IPCOR

IRISH PROSTATE CANCER OUTCOMES RESEARCH

Annual Report 2018

Irish Cancer Society Research

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1. Foreword

Mr David Galvin, IPCOR Principal Investigator

David Galvin, IPCOR PI, Consultant Urologist, Mater Misericordiae and St Vincent's University Hospitals

It is a great honour for me and my co-investigators to present our third annual report from IPCOR, and for the first time, data about men who are included in the IPCOR registry. This project forms part of the Movember Foundation global strategy to establish prostate cancer outcome registries in several countries around the world, and is kindly funded through the Irish Cancer Society. This report is part of the IPCOR output and dissemination policy which will – in due course - also include individual reports for each of the IPCOR hospitals and clinicians.

IPCOR is a longitudinal study; a patient's medical journey develops over time and therefore, so does the data compiled by IPCOR. The data represents the initial registration and diagnostic details captured on men diagnosed with prostate cancer at the 16 participating IPCOR hospitals between February 2016 and December 2017. Future annual reports will contain additional clinical data across the patient journey, as well as patient reported outcomes.

To those involved in the IPCOR project, the production of this annual report containing clinical data is an enormous achievement. IPCOR is a study without comparison within Ireland. Its establishment has involved numerous novel pathways and solutions to overcome the many challenges that have presented themselves. Data protection is paramount and IPCOR has recently undergone a successful legal and GDPR compliance review. The principle that no patient, doctor or hospital will ever be identified in our public facing publications will always be honoured by the IPCOR investigators. We are grateful to the 16 IPCOR hospitals that facilitate IPCOR data collection within their campuses, and we would like to commend those hospitals, not only for their engagement with IPCOR, but for their commitment to improving prostate cancer outcomes for the men in their care.

Firstly, I would like to thank the men who are included in the IPCOR registry and who have completed quality of life questionnaires. I also want to acknowledge the enormous contribution being made by the clinicians treating prostate cancer across Ireland. Virtually every Urologist, Medical Oncologist and Radiation Oncologist in Ireland has facilitated the IPCOR research officers in collecting data in hospitals and private consulting rooms across the country, and for this, we are extremely grateful. The success of IPCOR and its data collection will in part be due to the data provided to it by the clinicians. Certainly, our research officers need assistance from doctors when recording prostate examination findings and disease stage and I would ask doctors to make a special effort to specify these findings clearly in notes and dictations. Our colleagues in Australia encountered the same issues when establishing their registry.

In 2014, IPCOR employed Dr Áine Murphy as our project manager, and she has worked passionately on behalf of IPCOR and the IPCOR men since then. We have now grown to a team of ten IPCOR employees. In the NCRI, we currently employ four research officers, Dr. Emer McCarthy (West), Dr Leah Bentham (South), CNS Lisa McGowan (Dublin South) and Dr Emma Heffernan (Dublin North). We also fund Dr Jean O'Connor (Clinical Data Manager) and Ms Christine Allan (Clinical Database Officer) and Ms Laura McGovern (IPCOR Clerical

Officer). One year ago, Ms Cara Dooley, joined IPCOR as our statistician, and we have to thank her for the data results that are in this report. We also employ a Research Assistant, Mr Amar Nath, in the Clinical Research Facility in Galway to administer the patient reported outcomes. I want to acknowledge those who have left IPCOR for their contributions, Mr Kenny Lynch and Ms Hazel Smith. Dr Leah Bentham is moving on, but she established many of the initial contacts in the Cork area and worked hard on setting up IPCOR, and we are very grateful for her contributions. This report, and future reports, are testimony to their hard work, passion and the value they place on this work. The NCRI appointed Dr Conan Donnelly as Research Manager one year ago, and in that time, Dr Donnelly has led major changes and improvements within NCRI. He has worked tirelessly on the IPCOR project and we look forward to future developments together as Investigators.

IPCOR has always believed that patient engagement is paramount. I want to thank Mr Jim Scott of Men Against Cancer (MAC), for his support, work and participation in the IPCOR Steering Committee. Jim was our first patient representative and played a crucial role in the development of IPCOR. He has handed over to Mr Tom Hope, and Tom is now playing a key role in the development of the IPCOR patient panel. IPCOR is bringing together a panel of men with prostate cancer to advise on all aspects of the project, including optimising our patient reported outcome measurement (PROMs) responses and evaluating outcomes. We have liaised with the HRB-funded IGNITE programme and others with experience in involving the public and patients in research to support our patient panel. Dr Emma Heffernan will soon be facilitating our inaugural meeting to review our patient facing documentation and annual report and to advise IPCOR on future outputs.

We are extremely keen to engage men with prostate cancer and the public, and are reaching out to our nurses in the Irish Association of Urology Nurses to promote IPCOR where possible, and wish to bring nursing representation to the Steering Committee.

Lastly, I want to acknowledge the enormous contribution of our funders, the Movember Foundation and the Irish Cancer Society. Despite living 12,000 miles away, Mr Paul Villanti, Executive Director of Programmes at the Movember Foundation, is a regular visitor to our shores and regularly joins Steering Committee meetings at 4am from Australia. His colleagues here, in the UK and Australia, Mr Neil Rooney, Mr Jack O'Connor, Ms Ruth Liley and Ms Ellie James, work hard to support our endeavours. I also thank Dr Robert O'Connor and his team in the Irish Cancer Society who have been an enormous support to IPCOR. We only hope that with sufficient time and funding IPCOR will be allowed to develop it's true potential and serve our men.

Dr Robert O'Connor, Irish Cancer Society

Dr Robert O'Connor, Head of Research, Irish Cancer Society

It is a great honour to be asked to contribute to the foreword of this highly valuable report on the state of prostate cancer among men in Ireland on behalf of the Irish Cancer Society.

One in eight men in Ireland will be diagnosed with this disease in their lifetime and annually nearly 3,500 of our grandfathers, fathers, brothers and sons sit down with a doctor to be told the worrying news that a cancer has been found in their prostate. Those numbers continue to rise, mostly as growing numbers of men live longer. This news will be devastating to them and their partners. IPCOR is an important project for Movember and ourselves which uses comprehensive information gathering tools to gather data on the ongoing and evolving prostate cancer experience of men in this country. In preceding decades, prostate cancer diagnoses were often a prelude to declining health and a high risk of death as the disease spread to other parts of the body. Today, research has driven staggering improvements in outcome. 9/10 men diagnosed will be alive and well a decade after their diagnosis. Roughly 35,000 men are living in our community having been through a prostate cancer diagnosis and associated treatment decisions, that's a population close to that of a city the size of Dundalk.

With such an improvement in outcome, the goal posts have to shift. We must look after our men and better understand their journey after diagnosis so we can best:

- Help guide treatment decisions they have to make
- Ensure equity and timely access to evidence-based supports
- Provide for the best possible quality of survival after diagnosis

A comprehensive and accurate understanding of the prostate cancer experience of men over time is the only way with which we can actually drive these improvements. While the report has many fascinating elements and shows a high standard of treatment and care which the NCCP has driven through, for example, with rapid access clinics and centralisation of high expertise clinics, it also highlights a number of important issues that need particular action, energy and focus.

1. There are clear inequities in important metrics between men treated in the public versus private system.
2. With the median age around retirement, approximately half of men diagnosed are of employment age. Men in general are enjoying longer lifespans too, so we have to adjust our thinking to take into account that these are active men who have a lot of life yet to enjoy and contribute.
3. There are enormous communication needs to help empower men to make the right choices for their long term health and the report provides clear evidence that there is a challenge of overtreatment that needs to be addressed. Further evolution of patient engagement will be vital going forward.
4. Pertaining to the IPCOR group itself, by its nature this is a long-term project and we, as a community, need to find a sustainable way to ensure that the organisation continues to thrive after the initial funding period concludes and when it will have the best opportunity to provide mature insight.

I'd like to conclude by thanking Mr Galvin, his team and the national collaboration the organisation represents on having the ambition, foresight and drive to undertake such a novel patient focused project. All of this is, of course, only made possible with the practical support of the men of Ireland, each of whom, by contributing to this work is helping make the future for men better.

1 Mr Tom Hope, Men Against Cancer

Mr Tom Hope, Men Against Cancer

As a patient representative and a committee member of Men Against Cancer (MAC), a prostate cancer support group, and a member of the IPCOR Steering Committee, I am delighted that this project has reached this milestone of being able to publish the first analysis of the data on men who have been diagnosed with prostate cancer in Ireland in 2016-17.

This information will expand over the next few years to provide analysis of the stage of the cancer at diagnosis, the treatment, the effectiveness of the treatment and the quality of life on their cancer journey. This should reassure men diagnosed with prostate cancer and their families that they are not alone, there are many men with similar diagnoses, that the treatment being offered in Ireland is effective and the Irish healthcare system compares well with other international healthcare systems.

2. Acknowledgements

IPCOR would like to acknowledge and extend our appreciation to men registered by IPCOR, the Investigators, Steering Committee members, the Scientific Advisory Board, IPCOR team members, colleagues at the NCRI and HRB-CRFG, clinicians and nurses and our collaborators Men Against Cancer, TrueNTH, patientMpower, Cancer Trials Ireland and the National Prostate Cancer Research Consortium for their active contribution and support of the registry.

3. Glossary

Table 1. Glossary containing acronyms and terms used in the report

Term	Meaning
Active Surveillance	When a person does not receive immediate treatment; rather, they have their health monitored regularly.
Advanced Prostate Cancer	Prostate cancer that has spread to other parts of the body.
Biopsy	The removal of a small sample of tissue from the body, for examination under a microscope, which helps to diagnose disease.
Bone Scan	A bone scan can show if prostate cancer has spread to the bones.
CAPRA score	Cancer of the Prostate Risk Assessment Score. A CAPRA score predicts an individual's likelihood of metastasis (i.e. the cancer spreading) and the chances of dying from cancer or from any cause.
CT	Computed Tomography. A CT scan uses x-rays to make detailed, cross-sectional images of the body.
CTI	Cancer Trials Ireland
CRDI	Clinical Research Development Ireland
De-identified data	Data that has had all personally identifiable information removed.
EORTC QLQ C30	A quality of life questionnaire developed by the European Organisation for Research and Treatment (EORTC). The questionnaire is designed to measure cancer patients' quality of life and physical, emotional, cognitive and social functionings.
EPIC-26	Expanded Prostate Cancer Index Composite (26 items). EPIC-26 is a survey that asks about the symptoms commonly present when living with prostate cancer. The survey asks about incontinence, bowel problems, impotence and levels of vitality.
EQ-5D-5L	A health related quality of life questionnaire developed by the EuroQoL Group taskforce.
Gleason Score	The Gleason grading system is used to indicate how aggressive the prostate cancer is, by assigning a grade or score. Scores range between 2 and 10; the higher the score, the more likely the cancer will grow and spread quickly. Scores of 2–6 are low grade, a score of 7 is intermediate grade and scores of 8–10 are high grade.
GP	General Practitioner
HRB-CRFG	Health Research Board Clinical Research Facility, Galway
HSE	Health Service Executive

Term	Meaning
Incontinence	The inability to hold or control the flow of urine or faeces.
Inter-quartile Range	Quartiles divide a rank-ordered dataset into four equal parts. The values that divide each part are called the first, second and third quartiles. First, second and third quartiles correspond to the observation at the 25th, 50th and 75th percentiles, respectively. The observation from the 25th percentile to the 75th percentile is referred as the interquartile range. An observation at the 50th percentile corresponds to the median value in the dataset.
IPCOR	Irish Prostate Cancer Outcomes Research
ISUP Grade	International Society of Urological Pathology grade. A revised grading system for prostate cancer based on the Gleason Score.
Localised Prostate Cancer	Prostate cancer that has not spread beyond the prostate gland. Also known as early prostate cancer.
MAC	Men against Cancer
Median	The middle value in a series of values that are arranged from smallest to largest.
MRI	Magnetic Resonance Imaging. MRI shows detailed images of soft tissues in the body using radio waves and strong magnets.
Metastatic	Metastatic cancer is cancer that has spread from another part of the body, also known as secondary cancer.
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry Ireland
NPCRC	National Prostate Cancer Research Consortium
Prostate-Specific Antigen (PSA)	A protein produced by prostate cells. It may indicate prostate cancer and can be used to monitor its recurrence post-treatment.
PROM	Patient-Reported Outcome Measure
R	R is an open-source programming language widely used by statisticians for data analysis.
RAPC	Rapid Access Prostate Clinics provide a fast, efficient service for men who need further tests to determine if they have prostate cancer. These clinics are funded by the NCCP in the 8 designated cancer centres in Ireland.
Staging	Assesses the disease's spread in the body.
TP	Transperineal biopsy
TRUS	A transrectal ultrasound-guided biopsy
TURP	Transurethral resection of the prostate

4. Executive Summary

IPCOR was funded in 2014 by the Irish Cancer Society and the Movember Foundation with the aim of establishing a national prostate cancer registry to follow men diagnosed with prostate cancer through their cancer journey. In collaboration with the National Cancer Registry Ireland (NCRI) and the Clinical Research Facility in Galway (HRB-CRFG), IPCOR allows us to systematically track the most important outcomes of Irish men diagnosed with prostate cancer. The IPCOR investigators include a Urologist, a Medical Oncologist, a Radiation Oncologist, a Cancer Epidemiologist and the Research Manager at the NCRI. Data collected involves both detailed clinical information and patient reported outcome measures (PROMs). Starting this year, IPCOR will publish annual reports containing data for patients, the public and stakeholders, in addition to contributing hospitals and doctors. Based on the accumulated data, the IPCOR investigators will then make recommendations to health care providers aimed at improving the quality of care of Irish men with prostate cancer.

Patients have been involved with IPCOR from the start, and a Patient Panel will shortly be formed to better guide the IPCOR research, PROMs collection and dissemination strategy. IPCOR also works with the Movember Foundation and TrueNTH Global Registry to share data so that patient outcomes in Ireland can be compared with those achieved in other countries. Men will also benefit from the TrueNTH patient portal and decision support tools which will be introduced in 2019. This portal will provide men with a suite of tools which aim to help them make the best treatment choice for their lifestyle based on research and the experiences of other men and will also include a place for men to track their symptoms.

The data published in this report shows:

- Over 4,800 patients were registered in IPCOR in 2016 and 2017, equating to approximately 250 men newly diagnosed with prostate cancer every month.
- The average age at diagnosis was 66 years
  - one-fifth of men diagnosed were < 60 years of age.
  - two-thirds of men diagnosed were < 70 years of age.
- Men under the age of 70 are more likely to be diagnosed via the NCCP Rapid Access Prostate Clinics in the public hospital system, than in the private hospital system.
- A typical man had a diagnostic biopsy 49 days after an elevated prostate specific antigen (PSA) blood test, and was informed of their prostate cancer diagnosis at 79 days following the PSA test.
- When these milestones are examined broken down by the public and private hospital systems, the time from PSA blood test to biopsy was shorter for patients who had their biopsy in a private hospital (32 days v 56 days) as was the time from PSA test to being informed of a prostate cancer diagnosis (55 days v 85 days). However, this is unlikely to be clinically significant.
- Approximately two-thirds of men were diagnosed with Gleason 3+3 (ISUP group 1) or Gleason 3+4 (ISUP group 2) prostate cancer, and one third with more aggressive disease (Gleason 4+3 - 5+5, or ISUP group 3 – 5).
- Younger patients were more often diagnosed with less aggressive disease, and older patients with more aggressive disease. There may be factors other than age that contribute to this e.g. patient co-morbidities.
- Four out of five men diagnosed with prostate cancer had no symptoms. However, older men were more likely to present with potentially cancer-related symptoms e.g. bone pain.
- MRI imaging has been rapidly adopted internationally for the identification and staging of prostate cancer. The benefits are that the subsequent biopsy is targeted and this improves the cancer detection rate. In addition, fewer repeat biopsies are needed (Kasivisvanathan et al. 2018, Ahmed et al. 2017). However, in Ireland the availability of scanners is limited leading to long waiting times.

  - Four out of every five men had a prostate MRI.
  - Of the men who underwent an MRI scan, 43% had their MRI before their biopsy.
  - Patients in the private service were three times more likely to have a pre-biopsy MRI.
  - Patients in the private service are three times more likely to access a pre-biopsy MRI. The benefits of this are that the subsequent biopsy is targeted and this improves the cancer detection rate. In addition, the need for repeated biopsies is lessened.
- In relation to the use of CT scans, as men's CAPRA risk score increased they received more staging CT scans, in line with expectation. The occasional use (<20% of patients) of CT imaging in low and intermediate risk disease requires further evaluation (Department of Health 2015).
- In a similar fashion, there is an association between the use of bone scans and a man's CAPRA score. Again the occasional use of bone scans in low and intermediate grade disease is generally unnecessary (Department of Health 2015).

Future Plans:

- In 2019, IPCOR will also publish its first hospital level and doctor level reports.
- IPCOR will continue to grow and will form research partnerships with the National Cancer Control Programme and Cancer Trials Ireland so that IPCOR can support clinical trials in Ireland.
- A Patient Panel will be convened to maximise patient engagement in IPCOR.
- The PROMs collection will recommence.
- The IPCOR website and IPCOR App will be further developed.
- IPCOR will further develop its relationship with Movember and the TrueNTH Global Registry, engaging in global research through the TrueNTH platform.
- IPCOR will offer the TrueNTH platform to men with prostate cancer in Ireland during 2019.
- The next IPCOR annual report will be published in November 2019.

