

Reviews Analyses

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Diagnostic technology in cardiovascular disease: review of noninvasive methods for population studies

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To aid the selection of appropriate diagnostic technologies, the literature on non-invasive methods for population studies of cardiovascular diseases was reviewed. Indications, limitations and cost-effectiveness are discussed. Most widely applicable are the standardized medical history, blood pressure and other measurements, resting electrocardiogram, chest X-ray, and selected tests of blood and urine. Useful in specialized studies are exercise testing, ambulatory monitoring, and peripheral arterial flow measurements. Ultrasound is valuable in the study of hypertensive and other myocardial diseases. Further methodological research is needed.

Frequent assessments of diagnostic technology in the management and study of cardiovascular disease appropriate to the various levels of care (primary, secondary, and tertiary) and types of health care systems (little developed, intermediate, and well developed) are needed by government and private physicians, clinics, hospitals, researchers, and health planners. Methods for population studies of cardiovascular disease were previously described at length in a World Health Organization monograph (1). The present review focuses on noninvasive^a methods for population studies that included measurement of the amount of disease in a population, distribution of disease within a population, and the natural history of disease. Due to space limitations, a comprehensive literature review will not be attempted. Excluded from consideration are cerebrovascular disease, venous and lymphatic disease, and instrumentation

for monitoring acute care. Special emphasis will be given to the published experience of the U.S. National Center for Health Statistics (NHCS) (2, 3). Under each heading, indications, limitations, and cost-effectiveness will be discussed briefly.

REVIEW OF METHODS

History and physical examination

History. Universally indicated is a medical history of the participant (1). Histories with varying focus form the basis for the NCHS Health Interview Survey (HIS) and important components of the NCHS Health Examination Surveys (HES) and National Health and Nutrition Examination Surveys (NHANES) (4-11). Table 1 lists some of the cardiovascular items in the examination survey histories. Family histories, which are often neglected, are also useful. The available standardized questionnaires should be used to identify symptoms of angina pectoris, myocardial infarction, and intermittent claudication (1, 9, 11, 12). Severity of symptoms of angina pectoris, rheumatic heart

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^a Noninvasive: "devices or procedures which do not require entering the body or puncturing the skin" (from *Tabers Cyclopedic Medical Dictionary*, 13th ed. Philadelphia, F. A. Davis, Co., 1977).

Table 1. Some medical history and related variables obtained on NCHS examination surveys^a

	HES 1960-70	NHANES I 1971-75	NHANES II 1976-80
Congenital heart condition		+	+
Heart condition	+	+	
Rheumatic fever	+	+	
Rheumatic heart disease			+
Heart murmur	+	+	+
Heart failure		+	+
Heart attack		+	+
High blood pressure	+	+	+
Stroke	+	+	+
Low blood pressure		+	+
Diabetes	+	+	+
Chest pain	+	+	+
Leg pain		+	
Shortness of breath	+	+	+
Heart medication	+	+	
Blood pressure medication	+	+	+
Special diet (type)		+	+
Smoking		+	+
Physical activity		+	+
Coffee/tea		+	+
Family history of diabetes			+
Chronic obstructive pulmonary disease		+	+
Birth control pills		+	+
Coronary prone behaviour			+
Alcohol intake		+	+

^a Some items obtained only for restricted age ranges or subsamples; see published survey descriptions for details.

disease, congestive heart failure (CHF) and other diseases should be graded by one of the available systems (13, 14). The classification of cardiac status and prognosis based on all available data, introduced in 1973 by the New York Heart Association, may be less useful in population studies than the earlier functional classification based on symptoms alone (13, 15, 16). A modification is available that is more suitable for classification of symptoms of angina (14). Histories may also be abstracted from medical records (17-20).

The validity of historical information is limited and varies with the method of obtaining it, the population, the type of health care system, and the questionnaire items (1, 17, 19, 21-24). The standardized question-

naires for angina pectoris, myocardial infarction and intermittent claudication have acceptable validity in developed countries, but the high apparent prevalence of angina pectoris in Africa and the Caribbean region indicates the need for studies of chest pain in nonatherosclerotic heart diseases (1, 25). Further work may be needed in standardizing questionnaires for assessing the history and symptoms of acute rheumatic fever, rheumatic heart disease, and idiopathic cardiomyopathy and in making more translations of all questionnaires (13).

