## **EDITORIAL**

## Does Combined Proactive Risk Assessment Lead to Safer Care?

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n this issue of *The Joint Commission Journal on Quality and Patient Safety*, Bender and colleagues present a novel approach to merge proactive and reactive risk assessment. Their innovative Combined Proactive Risk Assessment (CPRA) is a potentially powerful tool to improve health care's safety and reliability. Briefly, CPRA combines a common proactive risk assessment used in patient safety, the Health Care Failure Mode and Effect Analysis (HFMEA), and elements of reactive risk assessment such as incident reports (IRs) of safety events. A CPRA begins with an HFMEA and then uses IRs to validate its risk assessment. The authors provide evidence that the CPRA results in detection of more failure modes.

Bender et al. simulated a CPRA on the outpatient blood draw process at Veterans Health Administration (VHA) facilities in the United States. They used three previously completed HFMEAs at VHA facilities and created concept sheets for each process step and subprocess step. Next, they searched the VHA's IR database using key words from the concept sheets for safety events. IRs describe a range of unintended outcomes from near misses to severe patient harm and are a core feature of high reliability organizations. 1-4 Bender et al. cross-walked the IRs with the concept sheets. The IR data both identified the process steps with the highest risk of occurrence—85.8% of the IRs were in three of the seven process steps—and identified additional failure modes. The CPRA identified 310% more failure modes than the three HFMEAs. The use of reactive IRs corroborated that failure modes can reflect real-world risks.<sup>5,6</sup> The authors assume the identification of a larger number of risks will lead to better care. This may be true, but the relationship is more complex. Health systems have limited resources to design, implement, and tolerate change. Identifying and overcoming the barriers are important steps in improving health care delivery.

The CPRA offers a creative, technical solution to the problem of "too many IRs to learn from." Generally, only the most severe safety events are analyzed by root cause analysis (RCA). Yet, much can be learned from near-miss and low-harm safety events. An RCA can take 20 to 90 person-

hours to complete.<sup>8</sup> One 600-bed hospital reported receiving 15,000 incident reports a year—too many to analyze individually.<sup>9</sup> Hagley et al. sought to address this issue by providing brief analysis tools that take less than 20 personhours.<sup>10</sup> However, even brief tools leave most near-miss and low-harm safety events unaddressed. Bender et al. took a different approach, aggregating all IRs related to a specific health care process and categorizing them to create concept sheets. This allows all IRs—even descriptions of near misses—to be used to mitigate risks for future patients.

The CPRA has limitations. Although it identifies risks, it does not provide a model to implement improvements. A criticism of RCAs is the low number of implemented action plans; much work goes into the analysis, but little changes. This is also a limitation for the CPRA, which identifies problems rather than solutions. Solutions must still be identified, prioritized, and implemented. Redesigning a process, implementing change, and evaluation are still needed. It is possible that organizations could improve care more by focusing on better implementation rather than more prolific risk assessment.

A second limitation is feasibility. Bender et al. analyzed the blood draw process in the VHA system, which includes 1,255 health care facilities and used completed HFMEAs. A 2011 study from the Netherlands estimated that an HFMEA ranges in cost from €1,028 to €1,701 for a multidisciplinary team.<sup>12</sup> Further, Bender et al. accessed the VHA's vast IR database. Smaller organizations are unlikely to have access to a completed HFMEA or a vast IR database to supplement concept sheets. In addition, developing concept sheets will take hours for multidisciplinary teams to complete. Small facilities may be less able to afford the time required, arguing that "resources used to identify and correct systemic hazards are resources not used to provide care." Although zero harm is a worthwhile target, <sup>13</sup> there are trade-offs.

A third limitation is that relying on IRs to populate the concept sheets limits the potential benefits of the CPRA. IRs describe safety events, but there are other aspects to quality health care. The National Academy of Medicine (formerly the Institute of Medicine) describes quality health care as efficient, equitable, patient-centered, effective, timely, and safe—the six aims. <sup>14</sup> The CPRA could be improved if non-safety deviations from best practices also informed the concept sheets. We can learn from any deviation in a process, not only safety events.

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The effectiveness of the CRPA will need to be further evaluated in clinical settings. Bender et al. assessed their novel tool based on the number of failure modes identified and the accuracy of those failure modes. These metrics are appropriate for the pilot study, but they do not measure processes or outcomes in the blood draw process preand post-CPRA. Also, the question remains, how does the CPRA compare to HFMEA analysis based on safety and clinical outcomes? Are the extra steps in the CPRA beneficial? What do the empirical data suggest? Further, Bender et al. did not intend to have the CPRA as a standalone safety tool. RCA is required by multiple external accreditation agencies. Further evaluation will shed light on whether integrating the CPRA with other safety and quality tools will improve the quality of health care delivery.

Donabedian stressed a systems approach to quality. Yet, he balanced this with acknowledging the value of individuals. "Systems awareness and systems design are important for health professionals but are not enough. They are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system's success. Ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can then work backward to monitor and improve the system." <sup>15(p. 140)</sup> Health care delivery systems should not only focus on metrics; systems require compassionate individuals in the system. It is possible that CPRA will contribute toward this goal.

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