Use of Operations Research / Systems Science for Meeting the Challenge of Enhancing and Measuring Safety in individual Practices

An Interactive Workshop

Ranjit Singh, MB BChir, MA (Cantab) MBA, Associate Director, Patient Safety Research Center, Dept. of Family Medicine, SUNY at Buffalo. Clinical Center Room 155, 462 Grider Street, Buffalo, NY 14215

Ashok Singh MB BChir, MA (Cantab), Partner, Niagara Family Medicine Associates, Niagara Falls, NY.

Gurdev Singh MScEng PhD (Birm), Director, Patient Safety Research Center, Dept. of Family Medicine, SUNY at Buffalo. Buffalo, NY.

Overview

In this session, we will use PowerPoint presentations and exercises to cover the following:

2. Proposed approach based on the established methodology of Failure Modes and Effects Analysis (FMEA) which functions as a structured reflective process for safety improvement.
3. Experience with the methodology so far.

Participants will experience the adapted FMEA methodology by completing an abbreviated survey instrument, conducting an analysis, reviewing results, and proposing solutions to identified problems.

Upon completion of this interactive seminar, the participant should be able to:

1. Understand the need to treat each clinic as a unique complex adaptive system
2. Exploit the organizational safety memory of her/his clinic(s) by eliciting all the team members’ perceptions of error frequency and severity
3. Create self-empowered teams to identify, prioritize, and address the unique system vulnerabilities of each clinic

The attached document is intended to complement the materials that will be presented. It briefly outlines the background and rationale for the proposed FMEA approach.
Use of Operations Research / Systems Science for Meeting the Challenge of Enhancing and Measuring Safety in individual Practices

Background

The US Institute of Medicine\(^1\) sought a 50% reduction in errors during the period 2000 to 2005. Many important steps have been taken toward improved safety, but progress has been slow and far short of expectations\(^2,3\). The health-care industry has continued to lag behind the major safety developments that have taken place in other high-risk industries such as aviation, defense, nuclear, and chemical industries. Fragmentation, decentralization and the lack of a safety culture in health-care are among the major causes of this lag. In addition, health-care systems are highly complex, involving multiple diverse entities with sophisticated and unpredictable interactions that make them much more difficult to study.

Primary care physicians, who provide the vast majority of medical care, are struggling to provide the quality of care that they are trained to provide. They are working harder under the pressures of increasing overheads, competing demands, and decreasing rewards in an unpredictable environment (especially related to payers and malpractice) that causes instabilities\(^4\).

One of the most important challenges faced in trying to improve patient safety, in any setting, is that of identifying and prioritizing safety problems so that scarce resources can be directed most effectively.

Current strategies for identifying safety problems

Current strategies for identifying safety problems in health care are mostly based on error reports, and internal and external audits. The most common method is the use of voluntary error reporting systems (or ‘incident reports’). These reports can provide rich information but it is widely accepted that under-reporting is and will remain a norm due to fear of punishment. According to the IOM\(^1\) only 5% of known errors are typically reported. Reporting systems can also be abused; for example, reports are sometimes filed and counter-filed as a means of retaliation against colleagues. A shift toward a culture of safety that replaces the current culture of blame and punishment has the potential to improve the use of error reporting systems.

External audits are frequently conducted by 3\(^{rd}\) party payers in an attempt to identify potential quality problems and provide feedback to practices so that problems can be addressed. In the context of outpatient care these are often referred to as Practice Profiles. Evidence suggests that the majority of physicians are not influenced by Practice Profiles\(^5\). These profiles (based on clinical outcome measures, processes of care, patients’ perceptions of quality of care and resource utilization) often do not help their practices to identify needs for improvements or to devise interventions. The ‘Quality Gurus’ in other industries have argued that these kinds of measurement devices can be destructive and nonproductive and that they disregard variations in
processes and systems, and cause cynicism and poor morale in a culture that becomes divided into winners and losers.

Internal audits are also commonly conducted in an attempt to provide objective measures of performance. However most such audits yield only a limited view because they rely only on what is documented (e.g., in the medical record) and focus on very limited areas (e.g., a specific disease). One of their strengths is that they can be internally driven and provide practice-specific information that can be seen as more credible than that provided by external bodies.

An additional problem that is common to all the above strategies for identifying safety problems is that they tend to be driven by external regulatory forces (even internal audits are often done to meet external requirements). Such approaches typically produce less complete and less rich information than those designed primarily for internal learning and system improvement.

