Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

National Quality Review of Symptomatic Breast Disease Services in Ireland

Report of Quality Review Assessment At Mater Misericordiae University Hospital, Dublin

22 February 2010

About the Health Information and Quality Authority

The Health Information and Quality Authority is the independent Authority which has been established to drive continuous improvement in Ireland's health and social care services. The Authority was established as part of the Government's overall Health Service Reform Programme.

The Authority's mandate extends across the quality and safety of the public, private (within our social care function) and voluntary sectors. Reporting directly to the Minister for Health and Children, the Health Information and Quality Authority has statutory responsibility for:

Setting Standards for Health and Social Services – Developing the quality and safety standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services).

Monitoring Healthcare Quality – Monitoring standards of quality and safety in our health services and investigating as necessary serious concerns about the health and welfare of service users

Health Technology Assessment – Ensuring the best outcome for the service user by evaluating the clinical and economic effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

Health Information – Advising on the collection and sharing of information across the services, evaluating information and publishing information about the delivery and performance of Ireland's health and social care services.

Social Services Inspectorate – Registration and inspection of residential homes or children, older people and people with disabilities where applicable. Monitoring day- and pre-school facilities and children's detention centres; inspecting foster care services.

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1 Recommendations

The following represents the full list of recommendations for the Mater Misericordiae University Hospital, Dublin, listed by themes, each of which can be found within the relevant section in the main content of this report.

Recommendations

Theme: Governance

G1. The role of the Lead Clinician should be formalised with specific responsibility for the symptomatic breast disease service.

G2. An integrated governance structure for the symptomatic breast disease service at Mater Misericordiae University Hospital should be developed which includes a more formal approach to the monitoring and trend analysis of key National Quality Assurance Standards and National Cancer Control Programme performance indicators.

G3. The service should ensure that consultant breast surgeons have allocated operating theatre time.

G4. The service should ensure that a robust service level agreement with the third-party provider of radiation oncology services is finalised and implemented. A service level agreement should incorporate the essential components including those of access, quality and the provision of necessary performance information to ensure the timely delivery of a safe quality patient service and compliance with the National Quality Assurance Standards.

G5. The service should review the administrative requirements to effectively implement the service level agreement requirements for radiation oncology.

Theme: Multidisciplinary Approach

MDT1. The service should put arrangements in place to ensure that all clinical findings and multidisciplinary team decisions are clearly recorded.

Theme: Skills, Education and Training

SET1. The service should review the administrative requirements of the symptomatic breast disease service to facilitate the provision of in-service education by the clinical nurse specialists.

SET2. The service should ensure that a formal policy is developed to support and monitor continuous professional development.

Theme: Person-centred Care

PCC1. The service should review the facilities in relation to patient privacy in order to improve the delivery of patient-centred care.

Theme: Access

A1. The service should put a targeted programme of action in place to ensure that all patients triaged as urgent are offered an appointment within 2 weeks, with this target being met for more than 95% of patients.

A2. The service should put a targeted programme of action in place to ensure that all patients triaged as non-urgent are offered an appointment within 12 weeks, with this target being met for more than 95% of patients.

A3. The service should put a targeted programme of action in place to ensure that an urgently referred patient has all imaging done in the first visit, with this target being met for more than 90% of patients.

A4. The service should put a targeted programme of action in place to ensure that surgical intervention shall be carried out within four weeks of a definitive diagnosis with this target being met in more than 90% of patients.

Theme: Clinical Effectiveness

CE1. The service should incorporate specific symptomatic breast disease clinical audit activities, within the Hospital's clinical governance structure to systematically and critically analyse the quality of care provided.

2 Introduction

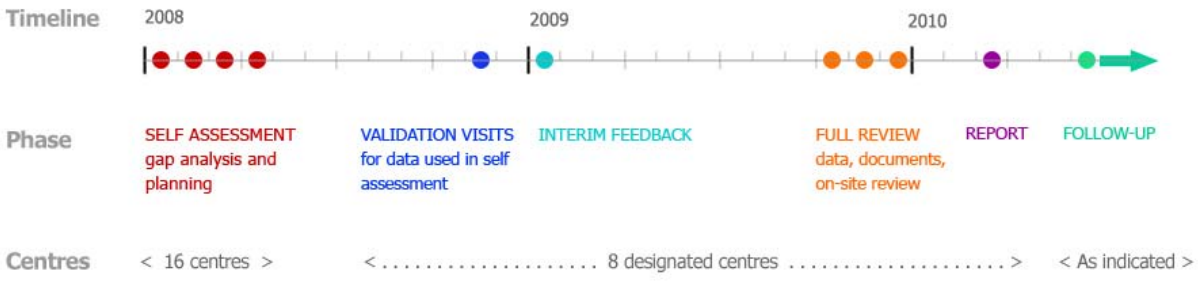
The Health Information and Quality Authority (the Authority) launched the *National Quality Assurance Standards for Symptomatic Breast Disease*[1] (hereafter referred to as the Standards) in May 2007 and advised all hospitals providing symptomatic breast disease (SBD) services that they should be meeting these Standards by the end of 2009.

In autumn 2007, the Authority announced the commencement of the National Quality Review Programme to establish how hospitals providing symptomatic breast disease services were meeting the requirements of the Standards. This report presents the findings from the Authority's review of the national symptomatic breast disease service in Ireland as they relate to the Mater Misericordiae University Hospital, Dublin. It provides an objective assessment of services as they were at the end of 2009.

Given the fluidity of services during the transition of breast cancer treatment services to eight designated centres, the Authority decided to adopt a dynamic approach to monitoring compliance and focus its efforts on both the quality of care and the effective management of the transition in the eight designated centres. The Authority's approach has been designed to reflect the continuous change programme that has been in train over the past two years and stage of development of the designated centres at a given point in time.

This led to a Quality Review Programme that involved five phases across a two-and-a-half-year period, as services centralised to the eight designated centres and as the centres progressed towards full establishment. Figure 1 summarises the timeline for the Authority's activity over this period.

Figure 1: Summary Timeline for the National Quality Review Programme during 2008 to 2010



The Standards provide a framework for the methodology for all phases of this Quality Review Programme. The Authority's activity and approach through each phase of the Review Programme to date is described below.

Phase 1: Self assessment, January to April 2008

This involved the 16 publicly funded hospitals then providing symptomatic breast disease services, undertaking a self-assessment of their performance against the Standards. To facilitate the development of a self-assessment tool, the Authority reconvened the Symptomatic Breast Disease Services National Quality Assurance Group in an advisory capacity. The tool was a self-assessment questionnaire structured according to the sections in the Standards, plus an additional section on preparing for transition. The questionnaire allowed centres to allocate a score for each requirement of the Standards according to where they believed their level of compliance to be. This enabled each hospital to systematically assess the extent to which its symptomatic breast disease services were meeting the requirements set out in the Standards, as well as considering its arrangements for managing service change.

In addition to publicly funded hospitals, the Authority invited private hospitals providing SBD services to participate voluntarily in the self-assessment process. As a result, 11 private providers undertook the self-assessment exercise.

In assessing their own performance, the Authority advised hospitals that any activities or methods used for deciding how they scored themselves should be in place for a minimum of three months in advance of the self-assessment to merit the assignment of a score. In any other case, the Authority indicated that a score of zero should be assigned.

A summary report was provided to the centres in relation to how they had self-reported compliance for each standard compared to what other centres reported.

Phase 2: Validation assessment process, autumn 2008

Having conducted the self-assessment process against the Standards, and fed back the overall outcomes to the eight centres, it was important to test the rigour of the data and processes used by hospitals to self-assess and declare their performance against the standards. **Given that the transition towards eight centres was already underway at this time, this part of the review process was focused only on the eight designated specialist centres.**

The aim of the validation assessment was for the Authority to corroborate the self-assessment scores awarded by the centres through reviewing and challenging the information used by centres to inform completion of their self-assessment questionnaire.

The Authority spent a day on site at each of the eight designated centres. Focusing particularly on those Standards with associated performance indicators, the objective was to validate the self-assessed scores through a review of the evidence used by the centre to complete the self-assessment questionnaire in April 2008. The Authority also sought evidence of how centres were *routinely* measuring performance against these Standards and what evidence they could provide to demonstrate that they were meeting the Standards on an ongoing basis.

Phase 3: Feedback to designated specialist centres, January 2009

Following the validation process, the Authority provided each centre with an interim report in order for the centres to focus their improvement requirements on any gaps in meeting the Standards at that time.

The interim reports took the form of a commentary on the quality of evidence used by the centres to complete the validation assessment questionnaire. This included recommended steps for the future (see Appendix 1).

The Authority had further on-site meetings in June 2009 at each centre to assess the robustness of implementation plans as centres progressed towards full implementation of the Standards by the end of 2009.

Phase 4: Quality Review Visit – October to December 2009

The designated centres were expected by the Authority to be compliant with the Standards by the end of 2009. As indicated from the outset of the Quality Review, the Authority planned a definitive assessment of progress with the implementation of the Standards and progressing towards full establishment as national designated centres towards the end of 2009. This phase of the National Quality Review involved an in-depth review of the performance of the designated specialist centres' compliance with the Standards through:

- a document review
- an analysis of activity
- a review of access and clinical data
- an on-site review of each designated centre which included validation of data against patient records
- qualitative interviews
- patient discussions
- observation of clinical areas.

Interviews were also undertaken with the NCCP.

The detailed methodology for this phase is described in Appendix 2.

In designing its assessment approach for this phase of the National Quality Review, the Authority took account of a number of factors, some of which arose from lessons learned in the self-assessment phase of the process. These included:

- the National Quality Assurance Standards, as they were written, are very detailed and contain a mixture of Standards, targets, indicators and guidelines for clinicians totalling 285 separate requirements
- the Standards are not prioritised or weighted in terms of importance
- as some centres were newly established and resources were still being identified, the eight centres were likely to be at different stages of development and not all aspects of the Standards would be embedded to the same extent in all centres – especially those centres consolidating after significant service configuration changes
- given the above, certain service and performance factors are essential for the provision of safe, high quality care and would cause significant concern if they were not in place.

However, it was a fundamental requirement that the Standards provided the basis for the assessment process given that these are the requirements approved by the Board of the Authority and mandated by the Minister for Health and Children. Therefore, taking account of the above issues, the Authority analysed all 285 requirements in the Standards to identify the key issues on which the assessment needed to focus in a patient-centred way. As a result, ***key representative standards*** from the Standards (see Appendix 3) were identified. To help shape the review, these representative standards were then grouped into seven ***generic themes***. These were:

- **Governance** (how the service is organised, how people are accountable and how decisions are made)
- **Multidisciplinary Approach** (the way different clinicians work together to ensure the best possible patient care)
- **Skills, Education and Training** (whether staff have specialist training for SBD services)
- **Person-centred Care** (how well patients are informed and involved in decisions about there care)
- **Data Management** (how well the centre collects, checks and uses information about patient care)
- **Access** (whether patients receive treatment at the right time and in the right place)
- **Clinical Effectiveness** (whether important clinical factors are delivered properly and whether the right facilities are in place).

Recognising that centres would be at different stages of development towards implementing the full range of standards, the Authority identified the most important

elements in each theme that must to be in place for quality and safety. These ***essential elements*** that each designated specialist centre must have as the foundation for safe, high quality symptomatic breast disease care are set out in **Figure 2.**

Some of these essential elements are fundamental to providing safe care for individual patients on a day-to-day basis (for example multidisciplinary teams and "triple assessment"[+]) and others are important for the sustainable and consistent delivery of quality care to all patients over time. For example, collecting and using data to monitor performance or ensuring that sufficient numbers of patients are treated by professionals in order that professionals maintain their expertise.

The Authority would regard the absence of these essential elements as raising serious questions about the reliability of quality and safety of services provided in any given centre.

These elements provided an important focus of the Review and the Authority's findings in relation to them are set out in this report. All of the essential elements are based on the Standards, with the exception of the Governance essential element which is derived from the Authority's recommendations from previous investigations in relation to SBD services.

[+] Triple assessment is an assessment of a patient by three main methods: clinical examination; diagnostic imaging; and clinical review of pathology samples (biopsies).

Figure 2: Essential elements for safe, high quality symptomatic breast disease care in specialist centres

Theme 1: Governance

Essential Element 1 (a)

A comprehensive integrated governance structure with an organisational framework that incorporates systems and processes must be in place to allow effective general and clinical decision making, incorporating risk management, clinical service delivery and evaluation.

Essential Element 1 (b)

The service will have robust clinical management, referral and patient pathways ensuring an effective integration of patient care.

Essential Element 1 (c)

The governance structure will include defined responsibilities for shared service delivery as specified in the contractual agreement with another service provider.

Theme 2: Multidisciplinary Approach

Essential Element 2 (a)

Core Team.
The symptomatic breast disease (SBD) service must have a:

- lead clinician
- consultant breast surgeon and team
- consultant histopathologist
- consultant radiologist and radiographer
- clinical nurse specialist breast care
- consultant radiation oncologist
- consultant medical oncologist
- consultant plastic and reconstructive surgeon.

Essential Element 2 (b)

The centre should hold at least one triple assessment clinic per week.

Triple assessment aims to achieve a non-operative diagnosis for patients through the delivery of:

- *clinical examination of the patient*
- *imaging by mammography and / or ultrasound*
- *pathology sampling.*

This approach minimises the need for open surgery in women with benign breast disease and permits definitive one-stage surgery in women with malignant disease, through the agreement of the clinical findings of the clinician, radiologist and pathologist. Clear communication between disciplines is essential in providing triple assessment to patients.

Essential Element 2 (c)

The multidisciplinary team (MDT) meeting must be held at least weekly. Patients discussed at the MDT meeting shall include all:

- new patients who have clinical or radiological / sonographic abnormalities
- patients who have had triple assessment
- patients following the first therapeutic operation
- patients for whom discussion at the meeting is deemed appropriate.

All members of the core team must attend the MDT meeting.

Decisions reached by the multidisciplinary team must be communicated to the patient and referring clinician.

Theme 3: Skills, Education and Training

Essential Element 3 (a)

Each member of the core team must have specific training and clinical expertise in breast cancer, must undertake continuing professional education and development on a regular basis with designated time for breast work.

Theme 4: Person-centred Care

Essential Element 4 (a)

The service must ensure that patients can access their care in a timely manner, have sufficient time, support and information in decision making and that their care pathway is integrated.

Integrated care encompasses shared decision making, enhanced by effective information processes, and local and regional support groups.

Essential Element 4 (b)

The centre must have a dedicated facility where the administrative, clinical and diagnostic areas are in close proximity.

The centre must be equipped with basic mammography, stereotactic mammography equipment and an ultrasound machine.

Theme 5: Data Management

Essential Element 5 (a)

Each centre shall have an information and data system that can be integrated with the other in-house systems.

Essential Element 5 (b)

Each centre must record basic data in relation to access, diagnosis, pathology, primary treatment and clinical outcomes.

Essential Element 5 (c)

There will be a data set, dictionary and standard operating procedure (SOP) for data validation.

