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INTRODUCTION

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This special section is the written record of the second National Institute for Clinical Excellence (NICE) conference, which drew together experts in the fields of health technology assessment (HTA) from around the world. It includes a significant perspective from the pharmaceutical industry, whose partnership with the manufacturers of technologies (pharmaceuticals, devices, etc.) is of paramount importance to the successful future of the input of HTA into healthcare delivery. The importance of HTA as the basis of clinical decision making has never been more apparent. All clinicians are aware of the requirement that they provide the most up-to-date health care for their patients, who in turn appropriately consider this as a right. The need to ensure that this care is based on reliable evidence of clinical effectiveness is paramount. In addition, the need for all healthcare systems to consider costs as well as benefits has led to a further imposition on those who provide care to take into account value for money when considering the implementation of a new technology.

The evidence base that is required for licensing purposes is quite different from that which is required to support evidence-based medicine in everyday clinical practice (i.e., 'the real world'). The evidence gap that exists between these two needs is often unfilled, and therefore clinical decision making is commonly not fully evidence based.

The use of HTA to fill this evidence gap has become a worldwide process. The way in which this is applied however, is, quite different in different countries. These differences, particularly when they relate to considerations of cost effectiveness, are based upon a number of factors, including differences between countries of:

- Legislative and administrative frameworks;
- The requirements of transparency and openness of processes;
- The resources available to handle the information requirements of HTA; and
- The economics of healthcare systems and the way in which individuals have access to and are reimbursed for treatment needs.

To deliver the concept of evidence-based medicine into frontline clinical practice, there are a number of stages of technology assessment and its outcome that must be considered:

- Assessment of the evidence for clinical and cost-effectiveness;
- Appraisal of the evidence in conjunction with the views of practicing clinicians and patients/carers in order to enhance the evidence base and relate data on efficacy/effectiveness and toxicity to everyday clinical practice;

- Formulation of pragmatic guidance on the basis of the appraisal to aid practicing clinicians in their decision making for individual patient needs; and
- Input of guidance produced into health policy decision-making processes on a national basis, requiring information on social, economic, and ethical implications of the implementation of the guidance.

The extent to which any or all of these stages are fulfilled varies dramatically between countries and healthcare systems. The ability of HTA to input directly into health policy is, however, the ideal of all of those involved in the process. The time scale for the development of guidance based upon HTA is crucial if the output is to be of use in patient care, but once again this varies widely from country to country. The NICE appraisals process takes about 8 to 12 months to complete. It aims to make its output of guidance as up-to-date as possible and is fed straight into health policy for the National Health Service. This is compared with the HTA process adopted by the Swedish Council for Technology Assessment in Health Care (SBU), which may take up to 3 years to complete a full review and produce an assessment, which is then reported to the Ministry of Health for action to be considered.

Full implementation of HTA and guidance is essential if evidence-based medicine is to be seen as having an impact directly at the doctor–patient interface. This requires effective dissemination of the output of the process in the first place and, equally important, the development of "ownership" by the target audience of the guidance itself. The latter is the more problematic because the HTA often is seen to be, at best, an interesting academic scientific exercise useful for reference purposes but divorced from the realities of clinical practice and, at worst, an infringement of so-called clinical freedom. Getting the balance right between science and pragmatism has been a major platform of the NICE appraisals process and, although it is still in its infancy, there has been a large measure of success. In particular, we believe this has been due to the transparency of the NICE process and the nature of the open consultation with a wide range of stakeholders, including patients/carers, professional groups, and manufacturers.

It is obvious from the range of contributions to this HTA symposium that there are many different ways in which to "crack this nut." The final conclusion that should be drawn from these essays must be that collaboration on a global scale is essential to reduce unnecessary duplication of effort, particularly in the assessment process and the production of systematic reviews, which are both time-consuming and costly. As part of this sharing of data, we should be working toward the development of commonly agreed methodologies in a similar fashion to the agreement for harmonization of standard data requirements for product registration. This is especially relevant for cost-effectiveness modeling. In addition, collaboration is needed in the sharing of experience of methods of dissemination and implementation of guidance and communication with the end users. This is more complex in view of the variation in healthcare systems, reimbursement practices, and country-specific issues of technology costs and cost-effectiveness. There is little doubt, however, that without this second phase the work of assessment and appraisal will have a much reduced impact on either the delivery of health care by the professionals or on national healthcare policy in general.

We are very grateful to all of our contributors, both for their presentations at the symposium and also for their time spent in producing a written record of this interesting and important worldwide issue.