The cost of obtaining the medical history is low and this method can be used in populations served by all levels of care and types of health care systems. Unfortunately, its effectiveness and validity are likely to be least in areas where access is limited to primary care or traditional practitioners and where health care systems are little developed. The assessment of symptoms may be more widely practised as a valid method.

Physical examination. In population studies of coronary heart disease, and hypertensive vascular disease, physical examination by physicians is in-

Table 2. Some physical examination and related variables obtained by physicians in NCHS examination surveys^a

	HES 1960-70	NHANES I 1971-75	NHANES II 1976-80
Blood pressure:			
Supine		+(1) ^{b, c}	+(1) ^b
Seated	+(3) ^c	+(2)	+(2) ^b
Resting pulse rate		+	+
Fundoscopy	+	+	
Neck veins	+	+	+
Palpation of peripheral arteries	+	+	+
Oedema of extremities	+	+	+
Cardiac auscultation	+	+	+
Cardiac palpation	+	+	+
Cyanosis		+	+
Irregular pulse		+	+
Diagnostic impressions	+	+	+
Severity rating		+	+
Certainty rating		+	+
ICD code		+	+

^a Some items performed on restricted age ranges or subsamples; see published survey descriptions for details.

^b One reading performed by a nurse.

^c Figures in parentheses are the number of readings.

creasingly replaced by standardized questionnaires for history and symptom evaluation, abstracting of medical records, measurement of blood pressure, heart rate, and body size by trained technicians, and by electrocardiography and other methods (1, 17, 19). Physical examination is still indicated (a) when other methods are inadequate, e.g., valvular and congenital heart disease or congestive heart failure; (b) when a physician's examination is being employed for other systems in multipurpose surveys, e.g., HES, NHANES (Table 2) (4-11); and (c) when exercise testing is to be performed. Standardized check lists should be used and physicians or other examiners trained, tested, and observed for quality control (1, 4-12). Data should be adequate for the application of objective diagnostic criteria, if possible by computer algorithm (12, 13, 26-28). Retinal vessels were evaluated by internists or paediatricians in HES and by ophthalmologists in NHANES using different check lists (5, 8, 9, 11). Retinal photographs may be useful in surveys (1). Peripheral arteries were evaluated by palpation in HES and NHANES (5, 8, 9, 11). Doppler flow measurements may also be useful in surveys (1). Great advances have been made in standardization of indirect blood pressure measurements including instrumentation, audio and video training systems, and automated devices (1, 29-31). In addition to height, weight, and subscapular and triceps skinfold thicknesses, the waist and hip girth should be measured to assess adipose tissue distribution (32-34). Date, time of day, room temperature, and body temperature should all be recorded to allow for circadian, seasonal, and environmental sources of variation.

Proved limited reliability or lack of validation of many variables in physical examinations has contributed to the move to quantitative methods and the use of objective criteria rather than physicians' impressions (1). Limited data on examiner variability in children and youths aged 6 to 17 years in HES have been published (35). Reducing examiners' variability in surveys employing large numbers of physicians is difficult; examiner effects should therefore be analysed.

The use of physicians is very costly, especially in highly developed systems. Costs might be cut using trained technicians or paramedics for most or all of a limited examination. The examination should be highly focused since many or most of the items on a general examination will never be used in data analysis; only items required for diagnostic criteria or hypothesis testing need be obtained.

Electrocardiogram

The resting twelve-lead electrocardiogram (ECG) is widely used in population studies of heart disease

prevalence or incidence (1, 4-11, 27, 28). In community heart disease registers or surveillance studies, ECGs are obtained from hospital records (17-20, 36). Whatever the source, of utmost importance are standardized procedures for recording, measurement and coding (1, 37). Recording and processing procedures used in HES and NHANES have been described as have criteria and analysis of ECG data from HES (4-12, 27, 28). Extensive data are available on repeatability and validity of manual measurements using the Minnesota Code which remains the method of choice for most major studies (1, 37). With high expectations for improvements in quantitative measurement and data handling, automated and semi-automated methods for recording and computer-assisted analytic programs are being used increasingly in mass surveys in the USA. Some diagnostic criteria are based on Minnesota Code categories (1, 17-18, 36). Despite the increased risk of coronary heart disease associated with certain ECG findings, some mass risk surveys omit the ECG, focusing on modifiable risk factors (19). Future NCHS examination surveys will continue to obtain ECGs on adults using automated methods for recording and computer reading for the Minnesota Code and left ventricular hypertrophy.

