The Prince Charles Hospital

Queensland Government
Queensland Health

The Prince Charles Hospital Cardiac Catheterisation Laboratory Annual Report 1st July 2014 - 30th June 2015

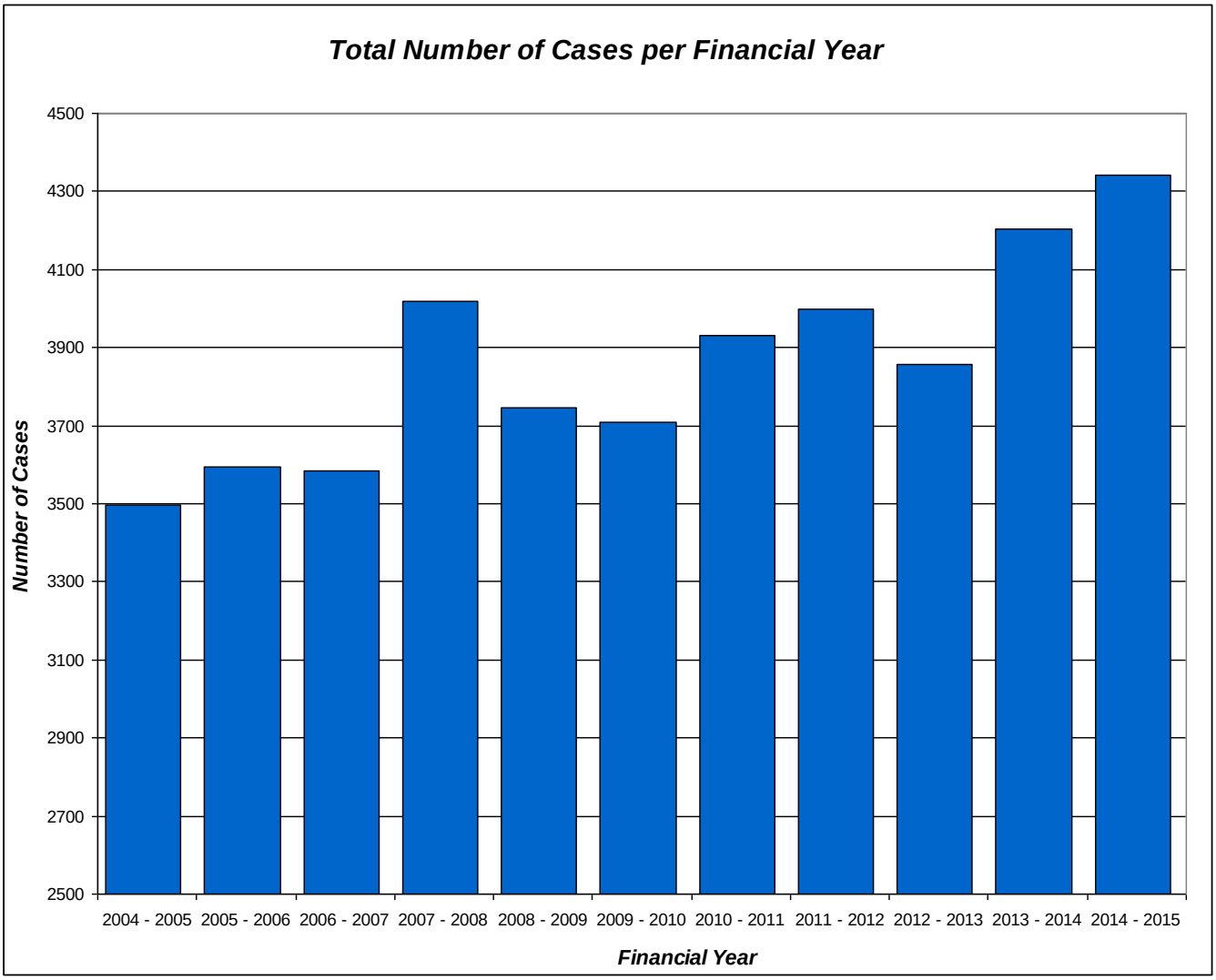
Prepared by: Michael Savage – Consultant Cardiac Scientist
Cardiac Catheterisation Laboratory

Contents

Clinical Year Report 2014 – 2015

Total Number of Cases – Financial Year

Financial Year	Total Number of CCL Cases
2004 – 2005	3,495
2005 – 2006	3,595
2006 – 2007	3,585
2007 – 2008	4,020
2008 – 2009	3,747
2009 – 2010	3,708
2010 – 2011	3,931
2011 – 2012	4,000
2012 – 2013	3,857
2013 – 2014	4,204
2014 – 2015	4,343



Patient Demographics

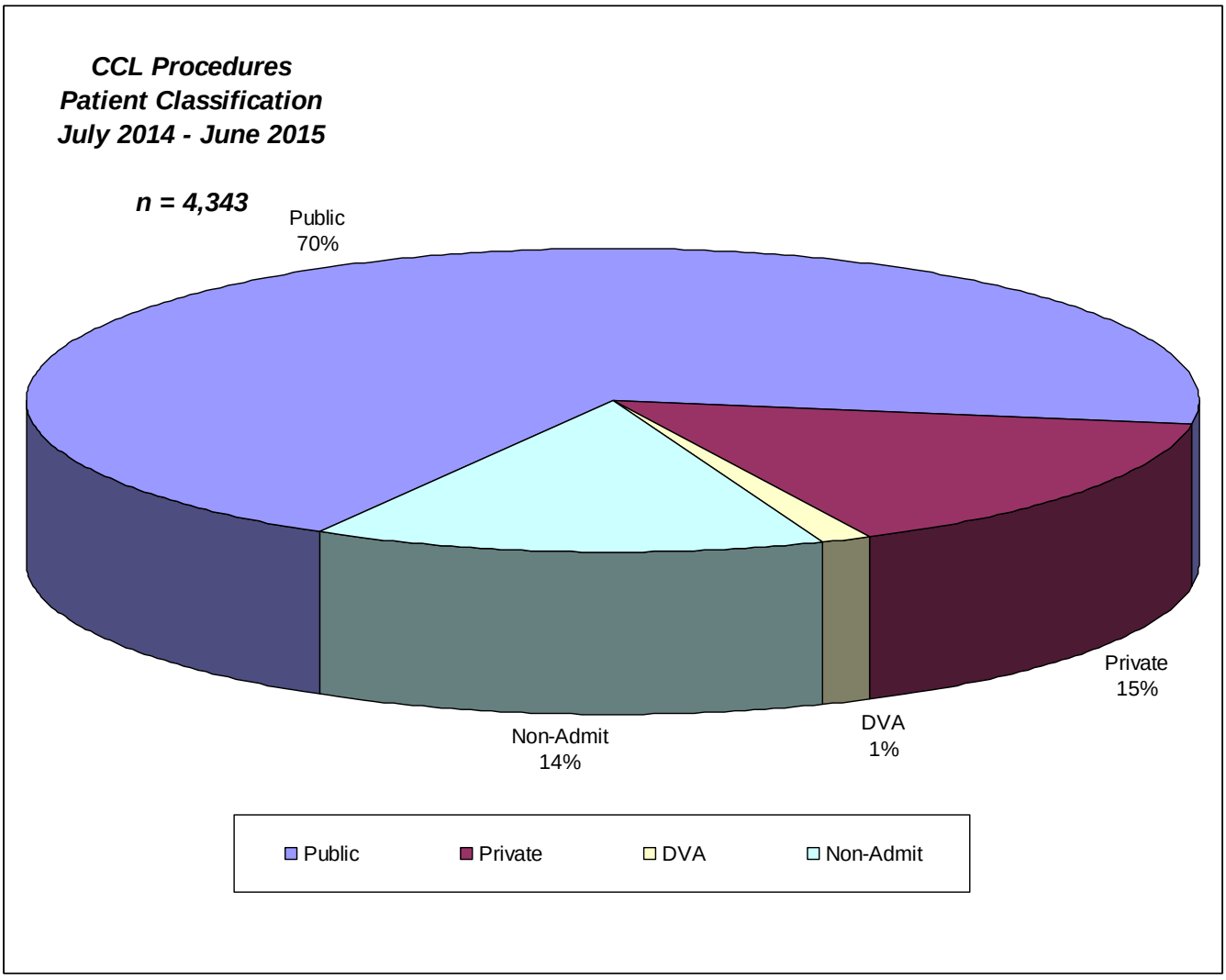
Total = 4,343

Adults (≥15 y.o.) **Total = 4,343 (100.0%)**

Patients Average Age: **66.1 ± 13.5** **(mean ± standard deviation)**

Female: **1,505 (35.1%)** Average Age: **67.2 ± 14.1**
Male: **2,838 (64.9%)** Average Age: **65.5 ± 13.1**

Patient Classification	Public	Private	DVA	Non-Admit	TOTAL
Patients Operated on in CCL	3,005	665	52	621	**4,343**

