Putting the "Action" in RCA²: An Analysis of Intervention Strength After Adverse Events

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Background: Safety event reporting and review is well established within US hospitals, but systems to ensure implementation of changes to improve patient safety are less developed.

Methods: Contributing factors and corrective actions for events brought to a tertiary care academic medical center's multidisciplinary hospital-level safety event review meeting were prospectively collected from 2020 to 2021. Corrective actions were tracked to completion through 2023. The authors retrospectively coded corrective actions by category and strength using the US Department of Veterans Affairs/Institute for Healthcare Improvement Action Hierarchy Tool.

Results: In the analysis of 67 events, 15 contributing factor themes were identified and resulted in 148 corrective actions. Of these events, 85.1% (57/67) had more than one corrective action. Of the 148 corrective actions, 84 (56.8%) were rated as weak, 36 (24.3%) as intermediate, 15 (10.1%) strong, and 13 (8.8%) needed more information. The completion rate was 97.6% (for weak corrective actions), 80.6% (intermediate), and 73.3% (strong) (p < 0.0001).

Conclusion: Safety events were often addressed with multiple corrective actions. There was an inverse relationship between intervention strength and completion, the strongest interventions with the lowest rate of completion. By integrating action strength and completion status into corrective action follow-up, health care organizations may more effectively identify and address those barriers to completing the strongest interventions that ultimately achieve high reliability.

The landmark 1999 *To Err Is Human* report launched a movement to reduce medical errors in health care.¹ Under the Centers for Medicare & Medicaid Services Conditions of Participation, hospitals were now required to track and respond to adverse events.² To address this requirement, hospitals moved to create safety event review infrastructures, including voluntary incident reporting systems. Such systems promote a culture of safety by empowering staff to call out adverse events and errors in patient care and by requiring root cause analyses for certain safety event reports. Despite these structures, progress to improve patient safety over the past 20 years has undeniably been slow.^{3–6}

One reason for this may be the lack of consistency in how organizations implement and follow up on changes after completing a root cause analysis. Although best practice guidelines emphasize the importance of taking action to improve safety—referred to as Root Cause Analysis and Action, commonly known as "RCA squared"⁷ (hereafter RCA²)—many organizations have not implemented them, and studies infrequently report on them.⁸ As a result, some safety experts have expressed concern about the capacity of incident reporting systems and root cause analyses to support meaningful patient safety improvements.^{9,10}

Ensuring that lessons learned from root cause analyses inform the design of corrective actions and later confirming that those corrective actions have been successfully implemented have been proposed as necessary to improve patient safety.¹¹ However, even when organizations follow RCA² principles and correction actions are completed, safety events may recur because of inadequately designed or sustained corrective action plans. If corrective actions do not protect against the multiple failure modes of a process, or if the interventions are all weak, the corrective actions may not reliably prevent the event from recurring. Weak refers to the magnitude of impact that changes have, including their depth, breadth, and durability.¹² Weak interventions, such as policy changes, are valuable parts of the quality improvement process, but if implemented alone are unlikely to result in meaningful or sustained improvement, as they too often put the onus on the individual provider to do the right thing. Accordingly, as outlined in the US Department of Veterans Affairs (VA)/Institute for Healthcare Improvement (IHI) Action Hierarchy Tool, strong actions (such as forcing functions) and intermediate actions (such as checklists) are preferred whenever feasible.

In the recent context of traveling/locums work, high rate of health care professional turnover, and movement of staff between different sites within a system, it is more important than ever for health care organizations to implement stronger interventions that are less reliant on specific individuals' knowledge or awareness and more reliant on changing underlying systems of care. Gathering consensus from diverse stakeholders and building resources to design and

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implement such change takes effort and time. Thus, in a health care environment with competing priorities and resource constraints, these strong interventions can be challenging to achieve.¹³ For these reasons and others, hospital safety staff may be inclined to settle for weak corrective actions. Staff tend to have training and experience in event review and analysis but not in designing systems to reduce risk.⁹ Furthermore, while they must grapple with limited resources for system improvements and a diffusion of responsibility for bringing change, they often carry the responsibility for quickly responding to external reporting agencies after safety events with completed corrective action plans.

