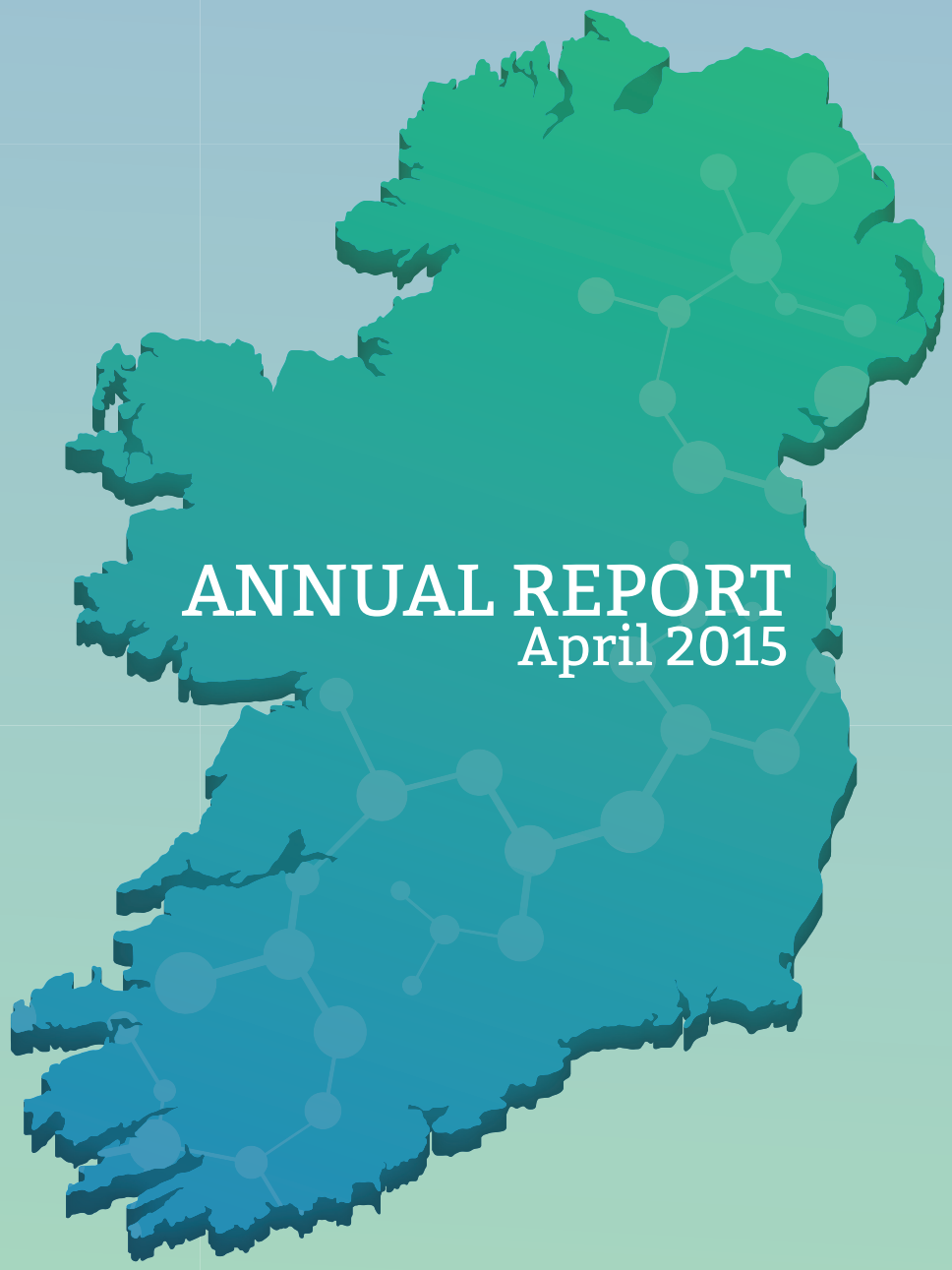
IPCOR

IRISH PROSTATE CANCER OUTCOMES RESEARCH



ANNUAL REPORT

April 2015

Irish Cancer Society Research

MOVEMBER FOUNDATION
CHANGING THE FACE OF MEN'S HEALTH

The IPCOR study is carried out by:

Molecular Medicine Ireland (MMI): MMI was established by the Royal College of Surgeons in Ireland, Trinity College Dublin, University College Dublin, NUI Galway, University College Cork, and their associated academic hospitals, as a partnership to accelerate the translation of biomedical research into improved diagnostics and therapies for patients. MMI's mission is to mobilise the strengths of the five partner institutions and their associated hospitals to build a sustainable national system to coordinate, support and promote translational and clinical research.

National Cancer Registry Ireland (NCR): 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 NCR 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.

HRB Clinical Research Facility in Galway (CRFG): The HRB Clinical Research Facility, Galway is a joint venture between Galway University Hospitals (GUH) and National University of Ireland, Galway (NUIG) which provides the infrastructure, physical space, facilities, expertise and the culture needed to optimally support patient-focused research and clinical studies.

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.

Funded by:

Movember Foundation: The Movember Foundation is a global charity raising funds and awareness for men's health. These funds deliver breakthrough research and support services to allow men to live longer, healthier lives. Since 2003, millions have joined the men's health movement, raising AUD $580 million and funding over 850 programmes through impact investments, focusing on prostate cancer, testicular cancer, poor mental health and physical inactivity. The Foundation's vision is to have an everlasting impact on the face of men's health.

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.

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Acknowledgements

The Irish Prostate Cancer Outcomes Research (IPCOR) study would like to thank all clinical and non-clinical staff in our participating hospitals, the Irish Society of Urology and the Irish Association of Urological Nurses for their support throughout the establishment of the prostate cancer registry. The IPCOR study is dependent on the continued support and participation of urological and oncological colleagues and hospital managers throughout the Republic of Ireland.

The IPCOR investigators would like to thank our colleagues in the National Cancer Registry for their guidance and expertise during the development of the IPCOR database and establishment of procedures for clinical data collection in the participating hospitals.

We acknowledge the support and input of the Irish Cancer Society, Movember Foundation and Men against Cancer during this crucial start-up phase of the study. We would also like to thank the Prostate Cancer Outcomes Registry – Australia and New Zealand whose contribution to the establishment of the IPCOR registry has been invaluable.

Team members

Mr. David Galvin	Consultant Urologist, IPCOR Principal Investigator Dublin Academic and Medical Centre St Vincent's University and Mater Misericordiae Hospitals
Prof Frank Sullivan	Consultant Radiation Oncologist, Professor of Radiation Oncology Co-Investigator National University of Ireland, Galway
Dr. Ray McDermott	Consultant Medical Oncologist, Co-Investigator Tallaght and St Vincent's University Hospitals,
Prof Linda Sharp	Professor of Cancer Epidemiology, Co-Investigator Newcastle University
Dr. Áine Murphy	Project Manager Molecular Medicine Ireland
Ms. Fiona Dwane	Data Manager National Cancer Registry Ireland
Dr. Leah Bentham	Research Officer National Cancer Registry Ireland

Foreword

Firstly, I would like to congratulate everyone who has contributed to the IPCOR project in a highly successful first year. This novel and ambitious project has had to face many unique challenges in its first year and has overcome each of these and now enters the exciting phase of clinical data collection. Future reports will be in a position to analyse this data and make recommendations, whereas this initial report provides details on the setup phase of the study. This enormous task has been expertly co-ordinated by Dr. Áine Murphy, project manager to IPCOR, without whom, this project would not have been successful. Her enthusiasm and attention to detail have gained respect for our project within the research community.

