



Guidance on the use and reporting of BNP / NT-ProBNP Testing in the Diagnosis of Chronic Heart Failure

**Greater Manchester & Cheshire
Cardiac & Stroke Network**

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Introduction

The Breathlessness (Heart Failure) Pathway is an identified priority within the Greater Manchester & Cheshire Cardiac & Stroke Network Strategy (2008-11). The focus of the Breathlessness Pathway will be to consider all aspects of Heart Failure (HF) services in order to maximise the health and quality of life for these patients. However, as the symptoms and signs of HF are often non-specific, making an accurate diagnosis of HF can be difficult. It is recognised that there are significant numbers of people with HF who are undiagnosed or inappropriately treated and some people are being treated who do not have HF. Therefore, appropriate diagnosis is an important factor which, with appropriate treatment and continued support, can improve quality of life and reduce morbidity and mortality¹.

The aim of these guidelines, developed by the BNP Steering Group, is to make recommendations on the use of BNP/NT-ProBNP as a diagnostic test for chronic Heart Failure. It is based upon currently available evidence which is complementary to the NICE Guidance published on 25 August 2010.

Definition of Heart Failure

NICE² describes HF “as a complex clinical syndrome of symptoms and signs that suggest impairment of the heart as a pump supporting physiological circulation”. This impairment can be caused by either structural or functional abnormalities and it is necessary to have evidence of these abnormalities in order for a diagnosis of HF to be made². Most commonly, patients with Left Ventricular Systolic Dysfunction (LVSD) and Heart Failure with Preserved Ejection Fraction (HFPEF) are those defined as having HF. However, these terms are limiting since there is variability of the left ventricular ejection fraction measured by different imaging modalities. There is no universal agreement on ejection fraction thresholds where a diagnosis of LVSD or HFPEF could be made. There is continued debate on identifying HF and therefore diagnosis relies on clinical judgement, appropriate investigations and, as there is no single diagnostic test for HF, BNP/NT-ProBNP testing provides a useful and reliable “rule out” method for excluding HF as a diagnosis².

There are a number of symptoms suggestive of HF which includes breathlessness, fatigue, exercise intolerance and fluid retention. The degree of exertion required to elicit symptoms such as breathlessness may be used to grade the severity of symptoms – though the severity of symptoms does not determine the severity of the heart problem:-

Table 1 : New York Heart Association Classification of HF Symptoms² :-

Class	Symptoms
I	No limitations. Ordinary physical activity does not cause fatigue, breathlessness or palpitation. (Asymptomatic left ventricular dysfunction is included in this category).
II	Slight limitation of physical activity. Such patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, breathlessness or angina pectoris (symptomatically mild heart failure).
III	Marked limitation of physical activity. Although patients are comfortable at rest less than ordinary physical activity will lead to symptoms (symptomatically moderate heart failure).
IV	Inability to carry out any physical activity without discomfort. Symptoms of congestive cardiac failure are present even at rest. With any physical activity increased discomfort is experienced (symptomatically severe heart failure).

There are many other symptoms including nocturia, anorexia, abdominal bloating and discomfort, constipation and cerebral impairment which are non-specific to HF and therefore cannot be relied upon when making a diagnosis. Similarly, the clinical signs of tachycardia, third heart sound and displaced apex beat have a less predictive value if found in isolation and although raised Jugular Venous Pressure (JVP) has a high predictive value of HF it is often not present².

BNP/NT-ProBNP Test

Natriuretic peptides are a range of cardiac and vascular derived hormones which are involved in cardiovascular homeostasis. Atrial natriuretic peptide (ANP) and B-type natriuretic peptide originate in the myocardial cells and are secreted in response to wall stress such as HF. However, clinical studies have shown that BNP/NT-ProBNP is a superior diagnostic and prognostic marker in congestive heart failure¹².

There are a number of different types of immunoassay which can detect the presence of B-type natriuretic peptides¹²:-

- Radioimmunoassays (RIA) employ gamma ray emitting radioactive isotopes to label the antigen-antibody reaction. The intensity of gamma rays is proportional to the concentration of BNP or NT-ProBNP in the sample.
- Enzyme Immunoassays (EIA) employ enzymes to label the antigen-antibody reaction. The most commonly used form is an enzyme-linked immunosorbent assay (ELISA), which consists of antibodies bound to enzymes that remain able to catalyze the reaction and yields a visually observed end product. The product of the reaction can be measured using colorimetry. Sandwich technology is utilised with ELISA in which a specific antigen is conjugated or fixed to a solid support medium, so that any unbound materials can be washed away as part of the test procedure.
- Fluorescent immunoassays (FIA) utilise a fluorescent label or enzyme label which act on a substrate to form a fluorescent product. Fluorescent measurements are inherently more sensitive than colorimetric measurements.
- Chemiluminescent immunoassays use a chemiluminescent label. The chemiluminescent molecules are bound to an antigen-antibody complex which produce light when they react.

The immunoassays can be used on point-of-care analysers and multi-parameter laboratory systems.

Guidance

CHD NSF Chapter 6 (Heart Failure), 2000¹

In 2000 the CHD NSF highlighted the difficulty of accurately diagnosing HF and that evidence suggested a significant under/misdiagnosis of the condition. The sensitivity and specificity of symptoms (dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea and oedema) are variable and therefore accurate diagnosis relies on investigation such as ECG/echocardiography. It acknowledged the variation in the practice of diagnosing and treating HF across the country and promoted the importance of developing a consistent approach throughout the NHS by advocating that *“primary care teams, PCTs and hospitals should work together to agree and put in place models of care that (i) identify people at high risk of HF (ii) assess and investigate people with suspected HF (iii) provide and document the delivery of appropriate advice and treatment (iv) offer regular review to people with established HF”*. Additionally, the framework also recommends that primary care, PCTs and hospitals agree *“local written protocols for managing people with suspected heart failure*

including the methods and indications for accessing investigations such as echocardiography”.

NICE Guidance 2003³ : Management of Chronic Heart Failure in Adults in Primary & Secondary Care

The 2003 Guidance made a number of key recommendations which included diagnosis, treatment, monitoring, discharge and supporting patients and carers. When considering diagnosis, the guidance recommended that historical diagnoses of HF should be reviewed and that future diagnosis should be made only when there has been careful consideration of:-

- Underlying abnormality of the heart
- Severity of the syndrome
- Aetiology
- Precipitating and exacerbating factors
- Identification of concomitant disease relevant to the management
- Estimation of prognosis
- Exclusion of other conditions with similar presenting symptoms

The Guidance provided a useful algorithm for the diagnosis of HF advocating the use of 12-lead ECG and/or BNP/NT-proBNP **where available** followed by echocardiography to exclude valve disease and assess the systolic (and diastolic) function of the left ventricle and detect intra-cardiac shunts.

