The Development of Measures of Outcomes
from a Clinical Laboratory Database

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Abstract: Dramatic changes are rapidly occurring in the health care industry. One force driving change involves the fact that the entity paying for health care services increasingly is not the direct user of those services. However, this new payer has needs beyond the requirements associated with routine delivery of services. The need to be able to measure provider performance and assess the value of those services is among the new payer needs. Measuring the outcomes of clinical practice is increasingly becoming a measure of the value and quality of the health care service.

Clinical outcomes involve linkages. Quality and value involve giving the right care to the right patient at the right time. Outcomes research involves identification of what works best for whom.

This paper will present definitions of outcomes research and analysis. It will also discuss the change in paradigm as laboratory medicine moves from systems of transactional delivery of service to managing the wellness of a population. The paper will conclude with two specific examples of outcomes measures derived from a laboratory data repository. These examples will involve identifying the best practice benchmarks and establishing measures of preventive health.

This paper presents two examples of outcomes measures that have been derived from clinical laboratory databases. One example is cited from the literature, while the other has been developed from a large relational database of clinical laboratory test results and patient demographic data. A brief discussion of outcomes is also presented.

As a background, clinical outcomes involve linkages. Specific conditions are linked to specific types of care for identifying what works best for whom. Outcomes have become important because delivery of health care will increasingly be measured upon value. Outcomes are the measure of value.

The health care delivery system is experiencing new challenges. We are challenged not only to provide the best care and treatment in response to illness; we are now challenged to more systematically prevent illness. Thus, the infrastructure of the health care delivery system is being transformed. Current health care systems have evolved so as to manage and respond to the consequences of disease prevalence within a population. As the dynamics of the health care reorganization progress, the system is being challenged to not only to respond to, but also reduce, the rate of illness within a population. Health care is being challenged to better manage wellness. Outcomes will be the engine as health care moves from transactional medicine to managing wellness.

The goals of outcomes research are to identify variations in patterns of care; evaluate costs of care; make decisions about resource allocation; assess quality of care. The tools of outcomes research are the tools

of total quality management:

- Observation
- Measurement
- Diagnostic Journey
- Remedial Journey
- Goals

Outcomes are measured as rates. An outcome always has a numerator and a denominator. Outcome rates must be constructed from explicit criteria that apply to specific conditions. Apples must be compared with apples to make meaningful decisions about benchmarks.

Two examples of laboratory based outcomes as contributions to outcomes initiatives are presented below:

- Analytical process
- Clinical Process

Outcomes Measure of an Analytical Process

This outcomes measure of an analytical process is taken form the Durand-Zaleski et al. (1993) article titled "Outcomes study of ordering patterns for tumor marker tests." The focus of their study was to establish measures in order to better manage the unnecessary use of laboratory tests, specifically, tumor marker tests. These investigators established measures that indicated:

- Requests for tumor markers accounted for 50% of all immunoassays
- Twenty-nine percent (50 / 170) physicians accounted for 80% of requests
- Laboratory test requisition was typical of most order forms in that test names were merely listed
- A separate booklet provided semi-quantitative information concerning the

clinical relevance of the assay
- Survey indicated that 50% of request lacked clinical justification

Researchers set out upon a diagnostic journey to find the root cause of the various measures of variation. They made some critical assumptions in that they recognized that physicians do not deliberately order the wrong test. Physicians, moreover, like most workers, do want to do the correct thing. Physicians, also as do most individuals, require real time process control feedback mechanisms in order to assuredly accomplish what is expected.

Analysis indicated that critical point to manage better feedback mechanism was at the time of the test request. Providing feedback at the time of the laboratory report was ineffective in changing ordering behavior. To accomplish this, the lab test requisition was modified. The requisition was changed from a standard form listing tests available to a matrix. In this matrix the target organ of concern was listed as column headings and the specific tumor marker of choice was listed as the row labels. This format formed a grid of squares. The boxes that matched the appropriate assay for the specific organ of monitoring remained clear. Boxes that associated inappropriate testing request were "blacked out" thus not permitting the inappropriate test for a particular organ of interest (Table 1).

What tools were used?

- Observation
- Measurement Pareto Analysis
- Assignable Cause Identification
- Fool-proof the system
- Measure the outcome by Cost of Poor Quality (COPQ)

OUTCOME		
	BEFORE	**AFTER**
Test Requests/Requisition	2.5	1.9
Max	11	7
Min	2	1
SD	2	2
COPQ		*$50,000/YR*

Table 1. Effect of changing requisition form on test ordering.

