One State's Approach to the Regulation of Cholesterol Screening

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Synopsis

In 1989 Maryland became the first State to enact legislation, separate from existing laboratory law, authorizing a comprehensive, self-supporting program to regulate cholesterol screening conducted outside of laboratories and physicians' offices.

This program requires a State permit to conduct cholesterol screening and oversees regulations that define minimum standards of quality assurance in such areas as personnel training, analytical quality control, counseling, and patient referral.

This paper is a review of some of the political and technical problems that Maryland faced and solved in developing and implementing an effective regulatory program.

BEFORE JULY 1, 1989, Maryland's laboratory law effectively prevented cholesterol testing outside of laboratories and physicians' offices by prohibiting a person from offering or performing a test for cholesterol unless that person either held a permit to operate a medical laboratory or held a license to practice medicine and performed in-office tests limited to his or her own patients (*1*).

By the spring of 1988, however, following the development of portable instrumentation and increased promotional efforts by instrument manufacturers and various retailers, nonlaboratory-based (off-site) public cholesterol screenings were being openly conducted in spite of existing Maryland law. Public and private interest groups also began to press the Maryland State Department of Health and Mental Hygiene (MSDHMH) to seek an amendment to existing laboratory law that would authorize off-site cholesterol testing.

This placed MSDHMH in a dilemma. The department was actively supporting programs to reduce coronary heart disease and was aware of evidence showing that cholesterol lowering not only reduces the risk of coronary heart disease but also provides important economic benefits for young and middle-aged adults, for individuals with severely elevated cholesterol, and for those with additional coronary risk factors (*2, 3*). At the same time, the department learned, while holding a number of training workshops on cholesterol testing in June 1988, that poorly trained personnel and inaccurate analytical instruments were misclassifying the cholesterol levels of many of Maryland's citizens. A report by the Inspector General of the Department of Health and Human Services and a number of scientific articles supported MSDHMH's workshop findings (*4–8*).

In July 1988 MSDHMH decided that its only acceptable option was to seek specific legislation allowing cholesterol testing outside a laboratory but, at the same time, sufficiently regulating that testing to effect both accurate results and reliable reporting and referral. What follows is an explanation of why and how Maryland went about developing and implementing this regulatory program.

The Legislative Initiative

Initially, the department had to decide whether to attempt regulating off-site cholesterol testing through the State's existing laboratory law, or through new legislation. MSDHMH decided on new legislation for several reasons. First, the Department wanted to limit off-site testing to cholesterol screening. Requiring that a law be passed before any clinical test can be conducted outside a medical laboratory sets a tough precedent for future off-site testing requests.

Second, the department felt that because Maryland's existing laboratory law was not intended to regulate out-of-lab testing, it might not provide the authority needed to regulate off-site testing. This very question eventually was raised in Florida, where it resulted in litigation (*9*).

Third, the legislative process requires that each bill introduced be accompanied by an estimate of its fiscal

impact. This provides a formal mechanism to request and obtain resources to implement a bill after it becomes law.

Legislation is usually enacted and implemented in response to problems that have become political issues. An issue that gains status on the political agenda does so by virtue of the conflict associated with it. When the conflict is considered unimportant, it remains outside the realm of politics and hence of government. In 1988, out-of-lab cholesterol testing was not yet seen as a problem by the general public. Before the issue could be addressed politically and an attempt made to solve it through legislation, the department first had to inform key legislators that there was a problem in that incorrect cholesterol measurements often misclassify people as to their risk of coronary artery disease, making an incorrect test worse than no test.

Most legislators, the public, and many health care providers incorrectly viewed cholesterol "screening" as a simple analytical procedure that could be performed easily and properly by someone with little or no training. As part of the educational process needed to alter this belief, MSDHMH chose to entitle the legislation "Cholesterol Testing" rather than "Cholesterol Screening" because neither the public nor most health care providers associate the same need for quality control and quality assurance with "screening" as they do with "testing."

Throughout the legislative process there was a lack of understanding on the part of some legislators, the public, and even some health care providers as to why off-site cholesterol testing should be regulated. They viewed it as a simple, quick procedure and had no concept of the many different parameters involved in obtaining accurate, reliable cholesterol measurements.

The biggest fear of a number of legislators was that the department would over-regulate the testing, push its cost way up, and make it less available to the public. At one committee hearing, a legislator boldly announced that he just had his cholesterol measured and "was still alive." The department expended much effort trying to get legislators to understand that an unreliable cholesterol measurement could be worse than no test result. This approach did not prove very successful. MSDHMH was more successful emphasizing the fact that no off-site cholesterol testing would be allowed unless the proposed bill became law because existing laboratory law prohibited off-site cholesterol testing.

