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

Summary

This report sets progress which has been made by the HSE in relation to recommendations proposed by HIQA arising from an 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. 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 SLAs for clinical services exchanged between the HSE and private sector. This matter will be brought to completion by the National Director for Commercial and Support Services.

1. 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 second investigation concerned issues arising from weaknesses in symptomatic breast services at a private provider which drew on services at Galway University Hospital (GUH) (see Appendix 1 for Terms of Reference). In response to recommendations (see Appendix 2), an implementation plan was developed in October 2008. It was published and accompanied by an apology to the individuals affected by the issues in the report. Two progress reports were publicly reported. It was agreed in 2009 with HIQA that the most appropriate next step was to review progress at a local (GUH) level and at national level 12 months on from publication of the investigation report. A meeting took place on the 29th of October 2009.

2. Progress at GUH

GUH reported arrangements with regard to its services for symptomatic breast services in October 2009.

- Implementation of National Quality Assurance Standards for Symptomatic Breast Disease Services
    - These standards have been implemented in GUH.
    - Regular multidisciplinary team meetings are in place and recorded.
    - The audit process using the National Standards for Symptomatic Breast Disease Services (2007) is in place and HIQA are undertaking external review.
    - In addition the NCCP receive monthly updates on the process as part of internal monitoring.
    - GUH have drafted a code of practice for institutions interacting with symptomatic breast service.

  These arrangements respond to recommendation 1 and 2.

- With regard to fine needle aspiration cytology services
    - Fine needle aspiration cytology is performed by one breast surgeon
    - A standard operating procedure is in place for the selection of patients who will benefit from this procedure
    - An audit against the minimum standards set by the UK NHS Breast Screening Program has been completed
    - The C1 to C5 classification system is used in reports

  These arrangements respond to recommendation 4.

- *With regard to cytology services generally,*
    - A single management system is in place with histopathology and cytology merged into a single department of anatomic pathology, administrated by a consultant pathologist.
    - A fine needle aspiration service has been developed with 3 consultant pathologists performing fine needle aspirates.
    - A quality management and document control system is in place
    - In addition Laboratory Management Review is undertaken in accordance with Standard 4.15 of ISO15189:2007(E).
    - The Department of Anatomic Pathology has had a pre-inspection visit by the Irish National Accreditation Board (INAB) on the 21st October 2009. A final inspection should take place in 3-4 months. The inspection is undertaken according to The International Standard ISO 15189 second edition 2007: Medical Laboratories – Particular Requirements for Quality and Competence.

  These arrangements respond to recommendation 5.

- With regard to the RCPI Faculty of Pathology Quality Assurance Programme
    - The department has implemented the Faculty of Pathology's Guidelines on histopathology quality assurance programmes.
    - This includes:
        - Intradepartmental consultation / peer review
        - Multidisciplinary case discussion
        - Incident Reporting and Risk management
        - Vertical case review / audit
        - Cytology Quality assurance with The College of American Pathologists.
        - The Apex laboratory Information System has been introduced to Anatomic Pathology.
        - A document control system is in place.(Q Pulse)

  These arrangements respond to recommendation 6.

2. Progress nationally

As with the first investigation, recommendations focussed on the development of symptomatic breast disease services. Within the HSE, the NCCP has responsibility for same and is driving compliance with the relevant national standards. Performance is internally monitored by the NCCP and is reported through the HSE Performance Report, which is publicly available (www.hse.ie). An external review is underway by HIQA which will provide independence assurance with regard to the status of the development of these services. 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.
- 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.

These arrangements respond to recommendations 1 and 4.

The exchange of diagnostic services between the public and private sectors was considered by the National Hospitals Office. It was concluded that

- A Service Level Agreement (SLA) should be put in place for any diagnostic laboratory and radiology services received by hospitals operated or funded by the HSE from private facilities.
- This SLA should include specification with regard to quality assurance and make provisions for effective management of same through the SLA.
- The indemnity for any diagnostic laboratory and radiology services received by hospitals operated or funded by the HSE from private facilities should be clarified with the Clinical Indemnity Scheme and made clear in SLA.
- A database to provide a central overview of these SLAs on an ongoing basis should be developed and maintained.

