Appraisal of carmustine implants and temozolomide for newly diagnosed high grade glioma

Tina Mitchell – Patient Expert comments

1. Whether I consider that all the relevant evidence has been taken into account

As a formal patient/carer expert, present at the Health Technology Appraisal meeting on 23rd November 2005, I strongly disagree with the preliminary recommendations that carmustine implants and temozolomide are technologies which are not recommended for people newly diagnosed with high-grade gliomas.

I do not believe that all the relevant evidence has been taken into account for the following reasons:-

- The patient perspective is not fully taken into account. Inspite of personal testimonies of those who have lived with someone with a high-grade glioma, there is no reference made to the value of extending the patients life and the impact that this can have on the whole family.

- The evidence does not reflect the patient's experience – time is not on the side of a patient with a high-grade glioma. Brain tumours account for one of the highest contributions of all cancers to "person-years of life lost" – years of life lost due to early death. Losing someone to this sort of cancer which affects the person physically and mentally, is agonising and this is not mentioned.

- These two technologies are ground-breaking for the brain tumour community and yet no reference has been made to this fact. They have been accepted in the US and many European countries as standard treatments so not only will we be left behind these countries, but we will be in danger of putting a halt to future research and treatments for brain tumour patients. No reference was made to the fact that during the meeting one of the clinical experts stated that if leukaemia therapies had been analysed in this way, the success of treatments for this disease would never have developed in the way they have.

2. Whether I consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate

- How can you compare cost effectiveness of one of these treatments with the life of a loved one – If it is your loved one who is given a short time to live following the diagnosis of a high-grade glioma and you

know there is a treatment available but you can't have access to it, how would you respond to them – "I'm sorry love, but as we can't afford to go privately to receive the treatment, you won't be able to have it which means that sadly you are going to die sooner than you should." I'd like to see one of the NICE committee saying that to their husband, wife or child. Or would they be able to afford to go private? I seriously question the statement "the committee are aware of the quality of life of a patient at all stages of the disease" because for the first time in decades, brain tumour patients have been given the opportunity to prolong their lives. I strongly believe that it is not sufficient to be aware of this, but to act upon it and make these technologies available.

- I would question why we are focusing on median survival rather than the long term benefits over a period of two years?

- The cost-effective reality is that conditions which are relatively low in incidence are going to be more expensive per individual. However, brain tumour patients should not be disadvantaged because they have a low incidence condition – it isn't their fault that they have a brain tumour. At least the costs are quantifiable as the numbers being considered are smaller.

- The technologies do not interfere with everyday life and the side effects are minimal. Temozolomide can be administered at home and is uncomplicated, it doesn't need a nurse, nor does it need expensive equipment in order for it to be administered.

- It is premature to use the MGMT methylation test to deny access to temozolomide as the trial is still on-going and is yet to be validated.

- Having been in the room at the time all the evidence from charities and clinical experts was being given, it does not appear that this evidence has been incorporated into the final decision. It seems that recommendations were made based purely on the economic model and without reference or referral to the evidence given. I would question the relevance of this model to brain tumours?

3. Whether I consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS

- Categorically no, I would like the committee to reconsider their recommendation. As these two technologies represent the first effective treatments for high grade gliomas in twenty years, I would like to see guidance which recommends their use for the treatment of newly diagnosed high-grade glioma patients.

- I do not feel it is appropriate to wait for clinical studies to include research into the impact on quality of life, long-term effectiveness, subgroups for which the treatments may be particularly cost effective or comparison with other chemotherapy regimens. As stated earlier, we

DO NOT have time to wait for these clinical trials. The life of a brain tumour patient is too short and too valuable to put these technologies on hold.

- Furthermore, if we wait until 2009 to review these technologies, not only is it unlikely we will have further clinical data (because research opportunities and funding will have been taken away) but also about 6,000 patients will have been denied treatment and the UK will fall behind Europe and the US standards. What will this say to the general public?

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