

**NACC Submission to NICE for the Health Technology Appraisal on
the use of tumour necrosis factor alpha (TNF α) inhibitors (adalimumab,
certolizumab pegol and infliximab [review]) and natalizumab for
Crohn's Disease
July 2007**

Executive Summary

Section 1.

NACC is a membership organisation with 30,000 members throughout the UK of whom 12,500 are people who have Crohn's Disease.

Sections 2 and 3

Crohn's Disease is a life-long, fluctuating condition that has a severe impact on patients' physical and psychological well-being and their quality of life. Reference is made to a major NACC survey of members in 1995 to illustrate this. Copies of the Survey Report and of NACC's booklets on Crohn's Disease and Surgery for Crohn's Disease are enclosed. A copy of NACC's video *Talkabout Crohn's* is included to show the impact of the disease on the individual lives of three young people.

Section 4

NACC conducted a survey for the HTA Submission of members who had experienced treatment with TNF α inhibitors. 183 patients who have Crohn's Disease replied, the great majority of whom had received infliximab. Members described the main difficulties that their Crohn's Disease was causing. Information is given about who suggested treatment, the delays before a decision was reached and how the treatment was funded.

Section 5

The members' experience was very positive, with 69% of the patients reporting a great improvement in their condition and 19% reporting some improvement. 60% described themselves as on continuing treatment and 69% described the effects of treatment as lasting. Of those who said the effects had not lasted or that their medical condition had not improved, the great majority still described the treatment as definitely or probably worthwhile. The complications experienced by members are described and their comments quoted to illustrate the benefits they reported. The experiences of children and of those with fistulae are summarised.

Section 6

A version of the EQ-5D was included in the survey. The scale was adapted to show members' assessment of their health before treatment as well as their current state. The overall improvement in health state is impressive.

Section 7

The potential benefits of treatment with TNF α inhibitors for those patients who are not responding to conventional medical therapy or who have fistulae, even if the benefits for some are short term, lead NACC to submit that these technologies as a class should be made available within the NHS within the terms of their European licences for Crohn's Disease. The NHS should allow clinicians with their patients to decide the most appropriate pattern of treatment from among all the therapies.

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I. Information on NACC

- 1.1. The National Association for Colitis and Crohn's Disease was founded in 1979 as a partnership of patients, their families and health professionals. The aims of the charity are to provide support and information to people who have IBD (Inflammatory Bowel Disease) and their families, to raise public awareness and understanding of IBD, to improve health services for patients who have IBD, to raise funds for research and to publish the useful results of research.
- 1.2. NACC is a membership association and currently has just under 30,000 members. There are 70 local NACC Groups throughout the United Kingdom, which provide educational meetings, opportunities for patients and their families to meet, and undertake local publicity and fundraising. NACC also has 10 IBD Patient Panels in England whose aim is to enable patients and health professionals to talk together about how services for IBD locally can be improved.
- 1.3. About 12,500 of NACC's members have Crohn's Disease. A similar number have Ulcerative Colitis and about 1,400 say they have IBD (Inflammatory Bowel Disease – either Crohn's, Colitis or Indeterminate). The remaining 3,000 members comprise relatives, friends and health professionals.
- 1.4. Copies of the NACC Plan and the NACC Review for 2005 are enclosed. **(9.1, 9.2)**
- 1.5. A Declaration of Interests in relation to this Submission can be found in Section 8.

2. Living with Crohn's Disease

- 2.1. Crohn's Disease is a long-term, chronic illness for which at present there is no cure. NACC estimates that there are 60,000 patients diagnosed with Crohn's Disease in the UK, with 3,000 - 6,000 people being diagnosed each year. The most common time for diagnosis is in the teens or early adulthood.
- 2.2. Crohn's disease affects the small intestine in about 30% of patients, the junction of the ileum with the caecum and colon in about 40%, the

large bowel in about 25% and the mouth, oesophagus and anus in about 5%.