Heart Failure Service Review: Pushing the Boundaries, Improving Services for People with Heart Failure 2007⁴

In July 2007 the Healthcare Commission published a review of HF services. This followed a previous report in 2004 by the Commission for Health Improvement which raised concerns over the varying levels of service provision and the lack of progress in implementation of the NSF (March 2000). The Healthcare Commission report concluded that although there had been progress since the earlier 2004 report, there was still a considerable variance in the accessibility and provision of services for patients with HF. The report made a number of recommendations relating to diagnosis, treatment, psychological support/rehab, patient experience and audit.

Greater Manchester and Cheshire Cardiac Network : Guidelines for the Management of Heart Failure⁵ Revised 2008

The Network developed a medical management algorithm based on establishing a diagnosis of LVSD with the option of using BNP/NT-ProBNP testing. The guidance provides a BNP/NT-ProBNP algorithm which indicates its use for those patients suspected of HF but with no previous heart failure history or evidence of pulmonary congestion/cardiomegaly. It also provides detailed guidance on drug therapy and lifestyle modification. Please note that these guidelines have since been superseded by NICE guidance.

Health Technology Assessment 2009⁶

Following the 2003 publication of NICE Guidance on Heart Failure, the HTA aimed to evaluate the different diagnostic tests available to primary care and “*provide recommendations on the optimal approach to diagnosis of HF in primary care*”. The assessment concluded that there was no difference between the diagnostic accuracy of BNP and NT-ProBNP and recommended that echocardiography was indicated in those patients presenting with “MICE” clinical features (Male, previous MI, basal

crepitations and oedema) and all others should undergo a BNP/NT-ProBNP test and referred for echocardiography based upon gender, with/without ankle oedema and BNP/NT-ProBNP levels. However, the HTA made recommendations that the clinical rule be evaluated together with BNP/NT-ProBNP testing and the diagnostic accuracy of automated ECG readings compared with that of a specialist.

Chronic Heart Failure : National clinical guideline for diagnosis and management in primary and secondary care, NICE Guidance no. 108, August 2010²

In the newly published NICE guidance an algorithm is presented summarising the recommendations for the diagnosis of HF. The diagnosing of HF goes beyond the confirmation of its presence and requires investigation into the underlying heart abnormality, the severity of the syndrome, aetiology, precipitating and exacerbating factors, presence (and effect) of concomitant disease and an estimation of the prognosis of the HF syndrome. It is recognised that there are a significant number of other conditions which may present with symptoms suggestive of HF and since the publication of the first NICE guidance in 2003, there has been new evidence published on the diagnostic accuracy of signs and symptoms of HF. The Guidance recognises the high negative predictive value of BNP/NT-ProBNP in the diagnosis of chronic HF and its value as a 'rule-out' test. The HTA 2009 had provided BNP/NT-ProBNP cut off levels based on the European Society of Cardiology recommendations (these included the use of MICE criteria of gender, previous MI, basal crepitations and ankle oedema [MICE]). However, the NICE Guidance did not support different levels for different clinical features as it felt this would be difficult to implement.

The NICE guidance proposes the following when a patient presents with suspected heart failure:-

- Take a careful and detailed history and perform a clinical examination and tests to confirm the presence of HF.
- Patients suspected of HF and with previous MI to be urgently referred for transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks.
- Patients suspected with HF but with no previous MI to undergo BNP or NT-ProBNP testing:-
 - BNP levels of >400pg/ml (>116pmol/l) or NT-ProBNP >2000pg/ml (>236pmol/l) to be referred for transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks.
 - BNP levels of 100-400pg/ml (29-116pmol/l) or NT-ProBNP 400-2000pg/ml (47-236 pmol/l) to be referred for transthoracic Doppler 2D echocardiography and specialist assessment within 6 weeks.
 - BNP levels of <100 pg/ml (<29 pmol/l) or NT-ProBNP <400 pg/ml (<47 pmol/l) in an untreated patient is unlikely to have HF.

BNP/NT-ProBNP levels can be lowered by obesity and certain drug treatments: diuretics, Angiotensin Converting Enzyme (ACE) inhibitors, beta-blockers (BB), Angiotensin receptor blockers (ARB) and aldosterone antagonists (AA). Similarly, BNP/NT-ProBNP levels can rise due to conditions other than HF (eg left ventricular hypertrophy (LVH), ischaemia, tachycardia, right ventricular (RV) overload, hypoxaemia [including pulmonary embolism], renal dysfunction [GFR <60ml/minute], sepsis, Chronic Obstructive Pulmonary Disease (COPD), diabetes, age of more than 70 years and cirrhosis of the liver].

- Perform transthoracic Doppler 2D echocardiography to exclude important valve disease, assess the systolic and diastolic function of the (left) ventricle and detect intra-cardiac shunts.
- Transthoracic Doppler 2D echocardiography should be performed on high resolution equipment by experienced operators trained to the relevant professional standards. Need and demand for these studies should not compromise quality.
- Ensure that those reporting echocardiography are experienced in doing so.
- Consider alternative methods of imaging the heart (eg radionuclide angiography, cardiac MRI or transoesophageal Doppler 2D echocardiography) when a poor image is produced by transthoracic Doppler 2D echocardiography.
- Consider a serum natriuretic peptide test (if not already performed) when HF is still suspected after transthoracic Doppler 2D echocardiography.

It should be noted that:-

- A serum BNP level less than 100 pg/ml (29 pmol/litre) or an NT-proBNP level less than 400 pg/ml (47 pmol/litre) in an untreated patient makes a diagnosis of HF unlikely.
- The level of serum natriuretic peptide does not differentiate between HF due to left ventricular systolic dysfunction and HF with preserved left ventricular ejection fraction.

