REDUCING DIAGNOSTIC ERROR THROUGH INTEGRATED SYSTEMS MANAGEMENT

A KNOWLEDGE BRIEF

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ABSTRACT

Over the past 75 years our ability to make accurate medical diagnoses at an earlier and earlier stage has grown dramatically as have the number of diagnosable and treatable diseases. Paradoxically, efforts to diagnose disease earlier have increased diagnostic uncertainty and so, increased risk for diagnostic and therapeutic error. This has led to the increased perception of error on the part of the patient and of a society whose expectations have grown with the rise of modern medicine. How do we establish effective and comprehensive control over our increasingly complex profession to reduce diagnostic error while improving the quality of healthcare and holding down skyrocketing costs? By implementing **Integrated Systems Management** [**ISM**] as a strategic approach to problem solving. This knowledge brief reviews the **ISM** concept which combines three interrelated and potentially conflicting areas of management that affect any human activity into a single integrate whole. Integration provides the comprehensive and effective control we seek; the overall goal being to achieve an acceptable balance between benefits and risks inherent in such a complex endeavor.

SITUATION

Over the past 75 years our ability to make accurate medical diagnoses at an earlier and earlier stage has grown dramatically as have the number of diagnosable and treatable diseases. However, this increased diagnostic capability has come at a steep price. Paradoxically, efforts to diagnose disease earlier has increased diagnostic uncertainty and so, increased risk for diagnostic and therapeutic error.[1-5] This has led to the increased perception of error on the part of the patient and of society whose expectations have grown with the rise of modern medicine. [6-7] As a recent Institute of Medicine report of September 2015 notes, the present approach to managing this complexity to reduce error has not been successful.[8]

PROBLEM: DEALING WITH THE COMPLEX INTERACTION OF THREE ASPECTS OF THE HEALTHCARE ACTIVITY

How do we establish effective and comprehensive control over our increasingly complex profession to:

- ➡ Reduce diagnostic error and
- ➡ Improve the quality of service to our patients while
- ➡ Holding down skyrocketing costs?

SOLUTION: INTEGRATED SYSTEMS MANAGEMENT

This knowledge brief presents the concept of **Integrated Systems Management** [**ISM**] as the best solution to the above stated problem.[9-11] **ISM** combines three interrelated and potentially conflicting areas of healthcare management into a single integrate whole. [See Table 1] Integration provides the comprehensive and effective control we seek; the overall goal being to achieve an acceptable balance between benefits and risks inherent in such a complex endeavor as health care.[12]

Table 1: Definition of Risk, Quality, and Utility in the Context of the Diagnostic Process.

RISK	**MAXIMIZE PATIENT SAFETY** WITH ACCURATE, PRECISE, AND TIMELY DIAGNOSES
QUALITY	**MINIMIZE PATIENT SUFFERING** AND INCONVENIENCE DURING THE DIAGNOSTIC PROCESS
UTILITY	**MINIMIZE PATIENT COSTS** AS A RESULT OF THE DIAGNOSTIC PROCESS

ADVANTAGES

Traditionally, most health care organizations pursue Risk Management, Quality Assurance, and Utilization Review as separate activities, often in separate departments. Most healthcare institutions focus on one, or at most, two of these three key areas of management and often confuse risk issues with quality issues. In addition, present methods used to manage healthcare activities are, at most, operational in scope, and often more technical with narrow focus of application. This is inherently inefficient and inevitably leads to suboptimal results due to lack of complete coverage combined with the adverse effect of conflicts that arise between departments.

In contrast, **ISM** is strategic in nature and solves this central management problem by establishing a single global authority over healthcare activities and provides the means of directing how health care managers operate. In addition, **ISM** does not preclude the use of any other management methodology because it is strategic, and they are all operational. So, for example Lean, Six Sigma, TQM, and other management approaches that might already be in use by a health care organization need not be abandoned.

The reason for this is that **ISM** requires that health care organizations investigate events, formulate solutions, and develop plans for improvement within the constraints established through an agreed-to prioritization of **Risk** – patient safety, **Quality** – patient experience, and **Utility** – patient cost.

ISM – A BRIEF OVERVIEW

To that end, to be useful, each element of **ISM** needs to be further refined before it can be used to manage complex healthcare activities. Table 2 illustrates this by introducing the concepts of prioritization, strategic goal setting, and the assignment of one or more measurable objectives to achieve these goals.