Essential Element 5 (d)
The data must be available for audit and the SBD team must hold regular audit meetings to enable monitoring of key performance indicators with the National Quality Assurance Standards.

Theme 6: Access
Essential Element 6 (a) The service must ensure that all patients referred for assessment are triaged and referred appropriately. **Essential Element 6 (b)** Patients requiring surgery, medical oncology and radiation oncology are seen and managed in a timely manner according to specified targets.
Theme 7: Clinical Effectiveness
Essential Element 7 (a) The centre must have the facilities to treat more than 150 newly diagnosed patients with primary breast cancer per year. The centre must provide care of breast disease from referral through to care of advanced disease encompassing clinical audit as the principal method to monitor clinical effectiveness. **Essential Element 7 (b)** The service should ensure that the necessary arrangements are in place to undertake effective clinical audit activities that include the systematic and critical analysis of the quality of care being provided, the procedures being used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.

The Authority developed a Quality Review Programme which provided hospitals with a framework to understand the evidence required to assess and demonstrate their performance against the Standards and to identify gaps in the quality and safety of their symptomatic breast disease services.

In order to take account of the realities of patients' experience, the Authority included a patient representative as a member of the Review team and discussions with patients as part of the process.

Phase 5: Local and national reporting of findings

This involves the publication of the findings of the review in two formats. A separate local report on the findings and recommendations, represented by this report, has been issued to each designated centre and has been published on the Authority's website (www.hiqa.ie) along with a national report on the overall findings of the Review.

Where there remained aspects of services still being bedding down at the time of the Authority's Review, tailored on-site follow ups will be undertaken as indicated during 2010.

This report presents the findings from the Authority's Quality Review of symptomatic breast disease services at Mater Misericordiae University Hospital against the Standards.

To summarise, the evidence on which these findings are based includes:

- documents provided by Mater Misericordiae University Hospital (see Document Request template, Appendix 4)
- access* and clinical effectiveness data+ for patients who had been newly diagnosed with primary breast cancer and seen at the centre during the 13-consecutive-week period from 1 June 2009 to 30 August 2009 (see Data Request template, Appendix 5)
- activity data for new patients seen for the five-month sample period from 1 June 2009 to 1 November 2009
- the findings of the Authority's on-site Quality Review on 17 November 2009 and 18 November 2009 including:
    - validation of data against a number of patient records
    - qualitative interviews with relevant staff
    - discussion with patients
    - the observation of clinical areas.

If improvements or changes were made following submissions, the Authority has reflected these, where appropriate, in the overall findings.

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* ***Access:*** *refers to the provision and evaluation of processes to ensure the timely delivery of care and treatment to patients.*

+ ***Clinical effectiveness:*** *the extent to which clinical interventions achieve desirable clinical outcomes by the provision of evidenced-based care with effective clinical audit processes.*

3 Overview

3.1 Mater Misericordiae University Hospital, Dublin

The Mater Misericordiae University Hospital (MMUH) is one of the eight cancer centres of the HSE's National Cancer Control Programme (NCCP), and one of two centres in the Dublin North East Network. The Symptomatic Breast Clinic, or Breast Health Unit, was established in 2000. It is located in the Eccles Unit of the National Breast Screening Programme – BreastCheck. The Breast Health service provides a comprehensive diagnostic and therapeutic service to women presenting with breast symptoms. The Breast Health service has approximately 9,000 attendances per year and approximately 450 breast cancers are diagnosed each year between the BreastCheck and Breast Health services[5].

Public radiation oncology services are currently provided by a third party provider.

In April 2008, the SBD service at MMUH, using a self-assessment questionnaire (to measure its performance against the Standards) that was issued by the Authority as part of the Quality Review Programme, self-reported its percentage compliance with the National Quality Assurance Standards in a range between 68.4% and 100%.

In October 2008, the Authority reviewed the information that the Hospital had used to determine its self-assessment scores. The Authority observed that the SBD service at MMUH:

- had completed the self-assessment questionnaire using information from a live data system, database extractions, an annual report, snap-shot audits and professional judgment
- had appropriate information technology (IT) systems and personnel in position to facilitate continuous routine monitoring of performance against the Standards
- did not provide evidence to demonstrate that the appropriate arrangements were in place to assure itself that it was meeting the Standards.

In January 2009, following this Review, the Authority made a number of recommendations to MMUH and the other hospitals (see Appendix 1).

In early 2009, the service at MMUH underwent a major refurbishment programme necessitating, in conjunction with the NCCP, the re-routing of patient referrals to the SBD services at Beaumont Hospital in Dublin and the Mater Private Hospital in Dublin. Cognisant of the impact the refurbishment would have on the centre's patient referrals during this period, the Authority revised the sample time periods of the data requested.

Consequently, in August 2009, for the purpose of the review, MMUH submitted activity data which provided a preliminary overview of the centre's activity for new patients seen

at the SBD centre for the five-month sample time period of between 1 June 2009 to 1 November 2009, illustrated in Table 1. **The figures below were reported by the centre in their data submission and were not validated by the Authority.**

Table 1: New Patient referral activity at the Mater Misericordiae University Hospital, 1 June 2009 to 1 November 2009

New Patient referral activity at Mater Misericordiae University Hospital 1 June 2009 to 1 November 2009	
Total number of new patients seen at MMUH's SBD service	1,820
Total number of newly diagnosed primary breast cancer patients	71

Table 2: New patient referral activity by urgent triage category reported by Mater Misericordiae University Hospital, 1 June 2009 to 1 November 2009

New patient referral activity by urgent triage category at Mater Misericordiae University Hospital 1 June 2009 to 1 November 2009	
Total number of new patient referrals received during the sample time period that were triaged as **urgent** by the SBD Service	746
Total number of new patient referrals triaged as **urgent** who were offered an appointment to be seen within 10 working days of the date of receipt of referral	465
Percentage of new patient referrals triaged as **urgent** who were offered an appointment to be seen within 10 working days of the date of receipt of referral	62%

Table 3: New patient referral activity by non urgent triage category reported by Mater Misericordiae University Hospital, 1 June 2009 to 1 November 2009

New patient referral activity by non urgent triage category at Mater Misericordiae University Hospital, 1 June 2009 to 1 November 2009	
Total number of new patient referrals received during the sample time period that were triaged as **non urgent** by the SBD Service	776
Total number of new patient referrals triaged as **non urgent** who were seen within **6 weeks** of the date of receipt of referral	173
Percentage of new patient referrals triaged as **non urgent** who were seen within **6 weeks** of the date of receipt of referral	22%
Total number of new patient referrals triaged as **non urgent** who were seen within **12 weeks** of the date of receipt of referral	520
Percentage of new patient referrals triaged as **non urgent** who were seen within **12 weeks** of the date of receipt of referral	67%

4 Findings

Introduction

The findings of the Quality Review are described hereafter, by theme, in accordance with the identified essential elements. The findings for each theme are summarised in a conclusion section at the end of each theme section, and reports if the key elements for the delivery of safe, quality care were in place at the time of the Review.

4.1 Theme 1: Governance

Governance

Governance refers to the organisational framework that incorporates systems and processes for effective decision making to enable and demonstrate the provision, management and evaluation of a high quality safe service.

It defines local and national reporting structures and identifies clinical and managerial lead persons accountable for effective timely decision making, risk management and service evaluation and delivery.

It includes defined responsibility for shared service delivery where there is a contractual agreement with another service provider.

Essential Element 1 (a)

A comprehensive integrated governance structure with an organisational framework that incorporates systems and processes must be in place to allow effective general and clinical decision making, incorporating risk management, clinical service delivery and evaluation.

Findings Essential Element 1 (a)

The symptomatic breast disease (SBD) service is a constituent of the Surgical Division at MMUH. At the time of the Review, the transfer of regional services to the SBD centre at MMUH had been completed. In early 2009, the SBD service underwent a major refurbishment programme necessitating, in conjunction with the NCCP, the re-routing of patient referrals to the SBD service at Beaumont Hospital and the Mater Private Hospital.

The centre reported that it had its full complement of core personnel with all SBD

consultant staff having dedicated work periods (known as sessions) committed to the service. The appointment of an additional consultant pathologist was pending, with post approval and funding having been granted.

The review of documentation, and interviews with staff, confirmed that the clinical and corporate governance arrangements were in place to support the SBD service. A consultant breast surgeon and radiologist shared the SBD services clinical lead role at MMUH. The role of lead clinician was evolving and was not fully formalised. This raised questions about the sustainability of the role which needs to be addressed in terms of role definition, objectives and time allocation. **(see G1)**

The SBD service is a constituent of the Surgical Division, clinically reporting to the chair of the surgical division with clear reporting mechanisms to the Chief Executive, Executive Committee, Board of Governors and Board of Directors.

At the SBD service at MMUH, the Lead Clinicians had overall strategic and professional responsibility for the delivery of the surgical and radiological components of the service, devolving operational responsibility to the Unit Manager. Consequently, the Lead Clinicians chair the Breast Health Unit Management Committee which meets monthly. The membership includes administration, nursing, data, and radiology staff. The terms of reference for this group include:

- operationally reviewing and monitoring the SBD service
- implementing all corporate policies and protocols
- enhancing inter-hospital communication and operational processes.

The minutes of these meetings confirmed that risk management processes were in place. However, at the time of the Review, there was no evidence of any sufficiently formal quality assurance mechanisms to monitor the full range of SBD services against the Standards. The Lead Clinicians identified the need to develop a more integrated governance structure to assure themselves that the service was meeting the Standards and reviewing delayed diagnoses.

This Breast Health Unit Management committee reports to the Breast Care Users Group, chaired by the Chief Executive. This committee has a large membership with wide representation from all relevant clinical, allied health professional and support services. A review of the minutes confirmed this committee monitors patient access times for clinical assessment and surgery, pertinent service delivery issues and outstanding clinical appointments. A review of attendance records confirmed a large number of apologies and non-attendances at each meeting.

The Authority concluded that the specific SBD service governance structure should be more integrated and should develop a more formal approach to the monitoring and

trend analysis of key Standards and NCCP performance indicators. **(see G2)**

Essential Element 1 (b)

The service will have robust clinical management, referral and patient pathways ensuring an effective integration of patient care.

Findings Essential Element 1 (b)

The Authority reviewed the SBD service's standard operating procedure for clinical leadership. This showed that once a patient attends a breast clinic, they become the clinical responsibility of the consultant assigned to that clinic. That patient remains under the care of that consultant throughout their clinical pathway, unless or until their care is transferred to another clinical service.

During interviews, and in reviewing the minutes of the Theatres Users Group, the Authority observed that the locum consultant of the SBD surgical team did not have allocated operating theatre time. This issue had been referred for the attention of the Chief Executive by the Breast Care Users Group. **(see G3)**

The multidisciplinary team (MDT) process is central to the management of symptomatic breast disease and includes triple assessment and MDT meetings. The Authority found that the SBD service had a well defined triple assessment process and multidisciplinary structure which was evidenced throughout the staff interviews, data validation exercise and patient healthcare record review.

The Authority confirmed that there was a clear patient pathway and general practitioner (GP) communication and referral process including a recent protocol to manage patient self-referrals. The effectiveness of these structures was evidenced by the integrated care pathway, the specialist breast care nurse's healthcare records and the SBD team's referral arrangements, particularly between medical oncology and radiotherapy. The patient healthcare record review and patient discussion group confirmed that patients had been informed of their treatment plans and consultant details.

Since 2007, the SBD service at MMUH had been providing a Magnetic Resonance Imaging (MRI) guided core biopsy service.

At the time of the Review, the service had an appropriate clinical management and referral process in place.

Essential Element 1 (c)

The governance structure will include defined responsibilities for shared service delivery as specified in the contractual agreement with another service provider.

Findings Essential Element 1 (c)

The service was managing challenges concerning timely access to public radiation oncology services provided by a third party. At the time of the Review, a service level agreement (SLA) had been recently developed. Such a SLA should incorporate access, quality and provision of necessary performance information to ensure the timely delivery of a safe quality patient service. **(see G4)** The document provided at the time of the Review did not deal effectively with the administrative support required to support the timely transfer of patient information from MMUH to the third-party provider. The MDT reported that, in the absence of increased administrative support, this will be a challenge. This should be given a high priority as it relates to a key aspect of service quality and safety. **(see G5)**

At the time of the Review, the service had a SLA for radiation oncology services. However, the effectiveness of this should be closely monitored.

Governance: Conclusion

The SBD service at the MMUH had corporate and clinical governance structures. The role and responsibilities of Lead Clinician was shared between a consultant surgeon and radiologist. There was an organisational framework that incorporated clinical decision making. However, the service needed to strengthen the governance arrangements through greater integration and formal monitoring with the Standards.

The SBD service had a well defined multidisciplinary structure with a clear patient referral, clinical pathway and leadership arrangements with GP communication and referral processes. However, all consultant surgeons do not have allocated theatre time.

The service should ensure the service level agreement with the third-party provider of radiation oncology is effectively implemented.

Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

Governance: Recommendations

G1. The role of the Lead Clinician should be formalised with specific responsibility for the symptomatic breast disease service.

G2. An integrated governance structure for the symptomatic breast disease service at Mater Misericordiae University Hospital should be developed which includes a more formal approach to the monitoring and trend analysis of key National Quality Assurance Standards and National Cancer Control Programme performance indicators.

G3. The service should ensure that consultant breast surgeons have allocated operating theatre time.

G4. The service should ensure that a robust service level agreement with the third-party provider of radiation oncology services is finalised and implemented. A service level agreement should incorporate the essential components including those of access, quality and the provision of necessary performance information to ensure the timely delivery of a safe quality patient service and compliance with the National Quality Assurance Standards.

G5. The service should review the administrative requirements to effectively implement the service level agreement requirements for radiation oncology.

4.2 Theme 2: Multidisciplinary Approach

Multidisciplinary Approach

Management of breast disease is centred around the multidisciplinary approach. This approach, with input from key essential specialties, facilitates optimum patient management decisions. This maximises the opportunity for the small number of inevitable false positive or false negative findings within a single specialty to be identified and corrected. It also enables the most appropriate integrated care plan to be developed.

Therefore, it is essential to ensure that patients attending specialist symptomatic breast disease services have access to care that is based on collective expert opinion of surgeons, radiologists, pathologists and oncologists with the support of other professions such as specialist nurses.

The clinical decisions reached should be discussed with the patient and the GP and the recommended treatment carried out within a defined time period. It is recognised that clinical decisions reached at the MDT may be modified due to patient choice and circumstances.

Essential Element 2 (a)

a) Core Team.
The symptomatic breast disease (SBD) service must have a:

- lead clinician
- consultant breast surgeon and team
- consultant histopathologist
- consultant radiologist and radiographer
- clinical nurse specialist breast care
- consultant radiation oncologist
- consultant medical oncologist
- consultant plastic and reconstructive surgeon.

Findings Essential Element 2 (a)

A review of the documentation submission by MMUH, and interviews, established that the service had the core staff required for a functioning multidisciplinary team which included:

- consultant breast surgeon and team
- consultant histopathologist

- consultant radiologist and radiographer
- clinical nurse specialist breast care
- consultant radiation oncologist
- consultant medical oncologist
- consultant plastic and reconstructive surgeon
- supporting clinical and administrative staff.