In light of the above, alternative approaches to safety improvement in primary care are needed.

This document presents an approach to safety improvement in ambulatory primary care settings based on the Systems Approach borrowed from the fields of management, safety science, and engineering. The methodology is based on the proactive approach of Failure Modes and Effects Analysis (FMEA) and is designed to empower the team members within a practice to identify quality/safety problems and prioritize them so that they can proceed to devise and implement feasible solutions. The process is practice-driven and encourages all workers and patients within the practice to work as a team, advancing toward quality and safety improvement.

**Devising an alternative strategy - Two Important Needs**

In devising methods for safety measurement and improvement, we suggest that the two most important needs that should be recognized and catered for are:

**Need 1. Creation of a Culture of Safety**

According to the UK Health and Safety Commission: The safety culture of an organization is “the product of individual and group values, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety programmes.” The Commission further states that “Organisations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures.”

Of the various strategies for continuing improvement in patient safety, creation of a culture of safety is widely accepted as the most effective and sustainable. In our view the important contributors to a culture of safety are:
a) Adoption of a systems approach that addresses fragmentation and decentralization and helps in capturing and understanding the complexities of the system;
b) Leadership that makes safety a priority and everyone’s responsibility, develops procedures for identifying and dealing with unsafe practices, and provides resources for error analysis and system redesign;
c) Creation of nonhierarchical teams built on mutual respect, trust, collaboration, cooperation and clear delegation;
d) Adopting a proactive/preventative approach by using prospective tools of systems analysis and exploiting technology (e.g. computer-based order entry and decision support systems);
e) Designing for recovery by making errors visible and detectable, making it hard to carry out irreversible actions/processes, making it easy to reverse inadvertent actions, and building barriers and redundancies;
f) Providing accurate and timely information (e.g. by exploiting relational databases and decision support systems);
g) Creating a learning environment in which error reporting (preferably voluntary) is non-punitive, confidential and accessible to all staff and patients with no restrictions on acceptable description; and
h) Creating awareness among the staff of the value of quality, which leads to improvement in patient and staff satisfaction that in turn energizes the empowered workers to maintain and continually improve quality, leading ultimately to increased profitability. This can be best described as a humanistic approach to safety management.

The Taylor system of separating planning from execution (proposed by Frederick Taylor in his 1911 book “The Principles of Scientific Management”) was based on the premise that workers lacked the education needed to participate effectively in the planning process. This approach is best described as a mechanistic approach to management. The humanistic empowerment concept, on the other hand, is compatible with most cultures and world trends in human relations. Self-organizing/supervising worker-teams are destined to become the dominant successor to ‘Taylorism’.

Need 2. Acknowledgment, Respect, and Treatment of Each Practice as a Unique Micro-system.

Ambulatory practices are complex organizations serving specific patient populations in specific office settings/environments with specific human and non-human resources. The paradigm of Complex Adaptive Systems (CAS) can be very helpful in understanding such organizations. Individual practices are seen as micro-systems within the healthcare macro-system. To survive and thrive, they have to be adaptive. Unlike a mechanical/electrical system, the various components of a health care system (mainly humans) are highly unpredictable in their behavior and their interactions. Health care systems respond to highly variable and uncertain external stimuli in a variety of unpredictable ways.
Each practice needs to be assessed and treated individually so as to inculcate and take advantage of the site-specific “strange attractors” of trust, mutual respect and collaboration between all the agents in the micro-system. The “strange attractors” in a CAS are the forces that produce, over time, order (pattern/predictability) in disorder (chaos/unpredictability). Thriving adaptive systems are endowed with simple rules, shared vision, and opportunities for innovation. Identification of problems, design of solutions, and their implementation must acknowledge the unique configurations of each practice as well as the ongoing and changing super-sensitive and nonlinear relationships between the entities (agents) inside and outside the practice. This means that ‘off-the-shelf’ solutions, particularly those based on national or international generalizations, are less likely to work\textsuperscript{15}. The main value of generalizations is in their ability to draw attention to issues. When it comes to improving quality of care in individual practices, we need to identify the unique problems of each practice and devise solutions that are tailored to the situation, in light of the current quality status, practice costs and the resources available.

Figure 1 illustrates the authors’ perception of the relationship between the currently used mechanistic approach and the humanistic approach proposed here.

The challenge is to identify the sources of safety problems in practices and prioritize them so that we can begin to place attention where it is most likely to yield improvements in safety.

