

Patient Safety & Trigger Tools

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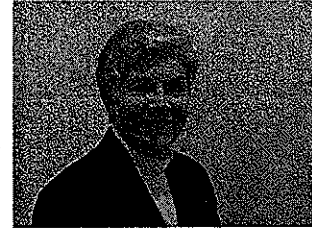
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Trigger Tools: A Risk Management Perspective

Mention the phrase "trigger tools" to a healthcare quality professional and what pops into her head? Perhaps it is forms, algorithms, and processes that are used to pinpoint medication or surgical adverse events. Ask a risk management professional to explain what is meant by trigger tools and he may describe a form or document to pinpoint actual or potential compensatory events stemming from adverse drug events, elopements from behavioral health units, or return rates to the operating room. Ask a CFO the same question and the response may relate to outstanding claims payments that have exceeded a sixty-day aging factor on accounts receivable. Ask someone who performs mock RAC audits, and the response may involve certain high-price, high-volume orthopedic or cardiac procedures for which there are missing inpatient data. Which of these descriptions is correct?

The answer may be that they are all correct. The term "trigger tools" has many different meanings in the healthcare field. Although contemporary use of the phrase "trigger tools" is often associated with the work of the Institute of Healthcare Improvement (IHI), the term actually covers a variety of warnings or alerts that are designed to cause healthcare professionals to stop and assess a situation with a view to avoiding patient harm. Similarly, well-designed trigger tools can be used by healthcare organization leaders and governance to avoid serious financial problems for their facilities.

From a risk management standpoint, trigger tools are a two-sided coin. When designed and used effectively, trigger tools can be utilized to address concurrent and prospective risk exposure. However, when utilized ineffectively, trigger tools may be the source of legal, regulatory, accreditation, and financial risk exposure. For risk management professionals, the time is ripe to take a role in shaping the

design and use of trigger tools to foster enterprise risk management initiatives in their healthcare organizations.

The Range of Trigger Tools.

All trigger tools have one thing in common: an alert that is designed to prompt critical thinking and timely, appropriate action. Trigger tools can be electronic signals, such as flashing screens on a computer monitor, auditory bells or a vibrating paging device attached to a physician's white coat. Trigger tools can be alarms that sound due to the actions of an individual. For example, a pressure sensor pad alarm may be triggered when an elderly resident gets up suddenly from his bed.

Trigger tools are often built into the systems used throughout the healthcare field: "smart" pumps, cardiac monitoring devices, neonatal and adult apnea monitors, and anesthesia equipment. The software programmed into such devices detects changes that set off the alarm, often an audible sound, or a flashing indicator.

Trigger tools can be hard copy documents that data abstracters use to pinpoint anomalous findings. Sometimes based on clinical codes, the hard copy tools may also use language recognition to pick up phrases and terms often associated with adverse events.¹

In broad terms, there are several categories of trigger tools. One category involves *concurrent clinical risk alerts*, such as abnormal lab values or indications that a troubled patient is making an elopement attempt through the door of a locked unit. Such real time or concurrent trigger tools are what has been described as active surveillance. It requires use of data just before or at the time of an adverse event to manage a risk or intervene to prevent harm.² It can also be low-tech, with a team using tools and observation triggers on a concurrent basis.³

The healthcare area has longstanding experience with the concurrent risk trigger tool. Alarm systems embedded into smart pumps and patient-generated call bells are two examples mentioned. With concurrent triggers, the focus may be on "at risk" or "high risk" patients. Such "at risk" individuals include long term care residents transferred to hospitals with congestive heart failure who are "at risk" for pressure sores, and post-surgical patients with a high risk of a constellation of complications.

Another type of trigger tool takes effect *subsequent to* an adverse drug event (ADE) or other types of adverse events (AE). The IHI Surgical Trigger Tool is illustrative of this category.⁴ It relies upon a list of items that point to possible surgical adverse events (SAEs). A positive trigger signals the need to delve more deeply into the patient's surgical record and other information to determine if an SAE took place during the operation.⁵

In quality-based patient safety work it is believed that much can be learned after an event has taken place. Emphasized is the need to learn from SAEs, ADEs, and AEs to change systems and processes. Indeed much of the scholarly research involving trigger tools has taken this approach.⁶ Electronic systems and manual tools, or a combination thereof, are deployed for this type of post-event trigger tool work. Such endeavors require well-developed algorithms and techniques applied consistently. Taking such an approach, post-event triggers can detect systemic process failures, human factors, and the like that are causes of, or contributing factors to, adverse events.

