Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the National Quality Review of Symptomatic Breast Disease Services in Ireland

22 February 2010

Safer Better Care

About the Health Information and Quality Authority

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

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

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

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

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

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

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

Foreword

I am pleased to introduce this first national report into the quality of symptomatic breast disease services in Ireland. Every year thousands of women are referred to symptomatic breast disease services for the investigation of concerning symptoms. The large majority will have benign breast disease and little or no further treatment is required. But, for others, a diagnosis of breast cancer will be the beginning of an anxious journey.

Patients have a right to expect high quality, reliable and safe care that is provided by competent staff in a timely way. National and international evidence shows the importance in achieving this through clearly defined patient care pathways. It is widely accepted that care should be built around a properly trained and equipped multidisciplinary team. This is because the individual disciplines involved in the diagnosis and initial treatment of people with symptomatic breast disease (general practice, surgery, pathology and diagnostic imaging) are not error free. By working as teams and comparing each others' findings, clinicians can identify differences (known as discordances) and, if necessary, check their findings or do more tests. This promotes learning and, more importantly, minimises misdiagnoses. This approach has been shown to benefit patients through more timely and appropriate provision of treatment and better survival rates.

As with other aspects of complex care, ensuring that clinicians have the specialist expertise to provide this type of care, and that they see enough patients to maintain this level of expertise, is vital. This has led many health systems – including Ireland – to create specialist centres for cancer.

Since the approval nearly three years ago by the Board of the Health Information and Quality Authority of the *National Quality Assurance Standards for Symptomatic Breast Disease Services*, and their subsequent mandating by the Minister for Health and Children, there have been a series of investigations into serious safety and quality concerns for women with breast disease and, at times, confidence in breast disease services has been significantly weakened.

However, the increased public and professional awareness as a result of these investigations provided a greater impetus and urgency for the need to drive improvements in the quality and safety of symptomatic breast disease services in Ireland.

And significant progress has been made. In that relatively short period we have come from a situation where over 30 publicly funded hospitals, and a number of private hospitals, were providing care to women with symptomatic breast disease – sometimes with little or no multidisciplinary working or use of data to assess performance – to a position where we now have eight national designated centres, with multidisciplinary teams using up-to-date equipment and beginning to use data to monitor performance and drive improvement.

This has required a significant change programme, and taken a huge effort by the eight designated cancer centres, involving the transition of services from other hospitals and the reconfiguration of staff, services and patients to accommodate this change. As we expected, our review found that the eight centres are at different stages of development in this process and there is still progress to be made in achieving a level of consistency and embedding fully the requirements for safety and quality across the service nationally.

This report reflects the findings of a National Quality Review of the symptomatic breast disease services that took place over a two and a half year period. The findings show that the main essential requirements were in place in the centres but, because some centres were still in transition at the time of the review, the Authority will be returning in due course to assess their progress.

It should be noted that breast cancer is only one type of cancer and cancer services as a whole need to progress and develop accordingly to derive similar benefits. The changes that have been made in improving the symptomatic breast disease services should be used as a template to be adapted and modified for other services.

In summary, great strides have been made, but these need to be embedded and made sustainable. Over the last two and a half years a platform for high quality safe care for people with symptomatic breast disease has been established, but further work and development are needed to ensure that current and future patients derive the full benefits of specialisation and consolidation of services in the designated centres.

The Health Service Executive, its National Cancer Control Programme (NCCP) and other service providers and key stakeholders, must continue to discharge their respective roles in order to maintain the momentum that has built up in bringing about sustainable change for the benefit of patients. In particular, further development of clinical governance arrangements, greater cohesion between the centres and the further development in the use and publication of data to drive improvements is needed. This will lead to increased consistency of patient experience and outcomes and must be a key target for the health system and the public.

Finally, I would like to acknowledge the cooperation of managers and clinicians in the designated centres and the NCCP in the conduct of this Quality Review. The designated centres, and the NCCP, deserve recognition for the changes implemented and the improvements made to date. In particular, I would like to thank the many patients who gave up their time to share their stories and experiences with us for the benefit of current and future patients.

Dr Tracey Cooper

Chief Executive Officer
Health Information and Quality Authority

Table of contents

Foreword ii

Executive Summary 2

1. Introduction 15

2. Setting the scene 17
2.1 Breast cancer 17
2.2 Background to the National Quality Assurance Standards for Symptomatic Breast Disease Services and the Authority's Quality Review Programme 17
2.3 Background to the National Cancer Control Programme 18

3. How the Authority has monitored the implementation of the Standards 22

4. Findings 31
4.1 Governance 31
4.2 Multidisciplinary Approach 43
4.3 Skills, Education and Training 50
4.4 Person-centred Care 55
4.5 Data Management 62
4.6 Access 69
4.7 Clinical Effectiveness 89

5. Conclusions and next steps 104
5.1 Establishing the eight centres 104
5.2 Implementing the National Quality Assurance Standards 105
5.3 Next Steps 108
Overall conclusions 111

6. References 115

7. Glossary of useful terms and abbreviations 117

Appendices 124
Appendix 1: Key Representative Standards 124
Appendix 2: Recommendations made by the Authority to centres in January 2009, following validation review 132
Appendix 3: Methodology - National Quality Review Programme – Phase 4 133
Appendix 4: Symptomatic Breast Disease Service Quality Review 2009 Documentation request prior to onsite quality review 139
Appendix 5: Data request prior to onsite quality review 148
Appendix 6: National Cancer Control Programme revised key performance indicators (July 2009) 160
Appendix 7: New patient referral activity by non-urgent triage category 165
Appendix 8: Useful contacts 166

Executive Summary

1 Introduction

This report presents the findings from the National Quality Review of Symptomatic Breast Disease Services that has been undertaken by the Health Information and Quality Authority (the Authority). This Review was undertaken in order to monitor progress with the implementation of the National Quality Assurance Standards (the Standards) for symptomatic breast disease (SBD) services in Ireland[1]. All designated centres were expected to be fully established as specialist centres and meeting the Standards by the end of 2009.

Since 2007, the National Cancer Control Programme (NCCP), established by the Health Service Executive (HSE) to lead the development of cancer services, has been engaged in a change programme to move the provision of SBD services from over 30 publicly funded centres to eight designated centres. The national Quality Review of Symptomatic Breast Disease Services by the Authority is the culmination of two and a half years of its interaction with the service since the launch of the Standards.

The Authority used the Standards, and findings from its own previous investigations, to identify **essential elements** that must be in place in designated centres to achieve safe, high quality care, the absence of which would be a cause for concern[2-4].

The findings of each individual centre's Quality Review are reported in detailed local reports published on the Authority's website (www.hiqa.ie). The important findings from these are summarised in the relevant sections of this report.

2 Setting the scene

Breast cancer is the second most common cancer in Ireland. Statistically, breast cancer accounts for 30% of all cancers in women in Ireland with approximately 2,500 new breast cancer cases diagnosed each year[5-6].

In Ireland, the Central Statistics Office reported that 731 women died from breast cancer in 2008 making it a significant public health issue[7]. Between 1994 and 2001, mortality from breast cancer was reported to be 33% higher in Ireland than in the United States and in the upper third of rates in European countries[8].

In 2005, the Department of Health and Children established a national quality assurance group for the symptomatic breast disease services. This group developed the *National Quality Assurance Standards for Symptomatic Breast Disease Services* setting out the requirements of a well functioning specialist breast centre. These Standards were subsequently approved by the Board of the Authority and then mandated by the Minister for Health and Children in May 2007.

The development and implementation of standards are important in defining what should be expected of the providers of services and provide the basis of service planning, development and continuous improvement. Standards also give patients and the public a clearer understanding of what they should expect from services.

During 2007, a number of serious concerns about the quality and safety of symptomatic breast disease services came to light. These included examples of delayed diagnosis of breast cancer and led to a number of investigations, including two undertaken by the Authority[2-3]. The HSE also conducted a review of symptomatic breast disease services at Midland Regional Hospital Portlaoise[9-10]. In the autumn of 2007, the Authority announced its decision to bring forward its intended Quality Review of the national symptomatic breast disease service. This was the starting point of a programme of work that has extended over the last two and half years and will continue into 2010.

In 2007, the HSE established a National Cancer Control Programme directorate to manage, organise and deliver a national cancer programme in Ireland. Under this national programme, all cancer care would be provided through a national system of four Managed Cancer Control Networks in the HSE's four geographical regions, each serving a population of around 1 million people and consisting of primary, hospital, palliative, psycho-oncology and supportive care with patient care being fully integrated between each of these elements within each network.

Breast cancer services were the first to be centralised into these eight centres. In June 2007, there were 33 hospitals providing breast cancer services. By December 2008, this had been reduced to 12 centres. This transition has continued in a staged process over the last two and a half years, culminating with the transfer of the last non-designated services into designated centres in December 2009.

3 How the Authority has monitored implementation of the Standards

The Authority's national Quality Review process was conducted over a two and a half year period. In undertaking this, the Authority had to take into account the national plan to move to eight designated centres. This meant that, over time, some existing services would be discontinuing, while services in the eight designated centres would be reshaping to accommodate patients from those centres ceasing to provide symptomatic breast disease services. Given the fluidity of services, it was important that the assessment process adopted by the Authority reflected this ongoing change.

The Authority adopted a flexible approach to monitoring compliance that involved **five phases** as services consolidated to the eight designated centres. These were:

- Phase 1: Self-assessment (January to April 2008)
- Phase 2: Validation assessment process (autumn 2008)
- Phase 3: Feedback to designated centres (January 2009)

- Phase 4: Quality review visit (October to December 2009)
- Phase 5: Local and national reporting of findings

The Quality Review visits (Phase 4) involved an in-depth review of the performance of the designated specialist centres' compliance with the Standards through:

- a document review
- an analysis of activity data
- a review of access and clinical data
- the findings of on-site reviews at the eight designated centres which included validation of data against patient records
- qualitative interviews
- patient discussions
- observation of clinical areas and interviews with the NCCP.

The Standards provided the basis for the assessment process given that these are the requirements approved by the Board of the Authority and mandated by the Minister for Health and Children. The Authority analysed all 285 requirements in the Standards to identify the key issues on which the assessment needed to focus. As a result, ***key representative standards*** from the Standards (see Appendix 1) were identified. To help shape the review, these representative standards were then grouped into seven ***generic themes***. These were:

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

Recognising that centres would be at different stages of development towards implementing the full range of standards, the Authority identified the most important elements in each theme that must to be in place for quality and safety. These ***essential elements*** that each designated specialist centre must have as the foundation for safe, high quality symptomatic breast disease care are set out in **Figure 3** in the main body of the report.

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

4 Findings

4.1 Governance

The absence of effective governance in healthcare implies a system solely dependent on an individual and their degree of professionalism and commitment to ensure that services are safe and of the right quality. Over time, this type of system is less safe, less organised, less accountable and less able to improve and manage change than where effective governance is in place.

The Standards, as drafted in 2006, do not describe in detail the governance requirements of designated centres. The Authority therefore drew on its findings from its previous investigations to frame its expectations in relation to what is expected for good governance.

Formalised arrangements

Since 2008, there has been substantial progress made in this area and all the centres now have in place governance arrangements in the form of specific committees and accountability relationships, though these vary in nature and effectiveness. As would be expected, centres which have been more recently in transition are less well progressed than more established centres.

Lead clinicians

All centres have made progress in establishing a nominated lead clinician to provide a focus for developing the service, monitoring quality and developing clinical governance. However, even in well established centres, this role is evolving and needs clearer definition through a written role description and terms of reference.

Monitoring performance

All centres now have, or are introducing, information technology systems and infrastructure and all are collecting a core set of data derived mainly from the Standards to help them monitor quality. This is a significant step forward compared to 2008. However, for many centres this remains a relatively new activity and, particularly where considerable service changes have happened, there remains work to do to embed this fully into the service.

Standardised processes

In response to the need for greater standardisation of some core processes, the NCCP has developed standardised referral forms for general practitioners (GPs) and a range of standard operating procedures (SOPs) for differing aspects of the symptomatic breast disease service. These have been distributed to the centres and are now being implemented locally.

Third-party providers

A recurrent theme from the Authority's monitoring activity has been the weakness of governance arrangements in the relationships with third-party providers. This is of particular relevance to SBD services. For example, in relation to access to radiation oncology (radiotherapy) and medical oncology and imaging services when these are not provided in the centres.

The absence of adequate specification of these relationships, for example through a service level agreement (SLA), is a significant cause for concern and could have adverse consequences for patients. This needs to be addressed both in local arrangements and nationally by the NCCP.

Governance nationally and the NCCP

The NCCP directorate of the HSE was created in autumn 2007 and an interim National Director was appointed. While at a national level the NCCP was responsible for driving implementation of national policy, translating this into change at the local level was complicated by the fact that hospitals were aligned to different accountability structures, some change had a political dimension and historically the designated centres were not oriented to working collaboratively.

These factors have meant that the NCCP had to negotiate change at a very local level. The consequence of this is twofold. Firstly, that it has taken two years for the NCCP to successfully achieve the physical creation of eight designated centres, with the last moves happening in December 2009. Secondly, the NCCP has been unable yet to fully develop the national systems and processes that will help drive the long-term benefits of creating designated centres.

Despite these challenges, the NCCP has successfully used its national position to coordinate the creation of eight physical centres with the requisite core resources, and has led important developments. For example, the development of key performance indicators (KPIs) to monitor quality.

Having established this platform, the focus of the HSE and its NCCP, in conjunction with the eight designated centres and other key stakeholders, must now shift quickly to leveraging the longer term sustainable benefits for patients from creating the designated centres.

4.2 Multidisciplinary Approach

The absence of effective multidisciplinary review and triple assessment was cited as a significant contributory factor into why diagnostic errors at the heart of previous misdiagnosis cases were not identified. This led to significant delays in the diagnosis and commencement of treatment for a number of patients[2-4, 9-10].

The Standards set out the core team that should be in place in the SBD service in the designated centres and that the multidisciplinary team (MDT) should meet at least weekly.

The NCCP, and designated centres, inherited a situation where staffing levels in the existing centres were based solely on historical development that had not progressed as part of a coordinated programme. To address this issue, the NCCP developed a 'benchmarking tool' to allow it to decide whether additional staff were needed. It then began a process of transferring resources from centres ceasing to provide SBD services, or allocating new resources, to address these historic disparities.

The Authority has noted that this investment in staffing has had a significant effect on the ability of some centres to implement the Standards.

The most significant progress since 2007 has been the transition from variable application of a multidisciplinary approach to patient care, to all eight centres now having clear arrangements in place for the multidisciplinary care of all patients. While there remain opportunities to further enhance the multidisciplinary aspects of patient care, through standardised processes and more interaction of clinicians between centres, the Authority is encouraged to have found this key element of care to be in place for all patients referred to the SBD service.

4.3 Skills, Education and Training

The Standards set out the principle that clinical, and other staff working in SBD services, should have specific training and education in this area. All centres had a spectrum of arrangements in place to assure the skill and expertise of its staff. In general, these were not specified within a clearly described framework and the HSE needs to develop guidance around this important area.

4.4 Person-centred Care

All centres have put in place arrangements for informing and involving patients in their care through, for example, specialist nurses, access to counselling and provision of information.

Patient discussion groups, conducted by the Authority, reported high levels of confidence in the teams within the designated centres. Where concerns were reported, these tended to be in relation to parts of the care pathway delivered outside of the main centre and in relation to the arrangements for delivering bad news for which centres should always put a great deal of thought in order to meet the broad range of people's needs.

A key enabler of person-centred care is information. Centres need to ensure that all relevant information about patients and their care is accessible, whether generated in the designated centre or outside.

4.5 Data Management

Having reviewed the data management processes and systems, and validated in detail a sample of patient data in the eight centres, the Authority concluded that, while there remains work to be done, significant progress has been made compared to 2008.

Data collection and management is now happening in all centres. However, while some centres have well established and mature systems, other centres had only appointed data managers in mid 2009 and were still specifying data management systems in late 2009.

There was a wide spectrum of data management capability with some well established systems and good clinical buy-in to using data. However, there remain centres where data collection is sporadic and seen by some staff within the centres as an extraneous burden to patient care. Such centres need ongoing support and evaluation to ensure that the full patient benefit of reliable, comparable data from all centres is realised.

4.6 Access

The Standards set out a number of time-based standards, with associated targets for achievement, for the 'access' to key steps in the care pathway for patients.

During 2009, some centres fell below the required performance in relation to offering appointments for 95% of patients triaged as 'urgent' within two weeks. In these cases, the centres acknowledged that they were not meeting the standard and measures were taken, such as additional clinics, to bring performance to the required limits. While it is not acceptable for these standards not to be met, where this was the case, monitoring of performance in this area prompted a number of examples of remedial action to ensure the Standards were being met. This approach should be part of the core management of the provision of SBD services.

All centres have faced challenges in meeting the standard for offering an appointment within 12 weeks to 95% of patients triaged as 'non-urgent'. Analysis of the activity in the centres over the last few years, shows that there has been a large increase in the total numbers of patients being referred to SBD centres and this increase appears to be among patients at a lower risk of cancer (mainly younger patients).

At a national level, the profile of patients being seen in the SBD service translates into large numbers of patients with benign disease being seen in a service oriented primarily to diagnosing and treating patients with malignant disease through multidisciplinary teams and triple assessment.

There needs to be a coherent response to the group of patients potentially waiting longer than they should be. The HSE and its NCCP should take the lead in helping centres develop a service response that reflects the changed profile of patients being referred to the SBD service through fully engaging with patients, the public, providers and other key stakeholders.

4.7 Clinical Effectiveness

The Standards set out a number of factors that support the delivery of clinically effective care. These include, for example, the volume of patients seen with newly diagnosed breast cancer in each designated centre. They also include a series of clinical performance indicators and the use of clinical audit to monitor clinical effectiveness.

Volumes of patients seen with newly diagnosed breast cancer

In order to provide high quality, safe care, specialist centres should see a critical mass of patients in order to maintain the skills and expertise of its clinicians. The principle of centralisation into designated centres is partly to achieve this critical mass.

The Authority requested patient activity, and the numbers of diagnoses, from the centres as part of its Review. Analysis of this demonstrated that each centre was seeing a volume of patients that was above that recommended in previous reports[2-3].

Having now established the eight centres, the NCCP should extend and refine its monitoring of activity to include the numbers of patients being seen by individual clinicians.

Clinical performance indicators

Each centre submitted clinical effectiveness data for all patients who were diagnosed with invasive breast cancer between 1 April 2009 to 30 June 2009. The Authority reviewed this data, that related to the clinical effectiveness indicators described in the Standards, and found that for the period covered by the data, all designated centres were meeting most of the requirements as set out in the Standards.

Clinical audit

Clinical audit constitutes the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides. It should be viewed as an essential and integral component of professional practice which will contribute to improved patient outcomes.

All eight centres had some clinical audit arrangements in place. SBD-patient-access data was analysed and used as a part of performance monitoring. In some centres, patient mortality and morbidity information was reviewed within the overall corporate surgical services. Some centres had more advanced and corporately integrated processes for SBD-specific clinical audit in place.

The Review found no evidence that any patient outcome information, generated through clinical audit, was being shared between the designated centres to facilitate comparisons in order to drive improvements nationally.

The incidence of a delayed diagnosis for a patient with breast cancer, although a rare occurrence, will unfortunately occur in the best centres in the world. When this happens, it is important that it is detected early and the patient is treated appropriately and promptly. An analysis of how it has happened, in order to minimise the likelihood of it happening again, is essential in any service. There was no evidence of a nationally agreed definition of delayed diagnosis, or a consistent approach across the eight centres, for clinicians, to audit and report these clinical incidents.

There needs to be a nationally agreed definition of delayed diagnosis for patients and a consistent approach across the eight centres for clinicians to report these incidents, including discussion with patients. These will allow the centres to develop improvement strategies, to reduce the risk of these rare incidents which have profound consequences for patients, and to put in place processes and behaviours to openly and effectively communicate with patients and their families.

Clinical audit arrangements must be put in place that focus on patient outcome measurements that allow the ongoing comparison of quality, clinical improvement and learning within and between the eight designated centres.

5 Next steps

Follow up on local reports

Having made recommendations in all of the local reports of the eight designated centres, the Authority has requested each centre to develop and publish robust local implementation plans for these. The Authority will be meeting periodically with the centres, and the HSE, to assess progress in implementing these recommendations.

In three of the centres, where governance and information systems were at an early stage of development, the Authority will be conducting further on-site reviews during 2010 to assess progress in creating a sustainable basis for further development. These centres are:

- Cork University Hospital
- Mid-Western Regional Hospital Limerick
- Waterford Regional Hospital.

Follow up on this national report

Having made a number of recommendations that apply nationally as contained in this Report, the Authority will engage in a series of meetings with the NCCP, and where necessary the wider HSE, to assess progress with implementing these recommendations.

National Quality Assurance Standards for Symptomatic Breast Disease Services

The Standards were launched nearly three years ago and the Authority would expect to review and update standards on a three-year cycle. In the meantime, a number of developments are underway, as part of implementing the recommendations of the Report of the Commission on Patient Safety and Quality Assurance, that will influence how and when such a review takes place. These developments mean that the Standards will need to be reviewed over the next year.

It should be emphasised that, until such time as the Standards are formally superseded, they remain in force and should be used by the NCCP, providers and patients as the basis for assuring the quality and safety of SBD services.

6 Concluding Remarks

From a position in 2007 when SBD services in Ireland were dispersed, unspecified and unmonitored, there are now eight designated centres established, albeit the last of these became operational in December 2009. Healthcare, by its very nature can never be error free and even in the best centres worldwide, errors occur. However, all centres now have in place the fundamental requirements for safe, quality care in particular: triple assessment, multidisciplinary team, core staffing and appropriate equipment. In addition, centres have begun to introduce standardised data collection and management systems. In general, the centres are meeting the key requirements set out in the Standards and have shown how the monitoring of their performance has led to action to improve performance for patients where required.

However, creating a successful national service is not simply about putting resources in place or establishing physical locations. Clinicians do not spontaneously become leaders, teams do not spontaneously become effective and, where they need to, established practices and behaviours take time to change. Some centres – especially (but not solely) those consolidating after recent major service change, need time and support to bed in successfully if patient safety and high quality are to be maintained and delivered on a stable and sustainable basis.