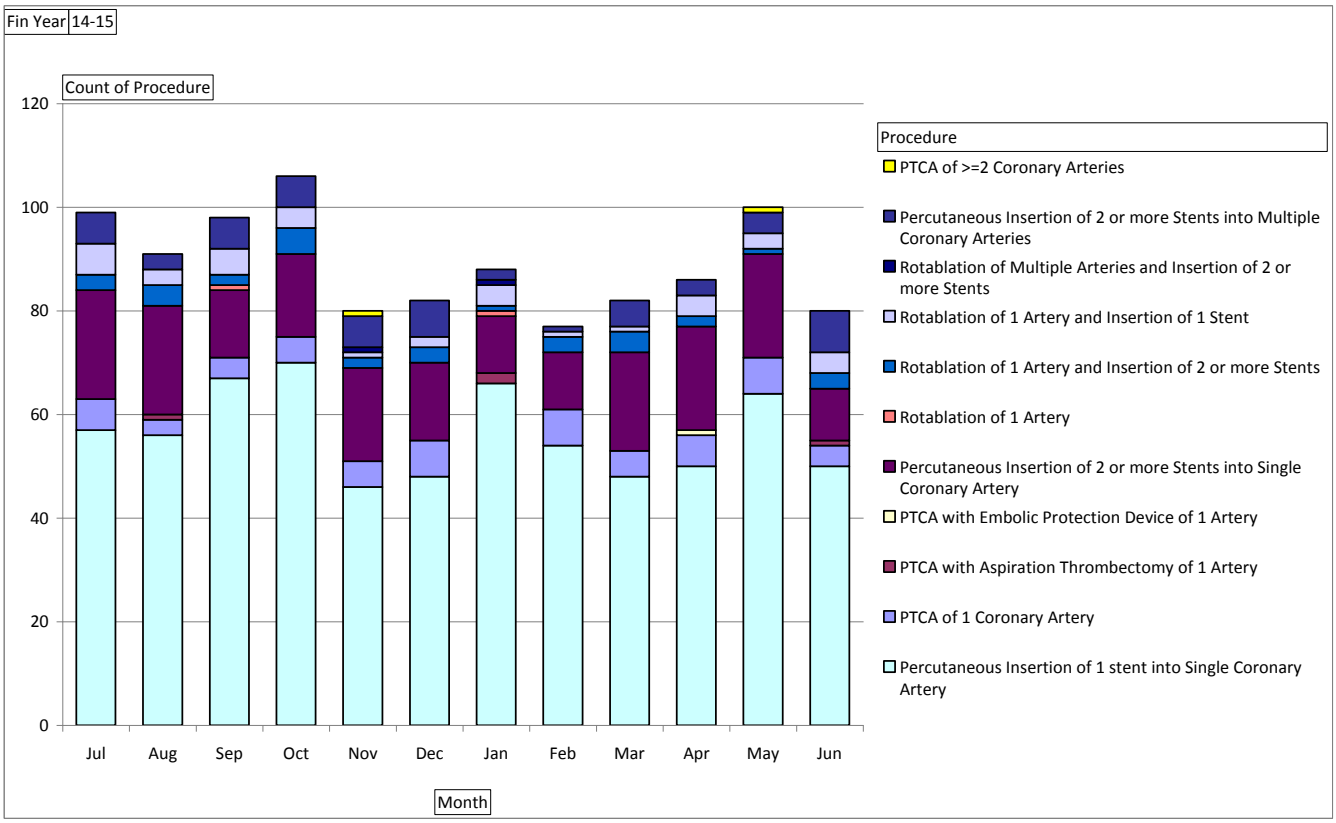


Total CCL Procedures Performed – Adults

PROCEDURES (ADULTS)		FINANCIAL YEAR (JULY 2014 - JUNE 2015)					FINANCIAL YEAR (JULY 2013 - JUNE 2014)				
		PUBLIC	PRIV.	DVA	NON-ADMIT	**TOTAL**	PUBLIC	PRIV.	DVA	NON-ADMIT	**TOTAL**
Coronary Angiography		2587	516	34	606	**3743**	2573	473	46	538	**3,630**
Device Closures	ASD	11	1			**12**	15	2			**17**
	LAA	4	4			**8**	7	3			**10**
	PDA	2				**2**	3				**3**
	PFO	12	1			**13**	8	2			**10**
	VSD	2				**2**					
Paravalvular Leak Closure		2				**2**	5	2			**7**
Percutaneous Valve		47	35	8		**90**	39	23	8		**70**
Mitraclip		8	10	1		**19**	6	7			**13**
Device Total		84	49	8		**141**	83	39	8		**130**
Dilatation / Stenting	Aorta										
	Pulmonary						2	1			**3**
	Renal	3	1			**4**	2				**2**
	Subclavian						1	1			**2**
	Vena Cava	2				**2**	1	1			**2**
Embolisation	Aorta		2			**2**					
	Bronchial										
	Pulmonary							1			**1**
	Subclavian		1			**1**					
Graft Study		324	35	4	48	**411**	300	43	6	37	**386**
IABP		52	7	1		**60**	43	3	1		**47**
ICE		21	4			**25**	20	6			**26**
IVC Filter							3	2			**5**
IVUS		52	15		4	**71**	68	13		3	**84**
FFR		239	38	1	5	**283**	191	30	2	15	**238**
OCT		40	6		1	**47**	48	7	1	4	**60**
PCI +/- Stents	No Stents	58	7	1		**66**	62	11	1		**74**
	Single Vessel	729	134	8		**871**	644	116	10		**770**
	Multi Vessels	50	9			**59**	48	8			**56**
	Rotablation	63	11	1		**75**	73	12	3		**88**
Total Angioplasty		899	160	10		**1069**	822	146	14		**982**
Pericardiocentesis		18	5	2		**25**	17	1			**18**
Renal Denervation		1	2			**3**	11	6			**17**
Right Heart Catheter		265	96	13	57	**431**	228	73	9	50	**360**
RV Biopsy		16	16		5	**37**	19	6	1	20	**46**
Septal Ablation (TASH)		3				**3**	5			1	**6**
Temporary Pacing		197	76	19		**292**	159	50	20	1	**230**
Transoesophageal Echo		70	42	7		**119**	56	31	7		**94**
Valve / Lead Screening		17	1		1	**19**	13		4		**17**
Valvuloplasty	Aortic	133	63	19		**215**	105	43	20		**168**
	Mitral	9	1			**10**	6	1			**7**
	Pulmonary	3				**3**	1				**1**
	Tricuspid										

TOTAL PATIENTS	**3,005**	**665**	**52**	**621**	**4,343**	2,976	589	71	568	4,204

Percutaneous Coronary Intervention



Angioplasty Nursing Service – Episodes of Care

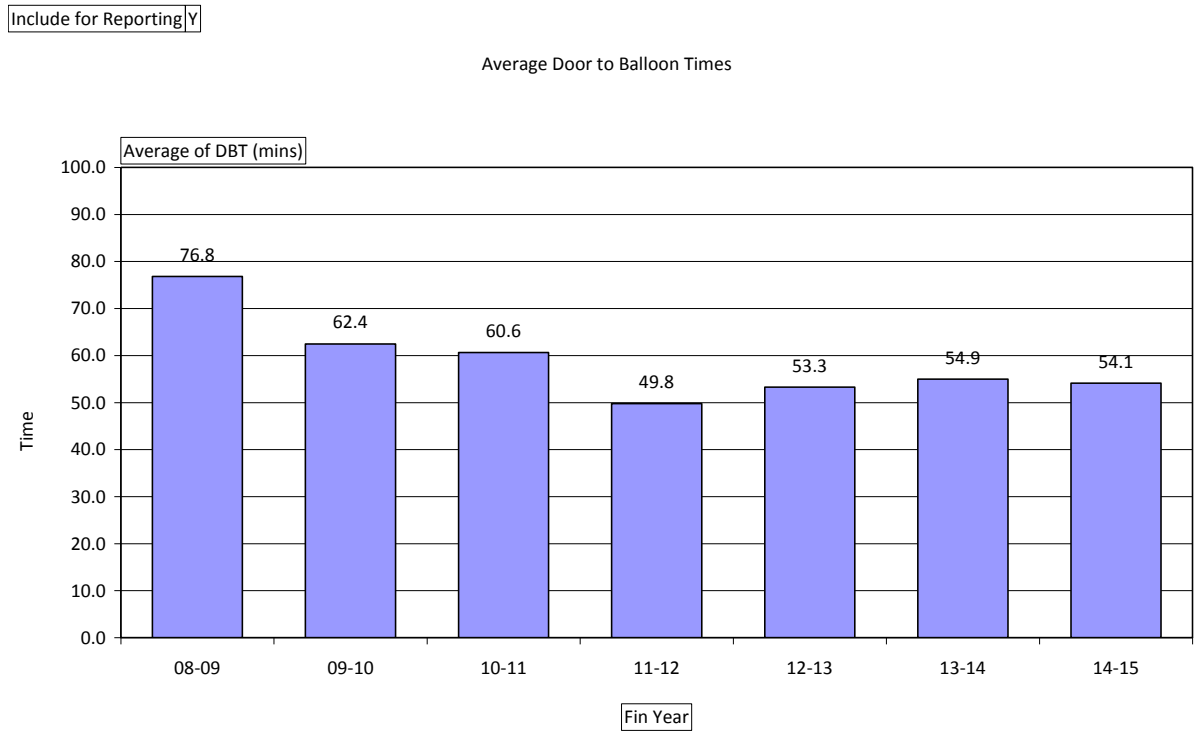
ANGIOPLASTY NURSING SERVICE		Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Total
Occasions of Inpatient Care		**99**	**91**	**98**	**106**	**80**	**82**	**88**	**77**	**82**	**86**	**100**	**80**	**1,069**
Outpatient Follow Up – Episodes of Care	**7 day**	77	63	77	73	53	57	50	64	57	51	71	69	**762**
	1 month	84	3	106	17	56	215	76	92	104	40	28	57	**878**
	12 month				29		1						1	**31**
	Unknown	1						1				6		**8**
	TOTAL CARE	**162**	**66**	**183**	**119**	**109**	**273**	**127**	**156**	**161**	**91**	**105**	**127**	**1679**

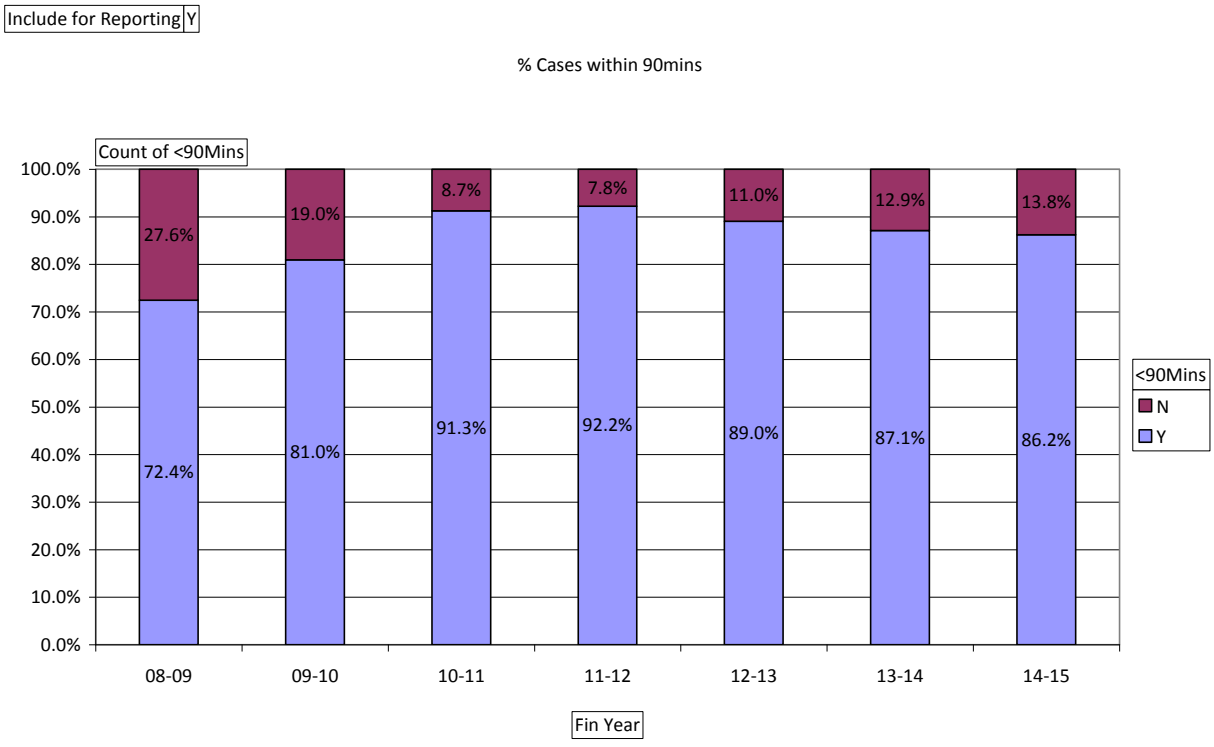
Primary PCI for STEMI

Total: 145

Patients Average Age: **62.0 ± 11.5** **(mean ± standard deviation)**

Female:	**35**	**(27.3%)**	Average Age:	**64.5 ± 13.2**
Male:	**110**	**(72.7%)**	Average Age:	**61.2 ± 10.8**





Interhospital Transfers

Total = 1243 (28.6%)

Interhospital Transfers

From 01/07/2014 to 30/06/2015

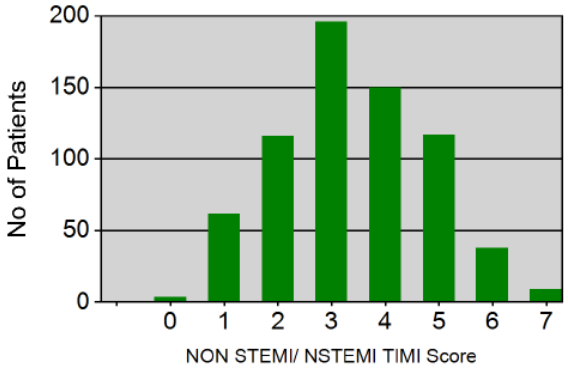
Total Identified :	**2285**
Procedure performed (excl.Cancelled after)	**2199**
inc. NOT Transferred	956
inc. Transferred	1243
Status: ED Admission	731
Status: InterHospital Transfer	1243
Status: QAS Primary PCI STEMI	93
Status: Outpatient	104
Status: ER- Primary PCI STEMI	12
Status: Emergency to CCL	15
Status: <Unknown>	1
Transferred (excl.Cancelled after)	**1243**
inc. Procedure performed	1243
Status: InterHospital Transfer	1151
Status: ED Admission	34
Status: QAS Primary PCI STEMI	54
Status: Outpatient	1
Status: Emergency to CCL	3
Discharged (excl.Cancelled after)	**0**
Removed from the list (Cancelled)	**86**
inc. Procedure performed	28
inc. Procedure NOT performed	58
Status: InterHospital Transfer	71
Status: ED Admission	11
Status: <Unknown>	2
Status: Outpatient	2
inc. NOT Discharged	86