Yet another category is what might be described as the *predictive trigger model*. For example, based on clinical data, the predictive model offers "warnings" or triggers that alert care providers to drug-drug interactions, food-drug interactions, drug underdosing and overdosing of pediatric patients in a certain weights range.

Predictive triggers need not be high-tech. A good example can be found in the work of the Malignant Hyperthermia Association that for a long time has encouraged the use of a series of simple questions to identify those at-risk for malignant hyperthermia or MH.⁷ The questions are posed to the patient and ideally a blood relative who is a generation older than the person who is scheduled for surgery. The questions include:

- Have you or anyone in your family ever had a problem with anesthesia?
- Have you or anyone in your family ever become ill from anesthesia and required hospitalization?
- Have you or anyone in your family every come close to dying from anesthesia?
- Do you recall if anyone in your family died as a result of anesthesia?

The questions asked of both the patient and the older relative. The answers provide a multi-generational perspective. If a positive answer is received "yes" or "I think so," the trigger alerts the anesthesia provider not to use the set of anesthetics known to provoke onset of MH. That the trigger has been activated

does not mean that there would be an intra-operative or post-operative MH episode. Rather, it is a warning that this is a patient from a family with an "at risk" history. Avoiding the known agents that cause MH can help avert untoward consequences. It also helps to heighten awareness among the surgical and post-operative care teams about a serious clinical risk exposure.

In today's world, with clinical and genetic testing for MH, predictive accuracy can be increased. However, it can be costly. The low-cost, low-tech, high-gain, communication process of a few simple questions demonstrates that predictive model triggers can and do work in clinical healthcare. Indeed, the screening questions help to identify those individuals who are candidates for further clinical or genetic pre-operative testing.⁸

Is one category of trigger tools better than the other? Not really. Indeed, a strong argument can be made for the importance of deploying all categories of clinical trigger tools.

The Potential Risk Management Benefits of Trigger Tools.

The trigger tool concept can be used in the enterprise risk management context to help senior leadership with fashioning financial alerts to address the undulating pattern of patient census, high-price service utilization, and uncertain reimbursement factors. Because enterprise risk management includes clinical risk and patient safety, there are many benefits to consider with broad trigger tool programs. Some may have an impact on patient care delivery whereas other outcomes could result in cost savings or measurable return on investment (ROI). A hypothetical case involving the costs associated with missing a "present on admission" or POA diagnosis reinforces this point.

An 83 year-old man was transported to an acute care facility from a nursing facility. The man had been a construction worker until he retired at age 71 when he injured his right knee. He had a history of two myocardial infarctions, three coronary stents, and late onset diabetes. He had been experiencing what a nurse described as a dry cough for several days when she asked the nursing facility physician to check in on him. The physician decided that the gentlemen needed to be transported to the hospital. "I think he has congestive heart failure and they need to help him get rid of the excess fluid," the doctor was purported to have told the man's daughter.

At the hospital emergency department, the intake nurse and the emergency room physician completed a thorough patient assessment that included use of what they described as a "POA Tool." In essence, it was a clinical checklist to prompt evaluations of geriatric patients for medical triggers that warrant further evaluation that were present at the time of admission. The tool included CHF, UTI, pressure sores and pressure areas, pneumonia, and suspected myocardial infarction.

The nurse was the first to speak up after the evaluation. "In my nursing judgment this is not CHF. I listened to his breathing and I think he has pneumonia," she said. The emergency physician replied, "I think you are correct. Also, I think he needs to be monitored carefully for the pressure area on his right elbow."

The emergency department nurse and physician followed protocol and documented their findings. They also explained why they ruled out the suggestion in the clinical transport document of CHF.

The elderly gentleman underwent diagnostic imaging that confirmed pneumonia. Under the care of the medical unit hospitalist team, the patient received appropriate treatment. The hospitalist team confirmed the "rule out" of CHF and they had a consultation from a wound care nurse regarding the pressure area on the patient's right elbow.

