

## REITERATIONS

# A controlled trial of multiphasic screening in middle-age: results of the South-East London Screening Study\*

The South-East London Screening Study Group

South-East London Screening Study Group (Department of Community Medicine, St Thomas's Hospital and Medical School, London SE1 1EH, England). A controlled trial of multiphasic screening in middle-age: results of the South-East London Screening Study. *International Journal of Epidemiology* 1977;6:357-63. The results of a controlled trial of multiphasic screening in general practice are presented. In 1967, 7229 individuals aged between 40 and 64 years were randomly allocated into either a Screening or Control group. The Screening group were invited to attend two screening sessions held about two years apart, while the Control group continued to receive conventional medical care. Both groups were then invited to undergo a health survey in 1972-73 which revealed no significant differences in morbidity between the two groups. Careful follow-up permitted detailed Screening-Control comparisons of various outcome measures—consultation and hospital admission rates, certified sickness absence from work, and mortality. Nine years after the initial screening, no significant differences were found between the two groups in any of the outcome measures. It is estimated that a similar screening programme for the entire middle-aged UK population would cost £142 million at 1976 prices.

## Introduction

In 1967, a long-term controlled trial of multiphasic screening for diseases of middle-age was embarked upon jointly by two group general practices in South London and the Department of Community Medicine at St Thomas's Hospital. The purpose of the study was to assess the value, if any, of introducing a general practice based screening service for 40- to 64-year-olds as an extension of the existing National Health Service.

This paper reports the results of the study, various aspects of which have been previously described.<sup>1-5</sup>

## Methods

The study was designed as a controlled trial (Figure 1) in which two large group practices in South London participated. Using age-sex practice registers, all persons aged 40-64 years in 1967 were identified and randomly allocated by family within general practitioner list into two equal groups designated Screening and Control (Table 1). The Screening group was then invited by

personal letter from their general practitioner to be screened. Each screening clinic operated an appointment system and was held in the evenings in local infant welfare clinics. They were staffed by nurses and specially trained local housewives who were aided and supervised by a doctor. At the clinics, a health questionnaire was administered and a series of clinical tests performed (Table 2). The questions and tests were selected, after extensive discussion and consultation, according to the twin criteria of diagnostic reliability and therapeutic significance.

The initial screening was carried out in 1967-68. Two years later, the Screening group was invited by letter to attend a second screening clinic, where a similar battery of tests was performed. These two screening sessions constituted the 'treatment' under assessment in the controlled trial.

At the first screening in 1967-68, the general practitioner conducted a physical examination on each individual. All information gathered at both screening sessions was passed to the general practitioners who decided what further investigations, diagnoses and treatments would be appropriate.

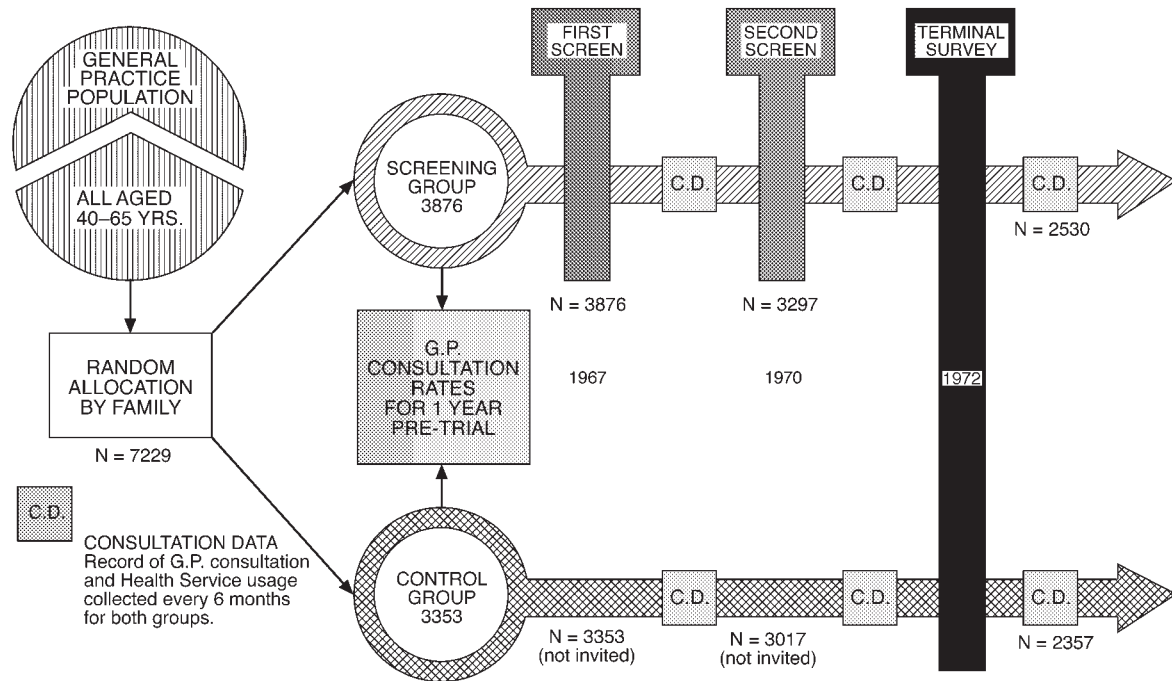
From the first day of screening, information was collected at six-monthly intervals on all consultations with the general practitioner, hospital admissions and periods of certified sickness absence. In addition, all deaths and departures from the study were carefully recorded in both screening and control populations.

It soon became clear that the migration rate from the study area was high—20 per cent of the study population over the first five

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**Figure 1** Screening study—overall plan. NB. N is the total number present at a particular point in time INVITED for screening. Changes reflect deaths, departures and administrative difficulties

**Table 1** Demographic details of the screening and control groups\*

Age (years) 1967/8	Men		Women	
	Control	Screening	Control	Screening
35-	15	17	104	112
40-	288	301	353	341
45-	362	371	405	417
50-	276	298	290	318
55-	261	313	288	315
60-	216	204	221	229
65+	37	43	16	13
Totals	1455	1547	1677	1745

Social class distributions at Final Comparison Survey compared with National Figures for 1966

Social Class (1972/3)	Control Group (N = 1950) %	Screening Group (N = 1958) %	National Data (G.R.O. 1966) %
I	2.4	2.3	2.9
II	12.5	12.1	14.6
III	52.8	52.8	49.1
IV	24.4	25.3	22.3
V	7.6	7.1	8.0
Not classified	0.3	0.5	3.0

\* This table includes those who were the spouses of the study population. The numbers are smaller than those recorded in Figure 1 due to more precise definition of the entry qualifications at the time of analysis.

years. In order that an additional assessment of outcome could be made before the residual population became unrepresentative of the original, a further method of evaluation was employed.

