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 Cork University Hospital

Date of Assessment: 29 June 2010

Patient Safety First

Working together for quality services

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 its 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 person centred standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services)

Social Services Inspectorate — Registration and inspection of residential homes for children, older people and people with disabilities. Inspecting children detention schools and foster care services. Monitoring day and pre-school facilities[1]

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

[1] Not all parts of the relevant legislation, the Health Act 2007, have yet been commenced.

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1. Recommendations

Theme: Governance

G1. Cork University Hospital should implement actions to mitigate risks identified in relation to inpatient access, medical oncology and the provision of outreach oncology services.

G2. The symptomatic breast disease service, with relevant stakeholders, should assess and manage on an ongoing basis, the potential risks associated with the amalgamation of the symptomatic breast disease service including BreastCheck.

G3. Cork University Hospital with the Health Service Executive, should consider the provision of the symptomatic breast disease service in the context of the overall provision of surgical services and ensure that the mechanisms and controls are in place to safely manage patient demand and capacity for the provision of elective and emergency surgical services.

G4. Cork University Hospital should review the structure and format of the symptomatic breast disease governance committee and meetings to reflect, review and effectively respond to the evolving needs of the symptomatic breast disease service.

G5. Cork University Hospital and the National Cancer Control Programme should ensure an alignment between their corporate and clinical governance arrangements for the provision of cancer services at Cork University Hospital.

G6. Cork University Hospital and the National Cancer Control Programme should evaluate the effectiveness and efficiency of their governance and operational arrangements to ensure the timely and sustainable delivery of symptomatic breast disease services to patients.

G7. Cork University Hospital should ensure the efficacy of the symptomatic breast disease services communication processes with the bed management department to ensure that patient information is communicated in a timely manner.

G8. Cork University Hospital, the National Cancer Control Programme and the wider Health Service Executive should put arrangements in place to plan, govern and manage existing and future patient activities at Cork University Hospital, particularly in relation to symptomatic breast disease services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

Theme: Multidisciplinary Approach

MDT1. The symptomatic breast disease service should introduce specific

multidisciplinary team audit activities as part of the multidisciplinary team meeting to further support effective functioning.

MDT2. The symptomatic breast disease service should ensure that all clinical details are effectively communicated and recorded in the healthcare record.

Theme: Data Management

DM1. The symptomatic breast disease service with the National Cancer Control Programme should ensure consistency in the definition of the date of definitive diagnosis used to calculate the national key performance indicators (KPI) relating to National Quality Assurance Standards 2.8 and KPI 5a.

Theme: Access

A1. The symptomatic breast disease service should ensure that the patient triage classification is recorded according to the National Quality Assurance Standards and National Breast Cancer General Practitioner referral guidelines.

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

Theme: Clinical Effectiveness

CE1. The symptomatic breast disease service should systematically and critically analyse the quality of care provided by developing and directing specific symptomatic breast disease clinical audit activities through the revised symptomatic breast disease governance structure.

2. Introduction

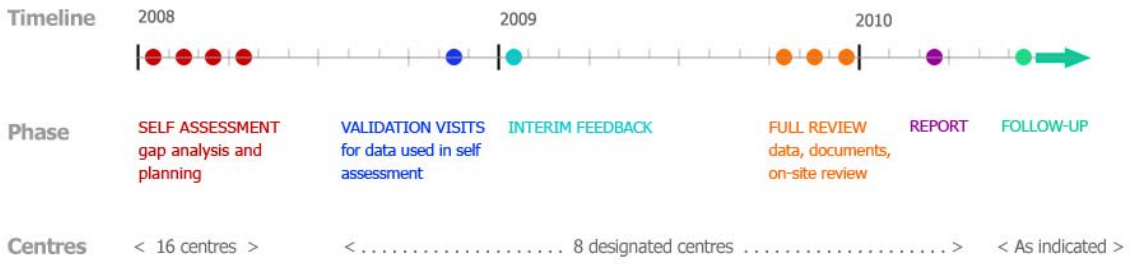
This report presents the findings of a Quality Review Assessment carried out in the Symptomatic Breast Disease (SBD) Service of Cork University Hospital (CUH) in June 2010, six months following the transfer of the SBD service from the South Infirmary Victoria University Hospital (SIVUH). This assessment forms part of the Health Information and Quality Authority's wider programme of quality review assessments of symptomatic breast disease services.

The Health Information and Quality Authority (the Authority) launched the *National Quality Assurance Standards for Symptomatic Breast Disease*[1] (hereafter referred to as the Standards) in May 2007 and advised all hospitals providing 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.

The Authority adopted a multi-faceted approach to monitoring compliance designed to reflect the continuous change programme that had been in progress over two-and-a-half years and the stage of development of the designated centres at a given point in time. This led to a Quality Review Programme that involved five broad phases. Figure 1 summarises the timeline for the Authority's activity over this period.

Figure 1: Summary timeline for the National Quality Review Programme from 2008 to 2010



Quality Reviews were conducted at each of the designated centres (including CUH) over the period of October to December 2009. In February 2010, the Authority published individual reports of the findings of this National Quality Review of Symptomatic Breast Disease Services as they related to each of the eight designated centres and included local recommendations to be implemented by each centre.

However, the 2009 Quality Review had been conducted prior to the re-configuration of symptomatic breast disease services in the HSE South, which included the transfer

of services from SIVUH to CUH. The Authority was of the view that the amalgamated service would be sufficiently different as to require a new full assessment. Accordingly, a further Quality Review visit was undertaken by the Authority at CUH during June 2010. While this is built on what had been learned during the original Quality Review assessment at Cork University Hospital in 2009[(2)], it was conducted as a stand-alone assessment of the new service.

For the purpose of consistency, the Quality Review adopted the same principles and methodology used by the Authority for the 2009 Quality Review (see Appendix 1). Similar to 2009, the Authority included a patient representative as a member of the Review team and undertook discussions with patients as part of the process in order to take account of the realities of patients' experiences.

This report is structured according to seven generic themes. These are:

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

The **essential elements** within each theme that each designated cancer centre must have in place 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"[+]). 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.

[+] 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 designated cancer centres

Theme 1: Governance

Essential Element 1 (a)

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

Essential Element 1 (b)

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

Essential Element 1 (c)

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

Theme 2: Multidisciplinary Approach

Essential Element 2 (a)

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

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

Essential Element 2 (b)

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

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

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

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

Essential Element 2 (c)

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

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

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

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

Theme 3: Skills, Education and Training

Essential Element 3 (a)

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

Theme 4: Person-centred Care

Essential Element 4 (a)

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

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

Essential Element 4 (b)

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

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

Theme 5: Data Management

Essential Element 5 (a)

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

Essential Element 5 (b)

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

Essential Element 5 (c)

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

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

Theme 6: Access

Essential Element 6 (a)
The service must ensure that all patients referred for assessment are triaged and referred appropriately.

Essential Element 6 (b)
Patients requiring surgery, medical oncology and radiation oncology are seen and managed in a timely manner according to specified targets.

Theme 7: Clinical Effectiveness

Essential Element 7 (a)

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

Essential Element 7 (b)

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

In summary, this report presents the findings from the Authority's Quality Review visit at CUH, which took place in June 2010. The evidence on which these findings are based includes:

- documents provided by CUH (see Documentation request template, Appendix 2)
- 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 January 2010 to 2 April 2010 (see Data request template, Appendix 3)
- activity data for new patients seen for the five-month sample period from 1 January 2010 to 1 June 2010
- the findings of the Authority's on-site Quality Review on 29 June 2010 including:
    - validation of data against a number of patient healthcare records
    - qualitative interviews with relevant staff
    - discussion with patients
    - the observation of clinical areas.

* ***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.*

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

After the on-site visit, the Authority requested further data from CUH which was not validated by the Authority:

- access 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 May 2010 to 31 July 2010. This was not validated by the Authority (see Data request template, Appendix 4)

The Authority would like to acknowledge the cooperation of managers and clinicians in CUH and the Health Service Executive's (HSE) National Cancer Control Programme (NCCP) in conducting this Quality Review and thank the patients who gave up their time to share their stories and experiences with us. The Authority would like to acknowledge with great gratitude, the late Christine Murphy Whyte from Europa Donna Ireland who, as part of the Review Team, gave so generously of her energy and time for the benefit of current and future patients.

3. Overview of the Symptomatic Breast Disease Service at Cork University Hospital

Cork University Hospital (CUH) – cancer services for Cork and Kerry

A Strategy for Cancer Control in Ireland (2006) advocated a comprehensive cancer control policy programme which is a whole population, integrated and cohesive approach to cancer involving prevention, screening, diagnosis, treatment, support, follow-up and palliative care. The HSE's National Cancer Control Programme (NCCP) is responsible for setting the future direction of cancer treatment in Ireland. Implementation of the NCCP for symptomatic breast disease services involved the transfer of all major cancer treatment – diagnostic, surgical and radiation oncology services to eight designated cancer centres. Medical oncology for patients under the care of the centres (including chemotherapy) will continue to be delivered at a number of locations identified and agreed by the NCCP. Patient support and palliative care services will also be provided at local level where possible.

CUH is one of the eight designated cancer centres and one of two centres in the southern region. The centre provides cancer services predominantly to people who live in counties Cork and Kerry, south Tipperary, west Waterford and southeast Limerick. The range of services encompasses tests to diagnose cancer, surgical cancer treatments, oncology consultations, chemotherapy and radiotherapy treatments.

At the time of this Quality Review in 2010, full amalgamation of symptomatic breast disease services to CUH was complete. SBD services had been transferred from SIVUH and Kerry General Hospital (KGH) to CUH, with an outreach oncology service available in KGH. The new cancer centre and refurbished histopathology facility at CUH had also opened.

In tandem, the transfer of BreastCheck, the National Breast Screening Programme (NBSP) to CUH coincided with the centralisation of SBD services. The southern unit of BreastCheck has a catchment area which includes Cork, Kerry, Waterford and Tipperary South. The screening component of BreastCheck is carried out at the BreastCheck mobile units and at the static unit adjacent to SIVUH. CUH provides the service for all BreastCheck patients diagnosed with breast cancer.

In June 2010, for the purpose of the Review, CUH submitted activity data which provided a preliminary overview of the centre's activity for new patients seen at the SBD service for the five-month sample time period between 1 January 2010 and 1 June 2010, illustrated in Table 1. **The figures below were reported by the centre in its data submission and were not validated by the Authority**.

