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**Authors**

Emerson, Jane F  
Jafari, Mahtab

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# Dyslipidemia Prevalence in a Laboratory Initiated Screening Program

JANE F EMERSON, MAHTAB JAFARI

**OBJECTIVE:** Evaluate utilization and diagnosis rates in a self-pay, self-referred screening program for dyslipidemia.

**DESIGN:** 301 patients self-referred to the clinical laboratory for lipid testing in a two-year period. The patient population that participated was characterized in terms of insurance status, gender, age, and known cardiovascular risk factors. Lipid profiles were characterized as measured by total cholesterol, triglycerides (TGs), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), and total cholesterol to HDL risk factor.

**SETTING:** Clinical laboratory in an academic medical center.

**PATIENTS:** Data from all patients that self-selected for screening were included.

**INTERVENTIONS:** Immediate laboratory results with both verbal and written interpretations and recommendations were provided to the patients.

**MAIN OUTCOME MEASURES:** Age, gender, insurance status, number of known risk factors, and lipid profiles in the subject group.

**RESULTS:** The mean age of participants was 57 years. Men (197) outnumbered women (104) by almost 2:1; most (94%) had health insurance. At presentation, 44% of the patients had more than one risk factor for coronary heart disease (CHD). 151 individuals (50%) had lipid findings that would require at least dietary intervention by NCEP guidelines.

**CONCLUSION:** A self-pay, self-referred screening program for lipid disorders is an effective means of improving screening and diagnosis rates. Patients with insurance were willing to pay for the convenience offered and men in particular were more likely to self-refer than women, independent of previous knowledge of risk factors or lipid disorders.

**ABBREVIATIONS:** CHD = coronary heart disease; HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein

*The peer-reviewed Clinical Practice section seeks to publish case studies, reports, and articles that are immediately useful, of practical nature, or demonstrate improvement in the quality of laboratory care. Direct all inquiries to Bernadette Rodak MS CLS(NCA), CLS Clinical Practice Editor, Clinical Laboratory Science Program, Indiana University, Fesler 409, 1120 South Avenue, Indianapolis, IN 46202-5113. brodak@iupui.edu*

cholesterol; NCEP = National Cholesterol Education Program; RF = risk factor; TG = triglyceride.

**INDEX TERMS:** cardiovascular; direct-access laboratory testing; dyslipidemia; lipids; risk factors; screening.

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*Jane F Emerson MD PhD is Chief of Clinical Pathology at the University of California, Irvine Medical Center, Orange CA.*

*Mahtab Jafari PharmD is Assistant Clinical Professor, Department of Medicine, University of California, Irvine CA.*

**Address for correspondence:** Jane F Emerson MD PhD, Chief of Clinical Pathology, Rt 38, University of California, Irvine Medical Center, 101 The City Drive, Orange CA 92868. (714) 456-7557, (714) 456-8272 (fax). jemerson@uci.edu

Dyslipidemia is a condition that satisfies the cardinal rules for promoting widespread screening. It is highly prevalent, asymptomatic, associated with disease which results in significant morbidity and mortality; screening is negligibly invasive; and effective interventions which are themselves relatively low risk and proven to decrease morbidity and mortality are available. Despite this, dyslipidemia continues to be under-diagnosed and too often unsuccessfully treated.<sup>1,2</sup> Various factors are attributed to a general lack of compliance in seeking medical care and following through with recommended treatment plans. These include, among others, lack of education, resistance to lifestyle changes, denial, adverse effects of pharmacological therapeutics, and personal inconveniences. Because of the magnitude of this public health problem, which accounts for the majority of deaths per year in the United States and over 100 billion dollars per year in direct and indirect healthcare costs, successfully addressing any of these factors will have significant benefit to the public.<sup>3</sup>

Lipid profiles are typically obtained on patients at the request of their personal physician following an office visit. Abbreviated screening, or cholesterol testing, is also available to the public through health fairs and at some pharmacies. Both of these approaches have features that may discourage utilization. Inconveniences and time requirements are cited as cause for avoiding or procrastinating office visits. Lipid testing in the health fair or drug store setting is limited in its scope and usually insufficient education and consultation are provided. Direct-access laboratory testing for lipid disorders and other conditions has been made avail-

able in a small number of institutions and the practice has been controversial. Anecdotal and hypothetical situations arguing both for and against such programs have been presented; however formal evaluations have not been documented.

