Report on progress in implementing recommendations arising from the report of the HIQA 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.

Summary

This report sets out progress which has been made by the HSE in relation to recommendations made by HIQA arising from an 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. Significant local and national progress has been made in relation to these recommendations and necessary arrangements are largely in place. A key outstanding action is with regard to a review of risk management at the Mid West Regional Hospital Limerick. The Regional Director for Operations for HSE West will ensure that it is completed and that a copy of the report together with implementation plan is brought to the HSE Board Risk Committee.

Introduction

The Health Information and Quality Authority (HIQA) was established through the Health Act 2007. It has a number of powers which include the power to undertake an investigation wherein there is a serious risk to the health or welfare of a person receiving those services; it may invoke this power autonomously or at the request of the Minister for Health and Children.

To date, HIQA has undertaken three investigations and issued recommendations to the HSE as a consequence. The first two investigations had a particular focus on breast services; the third investigation was more broadly concerned with the hospital reconfiguration agenda.

The first investigation concerned failings in symptomatic breast services provided to Ms Rebecca O Malley at Cork University Hospital (CUH) and Mid Western Regional Hospital (MWRH) Limerick (see Appendix 1 for Terms of Reference). Many of the recommendations concerned the development of symptomatic breast services (see Appendix 2 for Recommendations). An implementation plan was published by the HSE in June 2008. Publication of this plan was accompanied by an apology to Ms O Malley. Three progress reports were also publicly reported.

It was agreed in 2009 with HIQA that the most appropriate next step was to review progress at a local (CUH and MWRH Limerick) level and at national level 12 months on from publication of the investigation report. A meeting took place on 23rd June 2009.

1. Progress at CUH

CUH reported arrangements with regard to its services for symptomatic breast services in June 2009.

- Multidisciplinary Team Meetings are in place.
    - Lead Clinician – Prof. H. P. Redmond
    - Standard Operating Procedure in place –minutes collated
    - Attendance record of all meetings
    - Summary of each meeting with every decision allocated for action to named member of the MDM team

  These arrangements respond to recommendations 1 and 6.

- A suspected delayed diagnosis would be managed in the following manner:
    - Incident Management procedure would be followed
    - Risk Management Department would establish a review group to investigate incident.
    - Multidisciplinary Team resource would be made available for investigation.
    - A formal response from Lead Clinician would issue.

  These arrangements respond to recommendations 2 and 3.

- Psychological support services are in place:
    - Patient referrals made directly to Social Work Department
    - Patients have access to the Psyco-Oncology Clinical Nurse Specialist, Psychiatry service and via the Department of Psychiatry to Psychology Service
    - Patients are issued with full list of voluntary groups
    - Patients and families have access to voluntary support groups
    - Patients have access to named staff in the service

  These arrangements respond to recommendations 4.

- Arrangements for biopsy are as follows:
    - Core biopsy is the diagnostic modality at CUH for Breast evaluation
    - > 95% of core biopsies are image guided
    - Breast fine needle aspiration cytology is not used
    - Core biopsies are reported using the B1 – B5 system with classification of cancer type and grade
    - Template reporting with minimum dataset for breast cancer in place
    - Based on clinical assessment at clinic, 100% of patients have all diagnostic procedures at first attendance

  These arrangements respond to recommendations 5, 7, 8 and 9.

- Clinical governance arrangements for the service are as follows:
    - Dr. M. Henry and Dr. M. Boyd are responsible and accountable at Executive Management level for Clinical Governance
    - Ms. Geraldine Keohane assigned as the Management Team lead for the cancer programme.
    - HSE Integrated Quality, Safety and Risk Management Framework being implemented in the hospital.
    - Clinical Governance Framework in place
    - Pathology Laboratory awarded full CPA accreditation – March 2009
    - Patient Advocacy service in development

  These arrangements respond to recommendations 11.

- With regard to risk management function:
    - Review of CUH Clinical Governance function completed
    - Recommendations approved by Executive Management Board
    - Multidisciplinary Clinical Governance Committee established
    - Clinical Governance Risk & Quality Framework in place
    - Improved structure for management of complaints in place
    - Improved reporting structure to the Executive Management Board

  These arrangements respond to recommendations 12.