Table 1: New Patient referral activity at Cork University Hospital (1 January 2010 to 1 June 2010)

New patient referral activity at Cork University Hospital, 1 January 2010 to 1 June 2010	
Total number of new patients seen at the CUH SBD service	1964
Total number of newly diagnosed primary breast cancer patients	103

Table 2: New patient referral activity by urgent triage category reported by Cork University Hospital, 1 January 2010 to 1 June 2010

New patient referral activity by urgent triage category at Cork University Hospital, 1 January 2010 to 1 June 2010	
Total number of new patient referrals received during the sample time period that were triaged as **urgent** by the SBD Service	701
Total number of new patient referrals triaged as **urgent** who were offered an appointment to be seen within 10 working days of the date of receipt of referral	664
Percentage of new patient referrals triaged as **urgent** who were offered an appointment to be seen within 10 working days of the date of receipt of referral	95%

Table 3: New patient referral activity by non urgent triage category reported by Cork University Hospital, 1 January 2010 to 1 June 2010

New patient referral activity by non-urgent triage category at Cork University Hospital, 1 January 2010 to 1 June 2010	
Total number of new patient referrals received during the sample time period that were triaged as **non urgent** by the SBD Service	1263
Percentage of new patient referrals triaged as **non-urgent** who were seen within **12 weeks** of the date of receipt of referral	100%

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 report if the key elements for the delivery of safe, quality care were in place at the time of the review.

4.1 Theme 1: Governance

Governance

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

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

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

Essential Element 1 (a)

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

Findings Essential Element 1 (a)

Background

Implementation of the Cancer Control Strategy, which included setting up the NCCP for symptomatic breast disease services and transferring all major cancer treatment, diagnostic, surgical and radiation oncology services to eight designated cancer centres, commenced with the centralisation of SBD services in 2007. Completion of the centralisation of the SBD services took place in December 2009, with the transfer of the SBD services from SIVUH to CUH. The reconfiguration of the SBD services in the HSE South was unique given that it involved the relocation of a larger service in terms of the volume of breast cancer cases at SIVUH to a centre with smaller numbers which necessitated a major capital building programme together with the transfer of staff and resources.

The Authority was informed that a number of other initiatives were in place to support the implementation of the cancer strategy in the HSE South and in particular the centralisation of SBD services to CUH. These included the:

- additional developments in cancer services through the National Cancer Control Programme
- reconfiguration of clinical services
- day-to-day operational functions under the Integrated Services Directorate (HSE South)
- patient safety focus of the Quality and Clinical Care Directorate

During the 2009 review of SBD services at CUH, it was indicated to the Authority that there were plans for a number of organisational arrangements to be in place to accommodate the centralisation of SBD services. These included:

- the complete integration of SBD services from KGH and SIVUH
- a purpose-built symptomatic breast disease unit
- the provision of dedicated day-beds, including theatre and recovery facilities
- ring-fenced beds for patients requiring inpatient beds, to accommodate the centralisation of SBD services and the BreastCheck patients requiring surgical services
- a change management plan developed to support the above process with a project implementation group.

Integration and transfer of SBD services to CUH

At the time of the 2010 review, the transfer of breast surgical services from KGH and SIVUH, BreastCheck and Cork City histopathology services to CUH was complete and fully operational.

In relation to KGH, the Authority confirmed, through documentation review and interview, that the SBD service had transferred and the SBD service had the appropriate patient quality and safety controls in place with arrangements to continue the provision of SBD outreach medical oncology services and outpatient review services in KGH.

A review of the minutes of the SBD governance committee and interviews confirmed that it had been expected that the SIVUH would also provide an outreach medical oncology service. However, at the time of the 2010 review, it was reported to the Authority at interview, and during the review of facilities, that SIVUH was not providing the medical oncology service.

Consequently, it was reported by the SBD team at CUH that, as a result of the establishment of the mobile BreastCheck unit in Waterford in July 2009, there had been an increase in patient flow to CUH that had not been previously been accounted for. It was reported that all other cancer patients requiring oncology

services, had impacted on the capacity of CUH to effectively manage the increasing volume of patient referrals. This was confirmed to the Authority at the multidisciplinary meeting and by the clinical staff on the day oncology ward. **(See G1.)**

During the 2009 review, the CUH SBD team also indicated that additional capacity for the centralisation of SBD services at CUH would, as part of the regional re-configuration of services, be facilitated by the transfer of the ophthalmology services out of CUH to another facility in the HSE South region resulting in the conversion of the existing ophthalmology day-ward and theatre into a purpose-built day ward and theatre facility for the SBD services at CUH. However, at the time of the Review this had not happened resulting in day and inpatient accommodation and theatre services for SBD patients being provided in different areas within the CUH campus. **(See G2.)**

Additionally, the service indicated that the increase of patient referrals into the SBD service at CUH from the BreastCheck service based in SIVUH, and the satellite BreastCheck service located in Waterford city, had not been accounted for. This had resulted in an increased patient demand on the existing capacity at CUH.

As part of the transition, consultant surgeons transferred on a full-time or on a sessional basis from SIVUH to the CUH SBD service. At the time of the Review, the consultant surgical staff with a sessional commitment to the SBD service at CUH continued to be contractually employed by SIVUH or by BreastCheck. Surgeons continued to provide their general surgical and surgical on-call commitment at SIVUH.

The Authority explored the governance arrangements relating to the transferred consultant surgical staff and identified that these surgeons report directly through the governance arrangements of their employing organisation, namely SIVUH. However, while working on-site at CUH, these surgeons report on clinical matters to the CUH Clinical Director.

These arrangements highlighted a difficulty for individual consultants, and the service, in balancing the competing demands between SBD surgeons working in CUH while concurrently providing their contractual commitment to elective and emergency surgical on-call cover at SIVUH. Recognising that these arrangements are relatively new and still bedding down, nevertheless, the Authority identified the need to address this as a potential risk to the sustained delivery of high quality care within SBD surgical services at CUH and the availability of consultant surgeons who may be on call for emergency patients at SIVUH while simultaneously undertaking SBD work at CUH.

During the quality review, evidence emerged of challenges in balancing the competing demands of SBD and wider surgical priorities. Although not the central focus of this Review, and so not subject to detailed exploration by the Authority, this appeared to be linked to wider problems relating to the access to operating theatres for both elective and emergency surgical patients in CUH. When taken together with

other operational issues previously reported, the Authority concluded that there remained outstanding issues – subsequent to the transfer of services from SIVUH – that related to the effective management of the transition of the SBD service and, in particular, the demand and capacity management of patients at CUH. **(See G3.)**

The Authority consequently raised these issues with the HSE in advance of concluding this report, recommending the urgent assessment of potential risks associated with the transfer and amalgamation of the SBD service, and to the implementation of necessary mitigating actions.

In the broader context, CUH, the NCCP and the wider HSE should put arrangements in place to plan, govern and manage existing and future patient activities at CUH, particularly in relation to SBD services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

SBD Governance Arrangements

Nationally, the NCCP has delegated corporate responsibility within the HSE for overseeing the implementation of the *National Quality Assurance Standards for Symptomatic Breast Disease*. Locally within each cancer centre, in respect of SBD services the Hospital is corporately accountable to the NCCP and to the Regional Director of Operations (RDO) for its overall performance.

In CUH, the clinical and corporate governance function is structured using a clinical division model comprising of 15 clinical divisions, each with a lead clinician. The SBD service is a constituent of the surgical division. At the time of the Review, the SBD service had a nominated lead clinician who had a sessional commitment to the SBD service. In addition, at CUH the SBD Lead Clinician is chair of the surgical division and is a member of the Regional Cancer Steering Group.

The role of lead clinician is an evolving role. At national level, the NCCP has formally identified the role of the lead clinician as being to:

- support the clinical governance of the SBD service within the context of the overall clinical governance framework of the centre
- facilitate compliance with national standards and key performance indicators (KPIs)
- ensure the appropriate leadership, effective communication and dissemination of information for and within the multidisciplinary team
- play a leading role in reviewing systems of delivery, including involving patients/carers
- act as the clinical liaison with the NCCP
- ensure audit and data collection that enables and demonstrates compliance with national standards and KPIs.

The Authority confirmed that the role of the SBD Lead Clinician at CUH includes these functions with the post holder reporting directly through the governance

arrangements of CUH.

In monitoring the quality of the SBD services provided at CUH, the Lead Clinician reports operationally to the Chief Executive of Cork University Hospital Group and reports clinically to the Clinical Director of CUH. Nationally, the lead clinician shares a professional relationship with a nominated clinical liaison in the NCCP.

The SBD service had a SBD-specific governance group. This committee has a large membership with all clinical and non-clinical disciplines within the SBD specialty attending. The committee is operating within a planned timetable. The Lead Clinician is the chairperson with a nominated deputy.

The specific functions of this group include the:

- discussion of data and audit of breast services
- discussion of quality issues pertaining to breast services
- review of the current patient referral and pathway systems
- discussion of issues pertaining to the breast service and introducing changes as appropriate.

The Authority reviewed the terms of reference of this group, together with minutes of meetings, which confirmed that the group is utilising validated data, reviewing trends in information and monitoring compliance against clinical and non-clinical key performance indicators, analysing patient feedback, complaints and actual and potential incident reports. However, the meeting minutes were not structured to give a clear view of the resultant actions taken and/or the persons responsible for the actions.

In addition, the minutes reflected the large number of attendees at the group meetings and the complexity of issues associated with the centralisation of SBD services and a substantial change and integration programme. The Authority found that this led the group to be involved in several routine operational issues which detracted from the core function of the group. Consequently, the Authority concluded that the Lead Clinician should consider restructuring the meetings, review the group membership and redirect their focus to reflect the SBD service as an entity. **(See G4.)**

Clinical Governance and Management Arrangements

At the time of the Review, the Chief Executive of Cork University Hospital Group was having regular structured meetings with the NCCP Cancer Network Manager (South) reviewing financial allocation, service developments and key performance indicator reports. However, the Clinical Director at CUH did not attend these meetings. **(See G5.)**

In addition, the Authority reviewed the operational functioning of the SBD service in tandem with, and as a reflection of, the governance arrangements in place at CUH.