However, the SBD service identified the need to appoint an additional pathologist and to allocate operating theatre time to a recently appointed locum consultant breast surgeon.

At the time of the Review, the service had the core team in place.

Essential Element 2 (b)

The centre should hold at least one triple assessment clinic per week.

Triple assessment aims to achieve a non-operative diagnosis for patients through the delivery of:

- *clinical examination of the patient*
- *imaging by mammography and / or ultrasound*
- *pathology sampling.*

This approach minimises the need for open surgery in women with benign breast disease and permits definitive one-stage surgery in women with malignant disease, through the agreement of the clinical findings of the clinician, radiologist and pathologist. Clear communication between disciplines is essential in providing triple assessment to patients.

Findings Essential Element 2 (b)

The Authority confirmed that the service had an operational procedure, patient pathway and documentation process thereby ensuring an integrated approach for the delivery of triple assessment.

The clinic timetable confirmed a weekly scheduling of triple assessment clinics (TAC). The patient healthcare record review confirmed that clinical and radiology assessments were clearly identified and all examination scores were being recorded in the TAC / MDT meeting pro forma. The referring consultant ensures all appropriate patients details are referred to the multidisciplinary team meeting coordinator for inclusion at the next MDT meeting.
At the time of the Review, the Authority found that the service was holding a minimum of one weekly triple assessment clinic.

Essential Element 2 (c)

The multidisciplinary team (MDT) meeting must be held at least weekly. Patients discussed at the MDT meeting shall include all:

- new patients who have clinical or radiological / sonographic abnormalities
- patients who have had triple assessment
- patients following the first therapeutic operation
- patients for whom discussion at the meeting is deemed appropriate.

All members of the core team must attend the MDT meeting.

Decisions reached by the multidisciplinary team must be communicated to the patient and referring clinician.

Findings Essential Element 2 (c)

The Authority reviewed and confirmed that the service had a standard operating procedure (SOP) in place for the organisation and functioning of the MDT meeting. This SOP included security, patient confidentiality controls and attendees roles and responsibilities. All attendees had dedicated time to attend the MDT meeting and their attendance at the meeting was recorded.

The Lead Clinicians co-chair the MDT meeting and arrangements were in place to cover planned leave. The Authority confirmed that patients discussed at the MDT meeting included all:

1. New patients who have clinical or radiological / sonographic abnormalities.
2. Patients who have had triple assessment.
3. Patients following the first therapeutic operation.
4. Patients for whom discussion at the meeting is deemed appropriate.

At MMUH, the MDT meeting was coordinated by a dedicated post holder with the responsibility for organising and ensuring all patients' clinical details were available for the meeting. The Authority reviewed and verified the processes to ensure availability of this information. The Authority confirmed that the Unit Manager ensures that the TAC and MDT meeting data is regularly checked for accuracy and completeness and that any issues are recorded on the Data Entry Quality Assurance Form and monitored at weekly meetings.
A review of a selected number of patient healthcare records validated that all patients with a definitive diagnosis of breast cancer were discussed at the MDT meeting and all clinical decisions were recorded by the consultant in the TAC / MDT meeting pro forma. Throughout the review of patient healthcare records, detailed radiology reports were

observed. However, image guidance of core biopsies was not documented in all cases. In addition, detailed histology reports were observed although the presence of vascular invasion was not recorded in all cases. **(see MDT1)**

In addition, the Authority reviewed and confirmed the service's communication process to ensure all patients with a definitive diagnosis of breast cancer who are discussed at MDT meeting are contacted by the team. The patient discussion group confirmed that their GPs were aware of their diagnoses and the review of patient healthcare records confirmed that this information was being provided to GPs.

At the time of the review, the Authority found that the service had the MDT meeting and process in place.

Multidisciplinary Approach: Conclusion

The service was actively committed to delivering triple assessment through a multidisciplinary approach. The service had the necessary operational policies in place to ensure that the multidisciplinary team was involved in all clinical decision making and treatment planning. Wherever possible, patients were central to the MDT process and encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary multidisciplinary arrangements in place for the delivery of safe care. The Authority has made recommendations on the remaining areas to be addressed**.**

Multidisciplinary Approach: Recommendations

MDT1. The service should put arrangements in place to ensure all clinical findings and multidisciplinary team decisions are clearly recorded.

4.3 Theme 3: Skills, Education and Training

Skills, Education and Training

The theme of skills, education and training refers to the appointment of staff that have the required knowledge, credentials, skills and competencies to deliver a safe quality service. This includes the organisation's continuous professional development arrangements, in-service training and the monitoring mechanisms to ensure competency.

Essential Element 3 (a)

Each member of the core team must have specific training and clinical expertise in breast cancer, must undertake continuing professional education and development on a regular basis with designated time for breast work.

Findings Essential Element 3 (a)

The Authority found the service had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise.

By reviewing the documentation submitted by the Hospital, and during the on-site discussions with the team, there were several arrangements identified by the Authority whereby continuing professional development and competencies of staff were being monitored. The mechanisms within the SBD team included MDT meeting, peer interaction, quality review, clinical audit, clinical research and attending national and international courses, seminars and master classes.

The service reported that at MMUH, all consultant staff are expected and contractually bound to be academically involved by participating in teaching, training, research and ensuring evidenced-based clinical practices.

The Authority found that the specialist breast care nurses (SBCNs) had relevant qualifications and clinical experience. The specialist breast care nurses are registered on the national clinical nurse specialists register. During the review of facilities, the Authority established that ward-based teaching and mentoring support was provided by the specialist nursing team. However, the SBCNs and members of the MDT reported that a lack of adequate administrative support impeded them from allocating sufficient time towards in-service education. **(see SET1)**

The Authority reviewed and confirmed that the Hospital had:

- a staff induction programme

- a corporate education, funding and study leave policy
- in-service educational programme and timetable
- training and attendance records maintained for all staff
- team information pack
- triple assessment processes and multidisciplinary team meetings, ensuring peer review and agreement of clinical findings
- an SBD service clinical policy and guideline manual
- mandatory training in:

    - mammography
    - communication
    - PATS (Patient Analysis and Tracking System)
    - safe administration of chemotherapy.

Overall, the Authority found that the service had a number of arrangements in place to ensure that the core team has the necessary training and clinical expertise in breast cancer, and undertake continuous professional education and development on a regular basis.

However, the service should ensure that a formal policy is developed to support and monitor continuous professional development. **(see SET2)**

Skills, Education and Training: Conclusion

There was evidence that the service had a number of arrangements in place to ensure that the core team has the necessary training and clinical expertise in breast cancer, and undertake continuous professional education and development on a regular basis.

The specialist breast care nurses are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service.

Overall, the Authority found the SBD service at the MMUH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.

Skills, Education and Training: Recommendations

SET1. The service should review the administrative requirements of the symptomatic breast disease service to facilitate the provision of in-service education by the clinical nurse specialists.

SET2. The service should ensure that a formal policy is developed to support and monitor continuous professional development.

4.4 Theme 4: Person-centred Care

Person-centred Care

Person-centred care refers to the practices and protocols which ensure that the patient is central to the delivery of coordinated and integrated care. This care is delivered, as far as is reasonably practicable, in a safe environment.

Systems and processes should be in place to ensure the patient is fully informed of all treatment options. This encompasses shared decision making with care being enhanced by effective information processes, local and regional support groups.

Furthermore, this includes stakeholder involvement and ongoing monitoring and evaluation of service provision from the patients' perspective.

Essential Element 4 (a)

The service must ensure that patients can access their care in a timely manner, have sufficient time, support and information in decision making and that their care pathway is integrated.

Integrated care encompasses shared decision making, enhanced by effective information processes, and local and regional support groups.

Findings Essential Element 4 (a)

The Authority confirmed during the staff interviews, the on-site facility review and by reviewing patient healthcare records and documentation, that the SBD service at MMUH had the necessary arrangements in place to ensure a person-centred approach in the delivery of symptomatic breast disease services.

In order to explore the provision of patient-centred care from a patient's perspective, the centre was asked by the Authority to select six service users with a diagnosis of breast cancer for participation in a discussion group. In order to take account of the realities of the patients' experience, the Authority included a service user representative as part of the Review team who led the patient discussion group.

The patient group reported their personal experiences. It is important to note that the experiences of other service users may be different.

Five patients participated in the discussion group at the Mater Misericordiae University Hospital, all of whom were from Dublin. Three specific themes were explored:

- access
- clinical care
- information and support.

Person-centred care as reported by the patient discussion group at MMUH was as follows:

Access
It was reported that referral from their GP to the specialist clinic worked well for all patients and most commented on the timeliness and efficiency of the diagnostic process.

However, a six-month delay in having an annual mammogram was reported in one incidence.

Clinical care
All patients in the group reported very high levels of satisfaction with, and confidence in, their clinical care and the manner in which it was delivered at MMUH. They reported that the Standards in relation to the integration of their care pathway from referral, to diagnosis, to treatment were all met.

The patients in the group reported confidence in the multidisciplinary teamwork regarding their diagnoses and none had felt the need to seek a second opinion. All reported that they were happy with the time given to them to make necessary decisions.

Significant praise was given by the patient group to the specialist breast care nurses (SBCNs) and the oncology nurses, for their holistic approach to patient care, their availability and the emotional support they offered to patients.

The majority of those discharged home with their wound drains in place reported satisfaction with their discharge arrangements. However some delays in out of hours access via the emergency department was reported.

Patients receiving radiotherapy treatment at a public third-party provider expressed concerns in relation to timely access to this service and receipt of admission information.

Patients reported a lack of privacy at the time of diagnosis. The diagnosis is communicated by the consultant in the clinical examination room and patients are then led through a public waiting area, to the counselling room. The Authority confirmed this during the observation of clinical areas. **(see PCC1)**

Information and support

All of the patients in the group reported satisfaction with the amount and nature of the information given to them in relation to diagnosis and treatment.

All of the patients reported they had been given information on lymphoedema and none, to date, had experienced any problems in relation to this.

Among the group, there were inconsistencies in relation to the information and support they reported as having received regarding entitlements to prostheses, a medical card and home help.

Patients in the group reported they were satisfied with the information they received on cancer support services and most had availed of courses / services in ARC Cancer Support Centre. Two praised the *Look Good Feel Good* course which had been run by the service.

At the time of the Review, the Authority found that MMUH had the essential arrangements in place to deliver person-centred care. However, they should review the patient's physical journey from the clinical room to the counselling room.

Essential Element 4 (b)

The centre must have a dedicated facility where the administrative, clinical and diagnostic areas are in close proximity.

The centre must be equipped with basic mammography, stereotactic mammography equipment and an ultrasound machine.

Findings Essential Element 4 (b)

The Authority's review of the facility included the:

- symptomatic breast disease facility
- medical oncology day ward
- day ward, local and general procedures
- surgical inpatient ward.

The recently refurbished SBD facility is a stand-alone unit. It was observed that the infrastructure allows for patient privacy to be maintained and the facility includes an area for patient counselling, prosthesis and education rooms. The diagnostic imaging department has the essential imaging equipment and infrastructure to support the SBD service.

The day inpatient facility is a mixed gender ward. However, SBD patients are assigned to a specific area in the ward. The day oncology ward is five-day ward, with patient debriefing being done on the ward. If required, a private area is available.

The SBD service did not have access to ring-fenced beds, and the majority of patients were admitted to St Gabriel's ward. This ward had adequate facilities including a patient counselling room. When discharged, SBD patients can contact this ward should they require assistance, and are given out-of-hours contact details.

Person-centred Care: Conclusion

The symptomatic breast disease service has written information about breast disease, cancer and local support groups. Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment.

The Authority concluded that the SBD service at the MMUH had most of the necessary arrangements and facilities in place to deliver person-centred care. The Authority has made a recommendation on one area to be addressed.

Person-centred Care: Recommendations

PCC1. The service should review the facilities in relation to patient privacy in order to improve the delivery of patient-centred care.

4.5 Theme 5: Data Management

Data Management

Data management refers to the collection and provision of high quality, accurate, valid and timely data which provides, when validated and analysed, information and results that are disseminated to relevant parties and shared between similar service providers to support continuous improvement. This includes the identification and effective management of variances.

Essential Element 5 (a)

Each centre shall have an information and data system that can be integrated with the other in-house systems.

Findings Essential Element 5 (a)

Information management
The Symptomatic Breast Disease service used the following information systems:

- Hospital Information System (HIS) – patient demographics, appointment details and surgical procedures
- Patient Analysis and Tracking System (PATS) – symptomatic breast disease clinical information system
- Laboratory Information System – laboratory reports
- Radiology Information System – radiology reports.

Hospital Information System (HIS)
The HIS is used by all specialties at MMUH to manage patient referrals, specialty appointments and surgical procedures. This system is integrated with PATS for automatic importing of patient demographic and surgical procedure data.

Patient Analysis and Tracking System (PATS)
At the time of the Review, the centre confirmed the Patient Analysis and Tracking System (PATS), which facilitates data collection at all critical points in the patient pathway, was established at the Symptomatic Breast Disease Centre in 2005. The centre had a detailed data set and data dictionary. The team confirmed that identified users are issued with a PATS profile and password that permits access PATS.

The team reported that PATS had been interfaced with HIS, the laboratory and radiology information systems. The centre identified the need to further develop the system interface to facilitate automatic data entry of specific radiology and

histopathology result data fields.

The Authority found that the information and data system could be integrated with the other in-house systems.

Essential Element 5 (b)

Each centre must record basic data in relation to access, diagnosis, pathology, primary treatment and clinical outcomes.

Findings Essential Element 5 (b)

The Authority found that MMUH recorded most of the necessary data in relation to access, diagnosis, pathology, primary treatment and clinical outcomes.

However, the Authority found that the data pertaining to key performance information in relation to radiation oncology to ensure compliance with the National Quality Assurance Standards was not being collected. **(see DM1)**

Essential Element 5 (c)

There will be a data set, dictionary and standard operating procedure (SOP) for data validation.

Findings Essential Element 5 (c)

The Authority found that the service had the required data set and dictionary in place.

At the time of the Review, the Authority confirmed that there was a data capture policy in place which included a short overview of the data validation process. At interview the Unit Manager and Data Manager explained that data validation of surgical, pathology and radiology data, involving a review of 10% of charts, is carried out annually by the individual consultants and that the SBCNs validate the nursing section. The Authority confirmed that the TAC and MDT meeting data is regularly checked for accuracy and completeness and any issues are recorded on the Data Entry Quality Assurance form and monitored at weekly MDT meetings.

They confirmed there was an end-of-year reconciliation of data entry against clinic lists to monitor completeness of data entered.

The Authority concluded that the centre had a data set and dictionary and data validation policies in place. However, the centre should further develop their data validation policy and increase the frequency of a standardised data validation process that includes the patient healthcare record and necessary performance information to ensure the timely delivery of a safe quality patient service. **(see DM2)**

Essential Element 5 (d)

The data must be available for audit and the SBD team must hold regular audit meetings to enable monitoring of key performance indicators with the National Quality Assurance Standards.

Findings Essential Element 5 (d)

The service had information management systems that facilitated the timely collection of pertinent demographic, patient access and clinical information. This information was collected and was included in the service's annual report.

The Authority found that the service had a system in place to monitor key performance indicators with the National Quality Assurance Standards. However, the service should develop a formalised systematic approach to assure itself that it is meeting the Standards.

Data Management: Conclusion

The SBD service had a comprehensive integrated information management system with a well established Patient Analysis and Tracking System which facilitated data collection at all critical points in the patient pathway.

The centre had a data set and dictionary and a data capture policy in place which included an overview of the data validation process in place. The centre should further develop its data validation policy, increase the frequency of a standardised data validation process that includes the patient healthcare record and necessary performance information to ensure the timely delivery of a safe quality patient service, increase the frequency of data validation, and ensure the necessary formal monitoring arrangements are in place. The Breast Health Centre produces an annual report which includes all relevant patient demographic, access and clinical information.

The Authority concluded that the SBD service at the MMUH had most of the necessary data management arrangements in place. However, the service had no data pertaining to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider.

Data Management: Recommendations

DM1. The service should ensure that data pertaining to key performance information in relation to radiation oncology is collected to ensure compliance with the National Quality Assurance Standards.

DM2. The centre should further develop their data validation policy and increase the frequency of a standardised data validation process that includes the patient healthcare record and necessary performance information to ensure the timely delivery of a safe quality patient service

Themes 6 and 7: Access and Clinical Effectiveness

In early 2009, the SBD service at MMUH underwent a major refurbishment programme necessitating, in conjunction with the NCCP, the referral of patients to the SBD services at Beaumont Hospital and the Mater Private Hospital. To reflect the resulting impact on MMUH's patient referral data, the Authority revised the sample time periods of the data requested and was cognisant of this in reviewing patient access timelines.

Accordingly, the MMUH submitted access and clinical effectiveness data for patients newly diagnosed with primary breast cancer and seen at the service during the 13-week sample period from 1 June 2009 to 30 August 2009.

Based on the data submitted by the MMUH, it was identified that a total of 44 patients newly diagnosed with primary breast cancer were seen at the SBD service.

The Authority carried out an on-site validation of 25% of the patient healthcare records in order to assure the accuracy and reliability of the data submitted by the centre in relation to the access and clinical effectiveness data. To ensure confidence in the data submitted, the validation process included a review of the:

- clinical classification coding[±]
- diagnostic imaging and histopathology reports
- patient consent form
- MDT pro forma
- patient information records
- documented clinical decisions
- patient access and treatment timelines
- correspondence to the referring doctor
- referrals to other clinical specialties.

Based on this validation, the Authority concluded it could place reliance on the data submitted for the sample data set.

The section of the report that follows sets out what the Standards and some related NCCP key performance indicators (KPIs) (see Appendix 6) demonstrated for this sample group of patients for the 13-week sample period according to the themes of Access and Clinical Effectiveness. A description and reference code for the selected Standards and NCCP KPIs is provided with the Hospital findings below.

[±] ***Clinical classification coding:*** *relates to triple assessment scores for clinical examination, radiological result and histopathology result.*

4.6.1 Theme 6: Access

Access

Access refers to the provision and evaluation of processes to ensure the timely delivery of care and treatment to patients.

The service is designed so that patients' experience is determined by clinical need rather than other factors such as cultural differences or geographic location.

Essential Element 6 (a)

The service must ensure that all patients referred for assessment are triaged and referred appropriately.

Findings Essential Element 6 (a)

Patient triage processes

Triage is the process for directing patients with different levels of clinical urgency in a timely manner to the most appropriate part of the service. The SBD operational policy, on-site review and the review of patients' healthcare records confirmed that the GP-patient referral triage process was in place. All patient referrals were reviewed by the SBD Cancer Care Coordinator, triaged, stamped and registered. A comprehensive record was maintained in hard and soft copy. The senior registrar provided holiday cover for this service. The Authority reviewed and confirmed the operational process, monitoring and evaluation mechanisms in use by the SBD team.

The Authority found that the service had the necessary triage process in place.

Essential Element 6 (b)

Patients requiring surgery, medical oncology and radiation oncology are seen and managed in a timely manner according to specified targets.

MMUH submitted access and clinical effectiveness data for patients newly diagnosed with primary breast cancer and seen at the service during the 13-week sample period from 1 June 2009 to 30 August 2009.

The findings below set out what this data sample demonstrated according to the theme of Access. The Authority validated this data on-site and concluded that it could place reliance on the data sample submitted.
A reference code for the selected Standards and NCCP KPIs (1b and 5a) is provided with

the Hospital findings below.

Readers should note the corresponding explanatory notes (where applicable) which are based on further information provided by the service.

The following data reported relates to patients newly diagnosed with primary breast cancer and seen at the service during the 13-week sample period from 1 June 2009 to 30 August 2009.

PERFORMANCE MEASURE:	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Access for urgent patients	**TARGET**	**MMUH COMPLIANCE**
Patients triaged as urgent; **and subsequently newly diagnosed with primary breast cancer,** are offered an appointment to be seen within 10 working days of the date of receipt of referral (Standard 2.8).	>95%	52% * See Standard 2.8 below
Access for non-urgent patients	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Patients triaged as non-urgent; **and subsequently newly diagnosed with primary breast cancer,** are seen within 12 weeks of receipt of referral (KPI 1b)	>95%	* See KPI 1b below
Imaging	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Patients triaged as urgent; **and subsequently newly diagnosed with primary breast cancer,** receive imaging on the first visit (Standard 6.14).	>90%	74% * See Standard 6.14 below
Definitive diagnosis	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Patients triaged as urgent; **and subsequently newly diagnosed with primary breast cancer,** have a definitive diagnosis achieved within 10 working days of being seen at the centre (Standard 4.9).	>90%	79% * See Standard 4.9 below

Surgical intervention	TARGET	MMUH COMPLIANCE for 13 week sample
Patients with primary operable breast cancer, have surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnosis (KPI 5a).	>90%	50% * See KPI 5a below

What the data showed

*** Access for urgent patients (Standard 2.8)**

During the refurbishment period in early 2009, the service arranged to refer patients, in agreement with the NCCP, to either Beaumont Hospital or the Mater Private Hospital. The unit at MMUH has been fully operational since June 2009.

The data submitted by the SBD service indicated that 52% of patient triaged as urgent were seen within 10 working days during the sample time period of 1 June 2009 and 30 August 2009.

In consideration of the refurbishment work, and the aligned period of re-adjustment, the Authority reviewed the most recent data which indicated that MMUH was fully compliant at seeing urgent referrals within 10 working days since November 2009. **(see A1)**

*** Access for non-urgent patients (KPI 1b)**

To manage non-urgent patient referrals during the refurbishment, MMUH, in conjunction with the NCCP, arranged to re-route non-urgent patients to Beaumont Hospital in conjunction with additional clinics being held off-site. However, due to the volume of non-urgent referrals, the service at Beaumont Hospital was unable to see the full number of re-routed patients. Consequently, in conjunction with the NCCP, the MMUH retained a list of non-urgent patients to be seen on conclusion of the refurbishment programme. The unit at MMUH has been fully operational since June 2009. The data submitted by the SBD service indicated that in total only three patients were triaged as non-urgent and of these, one was seen within 12 working weeks.

The Authority reviewed the most recent data, which indicated that MMUH was, at the time of the Review, compliant for non-urgent referrals. However, this data only pertained to the two weeks prior to the Review. **(see A2)**

Imaging (Standard 6.14)

In line with MMUH's Access and Clinical Effectiveness data submission to the Authority, this Standard was achieved for 74% of urgent referrals. The centre provided a supporting narrative to this figure detailing the reduction in radiology consultant cover during this time.

Since the installation of the second mammogram machine and the availability of the full complement of clinical staff, the SBD service had increased the number of clinics from four to six per month and informed the Authority that radiology cover was always available to provide imaging for urgent patients on the same day. **(see A3)**

*** Definitive diagnosis (Standard 4.9)**

The centre reported that a definitive diagnosis was achieved within 10 working days in 79% of urgent referral patients.

However, clarification from the SBD team indicated that, prior to October 2009, its data management system collection point for the above Standard was not aligned to this definition. The service was in discussion with the NCCP in relation to this.

*** Surgical intervention (KPI 5a)**

Of the sample group of patients, 40 had surgery as their first line of treatment. Of these, 50% had surgery within 20 working days. The service provided a supporting narrative to this figure, outlining that the Breast Users Group Committee was reviewing surgical access. At the time of the Review, the locum consultant surgeon did not have formal theatre access time and the SBD service had no ring-fenced surgical inpatient beds available to it. **(see A4)**

Medical oncology
The entire sample patient group would not have reached the medical oncology phase of treatment, therefore the data validation exercise did not allow the centre to demonstrate compliance with the access Standards for medical oncology. However, the Authority confirmed that the SBD service was collecting data pertaining to medical oncology.

Radiation oncology
This service is provided to public patients by a third-party provider. The service was unable to demonstrate that it was collecting relevant information in relation to the radiation oncology access Standards. Throughout the review, clinicians indicated the need to improve availability of data in relation to this service. **(see DM1)**

Access: Conclusion

At the time of the Review, the SBD service at MMUH had been fully operational since June 2009 following refurbishment. Since re-opening, the service was reviewing the backlog of the non-urgent patient waiting list which had been deferred during the refurbishment with the agreement of the NCCP.

The SBD service at the MMUH had the capacity to effectively manage the necessary access times for urgent and non-urgent referrals. However, outstanding areas which should be addressed by the service include consultant operating theatre access and inpatient access.

The Authority concluded that patient access timelines for urgent and non-urgent triaged patients must be bedded down and the necessary monitoring controls integrated within the governance structure. In addition, to provide the optimum service and to effectively use the available clinical resources, it is essential that theatre and inpatient access is reviewed.

Access: Recommendations

A1. The service should put a targeted programme of action in place to ensure that all patients triaged as urgent are offered an appointment within 2 weeks, with this target being met for more than 95% of patients.

A2. The service should put a targeted programme of action in place to ensure that all patients triaged as non-urgent are offered an appointment within 12 weeks, with this target being met for more than 95% of patients.

A3. The service should put a targeted programme of action in place to ensure that an urgently referred patient has all imaging done in the first visit, with this target being met

for more than 90% of patients.

A4. The service should put a targeted programme of action in place to ensure that surgical intervention shall be carried out within four weeks of a definitive diagnosis with this target being met in more than 90% of patients.

4.6.2 Theme 7: Clinical Effectiveness

Clinical effectiveness: *the extent to which clinical interventions achieve desirable clinical outcomes by the provision of evidenced-based care with effective clinical audit processes.*

Clinical audit: *the systematic, critical analysis of the quality of care, including procedures used for diagnosis and treatment, use of resources and resulting outcome and quality of life for the patient.*

Essential Element 7 (a)

The centre must have the facilities to treat more than 150 newly diagnosed patients with primary breast cancer per year. The centre must provide care of breast disease from referral through to care of advanced disease encompassing clinical audit as the principal method to monitor clinical effectiveness.

Findings Essential Element 7 (a)

MMUH submitted access and clinical effectiveness data for patients newly diagnosed with primary breast cancer and seen at the service during the 13-week sample period from 1 June 2009 to 30 August 2009.

The findings below set out what this data sample demonstrated according to the theme of Clinical Effectiveness. The Authority validated this data on-site and concluded that it could place reliance on the data sample submitted.

A reference code for the selected Standards and NCCP KPIs (1b and 5a) is provided with the Hospital findings below.

Readers should note the corresponding explanatory notes (where applicable) which are based on further information provided by the service.

The following data reported relates to patients newly diagnosed with primary breast cancer and seen at the service during the 13-week sample period from 1 April 2009 to 30 June 2009.		
PERFORMANCE MEASURE	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Non-operative diagnosis	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
A non-operative diagnosis is achieved in malignant disease (Standard 6.16).	>90%	100%
Ultrasound of the axilla	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Patients with a diagnosis of invasive breast cancer shall have an ultrasound assessment of their axilla. Ultrasound of the axilla plays a central role in determining patients' suitability for sentinel node biopsy (Standard 6.21).	>95%	100%
Imaging prerequisites	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer (Standard 6.1).	>95%	98%
Histopathology data	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
To provide important and relevant data on patients with invasive breast carcinoma (Standard 7.13A): ▪ Histological tumour type is recorded.	>95%	100%
▪ Histological tumour grade is grade.	>95%	100%
▪ Invasive tumour size is	>95%	100%

recorded.		
▪ The presence or absence of vascular invasion is recorded.	>95%	84% *See Standard 7.13 A below
▪ Radial margin status in wide local excision specimens is recorded.	>95%	100%
▪ Posterior (deep) margin status is recorded.	>95%	100%
Hormone receptor status	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
Oestrogen receptor status is recorded (Standard 7.13 B).	>95%	100%
***HER2* status**	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
HER2 status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH) (Standard 7.13C).	>95%	100%
Ductal carcinoma in situ	**TARGET**	**MMUH COMPLIANCE for 13 week sample**
To provide appropriate data in patients with ductal carcinoma in situ (DCIS) (Standard 7.14): ▪ DCIS grade is recorded.	>95%	100%
▪ Radial margin status in wide local excision specimens is recorded.	>95%	100%

Pre-operative localisation	TARGET	MMUH COMPLIANCE for 13 week sample
Patients with clinically occult lesions, or where there are doubts about the location of the tumour, shall have pre-operative localisation guided by ultrasound or by stereotactic mammography equipment / X-ray (Standard 5.10).	>95%	*See Standard 5.10 below

What the data showed

*** Histopathology data (Standard 7.13 A)**

Targets were achieved for all requested data pertaining to Standard 7.13 A, with the exception of a patient with a lymphovascular invasion which the centre stated was recorded in 84% of cases. The Quality Review team observed during on-site patient healthcare record review, that a number of histopathology reports did not include a reference to the presence of lymphovascular invasion. **(see MDT1)**

*** Pre-operative localisation (Standard 5.10)**

Based on the Access and Clinical Effectiveness data submitted by MMUH for the 13-week sample time period from 1 June 2009 to 30 August 2009, the centre reported that a small number of patients were assessed as having a clinically occult lesion, of these, four had surgery. Three had pre-operative image-guided localisation and it was not clinically appropriate for the one. The Standard target is achieved.

Overall, the service had the essential elements as described in 7 (a).

Essential Element 7 (b)

The service should ensure that the necessary arrangements are in place to undertake effective clinical audit activities that include the systematic and critical analysis of the quality of care being provided, the procedures being used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.

Findings Essential Element 7 (b)

A key component of clinical audit is that performance is reviewed (or audited) with a supporting framework to enable improvements to be made if required. At MMUH, clinical audit of mortality and morbidity was undertaken as part of the general surgical division. At the time of the Review, specific SBD clinical audit was not integral to the quality assurance mechanisms within the SBD service. However, the SBD service did produce an annual report of patient activity.