The purpose of this study was to assess a self-pay, self-referred screening program in which immediate results and consultations are provided to the patient. The intent was to determine the types and prevalence of dyslipidemias newly diagnosed by this program and to characterize the patient population for which this type of healthcare delivery holds promise. The hypothesis was that complementing conventional healthcare delivery pathways by promoting direct-access laboratory testing for dyslipidemias, along with review of other risk factors for coronary heart disease (CHD), will improve diagnosis rates and treatment outcomes for certain patient populations. Conventional medical care delivery, characterized by physician-ordered testing following an office visit, deters some individuals from seeking appropriate care. This study provides the preliminary data needed to formally evaluate outcomes from this type of healthcare delivery.

## METHODS

A walk-in self-pay screening program for lipid profiles was made available to the general population. The clinical laboratory at the University of California, Irvine Medical Center was opened to patients, without appointment, two mornings a week. The service was minimally promoted; announcements were made through the medical center's community newsletter on two occasions.

Upon presentation for testing, patients completed a questionnaire addressing family medical history, medical history, aspects of lifestyle including exercise habits, dietary fat estimates, tobacco use, and alcohol use. On the questionnaire, medical history was obtained by subjects' selection of conditions phrased as high blood pressure, diabetes, heart attack, stroke, high cholesterol, and 'other' as a write-in. Family history was phrased similarly with a field to specify which relative(s) was (were) involved. Medical and family histories as reported by the patients were used to assess the number of CHD risk factors and were not confirmed by chart review or physical examination.

A capillary (fingerstick) sample of blood was analyzed on a Cholestech LDX System (Cholestech Corporation, Hayward CA) for total cholesterol, TGs, HDL, LDL, VLDL, and a cholesterol-to-HDL risk ratio was calculated. For cases in which the Cholestech system was unable to provide the complete profile because of analytes exceeding linearity ranges, a venipuncture was offered to the patients for subsequent testing on a Beckman LX20.

Patients were given printed results at completion of testing (approximately 5 minutes) and received a verbal consultation with either a clinical pharmacist experienced in lipid management or the medical director of the laboratory. Approximately 10 to 15 minutes were spent explaining results, addressing risk factors, answering questions

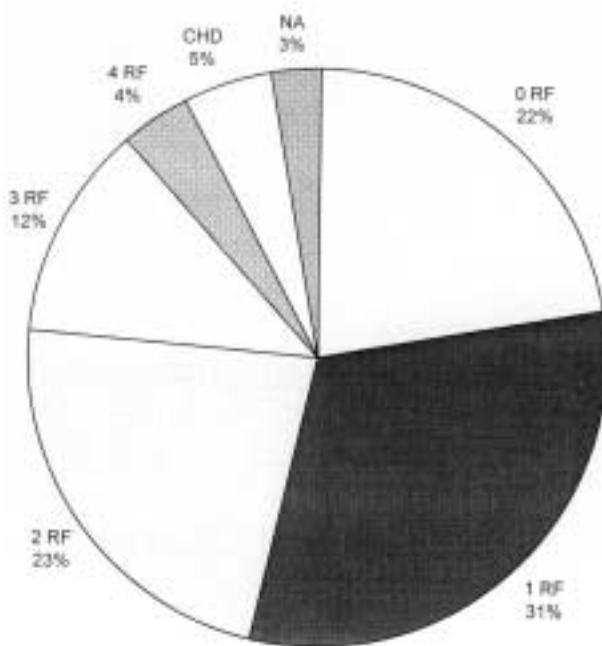
about the availability and effects of lipid-lowering medications, and encouraging patients to seek medical care from their primary care provider or specialist. A letter was mailed to each patient re-stating their results and general recommendations; a referral service was offered for those patients without providers.