At the time of discharge, the patient was pneumonia free, and the area of concern on the right elbow was resolved. Clinically appropriate discharge instructions were provided for continuing care at the nursing facility.

The intake trigger tool that is designed to facilitate prompt, effective diagnosis of patients with risk-prone ailments can expedite prompt, clinically prudent treatment. The right clinical trigger tool can reduce time-consuming and medically unnecessary tests and treatments, too. Such real-time or concurrent clinical tools do not eliminate medical judgment; rather, it assists clinicians in their decision-making process.

Some may argue that care providers do not need such diagnostic trigger tools. Others will admit that these decision-support or memory jogger technologies help care providers avoid errors in judgment or diagnosis.

Further, the clinical application of a trigger tool reinforces the idea of patient safety as an enterprise risk management process. When care providers “miss” a diagnosis or misdiagnose a patient’s condition there can be consequences that go far beyond medical malpractice litigation. A missed “Present on Admission” diagnosis translates into diminished reimbursement under the MS-DRGs. That care providers have a pattern of “missing” clinical diagnoses resulting in delays in care or delivery of medically unnecessary or inappropriate treatment may become the context for FPPE or corrective action activities. Should word spread that the acute care facility has an affinity for missed or inaccurate diagnosis, it can tarnish the reputation of the hospital. Complaints may be registered with the state agency or CMS that result in regulatory scrutiny. The upshot may be diminished market share and loss of community support. Taken together, the lack of attention to clinical delivery can impact the entire enterprise.

Trigger tools can be used by healthcare organizations for other purposes. For example, enterprise risk management trigger tools can prove very useful for hospitals and ambulatory surgery centers that are planning to build new physical plants or renovate existing facilities. Looking at the domains of risk – human capital, operations, hazards, legal-regulatory matters, technology and equipment, financial matters and reputation – the ERM trigger tool can be used as an alert system. Financial overrun projections coupled with equipment delays detected in using the ERM construction trigger tool would warrant an evaluation of the impact of these findings in the other domains of risk. The results may signal important decision-making requirements, including adjustments to the timeframe for hiring new associates to staff the facility, receiving other equipment to install in the building, and disruptions in the operations of the enterprise.

As with clinical trigger tools, the business side of healthcare can benefit from the use of well-designed approaches to risk identification, mitigation and resolution. The result can be quality safe, patient care, job satisfaction, staff retention, and strong market share. Thus, there are many benefits to trigger tool methodology that go far beyond clinical matters.

The Potential Risks in Clinical Trigger Tools Utilization.

Just as trigger tools offer great benefits to the healthcare field, it should be recognized that there are risk factors that merit serious attention. The downside of trigger tools involves legal and regulatory exposure, professional discipline and licensure action.

Much has been written about alarm fatigue and staff becoming desensitized to the alarm systems that go off in the course of a day.⁹ Although some are false alarms, others are not.

The failure to respond in a timely manner to an audible alarm can result in a delay in care. The result can be permanent injury or death.¹⁰

In other instances, care providers intentionally disable alarms put in place to warn that someone has gained unauthorized egress through a locked door. Such "triggers" are put in place as a part of security safety net to thwart patient or resident elopement. It is of little use if staff members disable the alarm device in order to sneak outside to make personal cell phone calls or to smoke cigarettes. That they fail to activate the alarm system upon their return compounds the situation, particularly when a patient elopes through that door.

When the standard of care calls for use of a clinical alarm, it is anticipated that staff will use the equipment to monitor patient status. If personnel do not know how to apply alarms, or the equipment does not work properly, one would expect clinical staff to seek assistance to rectify the situation. Policy and procedure as well as good clinical judgment should support such a process. However, when clinical personnel fail to follow recognized practices and harm results, one can anticipate litigation.¹¹

Sometimes legal action will follow from healthcare professionals ignoring data from trigger tools incorporated in clinical devices. They may be dismissive of the information, relying instead on their own judgment and suggest that there is something "wrong" with the data. Healthcare professionals seeking to learn from aircraft safety investigations have borrowed the term "spatial disorientation" to describe this phenomenon of providers ignoring correct instruments due to an inability to recognize erroneous provider assumptions.

