

7 Conclusions

The investigation team has reached the following conclusions.

Rebecca O'Malley's Misdiagnosis

This investigation has concluded that in respect of Rebecca O'Malley's misdiagnosis, the primary error was made by a consultant pathologist at CUH who interpreted a cytology tissue sample as suggestive of a fibroadenoma (a benign condition). Subsequent review - confirmed by this investigation - concluded that this slide showed malignant cells.

A wider review of this pathologist's work indicated this to be an isolated error in their tenure at CUH. A small number of such interpretive errors is a recognised feature of histopathology and cytopathology and hence the need for triple assessment for patient management.

Subsequent to the initial error, a multi-disciplinary meeting at the MWRH reviewing Rebecca O'Malley's case did not include a review of the relevant slides or a contribution from the reporting pathologist, as would be regarded as good practice. This was because the cytology reviews were conducted at another hospital, CUH, as part of an out-sourcing agreement. In these circumstances, arrangements should have been put in place to ensure pathology input at the multi-disciplinary team meeting. However, because there was nothing to suggest a fibroadenoma either by imaging or clinical test, the result was discordant. This discordance or disagreement between the clinical, imaging and pathology findings were not identified at this meeting. As a result, the opportunity to correct for the initial interpretive error was missed.

Quality Assurance of Cytology

The investigation identified that the quality of the cytology samples routinely presented for interpretation in CUH was poor. This indicates the need for a comprehensive quality assurance programme for FNA cytology.

There is also a need to reduce the reliance on fine needle aspiration (FNA) as a diagnostic tool in symptomatic breast disease except under clearly defined conditions.

Ms X's Experience

Taking a wider perspective, whilst the symptomatic breast disease service at the MWRH exhibited many aspects of a good quality service in terms of organisation, the experience of Ms X (including potentially sub-optimal diagnostic processes, delays and poor communication) further reinforces the need for greater emphasis on patient centred systems and processes.

Decision Making and Resources

In both services under review (symptomatic breast disease incorporating surgery and radiology at the MWRH and cytopathology at CUH) frontline clinicians raised concerns about the resources available to meet demand. Addressing these issues was not helped by what was reported as an inability for decisions to be made locally about resourcing priorities.

Linked to the concerns surrounding resources, the impact of the transition to the new HSE structures was cited as having an influence on the overall management environment. The investigation also identified examples of ineffective engagement between clinicians and managers.

The investigation team understands that since it concluded its work the National Cancer Control Plan directorate of the HSE has conducted a benchmarking exercise to assess the need for additional resources at the MWRH and CUH to move towards meeting the Symptomatic Breast Disease Standards. The team understands that the necessary funding has been allocated recently to allow key appointments to proceed.

Accountability

A recurrent message from interviews indicated a lack of clarity about roles, responsibilities, accountability and leadership within the system which had been accentuated by recent management changes and ongoing national negotiations.

Taken together, the hospitals managed by the HSE did not respond adequately to Rebecca and Tony O'Malley when they wanted to find out more about the mistake in diagnosis. Whilst individual managers and clinicians made efforts to resolve Rebecca O'Malley's concerns, there was a collective lack of accountability, cohesion and focus on the needs of the patient.

Despite being part of the same organisation, the hospitals were not able to coordinate an investigation and credible explanation of Rebecca O'Malley's misdiagnosis. This left Rebecca O'Malley feeling that her experience was not regarded as a priority and that she had to make the running in obtaining information. In addition, there was a disjointed, incomplete clinical and managerial response to the discovery of what was an adverse clinical incident with no root cause analysis being conducted.

In keeping with Rebecca O'Malley's wishes, this investigation has not sought to apportion blame. However, it is seeking to highlight the importance of clinical and managerial accountability and that this can never be diluted or abdicated by transitory organisational change. The effort of both should be integrated to promote high quality safe care. This implies the need for clear systems of governance that support decision making at every level but also challenge those making decisions to ensure they are always focused on the best interests of patients.

The Future

The findings have led the investigation team to make a number of recommendations which it believes will improve the quality of care offered to all women who present with symptomatic breast disease not only to Limerick and Cork but to all hospitals in Ireland where such services are provided.

The Authority will expect the HSE to performance manage the respective hospitals against the implementation of these action plans and consider at a corporate level where the recommendations should be applied nationally – for example as part of the National Cancer Control Plan. The Authority will agree with the HSE a time frame for the Authority to periodically monitor that the recommendations are being implemented.

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.

This active and visible demonstration of change and progress will be necessary in order to rebuild the confidence and trust of past and current patients and their families.

The investigation team strongly recommends that the senior management and clinical teams of all hospitals in Ireland who are providing symptomatic breast disease services should read this report, undertake their own baseline assessment against these specific recommendations and make the necessary changes in addressing where gaps exist.

Concluding Remarks

This investigation into the quality of care offered to Rebecca O'Malley and the management of her concerns by the clinicians, managers and institutions of the HSE, including the Mid Western Regional Hospital, Limerick and Cork University Hospital, would not have taken place without the extraordinary efforts of the patient and her husband.

These efforts were made to try and understand what had gone wrong, why it had gone wrong and what would be put in place, by the various responsible members of the clinical and managerial staff, to ensure that this would not happen again and that no other patients would suffer as a result of a similar error.

It is a salutary lesson to all involved in the pathway of care offered to Rebecca O'Malley that the system did not recognise that an error had been made, that the system did not protect her from a delay in diagnosis and treatment for her breast cancer and that when she was at her most vulnerable, the system did not respond in a way that recognised she was the most important person within her pathway of care.

Rebecca O'Malley has demonstrated, through her personal experience, that the system was inadequate and was not able to respond to her needs. Every effort must be made to ensure this cannot happen again and those involved in leading and developing the health service in Ireland must learn from her experience and recognise that they are in her debt for having the courage and resilience to bring her experience to their attention.