Establishing an Outcome Based National Tumour Registry for Prostate Cancer in Ireland
The Principles around which IPCOR was established:

1. IPCOR is a Clinical Research and Quality Improvement Project
2. It is led by Clinicians for Clinicians, Patients and Healthcare Providers
3. In addition, it is part of a Global effort funded by Movember to establish Prostate Cancer Registries across the world, the most mature of which is the Australian Prostate Cancer Registry
4. This International effort will allow direct comparisons of Clinical and Patient Reported Outcomes between countries and individual sites ("benchmarking") and drive improvements in prostate cancer care
5. Under Irish Legislation, the National Cancer Registry is allowed access to patient identifiable clinical information so IPCOR is being carried out with our partners in NCRI
Who is behind the IPCOR study?

IPCOR Investigators

David Galvin (Consultant Urologist)
Linda Sharp (Population Health Scientist)
Frank Sullivan (Consultant Radiation Oncologist)
Ray McDermott (Consultant Medical Oncologist)

IPCOR is carried out by a research partnership:

Funded by:

Collaboration with:
## Actual Case Numbers of Invasive Cancers for 2005 and Projected Case Numbers for 2010 - 2035

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>2005</th>
<th>2010</th>
<th>2015</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
<th>2035</th>
<th>% increase 2010 - 2020</th>
<th>% increase 2010 - 2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and Neck</td>
<td>277</td>
<td>352</td>
<td>452</td>
<td>573</td>
<td>709</td>
<td>882</td>
<td>1078</td>
<td>55</td>
<td>129</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>334</td>
<td>389</td>
<td>453</td>
<td>530</td>
<td>620</td>
<td>718</td>
<td>815</td>
<td>32</td>
<td>73</td>
</tr>
<tr>
<td>Stomach</td>
<td>453</td>
<td>468</td>
<td>491</td>
<td>516</td>
<td>545</td>
<td>569</td>
<td>581</td>
<td>10</td>
<td>21</td>
</tr>
<tr>
<td>Colorectal</td>
<td>2111</td>
<td>2422</td>
<td>2863</td>
<td>3402</td>
<td>4065</td>
<td>4805</td>
<td>5537</td>
<td>40</td>
<td>97</td>
</tr>
<tr>
<td>Pancreas</td>
<td>384</td>
<td>459</td>
<td>540</td>
<td>637</td>
<td>751</td>
<td>878</td>
<td>1016</td>
<td>39</td>
<td>91</td>
</tr>
<tr>
<td>Lung</td>
<td>1831</td>
<td>2084</td>
<td>2457</td>
<td>2906</td>
<td>3460</td>
<td>4086</td>
<td>4746</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>Melanoma skin</td>
<td>606</td>
<td>767</td>
<td>985</td>
<td>1247</td>
<td>1556</td>
<td>1918</td>
<td>2323</td>
<td>64</td>
<td>154</td>
</tr>
<tr>
<td>Female breast</td>
<td>2196</td>
<td>2720</td>
<td>3294</td>
<td>3976</td>
<td>4752</td>
<td>5670</td>
<td>6724</td>
<td>46</td>
<td>108</td>
</tr>
<tr>
<td>Gynaecological</td>
<td>1002</td>
<td>1146</td>
<td>1350</td>
<td>1587</td>
<td>1850</td>
<td>2154</td>
<td>2464</td>
<td>38</td>
<td>88</td>
</tr>
<tr>
<td>Kidney</td>
<td>375</td>
<td>501</td>
<td>542</td>
<td>625</td>
<td>731</td>
<td>870</td>
<td>1023</td>
<td>34</td>
<td>91</td>
</tr>
<tr>
<td>Bladder</td>
<td>474</td>
<td>497</td>
<td>543</td>
<td>594</td>
<td>650</td>
<td>705</td>
<td>745</td>
<td>19</td>
<td>42</td>
</tr>
<tr>
<td>Brain and CNS</td>
<td>306</td>
<td>382</td>
<td>448</td>
<td>530</td>
<td>634</td>
<td>757</td>
<td>896</td>
<td>39</td>
<td>97</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>601</td>
<td>804</td>
<td>996</td>
<td>1231</td>
<td>1514</td>
<td>1852</td>
<td>2233</td>
<td>53</td>
<td>129</td>
</tr>
<tr>
<td>Prostate</td>
<td>2415</td>
<td>2871</td>
<td>3437</td>
<td>4093</td>
<td>4828</td>
<td>5668</td>
<td>6559</td>
<td>43</td>
<td>97</td>
</tr>
<tr>
<td>All excl NMSC</td>
<td>15678</td>
<td>19060</td>
<td>23187</td>
<td>28110</td>
<td>33831</td>
<td>40399</td>
<td>47296</td>
<td>47</td>
<td>111</td>
</tr>
<tr>
<td>All cancers</td>
<td>21973</td>
<td>26283</td>
<td>31798</td>
<td>38379</td>
<td>46049</td>
<td>54780</td>
<td>63845</td>
<td>46</td>
<td>108</td>
</tr>
</tbody>
</table>

