Report on the Circumstances that led to the decision by HSE in August 2007 to:

- Suspend Breast Radiology Services
- Initiate a Clinical Review of Symptomatic Breast Radiology Service
- Place Consultant Radiologist on administrative leave

at Midland Regional Hospital, Portlaoise

24th January 2008
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Section 1 – Introduction

On November 7th 2007 the Secretary General of the Department of Health and Children, Michael Scanlon, on behalf of his Minister, wrote to Professor Brendan Drumm, CEO requesting an urgent Report on the circumstances which led to the decisions by the HSE to:

1) Suspend the breast radiology service
2) Place the consultant radiologist on administrative leave and
3) Initiate a clinical review of breast cancer services in the period November 2003 to August 2007
   at the Midland Regional Hospital, Portlaoise.

On 13th November 2007, Professor Brendan Drumm wrote to Michael Scanlon confirming the appointment of a group to undertake this review, led by Ms. Ann Doherty, National Director, Corporate Planning and Control Processes. The Terms of Reference for this review were agreed with the Minister for Health and Children on November 29th 2007.

Membership of Review Group
Ms. Ann Doherty, National Director, Corporate Planning and Control Processes, HSE
Mr. Barry O’Brien, Assistant National Director, Human Resources, HSE South
Ms. Mary Shore, Director of Quality, Risk and Consumer Affairs, St. Vincent’s University Hospital, Dublin

The group reserved the right to source appropriate additional support and advice as required.

Terms of Reference
- The review group will prepare a report for the CEO
- The report aims to establish factually all matters that led to the decisions taken

Methodology
The review group:
- Requested copies of all correspondence and documentation regarding the above issues
- Reviewed all correspondence and documentation internally and externally
- Conducted interviews with all relevant personnel who could inform the group and assist in establishing the facts.

The review group wishes to acknowledge the participation of all those who submitted information/documentation and/or met with them.
Section 2 – Background to Cancer Services in the former Midland Health Board

Cancer Services in Ireland: A National Strategy was published in November 1996. This document designated the Midland Regional Hospital, Tullamore as the lead hospital for cancer treatment services in the former Midland Health Board area, to co-ordinate the work of other hospitals in the region. The National Strategy stated that a Regional Service should have a Regional Director of Cancer Services (responsible for organising and auditing the region’s cancer services). Professor Donal Hollywood was appointed to this role.

The National Cancer Strategy 1996 emphasised:

- In essence, each hospital should develop its cancer services within the protocols and structure devised by the Regional Director in consultation with the hospitals and professions. It is critical that the regional services have close links with the supra-regional services, primary care facilities and palliative care so as to ensure rapid systems of referral, diagnosis and effective management.

- The larger hospitals within the regional services would manage the more common cancers such as those of the breast, bowel and lung, and would be of sufficient size to support a clinical team with staff and facilities to manage these cancers. Many of the smaller hospitals would not have the specialist staff or volume of cancer-related work to cater for certain cancers, since a minimum critical throughput of patients with different forms of cancer is necessary to provide effective care. Nonetheless, these smaller hospitals must form an integral part of the regional service. In particular they enable more patients to be treated close to their home where this is possible.

- All hospitals providing regional cancer services must have adequate diagnostic facilities to enable them to manage the type of cancers for which they are responsible under agreed protocols. In addition, specialist out-patient clinics should be available in designated smaller hospitals and these should have appropriate back-up from clinicians and specialist cancer nurses.

Professor Hollywood developed a Regional Cancer Plan for the Midland Health Board in 1998, following consultation with Consultants in each of the acute hospitals in the Midland Health Board (MHB). This plan was placed on the agenda of the Midland Health Board in March 1998 and adopted on September 28th 1998.

This plan recommended:
- Appointment of a Medical Oncologist
- Appointment of a Haematologist

to the Midland Regional Hospital, Tullamore with sessional commitment to the Midland Regional Hospital, Mullingar and the Midland Regional Hospital, Portlaoise.