- Arrangements for patient-focused communication include the following:
    - CUH Patient Forum
    - Patient Forum representation on
        - Cancer Centre project team
        - Hygiene committee
        - Decontamination committee
        - Cardiac and Renal project team

  These arrangements respond to recommendations 13.

- Governance arrangements are as follows:
    - CUH presently in transition from 15 Clinical Divisions to the directorate model as part of the implementation of the new Consultant Contract
    - Proposed Clinical Directorates
        - Directorate of Surgical Services
        - Directorate of Medical Services
        - Directorate of Diagnostic Services
        - Directorate of Women & Children

These arrangements respond to recommendations 14.

2. Progress at MWRH Limerick

MWRH Limerick reported arrangements with regard to its services for symptomatic breast services in June 2009.

- Multidisciplinary Team Meetings are in place.
    - Lead clinician - Ms Anne Merrigan
    - Discordant results would result in further discussion within the multidisciplinary team meeting.
    - A proforma meeting sheet and attendance register are in use.
    - Meetings are held weekly within regular working hours

These arrangements respond to recommendations 1 and 6.

- A suspected delayed diagnosis would be managed in the following manner:
    - HSE Incident Management Policy is in place and associated procedure would be followed.

These arrangements respond to recommendations 2 and 3.

- Psychological support services are in place and include the following:
    - Breast Care Nurse Specialists.
    - Oncology Services Social Worker.
    - Cancer Information & Support Centre.
    - Clinical Psychology Services.
    - Counseling services.
    - Advocacy Groups, contacts provided.
    - Reach to Recovery volunteer present at review clinic.
    - Complementary Therapies, reki, meditation and relaxation classes.
    - Liaison Psychiatry services.

These arrangements respond to recommendations 4.

- Arrangements for biopsy are as follows:
    - A Consultant Radiologist with a special interest in breast disease has been appointed and currently core biopsies are done under image guidance; as a result, the proportion of cases managed in this manner is approaching 100%.
    - This indicator will increase further with the appointment of the consultant radiologist with a special interest in breast.
    - Fine needle aspiration cytology is no longer used since 03/03/09.

- Core biopsies are reported using the B1-B5 classification system.
- Minimum dataset for breast cancer specimens used.
- Approximately 90% new patients triaged as urgent by the consultant have all their diagnostics at first visit.

These arrangements respond to recommendations 5, 7, 8 and 9.

- Clinical governance arrangements for the service are as follows:
  - General Manager and Clinical Director responsible for clinical governance.
  - HSE Integrated Quality, Safety and Risk Management Framework being implemented in the hospital.
  - Department of Histology, MWRH undergoing CPA Accreditation with conditional accreditation status awarded on 21/05/09 as an interim step pending full accreditation.
  - Hospital wide consumer patient forum being set up.
  - Independent patient advocates available. List of advocates circulated to all complaints officers.

These arrangements respond to recommendations 11.

- With regard to risk management function:
  - Risk management arrangements being reviewed by Risk Manager and Quality Manager from HSE Office of Quality and Risk and NHO respectively. Field work is complete and report being drafted. This will be complete in Q1 2010 and will be provided to the HSE Board Risk Committee for information.
  - The Hospital is implementing the HSE Quality, Safety and Risk Management Framework.
  - Risk advisor in post for hospital.
  - Regional Risk Committee in place chaired by Clinical Director.

These arrangements respond to recommendations 12.

- Arrangements for patient-focused communication include the following:
  - Patient satisfaction and OPD waiting time surveys conducted.
  - Breast service users' consumer panel 2008 – involved in patient information leaflet & layout of new unit.
  - Hospital forum with representation from service users, carers and hospital management being established.
  - Patient representatives on the Hygiene Services Committee.

These arrangements respond to recommendations 13.