5. About IPCOR

5.1 IPCOR Team

IPCOR Investigators

Mr David Galvin
Consultant Urologist,
IPCOR Principal Investigator
Dublin Academic and Medical Centre, St Vincent's and Mater Misericordiae University Hospitals

Prof Frank Sullivan
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Prof Linda Sharp
Professor of Cancer Epidemiology,
Co-Investigator
Newcastle University

Dr Conan Donnelly
Research Manager,
Co-Investigator
National Cancer Registry Ireland

IPCOR team

Dr Áine Murphy
Project Manager,
Clinical Research Development Ireland

Ms Cara Dooley
Statistician,
Clinical Research Development Ireland

Dr Leah Bentham
Research Officer,
National Cancer Registry Ireland

Ms Lisa McGowan
Research Officer,
National Cancer Registry Ireland

Dr Emer McCarthy
Research Officer,
National Cancer Registry Ireland

Dr Emma Heffernan
Research Officer,
National Cancer Registry Ireland

Ms Christine Allan
Clinical Database Officer,
National Cancer Registry Ireland

Dr Jean O'Connor
Clinical Data Manager,
National Cancer Registry Ireland

Ms Laura McGovern
Clerical Officer,
National Cancer Registry Ireland

Mr Amar Nath
Research Assistant,
Clinical Research Facility Galway

Mr Kenny Lynch
Research Officer,
National Cancer Registry Ireland

Ms Hazel Smith
Research Officer,
National Cancer Registry Ireland

5.2 Research Partnership

IPCOR is being carried out by a collaborative research partnership consisting of Clinical Research Development Ireland (CRDI), the National Cancer Registry Ireland (NCRI) and the HRB Clinical Research Facility in Galway (HRB-CRFG). The work is supported by the National Cancer Control Programme (NCCP).

Clinical Research Development Ireland (CRDI): Clinical Research Development Ireland is a not-for-profit research partnership comprising National University of Ireland Galway (NUIG), Royal College of Surgeons in Ireland, Trinity College Dublin, University College Cork, University College Dublin and the University of Limerick, their medical schools, associated academic hospitals and clinical research facilities, with the objective of accelerating the translation of biomedical research into improved diagnostics, therapies and devices for patients. More information about CRDI can be found on their website: www.crdi.ie

National Cancer Registry Ireland (NCRI): The National Cancer Registry is a publicly appointed body, established in 1991, to collect and classify information on all cancer cases which occur in Ireland. The NCRI collects information on all new cancer cases in Ireland, monitors trends and outcomes in different cancer types, promotes the use of registry data in research and the planning and management of services and publishes an annual report on cancer statistics. More information about NCRI can be found on their website: www.ncri.ie

HRB Clinical Research Facility in Galway (HRB-CRFG): The HRB Clinical Research Facility, Galway is a joint venture between Galway University Hospitals (GUH) and NUIG which provides the infrastructure, physical space, facilities, expertise and the culture needed to optimally support patient-focused research and clinical studies. More information about HRB-CRFG can be found on their website: www.nuigalway.ie/hrb_crfg/

In partnership with

National Cancer Control Programme (NCCP): The NCCP provides the necessary governance, integration, leadership, operational structure and core support services to create the essential framework for cancer control in Ireland. The goals of the programmatic approach are to improve cancer prevention, detection and increase survival rates. Content expertise for NCCP clinical guidelines and performance indicators is provided by practicing clinicians in the relevant area. More information about NCCP can be found on their website: www.hse.ie/eng/services/list/5/cancer/

5.3 Funding

The Irish Prostate Cancer Outcomes Research study is funded by the Movember Foundation in partnership with the Irish Cancer Society.

Movember Foundation: The Movember Foundation is the leading global charity raising funds and awareness for men's health. These funds deliver breakthrough research and support services to allow men to live happier, longer, healthier lives. Since 2003, millions have joined the men's health movement, raising over AUD $850 million and funding over 1200 programmes through impact investments focusing on prostate cancer, testicular cancer, mental health and suicide prevention. The Foundation's vision is to have an everlasting impact on the face of men's health. More information about the Movember Foundation can be found on their website: ie.movember.com

Irish Cancer Society: The Irish Cancer Society is a charity that aims to improve the lives of those affected by cancer. The Irish Cancer Society is the largest voluntary funder of cancer research in Ireland and supports research by funding innovative cancer research projects across the Republic of Ireland. More information about the Irish Cancer Society can be found on their website: www.cancer.ie

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5.4 Prostate Cancer and IPCOR

Prostate cancer is the most commonly diagnosed cancer in Ireland and accounts for almost 30% of the total number of cancers diagnosed in men (excluding the common but rarely fatal non-melanoma skin cancer). The National Cancer Registry Ireland estimate annual average incidence to be over 3,500 patients in the period 2016 to 2018 (National Cancer Registry Ireland, Annual Statistical Report, November 2018). This translates to a 12.5% risk of developing prostate cancer before the age of 75 and an average age of diagnosis around 67 years. In terms of mortality, from 2013 to 2015, prostate cancer accounted for 522 deaths annually making it the third most common cause of cancer death (just over 11% of the total cancer mortality). Trend data from the NCRI show significantly increasing prostate cancer incidence with around 1,000 cases per year in the early 1990s to over 3,600 in 2011 (National Cancer Registry Ireland, Annual Statistical Report, November 2018). These increases have, in part, been due to the use of opportunistic screening using the PSA test to diagnose prostate cancer at an earlier stage, which led to the diagnosis of many indolent cancers that may not have presented symptomatically during the man's lifetime. With improving treatment, a changing disease profile and a changing patient demographic, 5-year survival has increased significantly from 66% for patients diagnosed from 1994-1998 to 92% for those diagnosed from 2010-2014 (National Cancer Registry Ireland, Annual Statistical Report, November 2018).

Due to improving survival and increasing incidence, the number of men living with prostate cancer has increased year on year with an estimated 35,125 men with a history of prostate cancer at the end of 2016 and with prostate cancer incidence projected to increase to in excess of 6,000 by 2045 based on population ageing alone, prevalence is expected to continue to increase. These changing patterns in prostate cancer burden present significant challenges for service planning and patient care. We can no longer depend on routine incidence and survival data to measure the quality of care as prostate cancer is increasingly characterised as a chronic rather than acute disease.

IPCOR's longitudinal clinical and PROMs data will provide the information necessary to inform and improve care for men living with the disease and the consequences of its treatments. The IPCOR study aims to provide evidence-based data on men with prostate cancer and to make recommendations to clinicians, hospitals, decision-makers and the National Cancer Control Programme that promote improvements in care (see Table 2). To do this, we are collecting detailed clinical and patient-reported data on men's prostate cancer journeys from the time of diagnosis, throughout treatment and beyond. This will improve our knowledge of the disease and how it impacts men over their lifetime, providing the evidence on how best to improve care and use limited healthcare resources.

We also want to share our findings with the public, particularly men with prostate cancer and their families. The recent, large, population-based PiCTuRE study investigated the treatment decision making, treatment side-effects, well-being and health-related quality of life in men living with prostate cancer on the island of Ireland (see, for example, Sharp et al. 2015; F. J. Drummond et al. 2015; A. T. Gavin et al. 2015). However, there is little long term data, in Ireland or internationally, tracking men's experiences from diagnosis and throughout their treatments and beyond. This lack of information means that doctors are unable to inform men of their expected outcomes with any confidence. Our ambition is that men who are diagnosed with prostate cancer in the future, and their doctors, will be able to use the IPCOR data so that, together they can make informed decisions about treatments and understand the outcomes men can expect.

Table 2. IPCOR goals

1	**Create national standards for prostate cancer care in Irish hospitals.**
2	Collect data and produce reports that will **influence decision makers** to improve prostate cancer care.
3	Ensure decisions about prostate cancer care are transparent and based on **high quality data**.
4	Carry out **research studies** which investigate issues that impact men with prostate cancer e.g. dietary and lifestyle issues.
5	Compare Irish prostate cancer care with **care around the world** and ensure men in Ireland receive the highest standards of care.

5.5 IPCOR Data Collection

The IPCOR study is collecting data on men newly diagnosed with prostate cancer from 16 public and private hospitals across Ireland. These hospitals care for over 80% of all men with prostate cancer. With more funding in the future, we hope to collect data from all hospitals that diagnose and treat men with prostate cancer. For now, the study focuses on collecting data in the larger public and private hospitals.

The data presented in this report relates to men diagnosed with prostate cancer in 2016 and 2017, who received some (or all) of their care at one of the 16 hospitals shown in Tables 3 and 4.

Table 3. Public hospitals included in IPCOR.

Hospital	Area
1 St Vincent's University Hospital	Dublin South
2 St James's Hospital	Dublin South
3 Beaumont Hospital	Dublin North
4 Mater Misericordiae University Hospital	Dublin North
5 Tallaght University Hospital	Dublin South
6 St Luke's Radiation Oncology Network	Dublin
7 Cork University Hospital	South
8 Galway University Hospital	West
9 Mercy University Hospital	South

Table 4. Private hospitals included in IPCOR.

Hospital	Area
1 Galway Clinic	West
2 Bon Secours Hospital Cork	South
3 Mater Private Hospital	Dublin North
4 St Vincent's Private Hospital	Dublin South
5 Beacon Hospital	Dublin South
6 Bon Secours Hospital Dublin	Dublin North
7 Bon Secours Hospital Galway	West

IPCOR research officers are employed and trained by the NCRI and assigned to a number of IPCOR hospitals to collect the IPCOR dataset. Under the Health (Provision of Information) Act 1997, the NCRI are authorised to collect any data consistent with their purposes, including registration and research, without the requirement for patient consent. 2016, the research officers identify men newly diagnosed with prostate cancer in the hospitals and register them in the IPCOR database. Once men are registered, the research officers collect their demographic and diagnosis details, treatment information and outcomes.

The IPCOR study also collects patient reported outcomes data from men at the time of their diagnosis and annually

thereafter. This allows men to tell us about the impact being diagnosed with, and treated for prostate cancer, has had on their quality of life. We contact men by post and ask them to complete a short questionnaire at each time point which measures their quality of life and any side effects of the disease or treatment that they might be experiencing.

5.6 Clinician Support

IPCOR have contacted all clinicians involved in managing prostate cancer in Ireland and the majority have agreed, in principle, for men under their care to be contacted and asked to take part in IPCOR. Clinicians who have signed up to the study have supported the research officer in their hospital, and facilitated access to information on men newly diagnosed with prostate cancer through Rapid Access Prostate Clinics (RAPCs) and multi-disciplinary team (MDT) meetings. The research officers have built strong relationships with the clinicians, their teams and hospital staff which ensures that they have access to hospital systems such as hospital patient administration systems, medical records, and radiotherapy and chemotherapy clinic records so that they can collect the IPCOR data on all men registered in the study.

Table 5. Number and percentage of consultants in each specialty signed up to IPCOR.

Specialty	Number Invited	Number Signed up	% Signed up
Urologists	48	44	92
Medical Oncologists	14	11	79
Radiation Oncologists	16	14	88
Total	78	69	88

5.7 Ethical approval

The patient reported outcomes component of the study requires ethical approval from the Research Ethics Committees which govern each of the participating hospitals. The IPCOR study has received ethical approval from:

- Tallaght Hospital /St James's Hospital Joint Research Ethics Committee
- Clinical Research Ethics Committee of the Cork Teaching Hospitals
- St Vincent's Healthcare Group Ethics and Medical Research Committee
- Research Ethics Committee, Mater Misericordiae University Hospital and Mater Private Hospital
- Beaumont Hospital Research Ethics Committee
- Galway University Hospitals Research Ethics Committee
- Bon Secours Research Ethics Committee
- Beacon Hospital Research Ethics Committee

5.8 IPCOR collaborations

IPCOR is collaborating with the Movember Foundation funded TrueNTH Global Registry which aims to (i) identify the processes of care from around the world that lead to the best outcomes for men and (ii) develop strategies to implement these findings in healthcare systems across the globe (Evans et al. 2017). In total, registries from 13 countries are participating in the TrueNTH Global Registry. The benefits of this collaboration for IPCOR include the ability to benchmark prostate cancer care in Ireland with other systems around the world and to exchange knowledge with other international key opinion leaders. IPCOR will contribute data from 6 participating hospitals, shown in Table 6.

Table 6. The six TrueNTH hospitals

	Hospital
1	Mater Misericordiae University Hospital
2	St Vincent's University Hospital
3	Beaumont Hospital
4	St James's Hospital
5	Cork University Hospital
6	Galway University hospital

Men registered by IPCOR from these hospitals will be asked to consent to the sending of their de-identified PROMs data to the TrueNTH Global Registry where it will be hosted on a secure server at Monash University, Australia and used for research purposes.

As part of the TrueNTH collaboration, Ireland will have access to the TrueNTH Programme, a global initiative aimed at improving survivorship outcomes for men with prostate cancer. The TrueNTH programme includes a suite of tools and support aids that we will integrate into IPCOR, such as the symptom tracker tool, decision support tool and exercise videos.

IPCOR collaborates with patientMpower, a health technology software company, who created our electronic PROMs tool and app. This work was funded by a grant from Astellas Pharma Ireland. PatientMpower continue to develop content for our app and website. Through a new collaboration with ARC Cancer Centre, patient support videos have been developed which demonstrate pelvic floor exercises that can help men manage urinary and sexual dysfunction. Additional videos on fatigue and stress management are currently being prepared. These videos are designed specifically for men with prostate cancer and the content is delivered by a chartered physiotherapist. The videos are available on the IPCOR website and app. This work was funded by a grant from IPSEN Pharmaceuticals. Further funding has been awarded to us by Janssen

6. Data Analysis

6.1 Explanation of our Data

The study and the data collection has been described previously in the "About IPCOR" section. The report describes demographic and diagnostic information on 4,868 men diagnosed with prostate cancer in Ireland from February 2016 to December 2017. IPCOR collects data in 16 hospitals, however, one of the hospitals treats men but does not diagnose them. Therefore, the data described in this report was collected in 15 hospitals that diagnose men with prostate cancer.

Please note that the sample sizes will change in parts of the report as we do not yet have a full picture of men's journeys through treatment and beyond; this means the numbers of men included are higher for the earlier part of the journey and the events that all men undergo (e.g. PSA testing). The data will more accurately reflect men's journeys with each passing year. Future reports will contain information on treatment.

Hospitals have different systems to record patient data which can make it difficult to collect. IPCOR is a longitudinal study (i.e. it follows men over time from diagnosis) which gives us the opportunity to improve our data collection processes and the data will become more comprehensive each year.

In the majority of cases when we refer to a hospital, we are referring to the hospital to which a man was referred by his GP, where he was examined by his Consultant and underwent biopsy. For some patients, this pathway to biopsy may have happened in numerous hospitals.

The figures produced below are unadjusted. It is likely that some of the differences we see may be explained by other variables, for example, age, geography or other comorbidities a man may have. For this reason, all results should be interpreted carefully. IPCOR collects data for approximately 80% of all men newly diagnosed with prostate cancer in Ireland. IPCOR does not collect data from all hospitals in Ireland and may not be a fully representative sample of the whole country, the figures in the report cannot necessarily be extrapolated to all men diagnosed with prostate cancer in Ireland.

A comprehensive quality assurance report will be produced in 2019 to evaluate the completeness, timeliness and representativeness of the IPCOR data. This will largely be undertaken by comparison with data from the National Cancer Registry which will be possible for the first time when the NCRI publishes 2016 data in November 2018.

All analysis was carried out using R version 3.5.0 (R Core Team 2018).

6.2 Introduction to IPCOR's data

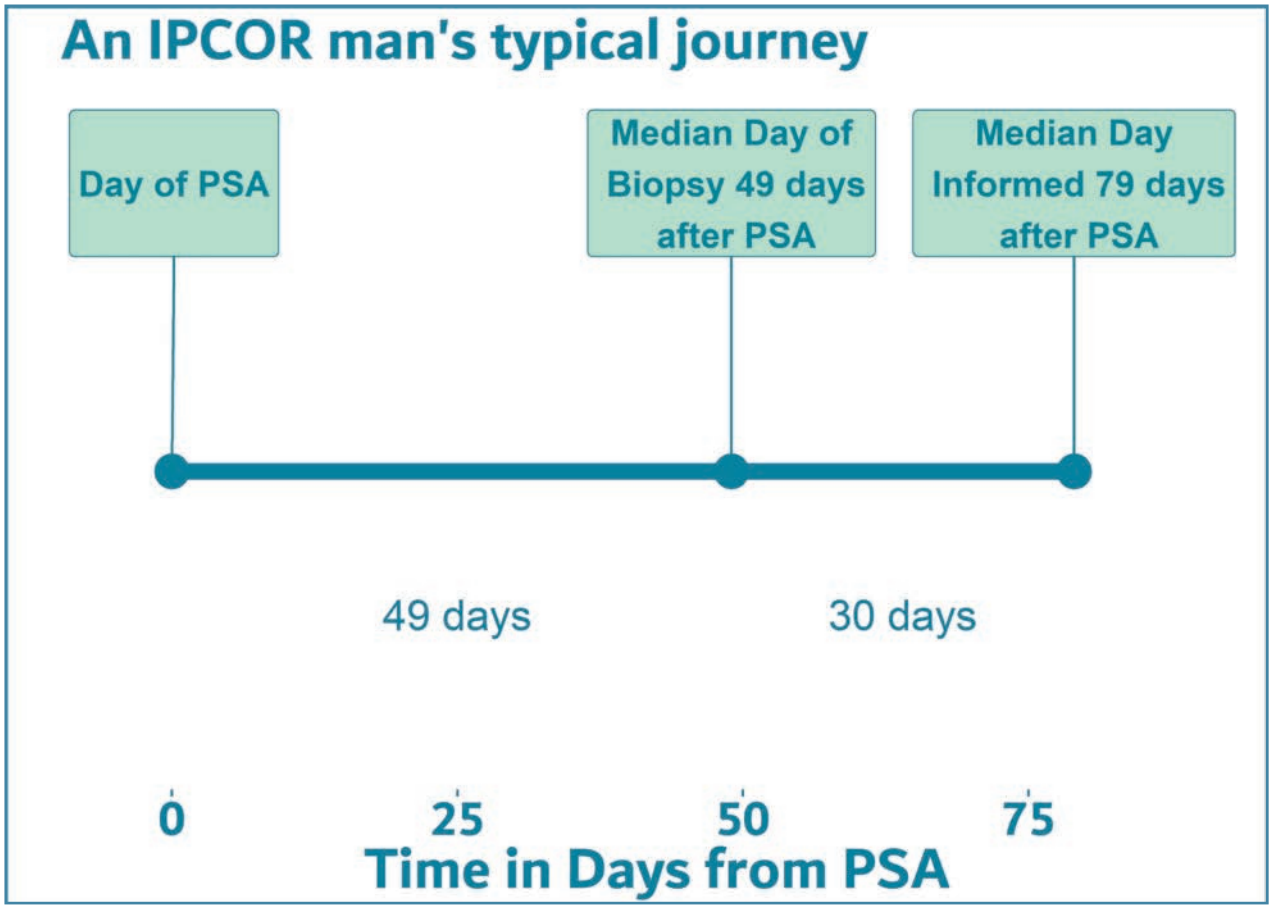

Figure 1. A timeline of a man's typical diagnostic journey.

