Briefing Document
Cardiac need in the South East

The South East of Ireland constitutes the counties of Waterford, Wexford, Tipperary, Kilkenny and Carlow, and in the 2016 Census comprised a population of 582,000 individuals. Prior to the Higgins report, Waterford Regional Hospital was the regional hospital providing complex care for the region. In particular, Catheter Laboratory (cath lab) based cardiology is delivered here, with the service commissioned in 2008, and activity has grown year on year.

A cath lab delivers diagnostic and interventional cardiology (angiograms for diagnosing heart disease, stents for heart attacks and blocked arteries, pacemakers for heart rhythm disturbances, primarily). These services are required as emergency and elective procedures. The access to these procedures is not spread uniformly across Ireland.

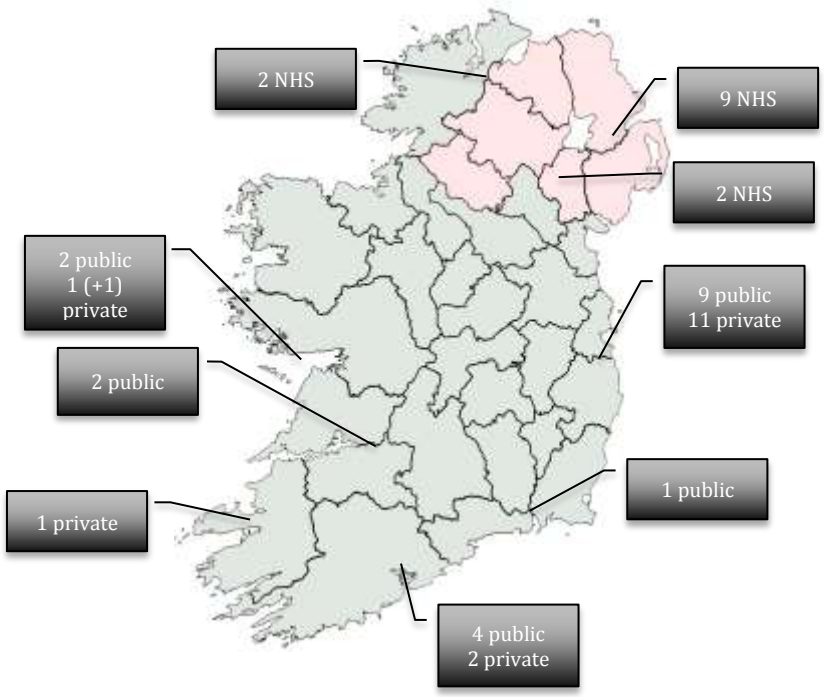

*Figure 1. Distribution of cath labs in Ireland. The population per lab in NI is 138,000; for Mid-west is 180,000; for South/Southwest (**excluding** South East) is 110,000; for Dublin is 125,000; for North/North West is 175,000. For the South East of Ireland is 500,000.*

Activity in the SE single cath lab has grown greatly since the inception of the lab. The demand for service has grown beyond the infrastructure committed to it.