**Table 2** Test used in multiphasic screening procedure

- (1) Self-administered symptoms questionnaire†
- (2) Interviewer-administered questions on occupational data
- (3) Anthropometry—height, weight, skinfold thickness
- (4) Visual testing—near, distant, visual fields\*
- (5) Audiometry
- (6) Chest X-ray
- (7) Lung function tests—peak expiratory flow rate, FEV<sup>1</sup>, FVC
- (8) Electrocardiogram—12 Leads
- (9) Blood pressure
- (10) Blood tests—Hb, PVC, blood urea, random blood sugar, protein-bound iodine, serum cholesterol, serum uric acid
- (11) Stool for occult blood†
- (12) Basic physician examination\*—skin, mouth, teeth, joints, abdomen for herniae, legs for varicose veins, breast and pelvic examination

\* Not carried out at terminal survey.

† Only carried out at first screening.

‡ Bennett AC and Ritchie K (1975) 'Questionnaires in Medicine' Nuffield Provincial Hospitals Trust.

This took the form of a survey of both the Screening and Control groups two years after the second screening. Essentially, this survey was a repeat of the previous screening procedures so that direct comparisons of clinical measurements (for example, blood pressure levels) in the two groups could be made.

## Results

For the purpose of this report, all the results are presented for the two practices combined unless otherwise stated.

### Response to screening

Of the 3297 individuals invited to the first screening, 2420 (73.4 per cent) took up the invitation. At the second screening, of the 2677 invited individuals, 1775 (65.5 per cent) attended. For the survey, efforts were made to encourage those who refused the initial invitation to attend the clinic or at least give some health information at home. Consequently, the response rate was higher than at the two screening sessions. Detailed response rates have been reported previously.<sup>4</sup>

### Yield and management of disease at screening

An average of 2.3 diseases per person screened was found at the initial screening. Fifty-three per cent of this morbidity was not previously known to the general practitioners. Ninety-five per cent of the unknown abnormalities were of a minor nature, being neither disabling nor life-threatening. Of the serious diseases discovered by screening 56.3 per cent were already known. For the majority of abnormalities revealed by screening, with the exceptions of anaemia and high blood pressure, little new therapeutic intervention was introduced, although advice on stopping smoking and weight reduction was given to all for whom it was appropriate.

At the screening two years later, the yield of disease was lower than at the first screening. For example, whereas 2.1 per cent (50 persons) were newly diagnosed as hypertensive following the first screening, only 0.5 per cent (9 persons) were newly diagnosed as such after the second.<sup>4</sup>

### Outcome measures of screening

The Screening and Control groups have been compared with respect to the various outcome measures (findings at the survey, general practice consultation rates, hospital admissions, sickness absence and mortality rates) over the first nine years since the start of the study.

#### (a) Comparisons at survey

The health survey of both Screening and Control groups revealed no significant differences between them in either the prevalence of symptoms or level of function. Prevalence figures for some of the measurements are illustrated in Table 3. A very thorough examination of all the outcome variables was undertaken using a multi-factor analysis<sup>6</sup> taking into account age, sex, social class, smoking habit, blood pressure, blood sugar, serum cholesterol and general practice group. No significant differences could be demonstrated between the Screening and Control groups.

#### (b) General practice consultation rates

The Screening population appeared to have a higher consultation rate than the Control group (Table 4). However, this was not statistically significant ( $t = 1.29$ ).

#### (c) Hospital admissions

Table 5 shows the results from the hospital admission data for the Screened and Control populations. It also illustrates the risk of at least one admission both overall and within specific disease groupings. None of the observed differences are larger than could easily have occurred by chance. In addition, considering all admissions there appear to have been more in the Screening group, but again the differences are not statistically significant.

#### (d) Certified sickness

There were no significant differences in certified sickness absence between Screening and Control populations. There were large differences between men and women, since many of the latter were not entitled to sickness certification. The figures for men showed that in both the Control and Screening groups overall 5.5 per cent of their time was lost through certified sickness absence. The proportion of time lost tended to rise up to the age of 60, thereafter it decreased.

#### (e) Mortality

There were no statistically significant differences in the mortality experience of the Screening and Control populations during

**Table 3** Some measures of morbidity—Screening versus Control groups at the concluding Health Survey in 1972/73 five years after the initial screening

	Control group N = 1950 (Max.)*%	Screened 1967/68 N = 1651 (Max.)*%	Refused screening 1967/68 N = 327 (Max.)*%	Total screening group N = 1978 (Max.)*%
<b>A. Questionnaire measures of general health</b>				
1. % claiming to have good or excellent health in the fortnight preceding the survey	56.5	53.2	56.7	53.6
2. % admitting to any major disability, e.g. inability to dress or undress themselves	1.8	2.0	5.0	2.5
3. % showing downward social mobility, i.e. a fall in social class over the preceding 5 years	27.4	27.4	27.1	27.4
<b>B. Cardiovascular disease</b>				
1. % with evidence of angina on questionnaire†	22.4	21.9	21.4	21.9
2. % with raised diastolic blood pressure $\geq 105$ mmHg (Ph V)	3.1	2.7	2.4	2.8
3. % with ischaemic changes on ECG‡	16.6	17.6	21.0	17.9
<b>C. Respiratory disease</b>				
1. % still smoking	50.8	51.5	56.2	52.3
2. % complaining of any bronchitic symptoms (MRC, 1966)	30.6	28.4	34.9	29.0

\* Maximum means that this was the largest of the denominators used to derive the percentages below. These denominators varied according to the information available for the multifactor analysis.

† Rose GA. *Bulletin of World Health Organisation* 1962;27:645.

‡ Rose GA, Blackburn H. WHO Monograph, Series No. 56, WHO, Geneva, 1968.