In January 1999, Comhairle na nOspideal approved the appointment of the Consultant Haematologist and a Consultant Medical Oncologist to the Midland Regional Hospital, Tullamore with a sessional commitment to the Midland Regional Hospital, Portlaoise and the Midland Regional Hospital, Mullingar. The Consultant Haematologist and Oncologist posts were advertised. The competition for the appointment of the two consultant posts, which had been suspended pending outcome of a Judicial Review, proceeded.

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The report on the Development of Services for Symptomatic Breast Disease\textsuperscript{3} was published in March 2000. This report emphasised:

*It is imperative that women with symptoms of breast disease are referred to diagnostic breast clinics. This is important, as mammography alone is not appropriate for women who have symptoms. Women with symptoms must have the benefit of triple assessment, (clinical examination, imaging and pathology assessment). No single test undertaken affords sufficient safeguard against breast cancer being missed. When all three tests are used in the appropriate clinical setting, diagnostic sensitivity and specificity rise. It is important to ensure that women themselves understand that screening is for healthy women without symptoms. They must not self-register when they discover symptoms but rather should attend a diagnostic symptomatic clinic, if their GP thinks appropriate.*

The report further indicated:

*The population of the Midland Health Board marginally supports one unit. There is a small breast service currently in Mullingar. There is no service in Tullamore. Patients currently travel to Portlaoise where a long established unit with considerable clinical expertise and a great deal of ancillary patient-focused and orientated support at medical and nursing level has been developed over many years. Bearing in mind that the great majority of women attending the clinic will not have cancer, it is not essential to locate the Breast Unit in the designated regional cancer centre. Because the delivery of breast services can largely be delivered in non emergency settings, it is unlikely to require high dependency support. However, there is concern that the peripheral location of Portlaoise in the Health Board might militate against achieving the critical mass of patients required for the Unit. There would be a case to be made for locating the Breast Unit in Tullamore because of its geographical location in the Health Board and because this would fit in with previous decisions made by the Health Board regarding the organisation of oncology and pathology services. It is essential that the available expertise that already exists within the Health Board should be fully utilised in the new Breast Unit and professionals with an avowed and continuing interest from the other hospitals should be allowed to participate. This will entail making provision for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit. Should the decision be to locate the Breast Unit in Tullamore then the existing and longstanding expertise of those involved in the Portlaoise unit should provide the basis of the service in Tullamore. This will ensure that a highly valued, quality service will be provided to all women in the Midland Health Board region.*

This Report was considered at the MHB Meeting in November 2000. The Board reiterated the decision that was made at the September 1998 meeting, i.e.

- Appointment of a Medical Oncologist
- Appointment of a Haematologist

to the Midland Regional Hospital, Tullamore with sessional commitment to the Midland Regional Hospital, Mullingar and the Midland Regional Hospital, Portlaoise.

The Letter of Determination (2001), issued by the Department of Health & Children and received by the Midland Health Board, provided an allocation for the development of a Breast Unit at the Midland Regional Hospital, Portlaoise only.

In April 2001, following a facilitation process at Board level involving consultant medical staff at the three acute hospitals, the Regional Director of Cancer Services and Management, a service model was developed for the provision of breast cancer services. It was reported to the review group that this was not a consensus view and there was a significant lack of agreement on pursuing an “outreach model” or “virtual centre”. This process resulted in the development of a Specialist Breast Unit at the Midland Regional Hospital, Portlaoise with outreach services to the Midland Regional Hospital, Mullingar.

Throughout the period 2000 – 2005, the Regional Director for Cancer Services advised the then Midland Health Board that the ideal situation would be to centralise cancer services at one unit, to avoid fragmentation.

Section 3 – Management Structures - Acute Services, Midland Regional Hospitals, Mullingar, Portlaoise and Tullamore

- National Director, NHO
- Network Manager
- General Manager
  - Hospital Manager, Midland Regional Hospital, Portlaoise
  - Hospital Manager, Midland Regional Hospital, Tullamore
  - Hospital Manager, Midland Regional Hospital, Mullingar
Midland Regional Hospital, Portlaoise

