



Clinical Audit Report

How current practice of Prostate Specific Antigen (PSA) testing fits with local and national guidelines

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Summary

Prostate cancer incidence in Northern Ireland increased from 471 cases in 1993 to 1,165 in 2016. The increase was linked to a rise in the use of PSA testing despite this test not meeting the standards for cancer screening.¹ It is not usually recommended for asymptomatic men with less than 10 years' life expectancy or those under 50 years who are considered high risk. It is recommended if there are symptoms which could suggest prostate cancer. Routine screening for prostate cancer is not national policy. In N. Ireland there is evidence of PSA screening which through over diagnosis has the potential to inflict harm to patients whilst also creating a financial burden for the Health Service.² 'Currently a third of prostate cancers in NI are diagnosed via PSA testing.

Aims and Objectives

The aim of this audit is to ascertain the patterns of PSA testing in each of Northern Ireland's (N. Ireland) General Practices from 2010-2016 and each of the 17 GP Federations and to feed this back to the GP practices and Federations with information on current guidelines.

Methods

The number of Prostate cancers diagnosed in each GP practice 1993-2016 was documented and presented.

PSA test results have been routinely collected by the N Ireland Cancer Registry (NICR) for verification of prostate cancer cases. Using this PSA database containing 908,105 PSA tests carried out in N Ireland from 2007 to 2016 the NICR was able to use a three year 'buffer' period (2007 – 2009) to identify patients with any and a first PSA test carried out from 2010 to 2016. First and all PSA tests ordered in primary care 2010-2016 in NI were identified and matched to GP practice from anonymised data on all PSA tests (n=426,923).

Data were anonymised for analysis. Comparisons were made across time periods 2010–2013 and 2014–2016. The trend of prostate cancers diagnosed since 1993,

the age of patients having a first PSA test, numbers of biopsies completed, and total and first PSA tests per GP practice are reported for the period 2010-2016.

PSA testing rates were age standardised to the Practice male population and compared to a NI average, with a ranking for each GP practice compared to the whole, using Standard Incidence Ratios (SIR). Similar data were also analysed for each of the 17 GP Federations. A retrospective case note review was undertaken for men with prostate cancer from the highest and lowest PSA testing GP practices (n=198). This was to test the hypothesis that men with prostate cancer diagnosed from a “high PSA GP practice” would be more likely to have presented asymptotically compared to patients from GP practices with a lower rate of PSA testing.

Key findings

- Between 1st January 2010 to 31st December 2016, 608,036 PSA tests were performed on 190,755 patients in N. Ireland at an estimated cost of £7.2 million.
- There were significant number of tests ordered in women (n=1,333).
- PSA testing in GP practices has increased from 2010 to 2016 whilst decreasing in hospitals. This may reflect the transitioning of services from secondary to primary care.
- The most common age range for PSA testing within hospitals was 70-79 years whereas within GP practices it is most commonly carried out in men aged between 60-69 years.
- Of the 608,036 PSA tests carried out in 2010-2016, 90,009 (14.8%) of these were first tests carried out by a GP. The most common age group for men to have a first PSA test requested by their GP was 50-59 years (31%) with a mean age of 57.99 years.
- Thirty nine point two percent of all first tests ordered in General Practice occurred in men under 50 and 29.9% in men over 80. *This despite guidelines which indicate a) testing in men under 50 only if they are high risk, or request a test and have informed choice. b) PSA testing is not usually recommended in men with less than 10 years life expectancy.*

- The majority (87.3%) of patients having a first PSA test requested by their GP had a PSA result <4 ng/ml compared to only 4.1% of patients receiving a result of 10ng/ml or higher.
- A higher PSA reading was more common in older compared to younger men.
- Overall, 106 GP practices were significantly lower than the N. Ireland average for requesting PSA tests during 2010-2013 in comparison to 86 GP practices in 2014-2016. In 2010-2013, 85 GP practices were significantly higher than the N. Ireland average compared to 68 practices for 2014-2016.
- Standardised incidence ratios (SIRs) varied markedly across GP ranging from 42 to 331 in 2010-2013 and from 24 to 256 in 2014-2016 where 100 is the N. Ireland average.

Recommendations

- The importance of discussing the advantages and disadvantages of the PSA test to patients as per NICE guidelines should be reinforced to all healthcare professionals as the negative effects of investigations and treatments following PSA testing have been recognised by Patient Reported Outcomes Studies..
- As it is recommended that PSA testing should be preceded by an informed discussion a separate form to request PSA tests with a tick box to indicate that such a discussion had taken place could improve adherence to guidelines regarding PSA tests.
- This audit should be repeated in three years to determine if there has been any change in practice.
- The PSA database held securely by the N.Ireland Cancer Registry has enabled this work and should be retained to determine the effect of this audit and any subsequent change to PSA request forms.

Background

The PSA test

There is ongoing debate about the use of PSA testing for prostate cancer detection.

Guidelines

The Prostate Cancer Risk Management Programme (PCRMP)³ published by Public Health England helps General Practitioners (GPs) give clear and balanced information to asymptomatic men who ask about Prostate Specific Antigen (PSA) testing. It indicates that the PSA test is available to any well man aged 50 and over who requests it. GPs should however engage in discussion with men to assure informed choice. They should use their clinical judgement to manage symptomatic men and those considered to have higher risk for prostate cancer who are aged under 50.

According to the National guidelines outlined by NICE National Institute for Health & Care Excellence clinical knowledge summary,⁴ (last revised July 2017) PSA testing should not be offered to the man until he has carefully considered the benefits and limitations of PSA tests. After this discussion, PSA testing may be offered to:

- Men older than 50 years of age who have asked for a PSA test.

And considered in men presenting with:

- Lower urinary tract symptoms (LUTS), such as nocturia, urinary frequency, hesitancy, urgency or retention.
- Erectile dysfunction.
- Visible haematuria.
- Unexplained symptoms that could be due to advanced prostate cancer (for example lower back pain, bone pain, weight loss).

It is also clearly stated within these guidelines that routine screening for prostate cancer is not national policy, however, evidence of PSA screening has been identified in N. Ireland.² PSA screening has the potential to inflict unnecessary harm to patients through treatments which have short and long term side effects including

urinary incontinence, impotence, bowel problems and the effects of hormone therapy⁵⁻⁹ whilst also creating a financial burden for the Health Service.

PSA testing is not usually recommended for asymptomatic men with less than 10 years' life expectancy.

Evidence suggests PSA screening could reduce prostate-cancer related mortality by 20% however with a risk of over diagnosis.¹⁰ Approximately 3 in 4 men with a raised PSA level ($\geq 3\text{ng/ml}$) will not have cancer.³ The PSA test can also miss approximately 15% of cancers.³ Before a PSA test, men should not have: an active urinary infection, ejaculated in previous 48 hours, exercised vigorously in previous 48 hours or have had a prostate biopsy in previous six weeks.³

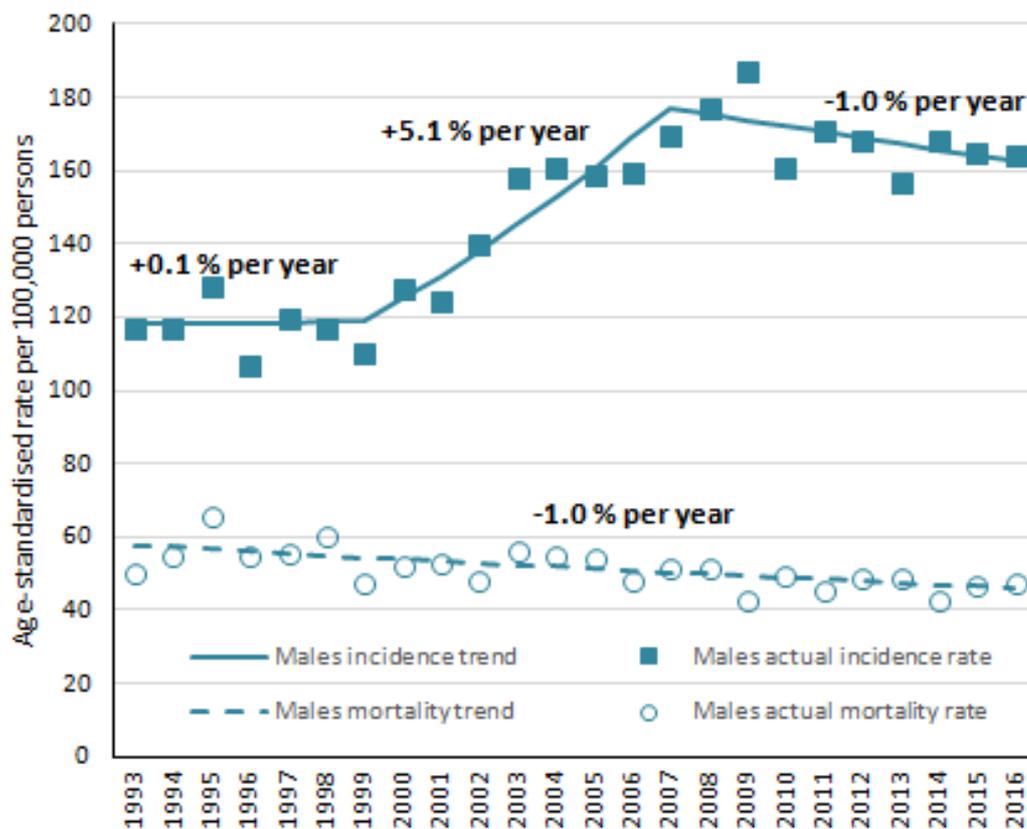
A recent study found that 75% of prostate cancer survivors reported at least one 'current' physical symptom 90% reported having at least one current symptom at some time since their treatment, with 29% reporting at least three.¹¹ The prevalence of these symptoms varied by treatment. Overall, 57% reported current impotence and this was highest after radical prostatectomy (RP, 76%) followed by external beam radiotherapy (ERBT) with concurrent hormone therapy (HT, 64%). Urinary incontinence (overall 'current' 16%) was highest after RP ('current' 28%; 'ever' 70%). Fourteen percent reported ongoing bowel problems with a third (33%) of these men having had EBRT treatment. Other symptoms included libido loss, breast changes, hot flashes and fatigue.¹¹

In addition to the psychological and physical impact of PSA testing and prostate cancer treatment, non-compliance with guidelines places a significant financial burden on the health service. In N. Ireland, the number of PSA tests per year is approximately 95,000 and with a conservative cost estimate of £12 per test,¹² this accounts for an annual spend of approximately £1.1 million on PSA tests alone. There are additional financial costs of further prostate biopsy and treatments. This is in addition to the psychological costs to men and their families of the worry of a possible or actual cancer diagnosis.

