Management, Governance and Communications issues arising from the Review of Breast Radiology Services at Midland Regional Hospital Portlaoise

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Management, Governance and Communications issues arising from the Review of Breast Radiology Services at Midland Regional Hospital Portlaoise

Section 1

1. Introduction

1.1 On 27th November 2007 the Minister for Health and Children wrote to the Chairman of the Board of the Health Service Executive requesting that the Board of the HSE undertake an immediate review of the management of all the events starting from, and subsequent to, the decisions by the HSE to suspend the breast radiology service at the Midland Regional Hospital Portlaoise, place a consultant radiologist on administrative leave, and initiate a clinical review of breast cancer services at the hospital.

1.2 This request was considered by the Board of the HSE at a special Board meeting on 27th November 2007. The Board decided to establish a Board committee, chaired by the HSE Board Chairman, to finalise terms of reference for the review and to engage an external independent person to assist in conducting it. The review was to be initiated immediately and concluded as a matter of urgency.

1.3 Terms of Reference for the Review were drafted by the Board Committee on 29th November 2007, and subsequently approved by the Minister for Health and Children. These are attached in full at Appendix 1.

1.4 On 7th December 2007 the Board of the HSE announced that I had agreed to act as the external independent resource to assist the Board in conducting the review, and that I would determine the facts in relation to the matters covered in the Terms of Reference. In conducting the review I was to examine relevant correspondence and documentation relating to the period in question, and conduct interviews with persons as necessary to establish the facts and complete a report for the Board.

1.5 I would like to thank all those who have given generously of their time in helping me conduct and conclude the review.
Section 2

2.1 Background

Arising from concerns expressed by some staff at Midland Regional Hospital Portlaoise (MRHP), a decision was made at a meeting at MRHP on 28th August to undertake a Review of Breast Radiology Services at MRHP, and to suspend breast radiology services at the hospital “pending the results of the proposed review”. The record of the meeting at which the decision was made shows that the Review of Breast Radiology Services discussed was to include a review of Mammograms and Ultrasounds, although confusion subsequently arose as to whether these were part of the same review, or were in fact separate reviews. This confusion came to the fore on and around the 22nd November when HSE gave evidence to the Joint Oireachtas Committee on Health and Children, including providing details of the ultrasound review and the numbers involved. Consequently, my review relates to management and communication of the process between end-August 2007 and end -November 2007.

2.2 Terms of Reference and Methodology

The terms of reference for my review (attached at Appendix 1) requested me to focus, in particular, on

a) the manner in which the HSE dealt with patients throughout the period
b) the governance and management of all aspects of the process, and
c) the communication arrangements with patients, internally within the HSE, and with the Department of Health and Children.

In carrying out my review I have spoken with a number of people directly, or indirectly, involved in the events surrounding the review of breast radiology services at Portlaoise (a list of the people I have spoken to is at Appendix 2). I have also reviewed copies of relevant correspondence and emails during the period, based on documentation supplied to me by HSE.

The record of events set out below is not exhaustive, but representative. Their significance, and the issues I have identified arising from this review, represent my interpretation based on what I have heard in interviews and read from the files. I believe that the imperative is to learn from the events so that weaknesses identified can be redressed, and that any similar difficulties can be avoided in the future. In this report I do not focus on the role of any specific individual/s in the process, because I believe that to do so would be unfair given the considerable pressure of work that people were under, but more importantly that by doing so I might create the erroneous impression that problems arose primarily from the action or inaction of individuals, rather than from what in my view were systemic
problems of governance, management, and communication. In my view these are the issues that need to be addressed in order to avoid any possible recurrence.

The rest of this report is divided into two sections:

Section 3 sets out what seem to me some of the significant dates and events relating to the review of Breast Radiology Services at MRHP over the period from end-August to end-November 2007.

Section 4 sets out my assessment of some of the key issues raised and findings, with specific reference to the areas of management, governance, and communications, as requested in the terms of reference.

Throughout the report I refer for convenience to the various levels of management within HSE as local management (referring to Midlands Regional Hospital Portlaoise), area management (referring to the HSE Midlands Hospital Network Office) and corporate HSE (to refer to other central management roles in HSE).