**Table 4** Average annual GP consultation rates for subjects in the study for more than one year; Control versus Screening totals: C = 2730; S = 2844

	Men		Women	
	Control	Screening	Control	Screening
Consultation rate by diagnostic group (ICD 1957)	N = 1244*	N = 1321*	N = 1486*	N = 1523*
Overall consultation rate	3.1	3.2	3.8	4.0
	(SE = 0.09)	(SE = 0.09)	(SE = 0.09)	(SE = 0.09)
<b>Neoplasms</b>				
ICD codes: 140–229 with 519.2 except 149, 166–169, 182–189 and 208–209	0.07	0.08	0.06	0.06
<b>Selected endocrine and metabolic diseases</b>				
ICD codes: 250–254, 260, 287–289.2, 786.4	0.03	0.04	0.07	0.09
<b>Mental, psychoneurotic diseases</b>				
ICD codes: 300–318.3, 320–326, 780.7, 781.9, 786.2	0.22	0.27	0.49	0.52
<b>Central nervous system diseases</b>				
ICD codes: 330–398 with 780–781.7 except 335–339, 346–349 and 358–359	0.21	0.20	0.21	0.22
<b>Cardiovascular diseases</b>				
ICD codes: 400–468 with 782.0–785.3 except 417–419, 423–429, 435–449, 454–459 and 784	0.13	0.14	0.12	0.08
<b>Respiratory disease</b>				
ICD codes: 003.1 and 241, 470–527 with 782.3–783.7 except 476–479, 484–489, 494–499, 503–506, 508–509 and 527.1	0.51	0.52	0.42	0.43
<b>Digestive disease</b>				
ICD codes: 530–545, 560–561, 570–578, 580–587, 782.8 and 784–785	0.19	0.20	0.15	0.16
<b>Skin disease</b>				
ICD codes: 690–698, 700–716, 788.2	0.14	0.12	0.14	0.17
<b>Diseases of bones and organs of movement</b>				
ICD codes: 720–727, 730–738, 740–749	0.29	0.31	0.31	0.30
<b>Accidents, poisoning and violence</b>				
ICD codes: N800–N822, N824–N848, N850–N856, N860–N936, N940–N963, N967–N999.5	0.13	0.15	0.11	0.12
<b>All others</b>	0.21	0.21	0.50	0.50

\* NB. Since we have restricted this table to those who were in the study for more than one year, the numbers are smaller than in Table 1.

**Table 5** Hospital admissions Control versus Screening 1967–1976

	Control group (N = 3132)		Screening group (N = 3292)	
Number of PEOPLE admitted once or more 1967–1976	862		944	
Rate per 1000 man/years at risk*	49.6		50.7	
Total number of ADMISSIONS* per 1000 man/years at risk	70.7		73.4	
<b>Hospital admissions by some of the principal diagnoses</b>				
	Control group		Screening group	
Principal diagnosis at admission ICD (1957)	Persons admitted once or more	Admission rate* per 1000 man/years at risk	Persons admitted once or more	Admission rate* per 1000 man/years at risk
<b>Neoplasms</b>				
ICD codes: 140–229 with 519.2 except 149, 166–169, 182–189 and 208–209	185	9.1	217	10.0
<b>Central nervous system</b>				
ICD codes: 330–398 with 780–781.7 except 335–339, 346–349 and 358–359	88	4.3	92	4.2
<b>Cardiovascular diseases</b>				
ICD codes: 400–468 with 782.0–785.3 except 417–419, 423–429, 435–449, 454–459, and 784	192	9.5	210	9.6
<b>Respiratory disease</b>				
ICD codes: 003.1 and 241, 470–527 with 782.3–783.7 except 476–479, 484–489, 494–499, 503–506, 508–509 and 527.1	79	3.8	71	3.2
<b>Digestive disease</b>				
ICD codes: 530–545, 560–561, 570–578, 580–587, 782–8 and 784–785	174	8.6	195	9.0
<b>All other diagnoses</b>	415	21.3	396	18.8

\* These rates have been calculated using different times at risk, because once a particular event occurs the individual is no longer at risk for that event. This means that the time the individual will be at risk depends on the event in question; obviously for total admissions the individual is at risk until he dies or is lost to observation.

the first eight years of the study. More detailed analysis using survival curves similarly failed to reveal significant differences. As an example, the survival curve for the sub-group which has the highest mortality, namely the older men, is shown in Figure 2.

Table 6 shows the death rates by cause taking into consideration the number of man-years at risk. No significant differences between the two groups were found for any cause of death, though a marked sex difference was apparent.

## Costs

The crude average cost of screening (followed by one general practitioner consultation where necessary) was estimated retrospectively; this cost excludes adjustments for alternative uses of capital. At 1967 prices the average figure was £6045 per 1000 persons screened. At 1976 prices, it is estimated that the cost of screening would be £12.27 (with a range from £15.39 to £9.35). This is a relatively low figure, being approximately a fifth of that charged by private screening organisations in the UK in 1976. Calculations suggest that once the screening clinics were operational, screening one extra person would cost still less—

£4.35 at 1976 prices—because most of the initial cost reflects expenditure on manpower and equipment required to establish the service.

## Discussion

Regular health 'check-ups' by doctors or screening clinics have become an accepted and valued part of the health services of many developed countries. The rationale of such examinations is two-fold—not only might they detect the so-called 'ice-berg' of unrecognised disease enabling the institution of earlier and presumably more effective treatment, but they might also identify potentially reversible risk factors such as high blood pressure.

The results presented in this paper must cast considerable doubt on many assumptions about the value of multiphasic screening in middle age. None of the outcome measures of mortality, morbidity or health service usage has been shown to be improved by screening. The screening service itself, however, appeared to have been generally well received by the population to which it was offered and this was reflected by the repeated response rates of over 70 per cent of those invited. The costs incurred by the clinics would amount to more than £142 million (at 1976 prices) if a similar programme were offered to the entire middle-aged UK population—assuming that the formidable administrative problems could be overcome.

The only other large-scale controlled trial of multiphasic screening to have published results is that of the commercially based Kaiser Permanente Group in California.<sup>7</sup> These workers failed to demonstrate any statistically significant differences in the overall death rates when the treatment and control groups were compared seven years after the start of the study. Certain specific cases of mortality in particular age groups did appear to show significantly improved rates in the screening group, but only three of the 60 statistical tests undertaken were reported as showing significant results, two in favour of the screening and one against it. This is approximately the same outcome that one would expect purely by chance.

