MedicalXpress

Expensive new cancer drugs have little effect on survival of many cancers

November 9 2016

Despite considerable investment and innovation, new cancer drugs approved in the past 10 years may have little effect on survival in adults with cancer, raising a number of concerns, argues an expert in *The BMJ* today.

Peter Wise, a former consultant at Charing Cross Hospital in London, says spending an annual six figure sum to prolong life by a few weeks or months "may be inappropriate" for many patients. In 2015, global sales of cancer drugs were around $110bn (£85bn; €95bn).

He calls for stricter drug approval criteria and improved consent processes "to achieve ethical treatment and reduce cancer costs."

Cancer survival has improved in recent decades, he explains. In the US, for example, five year relative survival in adults with solid cancer increased from 49% in to 68% over 40 years.

But how much of the improvement in cancer survival can we attribute to new drugs, he asks? Other factors are more likely to have been responsible. Many new drugs approved in the last decade prolonged life by just one to two months.

"The approval of drugs with such small survival benefits raises ethical questions, including whether recipients are aware of the drugs' limited benefits, whether the high cost:benefit ratios are justified, and whether trials are providing the right information," writes Wise, whose major

interests lie in the ethical elements of medical research and care.

He draws attention to limitations of cancer drug trials, such as the use of surrogate endpoints that allow earlier approval of new drugs, but are not always true indicators of survival benefit. And he warns that the marginal responses in clinical trials may not even apply to the majority of patients treated outside trials.

He is hopeful that the recent integration of the Cancer Drugs Fund into the National Institute of Health and Care Excellence (NICE) in England might make it possible to monitor the "real world benefit" of these drugs.

He also raises concern over the US Food and Drug Administration (FDA)'s accelerated and "breakthrough" category which, he says, compounds the risk of premature approval on limited evidence.

"The low bar of approval for these expensive drugs ignores the ethical principle of fairness and equity," he writes. "By promoting marginally better treatment of poorly responsive cancers it diverts valuable resources that might be better employed for other health needs, within and outside cancer care."

A lack of fully informed consent for cancer treatment is also a concern, often leading to misinformed patients with unrealistic expectations, he adds.

"Good cancer care demands empowerment of patients with accurate, impartial information followed by genuinely informed consent in both the clinical trial and therapeutic settings," he writes. "Ethical impediments to sound practice need to be addressed and corrected."

"Above all, the threshold for approval of new and existing cancer drugs

needs to be raised - using more meaningful disease specific criteria of risk-benefit and cost-benefit," he concludes.

More information: *The BMJ*, DOI: 10.1136/bmj.i5792