THE PHARMACY SCREENING PROJECT — AN EVALUATION OF PHARMACY-BASED SCREENING PROGRAMMES

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Objectives. The purpose of this study was to establish the proportion of pharmacies providing screening tests in the areas of Pretoria, Potchefstroom and Klerksdorp, the types of tests used and their cost to patients, the criteria employed to select high-prevalence groups, the attitudes of pharmacists towards screening, and their knowledge of test characteristics.

Setting. In Pretoria, 155 pharmacies were randomly selected and all 43 pharmacies in Potchefstroom and Klerksdorp were included.

Methods. The pharmacies included in the study sample were first contacted by telephone to identify those providing screening tests. Pharmacies that provided screening tests and agreed to participate in this study were then visited and a questionnaire was administered.

Results. 57% of the pharmacies provided at least one type of screening test. Blood pressure measurement, serum cholesterol, capillary glucose and pregnancy testing were the most common screening tests available. With the exception of blood pressure measurement, the screening tests were conducted less than 5 times per week. All respondents referred clients with abnormal results to general practitioners but only 35% of pharmacies kept records of the patients tested and the test results. The knowledge of pharmacists concerning the important features of screening tests, such as false-positive and false-negative rates, was poor. No quality control procedures for the screening tests were employed.

Conclusions. Providing pharmacists with specific training in the application and interpretation of screening procedures, and implementing quality control measures will reduce the number of false referrals or non-referrals, and will improve the quality of the service. If pharmacies are to play a meaningful role in screening for disease, coverage of the population will need to be increased substantially.

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Screening is defined as 'the presumptive identification of an unrecognised disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests are meant to distinguish apparently well persons who have (asymptomatic) disease or who have a risk factor from those who probably do not have the disease or risk factor. A screening test is not intended to be diagnostic.'[1] Persons with positive or suspected positive screening test results are usually subjected to further investigations that are often more expensive and invasive, or they are subjected to risk-reducing treatment, or they are referred to a physician for diagnosis and treatment in cases where the screening test was applied by someone other than a medical practitioner.

The application of screening tests to large, unselected populations is often defined as 'mass screening'. 'Case finding', on the other hand, refers to the situation in which clinicians search for disease or risk factors with screening tests in patients consulting them for reasons unrelated to the disease screened for. Criteria for screening relate to the disease (e.g. burden of disease and the need for a preclinical phase), the test itself (feasibility and accuracy) and the subjects being tested (e.g. psychological factors).[2]

From a public health point of view, one major requisite for effective screening is that such procedures must be accessible to the population at risk. It has been shown that screening and counselling by general practitioners can improve the risk factor profiles of patients. However, general practitioners often do not have sufficient time and facilities to offer services to all or most of their patients who would stand to benefit from screening.[3,4]

Community pharmacies, on the other hand, present an alterative setting in which to conduct screening programmes.[3] In 1986, the role of pharmacies in the UK was extended to include health education, the development of dispensing, diagnostic and screening services, and the provision of an advisory role in health care.[5,6] The major motivation for the extended role of pharmacies in health care provision is that they can offer screening to a larger population than general practitioners, partly because a typical pharmacy serves the population of several general practitioners, and partly because many people who visit pharmacies daily would not visit a general practitioner. Additional reasons are that it is often quicker and easier for people to walk into a pharmacy for a test, and that testing is usually cheaper when conducted in a pharmacy than when provided by a general practitioner, because no consultation fee is payable, and because pharmacies offer screening tests as an added service that is not part of their prime line of income generation. These combined factors make the provision of screening services through pharmacies an attractive option — not only is screening more affordable and accessible to individuals, but it can also potentially increase the coverage of screening programmes to include a larger section of the population.

However, the potential individual and public benefits of pharmacy-based screening programmes are not always achieved. Multiple testing may need to be done in some screening tests, such as blood pressure (BP) measurement, in order to obtain valid results, yet pharmacies do not always register patient details and test results,[7] which means that tests cannot be repeated when necessary. Furthermore, screening tests are never 100% accurate and will always produce a proportion of false results. False-negative results wrongly identify people as being free of disease or risk factors, whereas false-positive results wrongly identify people as having the disease or risk factors tested for. This can lead to a false sense of security and late disease presentation, and to inappropriate referrals and unnecessary costs, respectively. The proportion of false test results depends on the test itself, but also on the manner of application, repeat testing, quality control, and the prevalence of the condition tested for in the population visiting the pharmacy.