- Governance arrangements are as follows:
  - Clinical Director appointed of hospital.
  - Hospital Executive Management Team has been formed comprising Clinical Director, Director of Nursing and General Manager.
  - Weekly Cancer Services Management team meetings in place.
  - Monthly Breast Services Management Meetings in place with General Manager.
  - Monthly meetings with NCCP.

These arrangements respond to recommendations 14.

3. Progress nationally

Many of the recommendations focussed on the development of breast services (1-9) in line with plans developed by the National Cancer Control Programme (NCCP) and informed by the National Quality Assurance Standards for Symptomatic Breast Services. Through 2009, performance in relation to development and operation of these services was monitored by the NCCP and reported through the HSE Performance Report – these reports are publicly available (www.hse.ie). Of note in relation to the recommendations in the HIQA investigation:

- Multidisciplinary Team Meetings are in place in designated centres.
- All centres currently provide all diagnostics at first attendance to ≥90% of patients when clinically indicated.
- HSE Incident and Serious Incident Management Policies and Procedures provide the framework for response to delayed diagnosis.
- Specialist breast care nurses in all centres are at the forefront of information, support and counselling. All centres currently have access to some psychology services, counselling, social work and information and support from the professionals within the units.
- As part of the triple assessment process, stereotactic mammography machine and radiology-led image guidance are in place in all 8 centres. Utilisation is monitored.
- Fine Needle Aspirate Biopsy is used for primary diagnosis of breast cancer at St James's and Galway; the former centre is accredited for this purpose and the latter centre is in the process of securing accreditation. Both centres have audited this practice and use C1-C5 classification.
- All centres use B1-B5 classification for breast biopsies.
- NCCP/NHO are supporting the RCPI to develop and implement a histopathology and cytopathology quality assurance programme. An information day was held in July 2008. Development and roll out of the programme has commenced and guidelines issued to all centres in Q1 2009. National monitoring and reporting of Key Performance Indicators will commence in 2010.
- The NCCP is working with the NCRI to develop a national minimum cancer dataset, including a data dictionary.

An external review of breast services is underway by HIQA. This review will provide independence assurance with regard to the status of the development of these services to the Board of the HSE.

With regard to recommendation 10 and the delivery of patient centred services, a key initiative in this regard for the HSE has been the implementation of the new consultant contract, the appointment of clinical directors and the development of designated centres for assessment and treatment of symptomatic breast disease under the NCCP. The NCCP will produce an annual report from 2010 which will provide ongoing assurance in relation to the delivery of patient centred services. In the interim, it has developed a small set of Key Performance Indicators in consultation with HIQA and has reported on indicators agreed with the Department of Health and Children in the HSE Performance Report, which is publicly available. Patient information material has been developed through broad consultation including consultation with the public. In relation to patient centred services more broadly, HSE Consumer Affairs has implemented "YOUR SERVICE YOUR SAY" to capture

feedback from the public in support of their statutory rights and includes data on complaints in the HSE Annual Report.

With regard to clinical governance of symptomatic breast services, roles and responsibilities of NCCP and the National Hospitals Office will be managed through the Integrated Services Programme and the establishment of an Integrated Services Directorate. An accountability framework was defined for the National Hospitals Office as part of the implementation of the Integrated Quality, Safety and Risk Management Framework. This was clearly articulated in the business plan for 2009. Implementation of the Integrated Quality, Safety and Risk Management Framework was supported across all hospitals through 2009 by the National Hospitals Office Patient Safety and Healthcare Quality Unit. With regard to audit and assurance, as set out above, HIQA will provide external assurance to the HSE in relation to symptomatic breast disease services. With regard to external assurance of laboratory services which support designated centres, Mater Hospital and St. James hospital and Cork ae fully accredited. St Vincents's University Hospital is accredited other than immunology (awaiting assessment), and Beaumont is provisionally accredited. Limerick and Galway are engaged in pursuit of accreditation and Waterford is to commence accreditation process. Once fully operational, the RCPI Histopathology Quality Assurance Programme will be a key component of the assurance of services for symptomatic breast disease. Assurance of services is also supported by monitoring of indicators by the NCCP (reported through the HSE Performance Report, which is publicly available) and local audit.