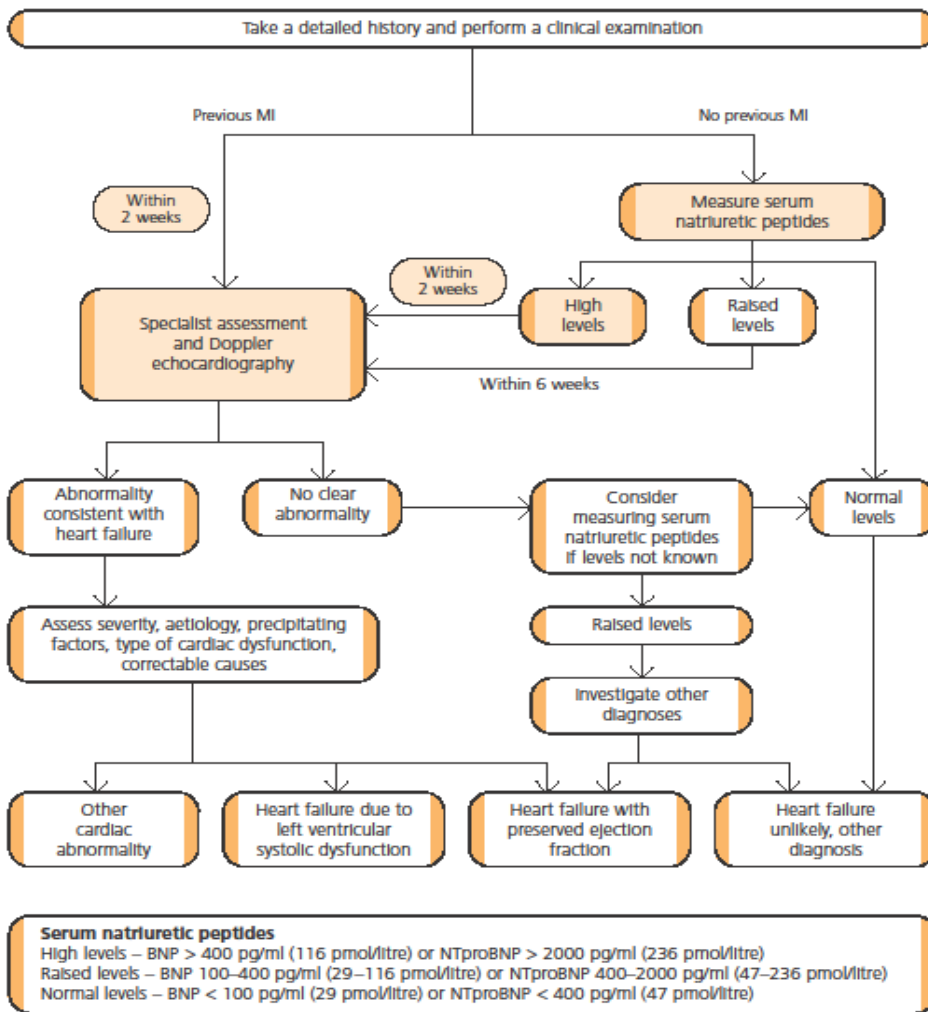
Perform an ECG and consider the following tests to evaluate possible aggravating factors and/or alternative diagnoses:-

- Chest x-ray
- Blood tests:-
 - Electrolytes, urea and creatinine
 - eGFR (estimated glomerular filtration rate)
 - Thyroid function tests
 - Liver function tests
 - Fasting lipids
 - Fasting glucose
 - Full blood count
- Urinalysis
- Peak flow or spirometry
- Exclusion of other disorders that may present in a similar manner
- When a diagnosis of HF has been made, assess severity, aetiology, precipitating factors, type of cardiac dysfunction and correctable causes.

The basis for historical diagnosis of HF should be reviewed and only patients whose diagnosis is confirmed should be managed in accordance with the NICE guidance.

If the diagnosis of HF is still suspected, but confirmation of the underlying cardiac abnormality has not occurred, then the patient should be referred for appropriate further investigation.

Diagnosing heart failure



source: *Chronic Heart Failure NICE Guidance 2010*

Please note that many laboratories may report in ng/L which is numerically the same as pg/ml.

Other recommended tests:

- ECG: Refer to Atrial Fibrillation pathway if AF detected
- Chest X-ray
- Blood tests: urea, creatinine, electrolytes, eGFR, full blood count, liver function tests, thyroid function tests, fasting glucose, and fasting lipids
- Urinalysis
- Peak flow or Spirometry

Non-HF causes of high NP: Left Ventricular Hypertrophy, ischaemia, tachycardia, Right Ventricular overload, hypoxaemia (including pulmonary embolism), renal dysfunction (eGFR<60 ml/min), sepsis, COPD, diabetes, age (>70 years), cirrhosis of the liver.

Factors causing low NP: Obesity and treatment with diuretics, ACEI, BB, ARB and AA.

Pathways for Cardiology Symptoms in Primary Care: The Primary Care Heart Failure Pathway (GMCCSN & Leading Lights Group)

The primary care heart failure pathway has been developed to provide guidance to the general practitioner in the assessment, investigation and initial management of patients with suspected HF (patients with LVSD). It acknowledges that currently only 20-25% of those referred for echocardiogram from primary care receive a diagnosis of HF. It recommends the use of BNP/NT-ProBNP testing as a 'rule out' for people with symptoms suggestive of HF prior to referral for echocardiography. The guidance recommends that continued follow up in the primary care setting should be undertaken by health care professionals (at least one GP and a nurse from the practice) who have attended an accredited education programme of which there are 3 levels.

Incidence & Prevalence of Heart Failure

The incidence of Heart Failure rises with increasing age:-

- 1 in 35 people aged 65-74 years
- 1 in 15 people aged 75-84 years
- 1 in 7 people aged 85 years and over

Source: Chronic Heart Failure: August 2010²

NICE estimate that there are approximately 900,000 people with a diagnosis of HF in the UK and almost an equal number who are currently asymptomatic². The Office of National Statistics 2010⁸ reports that the UK population is ageing gradually. In mid-2009 the number of people aged 85 years and over reached 1.4 million accounting for 2.2% of the population. The number of people of state pensionable age (men aged 65 years and over and women aged 60 years and over) exceeded those aged 16 years (and under) and accounted for 19% of the total population. By 2033 it is projected that the number of people aged 85 years and over will reach 3.3 million and that people in the age bracket of 60-74 years will rise from 8.8 million in 2008 to 11.9 million⁹.

