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Short title of proposal: Outcomes and PSA
testing in general practice

Faculty: Waikato Clinical School

Department: Medical & Health Sciences

3626510/911
UOA File #: _____ Grantor Ref. # 174

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Report type: ☐ Interim ☒ Final

Researcher's UOA ID #: 4252889

☐ Other (specify): _____

Project mentor/supervisor's name (inc. title)
(Only if named researcher is a postgraduate student)

Report due date: 10/01/12

Have all the parties involved in the research
project/programme viewed and endorsed this report?
☒ Yes ☐ No

Project Mentor's UOA ID#: _____

Declarations:

I, (the Researcher or Supervisor if a Postgraduate Student) have read the funder's reporting requirements and confirm that this report complies with these requirements. I certify that if required, all Institutional Research Approvals necessary for the conduct of this research have been obtained and will be maintained current for the duration of the research project.

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Researcher: Ross Lawrenson [Signature] Date: 14/12/2011

Mentor/Supervisor: _____ Date: ____/____/____
(If applicant is a Postdoctoral Fellow or Postgraduate Student)

I am satisfied that this report is an accurate statement of the research progress and confirm that it is suitable for release to the funder.

Head of Department: Ross Lawrenson [Signature] Date: 14/12/2011
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Project Identification:

UOA File #: 3626510/911

Grantor Reference: 174

Funder: Waikato Medical Research Foundation

RE: FINAL RESEARCH REPORT/ OUTCOMES AND PSA TESTING IN GENERAL PRACTICE

This letter serves as the final research report (for the above project) for the period ending December 2011.

What has been achieved?

The aim of this project was to identify men who had a PSA test undertaken in a given 12 month period (2010) and ascertain what happens to men with a raised PSA result. From this original intention we have been successful in completing the study as designed recruiting five GP clinics in the Waikato region, with a patient population of men 40 years and over; totalling 5918 men. Total amount of PSA tests for the five clinics in 2010 was 1480, with 147 of these having raised results.

We have investigated the frequency of PSA testing in general practice for these clinics, ascertaining the reasons why PSA tests were ordered. We explored the frequency of raised PA test by age and were able to uncover some insights into referral patterns for men with raised PSA levels.

The funding from the Waikato Medical Foundation has provided the team with opportunities to gain larger pools of funding for bigger projects. Following on from this has been the success of two major studies: HRC grant for the costs and complications of screening for prostate Cancer worth \$900,000 over three years and more recently a new commercially funded study exploring metastatic prostate cancer. For the HRC study we have also received funding for two additional PhD candidates from the University of Auckland Medical Research Foundation and the Ministry of Health.

There have been successful links made with GP clinics within the community and we have been fortunate in continuing to build on Dr Hodgson's existing networks for the larger part of the study. There has been multiple new connections made with other GP clinics in the wider Midland Region.

How was this achieved?

This was a population based pilot study with five clinics in the Waikato region. Local laboratory results were examined for all enrolled men, 40 years and over who had a PSA test during 2010. These were cross-referenced with data extracted from the GP Medtech system. Once this was retrieved data were

extracted from computerised records of general practices and linked to the PSA results and histology from laboratories. The testing rate and reason for testing was examined for different age groups. Men who were identified as having their first raised PSA in 2010 were then sent out a questionnaire from their GPs to determine their views on PSA testing. Another questionnaire was sent to GPs to determine their views regarding PSA testing. From these we were able to compare frequency of PSA testing comparing rural versus urban, Maori versus non Maori.

Findings:

For the study there were several significant findings.

Understanding the reasons why GPs undertake a PSA provided interesting insight into GP decisions around PSA testing. We found there were four main reasons why GPs ordered a PSA test. Opportunistic testing, which ranged from getting a PSA test with a routine medical check-up or other issues which were not associated with prostate related symptoms or history of prostate issues was practiced most extensively. Previous prostate problems, such as prostate cancer or previous raised PSA, or prostatitis were the second most common reason for testing. Third, patient initiated requests and finally those men with Lower Urinary Tract Symptoms (LUTS) such as incontinence, nocturia, and/or erectile dysfunction. This differed across age ranges (refer Figure 1: Reasons for testing).