Prostate cancer in N Ireland

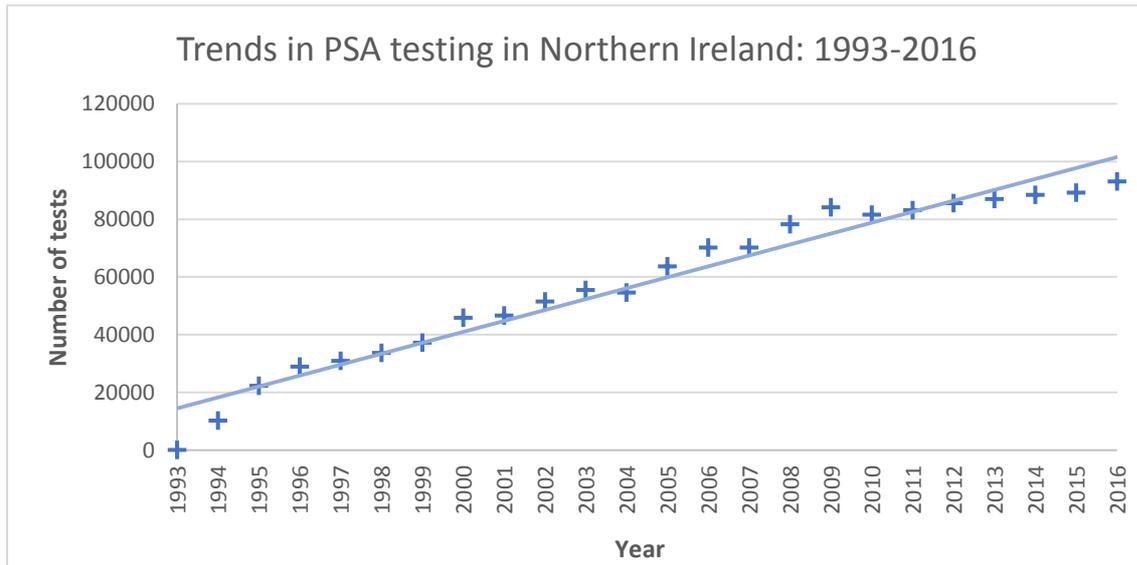
Over the past twenty years the number of prostate cancer cases diagnosed in N Ireland has more than doubled from 471 cases in 1993 to 1,165 in 2016, however, mortality rates have remained relatively constant with a decrease of -1.0% by year (Figure 1).¹ These trends reflect the increased use of PSA testing.

Figure 1. Trends in prostate cancer incidence and mortality in N. Ireland (1993-2016)



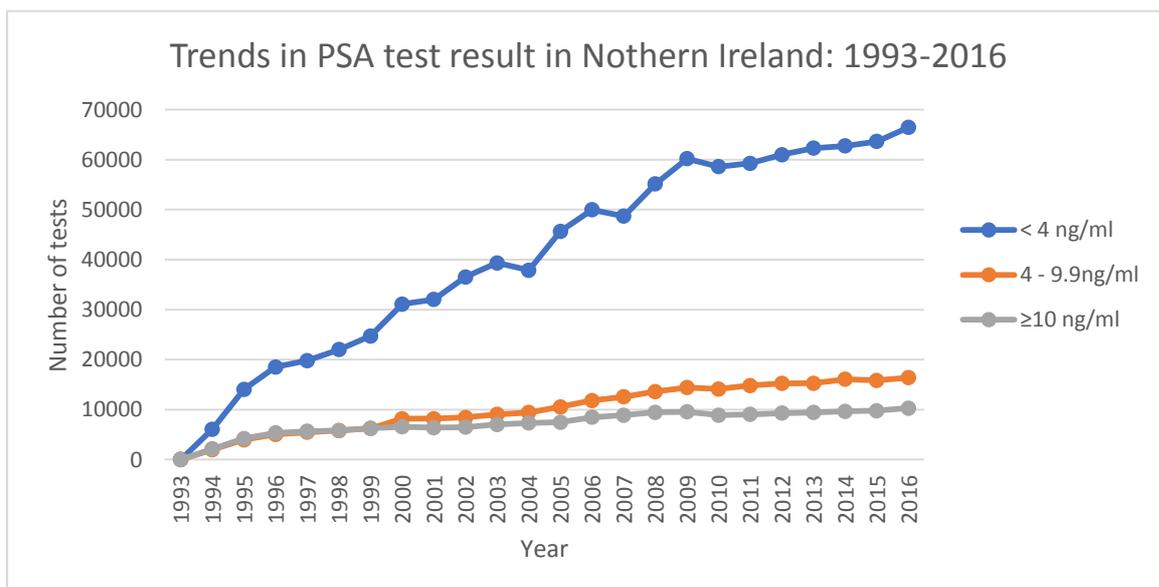
The total number of PSA tests carried out in N.Ireland 1993-2016 was 1,391,509. Figure 2 highlights the steady increase in rate of PSA testing since 1993.

Figure 2. Trends in PSA testing in Northern Ireland (1993-2016)



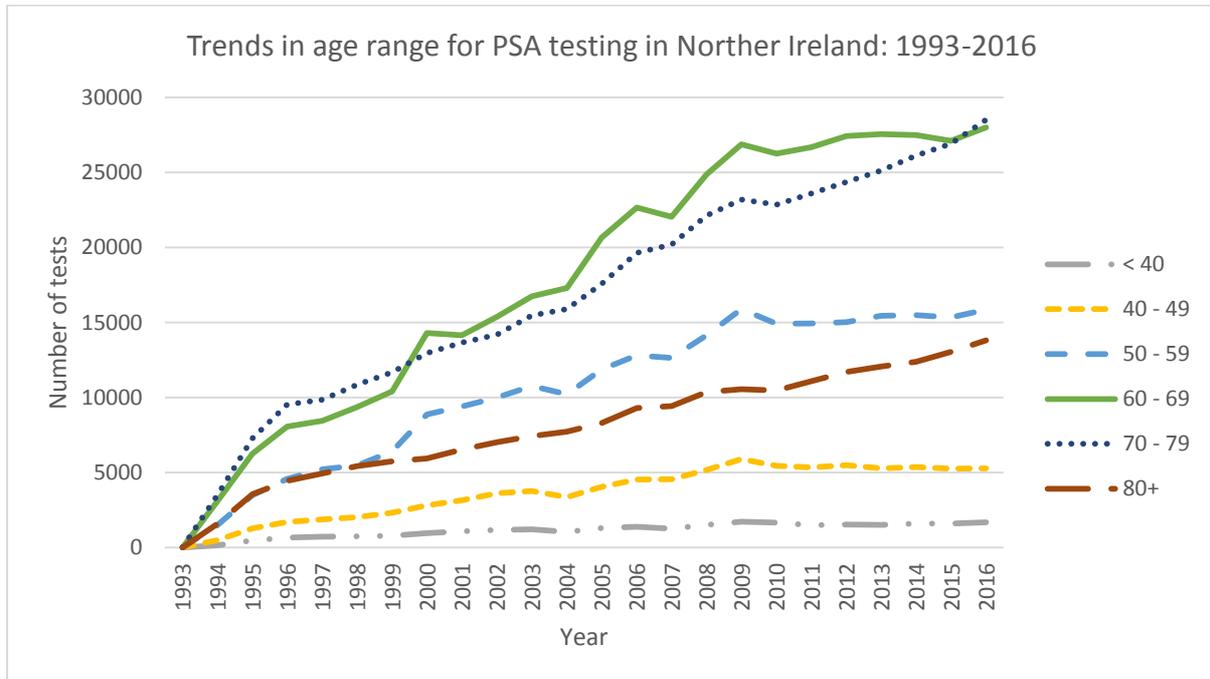
Of the number of PSA tests performed in N.Ireland between 1993-2016, the greatest increase is seen in tests which have a result of <4ng/ml (Figure 3) which is considered to be indicative of a low prostate cancer risk.⁴

Figure 3. Trends in PSA test result in Northern Ireland (1993-2016)



PSA testing has increased for all age groups during 1993-2016. The greatest increase was seen in those aged 60-69 and 70-79 years, however, PSA testing rates are also continuing to increase in those aged <40 and 80+ years (Figure 4).

Figure 4. Trends in age range for PSA testing in Northern Ireland (1993-2016)



The increasing numbers of PSA tests with results of <4ng/ml and in those aged below 50 and above 80 years suggest testing is not being carried out in agreement with National guidelines.

Audit Aim

To ascertain if we are meeting the current guidelines for PSA testing in N.Ireland.

Audit Objectives

1. To identify PSA testing rates in General Practice in NI from 2010-2016 adjusting for Practice population profiles (male patient numbers, age, and socioeconomic group)
2. To match PSA tests and biopsies to prostate cancer patients to identify new and repeat/monitoring tests
3. To identify GP practices with the highest and lowest request rates of PSA new tests
4. To undertake secondary care note review of highest and lowest requesting practices to determine how new tests match guidelines
5. To determine effect on PSA testing levels of Southern Area's removal of PSA tests automatically from routine blood tests

Audit Standards and Criteria

The standards used were taken from National Institute for Health and Care Excellence (NICE) documentation:

| Criteria | | Target (%) | Evidence | Strength* | Instructions for where to find data |
|----------|--|------------|------------------------|-----------|--|
| 1 | Consider a prostate-specific antigen (PSA) test and digital rectal examination to assess for prostate cancer in men with any lower urinary tract symptoms, such as nocturia, urinary frequency, hesitancy, urgency or retention or erectile dysfunction or visible haematuria. | - | NICE (NG12) & NICE CaN | C | Note review of patients referred from high PSA testing practices |
| 2 | Refer men using a suspected cancer pathway referral (for an appointment within 2 weeks) for prostate cancer if their PSA levels are above the age-specific reference range. | 100% | NICE (NG12) & NICE CaN | C | NICR PSA database linked to NI CaPPS system |
| 3 | Do not automatically offer a prostate biopsy on the basis of serum PSA level alone. [2008] | - | NICE CG175 | C | Note review of patients referred from high PSA testing practices |
| 4 | Men with prostate cancer who do not have chosen a watchful waiting regimen with no curative intent should normally be followed up in primary care in accordance with protocols agreed by the local urological cancer MDT and the relevant primary care organisation(s). Their PSA should be measured at least once a year. | 100% | NICE CG175 | D | PAS database used to identify watchful waiting and linked to PSA database |
| 5 | Check PSA levels for all men with prostate cancer who are having radical treatment at the earliest 6 weeks following treatment, at least every 6 months for the first 2 years and then at least one a year thereafter. | 100% | NICE CG175 | D | NICR used to identify radically treated patients and linked to PSA database |
| 6 | Active surveillance Yr1 – Every 3-4 months: measure PSA / Yr2-4 Every 3-6 months: measure PSA / >Yr4 – Every 6 months: measure PSA | 100% | NICE CG175 | D | PAS database used to identify active surveillance and linked to PSA database |

**Strength of Evidence*

A At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation

B Availability of well-conducted clinical & social care studies but no randomised clinical trials on the topic of the recommendation

C Expert committee reports or opinions and/or clinical experience of respected authorities. Absence of directly applicable clinical studies of good quality

D Recommended good practice based on clinical & social care experience (local consensus)

Methodology

The number of Prostate cancers diagnosed in each GP practice 1993-2016 was documented and presented.

