Patient Safety 2.0: Slaying Dragons, Not Just Investigating Them

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The purpose of patient safety work is to reduce avoidable patient harm. This requires us to *slay dragons*—to eliminate or at least mitigate risks to patients. Instead, current practice focuses almost exclusively on *investigating dragons*—tracking reports on the number and type of dragons that appear, how many villagers they eat and where, whether they live in caves or forests, and so on. Information about risks is useful to the extent that it informs effective action—but only to that extent. By itself, it does nothing to make patients safer. We cannot *investigate* a dragon to death. No more can we *risk assess* our way to safer care.

Recent research by Bates et al[1] adds new evidence to a long-simmering realization: the patient safety movement has stagnated. After a brief convulsion of innovation, the practice of patient safety has settled into a long period of bureaucratization,[2] bolstered by confidence in its (very real) good intentions and constrained by a hastily developed standard of practice that has not kept pace with advances in safety science.[3–6]

This stagnation has stymied safety improvement in a number of ways, but the field's continuing failure to focus on solutions all but guarantees that patient harm will continue unabated.

Healthcare has adopted tools from other safety-critical or high-reliability industries to address the causes of patient harm. Patient safety practitioners and frontline healthcare workers invest untold time and effort in incident reporting,[7] incident investigation (eg, root cause analysis and its various subcomponents[8–11]), and the occasional prospective risk assessment[12,13] (eg, once every 18 months to meet Joint Commission requirements). More rarely, organizations might use electronic health record trigger tools to help uncover adverse events.[1,14–16] These techniques provide important support for *risk assessment* (problem exploration)[17] but provide no direct support for *risk control* (designing and managing interventions to solve those problems).[18–21]

This approach might work in the industries where these tools originated, where they are used by safety and reliability engineers, experts in human factors, and others. These professionals receive extensive training in how to design robust safety solutions after a risk assessment. The clinicians who generally use these tools in healthcare, however, do not receive such training. As a result, they find it very difficult to design and mange effective solutions[22–26]—and the results are predictably poor. Current practice overwhelmingly results in risk controls that are weak, poorly targeted, and poorly managed.[8,20,25–27] It does little even to ensure that these "cures" are not worse than the disease.

Consider, for instance, the overwhelming number of electronic health record system alerts in many organizations. These are intended to advance safety. However, the low signal-to-noise ratio of these alerts makes them not only functionally useless but also actively harmful, because physicians simply do not have the time to find the needle in the haystack without drawing blood. They are trained by the electronic health record, itself, to ignore alerts as their default behavior.[28] More broadly, training/education is a mainstay of patient safety risk control but is *negatively* associated with reports of safety improvement.[29,30]

Although risk control has not been entirely ignored in patient safety, its most common manifestation in practice is the ritualistic invocation of plan-do-study-act (PDSA) cycles. Plan-do-study-act is a high-level framework for change, analogous to the scientific method. It is made up of a 4-step cycle that includes designing interventions (plan), implementing them (do), learning from the implementation experience (study), and then improving, adopting, or abandoning the intervention, based on that learning (act). It is often described as starting small and scaling up (eg, testing an intervention with 1 physician, then with 1 unit, 1 department, and so on).[31]

Unfortunately, the successful use of PDSA in healthcare is vanishingly rare.[32] At least in part, this is because applying PDSA in the real world of healthcare is far more complex than advertised, and there are no specific tools to enable the task.[31] This lack of operational support for risk control means that healthcare's enormous investment in risk assessment is often wasted—a lost opportunity to make patients safer and a squandering of scarce resources for improvement.

It is time for a new and reinvigorated approach to patient safety that focuses on changing outcomes, instead of collating them. *It is time to start slaying dragons*.

What would this look like in practice?

First, healthcare organizations should adopt structured tools for risk control practice. Several risk control toolkits have already been introduced. They provide the same kind of support for risk control that analogous tools like root cause analysis or failure mode and effects analysis provide for risk assessment. The difference is that these risk control tools were specifically designed for patient safety improvement.[23,24,33–38]

Unsurprisingly, structured risk control tools easily outperform the status quo of "shoot from the hip," but none have been widely adopted. The patient safety movement cannot ethically allow itself to remain settled into the comfort of an obsolete standard of practice.[39] This complacency echoes other examples in which ongoing patient harm has been treated as "inevitable" and "the cost of doing business," despite studies showing that it is possible to do better.[40]

Second, we need to expand the ranks of dragon slayers. Clinicians cannot go it alone—and should not have to. Healthcare organizations should engage with experts in sociotechnical intervention design, such as safety scientists, human factors and design experts, engineers, architects, sociologists, and public health practitioners, among others,[41–49] to help improve the patient safety risk control process. In the early days of the modern patient safety movement, this kind of interdisciplinary engagement was more common and gave rise to important advances. Since then, the healthcare industry has gradually retrenched and resiloed itself.[2] This time, it will be crucial to ensure a more intentional and sustained approach.