In securing and allocating resources to ensure that all centres are above the levels needed to deliver multidisciplinary care, the NCCP, working with other parts of the HSE and the designated centres, has successfully created a platform from which to build and improve for the future. The focus of the HSE now needs to shift from getting building blocks in place in terms of resources, to leveraging the strategic and service delivery benefits from consolidating specialist services – not just for breast cancer, but for other cancers too.

This report includes a number of recommendations intended to support this process. In addition, the Authority will carry out further on-site visits in 2010 to review progress in centres where some aspects of the service were at an early stage of development when they were reviewed in the autumn of 2009.

Recommendations

1. The HSE should formally establish a national network of the SBD lead clinicians with a view to identifying and addressing mutual development and support needs.

2. The HSE together with the designated centres should formally evaluate the implementation of Standard Operating Procedures on a phased and prioritised basis, to ensure that they are fully embedded and being applied consistently within and between designated centres.

3. The HSE should ensure that designated centres have robust governance arrangements in place, including a Service Level Agreement, to effectively manage relationships with third party providers. Such arrangements for the outsourcing of radiation oncology should be established promptly. These should cover the requirements of the Standards and in particular quality, safety and the formalised exchange of information.

4. The HSE should put in place formal national clinical governance arrangements, to ensure that the eight centres build on robust local clinical governance arrangements, in order to operate as a cohesive national clinical network for the purposes of clinical audit, sharing of good practice and problem solving.

5. The HSE should put specific actions in place to ensure that its new directorate structure incorporates a clear mandate for describing and implementing the National Cancer Control Plan. In particular this should include clarity in the governance, accountability, responsibility, authority and resource allocation for the eight designated centres.

6. The HSE should work with designated centres, to assess the organisational development needs of the newly established designated centres and introduce focused support as required.

7. The HSE together with the designated centres should carry out a risk assessment to identify areas in the designated centres where service continuity and sustainability, or the ongoing meeting of Standards, could be threatened by the absence of key staff and ensure that contingency plans are in place as needed.

8. The HSE should work with the designated centres, and the relevant training bodies, to develop a standardised framework for assuring the skills, education and training of staff in the centres are maintained at the necessary levels.

9. The HSE, with the designated centres, should establish effective ways of enhancing the continuity of patient care. This should include the introduction of the "Most Responsible Clinician" for patients within the SBD service. This should also be inclusive of aspects of care provided by third party providers.

10. The HSE should require all centres to have in place robust arrangements for ensuring that all information relevant to patients' care is accessible as needed by patients and clinicians, irrespective of where the care is provided or the information is generated.

11. The HSE should identify those designated centres where data management capability, and the use of data, are still in development and instigate ongoing evaluation and, where needed, provide focused support for those designated centres. This should include targeted support and development for SBD clinicians in the capture and use of data as an intrinsic facet of clinically effective care.

12. The HSE together with the designated centres should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians.

13. The HSE should coordinate, with the designated centres and the wider health system, the development of a differentiated service response that reflects the profile of patients being referred to the service, whereby patients with a lower risk of breast cancer are seen in a timely way and with the necessary clinical assessment.

14. The HSE together with the designated centres should develop mechanisms for monitoring the numbers of newly diagnosed patients seen and treated by individual clinicians with a view to developing benchmarks for the relevant clinical specialties.

15. The HSE should develop, with the designated centres, a national clinical audit programme for SBD services that includes as a minimum: patients triaged as non-urgent and subsequently diagnosed with breast cancer, delayed diagnoses, longer term clinical outcome and survival rates. The national key performance indicator set should be reviewed regularly based on the outcomes of these audits.

16. The HSE together with the designated centres should put in place arrangements to begin publicly reporting performance against the NCCP Key Performance Indicators during 2010.

17. The HSE should undertake a formal evaluation of the change programme that has created the eight designated centres with a view to identifying lessons for future similar programmes of change. The changes that have been made in improving the symptomatic breast disease services should be used as a template to be adapted and modified for other services.

18. The HSE should nominate a national director to be responsible for developing and monitoring an implementation plan for these recommendations and should ensure that these actions are delegated as necessary. It should put in place arrangements for reporting progress with implementation to the HSE Board and the public.

1 Introduction

This report presents the findings from the National Quality Review of Symptomatic Breast Disease Services that has been undertaken by the Health Information and Quality Authority (the Authority). This Review was undertaken in order to monitor progress with the implementation of the National Quality Assurance Standards (the Standards) for symptomatic breast disease (SBD) services in Ireland[1]. It comes at an important juncture in the development of the national SBD services, given that all designated centres were expected to be fully established and meeting the Standards by the end of 2009. It is therefore appropriate to report on progress to this point and signal where further work may be needed.

Since 2007, the National Cancer Control Programme (NCCP), established by the Health Service Executive (HSE) to lead the development of cancer services, has been engaged in a change programme to move the provision of SBD services from over 30 publicly funded centres to eight designated centres. The national Quality Review of Symptomatic Breast Disease Services by the Authority is the culmination of two and half years of its interaction with the services since the launch of the Standards. It is envisaged that the results of this Quality Review will provide service users and the public with an objective view of designated breast cancer centres, allow centres to compare their performance with that of others and provide the focus for sharing good practice.

The findings of each individual centre's Quality Review are reported in detailed local reports published on the Authority's website (www.hiqa.ie). The key findings from these are summarised in the relevant sections of this report.

This report draws on the main findings from these local reports, as well as the learning over the last two and a half years from the Authority's monitoring activity in the eight designated centres and its interaction with the National Cancer Control Programme. It provides an objective assessment of services, as they were at the end of 2009, and identifies further measures that are needed to ensure that the changes implemented are sustainable and deliver, in full, the benefits to patients associated with establishing a nationally specialist designated service.

International evidence, and recent experience in Ireland, have shown that certain service and performance factors are essential for the provision of safe, high quality care for people with symptomatic breast disease. The Authority used the Standards and findings from its own previous investigations to identify the **essential elements** that must be in place in designated centres to achieve this, the absence of which would be a cause for concern[1-4]. Where it is reported that those essential elements are in place, the public should have confidence that services have the essential attributes for safety and quality. However, in most centres there remain opportunities for improvement and, where necessary, the Authority has made specific recommendations to focus the sustainable improvement and continued development of SBD services. In some cases, the Authority will be returning to a centre in order to assess its continued progress, especially in centres that are still consolidating after a process of considerable change.

The Authority would like to thank the staff in the designated centres, the NCCP, patients who participated in the discussion groups, the Quality Review team which included a service-user representative from Europa Donna Ireland and all of the staff of the Authority who contributed to this Review.

Before describing the Authority's findings and conclusions in relation to symptomatic breast disease services, this report now sets the scene by describing the context and background to the SBD services and why the Quality Review programme was undertaken.

2 Setting the scene

2.1 Breast cancer

Breast cancer is the second most common cancer in Ireland. Statistically, breast cancer accounts for 30% of all cancers in women in Ireland with approximately 2,500 new breast cancer cases diagnosed each year[5-6]. It continues to be the most common malignancy in women. Internationally, breast cancer mortality rates have decreased slightly despite the rise in the incidence of breast cancer in the last two decades[11]. However, due to improvements in technology and treatment pathways, the prospects of long-term survival and improved quality of life are increasing. Although not nearly as common, men also develop breast cancer.

In Ireland, the Central Statistics Office reported that 731 women died from breast cancer in 2008 making it a significant public health issue[7]. Between 1994 and 2001, the mortality from breast cancer was reported to be 33% higher in Ireland than in the United States and in the upper third of rates in European countries[8].

Early detection of all cancers is the best strategy for reducing cancer deaths. If diagnosed early, breast cancer is treatable in most cases[12]. The most important objective in the delivery of symptomatic breast disease services is that all patients receive the best possible treatment giving them an opportunity for the best outcome regardless of where they live.

Public education about the importance of early detection, improvements in treatment and effective education and referral arrangements are important in improving breast cancer outcomes for patients. It is also important to note that 9 out of 10 women, who present to their general practitioner (GP) with breast symptoms, are found to have a non-cancerous condition[13]. Services should be planned and provided to recognise this, allowing patients at lower risk of cancer to be effectively and appropriately treated without compromising services for patients with higher risks. This issue is discussed further, later in this report.

2.2 Background to the *National Quality Assurance Standards for Symptomatic Breast Disease Services* and the Authority's Quality Review Programme

The development and implementation of standards are important in defining what should be expected of the providers of services and provide the basis of service planning, development and continuous improvement. Standards also give patients and the public a clearer understanding of what they should expect from services.

The need for developing specialist breast cancer centres was highlighted in the 2000 report, *Development of Services for Symptomatic Breast Disease: Report of the Sub-Group to the National Cancer Forum* [14]. This report found that the management of breast cancer services in Ireland differed in the way that it was being provided

between surgeons and hospitals, as did the volumes of patients being seen with many hospitals diagnosing less than 100 patients a year. Strong evidence exists to show that patients with breast cancer, when treated in a multidisciplinary setting, have a better prospect of long-term survival. The report stated that experience in other countries indicates that this arrangement is best achieved through the establishment of specialist breast cancer centres[11].

In 2005, the Department of Health and Children established a national quality assurance group for the symptomatic breast disease services. This group developed the National Quality Assurance Standards for Symptomatic Breast Disease Services setting out the requirements of a well functioning specialist breast cancer centre[12]. These standards were subsequently approved by the Board of the Authority and then mandated by the Minister for Health and Children in May 2007. At the time, the Authority requested a clear implementation plan for these Standards from the HSE and signalled its intention to undertake a National Quality Review of these services in the future in order to monitor compliance with the Standards once they had been implemented by the end of 2009.

During 2007, a number of serious concerns about the quality and safety of symptomatic breast disease services came to light. These included examples of the delayed diagnosis of breast cancer for a number of patients and led to a number of investigations, including two undertaken by the Authority[1-2]. The HSE also conducted a review of symptomatic breast disease services at the Midland Regional Hospital Portlaoise[13-14]. The impact of these incidents, and the associated media coverage, led to a reduction in public confidence in breast cancer services and, as a result, in the autumn of 2007 the Authority announced its decision to bring forward the National Quality Review of the national symptomatic breast disease services. This was the starting point of a programme of work that has extended over the last two and half years and will continue into 2010.

The approach taken by the Authority to monitoring the implementation of the Standards through a Quality Review programme is set out in Section 3 of this report.

2.3 Background to the National Cancer Control Programme

In 2007, the HSE established a National Cancer Control Programme directorate, to manage, organise and deliver a national cancer programme in Ireland. Under this national programme, all cancer care would be provided through a national system of four Managed Cancer Control Networks in the HSE's four geographical regions, each serving a population of around 1 million people and consisting of primary, hospital, palliative, psycho-oncology and supportive care with patient care being fully integrated between each of these elements within each network.

The emphasis in each network is described as being "on connection and partnership rather than on isolation and self-sufficiency, on distribution of resources rather than on centralisation, and on maximising the benefits for all patients"[15]. Figure 1 below shows the national organisation of the NCCP.

Figure 1:

National Cancer Control Programme Cancer Control Networks and Regional Cancer Centres

HSE Dublin North East

- Beaumont Hospital, Dublin
- Mater Misericordiae University Hospital, Dublin.

HSE Dublin Mid Leinster

- St James's Hospital, Dublin
- St Vincent's University Hospital, Dublin.

HSE South

- Cork University Hospital
- Waterford Regional Hospital.

HSE West

- University College Hospital Galway plus a satellite site in Letterkenny General Hospital, Donegal
- Mid-Western Regional Hospital Limerick.

Breast cancer services were the first to be centralised into these eight centres. In June 2007, there were 33 hospitals providing breast cancer services. By December 2008, this had been reduced to 12 centres.

The transition from over 30 publicly funded hospitals, providing primary diagnosis and treatment of breast cancer, to eight designated specialist breast cancer centres has occurred in a staged process over the last two and a half years, culminating with the transfer of the last non-designated services into designated centres in December 2009 (See Table 1).

Table 1: Date from when centres ceased to accept new referrals for symptomatic breast disease from 2007 to 2010+

Date	Hospital
Pre-2007	Monaghan General Hospital Bantry General Hospital, Cork Our Lady's Hospital, Cashel, Tipperary
September 2007*	Naas General Hospital, Kildare Midland Regional Hospital Tullamore, Offaly St Columcille's Hospital, Loughlinstown, Dublin Mallow General Hospital, Cork Louth County Hospital Cavan General Hospital Our Lady's Hospital, Navan, Meath Mid-Western Regional Hospital Nenagh Mid-Western Regional Hospital Ennis St Michael's Hospital, Dun Laoghaire, Dublin Roscommon County Hospital Portiuncula Hospital, Ballinasloe, Galway Mercy University Hospital, Cork
October 2007	Longford/Westmeath Regional Hospital, Mullingar, Westmeath Connolly Hospital Blanchardstown, Dublin
January 2008	South Tipperary General Hospital, Clonmel
April 2008	Midland Regional Hospital Portlaoise
October 2008	Kerry General Hospital
November 2008	St Luke's General Hospital, Kilkenny Wexford General Hospital
November 2008	Mayo General Hospital
April 2009**	St John's Hospital, Limerick
April 2009	Our Lady of Lourdes Hospital, Drogheda, Louth
August 2009	Sligo General Hospital
October 2009	The Adelaide and Meath Hospital Incorporating the National Children's Hospital, Tallaght
December 2009	South Infirmary Victoria University Hospital, Cork

Notes:

* *These hospitals were formally requested to discontinue symptomatic breast disease services at this time though it was acknowledged that some had already discontinued service in practice.*

** *Breast cancer surgery was discontinued in St John's Hospital Limerick in April 2009. New referrals were never seen at this hospital.*

\+ *Source: National Cancer Control Programme 2009*

By the end of 2009, all newly referred patients with symptomatic breast disease were being seen by the eight designated centres only (this includes Letterkenny General Hospital operating as a satellite of University College Hospital Galway, see table 2).

Table 2: Designated centres (hospitals) that will accept new referrals for symptomatic breast disease in 2010+

Designated centre (hospital)
Beaumont Hospital, Dublin
Cork University Hospital
Mater Misericordiae University Hospital, Dublin
Mid-Western Regional Hospital Limerick
St James's Hospital, Dublin
St Vincent's University Hospital, Dublin
University College Hospital Galway plus Letterkenny General Hospital (as a satellite of UCHG)
Waterford Regional Hospital

+ *Source: National Cancer Control Programme 2009*

This report now goes on to describe how the Authority has monitored compliance with the Standards over the last two and a half years.

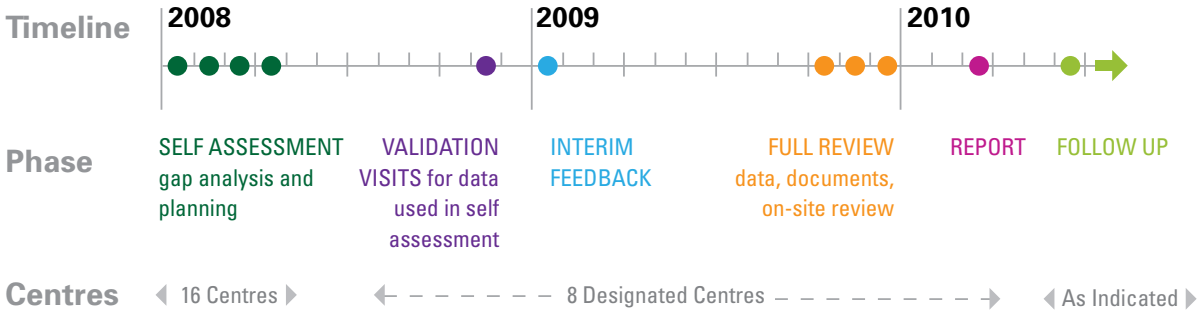
3 How the Authority has monitored the implementation of the Standards

The Authority's National Quality Review Programme was conducted over a two and a half year period. The Authority's approach has been designed to reflect the stage of development of the designated centres, at a given point in time, and to reflect the continuous change programme that has been in train over that period in line with the progress towards meeting the Standards by the end of 2009.

In autumn 2007, the Authority announced the commencement of a National Quality Review programme to establish how hospitals providing symptomatic breast disease services were meeting the Standards. In undertaking this process, the Authority had to take into account the fact that there was by then a national plan to move to eight designated centres, which should in turn facilitate the implementation of the Standards. This meant that, over time, some existing services would be discontinuing, while services in the eight designated centres would be reshaping to accommodate patients from those centres ceasing to provide symptomatic breast disease services.

Given the consequent fluidity of services, it was important that any assessment process adopted by the Authority reflected this ongoing and significant change. The Authority adopted a flexible approach to monitoring compliance and focused its efforts on both the quality of care and the effective management of the transition in the eight designated centres. This led to a Quality Review programme that involved **five phases** as services consolidated to the eight designated centres and these eight centres aimed to progress towards full establishment and compliance with the Standards by the end of 2009. Figure 2 summarises the timeline for the Authority's activity over this period.

Figure 2: Summary Timeline for the National Quality Review Programme During 2008 to 2010



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

Phase 1: Self assessment, January to April 2008

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

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

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

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

Phase 2: Validation assessment process, autumn 2008

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

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

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

Phase 3: Feedback to designated specialist centres, January 2009

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

The interim reports took the form of a qualitative statement of the performance of the centres against the Standards as demonstrated on the day of the validation visit, and included recommended steps for the future (see Appendix 2).

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

Phase 4: Quality review visit, October to December 2009

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

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

Interviews were also undertaken with the NCCP.

The detailed methodology for this phase is described in Appendix 3.

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

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

However, it was a fundamental requirement that the Standards provided the basis for the assessment process given that these are the requirements approved by the Board of the Authority and mandated by the Minister for Health and Children. Therefore, taking account of the above issues, the Authority analysed all 285 requirements in the Standards to identify the key issues on which the assessment needed to focus in a patient-centred way. As a result, ***key representative standards*** from the Standards (see Appendix 1) were identified. To help shape the review, these representative standards were then grouped into seven ***generic themes***. These were:

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

Recognising that centres would be at different stages of development towards implementing the full range of standards, the Authority identified the most important elements in each theme that must to be in place for quality and safety. These ***essential elements*** that each designated specialist centre must have as the foundation for safe, high quality symptomatic breast disease care are set out in **Figure 3**.

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

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

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

Figure 3: Essential elements for safe, high quality symptomatic breast disease care in specialist centres

Theme 1: Governance
Essential Element 1 (a) A comprehensive integrated governance structure with an organisational framework that incorporates systems and processes must be in place to allow effective general and clinical decision making, incorporating risk management, clinical service delivery and evaluation. **Essential Element 1 (b)** The service will have robust clinical management, referral and patient pathways ensuring an effective integration of patient care. **Essential Element 1 (c)** The governance structure will include defined responsibilities for shared service delivery as specified in the contractual agreement with another service provider.

Theme 2: Multidisciplinary Approach

Essential Element 2 (a)

Core Team.

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

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

Essential Element 2 (b)

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

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

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

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

Essential Element 2 (c)

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

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

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

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

Theme 3: Skills, Education and Training

Essential Element 3 (a)

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

Theme 4: Person-centred Care

Essential Element 4 (a)

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

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

Essential Element 4 (b)

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

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

Theme 5: Data Management

Essential Element 5 (a)

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

Essential Element 5 (b)

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

Essential Element 5 (c)

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

Essential Element 5 (d)

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

Theme 6: Access

Essential Element 6 (a)

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

Essential Element 6 (b)

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

Theme 7: Clinical Effectiveness

Essential Element 7 (a)

The centre must have the facilities to treat more than 150 newly diagnosed patients with primary breast cancer per year. The centre must provide care of patients with breast disease from referral through to care of patients with 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.

Phase 5: Local and national reporting of findings, February 2010

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

The Authority will continue to monitor compliance with the Standards during 2010.

To summarise the background to the findings that underpin this report, the evidence on which they are based includes the:

- documents provided by the eight designated centres (Appendix 4, Document request template)
- access and clinical effectiveness data for patients who had been newly diagnosed with primary breast cancer, and seen at the centre during the 13 consecutive week period from 1 April 2009 to 30 June 2009, which was provided by each centre (Due to refurbishment, the Mater Misericordiae University Hospital submitted data for the period 1 June to 30 August 2009) (Appendix 5, Data request template)
- activity data provided by each centre for new patients seen for the seven-month sample period from 1 January 2009 to 1 August 2009. (Due to refurbishment, the Mater Misericordiae University Hospital submitted data for the period 1 June 2009 to 1 November 2009)
- findings of the Authority's on-site Quality Review in each of the eight centres (between 12 October 2009 and 1 December 2009) including:
  - the validation of data against a number of patient records
  - qualitative interviews with relevant staff
  - discussions with patients
  - the observation of clinical areas.

This national report now sets out the main findings from the Authority's National Quality Review of symptomatic breast disease services over the last two and a half years, including the most recent detailed Quality Review in the eight centres and its interactions with the NCCP. Where appropriate, recommendations have been made to address areas for improvement.

4 Findings

Since autumn 2007, the Authority has been engaged in a programme of assessment and monitoring activity as SBD services have gone through a period of significant change and development. During this period, depending on their circumstances, services across the country have been discontinuing, moving or developing towards the creation of eight fully functioning designated centres that should be meeting the requirements of the Standards by the end of 2009.

As described previously, the Authority's programme has been designed to monitor the centres progress towards the full implementation of the Standards. Taking account of the fluid nature of services in this period, the Authority's work has been focused at both local (hospital) and national levels - providing commentary and feedback as needed to help those responsible for the development and delivery of services to maintain progress and address any areas of concern over this time.

This programme culminated in autumn 2009 with a comprehensive Quality Review in each of the eight designated centres. This section brings together the Authority's findings and observations and sets out its assessment of the current state of development of SBD services in Ireland using the generic themes described in section 3.

Detailed reports for individual centres are published at www.hiqa.ie. The findings under each theme for the individual designated centres are summarised in tables within this section.

4.1 Governance

Governance refers to the organisational framework that incorporates systems, processes and behaviours for effective decision making that 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, service evaluation and delivery.

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

The absence of effective governance in healthcare implies a system solely dependent on the degree of professionalism or commitment of individuals to ensure services are safe and of the right quality. Experience in Ireland and internationally suggests that, over time, this type of system is less safe, less accountable and less able to improve and manage change than where effective governance is in place. It is therefore fundamental to safe, high quality and sustainable services to have effective governance arrangements in place. In the case of SBD services, with

its multidisciplinary nature, the presence of robust governance arrangements, as a mechanism for monitoring performance against standards, is a fundamental requirement.

