PUBLIC CHOLESTEROL SCREENING

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This study was conducted to provide information regarding the prevalence, conduct and regulation of public cholesterol screening.

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PUBLIC CHOLESTEROL SCREENING

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EXECUTIVE SUMMARY

PURPOSE

This inspection was conducted to examine the prevalence, conduct and regulation of public cholesterol screening. The term *public screening* refers to screening which is conducted in public settings, as opposed to physician offices.

METHODOLOGY

Information was gathered through an extensive literature review, telephone interviews, and a special field survey in which we observed and participated in 71 public cholesterol screenings across the country. In all, 250 respondents were contacted.

BACKGROUND

According to a recent study by researchers from the Public Health Service, over 60 million adult Americans may currently have high blood cholesterol, placing them at risk of heart disease. Demand for screening is increasing significantly. This is due in part to public awareness of the dangers of high cholesterol. But it also results from expectations of ease, convenience, and low cost of public screening. Also, portable equipment has been developed which makes cholesterol measurement rapid and almost painless.

Thus far, the Federal role relative to cholesterol screening has been one of research and public education through the National Cholesterol Education Program (NCEP), a consortium of public and private groups created by the National Institutes of Health (NIH). The NCEP is charged with educating health professionals and the public in order to identify and treat all adults with high blood cholesterol. They have advised all adult Americans to "Know your cholesterol number" and endorse screening by a physician as part of an office visit, rather than screening in public settings. However, later this year, recognizing that public screening is growing, NCEP plans to issue policy recommendations regarding the role of public screening in the national cholesterol education effort.

Cholesterol screening is not federally regulated at present. However, the Clinical Laboratory Improvement Amendments of 1988 (CLIA of 1988), when fully implemented in 1990-91, will apply to screening. Regulations implementing the law should be issued shortly by the Health Care Financing Administration (HCFA).

FINDINGS

Public Cholesterol Screening In Many Areas Is Both Prevalent And Growing. Providers Of All Kinds Are Conducting Screenings.

- According to surveys by NIH and others, the percentage of adults who have had their cholesterol checked has gone from 35 percent in 1983 to 66 percent in 1989.

- Providers as varied as hospitals, public health departments, health clubs and grocery stores are conducting public screenings.

- Screening is taking place at shopping malls, pharmacies and many other types of community settings.

The Accuracy And Usefulness Of Public Cholesterol Screening Are Compromised By Poor Quality Assurance, Inadequate On-site Counseling, And Lack Of Referral To A Physician When Appropriate.

- The qualifications and training of staff conducting screening in the field survey varied widely, including persons both with and without health care experience.

- The basic rules of hygiene were frequently disregarded, raising concerns about the safety of public screening for staff and screenees alike.

- Staff conducting screenings frequently wore no gloves, or only one glove, yet handled money and collected blood. Many squeezed or "milked" screenees' fingers, which can affect the accuracy of test results by diluting the sample with material from between the cells, or by breaking down red blood cells.

- Education, counseling, and physician referral of screenees were often lacking.

- Researchers believe that portable analyzers used in public screenings can produce accurate results given adequate operator training, quality control, and attention to detail. However they question whether these conditions exist at most public screenings.

Current State And Federal Regulation Of Public Cholesterol Screening Is Minimal.

- Public cholesterol screening will be federally regulated, to some extent, under CLIA of 1988. However, many respondents are concerned that it will be determined to meet the waiver provisions, which would exempt providers from the performance standards and inspection provisions of the law.

- Sixteen States regulate public cholesterol screening, but the type and extent of regulation vary widely. In many other States, the need for regulation is being debated.

Some argue that screening is not a clinical laboratory test, and that it therefore does not need to be regulated.

RECOMMENDATIONS

The Department Should Discourage Public Cholesterol Screening Which Does Not Meet NCEP Guidelines.

We found numerous shortcomings which compromise the safety and effectiveness of public screening. The public, in general, is not aware of these shortcomings and does not know what to look for in safe, high-quality screenings. In addition, screening staff may be placing themselves, as well as screenees, at risk due to marginal observation of the basic rules of hygiene and infection control procedures. We therefore recommend that the Department publicly discourage screenings which are unregulated, and lack the education, counseling and referral components recommended by the NCEP.

The HCFA Should Not Apply The CLIA of 1988 Waiver Provision To Public Cholesterol Screening.

We believe that CLIA of 1988 is the appropriate mechanism to federally regulate public cholesterol screening and that the waiver provision should not be applied. Regulation of screening under CLIA of 1988 will ensure that screening providers are qualified and experienced. It will also require providers to register, disclose their activities, comply with Departmental performance standards, conduct proficiency testing and permit periodic inspections.

The majority of respondents in this study, as well as the NCEP, say that effective screening programs must provide education, counseling and referral of screenees. To ensure that providers include these elements in their programs, we recommend that the Department consider using the NCEP guidelines as a starting point to establish regulatory standards under CLIA of 1988.

