approval, however, cover all types of healthcare research (including RCT and RW data studies) and it is essential that the HRA considers RW data studies specifically, as progress is made towards addressing this important recommendation. This offers an opportunity for the UK to be a more attractive environment for the conduct of RW data studies.

• Skills and education

The strong links that the UK pharmaceutical industry has with the academic community are crucial in ensuring the appropriate skills are identified and developed to support this growing area of RW research. The pharmaceutical industry has a responsibility to ensure that the personnel involved in RW data projects locally have the appropriate knowledge level or, alternatively, to secure the necessary support for study design and collection, analysis and subsequent use of these data.

SUMMARY

It is well recognised that data about patients’ use of medicines in normal clinical practice, or in settings which reflect the reality of health care delivery – Real World data – are likely to become increasingly important in decisions that affect patients’ access to medicines.

The UK is already well placed to lead the world as a centre of excellence for the collection and use of this type of data. The plans announced in December 2011 have been welcomed and help move even closer to this goal. However, it is essential that ongoing consideration is given to the remaining challenges raised here if we are to optimise the benefits to the UK that could be afforded by this opportunity.

Footnotes


Available at: http://www.dh.gov.uk/en/Consultations/Responses/Consultations/DH_128226 (accessed on 14/12/11)

‘COST-PER-QALY IN THE US AND BRITAIN: DAMNED IF YOU DO AND DAMNED IF YOU DON’T’

Cost-per-Quality Adjusted Life Years (QALY) is the means by which the value of a medical intervention can be quantified, and is used by the National Institute for Health and Clinical Excellence (NICE) to determine the cost-effectiveness of medicines. This was the subject of the Office of Health Economics’ Annual Lecture, given on 15 November in London by Dr Milton Weinstein, Henry J Kaiser Professor of Health Policy and Management at the Harvard School of Public Health.

The lecture was something of a social commentary on the differences in attitudes in the UK and the USA regarding healthcare costs and, in particular, cost-effectiveness analysis costs per QALY. One quote by Dr Weinstein summed this up: ‘If you cannot tell from the title, you are the folks who do and we are the folks who don’t … In my country we do not touch cost-effectiveness analysis with a 10-kilometre pole: in this country you seem to have a love affair with it’.

Dr Weinstein gives a number of arguments deployed in the USA for not using cost-effectiveness analysis. The most prominent of these is that there is no relation between healthcare expenditures and health outcomes across hospitals in the USA. This, according to Dr Weinstein, is actually true – the association between overall expenditures and outcomes tends to be a ‘very fuzzy relationship’. Together with Jonathan Skinner of Dartmouth Medical School, Dr Weinstein recently wrote a paper published in the New England Journal of Medicine about what this weak relationship between expenditures and outcomes implies about the need for cost-effectiveness analysis.

What he showed in this paper is that healthcare expenditures are not used most efficiently. There are many situations in which many of the most cost-effective health services and interventions are under-utilised. For example, fewer than half of Americans over the age of 50 have ever had a colorectal screening exam; nor do people get their influenza vaccinations or pneumococcal vaccinations as recommended. For a state to cut its expenditures and improve health outcomes simultaneously, Dr Weinstein concludes it needs to increase the utilisation of highly cost-effective interventions like these and simultaneously cut back on less cost-effective...
Another argument, one that Dr Weinstein was co-chair of, is that QALYs do not reflect everything that people care about in healthcare. For example, there may be value in some genetic testing that tells people what risks they face as they proceed through life, or what risks their child faces. Even if you cannot do anything about it, there is the psychological value of knowing. Caring does not necessarily manifest itself in more QALYs but it is something that people value. Similarly, access to care, equity, and reducing disparities in society are things that people value but which do not reflect themselves in maximising QALYs. Dr Weinstein thought that NICE and Britain should be mindful of this, saying that ‘sometimes in one’s enthusiasm for the cost-effectiveness model – and I am certainly one of the enthusiasts – we need to temper that enthusiasm with the limitations and be mindful of the role that this type of analysis has among many other considerations – ethical, psychological and otherwise’.

Dr Weinstein posed a question - do the British take prescribed guidelines for cost-per-QALY modelling too seriously? The purpose of a model is to inform medical decisions and healthcare resource allocation. Modellers employ quantitative methods to gain qualitative insights. The purpose is not so much the number that comes out as to gain the qualitative insight. The tools of formal analysis are best employed to structure the clinical, epidemiological and economic evidence base in the service of better clinical practice decisions and public health priorities.

Finally, he noted that there is a role for deliberative processes through which individuals and stakeholders, including the general public, can get involved in conversations about how costs and benefits should be traded off against one and another, and with other ethical and psychological factors that people believe should go into decision-making.