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22 August 2005

SUBMISSION TO NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) HEALTH TECHNOLOGY APPRAISAL ON THE USE OF BEVACIZUMAB AND CETUXIMAB IN COLORECTAL CANCER

Introduction

The development of monoclonal antibodies in the treatment of cancer has led to major therapeutic advances in non-hodgkin's lymphoma and breast cancer, which have been clearly recognised and approved by NICE. The two agents discussed in the present document have both shown meaningful advances in colorectal cancer.

Bevacizumab is a humanised monoclonal antibody, which targets the vascular endothelial growth factor and thereby reduces new blood vessel growth (angiogenesis) and reduces the interstitial pressure within the cancer, thereby allowing improved chemotherapy access.

Cetuximab is a chimeric monoclonal antibody targeting the epidermal growth factor receptor, which stimulates a growth and survival pathway in the cancer cell. Blocking that pathway reduces cellular proliferation, angiogenesis, metastatic potential and resistance to chemotherapy and radiotherapy.

These agents have mechanisms of action that represent an entirely new approach to cancer therapy and are thus very important advances in the treatment of this common malignancy. Meaningful improvements in symptoms and survival have been achieved with the clinical use of these agents.

This document represents our considered view of these treatments as specialist oncologists in the UK and advisers to Colon Cancer Concern (CCC).

Signed.

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Colon Cancer Concern
THE BOWEL CANCER CHARITY

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1.0 Bevacizumab (Avastin[R]):

Bevacizumab has demonstrated increased response and significant improvements in survival when added to first line chemotherapy for advanced or metastatic colorectal cancer (MCRC), in combination with irinotecan and with 5-fluorouracil (5FU), compared to irinotecan and 5FU alone.

A summary of the evidence

1.1.0 In combination with irinotecan and bolus 5FU/folinic acid (in the IFL or Saltz regimen), bevacizumab (5mg/kg dose every 2 weeks) has been shown to significantly increase overall survival compared to IFL with placebo (20.3 versus 15.6 months, hazard ratio [HR] 0.66, p<0.001). Progression-free survival (PFS; 10.6 versus 6.24 months, HR 0.54, p<0.001), response rates (45% versus 35%, p=0.004) and duration of response (10.4 versus 7.1 months, p=0.0014) were also significantly improved (Hurwitz et al. 2004).

1.1.1 In patients who were considered unsuitable for treatment with a first line irinotecan containing regimen, the combination of bevacizumab (5mg/kg every 2 weeks) with bolus 5FU/folinic acid (Roswell Park regimen) has shown a trend towards improvement in median survival (16.6 versus 12.9 months, HR 0.79, p=0.16), response rates (26.0% versus 15.2%, p=0.055) and duration of response (9.2 versus 6.8 months, HR 0.42, p=0.088) compared to the same chemotherapy with placebo. The PFS was significantly longer in the bevacizumab arm (9.2 versus 5.5 months, HR 0.50, p=0.0002) (Kabbinavar et al. 2005).

1.1.2 An earlier phase II study randomised patients between treatment with Roswell Park 5FU or the same with two dose levels of bevacizumab (5mg/kg or 10mg/kg every 2 weeks). Compared with the chemotherapy alone, the addition of low dose bevacizumab resulted in statistically significant increases in response rate (40% versus 17%, p=0.029) and median time to progression (TTP; 9 versus 5.2 months, p=0.005). Median survival was longer in the bevacizumab arms but this was not statistically significant (21.5 months for low dose bevacizumab, 16.1 months for high dose bevacizumab and 13.8 months for chemotherapy alone) (Kabbinavar et al. 2003). A further phase II study assessed response in patients treated with the IFL regimen and bevacizumab. 43% of patients experienced a partial response and 6% a complete response (Giantonio et al. 2004).

Bevacizumab in previously treated patients and with other cytotoxic agents such as oxaliplatin and capecitabine

1.2.0 The TREE2 study randomised previously untreated patients with MCRC to treatment with oxaliplatin and bevacizumab (either 5mg/kg every 2 weeks or 7.5mg/kg every 3 weeks) with either infused 5FU (the modified FOLFOX6 regimen), bolus 5FU or capecitabine. Response rates for all three arms (63.4%, 42.9% and 56.9% respectively) were higher than the corresponding chemotherapy only arms of the preceding TREE1 study (46.9%, 32.0% and 37.5% respectively). Confirmed response rates were 49.3%, 34.3% and 37.5% respectively. At the time of last reporting, the median TTP and OS had not been reached (Hochster et al. 2005).

1.2.1 In the Eastern Cooperative Oncology Group (ECOG) E3200 study, patients who had previously been treated with irinotecan and a fluoropyrimidine, either alone or in combination, were randomised to treatment with oxaliplatin and infused 5FU (FOLFOX4) with high dose bevacizumab (10mg/kg every 2 weeks), FOLFOX4 alone or bevacizumab alone. The bevacizumab alone arm was closed early in March 2003 after a trend towards inferior efficacy was observed by the independent data monitoring committee. The addition of bevacizumab to FOLFOX4 in this patient group was associated with a significant improvement in median overall survival (12.9 versus 10.8 months, HR 0.76, p=0.0018), PFS (7.2 versus 4.8 months, HR 0.64, p<0.0001) and in overall response rate (21.8% versus 9.2%, p<0.0001). (Giantonio et al, 2005)

1.2.2 Bevacizumab has also been combined with cetuximab in a phase II study in patients who were refractory to irinotecan (the BOND2 study). Patients in this study were randomised to treatment with bevacizumab and cetuximab with or without irinotecan (CBI and CB respectively). The response rates were 37% and 20% respectively, and the TTP was 7.9 and 5.6 months respectively (Saltz et al. 2005).

Toxicity: Bevacizumab

Caution should be taken when treating patients who are at risk of: gastrointestinal perforation e.g. with active gastric ulcers or colitis; uncontrolled hypertension; arterial thromboembolism and are about to undergo, or have recently had surgery. Patients with untreated CNS metastases should not be treated with bevacizumab.

Recommendations: Bevacizumab

This is the agreed practice when it comes to the use of this drug in the UK.

- There is evidence to support the use of bevacizumab in first line therapy in combination with an irinotecan plus fluoropyrimidine combination in selected fit patients without risk factors for bevacizumab toxicity. This conclusion is compatible with the bevacizumab licensed indication. Although the IFL regimen used in the pivotal study is suboptimal, it is highly likely that this advantage will be seen with optimised fluoropyrimidine schedules based on infusional 5FU or capecitabine, which are used in the UK.

- There is evidence to support the use of bevacizumab in combination with single agent i.v. fluoropyrimidine in first line therapy in selected fit patients without risk factors for bevacizumab toxicity. This conclusion is in line with the bevacizumab licensed indication. The data from the FOCUS (Seymour, 2005) and LIFE (Pluzanska, 2005) trials indicate that sequential usage of chemotherapy starting with fluoropyrimidine therapy is an alternative approach for some patients. In addition this indication may be important for some patients who are fit for bevacizumab therapy but for whom combination chemotherapy is unsuitable.

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- Although the use of bevacizumab with other first line regimens lies outside the current EMEA licensed indication, clinicians expect that similar benefit should be seen with the addition of bevacizumab to other regimens such as oxaliplatin based combinations. A prospective registry of patients treated in the United States with bevacizumab off study reported that 47.7% of patients received the agent with the FOLFOX regimen, whereas only 13.9% of patients received bevacizumab with IFL (Kozloff et al. 2005).

  The data from the TREE2 study described previously is emerging evidence which supports this combination (Hochster et al. 2005).