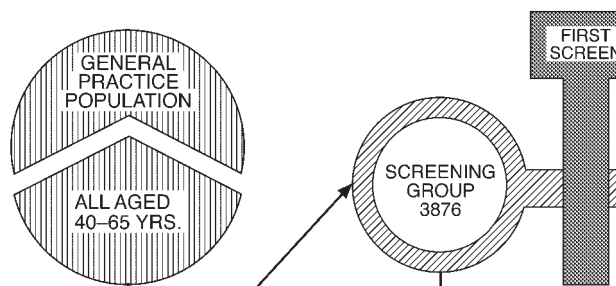


Figure 2 Survival curves of men over 60 years in 1967/8. Screening versus controls

Table 6 Death rates by cause Control versus Screening 1967-1975

Cause of death (First certified) ICD (1957)	Control group (N = 3132) Total time at risk = 18 404.4 man/years		Screening group (N = 3292)* Total time at risk = 19 672.3 man/years	
	No. died	Death rate per 1000 man/ yrs at risk	No. died	Death rate per 1000 man/ yrs at risk
Neoplasms				
ICD codes: 140-229 with 519.2 except 149, 166-169, 182-189 and 208-209	47	2.6	50	2.5
Central nervous system				
ICD codes: 330-398 with 780-781.7 except 335-339, 346-349 and 358-359	13	0.7	17	0.9
Cardiovascular disease				
ICD codes: 400-468 with 782.0-785.3 except 417-419, 423-429, 435-499, 454-459 and 784	52	2.8	84	4.3
Respiratory disease				
ICD codes: 003.1 and 241, 470-527 with 782.3-783.7 except 476-479, 484-489, 494-499, 503-506, 508-509 and 527.1	37	2.0	28	1.4
All other causes	20	1.1	17	0.9
Total deaths (all causes)	169	9.2	196	10.0

NB. Time at risk is less than for previous analyses due to delays in ascertaining cause of death.

Considerable confusion has arisen in recent years over the use of the term 'screening', which usually implies that the doctor has approached the patient in the first instance, rather than vice-versa. The term 'case-finding' has been applied to those tests undertaken by medical workers on patients who are already consulting for unrelated symptoms.<sup>8</sup> In the first five years of this study, 93 per cent of all patients on the lists within this age group had attended their doctor at least once.<sup>4</sup> Case-finding, rather than screening, may therefore offer a more attractive (and perhaps more effective) approach to early disease detection and prevention in the future.

Finally, the paucity of real medical benefit derived from this enormous outlay of effort and resources may disappoint screening enthusiasts. However, as Wilson and Jungner,<sup>9</sup> Sackett and Holland<sup>8</sup> and others have emphasised, the doctor-initiated search for unrecognised disease in healthy individuals carries with it a number of ethical obligations. If disease is found, an effective and acceptable treatment should be available. Any form of screening, including multiphasic, must therefore be judged on the basis of its demonstrable health benefits. Since these controlled trial results have failed to demonstrate any beneficial effect on either mortality or morbidity, we believe that the use of general practice based multiphasic screening in the middle aged can no longer be advocated on scientific, ethical or economic grounds as a desirable public health measure.

## Acknowledgements

The South-East London Screening Study has involved the participation of many individuals, only some of whom can be acknowledged by name. We would like to thank Drs U Kroll, IN

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# Commentary: A history of the South-East London Screening Study

Walter Holland

To be asked to write a commentary on one's own publication<sup>1</sup> after 25 years is flattering. In my attempt to respond to the Editor's invitation I thought that it might be of interest to consider the background to the study and the steps required to establish it.

The concept of screening and the criteria by which it is assessed are now well established. It is, however, worth recalling the 'spirit of optimism' that prevailed in the early 1960s. The concept of early diagnosis was tempting and the idea of a number

of tests being performed at one visit, rather like an MOT, even more so. The initiatives to develop this form of medicine was, of course, led by workers in the US, but rapidly permeated here.

An early example, in the UK, was the introduction of multiphasic screening in Rotherham. The Medical Officer of Health there was Dr Paddy Donaldson (father of our present Chief Medical Officer), a most imaginative Medical Officer of Health. For a number of years over a short time period (about 3 weeks) the public health department concentrated all its efforts on a screening clinic to which all adult inhabitants were invited. This rapidly became noticed and a short evaluation was done. Rotherham in the 1960s was a thriving industrial town with

heavy industry such as coal mines and steelworks. Unfortunately, the 'evaluation' was not positive. Although the clinic was busy, the majority of participants were women, relatively few men from the hazardous industries attended. But more worryingly, although quite a number of abnormalities were found, few led to treatment or were referred to the individual's GP, which was part of the problem of the separation of public health from the rest of the NHS at that time.

In 1962 one of the senior medical officers at the then Ministry of Health was Dr Max Wilson. He had appreciated that the spread of screening to the UK from the US would have profound implications. I had just returned from a period in the US where I had travelled widely and knew many of the groups involved in developing screening methods including Dr Lester Breslow at the California State Health Department. I knew Dr Wilson because we had worked together on a joint paper on the influence of weather on cardiorespiratory disease and he came to me for advice on whom to visit in the US.

On his return we discussed his findings, and for those at Rotherham we rapidly concluded that if screening was to be effective in the UK it had to be done in conjunction with general practice. As a result we discussed how this might be achieved. At this time general practice was not in great shape, there were few practices interested in, or willing to do research. We thought that the new, developing Health Centres might be a good location, and both Wilson and I visited quite a number either together or individually. Unfortunately, we were unlucky in persuading them to do an experiment. However, one practice at St Paul's Cray in Orpington had approached the Ministry to start a pilot project in multiphasic screening. The senior partners in this practice were used to research having taken part in a number of studies on acute infectious disease with the Public Health Laboratory Service and a former 'boss' of mine, Doctor (now Professor) Corbett McDonald. The number of patients on the list of this practice was, however, insufficient to provide a conclusive result. Doctors Woodall, Tuckman, Wilson and I then started to plan a study and we were fortunate that these local GPs were able to identify another nearby practice willing to participate. We then met our next difficulty—these GPs wished to be paid for the work as their income would probably diminish due to their efforts on our behalf. This was overcome (just about) with the 'formula' that the 'paid' practice were not co-authors of the study, in contrast to the first group. (Payment for research in general practice was also a major obstacle within the Ministry of Health at that time!)

