

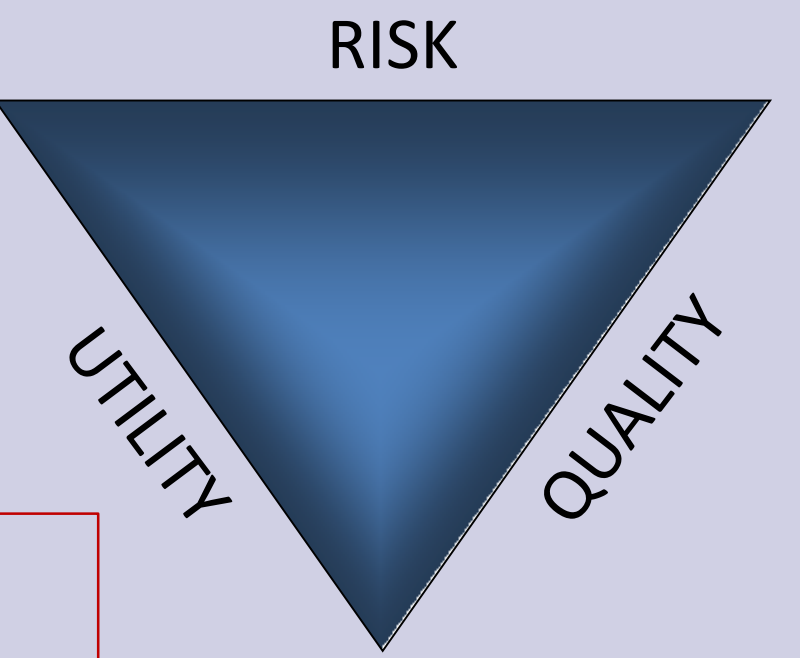
THE SCIENTIFIC METHOD

AS THE OPERATIONAL TOOL FOR EFFECTIVE REDUCTION OF DIAGNOSTIC ERROR IN MEDICINE



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1. Define the component parts of The Scientific Method.
2. Recognize how each component can direct effective and safe diagnostic processes.
3. Identify where in the diagnostic process The Scientific Method provides valuable feedback loops to help prevent error in diagnosis.

SITUATION

The purpose of healthcare is to direct professional activities toward the most favorable outcome for the patient. Accelerating technological advances have resulted in increased capability to diagnose. However, they have also increased the complexity of medicine and, so, the potential for error in diagnosis.

A critical systemic failure leading to this situation is the absence of an effective **Operational Management Tool** to organize, direct, and document the diagnostic effort so as to assure optimal patient outcomes and act as a basis for investigating and correcting error.

PROBLEM

What type of system should be put into place to successfully implement **Integrated Systems Management [ISM]** operationally to

Reduce Diagnostic Error?

SOLUTION

The optimal solution is **The Scientific Method [TSM]**.¹ TSM is a knowledge acquisition tool traditionally used by the scientific community that imposes a rigorous but flexible set of standards that require we always:

▶ **ESTABLISH SCIENTIFICALLY BASED FACT BEFORE WE ACT** ◀

Therefore **TSM** can be used in clinical diagnosis, to organize the patient chart, and direct investigation of medical error leading to unification of the entire healthcare process.

