

TITLE: How to ensure outputs of nutrition research will support high quality economic evaluation and thus inform policy

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ABSTRACT

Background

Economic evaluation is increasingly demanded by health agencies in making decisions about what to include in core services. (Examples include National Institute of Clinical Excellence (NICE) in the UK and Medical Services Advisory Committee (MSAC) in Australia). It is not enough to design a clinical trial to meet well known statistical or clinical requirements; trials must also provide useful data inputs to economic evaluation.

Aim

To describe the characteristics ideally incorporated into a well designed nutrition study to inform economic evaluation and nutrition policy.

Discussion

A set of desirable characteristics in designing a nutrition trial to support economic evaluation have been devised based on two decades of health economics health technology evaluation, including of nutrition interventions. The key aspects are:

Internal validity

Trial design - gold standard of an RCT still applies. But particular attention should be given to the design of the intervention (eg consider option of studying whole foods or whole diets rather than single nutrients) and selection of comparator (to include say diet and/or a possible pharmacotherapy arm and/or current diet advice (eg the American Heart Association diet).

External validity

- Carefully select the target/enrolled population – (eg consider selection of a high risk group, who will accumulate events more quickly, consider typical clinic or community population)
- Length of follow up –adequate follow-up is critical to describe maintenance of behaviours, and to measure effect on ‘real outcomes’. Follow-up of years would normally be desirable.

Outcomes

Selection of the appropriate outcomes is critical for the conduct of economic evaluation. Ideally this would include i) process, ii) intermediate and iii) final outcomes. Process outcomes are used to establish the fidelity of implementation; intermediate outcomes such as change in diet and bio-markers inform whether changes were as expected and help establish the causal pathway with final outcomes. Final outcomes include major health events (such as AMI, stroke, or death) and quality of life. It is these outcomes that are important to the population and to policy makers. It is far more powerful to measure these directly than to model from intermediate outcomes, which will typically be associated with considerable uncertainty.

Conclusion

Health economics can provide clear guidance to persons seeking to embark on nutrition trials regarding desirable characteristics to maximise the chance of policy translation.