PSA test results have been routinely collected by the NICR for verification of prostate cancer cases. After exclusions, the PSA database contains 850,657 PSA tests carried out on 226,214 patients in N. Ireland spanning 2007 to 2016. The NICR was able to use a three year 'buffer' period (2007-2009) to identify patients with any and a first PSA test carried out from 2010 to 2016. First and all PSA tests ordered in primary care 2010-2016 in N. Ireland were identified and matched to GP practice from anonymised data on all PSA tests (n=426,923).

Data were anonymised for analysis. Comparisons were made across time periods 2010–2013 and 2014–2016. The age of patients having a first PSA test, numbers of biopsies completed, and total and first PSA tests per GP practice are reported.

A prostate cancer diagnosis for each patient was obtained from cross checks with the NICR database 1993-2016. Numbers of first PSA tests ordered over time with PSA testing rates were standardised to the GP practice male population and compared to a NI average with a ranking for each of the 334 GP practices compared to the whole using Standard Incidence Ratios (SIR). See appendix 1 for an example.

Data were also analysed for each of the 17 GP Federations. See appendix 2.

A retrospective case note review was undertaken for men with prostate cancer from the highest and lowest PSA testing GP practices (n=198). This was to test the hypothesis that men with prostate cancer diagnosed from a "high PSA GP practice" would be more likely to have presented asymptotically compared to patients from GP practices with a lower rate of PSA testing.

Exclusions

A total of 57,448 PSA tests were excluded from the audit. Exclusion criteria included PSA tests performed on female patients (n=1,333). Insufficient samples (n=5,085), Free PSA tests or Free PSA ratios (n=43,770) were also excluded from the analysis.

Finally, quality control tests carried out by laboratories and other invalid tests were identified and removed (n=7,260).

Findings

Population

This population-based audit was carried out using data from the NICR PSA database. The original PSA database contained 908,105 PSA tests performed in N. Ireland spanning 2007-2016. During the data cleaning process, 57,448 PSA tests were excluded from the audit including 1,333 PSA tests undertaken on female patients. Furthermore, 3,211 tests could not be linked to a patient due to the PSA test having no health and care number (HCN) attached.

In the time-period 2010-2016, a total of 608,036 PSA tests were carried out in N.Ireland laboratories. These tests belonged to 190,755 patients (Table 1). Over a quarter of all tests (25.8%) were carried out in the Belfast Trust, closely followed by the Northern (23.5%) and Southern (20.9%) Trusts. The South Eastern Trust had the lowest number of tests.

The cost of PSA testing over the seven-year period has been estimated at approximately £7.2 million.

Table 1 - Number of PSA tests in N. Ireland 2010-2016

| Trust | Total | Cost (£) ^b |
|----------------------------------|-----------------|----------------------------------|
| Belfast | 156,716 (25.8%) | 1,868,054.72 |
| Northern | 142,685 (23.5%) | 1,700,805.20 |
| South Eastern | 81,142 (13.3%) | 967,212.64 |
| Southern | 126,908 (20.9%) | 1,512,743.36 |
| Western | 100,585 (16.5%) | 1,198,973.20 |
| Total PSA tests | 608,036 | 7,247,789.12 ^c |
| PSA patients ^a | 190,755 | |

^a <1% of tests (N=3,211) had no HCN therefore not assigned to a patient

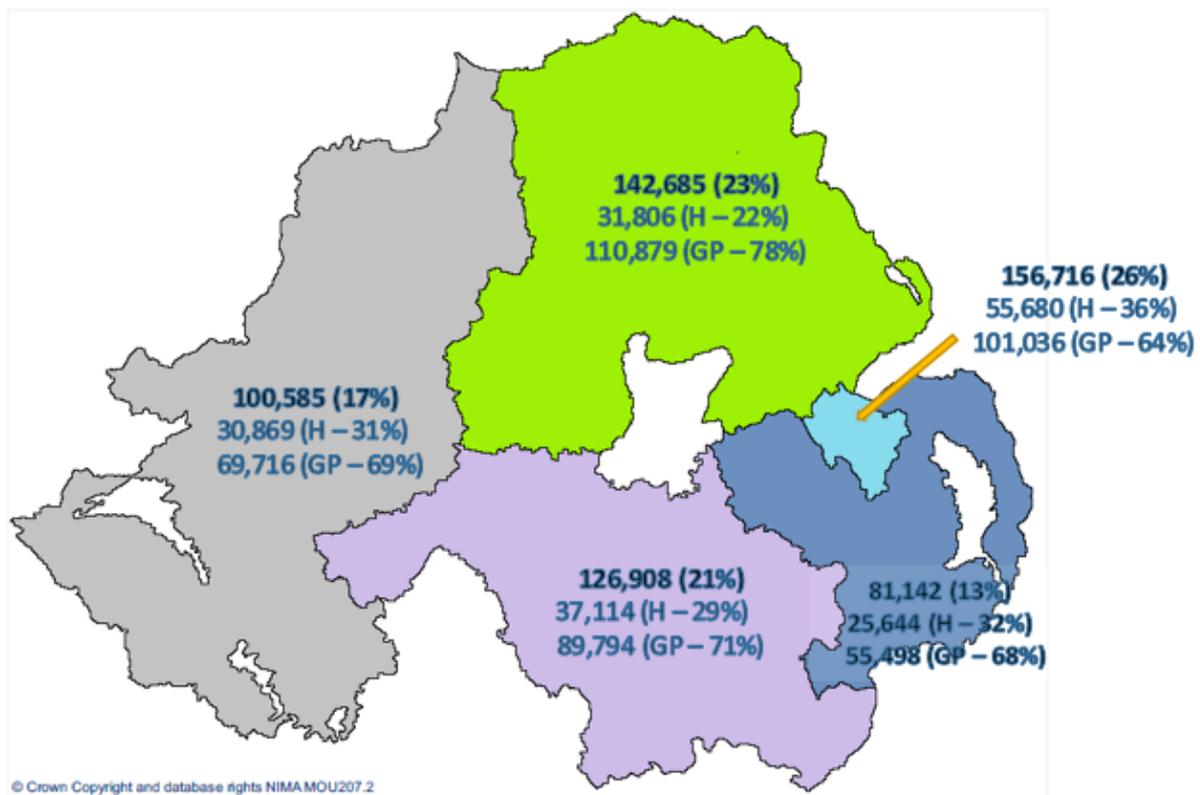
^b Cost estimated using data from SchARR prostate cancer screening report.¹²

^c Tests excluded from the analysis were not included in calculating the cost.

GP versus Hospital

181,113 (29.8%) tests were requested from a hospital source and 426,923 (70.2%) from a GP practice. Across all Trusts, GPs were the highest requestors for PSA tests (Figure 5). The Northern Trust had the highest percentage of GP requests (78%) in comparison to hospital requests (22%).

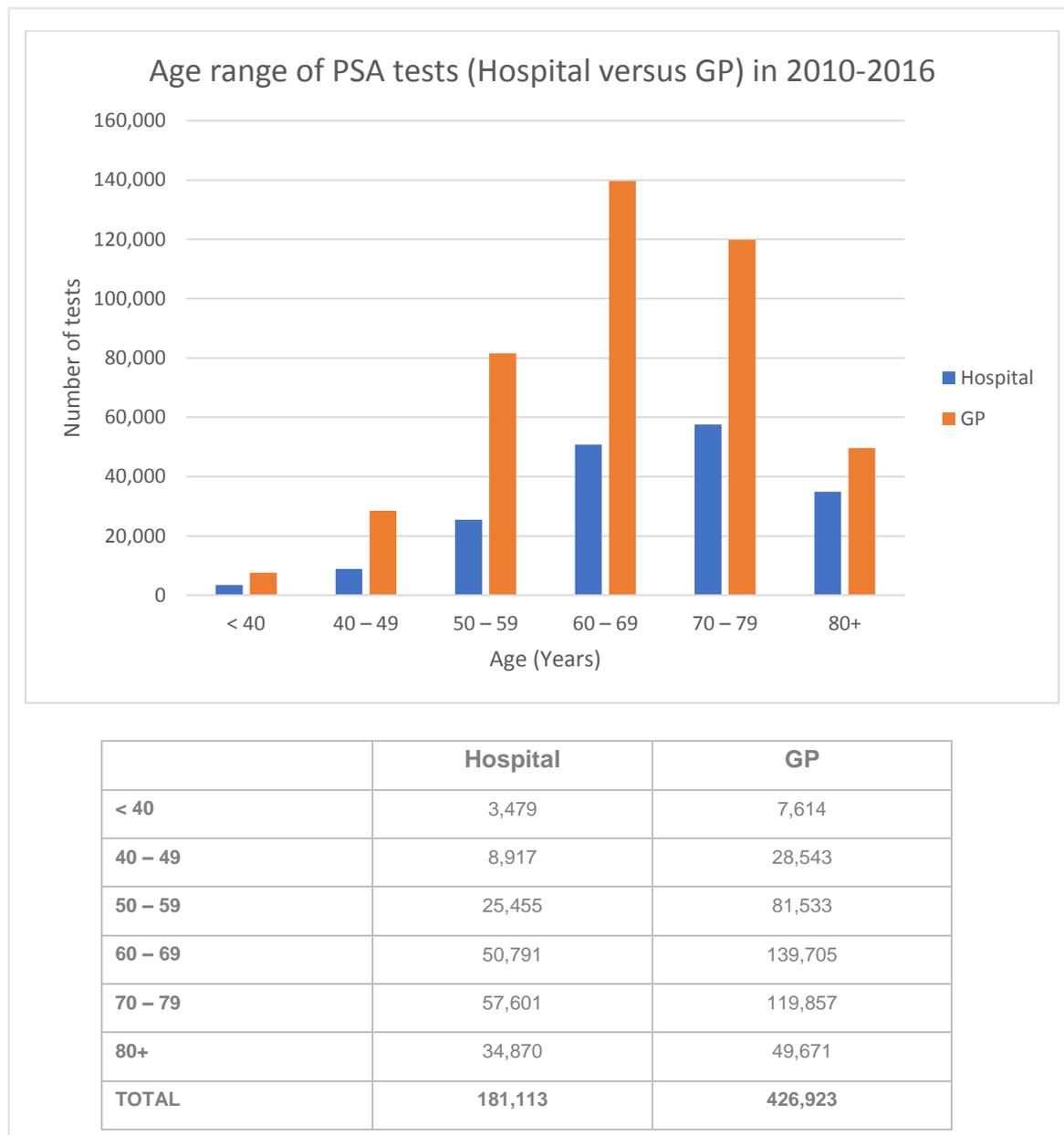
Figure 5 - Number of PSA tests by Trust 2010-2016 (Hospital versus GP)



Age range

The mean age for the population (see Figure 6) having PSA tests was 67 years with a range of 2-106 years. PSA testing in GP practices is carried out in a younger population in comparison to hospitals (Figure 6). The most common age range for PSA testing within hospitals was 70-79 years. This is on average higher than those undergoing PSA testing within GP practices where the majority of men are aged between 60-69 years.

