The Prince Charles Hospital

Queensland Government
Queensland Health

The Prince Charles Hospital Cardiac Catheterisation Laboratory Annual Report 1st July 2013 - 30th June 2014

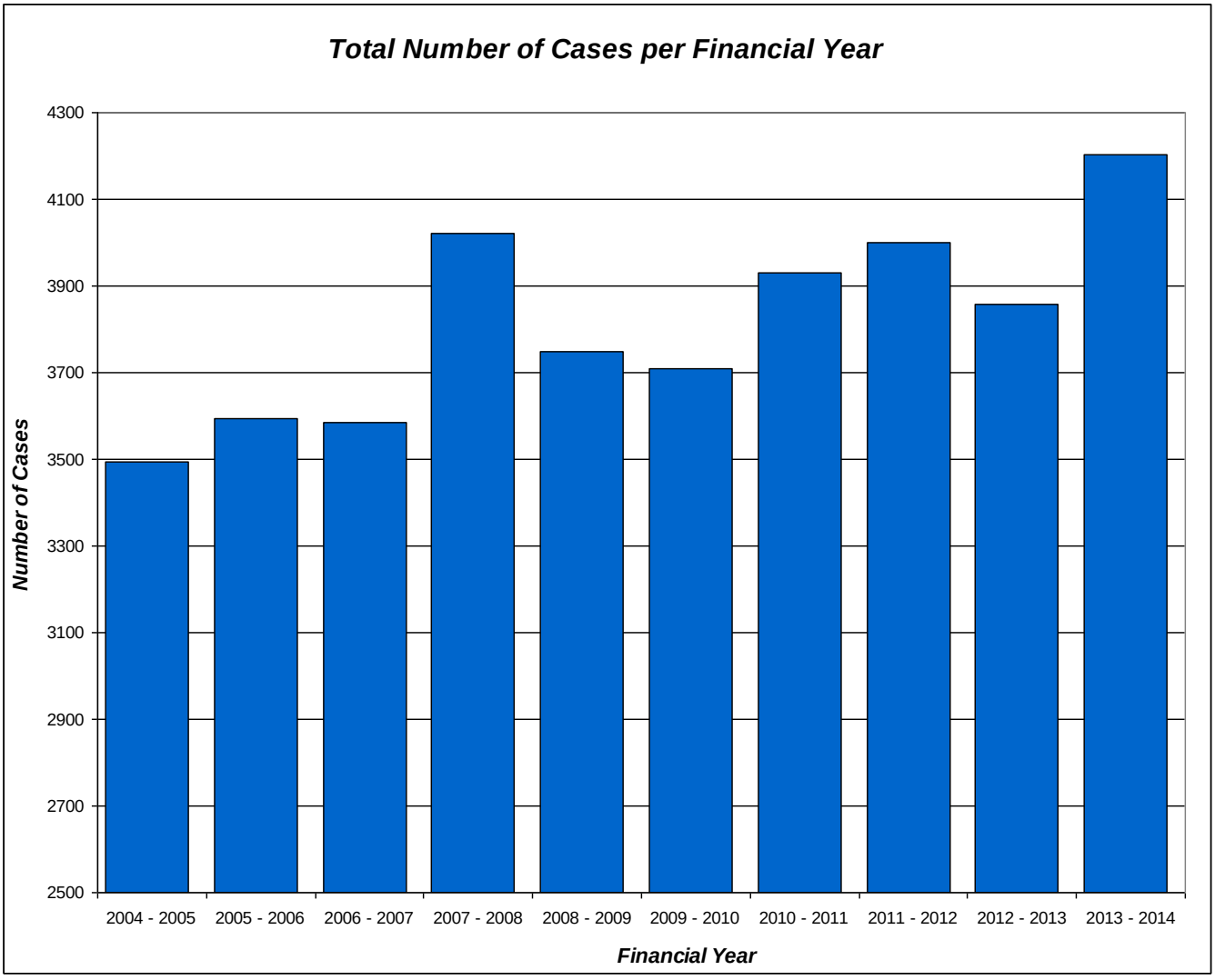
Prepared by: Michael Savage – Senior Cardiac Scientist
Cardiac Catheterisation Laboratory

Contents

Clinical Year Report 2013 – 2014

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



Patient Demographics

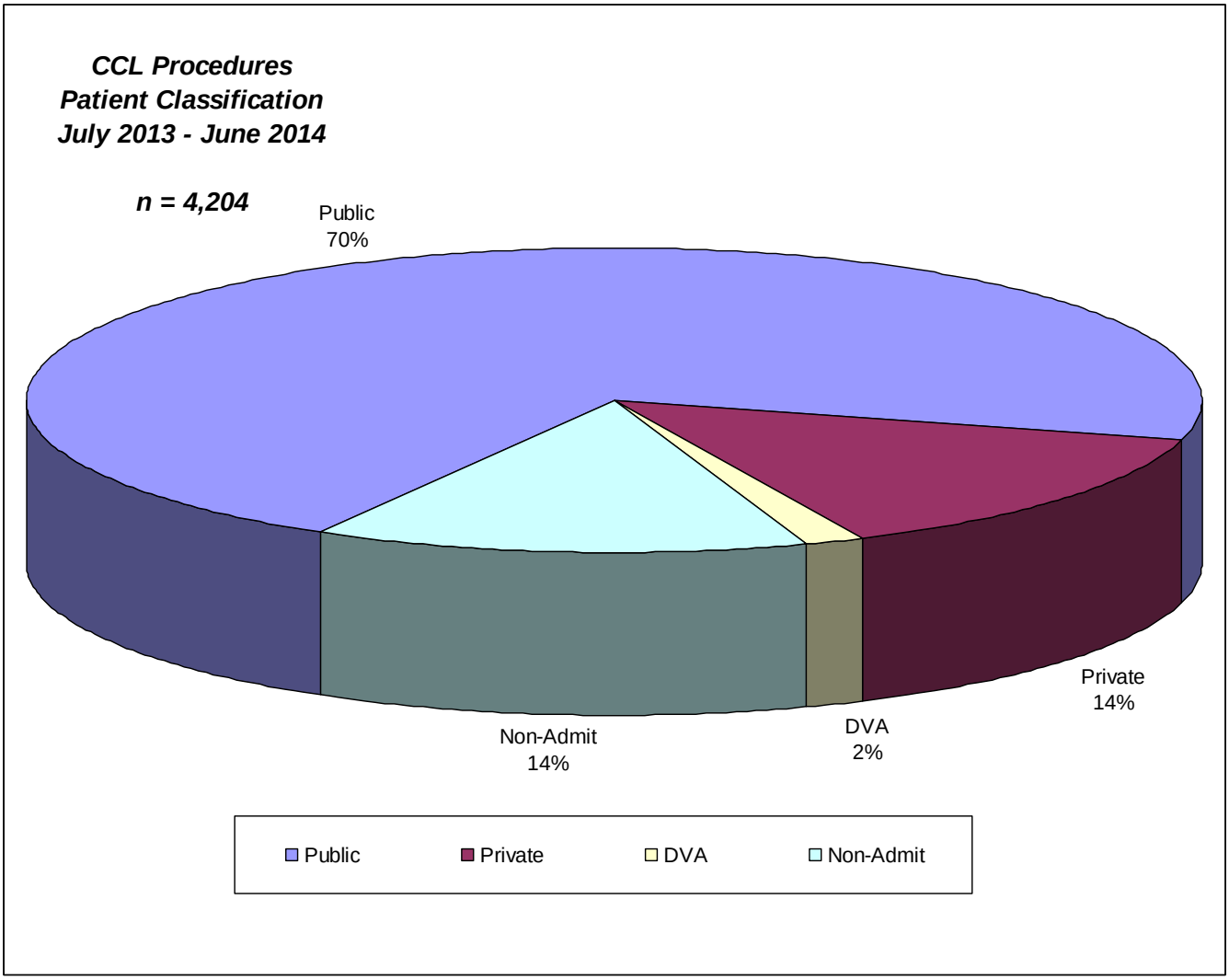
Total = 4,204

Adults (≥15 y.o.) **Total = 4,204 (100.0%)**

Patients Average Age: **65.7 ± 13.7** **(mean ± standard deviation)**

Female: **1,477 (35.1%)** Average Age: **66.7 ± 14.2**
Male: **2,727 (64.9%)** Average Age: **64.3 ± 13.3**