Our medical center noted many of these challenges, so we decided to enhance our RCA² processes by prospectively tracking corrective action plan completion. We then retrospectively classified corrective actions by strength to explore an association between completion status and intervention strength. In this article, we aim to describe the process we created and to report the benefits and challenges of this work.

METHODS

Setting and Reporting Structure

Beth Israel Deaconess Medical Center (BIDMC) is an approximately 700-bed tertiary care academic medical center affiliated with Harvard Medical School located in Boston. At BIDMC, there are approximately 8,500 patient safety event reports per year, most of which are near misses or risky states. Most events are identified through voluntary reports by frontline health care professionals, with others generated by reviewing the care of patients who experienced predefined adverse events (for example, neonatal deaths).

Patient safety event reports are initially triaged by a patient safety nurse within the centralized Department of Healthcare Quality. This triaging process determines whether the event must be reported externally (for example, Serious Reportable Events to the Department of Public Health or events meeting Board of Registration in Medicine reporting criteria). Events are then assigned to local operational managers for review and may be discussed at division or department safety/quality meetings. Although every event report is reviewed and managed, the small proportion externally reportable, unexpected inpatient deaths and those that represent significant risk or an important opportunity for organization-level improvement, are presented and reviewed at a bimonthly all-departmental patient safety review meeting-the Quality Improvement (QI) Directors meeting. Unexpected inpatient deaths are defined as any death of a patient with a full code status outside of the ICU. The QI Directors group reports to the Medical Executive Committee and the hospital board subcommittee focused on quality and safety (the Patient Care Assessment

Flow Diagram of Safety Event Review

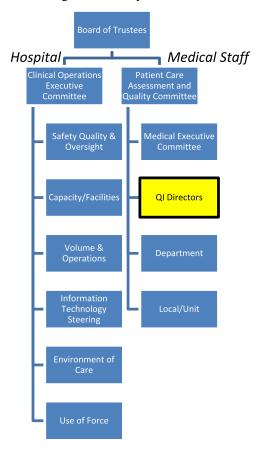


Figure 1: Shown here is the flow diagram of safety event review for this study.

and Quality Committee, Figure 1), and its membership includes physician representatives from all hospital departments, nursing and pharmacy leadership, and Healthcare Quality staff. To enhance the learnings from events and drive improvement, data on contributing factors and corrective actions are aggregated and summarized twice annually to the hospital Safety Quality and Oversight Committee, which includes additional operational leaders from the hospital and is cochaired by the associate chief medical officer and associate chief nursing director for quality (Figure 1).

Data Tools and Measurement

The day following each QI Directors meeting, the senior medical director of patient safety, the nursing director of patient safety, and the senior project manager of patient safety meet to code events using a Coding and Corrective Action Tracker (Appendix 1, available in online article). Events are categorized by Care Process, Contributing Factors, Preventability, and Corrective Action Plans.

The taxonomy of Care Processes and Contributing Factors (Appendix 2) was developed locally from a working knowledge of systems and human factors science and refined iteratively by Healthcare Quality leadership to align with the local environment. Care Processes group related actions in patient care, such as managing anticoagulation or discharging from the hospital, so that learning from events can be aggregated and more easily shared across organizational committees and workgroups charged with improving those aspects of care. BIDMC applies an aspirational definition of *preventability* that includes events in which the standard of care was not met and those in which a reasonable modification to the standard of care could be made to prevent future such events.

Events deemed to have been preventable are presented at QI Directors using cause maps—visual diagrams that illustrate the cause-and-effect relationships between contributing factors and the event.⁷ Each event's contributing factors are listed in a table and mapped to corrective actions. Corrective action plans are first developed through collaboration of the QI Directors event presenters with their local operational colleagues. These corrective actions are then reviewed and, if needed, modified at QI Directors. An event and its contributing factor(s) may not have corrective actions if the outcome is a known complication of the patient's illness or is a rare procedural complication. In other situations, events may have multiple contributing factors, each of which might be assigned more than one corrective action. Even nonpreventable events can have corrective actions if there are review findings that need to be addressed that are not causally related to the event.

Quarterly, the senior patient safety project manager and the senior medical director of patient safety request updates on pending corrective actions from QI Directors members and designees and log these updates on the Corrective Action Tracker. These updates are provided via e-mail and are the self-report of those initially assigned as Action Owners at QI Directors.

