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## The 100,000 Lives Campaign: Crystallizing Standards of Care for Hospitals\*

Alice G. Gosfield and James L. Reinertsen

### ABSTRACT

The 100,000 Lives Campaign has the attention of U.S. hospitals, professional groups, and the media. Its aim has been endorsed, and its planks are being implemented, by more than 2,300 diverse hospitals in every state. We posit that the six planks of the campaign have become national standards of care and propose four theories of liability for hospitals that ignore the campaign or fail to implement its planks. As a result of the campaign, hospitals and their boards now face a legal incentive to reduce needless deaths through six specific interventions.

In December 2004 the Institute for Healthcare Improvement (IHI) announced a campaign aimed at avoiding 100,000 hospital deaths "over the next 18 months, and every year thereafter."<sup>1</sup> The idea underlying the campaign is that if six evidence-based, proven interventions were reliably implemented in enough U.S. hospitals, 100,000 fewer patients would die each year. Endorsing the campaign immediately was an impressive array of organizations, including the American

Medical Association (AMA), the American Nurses Association (ANA), the Centers for Medicare and Medicaid Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Agency for Healthcare Research and Quality (AHRQ), the Association of American Medical Colleges (AAMC), and a large number of quality improvement organizations, state hospital associations, and other prominent associations and institutions. Initiated 14 December 2004 by Donald Berwick in a speech titled, "Some Is Not a Number, Soon Is Not a Time," the campaign is unprecedented in its specific commitment to producing measurable results in quality within a time certain, on a national scale.

**The six "planks" of the campaign platform.** Within five months after the campaign was announced, 2,300 of the nation's 6,000 hospitals had enrolled, constituting by IHI's count more than half of the hospital beds in the United States. By joining the campaign, hospitals committed to reducing the number of preventable deaths in their institutions by using one or more of the following six interventions or "planks" that constitute the

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campaign “platform.”<sup>2</sup> (1) A system of rapid-response teams to immediately bring skilled resources to the bedside of any patient who is progressively failing outside the intensive care unit (ICU) whenever a nurse is worried that the patient might be heading toward a “code blue.” (2) Reliable implementation of evidence-based care for acute myocardial infarction, including appropriate aspirin, beta-blocker, and angiotensin-converting enzyme (ACE) inhibitor administration and timely reperfusion, as measured by the JCAHO core measures and the CMS Seventh Scope of Work.<sup>3</sup>

(3) Prevention of adverse drug events by reconciling medications at all transitions in care. (4) Prevention of central line-associated bloodstream infection by reliably implementing a “bundle” of evidence-based services including hand hygiene, maximal barrier precautions, chlorhexidine skin antisepsis, appropriate care of the catheter site and administration system, and no routine replacement. (5) Prevention of ventilator-associated pneumonia by reliably implementing a “bundle” of evidence-based services including elevation of the head of the bed 30 degrees, daily sedation “vacations,” and daily readiness-to-wean assessments. (6) Prevention of surgical site infection using a “bundle” of evidence-based services including appropriate hair removal (clipping, not shaving), guideline-based timing and use of perioperative antibiotics, and tight perioperative glucose control.

**Basis of campaign planks.** The planks were chosen based on four factors. First, each plank is strongly supported by evidence in the medical literature that it prevents avoidable deaths and injuries.<sup>4</sup> With the possible exception of perioperative glucose control and the extent and types of surgical patients to which it should be applied, none of the interventions is particularly controversial. Many rest

on evidence that has been in place for ten or more years. Second, each plank has been implemented in a variety of settings, not just in isolated research environments, with impressive results. In other words, the planks do not just apply to special circumstances and institutional systems. Third, these interventions deal with common problems that are associated with thousands of deaths. Implementing each plank widely and reliably would greatly reduce the number of deaths that occur in hospitals. Finally, implementation of none of the planks requires major capital investments or information system redesigns. For example, hospitals do not need to purchase new beds to elevate the head of the bed for all ventilator patients. Similarly, reconciling medications at each transition point in a patient’s care can be done with simple nursing processes, not expensive computer systems.

**Implementation and participants.** Although implementation does not require capital, it does require investment of additional staff time, as well as reprioritization of resources, to support the measurement, change leadership, and other activities necessary to make these six practices reliable. So there are inevitably some costs associated with undertaking these efforts. That said, however, these interventions are practicable in virtually every hospital.