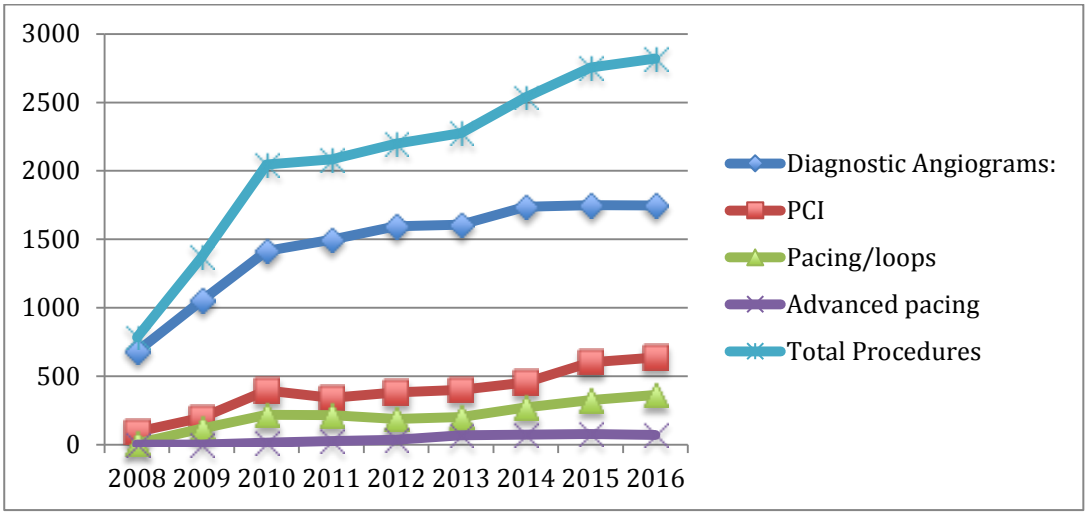

Figure 2: Growth in cath lab procedures at the SE cath lab has increased steadily, year on year, since the inception of the service 8 years ago.

This has resulted in major demand/capacity mismatch in the region, with a waiting list at the end of 2016 with over 700 patients on it, the longest waiting for over 2 years; the inpatient wait times for procedures was 6 days, on average, for a procedure that best practice says should be done within 48 hours. This means a loss of 2214 bed days annually. It was with these concerns over patient safety, and lack of resources, that application was made through the local and regional HSE hierarchy to seek additional resource. This culminated in the identification by the HSE Risk Register that the lack of a second facility was a critical risk, and the submission of a business case by the HSE South/South-West for a second cath lab to be built and staffed at UHW. This was queued for funding. At the formation of government in April, John Halligan TD, who had campaigned on the Cath lab issue in Waterford, attempted to negotiate his support for government around a commitment from the Department of Health to deliver the funding for the business case, as submitted. This was deemed impossible, without an external review. The Herity Report was then produced, and found that the SE cath lab service was indeed under-resourced, but found against the need for a second cath lab at UHW.

Furthermore, the report also found against the delivery of Primary PCI at UHW for the SE population, and recommended its withdrawal from the site. Emergency treatment of a heart attack is termed Primary PCI, and is a critically time dependent treatment. The treatment must be delivered within a time frame generally accepted as within 90 minutes of medical contact (GP, paramedic, Emergency Department). Clearly, geography is critical in determining the reality of this strategy. Withdrawal of the Primary PCI service at UHW raises grave concerns about the safety of the community in the SE, as, experientially, a 90 minute travel time is not achievable from the main population centres at South Wexford and Waterford city.

It is in the context of this narrative that local opposition has been strongly voiced by front line medical professionals, business groups, and the population in the SE at large. There is a strong perception that the decisions made and conclusions reached are invalid, that the SE population will suffer avoidable harm as a result, and that the economic prospects for the region will suffer as a result of a perceived lack of public health infrastructure.

The briefing document is divided into three broad sections. The first is a detailed critique of the Herity report. The second is a review of the primary PCI options at UHW. The last is a summary recommendation for actions by the health committee to advance the resolution of the situation in the South East.

I. Critique and analysis of the Herity Report

The Herity Report has been adopted as a valid representation of the SE cath lab service. Its recommendations have been adopted as government policy. The methodology and the outcome data have been disputed by local clinicians as not being a true reflection of reality. The adoption of the findings, without question, will lead to the loss of this service for the population of the South East of Ireland. This process has already started, with the Department of Health and HSE initiating outsourcing of the cardiac procedures for 340 patients in the South East to other institutions, within the last three months. I will critique three components of the report, and amend according to the realities on the ground in the SE, and present the corrected figures.

1. CATCHMENT AREA.

After an initial preamble, the report begins with a determination of 'effective catchment population' for the SE cath lab. The methodology chosen is the counting of patients who had coronary procedures in the SE cath lab, and determining what percentage of these patients had Waterford, Wexford, etc addresses. These percentages are then applied to the census populations of these counties, to determine what proportion of each county's population are in the SE cath lab catchment area.

