

## **Prostate Cancer Clinical Outcomes Database The Cancer Council South Australia Annual Report**

24 March 2011

### **Prostate Cancer Clinical Outcomes Database**

Principal Investigator: Kim Moretti Chair, Steering Committee

Principal Collaborators: Kym Horsell Deputy Chair, Steering Committee  
Kerri Beckmann member, Steering Committee  
Michael Chong member, Steering Committee  
Darren Foreman member, Steering Committee  
Jimmy Lam member, Steering Committee  
Jeff Roberts member, Steering Committee  
Peter Sutherland member, Steering Committee

Research Team: Dr Michael Chong, Dr Darren Foreman, Dr Kim Moretti, Dr Grant Buchanan, Ms Kerri Beckmann, Dr Carole Pinnock, Ms Tina Kopsaftis

Data Management: Tina Kopsaftis, Clinical Data Coordinator  
Scott Walsh, Data Manager

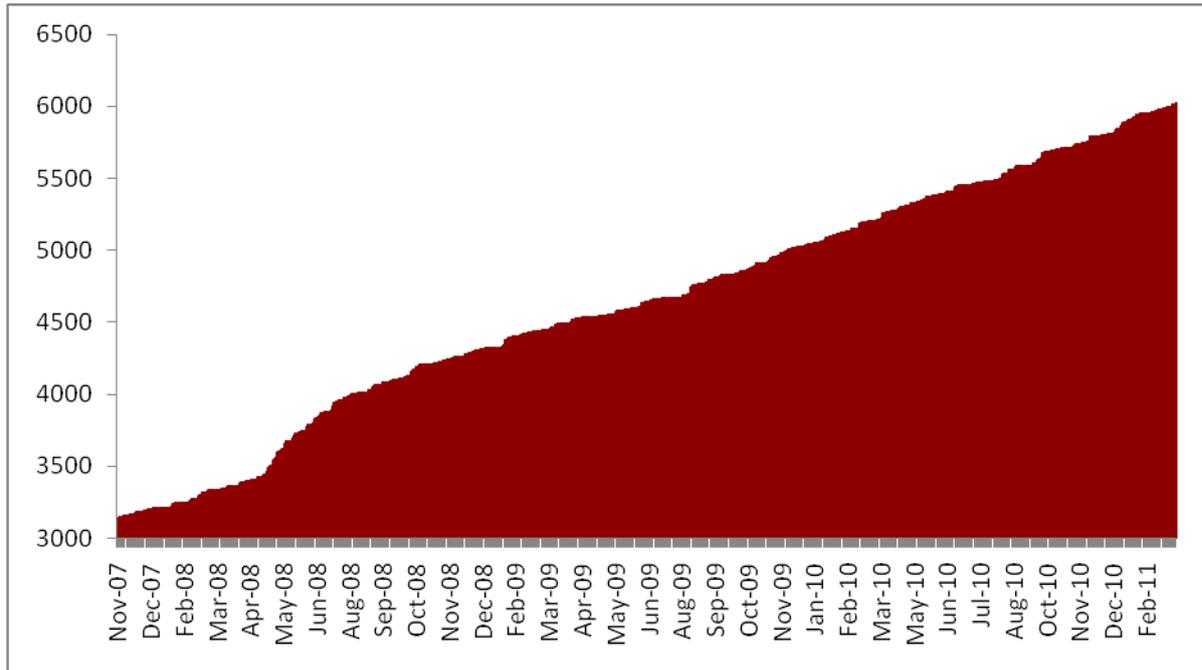


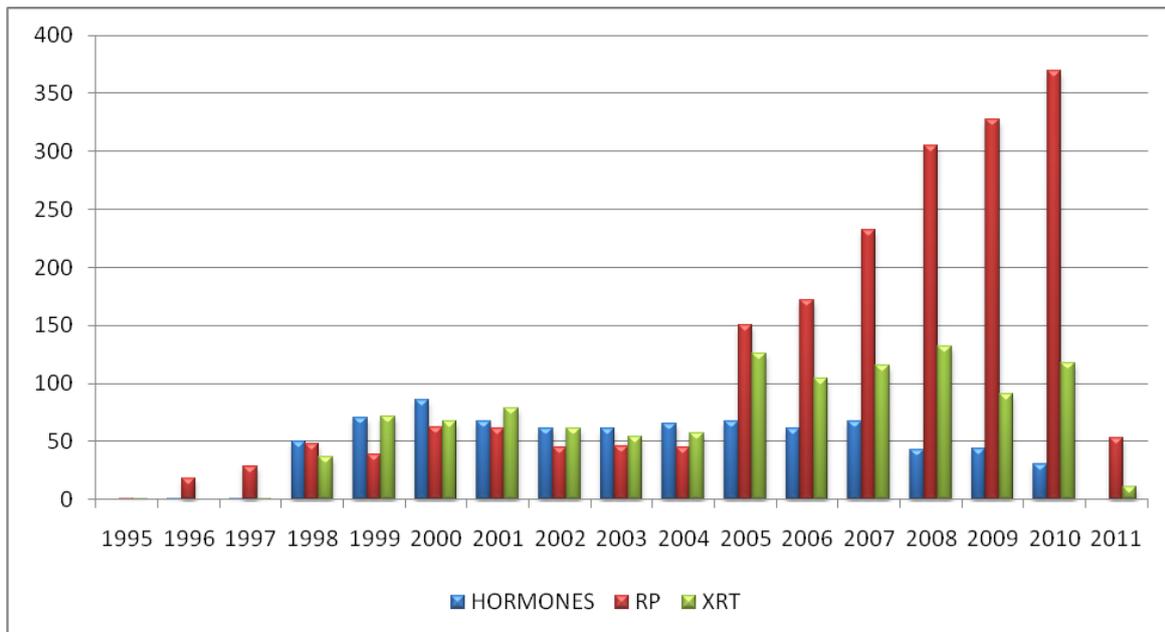
Figure 1 – Growth of the database to July 2010

### Summary: current status of the database

The SA Prostate Cancer Clinical Outcomes Database, established in 1998 and managed by a team at the Repatriation General Hospital (RGH), is an ongoing collaborative venture of RGH, Royal Adelaide (RAH) and Queen Elizabeth (QEH) and Flinders Medical Centre/Repatriation General hospitals. We were fortunate to receive a data infrastructure seeding grant in 2009 which has supported a number of important changes to take place in 2010. These are:

- Establishment of a steering committee with key stake-holder and consumer representation.
- Growing participation of private practice urologists with enhanced collection of consented private patient data
- Participation in national register of clinical quality databases and development of database documentation to support that
- Specialist trainee and registrar involvement in analyses of data and presentation to urological meetings including the European Association of Urology and American Urological Association
- Ongoing collaboration with international colleagues, particularly involving the validation of US predictive tools for use in Australian prostate cancer patients. We have had a meeting with Professor Peter Carroll, Prof and Chair, Department of Urology, University of California San Francisco, and are pursuing international collaborations with CaPSURE, a large community-based prostate cancer outcomes registry in the US.