The science supporting each plank and the evidence of success in their application are made known on the IHI Web site in a completely transparent manner; the names of hospitals and health care systems in the campaign also are posted there. Hospitals from all fifty states participate, and the institutions span the entire spectrum—from thirty-bed rural hospitals to community medical centers to large for-profit and not-for-profit hospital systems to the most prominent academic medical centers—in every kind of health care market.<sup>5</sup> These hospitals are now

implementing one or more planks, and the campaign has attracted considerable media attention.<sup>6</sup>

**Legal accountability.** Some may argue that the widespread emphasis on these six specific interventions might divert attention from other potentially more worthy quality initiatives. Our interest in this consideration is not the issue of priorities and choices among quality interventions; it is about the legal implications of the campaign itself, given that it already exists, and the potent effect of the 100,000 Lives Campaign on U.S. hospitals’ legal and malpractice risks.

This campaign’s appeal is based on a clear, compelling set of moral, scientific, and practical drivers. In this paper we call attention to an additional driver—a legal argument—that supports both participation in the campaign and vigorous implementation of its planks. In our view, the mere fact of the campaign—the highly public nature of its announcement; the broad support of prominent national organizations; and the breadth, geographic dispersion, and diversity of its participating hospitals—raises the legal stakes for all hospitals, whether campaign participants or not, by bringing to the foreground and making highly visible six national standards of care, for which hospitals and their boards will now be held legally accountable.

There is some precedent for our view. Some have considered that the purchasing principles of the Leapfrog Group have the potential to create legal liability for hospitals by becoming new standards of care, and this has raised concern.<sup>7</sup> We believe, however, that instead of viewing the standards of care raised by the 100,000 Lives Campaign as a threat, hospitals and health care leaders should understand and harness these legal forces to help them drive the implementation of the planks throughout the country, as quickly as possible. We already know that moral,

scientific, and even market forces have proved insufficient to compel all hospitals to make necessary improvements in safety.<sup>8</sup> If health care leaders aim to reduce needless deaths, the question raised by this campaign might be, “Is it possible that malpractice liability could be a positive force for reducing needless deaths?”

## UNDERSTANDING HOSPITAL LIABILITY

Four elements must be present and proven for a plaintiff to prevail on a medical malpractice cause of action: (1) a duty to act; (2) a breach of the applicable standard of care; (3) the occurrence of an injury; and (4) a causal connection between the breach of the standard and the injury. For many years, U.S. hospitals escaped full accountability for the medical errors committed within them on the basis of charitable immunity, or on the belief that hospitals do not engage in the actual provision of services but rather merely provide facilities in which others—most notably, physicians and surgeons—render professional services.<sup>9</sup> Beginning in 1965 with the famous *Darling* case, courts have increasingly found that the hospital is not just a place that offers its facilities to others to ply their trade.<sup>10</sup> Rather, in many states the hospital has direct corporate liability for negligence, which cannot be delegated, and in still more states it could have vicarious liability for the actions of its agents.

**Direct corporate liability.** More recently, the legal duties of a hospital as a direct provider in its delivery of care with direct corporate liability for negligence have been captured succinctly in the case of *Thompson v. Nason Hospital*.<sup>11</sup> The hospital has a duty to use reasonable care in maintaining safe and adequate facilities and equipment; a duty to select and retain only competent physicians; a duty to oversee all people who practice medicine within its

walls; and a duty to formulate, adopt, and enforce adequate roles and policies to ensure high-quality care for patients. This accountability is both broad and deep, and it ultimately rests with the hospital board.<sup>12</sup> Even in the context of vicarious liability, which avoids viewing the hospital as a direct provider of care, the hospital can be held legally accountable for the negligent actions of those it holds out to the public to perform its services. Traditionally, this is the basis for hospital liability for the actions of independent emergency physicians and other hospital-based physicians as well as nurses, based on the hospital’s selection of the staff who render care and the hospital’s holding those individuals out to the public as their agents. This liability also relates to the hospital’s duty to supervise and make sure that personnel follow its processes and procedures.<sup>13</sup>

**Quality requirements.** This new view of the role of hospitals in legal terms—particularly the duty to adopt and enforce policy and roles to ensure quality—coincides with a far older recognition of a number of fundamental quality requirements that are built into hospital systems: that is, that the delivery of services in hospitals requires calling into play a range of behavior, services, personnel, and practices that create a “system” of care. Perhaps the most recognizable example of this is how hospitals apply the various processes that make up the modern system of surgical sterile technique. Over many decades, a set of practices and rules has evolved such that it would be inconceivable for any hospital to run its surgical system without rigorous processes, roles, and policies to ensure sterility of instruments; scrubbed, gowned, gloved, and masked professionals; and a sterile field of operation. If a physician willfully violated these policies, he or she would not even be permitted to enter the operating room, let alone perform surgery, and the

hospital board would undoubtedly act to remove surgical privileges if he or she persistently ignored this rule. The board would act for two reasons: its duty to act in the interests of patients (the mission of the hospital), and also because failure to enforce its policies would create a major legal liability for the hospital.