COMMENTS

Regarding our first recommendation, we believe we are in agreement with PHS that the NCEP guidelines must be followed. However, based on what we found in our study, we are unable to accomodate the word changes suggested by PHS to encourage public cholesterol screening. We will be able to determine if we are in full agreement with the PHS when we receive their action plan for enforcing use of the NCEP guidelines.

Since the release of our draft report in November 1989, HCFA has stated that public cholesterol screening will be regulated under CLIA of 1988. Furthermore, the HCFA Administrator, in testimony before the Senate Committee on Labor and Human Resources and the Senate Subcommittee on Oversite of Government Management, indicated that public cholesterol screening would not be waived. This means that laboratories or sponsors of public screenings must meet specific performance and other requirements before being certified to conduct public testing. These requirements are currently being developed within the Department and should be issued shortly.

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INTRODUCTION

PURPOSE

This report describes the prevalence, conduct and regulation of public screening for cholesterol. The term *public screening* refers to screening conducted in public settings, as opposed to physician offices.

BACKGROUND

This inspection was conducted in response to a request by the Chairman of the House Subcommittee on Regulation and Business Opportunities, to provide information concerning mobile health services, that is, services offered outside the traditional settings of a hospital, clinic, or physician's office. This is one in a series of reports answering the request.

Public cholesterol screening is the most prevalent and visible type of mobile health service. According to a recent study conducted by researchers from the Public Health Service, over 60 million American adults may currently have high blood cholesterol, placing them at risk of heart disease. Demand for screening is increasing significantly. This is due in part to public awareness of the dangers of high cholesterol. But it also results from expectations of ease, convenience and low cost of public screening. Also, the development of portable equipment that uses a fingerstick blood sample has made cholesterol measurement rapid and almost painless.

Coronary heart disease (CHD) is the major cause of death and disability in the United States. It accounts for more deaths annually than any other disease, including all forms of cancer combined. According to the National Center for Health Statistics and the American Heart Association, over 1.5 million heart attacks occur each year in the United States, and more than 520,000 die from them. Coronary heart disease is estimated to cost over $80 billion a year in health care costs, lost wages, and productivity.

Thus far, the Federal role relative to cholesterol screening has been one of research and public education. Screening is not reimbursable under Medicare, although both diagnostic tests and treatment for high blood cholesterol and coronary heart disease are covered. Screening is not federally regulated at present. However, when it is fully implemented in 1990-91, Clinical Laboratory Improvement Amendments of 1988 (CLIA of 1988), which brings all clinical laboratories under Federal regulation, will apply to screening. The regulations implementing the law should be issued shortly by HCFA.

In 1984, the Federal Government's fight against CHD gained momentum. Following the completion of a major study which linked high blood cholesterol and heart disease, NIH convened a national conference which recommended that both physicians and the public be

informed about the role of high cholesterol in CHD, and that high blood cholesterol be aggressively treated. They advised all adult Americans to obtain a blood cholesterol measurement and recommended physician screening, as a part of routine health examinations, as the best way to identify persons with elevated cholesterol.

In 1985, NIH launched the National Cholesterol Education Program (NCEP) to implement these recommendations. The NCEP is a consortium of practitioners, public health professionals, voluntary health organizations, and government agencies coordinated by the National Heart, Lung, and Blood Institute. Its mandate is to educate health professionals and the public in order to identify and treat all adults whose high blood cholesterol places them at risk for CHD.

In 1987, an NCEP Adult Treatment Panel established guidelines on the detection, evaluation, and treatment of high blood cholesterol. They advised all adult Americans to "Know your

<200 mg/dL *	Desirable blood cholesterol
200-239 mg/dL	Borderline high blood cholesterol
>240 mg/dL	High blood cholesterol

* milligrams per deciliter

cholesterol number" and established cutpoints for the classification of blood cholesterol:

The guidelines call for physician screening and emphasize the importance of clinical judgment and patient management. They designate dietary therapy as the cornerstone of treatment for high blood cholesterol.

In 1988, stressing the need for accurate, standardized cholesterol measurement, an NCEP Laboratory Standardization Panel recommended that: (1) all laboratories achieve cholesterol measurement no greater than five percent from true value; (2) all cholesterol measurement in the country be standardized; (3) all laboratories adopt the NCEP cutpoints for identifying persons at high risk; and (4) portable analyzers be further evaluated before being adopted for routine use with patients. The Panel stressed the importance of quality control and operator training with such instruments.

While the NCEP continues to endorse only physician screening, it recognizes that public screening is widespread and recently issued formal recommendations regarding the conduct of public screening which will be discussed in this report. Later this year, NCEP will issue

policy recommendations on the role of public screening in the national cholesterol education effort.