Eventually, broad support for the legislation came from many legislators, nonprofit health care organizations, and local health departments. Strong support was provided by academic and clinical experts on cholesterol testing, the Maryland affiliate of the American Heart Association, the Maryland High Blood Pressure Commission, and MSDHMH for the section in the proposed bill that called for "...regulations that assure the citizens of this State that cholesterol testing conducted outside a permanently located medical laboratory meets appropriate national standards of quality assurance" (*10*).

Various interest groups lobbied for a number of amendments to the original bill. These were accepted by MSDHMH as compromises that would help assure the bill's passage. Legislators supported requirements that persons conducting off-site cholesterol testing first obtain a State permit to operate, and that sufficient fees be charged to make the regulated industry cover the full cost of the regulatory program.

Analytical instrument manufacturers lobbied for an amendment that specifically prohibited any regulation that would require cholesterol testing personnel to be certified in a medical laboratory specialty. County and local health departments sought a section that allowed them to obtain MSDHMH's approval to perform off-site cholesterol testing without a permit, if they met the same standards as persons holding a permit.

These compromises paved the way for broad support from elected leaders and politically active special interest groups and led to fairly smooth passage of the bill, which became law on July 1, 1989.

Drafting and Promoting Regulations

In the fall of 1988, MSDHMH formed a Cholesterol Advisory Panel to help the department draft regulations that would be required under any cholesterol testing law. Eleven panel members, representing private industry, clinical and laboratory scientists, several nonprofit public health organizations, and MSDHMH, met monthly from November 1988 through March 1989.

The major problems that were solved in developing and adopting effective cholesterol regulations included appropriate technical standards, an equitable fee schedule, and sufficient public comment and acceptance of the proposed regulations to assure their promulgation and implementation.

Technical standards. A paragraph in the law requiring that regulations meet national standards greatly simplified the development and justification of technical standards. Most of the standards dealing with quality assurance and analytical quality control were based on recommendations of the National Cholesterol Education Program (NCEP) (*11, 12*).

Maryland's regulations for off-site cholesterol testing start off with administrative sections that cover definitions, MSDHMH regulatory responsibilities, and the issuance of permits (*13, 13a*). Since many of the per-

Table 1. Projected revenue (fees) from State regulation of Maryland's out-of-laboratory cholesterol testing for first 5 years

Year	Number of permits issued			Application fees[1]	Permit fees	Total fees
1	[2]30	[3]5	[4]5	$2,000	$23,000	$25,000
2	35	6	6	$2,350	$27,100	$29,450
3	40	7	7	$2,700	$31,200	$33,900
4–5	40	8	8	$2,800	$32,800	$35,600

[1]At $50 per permit application.
[2]At $500 for fewer than 6 testing sites and fewer than 21 testing events, where each day of testing is 1 event.
[3]At $700 for 6–10 testing sites and 21–40 testing events.
[4]At $900 for more than 10 testing sites or more than 40 testing events.

Table 2. Projected costs of regulating Maryland's out-of-laboratory cholesterol testing for the first 5 years

Cost	Year 1	Year 2	Year 3	Year 4	Year 5
Salary[1]	$24,120	$25,525	$27,055	$28,691	$30,272
Other[2]	$5,820	$2,727	$2,823	$2,922	$3,024
Totals	$29,940	$28,252	$29,878	$31,613	$33,296

[1]1 laboratory scientist.
[2]Office supplies, mileage, communications.

sons who would be applying for, or working under, a permit would not have formal education or experience in clinical testing, 28 definitions, ranging from "analyte" and "calibrator" to "proficiency testing" and "reference laboratory," were needed to facilitate a basic understanding of terminology used throughout the regulations. The MSDHMH's regulatory responsibilities include site inspection and approval, permit issuance, billing and fees collection, monitoring proficiency testing, documenting regulatory noncompliance, and initiating adverse actions. Except for an MSDHMH-approved service provided by a county or local health department, all off-site cholesterol testing in Maryland requires a permit.

The regulations' technical sections begin with standards on personnel training. These include general requirements for all employees of the permit holder who work at the testing site and specific minimum requirements for people serving as phlebotomists, analytical system operators, and counselors. General training must include such topics as confidentiality of test results and proper disposal of special medical waste. Phlebotomists and analytical system operators must have basic training in safe techniques for infection control. Instrument operators must also receive 4 hours of classroom discussion on the instrument they will operate and its quality control, 3 hours of class-supervised cholesterol testing, and completion of at least 25 supervised tests in the field. Employees who provide counseling or educational materials to testees must receive a minimum of 8 hours of defined counselor training that covers the NCEP's referral process and step 1 diet (*11a*).