PCT Population Profile

The NHS Information Centre provides details of GP registered population at PCT level together with an age profile¹⁰. The most currently available data is based on the Attribution Dataset for 2009 (Appendix 1). This allows a more accurate calculation of HF incidence at this level. However, it is limited to the population that are registered with a GP and therefore is not representative of the whole population within a PCT area:-

Table 2 : GP Registered Population Profile

GP Registered Population Profile			
PCT	Age 65-74 (males & females)	Age 75-84 (males & females)	Age 85 and over (males & females)
Ashton, Leigh & Wigan	27,776	15,035	5,197
Bolton	21,600	13,685	5,057
Bury	15,162	9,343	3,581
Heywood, Middleton & Rochdale	15,620	10,206	3,649
Manchester	28,843	19,989	7,975
Oldham	17,534	10,236	4,263

Salford	17,631	11,495	4,443
Stockport	24,842	16,916	6,485
Tameside & Glossop	18,405	11,239	4,581
Trafford	17,020	12,036	4,769
Central & Eastern Cheshire	41,397	27,007	10,587
TOTALS	245,830	157,187	60,587

Source: NHS Information Centre, Attribution Dataset 2009¹⁰

Table 3 : GP Registered Population Profile with Incidence Rates

Incidence of Heart Failure by PCT				
PCT	Age 65-74 (males & females)	Age 75-84 (males & females)	Age 85 and over (males & females)	Totals
Ashton, Leigh & Wigan	794	1002	742	2,538
Bolton	617	912	722	2,251
Bury	433	623	512	1,568
Heywood, Middleton & Rochdale	446	680	521	1,647
Manchester	824	1333	1139	3,296
Oldham	501	682	609	1,792
Salford	504	766	635	1,905
Stockport	710	1128	926	2,764
Tameside & Glossop	526	749	654	1,929
Trafford	486	802	681	1,969
Central/Eastern Cheshire	1,183	1,800	1,512	4,495
TOTALS	7,024	10,477	8,653	26,316

It is worth emphasising that the above table relates to the “incidence” of HF amongst the GP registered population of Greater Manchester PCTs. It **does not** take into account the prevalence of the condition and therefore the numbers per PCT will be greater than shown in Table 3.

NICE² quote the Olmstead US study which showed a prevalence of HF of 2.2% in the population aged 45 years and over.

Illustrative Example : Bolton PCT

In Bolton there are 57 GP practices and therefore on average each GP practice would expect to see 39 patients presenting with HF (incidence) and a prevalence of 41 patients.

Table 4 : NHS Bolton (PCT) Population Profile Prevalence of HF

PCT	Male & Female Population 45 years to over 85 years	Prevalence of HF
Bolton	106,428	2,341

Please note these represent an average per GP practice and numbers will differ depending upon patient demographics.

The PCT populations in the 45 years and over age brackets are as follows:-

Table 5 : GP registered populations by gender and age (Females)

PCT	Females 45-49	Females 50-54	Females 55-59	Females 60-64	Females 65-69	Females 70-74	Females 75-79	Females 80-84	Females 85 & over
ALW	10,963	9,293	9,528	10,266	7,904	6,303	5,031	3,742	3,729
Bolton	9,426	8,075	7,793	8,120	6,245	4,942	4,448	3,577	3,552
Bury	6,782	5,591	5,643	5,689	4,242	3,847	3,116	2,325	2,579
CE									
Cheshire	17,044	14,744	14,615	15,599	11,492	10,206	8,562	6,949	7,266
HMR	7,259	6,619	6,299	5,950	4,368	3,809	3,383	2,647	2,514
Manchester	13,959	11,660	10,123	9,582	7,801	7,353	6,549	5,136	5,436
Oldham	7,790	6,765	6,561	6,625	4,963	4,215	3,401	2,705	3,023
Salford	7,331	6,258	5,870	5,953	4,794	4,402	3,767	2,944	3,135
Stockport	10,689	9,144	8,598	8,901	6,846	6,342	5,694	4,365	4,591
Tameside & Glossop	8,559	6,850	6,877	6,770	5,278	4,476	3,715	2,929	3,153
Trafford	7,984	6,622	6,146	6,006	4,715	4,485	3,911	3,002	3,131
TOTAL	107,786	91,621	88,053	89,461	68,648	60,380	51,577	40,321	42,109

Table 6 : GP registered populations by gender and age (Males)

PCT	Males 45- 49	Males 50-54	Males 55-59	Males 60-64	Males 65-69	Males 70-74	Males 75-79	Males 80-84	Males 85 & over
ALW	10,713	9,232	9,366	10,015	7,821	5,748	3,954	2,308	1,468
Bolton	8,947	7,895	7,935	7,920	5,842	4,571	3,323	2,337	1,480
Bury	6,525	5,562	5,538	5,407	3,883	3,190	2,279	1,623	1,002
CE									
Cheshire	17,146	14,840	14,645	14,921	10,824	8,875	6,851	4,645	3,321
HMR	7,073	6,363	6,309	5,585	4,058	3,385	2,482	1,694	1,135
Manchester	13,993	12,008	10,742	9,058	7,302	6,387	4,978	3,326	2,539
Oldham	7,458	6,452	6,384	6,232	4,665	3,691	2,468	1,662	1,240
Salford	7,880	6,473	6,112	5,808	4,364	4,071	2,963	1,821	1,308
Stockport	10,324	9,056	8,674	8,343	6,247	5,407	4,133	2,724	1,894
Tameside & Glossop	8,148	6,798	6,977	6,968	4,852	3,799	2,753	1,842	1,428
Trafford	7,761	6,583	5,938	5,365	3,899	3,921	3,139	1,984	1,638
TOTAL	105,968	91,262	88,620	85,622	63,757	53,045	39,323	25,966	18,453

Source: NHS Information Centre, Attribution Data Set 2009¹⁰

Therefore the prevalence (2.2% of the population) of HF across the 11 PCTs in Greater Manchester and Cheshire would amount to:-

Table 7 : Estimated HF Prevalence across Greater Manchester and C/E Cheshire

Age Groups	Prevalence Figure
All persons 45-59	4,703
All persons 50-54	4,023
All persons 55-59	3,887
All persons 60-64	3,852
All persons 65-69	2,913
All persons 70-74	2,495
All persons 75-79	2,000
All persons 80-84	1,458
All persons 85 years and over	1,332
<u>TOTAL</u>	<u>26,663</u>