Laboratory results were interpreted according to National Cholesterol Education Program (NCEP) guidelines. For patients with less than two CHD risk factors, LDL values above 160 mg/dL were classified as undesirable and requiring intervention. For patients with two or more risk factors, the decision level for LDL was greater than or equal to 130 mg/dL; with a history of CHD the decision level was greater than or equal to 100 mg/dL. The decision level for HDL was less than or equal to 35 mg/dL. TGs above 200 mg/dL were classified as undesirable for all patients.

## RESULTS

A total of 301 patients participated in this program over a two-year period (August 1998 through July 2000). Men (197, 65%) outnumbered women (104, 35%) by almost 2:1. Subjects ranged in age from 26 to 86 years (mean age  $57 \pm 13$ ). 94% of the subjects had health insurance.

**Figure 1.** Distribution of number of known risk factors at presentation for lipid screening



Distribution of number of known risk factors (RF) for CHD at presentation. Number of RF was determined by answers to a questionnaire as described in the text. Three percent of the subjects did not provide the information; that data is denoted 'NA'.

Figure 1 charts the distribution of number of risk factors present in the participants. Forty-four percent of the subjects had more than one risk factor for CHD and 5% reported a history of CHD. Using NCEP guidelines, 87 (29%) were found to have LDL values above target, 69 (23%) had triglycerides above recommended levels, and 62 (21%) had HDL values below desirable. Overall, 151 patients (50%) had a condition that would require at least dietary intervention. Categories of lipid disorders found at screening are shown in Figure 2. Nine percent had combined LDL and TG elevations, 20% had elevated LDL only, 14% had elevated TG only, and 7% had low HDL only.

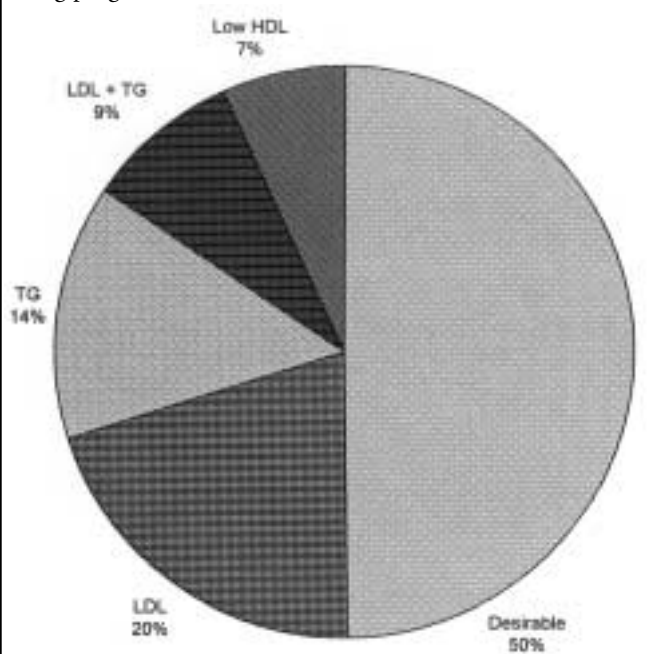
Of the subjects for whom lipid findings warranted interventions, 34% were previously undiagnosed. Of the total number of participants, 17% were found to have a previously undiagnosed dyslipidemia for which intervention is recommended by NCEP guidelines. By gender, 49% of the women presenting had no knowledge of a previously diagnosed lipid disorder and 41% of the men were previously undiagnosed (Figure 3). Of the total number of participants, 33% had a previous diagnosis of lipid disorder but were not currently treated to target values.

**DISCUSSION**

No-appointment, self-pay screening as a method of accessing medical care was utilized by a population that in the majority was insured. The types of patient that self-selected for this program included both those with known risk factors for CHD and those without. During consultations, patients cited convenience and immediate consultation as factors inducing them to make use of the service. Patients in whom a lipid disorder had been previously diagnosed but who had ceased to comply with treatment recommendations reported that the availability of this program served to encourage them to return to their providers or seek new ones. Some patients made use of this service to monitor their treatment themselves, reporting that more frequent monitoring was an aid to compliance. However, previous knowledge of a lipid disorder did not seem to be a major factor in determining those patients that self-select for this screening for either men or women; in both groups, roughly half had no previous diagnosis.