Figure 1 shows the timeline of a man's typical diagnostic journey. At the start of the journey, a man attends his GP who carries out a PSA test. The results of the PSA test show an elevated PSA level leading to the GP referring the man to a urology clinic for further tests for prostate cancer. The man then has a prostate biopsy and a diagnosis of prostate cancer is confirmed by a pathologist. The man is informed of his diagnosis by his clinician. The interrogation of this timeline is important as this represents the initial journey of thousands of men diagnosed with prostate cancer every year. This journey needs to be supported to benefit the man, his partner and his family.

7. Demographic characteristics

7.1 Number of men diagnosed per month and year

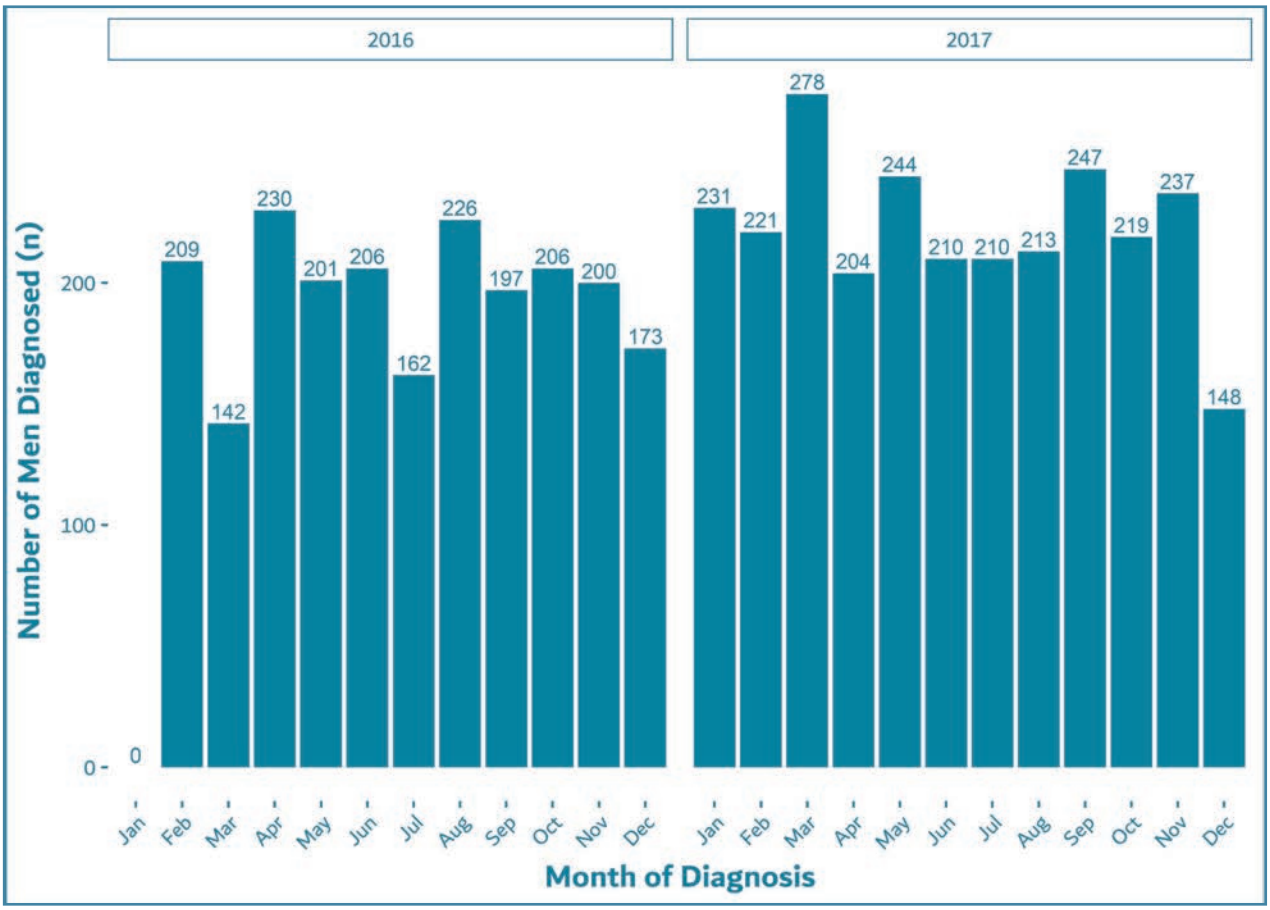

Figure 2. Number of men registered to the IPCOR database from February 2016 to December 2017 categorised by month and year (n = 4814).

Figure 2 shows the month and year of diagnosis for the men registered in IPCOR. The number of men registered per month has increased slightly from 2016 to 2017, as the project expanded, with on average 222 men diagnosed with prostate cancer each month in 2017.

7.2 Number of men diagnosed per IPCOR hospital

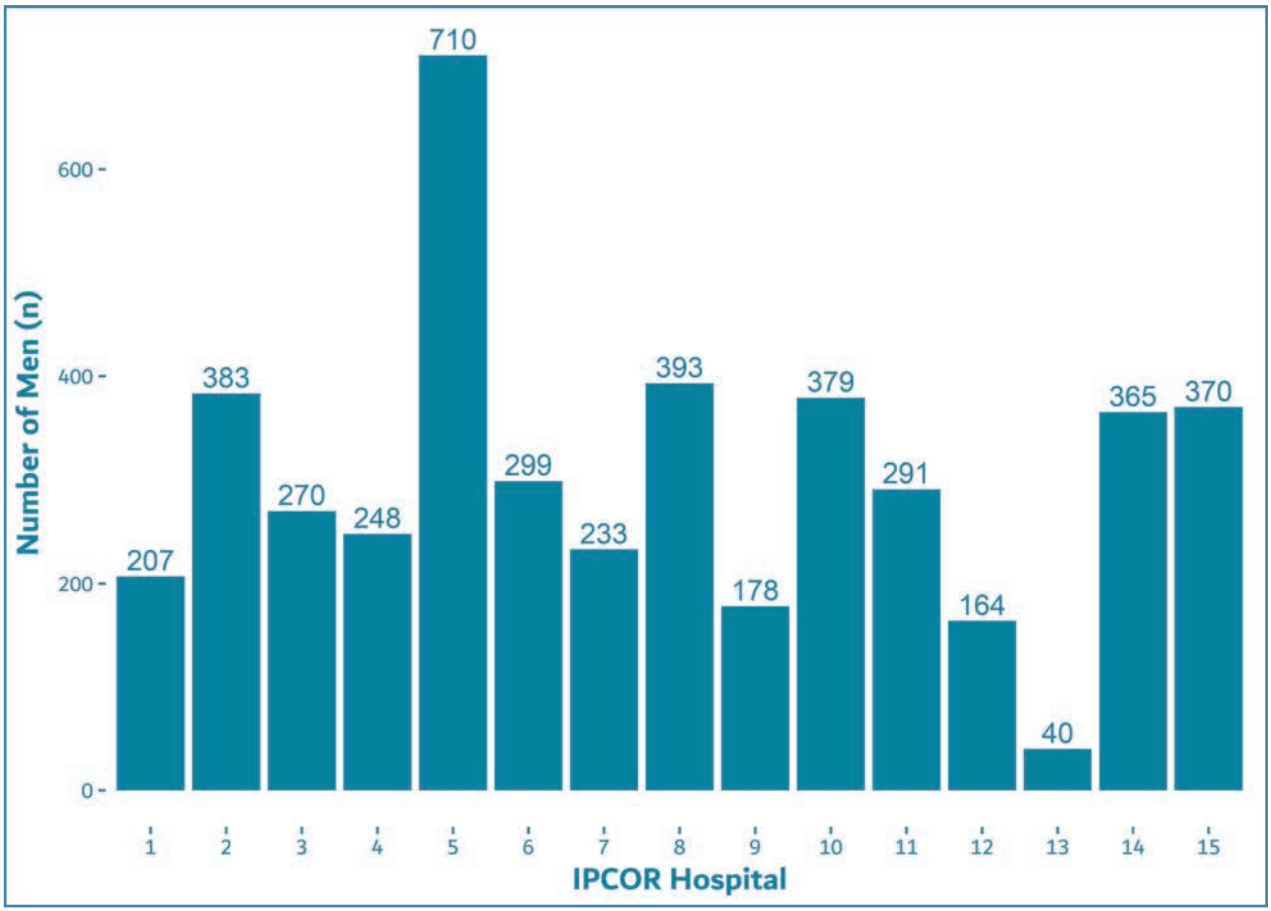

Figure 3. Number of men diagnosed per IPCOR hospital in 2016 and 2017 (hospitals 1 – 15, n = 4530).

Figure 3 shows the number of men registered in each of the 15 IPCOR diagnosing hospitals between February 2016 and December 2017. There is a large variation in the number of men registered in the hospitals, this may be due to the size of the hospitals or their catchment area.

7

7.3 Age of men at diagnosis

Table 7. Age of men at the time of their prostate cancer diagnosis in 5-year categories.

	Number of Men (n)	Percent (%)
<45	24	0.5
45-49	79	1.6
50-54	291	6.1
55-59	643	13.4
60-64	925	19.2
65-69	1244	25.9
70-74	860	17.9
75-79	491	10.2
80-84	194	4.0
85+	58	1.2
Total	4809	100.0

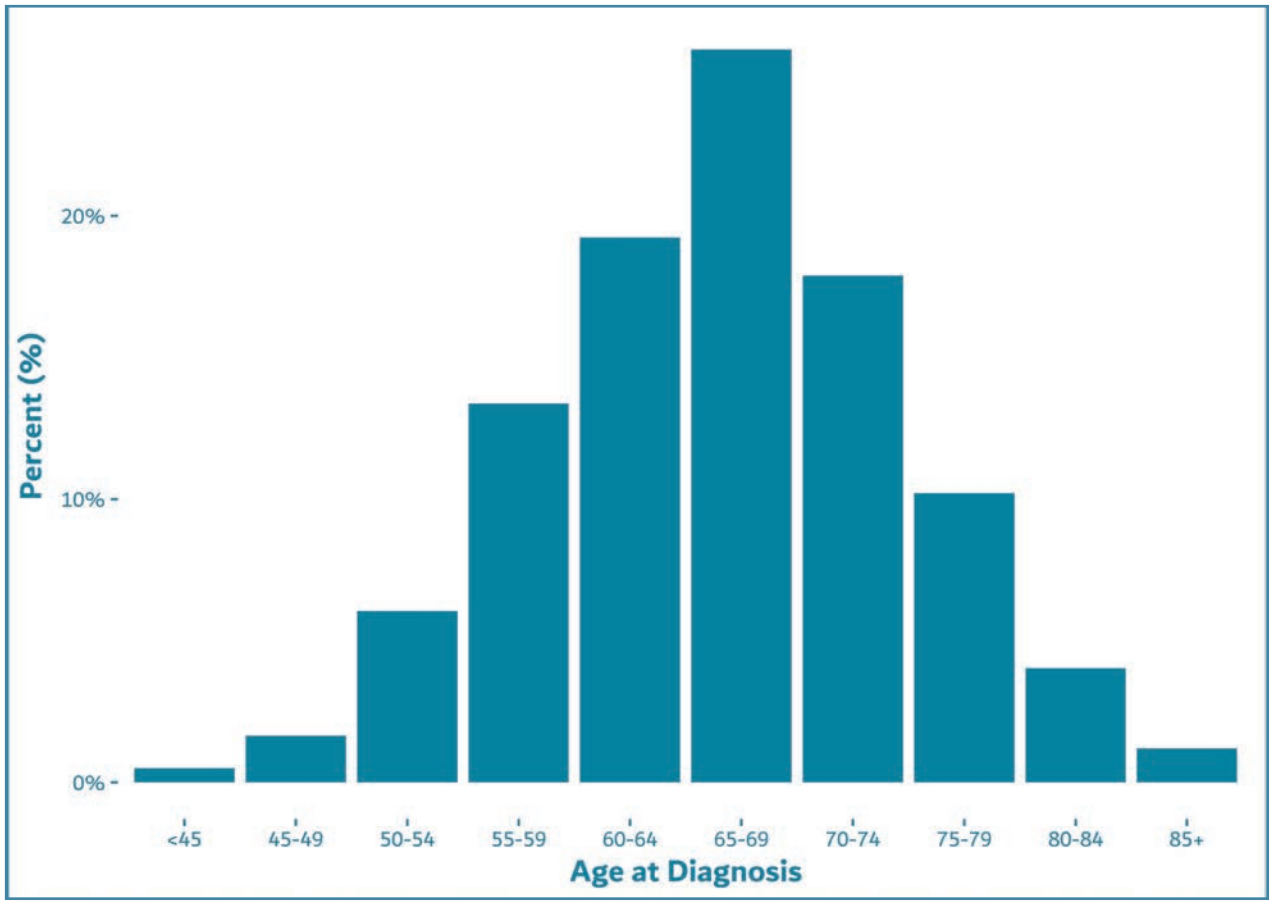

Figure 4. The age of men at the time of their prostate cancer diagnosis in 5-year age categories (n = 4809).

Table 7 and Figure 4 show the average age at which men are diagnosed is approximately 67 years of age, with approximately 20% of men aged in their 50s and 45% of men in their 60s. Less than 3% of men are under 50 and just over 5% of men are diagnosed over the age of 80.

Figure 4 shows that prostate cancer is a diagnosis made commonly in men during their working life. Despite perceptions, this is not only a disease of old men. Approximately two-in-five men (41%) are under 65 and two thirds of men diagnosed are under 70, so as retirement age continues to increase, more men will be diagnosed during their working life.

Their diagnosis could have an impact on their occupation or career, financial position, and their relationship with their partner and children. This can create anxiety, stress and depression in men at a busy time in their lives. Older men may also suffer many of the same psycho-social symptoms often with less social support structures and additional comorbidities. As men's working lives are increasingly prolonged with increasing life expectancy, the impact of a prostate cancer diagnosis is likely to increase over time (Zajdlewicz et al. 2017, S. K. Chambers et al. 2017).

7.4 Type of Diagnosing Hospital

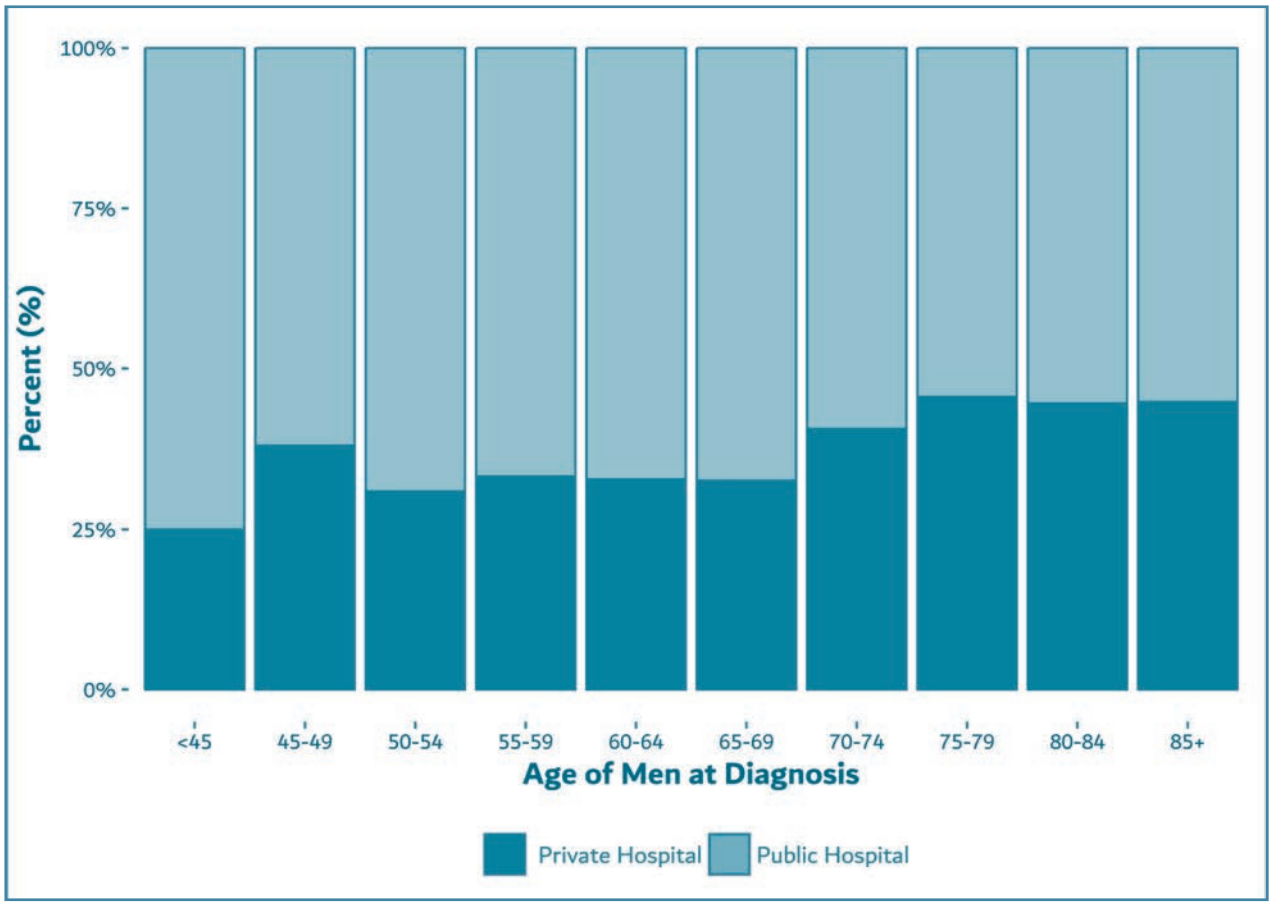

Figure 5. The age of men at diagnosis in public and private hospitals (n = 4830).

7

Figure 5 shows the percentage of men in each age category who are diagnosed in a public or private hospital. 64% of the men attended a public hospital. Men who are younger than 70 are slightly less likely to attend a private hospital, this may be due to the success of the NCCP Rapid Access Prostate Clinics (RAPC) in 8 public hospitals, which we discuss in the next section.