Private organizations and groups, especially within the medical community, have also become increasingly involved in the issue of cholesterol screening. For example, the American Medical Association, which endorses physician screening, recently launched a Campaign Against Cholesterol to increase public awareness of cholesterol and educate the public regarding methods for controlling cholesterol through diet. National sponsors of the Campaign include Kellogg Company, Boyle-Midway Household Products, Inc., and Merck, Sharp & Dohme. And the Voluntary Hospitals of America sponsored a special program on April 26, 1989 called Countdown USA, where over 400 hospitals screened thousands of Americans in community settings.

SCOPE AND METHODOLOGY

Information was gathered through an extensive literature review, telephone interviews, and a special field survey in which we observed and participated in 71 public cholesterol screenings across the country. Appendix A describes the survey methodology.

The literature reviewed consisted of Federal and State laws, regulations and guidelines, research papers, studies, reports, and newspaper articles.

Discussions were held with nearly 250 persons, including:

- Department of Health and Human Services officials, especially in the Public Health Service and Health Care Financing Administration (HCFA);
- persons from the Office of Technology Assessment and the General Accounting Office;
- persons in all 50 States and Washington, D.C. responsible for oversight of clinical or physiological health services;
- representatives of professional associations, State hospital associations and State consumer fraud agencies;
- experts with special perspectives on the issue; and
- equipment manufacturers.

When this report refers to respondents, it is discussing opinions expressed in these interviews.

FINDINGS

Public Cholesterol Screening In Many Areas Is Both Prevalent And Growing. Providers Of All Kinds Are Conducting Screenings

> "Cholesterol testing has leapfrogged beyond anything that has been done in portable testing in terms of rapid growth. Tests are easy, cheap, and practically public policy"

Numerous comments such as this from respondents attest to both the prevalence and growth of public cholesterol screening. While there are no reliable national statistics on prevalence, surveys by NIH and others reflect that the percentage of adults who have had their blood cholesterol checked, whether in a physician's office or in a public setting, has gone from 35 percent in 1983 to an estimated 66 percent in 1989. In early 1987, a *Wall Street Journal* article reported that about 100 million cholesterol tests were performed in the U.S. in 1986, at a cost to patients and insurers of between $1 billion and $1.5 billion.

A wide variety of public and private providers, with or without health care experience, are conducting screenings at sites as diverse as shopping malls, pharmacies, health clubs and village halls. Hospitals and other health care providers, public health departments, private agencies and organizations, employers, and businesses such as pharmacies and grocery stores all sponsor screenings. State respondents who oversee clinical laboratories, especially, confirm that providers of all types are conducting screenings.

All State respondents report that screening is occurring in their States, and 60 percent say that it is very prevalent. Early this year, the *National Intelligence Report* stated that one company alone in Florida was screening 25,000-30,000 people a month at $7 each.

Currently there are some 25 cholesterol measurement devices on the market. However, three portable analyzers in particular are being heavily used in public screenings. Many State respondents report that equipment manufacturers are aggressively marketing and that demand is high. A manufacturer respondent confirmed that the market is both lucrative and growing.

While manufacturers say that they sell primarily to people with medical qualifications, some acknowledge that "anyone who has the money" can buy the equipment. For entrepreneurs, there is money is to be made in public screening. A manufacturer respondent described one woman who gave up nursing to conduct screenings and grossed over $100,000 in less than 10 months.

While screening is sometimes provided as a public service, more often it serves as a public relations tool, marketing ploy, or money-maker for the sponsor. For-profit sponsors, such as retail stores, draw people in with ads and signs in their windows urging people to "Take the test that could save your life!" or warning: "Cholesterol Kills!"

Many hospitals sponsor and conduct screenings, often for public relations or marketing purposes. Eight out of 10 respondents from State hospital associations estimated that at least half of the hospitals in their States conduct some screening, especially larger hospitals in urban areas. A physician said that his hospital screened 11,000 people in 3 days at malls. A State respondent described another hospital-sponsored program that screened 22,000 people in 4 days.

Pharmacies also appear to be heavily involved in screening. A survey of the top 100 pharmacy chains conducted by *Drug Store News* showed that: (1) four times as many chains were offering screening in 1988 as in 1986; (2) on average, 111 customers were screened per day per store; (3) half the respondents said they did screening to contribute to their health care image and "build traffic"; (4) nearly half said they offer screening four or more times a year; and (5) over half said they collaborate with an outside group to provide screening. Most respondents reported charging a fee (with the average just over $6), usually to cover costs rather than make a profit.

The Accuracy And Usefulness Of Public Cholesterol Screening Are Compromised By Poor Quality Assurance, Inadequate On-site Counseling, And Lack Of Referral To A Physician When Appropriate.

Many respondents, including 80 percent of the State respondents, believe that the effectiveness of public screening is often compromised by serious shortcomings relative to both the screening environment and process. To complement discussions with respondents, OIG staff conducted a special field survey in which they observed and participated in 71 public screenings across the country. A checklist which was developed with the NCEP "Recommendations Regarding Public Screening for Measuring Blood Cholesterol" as a reference, was used to record observations. The methodology used in the field survey is described in appendix A.