SLAs were drafted by the Contracts and Utilisation Division of the NHO to support services procured by HSE operated or funded providers from private providers and services provided by HSE operated or funded providers to private providers. The National Director of the National Hospitals Office will request that the National Director of the Commercial and Support Services Directorate now bring this work to completion.

These arrangements respond to recommendation 2.

The sharing of learning from the management of the incident at GUH was achieved through a Master Class led by the Director of the Serious Incident Management Team at the Royal College of Physicians in Ireland in October 2009. This was the first such event where the HSE Senior Managers, Clinical Directors, Directors of Nursing, Allied Health Professional Leads, Risk Managers, Quality Officers, External stakeholders from Department of Health & Children, HIQA, CIS and Patient Advocates came together to learn from incidents. There were over 200 attendees.

These arrangements respond to recommendation 3.

NCCP and 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. A Steering Group is in place to oversee implementation and HIQA sit as observers on this group. A representative from HSE ICT is also in attendance to manage ICT issues as they pertain to implementation. National Reports will become available in 2010.

These arrangements respond to recommendation 6.

Contributory factors to the issues which gave rise to the HIQA investigation included human resource management. The HR Directorate in the HSE has made significant progress towards addressing two broad issues:

(A) The need for the HSE to minimise reliance on temporary and locum staff

- *Workforce Planning Strategy*
  A Workforce Planning Strategy, prepared by the HSE and the DoHC, was recently published. The strategy aims to ensure that strategic and operational workforce planning processes are established as key activities in the health services and that staff recruitment is more responsive to changing service needs. An Assistant National Director for Succession Management within the HR Management Team has responsibility for implementation of the Workforce Planning Strategy and driving alignment of workforce planning with the service and financial planning cycles in the HSE in conjunction with HSE Corporate Control and Planning Directorate.
- *Minimise time lags in the appointment of permanent staff and consequent reliance on temporary staff*
  Temporary consultants are often employed on fixed purpose contracts to fill vacant permanent posts pending the filling of the post on a permanent basis. The management of the process for filling permanent consultant posts has now been centralised to the National Recruitment Service (NRS) in Manorhamilton during 2009. The process of recruitment of permanent consultant staff - which was formerly undertaken locally – is now managed and tracked centrally on a national basis. A weekly report is provided by the NRS to the Integrated Services Directorate and the Consultant Appointments Unit regarding the timescales associated with progressing permanent consultant posts. The timescale is currently on average 4 months form approval of a post to recommendation of a suitable candidate by the Public Appointment Service.

(B) Mitigate the key risks associated with recruitment of locum and temporary staff

- *Circular 14 / 2009 – revised procedural arrangements for the appointment of medical consultants*
  Circular 14 / 2009 was issued to all HSE and HSE funded agencies in May 2009. The circular includes comprehensive recruitment, monitoring and reporting procedures regarding the recruitment of locum and temporary consultant staff and ensures that the HSE now has a robust policy and set of procedures to be followed when recruiting such staff. The circular provides a step by step guide and includes an accompanying toolkit for recruitment mangers.The revised procedures are intended to ensure that
  - Persons employed as consultants are appropriately qualified and competent to provide consultant services
  - The HSE complies with the terms of its recruitment licence in the appointment of temporary and locum consultants
  - Those accountable and responsible for the recruitment of temporary and locum consultants are aware of their responsibilities
- *Qualifications*
  The HSE has changed the qualifications for consultant posts to make inclusion on the relevant specialist division of the Register held by the Irish Medical Council a **mandatory requirement** for all new appointees to permanent, temporary or locum consultant positions.
- *Formal agreements with specialist recruitment agencies*
  The HSE has almost completed the procurement of a national contract for the provision of locum consultants and NCHDs. SLAs are being finalised with a number of successful companies which will provide locum consultant and NCHD staff to the health service. These contracts formalise the relationship

between the health service and specialist recruitment agencies. Agencies will be required to supply locum consultant and NCHD staff to the health service in line with the requirements set out in the contract – including the requirement that all staff will be appropriately registered with the Irish Medical Council.
When the contracts are signed, all HSE and HSE funded agencies will be advised by way of a circular signed by the National Director of HR of the new arrangements for engagement with specialist consultant and NCHD recruitment agencies. Manpower managers in hospitals have been briefed in relation to the new arrangements.