This is a fundamentally flawed methodology. This method is only valid if the access to the service is unconstrained; i.e., that all who would avail of the service can do so without restriction. At end 2015, the waiting list for the SE cath lab was >500 patients, clearly indicating a constrained service, invalidating the methodology used. This is because a constrained service that cannot accept referrals encourages a strong referral bias away from the SE cath lab.

Key to proper evaluation of the effective catchment is the clinical preference of the clinicians and, by proxy, the patients, in the SE.

- From Dr. Colwell at South Tipperary General Hospital, in 2016, there were 738 out- and in-patient referrals for coronary angiograms. Approximately 50% (369) of these were referred to Cork. Dr. Colwell confirms that, in general, patients would prefer to the SE cath lab for their procedure, but are dissuaded by the long inpatient and outpatient wait times. However, some would have opted for Cork anyway, so we can reasonably estimate that approximately 200 patients, largely from South Tipperary, would have had their procedure performed at the SE cath lab were that option available. A reasonable estimate is that 33% would have had private insurance. This would imply 66 private patients and 134 public referrals that would have been allocated to UHW if the facility had capacity.
- Similarly, Dr. Buckley in Wexford has estimated a minimum ~300 (200 public, 100 private) inpatients transferred to Dublin hospitals in 2016, from Wexford General Hospital, and 80-100 referred to Dublin private hospitals for outpatient cath lab procedures. The expressed preference of the consultant body there is that these patients would be *preferentially* referred to the SE cath lab, were that option available.
- This gives an additional 334 (200+134) public patients who should have been acknowledged as contributing to the effective catchment area for the SE cath lab, and an additional 266 (200+66) private cases.

- Furthermore, a number of patients were brought out-of-region by Waterford consultants to a private hospital, due to the lack of local access; there were 202 for 2016; of whom 31 had non-coronary procedures, and 171 had coronary procedures.
- Finally, there were 185 coronary cases added to the SE waiting list in 2015. This is Dr. Herity's estimate, and was not included in his population calculations We assume these are largely public patients.
- This gives a grand total of 956 patients (519 public, 437 private) in the SE who were transferred out-of-region to other public/private institutions, for coronary procedures, against the natural referral practice, or were put on the waiting list, and who *were not accounted for in the Herity Report methodology for catchment area calculation*.
- These figures are a 50% increase in the figures used by Dr. Herity to calculate his catchment population. However, this is *still* likely to be a substantial underestimate, as the referral directions for Kilkenny, Carlow and North Tipperary are also likely to be underestimated due to the same 'constraint bias' demonstrated above. Estimates for this dataset, however, are not available.

2. IS ACTIVITY IN THE CATH LAB CONSISTENT WITH THE CATCHMENT AREA?

The second part of the report examines whether the activity carried out in the SE cath lab for 2015 is consistent with the catchment area identified. The report finds that the activity performed in the SE cath lab is consistent with what one would expect from the calculated 'effective catchment area'.

- This statement is nonsense. The 'effective catchment area' in the report was directly calculated from the coronary activity performed in the cath lab, so mathematically *must* be consistent with it. If we look at the number of pacemakers implanted in 2015, however, which is the only other procedure performed in large numbers in the SE cath lab, *and which was not used to calculate catchment,* the figure is 36% higher than what one would expect from the calculated catchment area. This suggests that the catchment calculation is incorrect, and a gross underestimate of the true value.
- However, the pacemaker implant rate for 2016, including those taken out of region for private treatment by UHW consultants, is 209; for an implant rate of 413 pacemakers per million (a quoted reference in the Herity report), that would equate to an expected population of 506,000.

3. BENCHMARKING

The third part of the report takes actual numbers of procedures performed in the SE cath lab and applies a benchmarking process, derived from UK NHS data, to determine the actual amount of cath lab time required for the given procedural volume.