- 2.3. In Crohn's Disease the inflammation occurs in patches and can penetrate deeply into the layers of the intestinal wall. The disease tends to take either a stricturing or a fistulising form. Strictures are narrowings of the intestine where the inflammation creates scar tissue in place of the normally flexible intestinal wall. Fistulae are the result of the deep ulceration that Crohn's can cause and may occur in the abdomen between loops of the intestine or in the rectum or between the vagina and rectum. Fistulae can fail to heal with conventional treatment.
- 2.4. Patients are likely to experience periods of active and less active disease, and these will come and go quite unpredictably. Active disease is usually treated with steroids and, increasingly, immunosuppressive drugs. Many patients can expect to have surgery at some point to remove diseased sections of the bowel that are not responding to drug therapy or where scarring has produced an obstruction. About 80% of patients will require surgery within 20 years of diagnosis; 20-40% will require their first surgery within 3 years of diagnosis. The normal management of Crohn's Disease is described in the NACC booklets that we have enclosed. **(9.3, 9.4)**
- 2.5. Extra-intestinal symptoms are quite common, with inflammation affecting the joints, eyes or skin. Depending on the location and severity of their active disease, patients can experience significant pain, loss of weight, loss of appetite, nausea, continual diarrhoea, urgency, rectal bleeding, feverishness, utter lack of energy. Even when their disease is much less active, patients describe an underlying lack of well-being and sense of feeling well.
- 2.6. The majority of patients with moderate or severe Crohn's Disease require some form of maintenance therapy. Traditionally, patients have needed long-term treatment with significant doses of steroids. The potential side-effects from these are well-known, and patients have a particular concern about osteoporosis. Increasingly, immunosuppressive therapies are being used to reduce dependence on steroids. About 15% of such patients prove to be intolerant of immunosuppressive therapy and about 40% are likely to relapse within a year. Surgery will be considered for these patients, but many patients naturally wish to avoid major surgery if possible and we estimate that perhaps 10-15% of patients are not suitable for surgery that the patient would find acceptable.
- 2.7. Repeated relapses exact a toll on people's lives, both physically and psychologically, gradually reducing what they may regard as their 'normal' level of quality of life, activity or health to lower and lower levels.

3. The Impact of Crohn's on People's Lives

- 3.1. In 1995 NACC commissioned a major survey of the impact of IBD on the lives of members. 3,000 members were randomly selected to

receive questionnaires and 80% responded. The results were published as the 'NACC Audit of IBD' and a copy is provided with this submission. **(9.5)**

- 3.2. Some specific findings of the survey are mentioned here as being relevant background to the appraisal of infliximab.
- 3.3. 25.6% of all patients with Crohn's Disease had had to give up work altogether at some point because of their illness. For those whose IBD was classified as 'severe' the proportion rose to 30.3%. 31.6% of all patients with Crohn's Disease had had to reduce their working hours.
- 3.4. Members were asked to report the complications associated with their IBD. 30.6% of members reported they had arthritis, 23.0% of members with Crohn's reported skin problems, 22.3% reported fistulae, 31.7% reported anaemia and 28.4% reported mouth ulcers.
- 3.5. 60.2% of those members who had Crohn's Disease had had surgery for their IBD. 68% of respondents whose Crohn's was classified as severe had had surgery.
- 3.6. A section of the questionnaire asked members which aspects of their condition had greatest impact on their quality of life. These included problems of urgency and frequency and the effect this had on all aspects of life, work, social activities and travelling; the difficulty of planning any aspect of life when the condition was so unpredictable; the social difficulties caused by wind and smells; the severe tiredness and lack of energy restricting all aspects of life, but particularly children, family and leisure; the effect of continual pain and its effect on mood and emotional reserves.
- 3.7. Members were also asked about their greatest worries. These were fear of cancer, of surgery (either first or further surgery) and fear of future dependence; concern at the prospect of life-long illness and treatment; worry about incontinence and about the effect their disease had on their partner or family. (50% expressed some worry about the effect on their relationship with their partner and 13% were very worried about this.)
- 3.8. Just over 20% of patients with severe Crohn's felt that their illness had a great effect on their family life and relationships, with close to 30% reporting that there was a great effect on their sexual activity and relationships.
- 3.9. The results of the survey have been provided as a background guide to the impact that IBD generally has on patients and their families. The patients for whom infliximab would be considered under the present licensing are among those most severely affected by Crohn's and therefore are likely to be experiencing many of the effects described.
- 3.10. We are providing a short video of three young people describing their experience of Crohn's through teenage and early adulthood and we hope that the committee will take the opportunity to see the impact of Crohn's expressed not as survey results but in terms of three individual lives. **(9.6)**