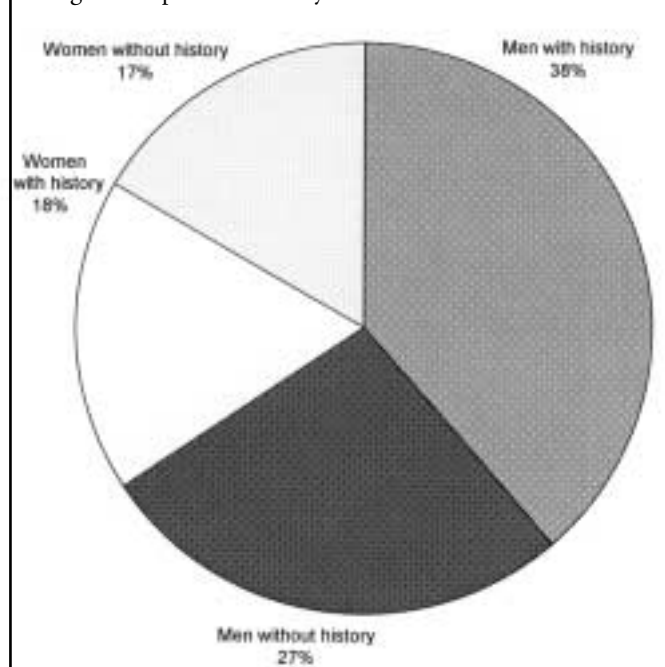
Women are characterized as using more healthcare services than men.<sup>4</sup> Of note is that men used this service at a rate of almost twice that of women. For men in particular, this entry point into medical care may effectively capture more patients than the con-

**Figure 2.** Dyslipidemias found in the self-referred screening program



Findings from the lipid panel performed on this self-referred population. 'Desirable' indicates LDL, TG, and HDL were desirable according to NCEP guidelines and accounting for number of CHD risk factors. 'TG' denotes elevated triglycerides; 'LDL+TG' denotes elevations in both LDL and TG; 'LDL' denotes LDL levels above target values; 'Low HDL' indicates HDL levels below desirable.

**Figure 3.** Participants with and without previously diagnosed lipid disorders by sex



A comparison of the self-referral pattern for men and women and the dependence on previous knowledge of a lipid disorder. Forty-nine percent of the women and 41% of the men presenting had no knowledge of a lipid disorder.

ventional office-visit approach. Evidently, the rate of diagnosis of lipid disorders would be improved by making this type of program widely available. Whether this approach results in a higher rate of successfully treating dyslipidemia deserves formal study.

### CONCLUSIONS

The prevalence of dyslipidemia in this patient group was over 50%. The majority of these, 60 subjects (20%), had an isolated increase in LDL. Elevated TGs accounted for 14%, 9% had combined elevated LDL and TGs, and 7% did not have elevated lipids but had HDL levels below desirable. Of the patients with dyslipidemia, 34% were previously undiagnosed.

A screening program, which increased convenience for patients and provided sufficient education was utilized and paid for by the

patients, 94% of whom had health insurance and alternate means of obtaining medical care. The male to female ratio of patients that self-selected for this program indicates that this may be an effective means to increase diagnostic and treatment rates in men.

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Recipients of the *Clinical Laboratory Science (CLS)* Distinguished Author Awards are chosen by *CLS* readers and editorial board members. Nominations are based upon originality, quality of writing, and relevance and value to the clinical laboratory science profession. The Editorial Board of *CLS* is pleased to announce the following recipients of the 2001 Distinguished Author Awards:

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### **Reports and Reviews/Research Sections**

Mary E Koenn MS, Beverly A Kirby MS, Linda L Cook MD FCAP FASCP, Julie L Hare, Sharon H Hall, Paula M Barry, Cheryl L Hissam, and Stephanie B Wojcicki for their article *Comparison of Four Automated Hematology Analyzers* in the Fall 2001 issue of *CLS*.

### **Focus Section**

Teresa S Nadder PhD CLS(NCA) and Michael R Langley CLSp(MB) for their article *The New Millennium Laboratory: Molecular Diagnostics Goes Clinical* in the Fall 2001 issue of *CLS*.