The unique and limited environment of electronic healthcare data collection in Ireland, which is without legislative support for modern research and registry work, creates challenges, and solutions are found through collaboration and compromise. The work of our collaborators the National Cancer Registry, Molecular Medicine Ireland and the Clinical Research Facility in Galway has allowed this project to reach its first year goals. We have worked closely with Professor Linda Sharp, and Ms. Fiona Dwane in the NCRI developing a superb clinical database and in hiring research officers. I wish to recognise the role of Mr. Paul Barry in MMI in facilitating the IPCOR project and the support he has given our project manager, Dr Áine Murphy and I. We welcome the involvement of the clinical research facilities/centres throughout Ireland that can facilitate this important clinical work. The generous and co-operative role played by funders the Irish Cancer Society and Movember Foundation is warmly appreciated especially the relationship we have built with Dr. Amanda Daly, Dr. Sinéad Walsh, Dr. Aisling O'Connor, Dr. Robert O'Connor, Mr. John McCormack and Mr. Paul Villanti. We have reached funding agreements for five years through collaborative discussion and continue to be engaged in Movember Foundation efforts globally to combat prostate cancer. I wish to acknowledge the ongoing support from the Prostate Cancer Outcomes Registry – Australia and New Zealand and Dr. Sue Evans who has guided us based on their experience setting up a similar registry in Australia. It is also important to note that the IPCOR project is just one part of the Irish Cancer Society's funding of prostate cancer research in Ireland, which also includes the Prostate Cancer Research Consortium (PCRC) and iPROSPECT. These 3 studies supplement each other and collaborate on an ongoing basis.

I also wish to acknowledge the roles played by all clinicians and nurses in Ireland involved in prostate cancer treatment. It is only through their work and efforts to improve care for our patients that a project like IPCOR will succeed. This project has the overwhelming support of virtually all Urologists, Radiation Oncologists and Medical Oncologists in Ireland and its profile remains high. We have run a very successful physician enrolment campaign and received ethical approval in all 17 hospitals for the project to start collecting clinical data. This study also has the support of Men Against Cancer (MAC), a national support group for men with prostate cancer and their families.

With personnel being employed for data collection and the database finalised, we now enter an exciting and ambitious phase of data collection on men with prostate cancer and I look forward to future annual reports.

David Galvin, Principal Investigator

Executive Summary

The first annual report of the Irish Prostate Cancer Outcomes Research (IPCOR) study describes the framework developed for establishing a national, longitudinal, prospective and population based prostate cancer registry. The study hopes to access the processes of care and the outcomes of men diagnosed with prostate cancer in the Republic of Ireland.

The IPCOR study is proudly funded and supported by the Movember Foundation and the Irish Cancer Society for a five year period. The study will collect clinical and patient reported outcome data on newly diagnosed prostate cancer patients before treatment commences and annually thereafter. IPCOR aims to monitor, benchmark and publicly report annually on the outcomes of prostate cancer treatment and care in the Republic of Ireland. The study will provide risk adjusted, evidence based data and recommendations to clinicians, hospitals and decision makers, such as the National Cancer Control Programme (NCCP), that promote improvements in prostate cancer care. IPCOR will compare our national results with similar international studies, such as those in the UK and Australia, to ensure that Irish patients are receiving the highest standards of care in the world.

During the first year of the study, the framework for establishing the IPCOR registry was set up and significant milestones for the study were achieved.

- The IPCOR governance structure was set up and comprises a steering committee, management committee and data management committee. A scientific advisory board and sustainability working group have also been established to provide guidance and advice to the steering committee regarding the strategic direction of the study.
- An implementation plan for the establishment and running of the IPCOR registry was devised and approved by a panel of international experts.
- The study has received ethical approval from ten Research Ethics Committees which govern the 17 hospitals from which newly diagnosed prostate cancer patients will be identified.
- The study has received the support of prostate cancer treating clinicians ie. urologists, medical oncologists and radiation oncologists. These clinicians have consented to IPCOR contacting their prostate cancer patients to ask them to participate in the patient reported outcome component of the study.
- The clinical dataset, which the IPCOR study aims to collect, has been selected and will be piloted during the first phase of the study to determine the feasibility of collecting each data item. The dataset will then be refined, finalised and collected for all men who are recruited to the study.
- The questionnaires to be administered to men with prostate cancer to assess their quality of life have been selected. A prostate cancer specific quality of life questionnaire, EPIC-26, will be used along with EORTC QLQ-C30 and EuroQol EQ-5D-5L which measure generic aspects of a patient's quality of life. These questionnaires will be completed by men before treatment commences and annually thereafter.
- The two IPCOR databases, the clinical database at the National Cancer Registry and the Patient-reported Outcomes Measurements (PROMs) database at the Clinical Research Facility in Galway (CRFG), have been developed and have undergone testing. The databases

will ultimately be merged using a unique patient identification number to form the IPCOR registry.

- A research officer has been recruited by the IPCOR study to begin identifying men newly diagnosed with prostate cancer and collecting the clinical dataset in hospitals in the southwest of Ireland.
- The IPCOR registry has aligned its clinical and PROMs data collection with the dataset recommended by the International Consortium for Health Outcomes Measurement (ICHOM) Prostate Cancer Working Group to allow for international benchmarking.
- The IPCOR study has liaised with colleagues involved in similar prostate cancer registry endeavours in the UK and Australia to ensure comparability across all studies.
- IPCOR team members have met with researchers, both academic and industry based, who are interested in collaborating to foster novel research into prostate cancer causes, treatments and care.

1. Background

The 2006 Strategy for Cancer Control in Ireland outlined the need for more cancer research extending over a number of key areas and specifically highlighted epidemiological and health services research as current areas of deficit. There is no collaborative clinical research in prostate cancer in Ireland and as a result there is a paucity of information. In 2012, 3,384 men were diagnosed with prostate cancer in Ireland (Cancer Factsheet-Prostate 2015, National Cancer Registry Ireland). Irish men now have a one-in-seven chance of developing prostate cancer (Cancer Factsheet-Prostate 2015, National Cancer Registry Ireland), and prostate cancer incidence rates in Ireland are the highest in Europe and amongst the highest in the world (Ferlay et al 2010). This dearth of information may negatively impact clinical outcomes of prostate cancer patients in Ireland.

As clinicians, we are unable to inform these patients of their expected clinical outcomes with any accuracy, as no Irish data currently exists beyond overall and cancer-specific survival. Information is lacking on key intermediate clinical outcomes such as risk of recurrence or rates of treatment failure. Nothing is known about patterns of treatment beyond the first year after diagnosis. Moreover, while it is well known that most prostate cancer treatments are associated with side-effects (such as impotence or incontinence) there is little robust, population-based, longitudinal data on men's experiences of care, functional and psychological wellbeing and health-related quality-of-life. We often rely on international figures and the outcome of many of our patients is unknown. As Irish clinicians, we strive to improve our patient's outcomes, both clinical and patient-reported. We have a strong desire to benchmark our results with international standards. Our vision is to collect detailed clinical and patient-reported data on Irish men's prostate cancer journey, both to better inform patients of their prospects and to inform future care delivery, knowledge of the disease and best use of health care innovations and resources.