Perhaps the worst-case scenario involves a healthcare professional turning off the trigger tools. "The device is not working properly," "We do not have the correct size leads for this patient," or "there has got to be something wrong with the device because the alarm keeps going off every few minutes." Rather than resolving the "problem" with the trigger tool device, a work around or "judgment call" is made to ignore the warning.¹²

The issue with ignoring trigger alarms is not restricted to clinical personnel at the bedside of the patient in a hospital setting. As was seen in a reported New Jersey

case,¹³ a community pharmacist chose to override the trigger warning set off when he dispensed medication to an older patient. The clinical algorithm in the pharmacy software detected the anomaly and automatically, the computer display provided the alarm or trigger. The software, however, permitted a manual override. The pharmacist ignored the trigger warning. The patient received the wrong dosing schedule of the medication. The compliant patient followed the written instructions on the label, actions that led to an adverse outcome and irreparable injury.¹⁴

Later on, during a deposition in the case, the pharmacist admitted that he was not familiar with the proper way in which to dispense the medication. Yet he overrode the trigger warning.¹⁵ Not only could such a case culminate in successful litigation by the plaintiff, it may also be the basis for professional licensure action for unprofessional conduct.

Trigger tools are only as good as the healthcare professionals who respond to audible or visual alarms, decisional support systems, and alerts on computer displays. If care providers delay in responding, ignore or override information, or worst yet, turn off the trigger alarms, the very process that could save a patient's life can become the key piece of evidence in the plaintiff's case for proving health care professional liability.

Trigger tool clinical liability risk exposure extends to healthcare organizations and physician practices, too. If a nursing facility knows that staff members are disabling security door alarms in order to "grab a smoke" and fail to take corrective action, it sends a clear message that it is "okay" to engage in such behaviors. Enabling non-adherence resulting in foreseeable injury or death is powerful evidence in the hands of litigants. If hospitals know that clinical personnel regularly ignore telemetry alarms because the devices send "false signals," not taking action to repair equipment or to reinforce compliant practices is useful evidence in negligence actions.

Medical group practices are just as vulnerable. If they know that patients wearing cardiac monitoring devices are sending dialed-in data indicative of serious electrophysiology anomalies, the failure to respond to the warnings and inform patients of the need for prompt intervention could be the context for litigation. This is especially true if the patient "throws" a serious episode and cannot get to a hospital in a timely manner. It is no excuse that the cardiac devices were not "monitored" for a brief period of time on a holiday weekend.

Trigger tool algorithms and alarm systems do not replace the need for sound clinical judgment. The “wake up” call bears evaluation, a determination, and clear action. If the action step is to take a different approach, the care provider should indicate what pathway will be followed and why. If the action step is to act on this data and modify the care plan, so be it. When used properly, clinical trigger tools are sentinels in the patient safety net and part of the constellation of measures found in risk elimination, prevention, reduction, and minimization.

Business Risks with Improperly Used Trigger Tools.

Healthcare organization management and governance must use wisely the precious resources at their disposal. As the stewards of the organization, they are accountable for prudent use of the facility's funding, equipment, and service capacity. The governing body has a fiduciary responsibility for making difficult choices, whether it is to open a new service line, to build a new patient tower, or to close down the Alzheimer's Unit in a skilled nursing facility because it is too expensive to sustain operation of the program.

Trigger tools on the business side of healthcare are as good as the management team and governing body that use the output to guide the organization. The data comes from a variety of business analytical triggers: FMEAs, gap analysis, heat maps, internal and external market scans, financial projections, patient census, resource utilization, operating costs, and more. But if the management team or the governing board do not act promptly, effectively, and decisively based on the trigger tool data, like their clinical counterparts, there can be serious risk exposure. Termination of the leadership team is one potential consequence. Breach of fiduciary trust is another for the governing body. And for the facility, the need to shutter the doors for lack of sufficient funding to sustain operations is possible.

As the healthcare field moves slowly into the world of Accountable Care Organizations or ACOs, there will be more of an imperative for solid business risk trigger tools. Aligning physician groups with hospitals while trying to deliver quality care and share savings will be a tall order, especially if as stand-alone entities there is ineffective utilization of the business trigger tools already available or in operation.

Risk Management Strategies for Trigger Tool Development and Use.