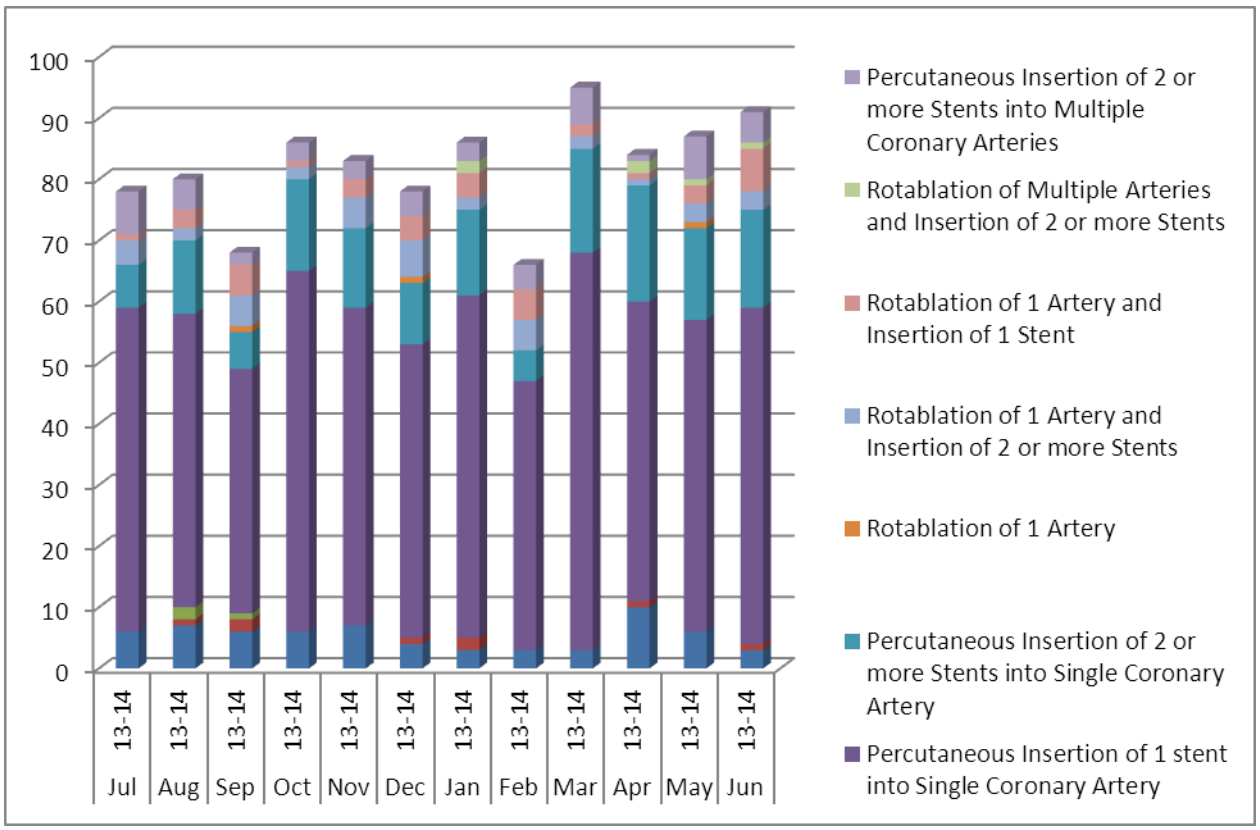
Patient Classification	Public	Private	DVA	Non-Admit	TOTAL
Patients Operated on in CCL	2,976	589	71	568	**4,204**



Total CCL Procedures Performed – Adults

PROCEDURES (ADULTS)		FINANCIAL YEAR (JULY 2013 - JUNE 2014)					FINANCIAL YEAR (JULY 2012 - JUNE 2013)				
		PUBLIC	PRIV.	DVA	NON-ADMIT	**TOTAL**	PUBLIC	PRIV.	DVA	NON-ADMIT	**TOTAL**
Coronary Angiography		2573	473	46	538	**3,630**	2,678	417	46	212	**3,353**
Device Closures	ASD	15	2			**17**	12				**12**
	LAA	7	3			**10**	3	2			**5**
	PDA	3				**3**	3				**3**
	PFO	8	2			**10**	3	3			**6**
	VSD						2	1			**3**
Paravalvular Leak Closure		5	2			**7**	2				**2**
Percutaneous Valve		39	23	8		**70**	48	23	12		**83**
Mitraclip		6	7			**13**					
Device Total		83	39	8		**130**	73	29	12		**111**
Dilatation / Stenting	Aorta						1				**1**
	Pulmonary	2	1			**3**	1				**1**
	Renal	2				**2**					
	Subclavian	1	1			**2**	2				**2**
	Vena Cava	1	1			**2**	1				**1**
Embolisation	Aorta						3				**3**
	Bronchial										
	Pulmonary		1			**1**					
	Subclavian										
Graft Study		300	43	6	37	**386**	292	28	7	15	**342**
IABP		43	3	1		**47**	66	3			**69**
ICE		20	6			**26**	19	4	1		**24**
IVC Filter		3	2			**5**					
IVUS		68	13		3	**84**	67	9	2	1	**79**
FFR		191	30	2	15	**238**	162	33	3	2	**200**
OCT		48	7	1	4	**60**	64	12			**76**
PCI +/- Stents	No Stents	62	11	1		**74**	41	2			**43**
	Single Vessel	644	116	10		**770**	688	102	12		**802**
	Multi Vessels	48	8			**56**	49	2			**51**
	Rotablation	73	12	3		**88**	75	11			**86**
Total Angioplasty		822	146	14		**982**	895	118	12		**1,025**
Pericardiocentesis		17	1			**18**	18	5			**23**
Renal Denervation		11	6			**17**	18	3			**21**
Right Heart Catheter		228	73	9	50	**360**	238	76	9	9	**332**
RV Biopsy		19	6	1	20	**46**	17	10		4	**31**
Septal Ablation (TASH)		5			1	**6**	3				**3**
Temporary Pacing		159	50	20	1	**230**	174	47	17		**238**
Transoesophageal Echo		56	31	7		**94**	49	18	8		**75**
Valve / Lead Screening		13		4		**17**	4				**4**
Valvuloplasty	Aortic	105	43	20		**168**	113	41	16		**170**
	Mitral	6	1			**7**	4	3			**7**
	Pulmonary	1				**1**	2				**2**
	Tricuspid						1				**1**
TOTAL PATIENTS		**2,976**	**589**	**71**	**568**	**4,204**	3,069	505	66	217	3,857

Percutaneous Coronary Intervention



Angioplasty Nursing Service – Episodes of Care

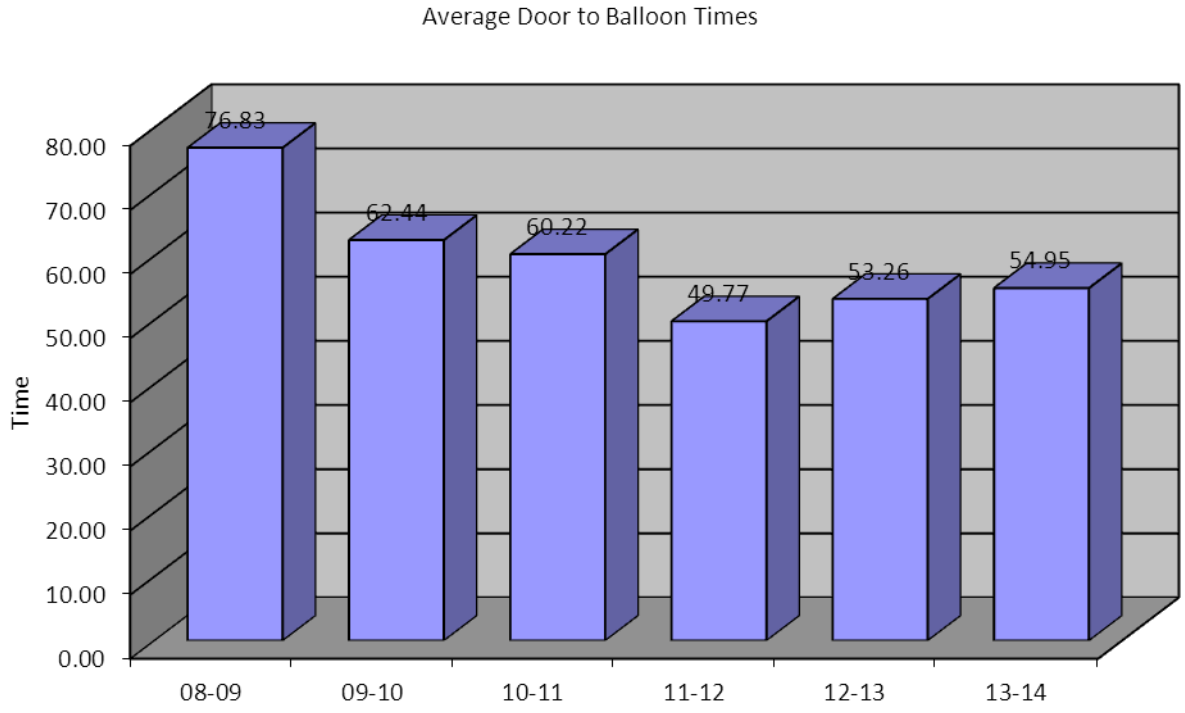
ANGIOPLASTY NURSING SERVICE		Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Total
Occasions of Inpatient Care		**78**	**80**	**68**	**86**	**83**	**78**	**86**	**66**	**95**	**84**	**87**	**91**	**982**
Outpatient Follow Up – Episodes of Care	**7 day**	75	82	58	79	73	84	69	50	59	62	96	54	**841**
	1 month	29	88	6	69	72	9	24	89	98	72	80	68	**704**
	6 month													
	Unknown	1			1									**2**
	TOTAL CARE	**105**	**170**	**64**	**149**	**145**	**93**	**93**	**139**	**157**	**134**	**176**	**122**	**1547**