8. Patient access to care

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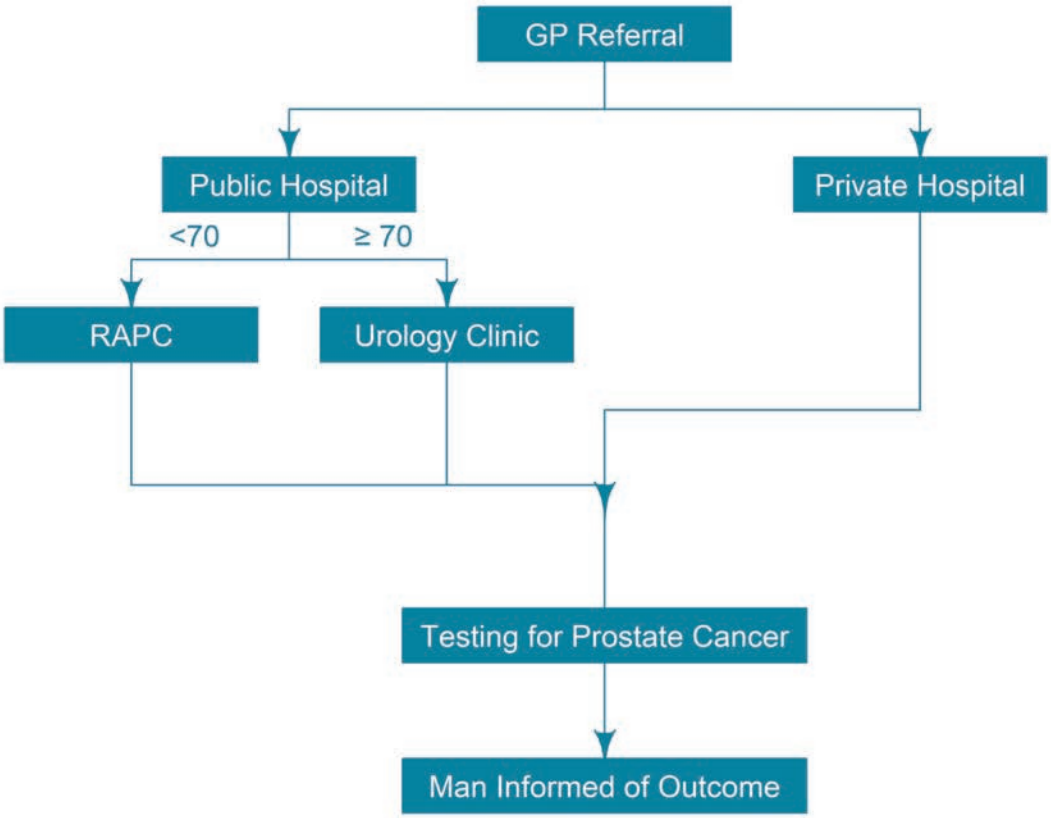

Figure 6. The referral pattern of men in Ireland.

GPs refer men who may have prostate cancer to urology departments for further tests. Men younger than 70 years of age are referred to a RAPC which provides an efficient service to test for prostate cancer, while men who are over 70 are referred to a general urology clinic in a public hospital. Men may choose to attend the urology department in a private hospital.

In RAPC, men under the age of 70 are seen within a 20-day period following referral by their GP (O'Kelly et al. 2013). Some private hospitals have seen this change in referral practice in younger men and have instituted their own rapid access prostate services, which can only benefit men with prostate cancer further.

In this report, we subdivide men who were diagnosed in public hospitals into two categories, men under 70 and men 70 and over to examine the effect of the RAPC. There may be other factors that affect men's care that we have not accounted for here, e.g. other comorbidities, so not all differences between the public and private hospitals will be due to the effect of the RAPC alone.

8

8.1 A man's typical diagnostic journey

A man's diagnostic journey starts with the level of PSA in the blood being tested as an indicator for a man's risk for prostate cancer. Generally, the risk of having prostate cancer goes up as the PSA level goes up. It is important to note, however, that just because a man has a PSA level of 4 ng/mL or higher, it does not mean that he has prostate cancer; for example, he may simply have an enlarged prostate, which is increasingly common as men age. Men with a PSA level between 4 ng/mL and 10 ng/mL have about a 1-in-4 chance of having prostate cancer. If the PSA is more than 10 ng/mL, the chance of having prostate cancer is over 50%. If the PSA level is very high, the cancer is more likely to have spread beyond the prostate.

The NCCP have determined GP referral values (National Cancer Control Programme, 2018) i.e. the PSA levels at which GPs should refer a man to a RAPC or urology department for further tests for prostate cancer. These values are shown in Table 8.

Table 8. NCCP GP Referral Values for PSA (ng/mL)

Age	PSA Level
< 50	≥ 2
< 60	≥ 3
< 70	≥ 4
≥ 70	≥ 5

When the man is referred for further tests, the next step is a biopsy of the prostate gland. Various types of biopsies may be carried out and these are discussed in more detail in Section 9.2. If cancerous cells are present in the biopsy, a prostate cancer diagnosis is confirmed and the man is informed. This is the journey that is mapped below, by displaying the median number of days each of these steps took based on the men registered in IPCOR. Additionally, a man may have a scan before or after his biopsy, this is discussed in Section 9.6.

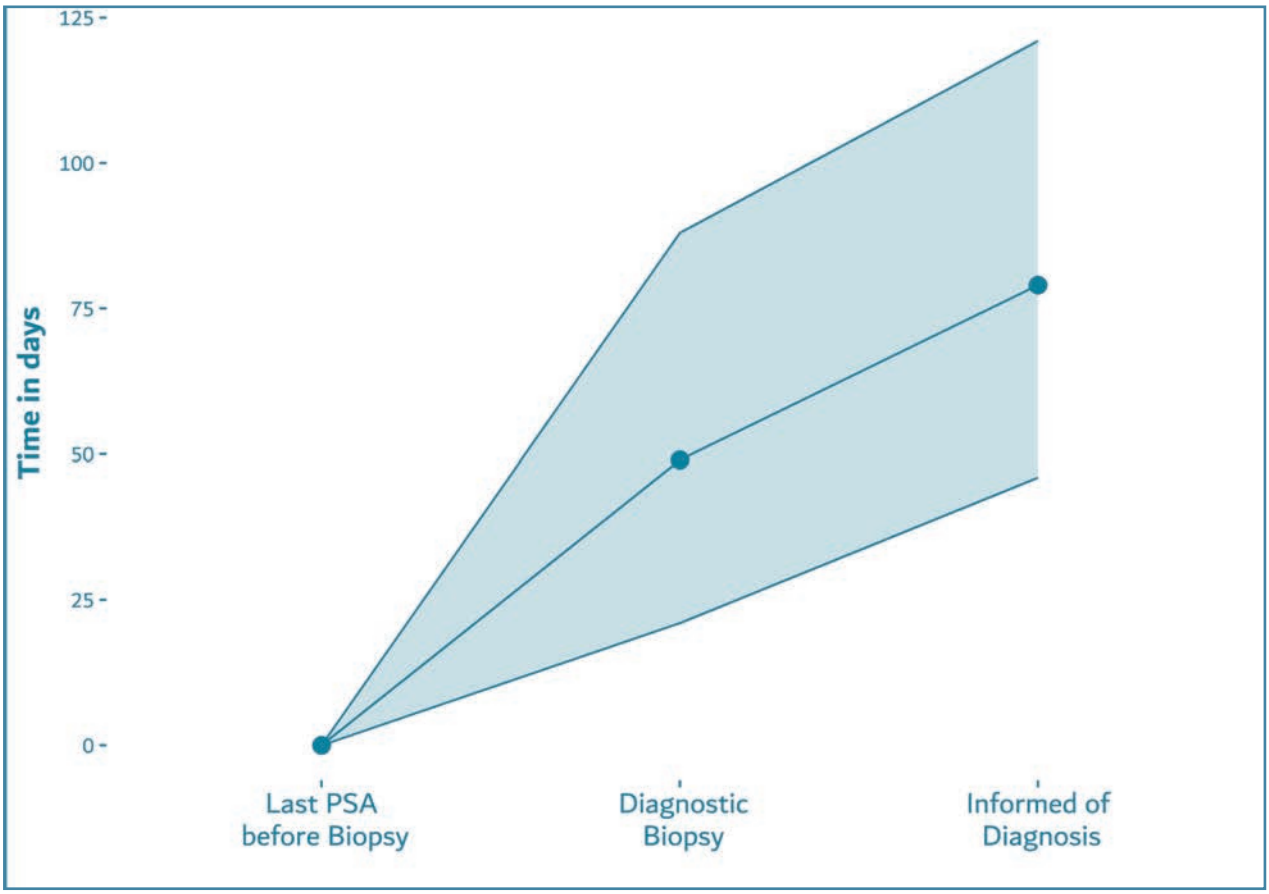

Figure 7. Timing a man's average journey from last PSA test before biopsy, to his biopsy and to being informed of his cancer diagnosis. The shaded area shows the inter-quartile range.

Figure 7 demonstrates the median waiting time in Ireland for men undergoing testing for prostate cancer. The graph shows the time from the date of the last PSA test before biopsy, to the biopsy date and the date the man was informed of their diagnosis. The median times for the men in the IPCOR sample are depicted. The shaded area on the graph shows the inter-quartile range, this range contains the waiting times of the middle 50% of men. 25% of men in the sample experienced shorter waiting times and 25% of men experienced longer waiting times. Table 9 displays the summary statistics shown in Figure 7.

Table 9. Summary statistics for men's diagnostic journey.

Days from PSA test to:	n	Median	First Quartile	Third Quartile	Inter- quartile Range
Biopsy	3394	49	21	88	67
Informed	2160	79	46	121	75

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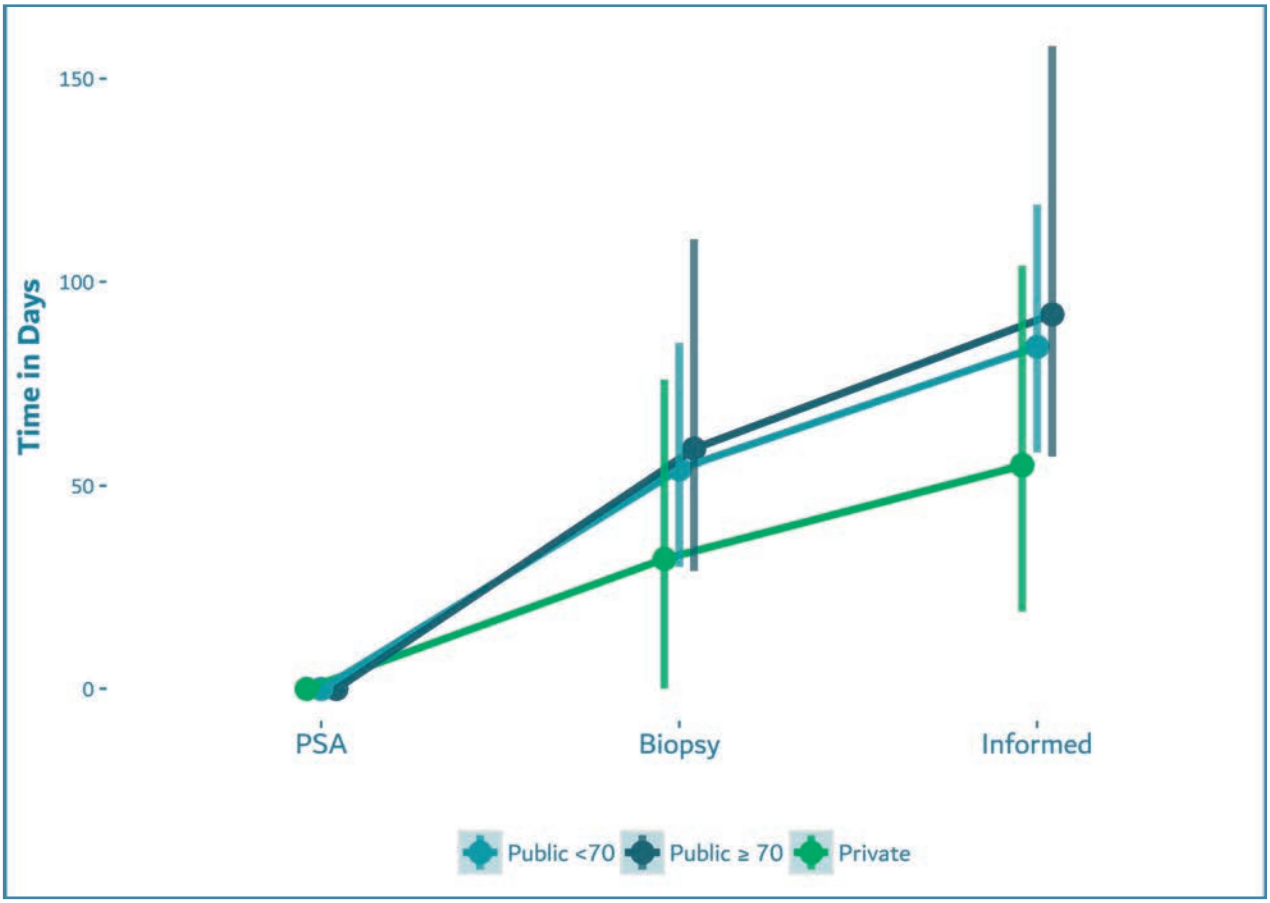

Figure 8. Timing the man's average journey from last PSA test before biopsy, to his biopsy and to being informed of his cancer diagnosis in public and private hospitals. The vertical lines show the inter-quartile range.

In Figure 8 men's diagnostic journeys are compared in the public and private hospitals using the median number for days from the PSA test and the interquartile range. The time from PSA blood test to biopsy was shorter for patients who had their biopsy in a private hospital (32 days v 56 days) as was the time from PSA test to being informed of a prostate cancer diagnosis (55 days v 85 days).

Table 10. Summary statistics for men's diagnostic journey.

Event	Days from PSA to	n	Median	First Quartile	Third Quartile	Inter-quartile Range
Public <70	Biopsy	1634	54	30	85.0	55.0
	Informed	1113	84	58	119.0	61.0
Public ≥ 70	Biopsy	631	59	29	110.5	81.5
	Informed	411	92	57	158.0	101.0
Private	Biopsy	1121	32	0	76.0	76.0
	Informed	633	55	19	104.0	85.0

9. Diagnostic testing

9.1 PSA level of last PSA before diagnosis

Table 11. Summary of PSA levels (ng/mL) of last PSA measured before diagnosis.

Variable	n	Median	First Quartile	Third Quartile	Inter-quartile Range
PSA Level	4529	7.6	5.6	11.82	6.22

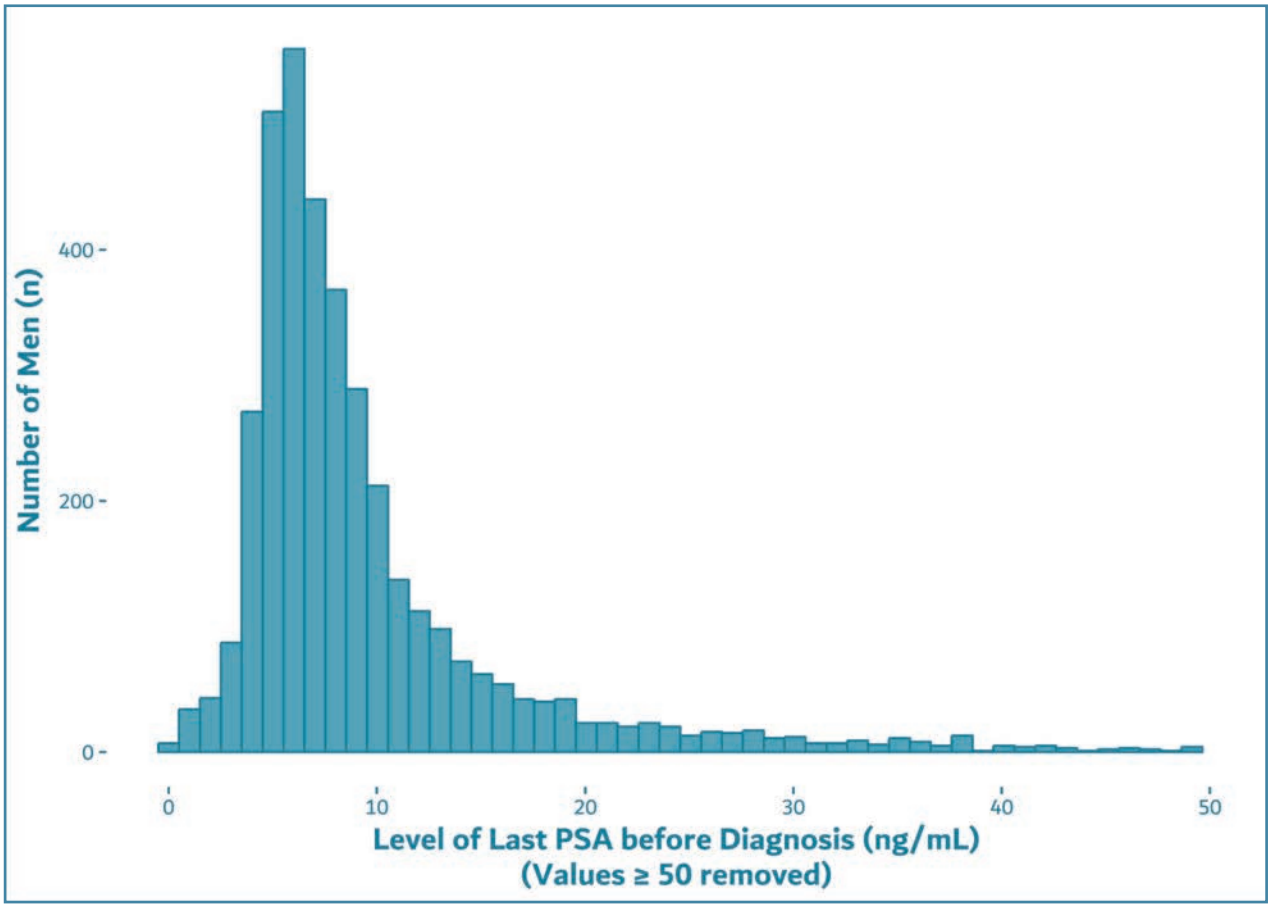

Figure 9. Histogram of PSA level of last PSA measured before diagnosis (n = 4274).
Note: n = 255 PSA values ≥ 50 ng/mL have been removed to aid comparison.