At screenings everywhere, staff are subject to considerable distraction and there is a notable lack of privacy.

> The NCEP recommends that screening environments provide (1) privacy for blood sampling, confidentiality of results, and discussions between participants and staff; and (2) adequate staffing and equipment to minimize a "stressed, hurried environment that is associated with poor quality." They recommend that the analyzer used "optimally should provide hard copy readout," both to minimize transcription errors and maximize screenee privacy.

Screenees described the environment at numerous screenings in the field survey as "highly public," with little or no privacy. Blood was almost always collected in full view of other

screenees. Only 25 percent of the screenees said that test results were kept confidential: "Names and numbers were called out for all to hear." Few screenees reported that their discussions of test results with staff were kept confidential. Almost no one received a hard copy readout of test results. In fact, an analyzer with only a digital readout was used in over two-thirds of the fingerstick screenings.

There were plenty of distractions. Screenings attended by hundreds were often described as "a major production" or even "frenetic." At others, screening was conducted in cramped quarters such as the aisles of stores or pharmacies, in full view of customers, often with only one or two staff to handle everything. Over half the screenees reported that staff were subject to distraction while performing analysis. One man at a table by the revolving doors in a lobby was running three analyzers, handing out test results and counseling screenees. Distracted by passing traffic and screenees requesting their "number," he became confused about whose results came from which machine and broke off discussion in mid-sentence with a woman who had a high test result.

Hospitals passed out literature on their services, advertised take-home meals and conducted a drawing for a gift certificate. In one instance, local politicians dropped in to campaign. Stores offered money-off coupons and sold fish oil and oat bran. A surgicenter gathered screenees for a sales pitch, and a nurses association and school recruited students. Screenees were urged to pay for special health assessment questionnaires or take extra tests such as a "comprehensive blood test panel" or body composition analysis. A screening company and an equipment manufacturer handed out marketing material.

The qualifications and training of staff conducting screening vary widely.

> The NCEP recommends that staff be appropriately trained and stresses the importance of professional appearance and conduct.

Screenees informally questioned staff who took blood and performed analysis about their qualifications. Staff varied widely, from health professionals such as nurses and medical technologists, to people with no professional experience and minimal training from the screening company, like the "Certified Screening Technician" with no medical background who had just come to town and learned about the job in the paper.

At for-profit screenings, many screenees reported that staff were uncommunicative, acted defensive about their background, or appeared "nervous" or "disorganized." At a pharmacy, the man collecting the sample appeared nervous. After fumbling with the lancet, gauze and blood tube, he remarked to the other staff person: "Well, I'm sorry, I really messed that one up." They discarded the sample.

A few screening staff remarked that medical experience was not necessary to do screening. One recommended "a good background in public relations and marketing," and another remarked: "Anyone could do this with no problem. The fingerstick is easy and the machine does the rest!"

Many respondents questioned the qualifications of staff at screenings: "I've seen ads in the paper for people to learn to do cholesterol screening where the main requirement seems to be that they own a car." Respondents from two companies who produce analyzers confirmed that, since their equipment is so easy to operate, people with no medical training could learn to use it, although they also stressed the importance of staff training and competence.

At many screenings, there is considerable laxity relative to quality assurance.

> The NCEP recommendations call for good sample collection techniques and recommend that screenees remain seated for five minutes prior to giving blood, to stabilize blood volume.

- Almost 60 percent of the screenees who gave blood with a fingerstick had their fingers squeezed, or "milked," which can affect the accuracy of test results. "Milking" may dilute the sample by introducing material from between the cells, giving a lower than normal result. Or it may break down red blood cells, turning the plasma pink; analyzers that obtain test results based on the color of the sample will get a false result. The analyzer used in 70 percent of the fingerstick screenings in the field survey uses this technology.
- Only 13 percent of screenees were advised to sit for 5 minutes prior to sample collection.

Many respondents expressed concern about a lack of quality assurance at screenings. Some laboratorians believe that for-profit providers short-circuit quality control to minimize operating costs and maximize profits, or choose equipment based on cost and ease of operation rather than accuracy. For these reasons, many express concern that "people are making big decisions about what they are going to do based on what may be a very lousy test result," especially given an overly trusting public who "believes that the number coming out of a machine is carved in stone."

The basic rules of hygiene are frequently disregarded, raising concern about the safety of public screenings for screenees and staff alike.

> The NCEP recommendations state that staff should understand infection control and prevention techniques.

- Screenees at a few for-profit screenings questioned hygienic conditions, finding bloodstained tablecloths and gauze, staff wearing bloody gloves, or staff who "just turned over a bloody mat and didn't replace it." At a pharmacy, staff were observed inspecting lancets lying on the table because they were afraid they had put a used one back in with the new ones.
- Some staff who wore no gloves, or only one glove, both handled money and collected blood samples.
- A third of those collecting blood did not wear gloves, including all who performed venipuncture. Of those who did wear gloves, only half changed them with each new screenee.
- At one site, a staff person was observed removing a broken tube with a jagged edge from a centrifuge with her bare hands, smearing blood all over her fingers in the process.
- Staff used a container marked "biohazardous waste" to dispose of needles and lancets less than half the time. Common use garbage containers, including a coffee can, were used for disposal almost 20 percent of the time. However, no needles or lancets were observed to be reused.
- Some State respondents report having seen dirty or unkempt sites.