Instrumental and procedural problems have been discussed that limit validity and repeatability (1, 37). Adequate expertise and resources must be available to avoid malfunctions of automated systems which may cause loss of data or the need to repeat all measurements by manual systems. Adequate treatment of this technology is beyond the scope of this review.

The costs of ECG recording, processing, coding, and interpretation are considerable but justified in populations with high heart disease prevalence, e.g., the elderly and middle-aged males in the USA and Europe, given its well-defined if limited effectiveness in detecting previous myocardial infarction and left ventricular hypertrophy (12, 38, 39). However, in low prevalence groups, standardized questionnaires may be more cost-effective. Such questionnaires may also identify high-prevalence population subgroups which may then be surveyed by ECG.

Chest X-ray

A posterior-anterior (PA) teleroentgenogram is indicated in population studies of hypertensive, valvular, congenital, and syphilitic heart disease and of cardiomyopathies (1). PA chest X-rays were included in HES and in NHANES I and II (4-12). Qualitative interpretations were made of cardiac enlargement in HES (12, 35). Heart and aortic diameters can be reliably measured (1, 40). Studies are under way of pulmonary vascular patterns consistent with pulmonary hypertension and of heart

Table 3. Some laboratory studies obtained in NCHS examination surveys^a

	HES I 1960-61	HES III 1966-70	NHANES I 1971-75	NHANES II 1976-80
Blood:^b				
Total cholesterol	+	+	+	+
Triglyceride				+
High-density lipoprotein				+
Glucose tolerance	+			+
Sodium			+	
Potassium			+	
Calcium			+	
Magnesium			+	
Creatinine			+	+
Uric acid	+	+	+	
T4, T3 ^c			+	
Haemoglobin		+	+	+
Haematocrit		+	+	+
White blood cell count			+	+
ABO blood group		+		
Sedimentation rate			+	
Carboxyhaemoglobin				+
Syphilis serology	+		+	+
Urine:				
Qualitative screen				+
Sediment			+	+

^a Many tests performed only on restricted ages or subsamples; see published survey descriptions for details.

^b Biochemical determinations made on serum.

^c Thyroid hormones: T4, thyroxine; T3, triiodothyronine.

volume estimates in NHANES. The presence of any pulmonary lesions was also noted.

Limited data on between-observer variation in qualitative readings in HES have been published (12). Further data are needed on validity of X-ray assessment of cardiac and chamber enlargement (40). The infrequent use of measurement of frontal diameters in the USA greatly limits the utility of chest X-ray data (1). Even with lateral films the assessment of specific chamber enlargement may be inadequate (1, 40).

Although costs are relatively modest, they may not be justified in surveys whose focus is coronary heart disease or in populations with low prevalence of heart or lung disease, especially in view of the radiation exposure.

Laboratory tests on blood and urine

Biochemical tests of blood and urine and haematology tests are indicated in population studies to

assess cardiovascular risk and renal sequelae of hypertensive disease (1). Some of the tests used in NCHS examination surveys are summarized in Table 3 (4-11). Coronary risk surveys may include HDL (high-density lipoprotein) cholesterol sub-fractions, apoproteins, triglycerides, and plasma fibrinogen. Specialized surveys, cohort studies, and clinical trials may include other measures of thrombotic and thrombolytic factors (41), lipoproteins, urinary sodium, potassium, and calcium excretion (42), and household water hardness and trace metal concentrations (8). Laboratory data abstracted from medical records are used in cohort and surveillance studies and trials for validation of acute events by criteria (17-20). Immunological and bacteriological methods may be needed in specialized studies of diseases related to infections, e.g., rheumatic heart disease, syphilitic heart disease, Chagas' disease, myocarditis, and renal disease.