The Standards, as drafted in 2006, do not describe in detail the governance requirements of designated breast centres. The Authority therefore drew on its findings from its previous investigations to frame its expectations in relation to what is expected for good governance. Although not described in detail by the Standards, the Authority's national recommendations relating to SBD services, made in 2008[1-2], are sufficiently explicit about governance to have allowed designated centres to begin developing their local arrangements using those recommendations. All centres were advised of this prior to the on-site reviews.

In addition to the centres' own governance arrangements, the interaction with the NCCP directorate of the HSE and the NCCP's governance of the transition process, has been and remains a key component to the quality, safety and reliability of the centres.

4.1.1 Governance in the designated centres in 2008

The Authority commented on governance arrangements following the self-assessment process and subsequent validation visits in 2008. At that stage, it was clear that there was wide variation between the centres with some well established, mature arrangements and embedded practices for monitoring performance and addressing any issues in place in some centres. In other centres, there were almost no formal governance arrangements in place for the service.

Subsequently, very few of them (including those with established governance structures) had in place any formal arrangements to report on, or routinely monitor, performance against the Standards. There was not a wide understanding among managers or clinicians of the importance of this aspect of quality management as a means of assuring themselves, their patients and the public that the Standards were being met. Consequently, most centres struggled to reliably populate the self-assessment questionnaire other than by carrying out time consuming retrospective audits or simply relying on professional opinion. The view was expressed to the Authority by some clinicians that they had never expected to be measured against the Standards.

Following the Authority's validation visits in 2008, the Authority wrote to all centres and the NCCP emphasising the importance of establishing clear governance arrangements as a vehicle for implementing routine monitoring of performance against the Standards (see Appendix 2) in order to demonstrate that they were meeting the requirements of a high quality, safe and reliable service for patients.

The Authority also commented on the fact that core processes, such as patient referral and the conduct of multidisciplinary teams (MDTs), were not standardised between the centres. This created the potential for variable patient experience and use of resources.

4.1.2 Overall position in the designated centres at the end of 2009

Formalised arrangements

Since 2008, there has been substantial progress made in this area and all the centres now have in place governance arrangements in the form of specific committees and accountability relationships, though these vary in nature and effectiveness. As would be expected, the centres which have been more recently in transition are less well progressed than more established centres. All centres need to embed the systems and practices to allow sustainable performance and improvement for patients. In most centres there is a need, to varying degrees, for greater clarity in managing risks within SBD services and responding to adverse incidents in the context of other local arrangements.

Lead clinicians

All centres have made progress in establishing a nominated lead clinician to provide a focus for developing the service, monitoring quality and developing clinical governance. However, even in well established centres, this role is evolving and needs clearer definition through a written role description and terms of reference. Some of the lead clinicians are newly nominated and would benefit from focused support to help them establish themselves in the role. A specific programme to develop lead clinicians and help them establish a supportive network would help accelerate the development of the service nationally and increase the value added by this role overall.

Recommendation 1

The HSE should formally establish a national network of the SBD lead clinicians with a view to identifying and addressing mutual development and support needs.

Monitoring performance

Subsequent to discussions regarding the routine monitoring of performance against the Standards, the NCCP coordinated the development of a set of key performance indicators (KPIs) to be collected by all centres on a routine basis (see Appendix 6). These are discussed further under the Data Management section. In parallel, the NCCP began an investment programme in information technology (IT) and data collection infrastructure. All centres now have, or are introducing, IT systems and infrastructure and all are collecting a core set of data derived mainly from the Standards to help them monitor quality. This is a significant step forward compared to 2008. However, for many centres this remains a relatively new activity and, particularly where considerable changes in services have happened, there remains work to do to embed this fully into the service.

Standardised processes

In response to the need for greater standardisation of some core processes, the NCCP has developed standardised referral forms for general practitioners (GPs) and a range of standard operating procedures (SOPs) for differing aspects of the symptomatic breast disease service[16]. These have been distributed to the centres and are now being implemented locally. Over time, and through ongoing inclusive engagement with primary care, this will help ensure that the core experience of patients and the use of resources is the same in all of centres.

Recommendation 2

The HSE together with the designated centres should formally evaluate the implementation of Standard Operating Procedures on a phased and prioritised basis, to ensure that they are fully embedded and being applied consistently within and between designated centres.

Third-party providers

A recurrent theme from the Authority's monitoring activity has been the weakness of governance arrangements in the relationships with third party providers. This is an issue that has been highlighted previously by the Authority as a quality and safety risk[3]. This is of particular relevance to SBD services. For example, in relation to access to radiation oncology (radiotherapy) and medical oncology when these are not provided in the centres. The Authority found that the move of patients from one care setting to another was not always subject to adequate governance arrangements, including the exchange of information, leading to the potential for poor continuity of care for patients.

A further consequence of this was the inability to monitor whether the Standards were being met in all aspects of patient care. The Authority found this to be the case particularly for radiation oncology services. A number of patients, who were interviewed as part of the Quality Review, supported this finding.

The absence of adequate specification of these relationships, for example through a service level agreement (SLA), and the lack of robust arrangements for the monitoring of third-party services, is a significant cause for concern and could have adverse consequences for patients. For example, there is potential for the breakdown in the continuity of patient care and the absence of the data for quality monitoring along the full patient pathway. This needs to be addressed both in local arrangements and nationally by the NCCP.

Radiation oncology (radiotherapy)

A significant component of the National Cancer Control Programme is the implementation of a national plan for radiation oncology in order to bring radiation treatment services in Ireland up to international best practice. This is a multi-year plan with committed operational and capital funding which plans to see the creation of a national network of radiotherapy facilities on six sites by end of 2014, with the first phase (two new facilities in Dublin) being completed by the end of 2010. These facilities will be situated on the sites of six of the eight designated cancer centres.

This development is essential. However, in the interim period, the Authority has recommended to each centre and the NCCP that they must ensure that the interface with existing providers is properly controlled. For example, through robust service level agreements that cover the quality and safety of the service provided, including exchange of performance data for monitoring the Standards. The HSE and its NCCP needs to take a national overview of this aspect of patient care for all cancer patients while the new facilities and arrangements are under development.

Recommendation 3

The HSE should ensure that designated centres have robust governance arrangements in place, including a Service Level Agreement, to effectively manage relationships with third party providers. Such arrangements for the outsourcing of radiation oncology should be established promptly. These should cover the requirements of the Standards and in particular quality, safety and the formalised exchange of information.

4.1.3 Governance nationally and the NCCP

The NCCP directorate of the HSE was created in autumn 2007 and an Interim National Director was appointed. The NCCP was given the task of implementing the national cancer control plan and focused immediately on the necessary change programme for SBD services.

The NCCP was created as another entity in an already complex environment which included voluntary hospitals and the former National Hospitals Office of the HSE. This meant that, while at a national level the NCCP was responsible for driving implementation of national policy, translating this into change at the local level was complicated by the fact that hospitals were aligned to different accountability structures, with clinicians in some centres who did not see themselves as linked into any accountability structure. In addition, some of the necessary changes had a political dimension to the change process. While latterly there have been examples of collaborative working, the NCCP had to address the fact that initially the designated centres saw themselves as competitors, in relation to resources and reputation, and were not oriented to working collaboratively.

Consequently, these factors have meant that the NCCP could not simply assert its national mandate to introduce local changes, but had to negotiate change at a local level. The consequence of this is twofold. Firstly, that it has taken two years for the NCCP to successfully achieve the physical creation of eight designated centres, with the last moves happening in December 2009. Therefore, there remains further significant bedding in of some designated centres before they can be regarded as being fully established specialist centres.

Secondly, the need for this very local engagement has meant that the NCCP has been unable to fully develop the national systems and processes that will help drive the long-term benefits of creating sustainable designated centres – namely the ability to share good practice and compare information on quality and outcomes to drive consistency, reliability and the continuous improvement of care for patients.

Despite these challenges, the NCCP has successfully used its national position to coordinate the creation of eight physical centres with the requisite core resources, and has led key developments, for example, the development of KPIs to monitor quality.

Having established this platform, the focus of the HSE and its NCCP, in conjunction with the eight designated centres and key stakeholders, must now shift quickly to leveraging the longer term benefits for patients from creating the designated centres by ensuring that they operate, and are organised, more cohesively as a national clinical network in order to support sustainability and continual improvement in the patient care.

Recommendation 4

The HSE should put in place formal national clinical governance arrangements, to ensure that the eight centres build on robust local clinical governance arrangements, in order to operate as a cohesive national clinical network for the purposes of clinical audit, sharing of good practice and problem solving.

To assist the NCCP in doing this, the HSE should ensure that its new directorate structure provides a clear mandate for the NCCP and other directorates in driving forward the next stage of creating sustainable high quality, safe cancer services. This must include clarity in the governance, accountability, responsibility, authority and resource arrangements required to further develop this, and other cancer services, on a national basis.

Recommendation 5

The HSE should put specific actions in place to ensure its new directorate structure incorporates a clear mandate for describing and implementing the National Cancer Control Plan. In particular this should include clarity in the governance, accountability, responsibility, authority and resource allocation for the eight designated centres.

The findings under the Governance theme for each of the designated centres are summarised in the following table:

1. Governance (Essential Elements)

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.

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

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

Governance conclusions:	
Beaumont Hospital (BH)	■ The SBD service at BH had a comprehensive integrated corporate and clinical governance structure. There was a robust organisational framework that incorporated systems and processes for effective general management and clinical decision making. ■ The SBD service had a comprehensive structure and mechanism to monitor and evaluate compliance with the Standards and the NCCP key performance indicators. ■ The SBD service had a well defined multidisciplinary structure which was supported by a standard operating procedure. To facilitate integrated patient care, there were clear referral, clinical pathway and leadership arrangements, along with clear general practitioner (GP) communication and referral processes. The service should ensure the service level agreement with the third-party provider of radiation oncology is finalised and implemented. ■ Overall, the Authority concluded that the SBD service at BH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

Cork University Hospital (CUH)	■ At the time of Review, the SBD service at CUH was in a transition phase. The reviewed service had corporate and clinical governance structures to support the delivery of a quality service at that time. ■ However, as clinical services and staff transfer from South Infirmary Victoria University Hospital (SIVUH), information management systems go live, infrastructural arrangements are finalised and patient volumes increase, it is critical that existing corporate and clinical governance structures are reassessed to ensure that they are fit for purpose, effective and robust. ■ Overall, the Authority concluded that, while there were some clear clinical and executive reporting mechanisms, the governance structure specific to the SBD service at CUH was in a developmental phase and will require re-assessment.
Mater Misericordiae University Hospital (MMUH)	■ The SBD service at the MMUH had corporate and clinical governance structures. The role and responsibilities of Lead Clinician was shared between a consultant surgeon and radiologist. There was an organisational framework that incorporated clinical decision making. However, the service needed to strengthen the governance arrangements through greater integration and formal monitoring with the Standards. ■ The SBD service had a well defined multidisciplinary structure with a clear patient referral, clinical pathway and leadership arrangements with GP communication and referral processes. However, all consultant surgeons do not have allocated theatre time. ■ The service should ensure the service level agreement with the third-party provider of radiation oncology is effectively implemented. ■ Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

Mid-Western Regional Hospital Limerick (MWRHL)	▪ The SBD service at MWRHL had clear patient referral, clinical pathway and clinical leadership arrangements with clear GP communication and referral processes. There was an organisational framework that incorporated effective clinical decision making. ▪ The service should ensure the service level agreement with the third-party provider of radiation oncology services is finalised. ▪ At the time of the Review, the service had a governance structure and organisational framework in place†. However, this was in an early stage of development. The Authority concluded that these governance arrangements would require a period of adjustment before a judgment on their effectiveness could be made and will need to be re-assessed by the Authority. † *The local and network governance arrangements are in line with the Authority's recommendations in the Report of the investigation into the circumstances surrounding the provision of care to Rebecca O' Malley.*
St James's Hospital (SJH)	▪ The SBD service at SJH had a comprehensive corporate and clinical governance structure. There was an organisational framework that incorporated systems and processes for effective general management and clinical decision making. The SBD service monitored and evaluated compliance with the Standards, NCCP and hospital-specified key performance indicators through the Hospital's Breast Care Quality Review and Improvement Group. ▪ The SBD service had a well defined multidisciplinary structure which was supported by a standard operating procedure. To facilitate integrated patient care, there were clear patient referral, clinical pathway and leadership arrangements with clear GP communication and referral processes. The service should ensure the service level agreement with the third-party provider of radiation oncology is finalised. ▪ Overall, the Authority concluded that the SBD service at SJH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

St Vincent's University Hospital (SVUH)	■ The SBD service at SVUH had a comprehensive corporate and clinical governance structure. There is an organisational framework that incorporates effective clinical decision making, monitoring and evaluating compliance with the Standards, NCCP and hospital-specific key performance indicators. The SBD service had clear patient referral, clinical pathway and leadership arrangements with clear GP communication and referral processes. ■ The service should ensure a service level agreement with the third-party provider of radiation oncology is finalised and implemented. ■ Overall, the Authority concluded that the SBD service at SVUH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.
University College Hospital Galway –satellite site Letterkenny General Hospital (UCHG and LGH)	■ The SBD service at UCHG and the satellite service at LGH had a comprehensive corporate and clinical governance structure. There was an organisational, regional and network framework that incorporated systems and processes for effective general management and clinical decision making in both sites. The multidisciplinary arrangements and patient management pathways in place ensured successful integration of services between the parent and satellite SBD services. ■ However, the service at UCHG had several committees in place which collectively oversaw the governance arrangements for SBD services. The interface between these committees was unclear. The Authority identified the need to develop a more integrated governance structure for the service to assure itself that it was meeting the Standards. ■ Overall, the Authority concluded that UCHG and the satellite symptomatic breast disease service at LGH had most of the necessary governance arrangements in place. The Authority has made recommendations on the remaining areas to be addressed.

Waterford Regional Hospital (WRH)	■ The SBD service at WRH had recently re-aligned its governance structure. This, in tandem with the development of the role of the Lead Clinician, requires a period of adjustment before a conclusion can be reached in relation to the effective integration and efficacy of these structures. ■ The SBD service must ensure the continuing sustainability of symptomatic breast disease services in order to effectively and efficiently manage the needs of its patients. ■ Full-time locum radiologist holiday arrangements should be finalised while the permanent appointment of a consultant radiologist and consultant breast surgeon was ongoing. ■ The Authority concluded that the corporate governance and clinical reporting arrangements would require a period of adjustment, with ongoing evaluation to ensure the sustainability, before a judgment on their effectiveness could be made and will need to be re-assessed by the Authority. ■ The Authority concluded that the integrated governance arrangements for SBD service at WRH will need to be re-assessed by the Authority.

4.2 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 designated 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 multidisciplinary team (MDT) meeting may be modified due to patient choice and circumstances.

Multidisciplinary approach to managing patients with breast cancer

Healthcare, by its very nature, can never be error-free and even in the best centres world-wide, errors occur. A multidisciplinary approach, including triple assessments, cannot eradicate error. However, it does reduce the likelihood of errors going undetected. The absence of effective multidisciplinary review, and triple assessment, was cited as a significant contributory factor into why diagnostic errors at the heart of previous misdiagnosis cases were not identified, leading to significant delay in the diagnosis and commencement of treatment for patients[2-4, 9-10].

The multidisciplinary management of symptomatic breast disease should involve a team of healthcare professionals with specific expertise and experience of managing SBD care. All potential breast cancer patients should be assessed, diagnosed and have their care pathway managed by such a team. This should be followed by a multidisciplinary review of these findings. This is recognised as best practice for the safest, most accurate diagnosis and treatment of the disease.

The Standards set out the core team that should be in place in the SBD service in the designated centres and that the multidisciplinary team (MDT) should meet at weekly.

4.2.1 Core team within the designated centres

The Standards specify that the 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.

The NCCP, and designated centres, inherited a situation where staffing levels in existing centres, including the eight designated centres, were based solely on historical development that had not progressed as part of a coordinated development, but was dependent on variable local success, or otherwise in securing resources. The disparity between centres was not necessarily related to workloads.

To address this issue, the NCCP developed a 'benchmarking tool', using one of the established Dublin centres as a template, to allow it to decide whether additional staff were needed in a given centre and of what kind of staff, for example, consultant surgeons, radiologists or pathologists. Having used this benchmarking tool, the NCCP began a process of transferring resources from centres ceasing to provide SBD services, or allocating new resources, to begin to address these historic disparities. Table 3 shows the posts allocated by the NCCP in this way.

Table 3: National Cancer Control Programme – posts allocated to the breast cancer services in 2009*

Post	Whole time equivalents
Consultant radiologist	6.5
Consultant anaesthetist	1.5
Consultant surgeon	2.5
Consultant medical oncologist	0.5
Consultant histopathologist	1
Anaesthetic registrar	1
Radiographers	10.5
Staff nurses	9
Clinical Nurse Manager 2	3
Clinical Nurse Manager 3	4
Clerical officer	9
Grade V (data manager)	4.5
Grade VI (breast unit manager)	1

* *Source: NCCP 2009*

Over the period of its Review Programme, the Authority has noted that this investment in staffing has had a significant affect on the ability of some centres to implement the Standards.

At times, the process has been slower than would be ideal. In the early stages, the slowness of appointment processes (commented on previously by the Authority[3]) hampered progress in recruitment, although in the last year these processes have become more streamlined. In addition, some areas of the country have found it more difficult to recruit than others. The consequence of these factors is that many centres have only just recruited staff into key posts. Therefore, a period of adjustment and development is needed before teams and individuals can be regarded as functioning at optimum levels.

The process of getting core resources into place has been a considerable achievement by the NCCP and the designated centres. However, creating successful clinical services does not happen overnight and getting staff physically into post is only the first step. The need for team and individual development during this period is very important in order to ensure that the centres evolve as fully functioning units with the appropriate leadership, governance, management, team working, communication and behaviours that are required for high quality, safe and reliable patient care.

Recommendation 6

The HSE should work with designated centres, to assess the organisational development needs of the newly established designated centres and introduce focused support as required.

Additionally, the Authority found examples where, although the core team were in place, single practitioners were responsible for a core dimension of the service. Consequently, if these individuals were absent due to leave or illness, service continuity and the meeting of Standards access targets could be at risk. This is not a sustainable situation. The HSE should keep this area under review and put arrangements in place to ensure that the resource base of the designated centres, and the ability to transfer the care of patients between centres with their agreement, allows the sustainability and continuity of the service.

Recommendation 7

The HSE together with the designated centres should carry out a risk assessment to identify areas in the designated centres where service continuity and sustainability, or the ongoing meeting of Standards, could be threatened by the absence of key staff and ensure that contingency plans are in place as needed.

4.2.2 Overall position in the eight designated centres at the end of 2009

The most significant progress since 2007 has been the transition from variable application of a multidisciplinary approach to patient care, to all eight centres now having clear arrangements in place for multidisciplinary care of all patients. This has been facilitated by the creation of the eight centres, investment in additional staff and the standardisation of the triple assessment process.

All eight designated centres had effective arrangements in place for triple assessment and each used a multidisciplinary approach to drive decision making and treatment planning through multidisciplinary team meetings

The Authority found that standard operating procedures were being implemented that require, for example, records to be kept of staff attendance at the MDT meeting. The process of standardising the recording of decisions taken at the MDT meeting is still underway and centres need to ensure that decisions are recorded clearly. All centres need to carry out regular audit of patient records to ensure that all clinical decisions are consistently recorded. Given the importance of this aspect of the SBD service, the HSE together with the designated centres should formally evaluate the application of these standard operating procedures on a phased basis to ensure that they are fully implemented (see Recommendation 2).

While there remain opportunities to enhance the multidisciplinary aspects of patient care through standardised processes and more interaction of clinicians between centres, the Authority is encouraged to have found this key element of care to be in place for all patients referred to the SBD service.

The findings under the Multidisciplinary Approach theme for each of the designated centres are summarised in the following table:

2. Multidisciplinary Approach (Essential Elements)

2(a) The symptomatic breast disease (SBD) service must have a core team (as per Standard 1.3)

2(b) The service 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 and pathology sampling.

2(c) The multidisciplinary team meeting must be held at least weekly. Patients discussed at MDT should include those in Standard 4.7. All members of the core team must attend MDT meetings. Decisions at MDT must be communicated to the patient and referring doctor.

Multidisciplinary Approach Conclusions:	
Beaumont Hospital (BH)	■ The service was actively committed to delivering triple assessment through a multidisciplinary approach. The service had comprehensive operational policies and evaluation processes to ensure that the multidisciplinary team was involved in all clinical decision making and treatment planning. ■ Overall, the Authority concluded that the SBD service at BH had the necessary multidisciplinary arrangements in place for the delivery of safe care.
Cork University Hospital (CUH)	■ 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. ■ In light of the evolving nature of the SBD service at CUH, including the opening of their new cancer centre, the integration of transferring services and staff from the SIVUH and the introduction of a new data system, the service must review and monitor MDT meeting arrangements to ensure that they continue to support the delivery of a high quality safe patient service. ■ There is a need to put in place arrangements to ensure timely transfer of patient information from Kerry General Hospital. ■ 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. However, this will need to be reassessed following the transfer of services from SIVUH.

Mater Misericordiae University Hospital (MMUH)	▪ The service was actively committed to delivering triple assessment through a multidisciplinary approach. The service had the necessary operational policies in place to ensure that the multidisciplinary team was involved in all clinical decision making and treatment planning. Wherever possible, patients were central to the MDT process and encouraged to participate in decisions about their treatment options and care. ▪ Overall, the Authority concluded that the SBD service at the MMUH had most of the necessary multidisciplinary arrangements in place for the delivery of safe care. The Authority has made recommendations on the remaining areas to be addressed.
Mid-Western Regional Hospital Limerick (MWRHL)	▪ The service was actively committed to delivering triple assessment through a multidisciplinary approach. Clinician decision making and treatment planning is supported by policies and procedures, and 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 the MWRHL had the necessary multidisciplinary arrangements in place for the delivery of safe care.
St James's Hospital (SJH)	▪ The service is actively committed to delivering triple assessment through a multidisciplinary approach and had comprehensive operational policies and evaluation processes to ensure that the multidisciplinary team was involved in all clinical decision making and treatment planning. Wherever possible, patients were central to the MDT process and were encouraged to participate in decisions about their treatment options and care. ▪ Overall, the Authority concluded that the SBD service at SJH had the necessary multidisciplinary arrangements in place for the delivery of safe care.

