NACC Response to the NICE Appraisal Consultation Document (November 2009)

Do you consider that all of the relevant evidence has been taken into account?

Yes

Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?

Yes in broad terms.

However, we note that the interpretations and judgments of the Committee have been subtly altered to support the changed recommendations without, so far as we are aware, any new evidence having been submitted or considered by the Committee compared to the previous ACD.

For example, 4.3.5:

The summary of the evidence from clinical specialists bullet point 3 which in the September 2009 ACD read
"the evidence from clinical practice now strongly favoured maintenance therapy"
becomes in the November 2009 ACD
"the evidence from clinical practice now strongly favoured a longer-term approach to treatment".
We are certain that the clinician experts would have referred to maintenance and question the appropriateness of this change.

An additional paragraph has been added to 4.3.5 in the November ACD which records that the committee concluded that the definition of maintenance treatment was unclear and agreed that the term 'planned course of treatment' was a clearer way of defining a longer-term approach to treatment for a *specified period of time*. (Our italics.)

Whilst planned course of treatment may indeed be a reasonable substitute for maintenance treatment and perhaps preferable in its implicit emphasis on planning, the Committee has introduced a new concept not previously discussed or justified, namely that such treatment with antiTNFs should be for a specified period of time.

This is a totally different approach to management than that in the September ACD where the decision of the Committee was to support current clinical practice – namely to have a formal review at 12 months and maintain continuity of treatment unless the patient is in full remission, in which circumstance the GETAID study suggests it is safe to stop treatment.

Similarly, in the September ACD (para. 4.3.10) the Committee was unclear about the effectiveness of treatment over periods longer than 1 or 2 years, suddenly in the November ACD (para 4.3.9) the uncertainty is about periods longer than one year. No justification is given for this shortening of the time horizon.

Also in para 4.3.10 the ACD reports the view of the Committee that it could not reliably identify a patient group with a sufficiently high rate of relapse that meant treatment should be continued after 12 months.

It is the nature of Crohn's Disease that there is some uncertainty in the progression of the disease in each individual patient and therefore identifying patients at risk of relapse is the essence of the clinical review process accepted by the Committee in

the September ACD. The clinician takes account of various indications of the progression of the disease and together with the patient decides on the most suitable treatment plan.

In summary, it seems that the Committee came up with a very different interpretation of the evidence and very different conclusions from exactly the same evidence base as it considered in the August 2009 meeting and published in the September ACD.

NACC attended the October Committee meeting as an observer. We noted that one of the Committee members specifically raised points of discussion which he acknowledged he had raised before and that had been overruled. These points seem to us to relate quite closely to the subsequent changes in recommendations incorporated into the ACD.

This is potentially important given that there were significant changes to the composition of the Committee – a new Chairperson and new Committee members. These members had not had the benefit of hearing patient or clinical expert comment – none were invited to be available at this meeting - and yet questions previously resolved at earlier Committee meetings seem to have been brought forward to be reconsidered by the Committee. This gives us great concern about the satisfactory continuity and consistency of the appraisal process, which as demonstrated by the contrast between the August and October meetings seems neither fair nor reasonable. If this ACD is confirmed in January it would seem a completely perverse outcome to a three-year process that has left many patients struggling to get access to anti-TNF treatment at local level.

Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

No.

The proposed arbitrary time limit on treatment of 12 months has no basis in the evidence or in clinical practice in the UK or the rest of the world.

For those patients in full remission at 12 months, the time limit will have no impact on their treatment – they would have stopped antiTNF therapy anyway under the review system proposed in the September ACD.

For those patients not in full remission but who have not 'failed' and had treatment withdrawn, the reality at 12 months is that many are likely to be living as near normal a life as they can with symptoms that have been much improved by the antiTNF therapy, but that fall short of complete remission. Continued therapy will be enabling these patients to continue their education, their employment, and their family roles. Even for those patients who are not responding as well, the antiTNF will provide a period of symptom containment that allows for the next stage of treatment, often surgery, to be planned and undertaken as an elective.

The revised recommendations in the November ACD condemn these patients to an arbitrary stopping of their treatment followed by a period of almost certainly worsening symptoms, additional hospital appointments and disrupted life until they 'requalify' for a further course of antiTNF therapy.

We suggest the overall cost-effectiveness of this scenario is questionable and it is certainly not accepted good clinical practice. In terms of the individual patients and their families, we believe it is unethical to withdraw a treatment that is working, albeit imperfectly, and require the patient to suffer increased ill-health and impaired quality of life to 'requalify'.

The positive argument for the '12 month review' approach.

The newer committee members may not be aware that the proposal for a review at 12 months was put forward to the Appraisal Committee by the IBD community as our united view of what constitutes best practice, taking account of safety concerns, patient-well-being, service efficiency and cost-effective use of the antiTNF therapies. The review process addresses the issue of not allowing ever-increasing numbers of patients to be unthinkingly continued on these therapies and also addresses the concern of the Committee to identify which patients are most susceptible to relapse and who should be eligible for continued treatment.

The wording of the September ACD with two possible changes would establish a very effective, fair and consistent pattern of clinical practice across England and Wales.

The possible changes are:

- the minor adjustments to the review criteria proposed by the British Society of Gastroenterology and Royal College of Physicians
- the adoption of the term 'planned course of treatment' which we feel does emphasise the importance of a treatment plan provided it does not imply an arbitrarily defined period of treatment.

The Review Process meshes very effectively with the approaches to multidisciplinary management of complex Crohn's Disease incorporated into the national IBD Standards published earlier in 2009 (www.ibdstandards.org.uk).

Other recommendations:

In our response to the previous ACD, we pointed out that the Committee has not made clear that patients who initially respond to an antiTNF but who subsequently lose response should be able to switch to a trial of the alternative antTNF. Trial evidence shows that this can be deliver successful outcomes for a significant proportion of these patients.

We fully support the increased emphasis in the November 2009 ACD on the importance of the creation of a Register of IBD patients that will enable the outcomes of antiTNF therapy to be properly audited and evaluated. We regard this as important not only in terms of future assessment of cost-effectiveness, but also to monitor the long-term safety of these drugs.

An important benefit of a Register of all IBD Patients would be to provide an alternative to the Silverstein data that has been such an issue in this appraisal.

iv) Are there any equality related issues that may need special consideration?

No.

30th November 2009

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