Researchers believe that portable analyzers are capable of producing accurate results. However, they as well as other types of respondents emphasize that operator training, quality control, and attention to detail are key in achieving reliable results in public screenings.

If the public is to be well served by public screening, equipment must be capable of producing reliable test results. While an assessment of the accuracy of the portable analyzers most used in public cholesterol screening is outside the scope of this study, discussions with expert respondents indicate that they have significant reservations about analyzer performance, especially in community settings. They are very concerned about the implications of inaccurate test results; they say that some screenees will be falsely reassured that they are not at risk, and others will be made unduly anxious, in addition to paying for unnecessary doctors visits and re-testing.

While most researchers believe that portable analyzers are capable of producing accurate results, they describe special problems related to their use in public settings. Temperature and humidity fluctuations, movement, and vibration can affect accuracy. Improper blood collection techniques can affect the integrity of the sample. Operators must be well trained. In short, researchers caution that "you must pay attention to everything."

One analyzer in particular is well known by many respondents and appears to be the most prevalent in public screening due to its relatively low cost, portability, and ease of operation. It was used in 70 percent of the fingerstick screenings in the field study. While the manufacturer deems it "absolutely perfect for screening," laboratorian respondents, particularly, expressed concern about its performance in community settings.

Manufacturers say that their equipment meets the NCEP standards for accuracy. They say that when their equipment gives inaccurate results, it is because operators are careless, do not follow the manufacturer's instructions, or "are not doing calibrations because it costs too much." All of them provide operator training and are participating with NIH and others in the development of a national training package for equipment operators. Some manufacturers will also help prospective screening providers find trained operators if needed.

In the field survey, we did not attempt to verify the accuracy of the test results, themselves, which screenees received. However, screenees did ask staff, "How accurate is my result?" Responses varied widely, including: within 2 points, 3 points, or 10 points either way; 95, 96, and 97 to 99 percent accurate; "very" or "fairly" accurate, or just "it's accurate." Some got different answers from different staff at the same site. A few who questioned their results were simply reassured, "it's accurate" or told that it "must be" accurate, since no one else had questioned their results.

Education, counseling and referral of screenees are frequently lacking, although hospitals are more likely to provide better quality educational material and physician referral.

The NCEP emphasizes that education of all screenees, and referral of those with high cholesterol to medical follow-up, are key elements of successful public screening, and further, that "receipt of only a cholesterol number by a participant is not sufficient in a screening program." They make several specific recommendations in this regard.

☐ Test values should be reported against the NCEP risk levels, on a form containing a concise statement of follow-up treatment guidelines.

While test results were almost always reported to screenees against the NCEP risk levels, hospitals were far more likely than for-profit sponsors to provide a concise written summary of treatment guidelines along with the test results.

☐ Screenees should be told the meaning and limitations of a single test result and informed of the need for more than one measurement to determine high cholesterol.

Less than 20 percent of screenees were told that screening is only a guide to potential problems rather than a diagnostic test, and only a third were cautioned about the limitations of a single cholesterol measurement. While release forms and literature handed out sometimes contained such information or advised periodic retesting, it was often buried in text or in very small print, and the impact on screenees is doubtful.

☐ All screenees should receive verbal and printed information on cholesterol, other CHD risk factors, diet, and dietary alternatives.

At for-profit screenings, test results were often handed to screenees on a simple flyer or pamphlet containing brief summary information on cholesterol and diet, and there was minimal discussion with staff. Hospitals, on the other hand, did a better job of counseling screenees about nutrition and diet than other providers and sometimes even had nutritionists and dieticians on staff. Many, though not all, also provided extensive written material.

☐ Sponsors should provide referral to physicians: (1) those in the borderline-risk category should be questioned and referred to a physician if other CHD risk factors are present, and if not, advised to be retested within a year; (2) those in the high-risk category should be referred to a physician.

Hospitals more frequently offered and provided physician referral than for-profit screeners, who rarely even mentioned referral. While literature given out by for-profits sometimes said that a screenee should consult a physician or be tested periodically, this was often buried in text and not explicit.

Of the 20 screenees in the borderline-risk category, only four were given the appropriate advice. Three venipuncture screenees picked up their test results later at a pharmacy, where the pharmacist handed them their results but provided no counseling or advice. Of the remaining 13 screenees, two-thirds were either given some printed material on diet and told to "watch what you eat," or told not to worry. One man who tested at 220 was told, "That's good." When he said he thought it should be 200, the screener replied, "You should see some of the ones in the 300's we've seen. Well, 220 is pretty good."

