

What kind of health economic input is appropriate in a feasibility study?

The NIHR has defined a feasibility study as research that estimates the parameters needed to design a future definitive study. * Such parameters include the variability around outcomes (to inform sample size calculations); the acceptability of randomisation to patients and clinicians; recruitment and follow up rates; questionnaire response rates; and treatment adherence. Crucially, feasibility studies should not provide estimates of treatment effectiveness because typically samples will not have the power to reliably detect between group differences.

Preliminary estimates of cost-effectiveness based on the small sample sizes typically seen in feasibility studies, coupled with high cost/high variability populations, may risk negative outcomes (i.e. intervention cost-ineffective) if, for example, one or two high cost individuals are randomised to the intervention group by chance. This may jeopardise future applications for definitive trials in otherwise clinically effective interventions.

Instead, the focus of health economics in feasibility studies should be limited to developing or refining service use schedules and other measures of outcomes such as health related quality of life.

There are several ways to collect preliminary resource use data such as patient focus groups, clinical opinion or incorporating resource use questions in qualitative research. In other words, asking patients and carers what resources are relevant to their current treatment and their future service use.

Methods of data collection could be piloted, such as the use of patient diaries, and assessed in terms of completion rates, errors and missing data. Results will identify resource data collection priorities (and what not to collect!), help adapt existing resource use instruments and assess the need for data collection from other sources, such as case notes. Feasibility studies can also include developing and piloting a data management database for the main study. Piloting a database is especially important in studies which use online questionnaires, or data extracted from the NHS sources (e.g. [Secondary Uses Service database](#)).

A feasibility study is a good time to examine the resource use associated with an intervention and savings or other service use impacts. This could be based on clinical opinion, observing workflows or examining clinical records. Feasibility studies may also help to estimate costs associated with the delivery of an intervention. The components may include administration, IT support, staff training or media campaigns. The likelihood of an intervention being cost-effective may well become clearer once the overall cost impact of the intervention is better understood.

Feasibility studies also offer an opportunity to explore the validity and sensitivity of alternative measures of quality of life that can be used to generate economic outcomes such as quality-adjusted life-years. In many areas, such as childhood conditions and mental health for example, there are controversies about the sensitivity and validity of standard measures like the EQ-5D-5L. The relative correlation of alternative measures with clinical outcomes may provide evidence to support one as the primary economic outcome in the definitive cost-effectiveness analysis.

Of course, it may also be that the existing methods of identifying and measuring economic outcomes in your disease area are already well-recognised and health economic involvement at the feasibility stage is unnecessary or minimal. In all cases it will be beneficial to obtain the opinion and support of a health economist either formally as a co-applicant, or as an informal collaborator or member of the trial steering committee.

1. It is often impractical and inadvisable to perform a full cost effectiveness analysis in a feasibility study
2. It may be more appropriate and useful to test the health economic methods for use in future definitive economic evaluations
3. These include feasibility of data collection and sensitivity of measures of health-related quality of-life or alternative economic outcomes
4. Health economists at RDS London can advise on the level of input suitable for a feasibility study

We have previously recommended [cost consequences analyses](#) (CCAs) as useful way to present the results from feasibility studies when it is not clear which costs and outcomes will be most relevant to future definitive trials. The costs and effects observed in a feasibility study can also be used in value of information modelling to determine whether the cost of a definitive RCT is worthwhile. While these approaches avoid the risks of premature comparative analysis, they both require substantial health economics input to value service use and quality-adjusted life years.

** These recommendations also apply to pilot studies which the NIHR define as a test run of the processes of a definitive study.*

Authors:

- Dr Natalia Hounsome, Health Economist, Queen Mary University of London
- Dr James Shearer, Health Economist, King's College London