Pharmacies in South Africa have offered screening tests since the late 1980s, but there is little information available on the number and types of tests employed, or on the quality of these tests. No evaluations have been done on the health impact and cost of pharmacy-based screening programmes in South Africa.

The purpose of this study was to establish the proportion of pharmacies providing screening tests in the Pretoria, Potchefstroom and Klerksdorp areas, the types of tests used and their cost to patients, the criteria employed to select high-prevalence groups, the attitudes of pharmacists towards screening, and their knowledge of test characteristics. This gives an impression of the quality, potential and limitations of pharmacy-based screening programmes in urban and rural areas of South Africa.

POPULATION AND METHODS

Out of a total of 305 pharmacies (262 in Pretoria and 43 in Potchefstroom and Klerksdorp), 198 were sampled. In Pretoria, 155 pharmacies were randomly selected (based on a 54% expected prevalence of screening found during a pilot study) to obtain a 95% confidence interval (CI) of less than 10% around the actual estimates, after accounting for a 20% non-response. In Potchefstroom and Klerksdorp all pharmacies were included ($N = 43$).

These three areas were chosen to include an urban, metropolitan setting (Pretoria), as well as a more peripheral, rural setting (Potchefstroom and Klerksdorp).

The pharmacies included in the study sample were first contacted by telephone to identify those providing screening tests. Pharmacies that provided screening tests and that agreed to participate in this study were then visited and a questionnaire was administered. The questionnaire included 15 questions that had been piloted in 12 pharmacies in Johannesburg before being used in this study. The questions concerned general pharmacy information, the screening services offered, and the details of screening tests for BP, blood cholesterol, blood glucose, urine glucose, urine analysis, body mass index (BMI), pregnancy (excluding the sale of self-testing kits) and HIV status. Neither during the pilot study nor during this study were other screening tests being used. Data were recorded and analysed using Microsoft Excel.

RESULTS

The response rate for the first telephonic contact was 172 out of a sample of 198 (87%). In Pretoria, 132 of the 155 pharmacies responded (85%), and in Potchefstroom and Klerksdorp 40 out of 43 responded (93%). Reasons for non-response were missing telephone numbers (11), pharmacies that were closed down (8), no answer on the phone (4), same owner as another pharmacy (1), not able to speak English (1), or not willing to speak on the phone (1).

Of the 172 pharmacies that responded to the telephone questions, 98 (57%) provided screening tests. Of this number, 76 (78%) were visited and interviewed using a questionnaire. Reasons for non-participation were non-return of the questionnaire after requesting that it be faxed (7), irregular use of screening tests (5), lack of time (4), no reason (5), refusal to answer an English-language questionnaire (1), and various reasons (4).

In total, therefore, 72 questionnaires from an eligible 98 pharmacies were completed and analysed, giving an overall response rate of 73% (63% in Pretoria, 100% in Potchefstroom and Klerksdorp).

General information on pharmacies

Fifty-six respondents were pharmacists, 6 were nurses and 3 were pharmacists in training; information was missing for 7 respondents. Median work experience was 10 years (range 0.2 - 31 years). The median number of prescriptions per pharmacy per week was 300 (range 50 - 1 100), and the median number of clients per week was 750 (range 120 - 6 000).

BP testing was done in all 72 pharmacies and was the test most used by clients. Urine testing and body mass index (BMI) measurement were the least available tests (15% and 13% respectively). HIV testing was not done by any of the pharmacies in this study. Pregnancy testing and cholesterol testing were the most costly for clients (R17 and R15 respectively). BP testing and BMI determination were provided free of charge. The availability of the different tests, the median prices charged, and the median number of people using the tests are shown in Table I.

When dividing the median number of clients visiting the pharmacy per week (750) by the median number of people having a test per week, the proportion of clients tested is 2% for BP and less than 1% for the other tests.

Table I. Availability of different screening tests in pharmacies (N = 72), prices charged (in rands) and number of tests performed per week

	Pharmacies		Price		People/week	
	N	%	Median	Range	*N*	Range
Blood pressure	72	100	0	0 - 5	16	1 - 150
Blood glucose	59	82	6	0 - 15	4	0.25 - 50
Cholesterol	49	68	15	0 - 22.5	3	0.25 - 50
Pregnancy	41	57	17	0 - 20	2.5	0.25 - 40
Urine glucose	11	15	4	0 - 6	5	2 - 40
Urine analysis	11	15	2.5	0 - 5	4	0.25 - 40
BMI*	9	13	0	0	0.75	0.25 - 2
HIV	–	–	–	–	–	– –

* BMI = body mass index.

