The harms of promoting 'Zero Harm'

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In this issue, Amalberti and Vincent[1] ask 'what strategies we might adopt to protect patients when healthcare systems and organizations are under stress and simply cannot provide the standard of care they aspire to'. This is clearly a critical and much overdue question, as many healthcare organisations are in an almost constant state of stress from high workload, personnel shortages, high-complexity patients, new technologies, fragmented and conflicting payment systems, over-regulation, and many other issues. These stressors put mid-level managers and front-line staff in situations where they may compromise their standards and be unable to provide the highest quality care. Such circumstances can contribute to low morale and burn-out.

The authors provide guidance for addressing this tension of providing safe care during times of organisational stress, including principles for managing risk in difficult conditions, examples for managing this tension in other high-risk industries, and a research and development agenda for healthcare. Leaders at all levels of healthcare organisations should read this article.

These authors join others[2] who advise that we should shift our focus from creating absolute safety (meaning the elimination of error and harm) towards doing a better job of actively managing risk. I want to expand on this point to explore how an excessive focus on absolute safety may paradoxically reduce safety.

Striving for absolute safety—often termed 'zero harm'—is encouraged by some consultants, patient safety experts and regulators. Take for example the recently published book, *'Zero Harm: How to Achieve Patient and Workforce Safety in Healthcare'*,[3] edited by three leaders of Press Ganey, a large organisation that works with over 26 000 healthcare organisations with the mission of helping organisations improve patient experience, including improving safety. The book states, 'We will only reduce serious safety events, and improve organizations' overall performance, if every US healthcare system commits to zero harm as a sacred core value' (Harm, p254).[3] The book is commendable for presenting many accepted and effective practices for improving patient safety (many of which do not explicitly seek or argue for zero harm goals). Nine well-known leaders of exemplary US healthcare systems endorse the book. However, when I reflect on the field of patient safety research and my experience as a leader of efforts to improve patient safety, I can identify not only challenges, but potential harms of overemphasising zero harm goals.

Before I discuss these potential harms, I will first review the types of harms in healthcare and point out that some harms are inevitable and impossible to eliminate. This alone should cause reconsideration of zero harm goals. The patient safety movement began with studies that classified harms as either unpreventable or preventable (including negligent) adverse events.[4 5] *Unpreventable harms* include harms that are actually intended and necessary to treat disease—for example, the harm from a surgical incision to remove a ruptured appendix, and harms such as adverse drug reactions in a patient who has never received the medication before, or postoperative complications that we currently do not have the knowledge to prevent. Of course today's unpreventable harm may with more research be tomorrow's preventable harm. But nevertheless, at any given moment in history, there are harms for which we do not have the knowledge to prevent. It is primarily the responsibility of researchers and improvement experts, not the typical clinician or healthcare organisation, to understand how to prevent the unpreventable.

Preventable harms historically included those due to human errors, such as slips and lapses, negligent care, and those for which interventions have been tested and proven effective at preventing them, such as central line bloodstream infections,

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catheter-associated urinary tract infections and fatal blood transfusion reactions. It is this last group of harms that is most often explicitly targeted by zero harm efforts even though when perfectly implemented the interventions do not prevent all harms.

It is useful to further delineate preventable harms when thinking about the difficulty of reaching zero harm, specifically the harms that are unintended consequences of innovations or policies. There is a long history of social science scholarship in this area that patient safety stakeholders should consider.[6 7] Unintended consequences may arise from innovations such as electronic health records, or from simple changes in policies and workflow implemented by well-meaning leaders and quality improvement efforts. There are *unintended and unanticipatable harms* of new technologies, medications, procedures, workflow and policies. Even with state-of-the-art proactive risk analysis and systems modelling, we cannot anticipate and prevent every harm given the overwhelming complexity and unpredictability of healthcare and human behaviour. These harms may only be considered preventable after the first time they have happened—they cannot be anticipated because they arise from idiosyncratic and complex confluences of patients, providers, technologies, organisational policies, culture and the inevitability of human error. Finally, there are *unintended but anticipatable harms*.[8] For example, the electronic health record has introduced many unintended harms that could have been anticipated and prevented by following best practices of human-centred design.[9]

Thus, there are two groups of preventable harms that cannot be eliminated: first, the classic preventable adverse event or harm (eg, central line bloodstream infections) that can be dramatically reduced by following evidence-based best practice but will continue to occur at a low rate because the best practice is not always effective, or because of the inability of humans to always perfectly execute the best practice; and second, the unintended and unanticipatable harms that will continue to occur after new technologies, drugs, procedures and workflows are introduced. These are only preventable after they first appear and become known.