Trigger tools no longer reside in the domain of experts in healthcare informatics. Instead, trigger tools can be found embedded in clinical devices, decision support software, clinical practice pathways, and in the business analytics of the healthcare field. The failure to harness the power of trigger tools – clinical and business alike – remains a challenge for the healthcare field. It will take work to transform the situation from one of non-adherence, alarm fatigue, and burdensomeness into widespread acceptance and use. Along the way, in developing and using trigger tools, the liability risk exposures should not be ignored. Instead, one must guard against the untoward aspects of trigger tools. Risk management strategies to consider for this purpose include the following:

- 1. Set as a Goal Simple, Elegant, and Widespread Acceptance.**

Take a positive approach, designing practical, useful, trigger tools that are easy to utilize. Consider the range of trigger tool options, from low-tech abstracting to sophisticated approaches involving electronic record abstraction and natural language analysis.¹⁶ Recognize that the tools developed or adopted must fit the needs of the organization or medical practice. Think about concurrent, retrospective, and predictive trigger tools that will produce desired results.

- 2. Enlist the Help of the End-User Experts.**

Look to the content experts in the healthcare organization for their input on data capture, information utilization, and methodologies that are most appropriate for the organization. Recognize that content experts for concurrent tools may have recommendations that are quite different from those working on SAE, AE, or ADE trigger tools. Listen to the input of clinical personnel who must work with telemetry systems and other clinical devices. Ask them about system design, ergonomics, background noise with audible triggers, and what will work best in the environment of care. Make certain that the tools reflect the needs of the end-users.

- 3. Establish the Critical Success Factors for the Trigger Tools.**

Identify the measurable output requirements for selected trigger tools. Note that the critical success factors for concurrent tools will be different from those used in evaluating retrospective triggers. Understand that the same will be true for enterprise risk business analytic trigger tool output.

4. Emphasize: This is a Tool, Not a Replacement for Critical Thinking.

Stress the importance of using triggers as a tool to facilitate patient care and prudent business decision-making. Reinforce throughout the healthcare organization that trigger tools are not a substitute for clinicians and leaders exercise prudent judgment, critical thinking and good situational analysis.

5. Pilot Testing is Essential.

Utilize test modeling for all trigger tools. Work with device and software manufacturers to make certain that embedded triggers or alarms are set to the appropriate thresholds for the patient population and the environment of care. Have personnel test the alarm technology to make certain it is acceptable. Insist on adjustments that are supportive of patient safety. Understand that the same is prudent for business analytic trigger tools.

6. Educate! Educate! Educate!

Provide end users with the education needed to use trigger tool technology successfully. Do not ignore the needs of governance and leadership in educational programming on ERM trigger tools. Involve the medical staff in using trigger tools as part of the delivery of quality, safe and efficient patient care.

7. Monitor and Improve Trigger Tools.

Recognize that the data results from trigger tools may point to the need for revisions in education, tool design, or data analysis methodologies. Encourage improvements, taking into consideration developments in trigger tool technology across the globe for patient safety and quality improvement. Promote similar monitoring and improvement activities with respect to the ERM trigger tools used in governance, strategic planning, and financial management of the organization.

8. Documentation of Variance is Essential.

Emphasize the importance of recording clinical determinations that are different from predictive modeling trigger tool results. Document too, when it is necessary to disable the use of trigger tools built into technology, such as the detection of software anomalies, upgrades that require downtime review, etc. Explain the rationale for the variance and what steps were taken to support continuity of patient care. Consider similar approaches for rejecting trigger tool analytic outputs involving strategic decisions of the governing body and senior leadership. Recognize that the data may

encourage actions that are incongruent with laws, regulations, or anticipated external factors not well elucidated in the trigger tool models.

Conclusion.

Trigger tools reflect a range of hardware, software and even hardcopy documentation. Trigger tools warn healthcare leaders and providers to “check” or to make certain that a patient's clinical status may be problematic or could become so based on intended medications or treatment interventions. Trigger tools are audible or visual alarms that shout “warning” something *is wrong now!*

On the business side of healthcare, trigger tools offer the prospect of highly sensitive, analytical information that can be used by leadership and governance to make prudent choices for the healthcare enterprise.

However, trigger tools can become daggers rather than shields protecting patient safety. When used improperly or ignored the trigger tools can speak for themselves, telling clinical providers and leaders, “We told you so. We said this could happen.” The data from improper or substandard use of trigger tools can become the stuff of litigation and regulatory action.

