Failure to obtain relevant clinical information before reporting fine needle aspiration (98HDC16686, 29 June 2001)

Pathologist ~ General surgeon ~ Public hospital ~ Standard of care ~ Compliance with professional standards ~ Breast cancer ~ Clinical information ~ FNA ~ Pathology report ~ Quality assurance ~ Rights 4(1), 4(2)

A complaint was referred to the Commissioner by ACC. The investigation concerned the services received by a woman from a pathologist and a general surgeon, and the quality assurance systems of a public hospital.

The 33-year-old woman had a mastectomy for a ductal carcinoma in situ of the right breast. A breast reconstruction procedure was undertaken and a breast prosthesis was inserted. The expander portal for the breast implant was in the right lateral chest. About a year later an FNA (fine needle aspiration) was undertaken of a 1–2cm hard mass fixed to the chest wall lateral and inferior to the breast reconstruction, which, as it later became clear, was associated with the port site for the breast implant. A pathologist was asked to examine the FNA material. The brief history provided to the pathologist specified that the patient had a history of breast cancer and that there was a new nodule below a recent reconstruction. The pathologist was unaware that the patient's breast reconstruction included the insertion of a breast implant. The pathologist reported that there were malignant cells present in the FNA material. This was a false positive report. It was later determined that the FNA showed changes consistent with tissue reaction to the prosthesis and no evidence of malignancy.

A quality control system for the FNA examination of breast lesions should include the following features: review of slides by another pathologist, correlation of all cytology with histology, review of previous cytology and histology from the breast lesions previously reported as malignant and, significantly, that the pathologist is under an obligation to obtain all relevant clinical information before reporting an FNA.

The Commissioner held that:

1 the pathologist breached Rights 4(1) and 4(2) by failing to obtain all relevant clinical information before reporting on the FNA or to consider that the cells were a foreign-body reaction to the patient's breast implant. This was a major error, which a prudent pathologist would not have made;
2 the general surgeon did not breach the Code in excising the tissue reported as malignant, even though a CT report recorded no signs of tumour recurrence locally. Nor did he breach the Code in undertaking a wide excision of the port site and surrounding tissue, even though this damaged the breast implant and the pathology was later shown to be inaccurate; and
3 the public hospital breached Right 4(1) by failing to have a protocol or quality control system in place to ensure that its pathologists obtained all relevant clinical information or reviewed FNAs previously reported as malignant in order for effective comparisons to be made.