Quality assurance standards include requiring a standard operating procedure manual covering all training, testing procedures, and service activities. The regulations also contain requirements for pre-field evaluation of analytical systems (instruments) and in-field quality control. Standards of in-field quality control include testing two levels—200 and 240 milligrams per deciliter (mg/dl)—of control samples twice at the beginning of each day, and once after every 20 specimens. The regulations specify when quality control samples must be retested and when test specimens must be remeasured.

Other regulations require that blood be collected from testees in the sitting position, and that all personnel handling venous or capillary blood wear protective eyewear and clothing. Proficiency testing standards require daily split-sample testing in which a permit holder compares cholesterol test results obtained using each analytical instrument with results obtained by an approved reference laboratory.

Standards for field testing sites include basic space and environmental requirements, water and telephone access requirements, and specific requirements for food handling establishments. Additional regulations set minimum standards for releasing and reporting test results, and ban rebates, fee-splitting, and certain discounts.

A last regulation defines which testees must be referred for followup medical care and requires each permit holder to maintain and provide a list of local health organizations or institutions willing to accept referred persons.

Equitable fee schedules. Under the law, MSDHMH must set and collect sufficient fees to cover the full cost of administering the regulation of off-site cholesterol testing. There were two trains of thought taken into account when the program fees were set. The first was that permit holders who conduct more testing should shoulder a greater portion of the regulatory cost. The second was that fees should be sufficiently high so that few permits will be issued to permit holders who rarely conduct testing and who are much less likely to meet minimum standards of quality assurance and quality control.

This thinking, together with the requirement that fees cover costs, led to the projected fee schedule in table 1. Initial and renewal permit applications require a $50 fee. Annual permits, once approved, entail a $500,

$700 or $900 fee. The sliding scale for the annual permit fee is based on both the number of testing events and testing sites. The number of sites has a direct effect on the cost of the regulatory program because more sites mean more site inspections. The number of testing events has an effect on the permit holder's profit and ability to pay regulatory fees. For-profit permit holders can reduce costs per test and increase profits by holding more testing events. Non-profit permit holders usually hold only a limited number of testing events. Projected program costs, presented in table 2, consist of the salary for one public health laboratory scientist, who must implement and maintain the program, and the operating expenses of printing, office supplies, mileage, telecommunications, and postage.

Public comment and acceptance. The initial regulatory proposal was published in the Maryland Register on June 30, 1989 (*13*). A formal public hearing was held on August 10, 1989. The hearing process and 30-day written comment period yielded 39 pages of public comments which required 74 pages of responses by MSDHMH. All commentators were generally in favor of the proposal, its intent and purpose. Most comments fell into one of two groups, those that claimed permit fees were higher than necessary and those that took issue with various proposed minimum standards of quality assurance.

MSDHMH was unable to set lower permit fees because the law mandated a budget-neutral regulatory program. At least 40 permits would have to be issued before MSDHMH would break even the first year. Projected program costs could not be reduced because 90 percent were associated with the salary of its one employee. If program fees exceeded program costs after the first year, however, MSDHMH promised to amend the regulations to allow a lower-priced community-service permit. Such a permit could be issued to a non-profit permit holder who provides cholesterol testing free of any charge or testee donation and who limits testing to such noncommercial settings as churches, neighborhood recreation centers, and community agencies.

The proposed quality control standard that drew the largest number of technical comments from the public requires that control serum pools at two levels, near or bracketing the 200 and 240 mg per dl decision values, be run after every 20 test specimens. The regulated industry claimed that this NCEP recommendation was overly burdensome. The members of MSDHMH's Advisory Panel and other experts who presented testimony at the public hearing were strongly in favor of retaining this standard, however. It was retained for a number of reasons.

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First, as a recommendation of the NCEP, it was considered a national standard. Second, permit holders using portable analytical systems under field conditions would be subject to lower quality control standards than hospital and independent medical laboratories using more dependable instruments under more controlled conditions if the standard were omitted or reduced. The department could not justify reducing the standard because portable instruments exhibit different degrees of accuracy (*5–8, 14*). Third, large-scale public screening efforts, such as those conducted by Bachorik and coworkers, have not been hindered by adherence to the quality assurance protocols recommended by the NCEP (*5*).

The requirement that each new instrument be evaluated before it could be used in the field also drew many comments. Maryland's Advisory Panel felt that prefield evaluation was important because some portable instruments were shown to exhibit bias and lack of precision (*14*). Under Maryland's regulations, prefield evaluation of an instrument may be conducted either by the manufacturer or a licensed medical laboratory. In either case, prefield evaluation must provide an instrument purchaser with written documentation that a new instrument demonstrated acceptable performance within the quality control limits established for that instrument. This evaluation must employ samples near the 200 and 240 mg per dl decision levels and traceable to the National Reference System for Cholesterol Measurements established by the Centers for Disease Control. Since several analytical systems show greater imprecision when testing patient serums, compared to pooled serums (*14*), the department is presently considering an amendment to this regulation. The amendment would require actual patient specimens to be included as part of any pre-field evaluation.

