IPCOR

IRISH PROSTATE CANCER OUTCOMES RESEARCH

ANNUAL REPORT

April 2016

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, the Irish Society of Urology and the Irish Association of Urological Nurses for their support and help in establishing our research officers in our participating hospitals throughout the second year of the IPCOR study. The success of 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 (NCR) for their guidance and expertise throughout phase 1 of the study and the recruitment and training of research officers in procedures for clinical data collection in the participating hospitals. We would also like to thank our colleagues in the Clinical Research Facility in Galway (CRFG) for their ongoing work in developing the PROMs database.

The IPCOR team have established a fruitful collaboration with Patientmpower, a health technology company who have developed an electronic patient reported outcomes measurements (PROMs) collection tool which men can use to participate in the study and complete quality of life questionnaires. Patientmpower are also developing an app for men which will allow them to maintain a digital health record and aims to support effective patient-clinician interaction. We would particularly like to thank Eamonn Costello, CEO of Patientmpower, for his enthusiasm and dedication in developing these patient focused tools for the IPCOR study. We would like to acknowledge an educational grant from Astellas Pharma Ireland which funded this work. We would also like to thank the members of Men Against Cancer (MAC), a prostate cancer support group, who have provided their input and feedback for improving the usability of the tools for patients.

We acknowledge the support and input of the Irish Cancer Society research team and colleagues at the Movember Foundation during the second year of the study.

Investigators

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Team members

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Collaborators

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Foreword

As the principal investigator of IPCOR, I am immensely proud of our achievements to date. Spearheaded by our project manager, Dr Áine Murphy, the IPCOR project has expanded considerably in it's second year, achieving and in some cases surpassing many of our goals. The NCR recruited four research officers in the second year of the study. Each research officer has had to establish relationships and structures across the hospitals in their area to gather the necessary clinical data. Our four research officers (Leah, Hazel, Emer and Lisa) have worked tirelessly and enthusiastically to establish IPCOR in our major hospitals and have added greatly to the project's reputation across Ireland. Within the NCR, Ms Fiona Dwane has worked hard to develop the IPCOR database and to establish the registration officers in their roles. We have recently employed a database support officer at the NCR, Christine, who continues to develop our clinical database and who will oversee the issuing of Introduction packs to our patients.

One of the goals of IPCOR was to establish electronic PROMs collection in Ireland. Thanks to an educational grant from Astellas Pharma Ireland the establishment of a two-phase project with the award winning Patientmpower IT Company, became a possibility. Patientmpower have developed an online ePROMs website which will link to the IPCOR website (www.ipcor.ie) and this is now complete. Patientmpower are also designing an App that acts as a patient portal. We continue to work with our new partner at Patientmpower, Eamonn Costello, to achieve this fantastic improvement for patients. We are also in discussion with the TrueNth platform available in the USA to see if it can be established in an Irish setting. The PROMs collection will be commencing very shortly and is based in the CRFG with our collaborators Dr Aideen O'Doherty and Dr Susan Hennessy. Once the clinical data and the PROMs data are collected we are looking at ways of sharing the data within the IPCOR database with our global partners in Australia, USA, England and other countries to not only benchmark our outcomes globally but to learn from the centres that yield the best outcomes. Thanks to the ongoing efforts of the Irish Cancer Society and the Movember Foundation, we remain in the Global Action Plan (GAP) for prostate cancer and we meet annually to pursue our aims. I wish to acknowledge the ongoing support from Dr Sue Evans and Ms Shannyn Merlo in the Movember Foundation in assisting in the establishment of IPCOR. The Irish Cancer Society continues to be hugely supportive and I specifically wish to acknowledge the support of Dr Robert O'Connor in this regard. 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.

IPCOR is all about improving the experience and outcome for our patients, and this is always our primary goal. I thoroughly believe that with high quality clinical data and patient reported outcome data collection, together with international collaboration and engagement with our patients through our new patient portal, that we can transform prostate cancer care. We look forward to your ongoing support and working with you all in the future.

