What is the value of medicines and innovation for the patient?

There has been a lot of policy discussion around the question of “value” in relation to pharmaceutical products and other interventions. Anthony Mark Cutter, Natasha Burns, Julia Manning, Ginette Camps-Walsh and Sarah Wilson explain why there is a need for a system that can evaluate new interventions fairly and encourage medical companies to invest in more innovation and research while satisfying the individual needs of patients.

It is likely that new technologies will change the face of pharmacy practice. In particular, the mapping of the human genome, and the resulting focus on genetics in medicine is likely to create new forms of pharmaceutical intervention that are targeted towards the specific genetic traits within either broad patient groups or individual patients. As such, the advent of so-called “personalised medicine” emerging from the development of clinically applicable products from pharmacogenetic and pharmacogenomic science has been called “the next challenge for pharmacy.”

Putting genetics into pharmacy will logically change the role and practice of the customer-facing pharmacist (whether in community or hospital practice), and may ultimately greatly increase involvement in frontline patient care. There will be the opportunity and need to carry out more diagnostic testing before treatment to establish the appropriateness of some drugs. If the promise of “personalised medicines” is to be believed, this could result in increased patient compliance because patients could be prescribed medicines targeted to their specific genetic make-up, which would have fewest side effects.

In the UK, there has been a lot of policy discussion around the question of “value” in relation to pharmaceutical products and other interventions. For example, in 2007, the Office of Fair Trading published a report that recommended the Government change the Pharmaceutical Price Regulation Scheme from a system based on product and price controls to one that focused on the attribution of price based on the perceived value of the product in patient care, known as value based pricing (VBP).

As a result of this emphasis on value for new medicines in the PPRS agreement, the National Institute for Health and Clinical Excellence commissioned Sir Ian Kennedy to carry out a short study of valuing innovation (PJ, 25 July 2009, p90) aimed at addressing the following questions:

- What is the relationship between innovation and value?

Noticeably, the concept of value to the patient remains absent from the review’s terms of reference.

Theoretically, the concept of VBP, when applied in the pharmaceutical setting, places the patient at the centre of the decision-making process. However, in reality, it relies on the creation of a “generic patient” as a construct in order to assess appropriately the clinical value of product relative to other innovations. The result is that individual patients are potentially ignored in favour of the perceived value to the generic patient. Procedurally, there is no such thing as a “generic patient” and different patients have different priorities, values and needs.

In the context of technology assessment, when deciding whether to make a product available through the NHS, NICE currently uses a model that conducts a cost-benefit analysis by measuring cost against the quality adjusted life year (QALY). On the understanding that every drug is assessed on a case-by-case basis, the general marker of the cost-effectiveness of an intervention is between £20,000 and £30,000 per QALY. This approach mtextareaarily limits the concepts of “cost” and “benefit” to their financial values, which has the effect of creating the perception that individual lives can be attributed a financial value. This has resulted in a number of high-profile campaigns that have sought to challenge NICE decisions. These campaigns often involve terminally ill cancer patients, who are able to put a face to potentially anonymous decisions.

In its submission to the Kennedy review, Cancer Research UK points out that the pharmaceutical industry is investing heavily in oncology and suggests that: “The recent massive investment in new pharmaceuticals, particularly in cancer, and an increasingly informed and involved public, means that there are rising expectations in terms of the drugs that should be available on the NHS. It is no longer acceptable that constraints on NHS budgets lead to effective but expensive treatments not being available to cancer patients across the UK.”

Anthony Mark Cutter is head of Innovation in Society and Natasha Burns is research assistant, both at the International School for Communities, Rights and Inclusion, University of Central Lancashire. Julia Manning is chief executive and Ginette Camps-Walsh is director, both at 2020Health.org. Sarah Wilson lecturer in social pharmacy and ethics at the School of Pharmacy and Pharmaceutical Sciences, University of Central Lancashire.
Nevertheless, NICE continues to use the QALY-based cost-benefit analysis in its decision making, while the media publish articles that portray NICE in an increasingly negative fashion.

As the cost of innovation in pharmaceuticals and other health interventions continues to increase while simultaneously becoming more targeted (whether towards specific diseases, or specific genetic or genomic characteristics), the changing face of pharmacy necessitates the development of a new system for establishing and attributing value. Whether in the context of technology assessment or pricing, it is necessary to consider the concept of “the patient” in a manner that moves beyond a financial definition of value. As the Genetic Interest Group points out in its submission to the Kennedy review: “Whilst figures, such as cost or QALY, can provide a useful yardstick, they are crude and omit many factors that are significant for patients and families. For example, families living with a member affected by a chronic complex condition often struggle to create a network of inter-disciplinary inputs from different professionals employed by health, social care, education and voluntary sector bodies. Once in place, they are loath to disrupt it, creating lost opportunity costs arising from the need to stay put. If the condition affecting their family member becomes treatable then these may be reduced or removed, but the financial, psychological and other benefits that result are not taken account of in valuing the innovation.”

Whether or not medicine and pharmaceutical practice become more personalised in the sense envisaged within pharmacogenetic and pharmacogenomic medicine, there is a need for a system that can evaluate new interventions fairly and encourage medical companies to invest in more innovation and research while satisfying the individual needs of patients. In order to balance the public policy need to control spending within the healthcare system against the needs and desires of individual patients, it is necessary to move beyond a definition of “value” that is limited by financial and clinical constructs. To begin with, it is necessary to ask a single, dispassionate question: how do you define value?

References

The value of medicine

The think tank 2020Health.org is currently exploring the issue of value in medicine as part of a wider policy project on improving patient outcomes from new treatments. In this way, 2020Health.org will be one of the few organisations to explore what is value in medical treatment and how can it be measured and delivered.

2020Health.org would like to invite readers to participate in this consultation by visiting the website www.2020health.org.