CONCEPTUAL DEFINITION

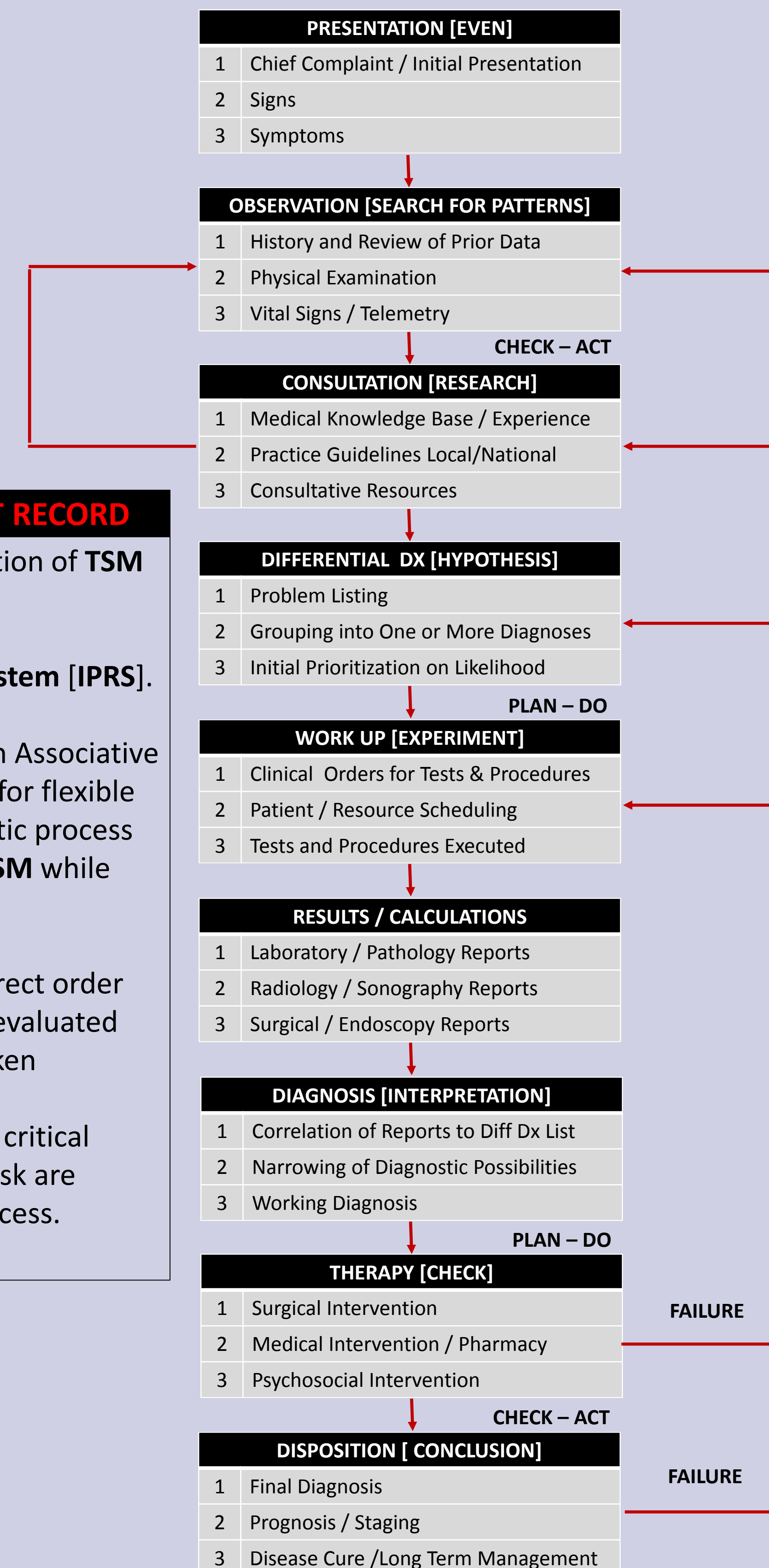
TSM provides a normative, nonjudgmental approach to establishing observational fact as distinct from speculation, hypothesis, and theory. **TSM** provides numerous cybernetic feedback loops that establish a structure for integrating elements most critical to successful clinical medicine.²

TSM directs clinical diagnosis through formulation of an hypothesis as to cause of clinical observations. Test results are evaluated, diagnoses confirmed or ruled out and checked by additional testing and/or therapeutic intervention to verify facts.