- *Recommendations to implement Lynott Report recommendations*
  The Lynott report made a number of recommendations to mitigate the risk associated with the recruitment of locum and temporary consultant staff. The recommendations in the Lynott report which was published in 2002 have been to a large extent overtaken by developments in the intervening period:
  - Medical Practitioners Act 2007 allows the Medical Council of Ireland to advise the employer where a registered medical practitioner is under investigation in another jurisdiction.
  - Circular 14/09 (see above) has mitigated a number of the risks identified in the Lynott report associated with the employment of locum and temporary consultant staff – requiring that temporary or locum consultant staff are appropriately qualified; and requiring that all the staff are interviewed, reference checked etc.
  - Consultant's Contract 2008 – which is offered to all permanent, temporary or locum consultants – requires employees to sign declarations that they are not under investigation in any other jurisdiction.

Audit and assurance of implementation of these initiatives is important. The HSE Office of Quality and Risk has undertaken an audit of some of the controls set out above. Audit by the Commission on Public Service Appointments (CPSA) is ongoing to ensure that the HSE operates recruitment activity in line with the terms of its recruitment licence. Managers and staff are aware of the need for strict adherence to both the licence and various codes of practice issued by the CPSA. Further audit and level 1 assurance will be undertaken by the HR Directorate in relation to (1) the centralisation of recruitment activity to the National Recruitment Services and (2) the operation of Circular 14/2009 when the new arrangements have been operational for a reasonable period of time.
These arrangements respond to recommendations 7-10.

Recommendations made in relation to service user involvement are managed through implementation of "*The National Strategy on Service User Involvement in Irish Health Services"* by HSE Consumer Affairs in acute hospital services, primary care and residential care. An Oversight Implementation Group, including service users, is in place. The National Strategy, the implementation of the HSE Integrated Quality, Safety and Risk Management Framework, and the report by the Commission on Patient Safety an Quality Assurance have created a momentum in Irish health services to work in partnership with service users. To drive service user involvement in acute hospitals in line with the National Strategy and to meet the requirements of the HSE Integrated Quality, Safety and Risk Management Framework HSE Consumer Affairs

in collaboration with the National Hospitals Office is developing a training and support programme for hospital staff to implement in 2009 and 2010.

HSE Consumer Affairs is also focusing on service user involvement in primary care and in partnership with the Combat Poverty Agency it has established a finding initiative designed to support and enable disadvantaged communities and groups to participate in local primary care teams (PCTs) and networks. The initiative is currently being evaluated.

In addition to above, a web-page has been developed to promote service user involvement amongst health professionals in the Health Service Executive (http://www.hse.ie/eng/services/ysys/SUI/). The web page is useful resource for both service users and health professionals in identifying methods and practices for service user involvement in the health services.

Specifically in relation to advocacy, 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. Following the development phase it is hoped that the programme will be integrated into all community units and nursing homes in the country. The proposed National Advocacy Programme will support health services to anticipate problems early, avoid complaints, develop appropriate and effective service provision and guarantee that service users will be at the centre of efforts to drive up the quality and safety of service provision in long-stay units. Based on this initiative, HSE Consumer Affairs has identified the need to develop a framework for advocacy services and advocacy practice in health services in Ireland. The framework which will be drafted in partnership with relevant stakeholders including the Department of Health and Children will outline:

- What is considered as advocacy, including the goals of advocacy – patient centred care, patient safety and patient involvement
- Ethical practice in advocacy
- How service users should be empowered to self-advocate
- Advocacy for people with special needs
- The role of relatives, the role of health care professionals
- Independent advocacy
- Supervision and support, training in advocacy
- Recommendations for health care services

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. Designated complaints officers 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. *These arrangements respond to recommendations 11.*

3. Conclusions

The National Director of the National Hospitals Office oversaw the 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 HS 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 the report recommendations not captured through the NCCP will be managed through the HSE Corporate 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.

To date, much of the work undertaken by the HSE in relation to service level agreements has focused on its relationship with voluntary providers of health and social care. This work has now become a Key Performance Indicator for the organisation and will be reported in its Performance Report in 2010. Completion of action in relation to SLAs exchanged with private providers is outstanding. The National Director of the National Hospitals Office has corresponded with the National Director for Commercial and Support Services to request that he take responsibility for completion.