St Vincent's University Hospital (SVUH)	▪ The service was actively committed to delivering triple assessment through a multidisciplinary approach and 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 were 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 SVUH had the necessary multidisciplinary arrangements in place for the delivery of safe care.
University College Hospital Galway –satellite site Letterkenny General Hospital (UCHG and LGH)	▪ The service was actively committed to delivering triple assessment through a multidisciplinary approach. It had the necessary operational policies to ensure that the multidisciplinary team is involved in all clinical decision making and treatment planning. Wherever possible, patients were central to this process and encouraged to participate in decisions about their treatment options and care. ▪ The SBD service at UCHG, the satellite service at LGH and the review service at Mayo General Hospital, had communication processes in place to ensure effective participation in a multi-site multidisciplinary meeting. ▪ Clinician decision making and treatment planning was supported by policies and procedures. ▪ Overall, the Authority concluded that the SBD service had most of the necessary multidisciplinary arrangements in place for the delivery of safe care. The Authority has made recommendations on the remaining areas to be addressed.
Waterford Regional Hospital (WRH)	▪ The service was actively committed to delivering triple assessment through a multidisciplinary approach and had the necessary operational policies and evaluation processes to ensure that the multidisciplinary team is involved in all clinical decision making and treatment planning. Wherever possible, patients were 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 WRH had the necessary multidisciplinary arrangements in place for the delivery of safe care. However, there were no clear locum arrangements in place for consultant radiologist cover. The Authority has made recommendations in relation to this that need to be addressed.

4.3 Skills, Education and Training

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 organisations' continuous professional development arrangements, in-service training and the monitoring mechanisms to ensure competency.

The multidisciplinary management of symptomatic breast disease should involve a team of healthcare professionals with specific expertise and experience in managing SBD care. Each member of the core team should come from various disciplines and have specific training and clinical expertise in breast cancer beyond that provided in their general professional training.

In order to keep pace with developments, and the rapid clinical application of new technologies and treatments, it is also necessary that each person involved in breast care takes part regularly in accredited courses.

4.3.1 Overall position in the eight centres at the end of 2009

All centres have the core specialist staff to deliver evidence-based SBD care.

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

The specialist breast care nurses have, as a minimum, the appropriate qualifications and experiences to be registered on the national clinical nurse specialists register. The SBD service at St Vincent's University Hospital also has in place an Advanced Nurse Practitioner in Breast Care.

In-service staff training and educational attendance records were maintained and monitored by the service and, where there were deficiencies in the in-service training programmes, the Authority has made recommendations.

As outlined in the Standards, each relevant training body should be encouraged to formulate a training programme for healthcare professionals coming in under its authority.

Recommendation 8

The HSE should work with centres, and the relevant training bodies, to develop a standardised framework for assuring the skills, education and training of staff in the centres are maintained at the necessary levels.

The findings under the Skills, Education and Training theme for each of the designated centres are summarised in the following table:

3. Skills, Education and Training (Essential Elements)

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

Skills, Education and Training Conclusions:	
Beaumont Hospital (BH)	▪ There was evidence that the service had a standard operating procedure for continuous professional development. All consultant staff have a contractual commitment to participate in teaching, research and ensuring evidence-based clinical practice. ▪ The specialist breast care nurses are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. ▪ Overall, the Authority found the SBD service at BH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise.
Cork University Hospital (CUH)	▪ 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. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.

Mater Misericordiae University Hospital (MMUH)	▪ There was evidence that the service had a number of arrangements in place to ensure that the core team has the necessary training and clinical expertise in breast cancer, and undertake continuous professional education and development on a regular basis. ▪ The specialist breast care nurses are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. ▪ Overall, the Authority found the SBD service at the MMUH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.
Mid-Western Regional Hospital Limerick (MWRHL)	▪ 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 are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. ▪ Overall, the Authority found the SBD service had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.

St James's Hospital (SJH)	▪ There was evidence that the service had a number of arrangements in place to ensure that the core team has the necessary training and clinical expertise in breast cancer, and undertake continuous professional education and development on a regular basis. ▪ The Hospital's staff recruitment and selection processes, staff induction and mentorship programme ensures controls were in place to monitor clinical competence and multidisciplinary performance. All consultant staff have a contractual commitment to participate in teaching, research and ensuring evidence-based clinical practice. ▪ The specialist breast care nurses are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. The centre should ensure that a formal policy is developed to support and monitor continuous professional development. ▪ Overall, the Authority found the SBD service had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.
St Vincent's University Hospital (SVUH)	▪ The Hospital's staff recruitment, and selection processes, staff induction and mentorship programme ensures controls are in place to monitor clinical competence and multidisciplinary performance. All consultant staff have a contractual commitment to participate in teaching, training, research and ensuring evidence-based clinical practice ▪ The SBD service has an advanced nurse practitioner, the specialist breast care nurses (SBCNs) are registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. ▪ Overall, the Authority found the SBD service had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.

University College Hospital Galway – satellite site Letterkenny General Hospital (UCHG and LGH)	▪ There was evidence that the service had a number of arrangements in place to ensure that the core team have specific training and clinical expertise in breast cancer. All consultant staff there have a contractual commitment to participate in teaching, research and ensuring evidence-based clinical practice. ▪ The Hospital's staff recruitment, and selection processes, staff induction and mentorship programme ensures controls are in place to monitor clinical competence and multidisciplinary performance. ▪ The specialist breast care nurses are registered on the national clinical nurse specialists register. ▪ The in-service training programme at UCHG included a mandatory training programme on chemotherapy administration which should be shared with the satellite service. ▪ Overall, the Authority found the SBD service at UCHG and LGH had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service at both sites should ensure that a formal policy is developed to support and monitor continuous professional development in the symptomatic breast disease service.
Waterford Regional Hospital (WRH)	▪ The Authority found the centre had a number of arrangements in place to ensure the core team had the necessary training and clinical expertise, and undertake continuous professional education and development on a regular basis. 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 specialist breast care nurses were registered on the national clinical nurse specialists register. In-service staff training and educational attendance records were maintained and monitored by the service. ▪ Overall, the Authority found the SBD service had a number of arrangements in place to ensure that the core team had the necessary training and clinical expertise. However, the service should ensure that a formal policy is developed to support and monitor continuous professional development.

4.4 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 the optimum care environment.

Systems and processes are 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 patient's perspective.

4.4.1 Person-centred care in the designated centres in 2008

The nature of symptomatic breast disease care, with its understandable potential to encompass emotional as well as physical trauma, makes it especially important that services are designed, delivered and evaluated with the needs of service users at the centre. The multidisciplinary (and sometimes multi-site) nature of breast care creates an even greater need for care that is systematically integrated so that the patient and those treating them know at all times what is happening.

In 2008, during the self-assessment and validation phases of the national Quality Review, the majority of centres said that they had in place arrangements to respond to the needs of patients – led usually by symptomatic breast disease nurses and incorporating written information and the use of more interactive mechanisms for providing support, for example, through support groups.

The Authority had concerns regarding the absence of processes to effectively manage the move of patients from one part of the service to another. For example, from surgery to radiation oncology (radiotherapy). This was manifested at its most basic as weak mechanisms for the transfer of patient information or data between clinicians, especially when they were practising within different institutions. A picture emerged from some centres of the patient themselves acting as the main integrating mechanism between different stages in the care pathway. For example by being asked to let their surgeon know when radiotherapy had been completed. This is unacceptable.

This issue, which echoed concerns identified in a previous Authority investigation[2-3], was highlighted to the designated centres and the NCCP as needing to be addressed following the Authority's validation visits in 2008.

More generally, over the last two and a half years, and possibly in response to the succession of public concerns about the quality and safety of symptomatic breast disease services, the Authority received regular communication from patients and their relatives expressing dissatisfaction with the standard of care.

4.4.2 Overall position in the designated centres at the end of 2009

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

The group reported their personal experiences, which may differ from those of other service users. However, in all centres, the overwhelming message reported by the participants in these discussions was very high levels of satisfaction and confidence in the care they had experienced or were experiencing.

Regarding aspects of their care for which choices were necessary, the patient group reported that they were satisfied overall with the information they received and the support given to make decisions about their care and treatment. These messages were generally supported by the Authority's own observations in its assessment of the centres.

These messages were generally supported by the Authority's own observations in its assessment of the centres.

However, the message did come from some patients that their experience of aspects of their care, delivered by departments or institutions outside the designated centre, tended to be more variable. The Authority separately identified that the flow of some data and information between institutions needs strengthening and that even within some centres, not all patient information is accessible in one place. Given that information is a key enabler of safe person-centred care, ensuring that all the necessary information is available to patients and the clinicians involved in their care is crucial. Therefore, centres must put measures in place to ensure that all relevant information about a patient is available irrespective of where their care is provided.

Leading on from this, it is not always clear in all centres at any given time, which clinician is responsible for the care of patients. Clearly, with multiple disciplines involved, different clinicians will be participating in patients' care, but ideally there should be a single clinician who takes overall responsibility for the patient. In other jurisdictions, this is achieved through the concept of the Most Responsible Clinician and in some countries this role has statutory status. This concept was also identified and recommended in the Report of the Commission on Patient Safety and Quality Assurance[17].

The benefit of this approach is that there is always one clinician keeping an overview of a patient's care and, whilst recognising that there are complexities in introducing such a concept, the Authority believes the gains in patient care and efficiency could be considerable and this approach should be explored by the HSE as part of its wider clinical governance framework.

Recommendation 9

The HSE, with the designated centres, should establish effective ways of enhancing the continuity of patient care. This should include the introduction of the "Most Responsible Clinician" for patients within the SBD service. This should also be inclusive of aspects of care provided by third-party providers.

Recommendation 10

The HSE should require all centres to have in place robust arrangements for ensuring that all information relevant to patients' care is accessible as needed by patients and clinicians, irrespective of where the care is provided or the information is generated.

The findings under the Person-centred Care theme for each of the designated centres are summarised in the following table:

4. Person-centred Care (Essential Elements)

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.

4(b) The service must have a dedicated facility where the administrative, clinical and diagnostic areas are in close proximity. The service must be equipped with basic mammography, stereotactic mammography equipment and an ultrasound machine.

Person-centred Care Conclusions:	
Beaumont Hospital (BH)	▪ The service has written information available about breast disease, cancer and local support groups. The specialist breast care nurses had directed an amount of effort to patient discharge planning and management and had conducted information sessions for public health nurse and primary care staff. ▪ Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment. ▪ The service should reassess the adequacy of patient facilities in the oncology day ward. ▪ The Authority concluded that the SBD service at BH had most of the necessary arrangements and facilities in place to deliver person-centred care. The Authority has made recommendations in the remaining areas that need to be addressed.

Cork University Hospital (CUH)	■ The centre has written information about breast disease, cancer and local support groups. Patients in the patient discussion group reported satisfaction with the level of information to allow them to consider options for treatment. ■ The Authority concluded that the SBD service at CUH, at the time of Review, had the necessary arrangements and facilities in place to deliver person-centred care. ■ However, at the time of Review, the cancer centre, operating theatre and SBD-specific day inpatient facility had not been fully commissioned to facilitate the transfer of services from SIVUH, therefore, the Authority will need to re-assess the SBD service at CUH once this transfer of services is completed.
Mater Misericordiae University Hospital (MMUH)	■ The symptomatic breast disease service has written information about breast disease, cancer and local support groups. Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment. ■ The Authority concluded that the SBD service at the MMUH had most of the necessary arrangements and facilities in place to deliver person-centred care. The Authority has made a recommendation on one area to be addressed.
Mid-Western Regional Hospital Limerick (MWRHL)	■ The SBD service at MWRHL had the essential facilities and arrangements for delivering person-centred care. The symptomatic breast disease service has written information about breast disease, cancer and local support groups. Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment. ■ The Authority concluded that the SBD service at the MWRHL had the necessary arrangements and facilities in place to deliver person-centred care.

St James's Hospital (SJH)	■ SJH had the essential arrangements in place to deliver person-centred care. The service has written information available about breast disease, cancer and local support groups. The specialist breast care nurses had directed an amount of effort to patient discharge planning and management and had conducted information sessions for public health nurses and primary care staff. ■ Wherever possible, patients were central to this process and encouraged to participate in decisions about their treatment options and care. ■ The discussion group with patients supported these findings. The patients in the group reported satisfaction with the level of information available to allow them to consider options for treatment. ■ However, the group reported the need to ensure all patients and their families receive sufficient support on discharge particularly in relation to wound drainage management. ■ The Authority concluded that the SBD service at SJH had the necessary arrangements and facilities in place to deliver person-centred care.
St Vincent's University Hospital (SVUH)	■ At the time of the Review, SVUH had the essential facilities and arrangements in place for delivering person-centred care. The service has written information about breast disease, cancer and local support groups. ■ Patients in the discussion group reported satisfaction with the level of information available to allow them to consider options for treatment. ■ Wherever possible, patients are central to this process and encouraged to participate in decisions about their treatment options and care. ■ The Authority concluded that the SBD service at SVUH had the necessary arrangements and facilities in place to deliver person-centred care.

University College Hospital Galway – satellite site Letterkenny General Hospital (UCHG and LGH)	■ The symptomatic breast disease service, at both sites, has written information about breast disease, cancer and local support groups. Patients that participated in both discussion groups reported satisfaction with the level of information available to allow them to consider options for treatment. ■ UCHG should reassess the adequacy of patient facilities in the oncology day ward. ■ The transport arrangements requirements for patients with shared care between UCHG and LGH should be assessed. ■ The Authority concluded that the SBD service at UCHG and the satellite SBD service at LGH had most of the necessary arrangements in place to deliver person-centred care. The Authority has made recommendations in the remaining areas to be addressed.
Waterford Regional Hospital (WRH)	■ WRH had the essential facilities for delivering person-centred care. The symptomatic breast disease service has written information about breast disease, cancer and local support groups. Patients reported satisfaction with the level of information available to allow them to consider options for treatment. ■ The Authority concluded that the SBD service at WRH had the necessary arrangements and facilities in place to deliver person-centred care.

4.5 Data Management

Data management refers to the collection and provision of high quality, accurate, valid and timely data which provides, when analysed and validated, 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.

As described in the Standards and internationally, the capture and use of data to inform improvements in quality and safety, is fundamental to the modern delivery of reliable clinical care.

Until 2009, very few centres were collecting data on a routine basis or appreciated the need to assure themselves, their patients and the public that quality and safety standards were being met. Some centres had developed their capability in this area to a significant degree, whereas others had almost no infrastructure or resources in place to capture meaningful data. The importance of addressing this situation arose at least in part from the self-assessment process in 2008, which highlighted the lack of any coherent approach to quality monitoring and specifically the significant variation in data management capacity between the centres.

Since 2008, the NCCP has set about trying to address this position through investment in IT and in data management staff. In addition, the overall increase in numbers of clinicians in some centres has allowed them to allocate time to collecting and more importantly analysing and responding to data about the quality and safety of care.

As alluded to previously, before 2009 there was no standardisation of what data SBD services should be collecting to monitor quality and safety of care.

4.5.1 Overall position in the designated centres at the end of 2009

The Authority reviewed the data management processes and systems and validated in detail a sample of patient data in the eight centres. It concluded that, while there still remains work to be done, significant progress has been made compared to 2008.

The Authority's main findings were that:

- data collection and management is now happening in all centres which is an important step forward
- some centres have well established, mature systems in place
- other centres had only appointed data managers in mid 2009 and were still specifying data management systems in late 2009
- in the transitioning centres, the migration of data from amalgamating services was still to happen
- in most centres there need to be more formal mechanisms for validating data.

As with governance systems, it is too early to say for some centres how robust and sustainable their data management systems are and they need ongoing support and evaluation to ensure that the patient benefit of reliable, comparable data from all centres is realised.

In summary, there was a wide spectrum of data management capability and utilisation. The Authority found that, compared to 2008, many clinicians have embraced the concept of using data to monitor and improve clinical care. However, some clinicians are not used to the routine monitoring of their practice and tend to regard the process of capturing data as extraneous to clinical care, rather than an intrinsic aspect of providing safe, high quality and reliable care for patients. Clinicians would benefit from focused support in the use of data in their practice to support provision of demonstrably effective clinical care.

Recommendation 11

The HSE should identify those designated centres where data management capability, and the use of data, are still in development and instigate ongoing evaluation and, where needed, provide focused support for those designated centres. This should include targeted support and development for SBD clinicians in the capture and use of data as an intrinsic facet of clinically effective care.

The findings under the Data Management theme for each of the designated centres are summarised in the following table:

5. Data Management (Essential Elements)

5(a) Each service shall have an information and data system that can be integrated with the other in-house systems

5(b) Each service must record basic data in relation to access, diagnosis, pathology, primary treatment and clinical outcomes.

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

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.

Data Management Conclusions	
Beaumont Hospital (BH)	■ The Authority found that at the time of the Review, BH was recording the necessary data in relation to access, diagnosis, pathology, primary treatment and clinical outcomes. ■ The centre demonstrated how it used information through the monthly Audit / Quality and Risk Group where performance indicator dashboard reports were monitored. ■ The SBD service had a detailed data set and dictionary using the Patient Analysis and Tracking System (PATS) to collate patient data. The required corporate policies and user access controls were in place. A corporate data validation process was in place for checking the accuracy, auditing and validation of data. ■ The Authority concluded that the SBD service at Beaumont Hospital had the necessary data management arrangements in place. However, the service was not routinely collecting data pertaining to the timely provision of patient waiting times for public radiation oncology service provided by the third-party provider.

Cork University Hospital (CUH)	■ At the time of review, the centre was using an Excel spreadsheet to collate basic data on access, diagnosis, pathology, primary treatment and clinical outcomes. The Patient Analysis and Tracking System was in the final stages of being configured with go-live planned for November 2009. A robust data validation process (which includes patient healthcare records) for checking the accuracy, auditing and validation of data should be developed to support the evolving symptomatic breast disease service at CUH and to ensure the necessary controls and processes are in place. ■ 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. The Authority will re-assess this following the reconfiguration and testing of the Patient Analysis and Tracking System.
Mater Misericordiae University Hospital (MMUH)	■ The SBD service had a comprehensive integrated information management system with a well established Patient Analysis and Tracking System which facilitated data collection at all critical points in the patient pathway. ■ The centre had a data set and dictionary and a data capture policy in place which included an overview of the data validation process in place. The centre should further develop its data validation policy, increase the frequency of a standardised data validation process that includes the patient healthcare record and necessary performance information to ensure the timely delivery of a safe quality patient service, increase the frequency of data validation, and ensure the necessary formal monitoring arrangements are in place. The Breast Health Centre produces an annual report which includes all relevant patient demographic, access and clinical information. ■ The Authority concluded that the SBD service at the MMUH had most of the necessary data management arrangements in place. However, the service had no data pertaining to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider. ■ The Authority concluded that the SBD service at the MMUH had most of the necessary data management arrangements in place. However, the Authority has made recommendations on the remaining areas to be addressed.

Mid-Western Regional Hospital Limerick (MWRHL)	■ At the time of the Review, the symptomatic breast disease service had no formal policies and data validation controls in place. The service did have a data set and dictionary for the access data base. The service in conjunction with the symptomatic breast disease centres at CUH and WRH was developing the Patient Analysis and Tracking System. This will facilitate data collection at all critical points in the patient pathway, with a go-live date being planned for December 2009. ■ The service should ensure that the appropriate data validation and control processes are in place. ■ The Authority concluded that the symptomatic breast disease service at MWRHL had most of the necessary data management arrangements in place. However, at the time of the Review the Patient Analysis and Tracking System was not fully operational, data validation processes were not in place and audit processes were underdeveloped. This will require re-assessment by the Authority.
St James's Hospital (SJH)	■ The SBD service had a detailed data set and dictionary using the Patient Analysis and Tracking System (PATS) to collate patient data. The required corporate policies and user access controls were in place. A corporate data validation process was in place for checking the accuracy, auditing and validating of data. However, at the time of Review, no evidence was available to the Authority to confirm that there was an SBD specific systematic data validation arrangement in place. ■ The service demonstrated how it used this information through the monthly Breast Care Quality Review and Improvement Group to monitor and improve the service and quality of patient care. ■ The service had no data pertaining to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider. ■ The Authority concluded that the SBD service at SJH had most of the necessary data management arrangements in place. However, the service had no data pertaining to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider.

St Vincent's University Hospital (SVUH)	■ The SBD service had a data set and data dictionary and was using the clinical information system to collate patient data. The required corporate policies and user access controls were in place. A data validation process was in place for checking accuracy, auditing and validating data. ■ The centre demonstrated how they used information through the monthly SBD Quality Improvement Group. ■ The Authority concluded that the SBD service at SVUH had most of the necessary data management arrangements in place. However, the service had no data pertaining to the timely provision of patient waiting times for public radiation oncology services provided by the third-party provider.
University College Hospital Galway –satellite site Letterkenny General Hospital (UCHG and LGH)	■ The service at UCHG was incrementally configuring and using the Patient Analysis and Tracking System (PATS) and planned to be fully live by December 2009. This system, once fully configured, will be set up at the satellite symptomatic breast disease centre at LGH. The PATS system in LGH should be configured to include the collection of the necessary medical and radiation oncology performance data to ensure compliance with the National Quality Assurance Standards. ■ UCHG and LGH both require a corporate policy and data validation process to be developed. ■ The Authority concluded that the SBD service at UCHG had most of the necessary data management arrangements in place. ■ The Authority concluded that the SBD service at LGH requires the configuration and introduction of the PATS system to ensure the necessary data management arrangements are in place.

Waterford Regional Hospital (WRH)	■ At the time of the Review, the SBD service was developing the Patient Analysis and Tracking System (PATS) which facilitates data collection at all critical points in the patient pathway. This was happening in conjunction with the SBD service at CUH and the Mid-Western Regional Hospital Limerick. The team reported the first phase of the system was introduced in September 2009 and that system configuration was underway. ■ The Authority concluded that the SBD service at WRH had most of the appropriate data management arrangements in place. ■ However, at the time of the Review the Patient Analysis and Tracking Systems were not live, data validation processes were not in place and audit processes were underdeveloped. This will require re-assessment by the Authority. ■ The Authority has made recommendations in the remaining areas that need to be addressed.

