**Management of breast cancer test results**
**15HDC01289, 28 March 2018**

*District health board ~ Carcinoma ~ Breast surgery ~ HER2 ~ Test results ~ Laboratory ~ Multidisciplinary meetings ~ Rights 4(1), 4(5)*

A woman in her sixties visited her GP regarding a lump in her right breast. She then attended a DHB Breast Service (DHB1), where a mass in her right breast was noted. That day, the woman underwent an ultrasound-guided right breast core biopsy. The biopsy pathology result identified carcinoma. At that stage, HER2 (human epidermal growth factor receptor-type 2) test results were pending. HER2 is a type of protein that positions on the surface of normal cells, sending messages to the cell to grow and reproduce. In HER2-positive breast cancer, cells may reproduce very quickly.

At the time, the standard process for any HER2 results that were equivocal was that they were to be sent for an additional clarifying test — a FISH (fluorescent in situ hybridisation) test performed separately at an external laboratory. FISH testing looks for gene changes in cells and is required to establish whether Herceptin or chemotherapy would be beneficial. FISH testing is reported as either being not amplified (negative), equivocal, or positive.

The woman met with a DHB1 general and breast surgeon. Treatment options were discussed with the woman, who chose the option of a mastectomy with immediate reconstruction. The breast surgeon sent an urgent request to the Plastics Department at another DHB (DHB2) to see the woman for discussion about surgery.

The result of HER2 testing was reported by the DHB1 laboratory as equivocal. FISH testing was reported as negative.

The woman saw a plastic surgeon at DHB2. Mastectomy and breast reconstruction was scheduled. The combined DHB procedure surgery was undertaken by the breast surgeon and the plastic surgeon at DHB2. When patients are admitted to DHB2, an “event” number is created in the name of the admitting surgeon. On the day of the procedure, tissue specimens obtained were sent from theatre to the DHB2 laboratory. Although the breast surgeon from DHB1 had requested the histology it was linked to the DHB2 “event” number and therefore to the plastic surgeon.

The system in place meant that results were only able to be sent to the clinician linked to the patient event number. The results were sent only to the DHB2 consultant and the results were then available to view on the DHB2 hospital electronic system, which was visible to DHB1 hospital staff through its IT system.

The management of the breast cancer issue remained under the care of the breast surgeon at DHB1. The woman was seen by the breast surgeon and given her results, with HER2 results pending. The case was discussed at the unit’s (multidisciplinary) MDM meeting and a decision was made to refer to oncology if the woman was HER2 positive. The HER2 result was reported by the DHB2 laboratory as equivocal and that FISH testing would be performed.

The results were reported to the DHB1 Breast MDM, and the MDM document records were updated as “HER2 equivocal. For FISH testing”. The DHB1 system in place at the time however did not monitor progress of equivocal HER2 results that were yet to be finalised.

There was no process in place for the MDM to further follow up patients with equivocal HER2 results awaiting FISH testing.

FISH testing was completed and reported as a positive result. Although the FISH amplified (positive) report was sent to the DHB2 pathology department, the report was not seen by the DHB2 pathology team until about 11 weeks later. Unfortunately, the delay that had already occurred was not noticed by pathology staff.

A breast specialty nurse became aware of the positive result and action was taken to immediately proactively place the woman's case for discussion at the next MDM. At the meeting it was decided that the woman would benefit from a medical oncology referral, for discussion about the possibility of chemotherapy.

**Findings summary**

The DHB2 system in place at the time did not accommodate the test result dissemination requirements of a patient undergoing a combined procedure, across two DHBs, as in this case. The system in place at the time did not alert the requesting clinician to the results. DHB2 did not provide services to the woman with reasonable care and skill and breached Right 4(1).

At the time of the events complained about, there was shared governance and responsibility across both DHB1 and DHB2 for the laboratory operations (as it was transitioning to an external laboratory service).

There was an approximately 12-week period, from when the FISH test was deemed necessary, until the laboratory staff saw the positive result. In addition, there was a failure to recognise the delay that had already occurred, meaning that the result was not actually acted on for some time. While it is acknowledged that the main delay occurred in laboratory process, overall the Commissioner considered the time taken was not acceptable. DHB2 and DHB1 did not ensure quality and continuity of services to the woman and breached Right 4(5).

There was no existing system in place at the time, including via the Breast MDM, to follow up progress of equivocal HER2 results that were yet to be finalised. DHB1 did not provide services to the woman with reasonable care and skill, and breached Right 4(1).

The Commissioner made a series of recommendations requesting follow-up information and evidence of the effectiveness of changes to process and corrective actions taken by the DHBs (liaising with the external laboratory) involved in this case.