### Hospital board’s responsibilities.

This now well-recognized hospital liability exposure gains additional importance in light of the post-*Enron/Allegheny* focus on the hospital board’s responsibilities. In the for-profit business world, the board bears a critical fiduciary responsibility to inquire about the financial data of the enterprise, a responsibility now made very specific in the Sarbanes-Oxley legislation.<sup>14</sup> In contrast, a hospital’s primary purpose, whether for-profit or not-for-profit, is measured by its clinical, not its financial, performance. Above all, the hospital board’s job is to steward the application of its resources to meet the three primary expectations of all patients when they come to a hospital: “Cure me if cure is possible; heal me even if cure is impossible; and while you’re doing that, please don’t harm me.”<sup>15</sup>

As hospital board members exercise their fiduciary role on patients’ behalf, the business-judgment rule remains the touchstone for determining whether they have breached their duty. This rule limits the liability for directors who act in good faith, provided they are fully informed and make an independent judgment that an action is in the best interest of the corporation.<sup>16</sup> But its application also requires that directors fulfill their duty to attempt in good faith to assure that a corporate information and reporting system exists and that it is adequate to assure the board that appropriate information will come to its attention in a timely manner.<sup>17</sup> Expert commentators have also observed that “the focus through

which board processes are interpreted by courts, regulators and interested parties has become much sharper.”<sup>18</sup> Included in that focus is stewardship for quality of care.

## CRYSTALLIZED NATIONAL STANDARDS?

The process by which a standard of care is created reflects the tenor of the times and is by no means immutable. Some standards of care for hospitals are explicitly codified—for example, by JCAHO. As of this writing, however, none of the six planks of the IHI campaign platform are formal standards by which accreditation is determined, although one (medication reconciliation) is a JCAHO “patient safety goal” for 2006, and measurements for several of the planks are part of the JCAHO voluntary “core measures.”

**Community versus national standards.** Legally, the applicable standard is determined in a relatively fluid manner: “Malpractice standards develop in a complicated way through the interaction of leaders of the profession, professional journals and meetings and networks of colleagues.”<sup>19</sup> A long-standing principle in U.S. malpractice law has been that the standard of care is determined by the “locality rule,” taking into account the prevailing custom within the local community where the malpractice occurred. Increasingly, though, this emphasis on local custom has been supplanted with reference to more national standards. Community standards are even giving way to less well-established, innovative, and developing standards. For example, in 1987, in *Washington v. Washington Hospital Center*, the court imposed on a hospital the standard of having provided pulse oximetry in association with anesthesia services, even though pulse oximetry was admittedly not yet widely in use.<sup>20</sup> Similarly, in *Burton v. Brooklyn Doctors Hospital*, the court found that the hospital breached the standard of care

when it provided too much oxygen to otherwise healthy premature babies because, at the time the case was heard, a number of studies had indicated that excessive oxygen could lead to blindness.<sup>21</sup> The increased availability of clinical information online and via other sources contributes to this notion of a national standard of care.<sup>22</sup>

Although not all jurisdictions adhere in lockstep to the national-standard concept, or the “reasonableness” standard as some have characterized it, the 100,000 Lives Campaign has, in a single stroke, created an extraordinary national sharpening of focus on a specific set of clinical practices, to make these practices into hospital policy, as it were.<sup>23</sup> The 2,300 hospitals’ act of signing up for the campaign and the campaign’s endorsement by major professional societies and other regulatory and accrediting agencies establish the status of the campaign planks as national standards of care. Although the science supporting the interventions might have already approached a standard of care according to traditional measures, their broad adoption by this widely publicized campaign has now crystallized each plank as a legal standard to be reckoned with.

**Legal liabilities.** We have concluded that there likely will be four types of legal liabilities for hospitals arising from the fact of the campaign itself: (1) failure to keep up with the science; (2) failure to follow adopted processes; (3) failure to inquire; and (4) failure to confront those who flout the campaign’s principles.

*Failure to keep up with the science.* The primary liability that the campaign itself will create arises from failure to keep up with the science. For hospitals that have volunteered to participate, and even more importantly for hospitals that have not, the increased attention to and publication of these interventions’ effects and value will raise the bar. The statement of the planks and

the ability of the processes to prevent deaths are not merely aspirational; the science that supports them is strong, of some duration, and acknowledged by substantial campaign enrollment statistics to be readily applicable. Therefore, the use of this science as a standard of care is a legitimate legal application and not one that raises the bar prematurely or inappropriately.