- Despite a statistically significant benefit in both OS and PFS in second line CRC in combination with FOLFOX, Avastin is currently not licensed in this indication. The data from the large randomised trial (Giantonio 2005) presented at ASCO 2005 shows a 2 month median OS benefit from the addition of bevacizumab in a medically 'fit' patient population

- There is no support for the use of bevacizumab in 3rd line treatment after progression on irinotecan and oxaliplatin. Such use of bevacizumab is not part of the authorized indication for the drug. Preliminary data from a non-randomised phase II trial indicate very modest anti-tumour activity (1% response rate) in this setting (Chen 2004).

- There is insufficient evidence to support the addition of bevacizumab to irinotecan and cetuximab after progression on irinotecan. Bevacizumab seems to add to the activity of cetuximab in terms of tumour response and time to progression in this setting. However, the data isn't yet sufficient to support its use

- There is no support for the use of single agent bevacizumab or continuous administration of bevacizumab after stopping chemotherapy. Single agent bevacizumab is not part of the licensed indication. In the pivotal study, patients were able to continue on single agent bevacizumab after discontinuation of chemotherapy due to intolerance of side effects. The benefit from this is not proven and the single agent efficacy of bevacizumab alone seems low (Chen 2004, Giantonio 2005) such that the bevacizumab alone arm was terminated due to inferior survival in the E3200 study.

- Bevacizumab should not be used in patients that are at increased risk of its clinically significant adverse side effects. This includes patients with:
  - A recent history (within 6 months or less) of arterial thrombotic events (myocardial infarction and cerebrovascular accidents)
  - Major surgery, open biopsy or significant trauma within 28 days prior to starting treatment
  - Serious non-healing wounds, ulcers or bone fractures
  - Hypertension uncontrolled despite medication
  - Baseline proteinuria >1g/day as defined by 24 hour urine collection
  - Chronic use of non-steroidal anti-inflammatories or aspirin in excess of cardioprotectant dose (>325mg per day)

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2.0 Cetuximab (Erbitux®)

Cetuximab meets a recognised unmet clinical need. Cetuximab offers an increased response and delayed progression when added to second and third line chemotherapy for advanced or metastatic colorectal cancer (MCRC), in combination with irinotecan.

A summary of the evidence

2.1.0 The main evidence for the use of cetuximab in MCRC is in patients with irinotecan refractory disease.

2.1.1 A phase II study (BOND) randomised patients to receive either cetuximab and irinotecan (at the same dose and schedule they had previously failed), or cetuximab monotherapy. The addition of cetuximab to irinotecan significantly increases response rates over cetuximab alone (22.9% versus 10.8%, $p<0.001$). Median time to progression was also significantly longer (4.1 months versus 1.5 months, $p<0.001$). However, there was no significant difference in median survival (8.6 versus 6.9 months, $p=0.48$), which may be due to the effect of treatment crossover in the cetuximab monotherapy arm (Cunningham et al. 2004).

2.1.2 Three phase II studies evaluated the efficacy of single agent cetuximab in patients who were refractory to prior chemotherapy including irinotecan, oxaliplatin and 5FU. Partial responses were observed in 9%-12% of patients with about a further 30% having disease stabilisation (Saltz et al. 2001, 2004, Lenz et al. 2005). Most patients who progressed showed evidence of treatment failure at the first CT scan after 6 weeks of therapy.

2.1.3 Cetuximab has also been combined with FOLFOX4 in a randomised study, conducted in the US, in patients with irinotecan refractory disease (the EXPLORE study). Unfortunately this study was closed prematurely, as a change in clinical practice favouring the use of oxaliplatin as first line treatment meant that the study could not recruit any more patients. Some results on the 102 patients recruited (out of an intended 1100 patients) have been reported, but the primary objective of overall survival has not been reported (Jennis et al. 2005, Polikoff et al. 2005).

2.2.0 Five phase II studies have reported safety and efficacy of cetuximab in combination with either oxaliplatin or irinotecan based regimens as 1st line treatment for metastatic CRC. The ACROBAT study (cetuximab + FOLFOX4) demonstrated an ORR of 74% (with a further 23% achieving disease stabilization). 9 patients (21%) underwent surgery for liver metastases, of which 7 achieved a potentially curative resection (R_0). The PFS for this study was 12.3 months (E. Díaz Rubio 2005).

A further phase II study (cetuximab + FUFOX) demonstrated an ORR of 54% with 7% of patients becoming operable for metastatic disease. (Seufferlein, 2005). One study (cetuximab + AIO) demonstrated an ORR of 67%, TTP of 9.8m and overall survival of 33 months. Five patients with initially unresectable liver metastases became eligible for secondary resection. (Folprecht, 2005); a second study (cetuximab + IFL) gave a PR of 48% (Rosenberg et al. 2002); a third study (cetuximab + FOLFIRI) gave a PR of 43% and an ORR of 88%. 5 patients with initially unresectable liver metastases underwent surgery. (Rougier et al, 2004).

2.3.0 Patients were selected for entry into the earlier clinical trials of cetuximab based on epidermal growth factor receptor (EGFR) positivity as determined by immunohistochemistry, for example using the FDA approved pharmDx kit (DakoCytomation). However, subsequent clinical trials of cetuximab in mCRC have failed to show a correlation between the intensity of staining and patient response to treatment or outcome, such as in the pivotal study described above (Cunningham et al. 2004).

2.3.1 The correlation mentioned in 2.3.0 is supported by a retrospective review of irinotecan refractory patients at a single institution who received cetuximab off-study and had documented EGFR negative tumours by Immunohistochemistry (Chung et al. 2005). Sixteen patients were included, fourteen of who received cetuximab with irinotecan. Four objective responses (25%, 95%CI 4-46%) were seen. These results suggest that patients who are EGFR "not detected" by current immunohistochemical methods are just as likely to respond to cetuximab as those who are EGFR positive. More recently initiated studies, including the current UK COIN trial, are therefore no longer requiring EGFR positivity to be demonstrated by immunohistochemistry as a requirement for study entry.

2.4.0 There is a large evidence base establishing the correlation of rash with efficacy (response & survival) for cetuximab plus irinotecan. Four studies (Cunningham 2004, Saltz 2001, Saltz 2004, Lenz 2004) with cetuximab in CRC (n>850 patients), and two randomised studies in other cancer indications (Bonner 2004, Saltz 2003) (n>1500 patients) have established this.

	n = 218	
Degree of skin reaction	**ORR**	**OS**
none	6.3 %	3.0 months
≥ Grade 2	33.6 %	10.8 months

Toxicity: Cetuximab

Caution should be taken to observe for hypersensitivity reactions in patients during and after cetuximab infusions (mostly likely to occur with the 1st and 2nd infusions). Symptoms of dyspnoea should be investigated. Skin reactions are commonly reported.

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Recommendations: Cetuximab

This is the agreed practice when it comes to the use of this drug in the UK.

- Cetuximab is recommended for use in combination with irinotecan in selected fit patients with previously treated MCRC who are irinotecan refractory.

- The availability of an active agent in this setting provides a new opportunity for therapy. There are relatively few patients who are fit for treatment in this setting, estimated at only about 5% of the metastatic disease population treated for mCRC.

- In the BOND study, 31% of patients eligible to begin cetuximab and irinotecan therapy had Progressive Disease at 6 weeks. This group achieved an average overall survival of only 5.9m, whereas those who obtained a partial response at 6 weeks achieved an overall survival of 16.6 months. Therefore, as a pragmatic cost-containment exercise, and to repeat the study conditions of BOND, one could consider an early evaluation of response (after 6 weeks therapy) and those patients showing progressive disease at this point should discontinue therapy.

