



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# National Quality Review of Symptomatic Breast Disease Services in Ireland

Report of the Quality Review Assessment  
at St James's 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 St James's 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.** The Breast Care Quality Review and Improvement Group at St James's Hospital should, as part of its responsibility, include the analysis and monitoring of delayed-diagnoses data to assure quality of care for patients with symptomatic breast disease.

**G3.** The service should review practice around the documentation of patient notes so that all information pertaining to a patient's care is complete and easily accessible from a single source.

**G4.** The service should ensure that a robust service level agreement with the third-party provider of radiation oncology services is finalised and implemented. This 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.

### Theme: Multidisciplinary Approach

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

### Theme: Skills, Education and Training

**SET1.** The service should ensure that a formal policy is developed to support and monitor continuous professional development.

### Theme: Person-centred Care

**PCC 1.** The symptomatic breast disease service should ensure all patients and their

families receive sufficient support on discharge particularly in relation to wound drainage management.

### **Theme: Data Management**

**DM1.** The service should ensure the continuous collection and monitoring of data in relation to radiation oncology in order to assure themselves that they are meeting the National Quality Assurance Standards.

### **Theme: Clinical Effectiveness**

**CE1.** The service should put a targeted programme of action in place to ensure 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, with the target being met in more than 90% of patients.

**CE2.** The service should incorporate specific symptomatic breast disease clinical audit activities within the clinical governance structure to systematically and critically analyse the quality of care provided.

## 2 Introduction

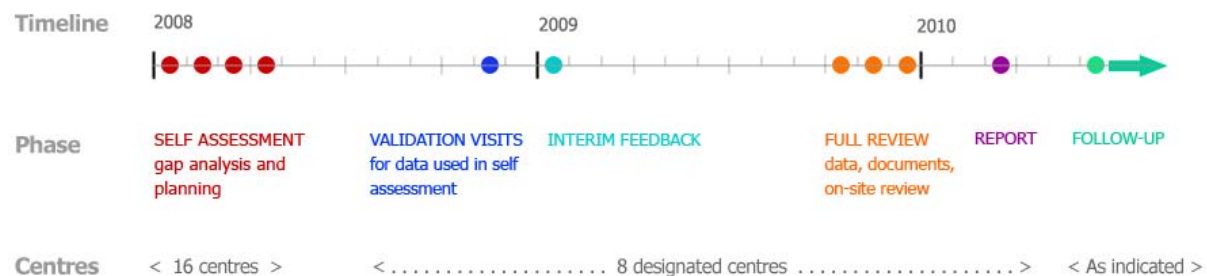
The Health Information and Quality Authority (the Authority) launched the *National Quality Assurance Standards for Symptomatic Breast Disease*<sup>(1)</sup> (hereafter referred to as the Standards) in May 2007 and advised all hospitals providing symptomatic breast disease (SBD) services that they should 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 St James's 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 their 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 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”<sup>+</sup>) 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.

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<sup>+</sup> 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**

<b>Theme 1: Governance</b>
<b>Essential Element 1 (a)</b>  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.
<b>Essential Element 1 (b)</b>  The service will have robust clinical management, referral and patient pathways ensuring an effective integration of patient care.
<b>Essential Element 1 (c)</b>  The governance structure will include defined responsibilities for shared service delivery as specified in the contractual agreement with another service provider.
<b>Theme 2: Multidisciplinary Approach</b>
<b>Essential Element 2 (a)</b>  Core Team. The symptomatic breast disease (SBD) service must have a: <ul style="list-style-type: none"><li>▪ lead clinician</li><li>▪ consultant breast surgeon and team</li><li>▪ consultant histopathologist</li><li>▪ consultant radiologist and radiographer</li><li>▪ clinical nurse specialist breast care</li><li>▪ consultant radiation oncologist</li><li>▪ consultant medical oncologist</li><li>▪ consultant plastic and reconstructive surgeon.</li></ul>
<b>Essential Element 2 (b)</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](http://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 St James's Hospital against the Standards.**

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

- documents provided by St James's 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 April 2009 to 30 June 2009 (see Data Request template, Appendix 5)
- access data for new patients seen for the seven-month sample period from 1 January 2009 to 1 August 2009
- the findings of the Authority's on-site Quality Review on 12 October 2009 and 13 October 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 St James's Hospital, Dublin

St James's Hospital is one of the eight cancer centres of the HSE's National Cancer Control Programme (NCCP), and one of two centres in the Dublin Mid-Leinster Network. The symptomatic breast disease (SBD) service at St James's Hospital provides services to patients with symptomatic breast disease, including breast cancer. The service provides cancer services to a regional catchment population which predominantly includes south-west Dublin, Kildare, Wicklow, Laois, Offaly, Longford and Westmeath<sup>(5)</sup>. BreastCheck, the National Breast Screening Programme (NBSP), is provided to this population.

The range of services encompasses diagnosis, staging and all aspects of cancer treatment except for radiation therapy services which are provided by a third-party provider. An on-site radiation oncology facility is currently under construction and is scheduled for completion in December 2011.

In April 2008, the SBD service at St James's Hospital, 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 Standards in a range between 63.2% and 100%.

In September 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 St James's Hospital:

- had completed the self-assessment questionnaire using information from a live data system, database extractions, monthly performance indicator reports, snapshot audits and professional judgment
- was routinely measuring performance against the Standards
- had the appropriate arrangements in place to assure itself that it was meeting the Standards
- was holding monthly activity meetings where a number of performance indicators were monitored with the outcomes reported to the executive management group.

