

**Independent Clinical Review of Provision
of a Second Catheterisation Laboratory
at University Hospital Waterford**

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Executive Summary and Recommendations

In May 2016 I was asked by the Minister for Health to undertake an independent clinical review of provision of a second cardiac catheterisation laboratory at University Hospital Waterford (UHW) and to present a report within six weeks

The analysis I have undertaken indicates that the needs of the effective catchment population for planned cardiac cath lab procedures can be accommodated in 12 weekly cath lab sessions of 4 hours each in a single cath lab. Hence a second cardiac catheterisation laboratory at UHW is not justified on this basis

Furthermore I concluded that the limited hours, daytime primary PCI service at UHW does not meet the BCIS standard of an absolute minimum of 100 primary PCI procedures per year and will not do so under the current model. It is my opinion that expanding the service to provide 24/7 cover is not a sustainable solution. Of the options available to resolve this situation, I concluded that UHW should cease the provision of primary PCI and that the interventional management of patients with STEMI from this region should be consolidated in Cork University Hospital and St James's Hospital, Dublin

Recommendations

- 1) The range of planned cath lab work that UHW currently undertakes for its catchment population should continue
- 2) The cath lab service at UHW should be funded and staffed to provide 12 sessions of planned cath lab activity weekly
- 3) A contingency for radiological equipment failure during a procedure, such as a portable fluoroscopy unit with an image intensifier, should be established if it is not in place already
- 4) The cardiology services in the South/South West Hospital group (and especially the teams at UHW and CUH) should agree a strategy that makes best use of their combined excellent skills, cath lab facilities and teams, in order to optimise clinical outcomes for all of the patients across the Hospital group
- 5) The current limited hours provision of primary PCI at UHW should cease, to allow the centre to focus on the much larger volume of planned cath lab work

If recommendation 5 is accepted, I make these follow-on recommendations:

- 6) Patients arriving to the emergency department at UHW should be considered as within a 90 minute drive time of Cork University Hospital and should be transferred there for primary PCI without delay, irrespective of the time of day or night
- 7) The interventional cardiologists at UHW should continue to make their primary PCI skills accessible for the benefit of patients, by taking part in the 24/7 primary PCI rota centred in Cork University Hospital
- 8) A group of local clinical stakeholders (including representatives of the ambulance service) should review the current operation of the Optimal Reperfusion Protocol (Appendix 3) for patients with STEMI in the South East who are more than a 90 minute drive time from a 24/7 primary PCI centre. The group should design the best future reperfusion protocol for these patients, which may be the existing strategy (thrombolysis with immediate transfer), a default helicopter transfer or an alternative strategy. The review should be led by the ACS Programme of the HSE

Conflict of Interest Statement

I have no conflict of interest in undertaking this review or in preparing this report

Introduction

Towards the end of May 2016, I was asked by the Minister for Health to undertake an independent clinical review of provision of a second cardiac catheterisation laboratory at University Hospital Waterford (UHW)

The terms of reference were as follows

- i. To consider the clinical need for a second catheterisation laboratory at University Hospital Waterford by:
 - Setting out the indications for cardiac catheterisation in the context of a comprehensive cardiac service;
 - Examining patient flows to determine the effective current and future population to be served by University Hospital Waterford for cardiac services;
 - Examining the needs of this population in respect of these indications for cardiac catheterisation;
 - Examining the workload of the existing laboratory with reference to normative workloads for a catheterisation laboratory in Ireland
- ii. To make recommendations on the need for a second laboratory based on the expert interpretation of the data and
- iii. To present a report to the Minister for Health within six weeks of establishment
- iv. The independent expert will engage with UHW, the ACS Programme, the Department of Health and the HSE. Data from UHW will be validated, analysed and compared with data from other settings. It will be necessary for the independent expert to analyse CSO data in relation to the current and projected

population of the region, as well as HIPE (Hospital Inpatient Enquiry) data and any other data necessary to analyse information in relation to the actual population using UHW

- v. The Secretariat will be provided by the Acute Coronary Syndrome Programme.

Following preparatory work, the review began on 7 June 2016 with a visit to UHW to tour the cardiology department and meet the clinical and management teams. This was followed by a visit to Cork on 16 June 2016 to meet the CEO of the South/South West Hospital group and to tour the cardiology department at Cork University Hospital with the clinical and management teams. I have also had detailed meetings with representatives of the Acute Coronary Syndrome Programme, the Department of Health, the National Ambulance Service and the Health Service Executive

Over the course of the review I have applied the following principles to the analysis undertaken, the conclusions reached and the recommendations made

1. The primary concern is the quality of care that patients receive
2. Conclusions and recommendations will be driven by data
3. Conclusions and recommendations will reflect scientific evidence as summarised in the published guidelines of relevant professional bodies

I would like to thank all of these people who met me at short notice and provided information and analysis. It has been clear throughout that the focus of all of these professionals is delivering the best possible care for the patients and populations for whom they have responsibility

1. Background to the Review

University Hospital Waterford is a sizeable teaching hospital providing a wide range of clinical services to the city and county of Waterford and regional services to a wider population of the South East of Ireland. It is a regional trauma centre with an emergency department seeing about 50,000 patients per year. It is the second largest hospital in the South/South West Hospital group¹ and delivers regional cancer services, nephrology services, ENT, ophthalmology and orthopaedics among many other specialties

The cardiology department provides a wide range of non-invasive and invasive cardiac services and is staffed by 3.5 consultant cardiologists, of whom 2.5 are currently in post. The rota for out-of-hours consultant cover for cardiac patients is shared between cardiologists and other physicians in the hospital

The hospital's cardiac catheterisation laboratory (cath lab) opened in 2008. There is funding for three interventional cardiologists at UHW; currently two are in post. Since 2009, three interventional cardiologists have left posts in UHW to take up consultant positions elsewhere in Ireland. Two consultants from other hospitals undertake cath lab sessions at UHW – one from Wexford General Hospital and one from South Tipperary General Hospital

Between 2008 and the present day, the range of cath lab procedures has expanded. The cath lab is now open Monday to Friday 9 to 5, with periodic extension of the working day in response to demand. The procedures performed are diagnostic cardiac catheterisation and coronary angiography, interventional diagnostic procedures (pressure wire and intravascular imaging), percutaneous coronary intervention, permanent pacemaker and implantable loop recorder insertion, implantable cardioverter defibrillator (ICD) insertion and cardiac resynchronisation therapy (CRT)

The team at UHW have supplied me with individual procedure-level data summarising almost 2,000 cardiac cath lab procedures undertaken in UHW in 2015 (Table 1.1)

There is no agreed South/South West Hospital group strategy for the treatment of patients with cardiovascular disease, nor for the location and future scope of cath lab services. A global strategy for the Hospital group is in preparation and is expected by the end of 2016

¹ The Establishment of Hospital Groups as a transition to Independent Hospital Trusts. A report to the Minister for Health, Dr James Reilly TD. February 2013

Procedure	Number
Coronary angiography alone	961
PCI alone	174
Coronary angiography and follow on PCI	354
Primary PCI	62
Permanent pacemaker (PPM) implants or revisions (majority assumed to be dual chamber implants)	179
Permanent pacemaker generator changes	25
Loop recorder implants or explants	90
Implantable cardioverter defibrillator (ICD) implants or revisions	38
Implantable cardioverter defibrillator generator changes	8
Cardiac resynchronisation therapy (CRT) implants or revisions	34
Cardiac resynchronisation therapy generator changes	2

Table 1.1 Numbers of cath lab procedures performed in UHW in 2015. Source: UHW

The cath lab service has come under pressure in recent years as evidenced by lengthening waiting times for inpatient procedures, a growing number of same-day procedural cancellations (84 in 2015) and growing outpatient waiting lists. Unplanned emergency cases (most commonly primary PCI) put particular stress on the service because they frequently result in knock-on cancellations of patients who were scheduled to have planned procedures on those days. These pressures on the cath lab team, combined with the commitment to provide primary PCI on a 9 to 5, Monday to Friday basis has led to a growing conviction that a second cath lab is required in UHW to keep up with the demand for planned and unplanned (emergency) activity

In May 2016 a commitment to resolve this question was made in the Programme for Government as follows²

² Programme for Partnership Government. May 2016

We are committed to the development of a second Cath Lab in University Hospital Waterford subject to a favourable recommendation from an independent clinical review of the needs of the region to be carried out within 6 weeks

The present report summarises that independent clinical review

I have considered the question under two different sets of criteria representing two different workstreams for cardiac cath labs:

1. Planned (scheduled) cardiac cath lab services – about 96% of the caseload
2. Unplanned (emergency) cardiac cath lab services – about 4% of the caseload

The challenges associated with the two workstreams are very different and the responsibilities associated with either workstream may justify the provision of a second cardiac cath lab

2. Setting out the indications for cardiac catheterisation in the context of a comprehensive cardiac service

A cardiac cath lab is a specialised clinical and radiological facility designed to perform a range of diagnostic and therapeutic invasive cardiac procedures under sterile conditions. It is typically staffed by a hospital cardiology team, consisting of medical, nursing, radiography, clinical physiology and managerial professionals. They are found in public and private hospitals – an example is shown in Figure 2.1 below



Figure 2.1 A cardiac catheterisation laboratory (cath lab)

Clinical indications

Patients coming for cath lab procedures can be grouped into five general clinical categories. There may be overlap so that a patient may present in more than one category at the same time or at different times. In decreasing order of frequency, indications for cath lab procedures are as follows:

- Suspected or known coronary artery disease
- Suspected or known cardiac rhythm disorders (arrhythmias)
- Suspected or known structural heart disease
- Suspected or known heart failure or cardiomyopathy
- Suspected or known vascular disease, including pulmonary vascular disease

Level of urgency

Within these clinical categories, patients may present with different levels of urgency.