The time to begin these changes is now. We cannot tabulate dragons into toothlessness. We have a moral obligation to take

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up arms and start *slaying dragons*. It is only by moving beyond analysis and grappling with the messy work of systems change that we will ever reduce the intolerable burden of patient harm.

REFERENCES

1. Bates DW, Levine DM, Salmasian H, et al. The safety of inpatient health care. *N Engl J Med*. 2023;388:142–153.
2. Wears R, Sutcliffe K. *Still Not Safe: Patient Safety and the Middle-Managing of American Medicine*. New York, NY: Oxford University Press; 2019.
3. Shekelle PG, Pronovost PJ, Wachter RM, et al. Advancing the science of patient safety. *Ann Intern Med*. 2011;154:693–696.
4. Vincent C. Science and patient safety. *CMAJ*. 2013;185:110–111.
5. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. *Health Aff*. 2005;24:138–150.
6. Card AJ, Ward JR, Clarkson PJ. Getting to zero: evidence-based healthcare risk management is key. *J Healthc Risk Manag*. 2012;32:20–27.
7. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2015;25:71–75.
8. Peerally MF, Carr S, Waring J, et al. The problem with root cause analysis. *BMJ Qual Saf*. 2017;26:417–422.
9. Card AJ. The problem with '5 whys'. *BMJ Qual Saf*. 2016;26:671–677.
10. Jun GT, Ward J, Morris Z, et al. Health care process modelling: which method when? *Int J Qual Health Care*. 2009;21:214–224.
11. Reilly JB, Myers JS, Salvador D, et al. Use of a novel, modified fishbone diagram to analyze diagnostic errors. *Diagnosi*. 2014;1:167–171.
12. Card AJ, Harrison H, Ward J, et al. Using prospective hazard analysis to assess an active shooter emergency operations plan. *J Healthc Risk Manag*. 2012;31:34–40.
13. Potts HW, Anderson JE, Colligan L, et al. Assessing the validity of prospective hazard analysis methods: a comparison of two techniques. *BMC Health Serv Res*. 2014;14:41.
14. Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff*. 2011;30:581–589.
15. de Wet C, Bowie P. The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records. *Postgrad Med J*. 2009;85:176–180.
16. Stockwell DC, Bisarya H, Classen DC, et al. A trigger tool to detect harm in pediatric inpatient settings. *Pediatrics*. 2015;135:1036–1042.
17. Bagian JP, Gosbee J, Lee CZ, et al. The veterans affairs root cause analysis system in action. *Jt Comm J Qual Improv*. 2002;28:531–545.
18. Card AJ, Ward JR, Clarkson PJ. Trust-level risk evaluation and risk control guidance in the NHS east of England. *Risk Anal*. 2014;34:1471–1481.
19. Card AJ, Ward JR, Clarkson PJ. Beyond FMEA: the structured what-if technique (SWIFT). *J Healthc Risk Manag*. 2012;31:23–29.
20. Card AJ, Ward J, Clarkson PJ. Successful risk assessment may not always lead to successful risk control: a systematic literature review of risk control after root cause analysis. *J Healthc Risk Manag*. 2012;31:6–12.
21. Wu AW, Lipshutz AKM, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. *JAMA*. 2008;299:685–687.
22. Lyons M, Woloshynowych M, Adams S, et al. *Error Reduction in Medicine: Final Report to the Nuffield Trust*. London, United Kingdom: Nuffield Trust; 2005.
23. Card AJ, Ward JR, Clarkson PJ. Generating Options for Active Risk Control (GO-ARC): introducing a novel technique. *J Healthc Qual*. 2014;36:32–41.
24. Card AJ, Ward JR, Clarkson PJ. Rebalancing risk management—part 2: the Active Risk Control (ARC) toolkit. *J Healthc Risk Manag*. 2015;34:4–17.
25. Iedema R, Jorm C, Braithwaite J. Managing the scope and impact of root cause analysis recommendations. *J Health Organ Manag*. 2008;22:569–585.