4. Survey of NACC Members who have been treated with TNF α inhibitors

- 4.1. We decided to collect current information on NACC members' experience of the technologies being appraised. A leaflet was enclosed with the Summer 2007 NACC News asking any member who had either been treated with biological therapies or been refused treatment with them to volunteer to complete a questionnaire. 320 members replied and were sent a questionnaire at the end of June 2007. 226 replies were received within the 15 days available for replies. 183 of the members who replied had Crohn's Disease, the remainder had Ulcerative Colitis. The following information relates just to those who had Crohn's Disease.
- 4.2. The questionnaire was in two parts – a NACC-designed survey of members' experiences and the EQ-5D varied to include an additional scale asking for members to rate their health status before treatment with TNF α inhibitors as well as 'today'. (9.7)
- 4.3. Of the patients with Crohn's Disease:

*181 had been treated or considered for treatment with infliximab
2 were being treated with adalimumab.
Of those who had received infliximab, 3 had subsequently been
treated with certolizumab and 13 with adalimumab.*

*76% were female - which is 10% higher than the expected proportion
for the
NACC membership.*

*9% were under 20
20% aged 20 – 29
32% aged 30 – 39
15% aged 40-49
14% aged 50-59 and
10% over 59.*

*36% had had Crohn's for 12 years or more,
21% for 7 - 11 years,
26% for 3 - 6 years and
15% for up to 2 years.*

*63% said Crohn's affected their small bowel (63%),
69% their large bowel
35% their rectum
21% other areas of the body*

*8% said their joints were affected
17% had fistulae or abscesses
4% had oral or skin inflammation*

48% had had surgery of some kind relating to their Crohn's

In the 12 months before treatment with a TNF α inhibitor:

*65% had been treated with steroids
66% with immunosuppressive drugs
52% with both steroids and immunosuppressive drugs.
10% reported no treatment with steroids or immunosuppressive drugs, but commonly received 5-ASA or antibiotic therapies.*

- 4.4. Members were asked to list the main difficulties their illness was causing at the time biological treatment was discussed. There were no prompts or tick boxes therefore the following percentages represent key words spontaneously used by respondents.

*51% - pain, often referred to as severe
14% - nausea, sickness or vomiting
39% - severe tiredness/exhaustion
41% - urgency and diarrhoea, often with bloody stools or mucus
25% - weight loss*

Many reported 2, 3 or 4 of these symptoms and then commented on the impact of Crohn's on their education or working life and their family or social life.

*44% referred to their education or working life being very affected.
51% referred to their family or social life being very affected.*

A complete listing of members' descriptions of the difficulties they were experiencing is enclosed (9.8)

- 4.5. Information on the decision to treat with a TNF α inhibitor.

*81% said a gastroenterologist suggested treatment
8% a surgeon
4% a nurse.
9% suggested the treatment themselves.*

44% said a TNF α inhibitor was suggested as a means of postponing surgery

42% of patients reported delay or uncertainty before they were told that treatment could be provided. (20 patients said they were told within four weeks, 13 in five to eight weeks and 36 in longer than 8 weeks.)

5% of the NACC members who responded to the survey did not receive treatment with a TNF α inhibitor. There were no specific statements that were clear-cut refusals to fund by the NHS; patients had been told they were not suitable or would be unlikely to benefit from treatment.

4.6. Of those who received treatment:

*89% were funded by the NHS,
6% were funded private insurance
7% said that they received treatment as part of a research trial.*

5. Members' Experience of Infliximab

5.1. 167 patients had received treatment with infliximab, 4 were waiting for a decision about use of infliximab and 2 were started on Adalimumab.