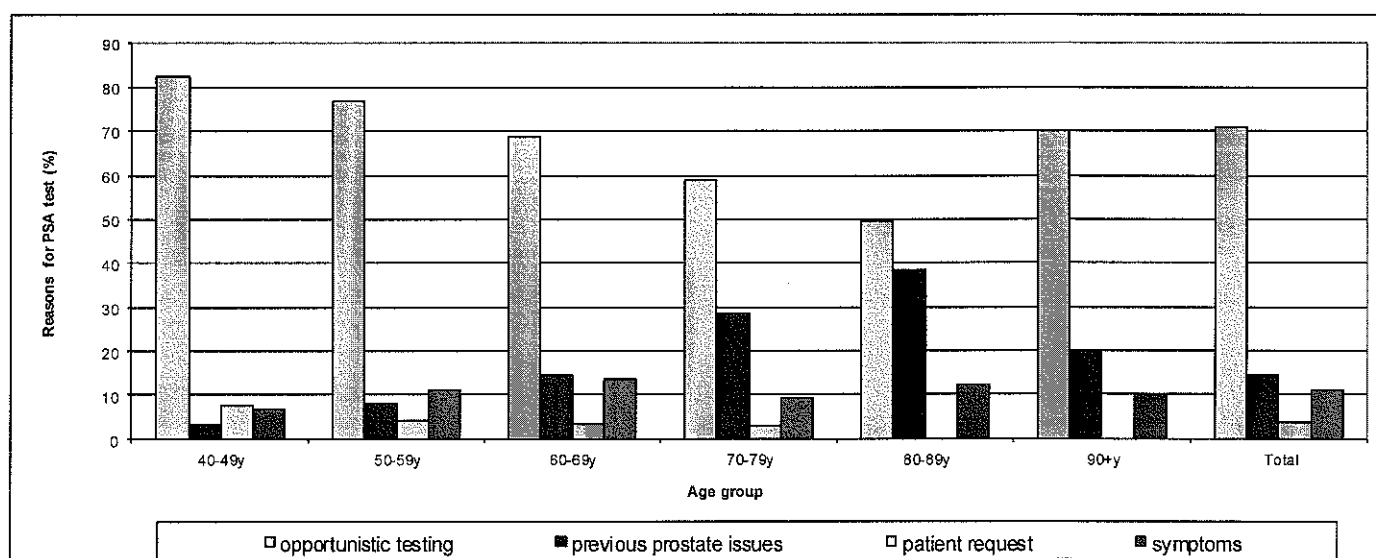


Figure 1: Reasons for testing

Men, 40 years and over, have a 25% chance of having a PSA test (1480/5918). Twenty one men were subsequently identified with prostate cancer. Māori were less likely to be screened at 13.6% with no new cases of cancer found in Māori. Ten percent of men were being tested because of previous pathology and another 10% were tested as part of an investigation of lower urinary tract symptoms (LUTS). Of the 80% of men who were asymptomatic when tested, 90% of tests were initiated by the GPs and less than 10% were because of patient requests. In spite of the fact that there is no evidence to suggest benefit from prostate cancer screening in those aged over 70 years, 28 percent of male patients over 70 in this sample were tested.

We found that twenty one of twenty three prostate cancers were identified through raised PSA testing. The majority (83%) were discovered because of a history of prostate problems or LUTS. Opportunistic testing yielded a much smaller amount of prostate cancers at 17%.