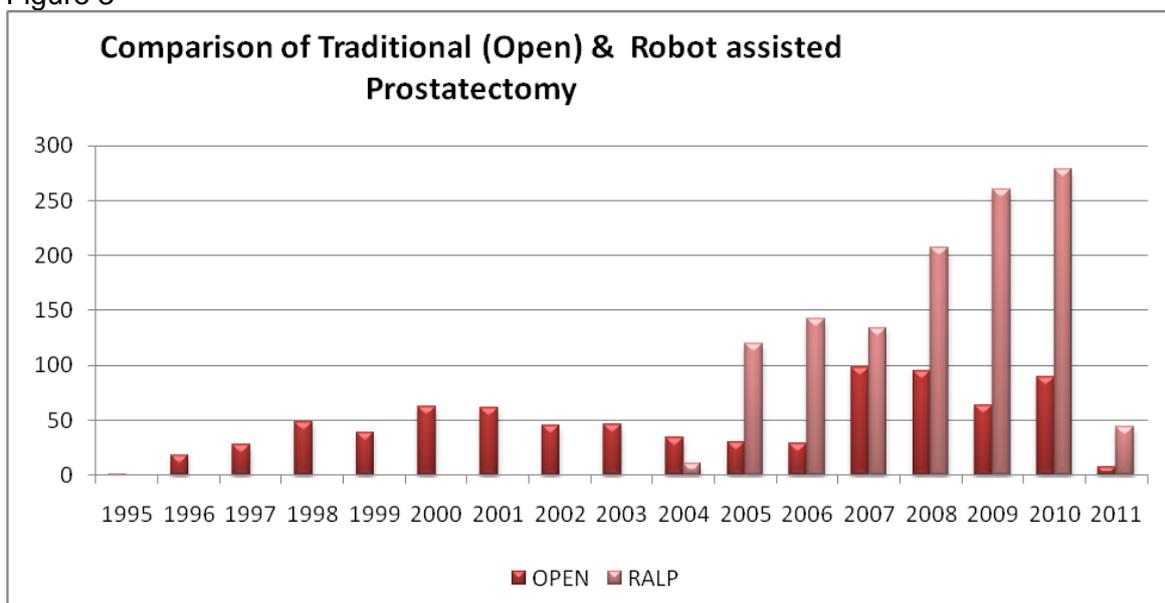
Currently, there are **6024** men with pathologically confirmed prostate cancer in the database, of which over **649** are consented private patients. We are currently adding over 800 patients per year. We estimate that the collection represents more than 30% of all SA diagnoses over the 10 year period that the database has been running. The database growth has accelerated since 2008 with the inclusion of consented private patients and data linkage through the previously reported e-Prostate (a linkage tool that sources data from within the OACIS Clinical Reporting Repository)



**Figure 2 – Distribution of treatment choices amongst patients within the database**

This figure shows a dramatic increase in the number of radical prostatectomies which coincides with the establishment of robot-assisted laparoscopic prostatectomy (RALP) and the RAH. Figure 3 shows a breakdown between the traditional open prostatectomy numbers and RALP.

**Figure 3**



## **Database Fields and Data Sources**

The database stores details required to perform complex analyses of patient outcomes. These data included demographic, diagnostic, treatment and follow up variables. For patients who are identified in a timely manner, baseline symptoms (using the shortened Extended Prostate cancer Index Composite – EPIC questionnaire) and later post intervention symptoms are collected. These data are used for risk adjustment so that clinical outcomes for comparable patients can be compared.

Currently, data collection is from a wide range of sources including case notes, the OACIS interface, private rooms (of consenting patients) and annually from Births, Deaths and Marriages. Increasingly we are working toward electronic collection of data, so that currently (apart from patient symptom questionnaires), no paper data collection tools are used. The introduction of electronic health record systems in private practice facilitates this, although these are primarily business tools.

## **Governance**

A steering committee comprising major stakeholders and research collaborators was established in April 2010. The committee was established with terms of reference and membership consistent with the Operating Principles for Australian Clinical Quality Registries drawn up on behalf of the Australian Commission on Safety and Quality in Healthcare. Its membership comprises urologists from the three contributing hospitals, a radiation oncologist, a Cancer Council SA staff member with experience in cancer registries and analysis and a prostate cancer consumer who is also a member of the Prostate cancer Foundation of Australia. The membership is listed on the front of this report. The chair, urologist Dr Kim Moretti is an energetic and committed advocate for the database with national networks within the urological community. He has already been very active in seeking funding for and promotion of the database.

The committee has formulated policy on ownership and access to the data, reporting, facilitation of research and database promotion. It has provided feedback and direction to the trainees and registrar undertaking analyses of the data. The committee has actively assisted with ensuring some clinical data items, normally poorly recorded are completed in clinical case notes and established a process for providing feedback to clinical services, where we receive unsolicited comments on patient information sheets that are relevant.

An affiliation with Adelaide University was established in late 2010 and we are currently developing an active working relationship with Flinders University.

### **Staff changes: New Data Manager**

Our previous data manager, David Tamblyn has taken up an appointment with Adelaide University. David joined us in 2004 and contributed enormously to the development of the database to its current capacity. We are extremely grateful to him for the achievements during this period. He retains an interest in and collaboration with the project.