Figure 6 - Age range of PSA tests (Hospital versus GP) in 2010-2016



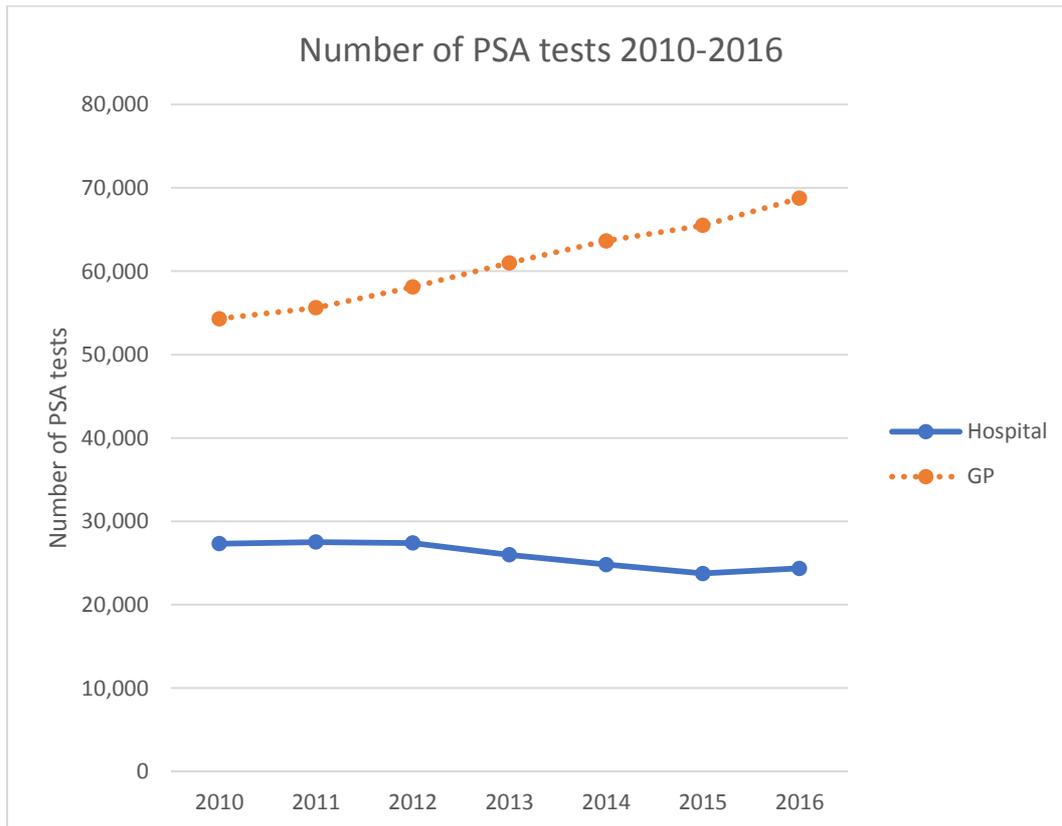
NOTE: Guidelines indicate a) testing in men under 50 only if they are high risk, or request a test and have informed choice. b) PSA testing is not usually recommended in men with less than 10 years life expectancy.

Of the 48,553 and the 84,541 PSA tests carried out on the under 50 and on the 80 and over age ranges, 33,119 and 25,303 patients were identified respectively. 185 (<1%) patients in the under 50 and 4,361 (17%) in the 80 and over age range had Prostate Cancer diagnosis.

PSA testing by year

The number of PSA tests carried out in GP practice has steadily increased from 54,301 in 2010 to 68,760 in 2016 (Figure 7). In contrast, PSA testing rates in hospitals have decreased overall from 27,315 in 2010 to 24,348 in 2016.

Figure 7 - Number of PSA tests 2010-2016 (Hospital versus GP)

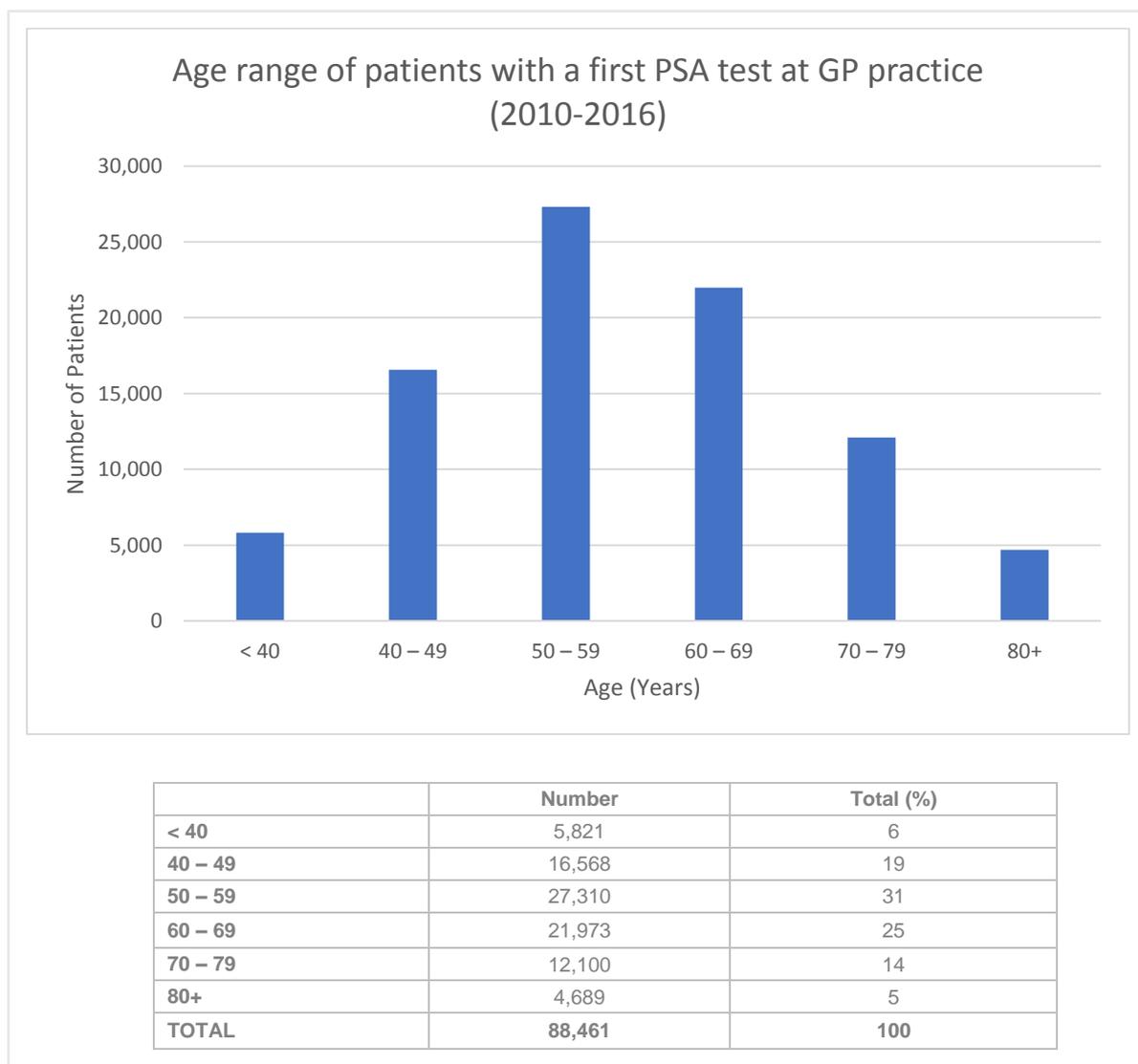


First tests

Of the 190,755 patients having undergone PSA testing in N.Ireland between 2010-2016, 88,461 (46.4%) of these patients were having initial/first PSA tests requested by a currently active GP practice.

The mean age of men receiving their first PSA test in a GP practice was 58 years with a range of 2-103 years. Figure 8 outlines the age range of men receiving their first PSA test in a GP practice from 2010-2016. Almost a third of men (31%) were aged between 50-59 years. Those who were 80+ years were the lowest group (5%) to receive an initial PSA test closely followed by those aged 40 or under (6%).

Figure 8. Age range of patients with a first PSA test at GP practice (2010-2016)



PSA test results

The majority (87.4%) of patients having a first PSA test requested by their GP had a PSA result <4 ng/ml compared to only 4.1% of patients receiving a result of 10ng/ml or higher (Table 2). Lower PSA test results were seen in a younger population as the most common age group for PSA result categories <4ng/ml, 4-9.9ng/ml and >10 ng/ml were 50-59 years, 60-69 years and 70-79 years, respectively.

Table - PSA value for first test at GP practice

| PSA Value (ng/ml) | Number of first tests by age | | | | | | Total (%) |
|-------------------|------------------------------|--------------------|--------------------|--------------------|------------------|------------------|--------------------|
| | <40 | 40-49 | 50-59 | 60-69 | 70-79 | 80+ | |
| <4 | 5,705 (6.45%) | 16,144 (18.25%) | 25,541 (28.87%) | 18,339 (20.73%) | 8,691 (9.82%) | 2,849 (3.22%) | 77,269 (87.35%) |
| 4 – 9.9 | 83 (0.09%) | 285 (0.32%) | 1,308 (1.48%) | 2,607 (2.95%) | 2,223 (2.51%) | 1,077 (1.22%) | 7,583 (8.57%) |
| ≥ 10 | 33 (0.04%) | 139 (0.16%) | 461 (0.52%) | 1,027 (1.16%) | 1,186 (1.34%) | 763 (0.86%) | 3,609 (4.08%) |
| Total | 5,821 | 16,568 | 27,310 | 21,973 | 12,100 | 4,689 | 88,461 |

Standardised Incidence Ratio

Eighty five GP practices in 2010-2013 and 68 GP practices for the 2014-2016 period had significantly higher PSA testing rates than the N. Ireland average.

One hundred and six GP practice PSA testing rates were significantly lower than the N Ireland average for requesting PSA tests during 2010-2013 in comparison to 86 GP practices in 2014-2016.