Figure 9 shows the distribution of PSA levels for men's last PSA test before diagnosis. The range of PSA levels is large with a median level of 7.6ng/mL and a maximum of 6275ng/mL. 87.2% of the men had PSA levels under 20ng/mL.

Table 12. Summary of PSA level of last PSA measured before diagnosis by public and private hospital.

Hospital Type	n	Median	First Quartile	Third Quartile	Inter-quartile Range
Public	2955	7.7	5.7	12.6	6.9
Private	1551	7.5	5.5	10.8	5.4

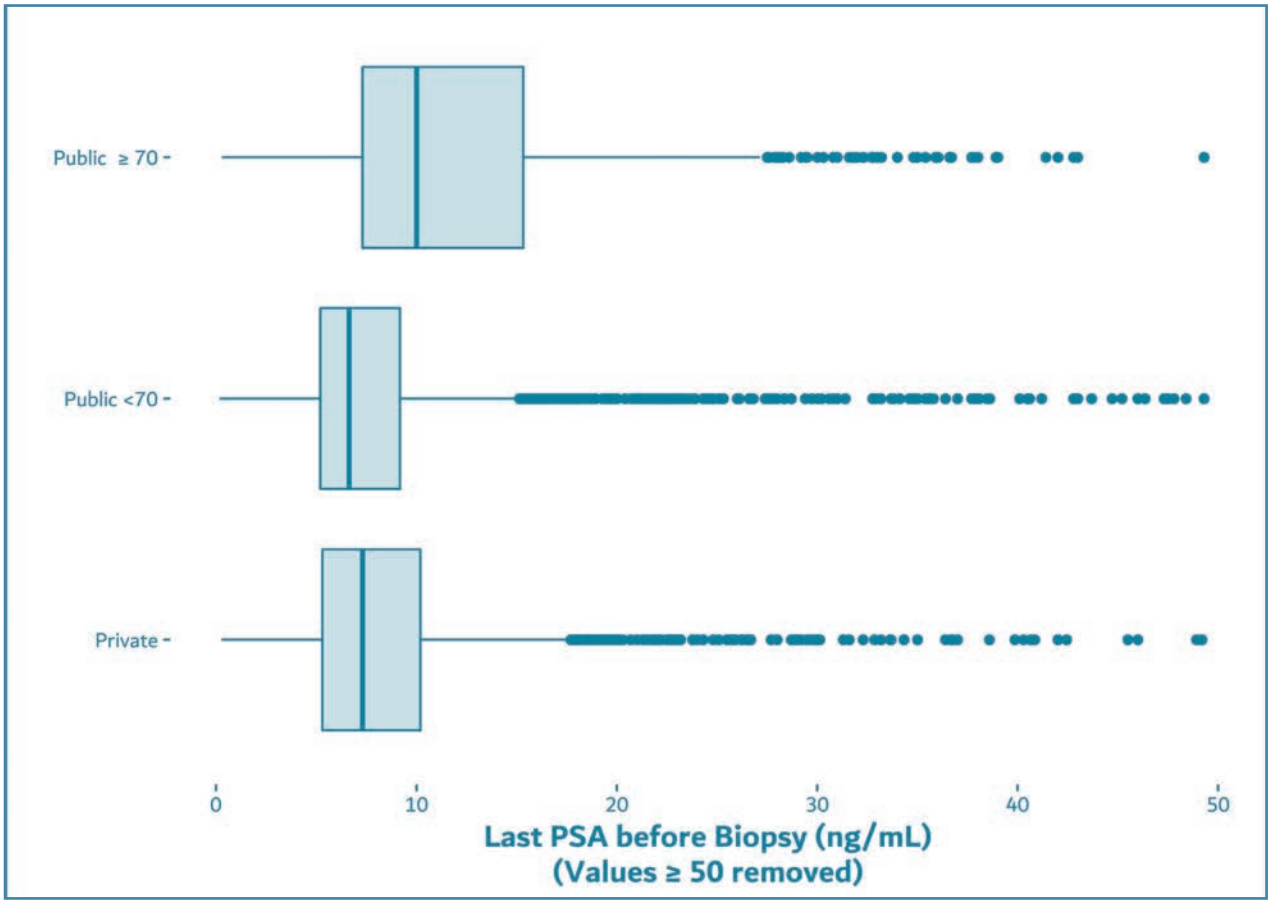

Figure 10. PSA levels (ng/mL) before diagnosis by patient age and by public or private hospital. Note: PSA values ≥ 50 ng/mL have been removed to aid comparison, 60 values are removed from the private category, 86 from the public < 70 category and 107 from the public ≥ 70

Figure 10 boxplots of the distribution of PSA levels of the last PSA a man had before his diagnosis, by public or private hospital. In the boxplot the middle line shows the median, the time below which 50% of men had their biopsy and above which 50% of men had their biopsy. The 'box' shows PSA levels for the middle 50% of men, or inter-quartile range, 25% of men had lower PSA levels and 25% of men had higher PSA levels. (The dots signify PSA levels that lie outside a value based on the inter-quartile range, this value is not clinically determined and is a statistical rule.)

Figure 10 shows that men over 70 attending public hospitals have higher median PSA levels (11ng/mL) than men under 70 attending public hospitals (6.8 ng/mL) and men attending private hospitals (7.5ng/mL). Men over 70 must have a higher PSA level before further tests for prostate cancer are initiated.

9.2 Biopsy

A biopsy of the prostate gland is usually required when there is a suspicion of prostate cancer. A transrectal ultrasound-guided (TRUS) biopsy is performed via the rectum because the prostate sits directly in front of the rectal wall and is therefore easily accessible via this route. As per NCCP guidelines, twelve cores are taken to sample different areas of the prostate. The disadvantages of a TRUS biopsy are that it is not always possible to access the front of the prostate and there is a small risk of serious infection.

Another form of biopsy is the transperineal (TP) biopsy which accesses the prostate via the perineum and is performed under a general anaesthetic. The advantages of a transperineal biopsy are that all parts of the prostate are accessible and cores can be taken from each part and there is a much lower risk of infection, as the skin of the perineum can be easily disinfected prior to the biopsy. The disadvantage is it costs more, and requires a man to be treated as an inpatient/day case as opposed to an outpatient.

Transurethral resection of the prostate (TURP) is a surgery that involves cutting away a section of the prostate and is used to treat urinary problems due to an enlarged prostate. Transurethral resection of the prostate is performed in men with urinary symptoms due to prostatic bladder outflow obstruction. The prostatic chips obtained are pathologically examined and prostate cancer may be detected incidentally.

Table 13. Number and percentage of men who had a TRUS, TP or TURP biopsy.

	TRUS (n)	TRUS (%)	TP (n)	TP (%)	TURP (n)	TURP (%)
Yes	4592	94.3	227	4.7	268	5.5
No	276	5.7	4641	95.3	4600	94.5
Total	4868	100.0	4868	100.0	4868	100.0

Table 13 shows the type of biopsy that men underwent. The TRUS biopsy was the most common biopsy type, 94.3% of men underwent a TRUS while 4.7% underwent a TP biopsy and 5.5% underwent a TURP. Some men had more than one biopsy which accounts for the total percentage of men undergoing biopsy being greater than 100%.

Biopsy cores

The NCCP recommends a TRUS biopsy with a minimum of 12 cores of tissue removed for examination as the standard throughout all 8 RAPC, and this type of biopsy has become the standard approach in Ireland.

9

Table 14. Summary of number of cores examined in men diagnosed with prostate cancer.

Variable	n	Median	First Quartile	Third Quartile	Inter-quartile Range
Number of Cores	4484	13	12	15	3

Table 14 demonstrates that the median number of cores obtained is 13 per patient, suggesting that standards consistent with NCCP guidelines are being maintained across the country. In a TP biopsy, many more cores are taken, and this may account for the much higher number of cores taken during biopsy. Data on biopsy cores is difficult to record, every effort has been made to record this data as accurately as possible.

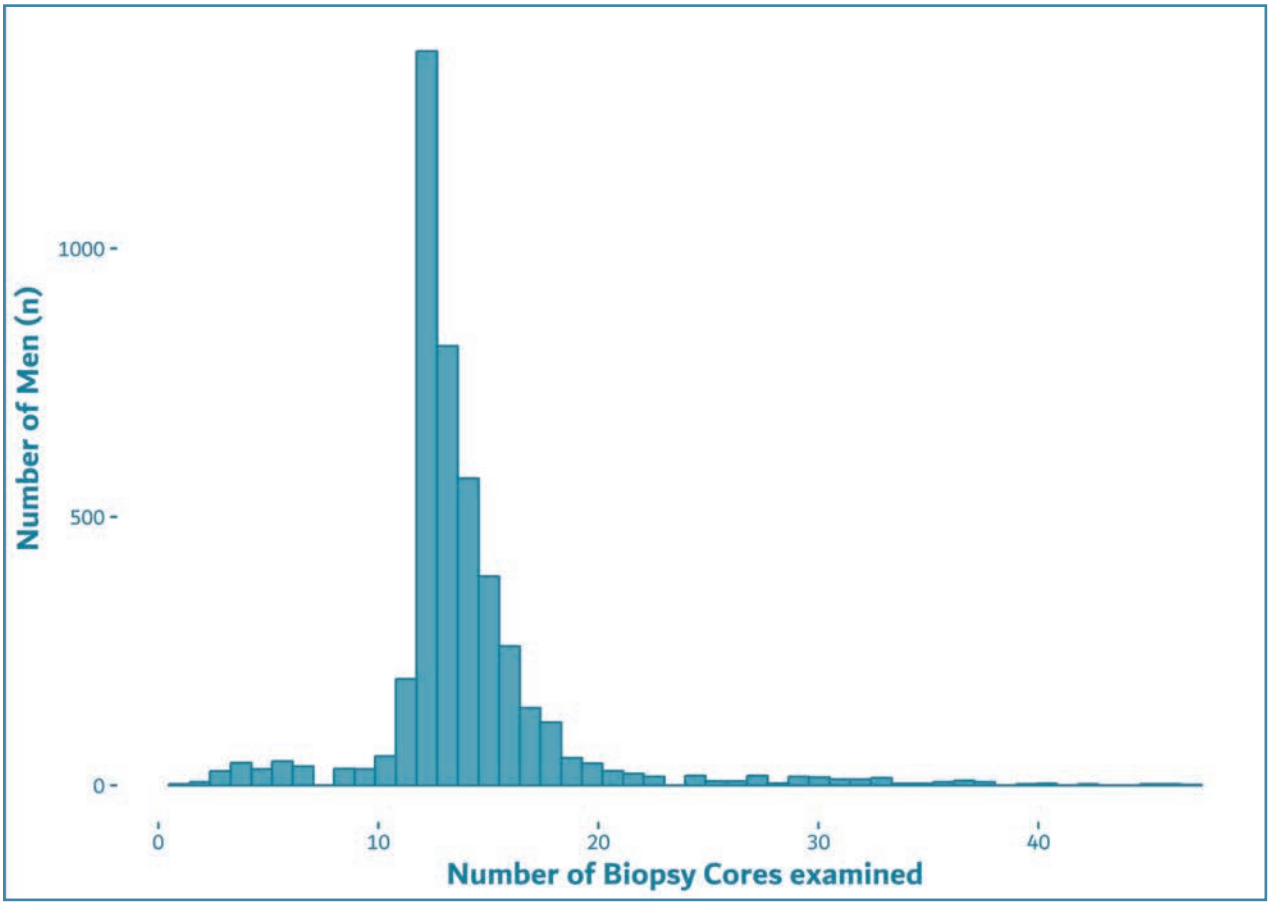

Figure 11. Number of biopsy cores examined in men diagnosed with prostate cancer (n=4484).

Figure 11 shows that the NCCP prostate cancer guideline recommending a 12 core TRUS prostate biopsy is widely implemented. The need for fewer number of cores for examination may be clinically indicated if a tumour is grossly apparent.

Number of positive cores

Table 15. Summary of number of positive cores in men diagnosed with prostate cancer.

Variable	n	Median	First Quartile	Third Quartile	Inter-quartile Range
Number of Positive Cores	4457	5	2	8	6

Table 15 shows that the median number of cores that are positive for cancer is 5.

Prostate cancer grading systems

A pathologist examines the cores of tissue taken during the biopsy under a microscope to determine whether or not the prostate contains cancerous tissue. If the prostate contains cancer, the cancer is classified by a Prostate Cancer Gleason Score (Grade). The score is derived from the major and minor grades (each 1-5) of the cancer and is an indicator of how quickly the tumour might grow and how likely it is to spread outside of the prostate gland (degree of aggressiveness), and ultimately the patient's prognosis. The Prostate Cancer Gleason Score ranges from 2 to 10. To determine the Gleason score, the pathologist looks at the patterns of cells in the prostate tissue. The most common cell pattern is given a grade of 1 (most like normal cells) to 5 (most abnormal). If there is a second most common cell pattern, the pathologist gives it a grade of 1 to 5. The pathologist takes the two most common grades together to make the Gleason score e.g. 3 + 4 = 7. If only one pattern is seen, the pathologist counts it twice, e.g. 3 + 3 = 6. A high Gleason score (such as 9 or 10) means that it is a high-grade prostate tumour which makes it more likely to grow quickly and spread.

In 2014, the International Society of Urological Pathologists released a revised prostate cancer grading system called the ISUP Grade Groups (Epstein et al. 2016). The new prostate grading system is an extension of the Gleason Score for determining the stage of prostate cancer and is designed to focus on better representing low grade disease to reduce unnecessary treatment of prostate cancer.

Table 16. Gleason score and ISUP grade groups.

Gleason Score	ISUP Grade Groups	Risk
Gleason 3+3=6	Grade 1	Low
Gleason 3+4=7	Grade 2	Intermediate Favourable
Gleason 4+3=7	Grade 3	Intermediate Unfavourable
Gleason 4+4=8	Grade 4	High
Gleason 9, 10	Grade 5	High

9

Table 17. Gleason score at diagnosis.

Gleason Score	Number (n)	Percent (%)
3 + 3	1646	35.0
3 + 4	1416	30.1
4 + 3	700	14.9
4 + 4	497	10.6
4 + 5	316	6.7
5 + 4	80	1.7
5 + 5	47	1.0
Total	4702	100.0

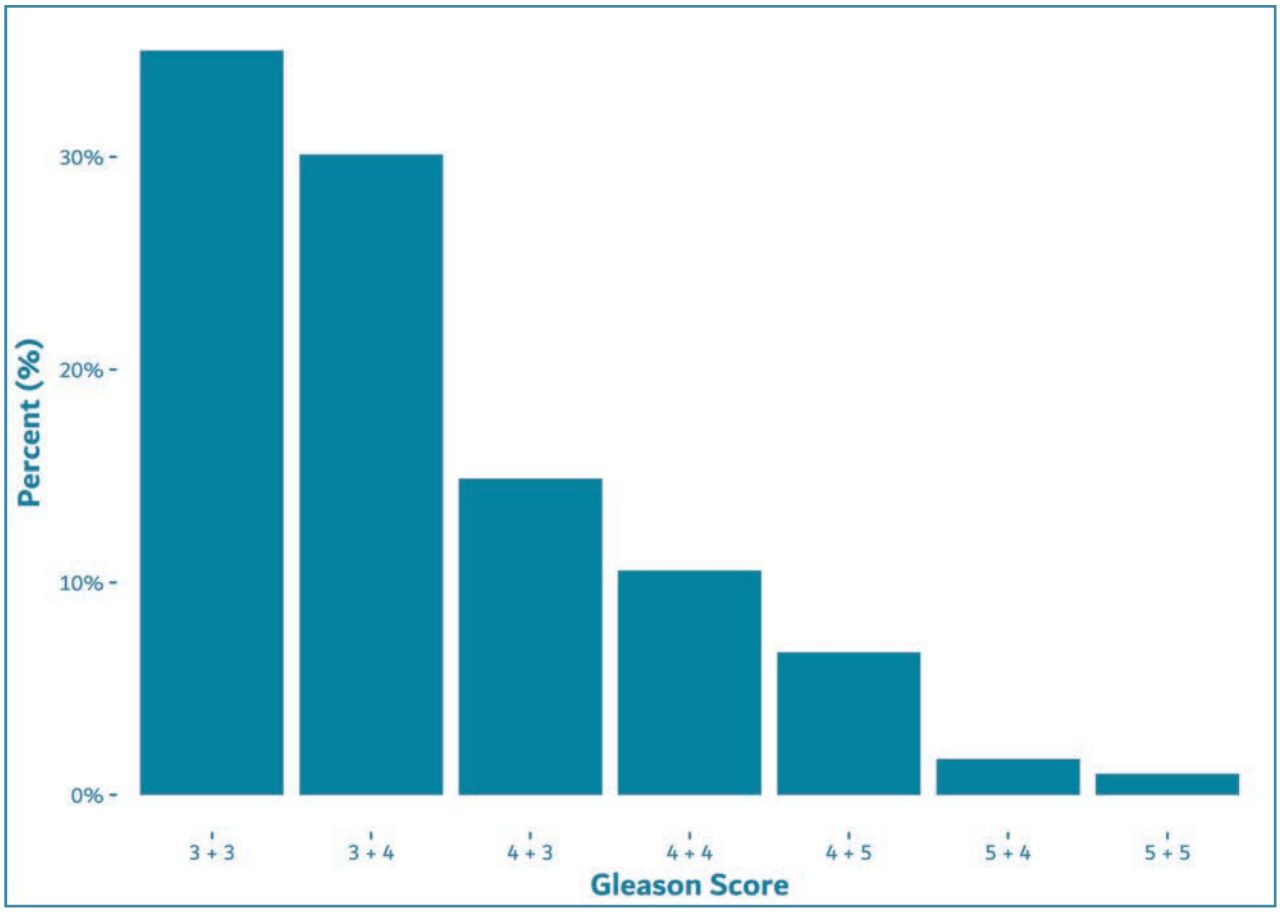

Figure 12. Gleason score at diagnosis (n=4702).