Specimen	Date	Ratio Result	Glycohgb Result	Sex	Age, Years
123456	1/1/96	7.3	10.9	M	45
234567	½/96	6.3	8.4	M	53
345678	1/3/96	6.4	4.9	F	71
456789	1/4/96	7.1	7.6	F	43
567890	1/5/96	8.4	10.9	M	
678901	1/6/96	5.9	8.9	F	22
789012	1/7/96	6.0	6.9	F	29
890123	1/8/96	4.4	7.1	F	65
901234	1/9/96	5.9	9.1	M	22

Table 2. Laboratory results aggregated within a population.

Outcomes Measurement of a Clinical Process

As discussed previously, transactional medicine is evolving to management of wellness. Wellness management involves the delivery of health care management not only to individuals in response to progressed illness, management of wellness very simply involves scheduling. Successful management of wellness of a population involves an integrated health care delivery system that appropriately screens individuals for the early detection of disease, effectively diagnoses illness and then effectively monitors therapy. The following demonstrates the evolution from transactional care to wellness management:

A lab request frequently initiates the process:

     From: Dr Jones
     To: The lab
     Re: Do These Tests
     Date: N
     HDL, Glycohgb, Lyme, ANA

A lab report is the response:

From:	The lab
To:	Dr Jones
Re:	Specimen 123456
Date:	N + 1
HDL	7.3
Glycohgb	10.9
Lyme	Neg
ANA	Neg
Other	

But within the context of a population individual lab results may be aggregated in a table (Table 2).

The data in a table (Tables 3 and 4) can provide more meaningful information as a distribution of results. An individual result is assessed in context to its relative position within a common population's distribution of results. What is the frequency of results within the risk levels of this measure of disease?

Then the data can then be viewed in the context of a relationship of related results (Table 5).

A set of patterns can then become apparent for the population (Table 6).

The pattern evolves to identify the proportion of individuals within the population that have the poorest measure of glycemic control and the highest risk for heart disease (Table 7 and 8).

A trend is suggested. How do individuals progress into the upper right quadrant of highest risk. Individuals for the most part are not born with these measures suggesting high risk. Individuals progress towards these high risk conditions over a lifetime. What is the direction of this progression? Is it clockwise, or in a counter clockwise direction, or is it a straight-line path? Is

there more than one mechanism (Table 9)?

In summary, outcomes measures are derived from data, and these data are available from many lab sources. The discipline of outcomes will become an important management tool of the future. The tools are changing. Increasingly an important tool of health care will be the tool used for the analysis of populations of data, i.e., the personal computer.

Selected References

1.   United Health Care Corporation. The Language of Managed Health Care and Organized Health Care Systems. United Health Care Corporation, Opus Center, Minnetonka, MN.

2.   Guadagnoli E, McNeil BJ. Outcomes research: Hope for the future or the latest rage? *Inquiry*. 1994;31:14-24.

3.   Epstein AM. The outcomes movement - Will it get us where we want to go? *N Engl J of Med.* 1990; 323:266-270.

4.   James, BC. Quality improvement in the hospital: Managing clinical processes. *The Internist*. 1993; 34:11-17.

5.   Laffel G, Blumenthal D. The case for using industrial quality management science in health care organizations. *JAMA*. 1989;262:2869-2873.