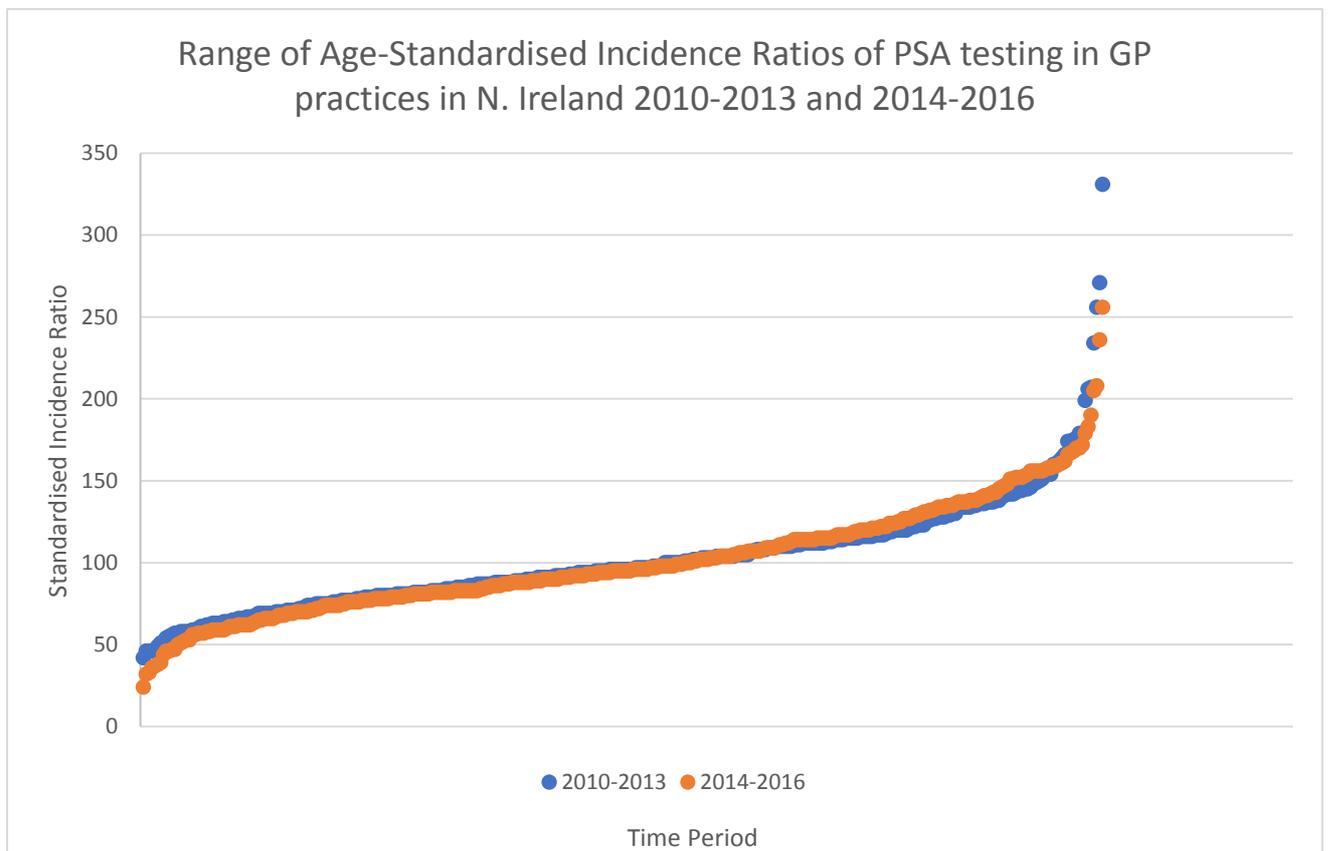
Table 3 - Number of GP practices above and below N Ireland reference for PSA requests

| | Lower | Average | Higher | Total |
|--------------------|-------|---------|--------|-------|
| 2010 – 2013 | 106 | 143 | 85 | 334 |
| 2014 – 2016 | 86 | 180 | 68 | 334 |

^a 2 practices missing due to no practice populations in 2010 & 2010-2015

Figure 9 illustrates the Standardised Incidence Ratios of PSA testing for all GP practices in Northern Ireland over two time-periods compared to the N Ireland average (100). For the earlier time-period of 2010-2013, the lowest rate of PSA testing for a GP practice was calculated at 42 and the highest rate at 331. In the later time period (2014-2016) these ranges have overall decreased with lowest rate of PSA testing in a GP practice reported at 24 and the highest at 256.

Figure 9. Range of Age-Standardised Incidence Ratios of PSA testing in GP practices in N. Ireland 2010-2013 and 2014-2016



Discussion

This is the first audit of PSA testing in General Medical Practice in N Ireland. NICE guidelines apply here although the Northern Ireland Cancer Network (NICaN) urology group has recently recommended that any prostate cancer referral from primary to secondary care should be based on at least two PSA tests. Almost 90,000 PSA tests were ordered here each year since 2010 with over two thirds (70.2%) ordered in primary care reflecting a shift towards primary care for prostate cancer diagnosis and management.¹³

There were significant number of tests ordered in women (n=1,333) and in men outside the 50-80 age range (n=133,094) indicating inclusion of PSA tests when a spectrum of blood tests is ordered.

The cut-off values for PSA results differ depending on the age and race of patient. Normal PSA level ranges from 0-4ng/ml, however, for younger men, aged 50-69 years, of any race, having a PSA result >3ng/ml should be referred urgently using a suspected cancer pathway to a specialist.

For the population of men in N Ireland having a first PSA test requested by their GP from 2010-2016, 87.3% had a PSA result <4ng/ml. This highlights that the vast majority of these men are considered to have a 'normal' PSA result and questions whether the PSA test is being used as per guidelines. In addition, higher PSA test results were most commonly seen in an older population which was expected as PSA increases with age as the prostate gets larger.¹⁴

Standardised incidence ratios (SIRs) varied markedly across GP practice ranging from 42 to 331 in 2010-2013 and from 24 to 256 in 2014-2016. This lower level in the later years may be suggestive of an increased awareness of the indications for PSA testing amongst GPs.

Several parts of this audit were not possible to complete successfully:

- 1. The secondary care note review in order to determine whether patients from high referring GP practices were more likely to be referred asymptotically.**

GP practices with the highest and lowest request rates of new PSA tests were successfully identified. However, after completion of the secondary care note review the analysis was unable to be completed due to the high proportion of “unknowns” in each sample resulting in loss of statistical power (Table 4).

Table 4. Investigation of prostate cancer symptoms in the top and bottom PSA testing GP practices.

| | GP practice PSA testing rate lower than NI average | GP practice PSA testing rate higher than NI average |
|---------------------|---|--|
| Asymptomatic | 18 | 14 |
| Symptomatic | 50 | 20 |
| Unknown | 32 | 64 |
| Total | 100 | 98 |

2. Southern Trust removal of PSA from routine blood tests

It was intended to determine the effect on PSA testing levels as a result of the Southern Area’s removal of PSA tests automatically from routine blood tests. Unfortunately, at the time of the audit action to remove PSA testing from the request form had not yet been implemented. An opportunity to revisit this in the future remains.

3. Identifying PSA testing rates in General Practice in NI from 2010-2016 adjusting for GP practice population profiles (male patient numbers, age, and socioeconomic group)

Socioeconomic group analysis was not possible as patient postcodes were not complete. If a socioeconomic group was to be allocated based on area of GP practice, this would provide an inaccurate representation of socioeconomic status.

Delays experienced

Throughout the audit process a number of delays were experienced:

- During the stages of early analysis, it was recognised that the number of PSA tests in the Western Trust was significantly lower than others, with very few patients residing in the Fermanagh/Tyrone area. It was identified that the data from the Erne lab system of the Western Trust was omitted from the original database received. These new datasets had to be cleaned and the data analysis repeated.
- During analysis of the data by GP Federation, it became evident that 20 GP practices from the Causeway GP Federation were significantly lower in terms of PSA tests for the year 2010, compared to 2011 onwards. Both Business Services Organisation IT Services (BSO-ITS) and the Northern Health and Social Care Trust labs were contacted to resolve this. It was explained that Causeway data were recorded in a separate area up to March 2010. A new extract was received with Causeway data from 2007 to November 2010 which meant that a further data analysis was required.
- A conflict of ethics between the NICR, Northern Ireland General Practitioners Committee (NIGPC) and BSO was found to be one of the major delays experienced during the audit process. Permission for Practice related linkages for the audit was initially denied on the basis of data agreements held. The NICR holds data pertaining to patients who have a cancer diagnosis, for which there is an agreement for data to be used, as this group has the ability to opt out. However, while data agreements exist for the data set pertaining to PSA testing where the majority of results belong to people who will not have prostate cancer it was felt that there was no opt out option. As a result a revised NICR information leaflet was produced which included mention of PSA tests and the advice of the Principal Advisory Committee has been sought.

Audit Limitations

- Clinical indications were not considered for any of the data within the PSA database. Without this information we are unable to provide context as to why each test was requested therefore cannot indicate whether the test was requested as per guidelines.
- A further limitation of the audit was the inability to allocate a GP practice to a patient at time of test. This has the potential to provide an inaccurate representation of the GP practices. In an attempt to account for this, the HSC Business Services Organisation Information and Registration Unit were contacted regarding information on the proportion of men over 50 years in Northern Ireland who transfer GP practice. Their findings indicate that the transfer rate is for years 2010 to 2016 ranged from 0.98 to 1.31 therefore we can conclude that this would have little effect on the findings.

Recommendations

The following recommendations have been made based on the PSA audit findings:

- Taking account of the negative effects of investigations and treatments following PSA testing highlighted by Patient Reported Outcomes Studies,⁶⁻¹⁰ it should be reinforced to all healthcare professionals the importance of discussing the advantages and disadvantages of the PSA test to patients as per NICE guidelines.
- As it is recommended that PSA testing should be preceded by an informed discussion, a separate form to request PSA tests with a tick box to indicate that such a discussion had taken place would this could improve adherence to guidelines regarding PSA tests.
- This exercise should be repeated in three years to determine if there has been any change in practice.
- The PSA database held securely by the N. Ireland Cancer Registry has enabled this work and should be retained to determine the effect of this exercise and any subsequent change to PSA request forms.

References

- (1) Northern Ireland Cancer Registry (NICR). Prostate Cancer. 2017; Available at: <https://www.qub.ac.uk/research-centres/nicr/CancerInformation/official-statistics/BySite/Prostate/>. Accessed Jun 21, 2018.
- (2) Gavin A, McCarron P, Middleton RJ, Savage G, Catney D, O'Reilly D, et al. Evidence of prostate cancer screening in a UK region. *BJU Int* 2004 Apr;93(6):730-734.
- (3) Public Health England. PHE PSA prostate cancer test guideline. 2016; Available at: <https://www.guidelines.co.uk/cancer/phe-psa-prostate-cancer-test-guideline-/252826.article>. Accessed July 19, 2018.
- (4) National Institute for Health and Care Excellence (NICE). Prostate Cancer. 2017; Available at: <https://cks.nice.org.uk/prostate-cancer#!diagnosisadditional:1>. Accessed Jun 20, 2018.
- (5) Drummond FJ, Kinnear H, Donnelly C, O'Leary E, O'Brien K, Burns RM, et al. Establishing a population-based patient-reported outcomes study (PROMs) using national cancer registries across two jurisdictions: the Prostate Cancer Treatment, your experience (PiCTure) study. *BMJ Open* 2015 Apr 17;5(4):e006851-2014-006851.
- (6) Donnelly DW, Donnelly C, Kearney T, Weller D, Sharp L, Downing A, et al. Urinary, bowel and sexual health in older men from Northern Ireland. *BJU Int* 2018 Feb 28.
- (7) Gavin AT, Donnelly D, Donnelly C, Drummond FJ, Morgan E, Gormley GJ, et al. Effect of investigation intensity and treatment differences on prostate cancer survivor's physical symptoms, psychological well-being and health-related quality of life: a two country cross-sectional study. *BMJ Open* 2016 Dec 19;6(12):e012952-2016-012952.
- (8) Morgan E, Drummond FJ, Coyle C, Sharp L, Gavin AT. Physical after-effects in men undergoing prostate biopsy in routine clinical practice: Results from the PiCTure study. *Urol Oncol* 2017 Oct;35(10):604.e11-604.e16.
- (9) Sharp L, O'Leary E, Kinnear H, Gavin A, Drummond FJ. Cancer-related symptoms predict psychological wellbeing among prostate cancer survivors: results from the PiCTure study. *Psychooncology* 2016 Mar;25(3):282-291.
- (10) Schroder FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, et al. Screening and prostate-cancer mortality in a randomized European study. *N Engl J Med* 2009 Mar 26;360(13):1320-1328.
- (11) Gavin AT, Drummond FJ, Donnelly C, O'Leary E, Sharp L, Kinnear HR. Patient-reported 'ever had' and 'current' long-term physical symptoms after prostate cancer treatments. *BJU Int* 2015 Sep;116(3):397-406.
- (12) Hummel S CJ. Option Appraisal: Screening for prostate cancer model update. Sheffield: In: SchARR, University of Sheffield. 2013.
- (13) Neal RD. The role of the GP in prostate cancer care. *Trends in Urology, Gynaecology & Sexual Health* 2008;13(5):27-30.
- (14) Oesterling JE, Jacobsen SJ, Chute CG, Guess HA, Girman CJ, Panser LA, et al. Serum prostate-specific antigen in a community-based population of healthy men: establishment of age-specific reference ranges. *JAMA* 1993;270(7):860-864.