Of the six screenees in the high-risk category, two were referred to their doctors and three were told that their results were "slightly high" or "not bad" and given little or no advice. One woman was told: "People's cholesterol rises with age, so 243 isn't that bad. It would probably be good to watch what you eat." A man of 20 with a level of 264 was told that his level was slightly high but given no advice.

- Screeners should use mail or telephone follow-up to ensure that referral advice is followed.

Two persons screened by hospitals received letters advertising special classes or programs, and another received a phone call asking if she had seen a physician as advised.

Respondents in this study stress that, while counseling and physician referral should be key elements of public screenings, they are lacking at many screenings: "Most people seem to just get a piece of paper with ranges on it." This disturbs them because "numbers in a vacuum are not a complete service." Some fear that screenees at risk will self-diagnose and treat rather than seeing a physician. In this sense, one pointed out, "a little knowledge is a dangerous thing."

Current State And Federal Regulation Of Public Cholesterol Screening Is Minimal.

Screening will, to some extent, be federally regulated under CLIA of 1988 when it is fully implemented in 1990-91. However, many respondents are concerned that screening will be determined to meet the waiver provisions of the law.

In October 1988, Congress enacted the Clinical Laboratory Improvement Amendments, for the first time bringing all clinical laboratories under Federal regulation. The law requires all clinical laboratories, regardless of the number of tests they perform, to meet several requirements in order to obtain a certificate, or license, in order to operate. The law provides a waiver provision, however. Laboratories employing "methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible," or which "the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly," may be issued a certificate of waiver exempting them from meeting specific performance standards outlined under the law.

Three-quarters of State respondents believe that public cholesterol screening will be covered under CLIA of 1988. However, many are unsure of how the Department will interpret or define public screening under the law. They believe that screening may be determined to meet the waiver provisions, which they say would be a "mistake." Many experts and laboratorians agree. Laboratorians, especially, favor regulation under CLIA of 1988 as the only way to ensure quality testing.

Sixteen States regulate public cholesterol screening, but the type and extent of regulation vary widely.

State respondents often express mixed feelings about regulation. However, over 80 percent favor some type of regulation to ensure minimum standards for quality control, staff training, and follow-up.

Sixteen States regulate screening, although four of them only recently passed legislation and their regulations have not yet been implemented. Some regulate under existing statutes and others through legislation specifically addressing screening. The extent and type of regulation varies widely, from paper compliance via submission of a special protocol to full licensure under a State's clinical laboratory statute. Appendices B and C summarize existing State regulation.

Screening poses special problems relative to regulation.

No matter what type of regulation, State respondents often described problems identifying providers in order to bring them into compliance: "By the time we hear about them, they're gone." Some likened themselves to detectives in trying to track down providers, relying on advertisements, word of mouth, complaints from other providers, or just plain "serendipity" to find them.

Some States reported being overwhelmed by both unlicensed providers operating illegally and the large number of providers applying for a license. Unprepared for the extra workload, they are still trying to catch up. Five respondents believe that their State regulations have been effective in curbing screenings by unlicensed providers. Two think that they are now aware of all screening providers operating in the State. One State limited the number of private entrepreneurs, that is, those who are not health professionals. They reported that now, screening done by physicians outside their offices, which is not regulated, has become very prevalent.

In many States, regulation is being debated.

Many States are just becoming aware of public cholesterol screening. While most State respondents favor regulation as a means to protect the public from inaccurate testing, misleading information and unscrupulous providers, there are a number of barriers to regulation, and opinion among groups both within and outside State Government is often split with regard to the need for regulation.

The most common barrier to regulation is lack of funding and staff. One State respondent said, for example that, "if screening were regulated, we would need to at least quadruple our staff." Many report that they are scrambling to come up with the funds needed under CLIA of

1988 to regulate physician office laboratories and cannot imagine where to find the funds to oversee screening. Another obstacle is that some see screening as a great boon to the public and do not want regulation that would put conscientious, proficient providers out of business.

One of the strongest barriers to regulation is a lack of consensus regarding whether screening constitutes a clinical diagnostic test or primarily an informational service to the public. In Michigan and Wisconsin, the State Attorney General has ruled that public cholesterol screening does not constitute a clinical laboratory test, since it is not ordered by doctors and providers are not involved in diagnosis and treatment. In Tennessee, while a special task force unanimously agreed that screening should be fully licensed, legal opinion was split regarding whether screening constitutes a clinical chemistry diagnostic test under State law. The public health commissioner is expected to rule shortly on whether screening will be regulated. In Florida, screening has become highly controversial. The Office of Licensure and Certification sent cease and desist orders to unlicensed providers some time ago to bring them under existing State regulation. They then filed an injunction against one provider who ignored the order. Although the case was recently settled out of court when the provider agreed to comply with the State's independent laboratory regulations, other providers continue to operate. State attorneys apparently have recommended that the State file similar injunctions against them. Recently, the governor vetoed a bill that would have greatly reduced State regulatory oversight of public cholesterol screening.