- There is insufficient support for the use of single agent cetuximab following progression on irinotecan based chemotherapy. The potential benefits are relatively small and therefore do not support the routine clinical use of cetuximab monotherapy.

- [redacted]

- There is no support for the decision to use cetuximab based on immunohistochemical detection of EGFR expression to select patients. The licensed indication states that the tumour should be tested for EGFR expression. However, EGFR positivity as detected by immunohistochemical methods has been shown to be an ineffective way of selecting patients for treatment with cetuximab, potentially depriving patients who may benefit from treatment from receiving this agent.

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Colon Cancer Concern
THE BOWEL CANCER CHARITY

NICE HEALTH TECHNOLOGY APPRAISAL

THE USE OF BEVACIZUMAB AND CETUXIMAB FOR THE TREATMENT OF ADVANCED COLORECTAL CANCER

SUBMISSION BY COLON CANCER CONCERN (CCC)

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Contents

More/....

Introduction

The development of two biological agents, bevacizumab and cetuximab, in the treatment of colorectal cancer is a very important scientific advance. It's also very exciting news for patients, as both treatments are targeted therapies, which have significant benefits in terms of increased survival times and improved quality of life.

The perfecting of targeted colorectal cancer therapies is a striking indication of the speed at which treatment of the disease has developed in recent years and of the increasing sophistication of the drugs concerned.

It seems like another lifetime - but is actually only a few years ago - when the only treatment for colorectal cancer was still 5FU with leucovoran, as it had been for nearly fifty years: a time when, if you wanted some peace at a treatment related conference, you went to the colorectal cancer session.

In recent years, however, there has been an explosion in the number of treatment options available for colorectal cancer patients, including the new chemotherapy treatments, irinotecan and oxaliplatin; oral chemotherapies such as capecitabine and uftoral; and now the biological agents bevacizumab and cetuximab. And if you want to attend a colorectal cancer session at a conference these days, you need to get there early because it's invariably standing room only.

The use of the full range of treatments, as sole agents or in combination; and in the metastatic and adjuvant (i.e. post surgery) settings is significantly extending patients' lives and improving their quality of life. Patients are now looking at potentially two additional years survival or more on combination chemotherapy, compared to a few months on 5FU alone. Bevacizumab and cetuximab are both central to this treatment revolution and have a key role to play in extending and improving patients' lives.

This submission sets out what having access to these biological agents means to patients; what the treatments' benefits are; what are their side effects; and what impact - both positive and negative - they have on patients and those who care for them. As part of this submission, we have included a range of patient case studies - five for each of the two treatments - that answer all these questions and more.

In addition, CCC has worked with three of the country's leading clinicians - who are also advisors to the charity - to produce a comprehensive document setting out the clinical case for bevacizumab and cetuximab, factoring in the results of the various trials and studies and other relevant information about both treatments.

We hope that this submission will be helpful to NICE in making its assessment of the use of bevacizumab and cetuximab for the treatment of advanced colorectal cancer.

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This document is dedicated to the memory of two colorectal cancer patients, [redacted] and [redacted] who died earlier this year. Both [redacted] and [redacted] did a great deal to raise awareness of colorectal cancer and both also benefited from these treatments, despite having difficulties in gaining access to them. We hope that following positive NICE and SMC guidance, these treatments will soon be made more widely available to many more patients who would benefit from them.

More/....

Colon Cancer Concern (CCC)

Colon Cancer Concern (CCC) is a leading colorectal cancer charity in the UK. CCC was founded in 1987 and has gradually grown to its current size of around 25 staff. Over the years we have developed our range of services and are now a major national charity dedicated to combating colorectal cancer (CRC) and improving the quality of those affected by the disease, through our four activity pillars, as follows:

- **Information:** We provide authoritative information, support and advice, to patients, carers, the worried well, the public and others. We have a dedicated Helpline, run by colorectal nurse specialists, who deal with hundreds of enquiries each month from people concerned about symptoms and other issues. This service is underpinned by a network of thirty expert advisors who offer us up to date advice and information about the disease

- **Education:** We provide CRC related educational programmes for colorectal nurses and other clinicians, in conjunction with the Royal College of Nursing and our nurse expert advisory board

- **Awareness:** We seek to increase awareness and understanding of the symptoms and prevention of colorectal cancer. We utilise our 45 foot information trailer, our website and a range of materials including leaflets, booklets, posters and stands to help us do so

- **Campaigning:** We campaign for equity of treatment and care for all colorectal cancer patients in the UK, including amongst key political audiences – Government Ministers, the Department of Health, the NHS, NICE, SMC, the Scottish Executive, Welsh Assembly, opposition parties, MPs, MSPs and AMs

Campaigning For Access To Treatments

The campaign to give colorectal cancer patients greater and more equitable access to treatments has been central to CCC's activities in recent years. This has been a fast moving arena in which there has been - as we've said - an explosion in the number of treatments that are potentially available and an increasing awareness, including in the media, of the various issues around treatments and CRC generally.

We are pleased to have had the opportunity in recent years to make submissions to various NICE and SMC technology appraisals of CRC treatments; to be able to represent the viewpoint of patients and those who care for them; and to attend, with patients, carers and clinicians, related NICE and SMC appraisal meetings - all of which we will continue to do in the future.

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Bevacizumab and Cetuximab – The Clinical Viewpoint

The biological agents bevacizumab and cetuximab are both complex drugs, which work in similar but different ways in combating colorectal cancer. In this submission and its appendices we have taken the opportunity to set out the case for both treatments from two important and distinct viewpoints: that of the clinician and the patient. Here, first of all, is our summary of the treatments from a clinical perspective.

Cetuximab (Erbitux)

The limited efficacy and lack of selectivity of standard therapies for treating metastatic colorectal cancer has led to the search for targeted therapies that can differentiate more effectively between malignant and normal cells.

More than 80% of colorectal cancers are found to "express" Epidermal Growth Factor Receptors (EGFR), which are involved in the spread of tumours to new sites in the body (metastasis). The over-expression of EGFR is often associated with poor prognosis in many solid tumours, including in colorectal cancer.

Cetuximab (Erbitux) is targeted at EGFR. It works by binding to and blocking EGFR, reducing both the invasion of normal tissues by tumour cells and potentially the spread of tumours to new sites. It is not a traditional chemotherapy agent, but a synthesised antibody (a substance that is formed normally by the body). It is targeted at tumour cells and therefore does not have the same side effects that are traditionally experienced with chemotherapy.

Studies have shown that cetuximab significantly enhances the efficacy of standard chemotherapy and offers patients a delay in disease progression by up to five months. Patients on cetuximab generally experience fewer side effects than those on standard chemotherapy and it is generally well tolerated in combination with irinotecan in comparison with other cancer treatment options.

The most commonly reported side effect from taking cetuximab is an acne-like skin rash, which is reported in more than 80% of patients. This has been shown to be associated with a positive response to the therapy and is reversible after treatment is completed.

Bevacizumab (Avastin)

Bevacizumab is a humanised monoclonal antibody, which inhibits the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues – which is known as angiogenesis. It is the first anti-angiogenic treatment to effectively slow tumour growth and extend patients' survival.

Bevacizumab targets and inhibits the activity of vascular endothelial growth factor (VEGF), which is a key cause of angiogenesis. Inhibition of VEGF causes reduction and normalisation of the tumour blood vessels, which can lead to regression of the blood vessels, forcing the tumour to become dormant or to regress.

More/....