During the on-site review, evidence of several areas of operational concern were identified which had the potential to impact on the sustainable compliance with one or more of the Standards by the SBD service. These included the:

- non-availability of non-consultant hospital doctor (NCHD) staff for some SBD outpatient department (OPD) services thereby limiting the potential productivity of this service together with a large variance in the number of patients seen per sessional commitment of individual consultants. This suggests that there may be a possible variation in the quality of service provided to individual patients
- timely availability in CUH of patients' radiological reports previously recorded in BreastCheck or at SIVUH
- ineffective management of annual leave arrangements for consultant staff with evidence of this impacting on clinic scheduling and the service's capacity to meet access targets for urgently referred patients.

The Authority concluded that these challenges, if not addressed, could potentially compromise the timely and sustainable delivery of SBD services according to the Standards. **(See G6.)**

In summary, at the time of the Review, the Authority found that the governance and operational management arrangements of the amalgamated SBD service at CUH was in a very early stage of development. These included the structure of the SBD governance group. This had led to a number of patient-care related issues to emerge, for example, the volume of OPD patient attendances per clinic, timely inpatient access processes and arrangements relating to balancing the elective and emergency commitments of consultant surgeons.

The Authority was sufficiently concerned about some aspects of these issues to raise them with the HSE in advance of the conclusion of this report.

The Authority concluded that a comprehensive integrated governance structure was not in place in full at the time of the quality review assessment of CUH, primarily due to the substantial changes associated with the service's ongoing transition to a single amalgamated SBD service following the recent reconfiguration. The Authority has made recommendations to this effect.

Essential Element 1 (b)

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

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

service.

The Authority reviewed and confirmed that the service had a documented clear patient pathway through the SBD service.

The multidisciplinary team (MDT) process is central to the management of symptomatic breast disease and includes triple assessment (TAC) and MDT meetings. The Authority found that the SBD service had a well-defined triple assessment process and multidisciplinary structure which was evidenced throughout the staff interviews, the data validation exercise and patient healthcare record review. These structures were supported by an approved policy and procedure document.

However, it was reported to the Authority during interviews that the service was becoming increasingly challenged to meet outpatient department (OPD) patient access timelines for urgent patients to be offered an appointment to be seen within 10 working days. **(See Access, Essential Element 6b.)**

Inpatient Pathway

The Authority reviewed the inpatient pathway and confirmed that there were ring-fenced inpatient and day procedure arrangements in place which were delivered in two separate areas in the hospital.

However, the review of the SBD governance group minutes, the review of facilities and interview with the team, established that maintaining satisfactory inpatient access was becoming increasingly difficult for the SBD service. The Authority confirmed that this, in addition to the areas highlighted in essential element 1 (a), was the result of underdeveloped operational mechanisms in relation to the timely notification and communication to the bed management department of MDT decisions regarding the admission of patients. At the time of the Review, the SBD service had begun to address this by agreeing a formal communication process between the clinical nurse specialist and the bed manager. **(See G7.)**

Medical Oncology

During interview, the medical oncology service was highlighted as an aspect of the SBD service which required further attention. During review of the minutes of the SBD governance group, and through interviews, the Authority confirmed that the SBD oncology service, in line with NCCP strategies, was to be delivered in CUH with outreach services provided in KGH and SIVUH. However, at the time of the Review, there were no SBD oncology services being delivered at SIVUH. Consequently, due to the increased volume of patients referred by the SBD service, BreastCheck and all other cancer services, the oncology services at CUH were increasingly challenged in maintaining a high quality service. This was observed and reported by the patient discussion group and was further confirmed by the Authority during the review of facilities.

Following the transfer of SBD oncology services from SIVUH, there had been no

corresponding transfer of trained oncology staff from SIVUH to CUH to manage the service. The oncology unit at CUH had recently reduced its oncology patient waiting lists through a number of local initiatives. However, the service raised concerns that, due to increased number of patients requiring oncology, sustainably meeting the Standards for the required oncology access times may prove a challenge

In addition, the Authority identified that the service had not created an oncology patient-liaison function or ward administrative support at CUH which potentially compromises the effective integration of the patient journey with other services. The Authority confirmed this during the patient discussion, the review of facilities and multidisciplinary team interview. The capacity of medical oncology services provided at SIVUH was outside the scope of the Review. However, the Authority has made recommendations for the relevant stakeholders to review the current arrangements in relation to the provision of oncology services.

Radiation Oncology

At the time of the Review, the Authority confirmed that the SBD radiation oncology services had the necessary patient referral, staffing and scheduling systems in place.

In summary, at the time of Review, the service had structured clinical management, referral and patient pathway processes in place. However, the sustainability of these arrangements, particularly in relation to timely OPD access, theatre, inpatient and medical oncology access is at risk and requires urgent attention. The Authority has made recommendations to this effect.

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)

At the time of the Review, the service had the necessary service level agreements in place.

Governance: Conclusion

At the time of the review, the transfer of breast surgical services from KGH and SIVUH to CUH was complete.

However, the Authority identified a number of governance and operational management issues reflective of the early stage of development of the recently amalgamated service which need to be addressed. These include the structure of the SBD governance group, absence of the Clinical Director from meetings with the NCCP, variation in the volume of OPD patient attendances per clinic and effective

inpatient access processes.

In addition, while the service had clinical management, referral and patient pathway processes in place, the sustainability of these arrangements, particularly in relation to timely OPD access, inpatient theatre access for SBD specific and BreastCheck referred patients and medical oncology access, is at risk and requires attention.

The centralisation of SBD services is a component of a wider change process which includes the reconfiguration of acute services in the HSE South with additional service developments at CUH. Although not a core focus of the Review and therefore not explored in detail by the Authority, the Authority was not satisfied that the arrangements to effectively manage the configuration of clinical services, including issues of demand and capacity management for patients, were strategically aligned and coordinated nationally, regionally and locally in order to effectively manage service transition.

In the broader context, CUH, the NCCP and the wider HSE should put arrangements in place to plan, govern and manage existing and future patient activities at CUH, particularly in relation to SBD services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

The Authority highlighted these issues with the HSE in advance of concluding this report recommending the urgent assessment of potential risks associated with the transfer and amalgamation of the SBD service, and the implementation of necessary mitigating actions. The HSE has responded in writing with an action plan to address the issues highlighted and committed to monitoring its implementation. The Authority has also made recommendations in relation to these issues within this report and will monitor their implementation through follow-up with the service and the NCCP.

Governance: Recommendations

G1. Cork University Hospital should implement actions to mitigate risks identified in relation to inpatient access, medical oncology and the provision of outreach oncology services.

G2. The symptomatic breast disease service, with relevant stakeholders, should assess and manage on an ongoing basis, the potential risks associated with the amalgamation of the symptomatic breast disease service including BreastCheck.

G3. Cork University Hospital with the Health Service Executive should consider the provision of the symptomatic breast disease service in the context of the overall provision of surgical services and ensure that the mechanisms and controls are in place to safely manage patient demand and capacity for the provision of elective and emergency surgical services.

G4. Cork University Hospital should review the structure and format of the symptomatic breast disease governance committee and meetings to reflect, review

and effectively respond to the evolving needs of the symptomatic breast disease service.

G5. Cork University Hospital and the National Cancer Control Programme should ensure an alignment between their corporate and clinical governance arrangements for the provision of cancer services at Cork University Hospital.

G6. Cork University Hospital and the National Cancer Control Programme should evaluate the effectiveness and efficiency of their governance and operational arrangements to ensure the timely and sustainable delivery of symptomatic breast disease services to patients.

G7. Cork University Hospital should ensure the efficacy of the symptomatic breast disease services communication processes with the bed management department to ensure that patient information is communicated in a timely manner.

G8. Cork University Hospital, the National Cancer Control Programme and the wider Health Service Executive should put arrangements in place to plan, govern and manage existing and future patient activities at Cork University Hospital, particularly in relation to symptomatic breast disease services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

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)

The SBD service at CUH had the core team required for an SBD service with SBD consultant staff having ring-fenced sessional commitments to the service.

However, at the time of Review, the SBD service reported that theatre and medical oncology services did not have the full complement of staff required for the volume of patient activity seen. This suggests the need for close monitoring of demand and capacity with implementation of identified actions, given that a long-term mismatch between patient demand and capacity could potentially compromise the sustainable compliance with the Standards. **(See G2.)**

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 process thereby ensuring an integrated approach for the delivery of triple assessment for patients.

The clinic timetable confirmed the weekly scheduling of triple assessment clinics (TAC). The data validation and review of medical records confirmed that patients' initial clinical findings were being recorded in the clinical assessment sheet, with imaging, and pathology findings recorded in the diagnostic referral sheet and patient healthcare record.

At the time of the Review, the Authority found that the SBD service at CUH was holding a minimum of weekly triple assessment clinics.

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 MDT meeting.

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

Findings Essential Element 2 (c)

At the time of the review, the SBD service at CUH was holding two types of MDT meeting, one to discuss patients following the TAC and the second to discuss those patients referred for surgery and / or oncology. The Authority reviewed and confirmed that the service had a standard operating procedure (SOP) in place for the organisation and functioning of both multidisciplinary meetings. This SOP included security and patient confidentiality controls. All attendees had dedicated time to attend the MDT meetings.

The role and responsibilities of the members of the MDT were clearly defined. While there was evidence of processes and protocols in place to support the functioning of the multidisciplinary team, the Authority noted that the SOP did not identify the audit and control processes in place to evaluate this. **(See MDT1.)**

The Authority confirmed that patients discussed at both MDT meetings include:

1. All patients with a clinical or radiological / sonographic abnormality.
2. All patients who have had triple assessment.
3. All patients following the first therapeutic operation.

4. Those for whom discussion at the meeting is deemed appropriate.

In the service, the MDT was coordinated by a dedicated post holder with the responsibility of organising and ensuring that all patients' clinical details and reports are available for the meeting. During the patient healthcare record review, the Authority reviewed and verified the processes to ensure the availability of this information. Detailed clinical reporting was observed. However, follow-up patients and privately referred patients in the sample group did not have their clinical classification codes recorded. **(See MDT2.)**

Clinical decisions and outcomes were recorded by the presenting clinician on the MDT meeting form. At the time of the Review, these were retrospectively entered by the Data Manager onto the Patient Analysis and Tracking System (PATS).