The principle that health care providers must remain current with the knowledge base has a history going all the way back into the mid-1800s.<sup>24</sup> In today’s world of evidence-based medicine and the explosion of the knowledge base, this liability could be more important than in the past.<sup>25</sup> Arguing that not all hospitals use the six planks will be an inadequate defense: “Negligence...cannot be excused on the grounds that others in the same locality practice the same kind of negligence. No degree of antiquity can give sanction to usage bad in itself,” a court said.<sup>26</sup>

The science supporting many aspects of the planks has been in existence for some time—decades, in the case of clipping as opposed to shaving of surgical sites. Although the evidence base for all of health care, including these six interventions, is continually evolving, the planks were chosen specifically because of the solidity of the current evidence base on which they rest. The bright campaign light now shining upon them will bring them into high relief and will make a stronger case for those who would find fault with hospitals that fail to adopt and implement them.

*Failure to follow their own processes.* For enrolled hospitals that proclaim their involvement with and commitment to implementing any of the six planks, policies and procedures will no doubt need to be adopted to make the commitment real. If they then fail to adhere to the policies, however, that failure will create additional exposure

because in the hospitals' commitment to the campaign, the hospitals "held themselves out" to that standard of care. This principle has been used in cases involving matters as simple as failing to put up side rails on a patient's bed. In *Hilzendager v. Methodist Hospital*, the hospital had adopted a written manual with criteria for the use of bedrails, and this manual was introduced in evidence as the standard to which it held itself out.<sup>27</sup> "Holding itself out to an articulated standard of behavior" can be said to have occurred for every hospital that has joined the campaign.

*Failure to inquire.* The obligation of a board to inquire into management's fulfillment of its responsibilities does not necessarily require the board's thorough and independent investigation, but it does require more than mere passive receipt of information. In fact, there is specific case law in which a hospital has been held liable for the malpractice of physicians with high rates of use of specific procedures on the grounds that pro forma reporting of utilization data to the board put board members on notice about the improper behavior—upon which they did not act—and the failure to act was itself the basis for liability.<sup>28</sup> Similarly, there is a longstanding chain of case law, as in *Johnson v. Misericordia Hospital* and its progeny, addressing hospitals' liabilities for failure to investigate data in medical staff applications for membership and clinical privileges.<sup>29</sup>

That hospital deaths that are now known to be preventable may occur creates a duty of care on the part of the board to responsibly investigate the reasons for such deaths. For a board to allow a hospital to enroll in the campaign and not pay heed to how or even whether it implements the planks would increase liability. Hospitals that have not enrolled will also have heightened exposure if they fail to inquire as to whether they have experienced preventable deaths. Given

the readily available science and widely accepted application of the campaign planks, hospital boards that fail to inquire into preventable deaths might be irresponsible as boards and almost certainly increase their hospitals' liability exposure.

*Failure to take action against those who flout the rules.* From the clear directives of *Thompson v. Nason Hospital*, the hospital has a duty both to enforce adequate roles and policies to ensure high-quality care and to oversee all of those who practice medicine within its walls. Hospitals that adopt policies in fulfillment of their participation in the 100,000 Lives Campaign will also take on pointed responsibility to act when the policies are not followed.<sup>30</sup> For example, just as a hospital board would be at risk for allowing a physician to ignore its policies and practices on sterile technique, the board would be at similar risk for allowing a physician to ignore the campaign plank policies regarding shaving surgical sites, timing of perioperative antibiotics, and insulin treatment to maintain normoglycemia in critically ill surgical patients. In effect, these policies will become logical extensions of the system of surgical wound infection reduction that we now call "sterile technique," and, as a result, it will be no more acceptable for a physician to ignore policies on timing of antibiotics than it would be to walk into the operating room in street clothes.

## PROBLEM AREAS

Given these kinds of liabilities, it is useful to speculate on which aspects of the six planks will be most likely to generate litigation for negligent breach of standards of care. Data now demonstrate that juries are more likely to find against hospitals than physicians. Hospitals typically pay in 50 percent of the cases filed against them, whereas physicians pay in only 30 percent. The median award against

hospitals is \$500,000. Of the top ten reasons that hospitals are sued, six are directly relevant to the planks of the campaign.<sup>31</sup>

(1) Negligent supervision of personnel and processes: This reason relates directly to planks that are adopted but not executed. (2) Delayed treatment: This argument could be used to find against a hospital that did not have a rapid-response team in place. (3) Lack of proper credentialing or technical skill: It could be argued that a hospital's medical executive committee or board that knows that a staff physician or other professional is not following its policies but that does not act to reduce his or her privileges is negligent in its privileging by allowing continued failure to meet clinical standards of performance for those services. (4) Unexpected death: This alone has been a basis for liability and might place non-campaign hospitals, in particular, at higher risk because of the number of lives that would be saved through the adoption of the planks. (5) Iatrogenic injury: Such injuries, including nosocomial infections, surgical site infections, and fractures, are a separate basis for lawsuits. In the campaign, surgical site infections, central line infections, and ventilator-acquired pneumonia all would fall squarely into this category—again, especially for noncampaign hospitals. (6) Lack of teamwork and communication: For virtually all of the campaign planks, reliable implementation is critically dependent on teamwork and communication.<sup>32</sup>

