

# **An Assessment of the Quality of Economic Evaluations of Self-care Support**

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## Executive Summary

In order to assess the economic evaluation literature on self-care support we

- examined the differences between self-care and conventional interventions and the implications for evaluations. These include difficulties in defining the intervention, the wide range of self-care interventions, contamination of control groups, length of follow up, lack of blinding, and greater need for subgroup analysis arising from the heterogeneity of patients
- adapted existing criteria lists for assessing the quality of economic evaluations to allow for the differences between self-care interventions and conventional interventions
- carried out a systematic search of 12 bibliographic databases to identify economic evaluations of self-care support
- applied the quality criteria list to the resulting 38 papers describing 35 interventions

The results of the analysis of the papers indicated that

- the general quality of economic evaluation papers was poor. Problems included a lack of proper control groups, short follow up periods, narrow definition of relevant costs, poor or opaque costing methodology, inadequate handling of uncertainty, and missing data ignored or dealt with inappropriately.
- the majority of the papers reported that self-care was a cost effective or cost reducing intervention.
- only 6 studies were UK based. Of these one reported that support for self-care was cost effective, two that it was not and three were inconclusive (and were not typical self-care interventions directed at patients). None of the UK interventions were of the same type as the current major policy initiative to promote self-care via the Expert Patients Programme.

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## **1 Introduction**

There is considerable policy interest in interventions to promote self-care, to improve patient health, empower patients and to redirect the use of the time of health professionals (Donaldson, 2003). The Expert Patients Programme (Department of Health, 2001), which aims to introduce lay led self-care training for patients with chronic conditions, is currently being rolled out across the NHS.

There is a potential need for systematic reviews of the evidence on costs and effects to guide policy. Such reviews requires a criteria list to guide reviewers. There are a number of existing criteria lists for the assessment of economic evaluations (for example: Drummond and Jefferson, 1996; Drummond et al, 1997; NHS Centre for Reviews and Dissemination, 2001). But these need adaptation and elaboration for application to evaluations of self-care support. For example, since the essence of self-care interventions is the substitution of care by the patient for care by health professionals, the valuation of the time and other costs incurred by patients is of particular importance.

Self-care interventions can be grouped into five categories: self-care networks (self-help groups); extended self-care support from pharmacies; information to support self-care; training in self-management of conditions; provision of tools for self-diagnosis. The original aims of the project were (a) to produce a set of criteria for assessing the quality of the economic content in studies of self-care support; (b) apply them to a purposive sample of 30 papers, agreed with the Department of Health, covering the five categories. The aim was both to road test the criteria list and to provide information on the quality of studies which appeared to be relevant for policy; (c) since the purposive sample was not derived from a systematic search the third aim was to estimate the size of the existing literature on the different types of self-care support, especially in self-care networks, and training in self-management, to inform decisions about the need for and content of a future systematic reviews of the evidence.

Aims (b) and (c) were subsequently modified after inspection of the initial purposive sample of papers. After the papers had been examined it appeared that only a small proportion (8 of 27) could be classed as economic evaluations in that they included estimates of the resource consequences of the intervention. We therefore extended the literature scoping exercise (part (c) of the original aims) which had been intended only to produce a count of potentially relevant papers on a range of bibliographic databases. We conducted a systematic literature search designed to produce papers, in any of the five categories of self-care support, to be assessed against the quality criteria list. The literature search produced an additional 30 papers to be assessed. Thus the project outputs are the quality criteria list and a systematic review of the methodological quality of 38 papers reporting economic evaluations of self-care interventions.

## **2 Methods**

### **2.1 Definitions**

The usual definition of an economic evaluation is an analysis of the outcomes and costs of an intervention compared with a specified alternative (Drummond et al, 1997). Historically most evaluations of interventions have been studies of effectiveness (changes in outcomes) though there is no logical reason for privileging either cost data or outcome data in a choice between interventions. Interventions with favourable outcomes may have high costs. Interventions with worse outcomes may be worthwhile if they reduce costs and release resources which can be used to produce higher valued outputs elsewhere. Judgements on whether intervention A is better than intervention B require information on all their effects, both on outcomes (such as health effects) and on their costs: an economic evaluation is required. Our aim was to produce a quality criteria list for assessment of economic evaluations of self-care interventions and to apply it to selected papers.

The production of health will always involve patient decisions and inputs, ranging from compliance with health professionals' prescriptions to self treatment based on the patient's monitoring of their condition. Health will also be affected by past patient decisions on diet, lifestyle and preventive care (which again may range from

compliance with professionals' prescriptions to self-care). As Barlow (2002) notes a number of definitions of self care can be found in the literature. The definition of self-care and support for self-care used in the Department of Health is quite broad: "Self-care is defined as the health and social care taken by individuals and groups towards their own health and well being as well as that provided to others in groups such as families, communities of interest or neighbourhoods." (Dost, 2000).

We adopted a working definition of self-care as patients taking decisions intended to alter the effect of acute and chronic conditions on their health, via their responses to symptoms, or monitoring their condition, or self treatment. The definition is still broad and the range of self-care interventions is correspondingly wide, ranging from self management of oral anticoagulants, via education programmes for diabetes patients, to making it easier for patients to self medicate by relaxing restrictions on the sale of certain types of drugs.

## **2.2 Criteria list for economic evaluations**

Following Ament et al (2002) we distinguish amongst *guidelines* (how to conduct an evaluation), *checklists* (post publication check to see if specific guidelines are met), and *criteria lists* used in systematic reviews to assess methodological quality. A number of guidelines, checklists and criteria lists for economic evaluations have been produced. Chiou et al (2003) identified 19 lists after a systematic search of the English language literature since 1990.

We obtained copies of the lists identified by Chiou et al (2003) and used them as the basis for our criteria list for self-care support evaluations. The criteria list consisting of 16 groups of questions is set out in Appendix A. There is considerable, though imperfect, agreement across the 19 lists examined by Chiou et al (2003) on the types of questions to be asked of economic evaluation studies. The general issues to be addressed in economic evaluations are the same across all types of interventions so our set of criteria and the reasons for them is very similar to those in previous lists.

The lists from Chiou et al (2002), Drummond et al (1997), NHS Centre for Reviews and Dissemination (2001), and Forbes et al (2002) were the most influential in designing our criteria list. Quality criteria were assessed for inclusion based on their importance in the quality assessments of economic evaluations in general and in addition their relevance to the evaluation of self-care support. Those criteria that were either fundamentally important for quality assessment of *any* economic evaluation (for instance the perspective of the study) were included, as were any criteria that were deemed particularly relevant to self-care (for instance the measurement of costs to include patients out of pocket expenditure).

We did not have the time or resources for a Delphi study and in any case the CHEC criteria list recently derived by a team of Dutch researchers from a Delphi study (Ament et al, 2002) was included in the set of lists found by Chiou (2002).

Reviews of effectiveness studies generally have a clear evidence hierarchy from double blinded RCTs, via observational studies to expert opinion. Coyle and Lee (2002) have proposed hierarchies for other types of data (resource use, unit costs, utilities) needed for an economic evaluation. Thus they suggest that resource use measured from prospective data collection or reliable administrative data for the specific study is better than unsourced data from the same jurisdiction which in turn is better than results from prospective data collection or administrative data from a different jurisdiction. We have not imposed such a hierarchy in our checklist since we feel that is difficult to formalise all aspects of data quality in such a way. For example one would have to make a judgement about whether it was better to have more recent data from a different jurisdiction or old data from the same jurisdiction.

We suggest 16 criteria grouped into 5 main categories: study specification, clinical evidence, economic assessment, analysis, results and implications (see Appendix A).

We do not present a detailed discussion for the rationale for the types of questions addressed since they are already well covered in the literature (see for example the discussions in Drummond and Jefferson (1996) or Drummond et al (1997)). However, because self-care interventions are rather different from most other health service interventions the specific questions which have to be answered in checking whether criteria have been fulfilled and the weights placed upon them differ. As our

discussion in the next section indicates, evaluations of self-care interventions are more difficult than evaluations of more conventional interventions.

## **2.2.1 Distinctive nature of self-care interventions**

### *2.2.1.1 Comparator intervention*

Interventions must be compared with something in order to assess their relative efficiency. Unfortunately the “something” is often less well defined in self-care interventions than in other interventions where the comparator is a placebo or another intervention. The usual comparator in self-care interventions is no active intervention (Weingarten et al, 2002). This has a number of drawbacks. First it makes it more difficult to compare interventions against each other and hence to choose the best. Second, patients will in most cases already be practising some form of self-care which may take a variety of forms with differing resource implications. For example, some individuals may respond to their chronic condition by self medication or self treatment, others may take time off work, and others may soldier on with reduced productivity. The evaluators must ensure that they consider all such possible resource effects.