With proper design and use, trigger tools can become a key piece in the fabric of the patient safety net. On the business side, such tools can help management and governance steer clear of financial challenges. The time is right to develop and use trigger tools as key ingredients in a holistic approach to enterprise risk management.

*If you would like assistance with developing a risk management approach to trigger tools,
please contact us at (860) 242-1302.*

¹ M.N. Cantor, H.J. Feldman, and M.M. Triola, "Using Trigger Phrases to Detect Adverse Drug Reactions in Ambulatory Care Notes," *QUAL SAF HEALTH CARE* 2007; 16: 132-134.

² M.K. Szekendi, C. Sullivan, A. Boob, J. Feinglass, D. Rooney C. Barnard, and G.A. Noskin, "Active Surveillance Using Electronic Triggers to Detect Adverse Events in Hospitalized Patients," *QUAL SAF HEALTH CARE* 2006; 15: 184-190.

³ R. Ursprung, J.E. Gray, W.H. Edwards, J.D. Horbar, J. Nickerson, P. Plesk, P. H. Shiono, G.K. Suresh, and D.A. Goldmann, "Real Time Patient Safety Audits: Improving Safety Every Day." *QUAL SAF HEALTH CARE* 2005; 14: 284-289.

⁴ See, F.A. Griffin and D.C. Classen, "Detection of Adverse Events in Surgical Patients Using the Trigger Tool Approach." *QUAL SAF HEALTH CARE* 2008; 17: 253-258.

⁵ *Id.*

⁶ See, e.g., M.N. Cantor, H.J. Feldman, *supra* note 1; M.K. Szekendi, C. Sullivan, *supra* note 2, F.A. Griffin and D.C. Classen, *supra* note 3. See also, M. Govindan, A.D. Van Citters, E.C. Nelson, J. Kelly-Cummings, and G. Suresh, "Automated Detection of Harm in Healthcare with Information Technology: A Systemic Review," *QUAL SAF HEALTH CARE* 2010; 19:e 11, and F. A. Griffin and R.K. Resar, "IHI Global Trigger Tool for Measuring Adverse Events," Second Edition, 2009.

⁷ See, www.MHAUS.org.

⁸ See, "MH Testing: What You Need to Know,:" accessed at: http://medical.mhaus.org/PubData/PDFs/dx_testing_options.pdf

⁹ Such matters have been the subject matter of newspaper accounts. See, for example, J. Ashton, "Alarm Fatigue' Blamed in Hospital Deaths," *Boston Globe*, February 19, 2011; L. Kowalczyk, "For Nurses, It's a Constant Dash to Respond to Alarms," *Boston Globe*, February 13, 2011 and L. Kowalczyk, "No Easy Solutions for Alarm Fatigue," *Boston Globe*, February 14, 2011.

¹⁰ *D. v. M.H.*, 408 S.E.2d 473 (Ga.App. 1991). See also, *F.J.W. v LPMC* 927 So. 2d 368; (La.Ct. App. 2005) (interlocutory appeal involving standard of care and bed alarms.)

¹¹ *D. v. M.H.*,

¹² For a thoughtful analysis on many of these issues, See, "Alarm Interventions During Medical Telemetry Monitoring: A Failure Mode and Effect Analysis," *Pennsylvania Patient Safety Authority*, March 2008, accessed at: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/mar5\(suppl_rev\)/Pages/mar5\(supplrev\).aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/mar5(suppl_rev)/Pages/mar5(supplrev).aspx).

¹³ *H. v. W-M S. Inc.*, 2009 U.S. N.J. Dist. LEXIS 113867 (December 7, 2009). See Also, F.A. Rozovsky, "The Danger of Ignoring Electronic Warning Communications." *Dialogues in Healthcare*, Vol 4., No. 8, 2010.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ H.J. Murff, F. FitzHenry, M. E. Matheny, N. Gentry, K.L. Kotter, K. Crimin, R. S. Dittus, A.K. Rosen, P. L. Elkin, S. H. Brown, and T. Speroff, and S. H. Brown, "Automated Identification of Postoperative Complications Within an Electronic Medical Record Using Natural Language Processing," *JAMA*, Vol 306, No. 8 848-855, August, 24/31, 2011.