



First Progress Report
on the Implementation Plan based on recommendations arising from HIQA report of the investigation into the circumstances surrounding the provision of care to Rebecca O' Malley in relation to her Symptomatic Breast Disease, the pathology services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick.

Reporting Period: June to August 2008

Q2*: June
Q3*: July to August
Q4*: September to November

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1. Introduction

HIQA produced a report arising from the investigation into the circumstances surrounding the provision of care to Rebecca O’Malley in relation to her symptomatic breast disease. Recommendation 15 of this report states **“The corporate HSE executive management team should nominate a specific director accountable for ensuring the development of an implementation plan for these recommendations. This should include a clear timeframe and milestones. Progress against the plan should be made public and reported to the Board of the HSE.”**

Ms Ann Doherty, Director of the National Hospitals Office, was nominated as the Director responsible for the development of the implementation plan.

The following stakeholders collaborated in the development of the implementation plan:

- Ms Ann Doherty, National Director , National Hospitals Office
- Prof Tom Keane, Director, National Cancer Control Programme
- Ms Edwina Dunne, Head of Quality and Risk
- Dr Mary Hynes, AND Quality and Risk and Customer Care, NHO
- Ms Mary Culliton, Head of Consumer Affairs, HSE
- Mr John Hennessy , Network Manager, Mid Western Hospitals group
- Ms Nora Geary, General Manager, National Hospitals Office
- Ms Yvonne Davidson, Project Manager, National Cancer Control Programme

Governance Process:

The implementation plan was approved by the management team of the HSE on Tuesday 10th June 2008. The plan was then submitted to DOHC and HIQA for their consideration. Ms O’Malley was also given an opportunity to comment. Feedback received was incorporated as appropriate. The Implementation Plan was presented to the Risk Committee of the HSE Board at its meeting on 23rd of July 2008.

Monitoring Processes:

The Implementation Plan was circulated to all Hospital Network Managers in June 2008. An interim status report on the implementation of all recommendations was provided by Network Managers in July 2008. The first progress report on the implementation plan will be made available in September 2008.

Progress on the implementation plan will be monitored on a quarterly basis by the Director of the National Hospitals Office. Progress reports will be submitted to HSE management team and presented to the Risk Committee of the HSE Board. HIQA and DOHC will also be provided with progress reports as agreed.

3. Explanation of the context for implementation

Development of the Implementation Plan was guided by exiting HSE policies such as the Quality and Risk Standard, the associated NHO Quality and Risk Framework, HSE Incident Management Policy, the National Cancer Control Plan and the “Your Service, Your Say, Customer Service Strategy 2008.” Details of these policies are outlined in Appendix 1 at the end of this document.