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

In August 2009, for the purpose of the review, St James's Hospital submitted activity data which provided a preliminary overview of the centre's activity for new patients seen at the SBD centre for the seven-month sample time period of between 1 January 2009



to 1 August 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 St James's Hospital  
 (1 January 2009 to 1 August 2009)**

<b>Patient referral activity at St James's Hospital 1 January 2009 to 1 August 2009</b>	
Total number of new patients seen at the St James's SBD service	1,746
Total number of newly diagnosed primary breast cancer patients	109

**Table 2: New patient referral activity by urgent triage category reported by St James's Hospital, 1 January 2009 to 1 August 2009**

<b>New patient referral activity by urgent triage category at St James's Hospital 1 January 2009 to 1 August 2009</b>	
Total number of new patient referrals received during the sample time period that were triaged as <b>urgent</b> by the SBD Service	377
Total number of new patient referrals triaged as <b>urgent</b> who were offered an appointment to be seen within 10 working days of the date of receipt of referral	327
Percentage of new patient referrals triaged as <b>urgent</b> who were offered an appointment to be seen within 10 working days of the date of receipt of referral	87%

**Table 3: New patient referral activity by non urgent triage category reported by St James's Hospital, 1 January 2009 to 1 August 2009**

<b>New patient referral activity by non urgent triage category at St James's Hospital, 1 January 2009 to 1 August 2009</b>	
Total number of new patient referrals received during the sample time period that were triaged as <b>non urgent</b> by the SBD Service	1369
Total number of new patient referrals triaged as <b>non urgent</b> who were seen within <b>6 weeks</b> of the date of receipt of referral	361
Percentage of new patient referrals triaged as <b>non urgent</b> who were seen within <b>6 weeks</b> of the date of receipt of referral	26%
Total number of new patient referrals triaged as <b>non urgent</b> who were seen within <b>12 weeks</b> of the date of receipt of referral	1070
Percentage of new patient referrals triaged as <b>non urgent</b> who were seen within <b>12 weeks</b> of the date of receipt of referral	78%

## 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 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 part of the cancer service at St James's Hospital.

The transition of services for people with symptomatic breast disease from the Adelaide and Meath Hospital, Incorporating the National Children's Hospital (AMNCH) in Tallaght, Dublin, to St James's Hospital was ongoing at the time of the Review, with the final phase of changeover to be completed by December 2009. The service reported to have its full complement of core personnel with all

SBD consultant staff having dedicated work periods (known as sessions) committed to the service.

The review of documentation and interviews with staff confirmed that there is a clear integrated clinical and corporate governance structure within a clinical directorate model to support the SBD service. This included a lead clinician, consultant breast surgeon, reporting to the clinical director of the GEMS (Gastro Endocrinology Medicine Surgery) Directorate. The Hospital had identifiable mechanisms to ensure timely reporting of any issues to the Hospital executive.

The Lead Clinician had full time sessional commitment to the SBD service only, and operational and strategic responsibility for the breast care service. However, the role of lead clinician was an evolving role and was not fully formalised. This raised questions about the sustainability of the role which needed to be addressed in terms of role definition, objectives and time allocation. **(see G1)**

The Lead Clinician is chairperson of the Breast Care Operational Group and of the Breast Care Quality Review and Improvement Group. The terms of reference for each committee, which were reviewed in 2009, are broadly similar each having a focus on:

- compliance with the Standards
- monitoring, responding and disseminating reports on breast-care-related complaints, risks, clinical incidents and near misses
- identifying and implementing opportunities for improvement.

However, the Breast Care Quality Review and Improvement Group had a more defined corporate and strategic direction with representation from all clinical specialties pertaining to the service and executive representation by the Deputy Chief Executive Officer. Both committees operate within a planned timetable, the chairperson providing feedback to each group.

The Breast Care Quality Review and Improvement group used data and trend-analysis reports to monitor compliance with key performance, clinical and non-clinical indicators. It analysed patient feedback and complaints. However, it did not analyse delayed-diagnoses data. **(see G2)**

At the time of the Review, the service had a comprehensive integrated governance structure and organisational framework in place.

### **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 operational policy which identified the patient referral, treatment pathway and clinical leadership arrangements, including a genetic and family history outpatient clinic and the arrangements in place to review patients referred back to the service. The Authority confirmed that once a patient attends a breast clinic, they become the clinical responsibility of the consultant breast surgeon assigned to that clinic. Patients remain under the care of that consultant throughout their clinical pathway, unless or until their care is transferred to another clinical service.

The multidisciplinary team (MDT) process is central to the management of symptomatic breast disease. The Authority found that St James's Hospital has a mature multidisciplinary team structure in place. This was evidenced throughout the data validation exercise, the patient healthcare record review and evaluation of the Hospital's specific standard operating procedures and review mechanisms.

There was a clear patient and general practitioner (GP) communication and referral process. The effectiveness of these structures was evidenced by the service's operational patient referral arrangements. The patients' healthcare record, particularly in the specialist breast care nurses' (SBCNs') records, confirmed that patients had been informed of their treatment plans and clearly demonstrated the integration of care and the patient support delivered. However, the SBCN records were stored separately from the patient healthcare record. **(see G3)**

The integration of patient care was supported by comprehensive information management systems with the capacity to capture a broad spectrum of data. The Patient Analysis and Tracking System (PATS) had been operational for several years. The system interfaced with other information management systems and the service used data to monitor and improve service delivery.

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 the timely access to public radiation oncology services that had, at the time of the Review, been provided by a third party. At the time of the Review, the service, the NCCP and the third-party provider were actively in discussion on formalising a service level agreement (SLA). These discussions included arrangements for sharing vital information in relation to key performance indicators. This information will allow the SBD service at St James's Hospital to more effectively monitor the referral, commencement and completion of radiation oncology treatment for its patients in line with the National Quality Assurance Standards. An SLA 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. It relates to a key aspect of integrated patient care and should be given a high priority. **(see G4)**

At the time of Review, the service did not have an SLA for radiation oncology services.

### **Governance: Conclusion**

The SBD service at St James's Hospital had a comprehensive corporate and clinical governance structure. There was an organisational framework that incorporated systems and processes for effective general management and clinical decision making. The SBD service monitored and evaluated compliance with the Standards, NCCP and hospital-specified key performance indicators through the Hospital's Breast Care Quality Review and Improvement Group

The SBD service had a well defined multidisciplinary structure which was supported by a standard operating procedure. To facilitate integrated patient care, there were clear patient referral, clinical pathway and leadership arrangements with clear GP communication and referral processes. The service should ensure the service level agreement with the third-party provider of radiation oncology is finalised.

Overall, the Authority concluded that the SBD service at St James's Hospital 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.** The Breast Care Quality Review and Improvement Group at St James's Hospital should, as part of its responsibility, include the analysis and monitoring of delayed-diagnoses data to assure quality of care for patients with symptomatic breast disease.

**G3.** The service should review practice around the documentation of patient notes so that all information pertaining to a patient's care is complete and easily accessible from a single source.

**G4.** The service should ensure that a robust service level agreement with the third-party provider of radiation oncology services is finalised and implemented. This 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.