### *2.2.1.2 Placebo and Hawthorne effects.*

When outcomes are heavily affected by patient expectations and beliefs, care must be taken to avoid Hawthorne effects: at least part of any change in outcomes from an intervention would arise for *any* intervention compared with an alternative of no active intervention. One of the studies we examined found that the control group (which had been called for an interview to explain the trial and to have baseline measurement taken but received no active intervention) had improved health and self efficacy (Groessler and Cronan, 2000). In more conventional interventions it is possible to allow for these effects by administration of placebo therapies to patients who are blinded to their allocation to the control and intervention groups. But, although it is feasible to blind those assessing the effects of an intervention (Lorig, 2003), neither placebo controls nor blinding subjects to their allocation are possible in the case of self-care support. Hence since Hawthorne effects are potentially present it will be



better to compare active interventions against each other rather than against a passive usual care control group.

#### *2.2.1.3 Control group contamination.*

There is a higher risk of control group contamination. Access to conventional drug or other clinical interventions typically requires the consent of the health professionals running the intervention. Such controlled access is more difficult to ensure with self-care interventions which are designed to reduce the role of the professionals. For example, with patient education materials, patients in the control group may get access to the materials if they are published or from members of the intervention group. Randomisation by centre rather than by individual can reduce some types of contamination.

#### *2.2.1.4 Specification of the intervention*

Trials of a self-care intervention are more likely to be pragmatic i.e. to take place in a normal health service setting. Given the complexities of health care systems, more care is required in specifying the likely consequences of the intervention to ensure that they are measured. For example, a self-care intervention for a chronic condition may reduce the demand for GP consultations by patients with the condition. It will obviously be essential to measure the number of consultations. But a reduced demand for consultations for a set of conditions will have knock on effects. The demand for GP consultations is rationed by waiting time for appointments. A reduced demand for one type of consultation will reduce the waiting time for all types of consultation if GPs continue to supply the same total number. Hence the reduced waiting time is an effect of the intervention which should be measured (Bojke et al, 2002). The specification of such system effects can often be subtle and require the construction of formal theoretical models to guide the collection of relevant data.

#### *2.2.1.5 Heterogeneity and subgroup analysis*

Analysis of the effects of the intervention for subsets of the control and intervention populations can be an ex post exercise in data mining for significant effects. However, if there are subgroups for whom the intervention is particularly beneficial or harmful

then this should be taken into account in the implementation and targeting of policy. There are number of reasons why there are likely to be policy relevant differences within the populations exposed to self-care interventions. First, at the baseline no active intervention control may differ for different groups in terms of how actively they are already self managing their conditions and how successful they are. Second, the effect of the self-care intervention may vary with observable characteristics of patients such as education or age. Third, some self-care interventions, such as the Expert Patients Programme (Department of Health, 2001), are designed to assist patients to manage a wide range of chronic conditions and it is possible that their effect may vary across conditions. Thus evaluations of self-care interventions may require fuller socio-economic data on individuals than is usual in trials of conventional interventions.

#### *2.2.1.6 Range of outcomes*

Self-care interventions are likely to have a wider range of outcomes since they are often intended both to improve patient health and to empower patients by giving them greater control of health affecting decisions. Hence evaluations need to include a wider range of outcome measures. For example, the ongoing evaluation of the Expert Patients Programme includes measures of self-efficacy to exercise regularly, to manage disease, to manage symptoms, and to manage depression, a measure of communication with health professionals, and subjective well being in a number of domains, in addition to a battery of more conventional physical and mental health measures (Rogers et al, 2002).

#### *2.2.1.7 Patient costs*

Evaluations should adopt a societal perspective and take account of costs wherever they fall. Given that self-care interventions are designed to alter the way patients manage their conditions, patient costs are likely to be more important than with more conventional interventions.

#### *2.2.1.8 Length of follow up*

Length of follow up is crucial in self-care interventions since follow up periods are often short (of the order of six months) and there is some evidence that beneficial effects last for quite short periods (Riemsma et al, 2002). One of the papers we reviewed had a 5 year follow up and reported that a beneficial effect of intensive self-care education for asthma patients apparent at 1 year was not apparent at 2 and 5 years (Kauppinen et al, 2001). Many self-care interventions involve patients with chronic conditions so that by definition one is interested in the long term health, wellbeing, and resource consequences.

There may be fundamental tradeoffs in designing trials of self-care support in respect of length of follow up. Longer follow up may provide important information on the time path of effects but it increases the risk of control group contamination in the absence of any barriers to control group patients adapting the same self-care techniques as the intervention group. Thus a reduction in the difference in outcomes between control and intervention groups over time may reflect a genuine reduction in the effect of the intervention on the intervention group or it may reflect an improvement in the condition of members of the control group who adapt the same self-care practices as the intervention group. It may be possible to distinguish these explanations by examining the trend in the levels of outcome of the two groups, in addition to the difference between their trends.

#### *2.2.1.9 Transferability of results*

The transferability of results to other settings is crucial (Drummond and Pang, 2001). In studies of conventional intervention issues of transferability are most usually raised for cost estimates. Differences in unit costs of resources between countries or over time mean that disaggregated data (volume and unit costs for different types of resource) are more likely to be useful in other settings. Note however that differences in unit costs across settings may imply that cost minimising input mixes may differ and so a simple recalculation of costs using the original study volume data but local unit costs can be misleading.

Transferability of outcome effects may be more of an issue for self-care interventions than other types of intervention. Cultural factors which affect patients' receptiveness to self-care support may influence both the no intervention baseline and the effect of an intervention. Thus it is important that the context of the intervention is clearly specified.

### **2.2.2 Criteria weighting**

Our criteria list has 16 items. It would be possible to produce an overall quality score for a study by applying weights to the different criteria. Thus Chiou et al (2002) used conjoint analysis to derive a set of weights for 16 criteria, with the resulting weights (out 100 total) varying from 1 if subgroup analysis had been pre-specified to 3 for disclosure of source of funding to 8 if the study conclusions were justified and based on the study results.

We do not use weights to derive a summary score. There is considerable debate about whether such summary scores are useful for clinical trials (Stearns and Drummond, 2002). Juni et al (1999) applied 25 different instruments for assessing the quality of clinical trials to a particular type of intervention and found that the results of meta analyses varied with the quality weighting of trials.

There are also unresolved questions as to what is best practice in economic evaluations, for example in discounting (Gravelle and Smith, 2001).

## **2.3 Literature search**

The papers to which the criteria list was applied were derived from two sources (see Figure 1). The first was a purposive sample of 27 papers on self-care support provided by DH experts knowledgeable in the field of self-care. The purposive sample was intended to cover several types of self care support: self care networks; self-diagnostic tools, equipment and devices; training in self-management of acute, minor or chronic illness; training of professionals to support self care; audio-visual and IT facilities to support self care; and any currently used self-care support approaches such as enhanced involvement of pharmacies in self-care. This was

initially intended to be the only source of papers checked against the criteria list but as it appeared on inspection (see section 2.4) that only 9 of these papers were economic evaluations it became necessary to use the results of the literature scoping exercise to provide additional papers to be quality checked.

The papers in the purposive sample supplied by the Department of Health were obtained, and keywords and indexing terms identified from them and used to help form a search strategy. The details of the search strategies and the twelve databases searched are set out in Appendix B.

The following databases were searched: NHS Economic Evaluations Database (NHS EED), Health Economic Evaluations Database (HEED), Database of Abstracts of Reviews of Effect (DARE), Health Technology Assessment Database, and the National Research Register using self-care terms and where appropriate, economic evaluation terms.

Other sources searched using the self-care terms where appropriate were as follows: National Guidelines Clearinghouse, National Coordinating Centre for Health Technology Assessment, Health Services Technology Assessment Text, Scottish Intercollegiate Guidelines Network, National Institute of Clinical Excellence (published appraisals), and the Campbell Collaboration.

No date or language limits were applied, though the fact that the search terms are in English implies some limitation. Most of the databases were started in 1995 though some of them included studies published before this date. In addition, MEDLINE was also searched for the period 1966-1994, using self-care terms and with the Centre for Reviews and Dissemination economic evaluations filter added to the search strategy. Thus the search has comprehensive coverage of published papers for the last eight years (1995-2002 inclusive).

Two of the eight papers from the original DH reference list classified as full economic evaluations and examined against the criteria list were not picked up by the search strategies applied to the databases. This was because one made no reference to costs or economics in the title or abstract and so would not be included in the databases

searched. The other did not use any of the 'self-care' terms within the strategy but used the phrase 'pharmaceutical support'. Although evaluations of community pharmacies self-care interventions were included in the project, this proved difficult to express in terms of a search strategy because of the many different ways this was described within titles or abstracts. Incorporating broader, more general terms resulted in retrieving a large number of irrelevant papers. As a result, pharmacy support terms were incorporated into the strategy, but the use of 'pharmaceutical' terms were severely restricted because of the large numbers of references to drugs being retrieved.

#### **2.4 Selection of studies for review against the criteria list**

The 27 papers on the DH purposive sample list were obtained and each read independently by two reviewers. The reviewers were unanimous in deciding that 9 of the papers were economic evaluations in the sense that they had attempted to measure the resource consequences of self-care interventions.