With regard to service user involvement, this is led nationally by HSE Consumer Affairs; central to this work is the implementation of "The National Strategy on Service User Involvement in Irish Health Services" across acute hospital services, primary care and residential care. This is overseen by an Implementation Oversight Group which includes service users and their representatives. A focus for this work is also provided by the Integrated Quality, Safety and Risk Management Framework which requires services providers to have processes in place for effective service user involvement. HSE Consumer Affairs and the National Hospitals Office plans to provide training to the acute hospital sector on service user involvement in support of the national strategy and the requirement of the Framework. Designated complaints officers are in place across hospitals operated or funded by the HSE in line with legislative requirements of Part 9 of the Health Act 2004 as part of the "YOUR SERVICE YOUR SAY" initiative. Efforts in relation to advocacy have focused on the residential care setting. The National Advocacy Programme was set up in January 2009 to empower older people in residential care to effectively voice their needs and wishes, access their entitlements and assert their rights. Each volunteer advocate was matched with an older person whom they would visit. As the basis of good citizen advocacy is a trusting relationship, volunteers have been asked for a minimum commitment of 18 months. Volunteers have undergone Garda clearance and training. The 'Advocacy Training Programme for Volunteers working with and for Older People in Residential Care Facilities' is run by the School of Community Studies, National College of Ireland. Volunteers were interviewed in March 2009 and the first training programme commenced in April 2009. HSE Consumer Affairs has identified the need to develop a framework for advocacy services and advocacy practice in health services in Ireland which is informed by this work and will have application more widely across the health services.

While reviews of risk management were initiated at the two hospitals subject to this investigation, throughout 2009 the NHO's Patient Safety and Healthcare Quality Unit supported the implementation of the Integrated Quality, Safety and Risk Management Framework across all HSE operated or funded hospitals through education and training materials and workshops. Development of Risk Registers was targeted as an early priority for hospitals. This is assured through reports received through the management line and through healthcare audit conducted by the HSE Office of Quality and Risk.

With regard to more general governance arrangements, an accountability framework further hospital system was defined for the National Hospitals Office as part of the implementation of the Integrated Quality, Safety and Risk Management Framework. A national service planning process is in place across the HSE in line with legislative requirements; progress in implementation of this service plan is reported publicly through the HSE Performance Reports. The national service plan is supported at a sub-national level by a tiered business planning process which spans from national directorate level through to individual hospital directorate level. Effective engagement of clinicians in management is achieved through the recent appointment of clinical directors and the implementation of the new consultant contract.

4. Conclusions

The National Director of the National Hospitals Office oversaw development of an implementation plan in relation to these recommendation based on input from relevant components of the HSE. Progress reports were collated. This report provides the Risk Committee of the HSE Board with the position in relation to these recommendations 12 months on from publication of that implementation plan. Ongoing internal monitoring and assurance of services for symptomatic breast disease will be provided by the NCCP through its system of audits and performance monitoring which will be reported publicly through the HSE Performance Report and its own Annual Report. External assurance will be provided to the HSE board by HIQA.

Elements in the report recommendations not captured through the NCCP will be managed through the HSE National Service Plan; progress will be available through the HSE Performance Report. Actions relating to service user involvement flow from the National Strategy which has an oversight and monitoring structure in place.

A final report on and implementation of recommendations arising from a review of risk management at MWRH Limerick is outstanding. The National Director of the National Hospitals Office will request that the relevant Regional Director for Operations within the new HSE structures to report to the Risk Committee of the Board in relation to this action.

Appendix 1: Terms of Reference of the first HIQA investigation

1. Introduction

In accordance with Section 9(1) of the Health Act 2007 the Health Information and Quality Authority (the Authority) will undertake an investigation into the circumstances surrounding the care of Rebecca O'Malley in relation to her symptomatic breast disease, and the provision of the symptomatic breast disease services provided by the Health Service Executive (the Executive) at the Mid Western Regional Hospital and pathology services provided by the Executive at Cork University Hospital.