Given these barriers, it appears to many State respondents that regulation will only occur if federally mandated and funded.

RECOMMENDATIONS

The Department Should Discourage Public Cholesterol Screening Which Does Not Meet NCEP Guidelines.

We found numerous shortcomings which compromise the safety and effectiveness of public screenings across the country. The public in general is not aware of these shortcomings, and does not know what to look for in safe, high-quality public screening programs. In addition, screening staff may be placing themselves as well as screenees at risk due to marginal observation of the basic rules of hygiene and infection control procedures.

For these reasons, we believe that the Department should publicly discourage public cholesterol screenings that are unregulated, and lack strong education, counseling and referral components as recommended by the NCEP.

HCFA Should Not Apply The CLIA of 1988 Waiver Provision To Public Cholesterol Screening.

We believe that CLIA of 1988 is the appropriate mechanism to federally regulate public cholesterol screening, since providers of public screening appropriately fall under the definition of "laboratory" or "clinical laboratory" in the law. We do not believe that screening meets the waiver provisions of the law. Even if it did, however, we recommend that the waiver not be applied, since Federal regulation of public screening is clearly called for in order to safeguard the public.

Regulation under CLIA of 1988 will ensure that screening providers are those with the best experience and qualifications to produce accurate and reliable test results. Furthermore, all providers will have to register and disclose their activities, comply with performance standards set forth by the Secretary, conduct proficiency testing, and permit periodic inspections.

The majority of respondents in this study, as well as the NCEP, say that effective screening programs must provide education, counseling and referral. To ensure that providers incorporate these elements in their programs, we recommend that the Department consider using the NCEP public screening guidelines as a starting point to establish regulatory standards under CLIA of 1988.

COMMENTS

We received comments on the draft of this report from both PHS and HCFA. In responding to our draft report PHS felt that the first recommendation should be rewritten as follows:

"The Department should encourage public screening for cholesterol when such screening meets (1) the guidelines established by the National Cholesterol Education Program (NCEP) and (2) the standards for good laboratory quality control established by the NCEP Laboratory Standardization Panel."

We are in agreement with PHS that the NCEP guidelines must be followed. However, based on what we found in our study, we are unable to accomodate the word changes suggested by PHS to encourage public cholesterol screening. We will be able to determine if we are in full agreement with the PHS when we receive their action plan for enforcing use of the NCEP guidelines.

With regard to coverage under CLIA, both HCFA and PHS stated that a decision would have to be delayed until proper deliberations were made in the context of developing the regulation to implement CLIA.

Since then, these agencies have been preparing the regulations. While these regulations have not as yet been released to the public, the HCFA Administrator, in recent testimony before the Senate Committee on Labor and Human Resources and the Senate Subcommittee on Oversight of Government Management, indicated that public cholesterol screening would not be waived under CLIA of 1988. This means that laboratories or other sponsors of public screenings must meet specific performance and other requirements before being certified to conduct public cholesterol testing. These requirements are currently being developed within the Department and should be issued shortly.

We wish to thank those in HCFA and PHS who commented on our report and we are pleased that our recommendations have been implemented.

APPENDIX A

Description of Field Survey Methodology

From March through June 1989, OIG's Office of Analysis and Inspections staff observed and participated in 71 screenings selected at random in ten States and Washington, D.C. The States were: New York, Pennsylvania, Georgia, Texas, California, Kansas, Missouri, Illinois, New Jersey and Massachusetts. In order to ensure that their experiences were those of the general public, screenees did not identify themselves as OIG employees.

Screenees recorded observations on the screening environment and process using a checklist developed with the NCEP "Recommendations Regarding Public Screening for Measuring Blood Cholesterol" as a reference. An assessment of the accuracy of test results themselves was beyond the scope of this field survey. However we did observe the conditions under which the tests were administered.

Sites included downtown office buildings, shopping malls, pharmacies, restaurants, libraries, churches and others. Some screenings were free, but most screenees were charged a few dollars. At most sites, blood was collected with a fingerstick, analyzed in a matter of minutes with portable equipment and the results given to screenees immediately. One brand of portable analyzer was used at 70 percent of these screenings. Eight screenees gave blood via a venipuncture, the sample was analyzed in a stationary lab and the results sent back a week later.

Hospitals sponsored a quarter of the screenings, many of them part of Countdown USA, a special effort on April 26, 1989 where over 400 hospitals belonging to the Voluntary Hospitals of America screened thousands of Americans in community settings. Pharmacies sponsored another 25 percent and other sponsors included grocery and health food stores, a church, a public health department and radio and TV stations. Half of the screenings were conducted by hospitals or small not-for-profit entities and half by for-profit entities, mostly companies specializing in screening or diagnostic testing, whether cholesterol screening only or an array of testing.