Evidence : The Local Experience & Current Service Provision

An assessment of current service provision of BNP/NT-proBNP services and echocardiography for primary care was conducted during August 2010. A brief questionnaire was circulated to the CVD Leads at Greater Manchester and Cheshire PCTs (Appendix 2) and also to the Lead Cardiac Physiologist/Cardio-Respiratory Manager at each Acute Trust in Greater Manchester and Cheshire (Appendix 3). The response rate from PCTs was 81% (9 out of 11) and from Trusts 55% (6 out of 11). The results of the questionnaires are summarised on the following pages:-

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BNP/NT-ProBNP Questionnaire : Results Summary

A brief questionnaire to scope out current service provision was circulated to Greater Manchester and C/E Cheshire PCTs (response rate 81%) and Acute Trusts in Greater Manchester and C/E Cheshire (response rate 55%) which revealed the following:-

Trust	BNP/NT-ProBNP Service established	BNP/NT-ProBNP Service Provider	Trust provides Echocardiography Service for Primary Care	Open Access Service to 1⁰ and 2⁰ care	Echocardiography Service Provider	Primary & Secondary Care Referral Proforma in place for the Echo Service	Referral Proforma for echo requires BNP + result	Any Other Comments
Stockport (Stepping Hill) Since March 2011 BNP is now used with the cut offs recommended by NICE	Yes as part of AQ	Acute Trust	Yes	1 ⁰ = yes 2 ⁰ = yes	Acute Trust	1 ⁰ = yes 2 ⁰ = yes	1 ⁰ = yes 2 ⁰ = use ACC/BSE guidelines	Further details available from Jane Drummond. Use BNP/NT-ProBNP cut off LOWER than in 2010 NICE Guidance:- NT-ProBNP >125ng/l for Males >150ng/l for Females >300ng/l for >70 yrs
UHSM (Wythenshawe Hospital)	Yes	Acute Trust	Yes	1 ⁰ = yes 2 ⁰ = no	Acute Trust	1 ⁰ = yes 2 ⁰ = yes	No	BNP testing used in HF clinic as prognostic rather than diagnostic tool
PAT Bury PCT:-	Yes	Private Provider – PDS	No	1 ⁰ =no 2 ⁰ =yes	Private Provider – PDS	1 ⁰ = yes	For HF MICE scoring system used, score of 9-11 will have a direct echo, score of 5-8 will have BNP first.	
Oldham PCT:-	No			Yes	Acute Trust	No	No	No plans to commission BNP Service in next 12 months

Trust	BNP/NT-ProBNP Service established	BNP/NT-Pro BNP Service Provider	Trust provides Echocardiography Service for Primary Care	Open Access Service to 1 ⁰ and 2 ⁰ care	Echocardiography Service Provider	Primary & Secondary Care Referral Proforma in place for the Echo Service	Referral Proforma for echo requires BNP + result	Any Other Comments
Mid-Cheshire (Leighton Hosp)	No		Yes	1 ⁰ = yes 2 ⁰ = yes	Acute Trust	1 ⁰ = yes 2 ⁰ = yes	No	BNP is available at an alternative lab site and is being looked at for this trust.
Salford Royal Hospital	No		Yes	1 ⁰ = yes 2 ⁰ = yes	Acute Trust	1 ⁰ = yes 2 ⁰ = no	1 ⁰ = No 2 ⁰	In negotiation with the PCT regarding whether BNP would be part of future referral criteria for open access echo from primary care.
PCT Reply	No			1 ⁰ = yes 2 ⁰		1 ⁰ = yes 2 ⁰		May commission BNP service in the future but no time frame.
Royal Bolton Hospital	No		Yes	1 ⁰ = yes 2 ⁰ = no	Acute Trust	1 ⁰ = yes 2 ⁰ = no	No	Although currently not available, Bolton PCT have agreed to fund BNP testing for pts with suspected HF & hope to launch the new service at the Acute Trust later this year. The new pathway will only be avail in 1 ⁰ initially but we will look to extend its use to 2 ⁰ care in the future.
Trafford	No		Yes	Yes- direct access to 1 ⁰ and 2 ⁰	<ul style="list-style-type: none"> Acute Trust & UHSM 	1 ⁰ = yes 2 ⁰ = yes	No	No plans to commission in the next 12 months.

Trust	BNP/NT-ProBNP Service established	BNP/NT-Pro BNP Service Provider	Trust provides Echocardiography Service for Primary Care	Open Access Service to 1 ⁰ and 2 ⁰ care	Echocardiography Service Provider	Primary & Secondary Care Referral Proforma in place for the Echo Service	Referral Proforma for echo requires BNP + result	Any Other Comments
Tameside	No – but plan to commission BNP service in next 12 months via community HF service		Acute Trust	Yes	<ul style="list-style-type: none"> Acute Trust GP Practice 	1 ⁰ = No 2 ⁰	N/A	
WWL	Yes (since 2005)	Acute Trust	Yes	Yes	<ul style="list-style-type: none"> Acute Trust ALW Community Health Care (provider arm of PCT) 	Yes	Yes	<p>Male <70 yrs = >100pg/ml</p> <p>Female <70 yrs = >150pg/ml</p> <p>Male/Female >70 yrs = >300pg/ml</p>
C/E Cheshire Trust (Macclesfield Hospital)	Yes	Acute Trust		Yes	<ul style="list-style-type: none"> Acute Trust GP Practice 	1 ⁰ = yes	No	We prioritise pts for an echo if they have a high BNP level. We have problems around turnaround of results

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Results of the Questionnaire

BNP/NT-proBNP Service

The results of the questionnaire (table on previous pages) indicate that a BNP/NT-ProBNP service accessible from primary care is being provided in Stockport, Bury, Wigan and C/E Cheshire. South Manchester Trust also provides a BNP/NT-proBNP service but this is used within secondary care (HF clinics using POCT) to assist in the prognostic assessment of HF patients. Three further areas are looking to establish a BNP/NT-ProBNP service in the near future (Bolton by the end of this year, Tameside during the next 12 months and Mid Cheshire are currently undertaking a scoping exercise). Where a BNP/NT-ProBNP service has been established this is provided either by the local Acute Trust or Private Provider (one area).

Echocardiography Service

All eleven areas questioned are providing an open access service (either to primary/secondary or both). The providers of the echocardiography service are local Acute Trust, Private Provider (1 area), other nearby Acute Trust, GP Practice or community service. Nine areas have in place referral proformas for the echocardiography service (either primary, secondary care or both). Two areas require there to be a positive BNP/NT-ProBNP test result before referral into the echocardiography service. One area uses lower BNP/NT-ProBNP cut off points than the 2010 NICE Guidance. One area uses a MICE score to determine whether the patient goes directly to echo or BNP/NT-ProBNP testing.