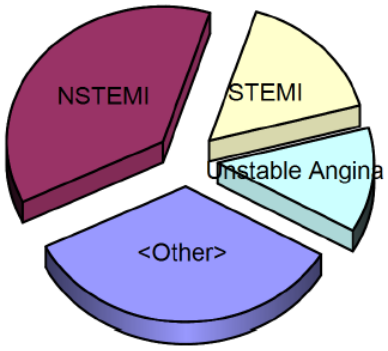
Genda / Age of Referrals:	**#**	**%**	**AVG years**	**StDeviation**
All	2285	100%	65.6	+/- 14.4
Male	1486	65%	65.0	+/- 14.0
Female	795	34.8%	66.8	+/- 15.1
Unknown	4	0.2%		

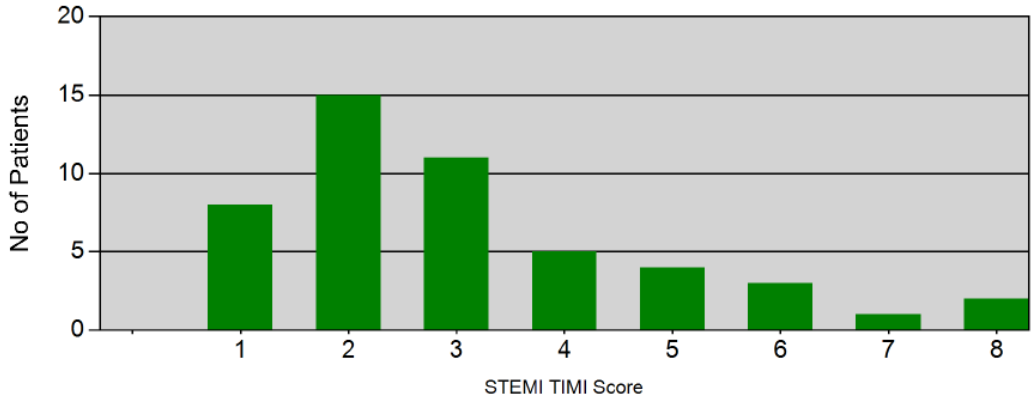
Waiting:	**#**	**%**	**AVG days**	**StDeviation**
...for Transfer	1301	57%	1.4	+/- 2.5
...for Procedure	2227	97%	2.6	+/- 4.2

Interhospital Transfers continued

ACS Types Identified:	2285	100%
Unstable Angina	286	12.5%
STEMI	364	15.9%
NSTEMI	850	37.2%
<Other>	785	34.4%







Diagnosis Identidied:	2285	100%
NSTEMI	859	37.6%
STEMI	361	15.8%
Unstable Angina	287	12.6%
Arrhythmia	141	6.2%
IHD-Other	117	5.1%
Valvular Heart Disease	106	4.6%
Heart Failure	84	3.7%
Cardiomyopathy	63	2.8%
Infected Cardiac Device	36	1.6%

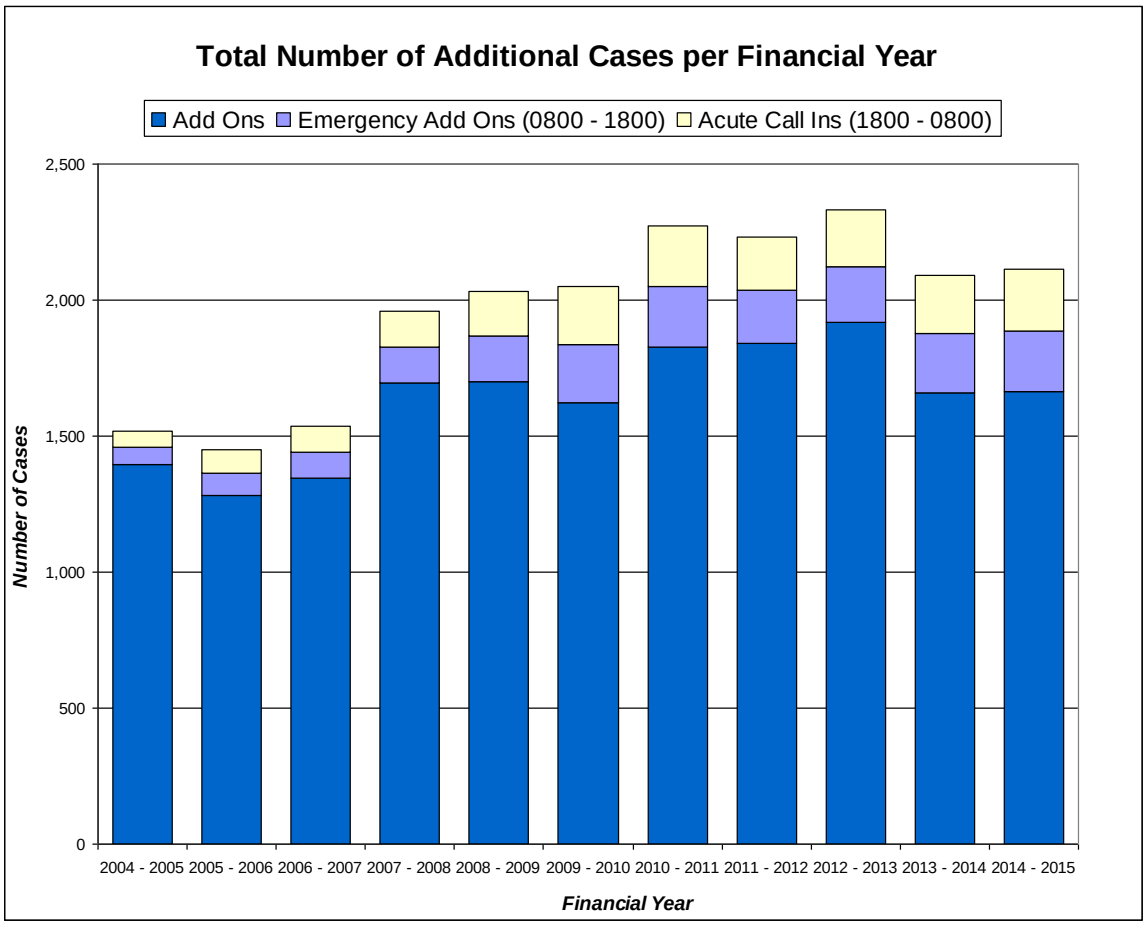
Pericardial Effusion/tamponade	34	1.5%
Positive Stress Test	28	1.2%
Endocarditis	28	1.2%
Stable Angina	26	1.1%
CHB	26	1.1%
Aortic Stenosis	18	0.8%
Out of Hospital Arrest	12	0.5%
ICD/PPM Failure	10	0.4%
Cardiac Arrest	6	0.3%
Myocarditis	6	0.3%
<Unknown>	6	0.3%
Congenital Heart Disease	6	0.3%
Suspected Rejection	4	0.2%
Pericarditis	4	0.2%
Aortic Dissection	3	0.1%
PE's	3	0.1%
Pulmonary Embolus/DVT	2	0.1%
STEMI Failed Lysis	2	0.1%
Thrombus	2	0.1%
NSVT	1	0%
Pulmonary Stenosis	1	0%
Atrial Myxoma	1	0%
LMD IABP	1	0%
Chest Pain for Investigation	1	0%

Reason of Removal from the list (Cancellation):	**86**	**100%**
No longer indicated	26	30.2%
Transfer to private health facility	12	14%
Medically unfit for procedure	10	11.6%
PT SELF DISCHARGED	7	8.1%
Transfer to other Q Health Facility	7	8.1%
Discharged home. For OPD angio appt	5	5.8%
For medical management	5	5.8%
Patient declined procedure	3	3.5%
Referred to EP dept	3	3.5%
Patient deceased	2	2.3%
Pt discharged. For OPD angio	2	2.3%
OPD angio	1	1.2%
<Unknown reason>	1	1.2%
Accepted for transfer to RBWH	1	1.2%
Surgical referral	1	1.2%

Additional Cases

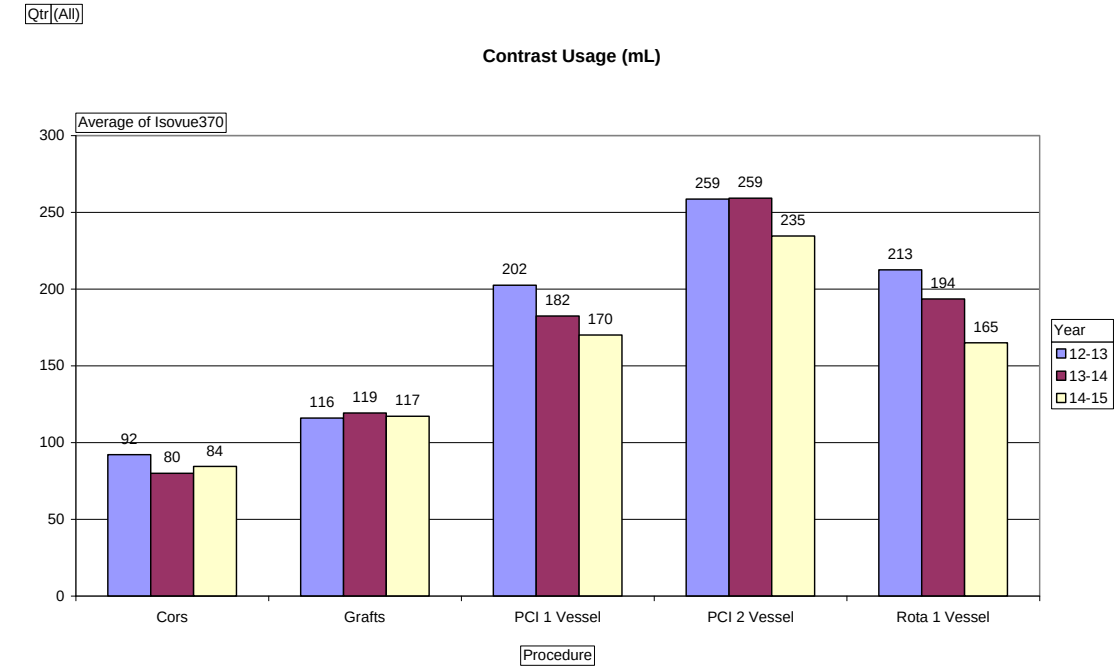
Total = 2,079 (47.9%)