Laboratory standardization is a recurring problem

both among laboratories and within laboratories over time (1, 43). Standardization programmes have been coordinated by WHO and the U.S. Centers for Disease Control, most notably for blood lipids (1). Details of specimen collection and storage are also important (1). Total serum cholesterol remains an effective laboratory measure of coronary risk, enhanced by measurement of HDL cholesterol (1). Laboratory tests may focus on renal disease in populations with low coronary but substantial hypertensive prevalence.

Exercise tests

The proceedings of recent symposia have reviewed assessments of cardiopulmonary fitness, work capacity, and cardiac ischaemia in populations (44, 45). With few exceptions, the treadmill, bicycle, or step tests are not indicated in large population studies of adults for diagnosis of latent coronary artery disease or other heart disease (46). An example of special applications in clinical trials was the Multiple Risk Factor Intervention Trial (MRFIT) in a population of men preselected for high risk of coronary artery disease (47). The utility of these tests is limited in population studies of cardiopulmonary fitness in adults owing to limitations and costs discussed below. The NCHS performed submaximal tests of fitness in children and youths in HES and a recent national study of children and youths has been reported (6, 7, 45, 48). However, no further use of exercise tests is currently planned by NCHS. Of greater value for population studies are standardized questionnaires for assessment of habitual physical activity (49, 50). First used in the 1985 Health Interview Survey, such instruments are contemplated for future NCHS surveys (51).

In white American male populations, the standard treadmill or bicycle ergometer exercise tests had a sensitivity of only about 50% and a predictive value of a positive test of only 5–46% for detecting latent coronary artery disease in apparently healthy persons (46). Further, although the specificity may be about 90%, potential iatrogenic problems or unnecessary health costs may arise from the large number of false-positive tests in a large survey (46). Performance may be even poorer for women and possibly for blacks and other racial groups (25, 46). Maximal or vigorous submaximal protocols may be unacceptable to large numbers of adults resulting in increased nonresponse or biased exercise test data in surveys of fitness (1, 45). Although safe and acceptable to children, youths, and young adults for the assessment of fitness, fixed-load submaximal tests have limited validity while maximal tests or maximal oxygen consumption measurements have excessive costs.

Technical difficulties in test standardization can invalidate data from population studies (45, 52). The validity may be questioned of fitness classifications based on low-level tests or inadequately validated questionnaires (1, 45, 49). Especially difficult with tests is relating the energy expenditure both to body mass and to the work performed (1, 45).

The costs of simple, low-level, fixed-load step tests may be low, but like the more expensive fixed-load treadmill or bicycle tests, the resulting data are of limited utility for assessing fitness and of very little value for diagnostic purposes in apparently healthy populations (1, 45, 46). Maximal tests are effective for assessing fitness but not for diagnosis in apparently healthy populations and their costs are extremely high if well standardized and monitored (1, 45, 46). Further, there is a low but measurable risk of complications even if persons with clear contraindications are excluded (46).

Ultrasound

One- or two-dimensional M-mode echocardiography may be indicated in population studies of hypertensive disease, other myocardial disease and valvular heart disease (1, 53). While the method has not yet been used in NCHS surveys, it has recently been added to the Framingham cohort study and offspring study and used in studies of left ventricular mass and blood pressure and of mitral valve prolapse (53–55). The number of all-listed procedures of diagnostic ultrasound of the heart for inpatients in U.S. hospitals increased from 65 000 in 1979 to 262 000 in 1984, the number for outpatients very likely being even greater (56). The increasing use of this procedure in developed countries may improve the validity of certain medical record diagnoses (20, 26).

Validity is limited unless standardized recording protocols and quantitative measurement techniques are used (1, 54, 57, 58). Images are often unsatisfactory in persons with obesity, emphysema or advanced age (54). Highly trained technicians and interpreters are needed for obtaining valid data. Diagnostic criteria remain controversial for mitral valve prolapse in asymptomatic populations (59). Recognition of structural abnormalities remains qualitative and subjective in many cases and hence subject to observer variation (1, 58, 59).