**Section 3**

**3.1 Overview**

The purpose of this review, as stated in the terms of reference, was to undertake an examination of the management of all events starting with, and subsequent to, the HSE decisions to suspend the breast radiology service at Portlaoise, place a consultant on administrative leave, and initiate a clinical review of breast cancer services at the hospital. Effectively this encompasses the period from 28th of August 2007, when these decisions were made, until end November 2007, when the decision was made to set up clinics in Portlaoise run by Prof Hill and Mr. Allen to follow up cases identified in the review of ultrasounds.

In all 3037 mammograms in respect of 2150 patients, and 648 ultrasounds in respect of 607 patients were clinically reviewed as part of the Review of Breast Radiology Services at Midland Regional Hospital Portlaoise. The mammogram review process and the ultrasound review process effectively related to two different cohorts of patients, with some small overlap in respect of patients covered by both.

I do not consider it relevant or necessary to set out every detail of communication during that period, which was often happening on a daily basis between various parts of the HSE and/or between the HSE and the Department of Health and Children. However a description of what I regard to be key points and events in
the process can conveniently, for the purposes of this analysis, be grouped into three periods. These are:

- the two weeks immediately after the 28\textsuperscript{th} of August that saw the review of breast radiology services established;
- the period from mid-September to the 21\textsuperscript{st} November when the review was ongoing;
- the period after 21st November when the details of the ultrasound review were communicated to the Oireachtas Committee.

3.2 The two weeks from 28\textsuperscript{th} of August

Arising directly from concerns expressed by the Director of Nursing at Portlaoise, a meeting of area and local hospital management was convened at Midland Regional Hospital Portlaoise (MRHP) on 28\textsuperscript{th} August which agreed that a Review of Breast Radiology Services provided at MRHP would be carried out, and that this would include a review of both mammograms and ultrasounds. At this meeting it was also agreed that the breast radiology service at the hospital would be immediately suspended pending the outcome of the review.

A note headed ‘Briefing note for the Minister’ was sent on 30\textsuperscript{th} August from the Midlands Hospital Network Office to the Department of Health and Children, and this note set out the details of what had been decided and also indicating, inter alia, that “St Vincent’s Hospital, in conjunction with Breastcheck, will facilitate the review of all radiology breast diagnosis carried out at MRHP since November 2003”. It also specified in this note the number of mammograms and ultrasounds conducted at MRHP since 2003, and that the review was likely to take one month.

It is relevant to point out that the reason why the concern about diagnosis at MRHP had arisen in the first place was because of a concern among some staff about the number of ‘false positives’ being reported. In other words it was believed that an unusually high number of breast radiology findings were being referred for a second opinion, and subsequently found to be negative. The concern was that the patients involved were being subjected to unnecessary anxiety and delay in relation to their diagnosis. The concern therefore related to over-diagnosis rather than under-diagnosis, and was not based on a concern that cancers were being missed. It is also relevant to point out that while a film exists in the case of mammograms, which can therefore be subsequently reviewed, ultrasound by its very nature do not leave a visual record, and so all that can be reviewed are the clinical notes attached to the patient record.

On 31\textsuperscript{st} August a formal request issued to the Consultant Radiologist, St Vincent’s Hospital, to carry out a review of the mammograms conducted at MRHP since November 2003. The Consultant Radiologist made it clear from an early date that while she and her team would carry out the review of the
mammograms, that they would not be in a position to review the ultrasounds, but would provide the criteria so that this element of the review could be carried out locally by the clinicians at MRHP. This she subsequently did.

On 3rd September a press release was issued by HSE Regional Office which indicated that St Vincent's Hospital, in conjunction with Breastcheck, would facilitate the review of "all radiology breast diagnosis" at MRHP, and that the likely duration would be one month. The press release also indicated that ‘any patient affected will be contacted directly by HSE’.

On 7th September a further press release issued from HSE indicating that the review had commenced, had a likely duration of one month, that ‘any patient affected’ would be contacted by HSE, and that a helpline had been established.

Around this time concern was being expressed by some within the process about the need to manage and co-ordinate the overall review process, and the potential for confusion if this did not happen.

