



R&D Briefing

Emphasis on Economic Evaluation

Relevance of Automated Databases

Application of health economics studies during the product life cycle

| Strategic contribution | R&D status | Type of studies |
|-------------------------------|-----------------------|------------------------|
| Input to clinical development | Late research | Burden of illness |
| | Phase I development | Cost of illness |
| | Phase II development | Quality of life scales |
| For pricing and re-imburement | Phase III development | Cost minimisation |
| | Launch | Cost benefit |
| Product differentiation | Launch | Cost effectiveness |
| | Marketing | Cost utility |

Figure 1 Health economics information is being generated throughout the product life cycle. It is used to support decisions regarding the continuing inclusion of drugs in the development portfolio, product pricing, reimbursement negotiations, formulary inclusion and also as a differentiating characteristic for prescribers.

- *As purchasers of healthcare increasingly seek evidence of the costs and benefits of competing treatments, particularly new products, the pharmaceutical industry is turning to health economics research to examine these parameters.*
- *How can the necessary information be generated? Which data elements are relevant to health economics research? What is the potential of alternatives, such as automated databases, compared to traditional data sources? Can individual databases be assessed and compared?*
- *No consistent approach to the selection and use of data sources for health economics research was apparent in a CMR International pilot study among industry representatives and academics. Only limited use is being made of automated databases to support health economics studies; a number of concerns need to be addressed before such databases can achieve their full potential.*

Perspective

Economic evaluations, despite their uncertainties and imperfections, are becoming an integral part of pharmaceutical development at all stages of the product life cycle (Figure 1). Not only does rising research and development (R&D) expenditure necessitate products with commercial advantage but also, in the face of increasing healthcare costs, purchasers require proof of the benefits and costs of competing interventions. As a consequence, the industry’s interest in outcomes research, which can examine these parameters, continues to grow.

Automated databases provide an observational data source that links demographic details and prescribing information with outcomes data for individuals from the general population. The extent to which such databases might provide data relevant to health economics research has yet to be formally evaluated.

Profile of a Pilot Study

By using structured interviews and the published literature, this CMR International pilot study sought to identify:

- the major data requirements for individual components of health economics studies;

- data sources in current use and the reasons for their selection;
- assessment criteria that might be used to evaluate and compare individual databases.

Enlightening Interviews

Four experts with involvement in health economics studies for international pharmaceutical companies, and five academics who provide company support in the areas of study design, data analysis and/or identification of data sources, participated in structured interviews. The consensus was that the data requirements for health economics studies fall into the following major categories:

- Study population and characteristics
- Relevant comparators
- Comparative efficacy and/or effectiveness
- Outcomes – clinical
 - quality of life
- Resources used
- Cost of resources

None of the data sources available at present can provide all these different categories of data (Figure 2). As a consequence, when conducting health economics research, companies and academics alike utilise a wide range of data sources, pre-eminently the clinical trial,

Information which can be derived from different data sources for health economic evaluations

| Data sources | Data requirements for health economic evaluations | | | | | | | |
|----------------------|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | Population Definition | Comparators | Efficacy | Effectiveness | Clinical Outcomes | Quality of Life | Resources Used | Costs |
| Clinical Trials | Information not available | Information not available | Information not available | Information can be derived | Information not available | Information not available | Information not available | Information can be derived |
| Automated Databases | Information not available | Information not available | Information can be derived | Information not available | Information not available | Information can be derived | Information not available | Information can be derived |
| Epidemiology Studies | Information not available | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information can be derived |
| Market Research | Information not available | Information not available | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information not available | Information can be derived |
| National Statistics | Information not available | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information can be derived | Information not available | Information can be derived |
| Disease Registers | Information not available | Information not available | Information can be derived | Information not available | Information not available | Information not available | Information not available | Information can be derived |
| Clinical Records | Information can be derived | Information can be derived | Information not available | Information not available | Information not available | Information can be derived | Information not available | Information can be derived |
| Patient Sourced | Information can be derived | Information can be derived | Information can be derived | Information not available | Information not available | Information not available | Information not available | Information can be derived |
| “Expert Opinon” | Information can be derived | Information not available | Information can be derived | Information not available | Information not available | Information not available | Information not available | Information can be derived |

Information not available (orange) Information can be derived (grey)

Figure 2 The data requirements for health economics studies fall into six major categories. None of the data sources currently available can provide information on all these categories. Companies therefore use a wide range of different data sources, but rely mainly on clinical trials.

even though many sources have not been formally evaluated in this context.

Automated Databases – the Answer?

Automated databases could have advantages in providing access to potentially far greater populations than possible with randomised controlled trials, so allowing for the effectiveness of therapeutic interventions to be examined in a ‘real world’ setting.