Appendix 1 – Letter to GP Practices



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Dear Dr.

Audit of PSA testing - the information is not intended for performance management but is for information purposes only.

Over the past twenty years the number of prostate cancer cases diagnosed in N. Ireland has more than doubled from 471 cases in 1993 to 1,165 in 2016. This increase is linked with increased use of PSA testing.

According to the National Institute for Clinical Excellence (NICE) clinical knowledge summary (last revised January 2014), PSA testing may be offered to:

- Men older than 50 years of age who ask for a PSA test.(and after discussion)
- Men with unexplained symptoms that could be caused by locally advanced metastatic prostate cancer.
- Men with obstructive lower urinary tract symptoms that could be caused by benign prostatic enlargement (which is common) or by locally advanced prostate cancer (which is rare).

(NICE. Prostate cancer. <https://cks.nice.org.uk/prostate-cancer> (accessed 28 July 2017)).

NOTE: Patients with established Prostate Cancer should continue to have PSA tests as clinically directed.

We in the N. Ireland Cancer Registry (NICR) have been funded by the Regulation & Quality Improvement Authority (RQIA) to undertake an audit of PSA use in N. Ireland (a full copy of the application is available on request).

As part of this work we provide below information for your Practice on FIRST and ALL PSA tests ordered from 2010-2016. We also include data on prostate cancers diagnosed since 1993, and prostate biopsies undertaken on men from your Practice. A final report will be published with summary data but not individual Practice level data.

The NICR team would like to thank you and your colleagues for taking the time to read this short report.

We would also like to stress that clinical indications were not considered for any of the data within the PSA database. We hope the audit allows easy visualisation of where current resources regarding PSA testing are being used and this in turn will hopefully help the Practise ensure compliance with current guidelines.

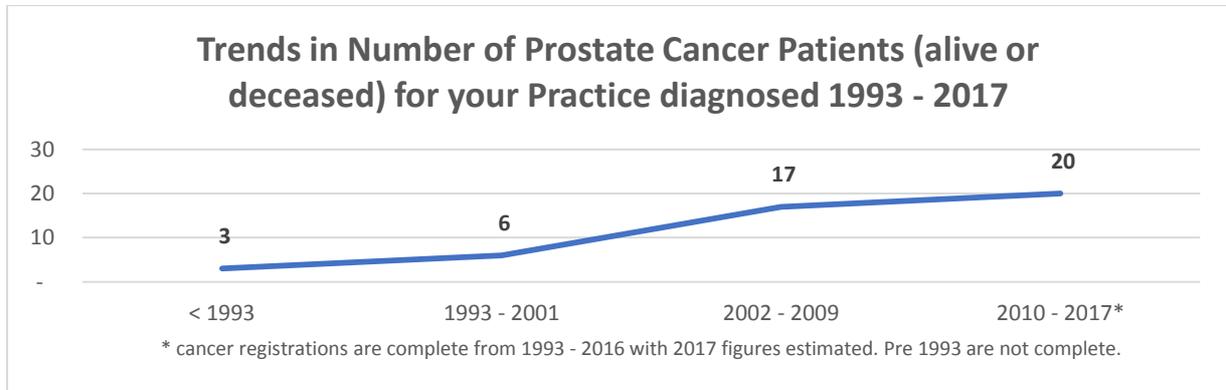
Anna Gavin .

Dr Anna Gavin
Director, N. Ireland Cancer Registry

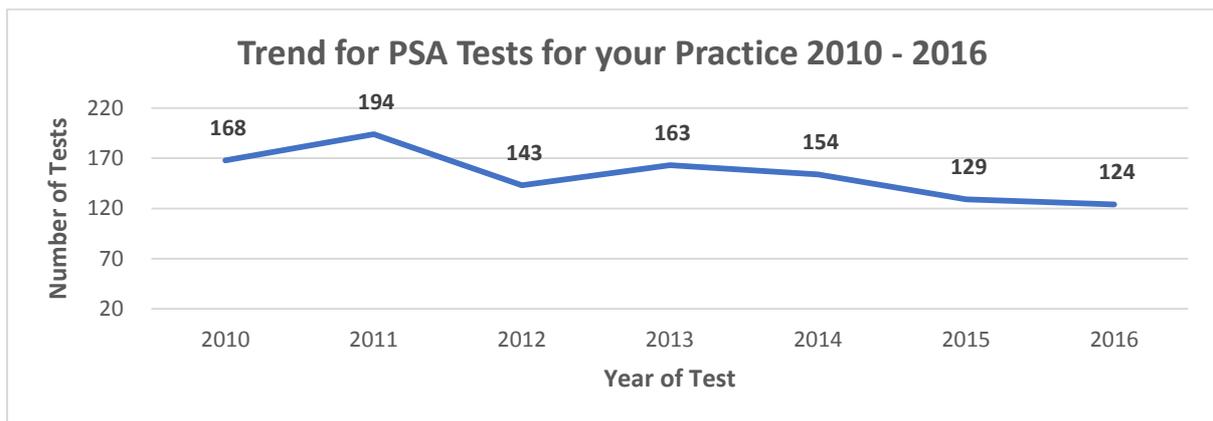
June 2018

Your Practice Data are as follows:

The number of Prostate Cancer Patients diagnosed within your Practice has increased over time.

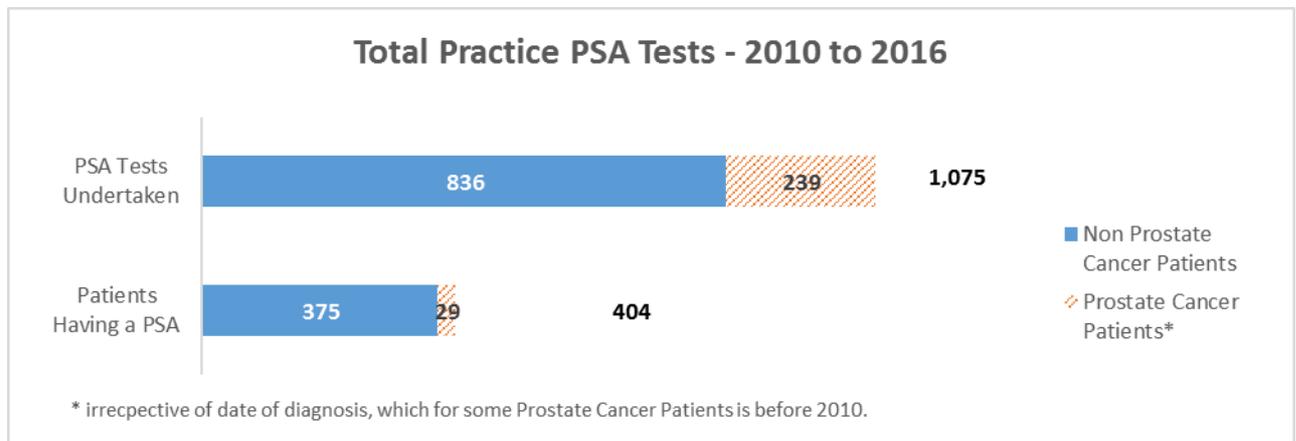


PSA Tests carried out on patients from your Practice have decreased from 2011.



(NOTE: Tests NOT Patients)

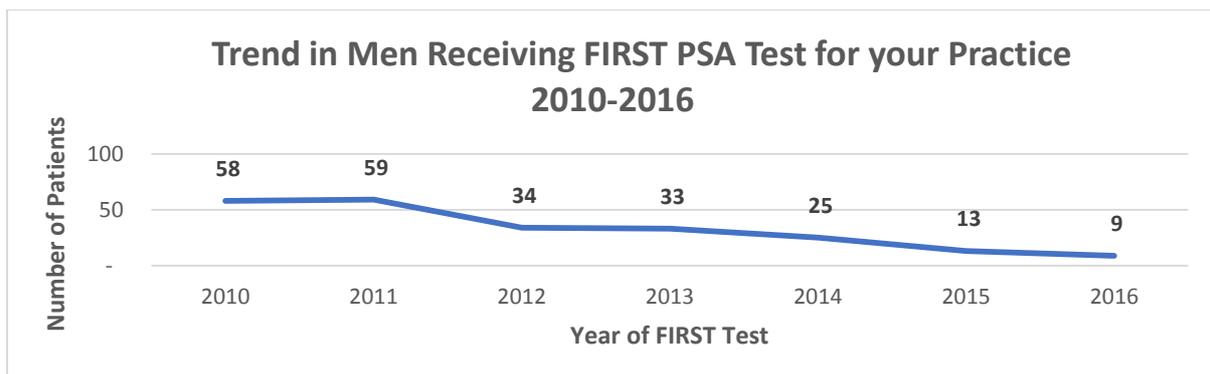
Below are the numbers for ALL PSA tests and corresponding patient numbers within your Practice for the 2010 to 2016 time period. The bars of the graph are further split to illustrate prostate cancer and non-prostate cancer patients



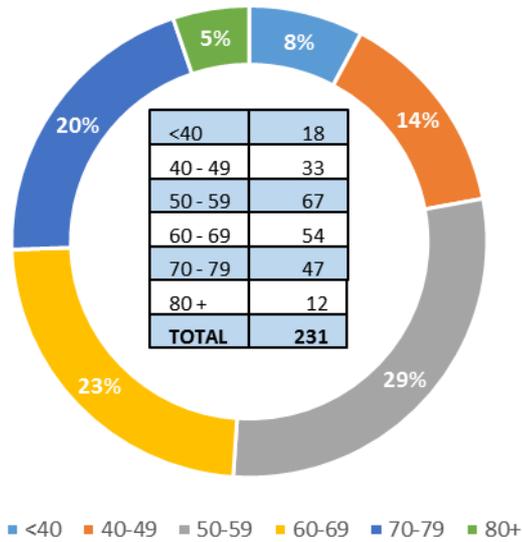
In your Practice an average of 8.24 tests were carried out on patients with prostate cancer, while 836 tests were carried out on 375 men who subsequently did not have a diagnosis of prostate cancer (2.23 tests per man).