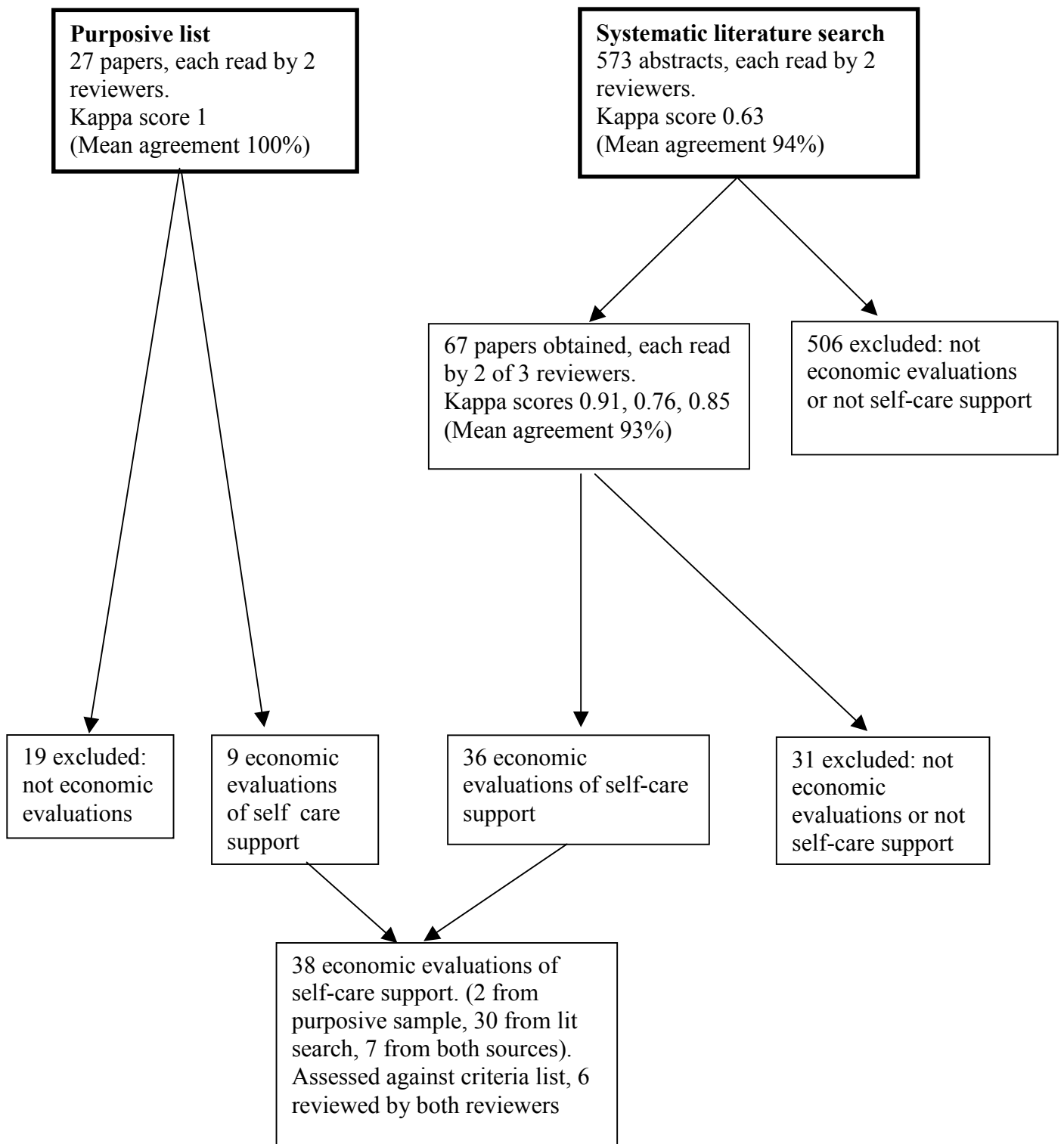
The systematic literature search produced an initial list of 573 papers. The abstracts for these papers were obtained and read independently by two members of the team. The full papers of those that were felt by both to be economic evaluations of self-care support were then obtained. Each of these 67 papers were then each read by two members of the team to determine if they were economic evaluations of self-care support. Some 36 papers satisfied these conditions. Seven of these papers were also in the purposive sample.

The two sources (purposive sample and systematic search) produced 38 papers in total for quality assessment against the quality criteria checklist. The purposive sample yielded 7 papers also produced by the systematic search and two which were not.

The 38 papers were then assessed against the criteria list separately by two reviewers, with 6 of the papers being assessed by two reviewers. For two (Gray et al, 2000; Kauppinen et al, 2001) of the six studies, there was complete agreement between both reviewers. For two other studies (Robinson, 2001; Schermer et al, 2002) mean

agreement was 95%. For the Lorig et al (2001) study mean agreement was 86% and for the Kruger et al study (1998) it was 77%.

**Figure 1. Selection of papers for assessment against criteria list**





### **3 Quality of papers on economic evaluation of self-care interventions**

#### **3.1 Quality of papers in review**

Tables describing the papers reporting full economic evaluations are provided in Appendices D and E. Appendix D summarises each paper and highlights the origin of the data (both country and date), the type of study (both economic and clinical), the location (both geographical and clinical setting), as well as the conclusions the authors reached and a comment on the strengths and weaknesses of the study. Appendix E indicates how each paper performed against the quality criteria checklist developed for this study.

Although we identified and analysed 38 reports of economic evaluations they were based on 35 interventions. Three of the papers (Kauppinen et al, 1998; 1999; 2001) were reports on the same Finnish intervention but at different lengths of follow up (1, 3 and 5 years). Since discounting is not relevant for a 1 year follow up but is for 2 and 5 year follow up the application of the criteria list yields potentially different answers for the three papers so we report them separately. Two other papers (Lorig et al, 1999; 2001a) were reports on the same US intervention. One paper (Lorig et al 1999) had a 6 month follow up with controls from a 6 month waiting list. The other followed up the patients for 2 years but the effect on the intervention group was contrasted with the effect on the waiting list control group who were given the intervention after 6 months. Again we decided that the method of estimating effects was sufficiently different that the criteria list could yield potentially different answers on the quality of the papers.

In reporting quantitative summaries we indicate whether we are considering 38 papers or the 35 interventions. If we had been performing a meta analysis or other quantitative synthesis of the data reported in the papers we would have treated the 38 papers as generating 35 observations. Whereas we suggest some overall qualitative summary conclusions about the quality of the evaluation design which are implicitly based on the 35 interventions.

The US provided half the papers (19/38), while Scandinavia (Norway, Finland Sweden and Denmark) provided data for 7/38. Only six papers had data originating in the UK. The fact that majority of these interventions were based in health care systems that are dissimilar to the UK, limits the generalisability of these studies to the UK setting.

All but one of the papers on self-care support were published after 1995. Although the date of data collection was not always specified, little data was collected pre-1990 (though the earliest included study (Lorig, 1993) uses data from 1984-1989). Most of the bibliographic databases searched started in 1995, but many of them contained papers published prior to 1995, and we also searched MEDLINE back to 1966. This suggests that there are unlikely to be many papers reporting economic evaluations of self-care support which we have missed because they were published before 1995. Older papers are also likely to be less relevant.

The most common form of clinical study design was the randomised controlled trial (RCT) (18/35), though a sizeable proportion had a design with no comparator group (such as a before and after study).

All of the papers, because of the nature of the search strategy, identified costs and consequences associated with an intervention, though only 12/38 could be considered cost-effectiveness analyses or cost utility analyses. The remainder were classified as cost consequence analyses where the incremental costs and outcomes were not formally compared, or in the case of uncontrolled studies, were not available (as there is no incremental cost or effect if there is no comparator).

The conditions to which the self-care interventions were applied varies. Asthma (7/35), diabetes (6/35), arthritis (3/35) and heart disease (2/35) are the most commonly specified conditions, while there were 3/35 general interventions aimed at “chronic disease”. Self-care of acute conditions (including patient self testing) was the subject of 4/35 interventions.

Four papers did not report the follow up period. Of those that did the modal follow up was 12 months; 4/34 had 6 months or less, 18/34 had 6 to 12 months, 5/34 had over 1 year to 2 years, and 8/34 had over 2 years.

Most of the papers conclude that self-care support is either cost saving or cost effective (or both) (28/38). Only two papers showed that self-care support was not cost-effective, while the remainder (8/38) were inconclusive. This may appear to broadly support the concept of self-care support but the majority of the studies of self-care support had significant flaws which limit both the internal and external validity. The most common flaws in the studies were:

- a) Costs were defined from a narrow perspective, for instance only considering the impact on primary care. Only 10/38 of papers had a societal perspective.
- b) Poor and opaque costing methodology (16/38 had inaccurate measures of costs or 16/38 did not adequately identify costs).
- c) No comparison group; 8/35 interventions had only before and after controls.
- d) Inadequate handling of uncertainty (either not performing sensitivity analysis or not presenting confidence intervals around mean estimates of cost and/or effect) (15/38 of papers)
- e) Missing data was either ignored or dealt with inappropriately (33 of 35 papers where there was missing data)
- f) Inappropriate statistical analysis (16/38 of papers)
- g) Short follow up.

We have discussed some of the special difficulties in conducting evaluations of self-care interventions in section 2.2.1 and these should be remembered in view of generally critical assessment of the papers.