At least partly in response to these concerns a Review Facilitation Group was established whose role, it would seem, was to manage and co-ordinate the overall process. Attendance at meetings varied somewhat but the group included General Manager Acute Hospital Services; Manager, Strategic Planning & Performance Management; Consultant Surgeon, MRHP; Consultant Radiologist, St. Vincent's Hospital; Hospital Manager, MRHP; and Director of Nursing, MRHP. Based on the records of meetings, this group met on three occasions: on 13th September, 11th October, and 6th November.

At the meeting on 13th September a discussion was held on both the mammogram and ultrasound elements of the review, both of which were described in the minutes of that meeting as being already under way at St Vincent's/Breastcheck, and locally at MRHP respectively. It was also agreed at this meeting that unlike the 2003-2007 review period initially agreed for the whole process, and now in place for the mammogram review, the ultrasound element would initially extend only as far back as 2005, and that based on this review it would be decided if it needed to go any further back.

At this stage the review was already clearly split into two parallel processes, one being carried out at St Vincent’s, and the other locally at MRHP. Around this time also, a draft protocol for the review, which indicated on separate flow diagrams the steps to be followed for the mammogram process at St. Vincent’s and the ultrasound process at MRHP, were circulated for discussion but were marked ‘draft for discussion’. It is not clear whether the draft protocol was ever formally agreed and adopted, or by whom. Similarly draft terms of reference for the review process as a whole were drafted. It is not clear to me if these terms of reference were ever formally agreed, or by whom.
While in theory, and based on the early documentation and terms of reference/protocol documents that were drafted and circulated, the mammogram and ultrasound elements were part of the same review, in practice they became separated. Subsequently, and particularly when missed cancers were identified as part of the review of mammograms, the mammogram element dominated attention both internally within the HSE, and in the media.

3.3 Period Two from Mid September to 21 November:

By mid-September the review of mammograms and ultrasounds was well under way, although the agreement of a protocol for the overall conduct of the review was still under discussion. In mid-September an update on the mammogram review from the Consultant Radiologist, St. Vincent’s Hospital, to HSE indicated that patients who has been reviewed and identified to be ‘in the clear’ should be written to, while others should be recalled to a clinic.

On 28th September a briefing note was sent from the Area HSE office to the Minister’s adviser, which outlined the scope of the review process, referred to the review dates from November 2003 to end August 2007 (although the review dates for the ultrasound element had been revised by then—see above), and also referred to both the mammogram and ultrasound elements of the review. It also indicated that the ultrasound review was to take place at MRHP. This note also indicated that the review would be completed ‘in a couple of weeks’. However the scoping document that formed this briefing note continued to bear the watermark ‘draft for discussion’.

The minutes of the meeting of the Review Facilitation Group of 11th October record updates on the mammography review provided by the Consultant Radiologist, St. Vincent’s Hospital. There was no reference to the ultrasound element of the review.

By mid-October it would appear that over half of the ultrasounds that had been selected for review had been completed, and some 48 patients were to be recalled to special clinics to be set up locally. Some delay was subsequently encountered in retrieving the remainder of the patient files, and the total ultrasound review was completed subsequent to the events of 21st and 22nd November.

At the start of November there was considerable media coverage of two patients who had been identified, as a result of the mammogram review, as having been misdiagnosed. Press Releases were issued by HSE area office on both 2nd and 7th November, both providing updates on the mammogram review, and indicating that it was close to completion. It was clear at this stage that the main focus now was on the mammogram review. The Press Release of 2nd November also
indicated that of the women recalled, seven had been diagnosed with breast cancer. However the Press Release of 7th November indicated that ‘the HSE can not anticipate the findings of the review’.

On 6th November the minutes of the meeting of the Review Facilitation Group show that there was a discussion of the rationale for the review of breast radiology services. The Consultant Radiologist, St. Vincent's Hospital updated the meeting on the finalization of her report on the mammography review. There is no reference in the minutes to any discussion of the ultrasound element of the review still in progress in MRHP.

On 6th November material for a Ministerial statement in the Dail was sent to the Department by the HSE Area Office and this referred to the ‘review of all breast diagnosis services at MRHP’ and that the review was being led by the Consultant Radiologist, St. Vincent’s Hospital. Later the same day a further document from a different source in HSE was sent to the Department. In this document were terms of reference for the review which referred to mammograms and ultrasounds (the time period 2003 to 2007 was still being referred to in this document, although these dates had been modified in respect of the ultrasound element of the review - see above). Apart from this reference in the terms of reference, the emphasis throughout this document was on the review of mammograms.

3.4 Period from 21st November to end November

In response to a request from the Department of Health and Children on 21st November, the HSE at area level clarified that “the study was broken into Mammography Review and a secondary ultrasound review” and that each covered different periods. On 21st November it became clear to all those involved in HSE (including at corporate level) and the Department, that a parallel review process for ultrasounds was still ongoing at MRHP.

In preparing to meet the following day with the Oireachtas Committee a decision was made by HSE management, in the interests of full disclosure, that when giving evidence to the Committee reference should be made to the ongoing ultrasound review. The Department was made aware of this decision but did not participate in making the decision on the basis that it was a matter for HSE management. However final figures on the numbers to be recalled as a result of the ultrasound review were not available before the meeting with the Oireachtas Committee, and indeed could not have been because the review was still ongoing.

At the meeting with the Joint Oireachtas Committee on Health and Children on 22nd November the HSE announced that 97 women who were reviewed under the ultrasound process were being recalled for further investigation (in fact the
number eventually offered a recall was 130). This led to the setting up of the special clinics in Portlaoise. This information caused some surprise and considerable adverse media attention, mainly relating to the fact that the ultrasound element of the review had not been generally known about, and the women concerned had not yet been notified. The announcement also created the potential at least in the public mind, for further identification of misdiagnoses.

A number of press releases from the HSE followed which clarified the situation with regard to the ultrasound review and the arrangements for the follow-up clinics.

A further briefing note prepared for the CEO on 27th November provided comprehensive details of both elements of the review process and the status of all patients involved.

In fact the review of ultrasounds did not show up any misdiagnosis, while as already reported the number of missed cancers arising from the mammogram review was nine.

The above description does not purport to provide a comprehensive account of all the communications and correspondence over the period. While I am conscious that including some elements and not others inevitably involves interpretation, I believe that the above provides a fair representation of the key events, and fairly point to the key issues that need to be considered and addressed. It is to those issues that I next turn my attention.

Section 4

4.1 Management and Governance

It is first important to acknowledge again that at no time during my review have I identified any suggestion of wilful neglect by any individual/s involved in the process, but rather that many of the people involved were working under significant pressure, with multiple important matters vying for their attention. This is a point to which I return later.

1. I believe that there was a fundamental weakness in the management and governance of this process from the outset, because there was no authoritative co-ordination and management role established for the review process as a whole. The Review Facilitation Group did not work effectively. It met on three occasions and this does not reflect the kind of urgency and level of oversight that should have been accorded a matter of this importance. Attendance varied from one meeting to another. The Group did not sign off terms of reference or protocols for the review process, which one would have expected. It did not exert control over the
integrity of the communications process either with patients, with the Department, or internally. It did not maintain sufficient oversight of the two elements of the process, mammography and ultrasound, and the second and third meetings were dominated by the mammography review process with little or no reference to the status of the ultrasound review. It could be argued that to be fully effective such a Review Group should have included independent, external expertise.

A number of consequences flowed from this lack of overall management and governance of the process:

- Communication throughout the period was inconsistent, and sometimes contradictory
- While in theory the review was to incorporate both the review of mammograms carried out at St Vincent's and the review of ultrasounds carried out by the team at MRHP, in practice the two processes became separated, with the mammography review dominating briefings and discussions up to late November.
- Different people in the system seemed to have different understandings of what was going on, contributing to confused communications
- There was lack of clarity about the nature and status of the terms of reference and methodology. Had these been clearly established and signed off at the outset by a group or individual that was clearly in charge of the process as a whole, then much subsequent confusion could have been avoided.

Hence, in my view the difficulties and confusion that subsequently arose, culminating in the events surrounding the Joint Oireachtas Committee meeting on 22nd November, were not surprising.