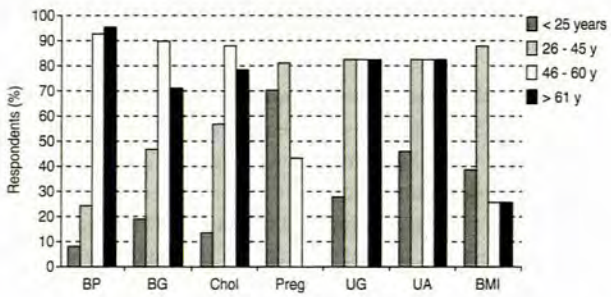

Fig. 1. Age distribution of users of different screening tests (BP = blood pressure; BG = blood glucose; Chol = cholesterol; Preg = pregnancy; UG = urine glucose; UA = urine analysis; BMI = body mass index).

Fig. 1 shows the age distribution of those screened. The majority of tests were administered to people over the age of 45 years, the exceptions being BMI determination and pregnancy testing.

Overall, the various tests, excluding pregnancy tests, were administered to men and women in almost equal proportion (Fig. 2). However, BP, blood glucose and BMI testing were administered mostly to women, while cholesterol and urine tests were more frequently administered to men.

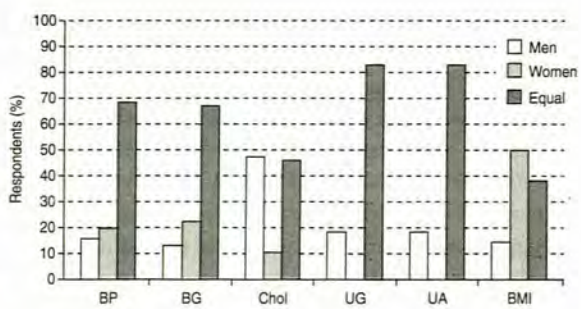

Fig. 2. Gender distribution of the users of different screening tests (BP = blood pressure; BG = blood glucose; Chol = cholesterol; UG = urine glucose; UA = urine analysis; BMI = body mass index).

Procedures used in administering screening tests

In 56 pharmacies (78%), the tests were conducted in a separate, private area (mini-clinic), while in 16 pharmacies the screening was done across the counter (1) or in a corner of the pharmacy (15). Permanent records of clients and their test results were kept in only 25 pharmacies (35%).

In 56 pharmacies (78%) screening was conducted by pharmacists, in 3 pharmacies by a nurse, and in 13 pharmacies by either a pharmacist or a nurse.

Of the 71 respondents to this question, 67 (94%) said they had had special training to perform the screening tests. Some examples of courses mentioned were courses by the South African Pharmacy Council (13) and by the manufacturers (7), and university-based pharmacotherapy courses (5).

Table II. Number/proportion of pharmacists repeating tests in case of abnormal results, and the frequency of repeat testing

	BP	BG	Chol	Preg	UG	UA	BMI
No. offering test	72	59	49	41	11	11	7
No. (%) repeating test	71 (99)	37 (63)	21 (47)	10 (24)	3 (27)	3 (27)	1 (14)
Frequency of repeat testing							
Median	2	2	2	1	2	1	2
Range	1 - 7	1 - 4	1 - 4	1 - 2	2	1	2

BP = blood pressure; BG = blood glucose; Chol = cholesterol; Preg = pregnancy; UG = urine glucose; UA = urine analysis; BMI = body mass index.

Table II shows the number and proportion of pharmacists who would repeat a test in case of abnormal results. BP readings and blood glucose tests were most likely to be repeated, whereas pregnancy tests were only repeated in 24% of the pharmacies. Most tests were repeated twice.

Screening tests may be used to follow up patients. Table III shows the proportion of clients who came back regularly for subsequent testing, as estimated by the pharmacists. In 52% of pharmacies in Potchefstroom and Klerksdorp more than 75% of the clients came back regularly for a screening test, while in Pretoria the proportion of regularly screened people was more or less equally distributed between 0 and 100% in the 45 pharmacies.