Data Analysis

To focus on the completion of corrective actions, our analysis included only events that had at least one corrective action. We tracked the completion of corrective actions for at least 16 months after the event was presented at QI Directors (longer for those events that were presented earlier in our analysis period).

Although the QI Directors presenters may initially designate a strength of their corrective actions, they may do so in a nonstandardized or inadvertently biased fashion. Because of this, the VA/IHI Action Hierarchy Tool was applied retrospectively to the Corrective Action Tracker to generate high-quality data for analysis. Before this was done, the Action Hierarchy Tool was enhanced to account for common corrective actions in the BIDMC environment. The strong category incorporated certain electronic health record (EHR) changes, as well as new clinical workflows and new procedures for communication that went beyond the intermediate standardized communication tools and enhanced documentation. Within the intermediate category, we included EHR warning alerts, cognitive aids included in policies/procedures, and standardized communication that involved more than two people. The "weak" category encompassed feedback on individual performance issues and new procedures/policies without a corresponding change in a tool or documentation to assess that process.

Before retrospectively coding the category and strength of corrective actions, the senior medical director of patient safety [J.Z.], the senior project manager of patient safety [S.T.], and the nursing director of patient safety [D.F.] met to ensure consistent application of the Action Hierarchy Tool.⁷ The Coding and Corrective Action Tracker for patient safety events reviewed at QI Directors in calendar years 2020 and 2021 was then reviewed by J.Z., who coded the corrective actions by category and strength of intervention. The additional category of "other" was applied to actions that did not fit the available options. "Further Review Needed" was used to indicate when additional data collection or inquiries were needed to understand the event or develop the corrective action. S.T. reviewed the initial coding by J.Z. and logged items they would have coded differently, and in a subsequent meeting coding discrepancies were reviewed by D.F. to reach consensus.

Summary statistics of intervention completion and strength of intervention were presented as proportions. As it may be challenging for organizations to identify a strong corrective action for every contributing factor, the proportion with intermediate or strong corrective actions may be a more pragmatic metric to track. For this reason, for some analyses we compared the proportion of events that had an intermediate or strong corrective actions⁷ to the proportion of events with only weak corrective actions. Completion of corrective actions by intervention strength and comparison of intermediate/strong and strong corrective actions for preventable vs. nonpreventable events were conducted with a two-sided chi-square test with significance of $p \leq 0.05$.

The Institutional Review Board of BIDMC deemed that this analysis did not represent human subjects research.

RESULTS

Event Reviews

From January 1, 2020, through December 31, 2021, there were 38 QI Directors meetings with a total of 138 event reviews. There were 71 events without corrective actions, including 23 unexpected deaths. Of the 67 events with corrective actions, including 3 unexpected deaths, 55 (82.1%) were deemed preventable, and 12 (17.9%) were deemed nonpreventable. Fifteen different contributing factor themes were identified. Common themes were existing process problematic/insufficient, cognitive error, lack of standard process, knowledge deficit, at-risk behavior, suboptimal teamwork, and technical error. Adverse outcomes represented in these events included bleeding, venous thromboembolism, fall with injury, delayed diagno-

Corrective Actions by Strength and Category					
	Number of Corrective Actions	Total Corrective Actions (n = 148; %)	Corrective Actions Completed	Number of Corrective Actions Completed/ Number of Corrective Actions (%)	
Strong	15	10.1	11	73.3 [†]	
Standardized equipment or process	9	6.1	9	100.0	
Tangible involvement by leadership	4	2.7	1	25.0	
Simplify process	1	0.7	1	100.0	
Engineering control (forcing function)	1	0.7	0	0.0	
Intermediate	36	24.3	29	80.6 [†]	
Standardized communication tools	8	5.4	7	87.5	
Software enhancements, modifications	8	5.4	7	87.5	
Checklists/cognitive aids	8	5.4	6	75.0	
Education using simulation-based training	6	4.1	5	83.3	
Enhanced documentation, communication	4	2.7	2	50.0	
Increase in staffing/decrease in workload	2	1.4	2	100.0	
Weak	84	56.8	82	97.6 [†]	
Training	59	39.9	57	96.6	
New procedure, memorandum, or policy	20	13.5	20	100.0	
Warnings	2	1.4	2	100.0	
Double checks	1	0.7	1	100.0	
Other	2	1.4	2	100.0	
Further review needed	13	8.8	4	30.8	
TOTAL	148		126	85.1	

Table 1. Corrective Action Categories by Strength of Intervention*

* Action Hierarchy Tool adapted from RCA²: Improving Root Cause Analyses and Actions to Prevent Harm.' $\dagger p < 0.0001$.

sis, medication error, retained foreign body, and wrong-site procedure.

