NHS Suffolk policy: On-going access to treatment following third party funding including clinical trials

**Purpose of document:**
To set out NHS Suffolk’s policy on funding of treatment following third party funding including clinical trials.

**Target audience:**
NHS Trusts, Independent Providers, Clinicians, patients

**Version 1 - January 2011. Policy effective from the 17th of January 2011**

**Policy Summary:**
- This policy sets out the Suffolk PCT’s position on NHS funding after cessation of third party funding including clinical trials.
- Although NHS Suffolk is supportive of research initiatives and encourages trial participation it also has to take account of the interests of the wider population and the legal requirement not to exceed its allocated resources.
- NHS Suffolk will not provide pick up funding at the end of third party funding including cessation of clinical trials unless approval has been given by the PCT or another NHS commissioner before treatment was started.
- When a clinical trial is planned, patient expectations should not be raised indicating NHS funding will be available to enable the patient to continue to receive the trial treatment after the trial has ended and this position should be included in the patient information leaflet. Trusts should endeavour to further strengthen their research governance arrangements regarding third party funding.
- NHS Suffolk will exercise its discretion while deciding funding to enable a patient leaving a clinical trial to access continuing treatment if:
  - The patient was funded by a non-commercial research body;
  - It has been demonstrated that the patient has benefited clinically from treatment;
  - NHS Suffolk determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and NHS Suffolk can afford that expenditure.
- The standard statement in NICE Technology appraisals “people who are currently receiving the drug for the treatment of the condition and whose circumstances do not meet the criteria set out in this Technology appraisal should have the option to continue treatment until they and their clinicians consider it appropriate to stop” will not be applicable to patients coming off clinical trials unless the funding for these patients has been explicitly authorised by the commissioners in advance of commencement of the trials.

Authors: Miranda Sutters, Specialty Registrar in Public Health & Dr P Badrinath, Consultant in Public Health Medicine

(Developed based on policy of West Midlands Strategic Commissioning Group and policies of various PCTS in England)
1. Definitions

A clinical trial is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.

Third party funding: This includes funding from any source apart from NHS funding. Some of the sources could include self pay, charity funding, compassionate funding and pharmaceutical industry funding. This is not an exhaustive list as there are many other potential sources of non NHS funding.

Treatment costs, in the context of clinical trials, are the patient care costs which would continue to be incurred by the NHS if the service in question continued to be provided after the clinical trial had ceased.

Excess treatment costs are incurred where patient care is provided which differs from the standard treatment, in that it is either an experimental treatment or a service in a different location from where it would normally be delivered. The difference between the total Treatment Costs and the cost of the standard treatment (if any) constitutes the excess treatment costs.

NHS pick-up of trial funding refers to the situation where an NHS patient has been entered into a third party-sponsored clinical trial and where funding is being sought from the NHS to provide continued treatment after the trial has finished.

Non-commercial clinical trials are clinical trials which are funded by charities or other public bodies such as the Medical Research Council or the National Institute of Health Research.

Responsible Primary Care Trust means the Primary Care Trust which discharges the Secretary of State's functions under the National Health Service Act 2006 for an individual patient.

NHS Directions are legally binding instructions to primary care trusts, health authorities, special health authorities and NHS trusts issued by the Secretary of State under section 8 of the National Health Service Act 2006.
**NICE’s Technology Appraisals** are a specific form of Guidance published by NICE which is covered by NHS Directions issued in 2003. The Directions provide that primary care trusts shall make funding available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.

2. The policy

NHS Suffolk will not automatically pick up funding of an intervention after third party funding has ended. This includes funding after clinical trials. When a clinical trial is planned, patient expectations should not be raised that NHS funding will be available to enable the patient to continue to receive the trial treatment after the trial has ended.

2.1 This policy applies to any patient who is the responsibility of NHS Suffolk.

2.2 Where a patient has been entered into a clinical trial and receives a non standard treatment, it is expected that where the patient derives benefit and requires further treatment following termination of the trial, the future pathway for such patients needs to be determined by the provider trust without undue disadvantage to the patient or affecting the quality of clinical care being delivered. Funding will not be available from commissioners in these circumstances.