Experience of using automated databases was limited to one of the five pharmaceutical companies and one academic unit; others interviewed had little knowledge of available databases, their characteristics or capabilities. While acknowledging their potential for

valuable contributions to some studies, interviewees expressed a number of real and perceived concerns surrounding, in particular, the apparent complexity, difficulty of access, lack of detail and perceived high cost of automated databases.

Commercial data providers revealed that, although expertise in the field of health economics is limited, they have a detailed knowledge of their company’s database and its capabilities.

Key characteristics

A number of characteristics govern the utility of a database for health economics research, including representativeness, quality and validity of the data set, and the data content; each needs to be evaluated in the context of a specific study requirement.

Outcome of the assessment of UK automated databases against defined study requirements

| | GPRD | DIN-LINK | MEDIPLUS | MEMO |
|--|------|----------|----------|------|
| Acute exacerbations of chronic bronchitis | | | | |
| Study population and characteristics | Y | P | P | Y |
| Relevant comparators | Y | Y | Y | Y |
| Outcomes | Y | Y | Y | Y |
| Use of resources | S | S | S | S |
| Alzheimer’s disease | | | | |
| Study population and characteristics | Y | Y | Y | Y* |
| Relevant comparators | Y | Y | Y | Y |
| Outcomes | N | N | N | N |
| Use of resources | S | S | S | S |
| <i>* In-patient diagnosis only</i> | | | | |
| Non-diabetic peripheral neuropathies | | | | |
| Study population and characteristics | Y | Y | Y | N* |
| Relevant comparators | Y | Y | Y | N/A |
| Outcomes | Y | Y | Y | N/A |
| Use of resources | S | S | S | N/A |
| <i>* Only severe peripheral neuropathy from in-patient diagnosis</i> | | | | |
| Incidence of CVS events in men | | | | |
| Study population and characteristics | Y | Y | Y | P |
| Relevant comparators | Y | Y | Y | Y |
| Outcomes | Y | Y | Y | Y |
| Use of resources | S | S | S | S |
| Y=Yes P=Probably S=Some of those required N/A=Not applicable N=No CVS=Cardiovascular system | | | | |

Table 1 Based on the key characteristics governing the utility of a database for health economics research, criteria for assessing individual databases was developed. The assessment criteria provided a quick and consistent method for determining the ability of four UK automated databases to generate data relevant to four separate health economics studies which had been proposed by the industry.

Recommended actions to ensure effective use can be made of automated databases

| Pharmaceutical companies need to give consideration to: | Data providers need to: |
|--|--|
| <ul style="list-style-type: none"> ● allocating time and personnel to understand the unique characteristics of each resource; ● accessing pharmacoepidemiological skills; ● expressing information needs simply to the data provider; ● taking an iterative approach to study design; ● working with experts who understand automated databases; ● working with data providers to support data developments. | <ul style="list-style-type: none"> ● seek involvement with users at an early stage; ● address real and perceived industry concerns; ● expand the information held in automated databases. |

Table 2 Automated databases could have advantages for health economics studies, in providing access to potentially larger study populations where information on the effectiveness of therapeutic interventions can be examined. However, some work is necessary on the part of both data providers and industry, before the full potential of automated databases is realised.

Based on these characteristics, a set of criteria for assessing individual databases was developed, and tested by determining the usefulness of four UK automated databases (DIN-LINK, GPRD, MEDIPLUS and MEMO) to provide data relevant to outcomes research. In four separate health economic studies, each of which had been proposed by the industry (*Table 1*), these assessment criteria proved to be a quick and consistent method for determining the ability of a particular database to generate required data. They also provided an initial view on the likely quality of data sets.

These assessment criteria may provide a useful tool to potential users who lack relevant experience, to help evaluate the many automated databases currently available.

Realising Potential

The pilot study clearly demonstrates that automated databases, either alone or in conjunction with other data sources, have relevance for health economics research. Further consideration of these resources is therefore worthwhile. However, before the full potential of automated databases to support changing healthcare information needs is realised, some input and change of approach is required on the part of both data providers and the industry (*Table 2*). Only further experience with their application will determine whether more investment in automated databases is justified.

Copies of the full report, "Can the UK Automated Databases Provide Relevant Information for Health Economics Research?" which contains 74 pages, 10 figures and tables, and 5 appendices, can be obtained at a cost per copy of:

| | |
|-------------------------------------|------|
| Non-sponsoring organisations | £500 |
| Sponsoring pharmaceutical companies | FREE |

These can be ordered, quoting reference number CMR97-97R, from Shaida Dorabjee, Research Services Manager, at Centre for Medicines Research International.

(All cheques should be payable to Centre for Medicines Research International. Non-UK cheques should be in sterling and drawn on a London bank.)

January 1998

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