Cost Effectiveness

National Perspective

NHS Improvement produced a report¹¹ of projects at Blackpool, Bedford, West Hertfordshire and Plymouth which using the Scenario Generator demonstrated potential cost savings of 25-40% (25% where open access echo is available and 40% where it is not). In all areas where NHS Improvement has undertaken projects, implementation has been achieved within 6-12 months and cost savings have been realised within 6 months of implementation.

The Buyer's Guide to BNP assays¹² is a useful reference document when determining the cost effectiveness not only of BNP/NT-ProBNP testing but also of point of care test (POCT) compared with laboratory testing. It concludes that a cost saving can be made as BNP/NT-ProBNP testing results in a reduction in the number of patients requiring an echocardiogram. Cost efficiencies can also be derived from avoiding misdiagnosis (other investigations/treatments), avoidable hospital admissions, and for the patient a delayed or misdiagnosis can lead to a reduced life expectancy and quality of life. The guide quotes national and international studies which demonstrate the effectiveness of BNP/NT-ProBNP testing in the diagnosis of HF particularly as a rule out for HF due to their high negative predictive value. Very low levels of BNP/NT-ProBNP are a reliable indicator that HF is very unlikely whereas very high levels are highly suggestive of HF. However, the guide points out that local interpretation of values will be needed depending upon the type of test, type of assay and local laboratory guidance.

NICE has also produced a Costing Report¹³ which assists organisations to plan for the financial implications of implementing NICE Guidance. It is based upon assumptions about current practice and how this may be affected by implementing the NICE recommendations. The report identifies the NICE recommendations which will have a significant impact on resources which are; (i) the demand on echocardiography services, (ii) measuring natriuretic peptides (iii) offering supervised

rehabilitation. The Costing Report states that targets associated with delivering echocardiography (within 2 / 6 weeks depending upon BNP/NT-ProBNP levels) should not have a significant impact on costs though Trusts would have to assess their local circumstance. The costs associated with treatment (including drug therapy) and monitoring (apart from monitoring BNP/NT-proBNP levels) should not impact significantly on costs. There are potential savings associated with early diagnosis which may result in fewer hospital admissions. This has been quantified to a "23% reduced risk per patient being admitted to hospital within the first 6 months as a result of early diagnosis....and calculated to be £2,231 per hospital admission avoided" (based on a weighted average cost considering both long and short stay non-elective inpatient admissions for HF).

Local Experience

Central & Eastern Cheshire (January 2009) reported a saving of 45 echos as a result of introducing BNP testing and a reduction in waiting of 7.5 weeks. A Cost Saving (based on 45 echos not undertaken minus the cost of BNP test) Reported = £4k *Source: Powerpoint Presentation : "Implementation of the BNP – HF Rule Out Test Cheshire's Experience" 26.1.2009, Jayne Scott (principal Clinical Scientist) & Julia Curtis (Commissioning Manager)*

Stockport – Since the introduction of NT-ProBNP testing for primary care in 2005 the number of requests received by the Trusts has grown from 277 requests in 2005 to 3029 in 2010. This has resulted in the potential prevention of 1,777 echocardiograms. NT-ProBNP testing was introduced as part of the secondary care service in 2010 which prevented up to 95 echocardiograms.

Source: Stockport NHS Foundation Trust, G Burrows, 2011.

Cumbria & Lancashire – a computer pathway and cost modelling was undertaken by NHS Improvement using Scenario Generator software. The modelling predicted a significant cost saving by introducing natriuretic peptide testing across Lancashire and Cumbria : approximately £70,000 to £170,000 per annum per PCT. (The lower level savings relate to areas with direct access echo, as their costs are already estimated to be lower).

Source: Report¹¹ : NHS Improvement titled Appendix 1 "B-type Natriuretic peptide (BNP) testing Project"

Wigan - (January 2009) reported on an audit conducted 2005-6 and during 2008 which showed an expected annual saving of £17,320 – based on 2005/6 and 2008/9 tariffs.

Source: Powerpoint Presentation: "Is BNP cost effective in the diagnosis of HF in the community – the Wigan Experience". Sanjay Arya, Consultant Cardiologist, Wrightington, Wigan & Leigh NHS Trust, January 2009

The Cost of Tests/Investigations

There is no national tariff (Payment by Results) for BNP/NT-ProBNP testing but the Costing Report¹³ quotes a price per test of £27.71 (both tests have an equal price). However, locally this is in the region of £18 per test. The 2010-11 tariff for Direct Access Echocardiography (HRG RA60Z) is £87. The Costing Report quotes an ECG test costs £32 and an additional £52 per patient for additional drug therapy (to take into account those patients who receive an earlier diagnosis). The 2010-11 tariff for a Cardiology Outpatient first attendance is £215.

Other Costs

There are a number of other associated costs relating to the provision of a BNP service which need to be considered:

- POCT vs laboratory

There are a number of advantages and disadvantages in both modes of delivery. In terms of cost, POCT without economies of scale can make tests expensive and there is the additional cost associated with maintenance, repair and quality assurance. In terms of laboratory testing, economies of scale may be more attainable whilst there are costs associated with transporting samples to the hospital and concerns regarding possible sample deterioration. It is accepted that the transportation of samples will vary across areas and laboratories and arrangements would need to be agreed locally. Laboratory testing also necessitates a longer turnaround which may impact on the patient in terms of delay in receiving appropriate investigation and treatment. In order to ensure quality assurance, it is necessary to undertake a number of procedures (Internal Quality Control, IQC) which in a laboratory would be performed after each shift whilst POCT requires IQC to be undertaken with a single test (if one analysis is performed) which will impact on the cost of the test. In addition, it is mandatory for accredited laboratories to participate in the External Quality Assessment, EQA scheme which compares the accuracy and comparability of results between centres. The EQA scheme is not a mandatory requirement of POCT users, though it is recommended.

- **Equipment & Consumables**

The costs associated with equipment and their consumables (and shelf life) differ significantly between the different tests. Their use, together with quality control issues and the frequency of use (prevalence of HF in the population) will determine whether a laboratory or POCT is the most cost effective method of delivering the service.

- **Training / referral protocols**

Training is an important element particularly for POCT which are often carried out by non-laboratory personnel and therefore it is important that the healthcare professional conducting the testing is certified and re-accreditation takes place on annual basis. The Department of Health is currently developing an accreditation system for POCT. Most training for laboratory staff will be delivered by the supplier.