David Galvin

Mr David Galvin, Consultant Urologist

Executive Summary

The second annual report of the IPCOR study describes the progress made in establishing a national, longitudinal, prospective and population based prostate cancer registry. The IPCOR study is proudly funded and supported by the Movember Foundation and the Irish Cancer Society for a five year period. The study has begun identifying newly diagnosed patients in hospitals across Ireland and collecting the IPCOR clinical dataset as these men undergo treatment. The study will soon begin collecting patient reported outcome data from newly diagnosed prostate cancer patients before their treatment commences and annually thereafter. The goal of the registry is to assess the treatment outcomes for men with prostate cancer in Ireland and to understand the processes of care that contribute to these outcomes. The registry data will be used to improve outcomes for men with prostate cancer, to understand areas of unmet need and aid in the development of strategies to address these needs.

The IPCOR study has made significant progress in its second year towards achieving these goals:

- The IPCOR study has now successfully recruited four research officers and a database support officer who are employed by the NCR.
- Phase 1 of the study began with recruitment of the first research officer in May 2015 and her establishment in the hospitals in the South of Ireland, namely, Cork University Hospital, Mercy University Hospital and Bon Secours Cork. During phase 1, the clinical database for the IPCOR study was developed by colleagues in the NCR. The research officer, with input from colleagues in the NCR and the IPCOR team, determined the feasibility of collecting the proposed clinical dataset, made suggestions to improve the usability of the database and developed a data dictionary for all data items.
- The research officers are now established in 15 hospitals nationwide which was achieved through the support of clinicians, clinical nurse specialists and working with hospital CEOs, HR and IT departments. The research officers have a desk space and access to hospital systems such as pathology, radiology, medical records etc. Research officers have successfully accessed MDT meetings and built relationships with the necessary team members to efficiently and effectively identify newly diagnosed prostate cancer patients in a timely manner.
- Research officers have established procedures to ensure that men newly diagnosed with prostate cancer have been informed of their diagnosis before they are contacted by the IPCOR study.
- Three of the research officers began collecting the clinical dataset on newly diagnosed prostate cancer patients from February 1st 2016. The fourth research officer is now in place and has begun collecting data in the Dublin South hospitals. By the end of April 2016, over 250 men had been registered by the IPCOR study.

- The IPCOR study successfully secured funding of €45,633 from Astellas Pharma Ireland which has allowed IPCOR to collaborate with Patientmpower, a health technology software company. Patientmpower have worked with the IPCOR team to develop an electronic PROMs data collection tool. Men who wish to take part in the IPCOR study will have the option of logging into the electronic tool through the IPCOR website and consenting to the study and completing the quality of life questionnaires.

- Patientmpower are currently developing an IPCOR app which men will be able to download from the IPCOR website. The app allows men to maintain a digital health record. Men can use the app to record appointment times, their symptoms, questions they may have for their doctor, their PSA levels, their activity levels and men will be able to view the results of their PROMs data and compare themselves to the national averages of men undergoing the same treatment. The IPCOR team will also build content for the app which will provide information to men about various treatments, procedures and supports available.

- The IPCOR study was successful in our application to become a participating site for the Movember Foundation funded global study Prostate Cancer Outcomes-Compare and Reduce Variation. Thus, IPCOR will be collaborating with 10 countries and contributing both clinical and patient reported data from six Irish hospital sites to the global registry. The aim of this study is to identify the processes of care that lead to the best outcomes for patients and to implement these findings in sites across the globe.

- The IPCOR team published a featured cover story in the Spring Edition of Cancer Professional. The article was entitled “Bridging the data gap” and described the establishment and governance structures of the IPCOR registry. We also described the IPCOR registry and goals of the study in an article entitled “Taking the fight to Cancer” in the Medical Independent, 18th April 2016 Edition.

1. Background to the IPCOR study

Men in Ireland now have a one-in-seven chance of developing prostate cancer with 3,384 men being diagnosed with prostate cancer in Ireland in 2012[1]. Prostate cancer incidence rates in Ireland are the third highest in Europe[2] and over 500 Irish men die of advanced prostate cancer each year[1]. Thus, prostate cancer is a significant clinical problem in Ireland.

