A New Arena for Clinically Related Performance Goals: The Case of Cholesterol Management... or Is the Laboratory Responsible for Ensuring Quality Patient Care?

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Abstract: The treatment of hypercholesterolemia relies heavily upon laboratory data for proper case selection and management. Recently, the precision and accuracy of lipid testing has markedly improved, and further advances in this direction are likely to be dwarfed by the large biologic variability inherent in lipid measurements. Despite these improvements in laboratory testing, however, most individuals with hypercholesterolemia are not receiving proper therapy according to current guidelines. Barriers identified for poor physician adherence to recommended guidelines for hypercholesterolemia management include I) limited physician awareness of current recommendations; ii) lack of physician knowledge concerning proper use of drug therapy; and iii) the absence of health care delivery systems which facilitate lipid disorder management.

To overcome these barriers, more medically relevant performance goals may be sought to extend the influence of the laboratory into the clinical setting. Using existing computer technology, specific tasks for the laboratory to improve patient care may include I) sending laboratory-generated reminders to the clinician and/or patient to encourage cholesterol screening when appropriate; ii) reporting, along with cholesterol levels, the recommended LDL cholesterol goals appropriate for that specific patient, with a comment regarding whether drug therapy should be considered; iii) suggestions of specific therapeutic options for the clinician if the lipid profile had not reached optimal levels; and iv) close collaboration with health care delivery teams in the managed care setting to improve the turnaround time (speed) and costs of laboratory testing.

By assuming a more prominent role in the clinical setting, the laboratory may help to overcome existing barriers to the implementation of lipid-lowering therapy, thereby directly improving patient care.

Within the past two decades, knowledge that low density lipoprotein (LDL) cholesterol lowering correlates closely with reduced coronary heart disease (CHD) morbidity and mortality heralded an era where accurate lipid measurements suddenly became necessary to identify and treat individuals with lipid abnormalities.[1] Randomized studies

documenting that interventions to reduce LDL cholesterol significantly reduced coronary heart disease events confirmed initial epidemiologic associations,[2] and encouraged the formation of the National Cholesterol Education Program (NCEP) to develop national guidelines.[3,4] These practice guidelines recommended cholesterol screening for all adults, and suggested management algorithms to assure that patients were appropriately diagnosed and treated to achieve specific LDL cholesterol goals. Target LDL cholesterol goals vary for each patient, depending upon the number of cardiovascular risk factors present and the overall heart disease risk.

For meeting the performance goals outlined by the NCEP, accurate and precise laboratory tests are necessary to reduce the potential for incorrect classification of hypercholesterolemia.[5] In particular, accurate LDL cholesterol measurements are essential, as successful therapy hinges upon the ability of the patient to reduce LDL cholesterol below a specific level.[4] Because LDL cholesterol calculations depend upon total cholesterol, triglyceride and high density lipoprotein (HDL) cholesterol assays,[6,7] accurate and reliable measurements of all these lipid measurements are necessary.[8] Several publications have highlighted the importance of accurate measurements and pointed out the consequences of poor test precision and accuracy.[5,8-11] As a result, the Adult Treatment Program Laboratory Standardization Panel concluded that total cholesterol accuracy and precision should be reduced to less than 3%.[12]

With rapid technical improvements in commercially available autoanalyzers, accuracy and precision standards mandated by the Laboratory Standardization Panel appear to have been met. Recent papers report precision data well within 3% for total cholesterol, and also less than 3% for triglycerides and HDL cholesterol.[13,14] As a result of these improvements, the LDL cholesterol calculation also has improved accuracy and precision.[14] Because the large biologic variability inherent in most lipid measurements remains unchanged, total test variability will not be appreciably improved from further refinements in cholesterol, triglyceride and HDL cholesterol assays.[8]

Despite technical improvements in lipid testing, achievement of LDL cholesterol goals through appropriate treatment is currently substandard, suggesting that clinicians may not be using these tests properly.[15] Although at least 50% of patients with coronary heart disease will benefit from cholesterol lowering medications, surveys show that only between 8 and 30% receive it.[16-18] Therefore, modern advances in laboratory testing to improve test precision and accuracy have not correlated with the ability of the clinician to correctly use this laboratory information to implement NCEP guidelines.

