Forum

IHI Replies to "The 100,000 Lives Campaign: A Scientific and Policy Review"

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In their critical analysis of the Institute for Healthcare Improvement's (IHI's) "100,000 Lives Campaign,"[1] Drs. Wachter and Pronovost contribute the type of scrutiny that will help place the improvement of health care systems on the soundest possible scientific foundation. We welcome their inquiry. We do not agree at all with those who tried to dissuade them from publishing their views.

This campaign deserves study. After decades of limited traction in improving our troubled health care system, the campaign appears to have tapped into a new and promising level of energy, dialogue, and positive emotion in much of the health care workforce. We are eager to work with academicians to help us understand how and why this effort has aroused so much will and good work in an industry recently more often known for its morale problems than its great, latent spirit. In this response, we attempt to correct some of the misunderstandings in Drs. Wachter and Pronovost's commentary and to explain why we disagree with some of their policy conclusions. However, as we address those technical details, we hope that our readers and our critics will not lose sight of the opportunity for change on a massive scale that the campaign may have uncovered.

First, Drs. Wachter and Pronovost question the scientific grounds for our advocacy of rapid response teams. We were well aware of the important cluster randomized controlled trial by Hillman and colleagues published in *The Lancet* in 2005,[2] and we engaged in extensive and highly informative conversations with its authors. That study was complex, confounded by cross-contamination, significantly underpowered (the actual baseline event rate of 6.82 events per 1,000 was far lower than the 30 events per 1,000 that the authors predicted when they designed the study*), and overall found a major decrease in mortality rates through the study period in most sites. Technically, it is incorrect to interpret the study as "negative." Rather, it is inconclusive—neither negative nor positive.

Meanwhile, we have accumulated evidence from numerous hospitals of important benefits of rapid response capabilities. We favor evidence-based medicine, but we do not agree with enforcing standards of evidence in this case that ignore accumulated reports, time-series data, common sense, and sound logic. It would now be prudent, we believe, to guide programs of rapid response by a Bayesian view of the evidence, with a rather strong, positive, prior probability estimate of value, instead of privileging the null hypothesis. Evaluative research should continue, but, given the current state of knowledge, the consequences for patients of making a Type II error (concluding that rapid response teams are not effective when, in fact, they are) are far more costly than those of making a Type I error (concluding that rapid response teams are effective when, in fact, they are not).

Second, Drs. Wachter and Pronovost suggest that our reports mislead readers with claims that the mid-point estimate of lives saved (122,300) is exact and that the lives saved in participating hospitals are attributable to the campaign effort. In announcements, speeches,

* IHI's analysis of this study and its implications for the 100,000 Lives Campaign, titled "The 'MERIT' Trial of Medical Emergency Teams in Australia: An Analysis of Findings and Implications for the 100,000 Lives Campaign," is available at http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=2#Intervention%20Materials (in the Intervention Materials for Rapid Response Teams; last accessed Sep. 7, 2006).

papers, Web site materials, and dozens of local meetings and conferences, we tried to avoid either claim. We clearly stated the levels of statistical and methodological uncertainty around estimating whether fewer patients died in campaign hospitals during the campaign period than would have died had care not improved since 2004. We repeatedly acknowledged that the campaign joins many other efforts in the United States to make hospital care safer and better. We emphasized on many occasions that the campaign's measurement system was neither intended nor designed to permit confident attribution of the mortality reduction to the campaign itself. We acknowledge that occasional communications from the IHI did not restate these caveats as clearly as we wish they had, but in the overwhelming body of our communications we tried to keep the analysis and claims clear. Public media and press reports have indeed sometime made attributions and claims that go beyond ours, but the media are not under our control.

Third, the authors raise doubts about our severity adjustment methods. We know very well that the science of mortality risk adjustment is inexact and that the administrative data on which such analyses rely are sometimes flawed. However, we assert that the three independent assessments of the change in national patient risk used in our calculations are good enough for our stated purposes. Materials detailing these adjustments, which we would have been happy to provide to Drs. Wachter and Pronovost, are available from CareScience, Premier, and Solucient.*

Fourth, Drs. Wachter and Pronovost, as well as other observers, have questioned the various forms of extrapolation to missing data in our estimates. For campaign hospitals that submitted no data (slightly fewer than 14%), we applied an adjustment factor to the missing data that effectively reduced their projected performance by 50%. As we have previously stated, if we had assumed, even more conservatively, that not submitting data to the campaign meant that a hospital did not improve at all, the point estimate of lives saved would have been 114,400. Regarding our projection out to the full 18 months of the campaign, Drs. Wachter and Pronovost's conclusion that this projection was based on a maximum of 15 months of data from hospitals submitting data is factually incorrect. As explained in our recent article, hospitals that submitted mortality data submitted an *average* (not a maximum) of approximately 15 months of data.[3] The true number of hospital-months of data actually submitted was 39,196—slightly higher than the theoretical maximum that the authors calculate.