Source: NCRI, 2008
Scope and Recruitment

1. NCRI is present in all Irish Hospitals, both **public and private**, so provides an established system for data collection

2. IPCOR estimates that 90% of patients will be recruited through our largest 15 hospitals - (Funding limits data collection to these larger hospitals for now)

3. Hospital and Physician recruitment
   a) All **Physicians** treating prostate cancer were contacted and asked to **support** the study prior to grant approval
   b) **Local Leads** were established in each site, allowing Ethical approval and CEO approval to be obtained
   c) Before recruiting patients, **consent was obtained** from each Consultant to involve their patients in the IPCOR study
Governance Structure

**Management Committee**
- Peter Ryan, ISU Rep
- Frank O’Brien, Urology
- Ray McDermott, Med Onc
- David Gallagher, Med Onc
- Paul Villanti, Movember
- Sue Evans, Movember
- Jim Scott, Patient Rep
- Robert O’Connor, ICS
- Garret Durkan, Urology
- Stephen Finn, Pathology
- Isabella Bray, ICS
- Jerome Coffey, NCCP
- Fiona Dwane, NCRI

**Data Management Committee**
- NCRI Representative
- Julie Nossiter, NPCA UK
- Aine Murphy IPCOR
- Leah Bentham, TRO Rep
- Linda Sharp, Epidemiology

**Steering Committee**
- NCRi Representative
- Julie Nossiter, NPCA UK
- Aine Murphy IPCOR
- Leah Bentham, TRO Rep
- Linda Sharp, Epidemiology

**Project Management**
- Paul Barry, MMI
- Aine Murphy, Project Manager

**Sustainability Working Group**
- Liase with Scientific Investigators, Researchers, ICORG, Corporate Industry sustain the Registry

**NCRI**
- Representative
- Aine Murphy, IPCOR
- David Galvin, IPCOR
- Epidemiology Rep
- PROM Rep
- IAUN Rep

**Par Statin**
- Swedish NCR
- Andrew Vickers, MSKCC
- Paul Cathcart, NPCA UK
- Neil Martin, Dana Farber
- Mark Frydenburg, President USANZ
Global Networking

USA
- Andrew Vickers
- Niall Martin

Australia
- Paul Villanti
- Sue Evans

Global Prostate Cancer Network
- IPCOR – APCCR
- Reduce Variation Study
- Ironman Study

Ireland
- David Galvin
- Ray McDermott
- Frank Sullivan
- Linda Sharp
- Aine Murphy

UK
- Paul Cathcart
- Caroline Moore
- Julie Nossiter
Why are we collecting this data?

➢ We would like to analyse the data to determine the outcomes for men with prostate cancer and to assess men’s quality of life during and after treatment.

➢ We want to produce reports and provide recommendations to hospitals and the National Cancer Control Programme to improve prostate cancer care. (NB. No patient, doctor or hospital will ever be identified in any of our reports)

➢ Similar databases have been set up in Australia and the UK and we would like to compare our data with theirs to ensure Irish men are receiving the best standard of care in the world.

First Public report, available on www.ipcor.ie
What are the ultimate goals of the IPCOR study?

1. Create national standards for prostate cancer care in Irish hospitals

2. Collect data and produce reports that will influence decision makers to improve prostate cancer care

3. Ensure decisions about prostate cancer care are transparent and based on quality data

4. Carry out a variety of studies which investigate issues that impact men with prostate cancer e.g. dietary and lifestyle issues

5. Compare Irish prostate cancer care with care around the world and ensure Irish men receive the highest standards of care
IPCOR is Health Outcomes Research

- Outcomes Research is the foundation for measuring quality of healthcare
- It provides the tools for healthcare managers and policy makers to make improvements
- In practice it is the generation and use of Evidence to make Healthcare decisions for Providers and Consumers
- In its absence, Providers continue to fund interventions in the absence of high quality clinical and patient reported outcomes data
- IPCOR will provide the Evidence needed to drive change
So How does it all work?