For satisfactorily implementing hypercholesterolemia management guidelines, the question arises as to whether the laboratory should directly assist the clinician to properly use results of cholesterol testing. In other words, does the domain of the laboratory extend beyond ensuring adequate test accuracy and precision, particularly when the test is being incorrectly used by the clinician? Should laboratory performance standards include the responsibility to ensure the presence of a dialogue between laboratory and clinician to prompt the clinician to use laboratory information wisely? Should laboratory personnel provide guidance to the clinician to increase the likelihood that cholesterol testing is utilized correctly, leading to cardiovascular risk reduction and improved patient care? Currently, most laboratories only ascertain that each test is performed with appropriate

accuracy and precision, and report values along with appropriate normal/abnormal values for a specific reference population. Some laboratories have also included a table reviewing NCEP recommendations for total cholesterol, HDL cholesterol, triglycerides, and LDL cholesterol.

A ready familiarity with computerized processing of laboratory data and automated test reporting enables the laboratory to consider novel approaches to influence the clinician. Computerized information retrieval and display systems, like reminder systems, have been shown to have an impact on physician behavior. For example, introduction of a clinician's workstation to facilitate data retrieval resulted in a 32% reduction in laboratory testing charges in two bone marrow transplant units.[19] Similarly, physician test-ordering behavior can be improved through concurrently providing displays of past test results,[20] probability estimates of obtaining an abnormal result,[21] or test charges.[22] The potential for the computer to influence physician behavior has been recently reviewed.[23] These studies indicate that creative uses of computer technology can enhance clinician interpretation and implementation of laboratory data.

As the computerized medical record and comprehensive clinical databases become increasingly utilized, information systems are being refined which fully integrate all clinical data, including that obtained from the clinical examination and laboratory. With this technology, the potential of the laboratory to provide powerful decision support for the clinician becomes very realistic. For example, incorporating into the clinical database the patient's disease profile, risk factor status, and drug regimen allows an assessment of whether LDL cholesterol values have reached goal levels, and makes possible automated suggestions regarding further therapy. Such information can be used either by the clinician or by allied health professionals to re-evaluate and modify therapy until goal lipid values are finally achieved. This level of feedback has been demonstrated to be helpful in improving cholesterol management.[24]

Computerized reminders and/or feedback to improve hypercholesterolemia management and/or screening could include:

1) Prompts for cholesterol screening if the patient has not had a cholesterol measurement performed within the past 3 years. These reminders, generated for the clinician and/or the patient, are likely to improve screening rates and increase the number of patients receiving adequate treatment.

2) Interpretation of the triglyceride, HDL and LDL cholesterol values within the context of the NCEP guidelines, suggesting whether diet and/or drug therapy should be considered for the patient. The report could evaluate the specific risk factor status of the individual and advise the clinician whether goal levels have been achieved. This type of report would allow the clinician to apply appropriate treatment guidelines to his patient without memorizing all aspects of the guidelines.

3) Treatment recommendations including whether diet or drug therapy is appropriate, and specifying which drug or drugs would be reasonable considering the clinical setting. To implement this approach, clinical patient information and simple treatment algorithms could be

SMITH, ALCUS ID # 318 Age 61.9 Drug Trial # 41

Hypolipidemic Drug Therapy (Daily dose in grams, mg, capsules, or tablespoons)		
Colestipol:	Niacin: 1500	Gemfibrozil:
Psyllium:	Levastatin: 40	Fish Oil:

Major Illness		Other Risk Factors	
CHD:	No	Gender?	Yes
Diabetes:	No	Obese:	No
Htn:	Yes	Smoker?	No
PVD:		Fhx CHD:	Yes
CVA:		BOG LVH:	