- The methodology takes the time required to do one angiogram as value 1.0, and expresses all other cath lab procedures in 'angiogram equivalents', referred to hereafter as AEs.
- Experientially, the AE values quoted in the Report are clearly incorrect, and we undertook an analysis of our cath lab procedural times to determine the true values. Using the CVIS patient dataset, which logs procedure time from the patient coming into the cath lab to the time the operator leaves the patient (excluding the time it takes to move the patient off the table and remove them from the lab, and therefore a slight underestimate of true time), we found the AEs for 'angiography and follow-on PCI' and PCI only were 2.3 and 2.6 respectively. These corrected AE's have been included in the table, alongside those initially included in the Herity Report. Unfortunately, we do not have equivalent logged data for non-coronary procedures as this is not recorded in the CVIS dataset, so in the absence of a valid real-world AE for these procedures, we will use those used in the Herity Report.

	AE's (Herity Report)	Real world AE's
Angiography only	1	1
PCI only	1.7	2.3
Angiography and follow on PCI	1.7	2.6
Primary PCI	1.7	2.3
PPM implants/revisions (majority assumed to be dual chamber implants)	2.3	No data
PPM generator changes	1.7	No data
Loop recorder implants/explants*	1	No data
ICD implants/revisions, no GA	2.4	No data
ICD generator changes, no GA	2.1	No data
CRT implants/revisions (CRT-D counted under CRT as longer procedure time)	4.2	No data
CRT generator changes	2.0	No data

- Clearly, these increased ratios will significantly increase the local infrastructural needs for the population.
- Finally, the numbers of procedures performed in the SE cath lab have increased from 2015 to 2016. The current procedure tallys for 2016 are shown below,

alongside the numbers for last year, used in the Herity Report, and alongside the corrected AE values, to give the overall AEs per annum.

Procedure	Number (2015)	Number (2016)	Conversion factor for AE's	AE's for 2016
Coronary angiography alone	961	1115	1	1115
PCI alone	174	166	2.6	432
Coronary angiography and follow on PCI	354	463	2.3	1065
Primary PCI	62	75	2.3	173
Permanent pacemaker (PPM) implants or revisions (majority assumed to be dual chamber implants)	179	197	2.3	453
Permanent pacemaker generator changes	25	39	1.7	66
Loop recorder implants or explants	90	75	1	75
Implantable cardioverter defibrillator (ICD) implants or revisions	38	39	2.4	94
Implantable cardioverter defibrillator generator changes	8	10	2.1	21
Cardiac resynchronisation therapy (CRT) implants or revisions	34	35	4.2	147
Cardiac resynchronisation therapy generator changes	2	3	2.0	6
Total	1927	2217		3647

- Given the lack of any additional resourcing, the increase in activity is extraordinary, and a testament to the professionalism and application of the staff in the SE cath lab.
- This gives an angiography equivalent value of 3647, which is 32% higher than the Herity figure. However, this still doesn't include the additional procedural work transferred outside the region, identified in section 1. This was a figure of 771 patients undergoing coronary procedures; estimating a 33% PCI rate, this generates an additional 502 angiograms, and 258 angio/PCI procedures; there were an additional 31 non-coronary procedures (15 loop recorders, 4 CRT, 12 pacemakers).

- Finally, the Report then adds a notional 123 angiograms and 62 angio/PCIs to represent the annual additions to the waiting list; these are added to the table above to give a final estimate of the SE AE's:

Procedure	**N (2016)**	Conversion factor for AE's	AE's
Angiography only	1740	1	1740
PCI only	166	2.6	432
Angiography and follow on PCI	783	2.3	1801
Primary PCI	75	2.3	173
PPM implants/revisions (majority assumed to be dual chamber implants)	209	2.3	481
PPM generator changes	39	1.7	66
Loop recorder implants/explants*	90	1	90
ICD implants/revisions, no GA	39	2.4	94
ICD generator changes, no GA	10	2.1	21
CRT implants/revisions (CRT-D counted under CRT as longer procedure time)	39	4.2	164
CRT generator changes	3	2.0	6
Total			5068

- This final total, 5068, is the closest true estimate of the cath lab activity required to be resourced in the SE.
- Even maintaining the SE cath lab's impressive level of efficiency, this level of activity would require 1.69 cath labs; allowing for the lab to run at the 'median level of efficiency' as stated in the Herity report, which is 2493 angio equivalents per annum, would lead to a requirement of 2.03 cath labs in the South East.

