Effectiveness of biologics in rheumatology: improving the evidence base

This supplement arose from a workshop held in London in September 2010, sponsored jointly by Arthritis Research UK and the Medical Research Council (MRC) Trials Methodology Hub Network. The aim of the meeting was to bring together clinical rheumatologists, health economists and statisticians with an interest in the cost-effectiveness of biologic therapies in rheumatology.

The impetus for the meeting lay in how best to map the growing use of biologic therapies for inflammatory arthritis with the internationally recognized UK process for deciding which new pharmaceutical products will be recommended for use in the National Health Service (NHS). In the UK, no new treatments can be introduced into the NHS unless they have been approved by the National Institute for Health and Clinical Excellence (NICE) in England and Wales (or the Scottish Medicines Commission in Scotland). The key process at NICE is a cost-effectiveness analysis of a new product (or new indication for an existing product) in relation to appropriate comparators. For assessing biologics comparators not only include a placebo, such as MTX in MTX failures, but also other potential active comparators. Assessments may study a single biologic (Single Technology Assessment) or simultaneously assess the range of agents for a specific clinical indication (Multiple Technology Assessment) [1]. The most important evidence should be based on randomized controlled trials.

For most biologics in rheumatology, the trial evidence is not based on head to head comparisons between potentially similarly effective agents, although the latter questions are of most interest. Methods to analyse existing trial data to infer relative effectiveness, referred to as indirect comparisons or network meta-analysis, are described in this supplement [2].

Despite the limited likelihood of head to head trials being conducted, there is scepticism as to whether such statistical modelling can produce worthwhile conclusions on relative effectiveness. Thus, the aim of the workshop reported in this supplement was to explore the role of both network meta-analysis and value of information (VOI) methods that are a major area of interest for the Bristol MRC Trials Methodology Hub. Applying such methods to the existing data could provide useful insights into the additional information that could be obtained from head to head trials [3]. Such analyses are based on the robustness of the underlying cost-effectiveness models for the individual therapies. Given the considerable variability in those that have been developed, it is not surprising that, when applied, different models can emerge with different answers. Among clinicians, this does little to inspire confidence in the models, or decisions based on them.

This then explains the collection of papers in this issue. The series is introduced by a description of the major issues facing rheumatologists [4], and followed by an overview of the economic models, highlighting their differences and similarities [5]. Then the network meta-analysis and VOI methods are described [2, 3] and followed in their turn by descriptions of decision models constructed by three leading UK centres of excellence in Health Technology Assessment: Sheffield [6], West Midlands [7] and York [8]. All of these models have informed NICE appraisals of biologics (RA, for the first two models, and PsA for the York model). These examples are completed by a clinician’s view of the competing models [9].

The next stage will be a meeting focused on precise definition of the key properties that models of the natural history of inflammatory arthritis under biologic therapies should have, and an agreed vision of which data sources should be used to inform this model. This work should have wider applicability that can be suitably modified to apply in a range of different therapeutic contexts, and that can be used as a standard model in future decision making.

Both the workshop and the work now under way are predicated on the specific conditions of decision making in the UK. The relevance of this enterprise to health-care settings in other countries is clear. Decisions about (i) which treatments to use and (ii) which treatments to research, whether based on cost-effectiveness or on comparative efficacy, and however the latter is assessed, all require assumptions. A process of reaching an expert consensus on what these assumptions should be, based on the evidence available, provides a transparent approach allowing the assumptions to be open to criticism and debate. This is surely the best basis for evidence-based decision making.

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