REDUCING DIAGNOSTIC ERROR IN MEDICINE

THROUGH AN UNDERSTANDING OF THE EFFECT OF CHANGING NOSOLOGY ON THE DIAGNOSTIC PROCESS

MANX Enterprises, Ltd.®

1. Describe how the concept of a diagnosis has changed over time. 2. Explain how scientific advances have changed our understanding of disease. 3. Show how this change over time has influenced Diagnostic Error in Medicine.

SITUATION

The concept of a diagnosis is very complex and has changed over time as our definition of disease has changed. In essence, a disease is a theoretical construct based on flawed and incomplete observations of its various manifestations in the individual patient as modified by therapeutic interventions. Furthermore, this construct has not been constant over time, evolving from an initial set of clinical observations that were assigned a label, through a series of stages leading to a fundamental understanding of cause(s) and mechanism(s) by which clinical findings appear. Thus, at each stage, apparent and actual disease prevalence does not coincide, confounding the effort to **Reduce Diagnostic Error in Medicine**.

PROBLEM

How can we

RISK	*Maximize patient safety* through establishment of reliable diagnostic terminology and so, diagnostic criteria
QUALITY	*Minimize* discomfort and the pain *suffered* due to misdiagnosis caused by the low power of diagnostic criteria
UTILITY	*Minimize expenditure* of scarce resources through improved value of diagnostic criteria

SOLUTION

It is proposed that, to untangle the impact of the evolution of a disease, the:

- ➡ Entire process be fully defined using a comprehensive schema
- ➡ Empirical and mechanistic diagnostic categories be defined
- ➡ Diagnostic terminology be standardized regarding observational data
- ➡ Compilation of diagnoses for epidemiologic databases be controlled
- ➡ Impact of diagnostic classifications on epidemiologic data be tracked
- ➡ The process by which new diagnostic classifications are introduced be better defined and controlled through clinical and epidemiologic trials

IMPLEMENTATION

- ➡ A proposed set of stages in the evolution of a diagnosis are presented based on a review of the medical literature.
- ➡ A model schema is presented as a starting point for defining the entire process from initial labeling to final diagnostic set.
- ➡ This will facilitate determining what types of systematic error would most likely occur during each stage of the evolution of a diagnosis.
- ➡ And will facilitate measuring the impact these errors have on the implementation of new diagnostic classification systems and therapy.