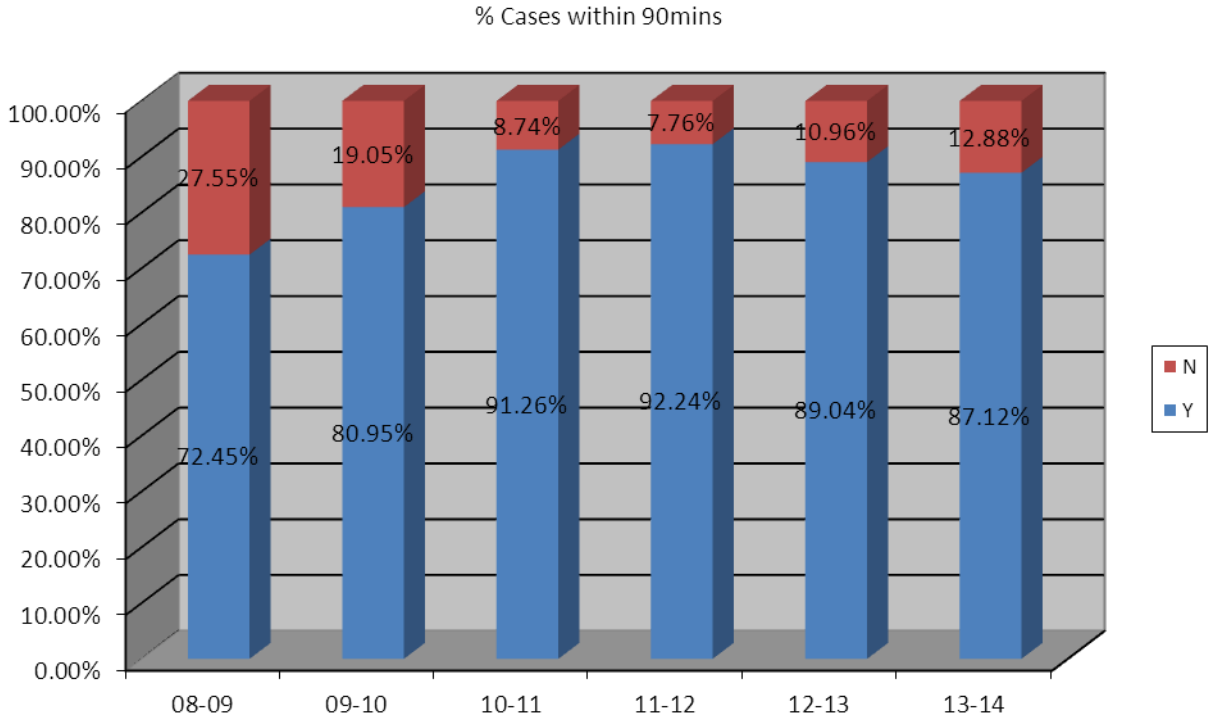
Primary PCI for STEMI

Total: 132

Patients Average Age: **64.0 ± 12.6** **(mean ± standard deviation)**

Female:	**36**	**(27.3%)**	Average Age:	**69.6 ± 12.81**
Male:	**96**	**(72.7%)**	Average Age:	**61.9 ± 12.93**





Interhospital Transfers

Total = 1521 (39.4%)

Interhospital Transfers

From 01/07/2013 to 30/06/2014

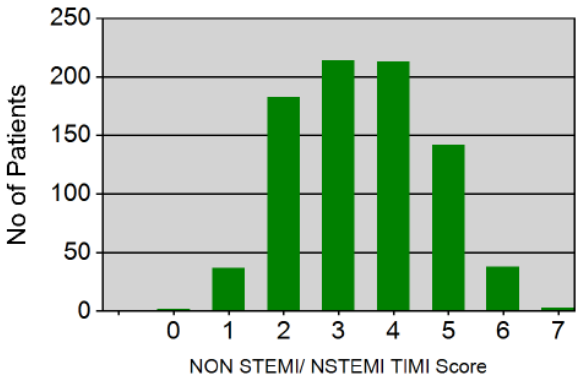
Total Identified :	**2496**
Procedure performed (excl.Cancelled after)	**2441**
inc. NOT Transferred	920
inc. Transferred	1521
Status: ED Admission	332
Status: TPCH Inpatient	460
Status: InterHospital Transfer	1403
Status: QAS Primary PCI STEMI	50
Status: Emergency to CCL	63
Status: Outpatient	77
Status: ER- Primary PCI STEMI	37
Status: Drip & Ship Post Lysis	8
Status: Drip & Ship Primary PCI	6
Status: Drip & Ship Failed Lysis	1
Status: <Unknown>	4
Transferred (excl.Cancelled after)	**1521**
inc. Procedure performed	1521
Status: InterHospital Transfer	1368
Status: Emergency to CCL	29
Status: ED Admission	56
Status: TPCH Inpatient	20
Status: Outpatient	17
Status: Drip & Ship Post Lysis	8
Status: Drip & Ship Primary PCI	6
Status: QAS Primary PCI STEMI	10
Status: ER- Primary PCI STEMI	6
Status: Drip & Ship Failed Lysis	1
Discharged (excl.Cancelled after)	**0**
Removed from the list (Cancelled)	**55**
inc. Procedure performed	20
inc. Procedure NOT performed	35
Status: InterHospital Transfer	48
Status: TPCH Inpatient	2
Status: Drip & Ship Post Lysis	2
Status: Outpatient	2
Status: ED Admission	1
inc. NOT Discharged	55

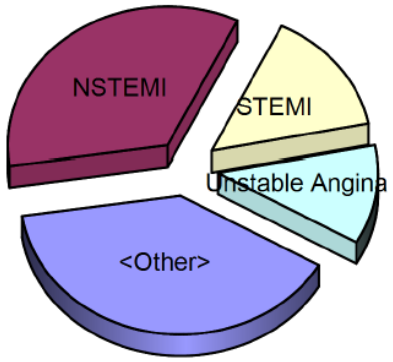
Interhospital Transfers continued

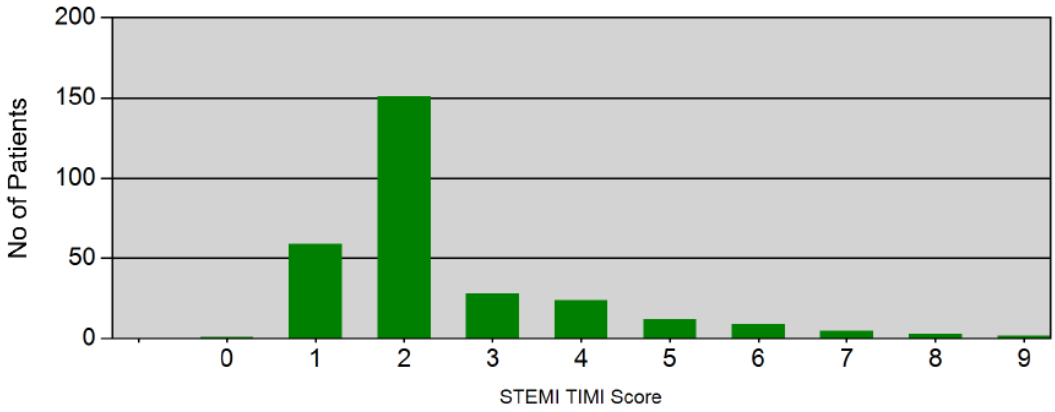
Genda / Age of Referrals:	#	%	AVG years	StDeviation
All	2496	100%	63.9	+/- 15.1
Male	1665	66.7%	63.0	+/- 14.9
Female	830	33.3%	65.6	+/- 15.3
Unknown	1	0%		

Waiting:	#	%	AVG days	StDeviation
...for Transfer	1561	63%	1.0	+/- 1.6
...for Procedure	2461	99%	2.2	+/- 2.9

ACS Types Identified:	2496	100%
Unstable Angina	286	11.5%
STEMI	366	14.7%
NSTEMI	862	34.5%
<Other>	982	39.3%