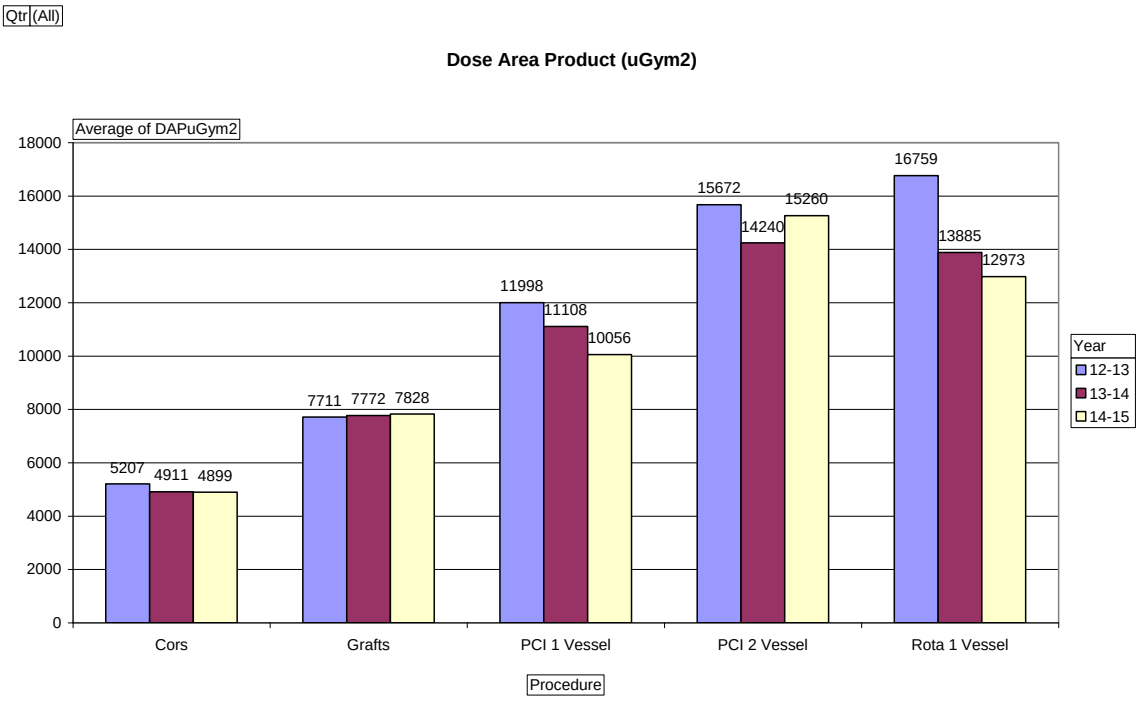
Additional Cases	Financial Year (2014 - 2015)	*Financial Year (2013 - 2014)*
Add-ons	1,658	1,661
Emergency Add-ons (0800-1800)	164	195
Acute Call-ins (1800-0800)	229	216
Total	2,079	2,072



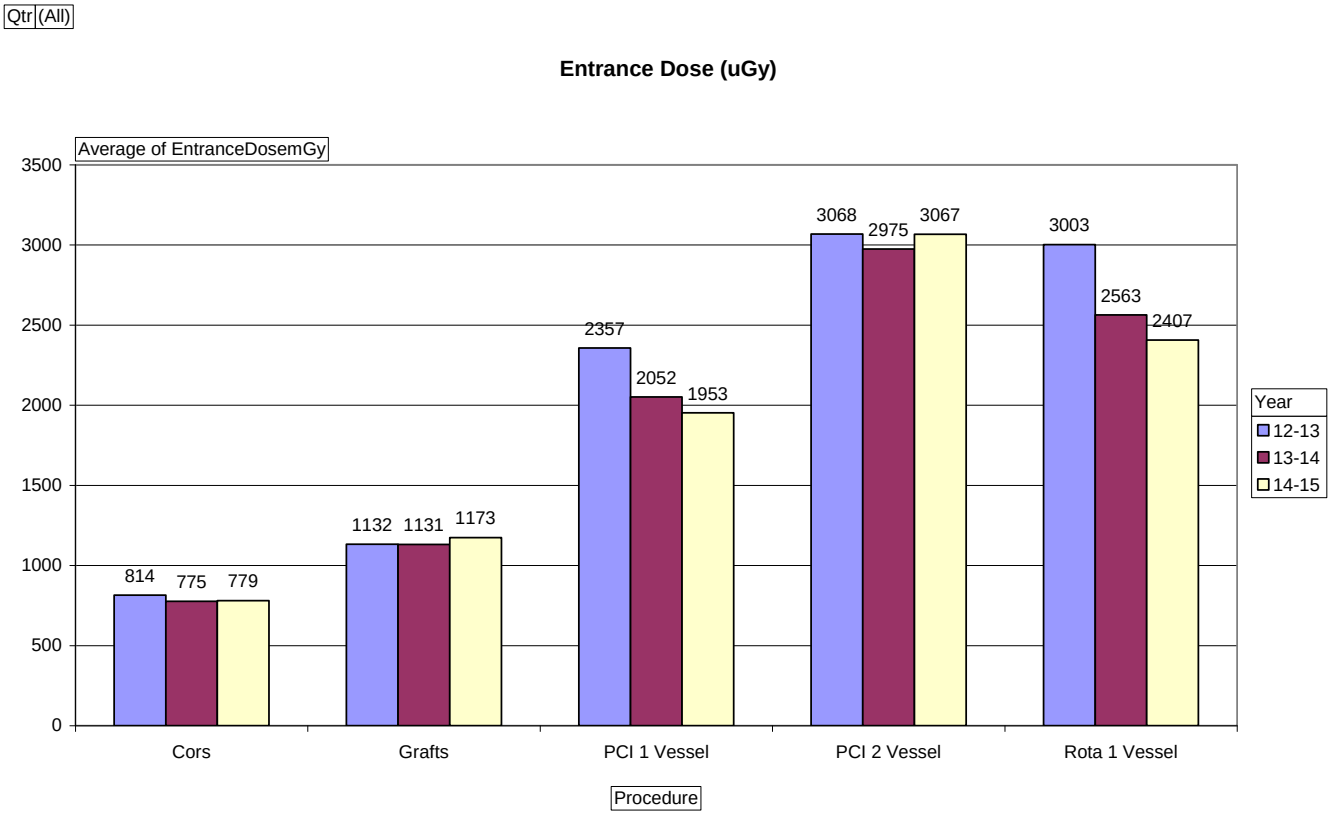
Radiation Dosages per Case

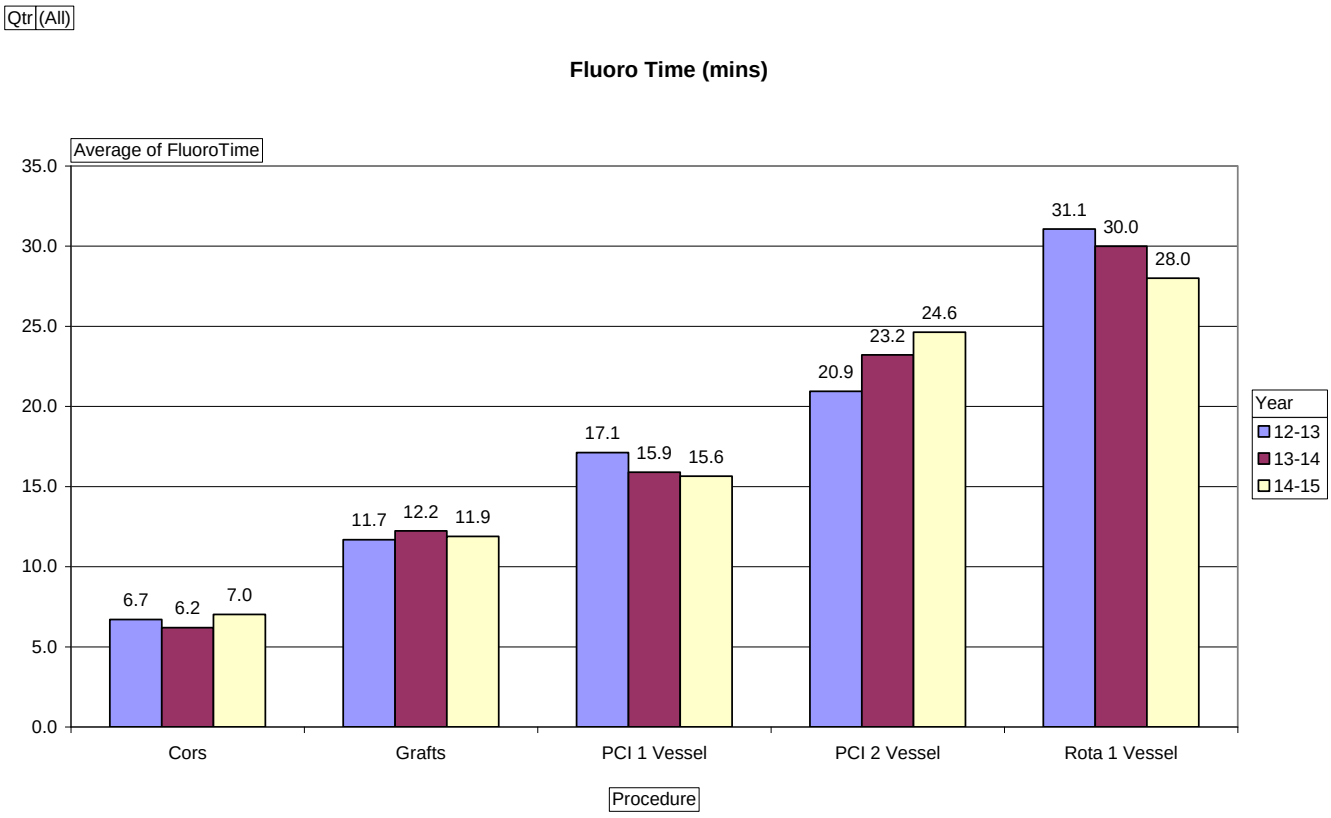
Procedure	Contrast (mL)		Dose Area Product (uGym2)		Entrance Dose (mGy)		Fluoroscopy Time (mins)	
	Median	Avg	Median	Avg	Median	Avg	Median	Avg
Selective Coronary Angiography	75	84	4050	4899	650	779	4.9	7.0
Graft Study	112	117	7326	7828	1068	1173	10.5	11.9
PCI and stenting of Single Vessel	170	170	8952	10056	1748	1953	13.4	15.6
Percutaneous Insertion of 2 or more Stents into Multiple Coronary Arteries	230	235	15340	15260	2847	3067	22.0	24.6
Rotablation of 1 Artery and Insertion of 1 Stent	155	165	11830	12973	2251	2407	26.3	28.0





Radiation Continued





Complications

Total = 222 (5.11%) **MACE = 10 (0.23%)**

COMPLICATIONS	REPORTABLE ADVERSE EVENTS (Financial Year 2014 - 2015)							
	1st QTR	2nd QTR	3rd QTR	4th QTR	TOTAL	% of Comp.	% of Cases	Financial Year (2013 - 14)
Access Site Occlusion		1		1	2	0.90%	0.05%	
Acute Respiratory Failure	1	3		1	5	2.25%	0.12%	
Anaphylactic/Allergic Reaction	1	3	1	2	7	3.15%	0.16%	6
Asystole	4	1	2	2	9	4.05%	0.21%	3
Atrial Fibrillation	1	1	2	2	6	2.70%	0.14%	5
Cardiogenic Shock	2				2	0.90%	0.05%	2
Dissection Coronary Artery	7	5	4	1	17	7.66%	0.39%	12
Emergency PCI	1				1	0.45%	0.02%	
Haematoma >5cm x 5cm	5	9	3	5	22	9.91%	0.51%	29
Heart Block	6	7	3	5	21	9.46%	0.48%	13
Hypotension	5	3	4	4	16	7.21%	0.37%	4
Other						0.00%	0.00%	2
Perforation of Artery or Vessel	1	1			2	0.90%	0.05%	4
Pseudoaneurysm		1			1	0.45%	0.02%	
Pulmonary Oedema	1	3		1	5	2.25%	0.12%	1
Radiation Reportable Dose	9	9	13	10	41	18.47%	0.94%	46
Retroperitoneal Bleeding		1		1	2	0.90%	0.05%	
Stroke			1	1	2	0.90%	0.05%	2
Sustained Bradycardia						0.00%	0.00%	1
Tamponade	2			1	3	1.35%	0.07%	1
Transient Ischaemic Attack	1			1	2	0.90%	0.05%	
Unplanned Return to CCL			1		1	0.45%	0.02%	
Vascular Injury	2	2		1	5	2.25%	0.12%	8
Vaso-Vagal	3	1	7	2	13	5.86%	0.30%	11
Ventricular Fibrillation	7	2	5	3	17	7.66%	0.39%	11
Ventricular Tachycardia	6	2	1	5	14	6.31%	0.32%	9
Vomiting	3	1		2	6	2.70%	0.14%	
TOTAL	**68**	**56**	**47**	**51**	**222**	**100.00%**	**5.11%**	**138**

MACE = Major Adverse Cardiac Event (Death, MI, Stroke, Urgent Revascularisation)	**10**	-	0.23%	**10**
Total Mortality in the Laboratory	**3**	-	0.07%	**2**
Complication Associated Mortality	**3**	-	0.07%	**1**
30 Day All Cause Mortality	**57**	-	1.31%	**33**
30 Day Post PCI Mortality	**7**	-	0.16%	**-**

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Ass Prof Darren Walters
Clinical Director
Cardiac Catheterisation Laboratory
Date:

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Michael Savage
Consultant Cardiac Scientist
Cardiac Catheterisation Laboratory
Date:

APPENDIX A - CARDIOLOGY RESEARCH

Cardiology Clinical Research Centre (CCRC)

July 2014 to June 2015

Name of Research Unit:
Cardiology Clinical Research Centre (CCRC)

Name of Program the Research unit operates within:
Cardiology Program

Head of Research Unit/Department:
Professor Darren Walters, Interventional Cardiologist, Executive Director Heart Lung The Prince Charles Hospital

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Present Service

Cardiology Clinical Research Centre at The Prince Charles Hospital is managed within the Cardiology Program. It is funded from income generated from commercially sponsored clinical trials and grants for investigator initiated research.