II. Primary PCI in the South East

The current optimal management strategy of acute heart attack (STEMI) is rapid transport to a centre capable of delivering primary PCI. This is a form of cath lab delivered therapy to open a blocked artery. Transferring a patient with a suspected heart attack in this way, for this procedure, is termed 'activating the Code STEMI protocol'. The key term '90 minutes' has come to dominate considerations for what constitutes acceptable delays in access to this treatment. The 90 minutes refers to the travel time from first medical contact to the performance of the procedure. This is the internationally accepted guidance (ESC)[1]. The Irish National Clinical Care Program has adopted the same strategy. The relevant section from the ESC guidelines is appended below, where the point is made that, broadly speaking, the *90 minutes is the point at which the benefit of Primary PCI over less effective treatments is lost*.

- It is acknowledged in the Herity Report that from Waterford eastward to Wexford there is a large part of the SE that is beyond 90 minutes travel time.
- The report estimates this population to be about 174,864.
- The numbers of patients expected to be, therefore, beyond this treatment option for acute heart attack, per annum, in this region, is 45 – 69, allowing for variation in reported incidences of primary PCI in various databases.
- The performance of Primary PCI mandates that a centre be performing >100 cases per year; last year (2016) UHW had 102 Code STEMIs and 75 primary PCIs. This is below the level of 100 primary PCIs; however, this must be understood in the context of a 9-5 service, 5 days per week.
- The report states 80 patients in 2015 were transferred to UHW as Code STEMIs, of which 51 were from this 'beyond 90 minute' region. The report then states that since the average travel time from UHW to CUH was clocked at 88 minutes, we can include the 25 patients in Waterford City as being within the 90 minute window. This is not correct, on several points:
    - If the 88 minutes is a mean travel time, then 50% of journeys are longer than this, so at the very least half of the 25 patients would expect a travel time longer that 88 minutes;
    - The 88 minute figure quoted in the Report is accredited to an ambulance survey of travel times. It presumably reflects travel times over the 24 hour period. Given that non-working hours travel times are significantly shorter, the 88 minutes is likely to be a significant underestimate of the travel time for these patients, who were transferred to UHW during 9-5 hours.
    - Furthermore, the travel time is simply the time from pick-up to destination, and does not include the transfer time from CUH/St James's from ED to the Cath lab and the procedure itself, what is termed the 'door to needle' time.
    - A local trial performed by Dr. Doyle, in association with the ambulance service, determined the true transfer time to be 97 minutes, but even this excludes the time required to take the patient from ED in CUH to the Cath lab,