**Proposed strategy**

Our goal was to develop a transferable systems methodology for tailoring a sustainable culture of safety, acknowledging the uniqueness of each practice, and endowing it with the relevant characteristics of a safety culture (listed a to h above).

The methodology aims to incorporate change management strategies through a motivated guiding coalition of all the practice staff with a clear shared vision. Empowerment, ownership, good team formation (which inculcate mutual respect, trust, understanding, collaboration, cooperation and work satisfaction) are sought to be the driving “strange attractors” of a learning, self-directed, adaptive and evolving organization\textsuperscript{16}. This approach should avoid ‘Taylorism’ that still tends to raise its unacceptable head in the context of health care quality management.

An established approach that is prospective and permits involvement of all team members to identify and prioritize safety and quality problems is Failure Modes and Effects Analysis (FMEA). This has been widely used in other high-risk industries and has been advocated by the IOM and National Academy of Engineers in their recent joint report\textsuperscript{17} as a means of analyzing a system to identify its weaknesses (‘Failure Modes’) and possible consequences of failure (‘Effects’), and to prioritize areas for improvement. The US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has required since 2002 that all accredited hospitals perform at least one prospective risk assessment each year following a series of steps that are based on FMEA\textsuperscript{18,19,20}. FMEA is a labor-intensive process that comes in several varieties but essentially involves the following parts:
a. Choose a specific process to study  
b. Assemble a team to conduct the analysis  
c. Identify the steps in the process  
d. Identify all the possible Failure Modes at each step  
e. Estimate the frequency and consequences (Effects) of each Failure Mode  
f. Prioritize areas for improvement  
g. Design interventions and/or system changes to address the highest priority areas  
h. Implement and measure the effects of the interventions

The process (as experienced in the health industry) is time-consuming, costly, and requires considerable expertise and experience to perform effectively. FMEA is being performed in hospital settings, where trained quality improvement personnel are likely to be available and where leadership is mandated by JCAHO to provide the necessary resources for this type of activity. The authors could find no reports in the literature of FMEA used in ambulatory settings, where typically these factors are not present. A further problem of the traditional FMEA approach is that it focuses on a very specific process (for example, the medication prescribing process) and therefore has potential only to improve a small part of the system. Small practices cannot afford to limit their quality improvement efforts to a narrow area at the exclusion of other potentially fruitful ones. In an attempt to overcome some of these practical barriers while maintaining the essential thrust of FMEA, we present here a method for performing a Practice-based FMEA. The process is designed to give a broad overview of the practice; we include almost all entities and activities within the practice. This avoids the problem of having to choose a narrow focus (part a above) but does limit the depth of analysis. The process is based on the 8 parts (a – h) listed above but simplified in the following 4-Step cycle (portrayed in Figure 2).

STEP 1: Assess baseline safety state via an Anonymous staff survey.

This corresponds to parts b - e of the traditional FMEA. In the Practice-based FMEA, the team consists of all workers in the practice. To achieve part c, we need to understand the system of care in the practice. This is done by first identifying the various entities in the practice (such as the patient, provider, nurse, and chart), listing the main interactions that take place between them, and then portraying them in a visual model. Figure 3 illustrates the model that was used in this study. It is based on a model proposed by the authors21. Like any model it is a simplified representation of the reality; it can be enriched and/or modified as appropriate to suit the purpose. In this case the model serves as a framework for the Practice-based FMEA process.

The model is limited to events that take place in the office itself, recognizing that much of ambulatory healthcare takes place outside of the office (e.g., in the home, lab, pharmacy, hospital facilities, ER) but that the immediate sphere of influence for which the practice has responsibility and can exert most influence is in the office itself. It focuses on assessment of the patient, shown on the left side of the model, and development of a management plan and any in-office implementation of the plan (e.g., giving shots), shown on the right side.
Parts d and e are accomplished by means of an anonymous survey distributed to all members of the practice staff; no one is excluded from the team.

The survey instrument was developed by the authors in an attempt to address, in a cost effective manner, the problem of measuring the rates and consequences of errors. It is anonymous and user-friendly and elicits the perceived rates of errors (Failure Modes) and their consequences (Effects) from all members of the practice staff. Instead of asking each staff member about their own personal error experiences it asks each staff about their perception of the whole practice. This approach takes advantage of practice-based experiential knowledge and, like the highly acclaimed Aviation Safety Reporting System, has three important attributes of (a) safety (immunity to blame and punishment) (b) simplicity and convenience and (c) worthiness and value (provides feedback and is a tool for development of improvement strategies and enhancement of staff self-esteem).