Bevacizumab (Avastin) (continued)

According to a recent clinical study of 923 patients, those who received bevacizumab in combination with conventional IFL chemotherapy (irinotecan/5FU/leucovorin) survived for an average 20.3 months, which is almost five months (30%) more than the group of patients treated with chemotherapy alone, who survived for an average of 15.6 months. This research is significant, as it shows the largest improvement in survival time reported in a Phase III clinical study for colorectal cancer that can be attributed to the addition of a single targeted therapy.

In terms of side effects: patients with untreated CNS metastases; at risk of gastrointestinal perforation; uncontrolled hypertension or arterial thromboembolism or who are about to undergo or have recently had surgery should not be treated with bevacizumab.

About The CCC Clinicians' Submission

In view of the complexity of bevacizumab and cetuximab, CCC felt it would be helpful to include the experts' opinion of their efficacy.

We have been working closely with three of our most senior clinical advisers - Professor David Cunningham and his team at Royal Marsden Hospital, London; Professor Tim Maughan at the Velindre Hospital, Cardiff; and CCC's senior medical advisor, Dr Rob Glynne-Jones at Mount Vernon Hospital, Northwood, Middlesex - in facilitating the preparation of a comprehensive document on the use of these treatments. **The CCC Clinicians' Submission is attached at Appendix B.**

CCC – Representing The Patient Voice

As a leading patient organisation, CCC is well placed to provide a platform for patients who have experience of colorectal cancer, including its treatment. Currently, CCC has around 400 colorectal cancer patient case studies on file, may of whom work with the charity in raising awareness, including through the media.

CCC aims to help patients make an informed decision about the treatment, management, care and support they receive. This is fundamental in today's health climate where shared decision-making - through a multidisciplinary team of healthcare professionals, patients, carers and patient support groups - has become established good practice. We campaign for improved choice and availability of treatments and access to the best possible care for all.

Bevacizumab and Cetuximab - The Patients' Viewpoint

We spoke to ten patients who had been prescribed either bevacizumab or cetuximab and have summarised their views below. **The full Patient Case Studies are attached at Appendix A.**

More/....

Patients on cetuximab (Erbitux)

Responses from those patients who have been on Erbitux were, in the main, very positive. Most reported that - after some initial discomfort, which could be associated with any change in their drug regime - they felt better compared to being on other chemotherapy drugs.

Overall, patients on Erbitux felt more energetic, regained their appetite and had a restored sense of well-being. They found they were able to lead more normal lives – for example, by visiting friends, eating meals and continuing to work when able to.

The most dramatic side effect reported was the skin reaction, which was experienced by all the patients we interviewed. However, they saw the reaction as being a "small price to pay" and psychologically they did not mind it, because it showed that the drug was having a positive effect on their body. The skin reaction was generally in the form of a rash on the face but was something could be managed.

Patients on Bevacizumab (Avastin)

Responses from those patients who have been on Avastin were, in the main, positive compared to other drugs they had taken as part of their bowel cancer treatment.

Several commentated on the "dramatic" and "amazing" effect on their health and well-being; on how much better they felt and how "easy" Avastin was. In particular, patients were pleasantly surprised by the lack of nausea they had. All said how convenient the Avastin aspect of their chemotherapy regime was – taking just 30 minutes to be administered compared to, in one case, 40 hours for 5FU.

The symptoms experienced by the Avastin patients we interviewed included: slight loss of hair (but not a dramatic loss); exhaustion; and random nose bleeds. However, each patient we spoke to expressed how these side effects were either less dramatic than those they had previously experienced on other treatments or were simply not as bad as they had expected.

Conclusions

It is clear, from what patients and clinicians tell us and from their invaluable contributions to this submission, that bevacizumab and cetuximab have a significant and positive impact on patients' lives and quality of life. They increase life expectancy and have fewer side effects and more benefits than many other treatments.

In addition, it is clear that these targeted therapies are the gateway to an exciting future, when each patient increasingly has the option of treatment that is tailored specifically to them.

Consequently, CCC warmly welcomes these treatments and calls on NICE to give them a positive appraisal and make them as widely available to patients as possible.

Colon Cancer Concern (CCC)
22 August 2005

Colon Cancer Concern
THE BOWEL CANCER CHARITY

NICE HEALTH TECHNOLOGY APPRAISAL

THE USE OF BEVACIZUMAB AND CETUXIMAB FOR THE TREATMENT OF ADVANCED COLORECTAL CANCER

SUBMISSION BY COLON CANCER CONCERN (CCC)

PATIENT QUESTIONNAIRES

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More/....

[redacted]

Bevacizumab (Avastin)
Interviewed August 2005

Quote

"Avastin has had a dramatic effect on my health and well-being. No-one expected me to move 'backwards' [i.e. get better] as quickly as has happened."

Profile

- [redacted]is 59 years old
- He is married with 4 children and 5 grandchildren
- He lives in [redacted] Gloucester
- He owns and runs Murray Estate Agencies, which has three or four offices around Gloucestershire

Family History

- His father died of leukaemia; his mother died of breast cancer; his grandfather died of bowel cancer

His experience

- After a few months of having blood in his stools, [redacted] doctor thought he probably had piles. However, as [redacted] also had severe intermittent abdominal pain, the doctor finally referred him for a colonoscopy that found a blockage

- [redacted] was diagnosed with colorectal cancer in September 2002 and admitted that month as an emergency to the Royal Gloucester Hospital, at which time his tumour was removed

- He had a Dukes C cancer, which had spread to the lymph nodes. Following surgery, he had 30 weeks of 5FU at the Cheltenham Hospital until May 2003

- He had regular blood tests and a clear colonoscopy until, in May 2003, blood tests picked up a high CEA count. A subsequent CT scan found inoperable tumours just behind the aorta at the top of the bowel and small lesions on the liver

- His local NHS offered him standard chemotherapy treatment – probably oxaliplatin (he doesn't remember) – but gave him only 9 months to live. [redacted] wrote to Professor Cunningham at the Royal Marsden Hospital for a second opinion and was offered a place on their trial of bevacizumab

- Since December 2004, he has had three sessions of chemotherapy; with each session lasting 12 weeks (4 x 3 weeks). He receives oxaliplatin intravenously; oral 5FU (capecitabine); plus bevacizumab also intravenously

More/....

- After the first session, the tumours had reduced by over 50% and the two liver lesions had disappeared completely. The scan after the second session showed further improvements. Professor Cunningham said they could not wished for better progress. The third trial session has just finished and the scan is now due.

Impact on his life/Lifestyle

- He is still working when treatment allows. He was very health conscious and fit before he was diagnosed and went swimming every morning. He still plays golf

Impact of the drug

- He feels the drugs have had a dramatic effect on his health and well-being

***

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

See above

1.2 How does having colorectal cancer affect day-to-day life?

It affects every person differently. My attitude is to keep busy

1.3 Are there any activities the patient is not able to do because of the condition?

I've had sore feet because of the side effects of oxaliplatin on my nerve endings. This has restricted some of my physical activities, but I still play golf

1.4 What is the impact of living with cancer on family, friends and employers?

Living with cancer affects my family almost more than me - the 'victim' - but everyone has been very supportive

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

I want the drugs to extend life expectancy – or provide a cure

More/....