Accordingly, the focus of the Investigation by the Authority will be on relevant aspects of the safety, quality and standards, including the governance arrangements, of symptomatic breast disease and pathology services provided by the Executive to Ms O'Malley and other patients, to ensure that best practice has been carried out and, if this is not the case, to ensure that where there may be serious risk to the health or welfare of a person receiving such services from the Executive, these risks shall be identified and recommendations can be made with a view to eliminating or ameliorating these risks for current and future patients. The Investigation shall be carried out within the following terms:

2. Terms

2.1. In respect of the period January 1st 2005 to 31st May 2007, the persons authorised to carry out the Investigation ("Investigation Team") will:

- 2.1.1. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of the services provided, and investigation undertaken, by the Executive to Rebecca O'Malley. The means of Investigation shall include (but not be limited to) inspection of medical records, imaging and slides.
- 2.1.2. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of pathology services provided by the Executive at Cork University Hospital with a view to identifying any circumstances which may give rise to a serious risk to the health or welfare of any person receiving or having received such services and further to make such recommendations as the Investigation Team see fit in relation to this.
- 2.1.3. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of symptomatic breast disease services provided by the Executive at (including but not limited to) the Mid Western Regional Hospital, Limerick with a view to identifying any circumstances which may give rise to a serious risk to the health or welfare of any person receiving or having received such services and further to make such recommendations as the Investigation Team see fit in relation to this.

2.2. If necessary the Investigation Team will carry out an investigation into one or more of the matters mentioned at 1.1, 1.2 and 1.3 above for such other period that the Investigation Team deems necessary if this becomes apparent during the course of the Investigation.

2.3. The Investigation shall be carried out in whatever manner and with whatever methodology the Investigation team believes is the most appropriate, having regard, in particular, to the clinical judgment of the Investigation Team. The scope of the Investigation will be limited to those patients and to those aspects of safety, quality, standards, and governance that the Investigation Team considers are most relevant and material to the Investigation.

2.4. The Investigation Team shall prepare a report outlining the Investigation, its findings, conclusions and any recommendations that the Investigation Team see fit to make.

2.5. If, in the course of the Investigation, it becomes apparent that there are reasonable grounds to believe that there is a serious risk to the health or welfare of any person and that further investigation is necessary beyond the scope of these terms of reference, the Investigation Team may in the interests of investigating all relevant matters, and with the formal approval of the Authority, extend these terms to include such further investigation within their scope or recommend to the Authority that a new investigation should be commenced as appropriate.

Appendix 2: Recommendations

Recommendation 1
A pathologist, together with a surgeon and a radiologist, all of whom should have a specific interest in breast disease, must always be present at a multi-disciplinary team meeting of triple assessment clinics. A discordant set of triple assessment results should trigger further discussion within the clinical team into the cause of such discordance.

Recommendation 2
Any patient who has a suspected delayed diagnosis of breast cancer should have immediate recourse to a multi-disciplinary team assessment with a formal response from a lead clinician. A delayed diagnosis should trigger a formal incident response including an internal root cause analysis, and the relevant senior management should be notified. The patient should be informed of the findings and outcome as a priority.

Recommendation 3
The HSE should urgently review the formal communications processes, policies and procedures which its hospitals uses to respond to patients when there is a serious incident, including communications within and between its hospitals.

Recommendation 4
Appropriate psychosocial support should be available to patients and their families at any stage during care for symptomatic breast diseases as recommended in the National Quality Assurance Standards for Symptomatic Breast Disease Services.3 (p.56)

Recommendation 5
When breast tissue sampling is required, a core biopsy should be performed under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities. Breast fine needle aspiration cytology should only be used when quality-assured with on-site cytopathology expertise.

