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UK kidney cancer patients face toxic, out-dated treatments with little hope of change

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Leading oncologist Professor Tim Eisen has expressed concerns that patients with advanced kidney cancer could be condemned to toxic, barely effective, 20 year-old treatments because the National Institute for Health and Clinical Excellence (NICE) is likely to rule out using all four of the new treatments it has assessed.

Writing in the December issue of *BJU International*, Professor Eisen, from the University of Cambridge, points out that although NICE has put its findings out for consultation, its provisional decision is that sunitinib, sorafenib, temsirolimus and interferon plus bevacizumab are too costly.

A further review is due to be carried out in January 2009, but Professor Eisen fears that NICE - which advises the UK Department of Health - may confirm its provisional advice that none of these treatments should be provided by the UK's National Health Service.

"We had hoped that NICE would approve at least one of these drugs, as they represent a major breakthrough and there are no suitable alternatives for the large majority of the 4,000 or so patients who might be considered for these drugs in the UK" says Professor Eisen.

"Given that sunitinib was investigated as a first line option, it seemed most likely that it would be approved.

"Our hopes were dashed when NICE released its consultation document.

It said that although the four drugs they looked at were clinically effective, they were not cost-effective."

Professor Eisen says that about one in ten patients benefit significantly from existing drugs to activate the immune system, leaving the other 90 per cent with no benefits, just a range of unpleasant side effects, including flu-like symptoms and depression.

He points out that a number of very effective treatments have been developed in the last three years, but he fears that when NICE issues its final recommendations next spring the hopes of UK clinicians and patients could be well and truly dashed.

For example sunitinib has already been adopted in advanced Western countries as the first-line therapy for patients who show no indication that they will react adversely to the drug.

However, Professor Eisen stresses that although the data on these new drugs is extremely encouraging, and represents the first major breakthrough in advanced kidney cancer in the last 25 years, none of them will cure the condition. But they can extend a patient's life. In the case of sunitinib, some patients have had their life expectancy doubled, giving them an extra year.

Professor Eisen says that the predicted outcome of the NICE consultation is depressing for a number of reasons.

"First, if an intervention which doubles progression-free and overall survival in a disease where nothing else works is deemed to be cost-ineffective, the chances of introducing any new cancer medication must be deemed remote. The prospect is that patients treated within the UK National Health Service must wait until therapies are off-patent and therefore become cheaper.

"Second, the NICE cost-effectiveness analysis is at variance with other cost-effectiveness analyses conducted in the USA, Sweden and other countries. In the media furore that greeted NICE's provisional decision there is no indication that the significant differences between the cost-effectiveness analyses from the UK and elsewhere had caused any pause for thought among the authorities.

"Third, the very great variability of the natural history of kidney cell carcinoma was not considered by NICE. From what we know of these medications already, a minority of patients can benefit very significantly.

"Finally, no provision is made for the importance of gaining even a few months of extra life for patients, despite the fact that these benefits are deemed to be extremely important by all patient groups."

Professor Eisen concludes that if the NHS is ever to introduce the benefits of novel targeted therapies, except in a very few circumstances such as herceptin in breast cancer, it must reconsider its assessment methods.

"Most doctors accept that however many resources are put into healthcare there will always be a need to ration new and expensive treatments" he says. "Equally, this realisation is spreading to all Western countries and NICE is being closely watched as a forerunner of control mechanisms elsewhere.

"The stark differences in options available for patients in the NHS and most other Western countries suggest that no internationally agreed model is possible at present. The development of an internationally validated tool to assess cost-effectiveness would allow for reliable comparisons of healthcare provision in different countries. Embedding the cost-effectiveness analyses into the pivotal clinical trials would reduce the unacceptable delays in reaching even a provisional decision

for patients within the NHS.

"Condemning these kidney cancer patients to toxic, barely effective 20-year old treatment should not be an acceptable option."

Publication: The National Institute of Health and Clinical Excellence rejects new treatments for renal cell cancer: Cinderella's invitation is cancelled. Eisen T. BJU International.102, p1491-1492. (December 2008).

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