4.6 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.

The Access Standards

The Standards identify a number of key stages in the care of patients with suspected or diagnosed breast cancer which should be completed within a given timeframe. For example, the time from referral of a patient to their first appointment or the time from a decision to carry out surgery until the surgery happens. These access targets are there to ensure that overall, patients have the key aspects of their diagnosis and treatment in a timely manner. This does not necessarily mean that the care of an individual patient would be compromised if the delivery of their care fell outside these limits when it is justified to do so, when, for example, there are good clinical or social reasons why this happens. However, incidents where performance does not meet these targets should act as a trigger for focused remedial action by the centre to bring waiting times back within the set threshold. This section explores some of the key issues identified by the Authority.

4.6.1 The use of data in the designated centres in 2008

Prior to 2009, as previously described, one of the main concerns about the centres was their lack of standardised or routine monitoring of performance against the Standards and this included the access targets. In addition, even where centres were monitoring waiting times, they were using different definitions of key steps in the patient pathway. For example, what was meant by "definitive diagnosis" varied between centres. These were standardised by the NCCP in 2009 in the form of key performance indicators (KPIs). The KPIs were adapted from the requirements of the Standards to allow designated centres and the NCCP to monitor performance. That these are now in place is a positive step. However, there is little historical data to track progress against these access targets prior to the establishment of these KPIs in 2009.

4.6.2 The review of activity data in the designated centres in 2009

The Authority requested the designated centres to provide the following data:

- Activity data for new patients seen for the seven-month sample period from 1 January 2009 to 1 August 2009. This data was not validated by the Authority.

(A) Activity data for patients triaged as 'Urgent'

The Standard states:

Urgent Referrals – to be seen within two weeks

A patient in one or more of the following categories shall be viewed as an urgent referral and shall be seen within two weeks:

1. Patients aged over 35 years with a discrete lump (unilateral, distinct, separate mass)
2. Patients with signs that are highly suggestive of cancer, such as:
   - Ulceration
   - Skin distortion
   - Unilateral nipple eczema
   - Recent nipple retraction or distortion
   - Discrete lumps
3. Patients whom the GP deems to have a high likelihood of breast cancer at any age
4. Patients with an acute breast abscess. Such patient require immediate referral

(Standard 2.1 / 2.8)

The NCCP adapted this standard to develop national breast cancer GP referral guidelines for urgent patients and relevant Key Performance Indicators (Appendix 6) (KPI 1a) as follows:

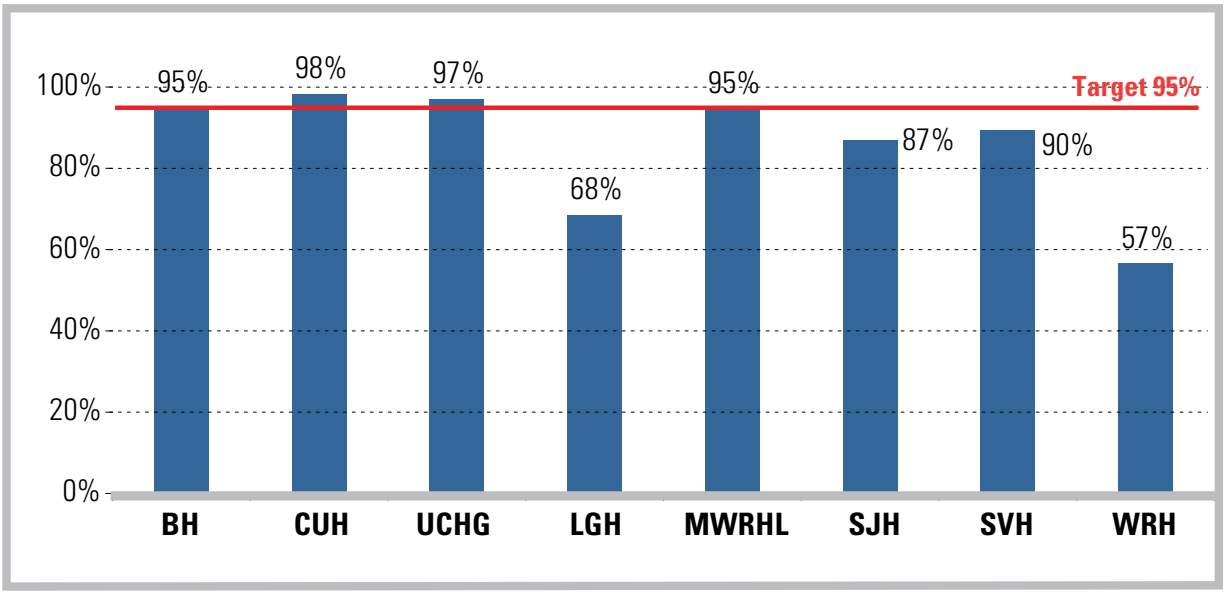
KPI 1a states:

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.

Standard 2.8 adapted (KPI 1a)

The submitted activity data demonstrated that not all centres were seeing patients triaged as urgent within the timelines required in the Standards (see Figure 4).

Figure 4. Percentage of new patients triaged as urgent who were seen within 10 days of referral to symptomatic breast disease services 1 January 2009 to 1 August 2009*



Source: activity data submitted by designated centres (excludes MMUH data as this pertains to period 1 June 2009 to 1 November 2009 due to reduced activity during refurbishment period April-May)

(B) Non-urgent and urgent activity data

The Standards state:

Early referrals – to be seen within six weeks.

A patient in one of the following categories shall be viewed as requiring early referral and shall be seen within six weeks:

1. Patients aged under 35 years with a discrete lump (unilateral, distinct, separate mass).
2. Patients with a persistently refilling or recurring cyst.
3. Patients with breast pain not responding to reassurance and simple measure, such as wearing a well supporting bra and simple analgesia.
4. Patients with nipple discharge:
   - Aged under 50 with bloodstained discharge
   - Aged over 50 with unilateral nipple discharge.

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 a specialist breast centre but where there is no clinical concern about breast cancer. These patients should be seen within 12 weeks.

(Standard 2.1)

The NCCP adapted this standard to develop national breast cancer GP referrals guidelines for non urgent patients and developed a Key Performance Indicator. This indicator (KPI 1b) does not distinguish between the early and routine categories:

KPI 1b states:

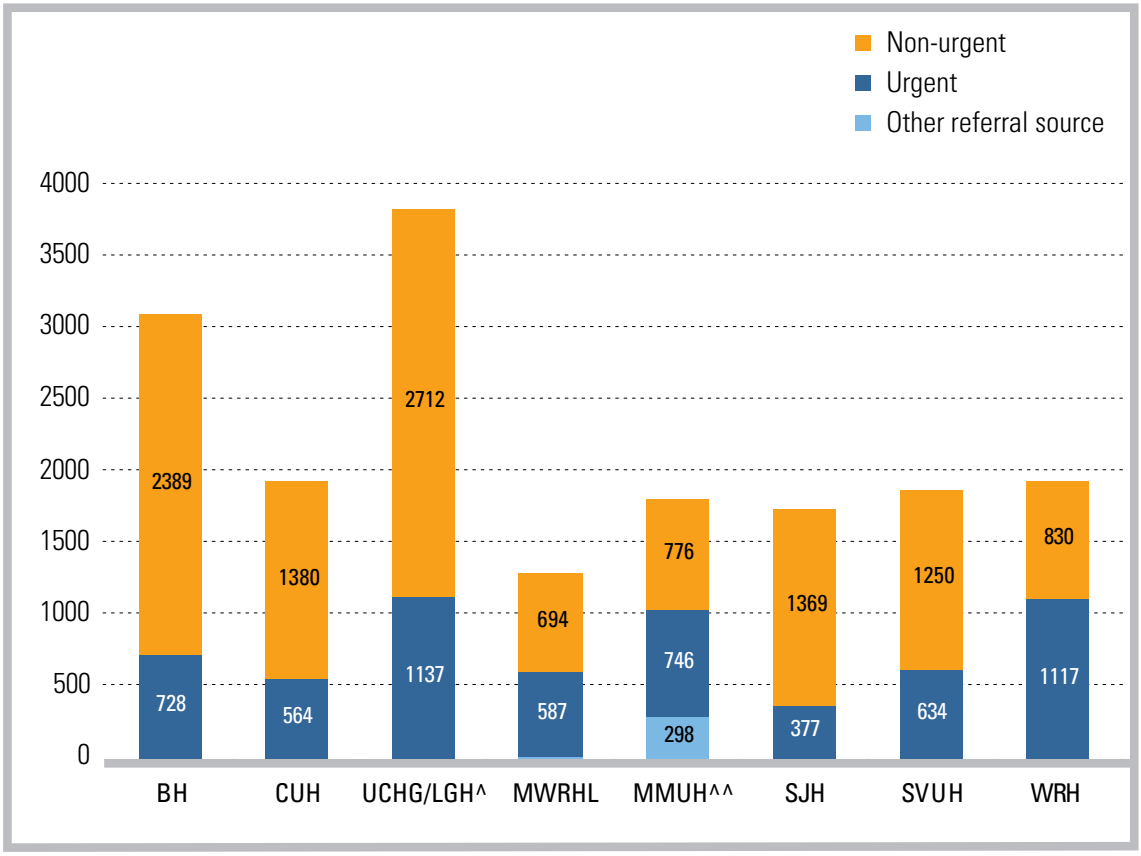
> **More than 95% of patients triaged as non-urgent by the cancer centre, shall be offered an appointment within 12 weeks (less than 84 days) of the date of receipt of a letter of referral in the cancer office.**
>
> **Standard 2.1 adapted (KPI 1b)**

The designated centres, and the NCCP, highlighted to the Authority that they had significant challenges in meeting the access Standards. The Authority analysed the submitted activity data (see Appendix 7) to clarify the origin of these challenges.

This activity data, submitted by the centres, suggests that there appear to be underlying differences between the numbers and triage categories of patients seen in the centres. The centres reported that in some cases, this was because historical waiting lists were still being addressed, but many other factors including the availability of BreastCheck screening in the area and the provision of family history clinics, may have contributed to this difference.

The activity data shows that the number of patients triaged as urgent, compared to those triaged as non-urgent, is very different. Figure 5 demonstrates this volume of "non-urgent" to "urgent" patients.

Figure 5. Number of new patients triaged as urgent or non urgent seen at Symptomatic Breast Disease Services by Centre 1 January 20009 to 1 August 2009



Overall total new patients:	17611	Total Non-urgent:	11400
Total Urgent:	5890	Total Other referral sources:	321

^ *UCHG/LGH denotes combined activity data for UCHG and satellite SBD service at LGH.*

^^ *note that MMUH data pertains to the period from 1 June 2009 to 1 November 2009 due to reduced activity during a refurbishment period of April to May. Other referral source for MMUH denotes Family History Clinic*

Other referral source for MMUH denotes Family History Clinic

A recent NCCP report [18] stated that in 2006, 23,500 patients were referred to SBD services with an average referral of 10 patients with benign diagnosis for every one patient diagnosed with cancer. This report projected that 32,000 patients would be seen in the SBD service in 2009, with an average of 15 patients referred with benign diagnosis for every one patient diagnosed with cancer. Further NCCP analysis (based on figures from five of the eight centres) suggested that this increase was driven by the referral of younger patients into the SBD service given that their data demonstrated that, almost 27% of attendees at clinics for patients triaged as "routine" were aged 34 years or younger compared to 10% of the attendees at clinics for patients triaged as "urgent".

The Authority, from the seven-month activity data submitted by the designated centres, compared the numbers of patients seen and diagnosed as having benign conditions with the numbers of patients diagnosed with primary breast cancer. This is demonstrated in Table 4 below and showed, for example, that in Beaumont Hospital, 22 patients

with benign disease were seen for every one patient seen who was diagnosed with primary breast cancer (demonstrated by a ratio of 22:1). This data for the seven-month period demonstrated that, across the centres, an average of 17 patients with benign disease were seen for every one patient diagnosed with cancer. The data shows a wide variation across the centres.

Table 4: Comparison of the numbers of patients seen and diagnosed as having benign conditions with the numbers of patients diagnosed with primary breast cancer in the eight centre.

1 January 2009 to 1 August 2009	
Hospital	**Benign: Malignant**
BH	22:1
CUH	18:1
UCHG	15:1
LGH	37:1
MWRHL	13:1
MMUH^	25:1
SJH	15:1
SVUH	14:1
WRH	15:1
All SBD centres	17:1

^ *MMUH data pertains to period 1 June 2009 to 1 November 2009 due to reduced activity during refurbishment period April-May*

The availability of screening in the local area, and the provision of family history clinics, also contributed to these referral patterns. The increasing and variable referral patterns may impact on the ability of all the centres to meet the access Standards.

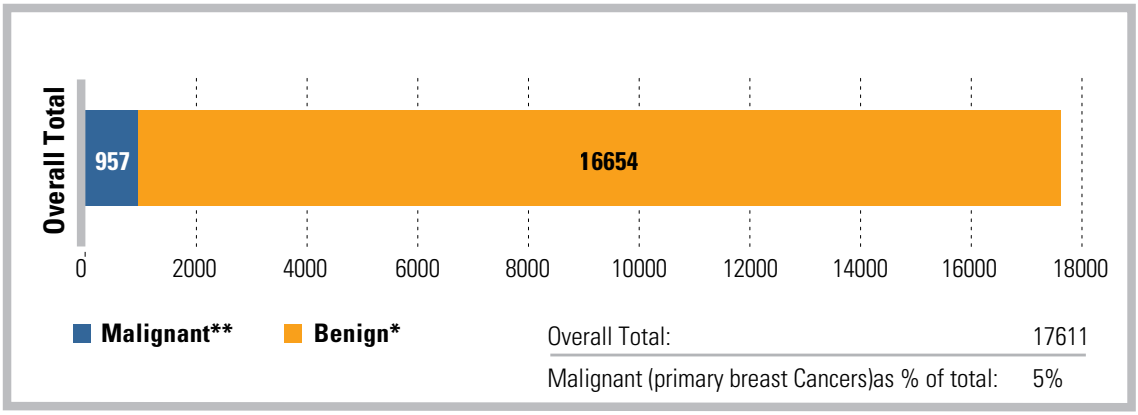
Regardless of the cause, this is an important observation because it highlights that variation in the experiences and clinical management of patients is not simply a function of the resources available in the centres. At least as influential are variations in the clinical practice and decision making of clinicians in general practice and in the centres. This is why it is so important for the NCCP to use its national overview to bring clinicians together in order to discuss, understand and address which variations arise genuinely from differing local need and which have no clear clinical basis in order to meet the Standards.

Recommendation 12

The HSE together with the designated centres should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians.

At a national level, the profile of patients being seen in the SBD service translates into large numbers of patients with benign disease being treated in a service oriented primarily to diagnosing and treating patients with malignant disease through multidisciplinary teams and triple assessment (see Figure 6)

Figure 6 Overall total number of new patients (benign/malignant) at all Symptomatic Breast Disease Services seen 1 January 2009 to 1 August 2009^



* *Benign denotes new patients who attended the SBD services and were subsequently diagnosed as non-cancerous*

** *Malignant denotes new patients who attended the SBD services and were subsequently diagnosed with primary breast cancer*

^ *note MMUH data pertains to period 1 June 2009 to 1 November 2009 due to reduced activity during refurbishment period April-May*

Resources have been focused on the higher risk urgent patients, leading to delays in the provision of care to those patients with benign disease. This is not only a source of anxiety for those patients having to wait to be seen, but is a very resource-intensive way of providing SBD services.

There needs to be a coherent response to the group of patients currently waiting longer than they should. The HSE, and its NCCP, should take the lead in helping centres, and primary care services, to develop a service response that meets the needs of this diverse population of patients, and that reflects the changed profile of patients being referred to the SBD service through fully engaging with patients, the public, providers and other key stakeholders.

Recommendation 13

The HSE should coordinate with the designated centres and the wider health system the development of a differentiated service response that reflects the profile of patients being referred to the service, whereby patients with a lower risk of breast cancer are seen in a timely way and with the necessary clinical assessment.

4.6.3 The review of access data in the designated centres in 2009

The Authority requested the designated centres to provide the following data:

- Access data [+] or patients who had been newly diagnosed with primary breast cancer and seen at the centre during the 13 consecutive week period from 1 April 2009 to 30 June 2009 provided by each centre. This data was validated on site by the Authority.

The Authority carried out an on-site validation of 25% of these patient's record in order to assure the accuracy and reliability of the submitted access and clinical effectiveness data. The Authority's validation process included a review of the:

- clinical classification coding
- diagnostic imaging and histopathology
- patient consent form
- MDT pro forma
- patient healthcare 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 sample set data submitted by all centres. In order to protect patient confidentiality, the Authority assigned a coded number to each patient record reviewed. All data validation records were referenced to this coded number, therefore, no patient-identifiable information was retained by the Authority. This process was conducted according to the Authority's statutory powers under section 8 of the Health Act 2007[19] and discussed with the Office of the Data Protection Commissioner prior to commencing the Quality Review.

Detailed performance of the centres regarding access targets for the period of the validated sample is included in the individual reports and summarised at the end of this section.

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

This section now highlights some of key issues identified through the Authority's analysis of the access data.

(A) Access data for patients triaged as urgent and subsequently diagnosed with primary breast cancer

The eight designated centres submitted access data for all patients triaged as urgent and subsequently diagnosed with breast cancer who were offered an appointment to be seen within 10 days of the date of receipt of referral for the period from 1 January to 1 August 2009. To provide a consistent comparison, the Authority analysed data relating to KPI 1a (previously described).

This access data showed that in four out of eight centres, more than 95% of patients triaged as urgent, and subsequently newly diagnosed with breast cancer, were offered an appointment to be seen within 10 working days and therefore were meeting Standard 2.8.

However, the Authority found that in late 2009, at the time of the on-site review, all centres demonstrated that they were meeting this Standard. This data is demonstrated in the table below in Table 5.

Table 5: Detailed performance of the centres regarding access targets, based on a sample of validated data submitted of patients diagnosed with invasive breast cancer between 1 April and 30 June 2009

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)			
Hospital	**Target**	**Hospital compliance**	**Additional notes**
Beaumont Hospital Dublin	>95%	72%	From September 2009, BH was meeting the Standard.
Cork University Hospital	>95%	96%	
Mater Misericordiae University Hospital, Dublin*	>95%	52%	MMUH SBDS Unit was refurbished in early 2009 and was not fully operational until June 2009. The Authority reviewed the most recent data which indicated that MMUH was meeting this Standard **since November 2009.**
Mid-Western Regional Hospital Limerick	>95%	100%	
St James's Hospital, Dublin	>95%	85%	As of May 2009, SJH was meeting this Standard.
St Vincent's University Hospital, Dublin	>95%	91%	
University College Hospital Galway	>95%	98%	
– satellite site at Letterkenny General Hospital, Donegal	>95%	100%	
Waterford Regional Hospital	>95%	90%	At the time of on-site review, WRH was meeting the Standard.

* *Mater Misericordiae Hospital data refers to time period of between June and August because of refurbishment of the centre.*

(B) Access data for patients triaged as non-urgent reported by the designated centres

The eight designated centres submitted access data for all patients triaged as non-urgent and subsequently diagnosed with breast cancer who were seen within 12 weeks of the date of receipt of referral for the period for the sample period 1 June 2009 to 30 August 2009.

There were small numbers of patients in this sample of data. Nationally, the Authority found that 89% of patients triaged as non-urgent and subsequently diagnosed with primary breast cancer were seen within 12 weeks of receipt of referral. Nevertheless, due to the potential for later diagnosis, this group of patients should be the subject of national clinical audit in order to determine whether closer monitoring through an amended KPI reflecting the Early and Routine categories described in Standard 2.1 is necessary. (see Recommendation 15).

(C) Access data for the diagnosis and treatment for all patients subsequently diagnosed with primary breast cancer during the period 1 April 2009 to 30 June 2009

The Authority also validated access data for the diagnosis and treatment Standards for patients diagnosed with invasive breast cancer during the period 1 April 2009 to 30 June 2009.

While some centres had not fully met these required Standards within the sample period, the monitoring systems that were beginning to be established in centres had identified the problem and triggered measures such as additional clinics, provision of 'ring-fenced' beds and additional staff to be put in place to improve performance in meeting the Standards.

While it is unacceptable that some patients waited longer than they should during the sample period, it is encouraging that access targets were being used to trigger remedial action in order to ensure that patients receive the timely care that they should expect and that the Standard is met. This ongoing monitoring and, where needed, corrective action needs to be maintained as a core element of managing these services.

These findings, which showed variable performance in meeting the Standards, are summarised in the following tables, Tables 6 to 8:

Table 6: Patients triaged as urgent and subsequently newly diagnosed with primary breast cancer, receive imaging on the first visit (Standard 6.14).