We have been fortunate to find someone with a health background; considerable systems design expertise and knowledge of SA Health Services data systems. Scott Walsh was involved as project manager in the development of the successful linkage tool, eProstate. He has a background

in nursing and is Health Informatics Coordinator for the Southern Area Health Service. Scott works 0.4FTE with the database. Since joining us in May 2010 has developed the SAPCCOD Data Dictionary, implemented a web-based patient summary report, consolidated the PCCOC document archive, extracted multiple datasets for analysis and commenced work on an architectural roadmap to transition from the current database a new platform within the next 2 years.

### **Database developments**

As a first steps we have established a new reporting repository database (CapStudies) which combines the data from the current collection databases into a single repository to support the extraction of research datasets and in addition, the development of a suite of automated, descriptive audit reports for collaborators.

### **Enhanced engagement with private Urologists.**

One of the pleasing outcomes of establishing the steering committee and the leadership of its chair is that we are developing good working relationships with private urologists and enhancing this part of the data collection. The database can provide an important service in reporting back to specialists their individual patient series. We can also provide assistance with setting up data collection systems so clinicians can collect high quality clinical data suitable for extraction and reporting. We currently provide assistance with analysis of patient series.

This function of the project may remove some of the barriers to clinicians contributing private patient data. It is an important goal of the database project. Audit and feedback on individual patient series has been shown to be an effective agent of quality improvement (Scott I, Intern Med J., 2009. **39**(6): p. 389-400).

### **Patient summary sheet: improving clinical practice**

The patient summary sheet (PSS) (Appendix 1) condenses the prostate cancer clinical history of a patient onto a single page and was originally requested by Urologists to assist them in a clinical consultation. Although all the data is present in the medical record, it is distributed in different sections and therefore not easily accessible in the limited time frame available. The format of the summary sheet has been further refined by the steering committee. The PSS tool can be accessed directly from within the SA-Health domain from the clinic rooms. The report runs in real-time to display all available information and presents it in a single page format with a graphical representation of PSA changes over time and a chronology of interventions. This has ethics approval for use at RGH, FMC and TQEH.

### **Recent Research Activity**

#### Comparison of the Kattan / MSKCC nomogram and CAPRA

The database team has engaged international collaboration from the Professor of Medicine, Epidemiology and Biostatistics at the Cleveland Clinic Lerner College of Medicine, Michael Kattan. Professor Kattan has pioneered the use of nomograms in prostate cancer. We have found that while international prediction tools are useful discriminators of risk, the absolute risk predictions vary widely. Current US prediction tools did not predict as well as one developed 10 years earlier in a US cohort. These findings have been presented at the Urological Society of Australian and New Zealand

SA section and been accepted for oral presentation at the national meeting next year. We are currently preparing a manuscript for publication,

### Androgen Receptor regulation in Prostate cancer and adjacent stromal tissue

In collaboration with Grant Buchanan of the Freemason's Foundation Centre for Men's Health, this study measures androgen receptor (AR) activity in stromal and epithelial compartments of prostate cancer and benign prostatic hypertrophy tissue in men diagnosed with incidental prostate cancer. The cohort was identified retrospectively from patients in the prostate cancer database. Tissue microarrays were constructed and immuno-histochemical staining for AR activity demonstrated a relationship between AR activity and clinical parameters (PSA, Gleason score) which differed between tissue compartments. Findings are consistent with epithelial androgens driving proliferation and PSA production in prostate cancer, while low stromal AR suggested a protective role of stromal androgen action in the prostate microenvironment.

We are currently submitting an abstract for American Urological Association meeting in 2011 and will present the findings also at the national Urological Society of Australia and New Zealand (USANZ) meeting. We hope these findings will support the submission of a NHMRC project grant next year.

### **Recent Presentations**

We are particularly pleased that 2 of the 3 presentations by specialist trainees and registrars received awards at the SA USANZ meeting. Dr Alex Jay won The St. Paul's ball for the best paper by a member of the SA Section of USANZ' for his paper on poorly differentiated, low PSA prostate cancer. Dr Sam Chopra won best paper of the SA Annual Scientific Meeting for his presentation on validation of US prediction tools in an SA population. The database has an important role in providing opportunities for engagement in research analyses of medical graduates who otherwise may have not had this experience. This is requisite of the SET specialist training program in urology.