The 2006 Strategy for Cancer Control in Ireland specifically highlighted a deficit in epidemiological and health services research in cancer. A lack of information about prostate cancer patients and their care may negatively impact clinical outcomes for prostate cancer patients. Clinicians are unable to inform patients of their expected clinical outcomes with any accuracy, as no 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. Recent population-based studies have investigated men's functional wellbeing and health-related quality of life as well as treatment side effects[3,4,5], however, there is little robust longitudinal data evaluating men's experiences from diagnosis and throughout their treatments. Novel agents have been developed for the treatment of advanced prostate cancer[6], however, the challenge remains to collect data that will inform clinicians on the most effective treatment regimes to improve progression-free survival and overall survival for metastatic prostate cancer patients. Thus, to address these issues, the Irish Prostate Cancer Outcomes Research study has established a national registry which captures high-quality information about newly diagnosed prostate cancer patients. The registry is currently collecting clinical data on newly diagnosed prostate cancer patients from the time of diagnosis and throughout their treatments and will soon begin collecting PROMs data.

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. The registry data will help us to identify areas of unmet need and develop and implement strategies to address these needs. By providing evidence-based data and recommendations to clinicians, hospitals, decision-makers and the National Cancer Control Programme (NCCP), the registry will promote equity in 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 and fostering research on such data, the registry will ultimately lead to the improvement of treatment regimes, patient care and maximise quality of life for men diagnosed with prostate cancer in the Republic of Ireland.

2. Developments in the second year of the study

2.1 Recruitment of IPCOR Personnel

Throughout year 2 of the study, the IPCOR study successfully recruited four research officers and a database support officer who are employed by the NCR. The research officers are assigned to 15 participating public and private hospitals in the areas of Dublin North, Dublin South, the West of Ireland and the South of Ireland while the database support officer is based at the NCR.

The research officers are now established in these hospitals nationwide with access to hospital systems such as pathology, radiology and medical records for the collection of clinical data on men with prostate cancer. Research officers have successfully gained access to MDT meetings and built collaborative relationships with the necessary team members to efficiently and effectively identify newly diagnosed prostate cancer patients in a timely manner while ensuring that these men have been informed of their diagnosis before they are contacted by the IPCOR study. These procedures are essential to the success of the IPCOR study and the wellbeing of patients who are contacted by the study. These achievements were accomplished with the help of the project manager and, crucially, through the kind support of hospital CEOs, clinicians, clinical nurse specialists, clinical research facilities and other hospital staff.

The database support officer will continue the development of the data entry system for the collection of IPCOR data, provide support to the research officers using the system and is responsible for inviting men who have been recruited to the IPCOR registry to participate in the PROMs component of the study. The database support officer is also responsible for linking the clinical database at the NCR with the PROMs database hosted in the CRFG and to provide the project manager with de-identified datasets to carry out quality assurance of the data periodically.

2.1.1 Biographies of newly recruited personnel

- Leah Bentham studied Medicine for 5 years at Newcastle University in the UK and graduated in 2010. She then worked as a Foundation Doctor for 2 years in the Northumbria Healthcare Trust and as locum doctor in A&E in various hospitals including a GP managed hospital in the Orkney Islands of Scotland. In 2013 Leah travelled to Fiji to carry out a 5 week volunteer project which involved living in a small village on a remote island and helping to build a nurse's station, teach in the local primary school and introduce and coach various sports to the children. Leah is now employed as an IPCOR research officer and covers the participating hospitals in the south of Ireland where she carried out phase 1 of the study.

- Hazel Smith was recruited to the IPCOR study as a research officer in December 2015 and has been assigned to the participating hospitals in Dublin North and the Beacon Hospital in Sandyford, Dublin. Hazel is a qualified midwife with over 6 years research experience in observational and interventional studies, audit and guideline development as well as creating and monitoring study databases. Hazel has presented her research at international conferences, has publications in peer-reviewed journals and is both a lead and co-author for the Cochrane Pregnancy and Childbirth Group. She is currently carrying out a PhD which is near completion.