Most cases that will be brought on these six theories of negligence will involve individual patients (or their estates) who will allege in their specific cases that the failure of the hospital to conform with the applicable standard of care caused injury or death. Each case will most likely turn on one plank at a time. But hospitals that have enrolled in the campaign and choose to implement only some of the planks

cannot expect to get a bye for having enrolled. It would be hard to imagine a plaintiff's lawyer forgoing the opportunity to raise the fact of such widespread public knowledge of all six planks and to assert that such knowledge creates a duty to use them all. Still, this liability will be even greater for noncampaign hospitals that have implemented none of the planks. It is the widespread adoption and endorsement of the campaign that calls into question any hospital's failure to implement these processes—all of them.

Intensified fear of malpractice liability could impede nascent quality efforts for some institutions. But if we are right, and these six interventions are treated as legal standards of care, they probably will get more attention and rigor in application, not less, than the many other quality improvement opportunities that are not included in the campaign. Whether that emphasis will disproportionately divert attention from other quality initiatives is not yet known; however, if the evidence for the planks is valid, the attention will save lives.

## IMPLICATIONS FOR HOSPITALS

The 100,000 Lives Campaign, by causing the adoption of a set of six practices to reduce needless deaths by more than 2,300 hospitals of every type, in all fifty states, has crystallized these evidence-based practices into national standards of care. This result creates a powerful legal reason for hospitals to adopt these practices, in addition to the moral, scientific, and practical motivations that compelled so many hospitals to sign up for the campaign, so swiftly. The implications are that hospital leaders should move quickly to adopt the six planks, with or without formal enrollment in the campaign. Simply stated, hospitals that choose to ignore these practices will do so at their own malpractice peril.

When hospitals do adopt policies

supporting these practices, they cannot simply pay lip service to them; they must execute these interventions with urgency, effectiveness, and scale. The planks cannot be viewed as isolated, merely aspirational "quality projects." They must become organizational policy and standard practice and must be overseen at the highest levels of governance authority.

It is our view that the increased legal liability that results from the campaign should be neither feared nor lamented. The prevention of needless deaths, using practical, available, and evidence-based practices, is a reasonable expectation of any hospital that renders services in the United States, and so we view legal pressure on hospitals to adopt and implement the campaign planks as appropriate and healthy. The predictable likelihood that plaintiffs' lawyers may look at the campaign and raise negligent failure either to adopt these interventions as policy, or more particularly, to implement them effectively, is proper and legitimate, where such failure has occurred.

As to the potential response by some that they might avoid additional legal risk by not enrolling in the campaign, we would argue that their reaction misses the point entirely. The implementation of these planks will prevent deaths and injuries that would otherwise occur, with or without enrollment in the campaign. Failure to wholeheartedly implement the planks will create liability for all hospitals, enrolled or not. There is certainly exposure for those who enroll but fail to implement, but it is likely not measurably greater than for those who do not make the attempt at all. The point of enrollment is to galvanize the operations, processes, and personnel of hospitals to make their commitment real. Although we cannot predict with confidence that the risk of lawsuits will decrease, logic tells us that if these interventions actually prevent specific harms to patients, then imple-

menting the planks should reduce the numbers of lawsuits brought on those grounds because the interventions would decrease the numbers of deaths and injuries that give rise to lawsuits.

Finally, we emphasize that the primary reason for hospitals to adopt and implement these evidence-based interventions is not legal, but moral. It is central to the mission of hospitals to use all means possible to prevent preventable deaths. If leaders know that these interventions work, and that the interventions can be practically implemented in virtually every U.S. hospital, they have a moral duty to act. But just in case that alone is not a strong enough reason to take action on these specific interventions, we call attention to one more: If hospital leaders and their institutions do not act, they will face malpractice risk.

## Editor's Notes

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- 30 C.L. Williams, "Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?" *Washington and Lee Law Review* 61, no. 1 (2004): 479–533.
- 31 M. Glabman, "The Top Ten Malpractice Claims—And How to Minimize Them," *Trustee* 57, no. 2 (2004): 12–16.
- 32 The remaining four topic areas include medication errors, diagnosis failures, failure of consent, and pain and suffering and emotional distress.