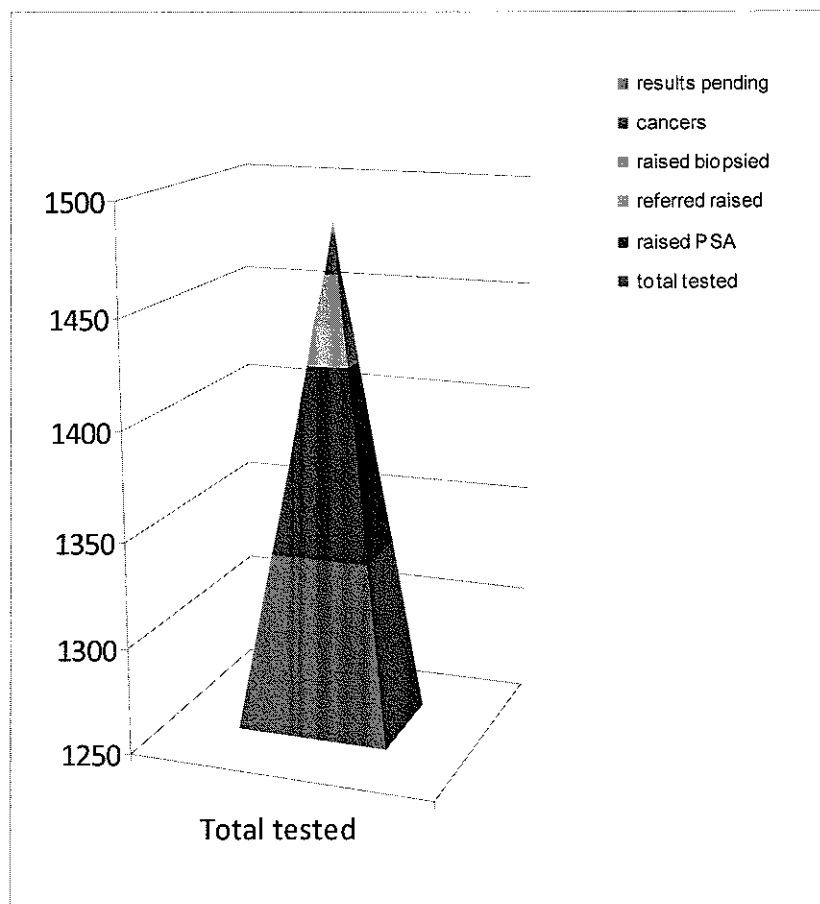


Figure 2: PSA test outcomes

Figure two illustrates that of the 10% (147) of raised PSA tests 40 % of these were referred on to specialists. Over 2/3rds of these referred men were biopsied and 16 of these men were found to have cancer.

We also circulated a questionnaire to the participating GPs and obtained a 70% response rate. We found that GPs in this Waikato-based study all said they opportunistically screened asymptomatic men. The GP questionnaire confirmed a broad professional opinion that PSA improves mortality. GPs predominantly held a strong belief in the value of screening. So whilst the majority of PSA testing was done opportunistically, it was four times more effective when screening was undertaken on patients presenting with previous prostate problems or LUTS.

Any issues arising:

Initially we had anticipated delays in gaining ethical approval which postponed the commencement of the fieldwork. However, once this was resolved we were able to successfully move forward at a rapid pace with the fieldwork, analysis and report writing. The findings of the project have now been submitted to the Journal of Primary Health Care and has been presented to groups of interested GPs. Please find a copy of the submitted manuscript for your reference.

Any further anticipated delays:

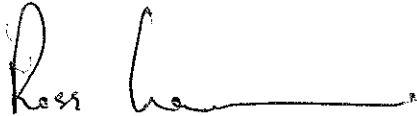
Project completed

Project Finances:

Project funds are all spent.

If there are any further queries or concerns please do not hesitate to contact me at any of the contact details provided.

Kind regards,

A handwritten signature in black ink, appearing to read 'Ross Lawrenson', with a long horizontal flourish extending to the right.

Professor Ross Lawrenson
Head of Waikato Clinical School and Professor of Primary Care
Principle Investigator for the Midlands Prostate Cancer Project

PSA Testing in General Practice

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ABSTRACT

INTRODUCTION In New Zealand Prostate Specific Antigen (PSA) testing has increased significantly; 275000 tests are done annually. Controversy exists around PSA testing as part of an unorganised screening program.