In decreasing order of frequency they are:

- As an elective outpatient – in public healthcare systems the timeframe from decision to procedure is typically measured in weeks to months
- As an urgent inpatient - in public healthcare systems the timeframe from decision to procedure is typically measured in hours to days
- As an emergency - the timeframe from decision to procedure is typically measured in minutes to a small number of hours

Level of procedural complexity

Some procedures are performed in most cath lab centres while others are restricted to supraregional centres. Supraregional procedures tend to be restricted because of:

- Procedural complexity
- Links to other supraregional services (such as cardiac surgery)
- Anticipated low volume and the need for concentration of skills
- Complexity of equipment used
- Complexity of the skills required by the supporting teams (such as clinical physiologists)

In 2012, twelve professional organisations in the USA published a combined consensus on the indications for diagnostic cardiac catheterisation³. They are similar to representative European guidelines which also cover indications for other cath lab procedures^{4,5,6}. Although not exhaustive, the indications for cardiac catheterisation may be summarised as in Tables 2.1 and 2.2 below. The procedural profile of UHW is similar to that in Table 2.1

³ ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/ SCMR/STS 2012 appropriate use criteria for diagnostic catheterization. Journal of the American College of Cardiology 2012; 59: 1995-2027

⁴ 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. European Heart Journal 2013; 34, 2281–329

⁵ 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. European Heart Journal 2015; 36, 2793-867

⁶ 2014 ESC/EACTS Guidelines on myocardial revascularization. European Heart Journal doi:10.1093/eurheartj/ehu278

Clinical category	Indication	Typical level of urgency	Most common procedures
Coronary artery disease (known or suspected)	Acute coronary syndrome	Urgent	Coronary angiography Percutaneous coronary intervention
	Stable coronary artery disease	Elective	
	Pre-operative evaluation	Elective	
Cardiac arrhythmias (known or suspected)	Bradyarrhythmias	Any	Pacemaker (temporary or permanent)
	Ventricular arrhythmias	Urgent or elective	Implantable defibrillator*
Structural heart disease	Valvular heart disease	Elective	Cardiac catheterisation
	Pericardial disease		
Heart failure and cardiomyopathies	Evaluation of cause	Elective	Cardiac catheterisation
	Treatment of arrhythmias	Urgent or elective	Implantable defibrillator*
	Cardiac resynchronisation	Elective	Cardiac resynchronisation therapy*

Table 2.1 Procedures performed in most cardiac catheterisation laboratories. *In some regions these procedures are consolidated in selected cardiac catheterisation laboratory centres

Clinical category	Indication	Typical level of urgency	Most common procedures
Coronary artery disease (known or suspected)	ST elevation myocardial infarction Unstable acute coronary syndrome Cardiogenic shock	Emergency	24/7 coronary angiography and percutaneous coronary intervention Haemodynamic support
Cardiac arrhythmias	Ventricular arrhythmias	Any	Ablation
	Other arrhythmias	Elective	Electrophysiological study +/- ablation
Structural heart disease	Valvular heart disease	Any	Balloon valvuloplasty or other transcatheter valve intervention
	Congenital heart disease (adult or paediatric)	Elective	Cardiac catheterisation Structural heart intervention
Heart failure and cardiomyopathies	Evaluation of cause	Elective	Myocardial biopsy
	Relief of outflow tract obstruction	Elective	Alcohol septal ablation
Vascular diseases	Pulmonary hypertension	Elective	Cardiac catheterisation and vasodilator challenge

Table 2.2 Procedures typically restricted to selected cardiac catheterisation laboratory centres

3. Examining patient flows to determine effective current and future population to be served by University Hospital Waterford for cardiac services

The catchment population served by the cardiology service at UHW (or any other hospital service) is a matter for interpretation. A starting point is to consider the total populations in each of the counties close to UHW, based on the 2011 and 2016 censuses

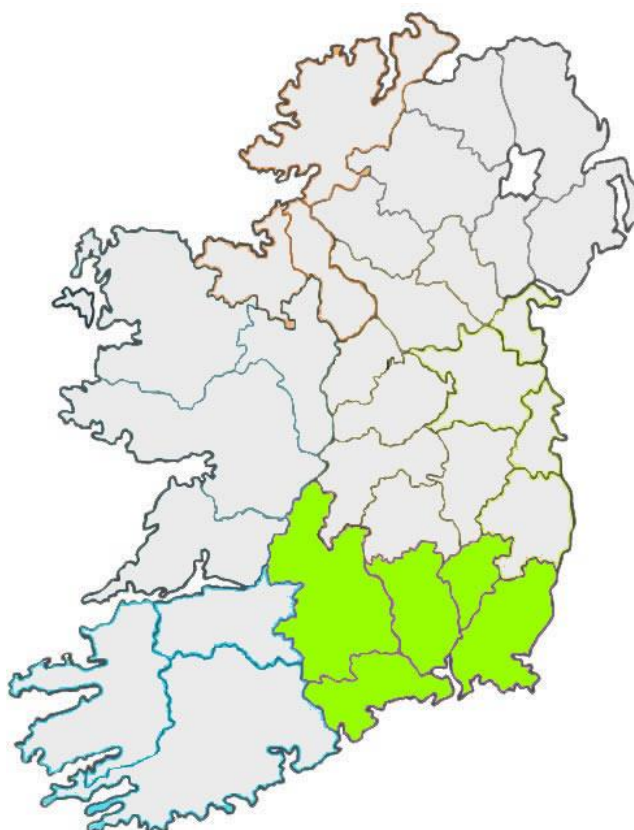


Figure 3.1 Counties of South East Ireland

	2011 census	2016 census
Carlow	54 612	56 875
Kilkenny	95 419	99 118
Tipperary North	70 322	71 370
Tipperary South	88 432	89 071
Waterford	113 795	116 401
Wexford	145 320	149 605
Total	567 900	582 440

Table 3.1 Populations of the counties of South East Ireland from recent censuses

It would be a mistake to assume that the *effective* catchment area of UHW is represented by every resident in each of these counties. It would not take account of different levels of hospital cardiac care provided by the various hospitals in the region, as well as their clinical linkages. Figure 3.2 shows the acute hospital network across Ireland, colour-coded by Hospital Group¹; Figure 3.3 focusses on the acute hospital network in the South East region

1.7 Map of Hospital Groups

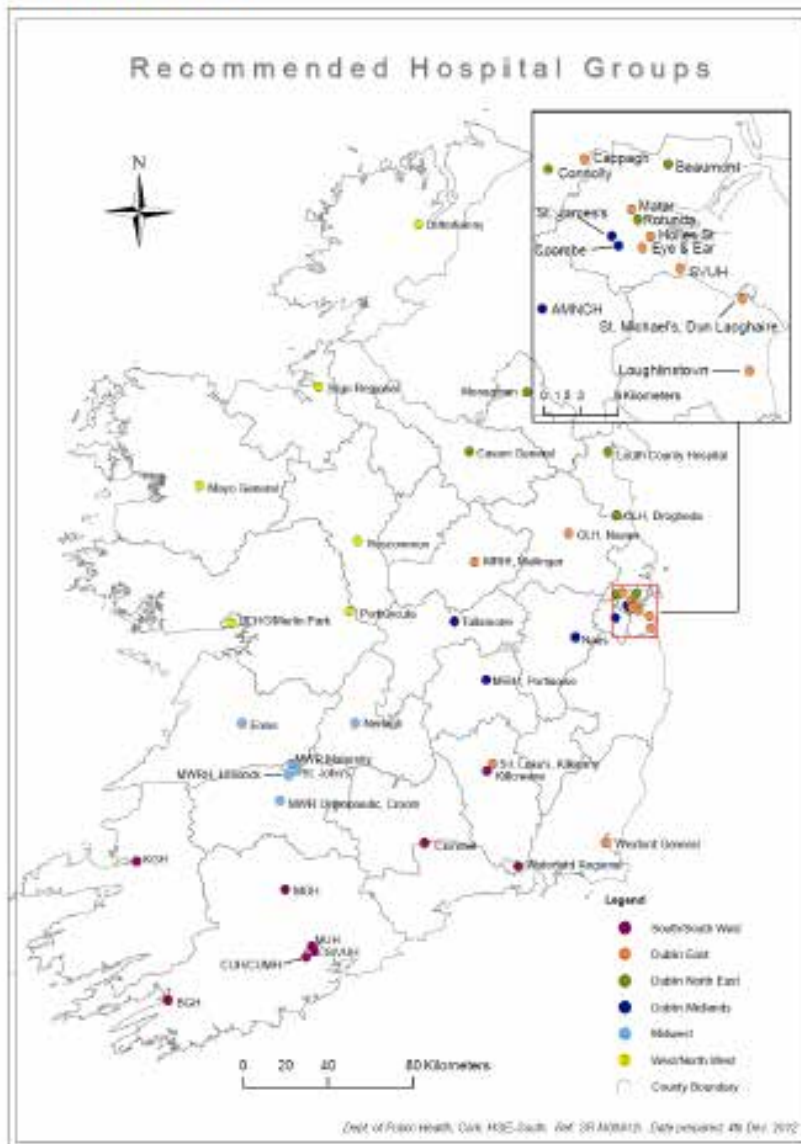


Figure 3.2 The acute hospital network across Ireland, colour-coded by Hospital Group¹