Of the six UK based interventions, one (Robinson et al, 2001) reported that self-care support was cost-effective; two (Lord et al, 1999; Fitzmaurice et al, 2002) reported that self-care support was not cost-effective, and three were inconclusive (Gray et al, 1999; Sinclair et al 1999; Watson et al, 2002.) The latter three are arguably less obviously forms of self-care interventions and are certainly different from the forms

of intervention commonly understood as self-care support. If they are discounted the published UK evidence base on economic evaluations of self-care support is very small.

While most of the papers exhibited some flaws, there were additional factors restricting their generalisability to the present day UK setting. The most important was that relatively few studies were of interventions in the UK. Hence resource and unit cost data may not be readily transferable and the outcome effects of self-care interventions may be culturally dependent.

### **3.2 Results from other reviews**

Other reviews of economic evaluations have also concluded that there were a distressingly high proportion of poor quality studies. Jefferson et al (2002) conducted a systematic search for surveys of methodological quality of economic evaluations carried out between 1990 and 2000, covering in total around 1000 original studies. They found that there were major methodological flaws in both published and unpublished studies, including a lack of clear description of the methods and a low quality of estimates of the effectiveness of evaluation. Surveys of particular aspects of methodology also suggest poor quality. Smith and Gravelle (2001) reviewed the practice of discounting in 147 studies where the time period was long enough (over 18 months) for discounting to be required. Some 28% of studies did not use any discounting and those that did adopted a variety of methods and rates.

Other reviews of studies on self-care support have also commented in varying degrees on the extent and quality of economic information in evaluations of self-care support. Barlow et al (2002) examined a range of self-care interventions, though they did not attempt a formal assessment of quality. They concluded that there was evidence that self-care interventions had beneficial effects for patients compared to no intervention. However, they were critical of several aspects of the studies: reports did not always contain sufficient detail to determine what the intervention was, there were short follow up (3 to 6 months being typical), small samples, and few calculations of effect size. They noted that only a few of the studies considered cost-effectiveness and that

there was a focus on the direct costs of intervention, with few examining indirect costs for patients.

Bower et al (2001) examined 8 studies of written interventions based on behavioural principles for patients with symptoms of anxiety and depression. Most reported significant advantages in outcomes with self help treatments. They too found methodological shortcomings and noted that there was no data on long term clinical benefits or on cost-effectiveness. They concluded (Bower et al, 2001, 838) that the “available evidence is limited in quantity and quality and more rigorous trials are required to provide more reliable estimates of the clinical and cost-effectiveness of these treatments”.

Norris et al (2001) examined 72 studies of self-care training in type 2 diabetes. Overall they found positive effects on knowledge, frequency and accuracy of self monitoring of blood glucose, self reported diet, and glycemic control in studies with short (less than 6 months) follow up. Few studies examined health care use and they found no economic studies which included indirect costs. Performance, selection, attrition, and detection biases were also common.

Weingarten et al (2002) examined 55 studies of disease management programmes directed at patients with chronic illness. Nearly half (24/55) were effective, usually compared with usual care, but they concluded that “little is known about the relative effectiveness and costs associated with different implementation strategies” (p928).

Kaltenthaler et al (2002) attempted to survey the literature for an economic evaluation of computerised cognitive behavioural therapy for depression and anxiety and concluded that the economic “literature reviewed was often of poor quality or was not relevant. ... There are therefore no data in the published literature that are useful for any modelling purposes or for establishing the cost-effectiveness of CCBT.” (p25).

## **4 Conclusions**

### **4.1 Quality of economic evaluations of self-care support**

The checklist developed to assess the quality of economic evaluations in the self-care support sphere was based on several previously published checklists. It was developed in order to highlight the different requirements of studies on self-care support.

The findings of this review of 38 papers describing 35 intervention studies are similar to those of other reviews of economic evaluations of self-care interventions. While the studies, as a whole, broadly support the concept of self-care, the quality of economic evaluations on average was poor and many suffered from serious methodological flaws. Commonly, studies dealt with narrow perspectives of cost that may not be appropriate for evaluation of self-care interventions. Missing data were not dealt with appropriately, especially for those who did not complete the intervention. The lack of transparency in the cost data and the absence of allowance for uncertainty around cost data were particularly noticeable.

The studies based in the UK were better conducted than average (5/6 were attached to RCTS, 4/6 conducted full cost-effectiveness analyses). These studies did not consider group interventions; those that did investigate group interventions were primarily US based and had quality flaws.

There is mixed evidence in favour of the cost-effectiveness of self-care innovations in the UK. At present a definitive conclusion is not possible.

Current evaluations taking place are likely to improve the knowledge base and lead to more informative data for policy makers.

### **4.2 Possibilities for further research**

There are a number of possible directions for future research on self-care support and we consider these in the light of the results of review of the quality of existing economic evaluations.

#### **4.2.1 Further literature search and review**

One of the original aims of the project was to establish the size of the literature on self-care interventions to determine if a systematic review was likely to be worthwhile. Because of the small number of economic evaluations in our original purposive sample we have conducted a systematic search of the literature for economic evaluations of self-care support using 12 bibliographic databases. Most of our databases started in 1995 though we also searched MEDLINE back to 1966. We are doubtful if attempting to extend the search, for example by hand searching journals for the period prior to 1995 would produce many additional studies and any found would be likely to be old and of dubious relevance for current policy.

#### **4.2.2 Meta analysis.**

The disparate nature of the interventions and outcomes and the methodological flaws in many studies suggest that attempts to produce better estimates of cost-effectiveness for particular types of intervention are unlikely to be fruitful. It would be possible to produce estimates of effect sizes by standardising different types of outcomes by the standard deviation of the effect for a range of outcome types, as in Weingarten (2002). However this would not provide useful information for policy making since it would not indicate which types of intervention were most cost effective.

#### **4.2.3 Modelling.**

Given the data presented in some of the trials it would be possible to construct Cost Effectiveness Acceptability Curves (CEACs) (Fenwick et al. 2001). For example, the data in Gray et al (2000) would generate estimates of the probability of the intervention (in this case monitoring of blood glucose levels) being cost-effective. While this may be useful in itself, it will not inform decision makers contemplating other forms of self-care support .

We conclude that the most policy relevant research on self-care support will be trials of specific interventions, provided of course that they are of a quality high enough to

generate the kind of data we have suggested is necessary for an economic evaluation. The data generated by the intervention can also be used for modelling to generate Cost Effectiveness Acceptability Curves and as the basis for Bayesian methods (Claxton, 1999) to produce estimates of the value of further research on particular aspects of the intervention.



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## Appendices

### A. Criteria List: Economic Evaluations in Self-care Support

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#### Study specification

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##### **1. Was the study question clear?**

- What was the objective of the study? How clear was it? Self-care interventions (SC) can be complex.
- What were the key costs/resources and outcomes assessed?

##### **2. Was a comprehensive description of the competing alternatives given?**

- Can you tell who? did what? to whom? where? and how often? Were the care pathways clearly identified
- Was a comprehensive description of the interventions provided (i.e. the delivery needs to be described in detail in order to standardise the delivery and to generalise the results)
- Were any alternatives omitted? Is it appropriate to have a do-nothing alternative; could the study design prevent people self medicating?
- For SC interventions given in groups, was the effect of group therapy allowed for (e.g. by inclusion of the comparator arm of group therapy without the intervention). What was the unit of analysis?
- Were baseline utility values and/or resource use given for alternative treatment arms?

##### **3. What was the perspective of the study?**

- Often economic studies use a health service perspective on the grounds that this approximates a societal perspective. In the case of SC evaluations, costs to patient, plus productivity changes should be explored.

##### **4. What was the study design?**

- RCT of comparator therapies, placebo controlled RCT, controlled before and after, cross sectional control, before after control, case reports, expert opinion.

##### **5. What was the economic study type?**

- Cost utility, cost-effectiveness, cost benefit, cost minimisation, cost consequences
-

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## Clinical evidence

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### 6. Given the type of study was the design adequate?

Sample.

- How was the sample size determined?
- Was sample size adequate to detect differences? No statistically significant differences may lead to inappropriate cost minimisation analysis.
- How was the sample selected?
- Is there evidence to suggest that the sample is appropriate for the study question? Did any subjects refuse to participate?
- Were there any in/exclusions criteria and if so were they appropriate?
- Did studies which were RCTs have proper randomisation process?

Contamination.

- Given that contamination of control groups is more likely in SC interventions, was contamination considered? Were attempts made to mitigate it?
- Was adherence/compliance with the intervention measured?

Sociodemographic characteristics of study populations.

- Were these reported?
- Were the study and control groups shown to be comparable at baseline in terms of socio-demographic characteristics?
- Factors such as chronicity, previous treatment, social adjustment, interpersonal difficulties and social circumstances may also impact on the outcomes

Compliance. Was compliance reported?

Is the setting described?

- Is the area/country identified?
- Where did the intervention take place (home, primary care, hospital...)
- Who delivered the intervention?
- How many centres were there?
- Was effectiveness established in a UK trial?

Dates.