The 67 events had 148 corresponding corrective actions. Fifty-seven of the 67 events (85.1%) had more than 1 corrective action, with a median of 2 corrective actions per event and a range of 1 to 7 (interquartile range [IQR] 25%, 75%: 2, 3). For the 55 preventable events, 123 corrective actions were identified-a median of 2 corrective actions per event with a range of 1 to 8 (IQR 25%, 75%: 2, 3)and for the 12 nonpreventable events, 25 corrective actions were identified-a median of 1 corrective action per event with a range of 1 to 5 (IQR 25%, 75%: 1, 3.5). Sometimes the discussion of the event led to additional questions that could not be resolved at QI Directors. Of the 148 corrective actions, there were 13 instances of "further review needed," or open questions requiring additional data or information to better understand the event or investigate existing needs to design corrective actions (Table 1^7).

Correction Action Completion and Strength

The senior project manager of patient safety agreed with 97.0% of the corrective action strength coding performed by the senior medical director of patient safety. After discussing the 4 discordant corrective actions among the three reviewers, 100% agreement was reached.

Of the 148 corrective actions, 84 (56.8%) were rated as weak, 36 (24.3%) as intermediate, and 15 (10.1%) as strong (Table 1⁷). Corrective actions mapping to preventable events were strong, intermediate, and weak 10.6%, 22.8%, and 56.9% of the time, respectively, whereas for nonpreventable events they were 8.0%, 32.0%, and 56.0%, respectively. The most frequent weak intervention was training. The most common intermediate interventions included standardized communication tools, software enhancements/modifications, and checklists/cognitive aids. The most frequent strong intervention was to standardize equipment or process. Representative examples of corrective actions are shared in Table 2. The completion rate by strength of intervention was 97.6% (weak), 80.6% (intermediate), and 73.3% (strong) (p < 0.0001). Overall completion of corrective actions for preventable vs. nonpreventable events was 87.8% and 72.0%, respectively.

Of the 67 events, 34 (50.7%) had at least one intermediate or strong corrective action, and 14 (20.9%) had at least one strong corrective action. Of preventable events, 29 (52.7%) had at least one intermediate or strong corrective action, and of nonpreventable events, 5 (41.7%) did (p = 0.0085). Of preventable events, 12 (21.8%) had at least one strong corrective action, and of nonpreventable events, 2 (16.7%) did (p = 0.0093).

Strength and Category	Example		
Strong			
Standardized equipment or process	Fire extinguishers installed in every operating room		
Tangible involvement by leadership	Coordinator hired to manage registry of abnormal radiology findings		
Simplify process	Outside hospital order for capsule endoscopy used instead of transcription into new order		
New devices with usability testing	Updated fecal management system used		
Engineering control (forcing function)	Cart with medical supply separates absorbable and nonabsorbable produce different drawers		
Intermediate			
Standardized communication tools	Addition of preferred location to operating room booking form		
Software enhancements, modifications	Added description of the need for and importance of genetic testing at provider order entry of allopurinol		
Checklists/cognitive aids	During morning huddle, team will review contrast allergy and premedication for all patients.		
Education using simulation-based training	Increase in central venous line trainings for faculty in the simulation center		
Enhanced documentation, communication	Wound care nurse to note number of sponges on wound vac drape		
Increase in staffing/decrease in workload	Call list established with redundancies for major intraoperative vascular injuries		
Weak			
Training	Case discussed at departmental morbidity and mortality conference		
New procedure, memorandum, or policy	New policy for postmortem imaging process when autopsy not possible or declined		
Warnings	Alert added to Omnicell to page the Stroke Fellow prior to administration of thrombolytics		
Double checks	Addition of technologist check during pathology specimen processing		

DISCUSSION

Our analysis of a single academic medical center's system for learning and driving improvement in response to safety event reports revealed that the majority (56.8%) of corrective actions were weak, although because most events had more than one corrective action, just over half of events had at least one intermediate or strong corrective action. Furthermore, we discovered an inverse relationship between corrective action strength and completion, with nearly all weak actions being completed within the analysis period, compared to four fifths of intermediate actions and only three quarters of strong actions.