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First Progress Report

■ = Action commenced

■* = Action commenced & will be ongoing

			Target Date						
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1.	A pathologist together with a surgeon and a radiologist, all of whom should have a specific interest in breast disease must always be present at a multi-disciplinary team (MDT) meeting of triple assessment clinics. A discordant set of triple assessment results should trigger further discussion within the clinical team into the cause of such discordance.	MDT meetings are in place in all of the 8 designated cancer centres					Directors NCCP/NHO/ Hospital Managers	National Quality assurance standards for symptomatic breast disease : 4.	MDT meetings in place in all 8 centres.
		<ul style="list-style-type: none"> All 8 designated cancer centres must keep accurate records of attendance at MDT meetings 	■*						All centres have been advised by NCCP of the requirement for accurate record keeping. Plan to audit in 4th quarter.
		<ul style="list-style-type: none"> Lead clinicians in each centre must ensure that discordant set of triple assessment results triggers further discussion within the clinical team into the cause of such discordance¹ 	■*						Chair of each MDT currently in place. Work underway to identify lead clinicians for each MDT team and advise them of responsibilities in Q3.
		<ul style="list-style-type: none"> Audit on above action must be carried in each designated centre 				■			<i>Plan to audit attendance records in 4th quarter.</i>
2.	Any patient who has a suspected delayed diagnosis of breast cancer should have immediate recourse to a multi-disciplinary team assessment with a formal response from a lead clinician. A delayed diagnosis should trigger a formal incident response including an internal root cause analysis, and the relevant senior management should be notified. The patient should be informed of the findings and outcome as a priority.	If a delayed diagnoses ² occurs the incident management policy must be invoked	■*				Director NCCP / Director NHO / Lead Clinicians / Hospital Managers	HSE incident management policy Root cause analysis documentation http://www.npsa.nhs.uk/patient-safety/improvingpatientsafety	All of Recommendation 2 is in place. All hospitals conform with an adverse incident policy. The HSE is currently standardising a national serious incident policy.
		Ensure lead clinicians are aware of their responsibilities in relation to notification of hospital managers.	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		Lead clinician is responsible for: <ul style="list-style-type: none"> Ensuring prompt review by multi disciplinary team 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		<ul style="list-style-type: none"> Carrying out review of cause 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		<ul style="list-style-type: none"> Completing an incident form as per HSE policy 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		<ul style="list-style-type: none"> Advising risk management 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		<ul style="list-style-type: none"> Notifying senior management 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
		<ul style="list-style-type: none"> Ensure prompt liaison with the patient 	■*						In place. Will be part of the NCCP audit scheduled for 4th Quarter 2008.
3.	The HSE should urgently review the formal communications processes, policies and procedures which its hospitals uses to respond to patients when there is a serious incident, including communications within and between hospitals	Refer to recommendation 2 regarding incident management policy which requires the lead clinician to ensure prompt liaison with the patient. <ul style="list-style-type: none"> Each designated centre must review the formal communications processes, policies and procedures which 				■	Director NHO / Hospital Managers	HSE incident management policy	Refer to Recommendation 2.
							Head of Consumer Affairs		<i>Currently in development led by Consumer Affairs.</i>

¹ Triple assessment refers to a process where three opinions on one case from a clinician, pathologist and radiologist are considered simultaneously. A discordant set of triple assessment results occurs when the three opinions are not in agreement.

² In the context of this recommendation, a delayed diagnosis refers to a situation where an individual is re-presenting with symptomatic breast disease and where triple assessment finds a diagnostic error in any component of the assessment during the initial presentation with symptomatic breast disease.

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		<p>hospitals use to respond to patients when there is a serious incident and ensure that best practice guidelines in relation to formal communication with patients in line with Serious Incident Management Policy are developed.</p> <ul style="list-style-type: none"> Develop best practice guidelines in relation to formal communication within and between hospitals in designated centres 			■				
					■		Director NCCP/ Director NHO		<i>NCCP have commenced preliminary discussions on the development of best practice guidelines.</i>
4.	Appropriate psychological support should be available to patients and their families at any stage during care for symptomatic breast diseases as recommended in the National Quality Assurance Standards for Symptomatic Breast Disease Services	<p>There is access on all of the 8 designated sites to psychology services, counselling, social work and information and support from the professionals within the units. Each unit also has links to local voluntary support centres (e.g. ARC house both in Dublin and Cork) and breast support groups.</p> <p>In addition the NCCP will in 2009:</p> <ul style="list-style-type: none"> Carry out a gap analysis on current psychological support services available to Patients and their families Develop psychological support services for Patients and their families 					Director NCCP	National Quality assurance standards for symptomatic breast disease: 11.2.	<p>All centres currently have access to some psychology services, counselling, social work and information and support from the professionals within the units. <i>Hospitals are currently developing guidelines for psychological support services. 5 of the 8 centres have specific psycho-oncology services, with Galway, Limerick and Waterford coming on stream in 2009 with psycho-oncology services..</i></p> <p><i>Planned for 2009</i></p> <p><i>Planned for 2009</i></p>
5.	<p>When breast tissue sampling is required, a core biopsy should be performed under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities.</p> <p>Breast fine needle aspiration cytology should only be used when quality assured with on-site cytopathology expertise</p>	<p>When breast tissue sampling is required, a core biopsy is performed under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities.</p> <p>The NCCP will ensure that hospitals carry out audit on a regular basis to ensure compliance³</p> <p>Establish current status of cytopathology services as part of an overall review of pathology cancer services by:</p> <ul style="list-style-type: none"> Carrying out an audit to establish current status of services On sites where this service is provided laboratory accreditation will be prioritised to assure quality 	■				Director NCCP / Hospital Managers	National Quality assurance standards for symptomatic breast disease : 7.	<p>As part of the triple assessment process, Steriotactic mammography machine and radiology-led image guidance are in place in all 8 centres.</p> <p><i>NCCP will perform an audit of cytopathology services in Q4 to ensure compliance with HIQA Standards.</i></p> <p>Audit has been carried out and results are currently being considered by the NCCP.</p>
6.	To ensure the effective management and review of patients, a functioning multi-disciplinary team meeting must be held at	Multi-disciplinary team meetings are being held at least weekly, as part of the normal working day.					Director NCCP	National Quality assurance standards for symptomatic breast disease : 4.	Confirmation received from NCCP that each centre is carrying out at least once weekly breast MDT meetings within the core hours. <i>Formal assurances will be sought through the audit process to</i>