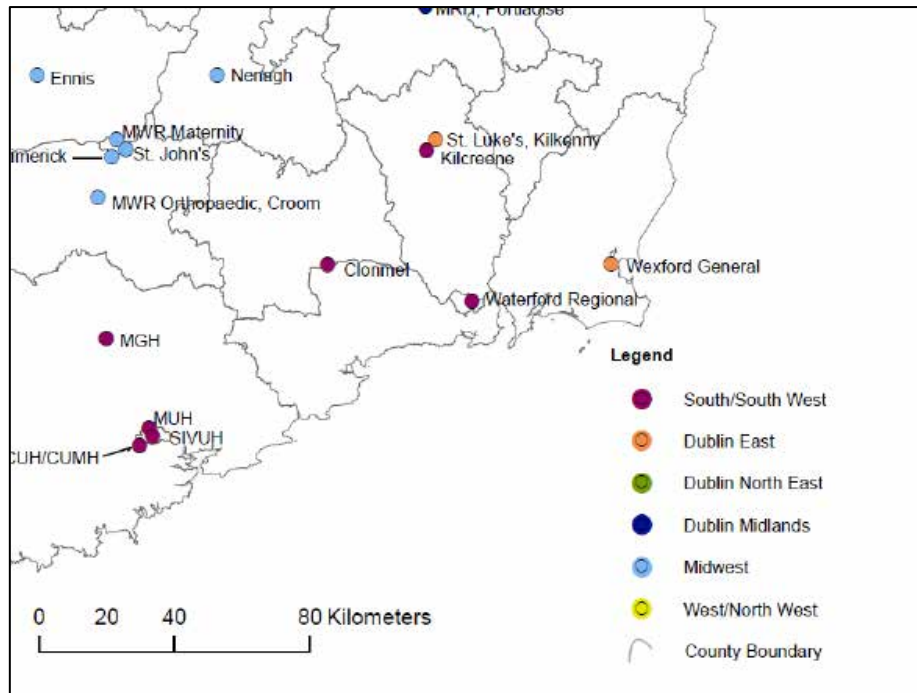


Figure 3.3 The acute hospital network in the South East, colour-coded by Hospital Group¹

It is useful to consider the different patterns of cardiology care provided across this hospital network to understand how patients flow through the services

1. Local general cardiology services – for the immediate local population

These are the services likely to be provided at some level by all of the local hospitals providing acute cardiology services across Ireland. Typically patients access these services by attending an Emergency Department, by referral by a local GP or by internal referral from cardiology or another service within the same hospital. Such services include acute coronary care, other inpatient cardiology care, cardiology outpatient clinics, cardiac rehabilitation and non-invasive investigations

These services are not the primary focus of this report. However it is possible to calculate the effective catchment population for any local hospital by analysing total admissions to that hospital broken down by county of residence and using those data to track where residents of different counties tend to be hospitalised

Intuitively we would assume that people are most likely to be admitted to their closest hospital and this is confirmed in an analysis of 352,143 hospital discharges across Ireland (Table 3.2)

	Hospital					County total	% to UHW
	South Tipperary General	St. Luke's, Kilkenny	UHW	Wexford General	Other		
County of residence							
Carlow	10	8 894	2 150	115	71	11 240	19
Cork	96	17	103	11	162 202	162 429	<1
Kilkenny	127	11 009	6 281	43	290	17 750	35
Tipperary North	2 621	451	376	4	8 635	12 087	3
Tipperary South	15 127	325	5 424	5	4 391	25 272	21
Waterford	606	142	24 781	162	3 570	29 261	85
Wexford	20	206	12 877	20 787	281	34 171	38

Table 3.2 All hospital discharges 2014 – by hospital and selected county of residence with particular focus on the South East region. Source: HIPE

Residents of Co Waterford are highly likely to be admitted to UHW (85% of admissions from the county) followed by residents of Wexford and Kilkenny. Residents of Cork and Tipperary North are very unlikely to be admitted to UHW. After UHW, the Cork hospitals (and especially CUH) are the next most frequent hospitals admitting Waterford residents. The observations are not surprising given the overall geography of the region (Figures 3.2 and 3.3)

Table 3.3 shows that these percentage admission distributions can be combined with census population data to estimate the effective catchment population for any hospital, including UHW. For total hospital admissions the value comes out as 216,401 for 2011 and 222,134 for 2016

	2011 census	% to UHW	UHW catchment population (2011)	2016 census	% to UHW	UHW catchment population (2016)
Carlow	54 612	19	10 376	56 875	19	10 806
Kilkenny	95 419	35	33 397	99 118	35	34 691
Tipperary North	70 322	3	2 110	71 370	3	2 141
Tipperary South	88 432	21	18 570	89 071	21	18 705
Waterford	113 795	85	96 726	116 401	85	98 941
Wexford	145 320	38	55 222	149 605	38	56 850
Total	567 900		216 401	582 440		222 134

Table 3.3 Estimation of the effective local hospital catchment population of UHW based on census data and hospital admission/discharge profiles

2. Local and regional services – for planned cardiac cath lab procedures

Not every acute hospital that admits cardiology patients has a cath lab. Indeed it is a minority that do. Hence, cath lab centres typically offer some level of regional cath lab service to other hospitals in their general vicinity. For referring hospitals and consultants, the choice of which cath lab centre to refer to is not solely determined by geography. Other factors that determine the choice include interprofessional relationships, previous positive or negative patient experience, how quickly the procedures can be performed and the range of procedures that are performed by the cath lab centre

Patients are referred for cardiac catheterisation procedures by a number of routes. Those coming for elective outpatient procedures tend to be put on a waiting list having been first seen in a cardiology outpatient clinic at the cath lab centre or in a referring hospital. Patients referred for urgent inpatient procedures tend to have been admitted to the coronary care unit or cardiac ward of the cath lab centre or one of its referring hospitals and to wait as an inpatient until the procedure can be performed

I have applied the methodology outlined above to estimate the catchment population of the UHW cath lab service. However instead of tracking total hospital admissions by county of residence, I tracked the admissions for cardiac catheterisation and percutaneous

coronary intervention by county of residence – these procedures account for the great majority of procedures undertaken in cath labs so are likely to be a fair representation of the overall effective population for cath lab procedures

	Hospital						County total	% to UHW
	CUH	UHL	SJH	SVH	UHW	Other		
County of residence								
Carlow	0	0	283	7	22	34	346	6
Kilkenny	10	0	307	5	117	19	458	26
Tipperary North	54	328	51	4	47	13	497	9
Tipperary South	205	36	3	0	306	23	573	53
Waterford	77	1	9	3	676	17	783	86
Wexford	1	3	56	120	541	63	784	69
Ireland	2466	2870	3534	1305	1733	8997	20905	8

Table 3.4 Hospital inpatient and daycase coronary procedures 2015 – by hospital and selected county of residence. Source: HIPE

For most counties the admission profile at UHW is very similar to that of the total admission profile (Table 3.2) with the following notable differences: lower percentage admission rates for residents of Carlow and Kilkenny and higher percentage admission rates for residents of Wexford and Tipperary South

These patterns are readily explained by the professional linkages (and cath lab sessions) of the consultant cardiologists in the relevant local hospitals: St Luke’s Kilkenny with St James’s Hospital Dublin; Wexford General Hospital and South Tipperary General Hospital with UHW (Figure 3.4)

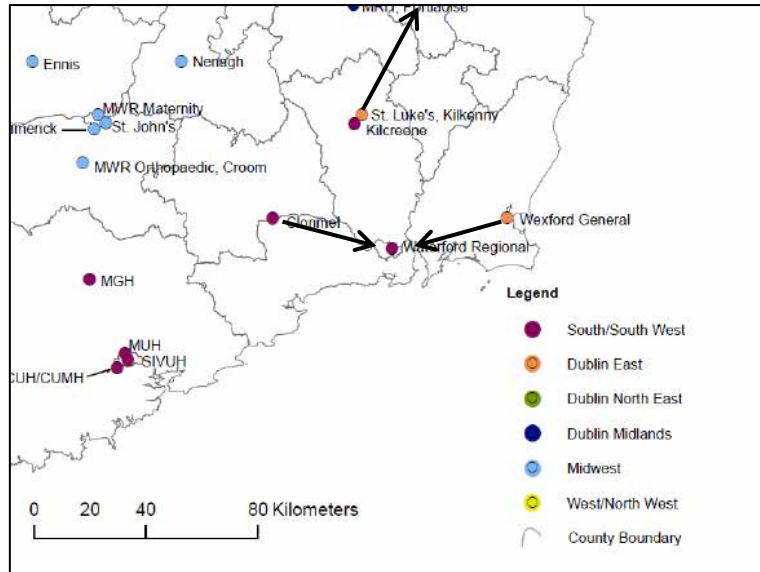


Figure 3.4 Established referral patterns for cath lab procedures into UHW with external referrals predominantly coming from Wexford General and South Tipperary General Hospitals (arrows)

This independent observation is mirrored by the analysis carried out by the UHW team and shown in Figure 3.5 below which confirms that the majority of patients coming to the UHW cath lab are residents of counties Wexford, Waterford or South Tipperary

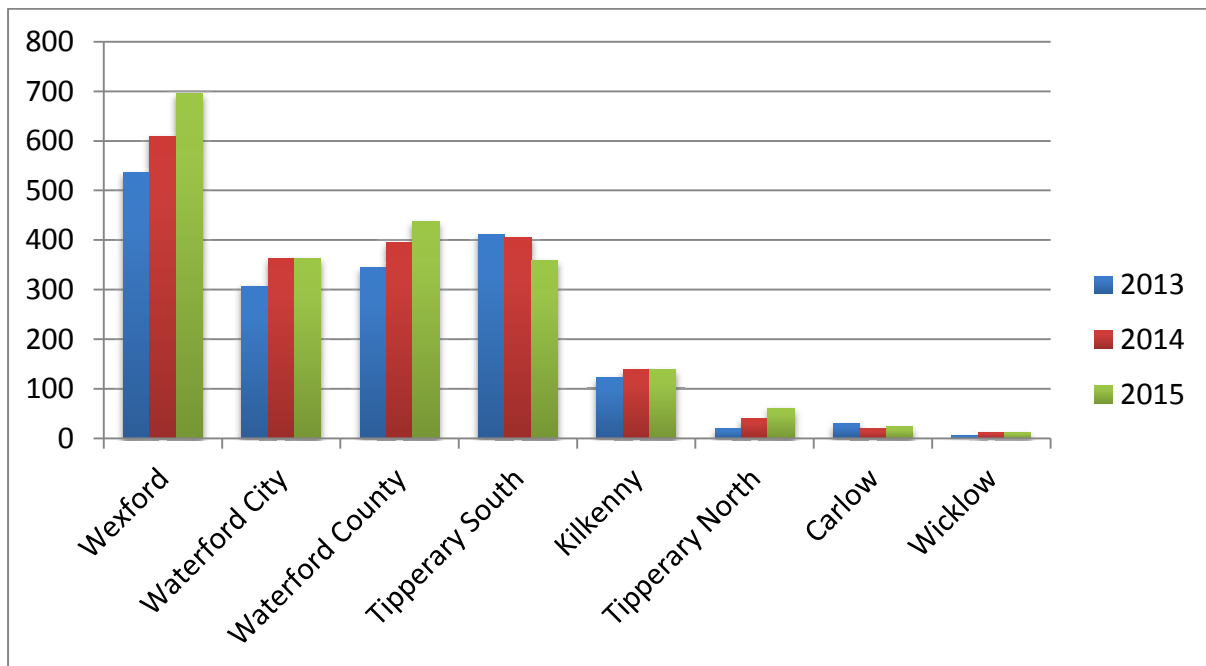


Figure 3.5. Discharge procedure code from UHW cath lab, years 2013-15, by county/city borough of residence. Source: UHW