- Emer McCarthy graduated with a medical degree in 2008. She was preciously involved in research with The Health Research Board on a project researching paediatric infectious disease. She was a Watts Medal finalist for this work. She worked as a junior doctor for a while before completing the Postgraduate Certificate in Health Protection from the Department of Public Health at UCC. She also worked on the TRUST Thyroid Trial with Professor Patricia Kearney of UCC. Her interests include cancer epidemiology. Emer is now employed as a research officer for the IPCOR study and has been assigned in hospitals in the west of Ireland.

- Lisa McGowan was recruited to the IPCOR study as a research officer in April 2016 and assigned to participating hospitals in Dublin South. Lisa trained as a nurse in St. Vincent's Hospital and completed a Bachelor of Nursing Studies (Honours) at Trinity College Dublin, graduating in 1999. Lisa worked at Quintiles, a Clinical Research Organisation where she was involved in monitoring drug trials and has been involved in breast cancer, multiple sclerosis and diabetes trials in hospital settings over the years. After nursing in Australia, Lisa worked at the St George's Hospital in London in the endocrinology unit. In 2012 she was appointed as a neuroendocrine tumour clinical nurse specialist and was also given responsibility for hepatocellular carcinoma and pancreatic cancer patients. She also completed a graduate diploma in adult cancer nursing at University College Dublin in 2011.

- Christine Allan was recruited to the IPCOR study as Database Support Officer in March 2016. Christine is from Australia, moving to the Netherlands in 2005 to study for a Master's in Archaeology at Universiteit Leiden before coming to Ireland to do research at the National University of Ireland, Galway. After working in cataloguing and database development in the heritage industry, she decided to return to university to gain a qualification in Computer Science, specialising in mobile and cloud software development. Christine is happy to be able to use her expertise and skills in database design, tech support and data management to make a valuable contribution to the IPCOR study.

2.2 Clinical data collection

Phase 1 of the study began with recruitment of the first research officer, Dr Leah Bentham, in May 2015 and her establishment in the hospitals in the South of Ireland, namely, Cork University Hospital, Mercy University Hospital and Bon Secours Hospital Cork.

During Phase 1 of the study, the research officer familiarised herself with the data collection practices and procedures of the NCR and the policies of data protection that must be adhered to. In addition, she studied prostate cancer care pathways in the Republic of Ireland such as types of treatment regimens and subsequent follow-up.

The research officer proceeded to contact Consultant Urologists in her assigned hospitals in Cork to introduce herself and inform them that the IPCOR study would begin shortly. The research officer then investigated how best to register men who have been newly diagnosed with prostate cancer and to follow these men over time in each hospital and established procedures to carry out these tasks. Crucially, the research officer also implemented procedures to confirm that a man will have received his diagnosis of prostate cancer before he will be contacted and asked to participate in the PROMs study. The research officer, with the help of the project manager, sourced a desk space and IT access to hospital systems as well as access to patient charts. The research officer built strong collaborative relationships with all members of the prostate cancer care team in each hospital which has been essential in allowing her to carry out her role for the IPCOR study.

To assess the procedures that had been implemented to identify prostate cancer patients, the research officer identified more than 200 patients prospectively in the three hospitals in Cork. This allowed the research officer to refine the processes for registering men into the IPCOR registry and ensure comprehensive and accurate registering of newly diagnosed prostate cancer patients.

To determine the necessary access and resources required to follow patients over time, the research officer selected 50 men diagnosed in Cork University Hospital and 50 men diagnosed in Mercy University Hospital in 2010 and completed the follow up clinical dataset on these men for the proceeding years.

As a result of Phase 1 of the study, the clinical dataset has been further refined leading to numerous improvements. For example, some data items on biopsy pathology have been removed as they are inconsistently recorded while complications of biopsy and treatment have been added. The research officers can also highlight if a patient has been lost to follow up to explain a lack of information in the dataset. A data dictionary was then developed which outlines the definition of each data item for all the research officers and ensures that the interpretation of each data item is consistent for each patient record in the study.

Phase 1 was completed in September 2015 and since then minor adjusts have been made to the database and data dictionary as required.