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

The prospects were originally not good (9 months survival) but getting a second opinion and being accepted on the trial has improved my prospects considerably

3.2 What positive and/or negative impacts in having the technology have on the disease?

I don't know

3.3 Which symptoms did the technology best or worse treat?

It's difficult to say because when the tumours were found I was feeling absolutely well

3.4 What difference did having the technology make to the patient's long-term health and well-being?

I feel the drugs have had a dramatic effect on my health and well-being. No-one expected me to move 'backwards' (i.e. get better) as quickly as has happened

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

Oxaliplatin side effects – nerve endings (sore feet, extreme temperature sensitivity, peeling skin on hands/feet); Capecitabine – finger nails (softened and fell off); Bevacizumab – aware of no side effects

3.6 What would the impact be if the technology had not been available?

My life would be a lot shorter. On the basis of the nine months I was originally given, I would have been dead by now, so I was very pleased that I got on the trial

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

It needs certain re-arrangements and takes at least two days out of my working life per week when in treatment

4.2 Was there anything about the technology that made it hard or easy to use?

No

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Fortunately, health insurance has covered the cost of treatment so far

More/....

[redacted]

Cetuximab (Erbitux)
Interviewed August 2005

Quote

"I've felt better and more energetic since being on Erbitux - the side effects have not been so severe. The main one was a rash on my face but the nurse said this was good news; that this was what they wanted."

Profile

- Aged 47
- Married with 1 son, aged 25
- Works as a builder
- Hobbies include football; supports Manchester United

Family History

- Mother had bowel cancer 11 years ago and had surgery followed by radiotherapy. She is now all clear and turns 70 soon
- Father died from bone cancer in 1997

His experience

- Around the time of his 20th wedding anniversary in December 2003, [redacted] began to experience symptoms – primarily that he couldn't stop going to the toilet

- He went back to work in January 2004, but the symptoms persisted until the middle of the month, so he went to his GP, who told him simply to 'eat more fibre'

- He returned a couple of weeks later knowing that something was not right

- GP did internal investigation and referred him to hospital where he was diagnosed with bowel and liver cancer in Feb 2004

- He hasn't had surgery but has been on the following chemotherapy regimes:
  - For 12 weeks from May 2004 he was on 5FU
  - For 8 days in Aug 2004 he had radiotherapy
  - For 12 weeks from Oct 2004 he continued chemotherapy (not sure which drug)
  - Since Feb 2005 he has been on cetuximab – this was originally in combination with irinotecan but now isn't with this combination

- He took part in the MABEL trial

More/....

Impact on his life

- He hasn't been able to work and has been off work for over a year now
- He can't walk very far without getting tired
- He wears a PICC line all the time which limits his ability to do things (such as work)
- He still goes to the toilet a lot
- His family and friends have been incredibly supportive around him, as have the hospital staff
- Financially they are okay because the mortgage is almost paid off and his wife works full time
- His wife's boss lets her have time off whenever she needs it as well

Impact of the drug

- He has not found there to be any dramatic side effects with Erbitux
- He was told he might get a rash, which did happen on his face (scabby) as well as a slight rash on his legs and arms. However nurses said this was good as the drug was obviously working and the rash only lasted three to four weeks
- He has also had mouth ulcers since being on Erbitux and his the skin around the tops of his two big toes have split, so he has to have them bandaged
- After the initial two weeks of taking Erbitux, he felt better, more energetic and more positive
- Initially when he started taking Erbitux he was constipated and continued to lose weight but then after a week this disappeared – his appetite came back for example, his well-being improved, he started to have more good days than bad days

Lifestyle

- Hospital visits are still once a week – same as before (pre-Erbitux)
- Taking the drug has been no different (nurse doing it for you, intravenously)
- Takes a few hours out of his day (goes every Friday; there between 9am and 3pm)

***

More/....

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

I couldn't stop going to the toilet for about 4 weeks. I was initially turned away by the GP

1.2 How does having colorectal cancer affect day-to-day life?

I have had to stop working; I'm financially okay; short of breath; can't walk very far; wear a PICC line all the time

1.3 Are there any activities the patient is not able to do because of the condition?

I cannot work and am not as active as before

1.4 What is the impact of living with cancer on family, friends and employers?

My wife has had to take time off work, but her employers have been very understanding

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

Although there were some initial bad side effects (as above – rash, mouth ulcers, skin split around big toes), these were manageable and short term anyway. After the initial two weeks, I felt better, more energetic, more positive, felt better in myself. My appetite came back. I now have more good days than bad

3.2 What positive and/or negative impacts in having the technology have on the disease?

Negative – side effects (as above – rash, mouth ulcers, skin split around big toes)
Positive – felt better, more energetic (as above)

3.3 Which symptoms did the technology best or worse treat?

I have stopped going so much to the toilet and have gained appetite

More/....

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Unknown as yet, but I am feeling more positive and energetic in the short term

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

I could put up with side effects (as above - rash, mouth ulcers, skin split around big toes)

3.6 What would the impact be if the technology had not been available?

Continuation of going to the toilet, weight loss etc

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

The drug made no difference in terms of the impact on my life. I went to the hospital for my chemotherapy at often as before (once a week)

4.2 Was there anything about the technology that made it hard or easy to use?

No. It was as before with the other drugs I had through chemotherapy

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Only loss of time (most of a day) when going to hospital. No other costs to report – my wife's uncle takes me to hospital

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More/....

[redacted]

Cetuximab (Erbitux)
Interviewed August 2005

Quote

"The side effects I've had from Erbitux can be controlled and even though I've been tired, it's no worse than how I felt while on oxaliplatin and irinotecan. I definitely feel better in myself as well. My appetite has come back and I can go about doing normal things – such as eating."

Profile

- Aged 38
- No children
- Lives now in Clapton-on-Sea after periods of working and living away through work
- Works as a project manager

Her experience

- Experienced blood in stools and changes in bowel habit while she was living in Germany in 2002/3
- GP diagnosed haemorrhoids
- On her return to England and on continuation of the symptoms, GP here also diagnosed haemorrhoids
- In August 2003 she started a new job in Bath and symptoms continued, which she put down to stress of new job
- Had blood tests and other symptoms began – nausea, weight loss, couldn't eat
- Eventually during a hospital appointment, doctors detected polyps which were indeed cancerous
- Eventually diagnosed in March 2004 with bowel cancer which had spread to the liver
- She hasn't had surgery. Her chemotherapy regime has been as follows:
    - Oxaliplatin and 5FU: March 2004, 8 sessions, 16 weeks, finished in July 2004
    - Sept/Oct symptoms arose again
    - Late 2004 put on irinotecan
    - Since end-March 2005 has been on Erbitux, once a week

More/....

Impact on her life and lifestyle

- She has had to give up work
- Feels tired on Erbitux but no more or less than when on oxaliplatin and irinotecan
- Recently her appetite has started to come back and she hasn't been feeling nauseous
- Felt very weak at the start of 2005 but now gets days when she feels more active, active enough to visit friends
- Now has chemotherapy every week (as opposed to every other week previously) and with Erbitux it takes 30 more minutes than before. However she doesn't mind this – is happy to go to the hospital more often as feels she's doing more to combat the disease

Impact of the drug

- [redacted] had a bad skin reaction, rash on her face, back and chest
- It lasted for about 3 to 4 weeks but now can be more controlled and is less severe and less itchy
- Sometimes flares up now and again and has done in the past two weeks
- Feels tired but no more or less than when on other chemotherapy regimes
- Appetite has come back and has less nausea

***

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

I experienced blood in stools and changes in bowel habit, then nausea, weight loss and not being able to eat later on

1.2 How does having colorectal cancer affect day-to-day life?

I have had to stop working due to tiredness

1.3 Are there any activities the patient is not able to do because of the condition?

I cannot work and am not as active as before

More/....