- Was the date of the intervention given?
- Were the dates for the effectiveness measures, resource use and price given?

Outcome assessment

- Is the method described?
- Was assessment blinded?

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## Economic analysis

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### 7. Were all the important and relevant costs and consequences for each alternative identified?

#### 7a Costs

- Was the costing undertaken on the same sample of people as that used in the effectiveness study?
- Was the costing undertaken pro/retrospectively?

- Self-care interventions may have more influence on self medication; with these interventions, these costs should be included.
- Formal and informal care costs may also vary more markedly in SC interventions as the person becomes better able to cope for him/herself and should be measured

#### **7b Consequences**

- SC interventions have been associated with improvements in outcomes such as empowerment, confidence etc.
- Were any adverse effects reported?
- Was quality of life measured?
- Appropriateness of outcome measures?
- Were patient preferences explored?

### **8. Were costs and consequences measured accurately (and credibly) in appropriate physical units? (e.g. hours of nursing time, number of physician visits, lost work-days, gained life-years)**

#### **8a. Costs**

- Where were unit cost data derived from? Were they derived from the study? Were they UK based? If not, are these estimates good estimates of opportunity cost in UK?
- Was study powered on costs?
- What resource quantities and costs were reported and were they reported separately and how were they estimated?
- What direct costs were included?
- What productivity changes were included? Were working days really lost?
- If required, were appropriate adjustments for inflation/currency conversion made?
- Prospective data for the study? From elsewhere?

#### **8b. Consequences**

- Use of outcome measures such as empowerment, motivation, perseverance. Have the measures been validated and are they reliable? Whose values were used and how many?
- Was the follow up period adequate? Was there loss to follow up? Was the outcome analysis built on intention to treat/treatment completers? Were the outcomes assessable within the timeframe? SC interventions may have little immediate impact on “hard” outcomes (mortality, life years gained etc);. If short follow up, is the link between intermediate outcome (confidence etc) and final outcome (e.g. QALY), well established?
- Direct or indirect measures of health effect? Health utility analysis?

### **Analysis**

#### **9. Was the statistical analysis appropriate given the design?**

- EG allowance for clustering, loss to follow up

#### **10a Was sub-group analysis performed?**

#### **10b If so were the groups pre-specified?**

- SC interventions often study a very heterogeneous population e.g. with number of conditions, age group.

#### **11. Were costs and consequences appropriately discounted?**

- Were discount factors applied to costs and outcomes if appropriate?
- Was a lower discount rate applied to outcomes if these were measured in volume terms rather than in value terms?

**12. Was an incremental analysis of costs and consequences of alternatives performed?**

- Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits or utilities generated?

**13. Was allowance made for uncertainty?**

Stochastic analysis of patient-level data

- Were details of statistical tests and confidence intervals given for stochastic data?
- Was uncertainty around cost-effectiveness expressed (e.g. confidence interval around incremental cost-effectiveness ratio (ICER), cost-effectiveness acceptability curves).
- Was sensitivity analysis used to assess uncertainty in non-stochastic variables (e.g. unit costs, discount rates) and analytic decisions (e.g. methods to handle missing data)?

Stochastic analysis of decision models

- Are all appropriate input parameters included with uncertainty?
- Is second-order uncertainty (uncertainty in means) included rather than first order (uncertainty between patients)?
- Are the probability distributions adequately detailed and appropriate? Was sensitivity analysis used to assess uncertainty in non-stochastic variables (e.g. unit costs, discount rates) and analytic decisions (e.g. methods to handle missing data)?

Deterministic analysis

- Was the method of sensitivity analysis used specified and justified (e.g. univariate, threshold analysis etc)?
- Was the choice of variables used in the sensitivity analysis justified and the ranges over which the variables are varied stated?

**14. Were missing data handled adequately?**

- As with most economic evaluations, missing data are likely to be a problem with SC interventions.

**15a. Was an economic model developed?**

**15b. If so was it appropriate, transparent and the methodology explicit?**

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**16 Study results and implications**

**16a. Were limitations of the study acknowledged and biases (and their potential magnitude and direction) discussed?**

- sources of funding acknowledged; declarations of competing interests

**16b. Were issues of generalisability discussed?**

- different country, different institutional setting, standard intervention, population groups.

**16c. Did the presentation and discussion of study results include all important issues?**

- Were any recommendations made by the authors regarding policy/practice?
  - Were specific recommendations made by the authors regarding the need for further research?
-



## **B. Search strategy**

### **NHS EED 1995-16.4.03**

Accessed via CAIRS T system

Searched 16.4.03

S self(w)care  
S self(w)manag\$  
S self(w) monitor\$  
S self(w)help  
S self(w)treat\$  
S (self(w)administer\$ andnot (self (w)administer\$ (2w)questionnaire\$ or  
self(w)administer\$(2w)interview\$))  
S self(w)medicat\$  
S self(w)diagnos\$  
S group\$(w)support\$  
S peer(w)support\$  
S expert(w)patient\$  
S ((pharmacist\$ or pharmacy or pharmacies) (2w) support\$)  
S ((pharmacist\$ or pharmacy or pharmacies)(2w) assist\$)  
S ((pharmacist or pharmacy or pharmacies)(2w) (advice or advise\$))  
S pharmaceutical(w)care  
S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13 or s14 or  
s15

### **DARE 1995-16.4.03**

Accessed via CAIRS T system

Searched 16.4.03

S self(w)care  
S self(w)manag\$  
S self(w) monitor\$  
S self(w)help  
S self(w)treat\$  
S (self(w)administer\$ andnot (self (w)administer\$ (2w)questionnaire\$ or  
self(w)administer\$(2w)interview\$))  
S self(w)medicat\$  
S self(w)diagnos\$  
S group\$(w)support\$  
S peer(w)support\$  
S expert(w)patient\$  
S ((pharmacist\$ or pharmacy or pharmacies) (2w) support\$)  
S ((pharmacist\$ or pharmacy or pharmacies)(2w) assist\$)  
S ((pharmacist or pharmacy or pharmacies)(2w) (advice or advise\$))  
S pharmaceutical(w)care  
S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13 or s14 or  
s15

S econom\$ or cost or costs or costly or costing or price or prices or pricing or pharmacoconomics  
S expenditure\$ andnot energy  
S value (1w) money  
S budget\$  
S s17 or s18 or s19 or s20  
S s16 and s21

## Health Technology Assessment Database

Accessed via <http://agatha.york.ac.uk/welcome.htm>

Searched 17.4.03

self-care or self-help-groups/Subject Headings Exploded  
OR self(s)care or self(s)manag or self(s)monitor or self(s)help or self(s)treat or self(s)administer or self(s)medicat or self(s)diagnos or group(s)support or expert patient or pharmaceutical care/All fields  
OR ((pharmacist or pharmacy or pharmacies) (s) (support or assist or advice or advise))/All fields

## National Research Register Issue 1 2003

Accessed via CDROM

Searched 22.4.03

SELF-CARE\*:ME  
SELF-HELP-GROUPS:ME  
(SELF next CARE)  
(SELF next MANAG\*)  
(SELF next MONITOR\*)  
(SELF next HELP)  
(SELF next TREAT\*)  
(SELF next ADMINISTER\*)  
(SELF next MEDICAT\*)  
(SELF next DIAGNOS\*)  
(GROUP\* next SUPPORT\*)  
(SUPPORT\* next GROUP\*)  
(PEER next SUPPORT\*)  
(EXPERT next PATIENT\*)  
(((PHARMACIST near SUPPORT\*) or (PHARMACY near SUPPORT\*)) OR  
(PHARMACIES NEAR SUPPORT\*))  
(((PHARMACIST near ASSIST\*) or (PHARMACY near ASSIST\*)) OR  
(PHARMACIES NEAR ASSIST\*))  
(((PHARMACIST near ADVISE\*) or (PHARMACY near ADVISE\*)) OR  
(PHARMACIES NEAR ADVISE\*))  
(((PHARMACIST near ADVICE) or (PHARMACY near ADVICE)) OR  
(PHARMACIES NEAR ADVICE))  
(PHARMACEUTICAL next CARE)

(((((((((((((#1 or #2) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #13)  
or #14) or #15) or #16) or #17) or #18)  
ECONOMICS:ME  
COSTS-AND-COST-ANALYSIS\*:ME  
ECONOMIC-VALUE-OF-LIFE\*:ME  
ECONOMICS-DENTAL:ME  
ECONOMICS-HOSPITAL\*:ME  
ECONOMICS-NURSING:ME  
ECONOMICS-PHARMACEUTICAL:ME  
((((((#20 or #21) or #22) or #23) or #24) or #25) or #26)  
(((((((ECONOM\* or COST) or COSTS) or COSTLY) or COSTING) or PRICE) or  
PRICES) or PRICING) or PHARMACOECONOMIC\*)  
(EXPENDITURE\* or BUDGET\*)  
(VALUE next MONEY)  
(#28 or #29) or #30)  
(#27 or #31)  
(#19 and #32)