The authors claim further that our calculation of the number of lives saved failed to account for secular trends in improvement, representing a "systematic error" in the calculation. As detailed discussions of this issue in IHI articles cited by the authors make clear,[3,4] including secular improvement trends in our estimate was not an oversight; it was our intent. We know that hospitals have been and will be engaged in changes designed specifically to save lives in addition to those fostered by the campaign. The campaign-period improvement associated with that historical trend was included in the measurement *by design*. We do agree that the question of what effect the campaign itself had on improvement is an important one, and we are currently working on analyses in an attempt to isolate that effect. However, we never intended the lives saved calculation to be that analysis.

Fifth, Drs. Wachter and Pronovost question the accuracy of self-reported, unaudited mortality data from hospitals. They stress that mortality data submitted by hospitals may be biased because of pressure on reporting hospitals to show improvement. Although bias might of course creep into reported mortality data, a recent study by the Joint Commission on Accreditation of Healthcare Organizations shows a high level of reliability in self-reported data—notably a 94.2% agreement on discharge status—and finds no evidence of intentional manipulation, even in submission of Joint Commission indicator data (whose measures are more complex and consequential to a hospital than the campaign mortality data).[5] Of course, some hospitals may have manipulated some reports, but we cannot join cynics who suspect that most or enough did to fundamentally change our findings.

Sixth, on the policy front, Drs. Wachter and Pronovost raise questions about the propriety of the IHI—a private, though nonprofit organization—"setting a national agenda for change." The claim that a private organization ought not to advocate a national agenda is questionable. Health

* Readers may send an e-mail to Andrew Hackbarth (ahackbarth@ihi.org) to request these materials.

care, to its great advantage, has seen many efforts by private groups to accelerate national improvement on specific topics in the public's interest, such as efforts by philanthropic foundations (for example, The Robert Wood Johnson Foundation's programs on substance abuse and access to care), by trade associations (the American Hospital Association's Campaign for Coverage), by specialty societies (The American Heart Association's Get with the Guidelines℠ program), by voluntary consortia (the Vermont-Oxford Neonatal Network), and by disease-focused interest groups (the Cystic Fibrosis Foundation). Dr. Pronovost's own inspired leadership in the brilliantly successful Keystone Project to improve intensive care is a strong, recent example on a regional level.[6] The 100,000 Lives Campaign joins a rich tradition of privately encouraged national improvement programs.

Further, the implication that IHI somehow set the agenda alone is misleading. We were deliberate in trying to select interventions that other national bodies had embraced, seeking to create an active national network through which we could pursue shared aims.[7] The campaign assembled a very broad coalition of partners, such as the Joint Commission, the American Medical Association, the American Nurses Association, the Leapfrog Group, many state hospital associations, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, patient and consumer groups, and specialty societies, that came together at our invitation to create, advise, and, in almost all cases, endorse the campaign.*

* A complete list of Campaign partners is available at http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=4#Partners.

Drs. Wachter and Pronovost question the campaign's level of accountability. In fact, transparency and open debate—at a level perhaps unprecedented in national health care improvement efforts—have been hallmarks of the campaign from its inception. During its first 18 months, the campaign included, at no cost to participants, vigorous Web-based discussion groups, more than 30 topic-specific national telephone conference calls with as many as 2,000 people on a single call, and more than 60 local and regional meetings and conferences with hospitals and sponsoring regional groups. All these encounters with the campaign have invited dialogue and questions and offered an open door to anyone to raise doubts and concerns.

We and our many partners are committed to drawing on this open discourse to inform and improve the next phase of the campaign. We can sense, as we hope that our critics also do, something quite wonderful associated with the 100,000 Lives Campaign, and we invite them to join us as we build on that momentum. J

The authors thank Jane Roessner, Madge Kaplan, Jonathan Small, Robert Lloyd, Frank Davidoff, Don Goldmann, and other IHI staff for their assistance in preparation of this response.

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The Authors Reply

We reiterate our admiration for the Institute for Healthcare Improvement (IHI), the concept of a campaign to encourage and facilitate the provision of safer care, and the execution of the 100,000 Lives Campaign. Our previous[1] and ensuing comments are based on our belief that patients, clinicians, and others ought to know, with scientific integrity, whether quality improvement efforts work. When hyperbolic estimates of benefits are presented as truth, we worry that quality improvement efforts—including the remarkable work of IHI and its partnering organizations, hospitals, and providers—are set back, not enhanced.

Berwick et al. are correct—IHI is neither the first nor the only private organization to establish national health care goals or to initiate a campaign to achieve them. However, no other such campaign in recent memory has been as successful in promoting action, attention, and admiration, and thus the interpretation of the results by providers, patients, policymakers, and the media is particularly consequential. Or, as Uncle Ben says to Peter Parker in the movie *Spiderman*, "with great power comes great responsibility."

Notwithstanding IHI's caveats, we believe that the following are widely held—and predictable—interpretations of the 100,000 Lives Campaign's intent and results:

1. The six "planks" represent practices that should be implemented by all hospitals in the United States.
2. The campaign saved 122,300 lives.

We will address these in turn, concluding with brief responses to some of the additional points raised by Berwick et al. that merit clarification beyond those discussed in our original article.