AIM To look at the use of PSA testing in a sample of general practices and investigate the reasons GPs undertook PSA testing.

METHODS Five Waikato general practices were investigated looking at PSA laboratory tests of men 40 years and over in 2010. These were compared against GP notes. Testing rates; reasons for testing; histology and referral/s were examined for different age groups. A questionnaire was then sent to the GPs to determine their views on PSA testing.

RESULTS Men, 40 years and over, had a 25% chance of having a PSA test. Of these, 71% were asymptomatic. Of PSA tests done on older men (70+ years), 56% were asymptomatic. Ten percent of all PSA tests were elevated. Twenty one of 23 prostate cancers were identified through raised PSA testing. Opportunistic testing yielded 4/23 (17%) prostate cancers; the rest (83%) had histories of prostate pathology or LUTS. The questionnaire confirmed GPs belief in the benefits of PSA screening and some difficulties in educating patients.

DISCUSSION All GPs in this study opportunistically screened asymptomatic men. The GP questionnaire confirmed a broad professional opinion that PSA screening is of value and improves mortality rates. So whilst the majority of PSA testing was done opportunistically, it was four times more effective when screening focused on patients presenting with previous prostate problems or LUTS.

KEYWORDS Prostate Specific Antigen (PSA), PSA testing, Screening, Prostate Cancer, General Practitioners

What is already known: Despite on-going debate regarding PSA testing in general practice PSA testing is frequently done on asymptomatic patients.

What this study adds: Opportunistic screening in asymptomatic men is commonly carried out and effective at identifying prostate cancer. While many studies have asked GPs for their views regarding screening of an asymptomatic patient, this study checked their views against their notes. Considerable and unnecessary opportunistic screening is going on in men aged 70 years despite no evidence of reduced mortality from Randomised Control Trials (RCTS) and good evidence of harm.

Introduction

Prostate Cancer is a common cause of male cancer in New Zealand with approximately 3000 new cases diagnosed each year and 560 deaths.¹ The natural history of prostate cancer is that it usually occurs in older men. It is slowly progressive with a long lead time to diagnosis and symptoms. Five year survival rates are also high at more than 80%.²⁻⁴ Consequently, prostate cancer would appear to be a good candidate for screening. The PSA test is helpful as a diagnostic tool in patients with established prostate cancer; however, while it is frequently used as a screening tool, the test has some limitations.⁵

General practitioners face conflicting messages about the need to screen. The Urological Society of Australia and New Zealand believe GPs should offer asymptomatic men a PSA test.⁶ This is advice that is based partly on the results of two randomised control trials, The European Randomised study of Screening for Prostate Cancer (ERSPC) and Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO). Both studies have shown reduced mortality in men who were screened between the ages of 50 and 69 years.^{7, 8} However, because of the acknowledged global issues of over diagnosis and harm caused by screening, the NZ Ministry of Health have followed the trend in other OECD countries. They have repeatedly avoided making any recommendations supporting a national screening program.^{5, 9}

What are GPs to do? Patients typically have a very straight forward understanding of the PSA test. A negative test means they do not have cancer, while a positive test will identify cancer early enough to allow curative treatment. They believe the risks of having a simple blood test are minimal.¹⁰ However, several studies confirm that patients' perception of risk is not accurate.^{11, 12}

In New Zealand, it is known that PSA tests are used widely with 275,000 tests a year being carried out principally ordered by GPs.¹³ In general, GPs would test asymptomatic men, but many tests are also being undertaken in men with lower urinary tract syndromes or previous history of prostate problems.¹⁴⁻¹⁹ What we do not know is why men are being tested and what happens to the men who have been tested and are found to have a raised PSA level.