Not all FIRST PSA tests were ordered in primary care, of the 404 men who had a PSA test between 2010 and 2016 in your Practice 231 (57%) had their first test in the Practice, the remaining 173 (43%) had their first PSA test elsewhere or before 2007 within the Practice.

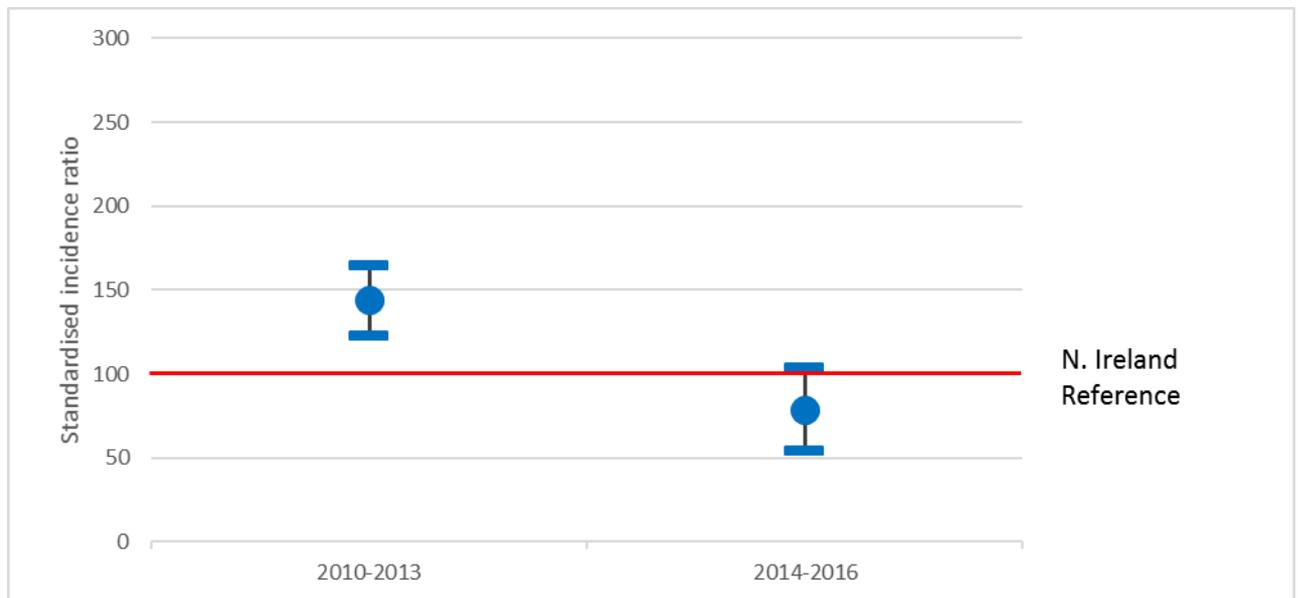
The figures below outline the trend in number of men with a FIRST PSA test ordered in your Practice 2010 – 2016 then the corresponding age ranges of these men.



Age Range of Men with a **FIRST PSA** Test Ordered by your Practice - 2010 to 2016



Incidence Ratio of PSA tests (standardised to the age of the male patients) in your Practice compared with the rest of N.Ireland average for the time periods 2010 – 2013 and 2014 – 2016 are shown below. This should facilitate your Practice to see where it stands compared with the testing rates of other Practices.



Prostate Biopsies

The NICR also holds information on all prostate biopsies performed in N.Ireland from 2007 to 2016. We were able to link these to PSA tests undertaken for the period 2010-2016 for your Practice. We recognise that there were other biopsies on patients outside of the time periods studied.

Of the 404 men from your Practice who has a PSA test during 2010-2016 365 (90%) did not require a prostate biopsy, 28 had one prostate biopsy and 11 had at least 2 biopsies, of these 39 men who had a biopsy 21 (54%) were diagnosed with prostate cancer.

For the 231 patients where their **FIRST** PSA test was in your Practice 13 had biopsies and 11 had a subsequent cancer diagnosed.

Methods

PSA tests have been routinely collected by the NICR for verification of prostate cancer cases. Using this PSA database containing 850,657 PSA tests carried out in N.Ireland spanning 2007 to 2016 the NICR were able to use a 3 year 'buffer' period (2007 – 2009) to identify patients with any and a first PSA test carried out from 2010 to 2016. Using source codes of who ordered the PSA tests the NICR were further able to identify patients with a FIRST PSA test carried out by a GP. Data were anonymised for analysis.

A prostate cancer diagnosis for each patient was obtained from cross checks with the NICR database. NICR registrations 1993 -2016 are complete with 2017 registrations currently from PAS only. Numbers of first PSA tests ordered over time with PSA testing rates were standardised to the Practice male population and compared to a regional average with a ranking for each Practice compared to the whole using Standard Incidence Ratios (SIR).

Acknowledgments

The N.Ireland Cancer Registry is funded by the Public Health Agency of N.Ireland and this audit work was facilitated by Regulation & Quality Improvement Authority (RQIA). Belfast Services Organisation (BSO) for help in data matching and validation.

Appendix 2 – Letter to GP Federations



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Dear Federation Administrator

Audit of PSA testing - the information is not intended for performance management but is for information purposes only.

Over the past twenty years the number of prostate cancer cases diagnosed in N. Ireland has more than doubled from 471 cases in 1993 to 1,165 in 2016. This increase is linked with increased use of PSA testing.

According to the National Institute for Clinical Excellence (NICE) clinical knowledge summary (last revised January 2014), PSA testing should be offered to:

- Men older than 50 years of age who ask for a PSA test.
- Men with unexplained symptoms that could be caused by locally advanced metastatic prostate cancer.
- Men with obstructive lower urinary tract symptoms that could be caused by benign prostatic enlargement (which is common) or by locally advanced prostate cancer (which is rare).

(NICE. Prostate cancer. <https://cks.nice.org.uk/prostate-cancer> (accessed 28 July 2017)).

NOTE: We recognise that patients with established Prostate Cancer should continue to have PSA tests as clinically directed.

We in the N. Ireland Cancer Registry (NICR) have been funded by the Regulation & Quality Improvement Authority (RQIA) to undertake an audit of PSA use in N. Ireland (a full copy of the application is available on request).

As part of this work we provided for each GP Practice the number of FIRST and ALL PSA tests ordered from 2010-2016. We also included data on prostate biopsies undertaken and cancers diagnosed since 1993.

There follows a summary of the findings for the GP Practices in your federation. We would also like to stress that clinical indications were not considered for any of the data within the PSA database. We hope the audit allows easy visualisation of where current resources regarding PSA testing are being used and this in turn will hopefully help Practises ensure compliance with current guidelines.

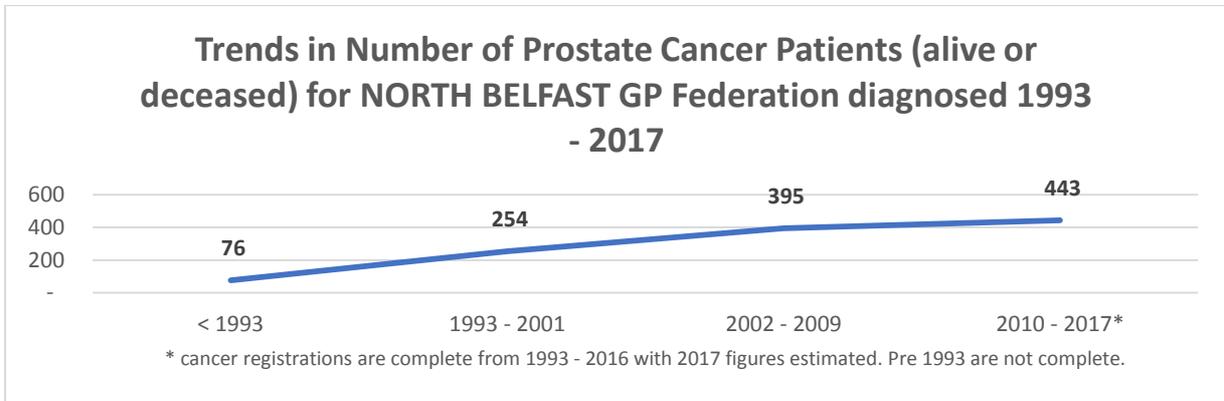
Anna Gavin .

Dr Anna Gavin
Director, N. Ireland Cancer Registry

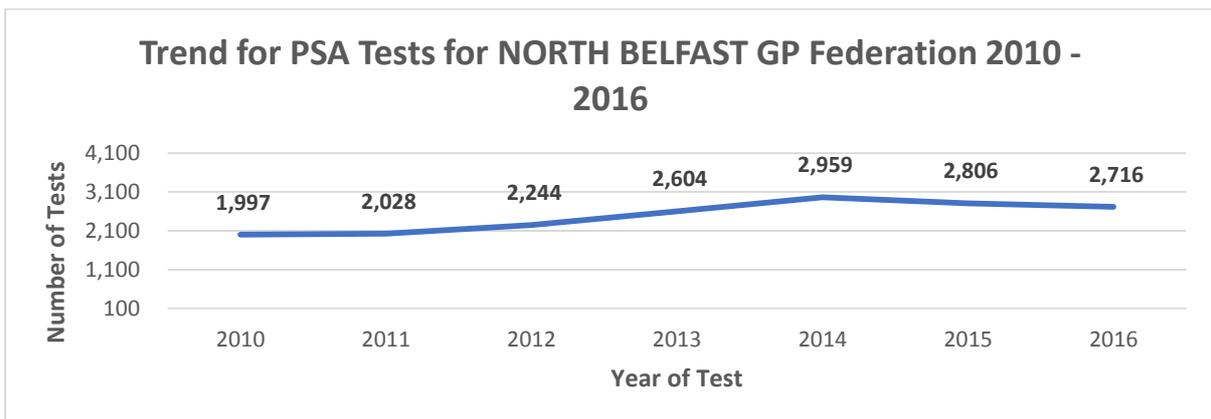
June 2018

Data for the NORTH BELFAST Federation are as follows:

The number of Prostate Cancer Patients diagnosed within the Federation has increased over time.