The Planks

Here, most of the debate centers on the campaign's rapid response team recommendation. On this, we agree with the findings of a recent consensus conference[2] that found the concept of rapid response systems (RRS, the new name promoted by the conference) to be promising, but that, whereas "there is robust evidence of unmet patient needs leading to adverse outcomes… there is insufficient evidence for accrediting organizations and government and regulatory agencies to require hospitals to provide an RRS."(p. 2472) Moreover, the consensus conference's review of the state of the evidence found that the "historical-control, single-center" studies that suggest outcome benefits "controlled for secular trends poorly, if at all."(p. 2471) Finally, the conference's analysis of the Hillman et al. study,[3] while laying out some of the same methodological and practical concerns as Berwick et al., came to the same conclusion as ours: "The only randomized, controlled trial to date showed no benefit of a [medical emergency team].[2](p. 2471)

The Bayesian approach suggested by Berwick et al. can create a tautology: the practice *should* work and therefore negative results *must* have been flawed and are to be disbelieved. We prefer an alternative approach in considering the present evidence regarding rapid response teams: there is clear evidence of unmet patient need, rapid response teams represents a promising approach with weak and anecdotal evidence of benefit, and therefore hospitals should be encouraged to experiment with the concept in the context of their resources and other priorities while awaiting more rigorous evidence of benefits, harms, and costs. Although IHI lacks regulatory authority, the inclusion of rapid response teams as one of the six campaign planks had the effect of creating tremendous pressure on hospitals to implement them (likely at the expense of other interventions), and an article (co-authored by an IHI consultant) even suggested that institutions could be sued if they lacked them.[4] The IHI 100,000 Lives press release[5] suggests this as well: "As a result of the Campaign, many patients have begun to enjoy a new *standard of care* [emphasis added]… hundreds of hospitals have also now instituted rapid response teams…"

The "Saved Lives"

Although "the media are not under [IHI's] control," we have carefully reread the IHI press release[5] and find little there that would allow all but the most sophisticated reader to distinguish between "the campaign saved 122,300 lives" and the following more scientifically accurate interpretation of the "lives saved" estimate: after

substantial risk adjustment based on administrative data that led to a fourfold increase in lives saved, no adjustment for historical trends in hospital mortality or for the impact of any other interventions that would have reduced the estimates, and an assumption that hospitals that did not submit data realized the same overall treatment effect as those that did, an analysis of mortality data showed that the hospitals that signed a pledge of participation in the campaign reported 115,363–148,758 fewer deaths.[6–8]

We remain particularly concerned about the impact of the secular trends and risk adjustment. To us, the decision to report "lives saved" without accounting for this historical trend in hospital mortality would be akin to performing a clinical trial of an anti-influenza drug that began at the tail end of flu season, and reporting the decrease in flu cases as being associated with the administration of the new agent. That the failure to account for these trends was purposeful ("our intent") and transparent does not make the approach any more scientifically sound or the failure of nonmethodologists to appreciate its impact any more surprising. In fact, the media were not alone in misinterpreting the results of the campaign or failing to heed IHI's advice to avoid institutional estimates of lives saved—since the end of the campaign, we have heard several hospital chief executive officers, chief medical officers, and medical school deans tout their institutions' "lives saved" as evidence of the vigor of their quality improvement efforts.

In addition, the difference between the unadjusted (33,000) and adjusted (122,300) "lives saved" reflects a change in patient severity of illness and case mix during a short period of time that would, to our knowledge, be unprecedented in health services research. In the absence of a new product line (such as a surgical or cardiac service) that recruits new groups of patients, severity of illness in hospitals tends to change very gradually—certainly not to this degree during an 18-month period. As such, an adjustment resulting in 89,000 additional saved lives continues to strain credibility.

Other Points

Although a point-by-point rebuttal is not necessary, we would like to point out what we consider to be two inaccuracies in the response by Berwick et al. First, they say that our "conclusion [that the ultimate lives saved estimate] was based on a maximum of 15 months of data is factually incorrect." We made no such statement. Instead, we used the "average" of 15 months of data reported by the IHI in our calculation of the maximum number of data points available for the analysis. We appreciate the authors' provision of the true number of data points (39,196). The fact that it is 1% higher than our estimated maximum provides little reassurance because it means that approximately 27% (1 – 39,196/54,000) of the data used to create the final "lives saved" estimate were in fact missing and were extrapolated from respondents' submissions.

Second, the section addressing the possibility of "bias" in the mortality numbers creates a straw man that we feel bound to address. We do not see ourselves as "cynics" accusing hospitals of "manipulating" their data but rather as students of epidemiology and evidence-based methods who know that humans, working with a predetermined belief (and hope) that a practice works and with an incentive system that rewards positive findings, are capable of producing biased results in ways that neither they nor investigators are even aware of or can anticipate. The rationale for controlled studies, audited data, and other accepted scientific methods is to protect not against fabrication but against the more subtle biases that can contaminate the work of well-meaning, honest individuals who deeply believe in what they are doing.

"Some is not a number," reads the campaign's slogan. No, it is not, but given the available information, "some"—or perhaps "we simply do not know"—would be a more accurate, scientifically defensible estimate of the lives saved by the 100,000 Lives Campaign than "122,300."

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