Table 2: Prioritization, Strategic Goals, and Measurable Objectives.

AXIS	#	GOAL	EXAMPLE MEASURABLE OBJECTIVE
RISK	1ST	PATIENT SAFETY	MINIMIZE HARM – INJURY AND DEATH
QUALITY	2ND	PATIENT COMFORT	REDUCE PAIN, SUFFERING, AND LOSS OF FUNCTION
UTILITY	3RD	DO WHAT WORKS	USE OF RESOURCES EFFICIENTLY AND EFFICACIOUSLY

MODIFIED FAILURE MODE AND EFFECT ANALYSIS AS THE IDEAL OPERATIONAL TOOL – A BRIEF OVERVIEW

The measurable objectives cited above in Table 2 can be further refined to facilitate implementation through a modified form of **Failure Mode and Effect Analysis** [**FMEA**]. **FMEA** has been validated in a number of areas – primarily manufacturing – as a preferred method to fully characterize risk in an activity.[13-16] It turns out we can apply **FMEA** to the field of health care by modifying the headings. In addition, **FMEA** provides an ideal framework for simultaneously evaluating any health care activity to also identify where quality can be safely improved, and costs safely reduced making it a perfect fit for implementing **ISM**. From this, solutions can be formulated to avoid, prevent, or mitigate error while simultaneously improving quality and reducing unnecessary expenditures. Below Table 4 Illustrates how **FMEA** can be used to Drive **ISM**.

Table 4. The Four Key Elements of Failure Mode and Effect Analysis

SYSTEM	LOGIC	**ORGANIZATIONAL SCHEMA** OF INPUT/WORK **FLOW**/DECISION **LOGIC**/OUTPUT
COMPONENT	TOOLS	**PHYSICAL PLANT**/INSTRUMENTS/SCANNERS/COMPUTERS/SOFTWARE/ETC.
PROCESSES	TASKS	**PROCEDURES** DEVELOPED TO USE **TOOLS** TO RUN THE **SYSTEM**
SERVICE	PEOPLE	QUALIFYING **PEOPLE** TO USE **TOOLS** TO EXECUTE THE **PROCEDURES** TO RUN THE **SYSTEM**

Note that any service-oriented activity can be broken down into these four basic and comprehensive elements. This greatly simplifies the management process and assures that any operational approach chosen or already being used is more effective because it requires that we consider all three management areas and all four categories of potential failure. For example, in the case of a medical school curriculum we would use **FMEA** to drive the management process to implement prioritized Risk, Quality, and Utility objectives through:

- Redesign the **System** that directs the educational and training activity through the four years
- Determine what physical plant, equipment, and other resources – **Tools** – are needed to run the **System**
- Develop **Processes** by which personnel – professors and students – use those **Tools** to run the **System**
- Establish teaching and training qualifications for using **Tools** by defined **Processes** to run the **System**

IMPLEMENTATION – PUSHING ON A STRING

Successful implementation of **ISM** requires a substantial effort to overcome the natural inertia of an institution and can be a daunting task especially when considering making change across an entire profession. The most effective means of overcoming a culture resistant to change is to change the culture. Only then can we proceed to redesign the activity and improve the cognitive functioning of the participants to reduce diagnostic error in medicine.[17-21] For example, in a medical school this would require convincing and redirecting the efforts of administrators, professors, and medical students in that order. The change sought can be most effectively achieved through the initiation of a cascade of cognitive development starting with orientating key personnel and ending with their gaining of experience that leads, hopefully, to the good judgment. And it this good judgment is what will lead to decisions that will drive meaningful change. The result: a redesigned medical school curriculum that positively affects the diagnostic acumen of its students in the face of increasing complexity and uncertainty. Below Table 5 illustrates this cascade.[18, 19]

Table 5. Cascade of Cognitive Development to Drive **Integrated Systems Management**.