Thus, the Irish Prostate Cancer Outcomes Research (IPCOR) study is establishing a national registry which captures high-quality information about newly diagnosed prostate cancer patients in the Republic of Ireland. The registry will collect clinical data about prostate cancer patients as well as the patient's self-reported experiences of care and health related quality of life. The registry also aims to foster future research into prostate cancer causes, treatments and care, which utilises both IPCOR data and patients' biological specimens.

For the first time, the IPCOR project brings together a collaborative partnership of all newly diagnosed prostate cancer patients and their physicians, the National Cancer Registry of Ireland (NCR), the HRB Clinical Research Facility in Galway (CRFG), the nation's major academic bodies represented by Molecular Medicine Ireland (MMI) and the National Cancer Control Programme (NCCP). The project is funded by Movember Foundation in partnership with the Irish Cancer Society. The research is being carried out by organisations at the forefront of health research in Ireland. MMI is a research partnership representing Ireland's five main academic institutions and their associated hospitals which aims to improve healthcare by facilitating clinical and translational research (www.molecularmedicineireland.ie). The NCR identifies, collects, records and reports information and conducts research relating to the incidence and prevalence of cancer and cancer related tumours in Ireland (www.ncri.ie). The CRFG provides infrastructure and expertise to support patient-

focused research studies and clinical studies with the goal of advancing patient care as quickly as possible (http://www.nuigalway.ie/hrb_crfg/).

IPCOR is a clinician led study. Mr. David Galvin, Consultant Urologist in St Vincent's University Hospital, St Vincent's Private Hospital and the Mater Misericordiae University Hospital is the Principal Investigator. The study's three co-investigators are: Dr. Ray McDermott, Consultant Medical Oncologist in St Vincent's University Hospital, St Vincent's Private Hospital and Tallaght Hospital, Professor Frank Sullivan, Consultant Radiation Oncologist in Galway University Hospital and the Galway Clinic and Professor Linda Sharp, Professor of Cancer Epidemiology at Newcastle University, UK and previously Head of the NCR Research Group.

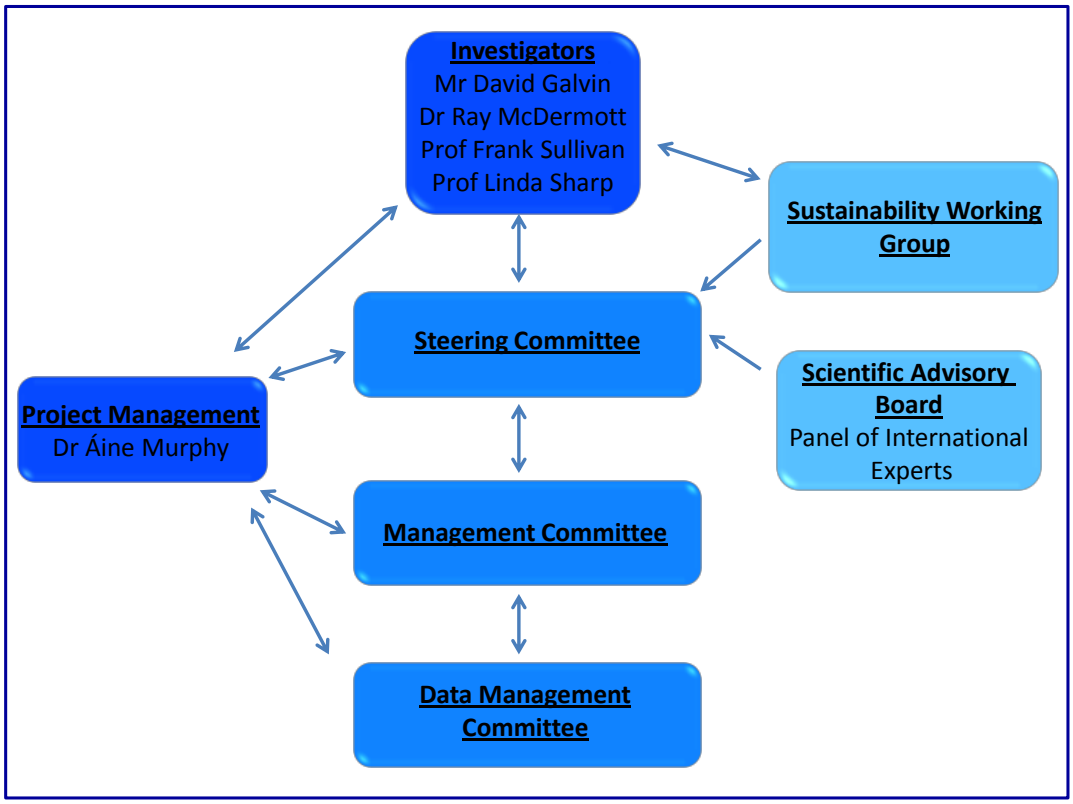
The registry will generate robust data on a range of important clinical outcomes of men with prostate cancer and assess processes, consistency and quality of prostate cancer care. By providing evidence-based data and recommendations to clinicians, hospitals, decision-makers and the National Cancer Control Programme, the registry will promote equal access to services and improvements in care nationally. By bringing together, for the first time, data on clinical and patient-reported outcomes that have been collected over time, the registry will ultimately lead to the improvement of patient experiences and maximise quality of life for men diagnosed with prostate cancer in the Republic of Ireland.

The main aims of the IPCOR study are to:

- Capture population-based representative data on the diagnosis, treatment and quality of life of men diagnosed with prostate cancer
- Monitor, benchmark and publicly report annually on the outcomes of prostate cancer treatment and care
- Provide risk-adjusted, evidence-based data and recommendations to clinicians, hospitals and decision makers that promote improvements in prostate cancer care
- Foster research that will use IPCOR data and patient's biological specimens to enhance our knowledge of prostate cancer and lead to improvements in care and survival
- Compare our national results with similar international studies, such as those in the UK and Australia, to ensure that Irish patients are receiving the highest standards of care in the world.

2. Governance

The organisational structure of the IPCOR study comprises of a Steering Committee, a Management Committee and Data Management Committee into which the lead investigators and the IPCOR project manager provide input, while the Scientific Advisory Board and the Sustainability Working Group provide recommendations to the Steering Committee.



2.1 Steering Committee

The Steering Committee has been established to strategically direct and govern IPCOR. It has ultimate responsibility for ensuring IPCOR meets its deliverables and milestones.

