Clinical Expert Statement Template

Thank you for agreeing to give us a personal statement on your view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them. Your statement can be as brief as you like, but we suggest a maximum of 8 pages.

If there are special reasons for exceeding this 8-page limit please attach an Executive Summary to your statement.

What is the place of the technology in current practice?

How is the condition currently treated in the NHS?
Structural brain imaging is not currently used routinely in the diagnostic assessment of patients with psychotic symptoms. To a large extent this is appropriate as at the moment structural brain imaging cannot be meaningfully used as a "diagnostic test" i.e. to confirm a particular diagnosis. Therefore, diagnosis is based on clinical presentation and medical history.

Is there significant geographical variation in current practice?
Most patients with psychosis are treated within generic community mental health teams although there are specialist teams available within a significant proportion of Trusts. When specialist teams are available the main difference to the generic teams is that they have a lower case load and therefore (in theory at least) better able to provide intensive input. It is rather doubtful that these teams are changing anything other than the rates of hospitalisation which is a significant outcome for the cost of services but does not reflect better social or clinical outcomes for patients.

Are there differences in opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
Both MR and CT technology are widely available within the NHS and there is no alternative. One could argue that the use of CT should be discontinued in the case of CNS disorders as it has absolutely no advantage over MRI. In my opinion, most clinicians will agree that brain imaging cannot be used to confirm the presence of a psychotic illness but may be useful, where clinically indicated, to exclude CNS disorders that involve gross brain morphological changes.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
There is an effect of diagnosis and age of onset in the prognosis of first episode psychosis. Patients with schizophrenia and related disorders have worse outcomes than other diagnostic groups; within diagnostic groups patients with very early (adolescent) onset have poor outcomes – to the extend that psychosis in the elderly is a sign of a neurodegenerative disease or other organic pathology (e.g. tumour) then prognosis is poor in this group as well.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
The application of CT/MRI requires specialist equipment (scanner etc) and facilities and specialist input (radiologist) in order to evaluate the outcome. Therefore it can only be implemented within specialist facilities but should be accessible to health professionals as needed.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?
I presume there is some variation across Trusts with regards to the use of CT/MRI for first episode psychosis but I do not know that anyone has studied or quantified this. I also do not know and cannot image any circumstances where neuroimaging could be used outside its indications.

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.
The problem with this question is that guidelines are usually disease rather than symptom specific. Psychosis is a symptom of several disorders but not a disease entity in itself. Therefore, I do not know of any guidelines for "Psychosis". In terms of the major psychiatric disorders, psychosis is commonly seen in severe mood disorders but is considered a hallmark of schizophrenia. Therefore, the guidelines on schizophrenia are perhaps the most relevant. There are approximately 30 international guidelines on the management of schizophrenia (Gaebel et al, Br. J. Psychiatry, 2005; 187: 248 – 255) and at best they make a passing reference to the contribution of neuroimaging.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology in clinical practice reflects that observed under clinical trial conditions. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting?
It is extremely unusual for structural brain imaging to be included in clinical trials. This is because clinical trials are mostly focused on symptom resolution or relapse prevention and structural brain imaging does not inform about these outcomes.

What, in your view, are the most important outcomes and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?
Clinical trials focus on acute and/or long-term symptom control. Emerging evidence (e.g. Lieberman et al 1: Arch Gen Psychiatry. 2005 ;62:361-70) suggests that different types of treatment in psychosis, such as atypical antipsychotics, may have a wider role perhaps conferring some degree of neuroprotection that could be significant in long-term disease outcomes. Neuroimaging has been instrumental in providing this type of evidence and therefore it may have a wider role in future clinical trials.

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?
I cannot think of any side-effects or adverse reactions that could be meaningfully discussed here.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, if already available, compares with current alternatives used in the UK.
Is the technology easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its use?
It is difficult to think of what we are meant to compare neuroimaging to in addressing this question. I cannot think of any disadvantages of using brain imaging at the level of the individual patient but for reasons already discussed if used for every single patient as part of their routine investigation it would increase costs with questionable benefits to the patient.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

As already mentioned brain imaging is currently used to exclude several types of CNS disease when patients' symptoms or other aspects of their presentation (e.g. family history) suggest that this is clinically necessary. I think the current rules for using or not using brain imaging for the clinical management of psychosis are appropriate and do not require modification.

Brain imaging may have the potential in the not so distant future to help with prognosis, with the identification of treatment response or to clarify the effects of treatment. It is appropriate and one would argue necessary that further research is conducted on these subjects and this could be done a worthwhile investment of R&D budgets within the NHS.

Any additional sources of evidence?

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Implementation issues

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Please note: The NHS is required by the Department of Health and Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.
If the technology is unlikely to be available in sufficient quantity or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and Welsh Assembly Government to vary this direction.
Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

It is my impression that brain imaging is used only in a minority of patients with psychosis when it is considered relevant on the basis of clinical presentation. It would not be justifiable to suggest that it becomes part of the routine investigation of such patients based solely on the presence of psychotic symptoms. This would increase demand and the cost of initial assessment of patients with questionable return in terms of improving clinical care or patient outcomes.