All patients within the Cardiology Program are considered potential participants for current research being undertaken by the Research Centre. Current studies include, treatment and prevention of aortic stenosis, mitral regurgitation, uncontrolled hypertension, acute coronary syndrome, heart failure and conduction disturbances. The Centre also undertakes studies on Diagnostic Medical and Cardiac Catheter Imaging modalities such as Intravascular Ultrasound, Optical Coherence Tomography and Magnetic Resonance Imaging (MRI) and software applications. In addition, various Registries on Trans Aortic Valve Replacement (TAVR) and Acute Coronary Syndrome (ACS) are also being maintained.

The Centre is also actively involved in providing support and advice to Authorised Prescribers (AP) and the patients who are receiving treatment under this scheme. The centre also ensures that the TGA guidelines and requirements for AP are being adhered to.

Metro North HHS is undertaking significant changes to the way health care is delivered with the implementation and development of clinical streams. This development will see a move from a facility- based structure to a service line focus across the HHS. Through collaboration and coordination there is an opportunity for clinicians to develop improved alternative service delivery models aimed to; improve access and capacity and ensure affordability and sustainability. Cardiothoracic services have been identified as one of eight clinical streams being developed across the HHS

Environmental Analysis

CCRC activities operate within the Cardiology Program, The Prince Charles Hospital. CCRC is located at Level 5 of the Clinical Sciences Building and has an office located at the Cardiac Catheter Laboratory on the Ground Floor of the hospital's Main Building.

The CCRC coordinates research across all areas within the Cardiology Program including Cardiac Medical Imaging research.

The Research Centre Manager (RCM) is responsible for ensuring best practice in operational work processes are in place to enable successful coordination of clinical trials and management of the centre. In addition the RCM is also responsible for managing the cost centre within their financial delegation and reports to the Assistant Director of Nursing and Business Manager. The RCM, is assisted by an Administrative Officer in the management of Research Regulatory Affairs (Ethics and Governance) and another Administrative Officer who assists in the management of finance, centre supplies, equipment and other duties as defined by the RCM. The RCM is also assisted by a Clinical Nurse (CN) with a management portfolio. This position includes a staff development role for the CCRC nursing staff , providing them with a learning opportunity and facilitates succession planning for the RCM role. The clinical trials and Authorised Prescriber Scheme are coordinated by the CCRC nursing staff. They are classified as Clinical Research Coordinators and are responsible for the day-to-day operational management of the trials and patient follow-up and support.

Service Partners

Good working relationships, communication and collaboration with other areas within TPCH, are critical in order to effectively coordinate clinical trials.

CCRC internal stakeholders include:

- Patients
- Employees
- Human Research, Ethics and Governance Unit
- Cardiac Investigations Unit
- Cardiac Catheter Laboratory
- Outpatient Department and Private Practice Clinic
- Hybrid Laboratory in Theatres
- Cardiology Wards and Coronary Care Unit
- Intensive Care
- Medical Staff
- Pharmacy
- Pathology

CCRC also work closely with the following external agencies and service providers

- Sponsors such as pharmaceutical companies
- Clinical research organisations
- Other Queensland Health Departments
- Other hospitals and research sites
- Therapeutic Goods Administration (TGA)
- General Practitioners and other specialists
- National Health and Medical Research Council (NHMRC)

Human Resource

Director of Cardiology Clinical Research Centre (CCRC): Prof Darren Walters
Email: Darren_Walters@health.qld.gov.au

Research Clinicians Dr OC Raffel, Dr R Denman, Dr M Pincus, Dr D Burstow, Dr H Haqqani, Dr. C Hamilton-Craig, Dr. B Bell, Dr. K Poon, Dr G Scalia, Dr D Platts, Dr. A Mishra, Prof M West, Dr A Incani, Dr JHN Bett, Dr. S McKenzie

Research Centre Manager: Mrs Maricel Roxas

Research Coordinators:

Current Staff: Tracy McCulloch, Steve Graves, Karen Trenorden, Sandra Phillips, Bo Janoshka, Ann Maree Ree, Kirsten Popplewell

Administrative Staff*:*

Current Staff: Julie Bailey-Bradshaw, Bernice Enever

Postal address:
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5th Floor, Clinical Sciences Building
The Prince Charles Hospital
Rode Road, Chermside QLD 4032
Telephone enquiry: +61 7 3139 4711
Fax: +61 7 3139 6140

Research Projects for the period July 2014 to June 2015

Structural/Device Trials

Centera

Safety and Performance Study of the Edwards CENTERA Self-Expanding Transcatheter Heart Valve

Sponsor Company: Edwards Lifesciences

Objective:

The purpose of this study is to assess the safety and device success of the Edwards CENTERA Transcatheter Heart Valve (THV) System in patients with symptomatic, severe aortic stenosis who are indicated for aortic valve replacement.

This is a non-randomized, prospective, multi-center safety and device success study. Up to two hundred (200) patients are planned to be implanted at up to 35 participating investigational centers in Europe, Australia and New Zealand.

Tendyne

Early Feasibility Study of Tendyne Mitral Valve System

Sponsor Company: Tendyne

Objective:

The purpose of this study is to generate initial insights into the safety of the Tendyne Mitral
Valve System with its associated procedure and observe the device performance on its intended function of reducing mitral valve regurgitation. Information garnered from this study may be used to improve the device system, improve implantation techniques, refine the patient population for whom the device is intended and/or form the basis for the development of subsequent clinical protocols

Portico

International long-term follow-up study of patients implanted with a PORTICO™valve

Sponsor Company: St Jude Medical

Objective:

The purpose of this clinical investigation is to further assess the performance and safety profile of the Portico Valve implanted, using the Delivery System and the Loading System, in patients with severe symptomatic aortic stenosis.

Solace

A Multicentre, Non-Randomised Controlled Study of the Safety, Performance, Quality of Life and Cost Effectiveness Outcomes of the Edwards SAPIEN XT™ Transcatheter Heart Valve in an Australian Population

Sponsor Company: Edwards Lifesciences

Objective:
To assess the safety and efficacy of the SAPIEN XT™ valve, to assess the impact on Quality of Life (QOL) after implantation of the SAPIEN XT™ valve and to examine cost effectiveness parameters associated with SAPIEN XT™ valve implantation compared with a matched cohort of patients managed with surgical aortic valve replacement in the Australian healthcare environment

The SOLACE-AU Trial is a multi-centre, prospective, consecutively enrolled, non-randomised, controlled clinical trial enrolling a minimum of 200 patients with severe symptomatic aortic stenosis.

Reprise II:

REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Evaluation of Safety and Performance

Sponsor Company: Boston Scientific

Primary Objective:

To evaluate the safety and performance of the Lotus™ Valve System for transcatheter aortic valve replacement (TAVR) in symptomatic subjects with severe calcific aortic stenosis who are considered high risk for surgical valve replacement.

Reprise NG DS:

REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of LotuS™ ValvE with the Next Generation Delivery System

Sponsor Company: Boston Scientific

Objective:

To confirm the acute performance and safety of the Lotus™ Valve with the Next Generation Delivery System when used with the current Lotus or Next Generation Lotus Introducer for transcatheter aortic valve replacement (TAVR) in symptomatic patients with severe calcific aortic stenosis who are considered high risk for surgical valve replacement.

REDUCE-HTN:

T**R**eatment of r**E**sistant hypertension using a ra**D**iofrequency perc**U**taneous transluminal angioplasty **C**athet**E**r

Sponsor Company: Boston Scientific

Primary Objective:

To assess the performance of the Vessix V2 Renal Denervation System™ for the treatment of medication resistant hypertension

CoreValve:

CoreValve® International Clinical Study: Percutaneous Aortic Valve Replacement (PAVR) with the Medtronic CoreValve® System, Australia/New Zealand (ANZ) Clinical Study

Sponsor Company: Medtronic

Trial description:
This is an international, multi-center, single arm, open label study for patients with severe symptomatic native aortic valve stenosis who undergo aortic valve replacement with the Percutaneous Aortic Valve Replacement (PAVR) Medtronic CoreValve® System.

Trial purpose and objectives:
To evaluate the performance, efficacy and safety of the percutaneous implantation of Medtronic's prosthetic aortic valve in patients with severe symptomatic native aortic valve stenosis who have an elevated surgical risk.

Data obtained via the clinical trial will facilitate global assessment of patients with severe native aortic valve stenosis with respect to such factors as gender, age, previous medical conditions, concomitant procedures, surgical complications, outcome and safety. Using standardized risk scores (e.g. STS and logistic Euroscore), procedural device success and complications, early and late clinical follow up outcomes will be assessed.

Enlightn: Int**E**r**n**ationa**l** non-randomized, s**i**ngle-arm, lon**g**-term follow-up study of patients with uncontrolled **H**yper**T**ensio**N**

Sponsor Company: St Jude Medical

The purpose of this post market clinical investigation is to further evaluate the safety and performance of the EnligHTN™ Renal Denervation System in the treatment of patients with uncontrolled hypertension.

Primary Objective:

Mean reduction in office Systolic Blood Pressure at six (6) months across all subjects post renal denervation and within sub-groups

Stents/Scaffolds/OCT/IVUS/FFR Trials

FLAIR

Prospective, multi-center, double blind, randomised study to test the safety of deferral of stenting in physiological non-significant lesions in a clinical population of intermediate stenoses using iFR and FFR

Sponsor Company/CRG: Imperial College London

Objective:

To assess whether the iFR is non-inferior to FFR when used to guide treatment of coronary stenosis with PCI.

ABSORB IV

A Clinical Evaluation of Absorb™ BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects with *de novo* Native Coronary Artery Lesions

Sponsor Company: Abbott Vascular

Objective:

To evaluate the safety and effectiveness of the Absorb BVS System compared to the XIENCE in the treatment of subjects, including those with diabetes mellitus, with ischemic heart disease caused by up to two *de novo* native coronary artery lesions in separate epicardial vessels.