The specific responsibilities of the Steering Committee include:

- Providing strategic direction to IPCOR including oversight of the management committee and data management committee
- Signing-off on the detailed project protocol at the start of the project, and any substantive amendments to the protocol throughout the project
- Finalising the clinical and patient-reported data items to be collected
- Liaising with international groups to ensure data is compatible for international comparisons
- Agreeing key clinical and patient-reported outcomes, and sign-off the statistical analysis plan

- Agreeing key performance indicators and use these to monitor the performance of IPCOR
- Reviewing recommendations of the Scientific Advisory Board and determining which should be implemented
- Reviewing and endorsing the management committee and sub-group policies, standard operating procedures and terms of reference.
- Resolving issues escalated by the scientific advisory group, management committee or data management committee or project staff
- Establishing policies for data access and publication of IPCOR data
- Reviewing on an ongoing basis budgetary management for the project
- Encouraging involvement of centres and clinicians nationwide
- Agreeing a dissemination plan
- Signing-off on IPCOR annual reports

Steering Committee members

- **Urology**
  - Mr. David Galvin (Principal Investigator)
  - Mr. Frank O'Brien
  - Mr. Garrett Durkan
  - Mr. Peter Ryan

- **Radiation Oncology**
  - Dr. Gerry McVey
  - Professor Frank Sullivan (Co-Investigator)

- **Medical Oncology**
  - Dr. David Gallagher
  - Dr. Ray McDermott (Co-Investigator)

- **Pathology**
  - Dr. Stephen Finn

- **Epidemiology**
  - Professor Linda Sharp (Co-Investigator)

- **Patient Representative**
  - Mr. Jim Scott, Men Against Cancer (MAC)

- **National Cancer Control Programme**
  - Dr. Jerome Coffey

- **Prostate Cancer Outcomes Registry-Australia and New Zealand**
  - Dr. Sue Evans

- **Movember Foundation**
  - Mr. Paul Villanti

- **Irish Cancer Society**
  - Dr. Amanda Daly/ Dr. Sinéad Walsh
  - Dr. Aisling O'Connor

- **Molecular Medicine Ireland**
  - Dr. Áine Murphy (Project manager)

2.2 Scientific Advisory Board

The **Scientific Advisory Board** is comprised of a small group of internationally renowned experts who will provide advice on the scientific, methodological, international standardisation and quality of care aspects of the research. The Scientific Advisory Board will review IPCOR processes and procedures, data and outcomes and will report to the Steering Committee. The Scientific Advisory Board (individually or as a group) will also be available to the Steering Committee for consultation on specific topics and potential changes to the strategic direction of IPCOR. The key responsibilities of the Scientific Advisory Board are:

- Provide independent advice to Steering Committee to address issues of clinical interest or methodological and quality of care significance that may arise
- Review and advise on outputs from IPCOR
- Review and provide comment on reports published by IPCOR
- Provide advice on international standards, collection policies and interpretation of data

The members of the Scientific Advisory Board are:

- Professor Mark Frydenburg (Clinical Director of the Prostate Cancer Research Group, Monash University, Australia)
- Dr. Andrew Vickers (Research Methodologist, Memorial Sloan Kettering Cancer Centre, USA)
- Dr. Neil Martin (Radiation Oncologist, Dana Farber Cancer Institute)
- Mr. Paul Cathcart (Consultant Urologist, University College Hospital London)

- Professor Par Stattin (Umeå University, Sweden and PI of PCBaSe Sweden)

2.3 Participating Hospitals and Clinical Representatives

The NCR has a statutory obligation to collect information, including treatment and outcome, on all new cases of cancer diagnosed in Ireland. All healthcare institutions in Ireland, both public and private, cooperate fully with the Registry which is exempt, under the Health (Provision of Information) Act 1997, from the provisions of the Data Protection Act 2003 with regard to information collection.

IPCOR represents an extension of the present data collection system at the NCR. NCR will employ IPCOR research officers to retrieve the additional information required by the IPCOR study and clinically follow patients over time. The research officers will collect data from the 17 hospitals that care for over 88% of all prostate cancer patients. There are many smaller hospitals caring for the other 12% of patients, but given the extra workload and resources required to capture data on the relatively small number of patients, the research officers will focus on data capture in the larger hospitals in both the public and private healthcare sector. It is worthwhile to note that the NCR will continue to capture the standard clinical dataset on all prostate cancer patients from all hospitals.

Below is the list of hospitals that are participating in the IPCOR study:

Public Hospitals	**Area**
St Vincent's University Hospital	Dublin South
St James' Hospital	Dublin South
Beaumont Hospital	Dublin North
Mater Misericordiae University Hospital	Dublin North
Tallaght (AMNCH) Hospital	Dublin South
University Hospital Waterford	South
Cork University Hospital	South
Galway University Hospital	West
Mercy University Hospital	South
University Hospital Limerick	West
Private Hospitals	**Area**
Galway Clinic	West
Bons Secours Hospital Cork	South
Mater Private Hospital	Dublin North
St Vincent's Private Hospital	Dublin South
Beacon Hospital	Dublin South
Bon Secours Hospital Dublin	Dublin North
Bon Secours Hospital Galway	West

2.4 Data security

The NCR will extend their current database to incorporate the additional data items and the clinical follow up of patients that the IPCOR study wishes to collect. The extended version of their database will be hosted in a secure fashion in the data centre at the head offices of the NCR in Cork. The data is backed up both on-site and off-site. Data management, including system support and maintenance, is conducted by dedicated NCR IT and Data teams.

The CRFG will develop and maintain the Patient-Reported Outcomes Measurements (PROMs) database in Galway. The CRFG use SlidePath Distiller for PROMs data collection which is stored securely on a HSE server. The CRFG also has a validated electronic questionnaire tool that may be used for the collection of PROMs data in the future. The database system enables a link to be sent via email to all participants, the data is then stored securely on a HSE server.

Both the clinical and PROMs databases will be merged at the NCR. Each patient will be assigned a unique IPCOR identification number which will allow the patient specific datasets to be linked. This combined database will be stored securely at the data centre at the head offices of the NCR in Cork. A copy of the combined IPCOR database, which has been de-identified, will be stored on a dedicated secure server at MMI.

IPCOR data security will be maintained using encryption of data, a managed and audited protocol for access, training and accreditation of personnel, role-based access and authentication of data.

3. Methodology

3.1 Clinician recruitment

Prior to the commencement of data collection in each of the 17 hospitals, Consultants who treat prostate cancer patients in Ireland (urologists, medical oncologists and radiation oncologists) have been contacted to inform them about the IPCOR study and its objectives and our wish to enrol their newly diagnosed prostate cancer patients into the registry. The clinicians have been asked to sign a letter of support and agree to IPCOR contacting their patients to ask them to participate in the PROMs component of the study and for use of their biological specimens in future ethically approved research. Clinicians who support the study will receive an annual report of their patient's outcomes.

To date, IPCOR has recruited 55 clinicians (86% of clinicians who were invited to participate have been recruited) who have agreed to their prostate cancer patients being contacted by IPCOR, 33 urologists, 10 medical oncologists and 12 radiation oncologists.