Our findings add to prior research. For example, a study across Hong Kong found that of corrective actions generated from root cause analyses, 82% were weak, 15% were medium, and 2% were strong.¹⁴ Another report looking at eight years of interventions in a New York academic medical center of similar size to ours found that more than 50% of solutions were weak in the categories of training/counseling and policy reinforcements/changes.¹⁵ While we and the aforementioned groups chose to use the Action Hierarchy Tool, our work goes further to recommend more attention to the proportion of events with at least one intermediate or strong corrective action as advocated by the RCA² model. Others have used alternative tools to grade intervention strength.¹² Regardless of the tool used, the proportion of corrective actions falling into each strength category is dependent on many factors varying across organizations including the local safety culture, the human factors lens of the review process, and knowledge of organizational resources available to implement change. Taken together, these findings suggest there are opportunities for many health care organizations to increase the strength of their corrective actions to improve patient safety.

Beyond examining the proportion of corrective actions by strength, our work also highlights the importance of developing systems for tracking completion of corrective actions. Without tracking data on completion, organizations cannot know how well they are mitigating the risks to safety that their analyses have identified. Similar to our structure, some academic institutions have proposed the use of a tracking worksheet to monitor progress on corrective action completion¹⁶; others have reported estimates of implementation rates between 45% and 70%-at or below what we observed.9 We go further in describing the novel idea of integrating strength of corrective action into the completion tracking process. We would argue these data are critical for organizations to track if they are committed to high reliability. Organizational leaders need to maintain situational awareness about corrective actions, their strengths, and their completion. Such awareness and support of implementation by leaders is a prerequisite to moving beyond weak corrective actions and addressing implementation delays.9

We also examined corrective actions by event preventability, which we believe is a novel approach. The statistically significant higher proportion of preventable events having intermediate/strong corrective actions compared to nonpreventable events may represent organizational commitment to stronger actions when patient harm was deemed avoidable. That said, our findings highlighted that nonpreventable events are also informative with regard to opportunities for improvement; nonpreventable events had a similar number of associated contributing factors and total corrective actions as preventable events.

Although many events had at least one intermediate or strong corrective action, almost half (47.3%) of preventable events did not. This may be partly explained by the need to respond quickly to external agencies with completed corrective action plans after preventable safety events. This pressure for rapid reporting of completed corrective actions encourages actions that are quick and easy to implement and may discourage stronger corrective actions that take time to develop and implement.

To address this conflict and achieve a balance between rapid reporting and strong corrective actions, changes may be needed by both external reporting agencies and health care organizations. Currently, the health care system encourages quickly reporting to external agencies on safety events and corrective actions, as doing so is mission-critical to keep the hospital doors open. There is reduced motivation to circle back to or dedicate additional resources to partially fixed problems when there is an ever pressing need to move on to the next priority. In addition, institutional leaders may be reluctant to enforce significant system-level change on staff in an era of high staff burnout and turnover, further raising the threshold to enact strong interventions. The reporting requirements and timelines to external agencies should be designed to lessen this tension by achieving reporting that is needed to intervene on ongoing and timesensitive patient safety risks, while also encouraging institutions to create enduring change to improve patient safety.

At the organizational level, there are also likely investments that would shorten improvement timelines without sacrificing corrective action strength. To increase completed intermediate or strong corrective actions, organizations may need to change their event review structure and increase leadership engagement. During the event review process, safety teams should ensure that analyses move beyond a single root cause and incorporate a contributing factor analysis that pushes reviewers to think about systemslevel causes and systems-level corrective actions.^{12,17} To produce stronger corrective action designs, our QI Directors meeting has evolved to de-emphasize time spent on reviews without improvement opportunities and increase time spent on designing corrective actions using evidencebased data. This evolution is supported by the recent report from the President's Council of Advisors on Science and Technology regarding a Transformational Effort on Patient Safety¹⁸ and may be even more impactful by including those with expertise in risk control, such as systems engineers,¹⁹ and using structured brainstorming tools²⁰ to encourage collaborative creation of stronger corrective actions. Organizations also could create workstreams for rapid-cycle improvement while simultaneously planning for long-term interventions. The latter would allow for additional time to gather consensus and resources to address complex problems.