Figure 12 and Table 17 show approximately one third of men are found to have low grade Gleason 3 + 3 (ISUP Grade 1) prostate cancer. Low volume Gleason 3+3 disease is suitable for active surveillance treatment (Stavrinides, Parker, and Moore 2017). Nearly two in three men are diagnosed with Gleason 3+3 and Gleason 3+4 prostate cancer which is generally associated with a good outcome.

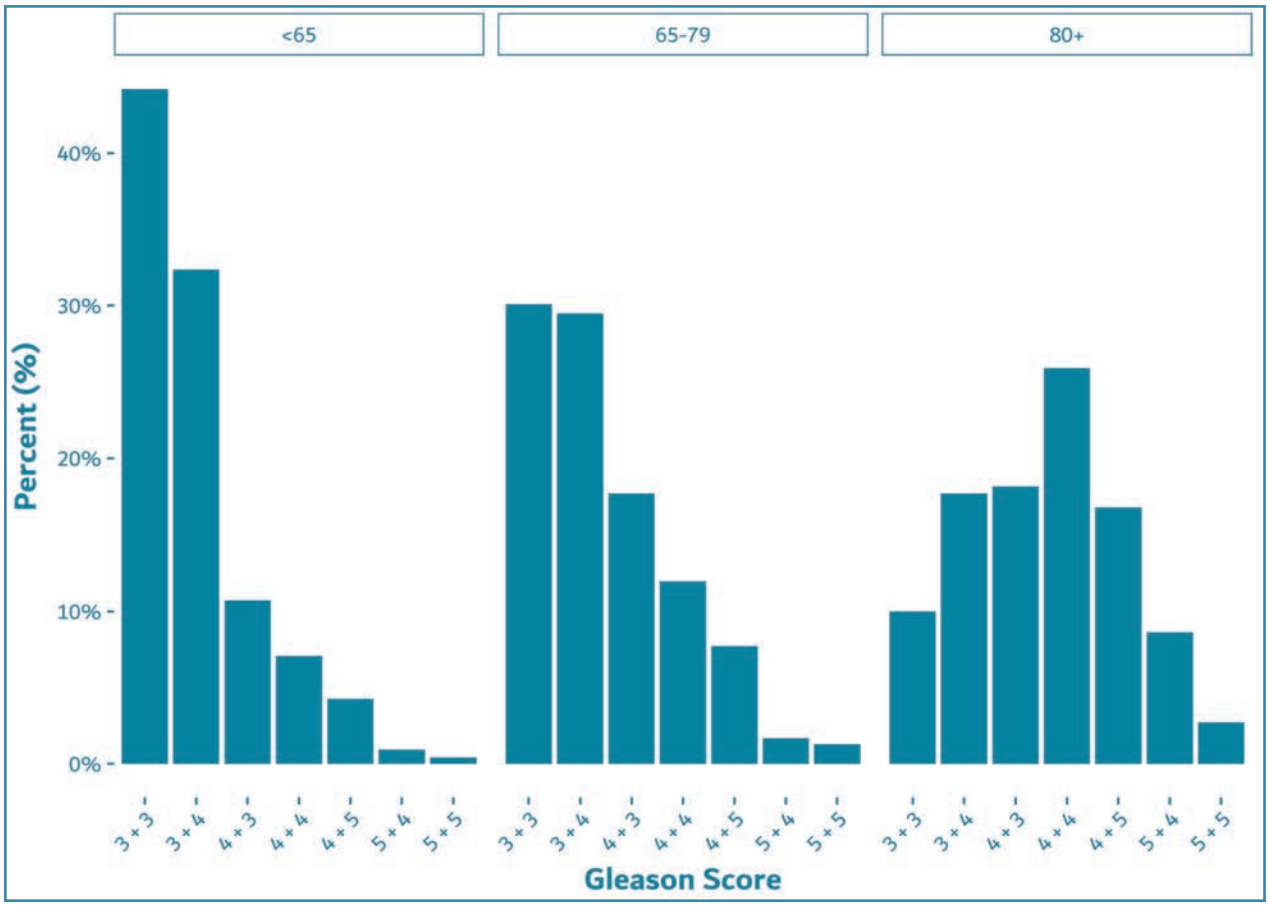

Figure 13. Gleason score at diagnosis by age (n=4868).

Figure 13 examines disease grade by age and reveals that higher grades are more commonly diagnosed in older men. It is reassuring that low grade disease is less likely to be diagnosed in men over 80 as clinicians are much less likely to biopsy men in this population without signs of more high grade disease. The advent of MRI imaging of the prostate has spared many older men unnecessary biopsies. Clinicians are naturally more cautious with younger men and have a lower threshold for biopsy. Published nomograms (for example, Walz et al. 2007, Suardi et al. (2008), Makarov et al. (2007)) or the Irish Prostate Cancer calculator (Foley et al. 2016) have been shown to reduce the need for biopsies but are not widely used in Ireland.

9

ISUP Grade Groups (New Gleason Score)

Table 18. ISUP grade groups at diagnosis.

ISUP Grade	Number (n)	Percent (%)
1	1649	35.0
2	1413	30.0
3	696	14.8
4	515	10.9
5	444	9.4
Total	4717	100.0

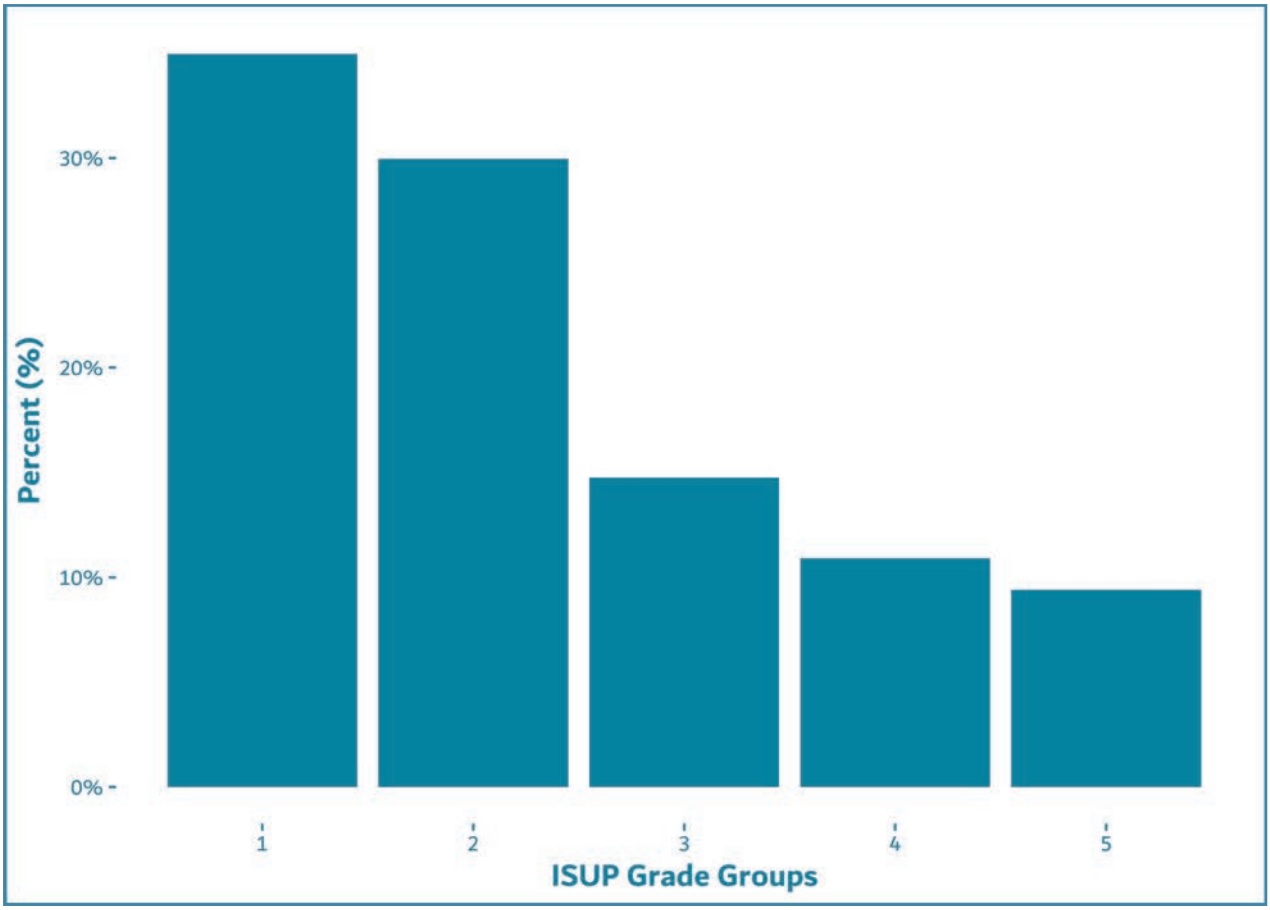

Figure 14. ISUP grade groups at diagnosis (n=4717).

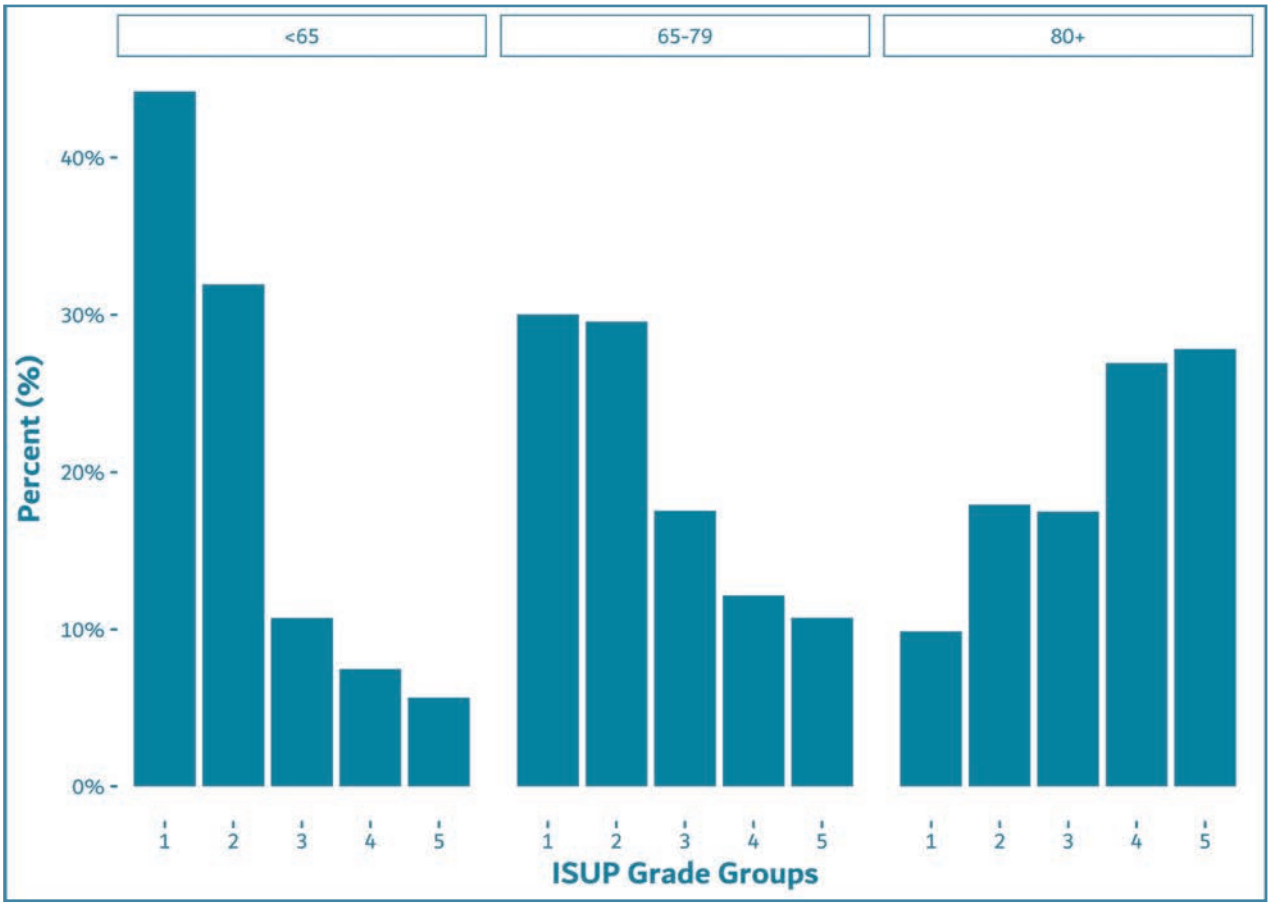

Figure 15. ISUP grade groups at diagnosis by age.

Table 18 and Figure 14 show men categorised according to the new ISUP grading system. In Figure 15, ISUP grading shows more clearly that the majority of men under 79 years of age are diagnosed with less aggressive disease (ISUP grade 1-2), whereas men over 80 are diagnosed with more aggressive disease (ISUP grades 3, 4 and 5).

There is a marked reduction in low grade prostate cancer and a higher incidence of high grade prostate cancer with age. Whether this represents a true phenomenon or just the judicious use of prostate biopsy will need to be determined. It appears that clinicians demonstrate a degree of clinical discretion, possibly influenced by MRI imaging, in determining the need for prostate biopsy as men age.

9.3 Method of presentation

In this section, the method of how men are presenting to their GP and urologist is examined. By reviewing the medical records, men are categorized as either presenting with symptoms due to their underlying prostate cancer or not. There has been much publicity against routine PSA testing recently and the United States Preventative Services Task Force recommended against routine screening in men 70 and older (US Preventive Services Task Force 2018). GPs in Ireland are advised by the NCCP to discuss the pros and cons of testing with men beforehand. PSA testing in primary care is not well characterised.

9

Table 19. Number and percentage of men by method of presentation.

	Number (n)	Percent (%)
Screening opportunistic	3340	81.7
Incidental	197	4.8
Symptoms	351	8.6
Unknown	201	4.9
Total	4089	100.0

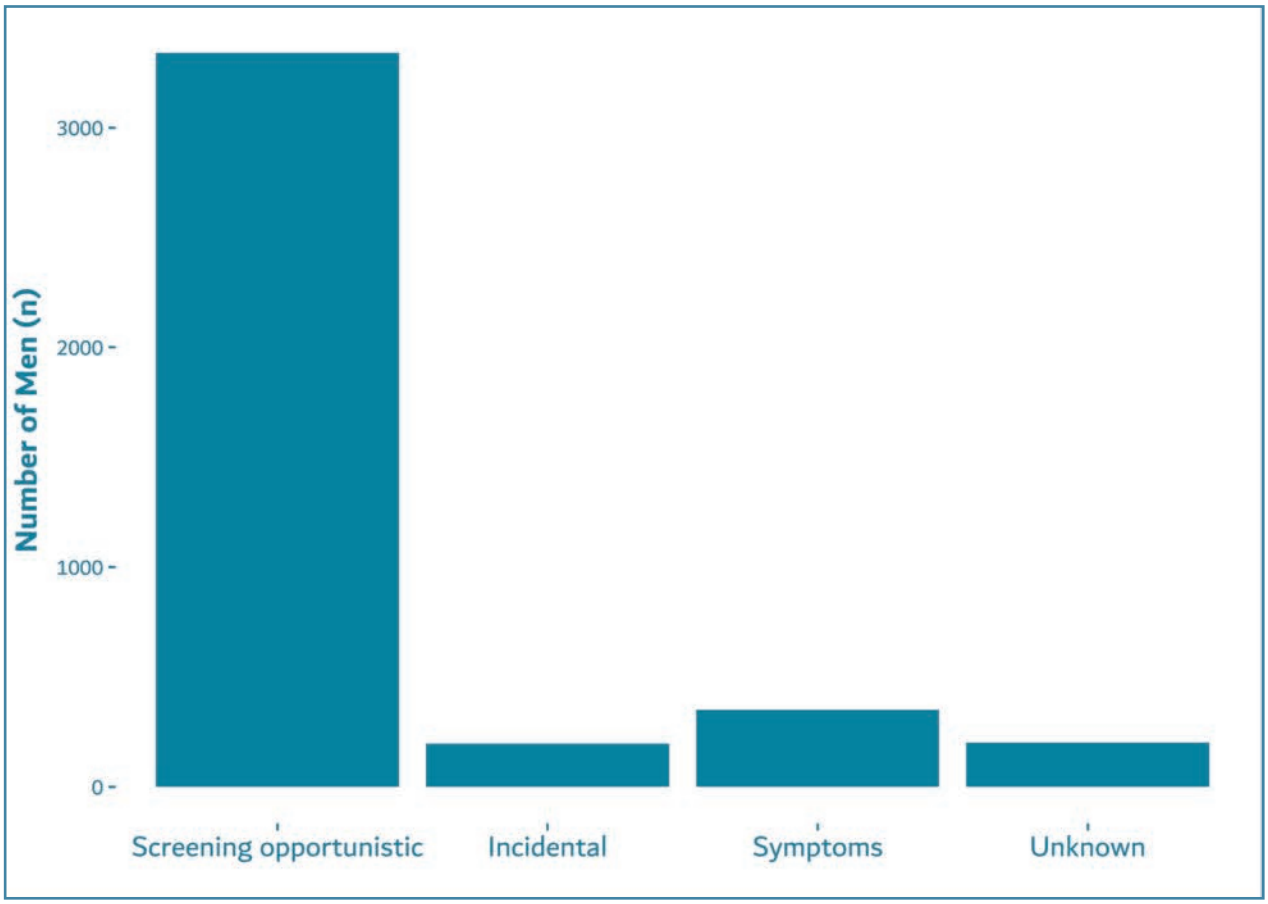

Figure 16. Number of men by method of presentation (n=4089).

Figure 16 and Table 19 show that prostate cancer is detected in three quarters of men by screening (i.e. PSA blood test). Men are commonly told to talk to their GP if they are experiencing symptoms such as urinary problems. However, the majority of men have no symptoms and their prostate cancer is first detected by an abnormal PSA level. Therefore, men should discuss PSA testing with their GP; early diagnosis of prostate cancer leads to better outcomes.