3.2 Ethical Approval

A clinical representative for the IPCOR study has been appointed for each of the 17 hospitals where patients will be enrolled in the study. The clinician acted as a local representative on the IPCOR ethical application at their hospital. Ethics applications were submitted to the 10 ethics committees which cover the 17 hospitals from which IPCOR will recruit patients and collect clinical data. IPCOR has received ethical approval from:

- Clinical Research Ethics Committee in Galway
- Clinical Research Ethics Committee in Cork
- Research Ethics Committee for the Bon Secours Hospital System
- HSE South-Eastern Area Research Ethics Committee
- St. Vincent's Healthcare Group Ethics and Medical Research Committee
- Mater Misericordiae University Hospital Research Ethics Committee
- HSE Mid-Western Area Research Ethics Committee.
- Tallaght/St James' Hospital Joint Research Ethics Committee
- Beaumont Research Ethics Committee
- Beacon Research Ethics Committee

3.3 Patient Identification

All men who have been newly diagnosed with prostate cancer in the 17 participating hospitals will be eligible for inclusion in the IPCOR study. Patients seen in both public and private hospitals will be included and those seen in the eight designated cancer centres within the public system and in other

hospitals will be eligible. Thus, the IPCOR study will develop a national and population-based registry.

Newly diagnosed prostate cancer patients will be identified through a rapid case ascertainment system which will be implemented by the research officer in the hospital. Rapid patient identification is essential to the project, as the first patient-reported outcome data will be collected in the interval between diagnosis and commencement of treatment. The rapid case ascertainment system will build on the processes already in place at the NCR and will be augmented by specific arrangements in individual hospitals. Therefore, men eligible to take part in the study will be identified to a high degree of completeness.

Over 95% of prostate cancers are histologically diagnosed and all histopathology laboratories, from both public and private institutions, currently send copies of cancer pathology reports to the NCR shortly after histological diagnosis. These reports generally provide clinical information on cancer stage, grade and surgical/biopsy procedures, as well as the basic demographic and identification data. Some laboratories report cases electronically but the majority still use paper forms, as their systems do not allow easy export of electronic data, so this may result in delayed notification of the cases to the NCR. Since the first patient-reported outcome data will be collected in the interval between diagnosis and commencement of treatment, reliance on pathological reporting to the NCR for case ascertainment is not feasible for the IPCOR study. Therefore, we will establish mechanisms to ensure more rapid routes for identification of men eligible to take part in the study. For example, currently approximately two-thirds of men with prostate cancer are diagnosed through the NCCP designated cancer centres either via their Rapid Access Prostate Clinics (RAPC) or directly through symptomatic services and/or urology clinics. The 8 designated cancer centres and some other large prostate centres have regular multidisciplinary team (MDT) meetings. In these centres, the research officers will set-up procedures for access to lists from the RAPC and from weekly MDT meetings. In other centres, local solutions will be established such as weekly access to clinic lists. Clinicians in each centre will be asked to designate a local contact (usually the urology nurse, or cancer nurse specialist) to have responsibility of liaising with the research officers, in order to optimise the efficiency of the process. Following current NCR processes, the research officers will also access other data sources to identify and capture any cases missed through these processes. These will include accessing hospital patient administration systems, radiotherapy clinic records, chemotherapy clinic records, and local HIPE (hospital in-patient episode) records.

Phase 1 of the IPCOR study will commence in the first quarter of Year 2. A recently employed research officer who is based in hospitals in the southwest of Ireland will set up procedures to identify newly diagnosed patients in a timely manner and to collect the clinical data on such patients. These procedures will form the basis of protocols developed for all participating hospitals, mindful that each hospital environment is different and may require local solutions.

Following their diagnosis, men will be sent written information about the study and will be informed that their clinical data will be provided to IPCOR. Patients will be asked to consent to:

- the sharing of patient and hospital-level data within the IPCOR project team
- participating in the patient-reported outcomes components of the study by filling in quality of life questionnaires annually

- linking their clinical and PROMs data to their biological specimens (such as biopsy tissue, radical prostatectomy tissue and tissue given to research studies)
- the use of their biological specimens in future ethically approved research studies.

Each patient will be assigned a unique IPCOR registration number at the time of initial identification which will link their clinical and PROMs data and their biological specimens.

3.4 Data collection

Research officers will be employed by the NCR and recruited specifically to collect the data required for IPCOR. Due to the unique position of the NCR in Irish law, it will allow us to ascertain and record data on all men with prostate cancer. Under the Health (Provision of Information) Act 1997, the NCR are authorised to collect any data consistent with their purposes, including registration and research, without the requirement for patient consent. Moreover, the methods used by the NCR to collect information on cancers in people resident in Ireland are those which have been shown by national and international experience to be the most effective. This is therefore the ideal model of data collection to ensure a population-based database with a high degree of completeness.

3.4.1 Clinical data

The provisional dataset to be collected by the research officers during the first phase of the study has been defined (Appendix III). The research officers employed by the NCR will collect clinical data items as per the Prostate Cancer Outcome Registry – Australia and New Zealand as well as additional items deemed to be important in the Irish context. The IPCOR study has aligned its clinical dataset with the dataset recommended by the ICHOM Prostate Cancer Working Group to allow for international comparisons of prostate cancer patients and their treatments and care. The first phase of the IPCOR study will assess the feasibility of collecting this clinical and treatment follow-up data from the hospitals. The IPCOR clinical dataset will be finalized following the completion of phase 1 of the study.

The clinical data will be collected in the hospitals and entered into the IPCOR database directly by the research officers. Every effort will be made by the research officers to collect all required data. Data will be collected in keeping with Irish data protection laws and guidelines published by the Health Information Quality Authority (HIQA).

When potentially eligible cases are ascertained, the research officers will abstract basic demographic and clinical information (including name, address, date of birth, grade and Prostate Specific Antigen (PSA) result). This will form the basis of the patient's registration record. A copy of each new cancer record will be automatically copied to the central NCR register in Cork. The research officers will complete the initial dataset from the medical record and other sources such as radiotherapy and oncology clinic records. The research officers will collect data on stage (clinical and pathological), morphology, and treatments received in the first year post-diagnosis (surgical procedures, radiotherapy, chemotherapy and hormonal treatment), hospitals attended and treating clinicians.

Each patient will be assigned a unique IPCOR registration number at the time of initial identification; this will be used to track patients over time and to facilitate the collection and management of the PROMs data.

The research officers will be responsible for actively following up patients on a yearly basis in order to abstract information on additional treatments received, treatment failure, recurrence, metastases etc. This will involve accessing various data sources, including HIPE records (which are available to the NCR and routinely linked to cancer registrations), radiotherapy and oncology clinic records, and the hospital records of each patient. Active liaison with GPs and others will be essential to ensure that as few patients as possible are lost to follow-up. The NCR already routinely links registrations with death certificates provided by the Central Statistics Office; this process will continue as usual and be used to provide robust information on date and cause of death. This process will also be essential to minimise the possibility of attempting to contact deceased patients as part of the collection of PROMs.

3.4.2 Patient Reported Outcomes Measurement (PROMs) data

IPCOR is committed to better understanding the patient experience throughout the disease course. We intend on collecting patient-reported outcomes at baseline and then annually thereafter. Validated tools will be used to collect general health and disease-specific quality of life. The approach adopted by IPCOR is consistent with the approach taken internationally to enable cross-continent benchmarking to be undertaken. The ICHOM Prostate Cancer Working Group has determined that the Expanded Prostate Cancer Index Composite (EPIC-26) should be used to assess disease-specific quality of life (Appendix IV). IPCOR will also utilise EORTC QLQ-C30 and Euroqol EQ-5D-5L to assess general health quality of life (Appendix IV). These PROMs questionnaires have been standardised and validated and are known to have good psychometric properties, they will be scored as determined by the questionnaire designers. PROMs data will be collected using postal questionnaires and a web-based data collection system.