To drive strong corrective actions to completion, organizations should ensure that senior leaders have situational awareness of where there are incomplete actions and unresolved resource needs. This focus on the failure to achieve the strongest corrective actions follows the principles of high reliability and improves the underlying structure that is necessary for robust improvements to occur. The completion status of corrective actions may be escalated through the same health care institution reporting structures that have been previously designed to systematize awareness of safety events and root cause analyses (Figure 1). Engaging those leaders within the organization who are empowered to shift priorities and resources is likely necessary to alleviate bottlenecks and reduce barriers to strong corrective action implementation. For example, it may be necessary to invest more in innovation and quality improvement by engaging experts in systems engineering and dedicating project management support.

Strengths and Limitations

There were multiple strengths to our analysis. We presented data from the most high-impact patient safety events in our organization over an extended period. These events all underwent multidisciplinary review and event coding that captured input from safety professionals, nursing, pharmacy, and physician leadership. The events thus reflected a diverse and representative sample of organizational processes. Our work also has several important limitations. In March 2020, early in the period on which we reported, the COVID-19 pandemic resulted in a lower than usual number of safety event reports. Although we did not directly quantify barriers to selecting and completing the strongest interventions, we suspect pandemic-related strains on clinical and administrative staffing and resources had a detrimental effect. In addition, we experienced limitations on our ability to modify the EHR during the period analyzed, which likely discouraged strong interventions. Finally, we did not assess what drove the successful creation and implementation of the strongest corrective actions. Replicating lessons learned from such achievements may lead to more successful corrective action implementation in the future.²¹

Limitations of our analysis included a lack of data on time between corrective action selection and completion and any post-completion intervention maintenance. Delays in completing corrective actions as well as the period of time after any impact from a short-lived intervention wanes may represent periods of unmitigated risk of event recurrence. In addition, some corrective actions on our Tracking Tool appeared to contain more than one action, and these were coded according to the highest strength action. The retrospective application of the Action Hierarchy Tool also had limitations, and others have proposed using similar frameworks to grade strength of interventions through proactive risk assessments.²² Our redesign of the Tracking Tool to include strength of corrective actions at the time of event coding will allow us to identify situations in which corrective actions are subsequently modified in ways that alter their strength, which may be an important area to explore in future work. Other limitations included that preventability as applied in our event review was not validated and, importantly, we did not track whether corrective actions prevented events of a similar type from reoccurring.

CONCLUSION

Our results provide insight into the reasons event reporting and investigation of safety events appear to not have made health care safer over time-because many corrective actions are weak and those that are strongest may not be getting implemented—but more research is needed. Future work should explore ways of increasing the strength of corrective actions stemming from investigation of safety events and examine whether tracking completion of those actions improves safety. Such work could also incorporate the concepts of timeliness and sustainability to describe the risky time periods between an event and when corrective actions are implemented, as well as the durability of those actions over time. Although improving the strength of actions, the timeliness of their implementation, and their durability may all be expected to improve patient safety, future research could also explore the proportion of events that represent recurrence of previously identified risks vs. manifestations of latent, previously unrecognized risks.¹² Tightening the action portion of RCA² may not have as much effect as we hope if a significant proportion of events are caused by latent risks.

Now more than ever, our health care organizations need to move beyond lessons learned to ensure that the corrective actions born out of the safety event review process contain more than isolated weak corrective actions. Investment will be needed to develop, implement, and sustain stronger corrective actions that incorporate human factors thinking and encourage the desired behavior. To achieve high reliability, organizational leaders need to track the strength and completion of corrective actions stemming from safety events and take action when strength or completion rates are low.

Conflicts of Interest. Dr. Weiss is a Deputy Editor for *The Joint Commission Journal on Quality and Patient Safety*. The authors appreciate the process of having a double anonymized review. Otherwise, there are no conflicts of interest to disclose.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jcjq.2024.03. 012.

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8 Jessica A. Zerillo, MD, MPH, et al.

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