The Authority reviewed and confirmed that the service's communication process to ensure that all patients with a definitive diagnosis of breast cancer are discussed at the MDT meeting, and are personally contacted by a member of the Specialist Breast Nurse Team, was acceptable.

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 phone by the clinical nurse specialist. In addition, the Authority confirmed that the consultant surgeon ensures that the general practitioner (GP) of a patient with a diagnosis of cancer is contacted by phone and informed of the diagnosis.

At the time of the Review, the Authority found that the SBD service at CUH had the MDT meeting and process in place.

Multidisciplinary Approach: Conclusion

The service was actively committed to delivering triple assessment through a multidisciplinary approach. It had comprehensive operational policies and evaluation processes to ensure that the multidisciplinary team is involved in all clinical decision making and treatment planning. Wherever possible, patients are central to this process and encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that, the SBD service at CUH, at the time of the Review, had the necessary multidisciplinary arrangements in place for the delivery of safe care. Where there remained opportunities for improvement, the Authority has made recommendations to this effect.

Multidisciplinary Approach: Recommendations

MDT1. The symptomatic breast disease service should introduce specific multidisciplinary team audit activities as part of the multidisciplinary team meeting to further support effective functioning.

MDT2. The symptomatic breast disease service should ensure that all clinical details are effectively communicated and recorded in the healthcare record.

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 that the SBD service at CUH 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 SBD team, there were several arrangements identified by the Authority whereby continuing professional development and competencies of staff were being monitored. The mechanisms within the SBD team include MDT meeting, peer interaction, quality review, clinical audit, clinical research and attending national and international courses, seminars and master classes. The service had a formal policy to support and monitor continuous professional development in the symptomatic breast disease service which will be monitored and evaluated annually by the service's audit quality and risk meeting. The first of these reviews was due to take place in May 2011, therefore the evidence of its findings was not available to the Authority at the time of the Review.

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

The Authority found that clinical nurse specialists in breast care have relevant qualifications and clinical experience and are registered on the national clinical nurse

specialists register.

The Authority reviewed and confirmed that the Hospital had:

- a corporate education, funding and study leave policyy
- in-service educational programme and timetable
- training and attendance records being maintained for all staff

- triple assessment processes and multidisciplinary team meeting ensuring peer review and agreement of clinical findings
- an SBD service clinical policy and guideline manual
- mandatory training in:
  - mammography
  - communication
  - education programme (pathology laboratory).

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

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. All consultant staff have a contractual commitment to participate in teaching, training, research and ensuring evidence-based clinical practice.

The specialist breast care nurses (SBCNs) are registered on the national clinical nurse specialists register. The in-service programme includes a mandatory training programme on chemotherapy administration, mammography and communication and staff attendance records were maintained.

Overall, the Authority found the SBD service at CUH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise.

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 review of facilities, patient healthcare record and documentation review, that the SBD service at CUH 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 service 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 CUH. Three specific themes were explored:

- access
- clinical care
- information and support.

Person-centred care as reported by the patient discussion group at Cork University Hospital was as follows:

Access
The group reported satisfaction with the timelines in relation to referral and diagnosis. However, some patients in the group referred to delays in receiving a start date for chemotherapy treatment and one patient reported receiving very short notice of admission for treatment.

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 CUH. In particular, those patients who had received all of their diagnostic procedures on the same day were highly appreciative of the manner of delivery and the effectiveness of the process. Those who were prepared for and enabled to return home after day-surgery were also very satisfied with their experience.

Many praised the dedication of the staff and the time and care afforded to them. All patients reported that they were happy with the level of care and emotional support they received from the specialist breast care nurses, with some describing the availability of nurses at the other end of the telephone being of major importance to them on their journey.

Patients in the group reported that they had sufficient time and information to consider treatment options before decisions were made. While none of the patients were informed that they were entitled to a second opinion, the majority of the group felt happy with the service and did not require a second opinion.

The majority of patients reported that the Standards in relation to the integration of their care pathway from referral to diagnosis to treatment were all met, and reported general satisfaction with the level of privacy in the Symptomatic Breast Unit.

However, all patients reported that during their patient journey, they had perceived pressures on staff in dealing with the volume of patients coming to the service. Consequently, some patients cited occasions where they felt the support structures in place did not fully address their needs.

Information and support
All patients in the group indicated that the key Standards in relation to patient information were met to their satisfaction. However, the degree to which the patients had read or assimilated this information varied. There appeared to have been differences in how lymphoedema was explained to patients and how this was understood. Some patients reported that they would have liked more information in relation to chemotherapy and time made available to discuss side-effects and how these could be managed.

The majority of the group were confident that their GPs had received their clinical information in a timely manner.

Patients with a strong family history of breast cancer reported satisfaction with how this was being dealt with in relation to their families.

Those patients in the group who had received information on support groups and the local cancer support centre had used these support services and found them beneficial.

At the time of the Review, the Authority found that the SBD service at CUH 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)

At the time of the Review, the construction of the cancer centre at CUH was complete. The review of the facility confirmed this as a stand-alone department with facilities including clinical examination rooms, counselling, mammography and ultrasound facilities.

The Authority's review of the on-site facility where the service was being delivered included the:

- cancer centre
- inpatient and day ward
- day oncology and radiotherapy unit.

The cancer centre consists of:

- eight consultant rooms
- two treatment rooms
- prosthesis / counselling room with separate adjoined fitting room.

The breast clinic shares a main reception with the colorectal service, with an additional sub-waiting area for breast patients, once checked in at main reception. The facility has four ultrasound machines and three mammography machines. The imaging area has an additional sub-waiting area for patients awaiting pre-operative imaging. The imaging area of the facility has one single-station reporting room and an additional three-station reporting room.

The breast clinic includes the administrative office for the clinical nurses specialists,

MDT (multidisciplinary team meeting) coordinator and cancer control office. There is a "quiet room" which is an additional area to provide support for patients and to provide psycho-oncology services.

Cancer Control Office

All referrals to the service are received through the Cancer Control Office (CCO). Referrals are received either by letter, fax, NCCP GP referral form, via Healthlink or internally (for example, from consultants' secretaries). Referrals are triaged by a consultant breast surgeon and allocated to the appropriate next OPD.

Inpatient and day procedure areas

Generally, SBD patients requiring public surgical inpatient admission were admitted to a ring-fenced general surgical ward. SBD day procedure patients were admitted either to the day procedure unit or to ring fenced day-beds located in a general surgical ward. The day procedures unit had a total of 19 beds and was being used primarily by the ophthalmology service and the SBD service. Included within this unit is a pre-assessment area, access to surgery, recovery area and discharge lounge. While the SBD service is not delivered within one specific dedicated area, the areas used by the service had the appropriate infrastructure to support a safe quality patient service.

Medical and radiation oncology area

The medical oncology (day ward) and radiation oncology suite included single clinical rooms and counselling rooms. At the time of the Review, the lymphoedema service for patients was adjacent to the medical oncology ward. During the review of the facilities, the medical oncology staff highlighted difficulties in finding sufficient time to deliver personalised care to patients.

At the time of the Review, the Authority concluded that the SBD service at CUH, had most of the necessary OPD, triple assessment, day procedures and radiotherapy arrangements and the required facilities in place to deliver person-centred care.

Person-centred Care: Conclusion

The service has written information about breast disease, cancer and local support groups. For the most part, patients in the patient discussion group reported satisfaction with the level of information to allow them to consider options for treatment.

The newly constructed cancer centre has the facilities to support the service. However, inpatient access and medical oncology services are challenged to meet the increasing demands of the SBD service.

The Authority concluded that the SBD service at CUH, at the time of the Review, had some of the necessary OPD, triple assessment, day procedures and radiotherapy

arrangements and the required facilities in place to deliver person-centred care.

However, in light of the centralisation of some cancer services and the increasing volume of patients requiring care, the current arrangements require ongoing evaluation by the service and the NCCP to ensure that they are sustainable in order to effectively and efficiently manage the needs of patients.

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 SBD service at CUH used the following information systems:

- Patient Analysis and Tracking System (PATS) symptomatic breast disease clinical information system
- patient management system
- Laboratory Information System – laboratory reports
- Radiology Information System – radiology reports
- Radiotherapy and Medical Oncology System – referral and treatment information.

The Authority found that the service had a number of information systems. At the time of the Review, the PATS system was fully operational. The radiotherapy and medical oncology system is a stand-alone system and arrangements were in place to enter the information from radiotherapy and medical oncology system onto PATS. The SBD clinical nurse specialists input directly onto PATS.

Essential Element 5 (b)

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

Findings Essential Element 5 (b)

The Authority verified that the service's web-based Patient Analysis and Tracking System (PATS) was fully operational. The Authority found that CUH recorded the 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)

At the time of the Review, the service had a data definitions document relating to PATS. Nationally, the NCCP is developing a complete data set and dictionary, the SBD service is involved in this programme.

Definitive diagnosis (Standard 4.9)

It was noted during the data validation that, following discussion at the diagnostic MDT meeting, a small number of patients required further investigations prior to agreeing treatment options at a second MDT meeting. Both MDT meeting dates were recorded as the date of definitive diagnosis.

For the purpose of this review, the date of the definitive diagnosis is taken as the date of diagnosis at the MDT meeting, as agreed by the NCCP. During the data validation, it was noted for this small number of patients, that the date of the first MDT meeting was used to calculate the performance indicator for Access for urgent patients (Standard 2.8) and the date of the second MDT meeting was used to calculate the performance indicator for Surgical Intervention (KPI 5a). During the interview, the Authority highlighted the need for the consistent use of one date of definitive diagnosis when calculating key performance indicators. The Authority advised the service to seek clarification regarding the data definition for date of definitive diagnosis through the NCCP. **(See Recommendation DM1).**

The service had a data validation process which included:

- monthly validation against a random selection of patients' healthcare records – 20% of new patients with a diagnosis on cancer are reviewed
- quarterly validation against a random selection of patients healthcare records – 5% of new patients with benign disease are reviewed
- multiple registries are included in all validation exercises.

At the time of the Review, the Authority found that the SBD service at CUH had the required data set, dictionary and standard operating procedure for data validation 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)

The SBD-specific governance committee, whose membership includes the clinical and non-clinical disciplines within the SBD specialty, review and monitor key performance indicators with the National Quality Assurance Standards.