### **HEED (Health Economic Evaluations Database) 1995-2003/Feb**

Accessed via CDROM.  
Searched 22.4.03

Ax= 'self care'  
Ax= 'self help'  
Ax= 'self manage'  
Ax= 'self managing'  
Ax= 'self management'  
Ax= 'self monitor'  
Ax='self monitoring'  
Ax= 'self help'  
Ax= 'self treat'  
Ax= 'self treatment'  
Ax= 'self administer'  
Ax= 'self administration'  
Ax= 'self medicate'  
Ax= 'self medication'  
Ax= 'self diagnose'  
Ax= 'self diagnosis'  
Ax= 'group support'  
Ax= 'support group'  
Ax= 'peer support'  
Ax= 'expert patient'  
Ax= 'pharmacist support'  
Ax= 'pharmacist advice'  
Ax= ' pharmacy  
Ax= pharmacies  
Ax= 'pharmaceutical care'

## **National Guidelines Clearinghouse**

Accessed via <http://www.guideline.gov/index.asp>

Searched 17.4.03

“self care” “self manag\*” “self help” “self treat\*” “self administer\*” “self medicat\*”  
“self diagnos\*” “group support\*” “peer support\*” “expert patient\*” “pharmaceutical  
care”

## **National Coordinating Centre for Health Technology Assessment**

Accessed via <http://www.hta.nhsweb.nhs.uk/>

Searched 17.4.03

self care, self manage, self help, self treat, self administer, self medicat, self diagnos,  
group support, peer support, expert patient, pharmacist, pharmacy, pharmacies,  
pharmaceutical care

## **Health Services Technology Assessment Text (HSTAT)**

Accessed via <http://hstat.nlm.nih.gov>

Searched 22.4.03

“self care “self help” “self mang\*” “self monitor\*” “self treat\*” “self administer\*”  
“self medicat\*” “group support\*” “expert patient\*” “peer support\*” “pharmacy  
support\*” “pharmacist support\*” “pharmacy advice” “pharmacist advice”  
“pharmaceutical care”

## **SIGN Guidelines (Scottish Intercollegiate Guidelines Network)**

Accessed via <http://www.sign.ac.uk/>

Searched 23.4.03

Fault on search engine. Visual inspection of publications

## **National Institute of Clinical Excellence (published appraisals)**

Accessed via <http://www.nice.org.uk/>

Searched 22.4.03

Self care, self help, self manag, self treat, self administer, self medicate, self diagnose,  
group support, peer support, expert patient, pharmacy, pharmacist, pharmacies,  
pharmaceutical care

## **Campbell Collaboration C2 Registered Systematic Reviews titles listing**

Accessed via <http://www.campbellcollaboration.org/Fralibrary.html>

Searched 23.4.03

No search engine. Visual inspection

## MEDLINE 1966-1994 (OVIDWEB)

Accessed via <http://gateway1.uk.ovid.com/ovidweb>

Searched 13.5.03

- 1 self care/ or blood glucose self-monitoring/ or self administration/ (15626)
- 2 self help groups/ (4757)
- 3 self manag\$.ti,ab. (1686)
- 4 self care.ti,ab. (4045)
- 5 self monitor\$.ti,ab. (1642)
- 6 self help.ti,ab. (2273)
- 7 self treat\$.ti,ab. (522)
- 8 ((self administer\$ adj2 questionnaire\$) or (self administer\$ adj2 survey\$) or (self administer\$ adj2 interview\$)).ti,ab. (4594)
- 9 self administer\$.ti,ab. (7803)
- 10 9 not 8 (3209)
- 11 self medicat\$.ti,ab. (1114)
- 12 self diagnos\$.ti,ab. (191)
- 13 (group\$ adj support\$).ti,ab. (920)
- 14 (peer adj support\$).ti,ab. (358)
- 15 expert patient\$.ti,ab. (24)
- 16 ((pharmacist\$ or pharmacy or pharmacies) adj2 support\$).ti,ab. (211)
- 17 ((pharmacist\$ or pharmacy or pharmacies) adj assist\$).ti,ab. (83)
- 18 ((pharmacist or pharmacy or pharmacies) adj2 (advice or advise)).ti,ab. (42)
- 19 pharmaceutical care.ti,ab. (566)
- 20 or/1-19 (35126)
- 21 economics/ (25947)
- 22 exp "Costs and Cost Analysis"/ (104972)
- 23 Value of Life/ (7030)
- 24 economics, dental/ (1452)
- 25 exp economics, hospital/ (12224)
- 26 economics, medical/ (5188)
- 27 economics, nursing/ (3590)
- 28 economics, pharmaceutical/ (1205)
- 29 or/21-28 (149166)
- 30 (econom\$ or cost or costs or costly or costing or price or prices or pricing or pharmaco-economic\$).tw. (176723)
- 31 (expenditure\$ not energy).tw. (7673)
- 32 (value adj1 money).tw. (321)
- 33 budget\$.tw. (8069)
- 34 or/30-33 (185401)
- 35 29 or 34 (270622)
- 36 letter.pt. (499936)
- 37 editorial.pt. (151241)
- 38 historical article.pt. (202035)
- 39 or/36-38 (846015)
- 40 35 not 39 (254146)
- 41 animal/ (3428453)
- 42 human/ (8011318)

- 43 41 not (41 and 42) (2662788)
- 44 40 not 43 (243289)
- 45 (metabolic adj cost).ti,ab,sh. (308)
- 46 ((energy or oxygen) adj cost).ti,ab,sh. (1471)
- 47 44 not (45 or 46) (241930)
- 48 47 and 20 (2537)
- 49 limit 48 to yr=1966-1994 (941)

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## D. Summary of economic evaluation papers

Author	Publication date	Date of clinical data	Origin of data	Condition	Setting for intervention	Clinical study type	Economic evaluation type	Intervention	Authors' conclusions	Comments on the study
Albisser et al	2001	NS	USA	Diabetes mellitus	Mixed model HMO	Before & after	CCA	Education, self-care training & computer-assisted self-care on outcomes in diabetes disease management	Education alone had no cost or outcome effects; adding self-care training or ongoing computer assisted self-care improved outcomes but increased costs.	12 m follow up. Cost data were point estimates; no measure of uncertainty was presented; no sensitivity analysis.
Berg et al	2002	2000	USA	Diabetes	Community	Before & after	CCA	Diabetes disease management	Intervention is associated with reduced costs and positive behavioural change	12 m follow up. Complete case analysis performed; no imputation of missing values. ICER not calculated; costs assessed were narrow
Cline et al	1998	1991-1993	Sweden	Heart disease	Hospital	RCT	CCA	Education and self-care, plus easy access outpatient clinic.	No effect on 1 year survival. Hospitalisation postponed and reduced; health care costs reduced.	12 m follow up. Basic economic evaluation methods adhered to but more sophisticated forms of analysis not undertaken e.g. costs were not compared alongside consequences. Modelled over 5 years. The outcomes included were limited and the cost analysis used to populate the model was not clear.
Elston Lafata et al	2000	NS	USA	Heart	Hospital	Decision model	CCA	Anticoagulation clinics & patient self-testing for patients on chronic Warfarin therapy.	Both interventions reduce patient and provider costs and reduce thromboembolic and hemorrhagic events compared with usual care. Patient self-testing is the most cost-effective alternative.	Modelled over 5 years. The outcomes included were limited and the cost analysis used to populate the model was not clear.
Engh et al	2001	NS	USA	Hip	Community	CCT	CCA	Self-testing of prothrombin time after hip arthroplasty	Patient self-testing is reliable and cost-effective for monitoring the anticoagulation status after total hip replacement in a select group of elderly patients.	6 w follow up. The cost analysis lacked transparency and no statistical analysis of costs was undertaken. Small sample.
Fitzmaurice et al	2002	NS	UK	CV	Primary care	RCT	CCA	Self-management of oral anticoagulation treatment compared with primary care management	Self-care in this population is as safe as primary care management but at significantly greater cost	6 m follow up. Only considered primary care costs; too narrow for an economic evaluation. Costs not subjected to sensitivity analysis
Gallefoss et al	2001	1994-95	Norway	Asthma	Outpatient dept	RCT	CEA	Self-care education programme.	Patient education improved patient outcomes and reduced costs	12 m follow up. Well conducted study. Wide assessment of costs including patient costs and productivity losses. Missing data not acknowledged.
Gallefoss et al	2002	1994-1995	Norway	COPD	Outpatient dept	RCT	CEA	Self-care education programme.	Education of patients improved patient outcomes and reduced costs in a 12-month follow-up	12 m follow up. Cost methodology not transparent. Statistical analysis of cost comparisons was limited
Ghosh et al	1998	1991-1994	India	Asthma	Hospital	RCT	CCA	Self-care training for asthmatics	Self-care training as part of clinical management of asthma can result in improvements in health status and reductions in hospital use.	12 m follow up. Some unit costs based on assumptions. Limited statistical tests. No physician costs included.
Glasgow et al	1997	NS	US	Diabetes	Primary Care	RCT	CEA	Behavioural dietary intervention.	Improvement in patient outcomes as measured on a dietary behavioural measure. Costs also increased.	12 m follow up. Well conducted study. Outcome measured were intermediate measures and the cost per % reduction in fat intake is difficult to translate to cost per QALY.
Gray et al	2000	NS	UK	Type 2 diabetes	Hospital	RCT	CEA	Intensive blood glucose control policy vs conventional dietary control	Intensive blood glucose significantly increased treatment costs but substantially reduced the cost of complications and increased the time free of complications	Median follow 10 y. Well conducted economic evaluation. No patient quality of life information
Groessler et al	2000	NS	USA	Chronic illness	HMO	RCT	CCA	Social support and/or education.	Costs reduced compared with control. All groups, including control, had improved health and self efficacy.	3 y follow up. A narrow range of costs were included. Outcomes considered were