### **SA Prostate Cancer Clinical Outcomes Database: 2010 Update**

C.Pinnock on behalf of SA Prostate Cancer Outcomes Database Steering Committee and Management Team. *Abstract submitted for presentation at the local USANZ meeting 11&12 September 2010*

**Clinical Profile of Veterans and Non-Veterans diagnosed with Prostate Cancer in the South Australian Prostate Cancer Outcomes Database.** Harbison, S. Chopra, C.Pinnock, Kopsaftis, S. Walsh. *Abstract submitted for presentation at the local USANZ meeting September 2010*

### **Poorly differentiated low PSA prostate cancer – how do these men perform?**

A Jay, C Pinnock, D Tamblyn, T Kopsaftis. *Abstract submitted for presentation at the national USANZ meeting in Christchurch New Zealand, February 2011 and local USANZ meeting September 2010*

**Comparative analysis of predictive accuracy of risk assessment tools in Australian Prostate Cancer patients** S Chopra, D Tamblyn, Y Chang Hong, C Pinnock, T Kopsaftis, M Kattan. *Abstract submitted for presentation at the national USANZ meeting in Christchurch New Zealand, February 2011 and local USANZ meeting September 2010*

**Active Surveillance – can we reduce the rate of failure?** S Chopra, M Chong, D Tamblyn, T Kopsaftis, C Pinnock. *Abstract submitted for presentation at the national USANZ meeting in Christchurch New Zealand, February 2011 and local USANZ meeting September 2010*

**Update on the current status of prostate cancer clinical outcomes database (PCCOD); recent analyses, presentations and publications, research summary for 2009; Future directions for 2010 and beyond.** Sam Chopra, David Tamblyn, Carole Pinnock, Tina Kopsaftis: Presented at the weekly Thursday urology meeting on 17/12/09 at RGH

**Is peri neural invasion in prostate biopsy predictive of cancer recurrence Post-radical prostatectomy?** S Chopra, C Pinnock, D Tamblyn, T Kopsaftis, P Sutherland (moderated poster presentation at the EAU meeting in Barcelona April 2010, podium presentation at USANZ, national meeting in Perth, February 2010. Pilot Data presented by Bax, K. and Fuller, A. at USANZ SA 2009 meeting.

**International validation of the CAPRA Score for predicting recurrence following radical prostatectomy: results from an Australian cohort.** S Chopra, C Pinnock, D Tamblyn, T Kopsaftis, A Esterman, P Sutherland (moderated poster presentation at the EAU meeting in Barcelona April 2010, podium presentation at USANZ, in Perth February 2010 and podium presentation at AUA, in San Francisco, May 29-June 3, 2010.

**External Validation of CAPRA Score amongst Radical Prostatectomy Patients from the Prostate Cancer Clinical Outcomes Database** S Chopra, C Pinnock, D Tamblyn, T Kopsaftis, P Sutherland (USANZ national meeting in Perth, February 2010).

#### Research Grants

- Daw Park Foundation – Chemokine Signalling in Prostate Cancer: \$23,000 November 2010.
- Flinders University/Flinders Medical Centre Foundation: Stromal androgen receptor activity in benign and malignant prostate tissue. Carole Pinnock, Grant Buchanan, Sam Chopra: \$17,500 July 2010

#### Conclusions

2010 has been a particularly successful year with major developments in our governance, database operations, staffing and research. With new directions and capacities provided by the steering committee, we are particularly excited by potential future directions for the project.