The survey is structured and based on the visual model discussed above. The survey focuses on 12 of the key entities and interactions shown in Figure 3 and dedicates a page to each. Each page has a list of failure modes that are known to occur in that specific part of the practice. The lists were developed by review of the literature and consultation with practices; they can be customized to incorporate special circumstances for any given practice if desired. The survey contains a total of 130 failure modes. Respondents are invited and encouraged to supplement this list. Figure 4 shows an example page from the 12-page survey instrument. As can be seen, the participants are asked to consider each of the listed errors in turn and, for each, to respond with their perception of the frequency of the error and the likely severity of the consequences. Explanations of the categorical choices are given at the bottom of each page. The visual model of the micro-system is repeated on each page to orient the respondent to the part of the office that is under consideration (highlighted on the page in red).

**STEP 2: Identify the Most Significant System Problems – using a process of consensus guided by Hazard scores.**

To assist in achieving part f of the traditional FMEA, survey responses are analyzed, yielding hazard scores that are fed back to practice staff as a whole.

Hazard scores are calculated for each error by multiplying the respective frequency with its consequence. To achieve this, the qualitative responses from the questionnaire are converted into quantitative ones, based on the following considerations and assumptions:

**Frequency (Probability):** Values were derived from their description and the average number of patients actually seen by the practice per week. For example the “frequent” probability of occurrence which was described as “One or more times in a week” is approximated to mean twice a week and, in a practice that sees 200 patients per week, is converted to 2 ÷ 200 = 0.01, or 10 times per thousand visits. Similarly the “remote” probability, described as “Less than once a year”, was converted to 0.5 ÷10,000 (with 10,000 patients seen per year) = 0.00005, or .05 times per thousand visits.
Severity of Consequence: “Minimal” severity was assigned a value of 1 and “Severe” given a value of 100. Figure 5 visualizes the relationship assumed (dashed line) between the qualitative and the quantitative equivalents in the proposed methodology. The shape reflects the assumption that the patients and staff are risk averse, meaning that they have a disproportionately high aversion for severe and moderate outcomes. The lowest dotted line portrays even a greater aversiveness to risk. The diagonal line can be seen as risk-neutral. The topmost dotted line portrays a risk preferring attitude. In the context of healthcare the risk-neutral and risk-prefering curves would appear to be irrational since they make little distinction between mild, moderate and severe outcomes. To test the effect of variations in the shape of this curve on the hazard rankings, sensitivity analysis was performed using various shapes. No significant effect on the rankings was found when the curve remained within the risk averse range.

Hazard Score: This is calculated as Frequency x Consequence. For convenience of conceptualization and consistency it was decided to scale the Hazard scores to a range of 0 (minimum) to 100 (maximum). The Table shows the resulting relative Hazard matrix that summarizes the various possibilities of frequency and severity.

For each “failure mode” for each respondent hazard scores are assigned by looking up the Hazard Matrix. Mean hazard scores are then computed for each failure mode for each subgroup (doctors, nurses and administrative) and for the practice as a whole.

For each subgroup and for the practice as a whole the hazards are listed in rank order (highest to lowest). The items at the top of the list are perceived, on average, to be the most hazardous problems in the practice and therefore should be considered for further attention. The data can be formatted in a variety of ways, broken down by practice component and/or by respondent sub-group. These data are presented to practice staff and used to stimulate discussion culminating in final decisions regarding priorities to be addressed.

It is important to emphasize that the purpose of ranking the Hazards is not to prescribe or stipulate prioritization but to aid ‘brain-storming’ and provide a focus for discussion. The practice staff should collectively make the final prioritization decisions based on a combination of the hazard rankings, feasibility, and other practice-specific factors. The method of reaching consensus should be tailored based on the prior experience and history of the practice, as well as the time and other resources available. Methods can range from simple discussion to adaptations of the Delphi technique.

STEPS 3 & 4: Establish and Implement Team-based solutions to the prioritized hazards

Parts g and h of the traditional FMEA (design, implement and assess interventions) are covered in these Steps. Having identified the safety issues that most concern its own staff, the practice will now be in a position to develop and implement strategies to address these issues. A variety of approaches are available to achieve this. In keeping with the philosophy of using internal expertise and promoting staff ownership of problems and solutions, the authors recommend that staff develop their own solutions based on their intimate knowledge of their own unique micro-system. To aid and guide
the design of safety interventions, the staff is given a brief presentation covering basic principles of system redesign based on IOM recommendations.