## 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 St James's Hospital and interviews established that the service had the core staff required for a functioning multidisciplinary team which included a:

- 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.

At the time of 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 a clear operational procedure, patient pathway and documentation and communication process thereby ensuring an integrated approach for the delivery of triple assessment.

The clinic timetable confirmed a weekly scheduling of the triple assessment clinic (TAC). The patient healthcare record review confirmed that the clinical, imaging and pathology findings were recorded in the clinical examination record, the triple assessment pro forma chart, the specialist breast care nursing clinical notes and entered by the data manager onto the Patient Analysis and Tracking System (PATS). This information was electronically submitted to the MDT meeting coordinator thereby ensuring the patients' clinical details could be discussed at the next appropriate MDT meeting. A number of the triple assessment clinic (TAC) pro forma were either illegible or not fully completed. The Data Manager confirmed that on occasion she had to clarify these records with clinicians before being able to input the data.



At the time of the review, the Authority found that the centre was holding a minimum of one weekly triple assessment clinic.

### **Essential Element 2 (c)**

The 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 multidisciplinary team (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 function of the MDT meeting. This SOP included security and patient confidentiality controls. All attendees had dedicated time to attend the MDT meeting, record their attendance and a quarterly attendance audit was maintained.

The role and responsibilities of the members of the MDT were clearly defined with arrangements in place to cover planned leave. Whilst there was evidence of processes and protocols in place to support the functioning of the multidisciplinary team, the Authority noted that the policy did not identify who had the specific responsibility of chairperson of the MDT meeting.

The Authority confirmed that patients discussed at the MDT meeting include:

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.

In the service, the MDT meeting was coordinated by a dedicated post holder with the responsibility of organising and ensuring all patients' clinical details and reports are available for the meeting. The Authority reviewed and verified the processes to ensure availability of this information.

Clinical decisions and outcomes were recorded by the presenting clinician on the MDT outcome pro forma and entered by the Data Manager onto PATS. A copy of the pro forma was also saved on the MDT coordinator's patient database.

The Authority reviewed a selected number of patients' records and validated that the MDT meeting outcome pro forma was entered onto PATS. However, during the Review it was noted that clinical examination classification codes were not always clearly recorded and that entries were not always legible. All decisions must be clearly recorded. In addition, it was noted that the assessment classification codes assigned following clinical and diagnostic imaging assessments were not consistent with the coding used in the NCCP key performance indicator. **(see MDT1)**

The Authority reviewed and confirmed that all patients with a definitive diagnosis of breast cancer were discussed at the MDT meeting.

Patients with a definitive diagnosis of cancer have a return visit organised within two working weeks. Patients requiring medical oncology, radiation oncology follow-up or repeat radiological investigations are contacted by telephone by a clinical nurse specialist.

In addition, the Authority confirmed that the consultant surgeon ensures that the GP of a patient with a diagnosis of cancer is contacted by telephone and informed of the diagnosis. However, the service acknowledged that there can be a delay in contacting GPs with a non-cancer diagnosis and this was under review by the SBD quality committee at St James's Hospital.

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 is actively committed to delivering triple assessment through a multidisciplinary approach and had comprehensive operational policies and evaluation processes 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 were encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that the SBD service at St James's Hospital had the necessary multidisciplinary arrangements in place for the delivery of safe care.

### **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 centre 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 are monitored. The mechanisms within the SBD team include MDT meeting, peer interaction, quality review, clinical audit, clinical research and attending national and international courses, seminars and master classes. As clinical staff were redeployed from regional services, a professional mentoring and staff induction programme was facilitated.

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

Clinical nurse specialists in breast care have relevant qualifications and clinical experience, and are registered on the national clinical nurse specialists register. During the facilities' review, the Authority confirmed as satisfactory, the ward-based teaching and mentoring support provided by the specialist nursing team.

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
- 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
  - safe administration of chemotherapy
  - education programme (pathology laboratory).

Overall, 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 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 SET1)**

### **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 Hospital's staff recruitment and selection processes, staff induction and mentorship programme ensures controls were in place to monitor clinical competence and multidisciplinary performance. All consultant staff have a contractual commitment to participate in teaching, research and ensuring evidence-based clinical practice.

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

Overall, the Authority found the SBD service 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 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, local and regional support groups.

##### Findings Essential Element 4 (a)

The Authority confirmed during the staff interviews, on-site facility review and review of patient healthcare records and documentation that the SBD service at St James's Hospital had the appropriate 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 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 St James's Hospital, all of whom were within 14 months of initial diagnosis and at varying stages of active treatment. The group included a mix of patients from both Dublin and outside Dublin. Three specific

themes were explored:

- access
- clinical care
- information and support.

**Person-centred care as reported by the patient discussion group at St James's Hospital was as follows:**

**Access**

All patients in the group reported they were satisfied with the level of contact between the service and their GP and the timelines experienced in relation to their referral, diagnosis and treatment – with the exception of the radiation oncology treatment, provided by a third party.

**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 in St James's Hospital. They reported the standards in relation to the integration of their care pathway, from referral to diagnosis through to treatment, were all met. In addition, these patients reported they were satisfied with the level of privacy afforded them. However, those patients discharged home with wound drains in place reported on the difficulties they experienced in relation to post-operative discharge and the management of their wound drains. They reported that these difficulties arose as a result of a lack of information in relation to the availability of community-based support when living a considerable distance from St James's Hospital. **(see PCC1)**

Patients in the group reported they had sufficient time and information to consider options of treatment before decisions were reached. All patients in the group were offered an opportunity to be accompanied by a person of their choice whenever needed. The patients from outside Dublin were offered overnight accommodation.

The discussion group confirmed the Authority's findings regarding challenges in securing timely access to public radiation oncology services.

**Information and support**

All patients in the group indicated that the Standards in relation to key information were met to their satisfaction.

While patients were made aware of support groups, due to geographic location (even for those in Dublin) and a reluctance to re-tell their story, they did not avail of these services.

Specialist breast care nurses (SBCNs) in the symptomatic breast disease (SBD) service



received particular praise for the time, care and support they offered. All patients in the group indicated that they would have liked that level of personalised care and support throughout their treatment.

Patients reported feeling comfortable in contacting SBCNs at the SBD service at any time, maintaining they were easy to talk to and provided significant emotional support. The role of the SBCN was found to be particularly important as a link for the patient between the different health professional teams and as a source of information and support.

At the time of the review, the Authority found that St James's Hospital had the essential arrangements in place to deliver person-centred care.

#### **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
- diagnostic imaging department
- medical oncology day ward
- day ward, local and general anaesthetic procedures
- surgical inpatient ward.

The service has a stand-alone administration and clinical outpatient facility. The infrastructure ensures patient privacy is maintained and the facility includes a counselling and prosthesis room. The department is easily accessible to the diagnostic imaging department which was reported to have the required equipment with the commissioning of a second mammogram machine planned for the end of 2009.

The service did not have dedicated ("ring-fenced") surgical inpatient or day-patient beds. However, all patients were admitted to a surgical inpatient facility. The day ward is easily accessible, facilitating patients requiring local or general anaesthetic. There was dedicated theatre operating time.

The day oncology ward includes private clinical examination rooms and counselling facilities.

Radiation oncology services were provided by a third-party provider.

At the time of the Review, the Authority found that St James's Hospital had the essential structures in place to deliver person-centred care.

### **Person-centred Care: Conclusion**

St James's Hospital had the essential arrangements in place to deliver person-centred care. The service has written information available about breast disease, cancer and local support groups. The specialist breast care nurses had directed an amount of effort to patient discharge planning and management and had conducted information sessions for public health nurses and primary care staff.

Wherever possible, patients were central to this process and encouraged to participate in decisions about their treatment options and care.

The discussion group with patients supported these findings. The patients in the group reported satisfaction with the level of information available to allow them to consider options for treatment.

However, the group reported the need to ensure all patients and their families receive sufficient support on discharge particularly in relation to wound drainage management.

The Authority concluded that the SBD service at St James's Hospital had the necessary arrangements and facilities in place to deliver person-centred care.

### **Person-centred Care: Recommendations**

**PCC 1.** The symptomatic breast disease service should ensure all patients and their families receive sufficient support on discharge particularly in relation to wound drainage management.

## 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)

The symptomatic breast disease service used the following systems:

- Patient Administration System (PAS) – patient demographics and appointment system
- Patient Analysis and Tracking System (PATS) – symptomatic breast disease clinical information system
- Picture Archive and Communication System (PACS) – radiology reports
- Laboratory Information System – laboratory reports.

### Patient Administration System (PAS)

PAS was used by all specialties at St James's Hospital to manage patient referrals and specialty appointments. This system was integrated with PATS for automatic importation of patient demographic data.

### Patient Analysis and Tracking System (PATS)

The Cancer Audit Programme at St James's Hospital was established in 1997 with the introduction of an electronic cancer information system in 2001. The Cancer Audit Manager has ultimate responsibility for the system with each specialty assigned a data manager.

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)**

At the time of review, the Data Manager was responsible for the accuracy and timeliness of data input, entered all patient information following MDT meetings, surgical procedures and investigation results.

The Authority confirmed that data entry clerical staff entered clinic information, with nursing staff entering their nursing notes, including all patient follow-up phone calls. PATS had been interfaced with other information systems. Histopathology text reports were imported directly to PATS and radiology reports were also copied on to the PATS system.

Currently, data is manually entered to specific fields. The service reported a plan of real-time data entry of surgical procedures by the surgical team and at the clinic by the clinical team.

At interview it emerged that 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. This reduces the service's ability to track patients through a vital part of their treatment pathway. Negotiations were underway between the service, NCCP and the third-party provider to put arrangements in place for the transfer of this data. This should be addressed as a priority. **(see DM1)**

The Authority found that St James's Hospital recorded most of necessary 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.

### **Findings Essential Element 5 (c)**

The service at St James's Hospital had a detailed data set and dictionary. The service was using the Patient Analysis and Tracking System (PATS) to collate patient data. The PATS system included two large registries for cancer and clinic data entry. The system facilitated data collection at all critical points in the patient pathway.

Corporately, St James's Hospital had a data (cancer) validation protocol which outlined the procedure in place for the checking accuracy, auditing and validating cancer data. Corporately, each registry was independently validated by another member of the audit team who cross-checked a randomly selected 10% of patient healthcare records in that particular registry.

The data (cancer) validation protocol described the operational practice in place to ensure the accuracy of SBD data. These include:

- all data managers complete regular quality assurance, error and completeness checks across all registries and across the entire data collection system
- data managers continually audit and carry out a validity check on their own data
- monthly and annual audits of all information are routinely done and presented to clinicians and management to review and to compare their data with national and international comparisons.

The Authority found that the service had the required data set, dictionary and standard operating procedure for data validation in place. However, at the time of Review, no evidence was available to the Authority to confirm that there was an SBD specific systematic data validation arrangement in place.

#### **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)**

Trend analysis data reports used to inform the centre's SBD Quality Review and Improvement Group were reviewed. However, there was no available information or evidence to suggest that the service conducts a formal monthly audit and validity check. The MDT identified the need for this validation process to be integral to the function of the SBD Quality Review and Improvement Group at St James's Hospital.

The Authority found that the service had a system in place to monitor key performance indicators with the National Quality Assurance Standards.

#### **Data Management: Conclusion**

The SBD service had a detailed data set and dictionary using the Patient Analysis and Tracking System (PATs) to collate patient data. The required corporate policies and user access controls were in place. A corporate data validation process was in place for checking the accuracy, auditing and validating of data. However, at the time of Review, no evidence was available to the Authority to confirm that there was an SBD specific systematic data validation arrangement in place.

The service demonstrated how it used this information through the monthly Breast Care Quality Review and Improvement Group to monitor and improve the service and quality of patient care.

The Authority concluded that the SBD service at St James's Hospital 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 the continuous collection and monitoring of data in relation to radiation oncology in order to assure themselves that they are meeting the National Quality Assurance Standards.

## 4.6 Themes 6 and 7: Access and Clinical Effectiveness

St James's Hospital 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 April 2009 to 30 June 2009.

Based on the data submitted by St James's Hospital, it was identified that a total of 60 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 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
- TAC and 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.

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\* **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, the on-site review and the review of patients' healthcare records confirmed the triage process of GP-patient referrals is in place at the service.

All patient referrals were reviewed by a member of the consultant surgeon team, triaged and stamped for verification. Dependant on the triage category, the patient was offered an appointment within 2, 6 or 12 weeks.

The Authority found that the service had the appropriate 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.

##### **Findings Essential Element 6 (b)**

St James's Hospital 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 April 2009 to 30 June 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 April 2009 to 30 June 2009.**

<b>PERFORMANCE MEASURE:</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
<b>Access for urgent patients</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
Patients triaged as urgent; <b>and subsequently newly diagnosed with primary breast cancer</b> , are offered an appointment to be seen within 10 working days of the date of receipt of referral (Standard 2.8).	>95%	85%  * See Standard 2.8 below
<b>Access for non-urgent patients</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
Patients triaged as non-urgent; <b>and subsequently newly diagnosed with primary breast cancer</b> , are seen within 12 weeks of receipt of referral (KPI 1b)	>95%	81%  * See KPI 1b below
<b>Imaging</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
Patients triaged as urgent; <b>and subsequently newly diagnosed with primary breast cancer</b> , receive imaging on the first visit (Standard 6.14).	>90%	88%  * See Standard 6.14 below

Definitive diagnosis <sup>+</sup>	TARGET	SJH COMPLIANCE for 13 week sample
Patients triaged as urgent; <b>and subsequently newly diagnosed with primary breast cancer</b> , have a definitive diagnosis achieved within 10 working days of being seen at the centre (Standard 4.9).	>90%	* See Standard 4.9 below
Surgical intervention	TARGET	SJH 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%	85%  * See KPI 5a bellow

**What the data showed**

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

The access and clinical effectiveness data submission to the Authority reported 85% of the sample group were offered an appointment within 10 working days of receipt of referral during the sample time period. The service reported an increase in patient referrals in March and April 2009 had impacted on their ability to meet urgent access targets. The service revised clinic schedules, in response, to provide additional clinics and capacity to address access timelines.

As of May 2009, all urgently referred patients had been consistently offered an appointment within 10 working days.

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

The Authority measured access for non-urgent referrals within 12 weeks of the date of receipt of a letter of referral in line with the NCCP KPI 1b.

St James's Hospital's access and clinical effectiveness data submission to the Authority reported that 81% of the above patient sample group were offered an appointment within 12 weeks of receipt of referral during the sample time period. In parallel to the

<sup>+</sup> For the purpose of this review, the date of the definitive diagnosis is taken as the date of diagnosis at the MDT meeting.

urgent access timelines, St James's Hospital reported an increase in patient referrals in March and April 2009 impacted on their ability to meet non-urgent access targets.

Since August 2009, the service was consistently achieving the access Standards targets for non-urgent referrals.

**\* Imaging (Standard 6.14)**

St James's Hospital's access and clinical effectiveness data submission to the Authority reported 88% of all new patients deemed urgent following specialist assessment in the breast clinic had imaging done in the first visit. However, three patients had radiology prior to attending the breast clinic. In excluding these patients from the sample group the Authority revised the data submitted to it by the Hospital, which resulted in 100% of the above patient sample group receiving imaging on the first visit.

A second mammography machine was planned to be commissioned before the end of 2009. However, the team indicated that should the number of patient referrals continue to increase, the service may be challenged in maintaining these targets particularly in relation to diagnostic imaging. Particular reference was made to the increasing need to access additional diagnostic imaging – for example magnetic resonance imaging (MRI).

**\* Definitive diagnosis (Standard 4.9)**

The Authority noted, during the on-site validation of 25% of the patient healthcare records for this sample group, that the service had identified the date of definitive diagnosis as the date of core biopsy. Therefore, the Authority was unable to determine the service's compliance with this standard.

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

The Authority measured access to surgery based on the revised timeline of 20 working days on the grounds of evidence-based best practice.

The access and clinical effectiveness data submitted by St James's Hospital showed 85% of the sample patient group had surgery within 20 working days of definitive diagnosis at the MDT.

The service provided a supporting narrative for five patients whose care did not meet this target, for example, due to a requirement for additional diagnostic investigations.

## **Medical oncology**

The entire sample patient group would not have reached the medical oncology phase of treatment. Therefore the data validation exercise did not include compliance with the access Standards for medical oncology. However, the service was able to demonstrate that it was collecting relevant information in relation to the medical oncology access Standards.

## **Radiation oncology**

This service was provided to public patients by a third-party provider. At the time of the review, negotiations were taking place between the service, the provider and the NCCP in developing a service level agreement. Throughout the review, clinicians and patients indicated the need to shorten access times and improve availability of data in relation to this service. At interview it emerged that the centre had no data pertaining to the timely provision of patient waiting times for public radiation oncology. This reduces the SBD service's ability to track patients through a vital part of their treatment pathway. This issue should be addressed as a priority. **(see DM1)**

At the time of the review, the SBD service at St James's Hospital had put the necessary arrangements in place to meet the access timelines for clinical assessment, surgery and medical oncology. The data submitted for the sample period indicated that the service was not meeting the Standards and NCCP KPI targets. However, the service had adequately addressed this and at the time of Review was compliant with the targets.

## **Access: Conclusion**

The data submitted for the sample period confirmed the centre was marginally below the access targets as determined by the Standards and NCCP KPIs. Access data was collected and trend-analysed by the Breast Care Quality Review and Improvement Group. As was the case in March / April 2009, the service had the ability to increase the number of SBD clinics to respond to increased demand. At the sample time and for the sample set requested, the SBD service was not meeting the access targets for urgent and non-urgent patient referrals. However at the time of the Review, the service was achieving the Standards access targets for urgent and non-urgent referrals, imaging on the first visit and admission to hospital after definitive diagnosis.

Diagnostic access was due to be further enhanced with the commissioning of a second mammography machine scheduled for December 2009.

The service did collect access and medical oncology treatment data. However, radiation

oncology data remained a deficit which needed to be addressed.

The Authority concluded that the SBD service at St James's Hospital had most of the necessary arrangements in place to ensure timely access to care.

## 4.6.2 Theme 7: Clinical Effectiveness

### Clinical Effectiveness

*Clinical effectiveness refers to 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)

St James's Hospital 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 April 2009 to 30 June 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 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.**

<b>PERFORMANCE MEASURE:</b>	<b>TARGET</b>	<b>SJH COMPLIANCE</b>
<b>Non-operative diagnosis</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
A non-operative diagnosis is achieved in malignant disease (Standard 6.16).	>90%	98%
<b>Ultrasound of the axilla</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
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%	95%
<b>Imaging prerequisites</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer (Standard 6.1).	>95%	98%
<b>Histopathology data</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
To provide important and relevant data on patients with invasive breast carcinoma (Standard 7.13A):		
<ul style="list-style-type: none"> <li>▪ Histological tumour type is recorded.</li> </ul>	>95%	100%
<ul style="list-style-type: none"> <li>▪ Histological tumour grade is recorded.</li> </ul>	>95%	98%
<ul style="list-style-type: none"> <li>▪ invasive tumour size is recorded</li> </ul>	>95%	100%
<ul style="list-style-type: none"> <li>▪ The presence or absence of lymphovascular invasion</li> </ul>	>95%	98%
<ul style="list-style-type: none"> <li>▪ Radial margin status in wide local excision specimens is recorded</li> </ul>	>95%	100%
<ul style="list-style-type: none"> <li>▪ Posterior (deep) margin status is recorded.</li> </ul>	>95%	95%

<b>Hormone receptor status</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
Oestrogen receptor status shall be recorded (Standard 7.13 B)	>95%	98%
<b>HER2 status</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
HER2 status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH) (Standard 7.13 C).	>95%	98%
<b>Ductal carcinoma in situ</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
To provide appropriate data in patients with ductal carcinoma in situ (DCIS):		
<ul style="list-style-type: none"> <li>▪ DCIS grade is recorded.</li> </ul>	>95%	*See Standard 7.14 below
<ul style="list-style-type: none"> <li>▪ Radial margin status in wide local excision specimens is recorded (Standard 7.14).</li> </ul>	>95%	*See Standard 7.14 below
<b>Pre-operative localisation</b>	<b>TARGET</b>	<b>SJH COMPLIANCE for 13 week sample</b>
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).	>90%	* See Standard 5.10 below
<p><b>What the data showed</b></p> <p><b>* Ductal carcinoma in situ (Standard 7.14)</b></p> <p>A small number of patients were newly diagnosed with DCIS. They were noted to have their DCIS grade recorded. <a href="#">Where</a> the target for radial margin status was not met, this was on the grounds of clinical exceptions</p> <p><b>Pre-operative localisation (Standard 5.10)</b></p>		



SJH stated that a small number of patients were assessed as having a clinically occult lesion. The majority of these patients did not have pre-operative localisation of the lesion and supporting narrative was provided by SJH to support this finding.

During the course of the review, it was noted that the attainment of the above Standard was under review at the Hospital's Symptomatic Breast Disease Governance Committee. **(see CE1)**

Overall, the services 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 St James's Hospital, clinical audit of the mortality and morbidity of patients was undertaken as part of the general surgical services. At the time of review, clinical audit processes specific to the SBD service were not in place. However the Lead Clinician recognised the need to develop and incorporate this within the service's clinical governance structure.

The Authority found that the service had some SBD specific clinical audit systems in place. However, these require further development and integration within the SBD governance structures. **(see CE2)**

### **Clinical Effectiveness: Conclusion**

The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 60 patients newly diagnosed with primary breast cancer were seen at the SBD service at St James's Hospital.

In general, the service demonstrated compliance with the selected clinical Standards and where there was a variance, this was explained on grounds of clinical exception. However, clinical audit specific to the symptomatic breast disease was underdeveloped.

The Authority found that the service had some SBD-specific clinical audit systems in place. However, these required further development and integration within the SBD governance structures.

The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at SJH had most of the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need to be addressed

### **Clinical Effectiveness: Recommendations**

**CE1.** The service should put a targeted programme of action in place to ensure 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, with the target being met in more than 90% of patients.

**CE2.** The service should incorporate specific symptomatic breast disease clinical audit activities within the 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 and as they progressed towards meeting these standards by the end of 2009.

In April 2008, St James's Hospital undertook a self-assessment exercise against the Standards and had a resulting score for all elements in a range between 63.2% and 100% compliance. St James's Hospital had completed the self-assessment questionnaire using information from a live data system, database extractions, monthly performance indicator reports, snap-shot audits and professional judgment.

In autumn 2008, the Authority found that St James's Hospital was using a database and was collecting data to routinely measure performance with the Standards and had the appropriate arrangements in place to assure itself that it was meeting the national Standards. The centre was also holding monthly activity meetings where a number of performance indicators were monitored.

In January 2009, the Authority issued a number of broad recommendations in relation to the implementation of effective governance arrangements to oversee the safe transition to a national 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 St James's Hospital 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 patient 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 St James's Hospital. The key conclusions are as follows:

## **5.2 Findings**

### **5.2.1 Governance**

The SBD service at St James's Hospital had a comprehensive corporate and clinical governance structure. There was an organisational framework that incorporated systems and processes for effective general management and clinical decision making. The SBD service monitored and evaluated compliance with the Standards, NCCP and hospital-specified key performance indicators through the Hospital's Breast Care Quality Review and Improvement Group

The SBD service had a well defined multidisciplinary structure which was supported by a standard operating procedure. To facilitate integrated patient care, there were clear patient referral, clinical pathway and leadership arrangements with clear GP communication and referral processes. The service should ensure the service level agreement with the third-party provider of radiation oncology is finalised.

Overall, the Authority concluded that the SBD service at St James's Hospital 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 is actively committed to delivering triple assessment through a multidisciplinary approach and had comprehensive operational policies and evaluation processes 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 were encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that the SBD service at St James's Hospital had the necessary multidisciplinary arrangements in place for the delivery of safe care.

### **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 Hospital's staff recruitment and selection processes, staff induction and mentorship programme ensures controls were in place to monitor clinical competence and multidisciplinary performance. All consultant staff have a contractual commitment to participate in teaching, research and ensuring evidence-based clinical practice.

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

Overall, the Authority found the SBD service 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**

St James's Hospital had the essential arrangements in place to deliver person-centred care. The service has written information available about breast disease, cancer and local support groups. The specialist breast care nurses had directed an amount of effort to patient discharge planning and management and had conducted information sessions for public health nurses and primary care staff.

Wherever possible, patients were central to this process and encouraged to participate in decisions about their treatment options and care.

The discussion group with patients supported these findings. The patients in the group reported satisfaction with the level of information available to allow them to consider options for treatment.

However, the group reported the need to ensure all patients and their families receive sufficient support on discharge particularly in relation to wound drainage management. The Authority concluded that the SBD service at St James's Hospital had the necessary arrangements and facilities in place to deliver person-centred care.

### **5.2.5 Data Management**

The SBD service had a detailed data set and dictionary using the Patient Analysis and Tracking System (PATs) to collate patient data. The required corporate policies and user access controls were in place. A corporate data validation process was in place for checking the accuracy, auditing and validating of data. However, at the time of Review, no evidence was available to the Authority to confirm that there was an SBD specific systematic data validation arrangement in place.

The service demonstrated how it used this information through the monthly Breast Care Quality Review and Improvement Group to monitor and improve the service and quality of patient care.

The Authority concluded that the SBD service at St James's Hospital 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**

The data submitted for the sample period confirmed the centre was marginally below the access targets as determined by the Standards and NCCP KPIs. Access data was collected and trend-analysed by the Breast Care Quality Review and Improvement Group. As was the case in March / April 2009, the service had the ability to increase the number of SBD clinics to respond to increased demand. At the sample time and for the sample set requested, the SBD service was not meeting the access targets for urgent and non-urgent patient referrals. However at the time of the Review, the service was achieving the Standards access targets for urgent and non-urgent referrals, imaging on the first visit and admission to hospital after definitive diagnosis.

Diagnostic access was due to be further enhanced with the commissioning of a second mammography machine scheduled for December 2009.

The service did collect access and medical oncology treatment data. However, radiation oncology data remained a deficit which needed to be addressed.

The Authority concluded that the SBD service at St James's Hospital had most of the necessary arrangements in place to ensure timely access to care.

### 5.2.7 Clinical Effectiveness

The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 60 patients newly diagnosed with primary breast cancer were seen at the SBD service at St James's Hospital.

In general, the service demonstrated compliance with the selected clinical Standards and where there was a variance, this was explained on grounds of clinical exception. However, clinical audit specific to the symptomatic breast disease was underdeveloped.

The Authority found that the service had some SBD-specific clinical audit systems in place. However, these required further development and integration within the SBD governance structures.

The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at SJH had most of the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need 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, St James's Hospital's symptomatic breast disease service was meeting the core quality and safety requirements set out in the Standards.

Overall, the service at St James's Hospital had the systems, processes and controls to deliver the added value and standards expected in a national specialist service and to ensure sustainability going forward.

St James's 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 St James's Hospital 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.

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## 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 NBSB)

**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<sup>\*</sup> 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
  - Lymph 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 9<sup>th</sup> 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
<b>1.1</b>	<b><u>Governance Structure</u></b> (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	
<b>1.2</b>	<b>Monitoring compliance with the National Quality Assurance Standards</b>	
	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	
<b>1.3</b>	<b>Clinical Leadership</b>	
	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.	
<b>1.4</b>	<b>Clinical Risk Management:</b>	
	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	
<b>1.5</b>	<b>Service Level Agreements</b>	



	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)	
<b>1.6</b>	<b>Core Personnel</b>	
	1.6.1 Complete the attached form (Appendix 1) detailing the full complement of core personnel to the symptomatic breast disease service	
<b>1.7</b>	<b>Confidentiality</b>	
	1.7.1 Standard operating procedure / policy for patient confidentiality	
<b>2. Person Centred Care</b>		
<b>No.</b>	<b>Documentation Required</b>	<b>Please tick if document is attached or state reason if not attached</b>
<b>2.1</b>	<b>Patient Information</b>	
	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	
<b>2.2</b>	<b>Patient Satisfaction with the symptomatic breast disease service</b>	
	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	

<b>2.3</b>	<b>General Practice</b>	
	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)	
<b>3. Multidisciplinary Approach</b>		
<b>No.</b>	<b>Documentation Required</b>	<b>Please tick if document is attached or state reason if not attached</b>
<b>3.1</b>	<b>Multidisciplinary Meeting</b>	
	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	
<b>3.2</b>	<b>Triple Assessment Clinic</b>	
	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	

<b>4. Skills, Education and Training</b>		
<b>No.</b>	<b>Documentation Required</b>	<b>Please tick if document is attached or state reason if not attached</b>
<b>4.1</b>	<b>Training and Competency</b>	
	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	
<b>5. Clinical Effectiveness</b>		
<b>No.</b>	<b>Documentation Required</b>	<b>Please tick if document is attached or state reason if not attached</b>
<b>5.1</b>	<b>Clinical Guidelines</b>	
	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	
<b>5.2</b>	<b>Clinical Audit</b>	
	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 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 <u>1 January 2009 – 1 August 2009</u>				
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 <b>new patients</b> 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 <b>urgent</b> by the SBD centre?	Numeric figure		
DaR.3	Of the total number of referrals received during the sample time period that were triaged as <b>urgent</b> by the SBD centre (see DaR.2), what is the total number and percentage of patients <b>offered an appointment</b> 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 <b>non-urgent</b> by the SBD centre?	Numeric figure		

Section A – continued				
ALL questions in Section A refer to data for				
a) the sample time period of <u>1 January 2009 – 1 August 2009</u>				
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 <b>non-urgent</b> by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within <b>6 weeks</b> 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 <b>non-urgent</b> by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within <b>12 weeks</b> 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		



<b>Section B</b>				
<b>ALL questions in Section B refer to data for</b>				
<b>a) the sample time period of the 13 consecutive weeks from <u>1 April 2009 – 30 June 2009</u></b>				
<b>b) the Patient Sample group – seen and newly diagnosed with primary breast cancer</b>				
<b>Question Reference</b>	<b>Question</b>	<b>Information Type</b>	<b>Please state numeric figure/percentage figure as requested</b>	<b>Please tick if providing supporting narrative and add narrative to DaR Appendix x</b>
<b>DaR.8</b>	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		
<b>DaR.9</b>	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 <b>urgent</b> by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
<b>DaR.10</b>	Of the total number of patients that were triaged as urgent (see DaR.9), what is the total number and percentage of patients <b>offered an appointment to be seen</b> within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
<b>DaR.11</b>	Of the total number of patients that were triaged as urgent (see DaR.9) and clinically assessed as 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		
<b>DaR.12</b>	Of the total number of patients that were triaged as urgent (see DaR.9), what is the total number and percentage of patients that had a definitive diagnosis achieved within 10 working days of being seen at the centre?	Numeric figure		
		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 <u>1 April 2009 – 30 June 2009</u>				
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 <b>non- urgent</b> 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 <b>6 weeks</b> 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 <b>12 weeks</b> 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		