Interpretation of screening test results

In order to assess the knowledge of pharmacists with regard to screening test characteristics, they were asked to estimate the

Table III. Estimated percentage of clients returning for repeat pharmacy screening

% returning for repeat screening	Pretoria		Potchefstroom & Klerksdorp		Total	
	N	%	*N*	%	*N*	%
No. of respondents	45		27		72	
0 - 25	12	27	0	0	12	17
26 - 50	15	33	5	19	20	8
51 - 75	14	31	8	30	23	32
76 - 100	10	22	14	52	24	33

proportion of false-positive and false-negative results for the different tests (Table IV). Overall, 12 respondents gave their best estimate of the expected proportion of false-positive results and 11 respondents estimated the expected proportion of false-negative results. The estimated false-positive and false-negative rates varied between 0.05% and 30%. For the urine analysis, urine glucose and BMI measurements no false results were anticipated at all. In no case did respondents refer to the need to know the background prevalence rate in order to interpret predictive vlaues.

Table IV. Number of respondents anticipating false-positive and false-negative results and the estimated rates for the different tests

	BP	BG	Chol	Preg	UG	UA	BMI
No. offering test and responding to this question	72	57	48	33	11	11	4
False-positive							
No. reported 'yes'	1	0	1	2	1	1	0
No. gave %	9	6	4	3	0	0	0
Median % estimated	10	10	7.5	10	–	–	–
Range	5 - 30	5 - 30	5 - 10	0.05 - 10	–	–	–
False-negative							
No. reported 'yes'	1	0	0	2	0	0	0
No. gave %	7	4	4	2	0	0	0
Median % estimated	10	10	10	5	–	–	–
Range	1 - 10	5 - 30	5 - 10	0.05 - 10	–	–	–

BP = blood pressure, BG = blood glucose; Chol = cholesterol; Preg = pregnancy; UG = urine glucose; UA = urine analysis; BMI = body mass index.

Further investigation showed that none of the manuals for the different tests most commonly used by pharmacists contained information on essential characteristics of the screening test results, such as false-negative and false-positive rates, positive or negative predictive values, or sensitivity and specificity of the tests. Telephonic enquiry to the importers/producers of these tests revealed that none had this information available in South Africa, but some claimed to be able to obtain this information from their organisations elsewhere.

All 72 respondents stated that clients would be referred to a general practitioner in case of abnormal test results. In most instances (68%) this was a written referral, using record cards, a referral letter or just the written test results. Thirty-six pharmacies referred by advising the client to consult a medical practitioner; 22 also phoned general practitioners to refer patients.

The criteria used by the respondents to interpret the screening test results originated mainly from the respondents' undergraduate education (69). Forty-six respondents also used criteria from handbooks, and 28 used criteria from product information.

In instances of abnormal test results, 12 of the 71 respondents to this question (17%) would occasionally prescribe medication to clients for the screened condition, 70 (99%) would explain the abnormal result to the client, and 70 (99%) would give verbal or written advice. Clients with abnormal test results were mostly referred to general practitioners (96%), but 15 respondents (21%) would also refer directly to a specialist. One respondent also referred to traditional healers.

Attitudes of pharmacists toward screening tests

All 71 respondents to this question believed that screening in pharmacies is of benefit to clients and to the health of the community. Sixty-four respondents (90%) believed that it benefits pharmacies as well. Sixty-five out of 70 respondents (93%) were positive about offering screening tests to the public, while 5 were not in favour (7%). Although not asked in the questionnaire, many pharmacists volunteered that they regularly detected new cases of disease (after referral of screened patients).

The number of pharmacies that actively recommend screening to clients is shown in Table V. With the exception of pregnancy testing, all tests were recommended frequently. The main reason for recommending a test was the presence of a sign or symptom of disease. People receiving medication were also often advised to undergo a screening test.

Very few pharmacists said they ever refused a test to clients.

Table V. Number of pharmacies recommending screening tests to their clients

	BP	BG	Chol	Preg	UG	UA	BMI
No. offering test and responding to this question	72	57	48	34	11	11	5
No. (%) recommending testing	65 (90)	50 (88)	38 (79)	11 (32)	10 (91)	9 (82)	1 (20)

BP = blood pressure; BG = blood glucose; Chol = cholesterol; Preg = pregnancy; UG - urine glucose; UA = urine analysis; BMI = body mass index.

BP testing was sometimes refused by 2 of the 72 respondents (3%) and blood glucose testing by 3 out of 57 respondents (5%), and pregnancy testing was refused occasionally by 1 out of 34 respondents (3%). The main reasons given for refusal were lack of time or no apparent symptoms.