Scenario Generator : Economic modelling of NHS Manchester

The NHS Improvement Team have provided an economic model, based on the population of NHS Manchester (for illustrative purposes only) to demonstrate the potential cost savings should a BNP service be introduced. The scenarios are obviously based on a number of assumptions which are described within Appendix 4. Based on these scenarios the range of savings to be made varied from £23k to £45k per year.

Referral & Diagnostic Pathway

Referral Protocols

As the questionnaire has revealed there are referral protocols already in use for the echocardiography service in some areas, the need and desirability of producing a common referral protocol needs further consideration.

Recommended Diagnostic Pathway

The NICE diagnostic algorithm (page 10) is recommended for those presenting with suspected HF. In order to avoid confusion the recommended cut off levels are provided here as ng/L and pg/ml. The inclusion of ng/L is to reflect the changes to national units of measurement and therefore assist the practitioner in interpretation:-

High Levels

- BNP >400ng/L or pg/ml

- NT-ProBNP >2000ng/L or pg/ml

Raised Levels

- BNP 100-400ng/L or pg/ml
- NT-ProBNP 400-2000ng/L or pg/ml

Normal Levels

BNP <100ng/L or pg/ml

NT-ProBNP <400ng/L or pg/ml

As certain drug therapies can affect BNP/NT-proBNP levels it is recommended that where possible blood collection for BNP/NT-proBNP testing should be undertaken prior to commencement of drug therapy. The interpretation of BNP/NT-ProBNP levels will require careful consideration if patients are already being treated for HF and therefore it is recommended that:-

- Patients with previous MI should be referred directly for echo
- Patients on medication should use local guidance on BNP/NT-ProBNP cut off levels.
- Patients not on medication should use the BNP/NT-ProBNP cut off levels as described by NICE 2010 but with the option to consider direct referral to echocardiography if clinically indicated.

It is the decision of local laboratories to determine the choice of assay and the importance of adhering to the assay terms of reference should be noted.

- If HF has been excluded by BNP/NT-ProBNP then an alternative cause is to be investigated and if none found then refer for echo if HF is still suspected.

Primary Care

The Pathways for Cardiology Symptoms in Primary Care : HF pathway⁷ provides guidance to the primary care community on the appropriate assessment, investigation and initial management of those patients suspected of having HF. It provides the general practitioner with a guide to pharmacological and non-pharmacological interventions, referral for specialist opinion, management in primary care and recommends attendance at an accredited educational programme. There are currently 3 levels of competence: Level 1 (Bronze) general practice management in accordance with QoF, Level 2 (Silver) requires attendance at an accredited educational programme provided by CLAHRC/cardiac network and Level 3 (Gold) where the general practice provides a Local Enhanced Service [LES] for HF.

There are a number of referral proformas already established to ensure there is appropriate and seamless referral on to echocardiography for those patients with a positive BNP/NT-ProBNP result.

Pathway of Care

NICE Guidance² recommends that the treatment of HF should be approached from four viewpoints; lifestyle, pharmacological treatment, invasive procedures and a treatment algorithm. Some sections (eg Lifestyle [except exercise training]) remain unchanged from the 2003 guidance. No further guidance is provided here as this falls outside the remit of this document.

Recommendations for Future Development

- The NICE Costing Report¹³ is a valuable resource which provides estimated costs and savings resulting from the use of BNP/NT-ProBNP for monitoring.
- An explanatory report and advice on a management plan should accompany the results of an echocardiogram together with the relevant READ code. As a minimum it is recommended that all patients with HF have a primary code of G58. This should be accompanied with a secondary code related to the aetiology such as G5yy9 for LVSD or G5yya for LVDD and 662p which will ensure the patient is recalled for a 6 month primary care review. This will provide valuable assistance to the general practitioner and avoid delay in the commencement of treatment and negate the need for repeat referrals.
- It is suggested that consideration should be taken in introducing BNP/NT-ProBNP test to the acute medical setting. This would improve diagnosis and ensure the patient follows the appropriate pathway of care.
- The Group suggests that consideration should be given to introducing BNP/NT-ProBNP testing as a prognostic tool. This would help to inform future clinical management eg intervention or palliative care.
- A cross regional collective audit could be introduced to confirm/refute the accuracy levels of BNP/NT-ProBNP and inform future practice.

Implementation Plan & Future Review of Service (post-implementation)

The BNP Steering Group will, facilitated by the Network, engage in a period of consultation with Stakeholders (Appendix 5). Following the stakeholder consultation, the guidance will be presented to the Cardiac Board for approval. The guidance will then be circulated to PCT commissioners, PEC Chairs and Commissioning Consortia pathfinders. A workshop to present the findings and encourage adoption of a BNP service locally will also be considered.

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BNP Steering Group Membership

- Chair: Sanjay Arya, Consultant Cardiologist, Wrightington, Wigan & Leigh NHS FT
- Deputy Chair: Simon Williams, Consultant Cardiologist, UHSM FT
- Philip Lewis, Consultant Cardiologist, Stockport NHS FT
- Mark White, GPwSI Cardiology, NHS Stockport
- Ivan Benett, GPwSI Cardiology & PBC CVD Lead for Central Manchester
- Christi Deaton, Professor of Nursing, University of Manchester
- Jackie Hall, Heart Failure Nurse Practitioner, Tameside General Hospital
- Gillian Burrows, Consultant Clinical Biochemist, Stockport NHS FT
- Amanda Schofield, Cardiac Programme Manager, GMCCSN
- Joanne Langton, Quality Improvement Manager, GMCCSN
- Alison Bali, Project Manager, GMCCSN

Appendix 1 : Attribution Dataset 2009 (GP registered populations)

***Available from the NHS Information Centre at
www.ic.nhs.uk***

Appendix 2 : PCT Questionnaire

To: CVD Leads Greater Manchester and Mid/C&Eastern Cheshire PCTs

BNP testing was identified as a priority within the Greater Manchester and Cheshire Cardiac & Stroke Network's Cardiac Strategy 2008/11 and following on from earlier work has now established a BNP Steering Group. The remit of the BNP Steering Group is to develop guidelines to assist in the development and expansion of BNP testing across the network. This initiative is being taken forward now to coincide with the publication of NICE Guidance which is expected to recommend the use of BNP testing, as a rule out of Heart Failure, for those patients without a previous history of MI. To assist in the development of Network guidelines we are seeking to scope out current service provision for the diagnosis of Heart Failure in your PCT. Therefore, I would be most grateful for your response to the following questions.