Hospital	Target	Hospital compliance	Additional notes
Beaumont Hospital Dublin	>90%	94%	
Cork University Hospital	>90%	85%	
Mater Misericordiae Hospital*	>90%	74%	
Mid-Western Regional Hospital Limerick	>90%	83%	.
St James's Hospital, Dublin	>90%	88%	A small number of patients had radiology prior to attending the breast clinic. In excluding these patients from the sample group the Authority revised the data submitted to it by the Hospital, which resulted in 100% of the above patient sample group receiving imaging on the first visit.
St Vincent's University Hospital, Dublin	>90%	100%	
University College Hospital Galway	>90%	100%	
Letterkenny General Hospital, Donegal (satellite site of University College Hospital Galway)	>90%	100%	
Waterford Regional Hospital	>90%	94%	

* *Mater Misericordiae Hospital data refers to time period of between June and August because of refurbishment of the centre.*

Table 7: Definitive diagnosis[†] (cancer) is achieved within two weeks of an urgently referred patient's attendance at the specialist breast centre (Standard 4.9)

Hospital	Target	Hospital compliance	Additional notes
Beaumont Hospital Dublin	>90%	98%	
Cork University Hospital	>90%	75%	Supporting narrative to this submission outlined exceptions in relation to a small number of patients who required further investigations in advance of presentation for multidisciplinary discussion.
Mater Misericordiae Hospital, Dublin	>90%	79%	The SBD team indicated that, prior to October 2009, its data management system collection point for the above Standard was not aligned to this definition. Currently, the service is in discussion with the NCCP in relation to this.
Mid-Western Regional Hospital Limerick	>90%	*	* During the on-site review, the Authority noted that for this Standard the date of definitive diagnosis at MWRHL is taken as date of core biopsy, thus the Authority was unable to determine the service's compliance with this Standard.
St James's Hospital, Dublin	>90%	*	* During the on-site review, the Authority noted that for this Standard the date of definitive diagnosis at SJH is taken as date of core biopsy, thus the Authority was unable to determine the service's compliance with this Standard.
St Vincent's University Hospital, Dublin	>90%	98%	
University College Hospital Galway	>90%	95%	
(satellite site: Letterkenny General Hospital)	>90%	100%	
Waterford Regional Hospital	>90%	100%	

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

Table 8: Patients with primary operable breast cancer, have surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnoses (NCCP KPI 5a)

Hospital	Target	Hospital compliance	Additional notes
Beaumont Hospital, Dublin	>90%	98%	
Cork University Hospital	>90%	94%	
Mater Misericordiae Hospital, Dublin	>90%	50%	The Authority noted at the time of the Review that the locum consultant surgeon did not have a formal theatre access time and the SBD service had no ring-fenced surgical inpatient beds available.
Mid-Western Regional Hospital Limerick	>90%	73%	Supporting narrative stated that a small number of patients whose care did not meet this target, for example, were due to additional investigations being required.
St James's Hospital, Dublin	>90%	85%	Supporting narrative stated that a small number of patients whose care did not meet this target, for example, were due to additional investigations being required.
St Vincent's University Hospital, Dublin	>90%	79%	At the time of the Quality Review, SVUH had put in place the necessary arrangements to meet the timelines for surgical interventions.
University College Hospital Galway (satellite site: Letterkenny General Hospital)	>90%	UCHG 93%	
	>90%	LGH 100%	
Waterford Regional Hospital	>90%	94%	

The findings under the Access theme for each of the designated centres are summarised in the following table, Table 9:

Table 9

6. Access (Essential Elements)	
6(a)	The service must ensure that all patients referred for assessment are triaged and referred appropriately.
6(b)	Patients requiring surgery, medical oncology and radiation oncology are seen and managed in a timely manner according to specified targets.

Access Conclusions:	
Beaumont Hospital (BH)	■ Activity data was collected, monitored and trend-analysed by the SBD Audit, Quality and Risk Committee. This Committee provides the necessary controls and mechanisms to effectively monitor access timelines and implement appropriate remedial actions as required, for example, increasing the number of SBD clinics to respond to increased demand. ■ The increase in referrals due to the transfer and amalgamation of services to BH during the sample time period impacted on the service's capacity to meet the Standard timelines for urgently referred patients. The service was actively negotiating with the NCCP and associate third-party provider to improve access timelines to radiation oncology. ■ At the time of the Review, BH was participating in the pilot of Healthlink in relation to electronic GP referrals directly to the SBD service. ■ The Authority concluded the SBD service at BH had most of the necessary arrangements in place to ensure timely access to care.

Cork University Hospital (CUH)	■ The service had the capacity to monitor access data. ■ In light of increasing referrals from the outreach BreastCheck screening programme in Waterford, the transfer of SBD services to CUH and the absence of inpatient ring-fenced surgical beds, the SBD service must continually monitor all access timelines for patients throughout the patient's care pathway. Further scope was also identified for trending, analysis and monitoring of referral patterns as the service evolves. ■ Although some of the selected access data submitted did not meet the accepted target, the centre submitted an explanatory note which provided the Authority further information in relation to the exception. ■ The Authority concluded that the SBD service at CUH had some of the arrangements in place to ensure timely access to care. However, this will need to re-assessed by the Authority following the transfer of services from SIVUH.
Mater Misericordiae University Hospital (MMUH)	■ At the time of the Review, the SBD service at MMUH had been fully operational since June 2009 following refurbishment. Since re-opening, the service was reviewing the backlog of the non-urgent patient waiting list which had been deferred during the refurbishment with the agreement of the NCCP. ■ The SBD service at the MMUH had the capacity to effectively manage the necessary access times for urgent and non-urgent referrals. However, outstanding areas which should be addressed by the service include consultant operating theatre access and inpatient access. ■ The Authority concluded that patient access timelines for urgent and non-urgent triaged patients must be bedded down and the necessary monitoring controls integrated within the governance structure. In addition, to provide the optimum service and to effectively use the available clinical resources, it is essential that theatre and inpatient access is reviewed.

Mid-Western Regional Hospital Limerick (MWRHL)	■ Following the appointment of core personnel, the SBD service at MWRHL had the capacity to effectively manage the appropriate access times for urgent and non-urgent referrals. This requires a period of adjustment with the appropriate monitoring controls integrated within the governance structure. ■ The Authority concluded that the SBD service at the MWRHL had some of the arrangements in place to ensure timely access to care. However, the Authority has made recommendations in the remaining areas that need to be addressed.
St James's Hospital (SJH)	■ The data submitted for the sample period confirmed the centre was marginally below the access targets as determined by the Standards and NCCP KPIs. Access data was collected and trend-analysed by the Breast Care Quality Review and Improvement Group. As was the case in March / April 2009, the service had the ability to increase the number of SBD clinics to respond to increased demand. At the sample time and for the sample set requested, the SBD service was not meeting the access targets for urgent and non-urgent patient referrals. However at the time of the Review, the service was achieving the access targets for urgent and non-urgent referrals, imaging on the first visit and admission to hospital after definitive diagnosis. ■ Diagnostic access was due to be further enhanced with the commissioning of a second mammography machine scheduled for December 2009. ■ The service did collect access and medical oncology treatment data. However, radiation oncology data remained a deficit which needed to be addressed. ■ The Authority concluded that the SBD service at SJH had most of the necessary arrangements in place to ensure timely access to care.

St Vincent's University Hospital (SVUH)	■ Access data is collected and trend analysed and reviewed by the SBD Quality Improvement Group. The Advanced Nurse Practitioner, supported by the necessary standard operating procedures, manages the triage process at SVUH. ■ At the time of the Review, the transfer of SBD services and staff to the SBD service at SVUH had been completed. Patient referrals were actively managed and the service, if required, had the capacity to provide additional clinics to meet access timelines. In tandem, the service includes an additional triage category for patients over 35 years of age requiring mammography. ■ At the time of Review, the service was achieving the Standards' access targets for early and non-urgent patients. However, access time for patients triaged as urgent and access time for inpatient surgery should be closely monitored. The Authority noted the service reported that it had been allocated ring-fenced surgical inpatient beds. ■ The centre does collect access and some on-site medical oncology treatment data. However, radiation oncology data is not collected. ■ Overall, the Authority concluded that the SBD service at SVUH had most of the necessary arrangements in place to ensure timely access to care. The Authority has made a recommendation on one remaining area to be addressed.

University College Hospital Galway **–satellite site Letterkenny General Hospital (UCHG and LGH)**	■ The SBD service at UCHG and the satellite SBD service at LGH had the capacity to monitor access data, which would be further enhanced with the completed introduction of the Patient Analysis and Tracking System (PATS). ■ Access timelines at both sites were influenced by inherited patient waiting lists. UCHG was compliant with the timelines for urgent referrals and at the time of the Review, UCHG was compliant with non-urgent access timelines. ■ LGH was compliant with the access timeline for urgent referrals and LGH informed the Authority that it had identified the need to address an existing patient list inherited by the newly appointed consultant breast surgeon in order to meet the access timelines for non-urgent referrals before the end of January 2010. The Authority was unable at the time of the Review to confirm the status of these arrangements. ■ At the time of the Review, it was unclear what the impact the transfer of services from Sligo General Hospital would have on the access timelines. ■ UCHG actively monitored and reviewed access timelines for medical and radiation oncology. However, LGH should ensure the Patient Analysis and Tracking System is configured to record medical and radiation oncology data. ■ The Authority concluded that the SBD service at UCHG had most of the necessary arrangements in place to ensure timely access to care. The Authority has made recommendations in the remaining areas to be addressed.

Waterford General Hospital (WRH)	■ In early 2009, the SBD service at WRH was challenged to meet the access timelines for urgent and non-urgent patients referred to the service and were actively looking to address the historic waiting list. ■ WRH indicated that this waiting list pertained to the large number of patients beings referred, the inadequate number of available consultant breast surgeons and radiology sessions and non-consultant hospital doctors (NCHDs) available to the SBD service. Since July 2009, the SBD service had been assigned a full-time register and senior house officer (SHO) and the consultant radiologist post has been advertised. In tandem, the SBD service had facilitated additional clinics and revised its triage process. At the time of the Review, the service was compliant with all access timelines for urgent and early appointments. However, there remained an access delay for patients referred as routine and who needed to be seen within 12 weeks of referral. ■ Overall, the Authority concluded that the SBD service at WRH had most of the necessary arrangements in place to ensure timely access to care for urgent and early referrals. However, it was not able to ensure timely access to care for patients. requiring to be seen within 12 weeks. This will need to be re-assessed by the Authority.

4.7 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.

The Standards set out a number of factors that support the delivery of clinically effective care. These include for example, the volume of patients seen with newly diagnosed breast cancer in each designated centre. They also include a series of clinical performance indicators and the use of clinical audit to monitor clinical effectiveness.

4.7.1 Volumes of patients seen with newly diagnosed breast cancer

In order to provide high quality, safe care, specialist centres should see a critical mass of patients in order to maintain the skills and expertise of its clinicians. The principle of centralisation into designated centres is partly to achieve this critical mass. As described in Section 2, the last two years has seen significant shifts in the flows of patients from over 30 centres down to eight. At the same time, the overall numbers of patients being referred into the SBD service has increased. In some cases the process of changing referral patterns is still unfolding.

The Authority requested activity and numbers of patients diagnosed with breast cancer from the centres as part of its review. These are set out in Table 10 below.

Table 10 Numbers of patients diagnosed with breast cancer seen in each centre

Hospital	Number of patients newly diagnosed with primary breast cancer (1 January 2009 to 1 August 2009)
BH	134
CUH	102
MWRHL	90
SJH	109
SVUH	125
UCHG/LGH	207
WRH	119
	Activity for 1 June 2009 to 1 November 2009*
MMUH	71

* *Note: MMUH data pertains to period 1 June 2009 to 1 November 2009 due to reduced activity during refurbishment period April-May*

This indicates that each centre was seeing a volume of above that recommended in previous reports[20].

Having now established the eight centres, the NCCP should extend and refine its monitoring of activity to include the numbers being seen by individual clinicians.

Recommendation 14

The HSE together with the designated centres should develop mechanisms for monitoring the numbers of newly diagnosed patients seen and treated by individual clinicians with a view to developing benchmarks for the relevant clinical specialties.

4.7.2 Clinical performance indicators

Each centre submitted clinical effectiveness data for all patients who were diagnosed with invasive breast cancer between 1 April to 30 June 2009. The Authority reviewed this data, relating to clinical effectiveness indicators as described in the Standards, and found that all designated centres were meeting most of the requirements as set out in the Standards. Tables 11 to 17 summarise these findings. **It should be noted that in some cases, in particular for Standards 6.1 and 7.13a, the reported compliance is based on small numbers.**

Table 11 A non-operative diagnosis is achieved in malignant disease (Standard 6.16)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>90%	100%
Cork University Hospital	>90%	98%
Mater Misericordiae Hospital, Dublin	>90%	100%
Mid-Western Regional Hospital Limerick	>90%	95%
St James's Hospital, Dublin	>90%	98%
St Vincent's University Hospital, Dublin	>90%	100%
University College Hospital Galway	>90%	98%
(satellite site: Letterkenny General Hospital)	>90%	100%
Waterford Regional Hospital	>90%	100%

Table 12. 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)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>95%	98%
Cork University Hospital	>95%	98%
Mater Misericordiae Hospital, Dublin	>95%	100%
Mid-Western Regional Hospital Limerick	>95%	91%
St James's Hospital, Dublin	>95%	95%
St Vincent's University Hospital, Dublin	>95%	97%
University College Hospital Galway* (satellite site: Letterkenny General Hospital)	>95%	UCHG 92%
	>95%	LGH 100%
Waterford Regional Hospital	>95%	100%

** The service provided a supporting narrative for this result which stated that ultrasound of the axillary nodes was not documented on a small number of patients' ultrasound reports. However, these patients did have sentinel lymph node injections.*

Table 13. Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer (Standard 6.1)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>95%	100%
Cork University Hospital*	>95%	88%
Mater Misericordiae Hospital, Dublin	>95%	98%
Mid-Western Regional Hospital Limerick	>95%	97%
St James's Hospital, Dublin	>95%	98%
St Vincent's University Hospital, Dublin	>95%	100%
University College Hospital Galway	>95%	100%
(satellite site: Letterkenny General hospital, Donegal)	>95%	100%
Waterford Regional Hospital	95%	100%

** The service noted clinical exceptions for a small number of patients in the group. In excluding these patients, 97% of the above patient sample group had pre-operative mammography with ultrasound examination.*

Table 13a. To provide important and relevant data on patients with invasive breast carcinoma (Standards 7.13A). This should be achieved in greater than 95% of cases.

Hospital	Beaumont Hospital	Cork University Hospital	Mater Misericordiae University Hospital, Dublin	Mid-Western Regional Hospital Limerick	St James's Hospital, Dublin	St Vincent's University Hospital, Dublin	University College Hospital Galway (including satellite site Letterkenny General Hospital)		Waterford Regional Hospital
Histological tumour type is recorded	100%	100%	100%	100%	100%	100%	**UCHG** 100%	**LGH** 100%	100%
Histological tumour grade is recorded	100%	100%	100%	100%	98%	100%	**UCHG** 100%	**LGH** 100%	100%
Invasive tumour size is recorded	100%	100%	100%	100%	100%	100%	**UCHG** 100%	**LGH** 100%	100%
The presence or absence of vascular invasion is recorded	100%	97%	84% *	97%	98%	100%	**UCHG** 100%	**LGH** 100%	100%
Radial margin status in wide local excision specimens is recorded	100%	100%	100%	100%	100%	100%	**UCHG** 100%	**LGH** 100%	100%
Posterior (deep) margin status is recorded	100%	100%	100%	100%	95%	100%	**UCHG** 100%	**LGH** 100%	100%

** Standards 7.13A (Mater Misericordiae University Hospital). Targets were achieved for all requested data pertaining to Standards 7.13 A with the exception of lymphovascular invasion which the service stated was recorded in 84% of cases. The Authority observed during the on-site review of patient records that a number of histopathology reports did not include a reference to the presence of lymphovascular invasion.*

Table 14. Oestrogen receptor status is recorded (Standard 7.13B)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>95%	100%
Cork University Hospital	>95%	100%
Mater Misericordiae University Hospital, Dublin	>95%	100%
Mid-Western Regional Hospital Limerick	>95%	100%
St James's Hospital, Dublin	>95%	98%
St Vincent's University Hospital, Dublin	>95%	100%
University College Hospital Galway (satellite site: Letterkenny General Hospital, Donegal)	>95%	UCHG 100%
	>95%	LGH 100%
Waterford Regional Hospital	>95%	100%

Table 15. *HER2* status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH) (Standard 7.13C)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>95%	100%
Cork University Hospital	>95%	100%
Mater Misericordiae University Hospital, Dublin	>95%	100%
Mid-Western Regional Hospital Limerick	>95%	97%
St James's Hospital, Dublin	>95%	98%
St Vincent's University Hospital, Dublin	>95%	97%
University College Hospital Galway (satellite site: Letterkenny General Hospital, Donegal)	95%	**UCHG** 100%
	>95%	**LGH** 100%
Waterford Regional Hospital	>95%	100%

Table 16. To provide appropriate data in patients with ductal carcinoma in situ (DCIS)

1. DCIS grade is recorded
2. Radial margin status in wide local excision specimens is recorded (Standard 7.14)

Hospital	Target	Hospital Compliance	Additional notes
Beaumont Hospital, Dublin	>95%	100%	
	>95%	100%	
Cork University Hospital	>95%	100%	
	>95%	100%	
Mater Misericordiae University Hospital, Dublin	>95%	100%	
	>95%	100%	
Mid-Western Regional Hospital Limerick	>95%	100%	
	>95%	100%	
St James's Hospital, Dublin	>95%		A small number of patients were newly diagnosed with DCIS. They were noted to have their DCIS grade recorded. Where the target for radial margin status was not met, this was on the grounds of clinical exceptions.
	>95%		
St Vincent's University Hospital, Dublin	>95%	100%	
	>95%	100%	
University College Hospital Galway (satellite site at Letterkenny General Hospital)	>95%	**UCHG** 100%	
	>95%	**UCHG** 100%	
	>95%	**LGH** *	* At LGH, no patients were diagnosed with DCIS during the sample period
	>95%	**LGH**	
Waterford Regional Hospital	>95%	*	* The service reported that no patients were diagnosed with DCIS during this sample period.
	>95%		

Table 17. 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)

Hospital	Target	Hospital compliance
Beaumont Hospital, Dublin	>90%	BH reported that a small number of patients were assessed as having a clinically occult lesion. All had pre-operative image-guided localisation. Standards target is achieved.
Cork University Hospital, Cork	>90%	CUH stated that a small number of patients were assessed as having a clinically occult lesion (classification S2). All had pre-operative image-guided localisation. Standards target is achieved.
Mater Misericordiae University Hospital, Dublin	>90%	
Mid-Western Regional Hospital Limerick	>90%	MWRHL reported that a small number of patients were assessed as having a clinically occult lesion (classification S2) and they had pre-operative image-guided localisation. Standards target achieved.
St James's Hospital, Dublin	>90%	SJH stated that a small number of patients were assessed as having a clinically occult lesion. The majority of these patients did not have pre-operative localisation of the lesion and supporting narrative was provided by SJH to support this finding.
St Vincent's University Hospital, Dublin	>90%	SVUH reported that a small number of patients were assessed as having a clinically occult lesion (classification S2) and all had pre-operative image-guided localisation. Standards target is achieved.
University College Hospital Galway (satellite site at Letterkenny General Hospital)	>90%	UCHG reported that a small number of patients were assessed as having a clinically occult lesion. Some of these patients had pre-operative image-guided localisation and it was not clinically appropriate for other patients. Therefore, the Standards target is achieved.
	>90%	LGH reported data in relation to patients being assessed as having a clinically occult lesion and having had pre-operative image-guided localisation. Based on this data, the Standards target is achieved.
Waterford Regional Hospital	>90%	WRH reported data in relation to patients being assessed as having a clinically occult lesion (classification S2) and having had pre-operative image-guided localisation. Based on this data, the standards target is achieved.

4.7.3 Clinical audit

Clinical audit constitutes the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides. It should be viewed as an essential and integral component of professional practice which will contribute to improved patient outcomes.

Clinical audit must be designed to measure and improve the quality of patient care, audit measures of outcome, for example, patient survival and their quality of life and compare these within and between centres and patient groups.

The Standards describe clinical audit as being essential for effective clinical practice and that it should be the principal method used to monitor clinical effectiveness.

4.7.3.1 Overall position in the designated centres at the end of 2009

All eight centres had some clinical audit arrangements in place. SBD patient access data was analysed and used as a part of performance monitoring. In some centres, patient mortality and morbidity information was reviewed within the overall corporate surgical services.

Some centres had more advanced and corporately integrated processes for SBD-specific clinical audit in place.

The Review found no evidence that any patient outcome information, generated through clinical audit, was being shared between the designated centres to facilitate comparisons in order to drive improvements nationally.

The incidence of a delayed diagnosis of a patient with breast cancer, although a rare occurrence, will unfortunately occur in the best centres in the world. When this happens, it is important that it is detected early and the patient is treated appropriately and promptly. An analysis of how it has happened, in order to minimise the likelihood of it happening again, is essential in any service. There was no evidence of a nationally agreed definition of delayed diagnosis or a consistent approach, across the eight centres for clinicians, to audit and report these clinical incidents.

All centres now have the clinical teams, a nominated lead clinician and the appropriate information management systems in place. It is essential that clinical audit is now further developed to ensure that clinicians collect the clinical data, compare it with nationally agreed and evidence-based clinical measures and make the necessary changes when these clinical measures are not met. Risk-adjusted and clinician-validated, clinical audit data should be published to facilitate comparison, across the eight designated centres, of outcomes for patients with breast cancer. This is essential for patient and public confidence in the quality of clinical care.

There needs to be a nationally agreed definition of delayed diagnosis for patients and a consistent approach across the eight centres for clinicians to report these incidents, including discussion with patients. These will allow the centres to develop improvement strategies, to reduce the risk of these rare incidents which have profound consequences on patients, and to put in place processes and behaviours to openly and effectively communicate with patients and their families.

Recommendation 15

The HSE should develop, with the designated centres, a national clinical audit programme for SBD services that includes as a minimum: patients triaged as non-urgent and subsequently diagnosed with breast cancer, delayed diagnoses, longer term clinical outcome and survival rates. The national key performance indicator set should be reviewed regularly based on the outcomes of these audits.

Clinical audit arrangements must be put in place that focus on patient outcome measurements in order to allow the ongoing comparison of quality, clinical improvement and learning within and between the eight designated centres.

Recommendation 16

The HSE together with the designated centres should put in place arrangements to begin publicly reporting performance against the NCCP Key Performance Indicators during 2010

The findings for individual designated centres for the Clinical Effectiveness theme are summarised in the following table, Table 18.

Table 18.

7. Clinical Effectiveness (Essential Elements)	
7(a) The service must have the facilities to treat more than 150 newly diagnosed patients with primary breast cancer per year. The service 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. 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.	
Beaumont Hospital (BH)	▪ The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 57 patients newly diagnosed with primary breast cancer were seen at the SBD service at BH. ▪ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at BH had the necessary arrangements in place to demonstrate clinical effectiveness.
Cork University Hospital (CUH)	▪ The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 45 patients newly diagnosed with primary breast cancer were seen at the SBD service at CUH. ▪ The Authority found that, in general, the service demonstrated compliance with the selected clinical standards and where there was a variance, this was explained on grounds of clinical exception. There is a need to incorporate specific symptomatic breast disease clinical audit activities within the centre's clinical governance structure. ▪ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at CUH had most of the necessary arrangements in place to demonstrate clinical effectiveness. However, the Authority has made recommendations in the remaining areas that need to be addressed.

