

**Liver biopsies for research
performed during surgery without consent
(00HDC07593, 30 August 2002)**

Surgeon ~ Gastrointestinal surgery ~ Biopsy ~ Informed consent ~ Pain management ~ Research ~ Record-keeping ~ Rights 4(1), 6(1)(d), 7(1), 7(6)(a)

A 44-year-old woman complained that during the performance of other procedures a surgeon conducted two liver biopsies, for which he did not obtain specific consent, as he saw it as a relatively trivial extension to a major operation. Independent surgical advice stated that the first biopsy taken during the gastric bypass operation may have been justified on clinical grounds, although most surgeons would not have taken one as it would not alter management. The second biopsy taken during the laparoscopic cholecystectomy would not be considered routine clinical practice in the absence of a specific abnormality.

The liver biopsies did not add significantly to the risk of the procedures, but a reasonable patient would want to be told that the surgeon proposed to perform such a non-standard procedure. The surgeon breached Rights 6(1) and 7(1) because he failed to inform the patient, prior to both biopsies, that they were non-standard procedures, and did not obtain specific consent.

Another aspect of the complaint was that during consultations with the patient, the surgeon collected data and completed questionnaires for his own information, without the patient's knowledge and consent. A detailed database had been compiled from information from each patient's personal record, and the surgeon had published the information internationally and used it to make improvements to his procedures.

The Commissioner reasoned that where a clinician performs tests or procedures that are not regarded as a routine or necessary part of clinical management by a responsible body of the relevant speciality, and the clinician collects such data for research and publication purposes, the test or procedure is properly classified as a research intervention. Accordingly, notwithstanding the view that the biopsy could be accepted as part of clinical care, the surgeon should have informed the patient that he was undertaking research and obtained her written consent, as required by Right 6(1)(d) and 7(6)(a).

The woman also complained that following surgery, when she telephoned the surgeon complaining of severe pain and bruising and having developed a haematoma, he failed to advise her to come in for an examination and instead prescribed stronger pain relief. However, the surgeon did not breach Right 4(1) because a gall bladder bed haematoma is a recognised complication of cholecystectomy and, on the balance of probabilities, cannot be attributed to the biopsy. The surgeon responded appropriately by ensuring that the patient received stronger pain relief.