The Authority found that the service had some SBD-specific clinical audit systems in place. However, at the time of the Review, these required further development and integration within the SBD governance structures. **(see CE1)**

Clinical Effectiveness: Conclusion

The Authority found that for the 13-week sample period from 1 June 2009 to 30 August 2009, a total of 44 patients newly diagnosed with primary breast cancer were seen at the SBD service at MMUH.

The Authority concluded that for the 13-week sample period from 1 June 2009 to 30 August 2009, the SBD service at MMUH had most of the necessary arrangements in place to demonstrate clinical effectiveness. However, a number of histopathology reports reviewed by the Authority did not include a reference to the presence of lymphovascular invasion. The Authority has made recommendations on the remaining areas to be addressed.

Clinical Effectiveness: Recommendations

CE1. The service should incorporate specific symptomatic breast disease clinical audit activities within the Hospital's clinical governance structure to systematically and critically analyse the quality of care provided.

5 Conclusion

5.1 Overview

The purpose of this review was to assess whether the eight designated centres were meeting the National Quality Assurance Standards. This journey began in autumn 2007 when the Authority announced the commencement of the National Quality Review Programme to assure members of the public by the end of 2009 as to whether hospitals providing symptomatic breast disease services were meeting the Standards and thereby have the systems, processes and controls to deliver and maintain the added value and standards expected in a designated centre.

There is evidence that the overall Quality Review Programme – together with the Standards – has been a focus for change and improvement in the quality and safety of symptomatic breast disease services. The Quality Review Programme provided guidance to the centres in their journey towards endeavouring to meet the Standards at a time of significant service change as the NCCP implemented the plan to move to eight designated centres, requiring a phased process to reflect the evolving nature of the service.

The early phases of the Quality Review Programme provided the eight centres with a focus for planning and prioritising actions needed as they continued to strengthen their arrangements for the SBD service as they progressed towards meeting these Standards by the end of 2009.

In April 2008, MMUH undertook a self-assessment exercise against the Standards and had a resulting score for all elements in a range between 68.4% and 100% compliance. MMUH had completed the self-assessment questionnaire using information from a live data system, database extractions, an annual report, snap-shot audits and professional judgment.

In autumn 2008, the Authority found that MMUH had the appropriate IT systems and personnel in position to facilitate continuous routine monitoring of performance against the Standards. However, the centre did not demonstrate that it was able to assure itself that it was meeting the Standards.

In January 2009, during phase 3 of the Quality Review Programme, the Authority issued a number of broad recommendations in relation to the implementation of effective governance arrangements to oversee the safe transition to a designated centre. These included the nomination of a lead clinician, developing and monitoring a prioritised implementation plan, and formalising a reporting mechanism to the National Cancer Control Programme.

At this stage in the National Quality Review Programme, the SBD service at the MMUH should be meeting the Standards. The Quality Review focused on seven identified themes derived from the Standards and work previously conducted by the Authority around symptomatic breast disease and patients' experiences. In doing so, it was essential that the Quality Review assessed and reflected patients' perception and actual experiences of the services provided and utilised pertinent information and data to assess the service.

This report and resulting conclusion details the performance of the symptomatic breast disease service at MMUH. These key conclusions are as follows:

5.2 Findings

5.2.1 Governance

The SBD service at the MMUH had corporate and clinical governance structures. The role and responsibilities of Lead Clinician was shared between a consultant surgeon and radiologist. There was an organisational framework that incorporated clinical decision making. However, the service needed to strengthen the governance arrangements through greater integration and formal monitoring with the Standards.

The SBD service had a well defined multidisciplinary structure with a clear patient referral, clinical pathway and leadership arrangements with GP communication and referral processes. However, all consultant surgeons do not have allocated theatre time.

The service should ensure the service level agreement with the third-party provider of radiation oncology is effectively implemented.

Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

5.2.2 Multidisciplinary approach

The service was actively committed to delivering triple assessment through a multidisciplinary approach. The service had the necessary operational policies in place to ensure that the multidisciplinary team was involved in all clinical decision making and treatment planning. Wherever possible, patients were central to the MDT process and encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary multidisciplinary arrangements in place for the delivery of safe care. The Authority has made recommendations on the remaining areas to be addressed**.**

5.2.3 Skills, Education and Training

There was evidence that the service had a number of arrangements in place to ensure that the core team has the necessary training and clinical expertise in breast cancer, and undertake continuous professional education and development on a regular basis.

The specialist breast care nurses are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service.

Overall, the Authority found the SBD service at the Mater Misericordiae University Hospital had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service

5.2.4 Person-centred Care

The symptomatic breast disease service has written information about breast disease, cancer and local support groups. Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment.

The Authority concluded that the SBD service at the MMUH had most of the necessary arrangements and facilities in place to deliver person-centred care. The Authority has made a recommendation on one area to be addressed.

5.2.5 Data Management

The SBD service had a comprehensive integrated information management system with a well established Patient Analysis and Tracking System which facilitated data collection at all critical points in the patient pathway.

The centre had a data set and dictionary and a data capture policy in place which included an overview of the data validation process in place. The centre should further develop its data validation policy, increase the frequency of a standardised data validation process that includes the patient healthcare record and necessary performance information to ensure the timely delivery of a safe quality patient service, increase the frequency of data validation, and ensure the necessary formal monitoring arrangements are in place. The Breast Health Centre produces an annual report which includes all relevant patient demographic, access and clinical information.

The Authority concluded that the SBD service at the MMUH had most of the necessary data management arrangements in place. However, the service had no data pertaining

to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider.

5.2.6 Access

At the time of the Review, the SBD service at MMUH had been fully operational since June 2009 following refurbishment. Since re-opening, the service was reviewing the backlog of the non-urgent patient waiting list which had been deferred during the refurbishment with the agreement of the NCCP.

The SBD service at the MMUH had the capacity to effectively manage the necessary access times for urgent and non-urgent referrals. However, outstanding areas which should be addressed by the service include consultant operating theatre access and inpatient access.

The Authority concluded that patient access timelines for urgent and non-urgent triaged patients must be bedded down and the necessary monitoring controls integrated within the governance structure. In addition, to provide the optimum service and to effectively use the available clinical resources, it is essential that theatre and inpatient access is reviewed.

5.2.7 Clinical Effectiveness

The Authority found that for the 13-week sample period from 1 June 2009 to 30 August 2009, a total of 44 patients newly diagnosed with primary breast cancer were seen at the SBD service at MMUH.

The Authority concluded that for the 13-week sample period from 1 June 2009 to 30 August 2009, the SBD service at MMUH had most of the necessary arrangements in place to demonstrate clinical effectiveness. However, a number of histopathology reports reviewed by the Authority did not include a reference to the presence of lymphovascular invasion. The Authority has made recommendations on the remaining areas to be addressed.

Overall Conclusion

Based on the evidence of this Quality Review, the Authority concluded that while there remained opportunities for improvement, and where indicated the Authority has made recommendations, the symptomatic breast disease service at the Mater Misericordiae University Hospital was meeting most of the core quality and safety requirements as set out in the Standards.

Overall, the service at the Mater Misericordiae University Hospital had, at the time of the Quality Review, the systems, processes and controls to deliver and maintain the added value and standards expected in a national specialist centre and to ensure sustainability going forward.

The Mater Misericordiae University Hospital should develop, publish and implement an action plan against the recommendations.

The Authority would like to acknowledge the cooperation of managers and clinicians in the designated centres and the National Cancer Control Programme in the conduct of this Quality Review. The SBD service at MMUH deserves recognition for the changes implemented and the improvements made to date. The Authority would also like to thank the service-user representative from Europa Donna Ireland and the many patients who gave up their time to share their stories and experiences with us for the benefit of current and future patients.

6 References

(1) National Quality Assurance Standards for Symptomatic Breast Disease Services – Developing Quality Care for Breast Services in Ireland Health Information and Quality Authority (2007).

(2) Health Information and Quality Authority. 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. Dublin: Health Information and Quality Authority; 2008.

(3) Health Information and Quality Authority. Report of the investigation into the provision of services to Ms A by the Health Service Executive at University Hospital Galway in relation to her symptomatic breast disease, and the provision of Pathology and Symptomatic Breast Disease Services by the Executive at the Hospital. Dublin: Health Information and Quality Authority; 2008.

(4) Health Information and Quality Authority. Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis. Dublin: Health Information and Quality Authority; 2009.

(5) Health Service Executive website. National Cancer Control Programme (NCCP), About NCCP/the Mater Misericordiae University Hospital. Accessible at: http://www.hse.ie/eng/services/find a service/hospscancer/national cancer control programme/About NCCP/The Mater Misericordiae University Hospital.html. Accessed January 2010

7 Glossary of useful terms and abbreviations

AMNCH: Adelaide and Meath Hospital, Incorporating the National Children's Hospital, Dublin

Axillary: pertaining to the armpit area, including the lymphnodes that are located there

BreastCheck: BreastCheck is a government-funded programme providing breast screening, and invites women aged 50 to 64 for a free mammogram on an area-by-area basis every two years (see NBSP)

Carcinoma: cancer of the cells covering the internal or external surfaces of the body

Chemotherapy: the treatment of disease, usually cancer, using chemical substances (drugs), the aim of which is to destroy cancer cells

Clinical audit: the systematic, critical analysis of the quality of care, including procedures used for diagnosis and treatment, use of resources and resulting outcome and quality of life for the patient

Clinical directorates: discrete service units in which all the service, workforce planning, budgeting and overall management arrangements are held by one team under the direction of the clinical director

Clinical examination coding: relates to triple assessment scores for clinical examination, radiological result and histopathology result

Clinical practice guidelines: clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances

Clinically occult lesion: A lesion or area of abnormal tissue which cannot be located under clinical examination.

CNS: clinical nurse specialist. The nurse specialist as a nurse who is prepared beyond the level of a nurse generalist and authorised to practice as a specialist in a branch of the nursing field

Computerised tomography (CT): the practice of taking images of the body in a number of selected planes using radiography, and thereby building a three-dimensional image of an area

Consultant: a consultant is a registered medical practitioner in hospital practice who, by reason of his / her training, skill and experience in a designated specialty, is consulted by other registered medical practitioners and undertakes full clinical responsibility for patients in his / her care, or that aspect of care on which he / she has been consulted, without supervision in professional matters by any other person. Consultants include surgeons, physicians, anaesthetists, pathologists, radiologists, oncologists and others

CPD: continuing professional development

CT: computerised tomography

DCIS: ductal carcinoma in situ

Ductal carcinoma in situ (DCIS): a non-invasive condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to other tissues in the breast

False negative case: a case that turns out (within a period of two years) to be carcinoma despite a negative cytology or core result (this will by necessity include some patients in whom an area different from the lesion was sampled but who present with an interval cancer)

False positive case: a case that was given the clinical examination cytology or biopsy code of C5 or B5 and which turns out at open surgery to be a benign lesion

Fine needle aspiration (FNA): use of a needle attached to a syringe to withdraw cells from a tumour

FISH: fluorescent in situ hybridisation

Fluorescent in situ hybridisation (FISH): fluorescence in situ hybridisation (FISH) is a test that "maps" the genetic material in a person's cells. This test can be used to visualize specific genes or portions of genes. FISH testing is done on breast cancer tissue removed during biopsy to determine whether the cells have extra copies of the HER2 gene. The more copies of the HER2 gene that are present, the more HER2 receptors the cells have. These HER2 receptors receive signals that stimulate the growth of breast cancer cells

Governance structure: The governance arrangements that clearly describe responsibilities, delegated levels of authority, reporting relationships and **accountability within an organisation**

GP: general practitioner

HER2: human epidermal growth factor receptor 2 is a protein involved in normal cell growth. It is found on some types of cancer cells, including breast and ovarian. Cancer cells removed from the body may be tested for the presence of human epidermal growth factor receptor 2 to help decide the best type of treatment

Histopathology: the study of diseased cells and tissues using a microscope

Hormone receptor status: the level of certain proteins, called hormone receptors, in cancer tissue. Hormones can attach to these proteins. A high level of hormone receptors may mean that hormones help the cancer grow

HSE: Health Service Executive

Invasive breast cancer: cancer that has spread from where it started in the breast into surrounding, healthy tissue. Most invasive breast cancers start in the ducts (tubes

that carry milk from the lobules to the nipple). Invasive breast cancer can spread to other parts of the body through the blood and lymph systems

IT: information technology

KPI: key performance indicator

Lymph nodes: lymph nodes are found throughout the body, and act as filters or traps for foreign particles and are important in the proper functioning of the immune system. They become inflamed or enlarged in various conditions, which may range from trivial, such as a throat infection, to life-threatening such as cancers

Lymphoedema: a condition in which extra lymph fluid builds up in tissues and causes swelling. It may occur in the arm if lymph vessels are blocked, damaged, or removed by surgery

Magnetic resonance imaging (MRI): a technology that uses radio waves and a powerful magnet linked to a computer to create detailed images of areas inside the body. These images can show the difference between normal and diseased tissue

Mammography: the use of film or a computer to create an X-ray image of the breast

Medical oncology: The specialty of medical oncology is dedicated exclusively to the study of cancer and how it is best treated, particularly with systemic therapy

Morbidity: a diseased condition or state. The incidence of a particular disease or group of diseases in a given population during a specified time period.