Table 3.5 combines these cath lab procedure patterns with census population data to estimate the effective catchment population of the UHW cath lab. The value comes out as 279,414 for 2011 and 286,147 for 2016. The latter value will be used for subsequent calculations of population need

	2011 census	% to UHW	UHW cath lab catchment population (2011)	2016 census	% to UHW	UHW cath lab catchment population (2016)
Carlow	54 612	6	3 276	56 875	6	3 413
Kilkenny	95 419	26	24 808	99 118	26	25 771
Tipperary North	70 322	9	6 328	71 370	9	6 423
Tipperary South	88 432	53	46 869	89 071	53	47 208
Waterford	113 795	86	97 863	116 401	86	100 105
Wexford	145 320	69	100 270	149 605	69	103 227
Total	567 900		279 414	582 440		286 147

Table 3.5 Estimation of the effective cath lab catchment population of UHW based on census data and population flow profiles for cath lab procedures

3. Referrals for emergency cardiac cath lab procedures (most often primary PCI)

These patient flows will be considered separately in a later section specifically considering the management strategy for patients with ST elevation myocardial infarction

Conclusion

1. Based on the 2016 census the effective catchment population for the UHW cath lab is 286,147

4. Examining the needs of this population in respect of the indications for cardiac catheterisation

In the previous section I have outlined what I estimate to be the effective catchment population for the cath lab in UHW, based on estimates of the population of Waterford and its surrounding counties, as well as regional patient flows. To recap I have calculated the referral population for planned cardiac cath lab procedures at UHW to be 286,147

The purpose of this section is to estimate the needs of this effective catchment population for cardiac cath lab procedures, based mainly on data from UK healthcare databases. These estimates of need will then be compared with the current annual procedural volume in the UHW cath lab, outlined in the Background section of this report

Cardiac catheterisation/coronary angiography

Different European countries report widely different contemporary rates of diagnostic cardiac catheterisation varying from 3,014 per million in Spain⁷ to 6,689 per million in Ireland⁸. This is likely to represent different clinical and data collection practices. The two most local rates from recent years are shown in Table 4.1

	Annual rates of cardiac catheterisation	
	6,689 per million population (Republic of Ireland, 2011)	3,829 per million population (United Kingdom, 2014)
Expected annual need among 286,147 people	1,914	1,096

Table 4.1

⁷ Garcia Del Blanco B, Hernandez Hernandez F, Rumoroso Cuevas JR, Trillo Nouche R. Spanish Cardiac Catheterization and Coronary Intervention Registry. 24th Official Report on the Spanish Society of Cardiology Working Group on Cardiac Catheterization and Interventional Cardiology (1990-2014). Rev Esp Cardiol (Engl Ed) 2015; 68: 1154-64

⁸ Jennings S, Bennett K, Shelley E, Kearney P, Daly K, Fennell W. Trends in percutaneous coronary intervention and angiography in Ireland, 2004–2011: Implications for Ireland and Europe. IJC Heart & Vessels 2014; 4: 35-9

Percutaneous Coronary Intervention (PCI)

In different regions of the United Kingdom, the rates of PCI range from 1,355 to 2,301 per million population annually with 2301 per million in Northern Ireland⁹. The figure in Ireland in 2011 was 1,825 per million⁸ (Table 4.2)

	Annual rates of PCI	
	1,825 per million population (Republic of Ireland, 2011)	2,301 per million population (Northern Ireland, 2014)
Expected annual need for PCI among 286,147 people	522	658

Table 4.2

Permanent pacemaker implantation

In different regions of the United Kingdom, the rates of new permanent pacemaker implants vary from 413 to 614 per million population annually with 413 per million in Northern Ireland in 2013/14¹⁰. The figure in Ireland in 2013 was 383 per million¹⁰ (Table 4.3)

	Annual rates of new pacemaker implantation	
	383 per million population (Republic of Ireland, 2013)	413 per million population (Northern Ireland, 2013/14)
Expected annual need for new pacemakers among 286,147 people	110	118

Table 4.3

⁹ PF Ludman. 2014 BCIS audit returns.

http://www.bcis.org.uk/documents/39F_BCIS_Audit_2014_23022016_for_web.pdf

¹⁰ British Heart Rhythm Society National Audit of Cardiac Rhythm Management Devices 2013-14. Available at

https://www.ucl.ac.uk/nicor/audits/cardiacrhythm/documents/annual-reports/CRM_National_Annual_Report_2013-14

Implantable cardioverter defibrillator (ICD) implantation

In different regions of the United Kingdom, the rates of new ICD implants vary from 66 to 78 per million population annually with 78 per million in Northern Ireland in 2013/14¹⁰. The figure in Ireland in 2013 was 126 per million¹⁰. (Table 4.4)

	Annual rates of new ICD implantation	
	126 per million population (Republic of Ireland, 2013)	78 per million population (Northern Ireland, 2013/14)
Expected annual need for new ICD's among 286,147 people	36	22

Table 4.4

Cardiac resynchronisation therapy (CRT) implantation (CRT-P and CRT-D combined)

In different regions of the United Kingdom, the rates of new CRT implants vary from 115 to 151 per million population annually with 115 per million in Northern Ireland in 2013/14¹⁰. The figure in Ireland in 2013 was 79 per million¹⁰ (Table 4.5)

	Annual rates of new CRT implantation	
	79 per million population (Republic of Ireland, 2013)	115 per million population (Northern Ireland, 2013/14)
Expected annual need for new CRT's among 286,147 people	23	33

Table 4.5

Table 4.6 summarises these estimated procedural needs compared with current UHW procedural activity. It indicates that the UHW activity is appropriate for the needs of its effective catchment population, and points to the need to take account of annual additions to coronary angiography waiting lists in order to ensure adequate capacity for the entire procedural requirements of the population

Procedure	Estimated catchment population need	Contemporary UHW activity (2015)	UHW activity appropriate to population need?
Coronary angiography	1,096-1,914	1,315	Yes
		+185*	
PCI	522-658	1,500	Yes
		+62*	
		652	
New PPM implants	110-118	155	Higher but within UK range
New ICD implants	22-36	31	Yes
New CRT implants	23-33	30	Yes

Table 4.6

*Taking account of ~185 annual additions to angiography waiting lists at UHW, STGH and WGH and a PCI per angiography rate of 33%

The UHW activity data indicate that it is providing 1,315 diagnostic cardiac catheterisation procedures (961 cath only +354 cath and follow on PCI) and about 185 patients annually are being added to waiting lists in UHW (about 120/year), Wexford General (about 35/year) and South Tipperary General Hospitals (about 30/year), mainly for coronary angiography. This indicates that a final estimated population need of 1,500 diagnostic cardiac catheterisation procedures annually which is well within the range of the local benchmarks

UHW performed 590 PCI's in 2015. Assuming a 33% PCI rate, there is a population need being added to waiting lists annually for a further 62 PCI's giving a final total of 652. This would be an appropriate rate for the population being served

In 2015, UHW performed a somewhat higher than expected number of new pacemaker implants (155). This would equate to a new pacemaker rate of 588 per million which is still well within the range of UK practice¹⁰. There were 31 new ICD implants and 30 new CRT implants, both entirely appropriate for the effective catchment population

Conclusions

2. The projected annual needs for cardiac cath lab procedures for the effective catchment population of UHW (286,147) are:
 - 1,096 to 1,914 diagnostic coronary angiograms
 - 522 to 658 PCI's
 - 110 to 118 new permanent pacemaker implants
 - 22 to 36 new ICD implants
 - 23 to 33 new CRT implants

3. The current activity at UHW, taken together with annual additions to waiting lists, indicates that UHW practice is in line with international benchmarks and is appropriate to the needs of the effective catchment population

5. Examining the workload of the existing laboratory with reference to normative workloads for a catheterisation laboratory in Ireland

In section 4, I concluded that annual volume of procedures being undertaken at UHW looks appropriate for the estimated catchment population with the caveat that capacity for annual additions to angiography waiting lists (about 185 patients per year) needs to be factored into capacity requirements

The purpose of this section is to calculate the annual number of cath lab sessions required to deliver this body of work based on benchmarks of cath lab productivity elsewhere. This annual numbers of sessions will then be translated into the weekly number of sessions required, which should in turn address the central question of whether the workload can be managed in one physical cath lab or two

The National Cardiac Benchmarking Collaborative (NCBC)¹¹ is a UK-wide collaborative of NHS Specialist Cardiac Centres. Formed in 2006, the aim of the NCBC is to improve the quality, efficiency and effectiveness of cardiac services, through regular benchmarking and comparison of participating centres. It has developed methods to enumerate the total activity, throughput and workload of cardiac cath labs and to present comparative data for annualised productivity so that different cardiac centres can benchmark against each other. The NCBC methodology is ideally suited to address the present question

Central to the assessment of cath lab activity, throughput and workload is a standard measure known as angiography-equivalents. These are calculated by using the average time taken to undertake each cath lab procedure, dividing this by the average time taken to undertake a coronary angiogram and thereby calculating the angiography-equivalent of each procedure