The planning of the study was a major undertaking since we had to ensure the co-operation of the local hospital to do the necessary pathological, biochemical and radiological investigations promptly. This was so that the results were available to the GP when the individuals visited to hear the results and have any necessary additional tests. The locale for the examination, the scheduling of tests, the participation of nurses and trained housewife volunteers was a major logistic exercise, as was the collection of the 'outcome' data, hospital visits, general practice consultations, time off work, use of Local Authority home-help services, etc.

Allocation to screening or control was done, at random, by family. We had expected that a number of the control group would wish to be screened. We were 'pleasantly' surprised that less than one per cent thought they were missing something worthwhile. Furthermore, 73% of the group invited attended

the examination. The problems of follow-up due to migration, etc., are described, and I will not comment further, except to emphasize that analysis of the results was complicated!

The study was innovative, for its time, in that it included an economic analysis. This certainly added to the antagonism which it generated, particularly from BUPA, who were, and continue, to promote the concept of multiphasic screening. What was particularly galling for them was that we showed that the cost of screening one person was about £12.00, while they were charging about £75.00.

The final straw was, of course, that our study did not show that multiphasic screening was of much benefit. My popularity with BUPA's Medical Director of that time was not high and there were some particularly difficult public debates.

Looking back on this study it is interesting, in the light of current events, to see how different life was. It was possible and relatively easy to gain the co-operation of the local authorities, volunteers were happy to co-operate in an experiment and they did not expect to be given an economic recompense. Patients were co-operative—and there was no pressure on us to 'dilute' our control group.

The result of the study demonstrated that regular multiphasic screening offered little advantage to the individual, as measured by morbidity, disability or physiological function. The frequency with which, on average, individuals visited their GP ensured that treatable abnormalities would be detected. Of course, we were working with a group of particularly good GPs, and maybe this result would not have been obtained in other less skilled practices. This, of course, does not mean that organized cervical cytology, breast scans, etc., should not be used, but that it needs to be done through properly organized general practices who should be responsible for both the invitation to screening and action on screening findings.

The results of the study did influence health policy, for a time. Although the direct costs of the service were relatively low, if introduced nationally they would have had a measurable impact on the costs of the NHS. Since there was very little, if any, benefit in terms of reduction of illness the policy implication was clear—there was no point in introducing check-ups into the NHS. There was no pressure from the patients included in the study for the service to be continued. This lack of pressure for regular screening services, except from some middle-class groups, who were perhaps influenced by BUPA, persisted in the UK for about 10 years after the publication of our paper. It was not until the late 1980s that the government of the day considered that regular check-ups would improve the service provided by GPs. The government of the day and the Department of Health officials, medical officers and Chief Medical Officer, were unaware, or had forgotten, the study they had initiated and funded. Letters to the Chief Medical Officer and *British Medical Journal* remained unanswered. Policy was only influenced by the concerted opposition of the medical profession led by a rousing, forthright article by Professor David Morrell, a Professor of General Practice.<sup>2</sup>

Since we completed our study the belief in the value of check-ups or multiphasic screening by many, but especially by managers and politicians, has always amazed me. Our findings were not unique. D'Souza<sup>3</sup> in a more complete description of the South-East London Screening Study comments and gives details of the other randomized controlled trials (RCT) of

multiphasic screening in the US and Sweden. All show similar results in terms of total mortality or morbidity, even if the West Coast, US study in its description shows a slight reduction in 3 of 60 tested comparisons of mortality. The message that merely finding an abnormality on screening does not mean that health is improved appears to be difficult to disseminate or accept, even after 40 years! Although we now accept that the RCT is the 'gold standard' in the evaluation of a treatment or service, the difficulties of executing one in such an emotive field often means that policy-makers are willing to accept other findings. This is particularly the case if they are more 'politically' favourable and if legitimate criticisms can be levelled at the RCT, such as 'it was done a long time ago', 'the sample size was small', 'the area it was done in is not representative of the country', 'the stated (not actual) results of other studies are different'.

Finally, two points need emphasis. This was a pragmatic trial introduced into two 'normal' practices. Although guidelines for investigation and treatment had been agreed at the start, and this might have influenced the behaviour of GPs for both the 'control' and 'test' groups, it is unlikely that multiphasic screening as envisaged would have an effect on improving health large enough to justify the extra resources required. The second point is that this trial could not have been done without the long-term complete dedication of the GPs involved as well as the staff from the academic department, in particular Harriet Trevelyan, Mike D'Souza, Tony Swann and David Stone.

One question the editors have asked me is what I would have done differently now. This is a difficult one to answer. I have recently re-read an article I wrote at about this time on prevention,<sup>4</sup> given as a keynote address at the Forum Davos 78 meeting on 'Limits of Medicine'. In this we emphasized that past successes in the battle against infectious diseases were mainly due to the improvement in living conditions and that further progress in their elimination depends not only on proper

methods of surveillance, advances in treatment and vaccine development, but also on further progress in diminution in poverty. For non-communicable disease prevention we referred to a number of studies which had shown the importance of habits established during the early years of life as well as disease in childhood. We considered that these indicated that it was more important to develop total educational strategies for both children and adults (parents and teachers) rather than concentrating on risk factors in adults. We emphasized the gaps that existed in evidence for prevention of the major causes of death at different ages (e.g. congenital anomalies in children) or disability (e.g. psycho-social illnesses, musculo-skeletal disorders) and suggested possible leads. Finally, we classified and described the need to differentiate between societal, governmental (public health we said) and individual measures if we were to be successful in preventing disease.

This illustrates how much more optimistic we were in 1978 on the role and acceptance of our findings and subject and how little has been achieved in actually implementing our suggestions and findings! Looking back, even if we had problems and even if many things are better now, research in our subject was easier 25 years ago!

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# Commentary: GP 'check-ups' still of limited value

Godfrey Fowler

Around the time of publication of this paper<sup>1</sup> there was growing discussion of the need for GPs to extend their role and become more proactive. Until then, the function of the GP was generally considered to be confined to treatment of the sick. Even such things as antenatal care, child health and immunization were largely the responsibility of 'public health'; and screening was

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no part of the GP's work; nor was health education ('health promotion' had yet to be invented). But—particularly after the landmark 'GP Charter'<sup>2</sup> of 1965 which encouraged the development of primary care teams through reimbursement of costs of practice premises and staff—progressive practices were taking on public health roles and moving into preventive work.<sup>3</sup>

This change was stimulated by a Government publication<sup>4</sup> 'Prevention and health: everybody's business' which emphasized

the importance of lifestyle as a contributor to ill-health, particularly cardiovascular disease. It called for action by individuals and health professionals and for a reorientation of local and national health services to place greater emphasis on prevention—both through activities at a population level and by better identification and management of high-risk individuals.