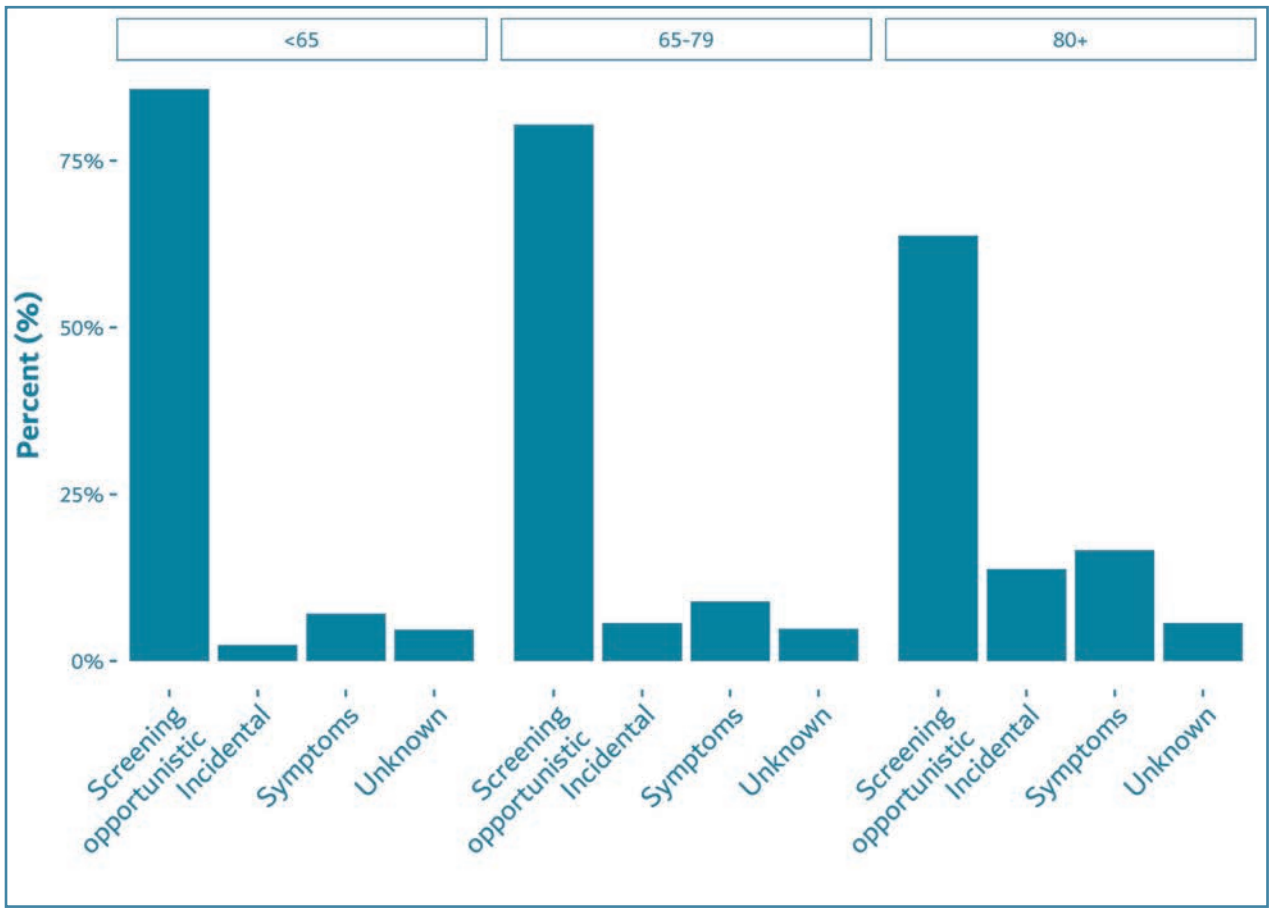

Figure 17. Percentage of men by method of presentation by age.

Figure 17 demonstrates that men over 80 are more likely to experience symptoms of prostate cancer prior to their diagnosis. As previously demonstrated in Figures 13 and 15, men over 80 are more likely to be diagnosed with more aggressive, high grade prostate cancer. The opportunity to detect these cancers earlier in a man's life may have been possible with earlier PSA testing.

9.4 Prostate cancer staging

Staging prostate cancer means assessing the extent of the disease's spread in the body. Often TNM staging is used. If the disease has spread far from the prostate (e.g. to bones), it is said to be metastatic prostate cancer. The M in TNM quantifies the metastatic stage (M0 = no spread, M1= spread). Similarly, if the spread involves the lymph nodes, the N in TNM clarifies the status of the lymph nodes, N0 = no nodal involvement, N1 = nodal involvement, NX= lymph nodes cannot be assessed. The T or tumour stage assesses the local stage of the cancer (T1c = impalpable tumour detected, T2 = tumour confined to prostate, T3 = tumour extends outside the prostate capsule, T4 = tumour fixed or invades adjacent structures). The classification of the tumours here is related to both clinical examination and radiology examination pre-treatment as per the AJCC guidelines (Edge and Compton, 7th Edition, 2010). Note: We present T2 and T3 not further classified into T2a, T2b and T2c or T3a and T3b, respectively, due to difficulties in collecting the data.

9

Tumour (T) stage

Table 20. Number and percentage of men in each clinical T stage category.

	Number (n)	Percent (%)
TX	7	0.2
T1a	78	2.1
T1b	63	1.7
T1c	742	19.8
T2	2186	58.2
T3	610	16.2
T4	68	1.8
Total	3754	100.0

Table 20 shows that 58.2% of men have prostate cancer confined to the prostate (T2) and 19.8% of men an impalpable tumour (T1) detected.

Nodal (N) stage

Table 21. Number and percentage of men in each clinical N stage category.

	Number (n)	Percent (%)
NX	402	11.6
N0	2842	82.1
N1	216	6.2
Total	3460	100.0

Table 21 that only 6.2% of men are presenting with prostate cancer with nodal involvement as per radiological examination. Prostate cancer that involves the lymph nodes is difficult to cure, and despite treatment, men are at a high risk of recurrence. Men often need several forms of treatment to try to eradicate the cancer.

Metastases (M) stage

Table 22. Number and percentage of men in each clinical M stage category.

	Number (n)	Percent (%)
M0	2463	91.3
M1	235	8.7
Total	2698	100.0

Table 22 shows that 8.7% of men present with cancer that has spread beyond the pelvis. Metastases are most common in the bones, lungs or liver and detected on CT or bone scan. Men with metastases will generally be treated with hormonal therapy and possibly chemotherapy.

9.5 Cancer of the Prostate Risk Assessment (CAPRA) Score

The CAPRA score is a risk assessment tool and predicts the likelihood of prostate cancer to spread to other parts of the body and the likelihood a man will die from prostate cancer (Cooperberg, Broering, and Carroll 2009). Table 23 shows how the CAPRA score is calculated using points assigned to: age at diagnosis, PSA at diagnosis, Gleason score of the biopsy, clinical stage and percent of biopsy cores involved with cancer. The CAPRA score ranges from 0-10 with a CAPRA score of 0 to 2 indicating low-risk, 3 to 6 indicating intermediate-risk and a CAPRA score of 7 to 10 indicating high-risk. CAPRA score can be used to aid the patient and doctor in making decisions about treatment. Men's outcomes should be consistent with their CAPRA score, the lower the score, the more favourable the patient's prognosis.

Table 23. CAPRA scoring rules.

Variable	Ranges	Points to be assigned
Age at diagnosis	Under 50	0
	50 or older	1
PSA at diagnosis (ng/mL)	2.0–6.0	0
	6.1–10.0	1
	10.1–20.0	2
	20.1–30.0	3
	Greater than 30	4
Gleason score of the biopsy	1–3/1–3	0
(primary/secondary)	1–3/4–5	1
	4–5/1–5	3
Clinical stage (T-stage)	T1 or T2	0
	T3a	1
Percent of biopsy cores involved with cancer (positive for cancer)	less than 34%	0
	34% or more	1

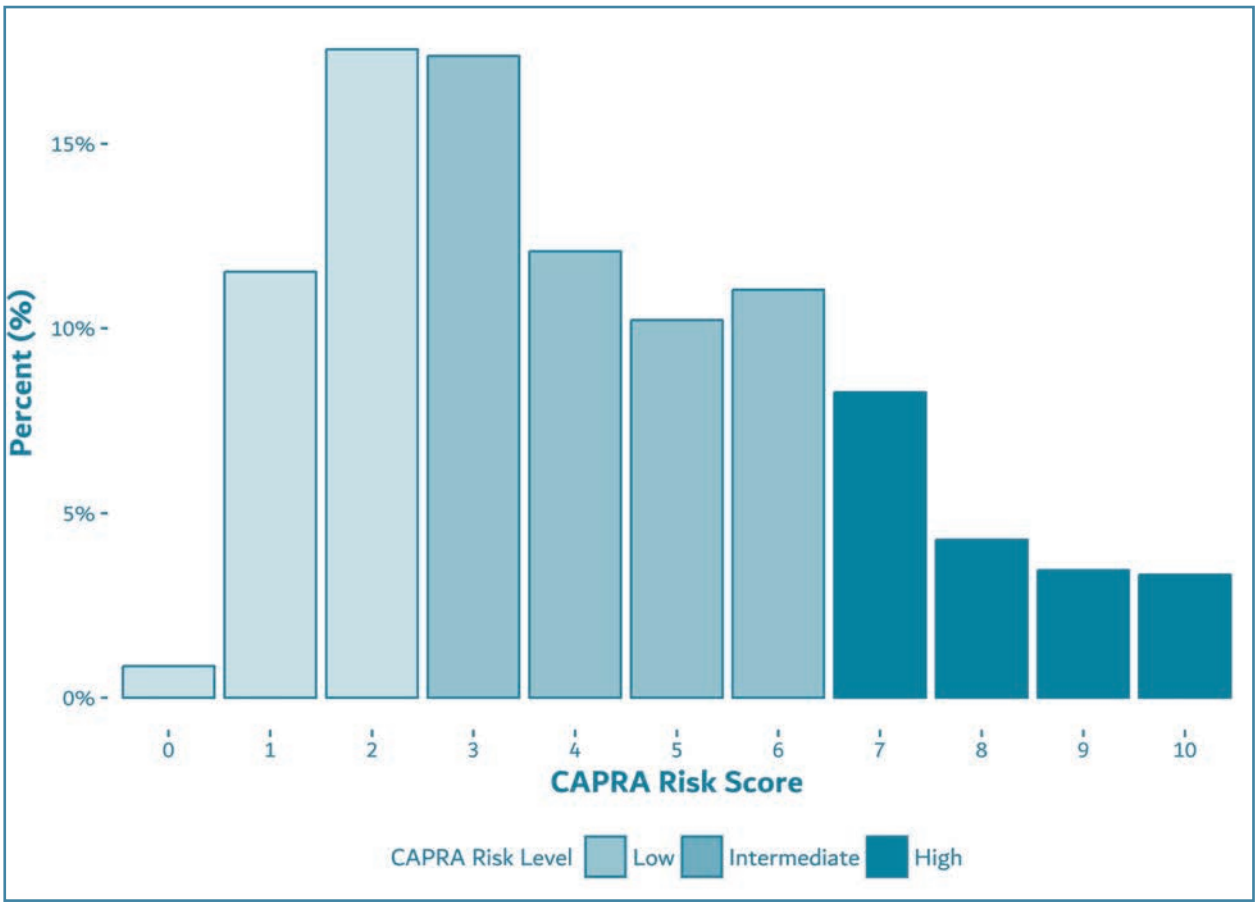

Figure 18. The percentage of men in each CAPRA risk score category (n = 3269).

Figure 18 shows the percentage of men in each CAPRA risk score category. 29.9 % of men are categorised as low-risk (have a score of 0-2), 50.7 % as intermediate-risk (have a score of 3-6) and 19.3 % as high-risk (have a score of 7-10).

9.6 Use of imaging in men with prostate cancer: MRI, CT and Bone scan

Magnetic Resonance Imaging (MRI)

MRI shows detailed images of soft tissues in the body using radio waves and strong magnets. A contrast material called gadolinium may be injected into a vein before the scan to see details better. MRI scans can give a very clear picture of the prostate and can be used to target the biopsy to specific parts of the prostate. MRI can also show if the cancer has spread outside the prostate into the seminal vesicles or other nearby structures which is important in determining a man's treatment options.

Computed Tomography (CT) scan

A CT scan uses x-rays to make detailed, cross-sectional images of the body. It can help determine if prostate cancer has spread into nearby lymph nodes or if the cancer has spread to distant sites in the chest, liver or bones.

Bone scan

A bone scan can show if prostate cancer has spread to the bones. To carry out a bone scan, a small amount of low-level

radioactive material is injected into a man, which settles in damaged areas of bone throughout the body. A special camera detects the radioactivity and creates a picture of the man's skeleton. A bone scan may suggest cancer in the bone, but to make an accurate diagnosis, further tests such as x-ray, CT or MRI scans, or even a bone biopsy might be needed.

Table 24. Number and percentage of men who had each type of imaging scan.

	MRI (n)	MRI (%)	CT (n)	CT (%)	Bone scan (n)	Bone scan (%)
Yes	3881	79.7	928	19.1	2870	59.0
No	987	20.3	3940	80.9	1998	41.0
Total	4868	100.0	4868	100.0	4868	100.0

Table 24 shows the number and percentage of men who had an MRI, CT or bone scan. MRI was the most common scan with nearly 80% of men having an MRI, 59% of men had a bone scan and 19% of men had a CT scan. The volume of imaging involved in prostate cancer diagnosis and staging across Irish hospitals is enormous and the efforts of radiology departments and radiologists must be recognized.

In the next section, we discuss MRI in more detail.

MRI

Table 25. Percentage of men having an MRI scan in public and private hospitals.

	Private	Public <70	Public ≥ 70
MRI % Yes	85.7	79.7	69.9
MRI % No	14.3	20.3	30.1
Total	100.0	100.0	100.0

Four-in-five men with prostate cancer underwent MRI scanning. Table 25 shows that 85.7% of men in the private system had an MRI, 79.7% of men who had access to the RAPC had an MRI and 69.9% of men in the public system over 70 had an MRI.

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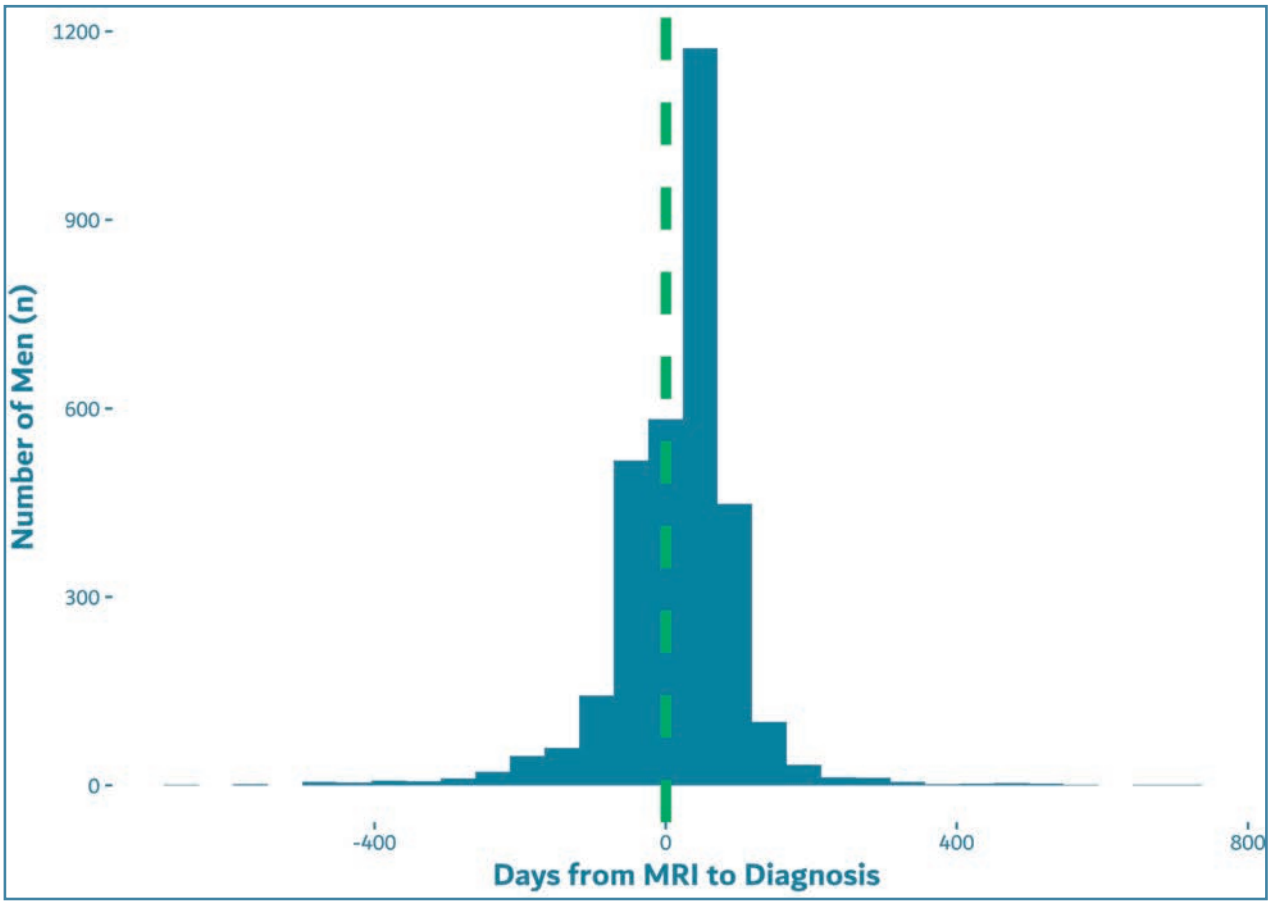

Figure 19. The distribution of the number of days from diagnosis to MRI for men diagnosed with prostate cancer. Times to the left of the green line are pre-biopsy MRIs and those to the right are staging MRIs (n = 3213).

Figure 19 shows the number of days from a man's biopsy to having an MRI. Data to the left of the green line shows men who had an MRI before their biopsy. The results of the MRI could be used to target their biopsy to areas of interest in the prostate. The data to the right of the green line shows men who had their MRI after their biopsy, therefore, the results from the MRI were used to stage their cancer.