5.2. *Of the 167 who had received infliximab, 3 had subsequently been treated with certolizumab and 13 with adalimumab.*

5.3. Of those who received treatment:

60% of patients described their treatment with a TNF α inhibitor as continuing

33% said treatment had stopped

8% said their treatment was under review

60% said the effects were the same on subsequent treatments

23% said the effects were not the same on subsequent treatments

69% said the effects had lasted

27% said the effects had not lasted

(The 46 patients who said the effects had not lasted were asked if they considered their treatment with a TNF α inhibitor worthwhile – 25 said definitely, 15 probably, 4 not worthwhile.)

25% said they had some complications during the treatment

73% said they had no complications

19% said they had complications between the treatments that they put down to

the TNF α inhibitor.

(The complications from infliximab were described as allergic reactions, anaemia, chest infections, fever, some nausea and/or muscle stiffness that could last a couple of days afterwards. Also mentioned as effects between infusions were chest pain, itching, vulnerability to infections and skin infections spreading. Slower infusions, sometimes with saline, and also covering steroid or ant-histamine injections were said to reduce the allergic reactions satisfactorily. Headaches were noted by some of the few patients receiving adalimumab.)

69% described the effect of the biological treatment on their **medical condition**

as a 'great improvement'

19% described it as an improvement.

7% said there was no change and

3% described their condition as worse.

(Of the 88% who said their medical condition had improved, 115 patients said the effects had lasted, 30 said they had not. [79%, 21%])

64% described the effect of the biological treatment on their **daily life** as a

'great improvement'

15% described it as an improvement.

14% said there was no change and

2% described their daily life as worse.

5.4. Of the 33% who said their treatment had stopped:

21 said this because the treatment was unsuccessful or the effects did not last

14 stopped because of complications (1 x pneumonia, 1 x TB)

4 thought cost was a factor

18 had improved significantly so treatment was stopped

In respect of the 8% who said their treatment was under review this was usually due to changed circumstances (e.g. pregnancy) or consideration of an alternative biological.

5.5. 109 members described an improvement or great improvement in their medical condition and said the effects lasted. Without prompting they mentioned:

<i>fistula closed up or draining less</i>	12%
<i>joints better</i>	7%
<i>pain free or greatly reduced pain</i>	28%
<i>less frequent and urgent bowel movements</i>	28%
<i>greater energy levels</i>	24%
<i>appetite improved</i>	8%
<i>weight gain</i>	12%
<i>overall improvement in health</i>	40%
<i>symptom free</i>	14%

5.6. 139 members reported an improvement or great improvement when asked about the difference a biological treatment had made to their life. Their replies are entirely unprompted and the different aspects of life that they chose to mention illustrates the wide variation in the outcomes that are most important to individual patients. Some take a broad view of 'being normal' or 'quality of life', others focus on very

specific aspects and others define an improved outcome in terms of the absence of symptoms or reduced hospital interaction.

<i>improved ability to work</i>	17%
<i>improved family life/relationships</i>	10%
<i>greater participation in social/leisure activities</i>	15%
<i>educational achievements</i>	4%
<i>improved mobility, getting out more</i>	9%
<i>improved ability to plan ahead</i>	5%
<i>improved sleeping</i>	4%
<i>improved psychological state</i>	9%
<i>fewer symptoms, reduced treatment</i>	22%
<i>better 'quality of life'</i>	9%
<i>feel better, feel 'normal'</i>	28%

