Patient/carer organisation statement template

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: **Richard Driscoll**

Name of your organisation:

NACC – The National Association for Colitis and Crohn's Disease

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- **Yes - Director**
- other? (please specify)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Infliximab provides an alternative medical therapy to be tried at the point where a patient is potentially facing colectomy. The removal of the colon and replacement by an ileostomy or ileo-anal pouch is a huge and life-changing decision for a patient to make; psychologically it is very important for the patient to feel that all medical options have been exhausted as they (and their partner/family) may then find it easier to accept the consequences of living with a stoma or pouch.

For some patients this will be their first attack of Ulcerative Colitis. For them, the possibility of removing their colon is arising so suddenly and can be even more difficult to accept. Even if infliximab fails to put them into remission and only gains a few weeks or months that is valuable time in which the patient can become better informed and prepare for their future with a stoma or pouch.

As stated below, the evidence shows that about half of the patients given infliximab will be saved from immediate colectomy. Follow-up of the one RCT of infliximab [Jarnerot] showed continued benefit for at least two years.

Given that in all 32 randomised-controlled trials of steroids for acute severe colitis the colectomy rate is 29% and that this has not changed between 1974 and 2006, it is very important that patients have access to this new treatment option.

Evidence of effectiveness:

Published data for infliximab vs. placebo in patients not responding to steroids shows 29% having a colectomy (single dose infliximab) as opposed to 67% placebo [Jarnerot]. Other series show 60% avoiding colectomy at 3 months [Lees] or half at 140 days [Jacobovits].

Experience suggests that the use of infliximab will avoid surgery in half of the patients and delay the need for surgery in up to 80%. Those patients responding to infliximab would then usually be treated with azathioprine or possibly receive one or more additional infliximab infusions.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

Remission of the disease in approximately half of the patients receiving the treatment.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**

Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Potential disadvantages include:

1 - The availability of an additional medical treatment option might lead to prolonged indecision about medical versus surgical therapy resulting in an unwise delay to the surgery. This can lead to a poorer outcome.

To avoid this it is essential that patients with acute severe Ulcerative colitis are managed by an IBD team (inflammatory bowel disease team experienced and knowledgeable in the care of these patients) with close collaboration between a gastroenterologist and colorectal surgeon and with the informed involvement of the patient in the decisions.

2 – Infliximab circulates in the body for several weeks after infusion which theoretically could lead to an increased rate of infection in patients who had to undergo surgery within a short time of their infliximab treatment.

This is the reason why patients so severely ill that surgery would be needed urgently are not usually considered for infliximab. For these patients ciclosporin would be the preferred medical option.

3 – Some patients may react to the infusion; therefore this has to be carefully monitored at the time of administration.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Unable to comment

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

See comment above on those patients needing urgent surgery.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Intravenous steroids are the standard treatment. Data from Oxford shows that only 40% respond completely to this treatment.

The current alternative treatments for those not responding to IV steroids are ciclosporin or surgery.

Ciclosporin has greater side-effects than infliximab, but would be the preferred alternative in patients facing urgent surgery as it disappears from the body very quickly.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

Factors encouraging patients and doctors to consider infliximab as preferable to ciclosporin are the known adverse events associated with ciclosporin and the considerable clinical experience with and apparent safety of infliximab in

Crohn's Disease. It is very important for infliximab to be available as an option for acute severe Ulcerative Colitis. A BSG study showed that ciclosporin was being much less used for rescue therapy than expected (Hawthorne, Travis 2006). The IBD Audit 2006 showed just 4% of patients receiving ciclosporin and the consensus view is that rescue therapy is being underused.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

Already stated above.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Unable to comment.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

There are some general concerns about the potential for anti-TNFs to cause lymphomas in all inflammatory diseases for which they are currently used, but this would seem to be a very minor consideration or concern in the context of their use for acute severe Ulcerative Colitis.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

A NACC Survey of patients who had received infliximab for Ulcerative Colitis showed that most patients reported that they benefited significantly from infliximab and that their quality of life had improved (patients scored their current health now and one year previously using the Euroqol scale). However, the number of patients was small and the survey was not designed to distinguish between use of infliximab in the sub-acute and acute severe contexts.

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

A significant number of patients would have the opportunity to avoid colectomy.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

A significant number of patients would have ‘unnecessary’ colectomies and NHS patients in England and Wales would have less favourable access to modern treatments than patients in other countries.

Are there groups of patients that have difficulties using the technology?

None that I am aware of.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

The following account is given by a patient who has recently experienced infliximab when admitted with acute severe Ulcerative Colitis. The patient wished to attend the Appraisal Committee meeting but was unable to have the time off work to do so.

The situation leading up to your hospital admission?

I started having abdominal pain in the evening on Fri 16th May 2008. I also kept trying to go to the toilet, but nothing was happening. It felt like there was a blockage there. The pain continued throughout the weekend, but was not too bad. I thought by Mon I would be at school no problem. Sunday night I was up all night going to the toilet every single hour. If I rolled onto my side the pain got worse + it made me need the toilet more. I had blood in my stool by now + it was a mixture of constipation + diarrhoea.