³ Please see attached Appendix. The priorities for and frequency of clinical audit in cancer services will be determined by the National Cancer Control Programme.

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	least weekly, as part of the normal working day. One representative from surgery, radiology and pathology must be available with patient information, including imaging, pathology and copies of relevant clinical reports	<ul style="list-style-type: none">Audit current practice in relation to the attendance and scheduling of MDT meetings		■					be carried out in Q4.
7.	Breast FNA cytology must be quality assured This should include: <ul style="list-style-type: none">Units using FNA aspiration as a diagnostic modality must audit the service to ensure minimum standards set by UK NHS Breast Screening Programme Audit should calculate sensitivity, specificity, positive predictive value of C5, false negative rate, false positive rate, inadequate rate, inadequate rate from cancers and suspicious rates.Any units not achieving the minimum standards should introduce initiatives to improve the diagnostic performance of the technique. If the minimum standards are not achieved FNA should not be used as a diagnostic modality.Reports must be clear and unambiguous using the C1-C5 classificationAny units only using FNA solely for breast lesions clinically thought to be benign, create a difficulty for pathologists to maintain diagnostic expertise for full spectrum of breast cytopathology and is therefore not recommended.	<ul style="list-style-type: none">As part of the NCCP a review of Pathology Cancer services a review of all aspects of Breast FNA service will be carried out as planned. Recommendation 7 will be addressed as part of this review.		■			Director NCCP	National Quality assurance standards for symptomatic breast disease : 7.	NCCP are currently communicating with all 8 centres to ensure that they are operating to a level which is compliant with HIQA Standards. They will be notified that there will be subsequent auditing in Q4.
8.	Core biopsies should be reported using the B1-B5 system with classification of cancer type and grade. Pathology reports of breast cancer resection specimens should use: <ul style="list-style-type: none">Template reporting with a minimum dataset for breast cancer specimensMicroscopic confirmation of invasive tumour size	<ul style="list-style-type: none">As part of the NCCP a review of Pathology Cancer servicesThe current reporting systems will be established.National Datasets for reporting breast pathology will be agreed.National guidelines and Datasets will be issued		■			Director NCCP	National Quality assurance standards for symptomatic breast disease : 7.	NCCP are currently communicating with all 8 centres to ensure that they are operating to a level which is compliant with HIQA Standards. They will be notified that there will be subsequent auditing in Q4. Data managers appointed to all 8 centres, data collection sets for access to services and live data developed, for sign off by NCCP Director. Data sets for breast pathology will be included in collection of national data sets.
9.	Clinical requirements at first attendance require triple assessment diagnostic procedures of clinical examination, imaging	Triple assessment diagnostic procedures are in place in the following centres: St Vincent's, St James.					Director NCCP		