At the time of the Review, 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

At the time of review, the Patient Analysis and Tracking System (PATS) to collate basic data on access, diagnosis, pathology, primary treatment and clinical outcomes was fully operational.

The Authority carried out a data validation process (which included a review of the patient's healthcare records) for checking the accuracy, auditing and validation processes in place to support the evolving symptomatic breast disease service at CUH.

The Authority concluded that, at the time of the Review, the SBD service at CUH had most of the necessary data management arrangements in place.

Data Management: Recommendations

DM1. The symptomatic breast disease service with the National Cancer Control Programme should ensure consistency in the definition of the date of definitive diagnosis used to calculate the national key performance indicators (KPI) relating to National Quality Assurance Standards 2.8 and KPI 5a.

4.6 Themes 6 and 7: Access and Clinical Effectiveness

As part of the follow-up visit to CUH, the SBD service was requested to provide the Authority with access and clinical effectiveness data for patients newly diagnosed with primary breast cancer. Data was submitted for the five-month period from 1 January 2010 to 1 June 2010, and for the 13-week sample period of 1 January 2010 to 2 April 2010. The purpose of this data request was to provide the Authority with an overview of the activity at the SBD service prior to the on-site Review, and details of key performance indicators pertaining to the service.

Based on the five-months data, it was identified that the SBD service at CUH had seen an increase in patient referrals in comparison to the average monthly referral for the same period in 2009. Due to the significant service change that has taken place since 2009, directly comparative data is not available. However, the submitted data suggests an increase of approximately 40% in both the total number of new patients seen at the CUH SBD service and the total number of newly diagnosed primary breast cancer patients. The five-month data was reported by the service and was not validated by the Authority.

In tandem, the transfer of BreastCheck, the National Breast Screening Programme (NBSP) to CUH coincided with the centralisation of SBD services. It was reported to, but not validated by the Authority, that this transfer, which included patient referrals from the mobile BreastCheck unit established in Waterford in July 2009, had resulted in an increase in patient flow to CUH that had not been previously been accounted for.

While the data for the 13-week sample period from 1 January to 2 April 2010 reflects that the service has met the targets pertaining to access and clinical effectiveness, concerns regarding the sustainability of the level of activity and the ability to meet targets into the future, were raised during interview and observation. More recent data was requested and, while not validated, this shows that the position has deteriorated, highlighting the need for continued vigilance in monitoring performance. This issue is further explored in Essential Element 6b of this report. Certain areas of the service have been identified in the following section of the report which require particular attention by the SBD service at CUH.

To assure the accuracy and reliability of the 13-week data sample submitted by the service in relation to the access and clinical effectiveness data, the Authority carried out an on-site validation of 25% of the patient healthcare records. To ensure confidence in the data submitted, the validation process included a review of the:

- clinical classification coding[¥]
- diagnostic imaging and histopathology reports
- patient consent form
- MDT forms

[¥] *Clinical Classification Coding: relates to triple assessment scores for clinical examination, radiological result and histopathology result.*

- 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 that 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) demonstrated for this sample group of patients for the 13-week sample period of 1 January 2010 to 2 April 2010, 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 service's findings below.

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

The Authority reviewed and confirmed that the service had a documented clear patient pathway through the SBD service. The Authority confirmed that the service had an SOP, utilising the NCCP classification system to effectively manage the patient triage processes. However, on reviewing the operational process during the review of facilities and the patient healthcare record review, the Authority identified varying terminology for recording patient triage, which could potentially cause an incorrect interpretation or scheduling of patient appointments. **(See A1.)**

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)

CUH 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 January 2010 to 2 April 2010.

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 service's 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 January 2010 to 2 April 2010.

PERFORMANCE MEASURE:	TARGET	CUH COMPLIANCE
Access for urgent patients	**TARGET**	**CUH COMPLIANCE**
Patients triaged as urgent, **and subsequently newly diagnosed with primary breast cancer,** are offered an appointment to be seen within 10 working days of the date of receipt of referral (Standard 2.8).	>95%	98% * See Standard 2.8
Access for non-urgent patients	**TARGET**	**CUH COMPLIANCE**
Patients triaged as non-urgent, **and subsequently newly diagnosed with primary breast cancer,** are seen within 12 weeks of receipt of referral (KPI 1b).	>95%	100%

Imaging	TARGET	CUH COMPLIANCE
Patients triaged as urgent, **and subsequently newly diagnosed with primary breast cancer,** receive imaging on the first visit (Standard 6.14).	>90%	98%
Definitive diagnosis [+]	**TARGET**	**CUH COMPLIANCE**
Patients triaged as urgent, **and subsequently newly diagnosed with primary breast cancer,** have a definitive diagnosis achieved within 10 working days of being seen at the centre (Standard 4.9).	>90%	98% *See Essential Element 5c
Surgical intervention	**TARGET**	**CUH COMPLIANCE**

[+] For the purpose of this review, the date of the definitive diagnosis is taken as the date of diagnosis at the MDT meeting.

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%	91%

What the data showed

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

As per the findings under Governance Essential Element 1(b), it was reported during interview that the service was becoming increasingly challenged to meet patient access targets linked to operational arrangements for managing the number of patients allocated to each clinic, dual location of some consultant staff, the number of NCHD staff available per clinic and the timely notification of annual leave by clinical staff. **(See G6.)**

The submitted data for the 13-week sample period demonstrated that the service was able to meet Standard 2.8 (target 95%) for urgently referred patients. However, based on the on-site findings, the Authority requested additional data on the day of the on-site visit which identified that 81.5% of urgently referred patients were offered an appointment within 10 working days for the month of May 2010. In addition, the service anticipated that this trend would also be reflected in the June figures.

Subsequently, the Authority requested access data for the 13-week sample period for 1 May 2010 to 31 July 2010 which demonstrated that 90% of urgently referred patients were offered an appointment within 10 working days for that sample period. This additional requested data was not validated by the Authority.

The Authority was unable to establish what specific arrangements the SBD service at CUH had in place to manage these operational issues and concluded that the service should put a targeted programme of action in place to ensure that all patients triaged as urgent are offered an appointment within 10 working days. **(See A2).**

Medical oncology and radiation oncology

The entire sample patient group would not have completed the medical and radiation oncology phase of their treatment. Therefore, the data validation exercise did not include compliance with the access Standards for medical and radiation oncology. **(See Governance Essential Element 1b.)**

Access: Conclusion

The data submitted for the 13-week sample time period from 1 January 2010 to 2 April 2010 demonstrated that the SBD service at CUH was compliant with the required access timelines.

However, in light of issues identified by the CUH SBD team, additional data requested by the Authority during the on-site review identified that the SBD service, in May 2010, was not meeting the national access targets for urgently referred patients to be seen within 10 working days. Additional data submitted for the 13-week sample period of 1 May 2010 to 31 July 2010 demonstrated that 90% of urgently referred patients were offered an appointment within 10 working days for that sample period.

Overall, the Authority concluded that the SBD service at CUH had some of the necessary arrangements in place to ensure timely access to care and has made recommendations in the remaining areas that need to be addressed to ensure sustainable compliance with the Standards by the service going forward.

Access: Recommendations

A1. The symptomatic breast disease service should ensure that the patient triage classification is recorded according to the National Quality Assurance Standards and National Breast Cancer General Practitioner referral guidelines.

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

4.6.2 Theme 7: 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)

CUH 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 January 2010 to 2 April 2010.

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 Standard is provided with the service's 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 January 2010 to 2 April 2010.

PERFORMANCE MEASURE:	**TARGET**	**CUH COMPLIANCE for 13-week sample**
Non-operative diagnosis	**TARGET**	**CUH COMPLIANCE for 13-week sample**
A non-operative diagnosis is achieved in malignant disease (Standard 6.16).	>90%	99%
Ultrasound of the axilla	**TARGET**	**CUH COMPLIANCE for 13-week sample**
Patients with a diagnosis of invasive breast cancer shall have an ultrasound assessment of their axilla. Ultrasound of the axilla plays a central role in determining patients' suitability for sentinel node biopsy (Standard 6.21).	>95%	97%
Imaging prerequisites	**TARGET**	**CUH COMPLIANCE for 13-week sample**
Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer (Standard 6.1).	>95%	96%

Histopathology data	**TARGET**	**CUH COMPLIANCE for 13-week sample**
To provide important and relevant data on patients with Invasive breast carcinoma (Standard 7.13A): ▪ histological tumour type is recorded.	>95%	100%
▪ histological tumour grade is recorded.	>95%	100%
▪ invasive tumour size is recorded	>95%	100%
▪ the presence or absence of vascular invasion	>95%	100%
▪ radial margin status in wide local excision specimens is recorded	>95%	100%
▪ posterior (deep) margin status is recorded.	>95%	100%
Hormone receptor status	**TARGET**	**CUH COMPLIANCE for 13-week sample**
Oestrogen receptor status is recorded (Standard 7.13 B).	>95%	100%
***HER2* status**	**TARGET**	**CUH COMPLIANCE for 13-week sample**
HER2 status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH) (Standard 7.13 C).	>95%	100%
Ductal carcinoma in situ	**TARGET**	**CUH COMPLIANCE for 13-week sample**
To provide appropriate data in patients with ductal carcinoma in situ (DCIS) ▪ DCIS grade is recorded.	>95%	100%

▪ Radial margin status in wide local excision specimens is recorded (Standard 7.14).	>95%	100%
Pre-operative localisation	**TARGET**	**CUH COMPLIANCE for 13-week sample**
Patients with clinically occult lesions, or where there are doubts about the location of the tumour, shall have pre-operative localisation guided by ultrasound or by stereotactic mammography equipment / X-ray (Standard 5.10).	>90%	*See Standard 5.10 below

What the data showed

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

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

At the time of Review 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)

Corporately, the clinical effectiveness committee has the function of determining policy development, clinical audit and clinical effectiveness within CUH.

Clinical audit of activity, mortality and morbidity is undertaken as part of the general surgical services**.**

At the time of the Review, the SBD service was using the MDT meeting to audit and review delayed diagnosis cases and the SBD-specific governance committee to review performance with the national key performance indicators for SBD. The multidisciplinary team identified at interview that they were now in a position to begin SBD-specific clinical audit and were intending to progress this through the SBD governance structures.

