From the Editor

The Elephant in Your Lobby

By Kenneth E. Spence

Does your Annual Risk Assessment capture your organization's biggest risk? The numbers associated with this risk are huge. The effect on the members of your community? Well, you cannot put numbers or words to it.

You are thinking, surely, something this significant has to show up in an annual risk assessment. Yet, the likelihood is that it is missed every year, and your senior management probably prefers it that way…year in, year out. Some things are just plain bad for business and should be kept on the QT.

To Err is Human is a study published in 1999—15 years ago, by the Institute of Medicine. The conclusion was shocking: an estimated 100,000 patients annually are dying in our nation's healthcare institutions from preventable medical errors.

This number had to be wrong, health leaders and others across the country thought. And they were right. The number was wrong—way wrong. The more accurate number is conceded to be in excess of 400,000 patients, as reconfirmed by a number of sources since, and in a 2013 *Journal of Patient Safety* article.[1]

People dying unnecessarily, one by one, in healthcare settings across the land tends not to make for newsworthy reporting. What is unsettling is that the daily numbers add up to about 1,100 people. People who do not need to die, but are doing so every day. Think about the entire population of a city the size of Miami or Cleveland being lost annually, or two 747-passenger planes crashing every day.

What is most disturbing is that the numbers have not changed in the 15 years since the report exposed the extent of the crisis. Plenty of effort and many millions of dollars have been spent to address this, but as a nation, we remain stuck at this number—right where we were.

The costs related to these preventable deaths are estimated at $1 trillion annually. Each year, healthcare expenditures in the US are around $3 trillion, so our foul-ups are a significant portion of the national healthcare budget.

"But, wait there's more!" as the guy on the TV infomercial says. An estimated 10,000 serious medical complications are occurring each day due to preventable errors. That's ten times the daily death rate due to errors.

One of our industry's fundamental tenets is 'do no harm,' which makes these numbers all the more stunning. However, they pale against the agony in the hearts of people when a loved one dies or is harmed because of an avoidable mistake.

Discussions surrounding these untoward events, when they occur, tend to be kept among a chosen few individuals. If you ask about these occurrences at your facility,

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[1] "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care," John James, PhD, *Journal of Patient Safety,* Sept. 2013 V.9 Issue 3, P122-128

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Time

These audits are time-consuming. It can take a great deal of time to complete the planning phase and understand the entity's 340B Program environment and patient definition. In addition, many potential issues are often identified during data analytics test work, and these issues might take time to research and understand.

Conclusion

Participation in the 340B Program can significantly affect the bottom line, saving a healthcare organization millions of dollars. As a result, program compliance is essential, and staying compliant requires the entity to navigate the inherent complexities and associated compliance risks of the program.

Often complicated and time-consuming, effective 340B Program compliance audits require you to understand the entity's specific patient definition and the systems and data elements used to deploy that definition. Audit planning is also important and data analytics testing adds substantial value by testing entire populations and identifying issues not easily found with sample testing. **NP**

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you may get a blank look coupled with assurances that *should* such a *rare* event occur, it would be immediately investigated by the most qualified senior people in the organization and fixed. No need to worry about that risk any more. It's fixed.

Oh, really? Then why are the numbers not changing? How is this being documented, tracked and reported? How have we become the notable exception to the national norm?

The higher up in an organization an executive sits, the more insulated he or she becomes from the specifics of how things work at lower echelons. Executives often lack the time to dig into the details to find root causes. More likely, the investigation is handed off to an assistant or small group to quietly scope out and report back. Are these the most skilled, experienced and objective persons to be doing this work?

Unfortunately, 15 years after the study was published, the numbers say the elephant is alive and well in your lobby. People are human and humans make mistakes. That is why we install preventative controls. However, when serious mistakes occur continually, the message is clear that there is something wrong with training, the design of the process, the system of controls, or possibly in the culture itself.

These tragic and worrisome problems happening seemingly unabated within our healthcare facilities, speak to the need for improved staff training, improved processes and improved systems of control. All these issues sit squarely in the bailiwick of internal audit.

Adverse events are complicated with many causal factors. Internal auditors are well trained in the art of investigation, assessment and evaluation, and in applying knowledge of internal control theory and practice. There is no risk that is more important, or calls more loudly for the skills of internal audit.

Beginning with the next issue of *New Perspectives*, we will feature a column on patient clinical quality and safety written by an industry pro. We will also be featuring a new column written by another recognized professional on IT Health, one component of which will include data integrity—an important aspect to support quality of care and safety. Further, during 2015 and beyond, *New Perspectives* will be bringing you articles that address clinical quality and audit management.

Our authors and columnists offer you the benefits of their expertise and experience to enhance your knowledge, and thereby your opportunities to improve training, process design, the controls systems, or the culture itself.

Sally Cutler ends eight years as our report writing columnist with this issue. We wish her well in retirement. Thanks, Sally, for making us all better writers.

May you enjoy your holiday time with family and friends. Best wishes for a prosperous and value-laden New Year. **NP**