Three of the research officers began collecting the clinical dataset on newly diagnosed prostate cancer patients from February 1st 2016 in Dublin North, the South of Ireland and the West of Ireland. By the end of April 2016, over 250 men had been recruited to the IPCOR registry. The fourth research officer is now in place and has begun identifying men and collecting data in the Dublin South.

2.3 Clinician recruitment

	No. Invited	No. Consented	% Consented
Urologists	41	37	90.2
Medical Oncologists	13	10	76.9
Radiation Oncologists	13	12	92.3

IPCOR has recruited the vast majority of urologists and medical and radiation oncologists who treat prostate cancer patients in Ireland. Our research officers are now in place in the participating hospitals and inform the project manager if a new clinician has taken up a post in the hospital or if a clinician has not been invited to participate in the study. The project manager then contacts the clinicians and invites them to take part in the study. This approach has been effective in increasing the number of clinicians who are participating in the IPCOR study.

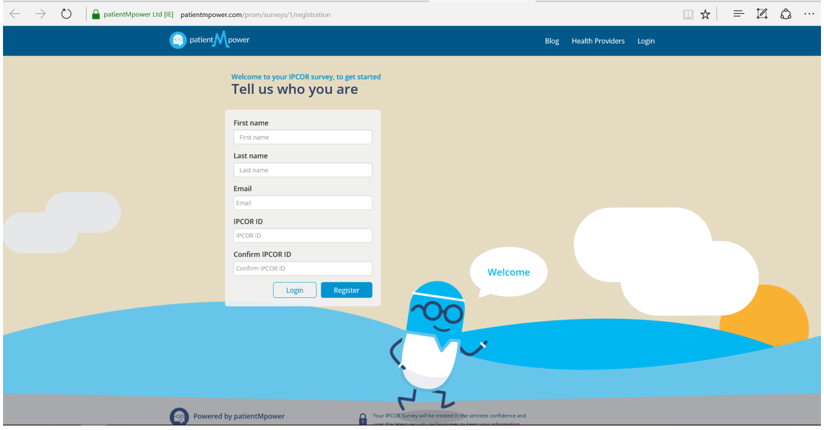
2.4 IPCOR Collaborations

2.4.1 Patientmpower

The IPCOR study successfully secured an educational grant from Astellas Pharma Ireland. This funding has been used to establish a strong collaboration with Patientmpower, a health technology software company. Patientmpower have collaborated with the IPCOR team to develop an electronic PROMs data collection tool.

When men are recruited to the IPCOR registry and have received their diagnosis of cancer from their clinician, the NCR will contact men on behalf of the IPCOR study and invite them to take part. Men will be sent a PROMs pack which contains an introductory letter to the study, a patient information leaflet which explains the study and how men can participate if they wish, consent forms and a booklet of quality of life questionnaires for men to complete. The paper consent forms and questionnaire booklet are to be returned to the NCR in the SAE provided. Men will have consented to the sharing of their identifiable information with the CRFG who will administer all follow up PROMs. The CRFG are currently developing the PROMs database that will house the PROMs data collected in paper-based format.

Alternatively, after receiving the information about the IPCOR study, men will have the option of logging into the Patientmpower electronic tool through the IPCOR website, consenting to the study and completing the quality of life questionnaires online. Men will be prompted via email and asked to complete subsequent follow up questionnaires at appropriate intervals. It is hoped that many men will choose the option of completing the consent forms and questionnaires electronically as this will reduce the cost of administering subsequent questionnaires and will also reduce the chance of data transcription errors when inputting data from paper to the PROMs database. The data collected in the PROMs electronic tool will be exported and compiled in the database in the CRFG along with the data submitted by men in paper format to form a comprehensive IPCOR PROMs database.



Welcome to your IPCOR survey, to get started

Tell us who you are

First name: First name

Last name: Last name

Email: Email

IPCOR ID: IPCOR ID

Confirm IPCOR ID: Confirm IPCOR ID

Your IPCOR Survey will be treated in the strictest confidence and

Log in screen for the Patientmpower electronic PROMs collection tool. Once men register for the study online, they can fill in consent forms and complete the questionnaires.