In 2014, the median time for an angiography procedure was 36 minutes between a patient entering the cath lab until they leave. A number of conclusions can follow:

- 6 angiography-equivalents should be possible in a 4 hour cath lab session
- Hence, 60 angiography-equivalents should be possible in a 10 session cath lab week

¹¹ <http://ncbc-nhs.com>

- Hence, 3,000 angiography-equivalents should be possible per cath lab in a 50 week year (allowing for servicing, breakdowns and public holidays)

In reality, UK centres did not typically achieve 3,000. Among the NCBC participating centres, the median was 2,493 per cath lab in 2014/15. The best performing centre achieved 3,246 angiography-equivalents

Table 5.1 shows that the cath lab at UHW performed 2,764 angiography-equivalents in 2015. This indicates a performance level about 11% above the NCBC median, although within the range of workload of a single cath lab in the NCBC (1,845-3,246)

Procedure	N	Conversion factor for angiography-equivalents	Angiography-equivalents
Angiography only	961	1	961
PCI only	174	1.7	296
Angiography and follow on PCI	354	1.7	602
Primary PCI	62	1.7	105
PPM implants/revisions (majority assumed to be dual chamber implants)	179	2.3	412
PPM generator changes	25	1.7	43
Loop recorder implants/explants*	90	1	90
ICD implants/revisions, no GA	38	2.4	91
ICD generator changes, no GA	8	2.1	17
CRT implants/revisions (CRT-D counted under CRT as longer procedure time)	34	4.2	143
CRT generator changes	2	2.0	4
Total			2,764

Table 5.1 2015 workload in the UHW cath lab translated into angiography-equivalents

*Loop recorders not included in NCBC – allocated 1 angiography-equivalent by me

GA – general anaesthetic

Table 5.2 shows the additional potential workload associated with the ~185 patients being added to waiting lists annually. This would require a total capacity of 2,992 angio equivalents (about 20% above the NCBC median, but still within the range of performance of NCBC centres)

Procedure	N	Conversion factor for angiography-equivalents	Angiography-equivalents
Angiography	123	1	123
Angiography and follow on PCI	62	1.7	105
Subtotal			228
Impact when added to total from Table 5.1 (2,764)			2,992

Table 5.2 Potential additional workload in the UHW cath lab from patients being added to waiting lists annually

Depending on individual perspective, a number of potential conclusions can be drawn from the data in Tables 5.1 and 5.2:

- The UHW cath lab should be able to deliver 2,992 angiography-equivalents within 10 sessions or
- The UHW cath lab needs to be funded and staffed to work an extra 2 sessions per week in order to deliver 2,992 angiography-equivalents, assuming it works at the median level of efficiency of an NCBC centre

The latter is a more reasonable conclusion. It is also clear that the overall procedural workload for the UHW effective catchment population is deliverable in a single cath lab

While in theory, building and staffing a second cath lab would create capacity for between 5,000 and 6,000 angiography-equivalent procedures in UHW, the data show that this level of capacity is not required by the effective catchment population

In terms of future population needs, Table 3.5 showed that the combined population of the South East increased by 2.6 % between 2011 and 2016. It is reasonable to project that it will increase by a similar percentage between 2016 and 2021 which would have a minimal effect on procedural needs. Unpredictable factors such as changes to guidelines,

introduction of new technology or changes in local population demographics may increase or reduce demand. However even an increase as large as 10%, would still be deliverable in a single cath lab (13.2 instead of 12 sessions weekly)

Table 5.3 is another way of analysing the data and estimates the number of weekly cath lab sessions required for each set of procedures, based on an expectation of how many such procedures could be carried out in a 4 hour session by an optimal performance against the NCBC standard. The current cath lab activity, plus 185 patients added to waiting lists annually, translates to an expected 10 sessions per week made up of ~8 sessions per week to accommodate publicly-funded patients and ~2 sessions to accommodate privately-funded patients

The median centre in the NCBC only achieves about five-sixths of this theoretical optimal efficiency (2,493/3,000 angio-equivalents). Therefore this calculated need for 10 sessions could rationally be translated into a real-world need for 12 sessions at UHW

Table 5.3 Cath lab sessions required for procedures carried out in UHW in 2015, separated by public vs private cases. Calculations assume a 50 week working year for the cath lab

Procedure	Public/private	N	Expected number per 4 hour session	Annual number of sessions required (assumes 50 week year)		
				Total	Public	Private
Cath only	Both	961	6	3.20		
	Public	742		2.47		
	Private	219		0.73		
PCI only	Both	174	3.5	0.99		
	Public	135		0.77		
	Private	39		0.22		
Cath and follow on PCI	Both	354	3.5	2.02		
	Public	288		1.65		
	Private	66		0.38		
Primary PCI	Both	62	3.5	0.35		
	Public	62		0.35		
	Private	0		0		
PPM implants/revisions (majority assumed to be dual chamber implants)*	Both	179	2.6	1.38		
	Public	134		1.03		
	Private	45		0.35		

PPM generator changes	Both	25	3.5	0.14	
	Public	19		0.11	
	Private	6		0.03	
Loop recorder implants/explants	Both	90	6	0.3	
	Public	65		0.22	
	Private	25		0.08	
ICD implants/revisions no GA	Both	38	2.5	0.30	
	Public	36		0.29	
	Private	2		0.02	
ICD generator changes, no GA	Both	8	2.9	0.06	
	Public	8		0.06	
	Private	0		0	
CRT implants/revisions (CRT-D counted under CRT as longer procedure time)	Both	34	1.4	0.49	
	Public	27		0.39	
	Private	7		0.10	
CRT generator changes	Both	2	3	0.01	
	Public	2		0.01	
	Private	0		0	
<i>Annual additions to waiting lists</i>					
Angio only	Public	123	6	0.41	0.41
PCI	Public	62	3.5	0.35	0.35
Total	Both			10.0**	
	Public			8.11	
	Private			1.91	

*Includes one temporary pacemaker insertion

**The effect of rounding means that totals do not add exactly

Conclusions

- The annual procedural needs for the effective catchment population of the UHW cath lab, including annual additions to waiting lists, could be delivered in 12 weekly sessions, assuming the cath lab works at the median productivity level for a UK centre
- Building a second cath lab is not justified to accommodate the workload. Instead the existing lab should be staffed and funded to work for 12 sessions of 4 hours each, every week

6. Specific focus on the treatment of patients with acute ST elevation MI and provision of primary PCI services

The purpose of this section is to appraise the role of UHW as a designated provider of primary PCI services for patients with acute ST elevation MI. This is undertaken under Term of Reference i. *To consider the clinical need for a second catheterisation laboratory at University Hospital Waterford by setting out the indications for cardiac catheterisation in the context of a comprehensive cardiac service*

Background national cardiovascular disease policy

The overarching national strategy for cardiovascular disease is outlined in the Department of Health's *Changing Cardiovascular Health. National Cardiovascular Health Policy 2010 – 2019* launched in May 2010¹². The policy establishes a framework for the prevention, detection and treatment of cardiovascular diseases; it seeks an integrated and quality-assured approach to their management in order to reduce their burden on overall population health

Among the broad range of cardiovascular disease management strategies, the policy made recommendations about the management of ST elevation myocardial infarction linked to the relevant European Society of Cardiology guidelines¹³:

- Patients with ST elevation myocardial infarction should be treated with primary percutaneous intervention (PCI) as first-line therapy if the time from first medical contact to primary PCI can be achieved within 120 minutes
- If PCI cannot be provided within 120 minutes of first patient contact, the patient should be assessed for thrombolysis as soon as possible
- Emergency PCI services should be delivered on a 24 hour, 7 day basis in a small number of centres, sited to maximise patient access and workforce expertise and coverage

¹² Department of Health and Children. *Changing Cardiovascular Health. National Cardiovascular Health Policy 2010 – 2019*. May 2010

¹³ Van de Werf F et al. Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation: the Task Force on the Management of ST-Segment Elevation Acute Myocardial Infarction of the European Society of Cardiology. *European Heart Journal* 2008; 29: 2909–45

The National Clinical Programme for Acute Coronary Syndrome (ACS) was initiated in 2010 as a joint venture between the Irish Cardiac Society (under the auspices of the Royal College of Physicians of Ireland) and the HSE to standardise the treatment of patients with ACS. Following extensive national consultation and examination of best international practice, the ACS Programme Model of Care¹⁴ was published in 2012 and an Optimal Reperfusion Service protocol was implemented nationally between October 2012 and January 2013

As part of the model of care, six primary PCI centres with formal arrangements with the national ambulance service were designated as follows:

- Dublin North East Mater Hospital (24/7)
- Dublin Mid Leinster St James's Hospital (24/7) and St Vincent's Hospital (24/7)
- South Cork University Hospital (24/7) and Waterford Regional Hospital (9/5)
- West University Hospital Galway (24/7)

Acute hospitals that were PCI centres but were not designated primary PCI centres were allowed to perform primary PCI for walk-in patients if they could do so within 90 minutes of diagnosis. Waterford Regional Hospital was the only centre designated to operate on a Monday to Friday, 9 to 5 basis. Outside of these hours, the National Ambulance Service brings patients fulfilling criteria for PPCI in the Waterford catchment area to designated 24/7 PPCI treatment centres in Cork or Dublin

By 2014, there were seven designated PPCI centres across Ireland, of which UHW remained the only designated centre operating on a restricted hours basis¹⁵. In 2016, there remain 7 PPCI centres although the national coverage has changed, with a new centre in Altnagelvin Hospital in Derry and the withdrawal of primary PCI services from St Vincent's University Hospital in Dublin. UHW remains the only primary PCI centre designated to operate Monday to Friday, 9 to 5. It is worth pointing out that the ACS Programme has recommended that "a minimum of 2 labs are recommended at PPCI centres to ensure

¹⁴ Health Service Executive and Royal College of Physicians of Ireland. Acute coronary syndromes programme. Model of care. March 2012