Appendix 1: Terms of Reference of the second 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 (the Investigation) into the provision of services to Ms A by the Health Service Executive (the Executive) at University Hospital Galway (the Hospital) in relation to her symptomatic breast disease, and the provision of pathology and Symptomatic Breast Disease Services by the Executive at the 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 the pathology and Symptomatic Breast Disease Services provided to Ms A and other patients by the Executive at the Hospital. The Investigation will seek to ensure that acceptable practice has been carried out and, if this is not the case, to ensure that where there may be serious risks to the health or welfare of a person receiving such services from the Executive, these shall be identified and recommendations can be made with a view to reducing 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 by the Executive at the Hospital, in respect of Ms A.
- **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 the 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. The means of Investigation may include (but not be limited to) inspection of medical records, imaging and slides.
- **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 the 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 sees 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 2.1.1, 2.1.2 and 2.1.3 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 sees 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
The National Standards for Symptomatic Breast Disease Services (2007) should be applied to all centres providing Symptomatic Breast Disease Services irrespective of whether they are in the public, private or voluntary sectors.17
Where the care of patients is shared across more than one facility or institution, arrangements must be in place to ensure effective governance, management and review. Regular multidisciplinary team meetings must be held (at least weekly) and in particular, clear leadership of care planning must be maintained.
Implementation of these standards should be subject to a co-ordinated process of quality review.

Recommendation 2
Where diagnostic services are provided by a third party facility (for example a HSE laboratory providing services for a private hospital), such an arrangement should be subject to a formal Service Level Agreement, or contract, which is effectively managed and regularly monitored to ensure appropriate governance and quality assurance of the service.
The HSE and voluntary hospitals should undertake a review of all such arrangements to ensure appropriate service agreements and monitoring are in place. Equally, private sector providers are strongly encouraged to review all relevant arrangements where care of their patients is shared between organisations.

Recommendation 3
UHG's experience in responding to this incident, including the process adopted for patient management, should be captured and used to inform the development and implementation of national guidelines for handling adverse incidents.

Recommendation 4
Units using breast Fine Needle Aspiration (FNA) as a diagnostic modality should do so only in an appropriate triple assessment context and with robust quality assurance. This should include:

- Clarifying the role of FNA cytology in the investigation of breast disease and applying agreed patient selection criteria
- Auditing the service against 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 rates
- Using the C1-C5 classification system to ensure reports are clear and unambiguous

Recommendation 5
A clearer direction is needed for the development and quality assurance of the diagnostic cytology service in UHG Pathology Department.

Recommendation 6
All pathology departments should implement the recommendations of the Faculty of Pathology's guidelines on histopathology quality assurance programmes in pathology laboratories. This incorporates, among other things:

- Intra-departmental consultation/peer review
- Multidisciplinary case discussion
- Incident reporting
- Vertical case review/audit

- Cytology quality assurance

Implementation of these recommendations must be supported by appropriate Information Technology systems.

Recommendation 7

The HSE should review workforce planning at national and local levels to ensure that recruitment of consultants is more responsive to changing service needs and reliance on temporary staff is minimised. This should include measures to reduce the time-lag between authorisation to appoint and staff taking up post.

Recommendation 8

It is recommended that the HSE Risk Sub-Committee progress and publish their work on mitigating risks associated with the employment of permanent and locum consultant staff. In the meantime, all local service providers should review recruitment policies and procedures to ensure robust verification and assessment processes are in place.

Recommendation 9

A formal policy for the recruitment of locum and temporary consultant staff should be established and implemented nationally to ensure more robust and effective arrangements and quality assurance mechanisms. This should include:

- Formalised agreements with specialist recruitment agencies which will include; their role, responsibility and area of accountability in the recruitment process. These agreements should be regularly monitored
- The provision for appointment panels to view and discuss all written references as part of the assessment process and before recommendation for appointment
- Account to be taken of existing competency levels of applicants as well as arrangements for their on-going development and support as temporary employees
- An agreed programme of audit against compliance

Recommendation 10

The recommendations of the Lynott Report (2002) should be implemented by the HSE and other service providers and compliance should be audited regularly

Recommendation 11

The role of independent advocacy services should be developed in all hospitals. These advocacy services should facilitate patients coming forward to raise concerns and have them addressed. Hospitals should encourage such services as part of a helpline and/or as part of patients' hospital attendance.

Recommendation 12

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 with milestones. Progress against the plan should be made public and reported to the Board of the HSE.