2. There was overall a lack of urgency in the response from corporate and area HSE to the review process prior to the revelations at the Oireachtas Committee on 22nd November. This was reflected partly in the looseness surrounding the management and governance process. It seems clear to me that getting adequate resources to conduct the review speedily and effectively was an issue, and especially in the early stages. In particular many of those involved in the review process, including at MRHP, had to undertake tasks related to the review while continuing to perform their everyday job. I was particularly struck by the level of urgency and resourcing committed to dealing with the ‘fallout’ from the ultrasound review after 22nd November, despite the fact that it was known these patients were in a much lower risk category, compared to the situation prior to that date. I cannot help but conclude that had the same level of urgency, attention, and resourcing been available throughout then many problems could have been avoided.
3. Related to the weaknesses in management and governance, and compounding the problem, there were too many people involved from different levels and areas within HSE without clarity about their roles and responsibilities within the process. Throughout the process there was insufficient clarity about whom, if anyone, had the most complete or up to date information, or who was responsible for providing definitive information on the status of the overall review.

4. The decision making process was fragmented, with insufficient clarity about decisions, who was making them, why they were being made, or when they were signed off.

5. Another issue which was drawn to my attention on a number of occasions was the fact that key people in the process were distracted by other important issues that they had to attend to during that period. Therefore there seems to be an issue about prioritizing, and particularly the need for dedicated resources to be devoted exclusively to manage critical incidents such as this.

None of the above is to suggest that the mammography review process at St Vincent's/Breastcheck was in any way deficient. On the contrary, the amount of work covered by this review within the time period was extraordinary. Nor was there any evidence whatsoever that the clinical review of ultrasounds at MRHP was deficient in any way, although there was perhaps inevitably less urgency in this process because it was overshadowed by the other element of the review, and the patients involved were in a lower risk category. I do have some concerns about the local administrative management relating to the retrieval of the relevant patient data at MRHP, especially for the ultrasound review, although this cannot be easily separated from the resourcing issue referred to above.

However my main concern relates to the management and governance of the overall review process. This goes back to the lack of authoritative management to control and monitor the process, get regular updates on progress, continuously link the two elements of the review, and manage all aspects of communications.
4. 2 Communications

In my view the inconsistency and lack of clarity in communications was an inevitable result of the deficiency in the overall management of the review process.

1. Specifically there was inconsistency and lack of clarity in the information provided in the press releases, with an ongoing release of numbers of patients affected. The ‘drip feed’ of numbers could only have heightened anxiety and uncertainty for those patients potentially affected. This approach also contributed to heightening confusion and adverse media comment. When it came to the presentation to the Oireachtas Committee on 22nd November, the political and media pressures surrounding the presentation, and the fact that numbers had been released on an ongoing basis throughout the review process, made the decision to release the numbers relating to the ultrasound review almost inevitable. The release of the numbers involved in the ultrasound review at the Oireachtas Committee (which were not final numbers) were therefore part of a pattern that had been established early on in the process. In my view numbers should not have been released at any stage of the review process until the whole review process was completed. I accept there was considerable pressure to release figures, but an authoritative management process with a sound protocol established from the outset, based on best practice, would have provided a robust basis for withstanding such pressures.

2. With regard to communications with patients generally I believe that in principle, and in keeping with best practice, all patients whose cases were being reviewed should have been written to at the beginning of the process. This, I understand, was originally the intention. However a judgment call was made at a later stage not to write to all patients, but rather to contact those who needed to be recalled, because there was a concern that if a patient contacted had subsequently had some procedure/diagnosis which was not known about, then the contact could cause unnecessary distress for that person. I understand the reason for this decision and the difficulty of making such a judgment call. A Helpline was established quickly, and it can be argued that any patients with concerns had access to this.

In general, however, I believe that the needs of the patients affected should remain to the fore in any such review process. I am concerned that sometimes the needs of patients can be compromised in the face of the constant pressure to provide ongoing information before the completion of such a review process. In particular the ‘drip-feed’ of numbers may have been designed to respond to these pressures, but could only have added to the anxiety of patients. I would also be concerned that the urgency and attention to the needs of patients demonstrated in the establishment of the
clinics in Portlaoise after 22nd November was not in evidence throughout the process.

