



# The Royal College of Pathologists' advice relating to the ownership, storage and release of pathology results – revised guidelines

*These guidelines were developed in response to enquiries from College members concerning various aspects of the storage and release of laboratory results.*

*They were published in the Bulletin in January 2002 (RCPATH Bulletin 2000;117:33–34). Subsequently, concerns were raised and the paper was discussed with the Medical Defence Union and Medical Protection Society. This is the revised guidance. The shaded sections indicate the revised paragraphs.*

## 1. The 'ownership' and storage of pathology results

The concept of a laboratory 'owning' results is not helpful. Only the patient can truly be said to own an individual result since it is part of their personal medical record. Pathology departments do, however, act as 'guardians' of data generated in their laboratories and should store or archive such material in ways which conform to the College guidelines in *The Retention and Storage of Pathological Records and Archives*<sup>1</sup> and the Data Protection Act.<sup>2</sup>

Results are usually returned to the general practitioner, hospital clinician, or the health care professional who requested the investigation. It is when health care workers other than the person who requested the investigation, or the patient, request or require this information from the pathology department that difficulties may arise.

*Bona fide* reasons for access may include:

- health care workers involved in the clinical care of a patient (i.e. in a therapeutic relationship with the patient) on a 'need to know' basis.<sup>3</sup> Clinicians often delegate obtaining pathology results to nursing or secretarial staff. In this context, both legally and ethically, the nurse or secretary would be standing in the shoes of the clinician, and should have been properly delegated the task in hand
- where the patient has given their permission
- in certain circumstances (see below) to the patient themselves
- overriding public interest, where disclosure should be confined to the appropriate person or authority
- notifiable disease, where notification should be as required by the regulations.

Consent and confidentiality have changed, and are changing, fast. There are also inconsistencies. It is important, therefore, to be able to justify disclosure. If in any doubt, check that the patient has given consent, or discuss with the medical defence societies.

Individual Trusts should have established standard operating procedures (SOPs) covering all aspects of the release of pathology results.

Interconnected information technology (IT) systems across split site Trusts allow easier access to such data. The allocation of appropriate passwords and levels of security access are expected to be an integral part of the operating procedures of such IT systems and the arrangements made should be approved by the Trust's Caldicott Guardian.<sup>4</sup>

Telephone, fax and email communications all have potential security problems and adequate precautions should be taken to confirm the identity of any recipient and appropriate security of the communication medium being used.

## 2. Release of results directly to patients

It is important to patients they are given truthful information about their medical conditions and many will wish to have some personal responsibility for healthcare decisions and to be involved in informed discussions of treatment options. Individuals are entitled to know their pathology results as they are entitled to see all their medical records, and there should be Trust procedures in place to allow this. There are, however, some potential problems related to giving out individual pathology results directly to patients, particularly by telephone. These include:

- a) the difficulty of establishing that they are who they say they are and hence ensuring confidentiality
- b) the problem of giving individual results in isolation to someone who might not understand their nature and might misinterpret their significance
- c) particular sensitivities over certain results, such as HIV tests or biopsies for suspected malignancy, which have serious clinical significance
- d) the possibility of undermining the established relationship between the patient and the clinician who is primarily responsible for their care.

The College supports the view that **pathology results that convey new diagnostic information should be given to the appropriate hospital clinician or general practitioner**, who can then explain their significance to the patient within the context of their discussions of the clinical problem as a whole. If there is a multi-disciplinary team concerned with the patient's care, an agreed written protocol (based on paragraphs 7–10 in Confidentiality: Protecting and Providing Information)<sup>5</sup> should be used in deciding whether it is appropriate to give results to other health care professional members of that team.

**Results of tests that are for the routine monitoring of an established condition or response to therapy could be issued directly to the patient.** This procedure should be agreed with the clinician and the pathology department at the time of the request and is particularly appropriate if it is proposed that the patient should adjust medication doses themselves, based on the results.

When results are released directly to patients, the following conditions should be observed:

- every effort should be made to confirm their identity
- the supervising clinician should be sent a copy of the results which have been released to the patient
- a written record should be kept of the actions taken.

### **3. Release of results to doctor-patients**

There are further complications if doctors request their own test results directly from the laboratory. They will presumably have a good understanding of the significance of such findings and, if they work in the same hospital or Trust, they may well be able to access pathology results on remote terminals anyway. However, it is felt that points a, c and d in Section 2 also generally apply to doctor-patients who should not be encouraged to self-investigate but should go through their general practitioner or appropriate hospital channels if they are unwell.

### **References**

1. The Royal College of Pathologists. *The Retention and Storage of Pathological Records and Archives (2<sup>nd</sup> edition)*. London: The Royal College of Pathologists, 1999.
2. The Data Protection Commissioner. *Data Protection Act 1998*. London: The Stationery Office Limited, 1988.
3. The Medical Defence Union. *Confidentiality*. London: The Medical Defence Union, 2001
4. Caldicott F. *The Caldicott Committee: Report on the review of patient-identifiable information*. London: The Department of Health, 1997. [www.doh.gov.uk/ipu/confiden/guard/index.htm](http://www.doh.gov.uk/ipu/confiden/guard/index.htm)
5. General Medical Council. *Confidentiality: Protecting and Providing Information*, London: General Medical Council, 2000.

**APPROVED BY COUNCIL  
NOVEMBER 2002**