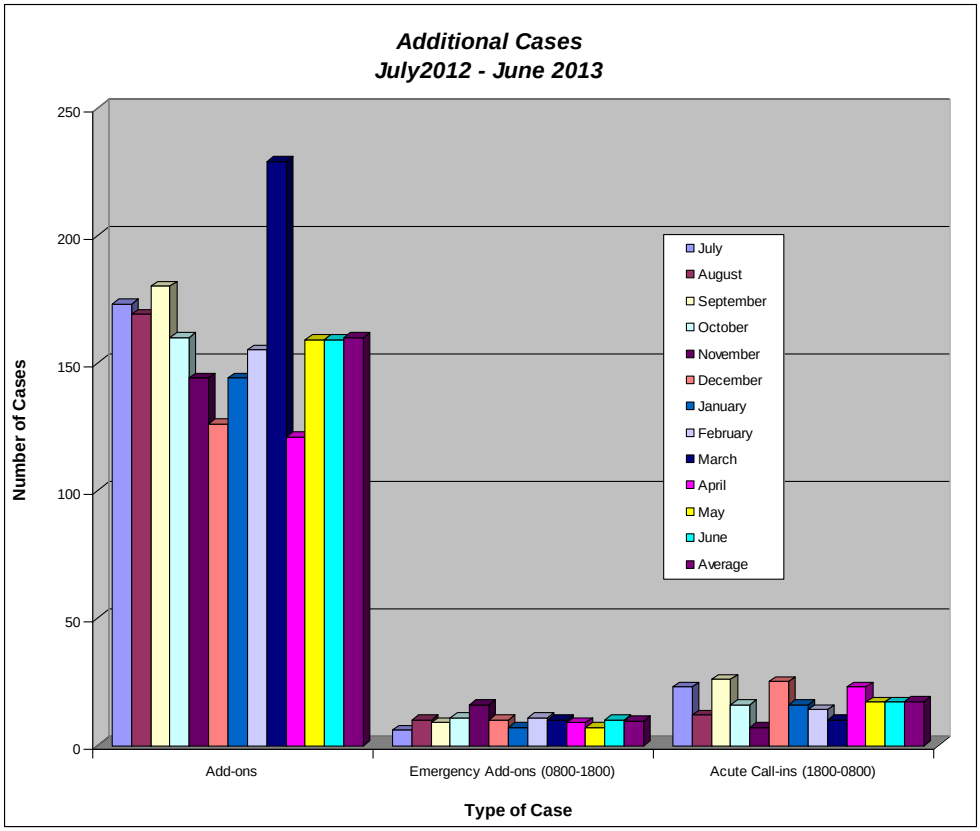
Diagnosis Identidied:	2496	100%
NSTEMI	864	34.6%
STEMI	357	14.3%
Unstable Angina	297	11.9%
Valvular Heart Disease	263	10.5%
Arrythmia	142	5.7%
IHD-Other	101	4%
Heart Failure	88	3.5%
Cardiomyopathy	65	2.6%
Stable Angina	46	1.8%
Infected Cardiac Device	36	1.4%
Pericardial Effusion/tamponade	35	1.4%
Endocarditis	33	1.3%
CHB	32	1.3%
Congenital Heart Disease	27	1.1%
Out of Hospital Arrest	21	0.8%
ICD/PPM Failure	18	0.7%
Cardiac Arrest	12	0.5%
Myocarditis	12	0.5%
STEMI Failed Lysis	11	0.4%
<Unknown>	7	0.3%
Suspected Rejection	5	0.2%
LMD IABP	5	0.2%
Thrombus	4	0.2%
Pericarditis	4	0.2%
Malignant Hypertension	2	0.1%
Atrial Myxoma	2	0.1%
Aortic Dissection	2	0.1%
NSVT	2	0.1%
Aortitis	1	0%
Pleural Effusion	1	0%
Pulmonary Embolus/DVT	1	0%

Reason of Removal from the list (Cancellation):	55	100%
Transfer to private health facility	11	20%
No longer indicated	8	14.5%
Transfer to other Q Health Facility	7	12.7%
Patient deceased	6	10.9%
Discharged home. For OPD angio appt	4	7.3%
BEING TREATED AS OUTPT	4	7.3%
Pt discharged. For OPD angio	3	5.5%
Medically unfit for procedure	3	5.5%
Accepted for transfer to RBWH	2	3.6%
PT SELF DISCHARGED	2	3.6%
Patient declined procedure	2	3.6%
OPD angio	2	3.6%
<Unknown reason>	1	1.8%

Additional Cases

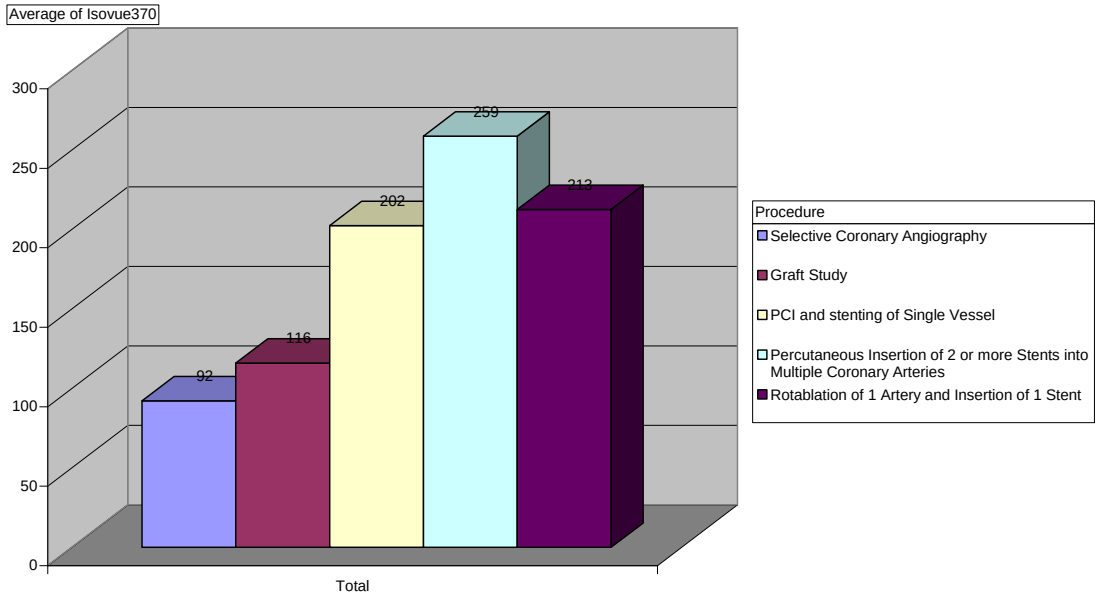
Total = 2,072 (49.3%)

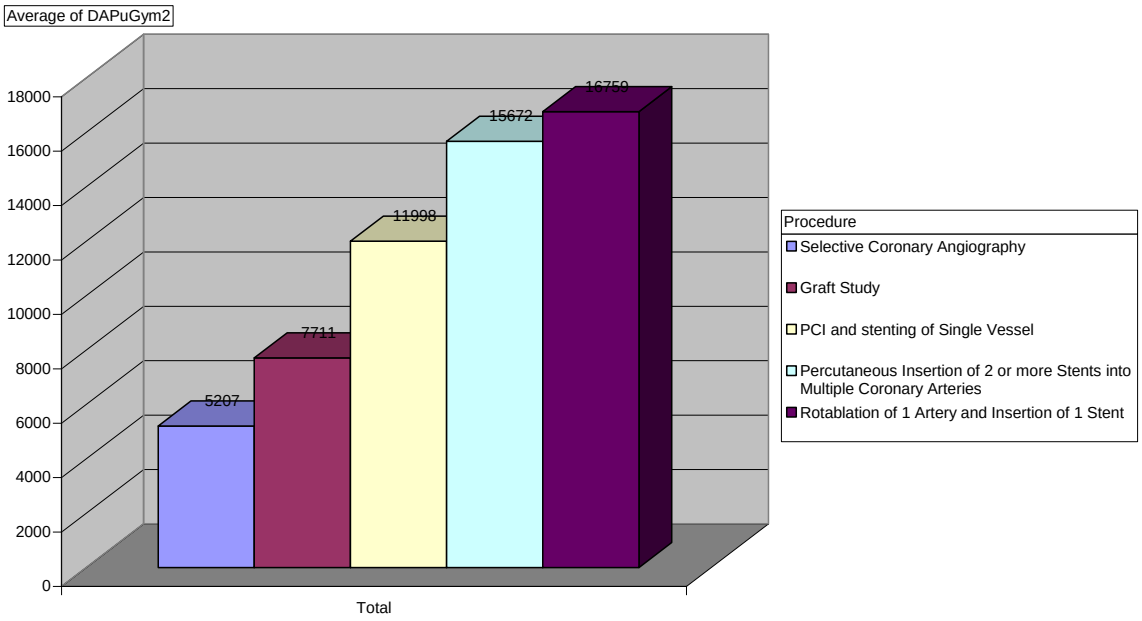
Additional Cases	Financial Year (2013 - 2014)	*Financial Year (2012 - 2013)*
Add-ons	1,661	1,919
Emergency Add-ons (0800-1800)	195	116
Acute Call-ins (1800-0800)	216	206



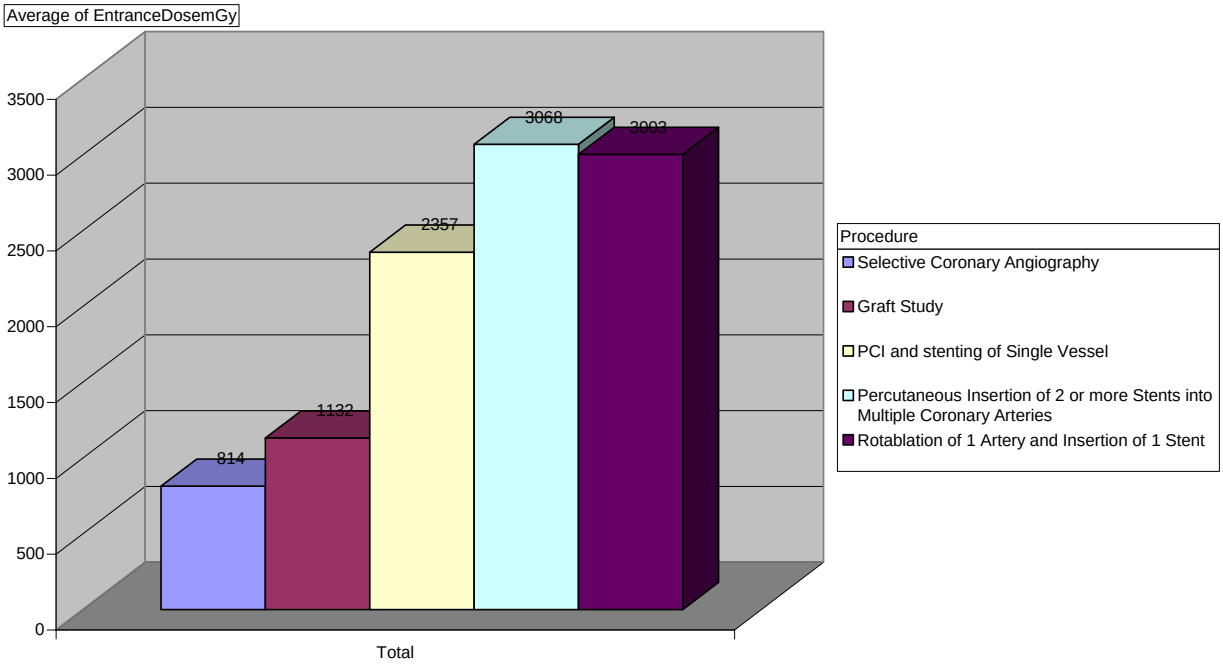
Radiation Dosages per Case

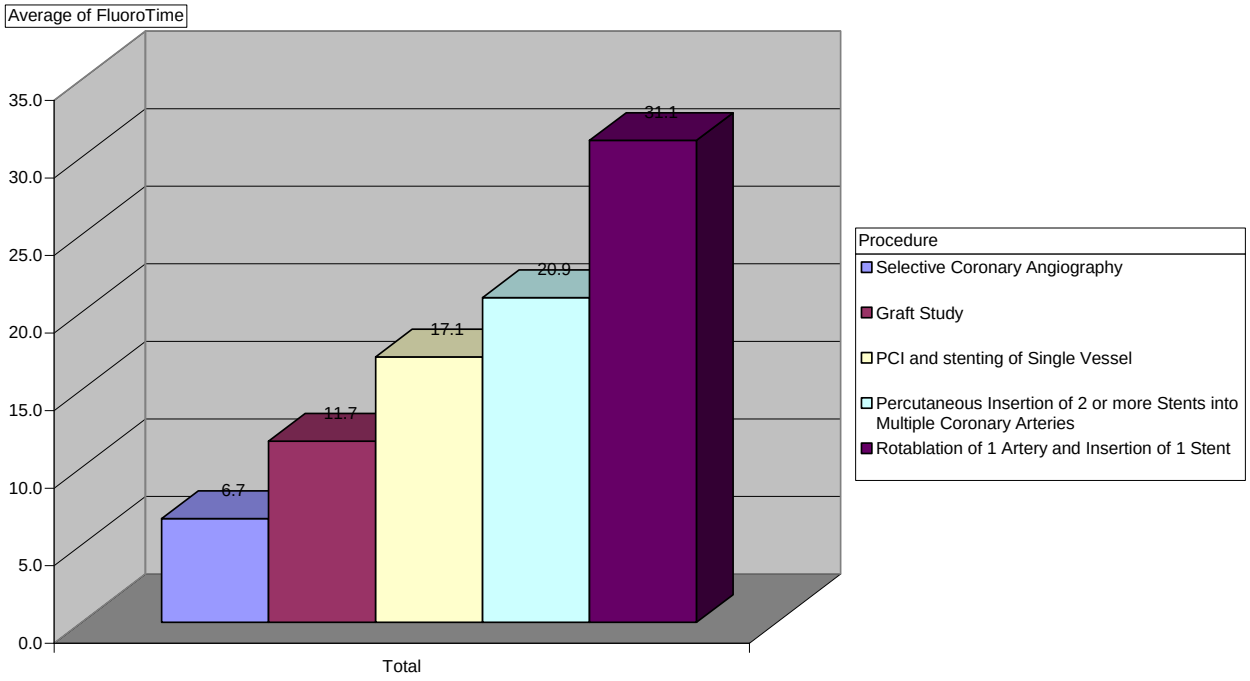
Procedure	Contrast (mL)	Dose Area Product (uGym2)	Entrance Dose (mGy)	Fluoroscopy Time (mins)
Selective Coronary Angiography	92	5207	814	6.7
Graft Study	116	7711	1132	11.7
PCI and stenting of Single Vessel	202	11998	2357	17.1
Percutaneous Insertion of 2 or more Stents into Multiple Coronary Arteries	259	15672	3068	20.9
Rotablation of 1 Artery and Insertion of 1 Stent	213	16759	3003	31.1





Radiation Continued


Average of EntranceDosemGy
3500
3000
2500
2000
1500
1000
500
0
814
1132
2357
3068
3003
Total
Procedure
Selective Coronary Angiography
Graft Study
PCI and stenting of Single Vessel
Percutaneous Insertion of 2 or more Stents into Multiple Coronary Arteries
Rotablation of 1 Artery and Insertion of 1 Stent


Average of FluoroTime
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
6.7
11.7
17.1
20.9
31.1
Total
Procedure
Selective Coronary Angiography
Graft Study
PCI and stenting of Single Vessel
Percutaneous Insertion of 2 or more Stents into Multiple Coronary Arteries
Rotablation of 1 Artery and Insertion of 1 Stent

Complications

Total = 138 (3.28%) **MACE = 10 (0.24%)**

COMPLICATIONS	REPORTABLE ADVERSE EVENTS (Financial Year 2013 - 2014)							
	1st QTR	2nd QTR	3rd QTR	4th QTR	TOTAL	% of Comp.	% of Cases	Financial Year (2012 - 13)
Anaphylactic/Allergic Reaction		2		1	3	2.2%	0.07%	*7*
Asystole	1	2			3	2.2%	0.07%	*3*
Atrial Fibrillation	1	1	1	2	5	3.6%	0.12%	*3*
Cardiogenic Shock		1	1		2	1.4%	0.05%	*1*
Death		2	1		3	2.2%	0.07%	*1*
Dissection Coronary Artery	3	3		6	12	8.7%	0.29%	*11*
Haematoma >5cm x 5cm	5	10	6	8	29	21.0%	0.69%	*9*
Heart Block	3	2	3	5	13	9.4%	0.31%	*15*
Hives		1	1	1	3	2.2%	0.07%	*4*
Hypotension	2	1		1	4	2.9%	0.10%	*8*
Other	2				2	1.4%	0.05%	
Perforation of Artery or Vessel	1		2	1	4	1.4%	0.05%	*5*
Pulmonary Oedema	1				1	0.7%	0.02%	*4*
Radiation Reportable Dose	4	2	3	4	13	9.4%	0.31%	*13*
Stroke		1		1	2	1.4%	0.05%	*2*
Sustained Bradycardia	1				1	0.7%	0.02%	*4*
Tamponade				1	1	0.7%	0.02%	*1*
Transient Ischaemic Attack								*1*
Vascular Injury	1	2	1	2	6	5.8%	0.19%	*10*
Vaso-Vagal	3	4	3	1	11	8.0%	0.26%	*16*
Ventricular Fibrillation	4		4	3	11	8.0%	0.26%	*12*
Ventricular Tachycardia	2	2	2	3	9	6.5%	0.21%	*9*
Vomiting								*4*
TOTAL	34	36	29	40	**138**	100%	3.28%	*155*

MACE = Major Adverse Cardiac Event (Death, MI, Stroke, Urgent Revascularisation)	**10**	-	0.24%	*6*
Total Mortality in the Laboratory	**2**	-	0.05%	*1*
Complication Associated Mortality	**1**	-	0.02%	*2*
30 Day All Cause Mortality	**33**	-	0.78%	*49*

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Dr Darren Walters
Clinical Director
Cardiac Catheterisation Laboratory
Date:

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Michael Savage
Consultant Cardiac Scientist
Cardiac Catheterisation Laboratory
Date:

CARDIOLOGY RESEARCH

Cardiology Clinical Research Centre (CCRC)

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

Name of Program the Research unit operates within:
Cardiology Program

Head of Research Unit/Department:
Associate Professor Darren Walters, Interventional Cardiologist, Clinical Director Cardiac Catheterization & Director of Cardiology, Executive Chair The Prince Charles Heart and Lung Institute

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Overview
The Prince Charles Hospital is the major tertiary level cardiothoracic referral hospital for Queensland, the largest such unit in Australia and one of the largest services of its type in the world.

Cardiology Program has an established and benchmarked history of excellence in service delivery and health outcomes. The program understands that to maintain and grow in excellence, it will require adequate resourcing to meet the increasing burden of cardiovascular disease and the professional and clinical responsibility to provide leadership through research, education and training and mentoring cardiac services in Queensland.

Research has been endorsed as a strategic priority by the Cardiology Program with the following supporting principles.

- Original research activities integrated with patient care
- Translating all research findings into practice to improve patient care
- Explore and evaluate innovations (procedures, devices, therapy)

Centre Profile

The Prince Charles Hospital Cardiology Clinical Research Centre is responsible for the conduct and maintenance of numerous medication and medical device trials. In addition, the Centre participates in many national and international registry studies that review current clinical technologies and practices that are being introduced into medicine.

These studies are multi-centred international and national clinical trials that investigate the treatment, management and follow up care of patients with a range of chronic and acute cardiac conditions and diseases. The clinical trials undertaken at this centre, include but not limited to randomised, controlled, unblinded and double blinded studies. The centre is also involved in comparative medication/device studies.

The department has access to cardiac services that support high level research: echocardiography, holter monitoring, exercise stress testing, ambulatory blood pressure monitoring, angiography, IVUS, CT and OCT.

We have a pharmacist dedicated to clinical trials in the hospitals main pharmacy. Pathology services are available on site. Our department has access to a monitored -80^{o}C freezer and centrifuge for specimens.

The study co-ordinators within the department are clinicians. They have backgrounds in cardiology, cardiac surgery, critical care and clinical trials. The Research administrative officers support the centre through business processes and developing HREC submissions.

Dr. Darren Walters has a keen interest in research, and a specific expertise in percutaneous transaortic valve implant, left atrial appendage occlusion device implant, platelet aggregation and anti-thrombotic drugs. He is director of the Cardiology Program and the Cardiac Investigation Unit. He meets with the research team fortnightly to oversee the progress of all trials running in the department.

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

Research Clinicians Dr OC Raffel, Dr JHN Bett, 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

Research Centre Manager: Mrs Maricel Roxas

Research Coordinators:

Current Staff: Tracy McCulloch, Helen Nahuysen, Steve Graves, Kirsten Popplewell, Melina Troncoso, Karen Trenorden

Previous Staff: Fran Alexander, Na Young Ha, Carey Hermann

Administrative Staff*:*

Current Staff: Ms Julie Bailey-Bradshaw, Bernice Enever

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5th Floor, Clinical Sciences Building
The Prince Charles Hospital
Rode Road, Chermside QLD 4032
Telephone enquiry: +61 7 3139 4711
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Currently Recruiting Research Projects:

Mitra Clip

Sponsor Company: Abbott Vascular

Objective:
The primary objective of the MitraClip System ANZ Clinical Trial is to gather real-world clinical and health-economic outcome data to support the long-term safety, efficacy and economic value of the MitraClip System in the continuum of therapies for treating Mitral Regurgitation.

Solace

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.

CoreValve:

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.

The objective of this clinical investigation will be to assess the EnligHTN™ Renal Denervation System in renal artery ablation for the treatment of 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

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)

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.

Objective: Identify OCT peri-procedural guidance parameter(s) for stent implantation that relates with patient outcomes in the hospital, at 30 days, and 12 months post intervention.

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.

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.

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:

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.

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

CAAN AF: Cardiac Resynchronisation Therapy (CRT) And AV Node ablation trial in AF

Sponsor Company: N/A Investigator Driven Study

Hypothesis: That atrio-venticular (AV) node ablation to increase true biventricular capture will improve survival and heart failure (HF) outcomes in CRT patients with Atrial Fibrillation (AF

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.

REVEAL LINQ:

Sponsor Company: Medtronic

Purpose: The Reveal LINQTM Usability Study will assess the functionality of the Reveal LINQTM device by assessing sensing performance and data transmission with the aim to support the market launch of the device

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).

ENHANCE:

Efficacy of the PreseNce of Right Ventricular Apical Pacing Induced Ventricular DyssyncHrony as a Guiding PArameter for BiveNtricular PaCing in PatiEnts with Bradycardia and Normal Ejection Fraction

Sponsor Company: St Jude Medical

Objective: To evaluate whether including an evaluation of the presence of right ventricular apical (RVA) pacing induced ventricular dyssynchrony as a guiding parameter for dual chamber pacemaker (DDDR) or cardiac resynchronization therapy pacemaker (CRT-P) device implant is superior to the standard DDDR implant procedures in patients with heart block and normal left ventricular ejection fraction (LVEF >45%).

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

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-co- tyrosol)carbonate.

Research Projects in Follow Up:

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

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.

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

Attain Performa

Sponsor Company: Medtronic

The purpose of this clinical study is to evaluate the safety and efficacy of the Medtronic Attain Performa Quadripolar Model 4298, Model 4398, and Model 4598 Left Ventricular (LV) leads

("Attain Performa leads") during and post the implant procedure. The study will also assess and characterize the interaction of the Attain Performa leads with Medtronic Quad CRT-D in CRT-D indicated patients.

Smart Touch THERMOCOOL® SMARTTOUCH™ Catheter for the Treatment of Symptomatic Atrial Fibrillation

Sponsor Company: Biosense Webster

The primary purpose of this registry is to obtain "real world" clinical use of contact force measurements during ablation procedures.

Coherex Wavecrest:

Sponsor Company: Coherex Medical

Primary Objective:

The primary study objective is to verify that under normal conditions of use the Coherex WaveCrest Left Atrial Appendage Occlusion System is a safe and effective LAA occlusion device. This investigation will be accomplished by: 1) implanting the device in patients with non-valvular paroxysmal, persistent, or permanent atrial fibrillation when anticoagulation is indicated for potential thrombus formation in the left atrium; 2) assessing LAA occlusion; and 3) monitoring adverse events at 45 days and/or up to one year post procedure.
The study will also be designed to demonstrate the safety of the Coherex WaveCrest Left Atrial Appendage Occlusion System by assessing: 1) ease of successful device insertion; 2) positioning accuracy; 3) placement stability; and 4) post-procedure adverse events. To achieve this objective, data will be collected before, during, and after the procedure.

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.

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.

INGEVITY: Active Fixation and Passive Fixation Pace/ Sense Lead Clinical Study

Sponsor Company: Boston Scientific

Objective:

The objective of this study is to gather data to establish the safety, performance and effectiveness of the INGEVITY Active Fixation and Passive Fixation Pace/ Sense Leads.

Currently Recruiting Authorised Prescriber Projects:

Edwards Authorised Prescriber:

The valve is known as the Edwards SAPIEN™ Transcatheter Aortic Valve. It is distributed by an Australian company called Edwards Lifesciences Pty Ltd. The SAPIEN™ 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
Bioflow	Biotronik - Safety and Clinical PerFormance of the Drug Eluting Orsior Stent in the Treatment of Subjects With single de novo Coronary Artery Lesions. A Randomised Comparison with the Xience Prime Everolimus-Eluting Stent in an Australian population with Diabetes Mellitus	Investigator Driven – Dr. Christopher Raffel
LATITUDE	Phase III trial comparing losmapimod vs placebo x 12 weeks on the incidence of MACE in subjects with ACS (NSTEMI and STEMI)	GSK
TEXT MEDS	Text Messages to improve medication adherence and secondary prevention	Clara Chow and Deborah Blair - George Institute
ABSORB III	A Clinical Evaluation of Absorb™ BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects with de novo Native Coronary Artery Lesions	Abbott
GLOBAL	Understanding novel genomic assocaition of CAD by using advanced cardiovascular imaging ofr CAD phenotyping and next generation whole genome phenotyping and sequencing	Global Genomics
ENLIGHTNMENT	A Multi-Centre, Randomized Trial of Renal Denervation to Reduce Major Cardiovascular Events in Patients with Treatment Resistant Hypertension	St Jude Medical
REDUCE HTN – GLOBAL PIVOTAL STUDY	Renal Denervation Using the Vessix **Reduce**™ Catheter and Vessix™ Generator for the Treatment of Resistant **H**yper**T**ensio**N**	Boston Scientific

CLOSED OUT

Biolux:

Sponsor Company: Medtronic

Objective:
To assess the feasibility and safety of the BIOTRONIK Drug Eluting Balloon when used as part of a provisional stenting strategy for the treatment of single *de novo* bifurcation lesions in native coronary arteries with reference vessel diameters for the main vessel and side branch of 2.0m-4.0mm.

Platinum Work Horse:

Sponsor Company: Boston Scientific

This study will compare the safety and effectiveness of two drug-eluting stents in the treatment of coronary artery disease: the PROMUS Element Everolimus-Eluting Coronary Stent System and the PROMUS™ Everolimus Eluting Coronary Stent System.

Protect PACE:

Sponsor Company: Medtronic

Primary Study Objective:
The objective of the study is to evaluate if RVHS pacing results in a clinically better LV function (as measured by LV ejection fraction) when compared to RVA pacing. This effect will be assessed by comparing echo data at baseline and pre-hospital discharge to echo data after 24 months of pacing.

Adaptive CRT:

Sponsor Company: Medtronic

The Adaptive CRT Study is a prospective, multi-center, randomized, double-blinded, worldwide IDE clinical trial to demonstrate non-inferiority of the aCRT algorithm compared to echo-optimized bi-ventricular CRT using Clinical Composite Score as a measure of patient outcome and aortic velocity time integral (AoVTI) as a measure of cardiac performance at 6 month follow-up. Inappropriate AV or VV delay settings related to the aCRT feature at six months will serve as the safety endpoint for this trial.

Advisa MRI:

Sponsor Company: Medtronic

The Advisa MRI System study is a prospective, randomized controlled, non-blinded, multi-center worldwide investigational study. The purpose of the Advisa MRI System clinical study is to confirm safety and effectiveness in the clinical MRI (Magnetic Resonance Imaging) environment when subjects receive MR scans up to 2W/kg Specific Absorption Rate (SAR) without positioning restrictions (MR scans may occur anywhere on the body).

Primary Objectives
• To assess the MRI-related complication-free rate one month post MRI.
• To demonstrate the non-inferiority of the MRI group compared to the control group with regard to the proportion of subjects who experience an increase less than or equal to 0.75V in 1) atrial and 2) ventricular voltage thresholds at 0.5ms from the pre-MRI/waiting period to one month post-MRI/waiting period.

Zomaxx:

Sponsor Company: Abbot Vascular

To demonstrate the safety and efficacy of the ZoMaxxTM Drug Eluting
Coronary Stent System in reducing the occurrence of target vessel revascularization (TVR) at 9 months in patients with single de novo lesions in native coronary arteries as compared to the TAXUSTM Express2 TM Paclitaxel-Eluting Stent.

PROTECT PCI:

Sponsor Company: Medtronic
The primary objective of this study is to compare stent thrombosis rate of the Endeavor® Zotarolimus Eluting Coronary Stent System versus the Cypher® Sirolimus-eluting Coronary Stent in a patient population requiring stent implantation.

Spirit Prime:

Sponsor Company: Abbott Vascular

To evaluate the safety and effectiveness of the XIENCE PRIME and
XIENCE PRIME LL Everolimus Eluting Coronary Stent System (EECSS) in improving coronary luminal diameter in subjects with symptomatic heart disease due to a maximum of two *de novo* native coronary artery lesions, each in a different epicardial vessel.

Cardiac Catheterisation Laboratory Staff

MANAGEMENT TEAM

Clinical Director	WALTERS	*Darren*
Cath Lab NUM	HITCHCOCK	*Rebecca*
Recovery NUM	COUSINS	*Margaret*
Director Cardiac Sciences	BOUCAUT	*Susan*
Snr Card. Scientist	SAVAGE	*Michael*
Snr Radiographer	CROWHURST	*Jim*
Business Manager	CARTWRIGHT	*John*
Clin. Nurse Co-ordinator	GRANT	*Denise*
DON-Cardiology	TIBBY	*David*

INTERVENTIONAL FELLOWS

INCANI	*Alex*
SAIREDDY	*Ramakrishna*
SUBBAN	*Vijaykumar*

HEART FAILURE AND ACHD FELLOWS

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HOFMEYR	Lou

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RAFFEL	*Chris*
SEDGWICK	*John*
SMALL	*Andrew*
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WHIGHT	*Christopher*

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DAVISON	*Oscar*
DENBESTEN	*Joel*
LINDEMANN	*James*
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SPERANZA	*Vicki*
TAYLOR	*Colleen*
WRIGHT	*Daniel*
WRIGHT	*Jeffrey*

NURSES

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BLACKBURN	*James*
BROOKE	*Debra*
BULL	*Lyn*
BYCROFT	*Melinda*
CARUANA	*Susan*
CEMBRANO	*Francis*
COUSINS	*Kate*
COUSINS	*Margaret*
DAHL	*Margaret*
DAVEY	*Megan*
DALL	*Sue*
DUFFY	*Denise*
EDDY	*Julia*
FARRELL	*Jo*
GEORGE	*Lisa*
GILL	*Suzanne*
GLORIA	*Jocelyn*
GOUGH	*Cathy*
GRANT	*Denise*
HARRADINE	*Leonie*
HARRICH	*Cherie*
HAWTHORNE	*Ian*
HITCHCOCK	*Rebecca*
HODGE	*Lillian*
HORNE	*Dianne*
HORTON	*Marc*
HYSLOP	*Katrina*
KLEISSL	*Sabine*
LEWIS	*Talya*
LITTLEJOHN	*Jessica*
LOHREY	*Karen*
MADAN	*Laly*
MCCLUAND	*Rebecca*
MCEWAN	*Lauren*
MELKSHAM	*Maretta*
O'BRIEN	*Cherie*
OLLEY	*Ferminas*
O'HARE	*Ruth*
PAGE	*June*
PERCY	*Lisa*
POLLARD	*Karen*
PAINE	*Arlene*
ROBERTSON	*Leonie*
ROBINSON	*Sarah*
RUGE	*Jessica*
SUMMERVILLE	*Elaine*
TAYLOR	*Cathy*
TREVASCUS	*Carla*
URMATAM	*Jenart*
WANNECK	*Allison*
WATSON	*Brooke*
WEBB	*Juanita*
WEINMAN	*Vanessa*
WILLIAMS	*Diane*
WILTON	*Alison*
YAZDANI	*Shohreh*

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HAMILTON	*Casey*
HEDRICK	*Judith*
JOHNSTON	*Leisie*
KEYS	*Jennifer*
KROLL	*Joanne*
LIDDICOAT	*Annelise*
O'KEEFE	*Katrina*
REDMOND	*Casey*
ROBINSON	*Brendan*
SERGEANT	*Phil*
SHAFFE	*Roslynn*
THOMAS	*Arianwen*
THOMAS	*Damien*
THOMPSON	*Dane*
THOMPSON	*Kate*
WALKER	*Erin*

APPENDIX A - PCI REPORT (JULY 2013- JUNE 2014)

THE PRINCE CHARLES HOSPITAL
CARDIAC CATHETER LABORATORY

Queensland Government

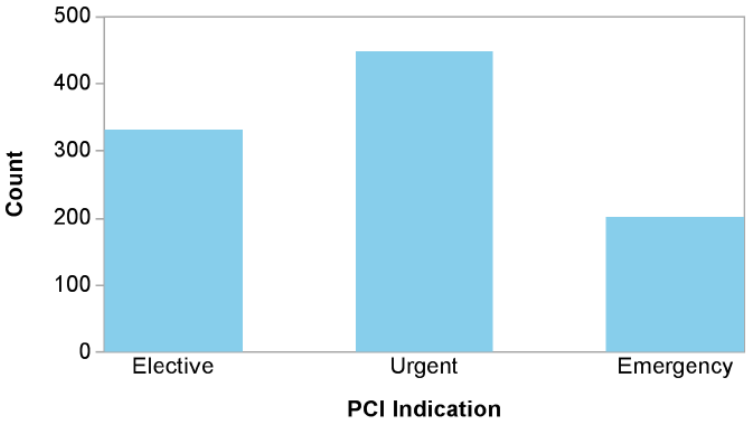
PCI Procedure Report

1/07/2013 - 30/06/2014

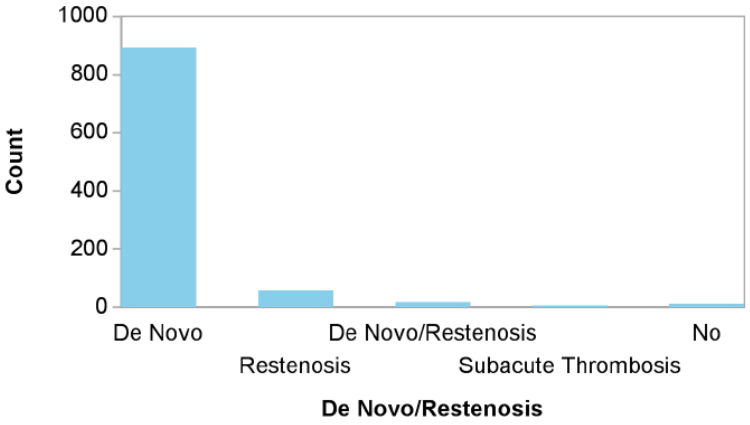
Patient Age			
Male	727	74.03 %	Av 63 +/- 12
Female	255	25.97 %	Av 68 +/- 12
	982	**100%**	**Av 64 +/- 12**

Indications

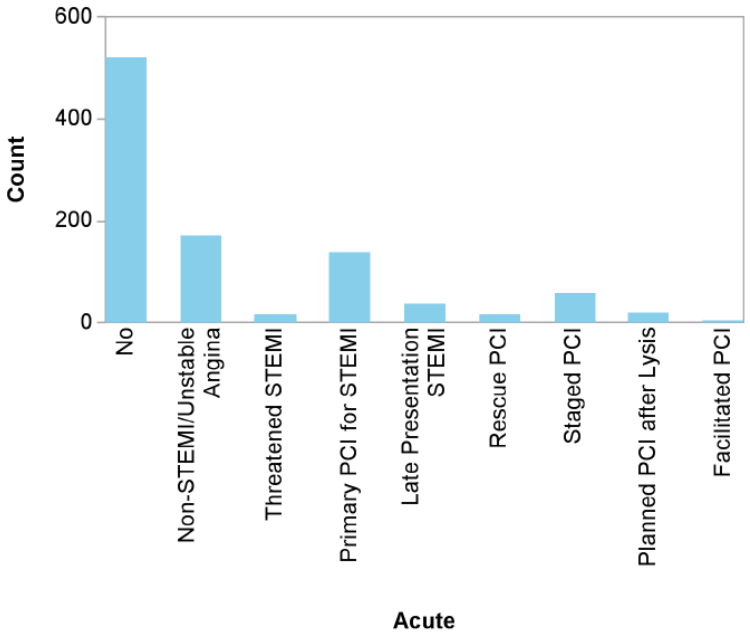
PCI Status	Number of Cases	%
Elective	332	33.81 %
Emergency	202	20.57 %
Urgent	448	45.62 %
	982	**100%**



De Novo/Restenosis	Number of Cases	%
De Novo	891	90.73 %
De Novo/Restenosis	16	1.63 %
No	11	1.12 %
Restenosis	60	6.11 %
Subacute Thrombosis	4	0.41 %
	982	**100%**



Acute	Number of Cases	%
Facilitated PCI	3	0.31 %
Late Presentation STEMI	36	3.67 %
No	520	52.95 %
Non-STEMI/Unstable Angina	172	17.52 %
Planned PCI after Lysis	21	2.14 %
Primary PCI for STEMI	138	14.05 %
Rescue PCI	18	1.83 %
Staged PCI	56	5.70 %
Threatened STEMI	18	1.83 %
	982	**100%**



Cardiac Indications	Number of Indications	% of total cases
Angina.	86	8.76 %
Cardiogenic Shock.	3	0.31 %
Chest pain.	477	48.57 %
Exertional dyspnoea.	92	9.37 %
Known coronary artery disease.	236	24.03 %
NSTEMI.	242	24.64 %
Out of hospital arrest.	19	1.93 %
Positive CT Coronary Angiogram.	50	5.09 %
Positive EST.	33	3.36 %
Positive stress echo.	20	2.04 %
Previous MI	64	6.52 %
STEMI.	182	18.53 %
Thrombolysed STEMI.	38	3.87 %
Unstable angina.	18	1.83 %
	1560	

Risk Factors	Number of Factors	% of total cases
Anxiety	123	12.53 %
Cerebrovascular Disease	77	7.84 %
CHF	38	3.87 %
Chronic Lung Disease	120	12.22 %
Current smoker	227	23.12 %
Depression	95	9.67 %
Diabetes	263	26.78 %
Dyslipidemia	618	62.93 %
Family History	324	32.99 %
Hypertension	618	62.93 %
Obesity	433	44.09 %
Renal Failure	49	4.99 %
	2985	

Lesions Risk	Number	% of total cases
Type A Lesion	100	10.18 %
Type B1 Lesion	282	28.72 %
Type B2 Lesion	174	17.72 %
Type C Lesion	597	60.79 %
	1153	

Approach	Number	% of total cases
Brachial	2	0.20 %
Femoral	607	61.81 %
Other	1	0.10 %
Radial	372	37.88 %
	982	**100%**

Complications	Number	% of total cases
Cardiogenic Shock	1	0.10 %
Death	1	0.10 %
Heart Block	7	0.71 %
Perforation of Artery or Vessel	2	0.20 %
Ventricular Fibrillation	10	1.02 %
	21	

Previous Procedures

Previous Procedures	Number	%
Previous CABG	147	14.97 %
Previous PCI	266	27.09 %
Previous valvular surgery	14	1.43 %
	427	

Technical Data and Lesion Characteristics

Stent Type	Number	%
Bare Metal Stent	370	29.18 %
Drug Eluting Stent	877	69.16 %
Covered Stent	3	0.24 %
Research Stent	18	1.42 %
	1268	**100%**

Technical Data and Lesion Characteristics

Guide Size	Number	%
1.0	3	0.23 %
5	10	0.76 %
6	1018	77.77 %
6.5	6	0.46 %
7	233	17.80 %
7.5	17	1.30 %
8	22	1.68 %
	1309	**100%**

Balloon Size	Number	%
Null	1	0.03 %
1.00	4	0.13 %
1.20	1	0.03 %
1.25	28	0.92 %
1.50	75	2.48 %
2.00	388	12.81 %
2.25	13	0.43 %
2.50	869	28.68 %
2.75	142	4.69 %
3.00	510	16.83 %
3.25	140	4.62 %
3.50	427	14.09 %
3.75	83	2.74 %
4.00	220	7.26 %
4.50	96	3.17 %
5.00	32	1.06 %
6.00	1	0.03 %
	3030	**100%**

Technical Data and Lesion Characteristics

Stent Width	Number	%
2.00	1	0.08 %
2.25	55	4.34 %
2.50	265	20.90 %
2.75	130	10.25 %
3.00	371	29.26 %
3.50	280	22.08 %
4.00	151	11.91 %
4.50	12	0.95 %
5.00	1	0.08 %
6.00	2	0.16 %
	1268	**100%**

Stent Length	Number	%
8	23	1.81 %
9	4	0.32 %
11	2	0.16 %
12	89	7.02 %
13	3	0.24 %
14	5	0.39 %
15	150	11.83 %
16	74	5.84 %
18	175	13.80 %
19	3	0.24 %
20	93	7.33 %
22	18	1.42 %
23	116	9.15 %
24	86	6.78 %
25	3	0.24 %
26	22	1.74 %
28	161	12.70 %
30	23	1.81 %
32	29	2.29 %
33	66	5.21 %
34	3	0.24 %
38	118	9.31 %
50	2	0.16 %
	1268	**100%**

30 Day Outcomes

Quality of Life	Number	%
Better	619	91.84 %
No Improvement	43	6.38 %
Worse	12	1.78 %
	674	**100%**

Access Site	Number	%
Active Bleeding	1	2.38 %
Bruising	27	64.29 %
Haematoma	12	28.57 %
Persistent Pain	2	4.76 %
	42	**100%**

Cardiac Rehab Attended	Number	%
Attended	294	43.17 %
Not Attended	387	56.83 %
	681	**100%**

Smoking	Number	%
Recommenced Smoking at One Month Post Procedure	24	88.89 %
Referred to Quit Programme	3	11.11 %
	27	**100%**

Exercise Compliance	Number	%
No	128	18.21 %
Yes	575	81.79 %
	703	**100%**

Medication Compliance	Number	%
No	2	0.28 %
Yes	712	99.72 %
	714	**100%**

Angina	Number	%
Class I (Strenuous Activity)	76	10.48 %
Class II (Ordinary Activity)	36	4.97 %
Class III (Marked Limitations)	47	6.48 %
Class IV (At Rest)	91	12.55 %
No Pain	469	64.69 %
Unknown	6	0.83 %
	725	**100%**

Adverse Events	Number	%
CVA	7	35.00 %
Death	1	5.00 %
Emergency PCI	2	10.00 %
MI	10	50.00 %
	20	**100%**