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	by mammography and/or ultrasound and pathology sampling. Prior to having invasive tests such as FNA or core-biopsy, all non-invasive tests should be considered, and if relevant, performed.	Beaumont, Mater, Galway, Cork, ⁴ Waterford and Limerick however not at first attendance. <ul style="list-style-type: none">Have in place triple assessment diagnostic procedures at first visit in all centres by the end 08 as additional staff are currently being recruited			■			National Quality assurance standards for symptomatic breast disease : 3	6 centres are currently compliant. <i>In Limerick and Waterford the recruitment of additional staff is in progress and will ensure all 8 centres are compliant.</i>
10.	Senior management, together with clinicians, should introduce new arrangements for the effective delivery of patient centred services. This should be measured, monitored and published in an annual report.	<ul style="list-style-type: none">New arrangements for the effective delivery of patient services are scheduled for introduction as part of the roll out of the new consultant contract and the National Cancer Control Plan.⁵ The NCCP will produce an annual report in a common format for all centres by 2010.			■		Director NHO Office		<i>In keeping with the implementation of the NCCP – Symptomatic Breast services are being re-aligned into eight centres. Services in Mullingar and Clonmel have been completely transferred. Services in Portlaoise, Castlebar, Tralee, Wexford, Kilkenny, and Drogheda will be completely transferred by year end. Work is ongoing to transfer services in Sligo, South Infirmary and Tallaght.</i>
		In 2008 the following will be carried out <ul style="list-style-type: none">Minimum data set with defined data definitions including waiting times will be agreedNational suite of patient information in a variety of formats will be agreedInformation currently in use in various centres will be collectedDraft of information will be circulated for national consultationAgreed suite of information disseminated nationally			■		Director NCCP	National Quality assurance standards for symptomatic breast disease : 14	
		NCCP will be responsible for: <ul style="list-style-type: none">data collection - based on common data setsReporting on PI's on a quarterly basis							Data managers in place. Data sets are agreed with a view to annual reporting for 2010.
		Consumer Affairs will be responsible for : <ul style="list-style-type: none">Collecting information on comments/compliments/complaints on each siteNational analysis will be carried out by Consumer							
								Comments, complaints and compliments are continually being collected in all 8 centres however collation on a national level has been delayed by the ongoing Industrial Action.	
								<i>Analysis of national data for 2007 to be completed end of Q4</i>	

⁴ Triple assessment occurs in Waterford and Limerick over two visits currently but will move to one visit as staff are recruited.

⁵ The new Consultant Contract and the National Cancer Control Plan will see the introduction of Clinical Directors, who work closely with managers, with the common objective to deliver patient centred services.

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		Affairs <ul style="list-style-type: none">Recommendations arising from complaints will be acted upon promptly and communicated to all sites			■				Protocol in development by HSE Consumer Affairs.	
11.	A robust clinical governance framework should be adopted at local, regional and national level. It should include as a minimum: <ul style="list-style-type: none">At National and Hospital level, a named individual at senior management level should be responsible and accountable for clinical governanceA quality and safety framework that includes a schedule of internal and external audits focusing on organisational and speciality specific standards (including NQAS for Symptomatic Breast Disease Services and the Faculty of Pathology’s Histopathology Quality Assurance Programme).Labs should engage in a recognised accreditation programme to assure robust clinical governance at laboratory level.A patient liaison programme, involving an independent advocate and a hospital appointed patient liaison person (at a senior level), as part of a complaints structure. The patient liaison person will be the principal point of contact with the patient and/or family.	At National level a “heads of agreement” policy will define roles and responsibilities in relation to clinical governance between the NCCP and the NHO <ul style="list-style-type: none">The NHO will agree an accountability framework as part the Quality and Risk Standard to clarify governance arrangements at hospital level between NHO and NCCP			■		Director NHO	National Quality assurance standards for symptomatic breast disease : 14	Heads of Agreement Policy drafted and being considered.	
		<ul style="list-style-type: none">Review and agree KPI’s for breast cancer servicesReport on KPI’s on a quarterly basisAnnual report in some centres in 2009 and in all centres by 2010 will provide will benchmark services against national Standards for symptomatic breast services		■		■	Director NCCP		Current KPIs in the HSE Service Plan are being reviewed and modified to ensure compliance with HIQA Standards.	
							■*			
		Refer to Rec. 5 above				■				
		Consumer affairs: <ul style="list-style-type: none">Workshop to be held at each hospital site to include senior clinical and non clinical senior management to agree Patient liaison arrangements as appropriate. These will be facilitated by consumer affairs and led by Hospital management in line with legislation and HSE Policy and will be held only with the attendance of senior management of each networkSenior lead for Patient Liaison service in place by September 2008	■				■		Head of Consumer Affairs	Workshops currently in planning phase with discussions ongoing between Consumer Affairs and Hospital Managers. Workshops have been rescheduled for Q4.
							■			
12.	Risk management arrangements at both hospitals should be reviewed to ensure they demonstrate clarity of purpose, transparency in decision making and accountability to safeguard high standards of treatment and care. This should include a review of their arrangements for managing risk.						Director NHO			