26. Dixon-Woods M. Why is patient safety so hard? A selective review of ethnographic studies. *J Health Serv Res Policy*. 2010;15(Suppl 1):11–16.
27. Iedema RA, Jorm C, Braithwaite J, et al. A root cause analysis of clinical error: confronting the disjunction between formal rules and situated clinical activity. *Soc Sci Med*. 2006;63:1201–1212.
28. Wachter R. *The Digital Doctor*. New York, NY: McGraw-Hill Education; 2015.
29. Mills PD, Neily J, Kinney LM, et al. Effective interventions and implementation strategies to reduce adverse drug events in the Veterans Affairs (VA) system. *Qual Saf Health Care*. 2008;17:37–46.
30. Mills PD, Neily J, Luan DD, et al. Using aggregate root cause analysis to reduce falls and related injuries. *Jt Comm J Qual Patient Saf*. 2005;31:21–31.
31. Reed JE, Card AJ. The problem with plan-do-study-act cycles. *BMJ Qual Saf*. 2016;25:147–152.
32. Taylor MJ, McNicholas C, Nicolay C, et al. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. *BMJ Qual Saf*. 2013;23:290–298.
33. Card AJ, Simsekler MCE, Clark M, et al. Use of the Generating Options for Active Risk control (GO-ARC) technique can lead to more robust risk control options. *Int J Risk Saf Med*. 2014;26:199–211.
34. Vacher A, El Mhamdi S, d'Hollander A, et al. Impact of an original methodological tool on the identification of corrective and preventive actions after root cause analysis of adverse events in health care facilities: results of a randomized controlled trial. *J Patient Saf*. 2017;17:483–489.
35. Wiegmann DA, Wood LJ, Solomon DB, et al. Implementing a human factors approach to RCA2: tools, processes and strategies. *J Healthc Risk Manag*. 2021;41:31–46.
36. Card AJ. The Active Risk Control (ARC) toolkit: a new approach to designing risk control interventions. *J Healthc Risk Manag*. 2014;33:5–14.
37. Card AJ. *The Active Risk Control (ARC) Toolkit*. 1st ed. Davenport, FL: Evidence-Based Health Solutions, LLC; 2011. Available at: http://www.activeriskcontrol.com/tools-and-templates.
38. Vacher A, D'Hollander A, El Mhamdi S, et al. Effectiveness of a tool for structuring action plan after analysis of adverse event. *Proc Hum Factors Ergonom Soc Annu Meet*. 2011;55:1631–1634.
39. Card AJ. What is ethically informed risk management? *AMA J Ethics*. 2020;22:965–975.
40. Pronovost P, Vohr E. *Safe Patients, Smart Hospitals*. New York, NY: Penguin Group; 2010.
41. Taylor E, Hignett S. Deep scope: a framework for safe healthcare design. *Int J Environ Res Public Health*. 2021;18:7780.
42. Hignett S, Jones EL, Miller D, et al. Human factors and ergonomics and quality improvement science: integrating approaches for safety in healthcare. *BMJ Qual Saf*. 2015;24:250–254.
43. Joseph A, Henriksen K, Malone E. The architecture of safety: an emerging priority for improving patient safety. *Health Aff*. 2018;37:1884–1891.
44. Carayon P, Wooldridge A, Hose BZ, et al. Challenges and opportunities for improving patient safety through human factors and systems engineering. *Health Aff*. 2018;37:1862–1869.
45. Card AJ. Patient safety: this is public health. *J Healthc Risk Manag*. 2014;34:6–12.
46. Mannion R, Braithwaite J. False dawns and new horizons in patient safety research and practice. *Int J Health Policy Manag*. 2017;6:685–689.
47. Ward JR, Clarkson PJ, Goodman-Deane J. *Systems Safety Assessment (SSA) Toolkit*. 2017. Available at: http://www.ssatoolkit.com/ssatoolkit/. Accessed 23 May 2023.
48. Catchpole K. Spreading human factors expertise in healthcare: untangling the knots in people and systems. *BMJ Qual Saf*. 2013;22:793–797.
49. Allen D, Braithwaite J, Sandall J, et al. Towards a sociology of healthcare safety and quality. *Sociol Health Illn*. 2016;38:181–197.