REVA FANTOM

Safety & Performance Study of the *FANTOM* Sirolimus-Eluting Bioresorbable Coronary Scaffold

Sponsor Company: REVA MEDICAL

Objective:

The primary objective of the study is to demonstrate the safety & performance of native coronary artery stenting using the FANTOM Sirolimus-Eluting Bioresorbable Coronary Scaffold by assessing the incidence of Major Adverse Cardiac Events (MACE) and the degree of Late Lumen Loss at 6 months post-implant.

Ilumien I: Observational Study of Optical Coherence Tomography (OCT) in Patients Undergoing Fractional Flow Reserve (FFR) and Percutaneous Coronary Intervention Stage I

Sponsor Company: St Jude Medical

Purpose: To define and evaluate OCT stent guidance parameters through prospective data collection in PCI procedures of de novo lesions.

Leaders Free:

A PROSPECTIVE RANDOMIZED COMPARISON OF THE BIOFREEDOMTM BIOLIMUS A9TM DRUG COATED STENT VERSUS THE GAZELLE™ BARE METAL STENT IN PATIENTS AT HIGH RISK FOR BLEEDING

Sponsor Company: Biosensors International

The primary safety and efficacy objectives of this study are:

Safety:
1) To demonstrate in CAD patients who are at high risk of bleeding and/or medically unsuitable for >1 month treatment with DAPT that the BioFreedom™ DCS followed by one month DAPT is non-inferior to the Gazelle™ BMS followed by one month DAPT as measured by the composite primary endpoint of cardiac death, myocardial infarction and definite/probable stent thrombosis at one year.
Efficacy:
2)To demonstrate in CAD patients who are at high risk for bleeding and/or medically unsuitable for >1 month treatment with DAPT that the BioFreedom™ DCS followed by one month DAPT is superior to the Gazelle™ BMS followed by one month DAPT as measured by the incidence of clinically driven target lesion revascularization (TLR) at one year.

OCT FFR:

Validation of Intravascular Optical Coherence Tomography Parameters With Fractional Flow Reserve for Assessment of Coronary Stenosis Severity

Sponsor Company: N/A Investigator Driven Study

This is a single centre, prospective study. ***The specific primary aims are***:

1. To evaluate the relationship between OCT parameters of lesion severity (minimum luminal diameter, minimal luminal area, diameter stenosis %, area stenosis %) and pressure wire FFR values in patients with intermediate coronary artery stenoses.
2. To validate & determine the OCT parameters and their specific values that best predict the physiological severity of a coronary stenosis based on an FFR value of <0.80.

APPOSE:

Apposition Assessed Using Optical Coherence Tomography of Chromium Stents Eluting Everolimus from Cobalt versus Platinum Alloy Platforms (APPOSE Trial)

Sponsor Company: N/A Investigator Driven Study

The objectives of the present study are to:

1. Examine stent strut geometry and apposition using optical coherence tomography in patients randomized to receive the cobalt-chromium everolimus-eluting (CoCr-EES, Xience Prime™) stent or the platinum chromium everolimus-eluting (PtCr-EES, Promus Element™) stent
2. Examine tissue coverage at 6 months of the Xience Prime™ and Promus Element™ coronary stents

RESTORE II:

ReZolve2™ Sirolimus-Eluting Bioresorbable Coronary Scaffold

Sponsor Company: REVA MEDICAL

Objective:

To evaluate the safety and performance of a Bioresorbable Scaffold in native coronary arteries that includes incorporation of slide & lock expansion technology and a new scaffold material which is a polycarbonate co-polymer of tyrosine analogs. This will be accomplished through the implantation and evaluation of the ReZolve2 Sirolimus-Eluting 3.0 x 18 mm Bioresorbable Coronary Scaffold comprised of Poly (I2DAT- cotyrosol) carbonate.

Evolve:

Sponsor Company: Boston Scientific

The objective of the EVOLVE Trial is to assess the safety and performance of the Evolution Everolimus-Eluting Coronary Stent System for the treatment of patients with a

de novo atherosclerotic lesion of up to 28 mm in length (by visual estimate) in a native coronary artery 2.25 mm to 3.5 mm in diameter (by visual estimate) compared to PROMUS Element.

This study is a prospective, multi-center, randomized, single-blind controlled trial to assess the safety and performance of two Evolution drug release rate formulations (Evolution Stent A and Evolution Stent B) for the treatment of patients with a de novo atherosclerotic coronary artery lesion of up to 28 mm in length (by visual estimate) in a native coronary artery 2.25 mm to 3.5 mm in diameter (by visual estimate) compared to PROMUS Element.

Evolve II:

A Prospective Multicenter Trial to Assess the Safety and Effectiveness of the SYNERGYTM Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGYTM Stent System) for the Treatment of Atherosclerotic Lesion(s)

Sponsor Company: Boston Scientific

Primary Objective:

To assess the safety and effectiveness of the SYNERGYTM Coronary Stent System for the treatment of subjects with atherosclerotic lesion(s) ≤ 34 mm in length (by visual estimate) in native coronary arteries ≥2.25 mm to ≤4.0 mm in diameter (by visual estimate)

Evolve II QCA:

A Prospective, Multicenter Trial to Assess the SYNERGYTM Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGYTM Stent System) for the Treatment of Atherosclerotic Lesion(s)

Sponsor Company: Boston Scientific

Objective:

To evaluate 9-month angiographic and intravascular ultrasound (IVUS) data for the SYNERGYTM Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY TM Stent System) in the treatment of subjects with atherosclerotic lesion(s) _34 mm in length (by visual estimate) in native coronary arteries _2.25 mm to _4.0 mm in diameter
by visual estimate

OPTIMA:

Sponsor Company: Investigator initiated trial supported by Biosensors International, Singapore

Optical Coherence Tomography Assessment of Intimal Tissue and Malapposition: A Randomized Comparison of Biolimus-Eluting Biodegredable Polymer and Everolimus-Eluting Permanent polymer Stents

The purpose of this study is to compare the BioMatrix Flex (Biolimus A9-Eluting) stent system with the Promus/Xience V/Xience Prime (Everolimus-eluting) stent system in a superiority trial using a super-high resolution imaging modality (optical coherence tomography, OCT).

B.E.A.C.O.N II:

Sponsor Company: Bio Excel

A multi-centre clinical registry of BioMatrix drug - eluting stent in Asia-Pacific countries. A prospective, multi-centre, observational, patient data registry program compiling data on patients receiving the BioMatrix Stent with the objective of assessing clinical outcomes in patients receiving the BioMatrix DES Stent during treatment of Real World, All-comer Patients. The primary endpoint for the study is Major Adverse Cardiac Events (MACE) defined as a composite of cardiac death, myocardial infarction (Q and Non Q wave), or ischaemia driven Target Lesion Revascularisation (TLR) at 12 months. Secondary endpoints consist of safety and efficacy data. The registry intends to enrol approximately 1000 patients from up to 15 participating centres within Singapore, Malaysia, Indonesia, New Zealand, Australia and Thailand. Up to the first 20 patients per site (total of 250) enrolled in the registry will have angiographic assessment at the 9 month follow-up visit to assess efficacy secondary endpoints. Other follow-up includes clinic visits at 30 days, 6 months, 12 months with ECG and phone contact at 90 days and 2 - 5 years annually.

MITRA CLIP MRI ECHO

Quantitative Assessment of Post-implant Function by MRI and Echo

Sponsor Company: N/A Investigator Driven Study

Objective:

a) To quantitate mitral regurgitation (volume and fraction) pre- and post-MitaClip using CMR and Echocardiography
b) To compare the inter-modal agreement, accuracy and reproducibility of CMR and Echocardiographic measures of regurgitation after MitraClip

DRUG Trials

Pioneer AF PCI

An OPen-label, Randomized, Controlled, Multicenter Study ExplorIng TwO TreatmeNt StratEgiEs of Rivaroxaban and a Dose-Adjusted Oral Vitamin K Antagonist Treatment Strategy in Subjects With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention

Sponsor Company: Jannsen Cilag

Objective:

The primary objective of this study is to assess the safety of 2 rivaroxaban treatment strategies and a dose-adjusted vitamin K antagonist (VKA) treatment strategy after PCI (with stent placement) in subjects with paroxysmal, persistent, or permanent non-valvular AF, based on the composite of Thrombolysis in Myocardial Infarction (TIMI) major bleeding, minor bleeding, and bleeding requiring medical attention events (known collectively as clinically significant bleeding) after 12 months of therapy.

REDUAL AF PCI

A prospective randomised, open label, blinded endpoint (PROBE) study to evaluate dual antithrombotic therapy with dabigatran etexilate (110mg and 150mg b.i.d.) plus clopidogrel or ticagrelor vs. triple therapy strategy with warfarin (INR 2.0 – 3.0) plus clopidogrel or ticagrelor with or without aspirin in patients with non valvular atrial fibrillation (NVAF) that have undergone a percutaneous coronary intervention (PCI) with stenting

Sponsor Company: Boehringer Ingelheim

Objective:

The main objective is to compare a dual antithrombotic regimen of 110mg dabigatran etexilate b.i.d. plus clopidogrel or ticagrelor (110mg DE-DAT) and 150mg dabigatran etexilate b.i.d. plus clopidogrel or ticagrelor (150mg DE-DAT) with a triple antithrombotic therapy (TAT) of warfarin plus clopidogrel or ticagrelor plus aspirin (warfarin-TAT) in patients with non valvular atrial fibrillation (NVAF) that undergo a PCI with stenting. The study aims to show non-inferiority of both doses of DE-DAT when compared to Warfarin-TAT in efficacy and safety. Efficacy will be determined by comparing a composite event rate of death, MI, stroke and systemic embolism (SE). Safety will be determined by comparing the rates of clinically relevant bleeding, assessed using the modified International Society of Thrombosis and Haemostasis (ISTH) major classification.

GLOBAL LEADERS

COMPARATIVE EFFECTIVENESS OF 1 MONTH OF TICAGRELOR PLUS ASPIRIN FOLLOWED BY TICAGRELOR MONOTHERAPY VERSUS A CURRENT-DAY INTENSIVE DUAL ANTIPLATELET THERAPY IN ALL-COMERS PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION WITH BIVALIRUDIN AND BIOMATRIX FAMILY DRUG-ELUTING STENT USE.

Sponsor Company: ECRI/Cardiolysis

Objective:

To determine in all-comers patients undergoing PCI under standardised treatment (including the BioMatrix family of drug-eluting stents and bivalirudin), whether treatment with 1 month of ticagrelor and aspirin followed by 23 months of ticagrelor monotherapy is superior with respect to the composite of all-cause mortality or non-fatal new Q-wave MI compared to treatment with 12 months of standard dual anti platelet therapy (DAPT) followed by aspirin monotherapy.

LATITUDE

A Clinical Outcomes Study to Compare the Incidence of Major Adverse Cardiovascular Events in Subjects Presenting with Acute Coronary Syndrome Treated with Losmapimod Compared to Placebo (PM1116197)

Primary Objective:

The primary objective is to evaluate the efficacy of oral Losmapimod 7.5 mg BID compared to placebo when added to standard of care in subjects with ACS on the time to first occurrence of adjudicated MACE (defined as CV death, MI, or severe recurrent ischemia [SRI-UR]) through 12 weeks of therapy.

GLACOV:

A Randomized, Multi-center, Placebo-controlled, Parallel-group Study to Determine the Effects of AMG 145 Treatment on Atherosclerotic Disease Burden as Measured by Intravascular Ultrasound in Subjects Undergoing Coronary Catheterization

Sponsor Company: AMGEN

Objective: To evaluate the effect of AMG 145 on the change in burden of coronary atherosclerosis as measured by percent atheroma volume (PAV) in subjects with coronary artery disease requiring angiography for a clinical indication who are taking atorvastatin.