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## COMMENTARY

# How High Is the Bar?

Maura Davies

Gosfield and Reinertsen's paper poses a number of interesting questions that merit examination in the Canadian context. They propose that the widespread adoption of the six streams of evidence-based practices included in the 100,000 Lives Campaign changes the standard to which hospitals will be held liable, regardless of whether they have enrolled in the campaign. They suggest that hospitals now have a legal incentive to ensure adoption of these practices. They propose that, instead of viewing the potential litigation as a threat, hospitals and healthcare leaders should understand and harness these legal forces to help them drive these changes. They go as far as suggesting that malpractice liability could be a positive force for reducing needless deaths.

This may be true in the context of a highly litigious American environment, but what about the Canadian setting? Safer Healthcare Now! is based on the 100,000 Lives Campaign. Across the country, hospitals and health regions are adopting one or more of the six streams of the campaign. Some organizations, including those already enrolled in the national ICU collaborative, had a head start and are well on their way in adopting these and other practices to improve patient safety, with promising preliminary results. Other organizations had a slower start and are still struggling to build the internal capacity to adopt and sustain these changes. The pace at which these patient safety practices are being

adopted is influenced by many factors, including the existing quality culture within the organization, commitment from the CEO, other senior leaders and boards, and the presence of strong clinical leadership, especially among physicians.

It is interesting to note the difference in the Canadian and American campaigns. When Don Berwick announced the campaign in December 2004, he stated, "some is not a number, soon is not a time." The campaign was notable for its specificity – 100,000 needless deaths avoided by 0900 hours on June 14, 2006. American hospitals enrolled in the campaign started to use hospital standardized mortality data (HSMD) as the Big Dot by which to measure hospital performance. The campaign began to gain significant momentum when the early adopters started to publicize their results in terms of lives saved.

In perhaps characteristic Canadian fashion, Safer Healthcare Now! adopted a much softer approach. No specific targets were set in terms of lives saved, and the campaign goal was more generally focused on enhancing patient safety. To the credit of the Canadian Institute for Health Information, standardized hospital mortality data are now available. Some organizations are starting to incorporate this measure into their performance dashboard and to use the data to focus quality improvement efforts.

Although considerable progress has been made, we have a very long way

to go. Even where there is corporate commitment, implementing changes in clinical practice is challenging. Gosfield and Reinertsen suggest that one of the reasons why the campaign strategies could now be perceived as new standards is because none of the planks requires major capital investments or information system redesigns in order to be implemented. They use the example that reconciling medications at each transition point in a patient's care can be done with simple nursing processes, not expensive computer systems. This vastly understates the change management that is required in making these changes, particularly in large complex health regions that involve multiple sites and the full continuum of care. It is no coincidence that adoption of rapid response teams has the lowest level of uptake in the Safer Healthcare Now! campaign. The reality is that these teams require an initial investment in staff. Many cash-starved hospitals and health regions are struggling to free up these resources, even though they can anticipate a payback in both patient safety and cost of care.

These differences notwithstanding, the bar is moving. One example is the incorporation of medication reconciliation in the patient safety practices now required by the Canadian Council on Health Services Accreditation (CCHSA). As CCHSA further develops new patient safety standards and patient safety indicators, there will be increasing pressure for health organi-



zations to change clinical practice and to demonstrate compliance with these new expectations.

This begs the question, when does a standard become a standard? In my opinion, at this point, we have not yet reached the Tipping Point where there has been sufficient adoption of the campaign strategies to view them as new standards. But that time is coming – we will eventually see these practices reflected in the practice guidelines of various professional groups and accrediting bodies. Many of us are not waiting until then and are already defining new expectations within our organizations. The motivation for doing this is not risk management, at least not in terms of avoiding litigation. It is about continuously improving the quality of our care and adopting practices where the evidence shows we can do things better. In my own organization, when recently reviewing a patient incident where a hospital-acquired infection contributed to the patient's negative

outcome, the issue of our infection control practices relative to one of the Safer Healthcare Now! bundles was part of our discussion, even though we have not yet enrolled in that part of the campaign.

We cannot ignore the fact that, even in the Canadian context, the fear of litigation exists. Like other Canadian health regions, we are trying hard to engage physicians in patient safety initiatives. Part of our change management strategy needs to address the resistance to “cookbook medicine” expressed by some physicians. Many of our physicians are passionate champions of patient safety, although sometimes the advice they get from their legal counsel could serve as a deterrent (for example, to participating in multidisciplinary reviews of critical incidents). In this environment, playing the “litigation card” could backfire and actually serve as a deterrent for them to be involved.

In conclusion, I agree that the

100,000 Lives Campaign and Safer Healthcare Now! are raising the bar and are influencing the standards of practice. I believe they have heightened awareness of patient safety and provided a focus for changes in practice that will significantly reduce the number of needless deaths. They will lead the way for other areas of evidence-based practice changes. They have helped us understand that hospital standardized mortality rates are a meaningful large system measure of quality.