PROMs will be measured between diagnosis and treatment (baseline) and on an annual basis thereafter thus providing information on these outcomes across the entire patient journey. The questionnaires will measure key PROMs including physical wellbeing (e.g. functional status) and health-related quality-of-life and utility in order to document their experiences and facilitate future evaluation of the cost-effectiveness of therapies.

All patients will be invited to complete baseline (before primary therapy) and annual questionnaires relating to physical well-being and health-related quality-of-life. In order to minimise patient burden, subsamples of men may in the future be invited to complete questionnaires relating to treatment decision making and experiences of prostate cancer care. Once a web-based portal has been developed, patients will be encouraged to complete web-based questionnaires to facilitate database entry. Where this is not possible, postal questionnaire and manual data entry will be carried out by the CRFG.

3.5 Risk stratification

The Cancer of the Prostate Risk Assessment (CAPRA) model will be used to categorize patients according to risk. 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 (Cooperberg *et al.,* 2005). A CAPRA score is valid across multiple treatment approaches such as radical prostatectomy, radiation therapy (brachytherapy or external-beam), primary androgen deprivation therapy, cryoablation, or active surveillance, and it predicts an individual's likelihood of metastasis, cancer-specific mortality, and overall mortality (Cooperberg *et al.,* 2009). A CAPRA score of 0 to 2 indicates *low-risk,* a CAPRA score of 3 to 5 indicates *intermediate-risk* and a CAPRA score of 6 to 10 indicates *high-risk.* The CAPRA model will be used to stratify patients in the IPCOR registry according to risk. The outcomes of these risk adjusted patients will be compared between peer organisations.

4. Analysis and Reporting

4.1 Outcomes reporting

IPCOR will publish a public report and clinical reports annually. The public annual report will contain outcomes for prostate cancer patients at a national level and will be available in a downloadable format on the IPCOR website (www.ipcor.ie). The public report will be circulated to all stakeholders and patient groups. The clinical reports will be aimed at clinicians and decision-makers with detailed clinical results facilitating decision-making and driving service improvements. This will be distributed to clinical groups involved in the study and the NCCP.

IPCOR aims to present its annual results at the NCCP National Prostate Forum held each November. This will allow for debate and feedback from the multi-disciplinary teams who have contributed to this study. The IPCOR study will be able to provide feedback to the NCCP on whether their guidelines for the treatment of prostate cancer have been implemented in each hospital.

4.2 Quality indicators

Examples of the types of quality indicators that IPCOR will report on are listed in the tables below.

Safe and Patient directed Care

1.	Percent of men failing primary treatment at 12, 24, 36 and 48 months	Important to identify those failing curative therapy
2.	Percent of men requiring adjuvant radiotherapy within 6 months of surgery (adjuvant)	Important to identify those failing curative therapy
3.	Patient assessment of their physical health/functional status at 12, 24, 36 and 48 months	To identify men with disability or functional limitations
4.	Patient assessment of their overall health-related quality of life at 12, 24, 36 and 48 months	To identify men with limitations in overall HRQoL
5.	Percentage of men with Intra-prostatic disease (pT2) with positive surgical margins after surgery	To quantify adequacy of surgical resection
6.	Percentage of men with Extra-prostatic disease (pT3) with positive surgical margins after surgery	To quantify adequacy of surgical resection
7.	Urinary, sexual and bowel function assessment performed at 12, 24, 36 and 48 months post primary treatment	Assess complications of treatment
8.	Skeletal Related Events (SRE) in patients receiving hormonal therapy	Crucial to record this important complication
9.	Percent of men requiring salvage radiotherapy (with a detectable PSA)	Important to identify those failing curative therapy
10.	Treatment complications will be collected using the Clavien-Dindo classification system	Treatment complications will be monitored

Appropriate Care

1.	Percent of men treated by radical prostatectomy with a detectable PSA at 3 months post prostatectomy	Surgery is considered a curative therapy
2.	Percentage of men with high risk disease receiving brachytherapy	Ideally suited to lower grades of disease
3.	Percentage of men with high risk disease treated by Active Surveillance	Ideally suited to the lowest grade of disease
4.	Percentage of men undergoing Radiotherapy for high grade disease receiving concomitant hormonal therapy	Combined therapy recommended for high risk disease
5.	All Complications recorded using the Clavien-Dindo classification for surgical morbidity	Reflects best practice and relates to improved outcomes

Access and Equity of care

1.	Time from initial referral to date of diagnosis	Delays may cause worse outcomes and increase patient anxiety
2.	Time from diagnosis to date of treatment commencement	Reflects good organisational management
3.	Distance travelled from residence to hospital of diagnosis and hospital of main treatment	Reflects access to healthcare
4.	% of cases diagnosed and/or treated at one of the 8 designated cancer centres, and how this varies by socio-demographic group	Reflects equity of access to healthcare
5.	Percentage of men with localised disease who received curative treatment, overall and by socio-demographic group and hospital	Reflects equity of access to healthcare

Data Quality to be measured by IPCOR

1.	Percentage of all patients identified and registered within 2-weeks/1 month/2 months/3 months and >3 months of diagnosis	Indicator of timeliness of case ascertainment by IPCOR
2.	Percentage of all prostate cancers in Ireland included in IPCOR	Indicator of completeness of case ascertainment by IPCOR
3.	Percentage of patients with missing/unknown data for each clinical data field	Indicator of quality of clinical data
4.	Percentage of patients from whom PROMs data was collected at baseline and each follow-up time point (i.e. response rates)	Indicator of representative the PROMs data is of the whole population
5.	Levels of missing data for individual PROMs questions and entire instruments	Indicators of acceptability of PROMs questions to patients
6.	Error rate in manual data entry of PROMs data	Indicator of accuracy of data entry

4.3 Access to data

Information contained within the IPCOR registry will routinely be used by IPCOR personnel to (1) assess quality of care provided to men with prostate cancer and (2) foster research leading to improvement in care and survival. IPCOR staff will have access to de-identified IPCOR registry data to enable the registry to achieve its objectives. Aspects of reports may include publication of aggregate data in peer-reviewed journals and at conferences. Reports will only contain aggregate data to ensure the confidentiality of hospitals, clinicians and patients.

Cancer researchers may request access to de-identified IPCOR data by completing a Data Access Form which can be downloaded from our website (www.ipcor.ie). Data requests will be reviewed by the IPCOR Steering Committee in accordance with our Data Access Policy and must be accompanied by relevant ethics committee certification. Requests from contributing clinicians, prostate cancer clinic staff and academic organisations and other bodies will be considered on a case-by-case basis by the Steering Committee and will be subject to a processing fee. Steering Committee reviewers will be asked to complete a review template to ensure that the proposed research complies with relevant ethical and legal obligations and is scientifically sound and feasible.

5. Sustainability of the IPCOR registry

Good quality disease registries enable all stakeholders in the health system to focus on measuring and improving outcomes and identifying best practices.

Combining a strong multi-disciplinary team with a large cohort of high quality data in the IPCOR prostate cancer registry will provide a sound basis for sustaining the registry. A sustainability plan will be prepared by the Sustainability Working Group to ensure the registry is maintained and further developed, beyond the five year timeframe of this project. The IPCOR study will look to governmental bodies, charities (not for profit organisations) and industry sponsors as well as internal and external partners to secure future funding.

