**Adequacy of patient consent for chemotherapy**

**Descriptor:**

Competent adult patients have a fundamental right to give or withhold consent to an examination.

**Background:**

This audit is worth carrying out because competent adult patients have a fundamental right to give or withhold consent to an examination, investigation or treatment. Many doctors have an inadequate understanding of the law and erratic or deficient processes for obtaining consent prior to a procedure have been identified as a major factor leading to litigation. Misconceptions commonly arise in relation to obtaining consent from minors and to the concept of competence to give informed consent.

## The Cycle

**The standard:**

• All patients undergoing interventional procedures, radiotherapy, chemotherapy or other treatment modalities should be given “sufficient information in a way that they can understand, to allow them to exercise their genuine right to make informed decisions about their care”

• A visual check should be made of treatment records to verify that consent for chemotherapy has been completed prior to administration of chemotherapy

**Target:**

100%

## Assess local practice

**Indicators:**

The percentage of patients who have undergone an interventional procedure who are able to answer “yes” to every question on the audit questionnaire (see Patient Questionnaire in Resources).

**Data items to be collected:**

Patients will be asked to complete the questionnaire during their first visit for chemotherapy treatment.

**Suggested number:**

50 patients randomly chosen by the departmental nursing staff from case records of new patients starting chemotherapy over a period of 4 consecutive weeks.

**Suggestions for change if target not met:**

• Ensure departmental protocol in place for nursing staff/ chemotherapy administrator to confirm consent form has been completed and signed by patient and consenting health professional before the patient receives first cycle of chemotherapy

• Ensure that those involved in consenting patients for chemotherapy have adequate training in the consent process during their induction period, and are aware of the importance of informed consent

• Departmental protocols should contain list of common acute and late toxicities for each chemotherapy regimen in current use

• Arrange for training in the medico-legal aspects of consent, consenting technique and the possible consequences resulting from inadequate arrangements

• Repeat date for commencing the next audit (following change): 3 months and/or 6 months

• Identify staff member responsible for introducing change

• Indicate date for reporting on the repeat audit

**Resources:**

- Personnel: Departmental nurse/ medical records staff be responsible for the distribution and collection of the questionnaires; audit assistant to collate the results

- Time: 10 minutes per patient (under 3 hours in total); 1 hour to collate the results

[**15\_Patient Questionnaire chemo.doc**](https://www.rcr.ac.uk/sites/default/files/audit_template/co/15_Patient%20Questionnaire%20chemo.doc)WORD - 46.5 KB

**References:**

1. Coldicott Y et al. The ethics of private examinations – teaching tomorrow’s doctors. BMJ 2003; 326: 97–101.
2. Department of Health. Supporting Doctors, Protecting Patients. London: The Stationery Office, 1999.Department of Health. Consent for examination or treatment (ref 25751). Leeds: DoH, 2001.
3. Department of Health. Reference guide to consent for examination or treatment. Leeds: DoH, 2001.
4. 4. Doyal L, Tobias JS (Eds). Informed Consent in Medical Research. London: BMJ Books, 2001.
5. General Medical Council. Good Medical Practice. London: General Medical Council, 1998.General Medical Council. Seeking Patients’ Consent: the Ethical Considerations. London: GMC, 1998.
6. Harrison A. Choice is a gift from the patient to the doctor, not the other way round. BMJ 2000; 320: 874.
7. Kravitz RL, Melnikow J. Engaging patients in medical decision making. BMJ 2001; 323: 584–585.Medical Defence Union. Consent to treatment. London: MDU, 1999.
8. Royal College of Radiologists, College of Radiographers, Royal College of Nursing and the Institute of Physics and Engineering in Medicine. Breaking the mould: roles, responsibilities and skills mix in departments of clinical oncology. BFCO(02)6. London: RCR, 2002.
9. Smith R. Informed consent: The intricacies. BMJ 1997; 314: 1059–60. See also BMJ 1997; 314: 1477–1483 and BMJ 1997; 315: 247–254.
10. Westberg K, Lynoe N, Lalos A et al. Getting informed consent from patients to take part in the clinical training of students. BMJ 2001; 323: 488.
11. Willison DJ et al. Patients’ consent preferences for research uses of information in electronic medical records: interview and survey data.BMJ 2003; 326: 373.

**Editor's comments:**

• There are many misconceptions regarding consent. This occurs particularly in relation to children’s, parents’ and partners’ rights and in respect of patients with a limited ability to give consent

• This audit could be conducted across the whole department and cover the work of all oncologists. The results could contribute to the contents of an individual’s revalidation folder as a personal audit

• The format of this audit is illustrative and is not intended to suggest that these are the only areas in which consent needs to be obtained. Consent has become a central issue in the delivery of healthcare, particularly since the Kennedy Enquiry into the excess death rate at the paediatric cardiac surgical unit in Bristol. Consent issues are still more complex in relation to clinical trials

**Submitted by:**

Taken from Clinical Governance and Revalidation 2003 RCR, updated by COASC 2009

**Published Date:**

Wednesday 6 May 2009

**Last Reviewed:**

Wednesday 28 September 2022