The costs of equipment, operating technicians, and interpretation are high. The median clinical cost of a M-mode test was US\$160 (range, \$127–300) and that of a 2-D test \$275 compared with \$8–64 for ECG (with research charges somewhat lower) in a U.S. study (60). Further studies are needed of cost-effectiveness in various applications and settings.

Ambulatory ECG and blood pressure measurements

Ambulatory (Holter) ECG recordings of various durations have been made in few population studies and clinical trials (61, 62). The NCHS demonstrated in a pilot test that a 2-hour recording taken while the examinee was engaged in other parts of the NHANES examination was feasible (11). Such recordings are likely to be included in future risk surveys. Recently, ambulatory indirect blood pressure monitoring techniques have been developed (63). They have not yet been considered suitable for large population studies.

In NHANES, an expert committee concluded that certain parts of the examination, e.g., the glucose tolerance tests, would affect the production of arrhythmias and make placement of the 2-hour recording within the examination protocol an important consideration (11). Limitations of repeatability and validity have been discussed elsewhere (61, 62, 64).

The costs of collecting, processing, and interpreting ambulatory monitoring data are high and the value of the descriptive and analytic analyses that are possible in cross-sectional surveys of apparently healthy populations are still ill-defined. Their value may be greater in cohort studies and clinical trials. Further study is required of the cost-effectiveness of various durations of ECG monitoring which have ranged from a 2-minute rhythm strip to 24 hours of monitoring in the few previous population studies (62, 64). Similarly undefined is the cost-effectiveness of ambulatory blood pressure monitoring in population studies (63).

Mechanocardiography, polygraphic methods, and spirometry

With few exceptions, mechanocardiographic or polygraphic methods are not indicated in population studies of cardiovascular disease. No NCHS survey has used them. In contrast, spirometry has been performed in HES and NHANES I and II examinations and will be used in future combined surveys of cardiopulmonary disease (65-68). Previously described were the data acquisition hardware including digital tape equipment, standard operation procedures, and a computer-assisted data analysis system for spirometry (67, 69, 70).

Serious observer variation has been documented with mechanocardiographic and polygraphic procedures (1). Methodological problems in children's spirometry have been documented at length by NCHS (65). The quality of data may be impaired by lack of participant cooperation or understanding, especially in children and populations or subgroups with language or cultural barriers to acceptance of the technology.

Tape-recording of heart sounds has been attempted in screening programmes for congenital or acquired valvular heart disease in children (71). However, the cost-effectiveness of such programmes compared with other detection methods requires further study. The forced-expiratory spirogram offers an effective tool for assessing chronic obstructive lung disease at all stages. Vital capacity has been related to cardiovascular risk (72). Manual measurements from spiograms are costly but may be cost-effective where personnel costs are low compared with the cost of sophisticated computer technology. As with ECG data recorded on magnetic tapes, the importance of strategies for safeguarding data from surveys to prevent disastrous data losses cannot be over-emphasized (65).

Methods for peripheral arterial disease

Standardized questionnaires for symptoms of leg pain and palpation of peripheral pulses may be supplemented with Doppler flow measurements over the posterior tibial and/or dorsalis pedis artery (1, 73). The use of an ultrasonic Doppler flowmeter may be contemplated for examination surveys. Ultrasound is also being evaluated by the U.S. National Heart Lung and Blood Institute for population studies of atherosclerosis of the carotid and femoral arteries.

Standardization of clinical examination of pulses is very difficult (1). Further experience with Doppler flow measurements in the National Heart Lung and Blood Institute and elsewhere will help establish their role in population studies (73).

Acceptable cost-effectiveness of examination tests is likely only in populations with high prevalence of atherosclerotic peripheral arterial disease. Standardized questionnaires are an advisable and inexpensive substitute even in these populations. Questionnaires may also be used to define subpopulations for examination testing. Low levels of interest and funding have hindered advances in the field and also analysis of previously collected data (73).