6.   Juran J, Gryna FM. Juran's quality control handbook. 4th edition. McGraw-Hill Book Company. New York, NY. 1988.

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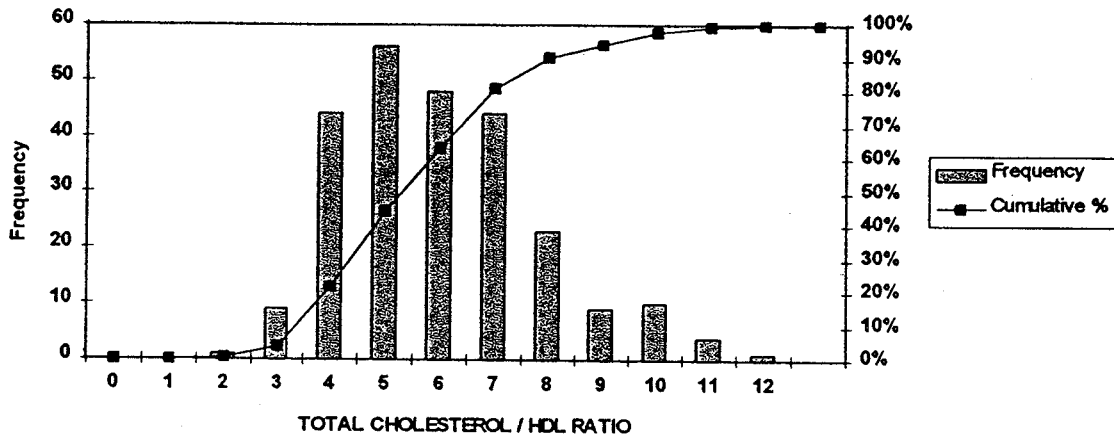
DISTRIBUTION OF CHOLESTEROL HDL / RATIO RESULTS

Table 3. Distribution of Cholesterol/HDL Ratio results.
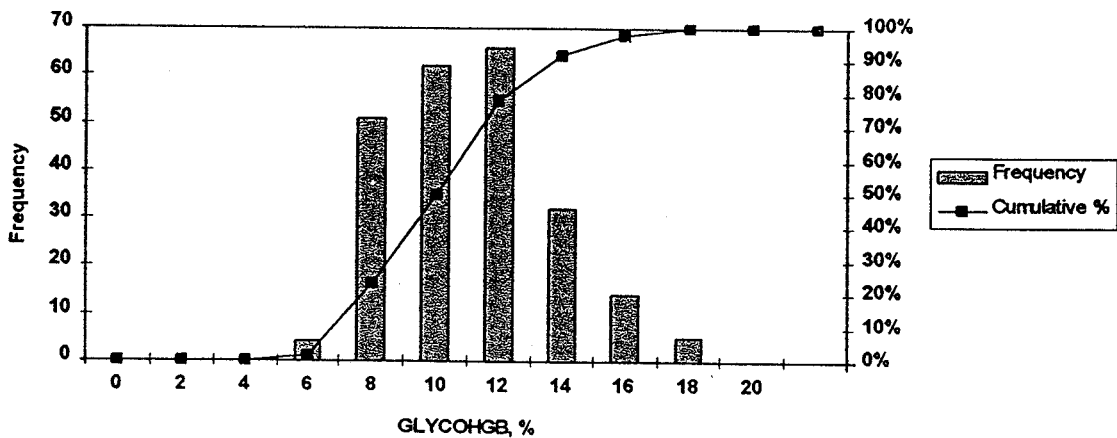
DISTRIBUTION OF GLYCOHEMOGLOBIN RESULTS

Table 4. Distribution of glycohemoglobin results.