This study was designed as a pilot for a larger project looking at costs and complications of screening. This pilot was to be run within the Waikato District Health Board. The Waikato region is a large geographical area covering 34890km² or approximately 13% of New Zealand's land mass; with a population of 353,000. There are a number of main urban areas in the region, including Hamilton. Unique to this region is the number residing in rural and isolated areas (23.8% compared with 14.3% for the total population).²⁰

Aims

The aim of this study is to examine the age specific rate of PSA testing in five general practices in the Waikato region during a 12 month period and to understand why they are being tested. We also examined the outcomes of testing.

Methods

This study was carried out in five practices with a total population of approximately 25,000 registered patients. Ethics approval was obtained (reference number NTY/11/02/019). GP permission was sought to access PSA results for all men who had received a PSA during 2010. Once permission was received the laboratory provided all PSA results for the given period attached to the GP and the clinic. We then looked at the notes and determined the

reason the PSA test was performed. These were coded under four themes: opportunistic testing, previous raised PSA or prostate problems, patient request and lower urinary tract symptoms (LUTS).

Each practice provided baseline data of their population of enrolled men over 40years, date of birth, National Health Index number (NHI). The age and PSA levels of those tested were recorded.

We analyzed the data looking at screening rates by age and reason for testing. We also analyzed referral rates to specialists for those with a raised PSA test looking at age, ethnicity and level of PSA test. A raised PSA was defined according to Pathlab recommendations: 40-49years >2.5ug/L; 50-59years>3.5ug/L; 60-69years >4.5ug/L; 70-79years >6.5ug/L; 80+ years >7ug/L.

Data were entered into an Excel spread sheet which included details such as: the National Health Index number (NHI), date of birth, and reason for testing all men 40 years and older. We looked at biopsy rates and results. We did this through reviewing GP notes and laboratory records.

A questionnaire survey consisting of 20 questions was later sent to the GPs in the practices to ascertain their views regarding PSA testing and their demographics. Data were collected and coded.

Results

We identified 5918 resident male patients aged 40 years and older in the five practices. During the 12 months 1480/5918 (25%) had been tested with at least one PSA test (The range varied 10-37% over the five practices). Testing was least likely in the 40-49 age group and declined slightly in the 80+ age group (see Table 1).

Overall 147/1480 PSA tests were elevated (10%), (Table 1). In those with an elevated PSA, 37% were referred to a specialist, a total of 55/147. The higher the PSA test the more likely the referral. Of the 55 referrals 39 had a biopsy, 21 out of these had prostate cancer, and 18 were benign.

However, there were 10 referrals to specialists with normal PSA test results. These had reasonable clinical grounds to do so (Fig 1). Two who were biopsied had cancer.

When we looked at the notes to ascertain the reason patients had a PSA test overall, 71% of the time GPs did this opportunistically; 14.3% when there was a history of prostate problems; 3.9% on patient request; 10.8 % with lower urinary tract symptoms (Fig 2). Thus of the 147 with raised PSA, 55 (37%) were referred to a specialist (Table 2).

GP Questionnaire Results

Of the 26 GPs in the five practices 18 questionnaires were returned (69%): ten male and eight females. The majority worked 5 or more sessions in joint practices and were aged in their 40's and 50's.

Sixty one percent agreed or strongly agreed that PSA screening reduced mortality rates. Fifty five percent were concerned regarding harm caused by PSA testing but the majority felt the benefits outweighed this. All bar one GP did PSA screening: mostly selectively and/or opportunistically, mainly focused on men aged between 50 and 70 years. Only 44% agreed

that all men over 40 should have at least one PSA test. Seventy two percent of GPs said they did a digital rectal examination and PSA test when checking for prostate cancer.

Certain questions looked at consultation restraints surrounding PSA explanations. Thirty nine percent of the GPs felt they needed more knowledge to advise patients. Fifty six percent felt it was difficult to give a balanced view to patients regarding PSA testing. The majority felt patients had difficulty understanding the issues despite the GPs best efforts and 61% said that patients elected to get the test anyway. However the majority did not feel pressured by patients to perform PSA screening. GPs were evenly divided in their views regarding such things as medico-legal concerns, time restraints and whether patients could in fact make up their own minds about PSA testing.