Our collaboration with Patientmpower has also led to the development of an IPCOR app which men will be able to download from the IPCOR website. The app will allow men to maintain a digital health record. Men can use the app to record appointment times, their symptoms, questions they may have for their doctor, their PSA levels and their activity levels. Men will be able to view the results of their PROMs data and compare themselves to the national averages of men undergoing the same treatment regimes. The IPCOR team plan to build content for the app which will provide information to men about various treatments, procedures and supports available.

Providing men with the opportunity to participate in the study online and to utilise the app to maintain a digital health record and receive treatment specific supportive content required amendments to our ethics application with 8 ethics committees. All of which have now been approved. These additions will significantly improve our interaction with patients throughout the study and are, therefore, worth the effort and delay in beginning the PROMs study. The PROMs component of the study will commence in September 2016.

2.4.2 Men against Cancer

IPCOR has strengthened our collaboration with MAC, a support group for men with prostate cancer. Men from MAC have kindly given their time to help the IPCOR study and provide feedback to us about our electronic PROMs collection tool and the app. Men from MAC were also very involved in our Prostate Cancer Research-Public Information Day hosted by MMI, with members chairing and speaking about their patient experience on the day and many members were in attendance. IPCOR hope to strengthen our collaboration with MAC in the coming period.

2.4.3 Cancer Trials Ireland

The IPCOR study has developed close links with Cancer Trials Ireland. Dr Áine Murphy, IPCOR project manager, presented the study at the Cancer Trials Ireland Genitourinary and Translational disease specific subgroup meetings in February 2016 with the goal of enrolling the IPCOR study in the Cancer Trials Ireland portfolio. The IPCOR registry could be used to identify appropriate patient cohorts for specific clinical trials and could provide relevant clinical and PROMs data on patients prior to their commencement on a clinical trial, subject to patient consent. Additionally, the altered treatment regimens and care pathways as well as the outcomes of such clinical trials are of particular interest to the IPCOR study. Therefore, a close association between IPCOR and Cancer Trials Ireland is mutually beneficial.

2.4.4 Prostate Cancer Outcomes – Compare and Reduce Variation study

The IPCOR study was successful in our application to become a participating site for the Movember Foundation funded global study: Prostate Cancer Outcomes-Compare and Reduce Variation. Thus, IPCOR will be collaborating with 10 countries and contributing both clinical and patient reported data on men newly diagnosed with prostate cancer from six Irish hospital sites to the global registry. The aim of this study is to identify the processes of care that lead to the best outcomes for patients and to develop strategies to implement these findings in sites across the globe.

2.4.5 Transdisciplinary Prostate Cancer Partnership (ToPCaP)

The IPCOR study has forged close links with ToPCaP, an international, multi-disciplined, organized consortium of prostate cancer researchers with access to a unique combination of facilities, data, biobanks and equipment that are pursuing the most urgent prostate cancer questions. Dr Áine Murphy attended the 8th Annual ToPCaP retreat in September 2015. The retreat was attended by international scientist and clinicians and the IPCOR registry was included in a list of resources that are available to the consortium and can be referenced and utilised in future funding calls.

ToPCaP consortium members at the 8th Annual retreat in Brooklodge Hotel, Co Wicklow on the 9th-11th September 2015.

3. Reporting Quality Indicators

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.

The quality indicators that the IPCOR study aims to report on have been updated and are represented in the tables below:

1. Safe and Patient directed Care

1.	Percent of men failing primary treatment at 12, 24, 36 and 48 months following radical therapy	Important to identify those failing curative therapy
2.	Percent of men failing hormonal therapy (first line treatment for metastatic disease)	These men have a poor prognosis
3.	Percent of men requiring adjuvant radiotherapy within 12 months of surgery	Important to identify those failing curative therapy
4.	Patient assessment of their physical health at 12 and 24 months	To identify men with disability and to intervene
5.	Patient assessment of their mental well-being at 12 and 24 months	To identify men with disability and to intervene
6.	Percentage of men with Intra-prostatic disease (pT2) with positive surgical margins (>1mm) after surgery	To quantify adequacy of surgical resection
7.	Percentage of men with Extra-prostatic disease (pT3) with positive surgical margins (>1mm) after surgery	To quantify adequacy of surgical resection
8.	Urinary, sexual and bowel function assessment performed at 12 and 24 months post primary treatment (EPIC-26)	Assess complications of treatment
9.	Skeletal Related Events (SRE) in patients receiving hormonal therapy	Important to record this important complication
10.	Overall survival at 5, 10 and 15 years following diagnosis	
11.	Treatment complications will be collected and reported	Treatment complications will be monitored.
12.	Total number of patients treated (by type of treatment – RP, RT, BT, AS, WW) at each hospital site	There is evidence that quality of care is impacted on by volume of patients treated.
13.	Clear documentation of clinical TNM stage in patient record	Documentation of clinical TNM provides evidence that a physical assessment has been undertaken
14.	PSA recorded at the time of diagnosis	

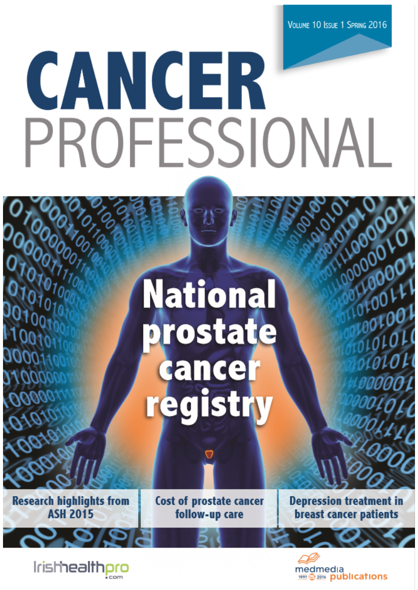
2. Appropriate Care

1.	Percentage of men with PSA level recorded post prostatectomy.	PSA levels for all men with prostate cancer who are having radical treatment should be checked at the earliest 6 weeks following treatment.
2.	Percentage of men with high grade disease who were given brachytherapy only (outside of national criteria – see guidelines)	Brachytherapy is NOT recommended for men with high grade prostate disease.
3.	Percentage of men with high risk disease (WHO grade 3 or higher) who were managed with active surveillance	Active surveillance is NOT recommended for men with advanced prostate disease.
4.	Percentage of men with high grade or advanced (non-metastatic) disease who receive combined hormonal therapy and radical radiotherapy	Adjuvant hormonal therapy is recommended for a minimum of 2 years in men receiving radical radiotherapy for localised prostate cancer who have a Gleason score of ≥ 8.
5.	Percent of men requiring salvage radiotherapy following surgery (with a detectable PSA) at 12, 24, 36 and 48 months.	Important to identify those failing curative therapy
6.	Percentage of Men with low risk disease who are managed with active surveillance initially, at 5 years and 10 years after diagnosis	Reflects best practice and relates to improved outcomes
8.	Percentage of men with pT2 disease with a PSA below detectable levels following prostatectomy	Reflects best practice and relates to improved outcomes
9	Percentage of men with pT3 disease with a PSA below detectable levels following prostatectomy	Reflects best practice and relates to improved outcomes

3. Access and Equity of care

1.	Time from initial referral to diagnosis (in days)	Delays may cause worse outcomes
2.	Time from diagnosis to treatment commencement (in days)	Reflects good organizational management
3.	Distance travelled from residence to (a) hospital of diagnosis and (b) hospital of main treatment	Reflects access to healthcare
4.	Percentage of men with localised disease who received curative treatment, overall and by socio-demographic group and hospital	Reflects equity of access to healthcare
5.	Percentage of all men with prostate cancer in Ireland who are enrolled in IPCOR study	Reflects validity of results and efficiency of enrollment system
6.	Percentage of men enrolled who complete the baseline questionnaire and each annual survey.	Validates results of study

4. Publications and Outreach



The IPCOR team published a featured cover story in the 2016 Spring Edition of Cancer Professional. The article was entitled "Bridging the data gap" and described the establishment and governance structures of the IPCOR registry.