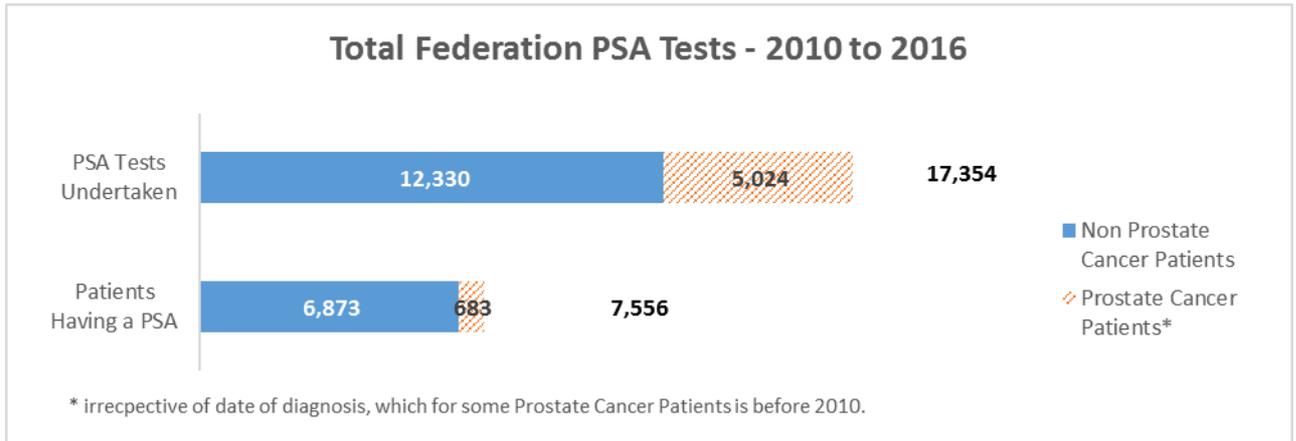


PSA Tests carried out on patients from Practices in the Federation have been increasing until 2014 then decreased.



(NOTE: Tests NOT Patients)

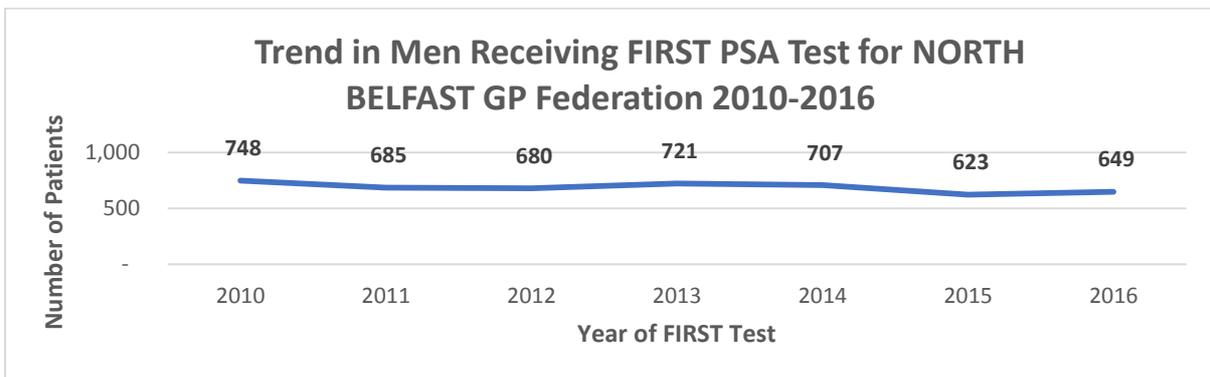
Below are the numbers for ALL PSA tests and corresponding patient numbers within the NORTH BELFAST Federation for the 2010 to 2016 time period. The bars of the graph are further split to illustrate prostate cancer and non-prostate cancer patients



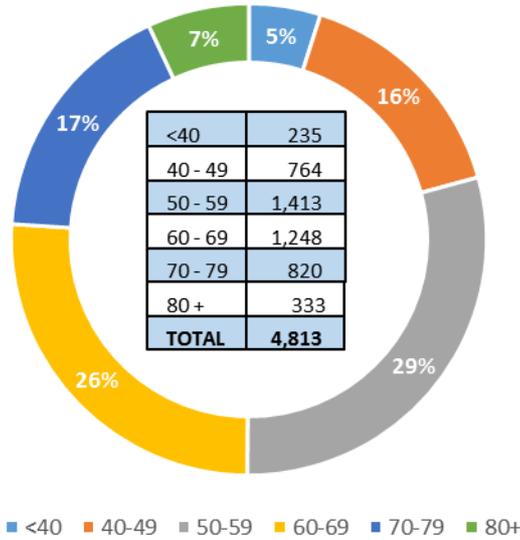
In your Federation an average of 7.36 tests were carried out on patients with prostate cancer, while 12,330 tests were carried out on 6,873 men who subsequently did not have a diagnosis of prostate cancer (1.79 tests per man).

Not all FIRST PSA tests were ordered in primary care, of the 7,556 men who had a PSA test between 2010 and 2016 in your Federation 4,813 (64%) had their first test within a GP Practice, the remaining 2,743 (36%) had their first PSA test elsewhere or before 2007 within a GP Practice.

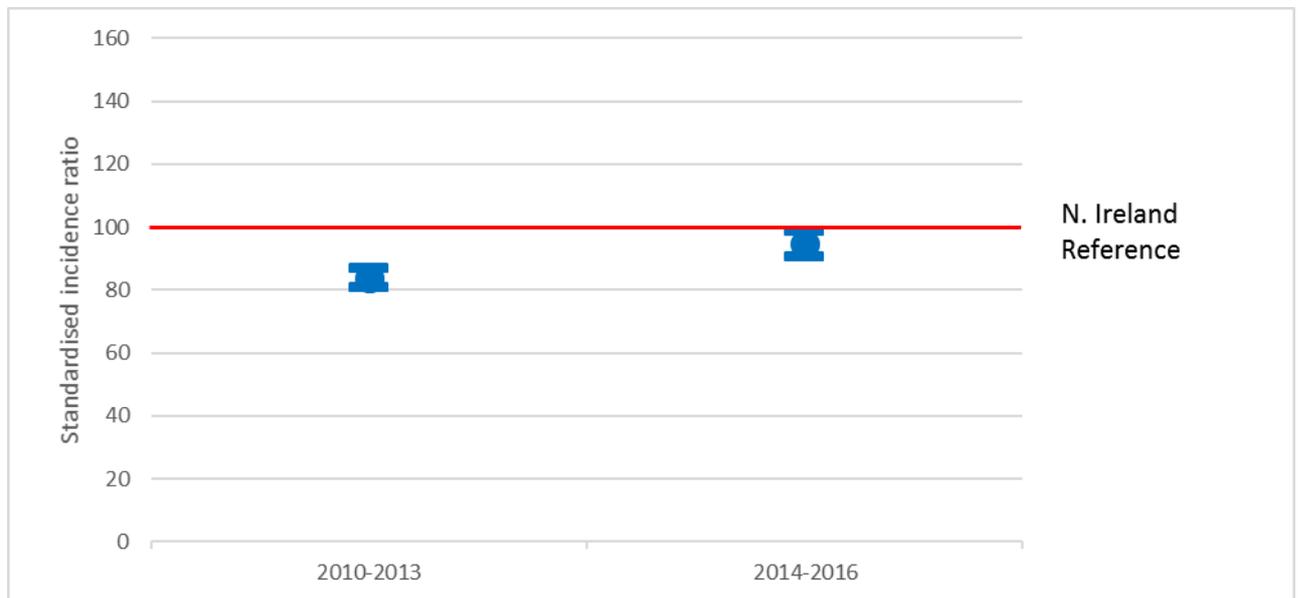
The figures below outline the trend in number of men with a FIRST PSA test ordered in GP Practices in NORTH BELFAST Federation 2010 – 2016 then the corresponding age ranges of these men.



Age Range of Men with a **FIRST PSA Test Ordered by
NORTH BELFAST GP Federation - 2010 to 2016**



Incidence Ratio of PSA tests (standardised to the age of the male patients) in your Federation compared with the rest of N.Ireland average for the time periods 2010 – 2013 and 2014 – 2016 are shown below. This should facilitate your Federation to see where it stands compared with the testing rates of other Federations.



Prostate Biopsies

The NICR also holds information on all prostate biopsies performed in N.Ireland from 2007 to 2016. We were able to link these to PSA tests undertaken for the period 2010-2016 to each GP Practices within your Federation. We recognise that there were other biopsies on patients outside of the time periods studied.

Of the 7,556 men from your Federation who has a PSA test during 2010-2016, whether in primary care or elsewhere, 6,628 (88%) did not require a prostate biopsy, 743 had one prostate biopsy and 185 had at least 2 biopsies, of these 928 men who had a biopsy 502 (54%) were diagnosed with prostate cancer.

For the 4,813 patients where their **FIRST** PSA test was within a GP Practice from your Federation 328 had biopsies and 176 had a subsequent cancer diagnosed.

Methods

PSA tests have been routinely collected by the NICR for verification of prostate cancer cases. Using this PSA database containing 850,657 PSA tests carried out in N.Ireland spanning 2007 to 2016 the NICR were able to use a 3 year 'buffer' period (2007 – 2009) to identify patients with any and a first PSA test carried out from 2010 to 2016. Using source codes of who ordered the PSA tests the NICR were further able to identify patients with a FIRST PSA test carried out by a GP. Data were anonymised for analysis.

A prostate cancer diagnosis for each patient was obtained from cross checks with the NICR database. NICR registrations 1993 -2016 are complete with 2017 registrations currently from the Patient Administration System (PAS) only.

Numbers of first PSA tests ordered over time with PSA testing rates were standardised to the Practice male population and compared to a regional average with a ranking for each Practice compared to the whole using Standard Incidence Ratios (SIR).

Acknowledgments

The N.Ireland Cancer Registry is funded by the Public Health Agency of N.Ireland and this audit work was facilitated by the Guidelines and Audit Implementation Network (GAIN) a unit within the Regulation & Quality Improvement Authority (RQIA). Belfast Services Organisation (BSO) for help in data matching and validation.

Regional Audit Project Team

| Name | Job Title/Specialty | Trust Area | Role within Project (Project lead, data collector, data analyse, data cleansing, report writing, internal reviewer, etc) |
|------------------|-------------------------------------|--|---|
| Anna Gavin | Director NICR | Regional- N. Ireland Cancer Registry | Report writing |
| Colin Fox | Registry IT Manager | Regional- N. Ireland Cancer Registry | Electronic data extraction |
| Gerard Savage | Data analyst | Regional- N. Ireland Cancer Registry | Report writing |
| Eileen Morgan | Statistician | Regional- N. Ireland Cancer Registry | Report writing |
| Nigel Hart | General Practitioner | General Practice | GP adviser |
| Margaret Grayson | PPI representative | NI Cancer Consumer Forum | PPI Adviser |
| Robert Mercer | Regional Clinical Audit Facilitator | Regulation and Quality and Improvement Authority | Audit & reporting adviser |
| | Tumour Verification Officer | Regional- N. Ireland Cancer Registry | Data collector |
| Michelle Doherty | Medical student | Regional- N. Ireland Cancer Registry | Report writing |



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