1.4 What is the impact of living with cancer on family, friends and employers?

Impact on employers – reasons as above

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

Although there are some bad side effects (skin rash), these can be controlled. I definitely feel better in myself

3.2 What positive and/or negative impacts did having the technology have on the disease?

Negative – side effects (as above – rash)

Positive – felt better, more energetic, appetite back (as above)

3.3 Which symptoms did the technology best or worse treat?

I have stopped feeling nauseous and have gained appetite

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Unknown as yet but am feeling more positive and energetic in short term

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

I've found I can put up with the side effects

3.6 What would the impact be if the technology had not been available?

Continuation of symptoms most probably

More/....

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

The drug had no difference in terms of the impact of my life – only that I now have to go to hospital once a week as opposed to once every two weeks – but I am in fact happier with this

4.2 Was there anything about the technology that made it hard or easy to use?

No – just an extra 30 minutes at the start of chemotherapy

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Only loss of time (most of a day) when I go to hospital

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More/....

[redacted]

Cetuximab (Erbitux)
Interviewed August 2005

Quote

"I don't know yet what difference having Erbitux has made to my long-term health and well-being but I do feel that the treatment has given me added life"

Profile

- Lives in Colchester, Essex
- Aged 62
- Married with 2 sons
- Occupation - construction worker/driver (now retired on health grounds)
- Former hobby – motor cycle biking

Family history

[redacted] never knew his mother. She left when he was very young and he was brought up by a large family of aunts and uncles. He always wanted to trace her and when he was off sick decided to do some research. He discovered that she had died of bowel cancer at the same age as [redacted] was diagnosed. His sons are now being screened. [redacted] thinks that if he had had knowledge of this and of the symptoms, he would have caught the cancer earlier

His experience

- He was diagnosed in 1997

- Symptoms: flu-type feelings, tiredness; aching legs; weight loss; blood. Went to doctor several times; eventually paid to have private consultation & barium enema; bowel blockage found

- Operated on first at Colchester General; large section of bowel removed, temporary stoma. Can't remember Dukes staging but no spread to lymph nodes and given no chemotherapy/radiotherapy

- Regained fitness, returned to work. For next two years felt very fit but on follow-up in 1999 was diagnosed with liver metastases. Colchester Hospital refused liver re-section so went to Basingstoke instead. Again no chemotherapy given

- Returned to work, then in 2001 developed small, persistent cough. Doctor thought possible asthma but nurse encouraged checking further and lung cancer secondaries found. Paul had never smoked. Opted to go to the Royal Brompton Hospital, but after 6 months of delays, finally went to the Essex Hospital for chemotherapy and radiotherapy

More/....

- Started on 5FU in August 2004, then moved on to Irinotecan and Erbitux as part of the MABEL trial. Paul was the first person to go on the trial at Colchester Hospital and took part in radio interviews with clinician (Bruce Sizer). Irinotecan made him feel very bad and so this was dropped and he continued on Erbitux until March 2005

- Currently scanned every three months. Recent scan showed two small spots on other lung but clinician thinks it is probably an infection and not a new cancer. Both liver and bowel are currently fine but he does have intense shoulder pain, which they think is a remnant of the bowel cancer and not bone cancer

- Currently feeling OK except for shortage of breath and can't walk far. This has got worse since end of treatment. Prone to chest infections

***

[redacted]

Patient Questionnaire

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

Symptoms as above

1.2 How does having colorectal cancer affect day-to-day life?

I have had to give up my job; now short of breath

1.3 Are there any activities the patient is not able to do because of the condition?

Motorcycling and general day-to-day activities requiring physical effort

1.4 What is the impact of living with cancer on family, friends and employers?

Lost hair twice and found some people didn't speak to me. Employer quite supportive

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

Was offered the Mabel trial and took it. I found irinotecan's side effects 'evil'. Felt terrible all the time and just wanted to close my eyes for days

More/....

3.2 What positive and/or negative impacts in having the technology have on the disease?

Don't know

3.3 Which symptoms did the technology best or worse treat?

Drugs only treat cancer pains – no others

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Unknown as yet – but feel the treatment has given me added life

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

Side effects of Erbitux:

- Breathlessness
- Nails 'coming apart' – skin by side of fingers and toes 'opens' so nails get 'looser'. Very difficult to hold or touch anything. This lasted for whole treatment and two months after
- Skin on feet rough as concrete but daily cream treatment helped
- Hair loss (grew back different colour)
- 'Pus-y' eyes – needed bathing each morning. This was most worrying symptom (especially since he has only one eye, having lost the other one in a car accident) but this stopped once the treatment was over

3.6 What would the impact be if the technology had not been available?

I don't know

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

Had treatment in hospital but as outpatient. Weekly regime, not too bad

4.2 Was there anything about the technology that made it hard or easy to use?

Chemo delivered via a drip (up to 4 hours)

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Costs? Time, transport, wife (professional driver) gave up work but I did not use any of the available grants

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More/....

[redacted]
Bevacizumab (Avastin)
Interviewed August 2005

Quote

"I did not experience any side effects while on the technology and the tumour size reduced while I was on the drug"

Profile

- Aged 71
- Married with 3 grown up children and grandchildren.
- Following a long career, now works part time in the drug research and development arena
- Occupation - construction worker/driver (now retired on health grounds)
- Hobbies include swimming and walking

His Experience

- Visited his GP in June 2002. Only symptom diarrhoea
- Referred to gastroenterologist - underwent flexible sigmoidoscopy
- Diagnosed with pre obstructive sigmoid and rectal cancer
- A secondary diagnosis of liver involvement was made post operatively
- Commenced on 5FU/oxaliaplatin in September 2002
- Regime tolerated until mild myocardial event occurred in June 2003 – chemotherapy discontinued
- Commenced in August 2003 on oxaliplatin/irinotecan/epithelial growth factor receptor until the end of 2003 when influenza developed chemotherapy discontinued
- Commenced on Avastin/5FU/irintotecan in November 2004
- Commenced on Xeloda/MitomycinC combination in May 2005 to date

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More/....

Patient questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

The only symptoms I experienced were weight loss and diarrhoea

1.2 How does having colorectal cancer affect day-to-day life?

I continue to work part time in drug development because without work there is no life

1.3 Are there any activities the patient is not able to do because of the condition?

I am unable to continue swimming due to concerns about immuno-suppresion making me more susceptible to infection. Having previously being able to walk 10 miles, due to the cancer I am now able to walk 1 mile at the most

1.4 What is the impact of living with cancer on family, friends and employers?

My family are grown up and have left home but they are always there to support me when required. The condition is 'no big deal' for me and I continue to work part time

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Reduction in tumour size

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

I did not experience any side effects while on the technology

3.2 What positive and/or negative impacts in having the technology have on the disease?

Positively - the tumour size reduced while on the drug; I can't think of any negative aspects apart from developing flu, which required cessation of the treatment

3.3 Which symptoms did the technology best or worse treat?

No symptoms from the technology

More/....

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Hope for remission

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

The only side effect I would not want would be haemorrhaging

3.6 What would the impact be if the technology had not been available?

The disease would have extended

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

There was no difference in using the technology, as I still had to attend the hospital every two weeks

4.2 Was there anything about the technology that made it hard or easy to use?

No difference

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

No extra costs as family and neighbours helped out

***

More/....

[redacted]

Bevacizumab (Avastin)
Interviewed August 2005

Quote

"The Avastin was so easy. Currently it only takes 1 day a fortnight and the side effects are minimal – no nausea, only some slight hair loss. Overall I count myself quite lucky."