**Experience with the methodology thus far**

The methodology has been applied in a number of primary care settings and has also been adapted for other applications including medication management in long-term care and post-operative pain control in the hospital setting. It has also been used to estimate the impacts on safety caused by the introduction of electronic medical records in primary care. Examples will be described in the presentation. Validity issues related to the survey will be discussed.

**Discussion**

The approach described is based not on measurement of actual events/incidents but on team members' perceptions of error frequency and severity. Therefore it is subject to various biases that are inherent in this type of survey approach. In addition, especially in smaller practices, anonymity may be hard to maintain and therefore some amount of underreporting may occur.

Nevertheless, we would argue that the perceptions of the workforce are important in assessing the safety needs in any organization and should therefore be sought and respected. Changes in these perceptions can also be useful measures of outcomes resulting from safety interventions. Analysis of these perceptions allows the staff in practices to identify and prioritize their own safety and quality problems without requiring generalization of data from other practices. The survey is anonymous and therefore relatively non-threatening and allows a glimpse of the whole ‘iceberg’ based on staff members’ combined experiences of problems and their likely consequences. The process is designed to engage all members of the practice staff in such a way as to create a common vision and empower and motivate them to take ownership of quality and safety.

The authors take the view that even though a precise answer to a question is not available this should not deter us from asking the question and seeking an answer. Or, put another way, “better an approximate answer to the right question than a precise answer to the wrong question.” At their best, practice profiles, audits and error reports are capable of giving pseudo-precise answers to very limited parts of the question. That is, they can tell us about the items that are included in the profile and about the kinds of errors that people are willing to report. But these are just the ‘tip of the iceberg.’ We suggest that the ‘Practice-based FMEA’ is one possible means of finding an approximation to the ‘whole iceberg’. In other words, the theoretical concept of “optimization” needs to be turned into a practical methodology based on the principal of “satisfization” that yields a common vision that is good enough.

This Practice-based Methodology can be seen as an “operationalized” version of FMEA for primary care office settings; this kind of approach is needed since medical practice staff lack the aptitudes, training and skills of safety experts.
References

TABLE: Hazard Matrix (Hazard = p x s)

<table>
<thead>
<tr>
<th>Severity (s)</th>
<th>Probability (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remote</td>
</tr>
<tr>
<td>Minimal</td>
<td>0.005</td>
</tr>
<tr>
<td>Mild</td>
<td>0.025</td>
</tr>
<tr>
<td>Moderate</td>
<td>0.1</td>
</tr>
<tr>
<td>Severe</td>
<td>0.5</td>
</tr>
</tbody>
</table>
Office Staff “Swimming in the Water” can each see various parts at various times

Why not take advantage of their knowledge and experience?

Figure 1: Authors’ perception of the relationship between the currently used mechanistic approach (“Tip of the Iceberg”) and the humanistic approach (“The whole Iceberg”)
Figure 2: Overall View of the System Improvement Methodology
Figure 3: Entities and their Interaction in an Office Setting
Footnote: The left half of the diagram represents the processes of Assessment of the patient, while the right side represents the processes required to make a Plan of care.
### Anonymous Error Survey

**Figure 4:** An Example Sheet from the Anonymous Survey Instrument

<table>
<thead>
<tr>
<th>Type/Cause of Error: Provider</th>
<th>Your Perception of the Probability of Occurrence</th>
<th>Your Perception of the Severity of Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequent</td>
<td>Occasional</td>
</tr>
<tr>
<td>Not taking into account:</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>patient's age, sex, weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient's medical problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient's medications and allergies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient's habits (e.g., smoking, alcohol, drugs, diet)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient's social/living conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient's family history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>results of previous tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>response to previous treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not making use of resources like books and internet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not making use of available external resources (consultation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider fatigued, stressed or ill</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider in a hurry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Chart**
  - **Assessment**
  - **Plan**
  - **Error**

<table>
<thead>
<tr>
<th>Your Perception of the Probability of Occurrence</th>
<th>One or more times in a week</th>
<th>One or more times in a month</th>
<th>One or more times in a year</th>
<th>Less than once a year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe or irreversible complications unrelated to the natural course of the illness (e.g., disability or loss of function or hospitalization)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild or moderate reversible complications unrelated to the natural course of the illness, not requiring hospitalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased length or severity of illness, not requiring hospitalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No increase in length or severity of illness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 5: Conversion of Severity (s) from Qualitative to Quantitative