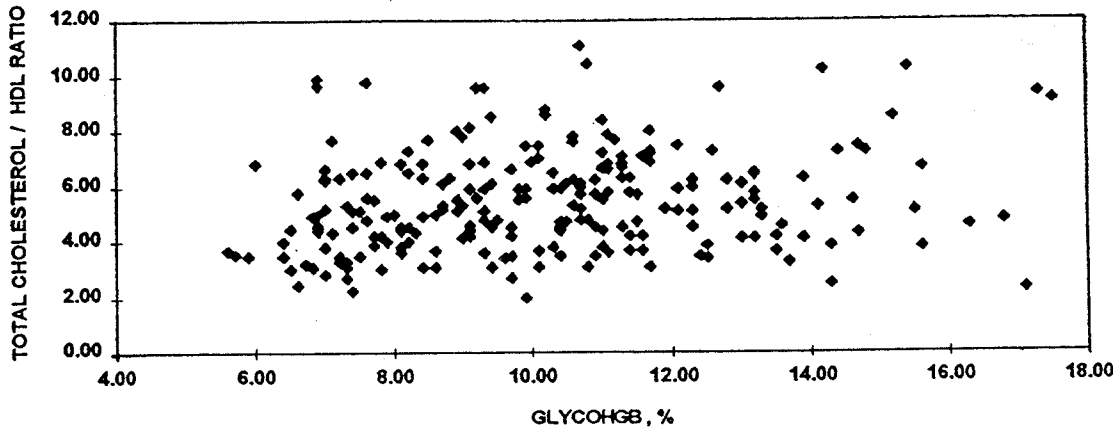## GLYCOHEMOGLOBIN vs TOTAL CHOLESTEROL / HDL RATIO

Table 5. Glycohemoglobin vs Total Cholesterol/HDL Ratio
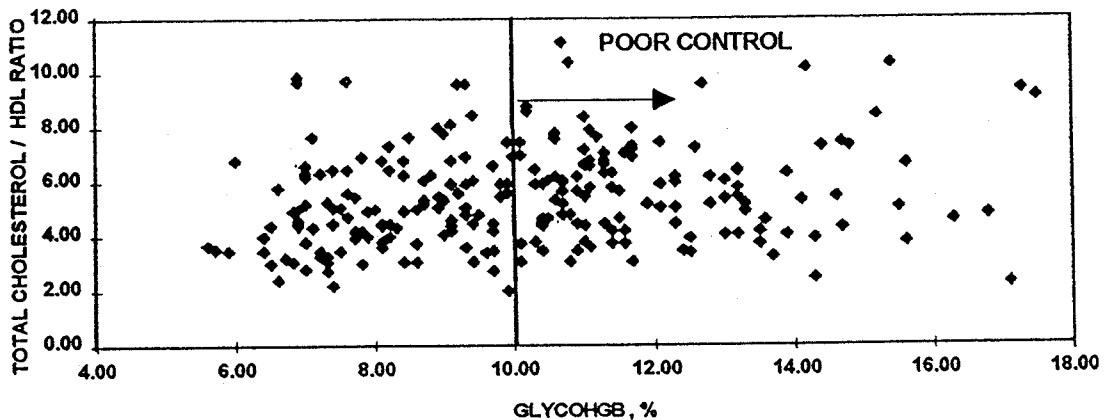
GLYCOHEMOGLOBIN vs TOTAL CHOLESTEROL / HDL RATIO

Table 6. Population in poor control.
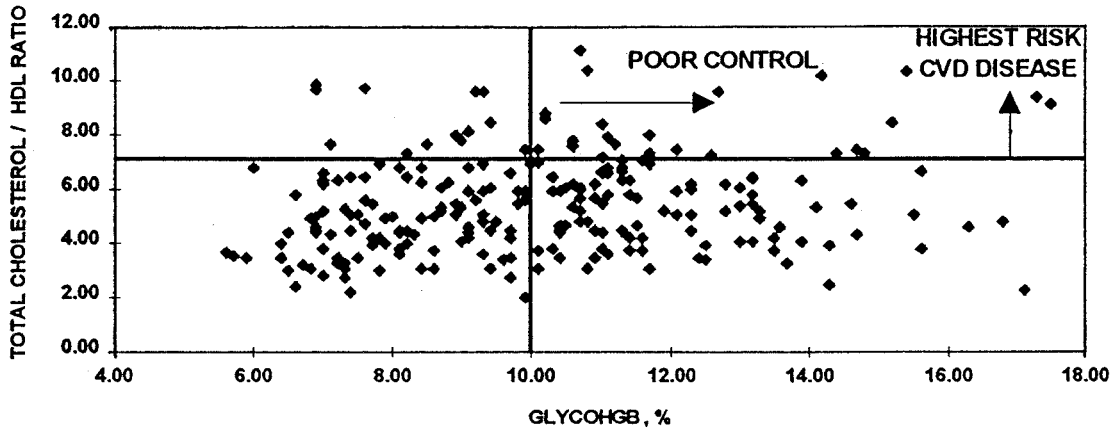
GLYCOHEMOGLOBIN vs TOTAL CHOLESTEROL / HDL RATIO

Table 7. Population at highest risk for heart disease.