➢ Patients identified at MDT and clinical data recorded – NCRI informed

➢ Patients made aware of IPCOR information leaflet in Clinic

➢ NCRI send a Consent form and Baseline PROMs to complete “Opt Out”

➢ Patient uses Paper based, Web based or App based method of completing PROMs

➢ The Research Officer completes the clinical data collection 6 to 12 months later

➢ The patient is invited to complete PROMs at 0, 6, 12, 24 and 36 months
### 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

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Examples of clinical data items to be collected by the IPCOR study
IPCOR aims to improve prostate cancer care and maximise men's quality of life
Just to make sure we don't offend you,

We need your consent to begin.

- I understand that researchers from hospitals, third level institutions and biopharma companies can apply to use my biological specimens and my accompanying de-identified data for research studies that have been approved by the relevant Research Ethics Committee and the IPCOR Steering Committee, including studies investigating the genetic influences related to cancer growth, early detection and treatment. I give permission for my de-identified data and biological specimens to be shared between different institutions.

- I understand that my involvement in the study is voluntary and that I may withdraw at any time, without giving reason, and without this decision affecting my future treatment or medical care. I understand I will not benefit financially should research lead to a new test or treatment.

- I understand that this project has been approved by the research ethics committee in my hospital.
Prostate cancer survey (short)

1. Over the past 4 weeks, how often have you leaked urine?
   - More than once a day
   - About once a day
   - More than once a week
   - About once a week
   - Rarely or never
4. How big a problem, if any, has each of the following been for you during the last 4 weeks?

<table>
<thead>
<tr>
<th></th>
<th>No Problem</th>
<th>Very Small Problem</th>
<th>Small Problem</th>
<th>Moderate Problem</th>
<th>Big Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Dripping or leaking urine</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>B. Pain or burning on urination</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>C. Bleeding with urination</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>D. Weak urine stream or incomplete emptying</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>E. Need to urinate frequently during the day</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Thank you for contributing to our survey.

You have helped us take a step forward in our research of Prostate Cancer. Your next survey will be on the 16/7/2016.

Download the Prostate Cancer App today

[App Store] [Google Play]
IPCOR App for iPhone and Android
Survey Tracker

Urinary Function

5/5 It's been tough but you are on the right track.
Data analysis will be performed by funded Epidemiologists located at NCRI and at the PROM centre in CRF Galway and scientific data research will be undertaken.

IPCOR will report in several ways:

- **Annual Reports will be of 2 types**
  1. General Report made available online to the general public
  2. Clinical Report available to all Clinicians, Hospitals and Stakeholders with recommendations by the IPCOR Researchers and Steering committee

- **Physician and Site Reports**
  1. Individual Physician reports detailing their patient’s outcomes
  2. Individual Hospital reports detailing their patient’s outcomes

- **Scientific Publications in peer reviewed journals**
Clinical Analysis and Reporting

① Safe, effective and patient-centered care
   a) Treatment failure at 12, 24 and 36 months (CAPRA risk stratified)
   b) Physical and Mental health at 0, 6, 12, 24 and 36 months
   c) Urinary and Sexual health at 0, 6, 12, 24 and 36 months
   d) Volume of patients and treatment at each site

② Appropriate Care
   a) Percent of men receiving hormonal therapy with RT in high grade disease
   b) Percent of men offered brachytherapy monotherapy in high grade disease
   c) Percent of men offered active surveillance with high grade disease