APPENDIX B

CHART OF STATE REGULATION

State Regulation of Public Cholesterol Screening

State	Lic., Reg. or Permit	Fees	Screening Staff Qualif.	QA Program	Proficiency Testing	On Site Inspec.	Patient Follow-up	Other Provisions	Exemptions
AZ	◆	◆		◆	◆	◆			
DE	◆	◆		◆		◆			Providers who do not market screening as a lab test
HI			◆			◆		Must be sponsored by locally licensed MD, who can be represented by signed document stating diagnosis..	Physician office lab
ID	◆				◆			Outside consultation by laboratorian 4 times/yr.	
IL*	◆			◆			◆		
KY	◆	◆	◆	◆		◆		Special protocol being developed.	Hospital-sponsored screening
ME	◆	◆	◆	◆	◆	◆			Hospitals & physician office labs
MD**	◆	recoups costs	◆	◆	◆	◆	◆		
NV	◆	◆	◆	◆	◆	◆	◆		
NJ	◆	◆	◆	◆	◆	◆	◆	Special protocol being developed. Must be done under auspices of licensed MD.	
NY	◆	recoups cost		◆		◆	◆	Test must be ordered by licensed MD. Entrepreneurs must be sponsored by NY licensed clinical lab.	Physician office labs
OR**	◆	recoups costs	◆	◆	◆	◆	◆		
PA	◆	◆		◆	◆		◆	Entrepreneurs must be associated with clinical lab as technical resource & PA-licensed MD as medical resource (can be same entity).	
RI**	◆	◆	◆	◆	◆		◆	Law says screening program "may be" supervised by clinical or hospital lab, and/or MD with R.I. license.	
WA**	◆	recoups costs	◆	◆	◆	◆		Effective 7/1/90. Law stipulates civil monetary penalty of up to $10,000 per day per violation of State guidelines.	Waiver provision to be defined
WY	◆	◆		◆	◆	◆	◆	Screening/testing must be ordered by WY licensed MD.	

* Providers are divided into 6 categories, each with a different waiver provision.

** Regulations are being developed.

APPENDIX C

Description of State Regulation

Licensure/Registration: In 15 States, providers must be licensed or register, either by site or provider. Hawaii is an exception, and Illinois exempts not-for-profit providers, who need only submit a protocol. Fourteen States charge a fee, which may be based on volume of business, number of staff or the provider's gross earnings. Only four States (NY, MD, OR and WA) calculate fees in order to recoup the costs of administering the program.

Staff Qualifications: State requirements vary widely. Some impose no requirements. Others mandate that staff be graduates of accredited laboratory programs. Some States set no staff requirements but mandate that a State-licensed independent clinical laboratory, hospital laboratory or physician be responsible for ensuring that staff are properly trained at all screenings. Others mandate that providers have a laboratory director or "qualified person" with certain degrees or experience. Illinois is unique in setting no requirements for not-for-profit providers, but requiring that staff of for-profit providers be technicians or laboratory assistants.

Quality Assurance Program: Fourteen States require that a quality assurance program be in place.

Proficiency Testing: Twelve States require that providers enroll in a nationally recognized proficiency testing program. Idaho even offers its own program.

On-site Inspection: Eleven States will conduct on-site inspections, although provisions vary all the way from an annual inspection at each site or selected sites; biennial inspection; inspection at the discretion of the State; inspection of randomly selected sites; or inspection following a failed proficiency test.

Patient Follow-Up: Nine States mandate that providers have patient follow-up provisions in their programs to ensure proper counseling and physician referral, although five are just now drafting regulations or guidelines (MD, OR, RI, KY, NJ). Pennsylvania also requires that the physician in charge contact patients within six weeks to stress the need for follow-up.

Provider Exemptions: Seven States exempt certain kinds of providers, including physician office laboratories (HI, NY); hospitals (KY); hospital and physician (ME); or a provider who does not market screening as a lab test (DE). Illinois has six categories of providers, each with different waiver or exemption provisions. Washington State is still developing waiver criteria.

APPENDIX D

Non-Compliance With NCEP Guidelines in Field Survey

Environment Should Allow Privacy And Confidentiality	%
Blood not collected in private	92
Results not kept confidential	73
Discussions not confidential	82
Persons doing analysis subject to distraction	56

Rules of Infection Control Should Be Observed	%
Work area dirty	11
Staff did not wear gloves	35
Staff did not change gloves with each new screenee	50
Container marked "**Biohazardous Waste**" not used for disposal of lancets/needles	56

Non-Compliance With NCEP Guidelines in Field Survey

Good Sample Collection Techniques Should Be Used	%
Finger "milked" to obtain blood	58
Screenees not advised to sit 5 minutes	87

There Should Be Counseling And Physician Referral	%
Screenees not cautioned that:	
■ Single measurement not a diagnosis	83
■ Test just an indication of level	68
Screenees with tests over 200 not told to see own physician	61
List of physicians for referral purposes not available	82