2 Summary of 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.

3 *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland. Dublin: Health Information and Quality Authority; 2007.*

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.[3 (pp15-16)]

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 rates*[2]
- *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 system*[2]
- *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.[4]

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*

2 *Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

3 *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland. Dublin: Health Information and Quality Authority; 2007.*

4 *Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD. Guidelines for breast needle core biopsy handling and reporting in breast screening assessment. J Clin Pathol 2004;57:897–902.* *See also Appendix 7, page 71.*

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*[5]
- *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*

3 *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland. Dublin: Health Information and Quality Authority; 2007.*

5 *Faculty of Pathology Histopathology QA programme. Dublin: Faculty of Pathology, Royal College of Physicians of Ireland; 2007.*

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.