2.3 NHS Suffolk will not provide pick up funding at the end of a trial unless approval has been given by NHS Suffolk before treatment (clinical trial) was started. Providers will need to produce evidence that approval was given.

2.4 If a clinical trial involves use of a PCT approved and funded drug as long as there are no extra costs to the commissioner, providers can continue to use this intervention after the trial has ended as this is part of standard funded treatment.

2.5 During the course of the trial if the intervention is approved by the commissioner through due process for standard use, patients will have continued access to the intervention after the trial has ended.

2.6 It is the responsibility of providers to ensure that patients are fully informed and consented before they agree to treatment that even if a treatment is shown to be clinically effective for that patient, it is NHS Suffolk’s policy not to provide funding for treatments which are not included within established PCT policies. Please see section 2.2 above.
2.7 NHS Suffolk will use its discretion in deciding funding to enable a patient leaving a clinical trial to access continuing treatment if:

2.3.1 The patient was funded by a non-commercial research body; and

2.3.2 It has been demonstrated that the patient has clinically benefited from treatment; and

2.3.3 The NHS Suffolk determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and the PCT can afford that expenditure.

2.8 Should NHS Suffolk agree to pick up funding, in this context, it does not represent a policy decision in relation to that treatment and, as such, sets no precedent for the funding of other patients. The treatment in question will be assessed and prioritised as a service development in the normal way.

2.9 The patient’s clinician has the right to apply to the individual funding panel (IFR) for consideration of the continuation of the funding. Such applications will be considered by the IFR Panel under the current IFR policy. Although it may be difficult to demonstrate the requirement of exceptionality under these circumstances, given that similar patients exist and funding for these has been declined.

2.10 NHS Suffolk will not have any liability to pay the provider under the acute services contract where the patient has been initiated on treatment before funding approval was sought from the PCT.

2.11 Provider trusts should endeavour to further strengthen their research governance arrangements regarding third party funding in order to ensure that patients are not disadvantaged in anyway or there is an adverse impact on the quality of clinical care.

2.12 The PCT will implement NICE technology appraisals in line with the Secretary of State’s Directions. The PCT accepts that it has a legal duty to make treatments available to patients whose clinical conditions come within the definitions in the appraisals, unless the treatments have been exempted by the Secretary of State within 3 months of the date of publication of the appraisal. These treatments will receive the highest priority during prioritisation.

2.13 The standard statement in NICE Technology appraisals “people who are currently receiving the drug for the treatment of the condition and whose circumstances do not meet the criteria set out in this Technology appraisal should have the option to continue treatment until they and their clinicians consider it appropriate to stop” will not be applicable to patients
coming off clinical trials unless the funding for these patients has been explicitly authorised by the commissioners in advance of commencement of the trials.

2.14 As criteria in the NICE TA are arrived at after detailed consideration of clinical and cost effectiveness information and in consultation with all stakeholders, providing funding for these patients who do not meet the NICE criteria goes against NHSS’s ethical framework for making decisions. Two key components of the ethical framework are clinical and cost effectiveness.

2.15 By prioritising the patients who do not meet the criteria stated in the NICE guidance for funding PCT would incur an opportunity cost and lead to unfair distribution of scarce NHS resources.

3. Documents which have informed this policy

- Current NHS Suffolk Strategic Plan
- Current NHS Suffolk current operational plan
- Current NHS Suffolk Ethical Framework for making decisions.
- The National Specialised Commissioning Group: Funding of treatments for patients leaving clinical trials (March 2008).
- The Medicines for Human Use (Clinical Trials) Regulations 2004. (Statutory Instrument 2004 Number 1031. The regulations for clinical trials are set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations, as originally passed, have been subsequently amended by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and may be further amended. PCTs are advised to seek advice to ensure that they are consulting the current version of the Regulations.
  www.wma.net/e/policy/b3.htm
- Department of Health: HSG(97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS.
- Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009)
- NHS Confederation Priority Setting Series, 2008
  http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx