necessary changes from 4/12/04 through 4/23/04 using small cycles of change. C. Modified Flag will be implemented facility-wide on 4/30/04. D. Use (data entry) and utility (staff feedback) of warning flags will be monitored on all units on 6/30/04. (Use: N = number of patients with known history of suicide attempt and notation in CPRS Problem List, D = number of patients with known history of suicide attempt, Threshold = 100%; Utility: N = number of staff who report looking for or using the warning flag, D = number of staff interviewed, Threshold = 100%). Number or rate of parasuicidal/suicidal events for three months before and three and six months after using the new flag will be calculated. Tabulated results for all measures will be distributed to each/all units and shared at the July 2004 Executive Committee of the Medical Staff for further action/evaluation.
	Use of different suicide assessment screens in inpatient, outpatient (including CBOC) and long term care increased the likelihood that patients are evaluated differently at each site.	1. Multi-disciplinary team chaired by Chief of Mental Health to standardize suicide assessment for all care settings. 2. Develop and implement suicide assessment related training module; computerized template; and algorithm/point of contact list for 24/7 referral of positive suicide screens.	A. Standardized assessment tool completed and approved by top management by 4/16/04. B. Training module, computerized template, and algorithm/point-of-contact 24/7 referral list pilot tested by CBOC, Pain Clinic, OPT Surgery, ER, and Units 1, 2 and 3 from 5/28/04 - 7/30/04. Use and utility will be monitored during the week of August 2nd as: Training (N = number of staff receiving training during pilot, D = total number of staff available during pilot, Threshold = 90%); Template (N = number of patients with known suicidal ideation and template completed, D = total number of patients with known suicidal ideation, Threshold = 100%); Algorithm/Point-of-Contact 24/7 referral list (N = number of patients screened as "high risk" and referred according to algorithm, D = total number of patients screened as high risk, Threshold = 100%). Number or rate of parasuicidal/suicidal events three months before and three and six months after the template is implemented in each site will be calculated. Tabulated results for all measures will be distributed to each/all pilot units and shared at the August 2004 Executive Committee of the Medical Staff for further action/evaluation and setting the schedule for facility-wide implementation.
	Lack of a standardized protocol for outpatient "no-show" follow-up increased the likelihood of additional no-shows and disengagement with treatment.	1. Multi-disciplinary team chaired by Chief of Mental Health to develop a procedure for contacting a patient who is a no-show. 2. Implement a no-show procedure.	A. Initial draft of no-show procedure will be developed by multi-disciplinary team chaired by Chief of Mental Health by 4/2/04. B. Psychiatry and primary care staff who treat patients with depression will pilot test ease of use and utility of no-show procedure and make necessary changes from 4/12/04 through 4/23/04. C. Modified no-show procedure will be implemented clinic-wide on 4/30/04. D. Use and utility (staff feedback) of no-show procedure will be monitored on psychiatry and primary care clinics who treat patients with depression on 6/30/04. (Use: N = number of patients with no-show procedure followed, D = number of patients who no-show for these clinics, Threshold = 100%; Utility: N = number of staff who report the no-show process was helpful, D = number of staff interviewed, Threshold = 100%). Number or rate of parasuicidal/suicidal events three months before and three and six months after using the new no-show process will be calculated. Tabulated results for both measures will be distributed to pertinent clinics and shared at the July 2004 Executive Committee of the Medical Staff, for further action/evaluation.

How to Make the Most of Actions and Outcome Measures *(continued from front page)*

(e.g., how to conduct a contraband search)

Additional study/analysis (e.g., drilling down and stratifying the data to find out what causes the highest percentage of falls)

Of note, any action is more likely to be successful if it is "pilot tested" (or the desired changes are simulated) before it's rolled out across a facility. Consider starting on one unit with the most willing volunteers. Ask staff and patients what worked well about the new process and what could be done to improve it. Peers will be the best people to help spread the change and it's well worth the time to ask for volunteers to try things out for a couple of weeks to get the kinks worked out. Build time for pilot testing into the overall action plan and the outcome measures strategy.

This overall process is like the "Model for Improvement" described by Langley, et al.[1] In writing the root cause statement, your RCA team describes what they've found caused or contributed to an adverse event or close call. Let's say the team decides bed alarms were not functioning properly and the preventive action involves making sure that patients no longer fall due to faulty bed alarms. The team's actions should delineate the changes to be made to improve the situation (i.e., eliminate or control the root cause). For example, engineering may be designated to check all bed alarms and repair/replace any faulty ones. If the team writes the actions in such a way that they can be modified, based upon pilot test feedback, the "Plan-Do-Study-Act" process, commonly known as PDSA, can be used to get even more staff buy-in. To tie the root cause and action together, the team's outcome measure should clearly state whether fixing the bed alarms would be an improvement: "No falls will be related to faulty bed alarms." Remember, lists of possible actions may be found in the NCPS *RCA Tools* and *HFMEA Process* flip books.

How to Make the Most of Outcome Measures

Once an action has been implemented, it's important to find out whether it's made things better or worse — and if there are any unintended consequences. The best outcome measures cover a realistic timeframe and take urgency into account (e.g., "this can never happen again starting tomorrow" versus "we need to orient all current and future staff"); sample a reasonable number of situations that are similar or related to the event; and are specific and quantifiable (numerators, denominators, thresholds).

Some events are rare (e.g., incorrect surgery, suicide) and some are more common (e.g., falls, medication mix-ups). To a large extent, event frequency will dictate the viewpoint or scope of the outcome measure. For example, it's hard to "prove" or demonstrate that a certain action will reduce the actual number of incorrect surgeries or inpatient suicide attempts if such events rarely occur. However, it is easy to show that actions like using the five-step Ensuring Correct Surgery process or doing rigorous contraband searches on locked units will make things quantifiably safer every day through elimination of specific vulnerabilities (i.e., misidentification reveals itself during the pre-surgical period; potential weapons are discovered and removed during admission). For frequently occurring events, it makes sense to aim at reducing them directly (i.e., decrease falls or extent of injuries due to falls, decrease medication mix-ups or complications resulting from mix-ups).

A good place to start in building outcome measures is to ask interviewees point blank: "How would you know if an action made a difference or not?" and "How would you measure it?" Interviewees are likely to have ideas about measurement that may escape the team's imagination. Some of their ideas may fall outside of comfortable and customary auditing procedures or medical record review processes. Interviewees will have experience-based ideas about what can be measured through simple observation, informal conversation or follow-up interviews, and what can require document review (and where to find it).

Always consider the observation processes which are already in place for RCA outcome measurement (maximize existing opportunities instead of creating new work). For example, if a leadership team already conducts walking rounds could they add observation related to the outcome measure? If medical records of interest are already being audited/reviewed, could an additional question or two related to the outcome measure be added? Consider sampling and observing the process over a short, defined period (e.g., a week or two). For example, observe nurses once per shift, on a periodic basis, administering medications using BCMA. Use the observation as a time to discover what isn't working but also to reward staff for correctly instituting a new procedure.

Some Examples

A general template and a few examples of root cause statements, actions and outcome measures related to suicide/parasuicide are provided in the table on Page 3. These examples draw from many RCAs in the patient safety information systems database, as well as the literature. *(An important note: the RCA teams at your facility may have developed actions and outcome measures that are different or better than the examples provided. The examples are designed to illustrate how to write clear, useful actions and outcome measures in general — not to provide advice for how best to reduce suicides/parasuicides.)*

Please feel free to share the table with RCA teams as a cognitive aid to help write actions and outcome measures — and stay tuned for future TIPS articles related to creating change!

[1] Langley GJ, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide, a Practical Approach to Enhancing Organizational Performance*. San Francisco, CA: Jossey-Bass;1996.

General Reference: Department of Veterans Affairs National Center for Patient Safety. DeRosier J, Stalhandske E. *Root Cause Analysis Tools* and *The Healthcare Failure Mode Effect Analysis Process.* (internal documents) Ann Arbor, MI, August 2002. Related information available at: *http://www.patientsafety.gov*.

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