For many healthcare leaders this understanding regarding the inevitability of many harms should lead them away from overemphasising zero harm goals. Interestingly, the editors and at least one of the experts who endorse the book *Zero Harm* seem to agree that zero harm is unattainable. The editors describe the goal of zero harm as a 'never-ending journey' (Harm, pxii),[3] and one of the expert endorsers says it is 'a journey into uncertain territory that goes on forever'. But others may think it is still good to strive for zero. After all, 'to do no harm' is a central tenet of healthcare. However, there are also potential harms we can anticipate when we strive for zero harm.

First, it is frustrating and demoralising for clinicians to be asked to strive for an unattainable goal. A basic tenet of quality improvement is to set a goal that is lofty, but still attainable. We cannot possibly equip clinicians with all the skills or support they need to prevent every type of harm. Why subject our front-line clinicians to an unattainable goal when they are already experiencing high rates of burn-out?

Second, the goal of zero harm is not measurable. Even for the limited set of preventable harms that could practically be measured, we do not have measurement systems that are reliable and valid enough to ensure patients that we have truly met or even made progress towards zero harm.[10 11] The safety measurement methods described to date also fail to capture all harms,[12 13] and we need to remember that harms are only one part of safety measurement.[14] The goal of zero harm is not only unattainable, it is unknowable.

Third, the goal of zero harm has unintended negative consequences when promulgated by regulators and organisational leaders who tie incentives to meeting the goal. For a goal that is unattainable and unmeasurable, external incentives are ineffective[15 16] and can motivate front-line clinicians, mid-level managers and even some executives to consciously or unconsciously hide events or argue about preventability, thereby taking the focus away from learning and improvement. For example, the US Veterans Healthcare Administration required facilities to make new appointments for patients within 14 days. Due to lack of resources, many facilities were not able to meet this goal, so employees used 'inappropriate practices' to make it appear that the goal was met.[17] A related negative consequence of overemphasis on zero harm is that given our flawed safety measurement systems we will continue to rely on clinicians to report harms. However, they can simply choose to not report[13] in order to meet a zero harm goal. Organizational research on goal setting supports this concern that high performance goals lead to unethical behavior.[18] Importantly, such unintended consequences might be attenuated by emphasizing learning and improving over achieving an outcome such as zero harm.[19]

Fourth, as Amalberti and Vincent argue,[1] to improve overall safety and reduce harm, we should focus on reducing risk instead of eliminating harm. This tension between focusing on risk versus harm has existed almost since the beginning of the patient safety movement, and it points to two different approaches to patient safety that are sometimes called safety I and safety II.[18–20]

Safety I posits that we can identify causal chains of events that lead to harm, and prescribe clear-cut interventions to prevent the harm. A safety I organisation is characterised by clear tracking and trending of an explicit set of safety events, and measuring compliance with protocols intended to prevent the harmful events. And because of the belief that the harms are

preventable by implementing known changes in linear systems, these organisations may hold leaders and front-line clinicians accountable for preventing the harms and may provide rewards and punishments for performance. This approach has resulted in advances in safety by preventing a limited set of preventable harms, but it is an overly simplified and mechanistic view of why harms occur.

Organisations should also adopt a safety II approach that posits that healthcare delivery is extremely dynamic, complex and unpredictable. In addition to having a limited set of protocols to prevent some events, safety II organisations will need to equip front-line workers with the skills to identify risks to patient safety and adapt their work environments to optimise safety. The safety II approach focuses on successes and adaptation in addition to examining failures. Safety II's emphasis on reducing risk over absolute safety, or zero harm, is needed given the inevitability of unintended and unanticipatable harms. Even the unanticipatable harms might be prevented in a safety II organisation where clinicians and managers are well versed in risk reduction, and not overly preoccupied, rewarded or punished for attempting to meet zero harm goals.

Given the clear practical and theoretical harms of promoting broad zero harm goals, and for the reasons given by Amalberti and Vincent, I encourage all patient safety stakeholders to resist an overemphasis on absolute safety, and instead draw on the strengths of both the safety I and safety II approaches. We should be clear about what types of harms can or cannot be prevented and anticipated, work to eliminate those where there is good evidence for preventability by adopting evidence-based practices, improve the ability of everyone responsible for safety to identify risks, conduct better risk analyses to anticipate and reduce unintended harms, measure and celebrate the routine adaptations that prevent harm, and reward organisational learning and improvement.

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