Question	Yes	No
(1) Do you currently commission a BNP / NT-Pro BNP service?		
(2) Who provides the BNP or Pro-NT BNP Service (a) Acute Trust (b) Private Provider (c) Other – please specify		
(3) If BNP / Pro-NT BNP is not currently available are there are any plans to commission in the next 12 months?		
(4) Do you currently commission an “open access” echocardiography service?		
(5) Who provides the Echocardiography Service (a) Acute Trust (b) Private Provider (c) Other – please specify		
(6) Are there primary care referral proformas/protocols in place for referral to the echocardiography service?		
(7) Does the referral protocol require a positive BNP result before echocardiography?		
(8) Any Other Comments		

The guidelines will be circulated to all stakeholders to ensure full engagement and provide an opportunity to comment on its content.

Thank you very much for taking the time to complete this short questionnaire **and we would be most pleased to receive your response by 9 September.**

Appendix 3 : Acute Trust Questionnaire

To: Cardiac Physiologist Lead/Cardio-Respiratory Manager, Greater Manchester and Mid/C&East Cheshire Acute Trusts

BNP testing was identified as a priority within the Greater Manchester and Cheshire Cardiac & Stroke Network's Cardiac Strategy 2008/11 and following on from earlier work has now established a BNP Steering Group. The remit of the BNP Steering Group is to develop guidelines to assist in the development and expansion of BNP testing across the network. This initiative is being taken forward now to coincide with the publication of NICE Guidance which is expected to recommend the use of BNP testing, as a rule out of Heart Failure, for those patients without a previous history of MI. To assist in the development of Network guidelines we are seeking to scope current service provision for the diagnosis of Heart Failure and therefore would be most grateful for your response to the following questions.

Question	Yes	No
(1) Do you currently provide an echocardiography service for Primary Care?	<input type="checkbox"/>	<input type="checkbox"/>
(2) Do you currently operate an "open access" echocardiography service for (a) Primary Care? (b) Secondary Care?	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
(3) Do you currently operate referral proformas from primary/secondary care? (a) Primary Care? (b) Secondary Care?	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
(4) Does the referral protocol require a positive BNP/NT-Pro BNP result before echocardiography?	<input type="checkbox"/>	<input type="checkbox"/>
(5) Is BNP or NT-Pro BNP currently available at the Trust?	<input type="checkbox"/>	<input type="checkbox"/>
(6) Any other comments [eg. Has any work been undertaken to develop a BNP Service / Are there any plans to develop to a BNP Service]		

The guidelines will be circulated to all stakeholders to ensure full engagement and provide an opportunity to comment on its content.

Thank you very much for taking the time to complete this short questionnaire **and we would be most pleased to receive your response by 9 September.**

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Appendix 4 : Scenario Generator Model based on NHS Manchester

Pathway Comparisons : Scenario Generator Modelling based on population of NHS Manchester

Results	lowest predicted annual saving	highest predicted annual saving
	23455.02	44986.43

M1 [100% open access echo]			
Result\Scenario	M1b (with SNP)		Annual predicted Saving
1) Pathways Costs	0		0
2) Steps Costs	135,252.23		35963.77
3) Workforce Costs	0		0
4) Block Contract Costs	0		0
Total Scenario Cost	135,252.23		35963.77
No. Wait Standard Breaches	0		0
Possible Breaches	0		0

Notes

Activity at 1968 100% open access echo referrals (£87) per year (0.4% population), no patients going to outpts and a cost of BNP at £18.18, with all current referrals being tested prior to referral and with 40% proving negative reducing echo demand to 1198 per year and SNP use at 1968.

M2 [as per NICE and 100% Open Access echo]			
Result\Scenario	M2b (NICE Guidance + 50% SNP)		Annual predicted Saving
1) Pathways Costs	0		0
2) Steps Costs	126,229.57		44986.43
3) Workforce Costs	0		0
4) Block Contract Costs	0		0
Total Scenario Cost	126,229.57		44986.43
No. Wait Standard Breaches	0		0
Possible Breaches	0		0

Notes

Activity at 1968 per year, Nice guidelines followed, with 50% going straight to echo (without SNP) as estimated likely to have history of MI, 50% having BNP of which then 30% are referred on to echo.[Proportions are estimated from known activity in other locations,] Resulting in SNP use of 970, and echo demand of 1299 (SNP would likely have excluded some of the MI group)

M3			
Result\Scenario	M3b (as is + SNP + inc activity)		Annual predicted Saving
1) Pathways Costs	0		0
2) Steps Costs	147,760.99		23455.02
3) Workforce Costs	0		0
4) Block Contract Costs	0		0
Total Scenario Cost	147,760.99		23455.02
No. Wait Standard Breaches	0		0
Possible Breaches	0		0

Notes

As is with total 25% increased activity of which 50% abnormal and referred on for echo. Giving SNP usage of 2459, and echo activity of 1244 .

M4 [as per NICE and increased activity]			
Result/Scenario	M4 (NICE guidelines and SNP)		Annual predicted Saving
1) Pathways Costs	0		0
2) Steps Costs	134,988.22		36227.78
3) Workforce Costs	0		0
4) Block Contract Costs	0		0
Total Scenario Cost	134,988.22		36227.78
No. Wait Standard Breaches	0		0
Possible Breaches	0		0

Notes

Activity starts at 1968 per year, Nice guidelines followed, with 50% going straight to echo (without SNP) as estimated likely to have history of MI, then 50% of 1968 + 25% increased activity having BNP of which 25% are abnormal and are referred on to echo.[Proportions are estimated from known activity in other locations,] Resulting in SNP use of 1212, and echo activity of 1349

KEY:

Pathway name

Description

M1	As is, all pts going to open access echo at £87, and SNP added on all
M2	NICE guidelines followed with 50% going to open access echo and 50% have SNP
M3	M1 plus 25% increased activity
M4	M2 plus 25% increased activity

Appendix 5 : Stakeholders

- Leading Lights Group
- Cardiac Board
- Pathology Network
- Cardiologists
- Cardiac Physiologist Leads
- CVD PCT Leads
- GM Heart Failure Nurses Group
- GM Heart Failure Steering Group
- PCT Directors of Commissioning
- PEC Chairs
- GP Commissioning Consortia
- GMCCSN Clinical Leads



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