Profile

- Aged 64
- A butcher
- Lives in Rotown, Surrey

His experience

- Symptoms included "stomach problems"
- His GP referred him to a consultant and he was diagnosed in November 2002, when he had surgery
- Had 5FU and irinotecan chemotherapy following surgery
- Had reversal surgery in November 2003
- In 2004 the cancer returned and he has been on Avastin since January 2005
- Chemotherapy takes 3 days a fortnight, although for the past month it has only taken 1 day a fortnight
- When 3 days – had the PICC line he would have to wear permanently

Impact on his life and lifestyle

- He has been able to continue work – apart from when he is in hospital on chemotherapy
- He wanted to get back to work as quick as possible, back to normality
- The only thing it prevents him doing is going swimming and it's also awkward to bath and shower because of the PICC line
- Employers, family and friends have all been wonderful

More/....

Impact of the drug

- Counts himself as quite lucky because he hasn't had bad, if any, side effects
- No nausea
- Only a bit of hair loss
- "Avastin is so easy"
- Initially when he had the PICC line he was self-conscious and found it restrictive

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Patient questionnaire [redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

I had stomach issues but thought it was down to other things

1.2 How does having colorectal cancer affect day-to-day life?

I've just tried to carry on as normally as possible. I've kept myself working but my employers send me home if they see me getting tired. It's also stopped me from swimming when I have the PICC line in

1.3 Are there any activities the patient is not able to do because of the condition?

It prevents me from swimming because of the PICC line I've had to wear. Showering and bathing can also be quite tricky

1.4 What is the impact of living with cancer on family, friends and employers?

My work is wonderful – they let me go home when they see I am tired. As have family and friends – but I want to continue as normal, as do they

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

More/....

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

The Avastin was so easy. Currently it only takes one day a fortnight and the side effects are minimal – no nausea, only some slight hair loss. Overall I count myself quite lucky

3.2 What positive and/or negative impacts in having the technology have on the disease?

Negative - Slight hair loss

Positive - No nausea, no more sleeplessness, I feel I've been very lucky

3.3 Which symptoms did the technology best or worse treat?

I've got over my sleeplessness, which I experienced with Irinotecan

3.4 What difference did having the technology make to the patient's long-term health and well-being?

As the chemotherapy is now just one day a fortnight (versus 3) I am feeling more positive overall

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

I was prepared to put up with any side effects but in reality these have been minimal - just slight hair loss

3.6 What would the impact be if the technology had not been available?

Continuation of symptoms most probably

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

My chemotherapy currently only takes 1 day a fortnight – it's so easy

4.2 Was there anything about the technology that made it hard or easy to use?

Just the PICC line – sometimes I feel a bit self-conscious about that

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Not particularly – just one day a fortnight right now

More/....

[redacted]
Cetuximab (Erbitux)
Interviewed August 2005

Quote

"The use of this technology has kept me going, with positive results, and has allowed me a 3 month break. I would be dead if it had not been available to me"

Profile

- 55 years old
- Married with 3 grown children and 1 grandchild
- Currently working fulltime as a librarian

Her experience

- At 52 years of age [redacted] experienced some weight loss and noticed some blood in her stools
- She had been on a diet so put the weight loss down to this
- She initially delayed going to her GP, but made an appointment following reading an article about colon cancer in a magazine
- Following a colonoscopy and CT scan, colon cancer was discovered in the sigmoid area with secondary liver disease
- At this point she was given six months to live
- [redacted] was commenced on a course of 5FU/oxaliplatin which achieved a reduction in the liver metastasis
- Following a laproscopic liver examination, [redacted] became septic, which resulted in the chemotherapy being discontinued for three months. The liver metastasis increased in size during this period
- In October 2004 [redacted] was commenced on a regime of irinotecan/Erbitux.
- Within 3 months the liver metastasis had reduced overall from 5.5 cms to 2.5 cms
- [redacted] is currently having 3 months off chemotherapy with a view to re-commencing on it following this break

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More/....

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

Weight loss and minimal rectal bleeding

1.2 How does having colorectal cancer affect day to day life?

I am still working and plan to continue to do so. The cancer has had a minimal effect on my life, as I haven't allowed it to. I have tried to be depressed, but I could only manage three minutes of that and then got very bored

1.3 Are there any activities the patient is not able to do because of the condition?

I have managed to carry on as normally as possible

1.4 What is the impact of living with cancer on family, friends and employers?

My employer has been wonderful in allowing me time off as required and my friends have been great as well. My husband believes that I will get better

Q2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure – make it disappear and allow me to keep going

Q3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

I have generally felt the same on both technologies, although the tumour reduction was the key to Erbitux. Both the hair loss and rash have not been good for me

3.2 What positive and/or negative impacts in having the technology have on the disease?

Positive impact - reduction in tumour size

3.3 Which symptoms did the technology best or worse treat?

Not applicable as I am prepared to put up with most things if it makes a difference

More/....

3.4 What difference did having the technology make to the patient's long-term health and well-being?

The use of this technology has kept me going, with positive results, and has allowed me a 3 month break

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

The side effects I experienced were acceptable as the ultimate aim was to prolong my life

3.6 What would the impact be if the technology had not been available?

I would be dead

Q4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

I was required to visit the hospital for three days every two weeks.

4.2 Was there anything about the technology that made it hard or easy to use?

No

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

No added real costs – I was covered by private medical insurance

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More/....

[redacted]

Bevacizumab (Avastin)
Interviewed August 2005

Quote

"The Avastin only takes 30 minutes at the beginning of my three day chemotherapy cycle to administer. It's the 5FU that takes 40 hours and requires me therefore to stay overnight in hospital."

Profile

- Aged 23
- Lives with parents near Guildford in Surrey
- Graduated two years ago from Durham University, did masters at Exeter University
- Has worked as operations manager for the family business for the last two years
- Business, which is run by his father, produces large industrial mixers and sells these to pharmaceutical companies

Family history

- Father currently undergoing chemotherapy for cancer of the oesophagus
- Grandmother died of bowel cancer

His experience

- Experienced headaches since Easter 2005, so went to neurologist
- Family friend (an ex-GP) said he should go and insist on a blood test, as he hadn't had one. Blood test showed his liver wasn't working
- The night before his blood test results, he had rectal bleeding. Two weeks later in May 2005 he was diagnosed with bowel cancer with liver secondaries
- Hasn't had surgery, no imminent plans for surgery
- Has only had four sessions of chemotherapy – 5FU, irinotecan and Avastin (although only three of these sessions were with Avastin)
- Has chemotherapy once a fortnight for 3 days, which he has to stay in hospital for. Avastin only takes 30 minutes to give – really minimal time, the 5FU takes 40 hours

Impact on his life and lifestyle

- He can't work for the 3 days a fortnight that he is in hospital but work have obviously been very understanding
- Lucky in that hospital is only 10 miles away, family can take him to and from hospital
- Said you "just get on with it"

More/....

Impact of the drug

- No nausea
- Sporadic headaches, not so bad as those he experienced before diagnosis
- Complete exhaustion where in bed for 3 days ("I walk for 5 steps then I can't walk any further")
- A few random nose bleeds
- No massive loss of hair, just a bit

***

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

I just had these really bad headaches and then just a bit of rectal bleeding the night before my blood test

1.3 How does having colorectal cancer affect day-to-day life?

I'm obviously not able to work on the days I'm in hospital having my chemotherapy. I've also been getting completely exhausted, with a real lack of energy

1.3 Are there any activities the patient is not able to do because of the condition?

I can't work when having my chemotherapy – currently three days a fortnight

1.4 What is the impact of living with cancer on family, friends and employers?

My family, friends and employers have all been great and have rallied round

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

I have not had other chemotherapy treatment so am unable to answer this question

More/....