The campaigns are making a difference. Organizations that are not adopting at least some of these practices need to be able to justify why. In the American system, the fear of litigation may help accelerate these changes. In the Canadian environment, I hope that this will not be the motivator, but if that's what it takes to save lives, so be it.

**About the Author**

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# A Conversation about Leadership and Quality with James Reinertsen and G. Ross Baker

James Reinertsen, MD, has worked as a physician, CEO and consultant on leadership, quality improvement and patient safety with leading healthcare systems around the world. What follow are excerpts from a conversation held at a dinner for healthcare leaders during the 7th National Conference on Quality in Toronto this February (2006). Reinertsen is a former CEO of Health System Minnesota and CareGroup, an academic and community hospital system in Boston. He currently heads The Reinertsen Group and leads the Institute for Healthcare Improvement's leadership development sector. The questions are posed by G. Ross Baker, PhD, professor in the Department of Health Policy, Management and Evaluation at the University of Toronto.

**Ross:** Jim, it's great to have you here at this meeting. I want to start by talking with you about the "100,000 Lives Campaign," which we are calling "Safer Healthcare Now!" in Canada. This work on patient safety has become one of the most exciting initiatives in American and Canadian healthcare and has led to greater energy and levels of commitment in quality improvement than we have ever seen before – more than 3,000 hospitals in the United States and more than 150 organizations in Canada. What is it about these campaigns that has created this energy and commitment?

**Jim:** My analysis is that three things came together. First, there was a criti-

cal mass of impatience. A lot of us have been working at this for a long time. And the Institute of Medicine (IOM) reports galvanized a lot of attention so that people began saying we have to do something about all these needless deaths in hospitals. I was on the IOM subcommittees that produced these reports and we thought that within a short time we would see major effect from the critical attention that was being channelled toward the problem. But the very slow pace with which these recommendations and issues were implemented across the system was increasingly frustrating. This led to growing impatience and there were a vanguard of leaders who were really ready to do more.

The second thing was the convergence of two kinds of evidence. For those that need research results, there was the scientific evidence from the medical literature about the six areas in the 100,000 Lives Campaign. The second type of evidence was the data from real hospitals. I can now show you run charts of mortality rates in ordinary places where implementing these sets of practices has led to a 40% reduction in mortality rates. We were learning not only from the science presented in the medical journals, but also from its application in the field. These two forms of evidence had converged.

The third thing had nothing to do with the evidence or timing. The third factor was the nature of the message. The dark side of the "100,000 Lives," is *100,000 deaths*. This had a visceral

impact that made it impossible not to sign up. How could you not enrol?

So leaders from 3,000 hospitals, 90% of all the beds in the United States, have publicly made a commitment to do this campaign. That's phenomenal.

**Ross:** The "100,000 Lives Campaign" target date is June 14, 2006, just a few months away, and the Canadian campaign runs until December 31 of this year. So the key question is: What happens then?

**Jim:** I call this the June 15 problem. Clearly a lot of people will be in mid-stride. The work won't stop. But some means of maintaining that momentum will be required as I see it, at least in the United States side of the campaign.

One thing that *will* begin in earnest after June 14 in the United States is the measurement and study phase of the work. I think this campaign is going to be analyzed in many ways. The 100,000 Lives Campaign is a fabulous laboratory for learning because it represents a sea change that has happened in the last year and a half. For example, we are very interested in the leadership factors that will distinguish the hospitals that get 20, 30, 40 and 50% reduction in mortality, from those that get nothing.

Everyone asks, "What's the next campaign going to be?" It's going to be hard to find something with the same focus and visceral grab of these interventions that leave you alive or dead. But I don't think it's going to be hard to find a platform of six more planks that

lead to dramatic improvements in care. People have to realize that nothing has ever enrolled this many hospitals and engaged this many people in a leadership role before.

**Ross:** Your comments about leaders' involvement in the campaign are very important. Many people in this room would probably agree that the leader's job is to lead the improvement of care in their organizations. But there are some who say, "My job as CEO is not to lead improvement, but to represent the hospital or system and make sure it's stable and profitable for my community." What do you say to these people?

**Jim:** This is a common response. Professional administrators will often say, "I wasn't trained as a pharmacist or a nurse or a doctor. Aren't the finances and the facilities my deal? Aren't the doctors supposed to do that alive or dead stuff? Do I have to go back and get a medical degree?" And the doctors, interestingly enough, will say, "Look, I'm responsible for my patients. That's my professional code. But I can't be responsible for the quality of the whole facility."

