

Consent Issues in Nuclear Medicine

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Introduction

This position paper from the Council of the British Nuclear Medicine Society discusses the implications for the practice of nuclear medicine of the consent policy of the Department of Health (as described in the Reference Guide to Consent for Examination or Treatment [1]).

General Issues

1. The guidance is specific to consent for physical interventions on living patients.
2. Valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a patient.
3. For consent to be valid, it has to be given voluntarily by an appropriately informed person. The person must have had the opportunity to ask questions and have been given time to digest the information received.
4. When a patient gives valid consent to an intervention, in general the consent remains valid for an indefinite duration unless it is withdrawn by the patient.
5. Some patients may wish to know very little about the treatment being proposed. If information is offered and declined, it is good practice to record this fact in the notes.
6. Validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent. Consent may be expressed verbally or non-verbally. An example of non-verbal consent is where a patient, after receiving appropriate information, holds out an arm for assessment.
7. It is good practice to take and document written consent when
 - a. the treatment or procedure is complex or involves significant risks
 - b. there may be significant consequences for patient's employment, social or personal life

- c. the treatment or procedure is being undertaken for research purposes
 - d. the procedure involves anaesthesia or sedation
8. The health professional providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins. The task of seeking consent may be delegated to another health professional, as long as that professional is suitably trained and qualified.
 9. People aged over 16 are entitled to consent to their own medical treatment without parental involvement. The refusal of a competent person aged over 16 may in certain circumstances be over-ridden by either a person with parental responsibility or a court.
 10. For children under 16, if the child is "Gillick competent" and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required.

Diagnostic Nuclear Medicine Procedures

1. Most routine diagnostic nuclear medicine procedures do not involve a "significant risk" (defined for this purpose as any untoward effect more frequent than 1 in 1000 [2, 3]). The list of routine diagnostic procedures includes all procedures mentioned in the ARSAC Notes for Guidance [4]. It should be noted that in the evaluation of risk for nuclear medicine procedures, non-radiation risks of the procedure should also be considered since these may be larger than those from radiation.
2. Patients are normally given advance information regarding the procedure(s) (for example, through patient information sheets). In such cases, providing it is clear that the patient understands and consents voluntarily, verbal (and non-verbal) consent can be obtained on the day(s) of the procedure(s).

3. Written consent may be obtained from pregnant patients who need the nuclear medicine procedure to clarify and/or confirm/exclude a clinical diagnosis. This is not a requirement and the decision regarding written consent can be taken at local/Trust level.
4. Written consent may be obtained from patients undergoing procedures such as myocardial perfusion imaging and captopril renography. This is not a requirement and the decision regarding written consent can be taken at local/Trust level.

Therapeutic Nuclear Medicine Procedures

1. Written consent is recommended for all patients undergoing therapeutic nuclear medicine procedures.

Research Projects

1. Any research project which is carried out on humans should be approved by an independent research ethics committee.
2. Written consent will have been obtained from patients as part of their recruitment into the study. Additional written consent to undergo nuclear medicine procedures as part of the study (either diagnostic or therapeutic) is not necessary.

Unlicensed Medicines

1. The person prescribing an unlicensed medicine has a professional obligation and a legal duty to explain to a patient the nature and purpose of medicine, significant predictable adverse side effects, possible complications and alternative treatments and to record this in the patient's notes [5]. This information can be provided through a patient information sheet.
2. As with all nuclear medicine procedures, consent is required. This can be verbal, non-verbal or written, depending on the assessment of risk, and will be a local/Trust decision. Written consent is not specifically required for the use of unlicensed products. In most cases it is expected that verbal consent will be sufficient.

3. Many products with licences for use in adults are classed as unlicensed when used with children. This is not because the products are thought to be unsafe for use in children, but because the tests which confirmed their safety and efficacy were conducted on adult volunteers. It is not generally considered ethical for normal, healthy children to be involved in such tests. Although unlicensed, these products have been in use for many years without any adverse effects on children. Their use is accepted as standard practice.

References

1. Reference Guide to Consent for Examination or Treatment, Department of Health. Published in April 2001. (www.doh.gov.uk/consent)
2. Calman KC. Cancer: Science and society and the communication of risk. British Medical Journal 1996; 313; 799-802
3. Paling J. Strategies to help patients understand risks. British Medical Journal 2003; 327; 745-8
4. Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources. Administration of Radioactive Substances Advisory Committee, December 1998. (<http://www.advisorybodies.doh.gov.uk/arsac/>)
5. Prescribing unlicensed drugs or using drugs for unlicensed indications. Drugs and Therapeutics Bulletin 1992; 30; 97-100

Review

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