The Authority found that the service had some SBD-specific clinical audit systems in place. However, at the time of the Review, these systems required further development and integration within the SBD governance structures. **(See CE 1.)**

Clinical Effectiveness: Conclusion

The Authority found that for the 13 week sample period from 1 January 2010 to 2 April 2010, a total of 90 patients newly diagnosed with primary breast cancer were seen at the SBD service at CUH.

The Authority found that the service demonstrated compliance with the selected clinical Standards. However, there is a need to incorporate specific symptomatic breast disease clinical audit activities within the service's clinical governance structure and the Authority has made a recommendation in relation to this.

The Authority found that the service demonstrated compliance with the Standards and the SBD service at CUH had the necessary arrangements in place to demonstrate clinical effectiveness.

Clinical Effectiveness: Recommendations

CE1. The symptomatic breast disease service should systematically and critically analyse the quality of care provided by developing and directing specific symptomatic breast disease clinical audit activities through the revised symptomatic breast disease governance structure.

5. Conclusion

5.1 Overview

The purpose of the National Quality Review 2009 was to assess whether the designated centres were meeting the National Quality Assurance Standards. The process 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 in place to deliver and maintain the added value and standards expected in a national designated centre.

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

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

Further to the National Quality Review conducted between October and December 2009, the Authority indicated that the symptomatic breast disease service at CUH was meeting the core quality and safety requirements as set out in the Standards. However, in light of the evolving nature and the pending reconfiguration of the symptomatic breast disease service to CUH, the Authority concluded that the service would require a further review to provide assurance that CUH would have the arrangements in place to provide high quality, safe care for patients with symptomatic breast disease.

This report and resulting conclusion details the performance of the symptomatic breast disease service at CUH at the time of the Quality Review visit in June 2010.

These key conclusions are as follows:

5.2 Findings

5.2.1 Governance

At the time of the review, the transfer of breast surgical services from KGH and SIVUH to CUH was complete.

However, the Authority identified a number of governance and operational management issues reflective of the early stage of development of the recently amalgamated service which need to be addressed. These include the structure of the SBD governance group, absence of the Clinical Director from meetings with the NCCP, variation in the volume of OPD patient attendances per clinic and effective inpatient access processes.

In addition, while the service had clinical management, referral and patient pathway processes in place, the sustainability of these arrangements, particularly in relation to timely OPD access, inpatient theatre access for SBD specific and BreastCheck referred patients and medical oncology access, is at risk and requires attention.

The centralisation of SBD services is a component of a wider change process which includes the reconfiguration of acute services in the HSE South with additional service developments at CUH. Although not a core focus of the Review and therefore not explored in detail by the Authority, the Authority was not satisfied that the arrangements to effectively manage the configuration of clinical services, including issues of demand and capacity management for patients, were strategically aligned and coordinated nationally, regionally and locally in order to effectively manage service transition.

In the broader context, CUH, the NCCP and the wider HSE should put arrangements in place to plan, govern and manage existing and future patient activities at CUH, particularly in relation to SBD services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

The Authority highlighted these issues with the HSE in advance of concluding this report recommending the urgent assessment of potential risks associated with the transfer and amalgamation of the SBD service, and the implementation of necessary mitigating actions. The HSE has responded in writing with an action plan to address the issues highlighted and committed to monitoring its implementation. The Authority has also made recommendations in relation to these issues within this report and will monitor their implementation through follow-up with the service and the NCCP.

5.2.2. Multidisciplinary Approach

The service was actively committed to delivering triple assessment through a multidisciplinary approach. It had comprehensive operational policies and evaluation processes to ensure that the multidisciplinary team is involved in all clinical decision making and treatment planning. Wherever possible, patients are central to this process and encouraged to participate in decisions about their treatment options and care.

Overall, the Authority concluded that, the SBD service at CUH, at the time of the Review, had the necessary multidisciplinary arrangements in place for the delivery of safe care. Where there remained opportunities for improvement, the Authority has made recommendations to this effect.

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. All consultant staff have a contractual commitment to participate in teaching, training, research and ensuring evidence-based clinical practice.

The specialist breast care nurses (SBCNs) are registered on the national clinical nurse specialists register. The in-service programme includes a mandatory training programme on chemotherapy administration, mammography and communication and staff attendance records were maintained.

Overall, the Authority found the SBD service at CUH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise.

5.2.4 Person-centred Care

The service has written information about breast disease, cancer and local support groups. For the most part, patients in the patient discussion group reported satisfaction with the level of information to allow them to consider options for treatment.

The newly constructed cancer centre has the facilities to support the service. However, inpatient access and medical oncology services are challenged to meet the increasing demands of the SBD service.

The Authority concluded that the SBD service at CUH, at the time of Review, had some of the necessary OPD, triple assessment, day procedures and radiotherapy arrangements and the required facilities in place to deliver person-centred care.

However, in light of the centralisation of some cancer services and the increasing volume of patients requiring care, the current arrangements require ongoing evaluation by the service and the NCCP to ensure that they are sustainable in order to effectively and efficiently manage the needs of patients.

5.2.5 Data Management

At the time of review, the Patient Analysis and Tracking System (PATS) to collate basic data on access, diagnosis, pathology, primary treatment and clinical outcomes was fully operational.

The Authority carried out a data validation process (which included a review of the patient's healthcare records) for checking the accuracy, auditing and validation processes in place to support the evolving symptomatic breast disease service at CUH.

The Authority concluded that, at the time of the Review, the SBD service at CUH had most of the necessary data management arrangements in place.

5.2.6 Access

The data submitted for the 13-week sample time period from 1 January 2010 to 2 April 2010 demonstrated that the SBD service at CUH was compliant with the required access timelines.

However, in light of issues identified by the CUH SBD team, additional data requested by the Authority during the on-site review identified that the SBD service, in May 2010, was not meeting the national access targets for urgently referred patients to be seen within 10 working days. Additional data submitted for the 13-week sample period of 1 May 2010 to 31 July 2010 demonstrated that that 90% of urgently referred patients were offered an appointment within 10 working days for that sample period.

Overall, the Authority concluded that the SBD service at CUH had some of the necessary arrangements in place to ensure timely access to care and has made recommendations in the remaining areas that need to be addressed to ensure sustainable compliance with the Standards by the service going forward.

5.2.7 Clinical Effectiveness

The Authority found that for the 13 week sample period from 1 January 2010 to 2 April 2010, a total of 90 patients newly diagnosed with primary breast cancer were seen at the SBD service at CUH.

The Authority found that the service demonstrated compliance with the selected clinical Standards. However, there is a need to incorporate specific symptomatic breast disease clinical audit activities within the service's clinical governance structure and the Authority has made a recommendation in relation to this.

The Authority found that the service demonstrated compliance with the Standards and the SBD service at CUH had the necessary arrangements in place to demonstrate clinical effectiveness.

5.2.8 Overall Conclusion

Based on the evidence of this Quality review, the Authority concluded that Cork University Hospital had in place the core requirements for quality and safety as set out in the Standards, including lead clinician, triple assessment, MDT approach, monitoring of key performance indicators and patient information.

However, the Authority identified a number of governance and operational management issues reflective of the early stage of development of the recently amalgamated service which needed to be addressed. These included the structure of the SBD governance group, absence of the Clinical Director from meetings with the NCCP, variation in the volume of OPD patient attendances per clinic, effective inpatient access processes and arrangements relating to consultant surgeons' off-site emergency on-call commitments which the Authority concluded should be risk assessed as a matter of urgency.

In addition, access difficulties for elective and emergency surgery and oncology services, along with under-developed consultant on-call arrangements, were identified. These difficulties, if not addressed, will compromise the sustainable compliance with Standards of the SBD service and urgent assessment is needed by the service.

The centralisation of SBD services is a component of a wider change process which includes the reconfiguration of acute services in the HSE South and additional service developments at CUH. Based on the findings of the Review, the Authority raised concerns that the arrangements to effectively manage the configuration of clinical services – including issues of demand and capacity management – were not strategically aligned and coordinated nationally, regionally and locally in order to effectively manage the service transition.

In the wider context, the Authority concluded that the HSE, and its National Cancer Control Programme, should identify any potential risks associated with the service and resource demands associated with the amalgamation of the SBD service and implement corrective actions to address the findings of this report. The HSE has subsequently confirmed to the Authority that these issues are currently being addressed.

CUH, the NCCP and the wider HSE should put arrangements in place to plan, govern and manage existing and future patient activities at CUH, particularly in relation to SBD services, other specialist cancer care, the reconfiguration of services and the interface with other hospitals in the region.

Cork University Hospital, supported by the NCCP, should develop, publish and implement an action plan against the recommendations of this report.

6. Next steps

The Authority will liaise with the NCCP, as delegated by the HSE, to ensure that the necessary actions are being taken to address the recommendations of this report.

Given the issues identified by the Authority in the course of this Review, and the early stage of development of the governance and operational management arrangements within the service, the service will require a follow-up review by the Authority in early 2011.

7. References

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

(2) Health Information and Quality Authority. *Report of the Quality Review Assessment at Cork University Hospital*. Dublin: Health Information and Quality Authority; 2010

(3) Health Information and Quality Authority. *Report of the investigation into the circumstances surrounding the provision of care to Rebecca O'Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick*. Dublin: Health Information and Quality Authority; 2008.

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

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

8. Glossary of useful terms and abbreviations

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

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

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

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

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

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

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

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

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

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

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

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

Consultants include surgeons, physicians, anaesthetists, pathologists, radiologists, oncologists and others

CPD: continuing professional development

CT: computerised tomography

DCIS: ductal carcinoma in situ

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

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

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

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

FISH: fluorescent in situ hybridisation

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

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

GP: general practitioner

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

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

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

HSE: Health Service Executive

Invasive breast cancer: cancer that has spread from where it started in the breast into surrounding, healthy tissue. Most invasive breast cancers start in the ducts (tubes that carry milk from the lobules to the nipple). Invasive breast cancer can spread to other parts of the body through the blood and lymph systems

IT: information technology

KPI: key performance indicator

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

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

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

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

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

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

MRI: magnetic resonance imaging

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

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

NBSP: National Breast Screening Programme (see Breastcheck)

NCCP: National Cancer Control Programme

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

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

NQAS: National Quality Assurance Standards for Symptomatic Breast Disease Services

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

PACS: Picture Archive and Communication System

PAS: Patient Administration System

PATS: Patient Analysis and Tracking System

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

Protocol: a detailed plan of a medical treatment or procedure

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

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

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

SBCN: specialist breast care nurse

SBD: symptomatic breast disease

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

SLA: service level agreement

Sonographic abnormality: an abnormality detected by ultrasound

SOP: standard operating procedure

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

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

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

TNM: tumour nodes metastasis

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

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

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

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

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

9. Appendices

Appendix 1

Methodology - Quality Review at Cork University Hospital, 2010

The Quality Review Follow up involved an in-depth review of the performance of the designated centre at Cork University Hospital. The Review followed the assessment methodology used for the Quality Review 2009 which 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, 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 5).