Network Manager
John Bulfin

General Manager
Joe Martin

Hospital Manager
Declan McCormack

Director of Nursing
M. Nolan

Catering
Housekeeping

Surgery
* P. Naughton

Medicine
* J. Connaughton

Paeds
* M. Conran

Obs/Gynaec
* J. Correstine

Anaesthetics
* B. Ward

A & E
* S. O’Rourke

Cardiac Rehab
Radiology
* Dr. Ramesh
Laboratory
* D Gilsenan
Physio
Maintenance

* Each Department is normally represented by a Senior Clinician in discussions with Management
Medical Board also in existence – no executive decision making functions
- Hospital Management Committee Meeting – monthly
  Attendees – General Manager Acute Hospital Services, Hospital Manager, Director of Nursing, Chair of Medical Board, Secretary of Medical Board

Denotes Job Description Reporting Relationship
Denotes Day to Day Working Relationship

4 Organisational chart provided to review group by the National Hospitals Office. The Review Group received other charts from some participants, which were not in complete accordance with the chart received from the NHO
Section 4 – Decisions

Decision 1: Suspend Breast Radiology Services
Decision Maker: Network Manager
Date of decision: 28/8/07

Circumstances leading to decision:

1. In late June 2007 the Clinical Nurse Specialist (CNS), Oncology/Breast Care, expressed concern to the Director of Nursing (DoN) regarding the time patients had to wait for diagnosis. This concern, which she understood was shared by colleagues, was based on complaints she had received from patients and on her own observation that there were instances where individuals had multiple diagnostic investigations in one, two or three locations and which had created a waiting period in some instances between four to eight months for an outcome. She also observed a difference in reporting between the original report from Radiology service in Portlaoise and in subsequent reports. This highlighted cases of over reporting to her.

2. DoN requested CNS to report specific incidents via Incident/Near Miss Report Forms.

3. CNS reported 8 instances where radiological diagnosis differed from reports at Midland Regional Hospital Portlaoise (MRHP) and St Vincent’s University Hospital (SVUH).

4. Incident/Near Miss Report Forms completed 26/7/07 and 13/8/07.

5. On receipt of completed Incident/Near Miss Report Forms, DoN highlighted her concerns in letter to Network Manager on 15/8/07.

6. Meeting arranged to discuss issues on 28/8/07 (this being the first available date on which all participants were available to meet).

7. Meeting on August 28th 2007 was attended by:
   - Network Manager
   - General Manager, Acute Hospital Services
   - Manager, Strategic Planning and Performance Management
   - Hospital Manager, Midland Regional Hospital Portlaoise
   - Risk Manager
   - Director of Nursing, Midland Regional Hospital Portlaoise
   - Clinical Nurse Specialist, Oncology/Breast Care

8. Decision to suspend breast radiology service made by Network Manager, based on the information available to him and the discussion at the meeting.


10. The Network Manager reports that no one raised objections with him about this decision.

11. Consultant Radiologist on duty was also informed of decision by the General Manager following the meeting on August 28th

12. See also Section 5 of this report.
Decision 2: Initiate a Clinical Review of Symptomatic Breast Radiology Service

Decision Maker: Network Manager

Date of decision: 28/8/07

Circumstances leading to decision:

1. In late June 2007 the Clinical Nurse Specialist (CNS), Oncology/Breast Care, expressed concern to the Director of Nursing (DoN) regarding the time patients had to wait for diagnosis. This concern, which she understood was shared by colleagues, was based on complaints she had received from patients and on her own observation that there were instances where individuals had multiple diagnostic investigations in one, two or three locations and which had created a waiting period in some instances between four to eight months for an outcome. She also observed a difference in reporting between the original report from Radiology service in Portlaoise and in subsequent reports. This highlighted cases of over reporting to her.

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5. On receipt of completed Incident/Near Miss Report Forms, DoN highlighted her concerns in letter to Network Manager on 15/8/07.

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7. Meeting on 28th August 2007 attended by:
   - Network Manager
   - General Manager, Acute Hospital Services
   - Manager, Strategic Planning and Performance Management
   - Hospital Manager, Midland Regional Hospital Portlaoise
   - Risk Manager
   - Director of Nursing, Midland Regional Hospital Portlaoise
   - Clinical Nurse Specialist, Oncology/Breast Care

8. Decision to suspend breast radiology service made by Network Manager, based on the information available to him and the discussion at the meeting.