③ Timeliness, equity and access to care
   a) Time from referral to Initial Treatment
   b) Effect of socio-economic status on access and treatment
   c) Geographical variation in treatment choice and outcomes
<table>
<thead>
<tr>
<th>From 2.16 to 6.17</th>
<th>N Value</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Men Registered</strong></td>
<td>3439</td>
<td>Dublin ML 947 (27%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dublin NE 803 (23%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South 855 (24%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>West 820 (23%)</td>
</tr>
<tr>
<td><strong>Mean Age</strong></td>
<td>65.5 years</td>
<td>(SD 8.2 years)</td>
</tr>
<tr>
<td><strong>Mean PSA</strong></td>
<td>7.58 (N=3221)</td>
<td>(5.53-11.7) interquartile</td>
</tr>
<tr>
<td><strong>Public Private</strong></td>
<td>2191 (63.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1234 (35.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>Screening</td>
<td>69%</td>
</tr>
<tr>
<td></td>
<td>Symptoms</td>
<td>7.9%</td>
</tr>
<tr>
<td><strong>DRE Findings</strong></td>
<td>Normal</td>
<td>36.3%</td>
</tr>
<tr>
<td></td>
<td>Suspicious</td>
<td>38.3%</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>25.2%</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Histological</td>
<td>98.4%</td>
</tr>
<tr>
<td></td>
<td>Clinical</td>
<td>0.9%</td>
</tr>
<tr>
<td><strong>Gleason Grade</strong></td>
<td>G3+3 – WHO1</td>
<td>1202 (34.9%)</td>
</tr>
<tr>
<td></td>
<td>G3+4 – WHO2</td>
<td>972 (28.2%)</td>
</tr>
<tr>
<td></td>
<td>G4+3 – WHO3</td>
<td>529 (15.3%)</td>
</tr>
<tr>
<td></td>
<td>G4+4 – WHO4</td>
<td>370 (10.7%)</td>
</tr>
<tr>
<td></td>
<td>G9 G10 – WHO5</td>
<td>310 (9.1%)</td>
</tr>
<tr>
<td><strong>Mean Number of Cores on Bx</strong></td>
<td>35.7%</td>
<td>(16.7 - 58.3) interquartile</td>
</tr>
</tbody>
</table>
How can IPCOR benefit Healthacare Providers?

- To support Interventions with the best clinical and patient reported outcomes

- Standardise expected outcomes for patients determined by prognostic (CAPRA) category

- Ensure patients receive optimal outcomes
  - Promote treatments that are clinically effective
  - Promote treatments that are cost effective
  - Promote treatments with the best patient reported outcomes
Very limited data publically available on the cost of funding Prostate cancer care

Cancer care in Ireland in 2009 costs €1.44 billion (Richard Sullivan Lancet Oncology 2013)

Prostate cancer care represented 8% of costs in Europe

This equates to €110 million in Ireland per year
Program Overview

The overall aims of the collaborative include, among others, evaluating and improving patterns of care in the radiographic staging of men with newly diagnosed prostate cancer, reducing biopsy-related complications and assessing repeat biopsy patterns, improving patient outcomes after radical prostatectomy, enhancing patient-centered decision making among men considering local therapy for early-stage prostate cancer, and understanding and reducing variation in the use of androgen-deprivation therapy. Participating practices submit data in a clinical...
Value Partnerships is a collection of patient safety, clinical quality and care process efforts that makes health care work better in Michigan.

Learn More
By comparing data and sharing observations, participants can identify best practices associated with improved patient outcomes, as well as share these best practices with other physicians throughout Michigan. Objectives include reducing complications from biopsy, improving outcomes after prostatectomy, and reducing variation.

For more information, go to musicurology.com.

Results

- Reduced by 50 percent the utilization of radiographic imaging for staging patients with low-risk prostate cancer.
- Improved medical record documentation of Clinical TNM Staging from 54 percent in 2012 to 76 percent in 2014.
- Developed specific care pathways aimed at reducing prostate biopsy-related hospital admissions, which has decreased biopsy related admissions by 50 percent.
- Established MUSIC Notable Outcomes and Trackable Events after Surgery (MUSIC NOTES) to define an uncomplicated early post-operative recovery, and facilitate comparison of these outcomes across diverse urology practices.
• The benefits of an Outcome based tumour Registry that should serve as the template for similar projects in other Cancer types in Ireland

• IPCOR has the potential to revolutionise Prostate cancer treatment in Ireland, and beyond, with Improved patient outcomes and efficiencies at it’s core

• The need for high quality data to direct change in our Healthcare Service has never been greater
I wish to acknowledge the enormous effort by a large number of individuals:

- Project Manager: Dr Aine Murphy, Dr Suzanne Bracken (Dublin)
- NCRI Data Manager: Fiona Dwane (Cork), Dr Conan Donnelly
- PROM CRF Manager: Aideen O’Doherty (Galway)
- IT, App and website development: Eamonn Costelloe
- Research Registrars: Leah Bentham, Jean O’Connor, Hazel Smith, Emer McCarthy and Lisa McGowan. And administrative staff in Cork (Christine) and Galway.
- Members of the Steering Committee, Data Committee, Management Committee and the International members of the Scientific Advisory Committee
- All the contributing Urologists, Medical Oncologists and Radiation Oncologists, hospital and nursing staff that continue to support this study
- Movember (Paul and Shannyn) and all the men and women that support the Mo
- Irish Cancer Society (Dr Robert O’Connor and Isabelle)
- All the Irish Men who’s have to deal with their diagnosis
How can you find out more about the IPCOR study?

@IPCOR_Ireland

Email: david@ipcor.ie