Recommendation 6
To ensure the effective management and review of patients, a functioning multi-disciplinary team meeting must be held at least weekly, as part of the normal working day. One representative from surgery, radiology and pathology must be available with patient information, including imaging, pathology and copies of relevant clinical reports

Recommendation 7
Breast fine needle aspiration cytology must be quality assured. This should include:

- Units using breast fine needle aspiration as a diagnostic modality must audit the service and achieve the minimum standards set by the United Kingdom NHS Breast Screening Programme (BSP). Audit should calculate sensitivity, specificity, positive predictive value of C5, false negative rate, false positive rate, inadequate rate, inadequate rate from cancers and suspicious rates2
- Any units not achieving the minimum standards should introduce initiatives to improve the diagnostic performance of the technique. If the minimum standards are not achieved, fine needle aspiration should not be used as a diagnostic modality
- Reports must be clear and unambiguous and use the C1–C5 classification system2
- Any units using fine needle aspiration solely for breast lesions clinically thought to be benign, create a difficulty for pathologists to maintain diagnostic expertise for the entire spectrum of breast cytopathology and is therefore not recommended

Recommendation 8
Core biopsies should be reported using the B1–B5 system with classification of cancer type and grade
Pathology reports of breast cancer resection specimens should use:

- Template reporting with a minimum dataset for breast cancer specimens
- Microscopic confirmation of invasive tumour size

Recommendation 9
Clinical requirements at first attendance require triple assessment diagnostic procedures of clinical examination, imaging by mammography and/or ultrasound and pathology sampling.3 Prior to having invasive tests such as FNA or core-biopsy, all non-invasive tests should be considered and if relevant performed.
Recommendation 10
Senior management, together with clinicians in both organisations, should introduce new arrangements for the effective delivery of patient centred services. This should be measured, monitored and published in an annual report.
Recommendation 11
A robust clinical governance framework should be adopted at local, regional and national level. It should include as a minimum:

- At National and Hospital level, a named individual at senior management level should be responsible and accountable for clinical governance
- A quality and safety framework that includes a schedule of internal and external audits. This framework needs to focus on both organisational and speciality specific standards, including the National Quality Assurance Standards for Symptomatic Breast Disease Services and The Faculty of Pathology's Histopathology Quality Assurance Programme
- Laboratories should engage in a recognised accreditation programme in order to assure robust clinical governance at the laboratory level
- A patient liaison programme, which involves access to an independent advocate and a hospital appointed dedicated patient liaison person, as part of a complaints structure. This patient liaison person, who should be at a senior level, will be the principal point of contact with the patient and/or family. They must be kept appraised of all developments in the case and have the responsibility to brief the patient and/or family in a timely fashion of these developments. Protocols should be established to implement such arrangements

Recommendation 12
Risk management arrangements at both hospitals should be reviewed to ensure they demonstrate clarity of purpose, transparency in decision making and accountability in order to safeguard high standards of treatment and care. This should include a review of their arrangements for managing risk.
Specifically they should:

- Ensure that structures, roles and lines of accountability are clearly defined and reviewed on a regular basis to ensure consistency and clarity of purpose
- Identify areas where there may be gaps in controls and/or assurances and put in place corrective action as required
- Ensure monitoring and reporting systems are timely and effective
- Ensure that all staff involved in the risk management process are appropriately qualified, trained and supported with adequate resources available to them to fulfil their role effectively
- Review arrangements for communicating risk management policies to all staff

- Ensure that risks associated with working with other organisations or partners are explicitly assessed and managed

Recommendation 13

The hospitals should establish an effective, patient focused communication strategy that addresses the needs of internal and external audiences. This should include:

- Ensuring that the views and perspectives of patients, service users and front line staff are taken into account
- Supplementing the formal communication process with regular visits to the 'shop floor' and face to face dialogue
- The effectiveness of this strategy should be reviewed on a regular basis.

Recommendation 14

Governance arrangements need to be strengthened to ensure:

- Clarity of delegated levels of authority, reporting relationships and accountability at local, regional and national levels
- Transparent business planning and decision making processes
- Effective engagement and involvement of clinicians in the executive management process

Recommendation 15

The corporate HSE executive management team should nominate a specific director accountable for ensuring the development of an implementation plan for these recommendations. This should include a clear timeframe and milestones. Progress against the plan should be made public and reported to the Board of the HSE.