Medically Relevant Laboratory Performance Goals: An Overview

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Abstract: Medically relevant laboratory performance goals are incompletely addressed by mathematical logic built upon biologic variability, analytic variability, analytic bias, and Bayesian reasoning. Relevant goals need to also include an understanding of the perceptions and preferences of patients, their partners, providers, payers and the population served.

Human thought is subject to predictable errors. Formal study of medical cognitive processes is new. We should expect medical decisions may be equally at risk as other decisions are to cognitive flaws. Common flaws include overconfidence, inadequate feedback from previous decisions, too close an attachment to one's first idea, attachment to the status quo, extrapolating the representative case to the general, inaccurate probability estimates and framing the wrong questions. Relevant laboratory testing processes will recognize cognitive traps and attempt to minimize their impact on medical decisions.

Relevant goals are more than analytical goals and also include doing the RIGHT test at the RIGHT point in the care process and facilitating the RIGHT intervention decisions. Designing relevant testing strategies includes avoidance of cognitive errors, accurate probability (Bayesian) calculations and pathophysiologically sound reasoning.

Building relevant goals will require using the mathematical constructs of the past and adding new insights into the preferences and perceptions which define the desired outcomes. How can we design programs to identify the relevant requirements for each part of the total testing process?

"Relevant" is defined as related to the matter at hand, pertinent or important. To be relevant, pertinent or important implies the item under consideration contributes to satisfying some need.[1] We have come to specify these needs as the desired outcomes from the health care process, which include among others the reduction of a complaint or dysfunction, reassurance of health and satisfaction with the care and the cost. It is unusual for the laboratory to independently satisfy one of these needs. The laboratory contributes to the process of care by facilitating good choices in uncertain situations.

Laboratory effort should always be focused on the desired outcomes of care (Figure 1). Relevance in laboratory testing means making a positive difference in the outcome.[2] The laboratory should continuously build upon its allocentric (outside the lab) focus while maintaining excellent inside the laboratory processes. The process requires framing the RIGHT clinical questions and selecting the RIGHT tests to perform in that situation. The tests must be performed at the RIGHT time after the RIGHT patient preparation. The analytical process must have the RIGHT precision, RIGHT accuracy (analytical