Many other comments on the initial regulatory proposal, including constructive suggestions for personnel training, operating analytical systems, other aspects of quality control, counseling, and referral, were accepted by MSDHMH and were printed as a reproposal in the

Maryland Register on November 17, 1989 (*13a*). The 30-day reproposal comment period produced a single page of comments, none of which were new or had not been responded to earlier. The drop in comments from 39 pages to only 1 page tended to show that public concern had been adequately heeded by the department. The regulations took effect in February 1990, approximately 20 months after MSDHMH began seeking regulatory authority.

Program Implementation

Application process. Application forms for a cholesterol testing permit were developed 6 months before the regulations were promulgated to allow time for the forms to be revised before being used. It also allowed MSDHMH to begin distributing permit applications before the regulations were formally promulgated. As a result, MSDHMH had additional time to review applications and consult permit applicants before the regulations took effect.

Presently, the permit application is an eight-page form that basically outlines the regulations. As potential permit holders fill it out, they must check off whether they are willing and able to meet the regulatory standards. This brings to their attention such requirements as personnel training, medical waste disposal, proficiency testing, counseling, and in-field documentation requirements at the very beginning of the permit application process.

During the year that a permit is in effect, a permit holder must submit the date and location of each testing event to MSDHMH at least 14 days before the event takes place. After approval is granted, the department issues a written notice to the permit holder. This notice of approval must then be publicly posted at the testing site throughout the testing event.

Split-sample proficiency testing. Permit holders are required to check the measurements of their instruments against those of a reference laboratory on a daily basis. Daily split samples for each instrument often prove difficult to obtain from staff members or testees. MSDHMH helped solve this problem by asking several large reference laboratories in the State to provide split samples to permit holders. Regulatory standards say no more than 20 percent of all samples tested can vary more than than 10 percent between pairs of split samples for each instrument over 10 consecutive testing days. The reference laboratories provide MSDHMH with the true split-sample test results, which are then used by the department to conduct regulatory spot-checks in the field and to review all split-sample results on a quarterly basis.

Conclusions

Maryland's experience in developing and implementing a comprehensive program to regulate out-of-laboratory cholesterol testing has shown that such a program can be effectively implemented through statutory and regulatory means without imposing an undue fiscal burden on either the regulated industry or a State's citizens. Some of the technical standards required under Maryland's law and regulations may appear rigid, but they are national standards that are being implemented across the country. Maryland's cholesterol testing law and regulations are now being reviewed as possible models for similiar programs in other States.

References

1. Md. Health Gen. Code Ann. §17–201 (1986).
2. NIH Consensus Development Conference: Lowering blood cholesterol to prevent heart disease. JAMA 253: 2080–2086, Apr. 12, 1985.
3. Oster, G. and Epstein, A. M.: Primary prevention and coronary heart disease: the economic benefits of lowering serum cholesterol. Am J Public Health 76: 647–656 (1986).
4. Inspector General's report on public cholesterol screening. DHHS Publication No. OAI–05–89–01330, Washington, DC, November 1989, pp. ii, 5–10.
5. Bachorik, P. S., et al.: Cholesterol screening: comparative evaluation of on-site and laboratory-based measurements. Clin Chem 36: 255–260 (1990).
6. Naughton, M. J ., Luepker, R. V., and Strickland, D.: The accuracy of portable cholesterol analyzers in public screening programs. JAMA 263: 1213–1217, Mar. 2, 1990.
7. Kaufman, H. W., et al.: How reliably can compact chemistry analyzers measure lipids? JAMA 263: 1245–1249, Mar. 2, 1990.
8. Bachorik, P. S., et al.: Accuracy and precision for total cholesterol as measured with the Reflotron cholesterol method. Clin Chem 35: 1734–1739 (1989).
9. Scott, B. State sues cholesterol screening group. Clin Chem News 15: 1,7, March 1989.
10. Md. Health Gen. Code Ann. §17–504(a) (1989).
11. Report of the National Cholesterol Education Program expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. Arch Intern Med 148: 36–69; (*a*) 40–48 (1988).
12. Recommendations regarding public screening for measuring blood cholesterol. Publication No. NIH 89–3045, U.S. Government Printing Office, Washington, DC, 1989.
13. Md. Admin. Reg. 16: 1449–1453; (*a*) 2510–2514 (1989).
14. Koch, T. R., et al.: Bias and precision of cholestrol analysis by physician's office analyzers. Clin Chem 33: 2262–2267 (1987).