When I hear such comments, I think about Paul O'Neill. Paul O'Neill was the United States Secretary of Treasury and, prior to that, the chairman and CEO of Alcoa. O'Neill said, "Leaders are responsible for everything in an organization, especially the things that go wrong." You can't say I did my part, but that other stuff over there is not my responsibility. You are responsible, because you are a leader. I like this view. It's uncompromising and clear. It's not compartmentalized.

**Ross:** You wrote an interesting article in *Health Affairs* recently where you suggested that the 100,000 Lives Campaign may change the burden of

proof in medical malpractice suits and help make the fear of malpractice a more positive force for patient safety. Can you tell us more about this?

**Jim:** In every state in the United States, the majority of hospitals, of all shapes and sizes, have enrolled in the 100,000 Lives Campaign and publicly said this is what they were going to do. They said this because they don't want people to die. That marked an extraordinary moment in American medical history, where the standard of care just took a sudden sharp change in favour of those six practices recommended in the campaign.

In the article I suggest that if you are a hospital leader who has signed on for this campaign, then a year from now, you will no more be able to run your hospital without a rapid response team, for example, than you could run your hospital without sterilizing your surgical instruments or any of the other things that are regarded as standards of care. If you don't, then you risk getting a lawsuit.

Let's take surgical site infections as an example. The plaintiff's lawyer is going to say, "My client had a bad outcome. And we understand that 80% of the hospitals in this state don't shave surgical sites anymore but you do. Your hospital committee minutes demonstrate that you've not been able to confront physicians that want to continue to shave surgical sites and my patient's chest was shaved. Here's your suit. You're not following the standard of care." And you will lose.

At the same time there is a positive side to this situation. Many hospital leaders are now reading and thinking about this argument. Several of the big hospital cooperatives in the United States, like the Voluntary Hospitals Association (VHA), have sent the *Health Affairs* paper out to all their hospitals

and are telling them to read this article. What the paper is doing is basically bringing up the rear of the class.

**Ross:** Jim, we all know that there are many good people, particularly young leaders, who face a dilemma when they work in an organization where quality and safety goals are not a priority. Do you tell these people to leave these organizations and go somewhere else?

**Jim:** This is a pretty common problem: the beautiful flower in a toxic waste dump. Or at least that's the feeling that a lot of people have in these situations.

I start by telling these people what *not* to do. I try to encourage people not to go down the victimhood road – the "if only" road. If only I had a chairman that supported this. If only I had a bigger budget. If only I had a better information system. Instead of taking a victimhood stance, I suggest they take a leadership stance: leaders take the situation they have and they start making something of it.

The second thing I would say is: learn really useful quality improvement skills. Invest in learning skills that will be useful to your organization and to your patients. Go out and learn something about flow management and reliability methods as applied to healthcare.

Then do this: take what you learned and harness your improvement work to existing organizational goals around efficiency and throughput. Look for results that get noticed by people that don't get it. By getting these results, you start to recruit others in your organization with social skills and courage. And you need to teach them.

The best way to spread the results is by telling stories. This is the last skill I would invest in and polish. Become a good storyteller. Collect stories about your results and tell them.

So you don't always have the authority to make things happen, but you do have the opportunity to get things started.

**Ross:** Jim, you have worked with IHI on many of the "pursuing perfection" organizations. What did they learn from being engaged in the relentless pursuit of perfection?

**Jim:** One of the things they've learned early on is that they vastly overestimated their improvement capabilities. There were seven organizations in the United States that were chosen from 237 applicants to participate in the [Robert Wood Johnson funded] Pursuing Perfection project. They were considered to be the exemplars of quality and safety. But both they and the evaluators who selected them overestimated their improvement capabilities. I think that's probably lesson one. In order to learn anything

you have to recognize what you don't know. So the first thing we learned was that these organizations, despite their accomplishments, still really did not know how to improve.

The second thing we learned was that these organizations thought they were getting a grant to do some improvement projects. What they didn't understand was that this grant was going to be the virus that would transform their organizations. This meant changing their entire organizational cultures. You couldn't accomplish what was required by implementing a few projects. So the leaders of these organizations had to ask themselves: "What does it mean if quality is our strategy and not just a nice thing to do professionally?" Learning how to make this transition was a big part of the overall learning.

A really interesting thing we learned was to frame quality aims, broad and wide around system-level measures –

measures like mortality rates, customer satisfaction and harm events per 1,000 patient days – not unit-specific or disease-specific measures, like the percentage of pneumonia patients that get the right antibiotic. That's a nice process-level measure, but you could get that done and a lot of other things could stay the same and you wouldn't have improved the system. You can't get to perfection by making islands of excellence or dabbling around in a few projects. You have to engage in a much deeper strategy.

**Ross:** Engaging leaders and creating a strategic focus on improving the quality of care are clear challenges for us all. Thank you, Jim, for sharing your insights and your wisdom with us tonight.

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