Differences between Pretoria and Potchefstroom/Klerksdorp

No major differences were found between respondents in Pretoria and in Potchefstroom/Klerksdorp. The pharmacies in Potchefstroom/Klerksdorp were generally smaller than those in Pretoria, and their median number of prescriptions was lower (235, range 50 - 840; and 375, range 100 - 1 100, respectively). The only two significant differences were that blood glucose testing was less available in pharmacies in Potchefstroom/Klerksdorp (63%) than in Pretoria (93%), while pregnancy testing was more available in Potchefstroom/Klerksdorp (70%) than in Pretoria (49%).

DISCUSSION

Although screening is intended to reduce disease load in individuals and communities, this aim is not always achieved. In contrast, several biases[2] may cause screening to appear to be effective without actually reducing disease load. For example, lead time bias occurs when the diagnosis is made earlier following screening than when routine care is pursued. If survival time is measured from the time of diagnosis this may be biased due to the fact that only the disease time and not the real survival time is increased. Length time bias is also possible. This is due to the early detection of a greater proportion of slow-growing tumours following a screening programme. Again, survival may appear to be increased, but only because of the more benign nature of tumours that are detected early on. Prostate cancer is an example in which both lead time and length time bias may occur.[8] Volunteer bias is also possible in screening programmes. Volunteers may exhibit exposures or outcomes (they tend to be healthier) that differ from those of non-volunteers.[9]

In addition, screening in itself may be harmful, both in cases where the screening test identifies an abnormality and in cases where no abnormality is detected. An example of the former is the screening of a working population for hypertension. Those diagnosed as being hypertensive had increased sickness absence, increased anxiety, and reduced self-perceived health status subsequent to the diagnosis. This was regardless of whether their hypertension warranted treatment or not.[10,11] Conversely people who are not identified as being sick during a screening test may be less likely to respond to advice on healthy lifestyle even though this would benefit them. They may, therefore, expose themselves to greater health risks following their labelling by the screening test as 'healthy'.[12]

Realising the potential of pharmacy-based screening

Case-finding is a way of screening in which people who visit the offices of health workers are screened for the presence of a disease that is unrelated to the reason for their visit. For example, routine BP checking is common in general practice even though most patients visit the practice for reasons unrelated to high BP. In South Africa, many lower income groups do not have access to such services as they cannot afford to visit private practitioners.[13] As screening performed in pharmacies is cheaper than screening performed by general practitioners, the provision of pharmacy-based screening services might make screening more accessible to lower income groups. For example, a cholesterol test conducted in a pharmacy will cost on average R15; when performed at the offices of a general practitioner it will cost the patient approximately R50 for the consultation plus R70 for a lipogram. This study could not confirm whether or not the users of pharmacy-based screening tests were indeed of lower socio-economic status and would not have had the benefit of the test if it had not been available in pharmacies. The main reason why this could not be confirmed was the virtual absence of records on the screening programmes at pharmacies.

From a public health point of view the main purpose of screening is the detection of new, sub-clinical cases of disease in a population. This study makes it clear that the public health value of screening services offered through pharmacies is questionable. Firstly, pharmacy-based screening programmes are not systematically applied. Consequently they will largely reach an already 'high-risk' population, namely people with symptoms or signs of disease, people already on medication, and those with certain risk factors. This study found that BP screening was only performed on 2%, and the other tests on less than 1%, of all clients who visited pharmacies weekly. Secondly, the clients who ask to be tested are probably already more aware of their health.[4] This suggests that the contribution of pharmacies in screening for disease on a population basis is low.

Nevertheless, screening services in pharmacies in South Africa are more available than elsewhere. This study found that 57% of pharmacies provide screening services, compared with 12 - 15% of pharmacies in the UK,[7,14] and 43% of pharmacies in British Columbia.[15] In this study the major reasons for offering tests were the convenience of the service to clients, and the contribution of screening tests to a more comprehensive service at pharmacies.

Quality of pharmacy-based screening

One of the major concerns in any screening programme is the validity of the results, and of consequent action. While the potential benefits of screening to individuals and the public health are obvious, the potential for delaying diagnosis (after false-negative results) and for incurring unnecessary costs both

for the individual and the health services as a whole (after false-positive results) are less well known. Both of these false rates are dependent on the quality of the test kits used, the quality of the procedures employed in testing, the background prevalence rate of the condition screened for, and the intelligent interpretation of and reaction to test results. A problem in any of those areas can increase either or both of these false rates. In this study, potential problems were found in each of these areas. This means that although well intended, pharmacy-based screening may potentially be more harmful than beneficial to individual patients in that it may actually increase health care costs without producing commensurate benefits. This cost increase will not only affect the private health sector but also the public sector if in fact it is mainly those without medical insurance who are using pharmacy-based screening, as they will subsequently depend on public sector care for further investigation and treatment.

