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Designing economic evaluations alongside clinical trials in maternal health care: A guide for clinical trial design

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Abstract

Background: Economic evaluations are being conducted with increasing frequency in the maternity care setting, with more randomized controlled trials containing a health economic component. Key emerging criticisms of economic evaluation in maternity care are lack of robust data collection and measurement, inconsistencies in methodology, and lack of adherence to reporting guidelines.

Methods: This article provides a guide to the design of economic evaluations alongside clinical trials in maternal health. We include economic concepts and considerations for the maternity setting and provide examples from the UK and Australia.

Results: There are many important considerations for the design of economic evaluations alongside clinical trials. To be effective, researchers must select types of economic evaluation, which align with their study objectives; choose an appropriate evaluation perspective, time horizon, and discount rate; and identify accurate ways to measure and evaluate health outcomes and costs.

Discussion: This guide is written for noneconomists and can be used for designing economic evaluations to be conducted as a part of clinical trials. We seek to improve the quality, consistency, and transparency of economic evaluations in maternal health.

KEYWORDS
health economics, RCT, value based healthcare

1 | INTRODUCTION

Maternity care is challenged by increasing rates of high cost medical interventions in low-risk service users without demonstrable improvement in health outcomes, and with evidence of significant long-term harm, including negative effects on physical, mental, and social, well-being for birthing people postpregnancy, as well as negative developmental effects for children over their lifetime.[1,2] Combined with low levels of satisfaction with care,[3] rapidly escalating costs,[4] and staff shortages,[5] these effects are cumulating in maternity service closures[6] and rare-but-tragic service failures.[7–9] This is leading to the "Triple Fail" of poor outcomes, poor patient experience,

and high costs.[10] These complex challenges highlight the urgent need for high value, cost-effective interventions in maternity care, to ensure best use of scarce resources to maximize health outcomes.

There has been a rapid increase in the number of economic evaluations of maternal health care, with 927 recorded in a recent review, and an annual publication rate of 83 in 2020, an increase from 32 in 2010, and 24 in 2000.[11] Many clinical trials are now routinely including an economic evaluation.[12] The increase in frequency of economic evaluation is likely in recognition of the increasing importance of the economic components needed for evidence generation in influencing decision-making for implementation.[13] Most high-income countries have a formal system for decision-making about public funding, based upon demonstration of cost-effectiveness. Therefore, for many new interventions or drugs related to maternal health care, the demonstration of cost-effectiveness through economic evaluation is now a vital component for ensuring uptake in routine practice.

Several challenges have been identified for the conduct of economic evaluation in the maternal healthcare setting. These are mostly related to the unique features of maternal health care—namely, that pregnancy is not an illness, that models of maternity care vary drastically between countries, and that two lives (woman and child) are involved, with potential lifelong influences for both if outcomes were not optimal. In addition, there are a wide range of outcomes to consider, very large and variable costs, and considerable uncertainty over long-term health outcomes.[14,15] Furthermore, previous reviews have highlighted the need for more consistency in maternal healthcare evaluations, with poor-quality reporting compliance.[16–18] Without robust, high-quality methods, economic evaluations may be biased and not identify true societal value. Any decision-making based on such studies may then lead to a misallocation of resources toward inefficient or low-value care, leading to higher costs to public funders and forfeited health benefits for women and children. As such, there is a clear need for guidance for researchers in designing economic evaluations for maternal health care—particularly at the stage of trial design—to ensure optimal data collection.

Therefore, the aim of this paper was to act as a guide for researchers designing economic evaluations of maternal health interventions alongside clinical trials, discussing some of the considerations researchers will need to make. This guide is written for a noneconomist audience. Similar guidelines are available for specific health conditions, and for economic evaluation generally,[19–22] but no recent (within the past 20 years) guides exist specifically for economic evaluations of maternal health care.[23]

2 | METHODS

This article is structured to cover each of the relevant methodological items* of the 2022 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklist,[22] provide discussion of economic issues of relevance to the area of maternal health, and provide example text articulating how to describe components of the evaluation. The example text, included as Files S1 and S2, is presented using both the Australian and the UK contexts as examples.

3 | RESULTS

3.1 | CHEERS Item 3: Objectives

The goal of the economic evaluation alongside a clinical trial should be carefully articulated. Economic evaluation practically seeks to identify the most efficient path forward by comparing the costs and outcomes of different courses of action (hereafter referred to as "interventions," although it is acknowledged that this term can have a different meaning in the maternity setting). Economic evaluations can be used to guide funding or clinical practice decision-making. Here, the researchers may need to consider who the decision-maker for any potential eventual implementation may be, and the information they require.