3.2 What positive and/or negative impacts in having the technology have on the disease?

Negative – Exhaustion. I am confined to my bed and can only walk about 5 steps and then have to sit down. A few random nose bleeds, some loss of hair but not loads

Positive – Only some hair loss not loads, some mild headaches but not as bad as before my diagnosis. I've also had no nausea

3.3 Which symptoms did the technology best or worse treat?

My headaches are now less severe

3.4 What difference did having the technology make to the patient's long-term health and well-being?

I was only diagnosed in May 2005, so it's probably too early to talk about long-term health and well-being

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

The nose bleeds and slight hair loss I find okay – things could be worse. (Reading between the lines, the interviewer thought the exhaustion that was the most frustrating thing for Luke)

3.6 What would the impact be if the technology had not been available?

Continuation of symptoms most probably

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

I have to spend three days in hospital every fortnight. It's not ideal but you just get on with it, but my work is great about it

4.2 Was there anything about the technology that made it hard or easy to use?

The Avastin itself only takes an extra 30 minutes to administer at the beginning of the 3-day cycle. It's the 5FU that takes 40 hours to administer

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

No carer or transport costs. My family takes and picks me up from the hospital

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More/....

[redacted]
Bevacizumab (Avastin)
Interviewed August 2005

Quote

"Astounding results so far [from being on Avastin], my clinician says. The tumours are decreasing very rapidly"

Profile

- Aged 70
- Married with two children and four grandchildren
- Lives a very active life; gardening is her passion

Her experience

- [redacted] has had several major operations throughout her life
- She's had no 'classic' symptoms, but did have a violent pain in the vagina starting around four years ago, which she has subsequently read on the internet has happened to some other bowel cancer patients
- She saw a consultant for this pain and was put on tablets, which slowly improved things
- Six months ago, in spring 2005, she suffered severe pain in middle/lower stomach area
- Her doctor diagnosed diverticulitis, but was worried and asked her to come back if the pain did not subside
- She returned to her GP and was quickly referred to a consultant who in April 2005 undertook a colonoscopy which found a tumour in the colon which had spread to the liver
- No operation; after other tests, she started on chemotherapy treatment, which was Avastin, irinotecan and 5Fu + vitamins (leucovoran) for three days every two weeks
- Currently has undergone five of the six treatments of the first session. Will probably undergo one more session
- Her consultant talks of 'astounding results' so far. The tumours are decreasing very rapidly
- No real side effects, she has carried on her life as normal, still very mobile, has not changed life – 'have to get on with it'
- Says 'the chemo is sometimes unpleasant but it is so worth it'

More/....

Patient Questionnaire

[redacted]

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

Pain in stomach, vaginal pain earlier – very severe

1.2 How does having colorectal cancer affect day-to-day life?

I try not to let it interfere, but avoid crowds and do not socialise as much as before

1.3 Are there any activities the patient is not able to do because of the condition?

Not really, I still do quite heavy work in the garden

1.4 What is the impact of living with cancer on family, friends and employers?

Friends and family have been very supportive but I have tried not to change my life

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

I want it to treat the whole cancer

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

No experience of any other treatment

3.2 What positive and/or negative impacts in having the technology have on the disease?

Ask consultant

3.3 Which symptoms did the technology best or worse treat?

I have had no symptoms apart from the first pain

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Too soon to tell but so far so good

More/....

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

Reddening and very tender finger tips; mouth ulcers; tiredness; has so far not lost hair

3.6 What would the impact be if the technology had not been available?

There would have been pretty terrible consequences if the drug had not been available to me. I imagine I would not have stood much of a chance

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

I can't fault the way I've been looked after at the hospital, which really helps get through the treatment

4.2 Was there anything about the technology that made it hard or easy to use?

Nothing unbearable. I can walk around with the PICC line – I just have to learn how to steer it!

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

BUPA covered. My husband is long retired, so helps out

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More/....

[redacted]

Cetuximab (Erbitux)
Interviewed August 2005

Quote

"Apart from numb hands and feet, I feel fine. The side effects have been more manageable. No one would notice otherwise, as I feel very well."

Profile

- Aged 59
- Married with 1 son
- Works as a transport manager
- Hobbies include old cars

His experience

- [redacted] suffered from ulcerative colitis and was always treated for that
- One Saturday in May 2003, he had terrible pains and went to hospital where he immediately went into surgery. During surgery a tumour was discovered and removed
- He had 12 weeks of chemotherapy between Sept and Dec 2003 (5FU)
- Currently he is on Erbitux (9th session) and has been on it for about six months. He has it every 3 weeks

Impact on his life

- Had about a year off work, but has since returned
- His work have been very understanding and let him come and go as he likes
- Family and friends have been wonderful
- Continued life as normally as possibly – keeps busy, goes on holiday

Impact of the drug

- Found side effects of the drugs to be much better on Erbitux than previous chemotherapy
- Initially had numb hands and feet. Apart from that, you wouldn't have noticed he had cancer as he looks well
- Did have a chest infection for 5 days since being on Erbitux when he was admitted to hospital but other than that nothing dramatic
- He had less energy when he was on 5FU

More/....

Lifestyle

- Hospital visits are still once every 3 weeks
- Takes same amount of time as with 5FU
- Infusional – Erbitux simply adds 30 minutes to chemotherapy
- Is having Erbitux in combination with irinotecan

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[redacted]

Patient Questionnaire

SECTION 1. WHAT IS IT LIKE TO HAVE THE DISEASE?

1.1 What symptoms and problems did the patient have as a result of colorectal cancer?

I suffered from ulcerative colitis, so any symptoms I had were assumed to have been that. I went immediately into surgery after severe pains

1.2 How does having colorectal cancer affect day-to-day life?

I stopped working for a year and felt tired on the initial chemotherapy

1.3 Are there any activities the patient is not able to do because of the condition?

No

1.4 What is the impact of living with cancer on family, friends and employers?

They have all been very supportive. Work lets me come and go as I feel fit

SECTION 2. WHAT WERE THE OUTCOMES THAT MOST MATTER TO PATIENTS?

2.1 Which aspects of having colorectal cancer does the patient want the technology to help with?

Cure!

SECTION 3. WHAT DIFFERENCE DID THE TECHNOLOGY MAKE?

3.1 How did the technology compare to other available treatments?

Despite numb hands and feet, I feel I have more energy on Erbitux and any side effects are more manageable

More/....

3.2 What positive and/or negative impacts in having the technology have on the disease?

Negative – numb and hand feet, chest infection

Positive – felt better, more energetic (as above)

3.3 Which symptoms did the technology best or worse treat?

Energy levels and general well-being

3.4 What difference did having the technology make to the patient's long-term health and well-being?

Unknown as yet but am feeling more positive and energetic in short term

3.5 Did the technology have any side effects? If so, which ones was the patient prepared to put up with and which ones did the patient find unacceptable?

Chest infection and numb hands and feet (as above) – are acceptable and I'm prepared to cope with them

3.6 What would the impact be if the technology had not been available?

Continuation of symptoms, feeling tired etc

SECTION 4. USING THE TECHNOLOGY

4.1 How well or badly did the use of the technology fit into the patient's life? For example, did the patient have to go to hospital to receive the technology?

The drug has made no difference in terms of the impact of my life. I go to the hospital for my chemotherapy as often as before (once every 3 weeks). It just takes 30 minutes extra to have Erbitux

4.2 Was there anything about the technology that made it hard or easy to use?

No – as before with the other drugs I have had through infusional chemotherapy

4.3 Were there any costs to patients or their families in using the technology, including time, transport costs and carer costs?

Only loss of time (most of a day) when going to hospital

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Colon Cancer Concern (CCC)
22 August 2005