It was this issue of high-risk 'screening' which the South-East London Screening Study had addressed in a randomized trial initiated in the mid-1960s. The trial had investigated the effect of inviting middle-aged patients in two large London general practices to a screening clinic where a health questionnaire was administered, a physical examination conducted and a battery of tests carried out. In essence, little of importance was found at the clinic which was not already known to the general practitioner. Over 9 years of follow-up no significant differences were found between Screening and Control groups in reported symptoms, GP consultation rates, hospital admissions, certified sick absence or mortality. It was therefore concluded that this 'multiphasic screening' conferred no health benefit and that general practice check-ups could not be justified. But it was also acknowledged that case-finding might have been effective—and that 93% of participants would have been eligible for this, having attended the practice for other reasons during the follow-up period.<sup>1</sup>

However, uncertainties about general practice 'health checks' continued and in 1981 the Royal College of General Practitioners published a report<sup>5</sup> 'Prevention of Arterial Disease in General Practice' which called for an active case-finding/opportunistic screening approach to detection and management of cardiovascular risk. This led to an evaluation<sup>6,7</sup> of its recommendations and to two further large randomized controlled trials of cardiovascular risk screening and intervention in general practice—the OXCHECK Study<sup>8-10</sup> and the Family Heart Study.<sup>11,12</sup>

These studies investigated nurse-conducted screening and intervention in middle-aged patients in about 30 practices in all. At one-year follow-up both studies found small but significant reductions in blood pressure and cholesterol levels, compared with controls, and in the case of the OXCHECK Study the effect was sustained at the planned 3-year follow-up.<sup>10</sup> An estimated 12% overall cardiovascular risk reduction was achieved in the Family Heart Study and a similar reduction in OXCHECK. Although the effects of these interventions were modest it was considered that their public health significance would be substantial—but that the workload involved and the resource implications would be great and probably not acceptable and feasible.<sup>13</sup>

Further doubt has been cast on the value of cardiovascular risk screening by a recent systematic review<sup>14</sup> of randomized controlled trials of multiple risk factor interventions for preventing coronary heart disease which included a meta-analysis of 14 trials. It concluded that the pooled effects of multiple risk factor intervention on mortality were insignificant and that changes in risk factors were modest—and that fiscal and legislative measures might be more effective.

While debate continues about the role of general practice in primary prevention, the strong evidence base for secondary prevention—particularly pharmacological interventions—in

those with established vascular disease has shifted the focus. Audits<sup>15</sup> show a major deficit in the implementation of measures of proven effectiveness in such patients and, in England, the recently published National Service Framework<sup>16</sup> emphasizes the priority which this issue should receive at the individual patient level in primary care. But it must be emphasized that such measures can only, however, be supplementary to a fiscal, public policy and public health approach at a population level which offers the major potential for cardiovascular disease prevention.<sup>17</sup>

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# Commentary: Learning in Lambeth—the South-East London Screening Study revisited

Stephen Leeder

As a callow youth from the colonies, I arrived at the Lambeth offices of St Thomas's Hospital Medical School Department of Clinical Epidemiology on a gloomy April Fool's Day 1974, the very day the NHS transmogrified into one of its (subsequently several) new structures. In Lambeth I discovered what Walter Holland and his colleagues had been up to by way of public health research in recent years. Dedicated research staff of eminence and skill were beavering away on projects to do with respiratory health, the health of schoolchildren and screening. I met the screening research workers, saw the data, and even worked on some of it, if with no great consequence, although for a post-doc it was a superb data set with which to 'play' in company with people who, in those early days of information technology, were at the forefront of computational and statistical innovation.

The South-East London Screening Study (SELSS) started in 1967 and was a trial of multiphasic screening for diseases of middle-age.<sup>1</sup> It began 2 years before the first man set his foot on the moon. Nine years after the initial screening 'no significant differences were found between the (screened and unscreened) groups in any of the outcome measures' which included hospital admissions, general practice consultations, certified sickness and mortality. Costs of screening were also calculated. Although the total cost of the study is not clear, it influenced policy at the time to avoid the expensive error of publicly supported multiphasic screening. Thus in the light of this study a policy for the use of public money for multiphasic screening would have needed to find justification in intangible or individual benefits not identified by it.

The SELSS was concerned with *screening* as used in the search for disease in people recruited for that search, rather than the pursuit of asymptomatic abnormalities in patients already consulting a doctor for another purpose. The latter has come to be accepted as *case-finding*. Since the SELSS was performed, remarkably few similar studies have been done. The results from these are similar to those from the SELSS. Yedidia conducted multiphasic testing in California cannery seasonal workers and found one or more abnormalities in about 40% of workers.<sup>2</sup> The Värmland scheme which tested a whole adult population in the county of Värmland in Sweden found one or more abnormalities in 31% of participants. These patients were grouped into six priority categories according to their expected need of medical care.<sup>3</sup> What became of them is not clear.

In a study of Kaiser Permanente Foundation Health Plan members in California, comparing the fate of subjects urged

to have annual multiphasic health check-ups for 16 years with that of subjects not so urged, the screened group experienced a 30% reduction in deaths from pre-specified 'potentially post-ponable' causes, largely associated with lower death rates from colorectal cancer and hypertension. In the Kaiser Permanente study, cervical screening and sigmoidoscopic examination for those aged  $\geq 40$  were included.<sup>4</sup> The two groups did not differ to a statistically significant degree in total mortality and the enthusiasm for screening decreased.<sup>4</sup>

The SELSS provokes four major topics for our reflection in an era where much that was pioneered by the study has become common practice. First, the study brilliantly demonstrated the applicability of randomized trials to answering questions of importance for health services that transcend the clinical setting. What medical practitioners generally accept as evidence can properly form but a part of all that must be considered in the formulation of health policy. Those of EBM persuasion lament the gap that exists between medical evidence and medical practice. However, a larger, more troubling space exists between the use that could be made of evidence in the health policies we construct and the use made of it in practice.