As part of the consenting process for the IPCOR project, patients will be asked to give their permission for their clinical and PROMs data to be linked to their diagnostic biological specimens and for the use of their specimens in future ethically approved research. The Sustainability Working Group will promote the use of the data and biological samples by researchers to maximise its potential in studies which investigate areas of oncology and population health. A charge-back system will be implemented to be used in future grant applications for fees for access to de-identified raw data and biological samples.

6. The value of the IPCOR registry

The IPCOR registry will be a valuable resource for monitoring, benchmarking and improving prostate cancer care in Ireland. Additionally, the registry data can be utilised for research to develop more effective treatments and treatment regimes, determine underlying causes of prostate cancer and stratify patients to predict health outcomes.

The IPCOR study will feed into multiple components of the research environment in Ireland and it is these interactions which will allow IPCOR to achieve its full potential and efficacy.

The Irish Cancer Society and Movember Foundation have made significant investments in basic and translational prostate cancer research. This includes funding the Prostate Cancer Research Consortium (PCRC) which has developed a number of bioresources for the collection of tissue, blood, urine and DNA from patient's pre radical prostatectomy and at the time of admission to rapid access clinics. Patients will be consented to link their IPCOR data, both clinical and PROMs data, to their PCRC biological specimens. This collaboration and sharing of data will significantly contribute to the research currently being performed by the PCRC.

IPCOR will collaborate with companies working in the area of prostate cancer therapeutics and diagnostic development. IPCOR will afford such companies the opportunity to access relevant de-identified information from the registry. Analysis of this data will enhance our knowledge of the baseline state of disease incidence and outcomes and can be used to identify relevant population cohorts for future clinical trials and diagnostic testing. The availability of this information in the IPCOR registry may positively influence industry to include Irish patients in current and future clinical trials.

Furthermore, IPCOR data will be instrumental in assessing the performance of therapies for prostate cancer and the impact of these therapies as reported by the patients themselves. It will be used to catalyse needed improvements in prostate cancer care and to advance and standardise care throughout the country. The advancements and standardisation of care, based on "real-life" data, will undoubtedly lead to savings in healthcare costs via reductions in variations and more effective and patient orientated treatments.

The IPCOR study will be a significant contributor to international prostate cancer research. IPCOR is collecting both clinical and PROMs data as recommended by the ICHOM Prostate Cancer Working Group and has aligned its data collection with that currently being carried out by the Prostate Cancer Outcomes Registry – Australia and New Zealand and the National Prostate Cancer Audit that is being carried out in the UK (England and Wales). These studies represent a unique opportunity to collaborate to evaluate prostate cancer care in Ireland, Australia, New Zealand, England and Wales and to foster research between the countries which will ultimately lead to improvement in care for patients with prostate cancer.

Appendix I:

Management Committee

The Management Committee have overall responsibility for the day to day management of the project, for planning, implementing and delivering milestones as well as the implementation of solutions to challenges as they occur. Any issues that cannot be resolved by the Management Committee will be escalated to the Steering Committee for resolution. The key responsibilities of the Management Committee will be:

- Provide advice to steering committee to address project direction
- Have responsibility for staffing, overall and financial management of IPCOR
- Review and monitor on an ongoing basis project status versus project plans
- Monitor, on an ongoing basis, data collection and quality processes
- Provide guidance to project team members
- Provide advice on the collection and interpretation of data
- Oversee timely and appropriate statistical analysis, reporting and publication on IPCOR data
- Review and provide comment on reports published by IPCOR
- Implement resolutions to issues that may arise during the course of the project

Membership:

Mr. David Galvin

Mr. Michael Faherty

Dr. Leah Bentham

Dr. Áine Murphy

Appendix II:

Data Management Committee

The Data Management Committee is comprised of personnel with expertise in epidemiology, statistical analysis, or in capturing and validating data either from a clinical or patient-reported outcomes perspective. This committee may establish subgroups to develop specific aspects of the clinical or PROMs data collection, QA or analysis as and when required.

The key responsibilities of this committee will be to:

- Provide advice on the collection and interpretation of data;
- Agree procedures for QA of clinical and PROMs data;
- Monitor and report on an ongoing basis, completeness, accuracy and timeliness of the data
- Liaise with the clinical sites regarding data quality, timeliness etc
- Suggest solutions to any problems with regard to data quality
- Develop and monitor policies for access to data and requests for status reports and ad-hoc data reports
- Development of the overall statistical analysis plan;
- Design of reports/tables for feedback of results to individual centres and clinicians
- Review publications arising from the Registry; and
- Facilitate data linkages with other groups and projects to increase the usefulness of the IPCOR data

Membership of Data Management Committee:

Professor Linda Sharp

Ms. Fiona Dwane

NCR biostatistician

PROMs researcher

Dr. Julie Nossiter

Dr. Áine Murphy

Appendix III:

Draft IPCOR clinical dataset

Tables of the draft IPCOR clinical dataset showing the variables, treatment variables and annual follow up to be collected for the IPCOR study with examples of data items in each variable category. The list of data items for each category is not exhaustive.

Variables
Patient Attributes
Names Address DOB Occupation First degree family members with prostate cancer
Diagnosis
Diagnosis date Symptoms at diagnosis Prebiopsy PSA level Imaging investigations
Tumour Characteristics
Method of Diagnosis Method of Presentation Clinical TNM stage
Initial Pathology
Date of biopsy % of all biopsy cores involved with cancer Gleason grade and sum Total number of nodes sampled Number of nodes with cancer Complications for biopsy
Management
First treatment Intent of First Treatment Radical Prostatectomy Radiotherapy ADT (chemical) ADT (Surgical) Chemotherapy Other systemic therapy Other therapy Watchful waiting Active surveillance

Treatment Variables
Surgery
Hospital name
Consultant code
Surgical Approach
Acute surgical complications
Acute medical complications
Surgical Pathology
Gleason grade
Extra prostatic extension
Seminal vesicle involvement
Margin involvement
Pathological TNM stage
Radiotherapy
External beam
Start date
Completion date
Dose (Gy)
Brachytherapy
Start date
Completion date
Dose (Gy)
Dose rate
Acute complications
Androgen Deprivation Therapy
Treatment phase
First treatment used
Second treatment used
Surgical castration
ADT complications
Chemotherapy
Agent/protocol used
Start and stop dates
Clinical trial status
Bone directed therapies
Chemotherapy complications

Annual Follow up
Disease relapse
Biochemical recurrence
Clinical recurrence
Local and systemic progression
Castrate resistance
Treatment of recurrence
Complications of chemotherapy
Patient's status

Appendix IV:

Patient-Reported Outcome questionnaires: EPIC-26, EORTC QLQ-C30, EuroQol EQ-5D-5L

EPIC-26

The Expanded Prostate Cancer Index Composite

Short Form

This questionnaire is designed to measure Quality of Life issues in patients with Prostate cancer. To help us get the most accurate measurement, it is important that you answer all questions honestly and completely. Remember, as with all medical records, information contained within this survey will remain strictly confidential.

Today's Date (please enter date when survey completed): Month_____Day_____Year_____

Name (optional): _____

Date of Birth (optional): Month_____Day_____Year_____

Please circle one number for each question

1. Over the **past 4 weeks**, how often have you leaked urine?

More than once a day..... 1

About once a day..... 2

More than once a week..... 3

About once a week.....4

Rarely or never..... 5

2. Which of the following best describes your urinary control **during the last 4 weeks**?

No urinary control whatsoever..... 1

Frequent dribbling..... 2

Occasional dribbling.....3

Total control..... 4

3. How many pads or adult diapers per day did you usually use to control leakage

during the last 4 weeks?

None 0

1 pad per day.....1

2 pads per day.....2

3 or more pads per day.....3

4. How big a problem, if any, has each of the following been for you **during the last 4 weeks**?

(Circle one number on each line)

0=No Problem, 1=Very Small Problem, 2=Small Problem, 3=Moderate Problem, 4=Big Problem

a. Dripping or leaking urine …..... 0, 1, 2, 3 or 4

b. Pain or burning on urination…..... 0, 1, 2, 3 or 4

c. Bleeding with urination…..... 0, 1, 2, 3 or 4

d. Weak urine stream or incomplete emptying…..... 0, 1, 2, 3 or 4

e. Need to urinate frequently during the day…..... 0, 1, 2, 3 or 4

5. Overall, how big a problem has your urinary function been for you **during the last 4 weeks**?

No problem..... 1

Very small problem..... 2

Small problem..... 3

Moderate problem.....4

Big problem.....5

6. How big a problem, if any, has each of the following been for you?

(Circle one number on each line)

0=No Problem, 1=Very Small Problem, 2=Small Problem, 3=Moderate Problem, 4=Big Problem

a. Urgency to have a bowel movement …..... 0, 1, 2, 3 or 4

b. Increased frequency of bowel movements…..... 0, 1, 2, 3 or 4

c. Losing control of your stools…..... 0, 1, 2, 3 or 4

d. Bloody stools …..... 0, 1, 2, 3 or 4

7. Overall, how big a problem have your bowel habits been for you **during the last 4 weeks**?

No problem..... 1

Very small problem..... 2

Small problem..... 3

Moderate problem..... 4

Big problem..... 5

8. How would you rate each of the following **during the last 4 weeks**?

(Circle one number on each line)

1= Very Poor to none, 2= Poor, 3= Fair, 4= Good, 5= Very Good

a. Your ability to have an erection?..... 1, 2, 3, 4 or 5

b. Your ability to reach orgasm (climax)? ..... 1, 2, 3, 4 or 5

9. How would you describe the usual QUALITY of your erections **during the last 4 weeks**?

None at all..... 1

Not firm enough for any sexual activity.....2

Firm enough for masturbation and foreplay only.....3

Firm enough for intercourse..... 4

10. How would you describe the FREQUENCY of your erections **during the last 4 weeks**?

I NEVER had an erection when I wanted one.....1

I had an erection LESS THAN HALF the time I wanted one..... 2

I had an erection ABOUT HALF the time I wanted one 3

I had an erection MORE THAN HALF the time I wanted one.....4

I had an erection WHENEVER I wanted one.....5

11. Overall, how would you rate your ability to function sexually **during the last 4 weeks**?

Very poor..... 1

Poor..... 2

Fair..... 3

Good..... 4

Very good..... 5

12. Overall, how big a problem has your sexual function or lack of sexual function been for you **during the last 4 weeks**?

No problem..... 1

Very small problem..... 2

Small problem..... 3

Moderate problem..... 4

Big problem.....5

13. How big a problem **during the last 4 weeks**, if any, has each of the following been for you?

(Circle one number on each line)

0=No Problem, 1=Very Small Problem, 2=Small Problem, 3=Moderate Problem, 4=Big Problem

a. Hot flashes…….....0, 1, 2, 3 or 4

b. Breast tenderness/enlargement.. …….. 0, 1, 2, 3 or 4

c. Feeling depressed..... ..... 0, 1, 2, 3 or 4

d. Lack of energy..... ..... 0, 1, 2, 3 or 4

e. Change in body weight ..... 0, 1, 2, 3 or 4

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Answers: 1. Not at All, 2. A Little, 3. Quite a bit, 4. Very much

1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase? 1 2 3 4

2. Do you have any trouble taking a long walk? 1 2 3 4

3. Do you have any trouble taking a short walk outside of the house? 1 2 3 4

4. Do you need to stay in bed or a chair during the day? 1 2 3 4

5. Do you need help with eating, dressing, washing yourself or using the toilet? 1 2 3 4

During the past week:

6. Were you limited in doing either your work or other daily activities? 1 2 3 4

7. Were you limited in pursuing your hobbies or other leisure time activities? 1 2 3 4

8. Were you short of breath? 1 2 3 4

9. Have you had pain? 1 2 3 4

10. Did you need to rest? 1 2 3 4

11. Have you had trouble sleeping? 1 2 3 4

12. Have you felt weak? 1 2 3 4

13. Have you lacked appetite? 1 2 3 4

14. Have you felt nauseated? 1 2 3 4

15. Have you vomited? 1 2 3 4

16. Have you been constipated? 1 2 3 4

During the past week:

17. Have you had diarrhoea? 1 2 3 4

18. Were you tired? 1 2 3 4

19. Did pain interfere with your daily activities? 1 2 3 4

20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television? 1 2 3 4

21. Did you feel tense? 1 2 3 4

22. Did you worry? 1 2 3 4

23. Did you feel irritable? 1 2 3 4

24. Did you feel depressed? 1 2 3 4

25. Have you had difficulty remembering things? 1 2 3 4

26. Has your physical condition or medical treatment interfered with your family life? 1 2 3 4

27. Has your physical condition or medical treatment interfered with your social activities? 1 2 3 4

28. Has your physical condition or medical treatment caused you financial difficulties? 1 2 3 4

For the following questions, please circle the number between 1 and 7 that best applies to you

1. Very Poor, 7. Excellent

29. How would you rate your overall health during the past week?
1 2 3 4 5 6 7

30. How would you rate your overall quality of life during the past week?
1 2 3 4 5 6 7

EuroQol EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

• We would like to know how good or bad your health is TODAY

• This scale is numbered from 0 to 100.

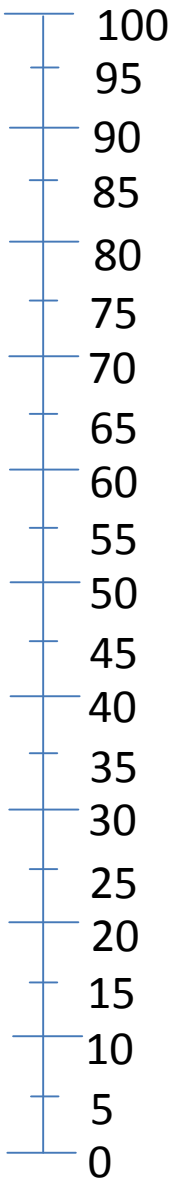
• 100 means the best health you can imagine. 0 means the worst health you can imagine.

• Mark an X on the scale to indicate how your health is TODAY.

• Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

The best health you can imagine



The worst health you can imagine

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National Cancer Control Programme