CONCLUSIONS

General principles that guide the selection and application of all the procedures mentioned here have been discussed elsewhere (1). Not to be forgotten are provisions for minimizing participant risks from radiation, electricity, infection, haemorrhage, mental distress, and medical emergencies as well as provisions for informed consent, confidentiality of data, and appropriate reporting of referrals and results. In 1980, the American College of Cardiology and the American Heart Association formed a Task Force on

Assessment of Cardiovascular Procedures to make recommendations regarding the appropriate use of technology in the diagnosis and treatment of patients with cardiovascular disease (46). The already published and forthcoming reports of this task force will be a valuable resource for those requiring current assessments of diagnostic technology. A wealth of information about the performance of noninvasive methods has been acquired by the NCH since the first of its examination surveys began in 1959. Much has been or will be published in the Series 1, 2 and 11 of *Vital and health statistics* (3). The NHANES I Epidemiologic Followup Study will permit the results of many tests to be related to subsequent risk of death

and cardiovascular disease (74). Some needed advances in noninvasive methods for future population studies include the following: development of a noninvasive system for imaging major coronary arteries for the detection of latent coronary artery disease; further assessment of the performance of many standard tests in population groups other than white males (25, 75); application of new technologies to bring down the equipment and personnel costs of echocardiography and other methods for use in mass surveys and in countries with limited resources; and further assessments of cost-effectiveness in various settings.

RÉSUMÉ

TECHNOLOGIE DIAGNOSTIQUE DANS LES MALADIES CARDIOVASCULAIRES: EXAMEN DES MÉTHODES ATRAUMATIQUES POUR LES ÉTUDES DE POPULATION

La technologie diagnostique dans les maladies cardiovasculaires doit être fréquemment réévaluée. On examine ici les méthodes atraumatiques utilisées pour les études de population avec leurs indications, leurs limites et leur rapport coût-efficacité. En premier lieu s'impose l'anamnèse au moyen de questionnaires normalisés. Sa validité varie selon la méthode, la population, le système de soins de santé et la question considérée. Toutefois, son coût est faible. L'examen physique par un médecin est indiqué dans les enquêtes portant sur les cardiopathies congénitales et valvulaires, dans les enquêtes à buts multiples, et avant les épreuves d'effort. Sinon, les questionnaires et la mesure de la tension artérielle par un technicien peuvent suffire. Il existe des méthodes normalisées pour la prise de la tension artérielle. L'examen médical peut en revanche être d'une fiabilité limitée ou inconnue et est coûteux.

L'électrocardiogramme au repos est largement utilisé dans les études de population, avec des protocoles normalisés d'enregistrement, de mesure et de codification (Minnesota Code). On utilise de plus en plus souvent des méthodes assistées par ordinateur. Le coût élevé en est justifié lorsqu'il s'agit de populations à forte prévalence de cardiopathies. La radiographie thoracique donne des mesures qualitatives et quantitatives de la taille du cœur dans les cardiopathies non coronariennes et sont d'un bon rapport coût-efficacité lorsque la prévalence de ces maladies est élevée. Les épreuves hématologiques et les

analyses d'urine sont indiquées pour évaluer le risque cardiovasculaire et les séquelles rénales de l'hypertension. Les enquêtes spécialisées peuvent exiger une analyse biochimique, hématologique, immunologique ou bactériologique. La normalisation des examens de laboratoire est un problème chronique; des programmes de normalisation de la mesure de la lipémie ont été coordonnés par l'OMS.

A quelques exceptions près, les épreuves d'effort ne sont pas indiquées dans les études de population à grande échelle portant sur la prévalence des cardiopathies en raison de leurs limites et de leur coût. Pour l'évaluation du risque, on utilise souvent des questionnaires normalisés portant sur l'activité physique habituelle. L'échocardiographie peut être indiquée dans les études de population portant sur l'hypertension, les autres myocardopathies et les troubles valvulaires. Pour une meilleure validité, on utilise des protocoles normalisés d'enregistrement et des techniques de mesure quantitatives. Le coût de ces opérations est élevé. La prise d'électrocardiogrammes en ambulatoire a été utilisée dans quelques études. Le coût en est également élevé. Les spiogrammes sont indiqués dans les enquêtes à buts multiples portant sur les maladies cardiaques et pulmonaires. Pour l'évaluation de l'artériopathie périphérique, les questionnaires normalisés et l'ultrasonographie Doppler peuvent être indiqués dans les populations âgées à forte prévalence. De nouvelles études de méthodologie sont nécessaires.

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