¹⁵ Health Service Executive and Royal College of Physicians of Ireland. Heart attack care in Ireland. Report of the national clinical programme for Acute Coronary Syndrome (ACS) on standardising treatment of patients with STEMI in 2014. December 2015

access at all times”¹⁵. That UHW is a designated PPCI centre but does not have a second cath lab is an inconsistency that needs to be addressed as part of the present report

In November 2014, an urgent review of the three designated 24/7 PPCI services in Dublin was precipitated by a declaration from one of the centres that it was no longer in a position to deliver a 24/7 primary PCI service¹⁶. An ACS Programme working group undertook a comprehensive review which led to a decision to consolidate primary PCI for Dublin and its hinterland into two centres: the Mater Hospital and St James’s Hospital. This revised arrangement was announced by the Minister and implemented in April 2015¹⁷

The text of the Minister’s response at the time is instructive

The provision of primary percutaneous intervention (PPCI) from three 24/7 centres in Dublin had proved unsustainable. In November 2014, the Acute Hospitals Division of the HSE requested the National Clinical Programme for Acute Coronary Syndrome (ACS Programme) to review the current configuration of PPCI services in Dublin, having regard to the requirement to deliver safe, sustainable services on the designated sites. The review looked at the number of centres that should be delivering PPCI in Dublin, where these centres should be located and the feasibility of maintaining 9 to 5 PPCI services on any cardiology intervention site. The rationale for two 24/7 centres for the delivery of PPCI in the greater Dublin area reflects the international trend towards the consolidation of such specialised services on smaller numbers of sites to allow for the concentration of volume and a larger critical mass of trained operators, working within a 24/7 team that is less dependent on individual personnel and is, therefore, more robust. This is about starting treatment the moment the paramedic arrives and getting patients to the right hospital in an emergency - rather than just the nearest one only to be transferred later after a delay

The importance of the statement is that it encapsulates the challenges faced by those designing systems for managing highly time-critical conditions like myocardial infarction, stroke, major trauma, emergency surgery and many others. These services must be

¹⁶ <http://www.thejournal.ie/st-vincent's-heart-attacks-1768099-Nov2014/>

¹⁷ Written response from Minister Leo Varadkar to Deputy Stephen S Donnelly 22 April 2015. <http://www.oireachtas.ie/documents/op/Nov14/Questions/pg131114.pdf>. Pages 180-1

- safe, sustainable and resilient
- predictable and unambiguous, especially for ambulance service and emergency department protocols
- capable of delivering the exceptional skillsets of highly-tuned teams at the most inconvenient times of the day or night and hence
- capable of delivering equal quality of care irrespective of the time of day or night

Inevitably, these criteria generate debate as to how local a service can be while at the same time meeting the rigorous demands outlined above. Such considerations are relevant to the present report

In 2015 the British Cardiovascular Intervention Society published standards for PCI including primary PCI in the UK¹⁸ which recommend that patients undergoing primary PCI should be treated in 24/7 PCI centres treating an absolute minimum of 100 primary PCI procedures per annum. The rationale behind this recommendation, reflecting all international primary PCI guidelines, has been outlined above but is worth reiterating. Outcomes for patients with time-critical conditions are dependent on the skillsets of highly-tuned teams capable of delivering equal quality of care irrespective of the time of day or night

In order for systems that manage such high-risk patients to be safe and effective, they have no option but to be predictable, unambiguous, fully sustainable and resilient. The previous difficulties that arose when a primary PCI centre proved unsustainable provide a cautionary note to those who are responsible for planning and implementing these services at a national level

In December 2015¹⁵ the ACS Programme published the *Heart Attack Care in Ireland 2014* Report outlining the position of the ACS programme at the end of the second year of implementation with particular reference to the management of STEMI. Table 6.1 below summarises the data from the report¹⁵ and also includes 2015 data which have been collated for the present report. Highlighted in yellow are the centres that do not meet the standard of an absolute minimum of 100 PPCI procedures per annum:

¹⁸ AP Banning, A Baumbach, D Blackman et al. on behalf of the British Cardiovascular Intervention society. Percutaneous coronary intervention in the UK: recommendations for good practice 2015. *Heart* 2015; 101: 1-13

- St Vincent’s University Hospital, Beaumont Hospital and Tallaght Hospital none of which are now designated primary PCI centres
- UHW which is designated as a PPCI centre on a Monday to Friday 9 to 5 basis

Centre	Year	PPCI	Thrombolysis, contraindicated, no RT or missing	Total
UCHG	2014	179	85	264
	2015	172	92	264
UHL	2014	176	5	181
	2015	203	12	215
CUH	2014	144	82	226
	2015	171	65	236
MMUH	2014	143	37	180
	2015	216	62	278
SVUH	2014	95	14	109
	2015	24	3	27
SJH	2014	196	39	235
	2015	318	42	360
WRH	2014	Data not available for 2014		
	2015	62*	2	59
AMNCH	2014	18	12	30
	2015	10	12	22
BH	2014	17	5	22
	2015	48	5	53
TOTAL	2014	968	279	1247
	2015	1219	295	1514

Table 6.1. Summary of treatments for ST elevation myocardial infarction in 2014 and 2015

*Data provided directly by UHW. RT = reperfusion therapy

Table 6.1 shows that the present service at UHW does not meet the standard of an absolute minimum of 100 PPCI procedures per annum as recommended by BCIS. Furthermore, the National Ambulance Service reports that the current 9 to 5 arrangement causes unwelcome confusion for paramedic crews when they are tasked to patients with ST elevation myocardial infarction shortly before 9.00 am or shortly before 5.00 pm

Alternatives to the present situation should be considered. There are two options:

1. Designation of UHW as a 24/7 primary PCI service or
2. Cessation of primary PCI services at UHW

It is beyond the Terms of Reference of this report to comment on the services in Beaumont Hospital and Tallaght Hospital

As a starting point to address this question, it is appropriate to review the present coverage of the population of the South East by 24/7 centres and the expected annual number of patients with ST elevation MI who would not be covered by these 24/7 centres

I requested an updated national map demonstrating the 60 and 90 minute travel times from the six centres that currently provide 24/7 primary PCI services across the Republic of Ireland. It is important to understand that these maps are the results of theoretical calculations rather than measurements of actual road journeys. They are drawn by combining information from the road network with estimates of blue light speed on different level of the road network

Figure 6.1 shows this map, and the geographical areas in the country that are within a 90 minute drive time of a 24/7 primary PCI centre (red lines and shaded red areas). The yellow and red lines are termed the 60 and 90 minutes isochrones respectively. A number of regions of the country are outside these boundaries and are seen in white, representing about 8% of the population of Ireland



Figure 6.1 National population coverage for primary PCI. Areas shaded red or yellow and bounded by a red line are within a 90 minute drive time of a 24/7 primary PCI centre

Figure 6.2 focusses on the South East and shows the geographical area not covered by a 90-minute drive time from an existing 24/7 centre (Cork University Hospital or St James’s Hospital, Dublin). The population of this region has been estimated as 170,267. To correct for the changes in population in counties Wexford and Waterford observed in the 2016 census I have increased this estimate by 2.7% to 174,864

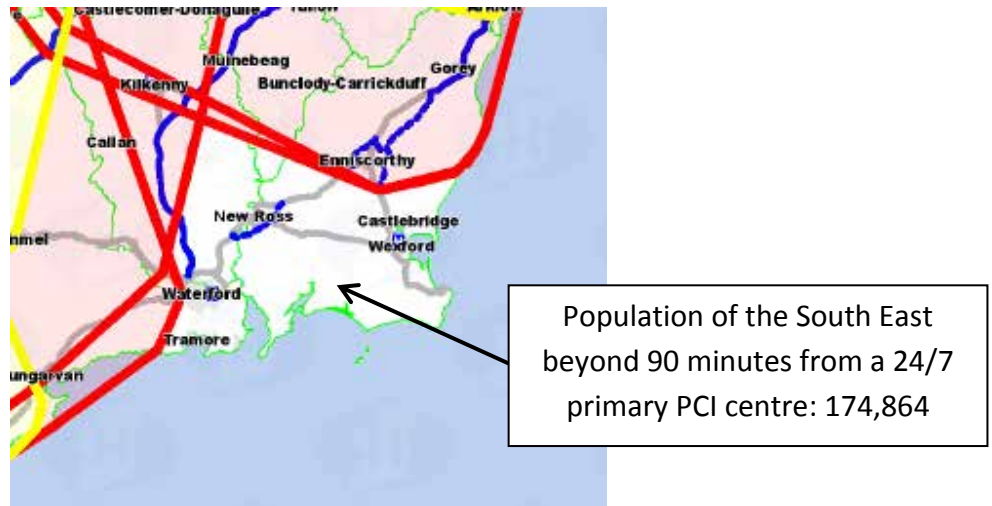


Figure 6.2 Area of South East Ireland not covered within a 90 minute drive time of a 24/7 primary PCI centre, shown in white. Source: HSE

To estimate the needs for primary PCI in this population I applied the methodology outlined previously in chapter 4. In different regions of the United Kingdom, the rates of primary PCI range from 391 to 435 per million population annually with 394 per million in Northern Ireland⁹. The figure in Ireland in 2015 was 1219 primary PCI’s in a population of 4.686 million, giving an estimated rate of 260 per million annually

	Annual rates of primary PCI	
	260 per million population (Republic of Ireland)	394 per million population (Northern Ireland)
Expected annual need for primary PCI among 174,864 people	45	69

Table 6.2

Based on these assumptions, and accepting that it is preferable for all patients within 90 minutes of a 24/7 primary PCI centre to be treated there, one would expect a need to provide an alternative pathway of care for between 45 and 69 patients with ST elevation MI per year if UHW was not a primary PCI centre (Table 6.2)

However 62 patients underwent primary PCI at UHW with a service that only operates Monday to Friday, 9 to 5, suggesting a greater population need. To investigate this

I requested patient level data from UHW about the 80 patients who activated the primary PCI pathway at UHW in 2015 (of whom 62 underwent primary PCI). The purpose was to identify the location of the patient at the time their diagnosis was made, in order to quantify how many would have been within a 90 minute drive time of Cork University Hospital or St James’s Hospital at the time of diagnosis.