TSM— OPERATIONAL SCHEMA TO REDUCE DIAGNOSTIC ERROR^{1,3}

STEP	CLINICAL	EXAMPLE
EVENT	Chief Complaint – Clinical Presentation	Sore Throat
OBSERVATION	History, Physical, Telemetry Looking for Patterns	Tonsillar Exudate
RESEARCH	Clinical Fund of Knowledge, Consultation	Infectious Diseases/Microbiology
HYPOTHESIS	Differential Diagnosis	Infection is Present
MATERIALS	Health Care Resources	Microbiology Laboratory Section
METHODOLOGY	Practice Guidelines, Personal, Institutional, National	Specimen Acquisition Techniques
EXPERIMENT	Tests and Procedures Ordered	Throat Culture Submitted to Lab
RESULTS	Reports of Test and Procedural Results	Streptococcus Grown
CALCULATIONS	Dependent on Type of Tests and Procedures Ordered	MIC Antibiotic Sensitivity
INTERPRETATION	Diagnoses Ruled In or Out	Infection is Present and Treatable
CHECK	Therapeutic Intervention Determined	Antibiotic Prescribed
CONCLUSION	Evaluation of Actual Outcome Against Expected Results	Clinical Follow Up of Outcome

TSM consists of a sequence of steps with multiple internal feed back loops that establishes a rigorous but flexible self-perpetuating cycle of observation, investigation, analysis, and action. A patient record model could include:



THE INTEGRATED PATIENT RECORD

An example of an implementation of **TSM** as the foundation of an

Integrated Patient Record System [IPRS].

The IPRS would be based on an Associative Database Model which allows for flexible reconfiguration of the diagnostic process to include a key elements of **TSM** while assuring:

- ▶ Each step is executed in correct order
- ▶ All information obtained is evaluated
- ▶ All necessary actions are taken

For clarity only the three most critical categories of information or task are shown for each step in the process.

CYBERNETICS

The Cybernetic Feedback System Requires All Clinical Information generated during the workup be:

- ▶ Evaluated
- ▶ Branch Points Followed
- ▶ Actions Taken
- ▶ In a timely manner.

Based on scientifically established:

- ▶ Knowledge
- ▶ Experience, and
- ▶ Judgment

With follow up monitoring of outcomes.

RCA, DEMING, TQM, ISO 9000 ARE SUBSETS OF TSM!⁴

TSM	RCA	DEMING
EVENT	EVENT DESCRIPTION	-
OBSERVATION	CHRONOLOGY OF EVENT	~CHECK - ACT
RESEARCH	-	-
HYPOTHESIS	POSSIBLE ROOT CAUSES	-
MATERIALS	INVESTIGATIVE TEAM	-
METHODOLOGY	METHOD	PLAN
EXPERIMENT	-	DO
RESULTS	FINDINGS	-
CALCULATIONS	-	-
INTERPRETATION	ROOT CAUSE	-
CHECK	CORRECTIVE ACTION(S)	CHECK - ACT
CONCLUSION	-	"ADJUST" [Variable]

MODEL: Establishment of Event Parameters

Presenting and follow-on observational information is entered into a predefined but flexible synoptic record-based **Electronic Health Record [eHR]**. Each entry can then be cross referenced to a composite knowledge base consisting of internet based search engine, facility and national level practice guidelines, customized article/book virtual library, automated diagnostic algorithms, and available expert consultants.

MODEL: TSM Creates a Closed System

Each event parameter stored in a separate synoptic record can be linked to one or more problem entries. These, in turn, can be linked to one or more diagnostic studies and their results.

This cluster of data can be interpreted manually or, using a differential diagnosis engine. Diagnoses are linked back to the cluster to it allowing for future reference and review.

Finally, each therapeutic intervention is linked to the diagnosis and problem listings with outcome fully documented to close the loop.

CONCLUSION

The judicious and rigorous application of **The Scientific Method** to design and run the diagnostic process, organize the patient chart, and investigate error, establishes the most effective means of assuring the correct diagnosis is rendered in a timely fashion and acted upon appropriately. In addition, the cybernetic feedback system assures that those failures that do occur are identified as soon as possible, their effects mitigated, and actions taken to branch back through the logical system until the correct diagnosis is identified or until it is determined there is none.

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 4. *Total Quality Management: In Its Prime or Past Its Peak?*; Medical Laboratory Observer, September 1994, pages 22-32
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