As part of this effort, the randomized trial has much to commend it. At a conference in Canberra, Australia, last year I argued that to address health inequality what we needed most urgently was evidence of interventions that successfully have reduced health inequalities. In fact, there are virtually none. Meanwhile, furrowed-brow conferences review the descriptive data that link the distribution of health according to economic status and social capital with little dependable evidence to guide the investment of the next dollar.

The second point the SELSS raises for consideration today is that, while accepting its results, it must be seen as a creature of the technology and practice of its time. The comprehensive first screening examination in 1967 included self-administered questionnaires, anthropometry, visual and auditory tests, lung function tests, ECG blood tests and tests for occult blood in the stool.<sup>5</sup> We now have evidence of the modest benefit of cervical cytological screening, mammography and tests for colonic abnormalities related to bowel cancer.<sup>6–8</sup> Not that this progress invalidates the SELSS. It simply means that, were multiphasic screening to be revisited now as a matter of public health policy, a new trial would be needed. Likewise, the management of screening and the conduct of the evaluative randomized controlled trials (RCT) would benefit from the capacity of information technology to amass and manage large amounts of data.

Third, much has been written about the importance of being able to offer the subject who is screened constructive help

if an abnormality is found.<sup>9</sup> There is no personal gain for an asymptomatic person to be converted into a patient by detecting an unidentified but untreatable condition. However now, with information from the human genome, this matter may need to be revisited. People other than the person screened profess an interest in genetic information when considering contracting life insurance policies. Genetic counselling may empower individual action that can spare future generations from serious disorders, as has been done humanely with screening for the Tay-Sachs gene among prospective marriage partners in the Ashkenazi Jewish community.<sup>10</sup> Thus the ethical context of screening has changed since the SELSS was conducted and this may bear upon the development of public policy. But again, assumptions should be tested and the example of the SELSS randomized controlled trial followed wherever possible.

Fourth, thinking more broadly, as Holland does in his reflections on this study, preventive medicine is evolving. Multiphasic screening was once a prominent point of enthusiasm for prevention through early detection. Now my opinion is that affluent countries have moved, allowing for the notable exceptions of immunization, HIV control and tobacco, away from population-based efforts in primary prevention. There is greater attention now on secondary prevention. This has followed brilliant pharmaceutical development of such agents as the statin lipid-lowering drugs. The power that medicine and the pharmaceutical giants can exert over the supply of these demonstrably effective agents and others like them, both by clinical prescription and by advocacy for their cost subsidy by governments, makes them an attractive option to the hard work of environmental or individual lifestyle change, and to all-of-government approaches to health gain through primordial prevention and community development.

However, in less affluent countries, these secondary preventive options are simply not affordable. Health promotion is thus now challenged to develop ways to match the commercial reach of globalization through efforts to combat the effects of widening gaps between technology-rich and technology-poor societies. As Jeffrey Sachs, Director of the Centre for International Development and Professor of International Trade at Harvard University, wrote in *The Economist* 'in our Gilded age the poorest of the poor are nearly invisible'.<sup>11,12</sup> Seven-hundred million people live in the 42 so-called Highly Indebted Poor Countries where a combination of 'extreme poverty and financial insolvency marks them for a special kind of despair and economic isolation'. Sachs comments that:

All the rich-country research on rich-country ailments, such as cardiovascular diseases and cancer, will not solve the problems of malaria. Nor will the biotechnology advances for temperate-zone crops easily transfer to the conditions of

tropical agriculture. To address the special conditions of the Highly Indebted Poor Countries, we must first understand their unique problems, and then use our ingenuity and co-operative spirit to create new methods of overcoming them.

The SELSS was a major step forward in health services research. Not only did it answer an important question about the cost and value of multiphasic screening within the public sector, it demonstrated that health service research can be done to a high order of rigour, and despite all that is said about the irrelevance of epidemiology to the development of health policy, it made a difference.

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# Commentary: On the report of the South-East London Screening Study

Jeremiah Stamler

The report of the South-East London Screening Study<sup>1</sup> neatly exemplifies the research paradox described recently by Stephen Jay Gould: ‘... straightforward facts enshrouded in difficult or ambiguous meanings’.<sup>2</sup> In a randomized controlled trial of people, baseline ages 40–64 years, from two South-East London general practices, two multifactor screenings 2 years apart (1967–1968 and 1969–1970) were associated with no significant differences between Screened and Control groups in 5-year incidence of disease morbidity or in 9-year rates of GP consultations, hospital admissions, certified sickness work absenteeism, or mortality. Straightforward data! But what do they mean? What conclusions can be drawn from them? Based on the last sentence of the report, the authors are apparently sure they have the answer: down with multiphasic screening of the middle-aged in general practice. But for this commentator, Gould’s words fit: ‘straightforward facts enshrouded in difficult or ambiguous meanings’.<sup>2</sup>

Why? The nub of the problem is embedded in the statement of Study *purpose*: ‘... assess the value, if any, of introducing a general practice based screening service for 40–64-year-olds as an extension of the existing National Health Service’.<sup>1</sup> Broad, general, vague; it could mean a multitude of things. And that’s it as to aims; no specific prior hypotheses or questions are stated. To get some idea about what the authors actually had in mind, one has to go through Methods and Results step-by-step.

That effort sheds light on some specifics, but leaves others in the dark. Thus:

1. Was health education and motivation for Screening group patients a component of the ‘... screening service ...’, e.g. in the personal letter of invitation from the GP? at the screening clinic at year-0 and year-2? in-between? Nothing is said about this. The retrospective estimate of costs (see Results) is interpretable as indicating zero or negligible resources for patient health education and motivation.

2. Since the ‘... two screening sessions constituted the “treatment” under assessment in the controlled trial’ (*sic!*), what resulted? Specifically, what ‘... further investigations, diagnoses and treatment ...’—in what percentages of patients—did GPs undertake based on information passed on to them from the two screening sessions? What resources were available for this? No details are tabulated. Table 4 shows similar GP consultation rates for Screened and Control groups during the 9 years of follow-up—overall, for men 3.2 and 3.1 (per person per year?), for women 4.0 and 3.8 (non-significant differences).<sup>1</sup> In Results, there is the further qualitative statement: ‘For

the majority of abnormalities revealed by screening, with the exceptions of anaemia and high blood pressure, little new therapeutic intervention was introduced, although advice on stopping smoking and weight reduction was given to all for whom it was appropriate’.<sup>1</sup> Meaning what? What percentage of patients? What kinds of ‘... therapeutic intervention ...’ and ‘... advice ...’?