Table 26. Number and percentage of men who had an MRI by type of MRI.

	Number (n)	Percent (%)
Staging MRI	1857	38.1
Pre-Biopsy MRI	1357	27.9
No MRI Recorded	967	19.9
MRI Type Unknown	687	14.1
Total	4868	100.0

In Table 26 the MRIs are categorised by type depending on whether they were performed before or after the man's biopsy. 27.9% of men had an MRI before their biopsies allowing for targeted biopsies which are more accurate (Kasivisvanathan et al. 2018). The recent PROMIS study recommended that pre-biopsy MRI as the gold standard (Ahmed et al. 2017), so it is encouraging to see that this practice is being adopted into Irish healthcare. 38.1% of men had a staging MRI following their diagnostic biopsy, 14.1% of men had an MRI but it is unknown if it was before or after their biopsy and 19.9% of men had no MRI recorded.

Table 27. Percentage of men in public and private hospitals having an MRI scan categorised by scan type.

	Private	Public <70	Public ≥ 70
Staging MRI	23.3	52.2	35.4
Pre-Biopsy MRI	48.5	16.0	18.4
No MRI Recorded	13.6	20.0	29.9
MRI Type Unknown	14.6	11.8	16.3
Total	100.0	100.0	100.0

Table 27 shows 48.5% of men diagnosed in private hospitals had a pre-biopsy MRI, whereas only 16% of men under 70 and 18.4% of men, aged 70 and over, diagnosed in public hospitals had a pre-biopsy MRI. Private patients are more likely to have their MRI done before their biopsy due to better access to MRI in the private healthcare sector. 29.9% of men, aged 70 and over, diagnosed in a public hospital had no MRI recorded, while 13.6% of private patients had no MRI recorded.

9

Imaging and CAPRA Risk Score

CT

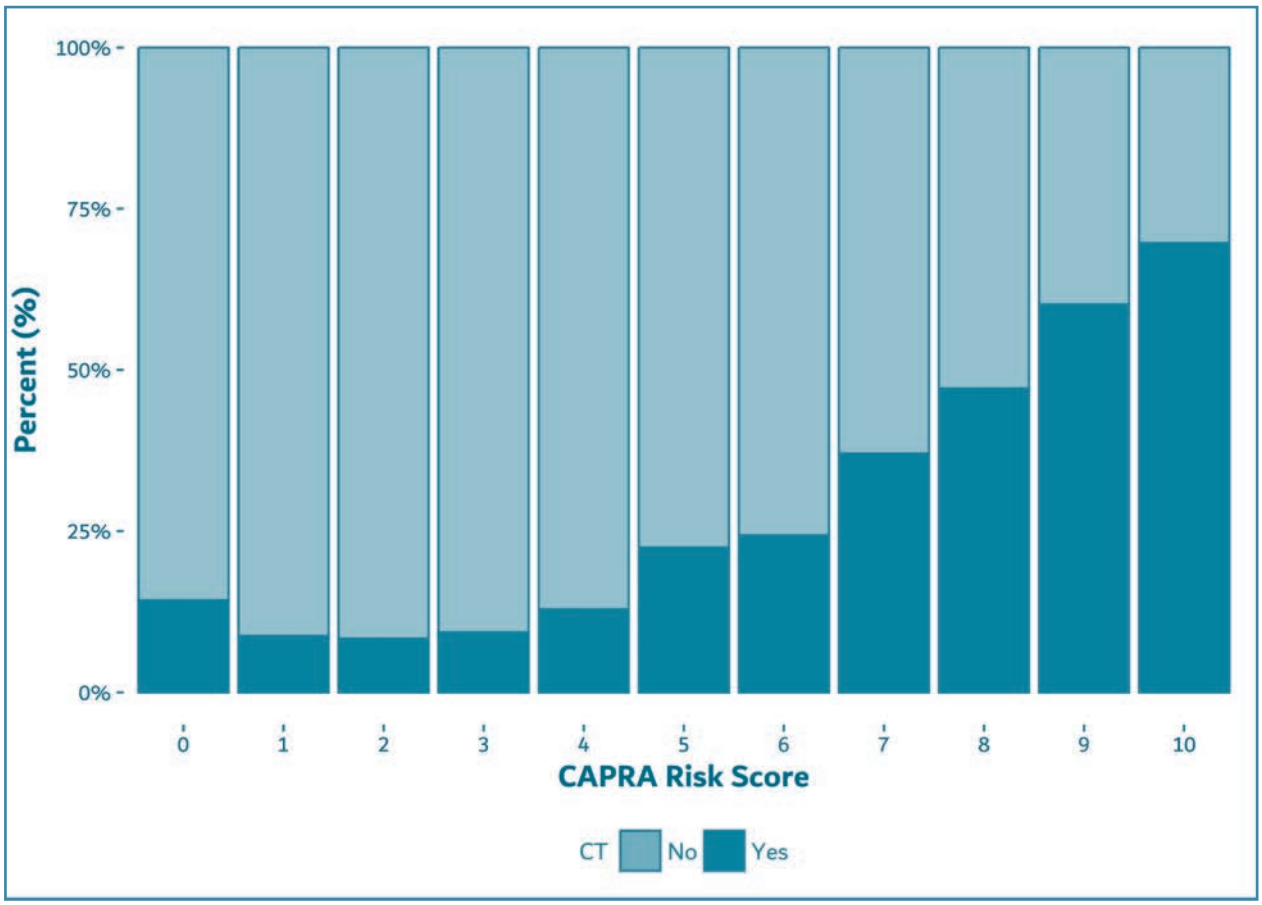

Figure 20. Percentage of men who had CT by CAPRA risk score (n =3269).

Figure 20 shows that as the risk score increases men are more likely to have a CT scan. 49.1% of men with a CAPRA score between 7 and 10 (i.e. high risk) had a CT scan. CT imaging in prostate cancer is used to identify possible metastases in men at risk of disseminated disease. As per NCCP prostate cancer guidelines, CT staging is recommended in high risk disease.

Bone scan

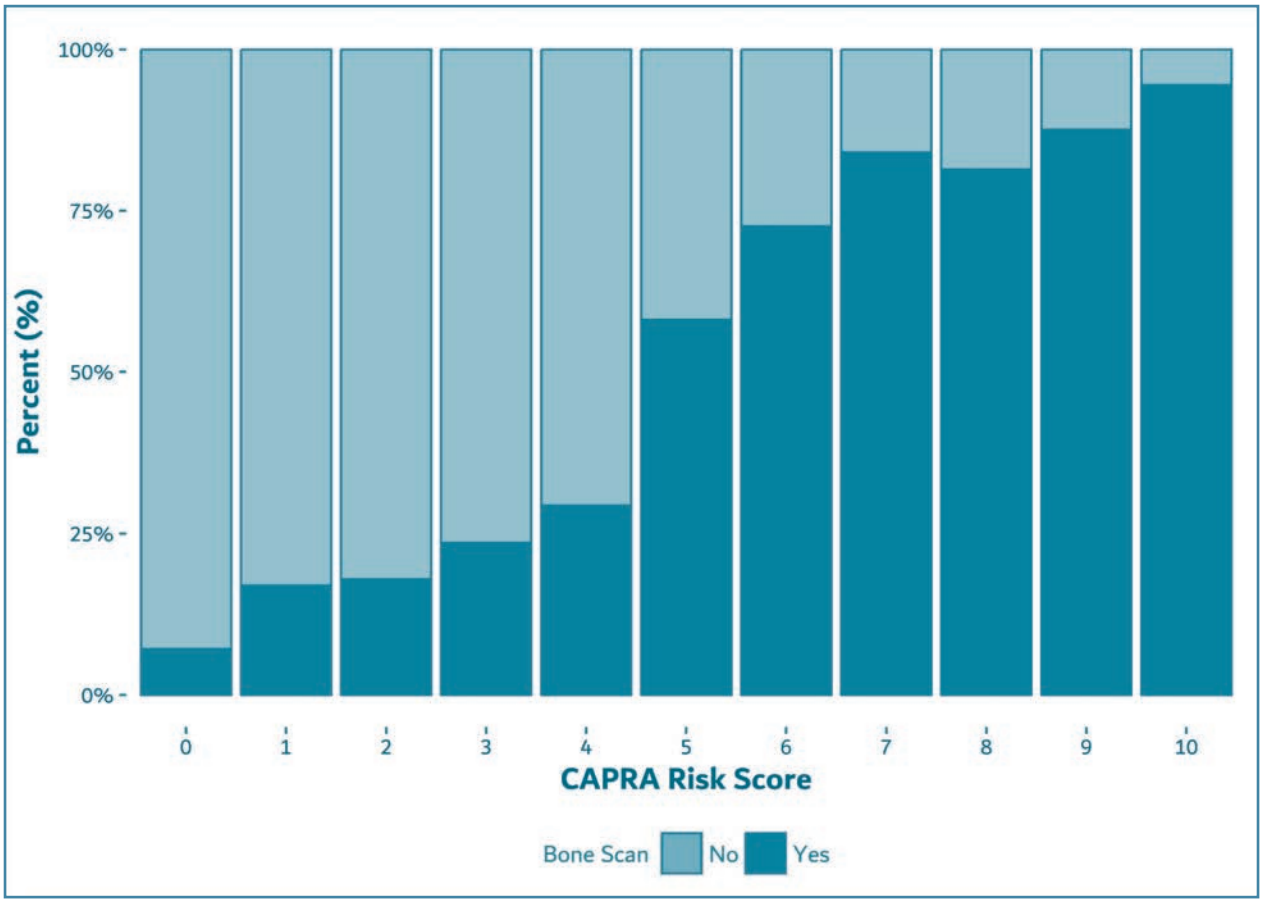

Figure 21. Percentage of men who had a bone scan categorised by CAPRA risk score (n =3269).

Figure 21 shows the percentage of men who had a bone scan categorised by their CAPRA risk score, as the risk score increases men are more likely to have a bone scan. 85.9% of men with a CAPRA score between 7 and 10 (i.e. high risk) had a bone scan.

Bone scan imaging in prostate cancer is used to identify possible metastases in men at risk of disseminated disease. As per NCCP prostate cancer guidelines, a bone scan is recommended in high risk disease.

9

MRI Type and CAPRA

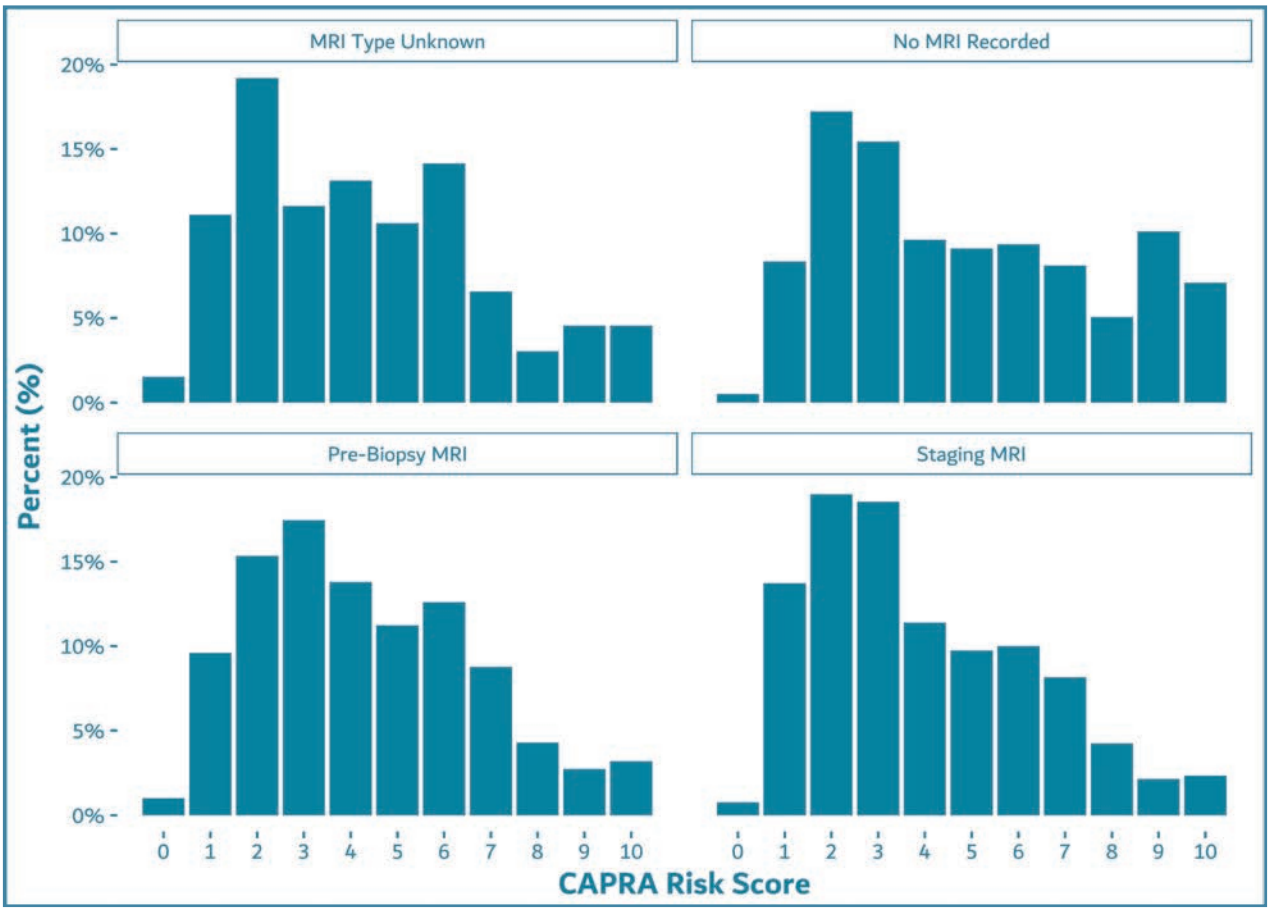

Figure 22. Percentage of men by MRI type and CAPRA risk score (n =3269).

Figure 22 demonstrates men who had no MRI recorded were more likely to have more aggressive high grade cancers than those who did undergo an MRI scan. This is possibly because they presented with disseminated disease and undergoing an MRI to stage localized disease was clinically irrelevant.

10. Future Plans for IPCOR

10.1 Publications

IPCOR will publish public-facing reports and individual hospital and clinician reports annually. This report represents our 3rd annual report; the first two reports detailing IPCOR's governance structures and establishment of the national registry. IPCOR will report to hospitals and clinicians on the current dataset by the end of Q2 2019. Annual Publications will include:

(a) A public-facing report
(b) Individual clinician report to each contributing clinician
(c) Individual hospital report to each contributing hospital

10.2 Research

As data on men's prostate cancer journey accrues in the registry over time, the ability to carry out high quality research into the disease, its outcomes and the care provided to patients is enhanced. The IPCOR investigators are charged with interrogating the data with the purpose of making recommendations to stakeholders and healthcare providers. The IPCOR data will be used to drive clinical research and to generate reports and peer-reviewed publications. The IPCOR investigators will lead a clinical research programme focusing on:

1. Geographical inequalities in access to timely care
2. Timely access to tests and treatment
3. Patient reported outcomes following treatment
4. National adoption of active surveillance guidelines
5. Clinical outcomes for cancer stage and grade

Research studies will be carried out in collaboration with the National Cancer Control Programme and Cancer Trials Ireland.

Independent researchers will also be invited to perform research on the IPCOR database. Applications for access to data can be made through the IPCOR website. All applications must be reviewed and approved by the IPCOR Steering Committee and de-identified data will be released in accordance with IPCOR policies and procedures.

10.3 Funding

The establishment of a national registry and the accumulation of valuable clinical and patient reported information on a cancer population takes years. Therefore, the IPCOR registry needs to be funded into the future. IPCOR is examining many ways of generating income and future funding, and is actively pursuing the following options:

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(a) Ongoing support from the Movember Foundation:
The Movember Foundation understands the potential of IPCOR to drive improvements in prostate cancer care in Ireland. The Movember Foundation supports IPCOR in achieving its full potential and has offered financial resources to IPCOR beyond the current funding period.

(b) Funding from Health Services Executive (HSE) or Department of Health:
IPCOR Principal Investigator, Mr David Galvin, is invited to speak at the next HSE Leadership Team meeting in 2019 where he will outline how IPCOR data can be used to enhance cancer care and will request future funding to sustain the core infrastructure of the registry.

(c) Funding from Grant applications:
IPCOR will seek to identify suitable and appropriate funding calls and work with our collaborators in the National Prostate Cancer Research Consortium to obtain research funding.

(d) Funding from third party pharmaceutical companies:
The Investigators will continue to leverage their collaborations with colleagues in the pharmaceutical industry to secure additional funding. IPCOR will also strengthen our collaboration with Cancer Trials Ireland with a view to the IPCOR registry supporting cancer drug trials in the future.

(e) Long term collaboration with National Cancer Registry:
IPCOR and the NCRI have an excellent and close working relationship. The NCRI wishes to pursue the development of an enhanced cancer data registry and aims to fund the IPCOR research officers to continue collecting IPCOR's comprehensive clinical dataset. While clinical data collection may be supported by NCRI in the future, additional resources are still required to collect PROMs, enhance engagement with clinical teams and to augment the IPCOR research portfolio.

Additional Funding

IPCOR received funding from:	Funded IPCOR Initiatives
Astellas Pharma Ireland	Electronic PROMs collection tool, patient app, clinical database development
Janssen Ireland	Psycho-oncology patient videos
IPSEN Pharmaceuticals	Physiotherapy patient videos

11. Investigators' Note

The clinical data contained within this report relates to the demographic and diagnostic information of men diagnosed with prostate cancer in 2016 and 2017. As IPCOR is a longitudinal study, our data will be more comprehensive each year. It is the ambition of the IPCOR Investigators that next year's report will include data on the treatments that men undergo and will report on key clinical outcomes that have been agreed with the Movember Foundation. While it will take many years to assess the long-term impacts of prostate cancer and its treatment, the goal of the Investigators is to ensure that the expanding IPCOR dataset is used to provide recommendations to healthcare decision makers which lead to improvements in prostate cancer care each year.

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Appendix I

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