The abdominal pain was severe. I am not one to complain about a little pain, but I was often crying out with pain. Lying flat on my back helped the pain a little. If I sat up, lay on my side, walked around etc... it felt like my abdomen was being crushed. (Later in hospital the pain was so bad that even morphine did not help – I could always feel the pain and therefore could not sleep at all. Every hour I opened my bowels day + night until intravenous steroids started to work.)

I went to the doctors first thing Mon morning + tried to explain it felt like a cross between constipation + diarrhoea + I also said I felt like there was a blockage there. The doctor gave me laxatives + said I could take pain killers. Nothing seemed to work. The pain was getting worse + by Tues I was lying down all day + had stopped eating + drinking as standing up + walking to the kitchen hurt too much. I was getting dehydrated without realising. I was still not too worried though + thought it would just clear. I thought it was perhaps just a stomach bug. Wednesday it was really bad + I went back to the doctors (I was hoping I would get sent to hospital at this point as I was desperate for the pain to go away, but trusted the doctor). Again I got laxatives + some tablets to relieve spasms (more for IBS I think). It was a 2 minute drive to the surgery + I was in absolute agony driving there, my stomach was getting crushed as I used the pedals with my feet. I was hunched over and almost crying as I told the doctor the pain I was in. I went home + tried the medication. Again it did nothing. I got worse + worse + at 10pm my husband took me to the A&E Dept at my hospital.

In hospital

I was admitted straight away after the blood test showed some abnormal results. My CRP was over 150 + I was put on a drip straight away to re-hydrate me. My potassium levels were also quite low. I thought I would get some medication + then be sent away. I had no idea I would be in hospital for 2 weeks. I was in A+ E to start with, then I was moved to the medical assessment unit, then I was in a short-term stay ward (they thought I had infectious diarrhoea), then finally to the gastro unit. During this time I had 3 X-rays.

Finally I was told I had colitis. The intravenous steroids started working, it was wonderful! The pain started to ease. Then after about 7 days they tried to change me to oral steroids. I responded very badly + the pain + bloody diarrhoea came back. They put me back on intravenous steroids + again I felt better + my stool was starting to get back to normal. After a couple of days again oral steroids were tried, but again they failed + I was once again in terrible pain + not sleeping etc. It was then that the gastroenterologist said he had hoped that the steroids would have worked + now wanted to try something else – Infliximab.

I was told a small number of people had to have surgery if the colitis flared up constantly. Deep down I was terrified at the thought of having surgery + having a colostomy bag, but tried not to think about it too much.

Infliximab

My doctor explained how infliximab worked + gave me some information to read. He explained it was a fairly new drug + explained the possible side effects. After reading the information, I signed a consent form. He said it should reduce the inflammation. He explained it could only be given intravenously + that it would be in my body for about 8 weeks + I may only need this one dose – it depended how my body reacted to it.

Having the drug was fine. No side effects at all. Although I was slightly concerned as I was being monitored all the time in case I reacted badly (I did wonder what they expected to happen!). But it only lasted about 2 hrs + I was used to having a drip in.

After the infusion

Have been feeling fine since leaving hospital on 4th June. I had 3 weeks off school to rest + regain my strength (I was so weak as I hadn't eaten for 10 days). Back at school now + feel absolutely fine, just a little tired. Colonoscopy showed the inflammation had gone down. An incredibly different picture from that of the sigmoidoscopy in hospital. Now I live my life just as I did before – a busy teacher enjoying an active life.

References:

Hawthorne AB, Travis SPL, BSG IBD Clinical Trials Network. Outcome of inpatient management of severe ulcerative colitis: a BSG IBD Clinical Trials Network survey. Gut 2002;50:A16.

Järnerot G, Hertervig E, Friis-Liby I, et al. Infliximab as rescue therapy in severe to moderately severe ulcerative colitis: a randomized, placebo-controlled study. Gastroenterology 2005;128:1805—11.

Jakobovits SL, Jewell DP, Travis SP. Infliximab for the treatment of ulcerative colitis: outcomes in Oxford from 2000 to 2006. *Aliment Pharmacol Ther* 2007;**25:**1055-60.

Lees CW, Heys D, Ho GT, et al. A retrospective analysis of the efficacy and safety of infliximab as rescue therapy in acute severe ulcerative colitis. *Aliment Pharmacol Ther* 2007;**26:**411-9.

Declaration of Interests:

Schering Plough is a Corporate Supporter of NACC making a donation of £20,000 in 2008. Half of these funds are unrestricted by the donor and have been applied to raising awareness in the NHS of Inflammatory Bowel Disease (IBD) and the need for national service standards for IBD. The remaining funds have supported specific NACC Publications for patients and health professionals in collaboration with other pharmaceutical companies.

Richard Driscoll
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