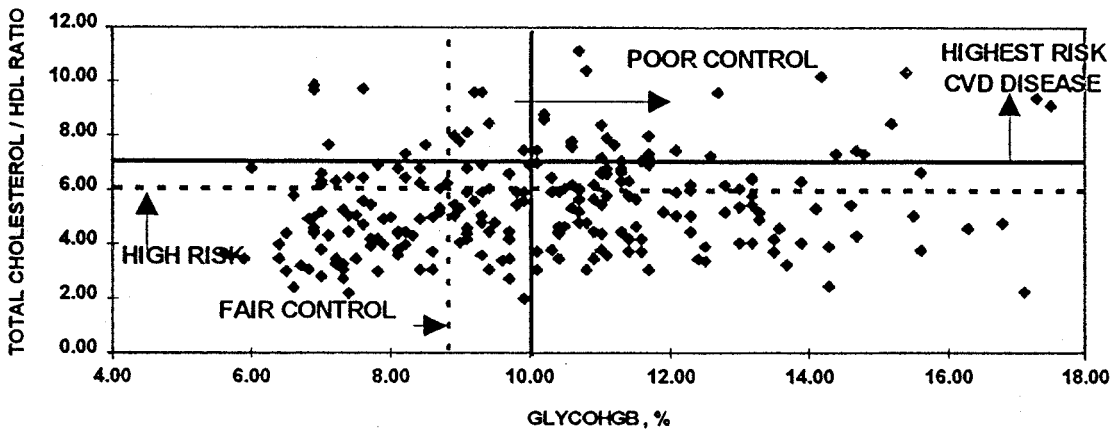## GLYCOHEMOGLOBIN vs TOTAL CHOLESTEROL / HDL RATIO
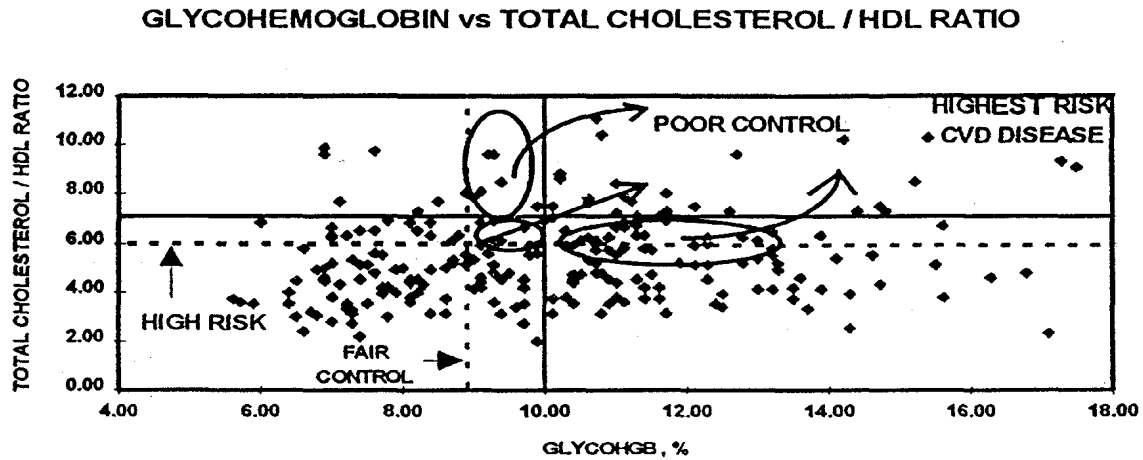

Table 8. Population in fair control.

GLYCOHEMOGLOBIN vs TOTAL CHOLESTEROL / HDL RATIO

Table 9. Possible directions toward high risk of CVD over life time.

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10.   Durand/Zaleski I, Rymer JC, Roudot-Thoraval F, Revuz J, Rosa J. Reducing unnecessary laboratory use with new test request form: Example of tumour markers. *The Lancet*. 1993;342:150-152.

11.   Garnick DW, Fowles W, Lawthers AG, Weiner JP, Parente ST, Palmer RH. Focus on quality: Profiling physicians' practice patterns. *Journal of Ambulatory Care Management*. 1994;17:44-75.

12.   Sloane MD. How to lower health care costs by improving health care quality. Results-based continuous quality improvment. ACQC Press. 1994.

Suggested Texts and Journals

1. "The 1993-1994 Medical Outcomes & Guidelines Source book. A Progress Report and Resource Guide on Medical Outcomes Research and Practice Guidelines: Developments, Data and Documentation." Published by Faulkner and Gray (1993).

2. "Report on Medical Guidelines & Outcomes Research" published by Capitol Publications Inc., 1101 King St., Suite 444, Alexandria, Virginia, 22314-2968,(800)655-5597.

3. "Outcomes Measurement and Management" published by The Zitter Group, 90 New Montgomery Street, Suite 820, San Francisco, California, 94105, (415)495-245.

4. "Medical Outcomes & Guidelines Alert" published by Faulkner and Gray Health care Information Center, 1133 Fifteenth Street, NW, Suite 450, Washington, DC, 20005 (215)967-7060.