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	Specifically they should: <ul style="list-style-type: none"> Ensure that structures, roles and lines of accountability are clearly defined and reviewed on a regular basis to ensure consistency and clarity of purpose Identify areas where there may be gaps in controls and/or assurances and put in place corrective action Ensure monitoring and reporting systems are timely and effective Ensure all staff involved in the risk management process are appropriately qualified, trained and supported with adequate resources available to them to fulfil their role effectively Review arrangements for communicating risk management policies to all staff Ensure that risks associated with working with other organisations or partners are explicitly assessed and managed 	<ul style="list-style-type: none"> Independent review as outlined in this recommendation to be carried out in both hospitals. Implement recommendations of review Provide training as part of the Quality and Risk standard 	■*						<p>Independent Review completed in Cork. Arrangements are underway for an Independent Review of Risk management procedure in Limerick in Q4. The recommendations of the independent review will be reassessed in light of the re-organisation of the HSE, the roll-out of Quality and Risk Framework and the establishment of Clinical Directorates under the new Consultant Contract.</p>
				■					Arrangements for communicating risk management policies are made through the NHO Executive management team.
				■					A decision has been made to manage this recommendation as part of the second HIQA report.
13.	The hospitals should establish an effective, patient focused communication strategy that addresses the needs of internal and external audiences. This should include: <ul style="list-style-type: none"> Ensuring that the views and perspective of patients, service users and front line staff are taken into account Supplementing the formal communication process with regular visits to the “shop floor” and face to face dialogue The effectiveness of this strategy should be reviewed on a regular basis	<p>“ Your Service Your Say” Consumer Participation Strategy launched May 2008</p> <ul style="list-style-type: none"> Working Group to be established to develop an action plan to build on the principles established in the strategy Implement Action Plan Monitor implementation on a Quarterly basis 		■			Head of Consumer Affairs		<p>Membership of Implementation Group being finalised with first meeting scheduled for October 1st 2008.</p>
					■				
					■*	Ongoing			
14.	Governance arrangements need to be strengthened to ensure: <ul style="list-style-type: none"> Clarity of delegated levels of authority, reporting relationships and accountability at local, regional and national levels Transparent business planning and decision making processes Effective engagement and 	<ul style="list-style-type: none"> As per recommendation 11 – Specific accountability framework included in Quality and Risk framework Clear business planning process in place through estimates and service planning processes. Continue development of 			■		Director NHO		
					■				
									Arrangements to further involve clinicians in the executive management process is being finalised under the new consultant

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	involvement of clinicians in the executive management process	Clinicians in Management initiative and clinical directorate structures to enhance business processes		■*					contract through the Clinical Director role.
15.	The corporate HSE executive management team should nominate a specific director accountable for ensuring the development of an implementation plan for these recommendations. This should include a clear timeframe and milestones. Progress against the plan should be made public and reported to the Board of the HSE.	• Director of NHO nominated to develop an implementation plan for above recommendations	■*		■	Plan in place	Director NHO		In place
		• All actions to have a responsible person and definite timelines					Director NHO		In place
		• Progress will be monitored on a quarterly basis and a report will be provided to the Risk Committee of the Board of the HSE					Director NHO		In place

Appendix 1

For downloading the ‘Quality and Risk Management Standard’ and other Quality and Risk documents: http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/

HSE approach to quality and risk management

The HSE is committed to delivering safe, high quality services. It is fulfilling this commitment through the following developments.