MRI: magnetic resonance imaging

Multidisciplinary team (MDT): a term used to describe a treatment planning approach or team that includes a number of doctors and other health care professionals who are experts in different specialties (disciplines)

Multidisciplinary team meetings: meetings where the multidisciplinary team discuss the results / care / treatment plan of the patient

NBSP: National Breast Screening Programme (see Breastcheck)

NCCP: National Cancer Control Programme

Network Manager: within the HSE structure, the network managers are responsible for a group of hospitals within a network

Non-urgent: the non-urgent triage category includes patients that have presented to the referring GP with signs and symptoms of breast disease and these patients should be seen at the centre within 12 weeks

NQAS: National Quality Assurance Standards for Symptomatic Breast Disease Services

Oestrogen receptor status: the presence or absence of oestrogen receptors (proteins to which oestrogen will bind) in cancer cells. If the cells have oestrogen receptors, they may need oestrogen to grow, and this may affect how the cancer is treated

PACS: Picture Archive and Communication System

PAS: Patient Administration System

PATS: Patient Analysis and Tracking System

Prosthesis: a breast prosthesis is a breast form worn either inside a bra or attached to the body

Protocol: a detailed plan of a medical treatment or procedure

Radial margin status: the margin status is described as negative or clean when the pathologist finds no cancer cells at the edge of the tissue having been removed in cancer surgery, suggesting that all of the cancer has been removed. The margin status is described as positive or involved when the pathologist finds cancer cells at the edge of the tissue having been removed in cancer surgery, suggesting that all of the cancer has not been removed

Radiation oncology (or radiotherapy): Cancer treatment that uses high-energy electromagnetic radiation such as X-rays to kill cancer cells. During radiotherapy, a significant amount of healthy normal tissue is sometimes irradiated. To reduce the side effects caused by this, the radiation dose is often split into a number of treatments, enabling the normal healthy tissue to recover before the next treatment is given

Radiological abnormality: an abnormality detected by radiation (such as X-rays) or other imaging technologies (such as ultrasound, mammography and magnetic resonance imaging) used to diagnose or treat disease

SBCN: specialist breast care nurse

SBD: symptomatic breast disease

Sentinel node biopsy: removal and examination of one or a few lymph nodes to which cancer cells are likely to spread from a primary tumour. Used to predict nodal stage of disease

SLA: service level agreement

Sonographic abnormality: an abnormality detected by ultrasound

SOP: standard operating procedure

Specialist centre: where disease specific care is delivered by specialist consultants and other specialist healthcare professionals

Stereotactic biopsy: a biopsy procedure that uses a computer and a 3-dimensional scanning device to find a tumour site and guide the removal of tissue for examination under a microscope

Symptomatic: individuals who have one or more symptoms (e.g. breast lump) that may be due to a disease (e.g. breast cancer)

TNM: tumour nodes metastasis

Triage category: category to which medical treatment is prioritised based on urgency (i.e. urgent, non-urgent)

Triage process: the process of assigning priorities of medical treatment based on urgency

Triple assessment clinic (TAC): a clinic at which clinical examination, imaging and pathology tests are carried out in the diagnosis of breast disease

Ultrasound: a procedure in which high-energy sound waves are bounced off internal tissues or organs and make echoes. The echo patterns are shown on the screen of an ultrasound machine, forming a picture of body tissues called a sonogram

Urgent: the urgent triage category includes patients that have presented to the referring general practitioner (GP) with signs and symptoms of breast disease and these patients should be seen at the centre within two weeks

Appendices

Appendix 1

Recommendations made by the Authority to centres in January 2009, following validation review.

In order to continue to support the transition from designated specialist centres to national specialist centres, the Authority therefore strongly recommends that each designated centre should:

1. Establish clear governance structures for overseeing the transition from a designated centre to a specialist centre. This should include the nomination of a senior manager / clinician to lead, be supported by, and accountable to the board / senior management team of the hospital in relation to progress towards this goal and the implementation plan as specified in recommendation 2 below. The structures should also take into account establishing formal linkages with all neighbouring hospitals that will be transferring the care for patients with symptomatic breast disease to designated centres, where applicable, and also a reporting mechanism into the National Cancer Control Programme.

2. Review the interim report* and develop a prioritised implementation plan to address the gaps in the outstanding requirements – this plan should be signed off by the National Cancer Control Programme.

3. Work with other designated centres, under the coordination of the National Cancer Control Programme, to agree and address areas in need of standardisation. For example, referral mechanisms, diagnostic reporting conventions and core patient pathways to ensure consistency in approach across the country.

4. Ensure that the main risks associated with the transition to becoming a specialist centre are identified and measures put in place to manage and mitigate against them (Section 13 of the self-assessment tool provided the important questions that centres should be addressing).

** Following the validation process, the Authority provided each centre with a tailored interim report. As this was feedback reported at an interim stage of an ongoing Quality Review Programme, the Authority did not publish the reports. The interim reports took the form of a commentary on the quality of evidence used by the centres to complete the validation assessment questionnaire. This included recommended steps for the future.*

Appendix 2

Methodology - National Quality Review Programme – Phase 4

1.1 Phase 4. Quality review visit, October / November 2009

Phase 4 of the Quality Review involved an in-depth review of the performance of the designated centres in order to assess their performance against the Standards. For the purposes of assessment, all 285 Standards were categorised into a format that facilitated the Quality Review.

The development of the assessment methodology for Phase 4 of the Quality Review Programme, covered in this report, involved two main stages:

- *categorisation of the Standards*
- *assessment process.*

1.1.1 Categorisation of the Standards

The National Quality Assurance Standards (the Standards), which were mandated in 2007, are structured according to the patient pathway from referral, through diagnosis, treatment and aftercare. This lends them to be easily used in the day-to-day management of the service. However, due to the multidisciplinary nature of the service, there is some crossover and repetition of Standards between the specialties of care that does not facilitate a straightforward assessment against the Standards. Consequently, for the purposes of assessment for Phase 4 of the Quality Review, all 285 Standards were categorised into a format that facilitated the Quality Review with a particular focus on the patient journey.

A number of key representative Standards were identified during the categorisation phase (see Appendix 3).

These included:

- those Standards that relate to key events of the patient experience from referral to treatment and beyond
- the fundamental patient quality and safety requirements
- clinical practice guidelines
- the essential requirements of the service.

These key representative Standards were subsequently categorised into a format that facilitated the Quality Review using seven generic themes as follows:

- Governance
- Multidisciplinary Approach
- Skills, Education and Training
- Person-centred Care
- Data Management
- Access
- Clinical Effectiveness.

Recognising that centres may be at different stages of development towards implementing the full range of Standards, the Authority identified the really important factors in each theme that must be in place for quality and safety. These ***essential elements*** that each designated centre must have in place as the foundation for safe, high quality symptomatic breast disease care are set out in **Figure 2** in the main report.

All the essential elements are based on the Standards with the exception of the *Governance* essential element, which is derived from the Authority's recommendations from previous investigations in relation to SBD services.

It is important to note that the Standards, as they were adopted by the Board of the Authority and mandated by the Minister for Health and Children, will remain in place and will continue to be used for monitoring the performance of designated centres until such a time that the Standards are revised.

The Authority used multiple sources of evidence to inform its assessment of the symptomatic breast disease (SBD) service at each designated centre. In drawing conclusions about the governance arrangements at the centre, the assessment was also guided by the recommendations from work previously conducted by the Authority in relation to symptomatic breast disease care.

1.1.2 Assessment Process

The themes of Governance; Multidisciplinary Approach; Skills, Education and Training; Person-centred Care; Data Management; Access and Clinical Effectiveness provided the foundation upon which the assessment process for Phase 4 of the Quality Review was designed and developed. A number of instruments and processes were identified to generate pertinent, consistent and reliable information. The assessment process can be broken down into three main stages.

1.1.3 Stage 1, Pre-visit

(i) Pre-visit documentation request (17 August 2009)

The Authority requested documentation (see Appendix 4) from the designated centre in advance of the on-site assessment visit in order to assess the documentary evidence of

the local arrangements. This documentation was submitted to the Authority within three weeks of the Authority's request.

(ii) Pre-visit data request (31 August 2009)

The Standards set out the elements for the provision of safe, high quality symptomatic breast disease care and define how the quality of service provided in such centres can be measured. The Standards include clinical practice guidelines, standards and quality objectives with outcome measures that are required by centres to assure themselves and the public that they are providing safe high quality care. In July 2009, the NCCP identified, from the Authority's Standards, a number of key performance indicators (KPIs). The NCCP requires each designated centre to report on their performance against these KPIs to the NCCP on a monthly basis.

The Authority requested the designated centres to submit data specific to the Standards selected by the Authority and some of the related NCCP KPIs in advance of the on-site assessment (see Appendix 5).

The data request related to two separate data samples: activity data, and access and clinical effectiveness data.

Activity data: seven-month sample period

- The first part of the data request related to activity data for new patients seen at the SBD service for the seven-month sample time period of 1 January 2009 to 1 August 2009. (Due to a refurbishment programme, the Mater Misericordiae University Hospital provided data for the period 1 June 2009 to 1 November 2009.)

This data informed the preliminary overview of the activity of the service.

Access and clinical effectiveness data: 13-week sample period

The second part of the data request related to access and clinical effectiveness data for a selected sample group of patients who had been newly diagnosed with primary breast cancer and seen at the service during the 13-consecutive-week sample period from 1 April 2009 to 30 June 2009. (Due to a refurbishment programme, the Mater Misericordiae University Hospital provided data for the period 1 June 2009 to 30 August 2009.) This sample time period was selected in order to review up-to-date performance data which was as close as possible to the time of the on-site assessment visit. The data requested related to specific access and clinical effectiveness Standards in the patient treatment pathway from first referral through to the first therapeutic operation.

The centres were also requested to submit documentation relating to their data management process, which included the centres' data set, data dictionary or data definition document and their standard operating procedure for validating data.

(iii) Review of pre-visit documentation received (September 2009)

In order to assess evidence of compliance, the Authority reviewed the documentation submitted by each centre against the Standards under the themes of Governance; Multidisciplinary Approach; Skills, Education and Training; Person-centred Care; Data Management; Access and Clinical Effectiveness.

(iv) Review of pre-visit data received (September/October 2009)

In order to assess evidence of compliance with the Standards, the submitted data was reviewed by the Authority. The Authority also reviewed the submitted documentation relating to the centres' data management processes in order to assess the services' capacity to collect required data for reporting against the Standards. The findings of this part of the process are described in Chapter 4 of the main report, Findings.

The Authority notified the centres of the date of the on-site assessment visit at least one month in advance of the visit. The centre also received a description of the format of the assessment process along with a programme for the on-site visit.

1.1.4 Stage 2, the on-site visit

The Authority met and engaged with key staff members of the symptomatic breast disease team and a number of service users at each designated centre. The on-site visit took place over the course of two days during October and November 2009. The main elements of the on-site visit were as follows.

(i) On-site documentation review

Where further documentation was required in addition to documentation received before the on-site assessment, it was reviewed by the Authority on site in order to assess evidence of compliance with the Standards.

(ii) On-site validation of data

The Authority carried out a data validation process on site. As part of this validation:

- the Authority cross-checked this data against the patient healthcare record for 25% of the sample group
- patient healthcare records were selected proportionately by diagnosis (invasive breast cancer / ductal carcinoma in situ) and by surgical (wide local excision / mastectomy) and non-surgical treatment to ensure a cross section of patients referrals were validated
- patient healthcare records were randomly selected within these categories
- a coded number was assigned to each patient healthcare record reviewed to ensure patient confidentiality.

The purpose of the validation of 25% of the patient healthcare records was to assure the accuracy and reliability of the data submitted by the centre in relation to the access and clinical effectiveness data for the selected sample group of patients newly diagnosed with primary breast cancer and seen at the centre during the 13-consecutive-week period.

(iii) Data system demonstration

As part of the on-site data validation, in order to demonstrate the centre's capacity to collect pertinent data pertaining to the patients care pathway, each centre demonstrated its data management information system to the Authority.

(iv) Observation in clinical areas

In order to obtain information about the centre's environment and physical facilities, the Authority visited a number of the centre's facilities. This included structural and equipment observation of both inpatient and outpatient diagnostic and therapeutic facilities.

(v) Interviews

The Authority interviewed relevant staff using a standardised set of questions based on the themes identified in the Standards. This afforded the opportunity for the centres to provide further information and the Authority to gain clarification on any issues that would inform the Authority's findings.

Interviewees at each centre included:

- chief executive officer / general manager
- lead clinician
- data manager
- specialist breast care nurse
- multidisciplinary team
- NCCP cancer network manager

- hospital network manager where relevant.

At each centre, an interview was carried out with the local representative of the NCCP in order to explore the relationship between the centre and the NCCP. This interview contributed to part of the national report.

(vi) Discussion group with patients

In order to explore the provision of patient-centred care from a patient's perspective, each designated centre was asked by the Authority to select six service users with a diagnosis of breast cancer for participation in an Authority-led discussion group. To take account of the realities of the patient experience, the Authority included, as part of the Quality Review team, a service-user representative who led discussion groups with a selection of patients.

1.1.5 Stage 3, following the on-site visit

The Authority's findings for phase 4 of the Quality Review have been published in two separate formats:

- an individual public report for each centre
- a national report outlining the key findings for the eight designated centres.

A draft report of each centres' assessment findings was issued to that centre for factual accuracy. The centres were invited to respond in writing to the Authority within five working days to make any comments on the draft report. Every comment received was carefully considered by the Authority prior to finalising the report.

1.2 Quality assurance

To maximise the consistency and reliability of the assessment process for Phase 4 of the Quality Review, the Authority put a series of quality assurance processes in place. These included:

- a single communication approach with all eight designated centres
- internal peer review at various stages during the development of the assessment methodology
- consistency in the design and development of the assessment methodology
- consistency in having a single team of assessors attending all eight designated centres as part of the Quality Review
- a standardised interview format
- the standardised collection and recording of information using an electronic assessment tool

- ensuring that there are clear links between judgments reached and the evidence on which they are based
- each assessment report being quality reviewed by Authority personnel, external to the Quality Review assessment team
- each centre being invited to review each individual draft report for the purpose of factual accuracy
- acceptance and sign off of the local and national reports by the Chief Executive and Board of the Authority

Appendix 3

Key Representative Standards

NQAS reference	NQAS
	Theme: Governance (Total 7)
1.1	Specialist breast centres shall provide care / services to a population size of approximately 300,000–350,000. They shall have facilities to provide care / service to more than 150 newly diagnosed patients with primary breast cancer per year. All specialist breast centres shall be separate entities, rather than part of a general surgical clinic, and shall have facilities for at least one triple-assessment clinic per week.
1.13	All personnel involved in specialist breast centres shall have allocated, dedicated time for satisfactory conduct of work.
4.4	The patient shall relate to a specific clinician at each stage of treatment, e.g. the consultant surgeon in the early stages of the disease, the consultant medical oncologist during the phase of adjuvant treatment, the consultant radiation oncologist and, where appropriate, the palliative care physician. These arrangements shall be explicit and understood by the patient.
13.1	The *Report on the Development of Services for Symptomatic Breast Disease* (2000) and, more recently, the National Cancer Forum (2006) have recommended that a certain number of specialist breast centres be developed in Ireland and supported by staffing and physical structure to allow each centre to operate to a high standard of care delivered with skill, compassion and efficiency to all patients with breast complaints.
13.2	The requirements for each centre have been set out and justified in previous documents and supported by publications from the international scientific and medical literature. Justification for specialised centres derives from the convincing evidence of improved outcomes, both in survival and quality of life, for patients treated by specialists in the context of a multidisciplinary team approach to care.

13.3	The nomination and designation of centres should be announced without further delay and resources allocated immediately to support each centre. Public support for and confidence in these centres can come only when they are active and measure up to the standards defined in this document.
13.6	It should be expected that detailed documentation of activity be recorded in each centre so that administrative and clinical audit can be undertaken. An identical and comprehensive data set of information should be in place in each centre so that the activity centres can be compared with each other regularly, probably once a year.
	Theme: Multidisciplinary Approach (Total 14)
1.2	The specialist breast centres shall hold at least one triple assessment clinic per week for newly referred patients with suspected breast disease.
1.3	A functioning multidisciplinary team must be available at the breast centre. The core personnel required for this team are: ▪ consultant breast surgeon and team ▪ consultant histopathologist ▪ consultant radiologist and radiographer ▪ clinical nurse specialist breast care ▪ consultant radiation oncologists ▪ consultant medical oncologists ▪ consultant plastic and reconstructive surgeons ▪ clinic staff ▪ administrative staff.
3.20	Following triple assessment, and when the diagnosis is of breast cancer, the patient shall be given an appointment for a return visit within two weeks so that the definitive diagnosis can be given.
3.27	Diagnostic procedures for breast disease requires triple assessment: 1. Clinical examination. 2. Imaging by mammography and / or ultrasound. 3. Pathology sampling.

4.1	A multidisciplinary breast team meeting shall be held at least weekly to discuss every patient who has had a core biopsy or FNA and to plan subsequent treatment for the patient.
4.2	A session must be allowed for attendance by representatives from all specialties at weekly team case management and audit meetings.
4.3	Information necessary for effective team functioning and clinical decision-making shall be available at each meeting, including a list of patients to be discussed, imaging and pathology and copies of relevant clinical and diagnostic information and reports.
4.6	Team members shall be prepared for the multidisciplinary team meeting. Preparation for and attendance at meetings shall be recognised as clinical commitments and time shall be allocated accordingly.
4.7	Patients discussed at the multidisciplinary team meeting shall include: (1) all new patients who have clinical or radiological / sonographic abnormalities, (2) all patients who have had triple assessment, (3) all patients following the first therapeutic operation, and (4) those for whom, at any time, discussion at the meeting is deemed appropriate.
4.8	Every patient undergoing core biopsy, surgical biopsy or fine needle aspiration (FNA) shall be discussed at the multidisciplinary meeting to ensure concordance of data.
4.9	A definitive diagnosis (cancer or a benign condition) shall be achieved within two weeks of an urgently referred patient's attendance at the specialist breast centre.
4.14	Local protocols shall be in place to ensure patient confidentiality during multidisciplinary meetings.
6.20	The consultant radiologist together with the consultant surgeon shall be centrally involved in the organisation of the diagnostic breast service. An immediate report shall be available to the consultant surgeon at the time of triple assessment.

14.2	Audit and other issues of relevance to data monitoring and management shall be discussed at the multidisciplinary team meetings.
	Theme: Skills, Education and Training (Total 10)
3.11	All clinical members of the breast care multidisciplinary team shall be trained in communication and counselling skills and shall maintain such training on a continual basis.
5.1	Individual consultant surgeons shall treat a minimum of 50 and a maximum of 150 new patients with breast cancer per year and must attend at least one diagnostic clinic per week.
5.34	Sentinel node biopsy shall be carried out only by surgeons who have had formal training in the technique and who have audited their accuracy in at least 30 cases.
6.9	Radiographers shall attend regular update courses.
6.12	In order to maintain expertise, a radiographer involved in mammography shall perform a minimum of 20 mammographic studies a week.
7.2	Consultant histopathologists involved in the delivery of the symptomatic breast pathology service shall participate in a quality assurance programme.
9.7	All healthcare professionals administering chemotherapy shall attend a training course at least once every two years.
10.2	The special breast care nurse (SBCN) shall have undergone specific training and have officially recognised qualifications in oncology and breast care. The training in Ireland currently involves the acquisition of an officially approved higher diploma in oncology and breast care.
12.1	All specialists involved in the care of patients with breast disease shall have undergone specific training in a specialist breast centre.
12.2	All members of the team shall undertake regular continuing professional education.

	Theme: Person-centred care (Total 14)
1.14	Each specialist breast centre shall have dedicated purpose-built physical facilities suitable for the care of patients with breast complaints.
1.15	The administrative and clinical examination areas and the diagnostic areas shall all be in close proximity, preferably in a single dedicated area.
1.18	Specific mandatory requirements include inpatient beds and dedicated operating time.
1.19	Each specialist breast centre shall be equipped with basic mammography and stereotactic mammography equipment, together with the required processing equipment and ultrasound machine.
2.7	At key points in the patient's clinical pathway, there shall be coordination and integration of services with the general practitioner (GP) and the specialist breast centre. ▪ key information shall be provided to GPs in relation to the services provided by the breast centre ▪ information and communication pertinent to the patient shall be provided to the GP in a timely manner.
3.1	The patient shall be offered clear, objective, full and prompt information in verbal, written and other appropriate formats. Special and minority needs shall be catered for.
3.2	Information provided in leaflets and other formats, both oral and written, shall be in clear and comprehensible language. Patient groups should be involved in their compilation and design.
3.5	Patients' preferences regarding who should accompany them at the time when their diagnosis and treatment are being discussed should be taken into account.
3.9	The patients' records shall include a checklist to show what information has been provided.

3.10	Patients shall be asked to provide feedback on their experience of the treatment, including all side effects, facilities and services. This feedback will be recorded.
3.19	Before attending, the patient shall receive information regarding procedures that may be undertaken at the specialist breast centre and the length of time they are likely to take.
3.21	A patient who is receiving a diagnosis of cancer shall have a clinical nurse specialist present at the time of consultation about the diagnosis. The specialist breast care nurse shall: ▪ be present to discuss the implications of treatment and provide advice and emotional support throughout the assessment process, and ▪ continue to provide information and support for the patient during the cancer continuum from diagnosis through to follow up.
11.2	Every patient shall have access to a Reach to Recovery or similar volunteer following breast cancer surgery.
11.5	Patients shall have access to a named person in the specialist breast centre with whom they can communicate at any time, usually the specialist breast care nurse.
	Theme: Data Management (Total 3)
14.3	There shall be agreed standardised data forms and definitions used to collect data in each unit. An IT system shall be in place to facilitate data collection.
14.6	A dataset definitions document will be required to outline clearly how each data field should be completed. This will ensure that no data field is open to interpretation and will speed up the data collection at each centre.
14.9	A minimum of 10% of the data should be validated and all data fields should be assigned a critical or a non-critical status. Guidelines listing the corrective actions to be taken will be required in cases where errors are found.

	Theme: Access (Total 8)
2.8	An urgent triaged patient referred by the GP is offered an appointment to attend the specialist breast centre within two weeks of receipt of the referral.
2.1.3	Routine Referrals – to be seen within 12 weeks. Routine referral relates to a patient whom the referring doctor considers to require an opinion or investigation at the specialist breast centre but where there is no clinical concern about breast cancer. These patients shall be seen within 12 weeks.
2.9	There shall be monitoring of breast centre capacity and demand to ensure an appropriate balance between urgent and non-urgent referrals. Following triage, the GP shall be informed of the waiting time.
6.14	An urgently referred patient has all imaging done in the first visit.
4.9	Definitive diagnosis of cancer is achieved within two weeks of an urgently referred patient's attendance at the specialist breast centre
4.11	A patient shall be offered admission for the first therapeutic operation within three weeks of definitive diagnosis.
11.8	Patient follow-up after primary therapy for early breast cancer shall be coordinated by one medical consultant skilled in the surveillance of cancer patients and breast examination. Rapid access to another member of the multidisciplinary team shall be facilitated as specific issues arise. A surgical oncologist is the most appropriate coordinating doctor for those patients who have been treated with surgery alone. For those patients who have received adjuvant chemotherapy, the coordinating physician should be a medical oncologist.
11.16	There shall be an open access policy to enable GPs or other healthcare professionals to refer patients back to the breast care team without delay if they suspect recurrent cancer or problems related to treatment for breast cancer.
14.1	Data regarding the patient's waiting times between referral and first appointment, between first appointment and receipt of diagnosis, and between diagnosis and surgery, shall be collected.

	Theme: Clinical Effectiveness (Total 11)
6.16	A non-operative diagnosis is achieved in benign and malignant disease.
5.32	For patients with sonographically normal lymph nodes and where the FNA or core biopsy does not demonstrate metastases, sentinel lymph node biopsy is recommended.
5.10	Patients with clinically occult lesions, or where there are doubts about the location of the tumour, shall have pre-operative localisation guided by ultrasound or by stereotactic mammography equipment / X-ray.
6.21	Patients with a diagnosis of invasive breast cancer shall have an ultrasound assessment of their axilla. Ultrasound of the axilla plays a central role in determining patients' suitability for sentinel node biopsy.
6.1	Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer.
7.13 A	To provide important and relevant data on patients with invasive breast carcinoma: • Histological tumour type is recorded ▪ Histological tumour grade is recorded ▪ Invasive tumour size is recorded ▪ The presence or absence of vascular invasion is recorded ▪ Posterior (deep) margin status is recorded ▪ Lympth node status is recorded
7.13 B	Oestrogen receptor status is available.
7.13 C	*HER2* status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH).
7.14	To provide appropriate data in patients with ductal carcinoma in situ (DCIS) ▪ DCIS grade is recorded ▪ Radial margin status in wide local excision specimens is recorded
8.4	The consultant radiation oncologist shall coordinate patient follow-up with surgery and medical oncology units.

9.11	Details of chemotherapy treatment shall be recorded by administering staff.

Appendix 4
Symptomatic Breast Disease Service Quality Review 2009
Documentation request prior to onsite quality review

Instructions for submitting documentation:

The Authority requests that:

1. All documentation is submitted in hard copy (copies of original documentation only)

2. Please indicate on each page as requested what documents you are submitting and the reasons why documents are not submitted.

3. All documents submitted should be referenced to the appropriate reference number on each page of this document.

4. All documentation, **including the completed documentation request checklist**, must be submitted **no later than 5pm on Wednesday 9th September 2009** to:

   The Health Information and Quality Authority,
   Healthcare Quality and Safety Directorate,
   Head Office,
   Mahon City Gate,
   Mahon,
   Cork

   5. Any queries in relation to documentation to be submitted should be emailed to _____@hiqa.ie

Under Section 12 of the Health Act 2007, the Authority request that you submit the following information: **1. Governance**		
No.	**Documentation Required**	**Please tick if document is attached or state reason if not attached**
1.1	**Governance Structure** (Indicate operation linkages and reporting structures between both)	
	1.1.1 Organogram for the Governance structure of the hospital	
	1.1.2 Organogram for the Organisation structure of the Symptomatic Breast Disease Service	
1.2	**Monitoring compliance with the National Quality Assurance Standards**	
	1.2.1 Terms of reference for the committee responsible	
	1.2.2 Membership of the committee	
	1.2.3 Scheduling of meetings for this committee from 1st January 2009 to week commencing 17th August 2009	
	1.2.4 Minutes of all meetings from 1st January 2009 to week commencing 17th August 2009	
1.3	**Clinical Leadership**	
	1.3.1 Standard operating procedure / Policy for clinical leadership, indicating the most responsible person for the patient as they transfer through the pathway of care.	
1.4	**Clinical Risk Management:**	
	1.4.1 Risk Management policy	
	1.4.2 Clinical Incident Reporting policy	
	1.4.3 Number of clinical incidents / adverse events pertaining to SBD services reported between 1st January 2009 and week commencing 17th August 2009	
	1.4.4 Quality improvement initiatives implemented as an action following investigation of identified incidents	

1.5	**Service Level Agreements**	
	1.5.1 Service Level Agreements or equivalent document for services being provided by a third party at any stage of the patients care pathway (i.e. pathology or radiology or other service)	
1.6	**Core Personnel**	
	1.6.1 Complete the attached form (Appendix 1) detailing the full complement of core personnel to the symptomatic breast disease service	
1.7	**Confidentiality**	
	1.7.1 Standard operating procedure / policy for patient confidentiality	
2. Person Centred Care		
No.	**Documentation Required**	**Please tick if document is attached or state reason if not attached**
2.1	**Patient Information**	
	2.1.1 Standard operating procedure / policy for developing and providing patient information	
	2.1.2 List names / titles of all patient information leaflets provided by the Centre, indicating on the list whether the leaflet was produced by the Centre or sourced externally	
	2.1.3 Checklist template used to document information provided to the patient	
	2.1.4 Consent policy for patients	
2.2	**Patient Satisfaction with the symptomatic breast disease service**	
	2.2.1 Patient Satisfaction data specific to symptomatic breast disease services from 1st January 2009 to week commencing 17th August 2009	
	2.2.2 Complaints policy	

	2.2.3 Number of complaints received and subsequent action plans for the symptomatic breast disease service from 1st January 2009 to week commencing 17th August 2009	
2.3	**General Practice**	
	2.3.1 Information pack for General Practitioners (GP) (to include any information pertaining to communication with GP's, including schedule of any GP information sessions)	
3. Multidisciplinary Approach		
No.	**Documentation Required**	**Please tick if document is attached or state reason if not attached**
3.1	**Multidisciplinary Meeting**	
	3.1.1 Standard operating procedure / policy for Multidisciplinary Meetings	
	3.1.2 Scheduling of meetings from 1st January 2009 to week commencing 17th August 2009	
	3.1.3 List of multidisciplinary membership	
	3.1.4 Agenda for all meetings from 1st January 2009 to week commencing 17th August 2009	
	3.1.5 Template used for recording information following multidisciplinary discussion	
3.2	**Triple Assessment Clinic**	
	3.2.1 Standard operating procedure / policy for Triple Assessment Clinics	
	3.2.2 Scheduling for Triple Assessment Clinics from 1st January 2009 to week commencing 17th August 2009	
	3.2.3 Standing Operating Procedure / policy to demonstrate how patients are referred to the triple assessment clinic	

4. Skills, Education and Training		
No.	**Documentation Required**	**Please tick if document is attached or state reason if not attached**
4.1	**Training and Competency**	
	4.1.1 Policy for continuous professional development for the multidisciplinary team	
	4.1.2 Policy to monitor and maintain competencies as per the National Quality Assurance Standards for the multidisciplinary team	

5. Clinical Effectiveness		
No.	**Documentation Required**	**Please tick if document is attached or state reason if not attached**
5.1	**Clinical Guidelines**	
	5.1.1 Standard operating procedure / policy for developing clinical guidelines for the symptomatic breast disease service	
	5.1.2 List of clinical guidelines in use in the symptomatic breast disease service	
5.2	**Clinical Audit**	
	5.2.1 Standard operating procedure / terms of reference for the clinical audit committee for symptomatic breast disease	
	5.2.2 Scheduling of meetings for this committee from 1st January 2009 to week commencing 17th August 2009	
	5.2.3 Agendas from 1st January 2009 to week commencing 17th August 2009	
	5.2.4 Minutes and action sheets from 1st January 2009 to week commencing 17th August 2009	

Appendix X Theme – Skills Education and Training

Name	Title	Speciality	WTE	Commenced Employment on:	Dedicated session commitments to the symptomatic breast centre (hours)	If sessions are not dedicated, indicate hours per week	Category (see below)
Name	**Title**	**Speciality**	**WTE**	**Commenced Employment**	**Dedicated session**	**If**	**Category (see below)**

				on:	**commitments to the symptomatic breast centre (hours)**	**sessions are not dedicated, indicate hours per week**	
							-
Categories: Permanent (P); Temporary (T); Full Time Locum (FL); Part-time Locum (PTL); Part-time Permanent (PTP); Part-Time Temporary (PTT)							

Appendix 5

Data request prior to onsite quality review

Symptomatic Breast Disease Service Quality Review 2009

Data request prior to on-site quality review

Hospital Name: _____

Instructions for completing this data request form:

The Authority requests that the following data request form is completed and submitted in hardcopy.