Risk Factor Totals: 3
Age Adjusted CHD Risk/10 yrs:
No Risk Factors: 10.6%

	Date of Last Lipid Profile	Number of Profiles	TC	TG	HDLC	LDLC	LDL/HDL	CHD Risk/10 yr
Baseline		2	286	126	35.5	225	6.33	26.8%
Drug Rx	12/8/92	3	241	139	36.0	177	4.92	22.8%
Change from Baseline			-16%	10%	1%	-21%	-22%	-15%

Absolute Risk Change: -4.0%

QA Corner

Yearly Drug Costs: $906 Rx too costly; Above 80th% ($444)

Cost per Unit Change in LDL/HDL Ratio: $643 Rx NOT Cost-Effective! Above 80th% ($462)

Keep Trying! Therapy has NOT achieved LDL goals or reduced LDL/HDL ratio by >30%.

Figure 1. Example of patient report comparing baseline results with results obtained during treatment.

programmed into the computer to provide this information to the clinician.

At the Medical College of Wisconsin and the Milwaukee Department of Veteran Affairs Medical Center, a computerized database integrating laboratory and pharmacy data with information derived from the clinical examination has been in existence since 1988 for use in the Lipid Disorder Treatment Program, and allows a comprehensive computerized assessment of patient progress. The database formats a report comparing baseline lipid profiles with those obtained during treatment and prepares a report available to the clinician as the patient is seen at the clinic visit (see Figure 1). The tabular printout allows the clinician to determine effectiveness of current drug therapy by comparing the mean of recent lipid values obtained on the current regimen with baseline values. A summary of risk factors is compiled to allow the clinician to quickly assess CHD risk, which is also computed according to risk estimates from Framingham.[25] Brief summary statements are provided to the clinician assessing whether NCEP goals have been achieved for that particular patient, describing whether therapy has been effective, and whether the response for that particular patient justifies the cost of therapy, in comparison with cost-effectiveness data from patients of similar risk status in the clinic. A similar report is prepared for the patient, describing his/her progress in simple terms.

Developing this system serves several goals. First, it enhances the efficiency of the clinic visit, allowing the clinician to spend more time discussing current patient concerns, rather than spending time locating important data scattered

in different places in the chart. Second, it automatically provides for storing clinical data which can be used to detemine the effectiveness of therapy administered within the clinic. This clinical data may also serve important quality monitoring functions. Third, it provides a structure to assist physician extenders in taking a more active role in clinical management of disease by using the computerized decision support as an initial basis for clinical decision-making. Fourth, it enhances communication with the patient through a computer generated personalized report specific for the patient discussing his/her progress.

At our own site, this computerized system has been effectively used in some of these areas. We have evaluated the effectiveness of cholesterol-lowering drug therapy administered in the clinic setting,[26] assessed our own ability to achieve defined lipid goals among our patients treated with cholesterol-lowering drugs,[27] evaluated the ability of allied health professionals to use this system effectively to implement cholesterol-lowering therapy, thereby serving as cost-effective "physician extenders",[28] and used this computerized infrastructure to test alternative approaches to improve administration of cholesterol-lowering drug therapy.[29,30]

Additional support that the laboratory could provide to improve clinician performance includes rapid performance of laboratory tests (within minutes or hours) so that the clinician can review results with the patient at the same visit, rather than scheduling a second clinic visit to discuss results and consider therapeutic changes. In addition, if screening total cholesterol and HDL cholesterol values are not normal, then the laboratory could consider performing other lipid tests automatically (perhaps using a direct LDL cholesterol assay if the patient wasn't fasting), thereby providing more information to the clinician and prompting further action if levels are undesirable.

In conclusion, by assuming a more prominent role in the clinical setting, the laboratory may help to overcome existing barriers to implementing lipid-lowering therapy, thereby directly improving patient care. The use of computer technology offers an ideal avenue for this process to proceed. In addition, this approach may have applicability to other areas in clinical medicine which rely heavily on laboratory support for therapeutic decision-making.

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