- 5.7. Seven patients aged 11 -18 responded to the survey. Their experience and comments were very similar to the adults who replied. 6 out of the 7 reported some or a great improvement in their condition and described the effects as lasting. Their EQ-5D improvement scores are recorded in Section 6.3.
- 5.8. 30 patients reported they had fistulae. 22 described treatment as providing a great improvement, 5 some improvement and 3 'no change'. 21 said the effects were lasting and 8 said they did not last. Some comments about their experiences are included below.
- 5.9. This is a selection of comments by members about their experience of a TNF α inhibitor, usually infliximab. Responses, positive and less positive, are selected from answers to Questions 15, 16 and 21. A complete listing of members' comments is enclosed. **(9.8)**.
- *Infliximab was brilliant for the first 18 months. I worked and gained a degree and had a great life you wouldn't have even known I had Crohn's, super drug. After 18 months, I developed antibodies and I was quite ill for a long time*
 - *Immediate movement, all symptoms subsided, bowel movement under control immediately, all other symptoms subsided within next 2 weeks. Fistula started healing (but hasn't healed completely) 3 x course of lafliximas, was back at work after the third one. Have been in remission since then. Still rebuilding strength and fistula is much improved but still there. Have been back at work full-time.*
 - *Like someone had flicked a switch with a miracle cure.*
 - *Until I stopped having it, it was brilliant: less pain no diarrhoea or blood, and I wasn't so tired. As I have stopped having infliximab all my symptoms have returned hence I have to go through surgery this year.*

- *After treatment the condition stopped getting worse - started to get better - a sort of 'respite'! Lasted 2+ months first time. 6+ weeks second time and one month third time.*
- *Within 5 days my life had improved hugely, within 2 years I was able to stop all treatment for 9 months to have a baby. I have completed a degree and am now at Cambridge University for teacher training.*
- *I have had 2 days off work in the past 9 months - with flu! No mouth ulcers - I can eat, I can go out. I have my life back. I can feel it wearing off at the 7 week point and know I need my top up.*
- *I feel I have got my life back. I can plan holidays, weekends away and my sickness at work has dropped from approx. 11 weeks per year to 4 days. I have periods where I feel fatigued/in pain/ have diarrhoea, but they are a lot shorter and a lot less severe.*
- *From November 2006 - Jan 2007 there was no discharge at all from fistula and the energy I had was wonderful. At the end of Jan 07, following some stress at work, the fistula again became active. Antibiotics were prescribed at this time and there was some relief.*
- *No pain, no sickness and normal bowel habits, yippee!*
- *After 2 weeks of having the infusion I woke up one morning and realised my pain had virtually gone. My exact words to my specialist were 'it's like a miracle'. I continue to have Infliximab every 8 weeks. Usually on the last week before it is due I feel slightly tired and achy joints*
- *Benefits, alleviated peri-anal conditions and diarrhoea which had been resistant to other medication. Reduced sensational connection between faecal and urinary functions. Stamina increase as if one had just rid oneself of a heavy cold and put down a 50 lb rucksack. Some stool formation with much reduced blood, mucus and puss. Walking gait nearly back to normal. Better continence.*
- *I have moved out of my parents' house. I am more confident at driving and meeting new people. I have a new job. I don't have to 'run' to the toilet. I have put on weight, I have come off steroids. I don't have stomach pain, I am stronger and have more stamina*
- *Instead of being fed via an NG tube all the time, I now only spend about one third of my life being fed through a tube.*
- *In 2001 after small bowel surgery. The whole operation scar opened leaving me with approx. 5 fistulas, I had to wear a wound bag. Treatment with Infliximab resulted in 4 fistulas healing, but after more Infliximab, we couldn't heal the last fistula - but I was in such less discomfort and pain I could then endure more surgery to rid me of the final fistula*

- *I have fistulas which swell and open my scar and faeces pours out, so infliximab keeps them at bay. I have 8 weekly infusions with a course of antibiotics in between.*
- *My last 2 infusions have lasted over a year. I have not had any time off work at all since my last infusion.*
- *Feel like I can live now rather than surviving.*
- *I am still not well enough to work but I manage to do some socialising. I still have problems with depression, which is inevitable with a chronic condition, but since receiving Infliximab I have been able to discontinue anti-depressants*
- *I am able to live a 'normal' life. Can exercise, have energy and enthusiasm, am also able to have a sexual relationship again with my husband*
- *I generally feel much better. Have been able to return to work part-time. Enjoy time with my 2 year old which I couldn't before. Go out for days without too much worry about going to toilet all the time*
- *My quality of life used to be measured daily by how my Crohn's had been. Now I can get on with my life without thinking about the Crohn's - it's something that gets in the way every now and then*
- *I can now carry on a normal life, where as before I was almost housebound*
- *Without it I would probably be crippled with arthritis and probably unable to work.*
- *Just to reiterate that personally my life has improved beyond belief - (don't know the long term benefits). I can't imagine the state I would be in had I not had the infliximab - I feel extremely strongly that these treatments should be available on the NHS to all who would benefit. (My family have certainly benefited from the 'new' me as well).*