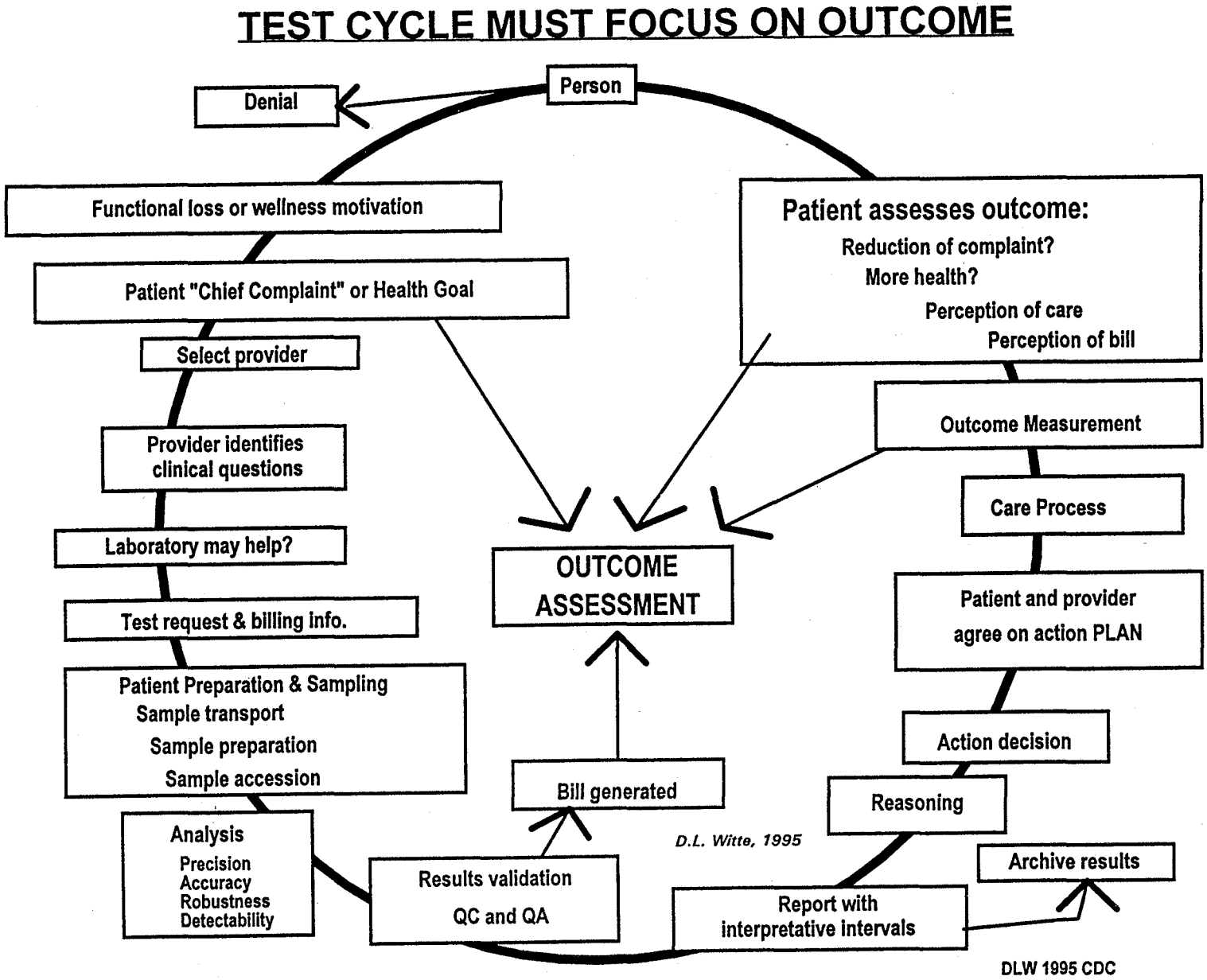

Figure 1. Laboratory efforts and outcomes of care.

specificity and calibration) and the RIGHT detectability (analytical sensitivity). The result must be reported with the RIGHT interpretive aids to facilitate the RIGHT decision process and the RIGHT choice of intervention. The RIGHT outcomes must be monitored with the RIGHT evaluative and accounting measures over the RIGHT time frame.

The analytical portion of the test cycle is the focus of Workshop 5. Much has been written about the contribution of random variation (common cause variation) and calibration bias relative to the medical relevance and analytical quality control. Much less is known about special cause variation ("blunders") in laboratories.[3,4] Elsewhere in this Institute Dr. Reed indicates a laboratory error rate of 1.1 per 1000 tests (or 1100 parts per million, PPM), and Dr. Hearn reported 27 errors in about 13,500 HIV tests or about 2000 PPM. We have studied methods comparison data where every sample had a duplicate result on the test method and singlicate from the reference method. Table 1 shows the frequency of common cause (arbitrarily chosen as 4-10 S.D. differences) and special cause (greater than 10 S.D. differences) errors in the test method results. If the Gaussian distribution approximates common cause random variation, then approximately one in 10,000 (or 100 PPM) errors are predicted to exceed about 4 standard deviations from the mean observed in a stable process. The data in Table 1 suggest we have measurable special cause variation in the analytical phase. Others have discussed the frequency of errors in the pre- and post-analytical phases.[3] Relevance includes careful consideration of common cause variation and bias, but the perception should be expanded to include pre- and post-analytical phases as well as special cause variation.

The broader focus of Workshop 8 includes pre- and post-analytical relevance (Table 2). Relevance means facilitating the right decisions. Decision making is thinking, the science of cognition. The papers in Workshop 8 illustrate intuitive, probabilistic, pathophysiologic and rule-based thinking processes. Each type of thinking is subject to bias and/or errors.[5-8] Cognition (how we think) is an important new area for study as part of the process of medical care and health promotion. Medical decisions and diagnoses are subject to the same errors in thinking as any other decision process when conditions are uncertain.[6,9-11] Neal Dawson discusses processes to avoid cognitive errors. Laboratorians have important opportunities to minimize errors by implementing effective reporting schema with decision aids and reference ranges.

Laboratorians are familiar with Bayesian probabilistic reasoning. Errors in judgment, however, can be caused by biased estimates of a test's clinical sensitivity and specificity. George Bergus outlines some of these errors which must be avoided in future test evaluation research.

Tests based on known pathophysiologic relationships illustrate causal reasoning. Joseph Keffer presents excellent examples. Gordon Schectman presents examples of rule-based, decision-making aids that improve the intermediate outcome of serum cholesterol.

Relevance is frequently measured in dollars. Unfortunately the majority of research has confused cost and charge.[12] Future research must identify the differences. The definitions of cost and charge will be difficult. Until we discontinue the common error of assuming charge is an appropriate proxy for cost, however, we will not make

Studies (n)	Tests	Common? 4-10 S.D.	Special? >10 S.D.	Total PPM
Routine cuvette chem (136)	146,393	61	43	710
Electrodes (7)	21,208	0	0	0
Immunoassays (23)	10,320	6	5	1,066

Table 1. Differences Between Replicates

- Framing the clinical questions
- Pre-analytical variation
- Analytical variation
  - Common cause (Cva)
  - Special cause (outliers)
  - Statistical process control
- Analytical bias
  - Calibration
  - “Robustness”
  - “Detectability”
- Biological normal variation
- Pathological variation
- Probability and prediction (Bayes)
- Pathophysiologic interrelationships
- Preferences of those served
- Minimization of cognitive errors
- Meeting outcome expectations
- Appropriate financial accounting

Table 2. Elements of Medically Relevant Laboratory Performance Goals

good societal health decisions. Society will benefit when we develop good understanding of the direct fixed, stepped and variable costs for providing a given health benefit. The indirect cost must also be considered, but identified appropriately, i.e., the RIGHT accounting schema.

Relevance is a perception and therefore only has meaning from a specific viewpoint.[1,13] There are many stakeholders in the processes of both disease care and health promotion. Research must consider the viewpoints of the person-patient, provider, payor and the population (4 P's). Too many research efforts focus narrowly on the viewpoints of one or two stakeholders, i.e., 2 of the P's consider policy without input from the other 2 P's. Research must take an enterprise wide or society wide viewpoint and consider expectations of all 4 P's.

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