

Why A Checklist Will Not Be Saving Your Life

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In a decision only a government agency could love, the Office of Human Research Protection recently shut down a quality improvement project being conducted by the Johns Hopkins University on using a five step checklist to prevent hospital infections.

The story begins in 2001 when Peter Pronovost, a critical care specialist at Johns Hopkins Hospital, decided to try checklists for inserting lines in Intensive Care Unit (ICU) patients. Research from a decade ago had shown that patient care in ICUs required 178 individual actions per day, many of which must not only be performed but be done in the proper sequence. The same research showed that nurses and doctors made errors in only one percent of these actions, an amazingly low amount. The amount added up, though, to two errors a day per patient.¹ While nurses and doctors are undeniably highly trained professionals, they are also human beings who will occasionally forget where they left their keys, what day of the week it is, and whether they completed step 51 of an 178 step process.

The idea of using checklists even for tasks performed by highly skilled professionals is not new. After the plane that became known as the B-17 crashed due to pilot error while being flown by the chief of test flying for the US Army Air Corps, a group of pilots created a checklist for flying the plane. Following implementation of the list, B-17s were flown 1.8 million miles without a single accident.²

With this background, the idea of a checklist for ICU doctors and nurses seems less strange, even in the face of our now super-specialized healthcare professionals. Pronovost started with the list regarding line insertions, which contained five steps: wash hands with soap; clean the patient's skin with chlorhexidine antiseptic; put sterile drapes over the entire patient; wear a sterile mask, hat, gown, and gloves; and put a sterile dressing over the catheter site once the line is in. These seem like obvious steps to take, but during a review of physician practices for one month nurses found physicians skipped at least one step in more than 33 percent of patients.³

The next step was to get hospital administrators involved and clearly give nurses the authority to stop physicians if they saw them skipping a step on the checklist. After one year, the 10-day infection rate went from 11 percent to zero. After 15 months, only two line infections had occurred. In that one hospital, the checklist prevented 43 infections, eight deaths, and \$2 million in costs.⁴

¹ Atul Gawande, *The Checklist*, THE NEW YORKER, Dec. 10, 2007, available at: http://www.newyorker.com/reporting/2007/12/071210fa_fact_gawande?printabl=true (last accessed Jan. 3, 2008).

² *Id.*

³ *Id.*

⁴ *Id.*

Pronovost then began creating more checklists with the help of colleagues, focusing on pain management and mechanical ventilation. Again, the results were positive. The checklists not only helped with memory recall, they also ensured a minimum standard of delivery in complex processes.⁵

With this amazing success in mind, Pronovost began traveling to promote the checklists, speaking in an average of seven cities a month while still working full-time. Some people were insulted by the idea that they needed a checklist, while others questioned whether the results would be similar at hospitals with fewer resources than the renowned Johns Hopkins Hospital. In 2003, Pronovost was able to put his checklists to a more real-world test. The Michigan Health and Hospital Association asked him to try the original checklist in all Michigan ICUs. This was a huge project and would bring the checklist concept to hospitals throughout the state, including constantly under-funded and over-crowded ones in Detroit.⁶

The initial response from doctors and nurses was skeptical, but, after reviewing Michigan's average ICU infection rates, Blue Cross Blue Shield of Michigan offered bonus payments to hospitals for participating in the program and the project moved forward. Executives, who did not want to be involved initially, were included, which became important to ensuring all ICUs had sufficient supplies to comply with the steps of the checklist. The results, published in December 2006 in the *The New England Journal of Medicine*, showed just how effective the checklist was. Within three months, infection rates dropped by 66 percent. Within the first 18 months, the average Michigan ICU outperformed 90 percent of ICUs nationwide, saving \$175 million dollars and more than 1,500 lives. Something as silly as a five step checklist had amazing power.⁷

So, once again Pronovost hit the road to present his work and findings nationwide. Sadly, there was very little interest. Pronovost estimated that within two years and at a cost of \$2-3 million, the checklist program could be implemented nationwide, but it seems like very few are interested. It has been said that the problem may be that Pronovost's solution is in fact too cheap, with no high profits or vast markets to sell it to the big players in American health care – drug companies and investors – no one is interested in helping promote the program.⁸ How short-sighted, particularly given the cost savings Pronovost was able to realize.

As if this alone was not sad enough, it appears the Office of Human Research Protection (OHRP) read the same *New Yorker* article that brought the checklist findings to the public at large. The OHRP response was drastically different than what some may have anticipated. The OHRP shut the program down, citing the lack of written informed

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ Maggie Mahar, *Pilots Use Checklists, Doctors Don't. Why Not?*, Health Beat, Dec. 14, 2007, available at: <http://www.healthbeatblog.org/2007/12/pilots-use-chec.html> (last accessed Jan. 3, 2008).

consent from all providers and patients involved.⁹ The Office was unimpressed by the fact that the study was approved by two institutional review boards or that the information collected was not sensitive and was well protected. It also did not care that the checklist could have been implemented without consent if Pronovost had not tried to monitor the results.¹⁰

The purpose of obtaining informed consent for human research studies is to ensure that patients are aware of the risks and benefits of being involved in the study and have consented, as necessary, to use of highly sensitive information. In the checklist study, there were no risks to the patients since using the checklist had no side effects and in essence ensured they got the care they should have been getting anyway. It is also hard to justify the OHRP's decision based on the use of sensitive information, since what was being released was summarized information on the lack of line infections. A count of the number of line infections in Michigan ICUs is about as far as it is possible to get in healthcare studies from sensitive patient information. How many people would believe their doctors should ask their consent before using a piece of paper that reminds them to wash their hands and use sterile dressings? It is hard to see who is being protected from what, other than the general public from realizing exactly how common preventable line infections really are.

The checklists show exactly what the Institute of Medicine has been saying for years to be true – we have a large number of errors that could easily be prevented with a simple system/process change. Pronovost has shown that there is a really cheap way to do it and save lots of lives and money. It's brilliant; it's amazing; and not only is the healthcare industry not really interested, but the government office meant to help protect us all has killed it. It would be an hilarious story if only it was not true.

⁹ Atul Gawande, *A Lifesaving Checklist*, THE NEW YORK TIMES, Dec. 30, 2007, available at: http://www.nytimes.com/2007/12/30/opinion/30gawande.html?_r=1&oref=slogin (last accessed Jan. 4, 2008).

¹⁰ Roy M. Poses, *Why Was This Quality Improvement Research Project Shut Down?*, HEALTH CARE RENEWAL, Dec. 31, 2007, available at: <http://hcrenewal.blogspot.com/2007/12/why-was-this-quality-improvement.html> (last accessed Jan. 4, 2008).