Mater Misericordiae University Hospital (MMUH)	■ The Authority found that for the 13-week sample period from 1 June 2009 to 30 August 2009, a total of 44 patients newly diagnosed with primary breast cancer were seen at the SBD service at MMUH. ■ The Authority concluded that for the 13-week sample period from 1 June 2009 to 30 August 2009, the SBD service at MMUH had most of the necessary arrangements in place to demonstrate clinical effectiveness. However, a number of histopathology reports reviewed by the Authority did not include a reference to the presence of lymphovascular invasion. The Authority has made recommendations on the remaining areas to be addressed.
Mid-Western Regional Hospital Limerick (MWRHL)	■ The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 46 patients newly diagnosed with primary breast cancer were seen at the service at MWRHL. ■ The service demonstrated compliance with most of the selected Standards. However, clinical audit specific to the symptomatic breast disease was in an early stage of development. ■ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at MWRHL had most of the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need to be addressed.

St James's Hospital (SJH)	■ The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 60 patients newly diagnosed with primary breast cancer were seen at the SBD service at SJH. ■ In general, the service demonstrated compliance with the selected clinical Standards and where there was a variance, this was explained on grounds of clinical exception. However, clinical audit specific to the symptomatic breast disease was underdeveloped. ■ The Authority found that the service had some SBD-specific clinical audit systems in place. However, these required further development and integration within the SBD governance structures. ■ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at SJH had most of the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need to be addressed.
St Vincent's University Hospital (SVUH)	■ The Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 51 patients newly diagnosed with primary breast cancer were seen at the SBD service at SVUH. ■ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at SVUH had the necessary arrangements in place to demonstrate clinical effectiveness.

University College Hospital Galway – satellite site Letterkenny General Hospital (UCHG and LGH)	■ For UCHG, the Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 72 patients newly diagnosed with primary breast cancer were seen at the SBD service at UCHG. ■ For LGH, the Authority found that for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 11 patients newly diagnosed with primary breast cancer were seen at the SBD service at LGH ■ The service at UCHG demonstrated compliance with the selected Standards and where there was a variance, an explanatory note was provided by the service. ■ The service at LGH demonstrated compliance with the selected clinical Standards. However, clinical audit specific to the symptomatic breast disease in both sites was underdeveloped. ■ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at UCHG and satellite site at LGH had most the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need to be addressed.
Waterford Regional Hospital (WRH)	■ The Authority found that, for the 13-week sample period from 1 April 2009 to 30 June 2009, a total of 42 patients newly diagnosed with primary breast cancer were seen at the SBD service at WRH. ■ Clinical audit specific to SBD services was at an early stage of development. ■ The Authority concluded that for the 13-week sample period from 1 April 2009 to 30 June 2009, the SBD service at WRH had most of the necessary arrangements in place to demonstrate clinical effectiveness. The Authority has made recommendations in the remaining areas that need to be addressed.

5 Conclusions

In 2007, the National Cancer Control Programme was established in order to provide the necessary governance and leadership to develop and drive the framework for the delivery of cancer services. The aim of this programme is to organise, manage and deliver a national cancer control service through four regional networks. The role of the networks will be to create essential relationships between the individual cancer centres and integrate them fully with all aspects of patient care.

In autumn 2007, the Authority announced that it would carry out a national Quality Review of SBD services which has taken place over a two and a half year period. This report sets out the Authority's main findings over that period and, in particular, the position at the end of 2009 when the Standards were expected to be implemented fully. This section sets out the overall conclusions drawn by the Authority.

5.1 Establishing the eight centres

Over the past two and a half years, the eight centres with the support of the NCCP and the HSE, have implemented a large and complex change programme in the face of a number of challenges including, in certain locations, public, political and clinical concern about some specific changes. This process has been complicated further by the complex institutional and professional accountability structures that exist in the health system. For example, voluntary hospitals are autonomous institutions not directly accountable to the HSE or its directorates and the accountability for hospitals within the HSE has historically been through the National Hospitals Office.

Nevertheless, the NCCP has exerted considerable influence by securing and allocating resources for staff, equipment and information infrastructure as needed to the designated centres, although this resource allocation role has sometimes dominated its role as the locus of implementing national policy on cancer services.

Significant progress has been made in the physical establishment of eight designated centres as the conclusion of a complex programme. This represents a major shift in the capability and capacity of the health system to deliver safe and quality care when compared to the position in autumn 2007.

The designated centres, and the NCCP, deserve recognition for the changes implemented and the improvements made to date. This has required significant work and commitment at all levels of the service including front-line staff.

Recommendation 17

The HSE should undertake a formal evaluation of the change programme that has created the eight designated centres with a view to identifying lessons for future similar programmes of change. The changes that have been made in improving the symptomatic breast disease services should be used as a template to be adapted and modified for other services.

5.2 Implementing the National Quality Assurance Standards

The Authority identified a number of essential elements from the Standards that it expected to see in place, recognising that the designated centres would be at different stages of development. Its conclusions in relation to these are set out below.

Governance

All designated centres have in place governance arrangements specifically to oversee the delivery of SBD services. Each has nominated a lead clinician as part of these arrangements but, in most centres, this role requires clearer definition and development. Whereas all centres are now collecting and using data to monitor quality, this is a recent development in most centres and will need focused support on to ensure the full benefits of reviewing performance both locally and nationally are realised. The governance of third-party provider relationships generally need to be formalised and strengthened to ensure safety, quality and care continuity are maintained at all steps of along patients' care pathway.

In summary, progress has been made in this area over the last two years. However, arrangements vary in their nature and effectiveness with some centres having well established clinical and managerial governance systems and others are at an early stage of development and in need of ongoing evaluation and support.

Multidisciplinary Approach

Multidisciplinary review and decision making, through triple assessment and multidisciplinary meetings, provide the cornerstone of safe, effective SBD care. The absence of appropriate arrangements for this has been cited as a significant contributory factor in previous investigations into delayed diagnosis. Facilitated by the creation of the eight centres, and investment in additional clinical staff in certain areas, perhaps the most significant progress since 2007 has been the transition from the variable application of this approach, to all eight centres now having clear arrangements in place for multidisciplinary care of all patients.

While there remain opportunities to further enhance this area, through standardised processes and more interaction of clinicians *between* centres, the Authority is encouraged to have found this key element of care to be in place for all patients referred to the SBD service.

Person-centred Care

All centres have put in place arrangements for informing and involving patients in their care through, for example, specialist nurses, access to counselling and provision of information. The patient discussion groups with the Authority, reported high levels of confidence in the teams within the designated centres. Where concerns were reported, these tended to be in relation to parts of the care-pathway delivered outside the main centre and in relation to arrangements for delivering bad news, into which centres should always put a great deal of thought. A key enabler of person-centred care is information and centres need to ensure that all relevant information about patients and their care is accessible, whether generated in the designated centre or outside.

Skills, Education and Training

The Standards set out the principle that clinical and other staff working in SBD services should have specific training and education in the area. All centres had a spectrum of arrangements in place to assure the skill and expertise of its staff. In general these were not described within a clearly described framework and the HSE needs to develop guidance around this important area.

Data Management

Having reviewed the data management processes and systems, and validated in detail a sample of patient data in the eight centres, the Authority concluded that, while there remains work to be done, significant progress has been made compared to 2008.

The important step forward is that data collection and management is now happening in all centres. However, while some centres had well established and mature systems, other centres had only appointed data managers in mid 2009 and were still specifying data management systems in late 2009. In centres transferring in patients and services from other hospitals, the migration of data from amalgamating services was yet to happen and in most centres, there needed to be more formal mechanisms for validating data.

In summary, there was a wide spectrum of data management capability with some well established systems and good clinical buy-in to using data. However, there remain centres where data collection was sporadic and seen as an extraneous burden to patient care. As with governance systems, it is too early to say for some centres how robust and sustainable their data management systems are and they need ongoing support and evaluation to ensure the patient benefit of reliable, comparable data from all centres is realised.

Access

The Standards set out a number of time-based Standards with associated targets for access to key steps in the care pathway for patients. The detailed performance of the designated centres assessed through data submitted to the Authority, is set out on pages 69 - 88 of this report. As described previously, the purpose of these targets is to provide triggers for remedial action if performance does not meet the requirement of the Standards.

The general findings in relation to access is that many of the required targets were being met by the centres. During 2009, some centres fell below the required performance in relation to offering appointments for 95% of patients triaged as urgent within two weeks. In these cases, the centres acknowledged that they were not meeting the Standard and measures were taken such as additional clinics to bring performance back within the required limits. While it is unacceptable for these Standards not to be met, where this was the case, monitoring of performance in this area prompted a number of examples of remedial action to ensure the Standards were being met. This should be part of the provision of SBD services.

All centres have faced challenges in meeting the standard for offering an appointment to 95% of patients triaged as non-urgent within 12 weeks. Analysis of the activity in the centres over the last few years shows that there has been a large increase in the total numbers of patients being referred to SBD centres and this increase appears to be among patients at a lower risk of cancer (mainly younger patients).

At a national level, the profile of patients being seen in the SBD service translates into large numbers of patients with benign disease being seen in a service oriented primarily to diagnosing and treating patients with malignant disease through multidisciplinary teams and triple assessment.

Resources have been focused on the higher risk urgent patients, leading to delays in the providing care to those patients with benign disease. This is not only a source of anxiety for those patients having to wait to be seen, but is a very resource-intensive way of providing SBD services.

There needs to be a coherent response to the group of patients potentially waiting longer than they should. The HSE and its NCCP should take the lead in helping centres develop a service response that reflects the changed profile of patients being referred to the SBD service through fully engaging with patient, the public, providers and other key stakeholders.

Clinical Effectiveness

Having established the eight designated centres, activity data reviewed by the centres shows the minimum recommended volumes of patients are being seen in all centres and the investment in additional staff has allowed all centres to have in place the core recommended staff.

There remain variations between centres in the numbers of certain clinical specialists and further reviews of activity and sustainability will be needed to ensure that resources are aligned to activity and that cover in some of the newer centres is maintained in order to ensure a sustainable service.

Establishing a clinical audit programme, including the review of delayed diagnoses and long-term outcomes is now necessary for the benefit of designated centres to be fully realised.

5.3 Next Steps

Having reported on progress to date, this section indicates the next steps by the Authority in relation to playing its part in maintaining momentum for improved cancer services.

Follow up on local reports

Having made recommendations in all local reports on the eight designated centres, the Authority has requested each centre to develop and publish robust local implementation plans for these. The Authority will be meeting periodically with the centres, and the HSE, to assess progress in implementing these recommendations.

In three of the centres where governance and information systems were at an early stage of development, the Authority will be conducting further on-site reviews during 2010 to assess progress in creating a sustainable basis for further development. These centres are:

- Cork University Hospital
- Mid-Western Regional Hospital Limerick
- Waterford Regional Hospital.

Follow up on this national report

Having made a number of recommendations that apply nationally, the Authority will engage in a series of meeting with the NCCP and, where necessary, the wider HSE to assess progress with implementing these recommendations.

National Quality Assurance Standards for Symptomatic Breast Disease Services

The Standards were launched nearly three years ago and the Authority would expect to review and update standards on a three-year cycle. In the meantime, a number of developments are underway as part of implementing the recommendations of the Report of the Commission on Patient Safety and Quality Assurance that will influence how and when such a review takes place. These include the:

- development of national standards for quality and safety which will apply to all publicly funded health services (excluding mental health). These standards are planned to be completed during 2010
- development of nationally agreed clinical practice guidelines
- increasing use of data and key performance indicators
- development of a national approach to clinical audit; and
- planning towards a universal licensing system for public and private healthcare providers – initially in the acute sector.

These developments mean that the Standards will need to be reviewed over the next year.

The Authority will work with key national and local interested parties to undertake a review of the National Quality Assurance Standards for Symptomatic Breast Disease Services (2007) to ensure they remain effective in the context of wider regulatory and clinical governance changes.

It should be emphasised that, until such time as the Standards are formally superseded, they remain in force and should be used by the NCCP, providers and the public as the basis for assuring the quality and safety of SBD services.

5.4 Concluding Remarks

From a position in 2007 when SBD services in Ireland were dispersed, unspecified and unmonitored, there are now eight designated centres established, albeit the last of these in December 2009. Healthcare, by its very nature can never be error free and even in the best centres worldwide, errors occur. However, all centres now have in place the fundamental requirements for safe, quality care in particular: triple assessment, multidisciplinary team, core staffing and appropriate equipment. In addition, centres have begun to introduce standardised data collection and management systems. In general, the centres are meeting the key requirements set out in the Standards and have shown how monitoring performance has led to action to improve performance where required.

However, creating a successful national service is not simply about putting resources in place or establishing physical locations. Clinicians do not spontaneously become leaders, teams do not spontaneously become effective and, where they need to, established practices take time to change. Some centres – especially (but not solely) those consolidating after major service change – need time and support to bed in successfully if patient safety and service quality are to be maintained and delivered on a stable and sustainable basis.

In securing and allocating resources to ensure that all centres are above the levels needed to deliver multidisciplinary care, the NCCP, working with other parts of the HSE and the designated centres, has successfully created a platform from which to build and improve for the future. The focus of the HSE and its NCCP now needs to

shift from getting the building blocks in place in terms of resources, to leveraging the strategic and service delivery benefits from consolidating specialist services – not just for breast cancer, but for other cancers too. This must include promoting greater cohesion between designated centres, more sharing of good practice and a clear programme to harmonise clinical practice and performance monitoring including reviewing delayed diagnoses and in the longer term, survival outcomes for patients.

To assure that the sustainability of changes made to date, the NCCP, wider HSE and key stakeholders will need to ensure that changes of staff and re-organisation do not distract from delivering the next stages of transformation towards sustainable, world-class cancer services.

In order to continue this momentum for continuous improvement in symptomatic breast disease services in Ireland, the Board of the HSE should ensure the delivery and the evaluation of safe, high quality symptomatic breast disease services. The HSE should nominate a National Director to oversee the development and implementation of an action plan for these recommendations. Regular progress reports on the implementation should be reported to the Board of the HSE and published.

Recommendation 18

The HSE should nominate a national director to be responsible for developing and monitoring an implementation plan for these recommendations and should ensure that these actions are delegated as necessary. It should put in place arrangements for reporting progress with implementation to the HSE Board and the public.

The overall conclusions in relation each of the designated centres are summarised in the following tables:

Overall Conclusions:	
Beaumont Hospital	Based on the evidence of this Quality Review, the Authority concluded that while there remain opportunities for improvement and where indicated the Authority has made recommendations, Beaumont Hospital's symptomatic breast disease service was meeting the core quality and safety requirements set out in the National Quality Assurance Standards. Overall the service at Beaumont Hospital had, at the time of the Quality Review, the systems, processes and controls to deliver and maintain the added value and standards expected in a national specialist centre and to ensure sustainability going forward. Beaumont Hospital should develop, publish and implement an action plan against the recommendations.
Cork University Hospital	Based on the evidence of this Quality Review, the Authority concluded that the symptomatic breast disease service at Cork University Hospital was, at the time of the Quality Review, meeting the core quality and safety requirements set out in the National Quality Assurance Standards. However, in light of the evolving nature of the symptomatic breast disease service at Cork University Hospital, the service will require further review by the Authority on the complete amalgamation of existing and transferring SBD services from SIVUH. Cork University Hospital should develop, publish and implement an action plan against the recommendations.

Mater Misericordiae University Hospital	Based on the evidence of this Quality Review, the Authority concluded that while there remain opportunities for improvement, and where indicated the Authority has made recommendations, the symptomatic breast disease service at the Mater Misericordiae University Hospital was meeting most of the core quality and safety requirements as set out in the National Quality Assurance Standards. Overall, the service at the Mater Misericordiae University Hospital had, at the time of the Quality Review, the systems, processes and controls to deliver and maintain the added value and standards expected in a national specialist centre and to ensure sustainability going forward. The Mater Misericordiae University Hospital should develop, publish and implement an action plan against the recommendations.
Mid-Western Regional Hospital Limerick	Based on the evidence of this Quality Review, the Authority concluded that while there remain opportunities for improvement, and where indicated the Authority has made recommendations, the symptomatic breast disease service at the Mid-Western Regional Hospital Limerick was meeting most of the key quality and safety requirements as set out in the National Quality Assurance Standards. At the time of the Review, the service's governance structure, necessary to ensure sustainability, was in an early stage of development. The Authority concluded that these governance arrangements would require a period of adjustment before a judgment on their effectiveness could be made and will need to be re-assessed by the Authority. The Mid-Western Regional Hospital Limerick should develop, publish and implement an action plan against the recommendations.

St James's Hospital	Based on the evidence of this Quality Review, the Authority concluded that while there remain opportunities for improvement and where indicated the Authority has made recommendations, St James's Hospital's symptomatic breast disease service was meeting the core quality and safety requirements set out in the National Quality Assurance Standards. Overall, the service at St James's Hospital had the systems, processes and controls to deliver the added value and standards expected in a national specialist service and to ensure sustainability going forward. St James's Hospital should develop, publish and implement an action plan against the recommendations.
St Vincent's University Hospital	Based on the evidence of this Quality Review, the Authority concluded that while there remain opportunities for improvement and where indicated the Authority has made recommendations, St Vincent's' University Hospital's symptomatic breast disease service was meeting the core quality and safety requirements set out in the National Quality Assurance Standards. Overall, at the time of the Quality Review, the service at St Vincent's' University Hospital had the systems, processes and controls to deliver and maintain the added value and standards expected in a national specialist centre and to ensure sustainability going forward. St Vincent's University Hospital should develop, publish and implement an action plan against the recommendations.

University College Hospital Galway (satellite site Letterkenny General Hospital)	Based on the evidence of this Quality Review, the Authority concluded that, while there remain opportunities for improvement, and where indicated the Authority has made recommendations, the symptomatic breast disease service at University College Hospital Galway and the satellite service at Letterkenny General Hospital was meeting most of the core quality and safety requirements set out in the National Quality Assurance Standards. Overall, at the time of the Quality Review, the service at University College Hospital Galway and the satellite service at Letterkenny General Hospital had the systems, processes and controls to deliver the added value and standards expected in a national specialist service thereby, ensuring sustainability going forward. University College Hospital Galway and the satellite service at Letterkenny General Hospital should develop, publish and implement an action plan against the recommendations.
Waterford Regional Hospital	Based on the evidence of this Quality Review, the Authority concluded that Waterford Regional Hospital had in place some of the core requirements for quality and safety as set out in the Standards, including lead clinician, triple assessment, MDT approach, audit of key aspects of the patient journey and patient information. However, some of the essential requirements relating to governance, data management and patient access were in an early phase of development. There remained opportunities for improvement and where the Authority indicated has made recommendations. The recently restructured clinical and corporate governance arrangements require a period of adjustment, with ongoing evaluation and support to ensure sustainability, before a judgment on their effectiveness can be made, and this will need to be re-assessed by the Authority. Waterford Regional Hospital should develop, publish and implement an action plan against the recommendations.

6 References

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

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

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

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

(5) Breast Cancer Ireland website: www.breastcancerireland.com

(6) National Cancer Registry Ireland. Cancer in Ireland 1994-2007 a summary. Accessible at: http://ncri.ie/pubs/pubfiles/summary_report_19942007.pdf. 2009.

(7) Department of Health and Children. Stastics/Health in Ireland: Key Trends 2009/ Heatlh of the Population. Accessible at: http://www.dohc.ie/statistics/key_trends_2009/ health_of_the_population/table_2-4.html. Accessed February 2010.

(8) Women and Cancer in Ireland 1994 – 2001, National Cancer Registry Ireland and The Women's Health Council, Dublin, February 2006.

(9) Department of Health and Children. Report on the Circumstances that led to the decision by HSE in August 2007 to: Suspend Breast Radiology Services, Initiate a Clinical Quality Review of Symptomatic Breast Radiology Service and Place Consultant Radiologist on administrative leave at Midland Regional Hospital, Portlaoise, Department of Health and Children; 2008.

(10) Department of Health and Children, Fitzgerald J. Management, Governance and Communications issues arising from the Quality Review of Breast Radiology Services at Midland Regional Hospital Portlaoise, Department of Health and Children; 2008

(11) Early Breast Cancer – from screening to Multidisciplinary Management, 2nd edition, G. Querci della Rovere, Ruth Warren and John R Benson, 2006

(12) Breast cancer in limited-resource countries: early detection and access to care, National Clearing House. Accessible at: http://www.guideline.gov/summary/summary. aspx?doc_id=9026&nbr=4885 U.S.A. January 2006. Accessed January 2010

(13) The Woman's Health Council. Survey of views & Perceptions of Women who attended Symptomatic Breast Clinics, The Woman's Health Council; 2000

(14) Department of Health and Children. Development of Services for Symptomatic Breast Disease – Report of the Sub-Group to The National Cancer Forum, Department of Health and Children, March 2000

(15) Health Services Executive website. Population Health. Cancer Care. Accessible at: http://www.hse.ie/eng/staff/FactFile/HSE_Approach/ Population_Health/Chronic_illness/Cancer.html. Accessed January 2010

(16) Health Service ExecutiveHealth Service Executive. National Cancer Control Programme. Health Professional Information. Breast Cancer Referral Form. Accessible at: http://www.hse.ie/eng/services/Find_a_Service/National_Cancer_Control_Programme/Health_Professional_Information/Breast_Cancer_Referral_Guideline.pdf
Accessed February 2010

(17) Commission on Patient Safety and Quality Assurance. Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance. Department of Health and Children; 2008

(18) Health Service Executive. National Cancer Control Programme. Quality Review of activity in the symptomatic breast clinics in the eight designated centres, 2005 and 2006 compared with 2009 year to date; 2009.