STAGE	CLASS	DESCRIPTION
ORIENTATION	ENCULTURATION	IMPRINTING **ORGANIZATIONAL VALUES** BY MISSION DEFINITION
PRIMING	SIGNALS	DEVELOPING **RECOGNITION OF PATTERNS** LINKED TO OUTCOMES
TRAINING	PROFICIENCY	MEMORIZING, RECALLING, AND **APPLYING RULES** - HEURISTICS
EDUCATION	KNOWLEDGE	LEARNING CONCEPTS TO FACILITATE **SOLVING COMPLEX PROBLEMS**
EXPERIENCE	COMPETENCY	**LEARNING FROM OUTCOMES** OF DECISIONS AND ACTIONS
JUDGMENT	RELIABILITY	**MAKING BETTER DECISIONS** UNDER UNEXPECTED SITUATIONS
WISDOM	INSIGHT	**AVOIDING SITUATIONS** WHERE THERE ARE NO GOOD DECISIONS

The result sought through this cascade is a comprehensive approach that assures close cooperation between those in the organization tasked with managing health care education, those tasked with teaching it, and those who receive the teaching.

INTEGRATED DOCUMENT MANAGEMENT SYSTEM

Implementation of **ISM** requires a well-organized, sustained effort. The only way to maintain this effort is through use of knowledge that has been attained through codification, dissemination, and application in a systematic way. This requires the implementation of an **Integrated Document Management System** [**IDMS**].[24] The **IDMS** is a top down hierarchical document structure shown below in Table 6. It begins with a brief, clear, mission statement from which all else flows and ends with detailed procedures consisting of only those tasks necessary to carry out the mission objectives as laid down in each policy, supplemented by guidelines to trouble shoot problems using knowledge gained through experience.[25]

Table 6. The Organization of Knowledge/Document Management Systems – In Brief.

MISSION	Purpose	Organization's **Reason for Existence**
mFMEA	Analysis	Investigation and **Evaluation of an Activity**
PLANS	Goals	One or more general goals for **Risk**, **Quality**, **Utility**
POLICIES	Objectives	Defining measurable objectives to **Support Goals**
PROCEDURES	Task Sets	**Organized Action** to achieve measurable outcomes
GUIDELINES	Trouble Shooting	**Codified Knowledge** gained through **Experience**
MONITORS	Surveillance	**Capturing and mitigating** critical errors in the **System**
FORMS	Data Collection	**Documenting** events, investigations, actions, results
REPORTS	Analysis	**Extracting knowledge** from accumulated experiences

BRINGING THE SYSTEM TOGETHER

Illustrated below are the basic steps in the strategic approach to reducing diagnostic error using **ISM** organized through the operational tools of **mFMEA** and **IDMS**.

Figure 1: A schematic overview of the ISM steps to reduce diagnostic error.

Establish Mission	Establish clear cut purpose for the activity
Target Outcomes	Determine what benefits are being sought
ISM Analysis	Identify Risk, Quality, and Utility Issues
Classify by mFMEA	Break down activity into System, Component, Process, and Service
Acceptable Risk	Balance maximum potential Risk against minimum expected Benefits
Risk Stratification	Prioritize which Risks to: Avoid, Prevent, Mitigate, and/or Insure
Design/Redesign	Redesign old activity or design new activity
Classify by mFMEA	Organize new design by mFMEA headings to facilitate planning
Develop Plans	Develop strategic and operational plans for implementation
Cognitive Cascade	Orient to goals, then train on procedures, and educate on experiences
Implementation	Initiate patch of an activity or implement an entirely new activity
Short Term Checks	Validate the activity to catch unexpected start up errors/failures
Correction/Rollback	Determine additional modification or rollback to prior activity as necessary
Long Term Monitors	Establish control over critical decision points and outputs
Codify Experience	Write final Policies, Procedures, Guidelines, and Forms
Disseminate	Broadcast documents and re-enforce changes with ongoing surveillance

Below, Table 7 illustrates a more detailed overview of the entire approach to implementing **ISM** that can be used to reduce diagnostic error in medicine. It is a starting point for a more comprehensive document for each specific application, such as a medical school curriculum, residency program, or newly established clinical department. This drives the process and assures the best chance for success in a difficult, complex, and rapidly changing environment.

Table 7. Basic Strategic Steps Required to Implement an Integrated Management System.