When test equipment is only used a few times per week the validity of results will decrease.[16] This study showed that except for BP testing, the number of tests performed is so low that quality may be compromised on the basis of expired chemicals, inexperience in performing or reading and interpreting test results, or other reasons. Furthermore, no pharmacy reported the existence of or their participation in quality control programmes, including regular calibration of equipment such as baumanometers.

The results of the questionnaire show that pharmacists' knowledge of test characteristics, such as false-positive or false-negative rates, was very poor. Only 12 respondents gave an estimate of the proportion of false-positives and 11 respondents estimated the false-negative proportion for the different tests. Even then these estimates are highly speculative given an absence of knowledge on background disease prevalence. Further investigation showed that none of the test manuals provided with the test kits contained any information on the validity of the different tests.

According to the ethical rules of the South African Pharmacy Council, pharmacists have to ensure that they have adequate training, knowledge and skills to perform screening tests and interpret the results.[17] Ninety-three per cent of the respondents in this study said that they had undergone specific training to perform screening tests, in addition to their professional education. However, this study shows that neither of these courses adequately prepared pharmacists to understand basic screening test characteristics or to apply this knowledge in such a way as to optimise use of screening tests. Clearly, existing education must be improved and should include review of screening tests and screening services in pharmacies. Education with regard to performing screening tests should be made compulsory for those wishing to offer services in their pharmacies.

The accuracy of pharmacy-based screening services would be greatly improved if pharmacies that offer screening services were provided with quality control systems similar to those used in routine laboratories.[16] Manuals relating to equipment and screening tests must provide information on the sensitivity and specificity of screening tests; they should also indicate how to increase the predictive value of screening tests by selecting patients at higher risk. To this end, the mandate of the Medicines Control Council should or could be widened to include the validation of procedures such as screening tests, as these, like medication, have the potential to produce both benefits and losses to individuals, insurers, and public health.

Actions taken as a consequence of screening test results

Confirmation of positive screening results by diagnostic testing is very important, partly because the statistical phenomenon of 'regression to the mean' will reduce the number of false-positive results on multiple testing. This study shows that it was only for BP and blood glucose testing that more than 50% of pharmacists repeated the tests when finding abnormal results.

In this study, 12 respondents (17%) said that they 'sometimes' prescribe medication after finding abnormal test results. Although the provision of non-prescribed medication is part of the extended role of pharmacists, this action might result in harm to patients when a false-positive diagnosis is made for serious conditions, such as those tested for in this study.

Only 35% of the pharmacies in this study kept permanent records of the clients tested, whereas in 65% of the pharmacies more than half of the people screened came back regularly for subsequent testing. Record keeping is, however, essential to the follow-up of patients with positive test results, those with medication provided by the pharmacists, and those with false-negative test results.

This lack of uniformity of practice and evaluation with regard to screening, reported in many primary health care settings, makes it difficult to assess the extent to which the population benefits from these activities.[18]

All 72 respondents in this study referred clients with abnormal test results to a medical practitioner, mostly to a general practitioner. Good communication between pharmacists and medical practitioners is important to ensure correct follow-up and treatment.[18] Unlike studies in the UK that show that general practitioners are not enthusiastic about the use of the screening tests in pharmacies,[19] many pharmacists in this study indicated that they never experienced problems with general practitioners. In some cases, general practitioners even referred patients to pharmacies for regular testing.

RECOMMENDATIONS

Screening has potential benefits for individuals whose disease may be detected early, and for public health by facilitating early, and often less costly, intervention. The added benefit of screening based in pharmacies is that it is less costly and more accessible. However, this study showed that the added potential is entirely unrealised. At most, pharmacy-based screening programmes have helped a few individuals, giving a 'competitive edge' to pharmacies that do provide such programmes. In order to fully realise the potential of pharmacy-based screening, the population screened must be greatly increased, the quality of the programmes must be improved, and correct, evaluated action must follow both positive and negative test results. If this does not happen, pharmacy-based screening may actually pose a danger to individuals through false-negative results, and may cost society dearly for unnecessary investigation and treatment as a result of false-positive tests. The potential costs are the subject of another paper. Only in this way will pharmacy-based screening become a valuable service that will contribute to reducing risk factors for disease and the improvement of health in South Africa.

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