<b>DaR.18</b>	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		
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<b>Section B – continued</b>				
<b>ALL questions in Section B refer to data for</b>				
<b>a) the sample time period of the 13 consecutive weeks from <u>1 April 2009 – 30 June 2009</u></b>				
<b>b) the Patient Sample group - seen and newly diagnosed with primary breast cancer</b>				
<b>Question Reference</b>	<b>Question</b>	<b>Information Type</b>	<b>Please state numeric figure/percent age figure as requested</b>	<b>Please tick if providing supporting narrative and add narrative to DaR Appendix x</b>
<b>DaR.19</b>	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		
<b>DaR.20</b>	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		
<b>DaR.21</b>	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		

<b>Section B – Continued note sub-sample group 1</b>				
<b>a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009</b>				
<b>b) the Patient Sample group - seen and newly diagnosed with primary breast cancer</b>				
<b>c) sub-sample group 1: Diagnosed with invasive breast cancer</b>				
<b>Question Reference</b>	<b>Question</b>	<b>Information Type</b>	<b>Please state numeric figure/percentage figure as requested</b>	<b>Please tick if providing supporting narrative and add narrative to DaR Appendix x</b>
<b>DaR.22</b>	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		
<b>DaR.23</b>	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 as having a clinically occult lesion (classification S2)?	Numeric figure		
<b>DaR.24</b>	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 <b>that had surgery</b> ?	Numeric figure		
DaR.26	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of <b>cases</b> that had the histological tumour <b>type</b> 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 <b>cases</b> that had the histological tumour <b>grade</b> 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 <b>cases</b> that had the histological tumour <b>size</b> 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 <b>cases</b> that had the presence or absence of vascular invasion recorded?	Numeric figure		
		Percentage figure to be submitted		

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

<b>Section B – Continued note sub-sample group 3</b>				
<b>a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009</b>				
<b>b) the Patient Sample group - seen and newly diagnosed with primary breast cancer</b>				
<b>c) sub-sample group 3: Patients with primary operable cancer</b>				
<b>Question Reference</b>	<b>Question</b>	<b>Information Type</b>	<b>Please state numeric figure/percentage figure as requested</b>	<b>Please tick if providing supporting narrative and add narrative to DaR Appendix x</b>
<b>DaR.35</b>	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		
<b>DaR.36</b>	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		
<b>DaR.37</b>	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		



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

<b>Section D</b>			
<b>Data Management</b>			
<b>Question Reference</b>	<b>Please provide a copy of the following documents/information</b>	<b>Tick if document is attached</b>	<b>If unable to provide document, please state reason in narrative – DaR Appendix x</b>
<b>DaR.43</b>	Copy of the SBD Centres Data Set		
<b>DaR.44</b>	Copy of the SBD Centres Data Dictionary or Data definition document		
<b>DaR.45</b>	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**

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

## 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.

<b>STANDARD 1: ACCESS</b>		
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%
<b>STANDARD 2: IMAGING</b>		
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

<b>STANDARD 3: DIAGNOSIS</b>		
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
<b>STANDARD 4: MULTIDISCIPLINARY WORKING</b>		
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%
<b>STANDARD 5: TIME TO TREATMENT</b>		
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%
<b>STANDARD 6: SURGERY – ACCURATE LOCALISATION</b>		
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%
<b>STANDARD 7: SURGERY – AXILLARY STAGING</b>		
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
<b>STANDARD 8: SURGERY – SPECIALISATION</b>		
8	Individual consultant surgeons shall assess and operate on a minimum of 50 new patients with breast cancer per year.	Volume
<b>STANDARD 9: SURGERY – ACCURACY OF SURGICAL INTERVENTIONS</b>		
9	For patients having breast conserving surgery, the number of therapeutic interventions shall be recorded.	Volume
<b>STANDARD 10: PATHOLOGY</b>		
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, <i>HER2</i> receptor status shall be recorded.	>95%
10c	For primary invasive tumours, <i>HER2</i> 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](http://www.cancer.ie/action)

ARC Cancer Support Centre: [www.arccancersupport.ie](http://www.arccancersupport.ie)

Biobank Ireland Trust: [www.biobankireland.com](http://www.biobankireland.com)

Breakthrough Breast Cancer: [www.breakthrough.org.uk](http://www.breakthrough.org.uk)

breastcancer.org: [www.breastcancer.org](http://www.breastcancer.org)

Breast Cancer Care: [www.breastcancercare.org.uk](http://www.breastcancercare.org.uk)

Breast Cancer Network Australia (BCNA): [www.bcna.org.au](http://www.bcna.org.au)

BreastCheck: the National Breast Cancer Screening Programme: [www.nbsp.ie](http://www.nbsp.ie)

BreastCheck: <http://www.breastcheck.ie>

Canadian Breast Cancer Foundation: [www.cbcf.org](http://www.cbcf.org)

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

Department of Health and Children: [www.dohc.ie](http://www.dohc.ie)

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

EUROPA DONNA - The European Breast Cancer Coalition: [www.europadonna.org](http://www.europadonna.org)

European Health Portal site: [http://ec.europa.eu/health-eu/index\\_en.htm](http://ec.europa.eu/health-eu/index_en.htm)

Fertile Hope [www.fertilehope.org](http://www.fertilehope.org)

Health Services Executive (HSE): [www.hse.ie](http://www.hse.ie)

Irish Cancer Society: [www.cancer.ie](http://www.cancer.ie)

ICORG (Irish Clinical Oncology Research Group): [www.icorg.ie](http://www.icorg.ie)

Marie Keating Foundation: [www.mariekeating.com](http://www.mariekeating.com)

National Breast Cancer Coalition: [www.natlbcc.org](http://www.natlbcc.org)

National Cancer Control Programme (NCCP): [www.cancercontrol.hse.ie](http://www.cancercontrol.hse.ie)

National Cancer Institute (United States): [www.cancer.gov](http://www.cancer.gov)

National Cancer Registry Ireland: [www.ncri.ie](http://www.ncri.ie)

Rethink Breast Cancer: [www.rethinkbreastcancer.com](http://www.rethinkbreastcancer.com)

Living Beyond Breast Cancer: [www.lbbc.org](http://www.lbbc.org)

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

Y-Me National Breast Cancer Organisation: [www.y-me.org](http://www.y-me.org)

Young Survival Coalition: [www.youngsurvival.org/](http://www.youngsurvival.org/)