Reviewer’s report

Title: Safety analysis over time: seven major changes to adverse event investigation

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Reviewer: Sarah Krein

Reviewer’s report:

I applaud the authors for this interesting commentary and appreciate the effort to push the envelope and field of patient safety with this type of reconceptualization and proposed changes to safety analysis. I certainly do not disagree with the general critique about the current state of safety analysis, the need to better address changes in healthcare delivery or even many of the proposed changes in practice, such as incorporating patients and families in the process. I do, however, find myself questioning some of the assumptions that appear to underlie the concept of "managing safety along the patient journey" and the potential consequences of what appears to me to be a substantial broadening in scope (and possibly definition) of incident analysis. Specifically, my major concerns are:

1) If the objective of this re-conceptualized version of safety analysis remains focused on "systems improvement", which I believe it is, then assessing care over long periods of time and across clinical settings presumes that such care is being delivered by a system of some sort. While this may be true in some countries, with my admittedly U.S.-centric perspective I find it difficult to conceptualize how one might track the patient journey across what could be an amalgam of different and often unconnected health care providers and settings. Even within those 'systems' in the U.S., such as the Department of Veterans Affairs (VA) healthcare system, patients can receive care delivered or managed by the VA but also care from other providers for which VA has no regulatory authority. While this system or lack thereof may be a fundamental patient safety 'flaw' in U.S. health care, another question raised by the systems issue is that of accountability. Thus, who or what part of the system would be accountable for any identified systems improvements or even initiating this type of safety analysis. Although there is some general discussion about analysis and improvement across organizational boundaries a more specific example of how this might work may be needed to convince readers such as myself as to feasibility and utility of this idea.

2) Related in part to the issue of accountability, I find myself struggling with several questions about scope and scope creep and the potential consequences. For example, as we dive into the patient journey and identify a host of issues including psychological and social issues how do we deal with things that are not within the purview of a healthcare system but undoubtedly impact care delivery? Moreover, what defines issues that might be safety related versus general quality improvement, i.e., what, if any, are the boundaries with this approach? Could the apparent broadening of timeline and scope dilute focus and resources and as such the potential for improvement? How effective is the strategy described as proportionate and strategic, examining fewer incidents in greater depth, at identifying actionable targets for system improvement? I do not expect specific responses to these questions necessarily but am simply trying to illustrate
concerns that come to mind with this revised vision of incident analysis and the potential for achieving true systems improvement and thus issues that may benefit from additional discussion and clarification.

I hope these comments are helpful and appreciate the opportunity to review this thought provoking work.

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