Figure 6.3 shows this analysis and indicates that the 80 patients break down into 29 that were conclusively within a 90 minute drive time of either Cork University Hospital or St James’s Hospital (green boxes), 25 that were conclusively beyond a 90 minute drive time (blue boxes). More detail on the other 26 patients (orange boxes) follows below

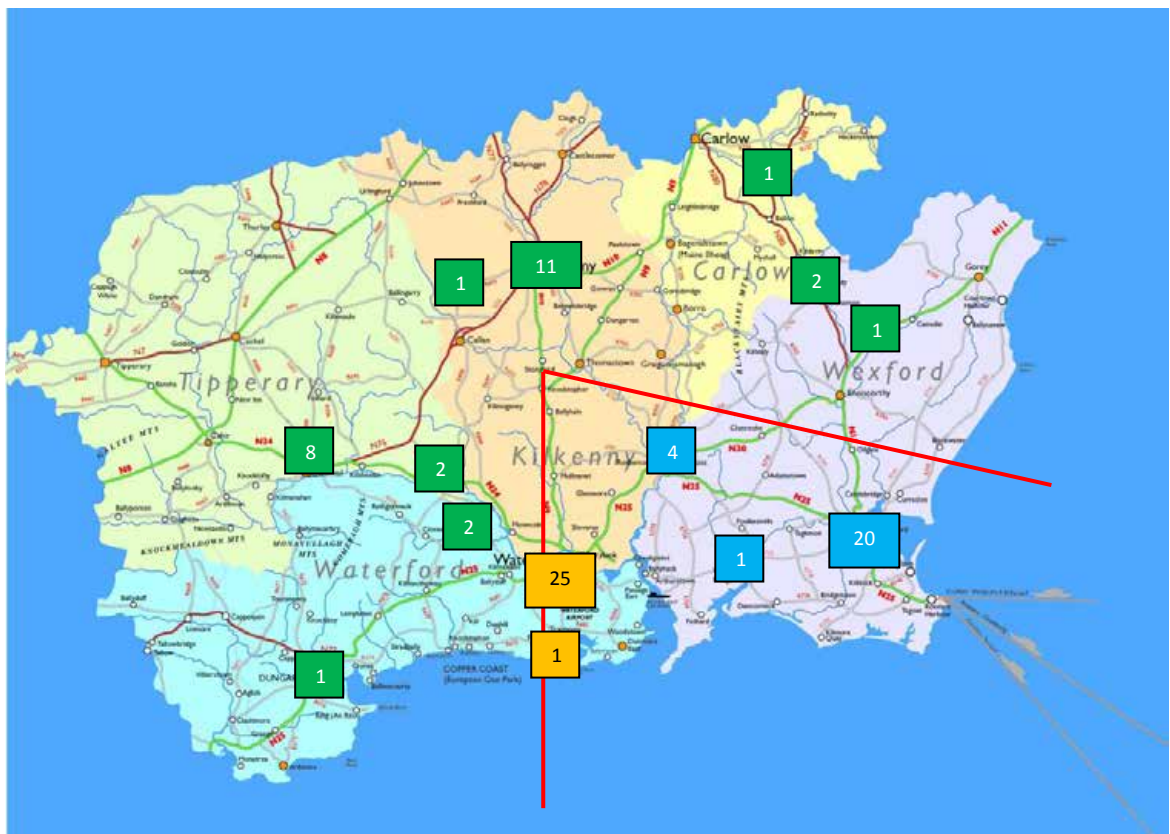


Figure 6.3 Geographic distribution of 80 patients at the time they activated the primary PCI service at UHW in 2015. See text for explanation of the different coloured boxes

Because of the proximity of UHW and Waterford City to the 90 minute isochrone of Cork University Hospital (CUH), I specifically requested real-world information from the National Ambulance Service about the actual times of contemporary blue light journeys from UHW to CUH

Of 36 emergency journeys between UHW and CUH undertaken between October 2015 and June 2016, the average journey time was 1 hour 28 minutes. Hence in real terms, UHW is within the 90 minute isochrone of CUH, although this cannot be assumed for the patient in Tramore. These observations change the distribution of Figure 6.3 which is now presented as Figure 6.4

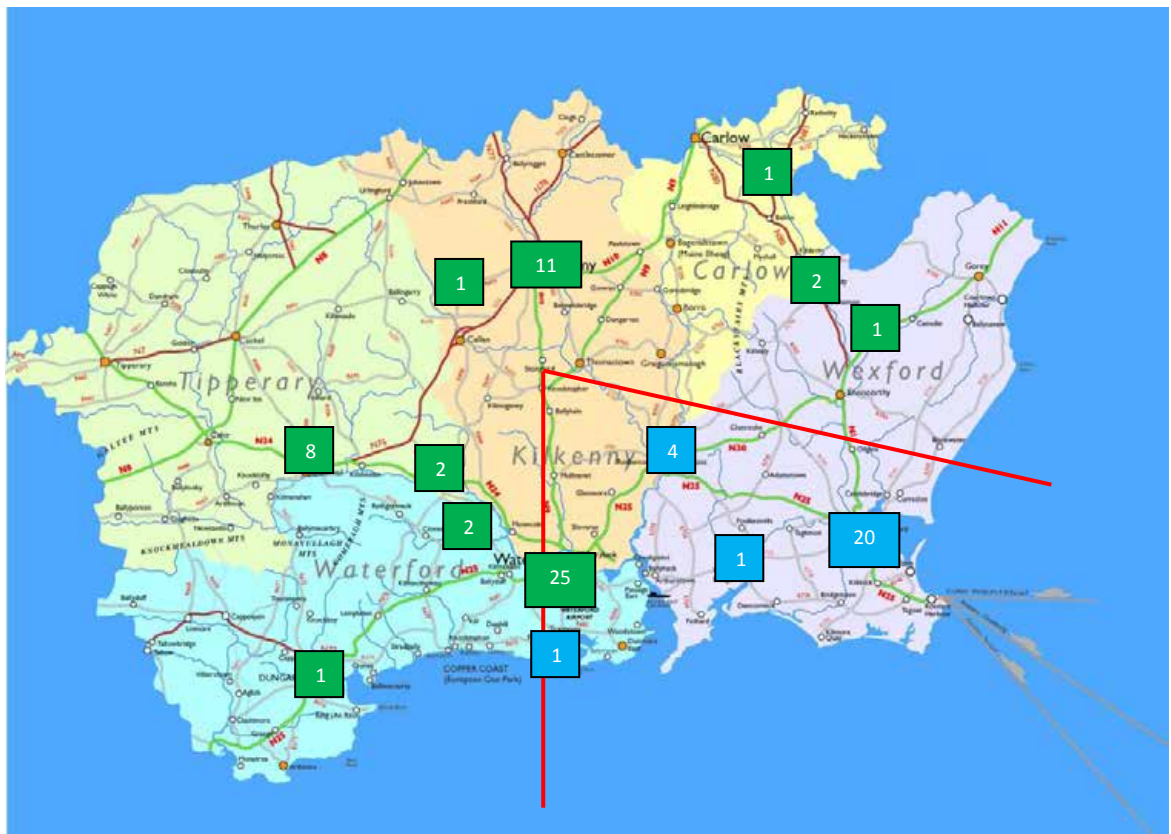


Figure 6.4 Geographic distribution of 80 patients at the time they activated the primary PCI service at UHW in 2015. See text for explanation of the different coloured boxes

Figure 6.4 illustrates that of 80 patients who activated the primary PCI service at UHW in 2015, 54 were within a 90 minute drive time of either CUH or St James’s Hospital. 25 or 26 patients were conclusively outside these 90 minute isochrones; this would correlate well with the population-based estimate of need outlined in Table 6.2 above (45 to 69 patients with ST elevation MI every year who need activation of a seamless alternative optimal reperfusion strategy as defined and monitored by the ACS Programme). Figure 6.4 shows that the hub of this pathway should actually be Wexford General Hospital, as that is where most of these patients will be diagnosed

A very consistent theme reported by the cath lab team at UHW was the degree to which cath lab throughput is disproportionately disrupted by the small number of primary PCI activations that are undertaken annually. Indeed the number of procedural cancellations in 2015 was almost exactly the same as the number of primary PCI activations (Figure 6.5). This is not to assume that every cancellation was due to a primary PCI but the similarity is striking when taken in context of the impact of primary PCI cases, as described by the UHW team

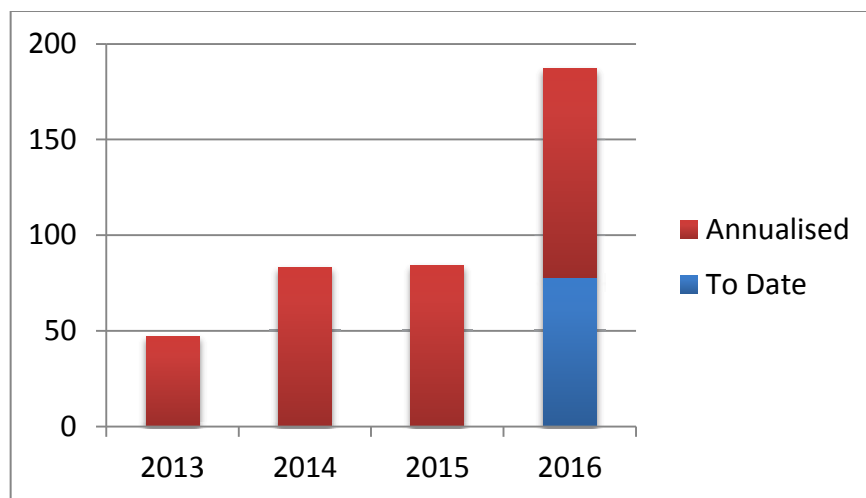


Figure 6.5 Number of same-day cath lab cancellations per year in UHW. Source: UHW