6. Analysis of EQ-5D Element of NACC Survey

6.1. The following table shows the percentages for all patients' assessment of their health state at the time of completing the questionnaire. Further analysis is being undertaken to provide separate tables for those who report their treatment as successful and those who reported the treatment as unsuccessful or as not having lasting effect.

	Mobility	Self-Care	Usual activities	Pain Discomfort	Anxiety Depression
No problems	64	82	43	24	58
Some problems	34	15	49	66	34
Extreme problems	0	2	6	8	6

- 6.2. In an ideal study we would have available similar tables based on the EQ-5D responses before and after treatment. This was obviously not available in our retrospective data collection, therefore we asked patients to estimate their health state 'today' using the EQ-5D scale and then to estimate their health state prior to treatment with a TNF α inhibitor. The responses are presented in ten groups.

Scale	Before treatment	Current health status
	%	%
100	0	2
90-99	0	17
80-89	1	20
70-79	1	23
60-69	2	11
50-59	5	8
40-49	11	6
30-39	16	5
20-29	22	5
10-19	17	1
0-9	21	0

This table shows the degree of improvement using the same scale points:

Scale showing extent of improvement	Number of patients	% of all patients
	%	%
100	1	0.5
90-99	7	4
80-89	13	7
70-79	16	9
60-69	27	15
50-59	28	15
40-49	27	15
30-39	14	8
20-29	21	12
10-19	13	7
0-9	3	15
No change	6	3
Change for the worse	6	3

- 6.3. The actual before and after health status scores for the children who responded to the study are shown below:

Before treatment	Current health status
20	60
45	85
26	92
5	90
2	80
10	75
2	10

7. NACC View of the Key Issues

- 7.1. The licenses for these therapies are for the treatment of severe, active refractory Crohn's. Traditionally, if the combination of steroids and immunosuppressive drugs is not successful, then surgery is likely to be the next option, with significant costs for the NHS and with major physical and psychological implications for the patient. The 1995 NACC survey showed that fear of surgery was the second greatest worry for patients. Most people will understandably wish to know that they have exhausted alternative therapies before being more prepared psychologically to accept the necessity for surgery.
- 7.2. The evidence suggest that the technologies being considered can offer up to two-thirds of these patients an additional period of good quality remission from symptoms and in respect of infliximab this seemed to be confirmed by the experience of members in our NACC Survey. We were not attempting in our survey to determine how long the periods of remission might continue, with or without maintenance treatment, but some members clearly felt that the TNF α inhibitor had reversed a pattern of deterioration in their symptoms.
- 7.3. Many members reported a significant benefit in their quality of life, restoring them for varying periods to a state closer to what they recall as good health or normal life. The importance of continued treatments for maintaining this improved health and quality of life was clear, albeit that the required treatment intervals seemed to vary from individual to individual. Further analysis of the time intervals for re-treatment was beyond the scope of our Survey.
- 7.4. We specifically asked members who felt that the benefits of treatment did not last whether they felt that the treatment was still worthwhile. The majority did think so. Even if it is only temporary, a period of improved symptoms or remission can have huge value both as a time of respite and recovery from the disease or to see a patient through a particularly significant event in their life. We know through our membership that individual people have benefited from such

remissions at times of university exams, for weddings and to become pregnant. A period of better quality of life may also help at times to place the patient in a better physical and psychological state for planned surgery.