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[1] Both randomized studies and registries have indicated that long delays to primary PCI are associated with worse clinical outcomes. Time delay to reperfusion is defined in section 3.4.1, above. The 'PCI-related delay' is the theoretical difference between the time of FMC to balloon inflation, minus the time from FMC to start of fibrinolytic therapy (i.e. 'door-to-balloon' minus 'door-to-needle'). The extent to which the PCI-related delay diminishes the advantages of PCI over fibrinolysis has been the subject of many analyses and debates. Because no specifically designed study has addressed this issue, caution is needed when interpreting the results of these *post-hoc* analyses. From randomized trials, it was calculated that the PCI-related delay that may mitigate the benefit of mechanical intervention varies between 60 and 110 min. In another analysis of these trials, a benefit of primary PCI over fibrinolytic therapy was calculated, up to a PCI-related delay of 120 min.66 In 192 509 patients included in the US National Registry of Myocardial Infarction (NRMI) 2–4 registry,41 the mean PCI-related time delay, where mortality rates of the two reperfusion strategies were comparable, was calculated at 114 min. This study also indicated that this delay varied considerably according to age, symptom duration and infarct location: from <1 h for an anterior infarction in a patient <65 years of age presenting <2 h after symptom onset, to almost 3 h for a non-anterior infarction in a patient >65 years of age presenting >2 h after symptom onset. Although these results were derived from a *post-hoc* analysis of a registry and reported delays are sometimes inaccurate, this study suggests that an individualized, rather than a uniform, approach for selecting the optimal reperfusion modality could be more appropriate when PCI cannot be performed expeditiously. Taking into account the studies and registries mentioned above, a target for quality assessment is that primary PCI (wire passage) should be performed within 90 min after FMC in all cases. In patients presenting early, with a large amount of myocardium at risk, the delay should be shorter (<60 min). In patients presenting directly in a PCI-capable hospital, the goal should also be to achieve primary PCI within 60 min of FMC. Although no specific studies have been performed, a maximum delay of only 90 min after FMC seems a reasonable goal in these patients. Note that these target delays for implementation of primary PCI are quality indicators and that they differ from the maximal PCI-related delay of 120 min, which is useful in selecting primary PCI over immediate thrombolysis as the preferred mode of reperfusion (*Table 10*).

and opening the artery, which would take 20 minutes in the best centres, giving a value far beyond the 90 minutes target.
    - The 88 minutes statistic is simply not credible.
    - In any case, these considerations must be understood in the context of the broader reality, which is that the 90 minute statistic is the time point where relative benefit of Primary PCI over poorer treatments is lost. Even if the travel time was, say 80 minutes, and there was no door-to-balloon time added, the benefit of the treatment would be lost.
- Given these considerations, were UHW a 24/7 service, there would be no difficulty reaching the 100 Primary PCI's per year; a conservative estimate is that it would perform 150 per annum.
- The benefit would not just be to the Waterford city/South Wexford population, but also to the wider South East region, where there would be a commensurate reduction in Code STEMI travel times, to well within the 90 minute 'minimal benefit' target, towards the 60 minute target where benefit is maximized.
- The pragmatic reality is that if UHW was provisioned with a second cath lab (as per Part I above) and an additional interventional operator (an additional consultant appointment is already recommended in the Herity Report), then there would be no rational impediment to it expanding its Primary PCI remit to, say, 7 days per week, 8am to 8pm, which would be within the standards set by the NCCP-ACS for delivery of a non-24/7 service, and would easily achieve the 100 case minimum dataset for Primary PCI. This could then form the basis for expansion to a 24/7 service.
- Furthermore, the likely population trends over the next decade are not 'minimal' as referred to in the Report; the absolute population growth may be small, but the demographic change will be to a significantly older, and proportionately more vasculopathic population, suggesting that the absolute burden of acute myocardial infarction, whether STEMI or non-STEMI will increase

III. How can the Oireachtas Joint Committee on Health help?

Under Terms of Reference (**a**).4.(a) and (c), the Joint Committee has a remit to hear and consider the official Departmental policy arising from the Herity Report. The Report is a scientific paper, in effect, and in the scientific world, no paper is considered publishable until it has been peer-reviewed. This is a process honestly and openly engaged upon, and ensures, in so far as it is possible, that scientific analyses and conclusions are robust and reliable.

It is our contention that no such process has occurred here – the Review was accepted as policy with no right of reply; in fact, the document was deliberately withheld from local stakeholders, until its formal publication. It has never been subject to formal scrutiny.

Were its conclusions of no great matter, then its publication in an obscure journal would be of no great consequence. However, the document has been entirely, wholeheartedly and enthusiastically accepted by the Department, as policy. The repercussions of this decision are profound, and will alter health care delivery of vital services in the SE for decades to come.

I would ask the committee to bring this document to the Minister, and to insist that there is no further delay with the implementation of appropriate resourcing for the cardiac service in the SE.