To focus on the major cardiovascular disease (CVD) risk factors responsible for extensive morbidity, disability, and premature death among UK middle-aged adults, the screening procedures included measurement of serum cholesterol and blood pressure (Table 2), and presumably smoking habit (from text and Table 3, but not Table 2). Nothing is said on the resources available to intervene on these risk factors. No data are given on cut-point(s) for serum cholesterol classification or on advice for patients with high values (however defined). The report says nothing about counselling to modify adverse eating (or drinking, or physical inactivity) patterns. The cut-point for raised blood pressure was high—diastolic (phase V)  $\geq 105$  mmHg. At 5-year follow-up, hypertensive patients so defined made up 2.7% of the Screened group and 3.1% of the Control group (group Ns of 1651 and 1950, respectively). These rates are obviously similar, but the trial was weak in statistical power to detect a meaningful impact on high blood pressure prevalence so defined. At 5-year follow-up, the percentage still smoking was similar in the two groups (Screened 51.5%, Control 50.8%). Since the major CVD risk factors were not impacted, the findings on CVD disease were as expected—no significant differences between the two groups in rates of consultation, morbidity, hospitalization, mortality. (I leave aside the question of group size and consequent statistical power to detect meaningful differences in these end points, not mentioned by the authors.)

3. The cited purpose of the study includes a potentially important qualifier: ‘... value of ... a screening service ... as an extension of the existing National Health Service’ (my emphasis—JS).<sup>1</sup> This is implicit recognition that the societal context of the trial could have influenced its outcome. The report deals hardly at all with this aspect. But it may have been, and probably was, important. To list societal factors possibly influencing the specific outcomes: policy commitment at the national level by the NHS and UK government to prevention of epidemic chronic diseases? Resources allocated? Budget of the NHS in 1967–1968 and the years of the trial? Proportion of the UK gross national product (GNP) dedicated to the NHS? Support staff (nurses, dieticians, physiotherapists, technicians, aides, clerks) available to NHS GPs, to assist with the add-on of work? Intellectual preparation of GPs and staff for a disease prevention and control effort? Availability of community public health resources to help with the effort? Their commitment and mobilization? Mass

media messages—advertising and other—influencing popular behaviour (adversely, favourably)? Special commercial interests (e.g. the tobacco, food, beverage industries) and their adverse influences? As decades of public health experience show, such societal factors are critical for public health efforts—their success or failure. While this commentator has only limited knowledge of the interplay of UK societal factors in the trial years 1967–1968 and thereafter, his general impression is that their overall impact was generally adverse, not favourable.

In this regard, the authors' observation in Discussion is relevant: 'The screening service ... appeared to have been generally well received by the population ...'.<sup>1</sup> Too bad that for the NHS patients the apparent inadequacy of the interventions resulted in a lost opportunity. Relevant also in this regard is the authors' statement as to costs: '... a relatively low figure, ... approximately a fifth of that charged by private screening organizations in the UK ...'.<sup>1</sup> From this commentator's limited knowledge about such private efforts in the UK, they serve the more affluent social strata (social classes I and II), which make up a small minority of the South-East London practices (Table 1). Their services are generally extensive, including health education, motivation, referral, and follow-up.

Again, the social context is relevant. During the post-World War II decades, social classes in the UK experienced similar trends in the coronary epidemic—with death rates initially higher for those of lower than for those of higher social classes, latterly with declining rates for the higher social classes, but plateaued or rising rates for lower social classes, with a consequent increase in the socioeconomic status (SES) gap. And, correspondingly, more adverse levels of major risk factors in those of lower SES e.g. smoking, blood pressure. The South-East London Study dealt mostly with patients from social classes III–V.

We are now in a new century—more than 30 years since the South-East London Study was launched. Much that may have seemed equivocal in 1967–1968 is now crystal clear e.g. as to the number one problem: epidemic CVD and the role of lifestyle-related major risk factors (my area of expertise). Their impact on CVD risks is continuous, strong, graded, independent, combinative and aetiologically significant. They can be prevented and controlled by safe nutritional-hygienic measures plus modern pharmacotherapy as indicated. The population is interested in their prevention and control, and (paced by higher socioeconomic strata) has acted favourably—albeit in a limited way still—to improve matters, despite the paucity of resources brought to bear to accomplish this, and the 'noise in the system' from vested commercial interests. At least from the US national surveys by the Department of Agriculture in the 1960s, improvements in lifestyles, specifically eating patterns, are

attributable mainly to influences on the population from two sources—health professionals and the mass media. These improvements, and their favourable impact on such major risk factors as serum cholesterol and blood pressure, account significantly for declining CVD death rates.

With this as background, what in the year 2001 is to be concluded about the South-East London Screening Study? At national and international CVD meetings, sessions are organized, particularly for clinicians, on 'How to ...'. The South-East London Screening Study is a historically useful case report on 'How not to ...'. It shows that a screening service is in fact *not* a treatment; contrary apparently to the authors' original concept, screening is a means to an end, not an end in itself. It can be useful when related components are in place to optimize the effort before, during, and after—and especially when, by virtue of sound national public policy and resources made available for sustained implementation of that policy, the societal context aids and abets the efforts of physicians and other health professionals, including their screening efforts.

To conclude, screening in general practice does not serve, despite support by the population, when done as in the South-East London Study in the 1960s (in the societal context of that time), and with virtually no resources available to the NHS general practices to intervene effectively with patients in relation to screening efforts and results.

Given the specifics of this very particular, limited, dated study, its negative results are not generalizable. Its findings cannot be soundly interpreted as an evidence-based foundation for the authors' concluding generalization—sweeping, unqualified, over-reaching, absolute—against all screening in general practice. That is simply warmed-over dogma.

As we first learned in the 19th and early 20th centuries in regard to epidemic infectious and undernutritional diseases, and then learned again in the second half of the 20th century in regard to epidemic non-infectious CVD and neoplastic diseases, their prevention and control is a sustained complex process, motley, variegated, involved, proceeding at multiple societal levels. The health care services sector is one of those levels, an important one, and screening—soundly employed—is one (among many) of its useful tools.

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