- 7.5. NACC feels it is essential that approval is specifically given for maintenance treatment with TNF α inhibitors to make it clear that continued treatment funded by the NHS is approved. The time intervals for such repeated treatment can be determined in relation to individual patients and some do not seem to need repeated treatments as often as the clinical trials have suggested. However, it is not satisfactory for patients to have to relapse before further treatment is authorised, with all the uncertainty about future treatment and the impact on health and quality of life that such a requirement would entail.
- 7.6. Infliximab is specifically licensed for treatment of fistulae in Crohn's which will not respond to conventional therapy. Fistulae are very distressing and disabling for patients and in many instances cannot be successfully treated. Infliximab has been shown to heal some fistulae where conventional therapy has failed. Since there is no satisfactory alternative treatment, no one with fistulae should be denied the chance to see if they respond positively to infliximab.
- 7.7. The use of infliximab for children with Crohn's Disease can now be considered following the European license for this. Relatively few members of NACC reported their experience of this therapy and therefore NACC sought the view of the Inflammatory Bowel Disease Working Group of the British Society of Paediatric Gastroenterology, Hepatology and Nutrition. Their view is that NICE should approve the infliximab for children. Their statement to NACC is enclosed **(9.9)**.
- 7.8. NACC members' experience shows a relatively low number of immediate complications in their treatment with TNF α inhibitors. Longer-term monitoring will be needed to determine whether there is eventually an increased cancer-risk or significantly greater vulnerability to infection. In the meantime the present level of knowledge concerning such risks should be discussed with patients so that they can participate in the decision about use of infliximab in an informed way. NACC also supports the view that a Register of patients treated with TNF α inhibitors should be established to facilitate this monitoring and ensure that patients can be given the best possible guidance on risks and benefits. Ultimately such a Register might also enable the better identification of which patients could benefit most from which therapies if linked with the genetic profile of the patients.
- 7.9. NACC submits that all three TNF α inhibitors and natalizumab should be made available to NHS patients on the basis of their European licenses at the time of appraisal. All Health Authorities should permit and fund the use of these technologies for the minority of Crohn's

patients for whom conventional medical and/or surgical treatment has failed or is inappropriate. Clinicians should have the freedom to discuss and decide with individual patients whether the balance of possible benefit, risk and their own clinical and life circumstances suggests treatment with one or more of these therapies should go ahead.

8. Declaration of Interests

- 8.1. One of NACC's governing principles is to work in partnership with relevant organisations. In respect of pharmaceutical companies NACC seeks to establish a co-operative relationship with all the companies active in IBD and accepts moderate financial support or services-in-kind for specific projects that will help to achieve NACC's objectives. The total value of such support from all companies in 2006 was less than £60,000.
- 8.2. All four companies involved in these technologies have provided £4,000 in support to NACC in 2006 and we anticipate may continue to do so in 2007. This support has been for a project supported by eight companies to provide 10,000 Information Packs for newly-diagnosed patients which NACC is distributing free to hospitals. The project was launched at a House of Lords Reception in October 2006 which was also supported by the same companies.
- 8.3. NACC received an educational grant of £2,500 from Elan to support NACC in facilitating the conduct of a survey of patients with Crohn's Disease via the NACC website to provide some cost-related information as part of the background to this HTA.
- 8.4. NACC is currently negotiating an educational grant from UCB to assist with developing several video clips of patients' experiences to enhance the NACC website.
- 8.5. NACC is affiliated to EFCCA, the European Federation of Crohn's and Ulcerative Colitis Associations, which is currently negotiating a Europe-wide patient education project with Abbott in which NACC will play a part. NACC is seeking an educational grant to cover its costs in this project.

9. Accompanying Materials

- 9.1 NACC Plan
- 9.2 NACC Annual Review 2005
- 9.3 NACC Booklet on Crohn's Disease
- 9.4 NACC Booklet on Surgery for Crohn's Disease
- 9.5 NACC Audit of IBD
- 9.6 NACC Video – Talkabout Crohn's
- 9.7 Copy of NACC Survey
- 9.8 Complete list of NACC Members' Comments from Survey
- 9.9 Statement from BSPGHAN re paediatric use of infliximab