HSE Quality and Risk Management Standard

The HSE Quality and Risk Management Standard ensures that healthcare quality and risk are effectively managed through implementation of an integrated quality and risk management system that ensures continuous quality improvement. The Standard sets out a ‘statement of standard’ together with supporting ‘criteria’ and brief ‘guidance’. Each criterion reflects the elements of a higher level management model describing a ‘system of internal control’ for a healthcare organisation, the risk management aspects of which conform to the requirements of the Australian/New Zealand risk management standard AS/NZS 4360:2004, which has been formally adopted as the process for managing risk in the HSE (Appendix 1).

Implementation of the HSE Quality and Risk Management Standard within the NHO

Once the HSE Quality and Risk Management Standard was established and approved in November 2007, it was necessary for the NHO to set out project plans in December 2007 for how its requirements would be met. These plans are reflected in the relevant sections of the national service plan 2008. They are currently reported on monthly via the Transformation dashboard⁶ reporting mechanism to the leadership team. The following is a progress report on the implementation of Quality and Risk systems in the NHO in line with organisational policy as set out in the HSE Quality and Risk standard (and AS/NZS 4360:2004 as a supporting standard).

I. Risk Management:

The NHO Executive has conducted a risk identification exercise at management team level and is now in the process of completing a full assessment of the risks identified in line with HSE policy. High priority risks for the NHO (based on agreed risk ratings) have been agreed and a number were escalated to the HSE corporate risk register.

II. The HSE Quality and Risk Standard:

A detailed implementation strategy and guidance document (NHO Framework for Quality and Risk) has been developed under the guidance of a steering committee and working group drawn from the hospital system.

A self assessment tool has been developed to provide management assurance on the framework at all levels in the system, including Hospital Network, NHO Executive, CEO and Board levels.

⁶ Project Management Tool, which the HSE use to access progress on the Transformation Projects in the HSE

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The Framework has been consulted on with HIQA to ensure alignment with the forthcoming HIQA standards. A major consultation and education process has been undertaken to introduce the Framework and Self Assessment process in its draft form to stakeholders. Staff consulted include: NHO Executive, all Hospital Managers and multi-disciplinary staff in each hospital network (350 staff across hospitals). Other external stakeholders that have been consulted include the Clinical Indemnity Scheme and the Medical Council.⁷

The Nurse Practice Development Units have been approached to determine how resources might be harnessed toward embedding the Quality and Risk framework.

Pilot sites have been identified and a specification drawn up for piloting the framework in 3 hospitals. The pilot will consider the options for validating the self assessment process and will also bring forward recommendations for reporting and monitoring the implementation of the framework.

National Cancer Control Programme

In 2006 the Minister for Health and Children launched HIQA approved standards/ guidelines for symptomatic breast care, National Quality Assurance Standards for Symptomatic Breast Disease.

With the formation of the National Cancer Control Programme the Minister announced that eight centres in the country would be designated centres for Cancer Surgery, two centres in each of four cancer control networks. With the appointment to the programme of a Clinical Director in November 2007 the initial aim of the programme has been to focus on breast services, with an aim to provide equitable access for patients to high volume surgeons, and multidisciplinary care, with a transition plan for non designated centres. The programme in 2008 has attempted to address service deficits and is aimed at providing equitable staffing levels and resources in centres. Early 2009 will see an audit process of the resultant activity levels in the eight centres with the aim to further resource the services aimed full compliance in each centre with the waiting time standards. The NCCP plans to transfer 90% of Breast Cancer services into the designated centre by end of 2009.

⁷ The Quality and Risk Framework is a response to the Quality & Risk Standard, which set out the structures and processes which hospitals should put in place to meet internal requirements for patient safety and healthcare quality. This includes a requirement for service user and community involvement.