Humphreys	2001	NS	USA	Substance abuse	Hospital	CCT	CCA	Comparison of professional encouragement of participation in 12 step self help groups vs cognitive behavioural therapy.	Patients treated in 12 step programmes had lower costs and higher rates of abstinence.	comprehensive. Evidence of Hawthorne effect.
Jacobsen et al	2002	NS	USA	Cancer	Hospital	RCT	CCA	Professionally administered stress management training or self-administered stress management training.	Self administered intervention improved QoL particularly mental health and reduced costs compared with professionally delivered comparator.	12 m follow up. Matched controls only. No allowance for uncertainty. Missing data not acknowledged, though imputation is implied by the analysis.
Kauppinen et al	1998	1991-1993	Finland	Asthma	Hospital	RCT	CEA	Intensive vs conventional patient education & supervision for self-care.	Intensive patient education had better outcome than the conventional programme only in terms of FEV1. No difference in HRQOL. Intensive intervention not superior to conventional programme in terms of either cost-effectiveness or monetary net benefit.	Fairly well conducted study. Not clear how missing data were dealt with.
Kauppinen et al	1999	1991-1993	Finland	Asthma	Hospital	RCT	CCA	Intensive vs conventional patient education & supervision for self-care.	No clear difference in costs or QoL, though disease specific measures showed improved outcomes	1 y follow up. Limited resource use information. Non-parametric tests were used to compared costs when commonly parametric tests are used
Kauppinen et al	2001	NS	Finland	Asthma	Hospital	RCT	CEA	Intensive vs conventional patient education & supervision for self-care.	No significant difference in costs or outcomes at years 3 or 5., though was tendency for the cost to be lower in the intervention group..	3 y follow up. Uncertainty around costs and effects reported; missing data not acknowledged. Same study as Kauppinen et al (1999)
Kruger et al	1998	NS	USA	Arthritis	Community	Decision model	CEA	Arthritis self-help course as adjuvant to conventional therapy.	Arthritis self-help course reduces costs and arthritis pain among individuals receiving conventional medical therapy.	5 y follow up. Limited resource use information. Uncertainty around costs and effects reported. Missing data not acknowledged. Same study as Kauppinen et al (1999)
Lahdensuo et al	1998	NS	Finland	Asthma	Community	RCT	CEA	Guided self-care	Guided self-care group had more healthy days at lower cost than the traditional treatment group	4 y time horizon modelled. Further information is required on the outcomes/effectiveness data
										1 y follow up. Minimal details of costing methodology. Limitations were not discussed, sensitivity analysis or any form of allowance for uncertainty was not performed

Lord et al	1999	1995-1997	UK	Osteoarthritis of knee	Primary care	RCT	CEA	Nurse led education programme	General practice based patient education is not an efficient use of health care resources. More costly and no impact on patient outcomes at 1 year	1 y follow up. Well conducted study. Study size may not have been adequate to detect clinical effect
Lorig et al	1993	1984-1989	USA	Arthritis	Community	Before & after	CCA	Arthritis self-management program	Health education in patients with arthritis reduces costs and improves outcomes	4 y follow up. Not a full evaluation. No comparator was used, narrow range of costs and no statistical analysis around the costs. Costs and effects were not measured appropriately.
Lorig et al	1999	NS	USA	Chronic disease	Community	RCT	CCA	Chronic disease self-management program (CDSMP)	Intervention group had improvements in variety of outcomes including self reported health, fatigue, disability. Had fewer hospitalisations and hospital days.	6 m follow up. Waiting list controls. Cost methodology used was limited and narrow
Lorig et al	2001a	NS	USA	Chronic disease	Community	RCT	CCA	Chronic disease self-management program (CDSMP)	One year after exposure to the program, most patients experienced statistically significant improvements in a variety of health outcomes and had fewer emergency dept visits.	1 and 2 y follow up but comparison with controls only for 6 m. Costs were included in the discussion only and a limited approach to costing was undertaken. Same study group as Lorig et al (1999).
Lorig et al	2001b	1997	USA	Chronic disease	Hospital	Before & after	CCA	Chronic disease self management program (CDSMP).	One year after exposure to the program, most patients experienced statistically significant improvements in a variety of health outcomes and had fewer emergency dept visits.	1 yr follow up. Only limited cost information provided. No controls.
Mattson Prince et al	1995	1993	USA	Tetraplegia	Community	CCT	CCA	Self-managed versus agency-provided personal assistance care.	Self managed group had better health, fewer rehospitalisations, greater life satisfaction, lower costs.	Limited cost and statistical analysis. No randomisation to intervention and control groups. Variable and unstated length of exposure to alternatives.
Mazzuca et al	1999	1993-1995	USA	Osteoarthritis of knee	Hospital	CCT	CCA	Individualised self-care education vs standard public education.	Individualised self education group had lower primary care costs but no difference in respect of utilisation and costs of outpatient, pharmacy, lab or radiology services.	1 yr follow up. The study did not investigate uncertainty in much depth and therefore it is difficult to assess how robust the findings are. No health measures.
Meier et al	2002	1997-1998	USA	Type 2 diabetes	Hospital	Before & after	CCA	Modification of guidelines to reduce the number of self-monitoring tests of blood glucose	Self-monitoring of blood fell, resulting in substantial cost savings without affecting glucose control.	6 m follow up. The cost methodology used was limited and narrow
Robinson et al	2001	NS	UK	Ulcerative colitis	Hospital	RCT	CCA	Guided self-care & patient-directed follow-up of ulcerative colitis	Self-care of ulcerative colitis accelerates treatment provision and reduces doctor visits and does not increase morbidity.	14 m median follow up. Cost analysis was limited to patient travel costs.
Rubin et al	1996	NS	USA	Urinary tract infection	Community	Decision model	CEA	Making oral antibiotics for urinary tract infection treatment available over the counter.	Costs of allowing OTC medication for UTI outweigh the benefits.	20 y time horizon. The model is a "black box". Unclear how estimates of effectiveness and cost-effectiveness generated.

Salkeld et al	1997	1990-1991	Australia	Heart disease	Primary care	RCT	CUA	General-practice based lifestyle change programs for people with risk factors for CV disease	Very high cost per QALY. Targeting high risk males would reduce cost per QALY to \$A30K. Lifestyle intervention had no significant effect on cardiovascular risk factors.	1 y follow up. The study design and methods used for the evaluation were quite well done.
Schermer	2002	1996-1999	Holland	Asthma	Health care	RCT	CUA	Guided self-care of asthma in primary health care	Intervention group had more QALYs, better asthma control, lower costs, fewer limited activity days. Intervention was cost effective on all outcomes.	2 y follow up. The study design and methods used for the evaluation were quite well done, including assessment of QALYs
Sinclair et al	1999	NS	UK	Smoking cessation	Community pharmacy	RCT	CEA	Training of community pharmacists to deliver advice to customers on smoking cessation based on "state of change" model.	Higher cessation rates amongst smokers in intervention group of pharmacies.	9 m follow up. Opportunistic recruitment of smokers. No consideration of contamination. Little investigation of uncertainty.
Starostina et al	1994	NS	Russia	Type 1 diabetes	Hospital	CCT	CCA	Intensive treatment and teaching programmes for type 1 (insulin dependent) diabetes mellitus comparing blood glucose to urine glucose self-monitoring	Both interventions led to improvement of metabolic control and reduced hospitalisations and sick leave days. The cost of USGM test strips is outweighed by discontinuing ineffective drugs.	2 y follow up. Cost analysis not clear. Unconventionally, reductions in resource use were monetized and used as a benefit measure in a CBA. No measures of effects on quality of life.
Taborski et al	1999	NS	Germany	Heart	Hospital	Before & after	CCA	Self-managed anticoagulant therapy	Overall therapy costs were reduced compared with physician monitoring from DM 2,061 to DM 1,342 pa per patient .	1 yr follow up. Cost analysis was unclear . Only primary care costs considered.
Tschopp et al	2002	NS	Switzerland	Asthma	Health care & community	Before & after	CCA	Self-care education booklet.	Intervention reduced hospitalisations, emergency consultations, overall health care costs and lost work days and improved quality of life.	12 m follow up. Unit costs not reported so costings unclear.
Volsko	1998	NS	USA	Paediatric asthma	Hospital	Before & after	CCA	Education for self-care	Intervention reduce emergency dept visits, hospitalisations, total cost of care.	7 m follow up. Very small sample. No patient costs considered. Limited costing methodology.
Von Korff et al	1994	1989-1990	USA	Back pain	Primary care	Not clear	CCA	Practice style in managing back pain	Practice style consistent with back pain self-care had similar long term pain and functional outcome at lower cost compared with practice style with more frequent prescription of bed rest and medication.	2 y follow up. Not a full evaluation. No comparator was used, narrow range of costs and no statistical analysis around the costs. Costs and effects were not measured appropriately
Watson et al	2002	2000	UK	Anti-fungals	Community	RCT	CCA	Educational outreach for community pharmacists to promote evidenced-based practice	Neither strategy (postal dissemination vs professional education session for promoting evidence-based community pharmacy) was effective in improving the appropriateness of OTC management of vulvovaginal candidiasis by community pharmacy staff.	Simulated patients to test effect on prescribing. Cost methodology and investigation of uncertainty was limited.