Discussion

All doctors in all five practices in the Waikato are opportunistically testing asymptomatic patients. This was confirmed by the GP questionnaire whereby all bar one GP said they practiced screening. Testing of asymptomatic men is common in New Zealand and this seems to be consistent with findings in other countries.¹⁵⁻¹⁷ Many studies have asked GPs and Primary Care doctors for their views regarding screening of an asymptomatic patient, we have gone one step further in this study and qualified why men are tested.

In our study, 25% of men 40 years and over were tested in 2010. This increased with age and GPs focused most of their screening on men aged between 50 and 69 years. This may in fact be worthwhile as the ERSPC study showed up to 20% reduction in mortality in men in this age group.⁸ What is of concern in our study is the number of PSA tests done on patients 70 years and over (28%) when there is little evidence to support benefits. A large number of these tests (56%) were done opportunistically. Overall age groups 71% of PSA tests were done for opportunistic reasons.

The National Screening Advisory Committee identified that nearly 50% of men 40 years and over had had a PSA test at some time which compared to only 18% during 2008.²¹ In a 2011 Health Committee inquiry into the early detection and treatment of prostate cancer 50% of men 50 years and over were estimated to have a PSA test over a 2 year period.²² The New Zealand Health Survey suggests that approximately 50% of men aged 50 and over had a PSA test in the previous 5 years of which 80% of these men were asymptomatic.²³ This represented a 40 % coverage rate in New Zealand in any one year. Our study found that there was a 25% chance of having a PSA test in 2010 if 40 years and over. If we limit it to 50 years and over the chance is 31%. These figures are consistent with these other reports. Our GPs generally believed the benefits outweighed harm and resulted in reduced mortality rates.

Ten percent of all PSA tests done were elevated. From these elevated tests 21 new cancers were diagnosed following biopsy.

There were ten referrals to specialists without raised PSA. There seemed to be reasonable clinical grounds to do so. Two of these ten were biopsied both of which proved to have cancer.

Although PSA testing on its own will miss some cancers, GPs using their clinical judgment are effective in picking up several more. Of those referred to a specialist (55 with raised PSA and 10 normal PSA) 63% were biopsied. We looked at the reasons for having the PSA test done and checked whether this was helpful in picking up those with prostate cancer. Having

a previously raised PSA or history of a prostate problem together with a raised PSA proved to be the most productive in identifying prostate cancers. From our study it is estimated that for every 1000 PSA tests done for patients with previous raised PSA or prostate problems approximately 66 new prostate cancers would be identified. There would be 18 new cancers for patients presenting with LUTS and only 4 new cancers for 1000 done opportunistically alone (i.e. those without symptoms or previous prostate problems). Therefore when diagnosing prostate cancer it is much more effective if GPs focus their PSA testing on men with previous history of prostate problems or LUTS.

GPs within our study expressed that they do find explanation to patients regarding PSA screening difficult. More education for GPs may prove beneficial. Most seem convinced that screening is beneficial despite clear evidence supporting improved mortality rates especially in the 70 years plus age groups.

One of the strengths of this study was that it was population based and that the researchers were able to link patient data with laboratory data. Collection of detailed data directly from clinical notes by the same researchers, including one clinician was also identified as a strength. Seeking GP views via a questionnaire and comparing it against their practice was likewise identified as a strength.

Weaknesses of this study include the purposeful selection of practices which might not reflect a true representation. We also had lower numbers of Māori than we were hoping to find precluding analysis by ethnicity. GP questionnaire numbers were small and may not be representative of the New Zealand populations overall. This study did not look at follow up after biopsy and any risk or benefits from the diagnosis of prostate cancer. These aspects are being followed up by the larger three year Midland Prostate Cancer Study of which this study represents the first pilot stage.