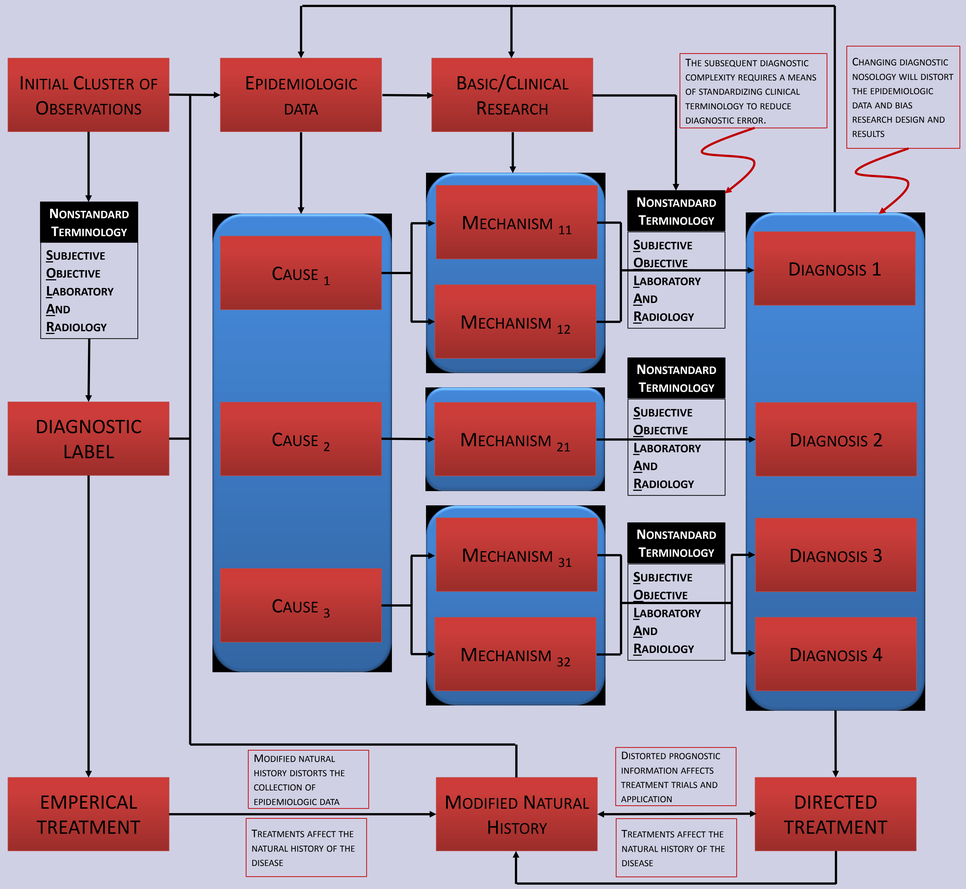
THE EVOLUTION OF A DISEASE OVER TIME

NATURAL HISTORY OF A DISEASE(S) AS A DIAGNOSTIC ENTITY

DIAGNOSTIC LABEL	A SET OF RELATED OBSERVATIONS IS GIVEN A NAME
CAUSE(S) OF DISEASE(S)	A CAUSE(S) EPIDEMIOLOGICALLY RELATED IN TIME TO OBSERVATIONS
MECHANISM(S)	MECHANISM(S) DISCOVERED LEADING TO CLINICAL DISEASE
MANAGEMENT/CURE(S)	THERAPY ALTERS THE NATURAL HISTORY AND SO, EPIDEMIOLOGY

It appears that a diagnosis generally evolves through at least four stages sometimes with one or more retracements. Cause(s), Mechanism(s), and Management/Cure(s) may be discovered after a disease is identified as a specific clinical entity and given a name. During the process, a disease may be subdivided into numerous separate entities based on cause and/or mechanism thereby increasing diagnostic and nosologic complexity.

INHERENT COMPLEXITY OF AN EVOLVING DISEASE IMPACTING THE DIAGNOSTIC PROCESS



REFERENCES – SELECTED:
1. Eddy DM Clanton CH; **The Art of Diagnosis: Solving the Clinicopathological Exercise**; New England Journal of Medicine Vol 306 No 21 May 1982 p 1263 – 1268.
2. Stevens SS; **On the Theory of Scales of Measurement**; Science Vol 103 No 2684 Jun 1946 p 677 – 680.
3. Vecchio TJ; **Predictive value of a Single Diagnostic Test in Unselected Populations**; New England Journal of Medicine Vol 274 No 21 May 1966 p 1171 – 1173.
4. Price RB Vlachcevic ZR; **Logical Principles in Differential Diagnosis**; Annals of Internal Medicine Vol 75 No 1 1971 p 75 – 89.
5. Leape LL; **Translating Medical Science Into Medical Practice: Do We Need a National Medical Standards Board?**; Journal of the American Medical Association Vol 273 No 19 May 1995 p 1534 – 1537.
6. Wolinsky H; **Paths to Acceptance: The Advancement of Scientific Knowledge is an Uphill Struggle Against 'Accepted' Wisdom**; European Molecular Biology Organization Vol 9 No 5 2008 p 416 – 418.
7. Schwartz LM Woloshin S; **Changing Disease Definitions: Implications for Disease Prevalence**; Effective Clinical Practice Vol 2 No 2 Mar/Apr 1999 p 76 – 85.
ACKNOWLEDGEMENTS: William S. Yamamoto, M.D., PhD. Clinical Engineering The GWU Medical School 1975 and 1979.

COST BENEFIT ANALYSIS

It becomes clear that, as a diagnosis evolves, it is often found to be more than one disease. In addition, the number of diagnostic criteria increase as well. This leads to increased complexity. The outcome of this is increasing apparent error along with the effects of lagging development and implementation of better diagnostic criteria.

Solving this problem will increase:

- ➡ Patient safety through more accurate diagnosis
- ➡ Quality of patient care more effective and timely therapy
- ➡ Value of the diagnostic process made more efficient and efficacious

EXAMPLE

As our knowledge of a disease progresses it often becomes evident that more than one cause is involved and, therefore, more than one disease has been subsumed under a single label.

This tendency, combined with the changing nature of how we define disease in general terms, has led to a change in the meaning of making a diagnosis and so the implications for the risk of **Diagnostic Error in Medicine**.

Illustrated on the left is a simplified schema of the evolution of a theoretical disease as a single diagnostic label into:

- ➡ Three different causes leading to
- ➡ Four distinct diagnoses via
- ➡ Five different mechanisms

To solve the problem a standardization of **Subjective, Objective, Laboratory and Radiologic** [**SOLAR**] terminology along with diagnostic nosology would provide the means of gaining control over the resulting complexity and allow for the generation of reliable epidemiologic data upon which to base clinical and policy decisions.

This concept is further explored in the allied posters.

CONCLUSION

Evolution of a diagnosis generally leads to more, not less complexity and, therefore, uncertainty in the diagnostic process.

Increasing complexity and uncertainty leads to increasing perception of the number and severity of diagnostic errors when seen against effective therapy.

It is vitally important to understand the historical development of disease classification and diagnostic criteria used at any time before embarking upon an effort to:

REDUCE DIAGNOSTIC ERROR IN MEDICINE