We also described the IPCOR registry and goals of the study in an article entitled "Taking the fight to Cancer" in the Medical Independent, 18th April 2016 Edition.

Both of these articles can be found on the IPCOR website, www.ipcor.ie/Research-and-Publications

Additionally, IPCOR team members have engaged in numerous outreach and public engagement activities during the current reporting period.

- The PI, Mr David Galvin, gave a presentation at the John Fitzpatrick Prostate Cancer Conference on the 22nd of April 2016 about the establishment of the IPCOR registry and the role the data could play in future research studies.

- Mr Galvin also presented at a workshop in University College Dublin entitled "Clinical decision support systems for Breast and Prostate Cancer" held on the 7th and 8th of March 2016. Mr Galvin highlighted the types of data collected by the registry and our willingness to become involved in consortia applying for both national and international funding.

- Mr Galvin spoke at the Irish Association of Urology Nurses on the 29th of January 2016 to describe the IPCOR study and garner the support of the urology nurses who have been invaluable in helping the research officers get established in their hospitals and accessing the necessary data.

- In November 2015, MMI hosted a Public Information Day on Prostate Cancer Research in association with MAC to highlight the depth and breadth of research in prostate cancer being carried out in Ireland, particularly the IPCOR and Irish Programme for Stratified Prostate Cancer Therapy (iPROSPECT) studies, and to encourage patients to participate in research. This day was organized by Dr Áine Murphy, IPCOR project manager and Dr Suzanne Bracken, programme coordinator for iPROSPECT. The event was chaired by Barry Cahill of MAC and featured talks by rugby legend, Tony Ward and Roger Brownlee, both patients of prostate cancer. Mr David Galvin spoke about the development of a national prostate cancer registry and the hope that registry data will be used to improve prostate cancer care in Ireland. Prof Ray McDermott, Co-investigator of IPCOR and PI of iPROSPECT, spoke about the iPROSPECT study which aims to deliver a programme of stratified oncology for patients with prostate cancer. The information day was very well attended by patients, representatives from patient bodies and cancer charities, as well as clinicians and researchers.

Mr David Galvin, PI of the IPCOR study, speaking about IPCOR at the MMI Prostate Cancer Research - Public Information Day on 11th November, 2015.

Prof Ray McDermott, co-investigator of the IPCOR study, speaking at the MMI Prostate Cancer Research – Public Information Day on 11th November, 2015.

5. Future work

While the IPCOR study has achieved many milestones throughout the current reporting period, there is more crucial work to be done in the coming year to ensure the full establishment of the registry and the success of the IPCOR study.

The primary goal for the IPCOR study for the coming year is to commence the PROMs component of the study. The CRFG are currently developing the database for the PROMs submitted on paper and aligning it with our electronic PROMs collection tool developed by Patientmpower. All electronically submitted PROMs data will be extracted and imported into the PROMs database in the CRFG, therefore there will be one IPCOR PROMs database containing PROMs data submitted online or in paper format. A research assistant will be employed at the CRFG who will oversee the follow up of patients at appropriate timepoints and who will be responsible for inputting paper based PROMs data and managing the IPCOR PROMs database. A PROMs researcher will also be recruited who will aid in the analysis of PROMs data for reporting and who will drive future PROMs research by utilising the data to investigate important research questions and by identifying interesting cohorts of patients for analysis.

In time, the clinical and PROMs databases will be merged at the NCR to create a comprehensive registry of all men recruited to the IPCOR study. A biostatistician will be employed to work on the study and to coordinate the analysis of both the clinical and PROMs data for reporting and publications.

The first clinical annual reports will be published at the end of the next reporting period. These reports will describe the analyses on the proposed quality indicators for an Irish population of newly diagnosed prostate cancer patients for the first time. Clinicians will receive private reports with specific analyses on the outcomes of the patients they have treated. Publication of these reports at the end of the next reporting period will allow for sufficient numbers of men to be recruited to the registry and extensive clinical and PROMs data collection leading to meaningful data analysis and reporting in our first clinical report.

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