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Editorial Comment

The pharmacoeconomics of spiralling cancer drug costs – Is there a viable solution?

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The IARC estimates that 27 million new cancer cases will be diagnosed in 2030.¹ This will place massive strain on institutionalised health systems already pressured under the current economic climate. During the decade leading up to 2004 spending on cancer drugs in the EU has increased from 840 to 6170 million euros² and in the United States during a similar period (1997–2004) this figure within Medicare rose from \$3 billion to \$11 billion.³ The stark and well known fact facing healthcare providers remains that this spending will become unsustainable, and probably already is. The ability to balance, on one hand the rising costs of drugs with short and long term constriction of budgets will define the accessibility of new and effective treatments to patients reliant on publicly funded healthcare.

The reaction thus far to the current economic situation has been mixed. In Spain and France for example government mandated cuts of branded pharmaceutical prices of up to 30% have been implemented. In the United Kingdom, however, pharmaceutical companies are currently free to set their own pricing, although a move to a value based pricing index has been suggested by 2014 that will take into account ‘drug efficacy and the potential benefit to society’ though measurement of this will be controversial.⁴

Although in the short term the measures briefly described above would decrease budgetary expenditure, in the long

term one may argue that the risk is a knock on decrease in investment in the very expensive arena of cancer drug development and innovation. In this issue of the *Journal*, Dranitsaris and colleagues propose a simple to understand and useful alternative to arbitrary government intervention in cancer drug pricing. Simply put, they propose a system of value based pricing based on the performance of the product and the wealth of the nation purchasing the drug.⁵ The paradigm they have used to illustrate this is that of metastatic colorectal cancer. The Gross Domestic Product (GDP) in the five countries they have studied to evaluate this index ranges from \$3100 to \$39,000, and as such if applied more broadly this range would include 140 countries. As an example if a new drug in colorectal cancer has demonstrated a 4 month survival benefit in a recent study, using GDP and Gini coefficients (a measure of distribution of wealth within a nation) the value based launch price in Argentina (per capita GDP \$15,000) would be \$630 per dose, whereas in Norway (per capita GDP \$50,000) this would be \$2775.

This proposition is not entirely new and the idea of value based pricing has been suggested in various forms previously.⁶ Indeed the demand for such a system, not only within Europe but globally has arisen from the awareness of the need of healthcare systems to annotate value to costly interventions. Last year the debate around ‘value’ permeated the

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United States healthcare system⁷ and cost-effectiveness in healthcare is a pillar of current reforms there. The debate occurred with greater intensity following the FDA approval of Sipuleucel-T (Provenge), a treatment for metastatic prostate cancer that costs \$93,000, with therapy deriving a median 4 month increment in overall survival.⁸ It is in this context that we should evaluate the value based pricing index proposed by Dranitsaris which incorporates not only efficacy measures, but affordability measures too.

What are the potential pitfalls with these variables? There are problems if we are using survival as the sole efficacy measure in cancer patients. In many metastatic cancers, for example breast cancer and colorectal cancer, multiple lines of treatment may be given before a new putative agent and overall survival benefits may be lost or diluted by cross-over, and instead outcome measures that becomes significant may simply be time to progression or even quality of life. The implications here are complex for an outcome measure for pricing. In cases where the effect of single agents on the course of a patients survival is difficult to assess, is it valid to consider other measures such as quality of life as a reasonable outcome for a value based pricing index? This is perhaps one question to be addressed in the debate that will follow between stakeholders. As far as an intrinsic affordability factor is concerned, this will be viewed by many physicians as fair and long overdue. Certainly the ability of a third party to negotiate drug prices is credited with part of the estimated 37% savings in 1 year seen in one in the Medicare Part D Programme.³ Any ability to negotiate prices is an improvement compared to the system that exists in countries such as the United Kingdom currently. Importantly 'negotiation' in context here is a nebulous term, open to interpretation and lobbying in ways that a *de facto* costing based on the fixed measures of affordability outlined above, is not.

What are the implications of value based pricing for rationing systems already in place? Although the United Kingdom National Institute of Clinical and health Excellence (NICE) has been widely praised for its attempts to address cost effectiveness of interventions, there have been criticisms in its handling of cancer drug rationing. It is a view held by many that the *Quality Adjusted Life Year (QALY)* is a flawed measure of assigning cost effectiveness,⁹ and its use in defining a threshold below which a publicly funded healthcare system will pay for a drug has been criticised. Furthermore with this rationing comes debate and the various consultations and processes that are in themselves costly in terms of time, infrastructure and expenditure.¹⁰ Although this infrastructure is changing in the United Kingdom, it follows that if a

cancer drug is already costed at launch to allow for efficacy and affordability, then much effort and time would potentially be saved in having to assign these values within organisations in individual nations. This presumably implies patients would have access to drugs quicker than is the case currently, and with less reliance on other measures of cost-effectiveness.

The palatability of this to the pharmaceutical industry, governments, and what this will mean for patients is evolving. It is clear an alternative to the status quo is needed, and stakeholders need to consider the long term sustainability of new innovations. Pharmaceutical companies should have some incentive to spending resources on research and development of new drugs to treat cancer 'better', as opposed to efforts devoted to marketing or prolonging patent lives of existing products with 'me too' formulations. Value based pricing with the integration of affordability as described by Dranitsaris and colleagues would seem to be an excellent and necessary starting point for this debate.

Conflict of interest statement

None.

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