3. In the communications internally within the HSE I have already referred to the multiplicity of individuals involved, without clarity about their precise role and status in the process. This led to confusion about who could communicate definitive information about the status of the overall review process.

4. In relation to the communication between the HSE and the Department, I would have some concerns about the quality of this process. This was partly due to the multiplicity of communication channels in operation involving different people within HSE, and different people within the Department and/or advisers to the Minister. Multiple channels of communication about the same issue can only lead to the confusion and lack of clarity that inevitably resulted.

The communication to the Oireachtas Committee on 22nd November about the numbers involved in the ultrasound review led to a degree of hysteria in the media, and undoubtedly caused more concern for the women potentially affected by the Review. The role of the Department seemed to be mainly to elicit information about the status of the Review, up to and including the meeting of the Joint Oireachtas Committee on 22nd November. I believe that a more shared approach between the Department and the HSE to dealing with the communication with the Oireachtas Committee, and in the immediate aftermath, may have achieved a greater degree of balance in the way in which the information was communicated, and could have avoided much of the negative portrayal of the health services that followed.

4.3 Conclusion

In summary the communications difficulties that arose cannot be separated from the weakness of management and governance in the process. In the midst of the intense activity surrounding the Review, the needs of the patients potentially affected receded.

While as already noted there were significant and competing pressures on many of the people who were involved in this process, in the final analysis my assessment is that fundamentally the problems arose from systemic weaknesses of governance, management, and communication for dealing with critical situations such as arose at MRHP in late August 2007. These are the issues that need to be tackled to avoid a recurrence.
Appendix 1

Terms of Reference for a review of the management of events following the HSE decision to initiate a clinical review of breast cancer services at the Midland Regional Hospital Portlaoise

1. The Minister for Health and Children has requested the Board of the HSE to carry out a review arising from the decisions by HSE management to suspend the breast radiology services at the Midland Regional Hospital Portlaoise, place a consultant on administrative leave and initiate a clinical review of breast cancer services at the hospital.

2. The purpose of the review is to undertake an immediate examination of the management of all the events starting from and subsequent to these decisions.

3. This review will focus, in particular, on the following aspects:
   a) the manner in which the HSE dealt with patients throughout the period;
   b) the governance and management of all aspects of the process; and
   c) the communication arrangements with patients, internally within the HSE, and with the Department of Health and Children

4. The review will be directed by the Committee established by the Board of the HSE for this purpose

5. The Board Committee will appoint an external independent chairperson* who will determine the facts relating to the aspects set out in point 3. above. S(he) will examine relevant correspondence and documentation relating to the period and conduct interviews with persons as necessary to establish the facts and complete a report for the Board Committee.

6. The review will be carried out and reported by the Board to the Minister as a matter of urgency.

*Arrangements for administrative support will be agreed with the appointed person.
Appendix 2

Meetings

I met with the following as part of this review (some individually and some as part of a group)

Karl Anderson, Personal Adviser to CEO
Dymphna Bracken, Area Communications Manager, Dublin/Midlands Hospital Group
John Bulfin, Hospital Network Manager, HSE
Alex Connolly, Head of Press, HSE Press Office
Tracey Conroy, Department of Health and Children
Mary Culliton, Head of Consumer Affairs, HSE
Prof Brendan Drumm, CEO, HSE
Yvonne Hanhauser, Clinical Nurse Manager, MRHP
Dr Tony Holohan, Chief Medical Officer, Department of Health and Children
Mary Hynes, Head of Quality and Risk, NHO
Mary Jackson, Department of Health and Children
Joe Lennon, Head of Communications, HSE
Joe Martin, General Manager, Acute Hospital Services
Declan McCormack, Hospital Manager, MRHP
Moss McCormack, Manager Strategic Planning and Performance Management, HSE Midlands Hospital Network Office
Mary Murray, St. Vincents Hospital
Peter Naughton, Consultant Surgeon, MRHP
Maureen Nolan, Director of Nursing, MRHP
John O'Brien, formerly National Director, National Hospitals Office
Dr Ann O Doherty, Consultant Radiologist, St Vincent’s Hospital
Michael Scanlan, Secretary General, Department of Health and Children
Ann Sheerin, Divisional Nurse Manager, MRHP