9. Concerns regarding the identified 8 false positive radiological diagnoses of potential breast cancers, as raised through the DoN.

10. Concern regarding the potential for false negative reports was also highlighted at the meeting of August 28th 2007. There is not full agreement from those present at the meeting on the content and extent of the discussion on false negatives on the day.

11. The Network Manager took the decision to initiate a Review of Breast Radiology services being provided at Midland Regional Hospital, Portlaoise, to be undertaken as soon as possible.

12. Consultants in Breast Surgery informed of decision after the meeting by the Network Manager on August 28th 2007.

13. Consultant Radiologist on duty informed of decision by the General Manager on August 28th 2007.

14. See also Section 5 of this report.
Decision 3: Place Consultant Radiologist on administrative leave
Decision Maker: National Director, National Hospitals Office (NHO)
Date of decision: 30/8/07

Circumstances leading to decision:

1. No Consultant Radiologist employed in Midland Regional Hospital, Portlaoise with special interest in breast radiology.

2. There are two Consultant Radiologists at Midland Regional Hospital, Portlaoise. One of these did the majority of the breast radiology work.

3. It has not been possible to recruit a Consultant Radiologist with a special interest in Breast Radiology to the Midland Regional Hospital, Portlaoise (2 national public competitions were unsuccessful).

4. It was the clinical practice of a consultant surgeon to send some mammograms for 2nd opinion to St. Vincent’s University Hospital. Since 2005, this arrangement was made with the approval and support of the Network Manager.

5. Evidence of variations between reports by Consultant Radiologist, Midland Regional Hospital, Portlaoise and St. Vincent’s University Hospital was highlighted at meeting of 28/8/07.

6. Following a report of a clinical incident in Midland Regional Hospital, Tullamore in January 2006, a risk management review was undertaken. The report of this review was completed in January 2007, with a recommendation for a clinical performance review. This is known as RM50. The summary of recommendations is included in Appendix 3. At their meeting on August 28th 2007 Management were aware that the recommendation of RM50 continued to be an outstanding issue.

7. The General Manager furnished to the Review Group minutes of the meeting of 28th August 2007. These minutes record the decisions of the meeting. There is not full agreement from those who attended the meeting of the 28th August 2007 either on the content or extent of the prior discussion. The Network Manager informed the review group that while he “was aware that one of the Consultant Radiologists had performed the majority of breast radiology, he felt that it was not appropriate to discuss an individual’s performance at such a meeting”. There is no reference to such a discussion in the minutes of the meeting.

8. Decisions 1 (suspension of breast radiology services) and 2 (initiation of clinical review) were communicated to the National Director of the NHO by the Network Manager.

9. On the 29th August 2007, the National Director discussed the matter with the Network Manager and the Assistant National Director, Quality, Risk & Customer Care. The National Director informed the Review Group that, in considering the matter, all 3 expressed reservations as to whether administrative leave was warranted in this case. The following day, the Director of the NHO, as the senior decision maker, made a judgement call, on the balance of the available information, to place a Consultant Radiologist on administrative leave, in the interests of patient safety.

10. See also Section 5 of this report.
Section 5 – General

Multidisciplinary Teams (MDT)
It was confirmed to the review group that, with the exception of Oncology services, there are no MDT meetings in relation to patients attending the symptomatic breast services in Portlaoise. This is also the case in the clinical governance arrangements within Midland Regional Hospital, Portlaoise. The review group found that the role of lead clinician, as envisaged in the Development of Services for Symptomatic Breast Disease, March 2000 (page 7 & 8), is not in place in Portlaoise.

Clinicians in Management
Consultant Medical staff were not invited to, nor were they present, at the meeting held on August 28th 2007, where two of the decisions were taken in relation to the Breast Radiology Services. It was also confirmed that this matter was not discussed by the Hospital Medical Board. The review group found that there were differing opinions as to why Consultant Medical staff do not regularly participate in management at the Midlands Regional Hospital Portlaoise.