In conclusion this study looked at PSA testing by GPs in five practices in the local Waikato setting. GPs in this study believed in the benefits of screening and were opportunistically testing focusing their screening on men aged 50 to 69 years. They were more likely to refer and a greater chance of picking up prostate cancer when PSA testing was done on men with previous history of prostate problems or LUTS. Using their clinical judgment GPs identified further prostate cancers even when PSA levels were within normal ranges. With regard to PSA screening several problems were identified in giving patients a balanced view.

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Table 1. The number and percentage (%) of men who received a PSA test and who had an elevated PSA in a 12 month period in 5 general practices by age

Age group	Total	No. of men with PSA test	%	No. of men with raised PSA	%
40-49y	1938	241	12.4	6	2.5
50-59y	1802	481	26.7	38	7.9
60-69y	1161	415	35.7	48	11.6
70-79y	694	244	35.2	32	13.1
80 +y	323	99	30.7	23	23.2
Total	5918	1480	25	147	9.9

Table 2. Number of men with raised PSA test, referrals, biopsies, and of men diagnosed prostate cancer grouped by reasons for PSA test

Reasons for PSA test	Raised PSA test	Referral	Biopsy	Diagnosis of prostate cancer
Opportunistic testing	28	6	5	4
Previous prostate problems	98	40	29	14
Patient requested test	2	1	0	0
LUTS	19	8	5	3
Total	147	55	39	21

Reasons for referral

- 6 with lower urinary tract symptoms > 1 biopsy > 1 diagnosed with prostate cancer
- 1 with abnormal digital rectal examination > 1 biopsy > 1 diagnosed with prostate cancer
- 2 with previous prostate cancer and rising but normal PSA level > no biopsy
- 1 with elevated PSA 2009 and upper normal range PSA 2010 > no biopsy

Figure 1. Patients with normal PSA level referred to a specialist and their outcomes

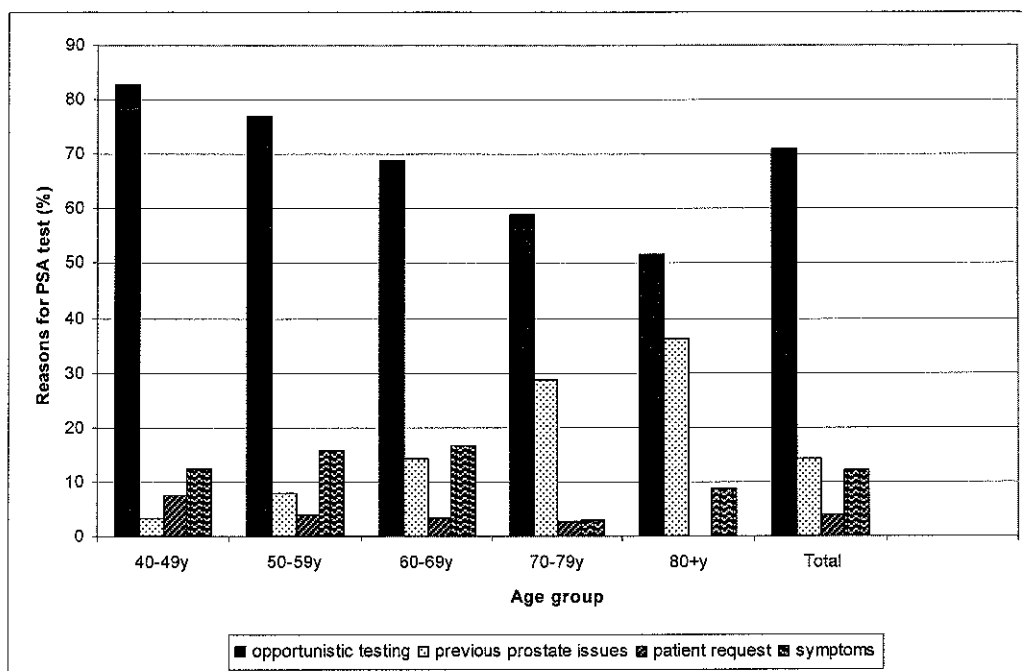


Figure 2. Proportion (%) of reasons for PSA test in Waikato general practices by patients' age.