(19) Health Act 2007. 2007

(20) O'Higgins N. Development of Services for Symptomatic Breast Disease. Report of the Sub-Group to the national Cancer Forum. Dublin: Department of health and Children: 2000

7 Glossary of useful terms and abbreviations

AMNCH:

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

Axillary:

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

BreastCheck:

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

Carcinoma:

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

Chemotherapy:

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

Clinical audit:

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

Clinical directorates:

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

Clinical examination coding:

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

Clinical practice guidelines:

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

Clinically occult lesion:

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

CNS:

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

Computerised tomography (CT):

the practice of taking images of the body in a number of selected planes using radiography, and thereby building a three-dimensional image of an area

Computerised tomography (CT):

the practice of taking images of the body in a number of selected planes using radiography, and thereby building a three-dimensional image of an area

Consultant:

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

CPD:

continuing professional development

CT:

computerised tomography

DCIS:

ductal carcinoma in situ

Ductal carcinoma in situ (DCIS):

a non-invasive condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to other tissues in the breast

False negative case:

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

False positive case:

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

Fine needle aspiration (FNA):

use of a needle attached to a syringe to withdraw cells from a tumour

FISH:

fluorescent in situ hybridisation

Fluorescent in situ hybridisation (FISH):

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

Governance structure:

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

GP:

general practitioner

HER2:

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

Histopathology:

the study of diseased cells and tissues using a microscope

Hormone receptor status:

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

HSE:

Health Service Executive

Invasive breast cancer:

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

IT:

information technology

KPI:

key performance indicator

Lymph nodes:

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

Lymphoedema:

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

Magnetic resonance imaging (MRI):

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

Mammography:

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

Medical oncology:

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

Morbidity:

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

MRI:

magnetic resonance imaging

Multidisciplinary team (MDT):

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

Multidisciplinary team meetings:

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

NBSP:

National Breast Screening Programme (see Breastcheck)

NCCP:

National Cancer Control Programme

Network Manager:

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

Non-urgent:

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

NQAS:

National Quality Assurance Standards for Symptomatic Breast Disease Services

Oestrogen receptor status:

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

PACS:

Picture Archive and Communication System

PAS:

Patient Administration System

PATS:

Patient Analysis and Tracking System

Prosthesis:

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

Protocol:

a detailed plan of a medical treatment or procedure

Radial margin status:

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

Radiation oncology (or radiotherapy):

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

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

SBCN:
specialist breast care nurse

SBD:
symptomatic breast disease

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

SLA:
service level agreement

Sonographic abnormality:
an abnormality detected by ultrasound

SOP:
standard operating procedure

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

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

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

TNM:
tumour nodes metastasis

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

Triage process:

the process of assigning priorities of medical treatment based on urgency

Triple assessment clinic (TAC):

a clinic at which clinical examination, imaging and pathology tests are carried out in the diagnosis of breast disease

Ultrasound:

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

Urgent:

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

Appendices

Appendix 1

Key Representative Standards

Standard Reference	Standard
	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)
2.1.3	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.
2.8	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.
2.9	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.
4.11	A patient shall be offered admission for the first therapeutic operation within three weeks of definitive diagnosis.
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.

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)
5.3	Non-operative diagnosis shall be achieved in over 90% of patients.
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.
6.1	Pre-operative mammography with ultrasound examination shall be regarded as a prerequisite for the assessment of the patient with primary operable breast cancer.
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.

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 2

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

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

1. Establish clear governance structures for overseeing the transition from a designated centre to a specialist centre. This should include the nomination of a senior manager / clinician to lead, be supported by, and accountable to the board / senior management team of the hospital in relation to progress towards this goal and the implementation plan as specified in recommendation 2 below. The structures should also take into account establishing formal linkages with all neighbouring hospitals that will be transferring the care for patients with symptomatic breast disease to designated centres, where applicable, and also a reporting mechanism into the National Cancer Control Programme.
2. Review the interim report* and develop a prioritised implementation plan to address the gaps in the outstanding requirements – this plan should be signed off by the National Cancer Control Programme.
3. Work with other designated centres, under the coordination of the National Cancer Control Programme, to agree and address areas in need of standardisation. For example, referral mechanisms, diagnostic reporting conventions and core patient pathways to ensure consistency in approach across the country.
4. Ensure that the main risks associated with the transition to becoming a specialist centre are identified and measures put in place to manage and mitigate against them (Section 13 of the self-assessment tool provided the important questions that centres should be addressing).

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

Appendix 3

Methodology - National Quality Review Programme – Phase 4

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

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

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

- categorisation of the Standards
- assessment process.

1.1.1 Categorisation of the Standards

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

A number of key representative Standards were identified during the categorisation phase (see Appendix 1).

These included:

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

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

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

Recognising that centres may be at different stages of development towards implementing the full range of Standards, the Authority identified the really important factors in each theme that must be in place for quality and safety. These essential elements that each designated centre must have in place as the foundation for safe, high quality symptomatic breast disease care are set out in Figure 3 in the main report.

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

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

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

1.1.2 Assessment Process

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

1.1.3 Stage 1, Pre-visit

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

The Authority requested documentation (see Appendix 4) from the designated centre in advance of the on-site assessment visit in order to assess the documentary evidence of the local arrangements. This documentation was submitted to the Authority within three weeks of the Authority's request.

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

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

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

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

Activity data: seven-month sample period

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

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

Access and clinical effectiveness data: 13-week sample period

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

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

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

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

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

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

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

1.1.4 Stage 2, the on-site visit

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

(i) On-site documentation review

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

(ii) On-site validation of data

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

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

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

(iii) Data system demonstration

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

(iv) Observation in clinical areas

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

(v) Interviews

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

Interviewees at each centre included:

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

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

(vi) Discussion group with patients

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

1.1.5 Stage 3, following the on-site visit

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

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

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

1.2 Quality assurance

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

- a single communication approach with all eight designated centres
- internal peer review at various stages during the development of the assessment methodology
- consistency in the design and development of the assessment methodology
- consistency in having a single team of assessors attending all eight designated centres as part of the Quality Review
- a standardised interview format
- the standardised collection and recording of information using an electronic assessment tool
- ensuring that there are clear links between judgments reached and the evidence on which they are based
- each assessment report being quality reviewed by Authority personnel, external to the Quality Review assessment team
- each centre being invited to review each individual draft report for the purpose of factual accuracy
- acceptance and sign off of the local and national reports by the Chief Executive and Board of the Authority

Appendix 4

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

Instructions for submitting documentation:

The Authority requests that:

1. All documentation is submitted in hard copy (copies of original documentation only)
2. Please indicate on each page as requested what documents you are submitting and the reasons why documents are not submitted.
3. All documents submitted should be referenced to the appropriate reference number on each page of this document.
4. All documentation, **including the completed documentation request checklist**, must be submitted **no later than 5pm on Wednesday 9th September 2009** to:

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

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

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

1. Governance

No.	Documentation Required	Please tick if document is attached or state reason if not attached
1.1	**Governance Structure** (Indicate operation linkages and reporting structures between both)	
	1.1.1 Organogram for the Governance structure of the hospital	
	1.1.2 Organogram for the Organisation structure of the Symptomatic Breast Disease Service	
1.2	**Monitoring compliance with the National Quality Assurance Standards**	
	1.2.1 Terms of reference for the committee responsible	
	1.2.2 Membership of the committee	
	1.2.3 Scheduling of meetings for this committee from 1st January 2009 to week commencing 17th August 2009	
	1.2.4 Minutes of all meetings from 1st January 2009 to week commencing 17th August 2009	
1.3	**Clinical Leadership**	
	1.3.1 Standard operating procedure/Policy for clinical leadership, indicating the most responsible person for the patient as they transfer through the pathway of care.	
1.4	**Clinical Risk Management:**	
	1.4.1 Risk Management policy	
	1.4.2 Clinical Incident Reporting policy	

	1.4.3 Number of clinical incidents/adverse events pertaining to SBD services reported between 1st January 2009 and week commencing 17th August 2009	
	1.4.4 Quality improvement initiatives implemented as an action following investigation of identified incidents	
1.5	**Service Level Agreements**	
	1.5.1 Service Level Agreements or equivalent document for services being provided by a third party at any stage of the patients care pathway (i.e. pathology or radiology or other service)	
1.6	**Core Personnel**	
	1.6.1 Complete the attached form (Appendix 1) detailing the full complement of core personnel to the symptomatic breast disease service	
1.7	**Confidentiality**	
	1.7.1 Standard operating procedure/policy for patient confidentiality	

2. Person Centred Care

No.	Documentation Required	Please tick if document is attached or state reason if not attached
2.1	**Patient Information**	
	2.1.1 Standard operating procedure/policy for developing and providing patient information	
	2.1.2 List names/titles of all patient information leaflets provided by the Centre, indicating on the list whether the leaflet was produced by the Centre or sourced externally	
	2.1.3 Checklist template used to document information provided to the patient	
	2.1.4 Consent policy for patients	
2.2	**Patient Satisfaction with the symptomatic breast disease service**	
	2.2.1 Patient Satisfaction data specific to symptomatic breast disease services from 1st January 2009 to week commencing 17th August 2009	
	2.2.2 Complaints policy	
	2.2.3 Number of complaints received and subsequent action plans for the symptomatic breast disease service from 1st January 2009 to week commencing 17th August 2009	
2.3	**General Practice**	
	2.3.1 Information pack for General Practitioners (GP) (to include any information pertaining to communication with GP's, including schedule of any GP information sessions)	

3. Multidisciplinary Approach

No.	Documentation Required	Please tick if document is attached or state reason if not attached
3.1	**Multidisciplinary Meeting**	
	3.1.1 Standard operating procedure/policy for Multidisciplinary Meetings	
	3.1.2 Scheduling of meetings from 1st January 2009 to week commencing 17th August 2009	
	3.1.3 List of multidisciplinary membership	
	3.1.4 Agenda for all meetings from 1st January 2009 to week commencing 17th August 2009	
	3.1.5 Template used for recording information following multidisciplinary discussion	
3.2	**Triple Assessment Clinic**	
	3.2.1 Standard operating procedure/policy for Triple Assessment Clinics	
	3.2.2 Scheduling for Triple Assessment Clinics from 1st January 2009 to week commencing 17th August 2009	
	3.2.3 Standing Operating Procedure/policy to demonstrate how patients are referred to the triple assessment clinic	

4. Skills, Education and Training

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

5. Clinical Effectiveness

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

Appendix X Theme – Skills Education and Training

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

Name	Title	Speciality	WTE	Commenced Employment 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 5

Data request prior to onsite quality review

Symptomatic Breast Disease Service Quality Review 2009

Data request prior to on-site quality review

Hospital Name: _____

Instructions for completing this data request form:

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

5. For the purposes of this data request exercise only, please note descriptions of the following terms will be used in this document:

   a. **Definitive diagnosis** – this is achieved following discussion and clinical decision being reached at the Multidisciplinary Team (MDT) meeting.

   b. **Patient with newly diagnosed primary breast cancer** – this refers to patients with a primary cancer in either the left or right breast or both and excludes patients with re-occurrences.

   c. **Patient with primary operable breast cancer –** patients that have been assessed as being suitable for surgery.

   d. **Non-urgent referrals** – refers to patients triaged as early or routine by the Symptomatic Breast Disease (SBD) centre

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

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

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

Section A

ALL questions in Section A refer to data for the sample time period of 1 January 2009 – 1 August 2009

b) the Patient Sample group – new patients seen at the Symptomatic Breast Disease (SBD) Centre

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.1	What is the total number of **new patients** seen at the SBD centre for this sample time period?	Numeric figure		
DaR.2	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre?	Numeric figure		
DaR.3	Of the total number of referrals received during the sample time period that were triaged as **urgent** by the SBD centre (see DaR.2), what is the total number and percentage of patients **offered an appointment** to be seen within 10 working days of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.4	Of the total number of new patients seen at the SBD centre (see DaR.1), what is the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre?	Numeric figure		

Section A - continued

ALL questions in Section A refer to data for a) the sample time period of 1 January 2009 – 1 August 2009

b) the Patient Sample group – new patients seen at the Symptomatic Breast Disease (SBD) Centre

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.5	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.6	Of the total number of referrals received during the sample time period that were triaged as **non-urgent** by the SBD centre (see DaR.4), what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.7	Of the total number of new patients seen at the SBD centre for the sample time period (see DaR.1), what is the total number of newly diagnosed primary breast cancer patients?	Numeric figure		

Section B

ALL questions in Section B refer to data for the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

the Patient Sample group – seen and newly diagnosed with primary breast cancer

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

Section B – continued

ALL questions in Section B refer to data for a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group – seen and newly diagnosed with primary breast cancer

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.13	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that were triaged as **non- urgent** by the SBD centre?	Numeric figure		
		Percentage figure to be submitted		
DaR.14	Of the total number of patients triaged as non-urgent (see DaR.13) what is the total number and percentage of patients seen within **6 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.15	Of the total number of patients triaged as non-urgent (see DaR.13) what is the total number and percentage of patients seen within **12 weeks** of the date of receipt of referral?	Numeric figure		
		Percentage figure to be submitted		
DaR.16	Of the total number of newly diagnosed primary breast cancer patients (see Dar.8), what is the total number of patients who had an imaging abnormality which was classified as R3, R4, or R5 identified and had a core biopsy performed?	Numeric figure		
DaR.17	Of the total number of patients who had a core biopsy performed (see DaR.16), what is the total number and percentage of biopsies that were image guided?	Numeric figure		
		Percentage figure to be submitted		
DaR.18	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number of patients whose definitive diagnosis was made at the MDT meeting?	Numeric figure		

Section B – continued

ALL questions in Section B refer to data for

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group - seen and newly diagnosed with primary breast cancer

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.19	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that were diagnosed with invasive breast cancer?	Numeric figure		
		Percentage figure to be submitted		
DaR.20	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of patients that had primary operable invasive breast cancer?	Numeric figure		
DaR.21	Of the total number of patients that had primary operable invasive breast cancer (see DaR.20), what is the total number and percentage of patients that had ultrasound of the axillary nodes?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 1

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group - seen and newly diagnosed with primary breast cancer

c) sub-sample group 1: Diagnosed with invasive breast cancer

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.22	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number and percentage of patients that were diagnosed without an operative procedure?	Numeric figure		
		Percentage figure to be submitted		
DaR.23	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19) what is the total number of patients that were assessed has having a clinically occult lesion (classification S2)?	Numeric figure		
DaR.24	Of the total number of patients that were assessed as having a clinically occult lesion (classification S2) (see DaR.23), what is the total number and percentage of patients that had pre-operative image-guided localisation before surgery?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 2

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group - seen and newly diagnosed with primary breast cancer

c) sub-sample group 2: Diagnosed with invasive breast cancer and had surgery

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.25	Of the total number of patients that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of patients **that had surgery**?	Numeric figure		
DaR.26	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **type** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.27	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **grade** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.28	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the histological tumour **size** recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.29	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the presence or absence of vascular invasion recorded?	Numeric figure		
		Percentage figure to be submitted		

Section B - Continued

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group - seen and newly diagnosed with primary breast cancer

c) sub-sample group 2: Diagnosed with invasive breast cancer AND HAD SURGERY continued

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.30	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had the posterior deep margin status recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.31	Of the total number of **patients** that were diagnosed with invasive breast cancer (see DaR.19), what is the total number of **cases** that had a Wide Local Excision?	Numeric figure		
DaR.32	Of the total number of **cases** that had a Wide Local Excision, (see DaR.31) what is the total number and percentage of **cases** that the radial margin status is recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.33	Of the total number of patients that had surgery (see DaR.25), what is the total number and percentage of **cases** that had HER-2 status recorded?	Numeric figure		
		Percentage figure to be submitted		
DaR.34	Of the total number of patients that had surgery (See DaR.25), what is the total number and percentage of **cases** that had oestrogen receptor status recorded?	Numeric figure		
		Percentage figure to be submitted		

Section B – Continued note sub-sample group 3

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group - seen and newly diagnosed with primary breast cancer

c) sub-sample group 3: Patients with primary operable cancer

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.35	Of the total number of newly diagnosed primary breast cancer patients (see DaR.8), what is the total number and percentage of patients that had primary operable breast cancer?	Numeric figure		
		Percentage figure to be submitted		
DaR.36	Of the total number of patients that had primary operable breast cancer (see DaR.35), what is the total number and percentage of patients that had surgery (providing surgery is the first line of treatment) within 20 working days of definitive diagnosis at the MDT meeting?	Numeric figure		
		Percentage figure to be submitted		
DaR.37	Of the total number of patients that had primary operable breast cancer (see DaR.35), what is the total number and percentage of patients that had pre-operative mammography with ultrasound carried out?	Numeric figure		
		Percentage figure to be submitted		

Section C – note new patient Sample group

ALL questions in Section C refer to data for

a) the sample time period of the 13 consecutive weeks from 1 April 2009 – 30 June 2009

b) the Patient Sample group –diagnosed with Ductal Carcinoma In Situ at MDT

Question Reference	Question	Information Type	Please state numeric figure/ percentage figure as requested	Please tick if providing supporting narrative and add narrative to DaR Appendix x
DaR.38	What is the total number of patients newly diagnosed with Ductal Carcinoma In Situ and seen at the SBD centre during the sample time period of 1 April 2009 – 30 June 2009?	Numeric figure		
DaR.39	Of the total number of patients newly diagnosed with Ductal Carcinoma In Situ and seen at the SBD centre during the sample time period (see DaR.38) what is the total number of **cases** of Ductal Carcinoma In Situ.	Numeric figure		
DaR.40	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases** that had a wide local excision?	Numeric figure		
		Percentage figure to be submitted		
DaR.41	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases** that had radial margin status recorded	Numeric figure		
		Percentage figure to be submitted		
DaR.42	Of the total number of **cases** of Ductal Carcinoma In Situ (see DaR.39) what is the total number and percentage of **cases** that had the histological tumour grade recorded?	Numeric figure		
		Percentage figure to be submitted		

Section D

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

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

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

Appendix 6

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

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

STANDARD 1: ACCESS		
Ref.	**Key Performance Indicator**	**Target**
1a	Referrals triaged as urgent by the cancer centre shall be offered an appointment within 10 working days of the date of receipt of a letter of referral in the cancer office.	>95%
1b	Referrals triaged as non urgent (i.e. early and routine) by the cancer centre, shall be offered an appointment within 12 weeks (less than or equal to 84 days) of the date of receipt of a letter of referral in the cancer office.	>95%
1c	A new patient deemed urgent following specialist assessment in the clinic (that is classified as S4, S5) shall have imaging (mammography or ultrasound) done in the first visit.	>90%
1d	Breast imaging requests (that is, mammography or ultrasound) shall be carried out within 12 weeks of clinical assessment.	>90%

STANDARD 2: IMAGING		
Ref.	**Key Performance Indicator**	**Target**
2a	Patients with primary operable breast cancer shall have pre-op mammography and ultrasound examination.	>95%
2b	A patient over the age of 35 years with a clinically palpable focal abnormality (that is classified as S3, S4 or S5) shall have mammography and targeted ultrasound examination.	>95%
2c	Core biopsies of breast shall be image-guided where an imaging abnormality which is classified as R3, R4 or R5 is identified.	>90%
Additional parameter	Consultant radiologists shall report on at least 1,000 mammograms annually.	1,000

STANDARD 3: DIAGNOSIS		
Ref.	**Key Performance Indicator**	**Target**
3a	Patients with invasive breast cancer shall be diagnosed without an operative procedure [open biopsy].	>90%
3b	For patients urgently triaged by the cancer centre and subsequently diagnosed with a primary breast cancer, the interval between attendance at the first clinic and the discussion at the multidisciplinary meeting where a B5 or C5 is first identified shall not exceed 10 working days.	>90%
Additional parameter	The number of benign open surgical biopsies shall be recorded.	volume

STANDARD 4: MULTIDISCIPLINARY WORKING		
Ref.	**Key Performance Indicator**	**Target**
4a	Breast investigations that generate a histopathology report shall be discussed at MDM.	>95%
4b	Patients with a diagnosis of breast cancer from the symptomatic service shall be discussed at MDM.	>95%

STANDARD 5: TIME TO TREATMENT		
Ref.	**Key Performance Indicator**	**Target**
5a	Surgical intervention shall be carried out within four weeks (20 working days) of the date of the multidisciplinary meeting when a B5 or C5 is first identified, provided surgery is the first treatment.	>90%
5b	For post-surgery patients, where adjuvant chemotherapy is not deemed necessary but require radiation therapy, patients shall commence radiation therapy within 12 weeks of the final surgical procedure.	>90%
5c	**For post-surgery patients, requiring adjuvant chemotherapy and radiation therapy, patients shall commence radiation therapy within four weeks of the last chemotherapy administration.**	**>90%**
5d	**For post-surgery patients, where adjuvant chemotherapy is required, administration shall commence within eight weeks of the final surgical procedure.**	**>90%**

STANDARD 6: SURGERY – ACCURATE LOCALISATION		
Ref.	**Key Performance Indicator**	**Target**
6a	Patients with a clinically occult lesion, that is classified as an S", shall have wire-guided localisation pre-operatively.	>95%
6b	Patients with a clinically occult lesion who have a wire-guided wide local excision shall have specimen mammography.	>95%

STANDARD 7: SURGERY – AXILLARY STAGING		
Ref.	**Key Performance Indicator**	**Target**
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		
Ref.	**Key Performance Indicator**	**Target**
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		
Ref.	**Key Performance Indicator**	**Target**
9	For patients having breast conserving surgery, the number of therapeutic interventions shall be recorded.	Volume

STANDARD 10: PATHOLOGY		
Ref.	**Key Performance Indicator**	**Target**
10a	For primary invasive tumours:	>95%
(a)	Histological tumour type shall be recorded.	Volume
(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)	**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

New patient referral activity by non-urgent triage category

	BH	CUH	MMUH+	MWRHL	SJH	SVUH	UCGH	LGH	WRH
Total number of new patient referrals received during the sample time period that were triaged as non-urgent by the SBD Service	2389	1380	776	694	1369	1250	1899	813	830
Total number of new patient referrals triaged as non-urgent who were seen within 6 weeks of the date of receipt of referral	1092	*	173	236	361	321	1244	256	170
Percentage of new patient referrals triaged as non-urgent who were seen within 6 weeks of the date of receipt of referral	46%	*	22%	34%	26%	26%	74%	31%	98%
Total number of new patient referrals triaged as non-urgent who were seen within 12 weeks of the date of receipt of referral	2389	1377	520	318	1070	1078	378	423	429
Percentage of new patient referrals triaged as non-urgent who were seen within 12 weeks of the date of receipt of referral	100%	99%	67%	46%	78%	86%	22%	52%	65%

\+ *Note that MMUH data pertains to the period 1 June to 1 November 2009*

* *Data not provided*

Source: Activity data submitted by designated centres (not validated by the Authority)

Appendix 8

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/

For further information please contact:

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

Phone: +353 (0)1 814 7400
email: qualityandsafety@hiqa.ie
URL: www.hiqa.ie