3.1.1 | Audience

The initial consideration for designing the objectives is understanding who the audience of the end results will be. Possibilities include the decision-maker for any potential implementation, which may be women as consumers of care, individual clinicians, health service mangers or administrators, government public servants, aide agencies, or Health Technology Assessment (HTA) agencies. In other cases, the economic evaluation may be targeted at a health economic or clinical academic audience.

*Nonmethodological items such as Title, Abstract, Introduction, Analytics, Results, and Discussion are not discussed. This guide is focused on data collection and design as a part of trial conduct and therefore does not cover model-based economic evaluations.

3.1.2 | Type of evaluation

There are five main types of economic evaluation: cost-minimization analysis (CMA); cost-consequence analysis (CCA); cost-effectiveness analysis (CEA); cost-utility analysis (CUA); and cost–benefit analysis (CBA). The type of evaluation used is dependent upon the health outcomes of the interventions in question, as outlined below. However, CEA and CUA are the most common. CMA is used when there is demonstrated equal clinical efficacy between treatment options. CMA considers which intervention is the least-cost option after equal effectiveness in terms of outcomes has been established.

Cost-consequence analysis is used when a value threshold is not established, and when decision-making is based on a number of factors. CCA seeks to assess a wide range of costs and consequences (outcomes) of the interventions being compared and reports them separately.

Cost-effectiveness analysis seeks to compare the differences in costs and outcomes of different intervention options as a ratio, to determine whether the additional cost of an intervention is justified by the additional outcomes it produces. CEA reports outcomes measured in terms of clinical units such as stillbirth, cesarean birth, or neonatal intensive care admission.

Cost-utility analysis is similar to CEA, in that it compares costs and outcomes of interventions, but with outcomes measured in quality-adjusted life years (QALYs). Converting outcomes to QALYs allows for comparisons between different types of interventions and between interventions from different clinical areas.

Finally, cost–benefit analysis seeks to monetarize both costs and outcomes, presenting the costs of the interventions and benefits produced in monetary terms. To choose the appropriate analysis, the researcher needs to consider which analysis type will allow the decision-making question to be answered.

3.1.3 | Use of modeling

Often economic evaluations will include a within-trial cost-effectiveness analysis and a modeled cost-effectiveness analysis. Economic evaluations ideally seek to capture the full benefits and costs of an intervention. Due to the known long-term implications of events in the perinatal time period,[24,25] this will often be a lifetime horizon for both the woman and the child. However, clinical trials in maternal health care rarely extend beyond the first year of postbirth.[26] As such, modeling may be required to capture the full extent of the costs and/or benefits of the interventions, and to capture the cost-effectiveness when applied at the population level (as opposed to the trial population). It is recommended that previously established, published models are used.[27] If there is no convergence between the costs and outcomes of the intervention and control groups during the follow-up time period (i.e., if there continues to be a difference in the observed costs or outcomes between the groups), then modeling should be considered. As such, the decision on whether to undertake modeling or not is generally made after initial analysis of within-trial results.

3.2 | CHEERS Item 5: Study Population

A detailed explanation of the study population is required, which is the population the intervention would be used in if it became a part of routine maternity care. This should include characteristics of women such as their risk classification (high-risk/complicated pregnancies or low-risk/uncomplicated pregnancies); certain demographic or clinical characteristics (e.g., parity, age, ethnicity, and previous cesarean birth); and the presence of any pre-existing medical conditions or conditions that developed during pregnancy (e.g., diabetes mellitus) or during the early postnatal period (e.g., sepsis). Descriptions of the child population resulting from pregnancy should similarly be included, as they will also be included as part of any follow-up postbirth. Any differences in the characteristics of population the intervention will be implemented in, and the sample from the clinical trial (for example, differences in age or risk status of women participating in the clinical trial compared with the population it will be implemented in) should also be highlighted and considered in the analysis.

3.3 | CHEERS Item 6: Setting and Location

Healthcare systems are heterogeneous in terms of delivery and funding of maternity care.[28,29] Across the maternity care spectrum, care may be delivered in a variety of settings and at different time points (community-based antenatal care, public or private hospital antenatal care, intrapartum care, and postnatal care) by different clinicians. Here, researchers should describe where and when the intervention is designed to be delivered, and particularly any unique local-level characteristics of care that are relevant. This will also have implications on the population. For example, if an intervention is delivered through community-based antenatal care practitioners, only women who can access antenatal care with community-based practitioners will be able to benefit.