Quality and Risk Structures
There is a significant investment within the HSE Midland area in the functions of quality and risk. There is no formal reporting relationship between Quality and Risk and hospital management. The review group found that the recommendations of RM50, which were made in January 2007 and which related to an incident in January 2006, remained outstanding as of 28th August 2007.

Roles and Responsibilities
The organisational chart provided to the review group by the National Director, NHO, detailed reporting relationships of key staff for Midland Regional Hospital, Portlaoise. The review group found that there was a difference of opinion regarding these formal reporting relationships, for example, the Hospital Manager in Midland Regional Hospital Portlaoise, described his job as similar to the role of the Senior Hospital Administrator in the former Health Board structure and his understanding was that the reporting relationship of the Consultants, together with the Director of Nursing (DoN), is to the General Manager. The DoN confirmed that her post reported to the Network Manager.

Single Service Multiple Sites 5
Acute hospital services in the HSE Midland area are described to the review group as a single hospital on three sites. The model for the provision of symptomatic breast disease services in the former Midland Health Board is at variance with the National Cancer Strategy. The review group was informed that this model led to problems with recruitment and fragmentation of services.

Decision Making
The review group found that the information and concerns of the CNS were being advanced in two separate processes. The first process was from the DoN directly to the Network Manager, the second from Risk Management through Hospital Management to General Manager level. The Review Group noted that there were different views as to the content and extent of the discussion at the meeting on the 28th August 2007. Further, there was no medical consultant at the meeting.

External influences
During the review a number of references were made to other external factors of which there was awareness at the time, i.e. the publicity surrounding cancer services at Barrington’s and misdiagnoses at Cork and Limerick. The decision makers confirmed that the decisions were in no way influenced by these external factors.

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5 See also Section 2, pages 2 and 3
Terms of Reference of Review

1. Following a request by The Minister for Health and Children the CEO of the HSE has established a group to review the circumstances that led to the decisions by the HSE in relation to the Midland Regional Hospital, Portlaoise to:-

   • Suspend the breast radiology services
   • Place the consultant radiologist on administrative leave
   • Initiate a clinical review of the breast cancer services

Review Group Membership
Ms. Mary Shore, Director of Quality, Risk & Consumer Affairs, St Vincent’s University Hospital, Dublin
Mr. Barry O’Brien, Assistant National Director, Humana Resources, HSE South
Ms. Ann Doherty, National Director Corporate Planning and Control Processes

The group reserved the right to source appropriate additional support and advice as it requires

Terms of Reference

• The review group will prepare a report for the CEO
• The report aims to establish factually all matters that led to the decisions taken

To complete this task the group will:-

• Request copies of all correspondence and documentation regarding (1) above
• Create a log of all documentation and correspondence received
• Review all correspondence and documentation internally and externally
• Conduct interviews with all relevant personnel who can inform the group and assist in establishing the facts

The group would like noted:
• This is not a clinical review
• Full co-operation from all staff involved is required

Time scale for completion
The group considers that this work will take between 4-5 weeks from approval of the TOR and approach

Week 1      Request all relevant documentation
Review of documentation received and supplementary documentation if required, sourced
Week 2      Conduct Interviews
Output from interviews returned to interviewees for validation for accuracy
Week 3      Review of all inputs
Week 4      Compilation of final report
Week 5      Final report submitted

Review Group Working - Ground Rules
- Confidentiality
- Respect for all views
- Transparency
- Just and fair approach
- Commitment to due process and natural justice
Minutes of Meeting – Version with full names redacted and replaced by titles

Date of Meeting: 28th August 2007

Venue: Midland Regional Hospital Portlaoise

Present:
- Mr. John Bulfin, Network Manager
- Mr. Joe Martin, General Manager Acute Hospital Services
- Mr. Moss McCormack, Manager Strategic Planning & Performance Management
- Mr. Declan McCormack, Hospital Manager
- Ms. Breda Dooley, Risk Manager
- Ms. Maureen Nolan, Director of Nursing MRHP
- Ms. Yvonne Hanhauser, Clinical Nurse Specialist, Breast Services (present for part of meeting)

Subject: Concerns regarding Breast Radiology diagnosis at Midland Regional Hospital Portlaoise