All of the aforementioned observations together lead me to conclude that the better of the two options that I outlined earlier in this section would be cessation of the primary PCI service at UHW and I will repeat the reasons below

- The centre does not meet the BCIS-recommended standard of an absolute minimum of 100 cases per year
- It is highly unlikely to do so while providing a Monday to Friday, 9 to 5 service
- There is insufficient local population need to justify an additional 24/7 primary PCI centre for South East Ireland, over and above what is already provided by Cork University Hospital and St James's Hospital
- There would be a significant risk that a 24/7 centre at UHW would not be able to guarantee a robust, sustainable rota of consultants and cath lab staff

- The current provision of daytime primary PCI has a disproportionately negative impact on the schedule of what is demonstrably an efficient cath lab that provides a wide range of planned procedures for its local catchment population
- More importantly the current provision of daytime primary PCI has a disproportionately negative impact on patients, many of whom travel long distances, only to have their procedures cancelled at short notice when an emergency arises

Conclusion

6. The present limited hours primary PCI service at UHW does not meet the BCIS standard of an absolute minimum of 100 primary PCI procedures per year and the limited hours arrangement causes uncertainty for paramedic crews. Of the options available to resolve this situation, the preferred option is cessation of primary PCI services at UHW

Conclusions and recommendations on the need for a second laboratory based on the interpretation of the data

Conclusions

1. Based on the 2016 census the effective catchment population for the UHW cath lab is 286,147
2. The projected annual needs for cardiac cath lab procedures for this effective catchment population are:
 - 1,096 to 1,914 diagnostic coronary angiograms
 - 522 to 658 PCI's
 - 110 to 118 new permanent pacemaker implants
 - 22 to 36 new ICD implants
 - 23 to 33 new CRT implants
3. The current activity at UHW, taken together with annual additions to waiting lists, indicates that UHW practice is in line with international benchmarks and is appropriate to the needs of the effective catchment population
4. The annual procedural needs for the effective catchment population of the UHW cath lab, including annual additions to waiting lists, could be delivered in 12 weekly sessions, assuming the cath lab works at the median productivity level for a UK centre
5. Building a second cath lab is not justified to accommodate the workload. Instead the existing lab should be staffed and funded to work for 12 sessions of 4 hours each, every week
6. The present limited hours primary PCI service at UHW does not meet the BCIS standard of an absolute minimum of 100 primary PCI procedures per year and the limited hours arrangement causes uncertainty for paramedic crews. Of the options available to resolve this situation, the preferred option is cessation of primary PCI services at UHW

Recommendations

1. The range of planned cath lab work that UHW currently undertakes for its catchment population should continue
2. The cath lab service at UHW should be funded and staffed to provide 12 sessions of planned cath lab activity weekly
3. A contingency for radiological equipment failure during a procedure, such as a portable fluoroscopy unit with an image intensifier, should be established if it is not in place already
4. The cardiology services in the South/South West Hospital group (and especially the teams at UHW and CUH) should agree a strategy that makes best use of their combined excellent skills, cath lab facilities and teams, in order to optimise clinical outcomes for all of the patients across the Hospital group
5. The current limited hours provision of primary PCI at UHW should cease, to allow the centre to focus on the much larger volume of planned cath lab work

If recommendation 5 is accepted, I make these follow-on recommendations:

6. Patients arriving to the emergency department at UHW should be considered as within a 90 minute drive time of Cork University Hospital and should be transferred there for primary PCI without delay, irrespective of the time of day or night
7. The interventional cardiologists at UHW should continue to make their primary PCI skills accessible for the benefit of patients, by taking part in the 24/7 primary PCI rota centred in Cork University Hospital
8. A group of local clinical stakeholders (including representatives of the ambulance service) should review the current operation of the Optimal Reperfusion Protocol (Appendix 3) for patients with STEMI in the South East who are more than a 90 minute drive time from a 24/7 primary PCI centre. The group should design the best future reperfusion protocol for these patients, which may be the existing strategy (thrombolysis with immediate transfer), a default helicopter transfer or an alternative strategy. The review should be led by the ACS Programme of the HSE

Appendix 1
Terms of Reference:

- i. To consider the clinical need for a second catheterisation laboratory at University Hospital Waterford by:
 - Setting out the indications for cardiac catheterisation in the context of a comprehensive cardiac service;
 - Examining patient flows to determine effective current and future population to be served by University Hospital Waterford for cardiac services;
 - Examining the needs of this population in respect of these indications for cardiac catheterisation;
 - Examining the workload of the existing laboratory with reference to normative workloads for a catheterisation laboratory in Ireland.
- ii. To make recommendations on the need for a second laboratory based on the expert interpretation of the data and
- vi. To present a report to the Minister for Health within six weeks of establishment.
- vii. The independent expert will engage with UHW, the ACS Programme, the Department of Health and the HSE. Data from UHW will be validated, analysed and compared with data from other settings. It will be necessary for the independent expert to analyse CSO data in relation to the current and projected population of the region, as well as HIPE (Hospital Inpatient Enquiry) data and any other data necessary to analyse information in relation to the actual population using UHW.
- viii. The Secretariat will be provided by the Acute Coronary Syndrome Programme.

Appendix 2

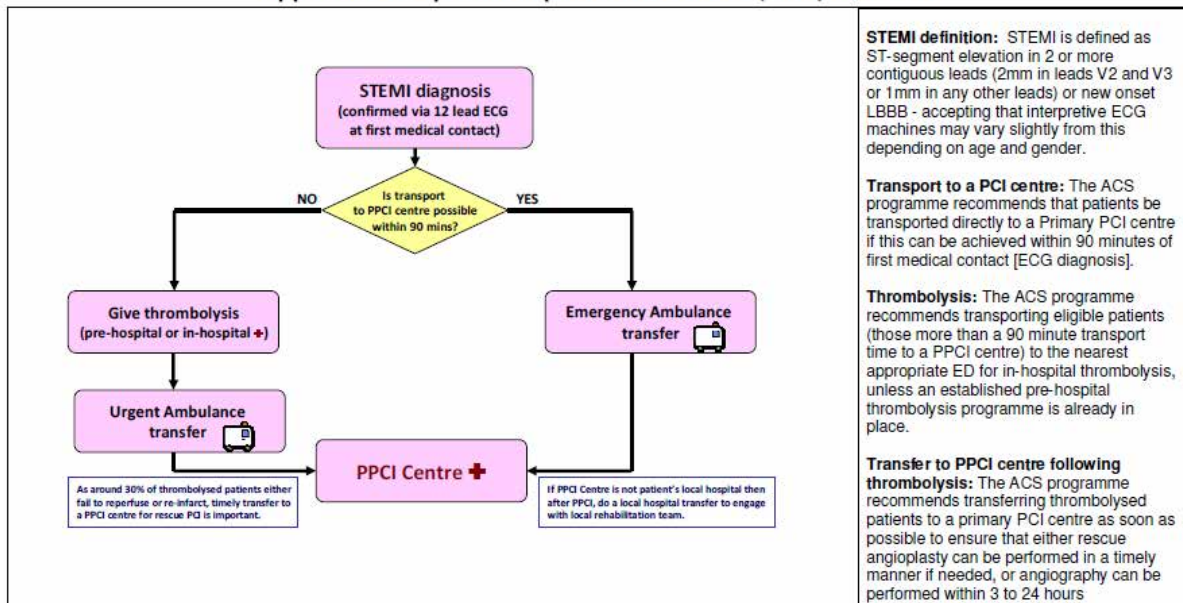
Glossary of Terms and Abbreviations

Cardiac catheterisation laboratory (cath lab)	A specialised clinical and radiological facility designed to perform a range of diagnostic and therapeutic invasive cardiac procedures under sterile conditions
Acute coronary syndrome (ACS)	A medical term encompassing a range of emergency conditions provoked by an acute shortage of blood supply to the heart
Myocardial infarction (MI)	A heart attack caused by partial or complete obstruction of a heart artery
ST elevation MI (STEMI)	A heart attack typically caused by complete obstruction of a heart artery. It is recognised by a specific pattern on an ECG (ST segment elevation)
Electrocardiogram (ECG)	A diagnostic test using electrodes on the skin to detect electrical traces from the heart
Coronary angiography	A specialised X-Ray procedure involving injection of contrast dye to demonstrate the condition of the heart arteries
Cardiac catheterisation	A procedure performed in a cath lab to measure pressures in the heart and usually to undertake coronary angiography at the same time
Percutaneous coronary intervention (PCI)	A procedure undertaken in a cath lab to treat coronary artery narrowing. It usually involves insertion of a metallic support structure – a stent
Primary PCI	An emergency PCI undertaken in a patient with an acute STEMI
Permanent pacemaker (PPM)	A device implanted under the skin usually used to treat abnormally slow heart rates
Implantable loop recorder (ILR)	A device implanted under the skin to detect suspected heart rhythm disorders (arrhythmias)
Implantable cardioverter defibrillator (ICD)	A device implanted under the skin usually used to treat abnormally rapid heart rates with either pacing or a shock
Cardiac resynchronisation therapy (CRT)	An advanced pacemaker used to coordinate electrical conduction through the heart in patients with heart failure
BCIS	British Cardiovascular Intervention Society
HIPE	Hospital In Patient Enquiry system
HSE	Health Service Executive
UHW	University Hospital Waterford

Appendix 3

The Optimal Reperfusion Protocol of the Acute Coronary Syndromes Model of Care¹⁴

Appendix 5: Optimal Reperfusion Service (ORS) Protocol



Acknowledgments

I would like to acknowledge the exceptional logistical support provided by Joan Regan, Emma Bradley and Paul Brosnan in the Department of Health and also the data collection and analysis undertaken by Dr Lois O'Connor in the Department of Health and Dr Siobhan Jennings and her team in the Health Service Executive

I would also like to thank Dr Stephen Green and Dr Rebecca Miles from the National Cardiac Benchmarking Collaborative (NCBC) for allowing me to reproduce their methodology and some of their benchmarking data