Notes:

CCA: Cost consequences analysis. Costs and effectiveness (consequences) are presented separately.

CEA: Cost-effectiveness analysis. Costs are expressed in monetary units and effectiveness is expressed in some single unit of effectiveness. When comparing two interventions the difference in cost and effectiveness between the two interventions is expressed as an incremental cost-effectiveness ratio (ICER), with the difference in cost in the numerator and the difference in effectiveness in the denominator

CUA: Cost utility analysis. A form of CEA in which the units of effectiveness are quality-adjusted life-years (QALYs).

## E. Summary performance of economic evaluation papers

Authors	Q1	Q2	Q3	Q4	Q5	Q6	Q7a	Q7b	Q8a	Q8b	Q9	Q10a	Q10b	Q11	Q12	Q13	Q14	Q15a	Q15b	Q16a	Q16a	Q16b	Q16c
Albisser et al	√	√	4	7	10	√	X	√	X	√	√	X	NA	NA	X	X	X	X	NA	√	12	√	√
Berg et al	X	√	3	7	10	√	X	X	X	√	√	X	NA	NA	NA	X	X	X	NA	√	13	√	√
Cline et al	√	√	3	5	10	√	√	√	X	√	X	X	NA	NA	X	√	X	X	NA	√	12	X	√
Elson Lafata et al	√	√	1	8	10	√	√	√	X	√	√	X	NA	√	√	√	NA	√	√	√	14	√	√
Engh et al	√	√	3	6	10	√	√	√	X	√	√	X	NA	NA	X	X	X	√	√	√	13	√	√
Fitzmaurice et al	√	√	3	5	10	X	X	X	X	√	√	X	NA	NA	X	X	X	X	NA	√	13	X	√
Gallefoss et al 2001	√	√	1	5	9	√	√	√	√	√	√	X	NA	NA	√	√	X	X	NA	√	12	√	√
Gallefoss et al 2002	√	√	1	5	9	√	√	√	X	√	√	X	NA	NA	√	√	√	X	NA	√	12	√	√
Ghosh et al	√	√	2	5	10	√	√	√	√	√	√	X	NA	NA	X	√	X	X	NA	√	12	√	√
Glasgow et al	√	√	3	5	9	√	X	√	√	√	√	X	NA	NA	√	√	X	X	NA	√	12	√	
Gray et al	√	√	3	5	9	√	√	X	√	√	√	X	NA	√	√	√	√	X	NA	√	13	√	√
Groessler et al	√	√	3	5	10	√	√	√	√	√	√	X	NA	√	√	√	X	X	NA	√	12	√	√
Humphreys et al	√	√	1	6	10	X	X	X	√	X	X	X	NA	NA	X	X	X	X	NA	√	12	√	√
Jacobsen et al	√	√	3	5	10	√	X	√	√	√	√	X	NA	NA	√	X	X	X	NA	√	12	√	√
Kauppinen et al 1998	√	√	2	5	9	√	√	√	√	√	X	X	NA	NA	√	√	X	X	NA	√	12	√	√
Kauppinen et al 1999	√	√	3	5	9	√	X	√	√	√	√	X	NA	√	√	√	X	X	NA	√	12	√	√
Kauppinen et al 2001	X	√	4	5	10	X	X	√	√	√	X	X	NA	√	X	√	X	X	NA	√	12	√	√
Kruger et al	√	√	1	8	9	√	√	X	√	√	X	X	NA	√	√	√	NA	√	√	√	14	√	√
Lahdensho et al	√	√	3	5	9	√	X	X	X	√	X	X	NA	NA	√	X	X	X	NA	X	14	X	X
Lord et al	√	√	1	5	9	√	√	√	√	√	√	X	NA	NA	√	√	X	X	NA	√	12	√	√
Lorig et al 1993	√	√	4	7	10	X	X	X	X	X	X	X	NA	√	X	X	X	X	NA	√	12	√	√
Lorig et al 1999	√	√	3	5	10	√	√	√	√	√	X	X	NA	NA	√	X	X	X	NA	√	12	√	√
Lorig et al 2001a	√	√	3	5	10	√	√	√	X	√	X	X	NA	NA	√	X	X	X	NA	√	12	X	√
Lorig et al 2001b	√	X	3	7	9	√	X	X	√	√	X	X	NA	NA	NA	X	X	X	NA	√	13	√	√
Mattson Prince et al	√	√	3	6	10	√	√	√	X	√	√	X	NA	NA	X	√	X	X	NA	√	12	√	√
Mazzuca et al	√	√	2	6	10	√	√	√	√	√	√	X	NA	NA	X	√	X	X	NA	√	12	√	√
Meier et al	√	√	3	7	10	√	√	√	X	√	X	X	NA	NA	X	X	X	X	NA	√	12	√	√
Robinson	√	√	4	5	10	√	X	X	X	√	X	X	NA	NA	X	X	X	X	NA	X	12	X	√
Rubin et al	√	√	1	8	9	√	√	√	√	√	√	X	NA	√	√	√	NA	√	√	√	12	√	√
Salkeld et al	√	√	3	5	11	√	√	√	√	√	√	√	√	√	√	√	X	√	√	√	12	√	√
Schermer et al	√	√	1	5	11	√	√	√	√	√	√	X	NA	X	√	√	X	X	NA	√	12	√	√
Sinclair et al	√	√	1	5	9	√	√	√	√	√	X	X	NA	NA	√	√	X	X	NA	√	12	√	√
Starotsina et al	√	√	1	6	10	√	√	√	√	√	√	X	NA	√	√	√	X	X	NA	√	13	√	√

Taborski et al	√	√	3	7	10	√	√	X	X	X	X	X	NA	NA	X	X	X	X	NA	X	14	√	√
Tschopp et al	√	X	3	7	10	√	√	√	√	√	X	X	NA	NA	NA	√	X	X	NA	√	12	√	√
Volsko	√	√	3	7	10	√	√	X	X	X	X	X	NA	NA	X	√	X	X	NA	X	14	√	√
Von Korff et al	√	X	3	7	10	√	X	X	X	X	√	X	NA	NA	NA	X	X	X	X	√	12	NA	√
Watson et al	√	√	3	5	10	√	√	√	√	√	√	X	NA	NA	X	√	X	X	NA	√	12	√	√
% √	95	92				89	68	68	58	87	58	3	3	26	50	61	5	13	13	89		84	97
% X	5	8				11	32	32	42	13	42	97		3	39	39	87	87	3	11		13	3
% NA													97	71	11		8		84			3	
	Q1	Q2	Q3	Q4	Q5	Q6	Q7a	Q7b	Q8a	Q8b	Q9	Q10a	Q10b	Q11	Q12	Q13	Q14	Q15a	Q15b	Q16a	Q16a	Q16b	Q16c

### Notes to tables D and E

√ = Yes , X = No, NA = Not applicable, NS = Not stated

#### Q1 Study clarity

#### Q2 Comprehensive description of competing alternatives

#### Q3 Perspective

- 1 = Societal (26%)
- 2 = Health care system & patient (8%)
- 3 = Health care system (55%)
- 4 = Not clear (11%)

#### Q4 Study design

- 5 = Randomised Control Trial (RCT) (55%)
- 6 = Case Control Trial (CCT) (13%)
- 7 = Before and after (24%)
- 8 = Decision model (8%)

#### Q5 Economic study design

- 9 = Cost-effectiveness Analysis (CEA) (32%)
- 10 = Cost Consequence Analysis (CCA) (63%)
- 11 = Cost Utility Analysis (CUA) (5%)

#### Q6 Design adequacy given study type

#### Q7a Relevant costs identified

#### Q7b Relevant consequences identified

#### Q8a Costs measured accurately

#### Q8b Consequences measured adequately

#### Q9 Statistical analysis appropriateness given the design

#### Q10a Sub-group analysis

#### Q10b Sub-groups pre-specified

#### Q11 Discounting

#### Q12 Incremental analysis

#### Q13 Allowance for uncertainty

#### Q14 Missing data handled appropriately

#### Q15a Economic model

#### Q15b Appropriateness of economic model

#### Q16a Type of funder

- 12 = Public/voluntary sector (70%)
- 13 = Private sector (16%)
- 14 = Do not state (14%)

#### Q16b Generalisability

#### Q16c Presentation and discussion of key results