5. For the purposes of this data request exercise only, please note descriptions of the following terms will be used in this document:
    a. **Definitive diagnosis** – this is achieved following discussion and clinical decision being reached at the Multidisciplinary Team (MDT) meeting.
    b. **Patient with newly diagnosed primary breast cancer** – this refers to patients with a primary cancer in either the left or right breast or both and excludes patients with re-occurrences.
    c. **Patient with primary operable breast cancer –** patients that have been assessed as being suitable for surgery.
    d. **Non-urgent referrals** – refers to patients triaged as early or routine by the Symptomatic Breast Disease (SBD) centre

6. This data request form must be submitted **no later Monday, 28 September 2009** to:

    The Health Information and Quality Authority,
    Healthcare Quality and Safety Directorate,
    Head Office,
    Mahon City Gate,
    Mahon,
    Cork

Under Section 12 of the Health Act 2007, the Authority requests that you submit the following information:

Section A				
ALL questions in Section A refer to data for a) the sample time period of 1 January 2009 – 1 August 2009 b) the Patient Sample group – new patients seen at the Symptomatic Breast Disease (SBD) Centre				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.1	What is the total number of **new patients** seen at the SBD centre for this sample time period?	Numeric figure		
DaR.2	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre?	Numeric figure		
DaR.3	Of the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre (see DaR.2), what is the total number and percentage of patients **offered an appointment** to be seen within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.4	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre?	Numeric figure		

Section A – continued				
ALL questions in Section A refer to data for **a) the sample time period of 1 January 2009 – 1 August 2009** **b) the Patient Sample group – new patients seen at the Symptomatic Breast Disease (SBD) Centre**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.5	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.6	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.7	Of the total number of new patients seen at the SBD centre for the sample time period (see DaR.1), what is the total number of newly diagnosed primary breast cancer patients?	Numeric figure		

Section B

ALL questions in Section B refer to data for
a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009
b) the Patient Sample group – seen and newly diagnosed with primary breast cancer

Question Reference	Question	Information Type	Please state numeric figure/percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.8	What is the total number of newly diagnosed primary breast cancer patients seen at the SBD centre during the sample time period of 1 April 2009 – 30 June 2009?	Numeric figure		
DaR.9	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that were triaged as **urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.10	Of the total number of patients that were triaged as urgent (see DaR.9), what is the total number and percentage of patients **offered an appointment to be seen** within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.11	Of the total number of patients that were triaged as urgent (see Dar.9) and clinically assessed has having S4 or S5 classification, what is the total number and percentage of patients that received imaging on the first visit?	Numeric figure		
		Percentage figure to be submitted		
DaR.12	Of the total number of patients that were triaged as urgent (see DaR.9), what is the total number and percentage of	Numeric figure		

	patients that had a definitive diagnosis achieved within 10 working days of being seen at the centre?	Percentage figure to be submitted		

Section B – continued				
ALL questions in Section B refer to data for **a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009** **b) the Patient Sample group – seen and newly diagnosed with primary breast cancer**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.13	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that were triaged as **non- urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.14	Of the total number of patients triaged as non-urgent (see DaR.13) what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.15	Of the total number of patients triaged as non-urgent (see DaR.13) what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.16	Of the total number of newly diagnosed primary breast cancer patients (see Dar.8), what is the total number of patients who had an imaging abnormality which was classified as R3, R4, or R5 identified and had a core biopsy performed?	Numeric figure		
DaR.17	Of the total number of patients who had a core biopsy performed (see DaR.16), what is the total number and percentage of biopsies that were image guided?	Numeric figure		
		Percentage figure to be submitted		

DaR.18	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number of patients whose definitive diagnosis was made at the MDT meeting?	Numeric figure		

Section B – continued				
ALL questions in Section B refer to data for a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009 b) the Patient Sample group - seen and newly diagnosed with primary breast cancer				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.19	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that were diagnosed with invasive breast cancer?	Numeric figure		
		Percentage figure to be submitted		
DaR.20	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of patients that had primary operable invasive breast cancer?	Numeric figure		
DaR.21	Of the total number of patients that had primary operable invasive breast cancer (see DaR.20), what is the total number and percentage of patients that had ultrasound of the axillary nodes?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 1				
a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009 **b) the Patient Sample group - seen and newly diagnosed with primary breast cancer** **c) sub-sample group 1: Diagnosed with invasive breast cancer**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.22	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number and percentage of patients that were diagnosed without an operative procedure?	Numeric figure		
		Percentage figure to be submitted		
DaR.23	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19) what is the total number of patients that were assessed has having a clinically occult lesion (classification S2)?	Numeric figure		
DaR.24	Of the total number of patients that were assessed as having a clinically occult lesion (classification S2) (see DaR.23), what is the total number and percentage of patients that had pre-operative image-guided localisation before surgery?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 2				
a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009 **b) the Patient Sample group - seen and newly diagnosed with primary breast cancer** **c) sub-sample group 2: Diagnosed with invasive breast cancer AND HAD SURGERY**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.25	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of patients **that had surgery**?	Numeric figure		
DaR.26	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **type** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.27	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **grade** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.28	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **size** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.29	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the presence or absence of vascular invasion recorded?	Numeric figure		
		Percentage figure to be submitted		

Section B - Continued				
a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009 **b) the Patient Sample group - seen and newly diagnosed with primary breast cancer** **c) sub-sample group 2: Diagnosed with invasive breast cancer AND HAD SURGERY continued**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.30	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the posterior deep margin status recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.31	Of the total number of **patients** that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of **cases** that had a Wide Local Excision?	Numeric figure		
DaR.32	Of the total number of **cases** that had a Wide Local Excision, (see DaR.31) what is the total number and percentage of **cases** that the radial margin status is recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.33	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had HER-2 status recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.34	Of the total number of patients that had surgery (See DaR.25), what is the total number and percentage of **cases** that had oestrogen receptor status recorded?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 3				
a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009 **b) the Patient Sample group - seen and newly diagnosed with primary breast cancer** **c) sub-sample group 3: Patients with primary operable cancer**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.35	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that had primary operable breast cancer?	Numeric figure		
		Percentage figure to be submitted		
DaR.36	Of the total number of patients that had primary operable breast cancer (see DaR.35), what is the total number and percentage of patients that had surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnosis at the MDT meeting?	Numeric figure		
		Percentage figure to be submitted		
DaR.37	Of the total number of patients that had primary operable breast cancer (see DaR.35), what is the total number and percentage of patients that had pre-operative mammography with ultrasound carried out?	Numeric figure		
		Percentage figure to be submitted		

Section C – note new patient Sample group				
ALL questions in Section C refer to data for **a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009** **b) the Patient Sample group –diagnosed with Ductal Carcinoma In Situ at MDT**				
Question Reference	**Question**	**Information Type**	**Please state numeric figure/percentage figure as requested**	**Please tick if providing supporting narrative and add narrative to DaR Appendix x**
DaR.38	What is the total number of patients newly diagnosed with Ductal Carcinoma In Situ and seen at the SBD centre during the sample time period of 1 April 2009 – 30 June 2009?	Numeric figure		
DaR.39	Of the total number of patients newly diagnosed with Ductal Carcinoma In Situ and seen at the SBD centre during the sample time period (see DaR.38) what is the total number of **cases** of Ductal Carcinoma In Situ.	Numeric figure		
DaR.40	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases** that had a wide local excision?	Numeric figure		
		Percentage figure to be submitted		
DaR.41	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases** that had radial margin status recorded	Numeric figure		
		Percentage figure to be submitted		
DaR.42	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases**	Numeric figure		

	that had the histological tumour grade recorded?	Percentage figure to be submitted		

Section D

Data Management

Question Reference	Please provide a copy of the following documents/information	Tick if document is attached	If unable to provide document, please state reason in narrative – DaR Appendix x
DaR.43	Copy of the SBD Centres Data Set		
DaR.44	Copy of the SBD Centres Data Dictionary or Data definition document		
DaR.45	Copy of the hospital/SBD Centres SOP/Policy for validating data		

DaR.46 List the names of the Clinical Information Systems used in your SBD Centre: DaR Appendix x

Narrative accompanying data request (reason if unable to provide data / any other relevant information	
DaR.1	
DaR.2	
DaR.3	
DaR.4	
DaR.5	
DaR.6	

Appendix 6

National Cancer Control Programme revised key performance indicators (July 2009)

To address the need for standardised, routine monitoring of performance against the Standards, the NCCP convened an **Expert Advisory Group on Breast Service Performance** from clinicians within the designated centres to agree an initial set of Key Performance Indicators. These are set out in the table below*. Some of these KPIs vary to some extent from the corresponding Standard on the advice of the Expert Advisory Group.

STANDARD 1: ACCESS		
Ref.	Key Performance Indicator	Target
1a	Referrals triaged as urgent by the cancer centre shall be offered an appointment within 10 working days of the date of receipt of a letter of referral in the cancer office.	>95%
1b	Referrals triaged as non urgent (i.e. early and routine) by the cancer centre, shall be offered an appointment within 12 weeks (less than or equal to 84 days) of the date of receipt of a letter of referral in the cancer office.	>95%
1c	A new patient deemed urgent following specialist assessment in the clinic (that is classified as S4, S5) shall have imaging (mammography or ultrasound) done in the first visit.	>90%
1d	Breast imaging requests (that is, mammography or ultrasound) shall be carried out within 12 weeks of clinical assessment.	>90%
STANDARD 2: IMAGING		
Ref.	Key Performance Indicator	Target
2a	Patients with primary operable breast cancer shall have pre-op mammography and ultrasound examination.	>95%
2b	A patient over the age of 35 years with a clinically palpable focal abnormality (that is classified as S3, S4 or S5) shall have mammography and targeted ultrasound examination.	>95%
2c	Core biopsies of breast shall be image-guided where an imaging abnormality which is classified as R3, R4 or R5 is identified.	>90%
Additional parameter	Consultant radiologists shall report on at least 1,000 mammograms annually.	1,000

STANDARD 3: DIAGNOSIS		
Ref.	Key Performance Indicator	Target
3a	Patients with invasive breast cancer shall be diagnosed without an operative procedure [open biopsy].	>90%
3b	For patients urgently triaged by the cancer centre and subsequently diagnosed with a primary breast cancer, the interval between attendance at the first clinic and the discussion at the multidisciplinary meeting where a B5 or C5 is first identified shall not exceed 10 working days.	>90%
Additional parameter	The number of benign open surgical biopsies shall be recorded.	volume
STANDARD 4: MULTIDISCIPLINARY WORKING		
Ref.	Key Performance Indicator	Target
4a	Breast investigations that generate a histopathology report shall be discussed at MDM.	>95%
4b	Patients with a diagnosis of breast cancer from the symptomatic service shall be discussed at MDM.	>95%
STANDARD 5: TIME TO TREATMENT		
Ref.	Key Performance Indicator	Target
5a	Surgical intervention shall be carried out within four weeks (20 working days) of the date of the multidisciplinary meeting when a B5 or C5 is first identified, provided surgery is the first treatment.	>90%
5b	For post-surgery patients, where adjuvant chemotherapy is not deemed necessary but require radiation therapy, patients shall commence radiation therapy within 12 weeks of the final surgical procedure.	>90%
5c	For post-surgery patients, requiring adjuvant chemotherapy and radiation therapy, patients shall commence radiation therapy within four weeks of the last chemotherapy administration.	>90%
5d	For post-surgery patients, where adjuvant chemotherapy is required, administration shall commence within eight weeks of the final surgical procedure.	>90%
STANDARD 6: SURGERY – ACCURATE LOCALISATION		
Ref.	Key Performance Indicator	Target
6a	Patients with a clinically occult lesion, that is classified as an S", shall have wire-guided localisation pre-operatively.	>95%

6b	Patients with a clinically occult lesion who have a wire-guided wide local excision shall have specimen mammography.	>95%
STANDARD 7: SURGERY – AXILLARY STAGING		
7	Patients with a diagnosis of primary operable breast invasive cancer shall have an ultrasound of the axillary nodes.	>95%
Additional parameters	The number of patients with sonographically normal lymph nodes and where the FNA or core biopsy does not demonstrate metastases and who have sentinel lymph node biopsies shall be documented.	Volume
STANDARD 8: SURGERY – SPECIALISATION		
8	Individual consultant surgeons shall assess and operate on a minimum of 50 new patients with breast cancer per year.	Volume
STANDARD 9: SURGERY – ACCURACY OF SURGICAL INTERVENTIONS		
9	For patients having breast conserving surgery, the number of therapeutic interventions shall be recorded.	Volume
STANDARD 10: PATHOLOGY		
10a	For primary invasive tumours: (a) Histological tumour type shall be recorded. (b) Histological tumour grade shall be recorded. (c) Invasive tumour size shall be recorded. (d) The presence or absence of vascular invasion shall be recorded. (e) Radial margin status shall be documented for all patients who have wide local excision. (f) Posterior (deep) margin status shall be recorded (g) Lymph node status shall be recorded where sampled.	>95%
10b	For primary invasive tumours, *HER2* receptor status shall be recorded.	>95%
10c	For primary invasive tumours, *HER2* receptor status shall be recorded.	>90%
10d	The histopathology report containing the prognostic data as outlined in 10a will be available within 10 working days.	>95%

** Source: NCCP 2009*

Appendix 7

Useful contacts

The following websites can provide information and support about all aspects of cancer, in particular breast cancer. General practitioners (GPs) and your healthcare team can also provide you with information about local support groups.

Action Breast Cancer (Irish Cancer Society): www.cancer.ie/action

ARC Cancer Support Centre: www.arccancersupport.ie

Biobank Ireland Trust: www.biobankireland.com

Breakthrough Breast Cancer: www.breakthrough.org.uk

breastcancer.org: www.breastcancer.org

Breast Cancer Care: www.breastcancercare.org.uk

Breast Cancer Network Australia (BCNA): www.bcna.org.au

BreastCheck: the National Breast Cancer Screening Programme: www.nbsp.ie

BreastCheck: http://www.breastcheck.ie

Canadian Breast Cancer Foundation: www.cbcf.org

Cancer Back up: http://www.cancerbackup.org.uk

Department of Health and Children: www.dohc.ie

Europa Donna: http://www.europadonnaireland.ie

EUROPA DONNA - The European Breast Cancer Coalition: www.europadonna.org

European Health Portal site: http://ec.europa.eu/health-eu/index_en.htm

Fertile Hope www.fertilehope.org

Health Services Executive (HSE): www.hse.ie

Irish Cancer Society: www.cancer.ie

ICORG (Irish Clinical Oncology Research Group): www.icorg.ie

Marie Keating Foundation: www.mariekeating.com

National Breast Cancer Coalition: www.natlbcc.org

National Cancer Control Programme (NCCP): www.cancercontrol.hse.ie

National Cancer Institute (United States): www.cancer.gov

National Cancer Registry Ireland: www.ncri.ie

Rethink Breast Cancer: www.rethinkbreastcancer.com

Living Beyond Breast Cancer: www.lbbc.org

The European Cancer Observatory: http://eu-cancer.iarc.fr.

Y-Me National Breast Cancer Organisation: www.y-me.org

Young Survival Coalition: www.youngsurvival.org/