Opening the meeting Mr. Bulfin (Network Manager) requested Ms. Nolan (Director of Nursing MRHP) to outline her concerns regarding the Breast Radiology service as set out in her letter of 15 August. Ms. Nolan (Director of Nursing MRHP) gave details of concerns expressed by the Clinical Nurse Specialist regarding the high number of false positives being recorded in Breast Radiology results at Midland Regional Hospital Portlaoise. It was also noted that some films are reported on locally while some are sent to S1. Vincent's for report. Details were also given of forms which were reported on by Radiologists at Midland Regional Hospital Portlaoise and were subsequently sent to S1. Vincent's for report with different clinical results coming from that Report. It is in these circumstances that the high level of false positives are being discovered.

Following a full discussion in the matter it was agreed that

1. a Review of Breast Radiology services being provided at Midland Regional Hospital Portlaoise to include Mammograms and Ultrasound films needs to be undertaken as soon as possible.
2. the Breast Radiology service at the Hospital should be suspended pending the results of the proposed Review.
3. Dr. V. Moodley, (the Consultant Radiologist) who carried out the vast majority of the Breast Radiology tests at the Hospital should be immediately informed that no further such tests are to be carried out at the Radiology Department, Midland Regional Hospital Portlaoise.

It was also agreed that relevant statistical information on Breast Radiology services would be urgently required to facilitate the Review. A discussion took place on the likely statistical requirements during which Ms. Hanhauser (Clinical Nurse Specialist, Breast Services) joined the meeting because of her knowledge of the service currently provided.

The following statistics were listed as being required:
1. Total number of mammograms
2. Total number of positive results
3. Total number of negative results
4. Total number referred for second opinion
5. Total number at variance with initial diagnosis

In the context of the proposed Review it was established that the following issues would need to be clarified:
1. Review period
2. Type of Review (patient care to be paramount importance)
3. Internal Radiologists involvement in Review
4. Timeframe

It was agreed that [Generic Manager Acute Hospital Services] would contact [a consultant radiologist] to inform her of the decision. [Network Manager] indicated that he had been in contact with the Consultant Surgeons at the Hospital to inform them of the situation.

This completed the business of the meeting.

General Manager
Acute Hospital Services
Appendix 3

Summary of Recommendations of Risk Management Report 50 (RM50)

Care Management Problem; Failure to diagnose fractures on cervical Computerised Tomography Scan

Recommendation

1. That a clinical performance review should be conducted in relation to this specific aspect of the incident i.e. Consultant Radiologist C failure to diagnose fractures from the computerised tomography scan conducted on Patient X be examined by a suitable qualified clinical expert or peer. This clinical performance review should be conducted in a manner that is compliant with Data Protection and Confidentiality requirement of the HSE. It should be conducted in a manner that treats the clinician reasonably, fairly, impartially and in a supportive manner in all aspects of the review process, and recognises his / her right to natural justice. The purpose of the clinical performance review would be to determine - by competent investigation -whether or not clinical performance issues and / or patient safety issues exist. If clinical performance issues and / or patient safety issues are identified by competent clinical performance review, an additional purpose will be to obtain advice from the competent reviewers about how to manage the issues raised so as to ensure optimal patient safety and to ensure that the clinician is adequately supported to do the job for which he / she is employed going forward.

2. The issue of introducing structured systems of performance management for clinical personnel is explored and resolved without delay.
Appendix 4

Issues Raised by Participants

The Review was not conducted as a judicial or disciplinary process. In particular, formal evidence was not taken. Participants were not cross-examined or re-examined. Such processes are not appropriate, nor are they permitted by the Terms of Reference. The Review Group has endeavoured to establish certain facts in accordance with its Terms of Reference. This Report does not purport to say that all facts have been established. The Review Group acknowledge that they were not able to resolve some intractable disputes of fact but the Review Group is satisfied it has acted in accordance with its Terms of Reference.

A number of participants disagreed with some of the emphasis of the Report and/or with the wording of the Report when furnished to them in draft form. The Review Group has been requested to vary the report in some respects. The Review Group has carefully considered all responses in the formulation of this Report and has incorporated such responses as are appropriate. A number of significant issues were raised by the participants but they fall outside the Terms of Reference.