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 have been 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[3][4][5].

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 follow up assessment of the symptomatic breast disease (SBD) service at Cork University Hospital. 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[3][4][5].

1.1.2 Assessment Process – Quality Review Follow up

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 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 (13 May 2010)

The Authority requested documentation (see Appendix 2) 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 five weeks of the Authority's request.

(ii) Pre-visit data request (13 May 2010)

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) (Appendix 6). 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 Documentation request template, Appendix 3).

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

Access and clinical effectiveness data: 13-week sample period of 1 January 2010 to 2 April 2010

This 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 January 2010 to 2 April 2010. 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.

Activity data: seven-month sample period

- This 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 2010 to 1 June 2010.

This data informed the preliminary overview of the activity of the service and was requested for a time period that allowed for the service to collate the data sample for the longer time period of 5 months

(iii) Review of pre-visit documentation received (June 2010)

In order to assess evidence of compliance, the Authority reviewed the documentation submitted by Cork University Hospital 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 (June 2010)

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 CUH 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 CUH. The on-site visit took place on 29 June 2010. 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 the access and clinical effectiveness data for the 13-week period of 1 January 2010 to 2 April 2010, 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 of 1 January 2010 to 2 April 2010

(iii) 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.

(iv) 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

service to provide further information and the Authority to gain clarification on any issues that would inform the Authority's findings.

Interviewees included:

- chief executive officer / general manager
- lead clinician
- data manager
- multidisciplinary team
- NCCP Cancer Network Manager, HSE South.

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.

(v) Discussion group with patients

In order to explore the provision of patient-centred care from a patient's perspective, the service 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

Access data: 13-week sample period of 1 May 2010 to 31 July 2010

(i) The Authority requested further access data from Cork University Hospital which was not validated by the Authority (see Data Request template, Appendix 4)

(ii) The Authority's findings of the Quality Review have been published as an individual public report specific to Cork University Hospital. A draft report of the assessment findings was issued to the service for factual accuracy. The centre was invited to respond in writing to the Authority within ten 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:

- open communications with the centre in relation to the process
- internal peer review at various stages during the development of the assessment methodology
- consistency in the design and development of the assessment methodology
- 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
- the service being invited, to review the draft report for the purpose of factual accuracy
- acceptance and sign off of the reports by the Chief Executive of the Authority.

Appendix 2

National Quality Review of Symptomatic Breast Disease Services in Ireland – Follow up 2010

Documentation request prior to onsite quality review follow up

Instructions for submitting documentation:

The Authority requests that:

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

2. Please indicate as requested the documents you are submitting and the reasons why some documents are not submitted.

3. All documents submitted should be referenced to the appropriate reference number on this Excel workbook.

4. All documentation, including this completed documentation request form, must be submitted no later than 5pm on **18 June 2010** to:

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

5. In addition, ***please return an electronic copy of your completed documentation request Excel workbook*** to _____@hiqa.ie, no later than 5pm on **18 June 2010**.

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

2009 Rec. Reference		Document Request - CUH	Please state whether document is attached or state reason if not attached
G2	**1**	**Governance**	
	1.1	**Governance Structure** (Indicate operation linkages and reporting structures between both)	
	1.1.1	Organogram for the Governance structure of the hospital	
	1.1.2	Organogram for the Organisation structure of the Symptomatic Breast Disease Service	
G2	**1.2**	**Monitoring compliance with the National Quality Assurance Standards**	
	1.2.1	Terms of reference for the committee responsible	
	1.2.2	Identify chairperson of the committee	
	1.2.3	Membership of the committee	
	1.2.4	Scheduling of meetings for this committee from 1st January 2010 to week commencing 10th May 2010.	
	1.2.5	Minutes of all meetings from 1st January 2010 to week commencing 10th May 2010	
	1.3	**Clinical Leadership**	
G1	1.3.1	Standard operating procedure/Policy for clinical leadership, indicating the most responsible person for the patient as they transfer through the pathway of care.	
	1.4	**Clinical Risk Management:**	
G5	1.4.1	Number of clinical incidents/adverse events pertaining to SBD services reported between 1st January 2010 and week commencing 10th May 2010	
	1.4.2	Quality improvement initiatives implemented as an action following investigation of identified incidents	

G5	1.4.3	SBD specific risk register and appropriate control mechanisms identified	
	1.5	**Core Personnel**	
	1.5.1	Complete the Excel worksheet marked (Appendix X) detailing the full complement of core personnel to the symptomatic breast disease service	

	2	**Person Centred Care**	
	2.1	**Patient Information**	
G5	2.1.1	List names/titles of all patient information leaflets provided by the Centre, since the amalgamation of the SBD services from the South Infirmary Victoria University Hospital (SIVUH) to Cork University Hospital. (CUH)	
	2.2	**Patient Satisfaction with the symptomatic breast disease service**	
G5	2.2.1	Patient Satisfaction data specific to symptomatic breast disease services from 1st January 2010 to week commencing 10th May 2010	
	2.2.2	Number of complaints received and subsequent action plans for the symptomatic breast disease service from 1st January 2010 to week commencing 10th May 2010.	
	2.3	**General Practice**	
G5	2.3.1	Pertaining to the amalgamation of the SBD services from the SIVUH to CUH- Information pack for General Practitioners (GP) (to include any information pertaining to communication with GP's, including schedule of any GP information sessions)	
	3	**Multidisciplinary Approach**	
	3.1	**Multidisciplinary Meeting**	
G3	3.1.1	Standard operating procedure/policy for all SBD specific Multidisciplinary Meetings.	
MDT4	3.1.2	Standard operating procedure to ensure the timely transfer of pertinent patient data from Kerry General Hospital	
	3.1.3	Scheduling of meetings from 1st January 2010 to week commencing 10th May 2010	
	3.1.4	List of multidisciplinary membership	
G4 / MDT3	3.1.5	Template used for recording information following multidisciplinary discussion	
	3.2	**Triple Assessment Clinic**	
MDT1	3.2.1	Standard operating procedure/policy for Triple Assessment Clinics	

MDT1	3.2.2	Standing Operating Procedure/policy to demonstrate how patients are referred to the triple assessment clinic	
G4 / MDT3	3.2.3	Triple assessment proforma /patient record template	
	4	**Skills, Education and Training**	
	4.1	**Training and Competency**	
SET1	4.1.1	Policy for continuous professional development for the multidisciplinary team	
	4.1.2	Policy to monitor and maintain competencies as per the National Quality Assurance Standards for the multidisciplinary team	

	5	**Clinical Effectiveness**	
	5.1	**Clinical Audit**	
MDT2 /CE1	5.1.1	Standard operating procedure/terms of reference for the clinical audit committee for symptomatic breast disease	
	5.1.2	Scheduling of meetings for this committee from 1st January 2010 to week commencing 10th May 2010	
	5.1.3	Agendas from 1st January 2010 to week commencing 10th May 2010	
	5.1.4	Minutes and action sheets from 1st January 2010 to week commencing 10th May 2010	
	5.2	**Data management**	
DM1/ A1	5.2.1	Standard operating procedure/policy for SBD specific data validation	
G5	5.2.2	Standard operating procedure/policy to safely amalgamate the SBD specific SIVUH data with that of the SBD service at CUH.	
DM2	5.2.3	Evidence of the data validation process from January 1st 2010 to the week commencing 10th May 2010.	

Appendix X Theme – Skills Education and Training

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

Categories: Permanent (P); Temporary (T); Full Time Locum (FL); Part-time Locum (PTL); Part-time Permanent (PTP); Part-Time Temporary (PTT)

Appendix 3

National Quality Review of Symptomatic Breast Disease Services in Ireland – Follow up 2010
Data request prior to onsite quality review follow up

Instructions for completing this Data Request Form

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

1. 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

2. This data request form must be submitted no later than 5pm on **18 June 2010** to :

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

3. In addition, ***please return an electronic copy of your completed data request Excel Workbook*** to _____ @hiqa.ie, no later than 5pm on **18 June 2010**

4. 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 requests that you submit the following information:

Section A

ALL questions in Section A refer to data for
a) the sample time period of the 13 consecutive weeks from 1 January 2010 – 2 April 2010
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.1	What is the total number of newly diagnosed primary breast cancer patients seen at the SBD centre during the sample time period of 1 January 2010 - 2 April 2010?	Numeric figure		
DaR.2	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that were triaged as **urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.3	Of the total number of patients that were triaged as urgent (see DaR.2), what is the total number and percentage of patients **offered an appointment to be seen** within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.4	Of the total number of patients that were triaged as urgent (see Dar.2) and clinically	Numeric figure		

	assessed has having S4 or S5 classification, what is the total number and percentage of patients that received imaging on the first visit?			
DaR.5	Of the total number of patients that were triaged as urgent (see DaR.2), 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		
DaR.6	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that were triaged as **non- urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.7	Of the total number of patients triaged as non-urgent (see DaR.6) what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.8	Of the total number of patients triaged as non-urgent (see DaR.6) what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.9	Of the total number of newly diagnosed primary breast cancer patients (see Dar.1),	Numeric figure		