#	STEP	CONCEPT	DESCRIPTION OR EXAMPLE
1	MISSION	PURPOSE	Screening, Diagnosis, Prognosis, Therapy, Management, etc.
2	OUTCOMES	BENEFITS	⇧***Patient Safety*** ⇧Quality of Service ⇧Efficiency and Efficacy
3	ISM ANALYSIS USING mFMEA	RISK QUALITY UTILITY	Determine potential adverse outcomes Determine potential quality issues Determine appropriateness of intended use and total cost
4	***DETERMINE ACCEPTABLE RISK***	FMEA – Data Collection and Risk Assessment	Establish maximum ***Acceptable Risk*** for benefits attained: Determine most critical risks, attempt to estimate: Frequency Severity Perception of cost to patient and society
5	***RISK*** STRATIFICATION	AVOID	Determine if the activity should be implemented/continued
		PREVENT	Determine adverse events to be prevented if implemented
		MITIGATE	Determine what residual ***Risk*** can be monitored and mitigated
		INSURE	Determine what adverse outcomes should be insured against
6	ACTIVITY REDESIGN	FMEA	The four basic components of the activity are assessed
	USING mFMEA	SYSTEM	Design logical flow – safest way to achieve intended outcome
		TOOLS	Establish what are the right physical resources to do the job
		PROCESSES	Develop best procedures to complete each task in order
		SERVICES	Establish minimal personnel qualifications to run the system and develop the cognitive cascade to achieve these
7	DOCUMENT SYSTEM	DOCUMENTS	Integrated Document Management System [**IDMS**] to codify activity
	Documents drive	MISSION	Brief statement of the purpose of activity along ISM lines
	Implementation	PLANS	**Strategic**: Goals – Written by Leadership/Chief Clinicians **Operational**: Objectives – Written by Middle Management **Technical**: Tasks – Written by those who carry them out
		POLICIES	Each measurable objective is established in a short policy
		PROCEDURES	Each self-contained set of tasks is organized procedurally
8	SYSTEM PATCHES	GUIDELINES	Codification/Dissemination of f experience gained
		FORMS REPORTS	Data acquisition to monitor and evaluate activity for meeting ***Risk***, *Quality*, and *Utility* Goals through Measurable Objectives

EXAMPLES – IN BRIEF: HOW ISM AND mFMEA ARE USED TOGETHER TO REDUCE DIAGNOSTIC ERROR IN MEDICINE

EXAMPLE 1:

A large reference laboratory Pap smear division that examined over 200,000 cases per year experienced a 5% error rate causing over 10,000 incorrect reports. One significant cause of adverse outcomes was an imbalance between Risk and Quality illustrated below in Table 8:

Table 8. **ISM/mFMEA** Grid Showing Inappropriate Goal/Objective Prioritization Leading to Patient Harm.

ELEMENT	PRIORITY	GOAL	OBJECTIVE(S)
QUALITY	Over Emphasized	Physician convenience/Patient anxiety	Turn-around-time
RISK	Under Emphasized	Patient Safety/Cost due to error	Computers/Service support

Priority placed on turn-around-time [**PROCESS**] using inefficient data entry forms [**SYSTEMS/TOOLS**] in the face of inadequate computer resources [**TOOLS**] and personnel training [**SERVICE**] led to significant adverse outcomes harming patients [**SAFETY**], damaging the reputation of the laboratory [**QUALITY**], and raising total cost of doing business [**UTILITY**]. These were corrected using **ISM** to establish a balance between safety and quality that lead to:

- Redesign of the PAP smear activity to eliminate as many points of known error as possible
- Establishment of monitors capture and mitigate errors that could not be completely prevented
- Writing guidelines defining how to best mitigate errors identified through monitoring
- Orienting, training, and educating administrator, technologists, and pathologists

Some of the benefits achieved:

- Approximately 95% of administrative errors were eliminated [**RISK**]
- Improved Physician acceptance [**QUALITY**] and correct interpretation of the report [**RISK**]
- Reduction in personnel time in administrative support was achieved [**UTILITY**]
- Reduction in pathologist time in case review was achieved [**UTILITY**]

EXAMPLE 2:

A hospital Coumadin Clinic wished to implement Point of Care Testing [**POCT**] for PT/INR to make it more convenient for the physicians and patients while reducing the risk of thrombosis due to delay in modification of Coumadin dosage imposed by waiting for results from the main laboratory.[26,27] The imbalance between Risk and Quality is shown in Table 9:

Table 9. **ISM/mFMEA** Grid Showing Inappropriate Goal/Objective Prioritization Leading to Patient Harm.