Signed:



Chair: Kim Moretti MBBS, FRACS (Urol)



Executive Officer: Carole Pinnock AM, PhD  
15 November 2010

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# Appendix 1: Patient Summary Sheet

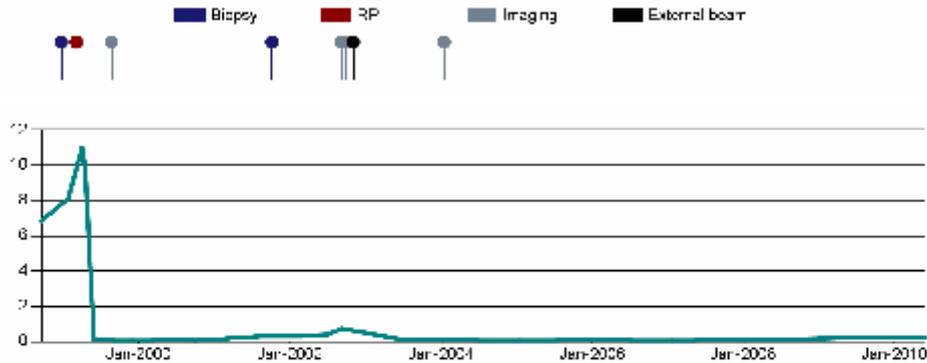


## CAP Outcome Database

Summary for: Alan Smithee (DOB: 25/12/1899)

123456 (FMC): 456789 (RAH): 654321 (RGH): 987654 (RAH)

### PSA and Treatment History



### Biopsy

#### Diagnostic Procedure: TRUS guided needle biopsy

Date: 10/02/1999 Positive cores: 2 of 6  
 Age at Biopsy: 100 Gleason: 4 + 4 = 8  
 Location: Private Rooms Perineural Invasion: Yes  
 Laboratory: Gribbles High Grade PIN: No

#### Procedure: TRUS guided needle biopsy (Result: Negative)

Date: 31/10/2001 Positive cores: 0 of 4  
 Age at Biopsy: 102  
 Location: RGH - Repatriation  
 General Hospital  
 Laboratory: Southpath  
 Urologist: White

### Radical Prostatectomy

Date: 20/04/1999 RGH - Repatriation General Hospital  
 Gleason: 4 + 5 = 9 T3a-N0-M0

#### PATH DETAILS

Surgical Margins: Negative / ECE: Yes / SV Invasion: No / Tumour Volume: 8.19

### Radiotherapy Radical External beam

Started 18/11/2002 Stopped 08/01/2003  
 Dose: 61 Fraction: 34  
 MRI negative. XRT: in first phase the lesser pelvis received 45 Gy in 25 fractions, then the tumour bed received a further 16.2 Gy in 9 fractions. Rad Onc BORG

### Imaging

Date	Type	Result
24/09/2002	WBBS (Whole body)	Result: No Distant Mets
14/10/2002	MRI (Pelvis)	Result: No Distant Mets
21/01/2004	Ultrasound - Other (Testes)	Result: No Distant Mets

### PSA

Date	Lab	Result
03/10/2001	IMVS	=0.30ng/ml
05/03/2002	IMVS	=0.33ng/ml
03/07/2002	IMVS	=0.41ng/ml
09/09/2002	IMVS	=0.68ng/ml
13/06/2003	IMVS	=0.17ng/ml
21/11/2003	IMVS	=0.09ng/ml
14/01/2004	IMVS	=0.10ng/ml
30/06/2004	IMVS	=0.05ng/ml
17/01/2005	IMVS	<0.05ng/ml
08/07/2005	IMVS	<0.05ng/ml
30/01/2006	IMVS	<0.10ng/ml
13/07/2006	IMVS	<0.05ng/ml
22/01/2007	IMVS	=0.08ng/ml
02/05/2007	IMVS	=0.07ng/ml
12/10/2007	IMVS	=0.10ng/ml
15/05/2008	IMS-LAB	=0.10ng/ml
29/10/2008	IMS-LAB	=0.14ng/ml
20/05/2009	IMS-LAB	=0.18ng/ml
23/10/2009	IMS-LAB	=0.19ng/ml
24/05/2010	IMS-LAB	=0.19ng/ml

### Treatment

<b>Radical Prostatectomy</b>	
Started	20/04/1999
<b>Radiotherapy Radical - External beam</b>	
Started	18/11/2002
Stopped	08/01/2003

The information presented in this report has been collected for research purposes. While every effort is taken to ensure its accuracy, it should not be used as the basis for treatment decisions. There may be new, additional, or more recent information which is relevant to the care of this patient.