	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?			
DaR.10	Of the total number of patients who had a core biopsy performed (see DaR.9), what is the total number and percentage of biopsies that were image guided?	Numeric figure		
		Percentage figure to be submitted		
DaR.11	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number of patients whose definitive diagnosis was made at the MDT meeting?	Numeric figure		
DaR.12	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that were diagnosed with invasive breast cancer?	Numeric figure		
		Percentage figure to be submitted		
DaR.13	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.12), what is the total number of patients that had primary operable invasive breast cancer?	Numeric figure		
DaR.14	Of the total number of patients that had primary operable invasive breast cancer (see DaR.13), what is the total	Numeric figure		
		Percentage figure to be submitted		

	number and percentage of patients that had ultrasound of the axillary nodes?			
Section A – Continued note sub-sample group 1				
a) the sample time period of the 13 consecutive weeks from 1 January 2010 - 2 April 2010 b) the Patient Sample group - seen and newly diagnosed with primary breast cancer **c) sub-sample group 1: Diagnosed with invasive breast cancer**				
DaR.15	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.12), what is the total number and percentage of patients that were diagnosed without an operative procedure?	Numeric figure		
		Percentage figure to be submitted		
DaR.16	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.12) what is the total number of patients that were assessed has having a clinically occult lesion (classification S2)?	Numeric figure		
DaR.17	Of the total number of patients that were assessed as having a clinically occult lesion (classification S2) (see DaR.16), 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 A – Continued note sub-sample group 2				

a) the sample time period of the 13 consecutive weeks from 1 January 2010 - 2 April 2010 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**				
DaR.18	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.12), what is the total number of patients **that had surgery**?	Numeric figure		
DaR.19	Of the total number of patients that had surgery (see DaR.18), what is the total number and percentage of **cases** that had the histological tumour **type** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.20	Of the total number of patients that had surgery (see DaR.18), what is the total number and percentage of **cases** that had the histological tumour **grade** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.21	Of the total number of patients that had surgery (see DaR.18), what is the total number and percentage of **cases** that had the histological tumour **size** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.22	Of the total number of patients that had surgery (see DaR.18), what is the total number and percentage of **cases** that had the presence or absence of vascular invasion recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.23	Of the total number of patients that had surgery (see DaR.18), what is the total number and	Numeric figure		
		Percentage figure to		

	percentage of **cases** that had the posterior deep margin status recorded?	be submitted		
DaR.24	Of the total number of **patients** that were diagnosed with invasive breast cancer (see DaR.12), what is the total number of **cases** that had a Wide Local Excision?	Numeric figure		
DaR.25	Of the total number of **cases** that had a Wide Local Excision, (see DaR.24) what is the total number and percentage of **cases** that the radial margin status is recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.26	Of the total number of patients that had surgery (see DaR.18), what is the total number and percentage of **cases** that had HER-2 status recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.27	Of the total number of patients that had surgery (See DaR.18), what is the total number and percentage of **cases** that had oestrogen receptor status recorded?	Numeric figure		
		Percentage figure to be submitted		
Section A – Continued note sub-sample group 3				
a) the sample time period of the 13 consecutive weeks from 1 January 2010 - 2 April 2010 b) the Patient Sample group - seen and newly diagnosed with primary breast cancer **c) sub-sample group 3: Patients with primary operable cancer**				
DaR.28	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that	Numeric figure		
		Percentage figure to be submitted		

	had primary operable breast cancer?			
DaR.29	Of the total number of patients that had primary operable breast cancer (see DaR.28), what is the total number and percentage of patients that had surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnosis at the MDT meeting?	Numeric figure		
		Percentage figure to be submitted		
DaR.30	Of the total number of patients that had primary operable breast cancer (see DaR.28), what is the total number and percentage of patients that had pre-operative mammography with ultrasound carried out?	Numeric figure		
		Percentage figure to be submitted		
Section B – note new patient Sample group				
ALL questions in Section B refer to data for a) the sample time period of the 13 consecutive weeks from 1 January 2010 – 2 April 2010 **b) the Patient Sample group –diagnosed with Ductal Carcinoma In Situ at MDT**				
DaR.31	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 January 2010 - 2 April 2010?	Numeric figure		
DaR.32	Of the total number of patients newly diagnosed with Ductal Carcinoma In Situ and seen at the SBD centre during the	Numeric figure		

	sample time period (see DaR.31) what is the total number of **cases** of Ductal Carcinoma In Situ.			
DaR.33	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.32) what is the total number and percentage of **cases** that had a wide local excision?	Numeric figure		
		Percentage figure to be submitted		
DaR.34	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.32) what is the total number and percentage of **cases** that had radial margin status recorded	Numeric figure		
		Percentage figure to be submitted		
DaR.35	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.32) what is the total number and percentage of **cases** that had the histological tumour grade recorded?	Numeric figure		
		Percentage figure to be submitted		

DaR Appendix X

Narrative accompanying data request (reason if unable to provide data / any other relevant information

DaR.1	
DaR.2	
DaR.3	
DaR.4	
DaR.5	
DaR.6	
DaR.7	
DaR.8	
DaR.9	

Activity Data for the Five month period of 1 January 2010 – 1 June 2010 was requested by the Authority at a later date. This was to allow for the service to collate the data sample for the longer time period of 5 months.

All questions below refer to data for **a) the sample time period of 1 January 2010 – 1 June 2010** **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
DaR.1	What is the total number of **new patients** seen at the SBD centre for this sample time period?	Numeric figure	
DaR.2	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre?	Numeric figure	
DaR.3	Of the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre (see DaR.2), what is the total number and percentage of patients **offered an appointment** to be seen within 10 working days of the date of receipt of referral?	Numeric figure	
		Percentage figure to be submitted	
DaR.4	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre?	Numeric figure	
DaR.5	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure	
		Percentage figure to be submitted	

DaR.6	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure	
		Percentage figure to be submitted	
DaR.7	Of the total number of new patients seen at the SBD centre for the sample time period (see DaR.1), what is the total number of newly diagnosed primary breast cancer patients?	Numeric figure	

Appendix 4
National Quality Review of Symptomatic Breast Disease Services in Ireland – June 2010

Data request Cork University Hospital (CUH) 30 September 2010

Instructions for submitting data:
Under section 73(5i) of the Health Act 200, the Authority requests that the following data request form is completed and submitted in hardcopy.

1. 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

2. This data request form must be submitted no later than **5pm Thursday 14 October 2010**

The Health Information and Quality Authority,
Healthcare Quality and Safety Directorate,George's Court
George's Lane
Dublin 7

In addition, please return an electronic copy of your completed data request Excel Workbook to **_____@hiqa.ie**, no later than **5pm on Thursday 14 October 2010**

4. 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 requests that you submit the following information:

Section A

ALL questions in Section A refer to data for
a) the sample time period of the 13 consecutive weeks from 1 May 2010 – 31 July 2010
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 A
DaR.1	What is the total number of newly diagnosed primary breast cancer patients seen at the SBD centre during the sample time period of **1 May 2010 - 31 July 2010?**	Numeric figure		
DaR.2	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that were triaged as **urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.3	Of the total number of patients that were triaged as urgent (see DaR.2), what is the total number and percentage of patients **offered an appointment to be seen** within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		

DaR.4	Of the total number of patients that were triaged as urgent (see Dar.2) and clinically assessed has having S4 or S5 classification, what is the total number and percentage of patients that received imaging on the first visit?	Numeric figure		
		Percentage figure to be submitted		
DaR.5	Of the total number of patients that were triaged as urgent (see DaR.2), 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		
DaR.6	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that were triaged as **non-urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.7	Of the total number of patients triaged as non-urgent (see DaR.6) what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.8	Of the total number of patients triaged as non-urgent (see DaR.6) what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		

DaR.9	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number of patients whose definitive diagnosis was made at the MDT meeting?	Numeric figure		
DaR.10	Of the total number of newly diagnosed primary breast cancer patients (see DaR.1), what is the total number and percentage of patients that had **primary operable breast cancer?**	Numeric figure		
		Percentage figure to be submitted		
DaR.11	Of the total number of patients that had primary operable breast cancer (see DaR.10), what is the total number and percentage of patients that had surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnosis at the MDT meeting?	Numeric figure		
		Percentage figure to be submitted		

DaR Appendix A	
Narrative accompanying data request (reason if unable to provide data / any other relevant information	
DaR.1	
DaR.2	
DaR.3	
DaR.4	
DaR.5	
DaR.6	
DaR.7	
DaR.8	
DaR.9	
DaR.10	
DaR.11	

Appendix 5

Key Representative Standards

Standard Reference	Standards
	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 dataset 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 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 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 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 shall be offered an appointment in 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 should have all imaging in the first visit. A patient requiring early referral (see 2.1.2) shall have imaging within six weeks, and routine imaging shall be done within twelve weeks.
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
4.11	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 co-ordinated 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 co-ordinating doctor for those patients who have been treated with surgery alone. For those patients who have received adjuvant chemotherapy, the co-ordinating

	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	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 shall be regarded as a prerequisite for the assessment of the patient with primary operable breast cancer.

7.13 A	The following data shall be recorded in invasive breast carcinoma: • Tumour type • Tumour grade • Tumour size: invasive tumour size and whole tumour size, including ductal carcinoma in situ (DCIS) • Lymphovascular invasion • Radial margin status • Posterior (deep) margin status • Skin involvement Multiple tumours shall be recorded and information relevant to each tumour documented. The overall number of lymph nodes and the number containing metastases shall be recorded.
7.13 B	Hormone receptor status shall be recorded.
7.13 C	Her-2 status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH).
7.14	Ductal carcinoma in situ (DCIS): The following data shall be recorded in ductal carcinoma in situ (DCIS): • DCIS grade • DCIS size • Radial margin status • Posterior (deep) margin status • Presence or absence of microinvasion/invasion. • Hormone receptor status on clinical request.
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 6

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

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

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

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

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

** Source: NCCP 2009*

Appendix 7

Useful contacts

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

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

ARC Cancer Support Centre: www.arccancersupport.ie

Biobank Ireland Trust: www.biobankireland.com

Breakthrough Breast Cancer: www.breakthrough.org.uk

breastcancer.org: www.breastcancer.org

Breast Cancer Care: www.breastcancercare.org.uk

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

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

BreastCheck: http://www.breastcheck.ie

Canadian Breast Cancer Foundation: www.cbcf.org

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

Department of Health and Children: www.dohc.ie

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

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

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

Fertile Hope www.fertilehope.org

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

Irish Cancer Society: www.cancer.ie

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

Marie Keating Foundation: www.mariekeating.com

National Breast Cancer Coalition: www.natlbcc.org

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

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

National Cancer Registry Ireland: www.ncri.ie

Rethink Breast Cancer: www.rethinkbreastcancer.com

Living Beyond Breast Cancer: www.lbbc.org

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

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

Young Survival Coalition: www.youngsurvival.org/