GADACAD:

Multicenter open-label study to evaluate efficacy of gadobutrol-enhanced cardiac magnetic resonance imaging (CMRI) for detection of significant coronary artery disease (CAD) in subjects with known or suspected CAD by a blinded image analysis

Sponsor Company: Bayer

Objective: The primary efficacy objectives of this study are to demonstrate that sensitivity and specificity of gadobutrol-enhanced CMRI exceed prespecified minimum performance thresholds (MPT) of 60% and 55%, respectively and to show superior sensitivity over unenhanced wall motion CMRI at vasodilator rest/stress for the detection of significant CAD.

MODIFY:

Effects of ivabradine on plaque burden, morphology and composition in patients with clinically indicated coronary angiography. A randomised double-blind placebo-controlled international multicentre study.

Sponsor Company: Servier

Purpose: The purpose of this study is to demonstrate the beneficial effect of ivabradine on plaque burden, morphology, and composition, as well as on arterial wall shear stress (WSS) in patients with Coronary Artery Disease (CAD) who have a clinical indication for coronary angiography.

Objective: The primary objective of this study is to evaluate the effect of ivabradine treatment for 18 months on
atherosclerotic disease progression as assessed using coronary Intravascular Ultrasound (IVUS).

ODYSSEY:

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of SAR236553/REGN727 on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome

Sponsor Company: SANOFI

Primary objective
The primary objective of this study is to compare the effect of SAR236553 with placebo on the occurrence of cardiovascular events (composite endpoint of coronary heart disease (CHD) death, non-fatal myocardial infarction (MI), fatal and non-fatal ischemic stroke, unstable angina requiring hospitalization) in patients who have experienced an acute coronary syndrome (ACS) event 4 to 16 weeks prior to randomization and are treated with intensive statin therapy (defined as atorvastatin 40 or 80 mg, or rosuvastatin 20 or 40 mg) or at maximally tolerated dose of these given statins, or other non statin LMT(s).

REGISTRY

CONCORDANCE:

Sponsor Company: Concord Hospital

The CONCORDANCE registry is an investigator initiated ACS registry designed by an independent steering committee with expertise in diverse areas of cardiovascular research. Specific objectives include:

- To provide data to health care providers and hospitals to characterize existing and evolving practice patterns, delivery of care, and resource utilization in the management of ACS across Australia;
- To document the association between systems of delivery of care as determined at government, area and individual hospital levels and implementation of evidence based guidelines;
- To document and inform the appropriate use of medications in the Australian ACS population, including higher risk subsets not well represented in clinical trials;
- Identify mechanisms whereby data collection within a hospital can be incorporated into a sustainable component of clinical practice to allow internal and external standards and benchmarking of treatment patterns and patient outcomes;

OCT Registry:

The Massachusetts General Hospital Optical Coherence Tomography Registry (The MGH OCT Registry)

Sponsor Company: N/A Investigator Driven Study

The aims of the project will be to 1) identify plaque characteristics on OCT that are associated with adverse cardiac events including myocardial infarction and 2) to identify characteristics of stented arteries that are associated with adverse events including restenosis and stent thrombosis. Because detailed clinical, angiographic and intravascular imaging data will be gathered from a large number of patients with clinical follow-up, we anticipate that the registry will be a tremendous resource for additional research questions going forward.

TEXT MED

TEXT messages to improve MEDication adherence & Secondary prevention

To determine in a randomised controlled trial of patients with ACS the effect of a semi-personalised secondary prevention support program sent via mobile phone text message on:

a. Primary outcome: - proportion taking appropriate medications for the secondary prevention of CVD at 6 months and 1 year
b. Secondary outcomes: -
    i. Objective measures of risk factors – cholesterol and blood pressure
    ii. Lifestyle modification – smoking quit attempts, regular physical activity, diet
    iii. Major CV events and mortality

MARS REGISTRY

This is an Asia-Pacific multi-centre international observational registry of patients with mitral regurgitation treated with the MitraClip to determine the following:

1) Primary efficacy endpoint: This is freedom from: surgery for mitral valve dysfunction, death, and MR > 2+ (moderate to severe (3+) or severe (4+) mitral regurgitation) at 1, 2, 3 and 5 years.
2) Secondary efficacy endpoint: Improvement in various echocardiographic parameters, functional class and quality of life scores. Freedom from major adverse cardiovascular events (MACE) defined as MI, stroke, heart failure.
3) Primary safety endpoint: Safety at 30 days or hospital discharge, whichever is longer, is defined as freedom from major adverse events (MAE), defined as a combined clinical endpoint of death, myocardial infarction, reoperation for failed surgical repair or replacement, non-elective cardiovascular surgery for adverse events, stroke, renal failure, deep wound infection, ventilation for greater than 48 hours, GI complication requiring surgery, new onset of permanent atrial fibrillation, septicemia, and transfusion of 2 or more units of blood.

Authorised Prescriber

Edwards Authorised Prescriber:

The valve is known as the Edwards SAPIEN^{TM} Transcatheter Aortic Valve. It is distributed by an Australian company called Edwards Lifesciences Pty Ltd. The SAPIEN^{TM} Transcatheter Aortic Valve is approved for use in Europe but it is not currently approved for use by the Therapeutic Goods Administration (TGA) in Australia. Its use in this case is therefore under Special Access Scheme from TGA Authorised Prescribers.

Corevalve Authorised Prescriber:

The valve is known as the Medtronic CoreValve® System or Corevalve Evolut for patients with severe symptomatic native aortic valve stenosis who undergo Percutaneous Aortic Valve Replacement (PAVR). It is distributed by Medtronic Austrasia Pty Ltd. This is not currently approved for use by the Therapeutic Goods Administration (TGA) in Australia. Its use in this case is therefore under Special Access Scheme from TGA Authorised Prescribers.

ABSORB Scaffold

The Absorb Bioresorbable Vascular Scaffold is a temporary scaffold indicated for improving coronary luminal diameter that will eventually resorb and potentially facilitate normalization of vessel function in patients with ischemic heart disease due to *de novo* native coronary artery lesions. The treated lesion length should be less than the nominal scaffolding length (12 mm, 18 mm, 28 mm) with reference vessel diameters > 2.0 mm and < 3.8 mm.

Upcoming Research Projects

Trial	Desciption	Sponsor
GEMINI	A Randomized, Double-Blind, Double-Dummy, Active-controlled, Parallel-group, Multicenter Study to Compare the Safety of Rivaroxaban versus Acetylsalicylic Acid in Addition to Either Clopidogrel or Ticagrelor Therapy in Subjects with Acute Coronary Syndrome	Janssen Cilag
REVELUTION	A Clinical Evaluation of the Medtronic Polymer-Free Drug-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions (Polymer-free DES Trial)	Medtronic
SPIRE 1	Phase III studies with PCSK9 inhibitor in reducing the occurrence of major cardiovascular events in high risk patients (LDL-C ≥70 mg/dL (1.81 mmoL/L) and <100 mg/dL (2.59 mmol/L) or non-HDL-C ≥ 100 mg/dL (2.59 mmol/L) and <130 mg/dL (3.36 mmol/L)	Pfizer/Julius Clinical
SPIRE 2	Phase III studies with PCSK9 inhibitor in reducing the occurrence of major cardiovascular events in high risk patients (LDL-C ≥100 mg/dL (2.59 mmoL/L) or non-HDL-C ≥ 130 mg/dL (3.36 mmol/L)	Pfizer/Julius Clinical
GLACOV OPEN LABEL	A Multicenter, Open-label Extension (OLE) Study to Assess the Long-term Safety and Efficacy of Evolocumab	AMGEN
REPRISE III	REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Randomized Clinical Evaluation	Boston Scientific
BARDTRUE FLOW	Clinical Study to Evaluate A New Valvuloplasty Balloon For TAVI Predilatation	Bard

FINESSE	A multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled study to evaluate the efficacy and safety of finerenone compared to eplerenone on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction after recent heart failure decompensation and additional risk factors, either type 2 diabetes mellitus or chronic kidney disease or both	Bayer

APPENDIX B - Cardiac Catheterisation Laboratory Staff

MANAGEMENT TEAM

Clinical Director	WALTERS	*Darren*
CCL/Recovery NUM	COUSINS	*Margaret*
Director Cardiac Sciences	OROLA	*Leilani*
Snr Card. Scientist	SAVAGE	*Michael*
Snr Radiographer	CROWHURST	*Jim*
Business Manager	BEILBY	*Mark*
Clin. Nurse Co-ordinator	LEWIS	*Talya*
DON-Cardiology	PODGER	*Maria*

INTERVENTIONAL FELLOWS

SAIREDDY	*Ramakrishna*
SHAW	*Elizabeth*
MURDOCH	*Dale*

HEART FAILURE AND ACHD FELLOWS

WONG	*Yee Weng*
BURNS	*Kylie*

CARDIOLOGY REGISTRARS

ALFRED-MOHAN	*Raj*
EMAMI	*Mehrdad*
GLUER	*Robert*
HANNA	*Joseph*
KYRANIS	*Stephen*
LATONA	*Jilani*
MARKHAM	*Ryan*
MAXWELL	*Ryan*
RATEESH	*Shruti*
SINHAL	*Navin*
TJAHJADI	*Catherina*
WEE	*Yong*

ADMINISTRATION

CRITCHELL	*Carol*
DOHERTY	*Denice*
EDMONDS	*Suzanne*
EKERT	*Kellie*
HANCOCK	*Grant*
HARTLEY	*Kylie*
LOVEWELL	*Jennifer*
PRATT	*Tracy*
SAUL	*Tim*

CONSULTANTS

BELL	*Brendan*
BETT	*Nicholas*
INCANI	*Alex*
JAVORSKY	*George*
McKENZIE	*Scott*
MISHRA	*Akshay*
MURDOCH	*Dale*
NICOLAE	*Mugur*
PINCUS	*Matthew*
RADFORD	*Dorothy*
RAFFEL	*Chris*
SEDGWICK	*John*
SMALL	*Andrew*
WALTERS	*Darren*
WEST	*Malcolm*
WHIGHT	*Christopher*

VISITING CARDIOLOGISTS

HARDING	*Scott*
ARONEY	*Con*
ZHANG	*Michael*

CARDIAC SCIENTISTS

BLACK	*Paul*
BRIGHTWELL	*Jason*
BUSH	*Natalie*
COLLINS	*Dean*
COOK	*Hannah*
COX	*Brad*
DAVISON	*Oscar*
LAM	*Kevin*
LANGHAM	*Nikita*
LAW	*Hannah*
LEE	*Abbie*
MEIN	*Geraldine*
O'RIORDAN	*Dean*
PAITRY	*Sarah*
PARFITT	*Melissa*
ROSE	*Emma*
SAVAGE	*Michael*
SECOMB	*Amy*
TAYLOR	*Colleen*
TOWNSEND	*Simon*
WRIGHT	*Daniel*

CCL NURSES

ALEXANDER	*Lisa*
ALLANSON	*Michelle*
AMMENHAUSER	*Rebecca*
BICKNELL-GRIST	*Michele*
BRENNAN	*Fiona*
COUSINS	*Margaret*
COX	*Sharon*
EDDY	*Julia*
GLORIA	*Jocelyn*
HILLIER	*Evelyn*
HODGE	*Lillian*
HORNE	*Dianne*
HORTON	*Marc*
LEWIS	*Talya*
LITTLEJOHN	*Jessica*
MADAN	*Laly*
MCCLUAND	*Rebecca*
McKINLAY	*Judith*
MOORE	*Cathy*
REICHELT	*Elise*
ROBERTSON	*Leonie*
ROBINSON	*Nigel*
ROBINSON	*Sarah*
SMITH	*Tammy*
TREVASCUS	*Carla*
URMATAM	*Jenart*
WEBB	*Juanita*
WEINMAN	*Vanessa*

