The Royal College of Pathologists
Pathology: the science behind the cure

Guidance on consent for the processing and analysis of clinical samples following an initial consultation

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1. Introduction

1.1. Samples of tissue, blood, body fluids or other biological materials are often obtained for analysis following a clinical consultation. The clinician (healthcare professional with clinical contact) seeing the patient takes a history and may perform a clinical examination before deciding which tests to perform. In the case of surgery, it will be decided to remove a piece of tissue for therapeutic and/or diagnostic reasons.

2. Consent

2.1. In order to proceed, it is necessary to obtain the patient's valid consent (see the Ethics Committee paper, A brief guide on consent for pathologists, September 2008). In each case, it is the responsibility of the clinician to ensure that the patient understands the reason for making the request for an examination and the range of tests that may be involved. Those reasons for investigation should be conveyed clearly to those undertaking the examination.

It is important to remember that the initial consent is likely to involve a request to investigate what is wrong, rather than to perform a specific set of analyses. Clinicians must also consider whether or not to document the consent they have obtained.

2.2. General Medical Council guidance states that discussions with patients should be tailored according to:

(a) their needs and wishes
(b) their level of knowledge about, and understanding of, their condition, prognosis and the treatment options
(c) the nature of their condition
(d) the complexity of the treatment, and
(e) the nature and level of risk associated with the investigation or treatment.

3. Analysis

3.1. Once the sample has been obtained, the healthcare team works together to solve the clinical problem posed by the consultation. The sample may be sent to pathologists and scientists who have no direct contact with the patient involved. At any step of the analysis, the results obtained may point in a direction that was not immediately foreseen by the clinician who explained the original plan of investigation.

3.2. If it is believed that investigations should be performed which appear to fall outside the scope of the original consent given by the patient, or there are particular sensitivities around the condition for which the pathologist wishes to test, the General Medical Council states that the pathologist must contact the treating doctor and establish whether further discussion with, and consent from, the patient is necessary before proceeding.

3.3. There have been advances in the diagnosis of many other conditions, providing potential knowledge that may have a profound effect on a patient's future. In particular, advances in genetics may allow the prediction of the development of such conditions as Huntington's chorea or breast cancer in apparently healthy individuals. Clinicians and pathologists must consider very carefully the potential consequences of performing sensitive tests without explicit consent.

3.4. In many pathology disciplines, multi-test profiles are commonly used and may yield important results on tests not originally specified by the requesting clinician, such as uraemia, hypercalcaemia, leukaemia or lymphoma. Similarly, for histopathologists, it is commonplace for the results of microscopy or other analyses to lead clearly towards a previously unforeseen diagnosis. In some cases, the unexpected finding will lead to resolution of the patient's fears, such as a diagnosis of glandular fever rather than a lymphoma.

4. Principles

4.1. All healthcare professionals accept that the purpose of any investigation is to solve a clinical problem, the origin of which is a consultation at which valid consent was obtained.

4.2. If consideration is to be given to extending the investigation beyond the list of tests that have been specifically requested and for which consent should therefore have been obtained, then those responsible must satisfy themselves that either:

- the course of action lies within the overall nature of the problem

or:

- the information revealed by the results available requires immediate further investigation because of the clinical importance of the situation and obtaining further explicit consent from the patient is impractical.

and:

- the investigation is in the best interests of the patient.

4.3. Patients have the right to exclude the performance of specific tests.

4.4. Any important information obtained during an investigation cannot be ignored. It is a general principle that such information, however obtained, be explained to the patient by an appropriate member of the investigating team, which includes both clinicians and pathologists. There may, however, be some circumstances, for instance unexpected and potentially distressing information on paternity, where a clinician should take the appropriate steps to establish whether a particular piece of information should only be disclosed to the most appropriate family member.

4.5. If it is apparent that a field of enquiry has been opened up that is remote from the original investigation, the requesting clinician should be contacted to consider the advisability of obtaining further consent. This is a matter of professional judgement and healthcare professionals must be prepared to defend any decisions taken on a patient's behalf as being in the patient's best interests and that the interests being protected are important enough to outweigh the normal objective of providing maximum autonomy for the patient.

5. References

See: G034 A brief guide on consent for pathologists.