ELEMENT	PRIORITY	GOAL	OBJECTIVE(S)
QUALITY	Over Emphasized	Physician convenience/Patient convenience	Time on the phone and Patient returns
RISK	Acceptable Emphasis	Timely change in Coumadin dose to prevent bleeding	Prevent rise in PT/INR
RISK	Under Emphasized	Patient safety/Cost due to instrument reliability	Tool/Service Qualification

Inherent limitations of the **POCT** instrument [**TOOLS**] were not considered nor was the lack of adequate proficiency in use of the **POCT** instrument by clinic personnel [**SERVICE**]. In addition, there was a lack of understanding that validation studies, relying on simple linear comparisons, did not establish reliability at the Medical Decision Point [**MDP**] where changes in Coumadin dosage would be made [**PROCESS**]. Finally, there wasn't an overall logic by which **POCT** results were integrated into the diagnostic decision-making activity [**SYSTEM**].

The result was systematic over treatment of PT/INR results at or near the **MDP**. A rise in bleeding events ensued. One event was clinically significant which led to re-evaluation of the entire activity. Application of **ISM** to the problem yielded a much-improved activity as follows:

- Guidelines establishing when to use of POCT were implemented [**SYSTEM**]
- A switch was made to a more reliable instrument [**TOOLS**]
- Better training was introduced to assure proficiency and competence [**SERVICE**]
- Laboratory confirmation was required prior to changing Coumadin dosage [**PROCESS**]

LIMITATIONS

There is overlap between Risk, Quality, and Utility that cannot be eliminated. For example, loss of function could be caused by an error committed during a diagnostic work up. This could be categorized as both a risk and a quality issue. There are also potential conflicts between the three areas of management. This is illustrated in example two above where quality issues regarding patient and clinician convenience were improperly balanced against patient safety.

Next, management is often working with an activity that cannot be completely replaced but can only be partially redesigned or patched. Often much of what goes on in an activity is known only to a few people or a single person who may not be fully cooperative with the investigation and redesign effort. One must also consider that there may be people with a vested interest in the original activity. In addition, extant physical plant, equipment, and supplies may further limit what can be done. This and other unknowns can impose significant limitations on the effectiveness of any management approach to problem identification and solution. However, these limitations are not unique to **ISM** and plague all operational management methodologies.

Also note that design of a new activity or redesign of an old activity requires two passes using **mFMEA**:

- Categorizing an activity's significant risks, quality issues, and costs
- Categorizing solutions under consideration to assure all aspects of the activity are addressed

This is not an easy endeavor and requires strong leadership to motivate personnel, proper resource management to support implementation, and effective command to assure the correct strategic and operational decisions are made.

Finally, **ISM** imposes an additional burden. This occurs because **ISM** requires that we attempt to determine what **Risks** are taken to achieve a specified level of **Quality** and **Utility** ***before*** making any changes. Doing this can lead to conflict over prioritization of goals as well as resistance to specific objectives which often place unwanted expectations on those affected by them. Yet, in the long run, this very conflict will raise and hopefully resolve issues before the move to implement change, not after when it is too late to prevent them from causing project failure.

EXCEPTIONS

Although the prioritization established is Risk first, this is a general rule only. Under certain circumstances, it may not be appropriate. For example, reducing patient suffering trumps patient safety in the terminally ill. Therefore, the use of centrally acting pain medications in this case would not be as much of a safety concern as it would be a means of assuring the patient's comfort.

CONCLUSION

Effective **Integrated Systems Management** provides a unique strategic approach to healthcare administration that complements and enhances presently used operational methods. It requires careful investigation of each health care activity to delineate if and how to implement an improved **System of Logic** that uses **Physical and Informational Components**, via a well-defined **Process**, carried out by properly prepared **Personnel** to achieve well defined **Goals** through **Measurable Objectives** based on a **Mission** to balance **Risk**, **Quality**, and **Utility**. The judicious application of **Integrated Systems Management** to address the increasingly complex field of healthcare to reduce diagnostic error is made more successful if pursued through the application of modified Failure Mode and Effect Analysis and establishment of an Integrated Document Management System to capture knowledge.

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