RECOVERY

APPLIN	*Maddy*
BROOKE	*Debra*
BYCROFT	*Melinda*
CHEN-REDDICLIFFE	*Chi*
COUSINS	*Kate*
DAVEY	*Meagan*
FLYNN	*Cathy*
GILL	*Suzanne*
HARRICH	*Cherie*
HOFFMANN	*Ann-Marie*
JONES	*Christie*
KLEISSL	*Sabine*
LOHREY	*Karen*
McEWAN	*Lauren*
PAINE	*Arlene*
MELKSHAM	*Maretta*
MILLER	*Melissa*
O'HARE	*Ruth*
PAGE	*June*
SPINKS	*David*
SUMMERVILLE	*Elaine*
TAYLOR	*Cathy*
WANNECK	*Allison*
WILTON	*Allison*
YAZDANI	*Shohreh*
MELKSHAM	*Maretta*
MILLER	*Melissa*
O'HARE	*Ruth*
PAGE	*June*

RADIOGRAPHERS

AHMED	*Mansoor*
BARBOUR	*Scott*
CAMPBELL	*Doug*
CASSIDY	*Rhiannon*
CHEAL	*Alisa*
CROWHURST	*James*
DRANSFIELD	*Jayahna*
HAMILTON	*Casey*
HEDRICK	*Judith*
JOHNSTON	*Liesie*
KEYS	*Jennifer*
KROLL	*Jo-Anne*
LIDDICOAT	*Annelise*
O'KEEFE	*Katrina*
ROBINSON	*Brendan*
SIMIC	*Jade*
SUARNA	*Amber*
THOMAS	*Damien*
THOMPSON	*Kate*
TURNER	*Arianwen*

APPENDIX C - PCI REPORT (JULY 2014- JUNE 2015)

THE PRINCE CHARLES HOSPITAL
CARDIAC CATHETER LABORATORY

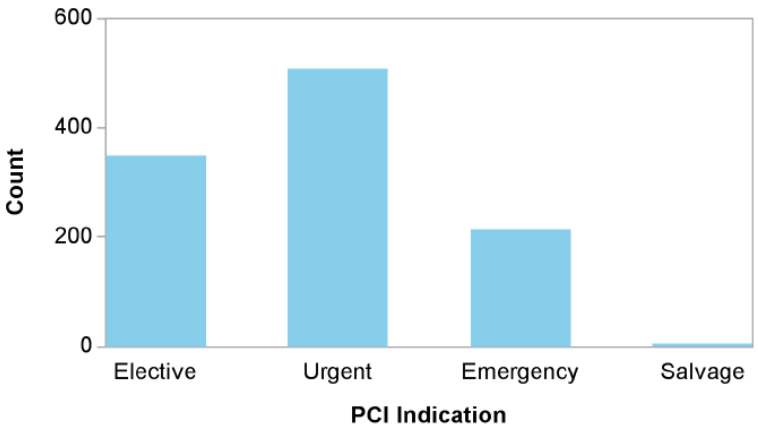
PCI Procedure Report

1/07/2014 - 30/06/2015

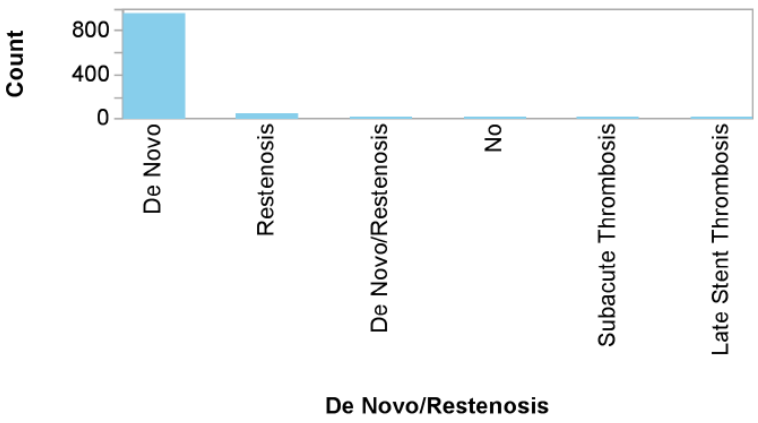
Patient Age			
Male	799	74.74 %	Av 64 +/- 12
Female	270	25.26 %	Av 67 +/- 13
	1069	**100%**	**Av 65 +/- 12**

Indications

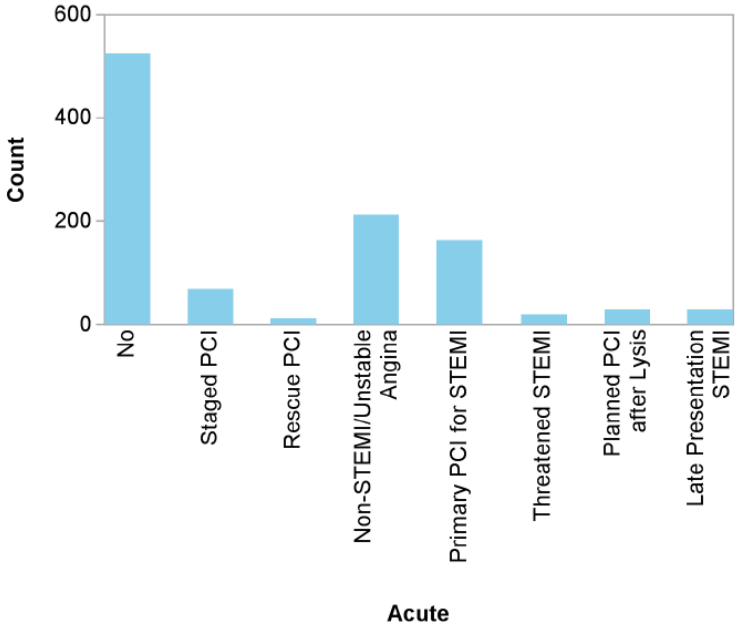
PCI Status	Number of Cases	%
Elective	350	32.74 %
Emergency	212	19.83 %
Salvage	1	0.09 %
Urgent	506	47.33 %
	1069	**100%**



De Novo/Restenosis	Number of Cases	%
De Novo	970	90.74 %
De Novo/Restenosis	26	2.43 %
Late Stent Thrombosis	1	0.09 %
No	8	0.75 %
Restenosis	58	5.43 %
Subacute Thrombosis	6	0.56 %
	1069	**100%**



Acute	Number of Cases	%
Late Presentation STEMI	29	2.71 %
No	525	49.11 %
Non-STEMI/Unstable Angina	215	20.11 %
Planned PCI after Lysis	29	2.71 %
Primary PCI for STEMI	164	15.34 %
Rescue PCI	15	1.40 %
Staged PCI	70	6.55 %
Threatened STEMI	22	2.06 %
	1069	**100%**



Cardiac Indications	Number of Indications	% of total cases
Angina.	69	6.45 %
Cardiogenic Shock.	5	0.47 %
Chest pain.	594	55.57 %
Exertional dyspnoea.	153	14.31 %
Known coronary artery disease.	304	28.44 %
NSTEMI.	265	24.79 %
Out of hospital arrest.	10	0.94 %
Positive CT Coronary Angiogram.	57	5.33 %
Positive EST.	42	3.93 %
Positive stress echo.	25	2.34 %
Previous MI	76	7.11 %
STEMI.	203	18.99 %
Stable angina.	4	0.37 %
Thrombolysed STEMI.	40	3.74 %
Unstable angina.	28	2.62 %
	1875	

Risk Factors	Number of Factors	% of total cases
Anxiety	82	7.67 %
Cerebrovascular Disease	76	7.11 %
CHF	48	4.49 %
Chronic Lung Disease	165	15.43 %
Current smoker	249	23.29 %
Depression	110	10.29 %
Diabetes	318	29.75 %
Dyslipidemia	689	64.45 %
Family History	411	38.45 %
Hypertension	736	68.85 %
Obesity	434	40.60 %
Renal Failure	100	9.35 %
	3418	

Lesions Risk	Number	% of total cases
Type A Lesion	80	7.48 %
Type B1 Lesion	404	37.79 %
Type B2 Lesion	193	18.05 %
Type C Lesion	614	57.44 %
	1291	

Approach	Number	% of total cases
Brachial	1	0.09 %
Femoral	505	47.24 %
Other	1	0.09 %
Radial	562	52.57 %
	1069	**100%**

Complications	Number	% of total cases
Asystole	1	0.09 %
Heart Block	1	0.09 %
Pulmonary Oedema	1	0.09 %
	3	

Previous Procedures

Previous Procedures	Number	% of total cases
Previous CABG	141	13.19 %
Previous PCI	266	24.88 %
Previous valvular surgery	16	1.50 %
	423	

Stent Type	Number	%
Drug Eluting Stent	1148	81.42 %
Bare Metal Stent	260	18.44 %
Covered Stent	2	0.14 %
	1410	**100%**

Technical Data and Lesion Characteristics

Guide Size	Number	%
Null	4	0.28 %
5	8	0.55 %
6	1143	78.88 %
6.5	8	0.55 %
7	227	15.67 %
7.5	20	1.38 %
8	39	2.69 %
	1449	**100%**

Balloon Size	Number	%
Null	2	0.06 %
1.00	2	0.06 %
1.10	2	0.06 %
1.20	1	0.03 %
1.25	57	1.61 %
1.50	103	2.92 %
2.00	541	15.31 %
2.25	20	0.57 %
2.50	1067	30.20 %
2.75	163	4.61 %
3.00	588	16.64 %
3.25	157	4.44 %
3.50	432	12.23 %
3.75	97	2.75 %
4.00	194	5.49 %
4.50	72	2.04 %
5.00	30	0.85 %
5.50	2	0.06 %
6.00	3	0.08 %
	3533	**100%**

Technical Data and Lesion Characteristics

Stent Width	Number	%
2.00	1	0.07 %
2.25	110	7.80 %
2.50	323	22.91 %
2.75	148	10.50 %
3.00	395	28.01 %
3.25	15	1.06 %
3.50	289	20.50 %
4.00	119	8.44 %
4.50	5	0.35 %
5.00	5	0.35 %
	1410	**100%**

Stent Length	Number	%
8	21	1.49 %
9	3	0.21 %
11	3	0.21 %
12	94	6.67 %
13	2	0.14 %
14	8	0.57 %
15	187	13.26 %
16	57	4.04 %
18	226	16.03 %
20	52	3.69 %
22	37	2.62 %
23	175	12.41 %
24	53	3.76 %
26	44	3.12 %
28	159	11.28 %
30	29	2.06 %
32	18	1.28 %
33	112	7.94 %
34	5	0.35 %
38	125	8.87 %
	1410	**100%**

30 Day Outcomes

Quality of Life	Number	%
Better	926	90.87 %
No Improvement	72	7.07 %
Worse	21	2.06 %
	1019	**100%**

Access Site	Number	%
Bruising	9	50.00 %
Haematoma	7	38.89 %
Persistent Pain	2	11.11 %
	18	**100%**

Cardiac Rehab Attended	Number	%
Attended	324	34.39 %
Not Attended	618	65.61 %
	942	**100%**

Smoking	Number	%
Recommenced Smoking at One Month Post Procedure	32	91.43 %
Referred to Quit Programme	3	8.57 %
	35	**100%**

Exercise Compliance	Number	%
No	217	21.61 %
Yes	787	78.39 %
	1004	**100%**

Medication Compliance	Number	%
No	5	0.55 %
Yes	907	99.45 %
	912	**100%**

Angina	Number	%
Class I (Strenuous Activity)	78	7.60 %
Class II (Ordinary Activity)	73	7.12 %
Class III (Marked Limitations)	21	2.05 %
Class IV (At Rest)	83	8.09 %
No Pain	767	74.76 %
Unknown	4	0.39 %
	1026	**100%**

Adverse Events	Number	%
CVA	5	83.33 %
Death	1	16.67 %
	6	**100%**