3.4 | CHEERS Item7: Comparators

3.4.1 | Intervention

Next, researchers must provide a clear description of the proposed intervention. The description should align with that in the clinical trial protocol and should include a detailed description of relevant factors such as who provides care and where and when it is provided.

3.4.2 | Comparison

For a within-trial analysis, the comparator will be determined by the comparison group in the clinical trial. The description of the comparison should align with that in the clinical trial protocol and will often represent current standard care. However, due to the heterogeneity of maternity care across and between countries, a clear description of what standard care is, or what the comparison should be, must be provided, including relevant factors such as who provides care and where and when they provide it. Modeled economic evaluations may also include other interventions which the proposed intervention is designed to replace in clinical practice. For example, when deciding on whether to implement continuity of midwifery care, comparisons may be standard public hospital midwife-led antenatal care and community-based private midwife shared care.

3.5 | CHEERS Item 8: Perspective

Researchers should identify the perspective from which the analysis will be conducted, which in turn influences the types of costs and outcomes included in the study. Common options include societal, government, health funder, hospital, or individual perspectives. It is common for the societal perspective to be seen as the most "correct" perspective in order to capture the full costs and benefits[30]; but in practice, the healthcare funder is the most used perspective in maternity care economic evaluations.[11] The choice of perspective will likely be driven in part by a combination of what costs and outcomes will be affected (i.e., who pays and who benefits), as well as the researcher's target audience for the economic evaluation. Factors such as the type of health system and funders should also be considered. For example, when maternity care is mostly funded by hospital funders,[31] the researcher may wish to consider only a public hospital funder perspective. Alternatively, if an intervention has effects across multiple funders, a broader health system perspective may be warranted (for example, a cesarean wound infection prevention intervention that is implemented in a hospital setting but has benefits in the primary care/community setting). If a health funder or societal perspective is adopted, clear differentiation of costs according to different funders is recommended to ensure that any cost-shifting from one funder to another is identified.

3.6 | CHEERs Item 9: Time horizon

The time horizon is the length of time over which costs and outcomes are considered for the intervention and standard care. Maternity care covers a defined period of time for service practitioners, generally beginning around 12 weeks when women may attend their first routine antenatal appointment and ended at 6–8 weeks of postpartum, when women are usually offered a final check with their doctor. However, the likely cost and outcome implications could extend much longer than 6–8 weeks postnatally, due to long-term effects on women's and children's health, as outlined above. The time horizon of within-trial cost-effectiveness analysis will often be determined by the main trial outcome measurement time points but should be as long as is practically feasible. Modeling allows longer time horizons to be considered, but comes with the introduction of considerable uncertainty in terms of long-term cost and outcome estimation.[32] For interventions that have large upfront costs and long-term health benefits, shorter time horizons will generally result in lower cost-effectiveness than if a longer time-horizon is used to allow the longer term health benefits to be included. For example, neonatal intensive care has very high short-term costs, but if the neonate survives, a lifetime of health benefits that could potentially be accumulated.[33]

3.7 | CHEERs Item 10: Discount rate

Discounting is used to reduce the value of future cost and health outcomes. The discount rate is an annual percentage by which future costs and outcomes are reduced. Accepted discount rates vary between countries but are generally between 2% and 5%.[34] For example, a $10,000 surgery that is expected to be needed within 5 years would only be valued at $8145. Discounting is applied to reflect social preferences for immediate outcomes and relative importance given to immediate expenditure versus expenditure in the distant future. Discounting thus reduces the value of costs and outcomes occurring more than 1 year in the future. This has important implications for interventions that have

large upfront costs and long-term health benefits as is often the case in maternity care, as higher discount rates will lower cost effectiveness. The discount rates can be the same or different for costs and outcomes. Alternate discount rates can be tested in sensitivity analysis to demonstrate the effect of different time preferences. For example, if an antenatal intervention was demonstrated to reduce low birthweight and the economic evaluation considered the long-term health benefits measured in quality-adjusted life years (QALYs) to children over their lifetime, then these health benefits as well as any long-term costs would be discounted.

3.8 | CHEERs Item # 11: Measurement of Outcomes

Depending upon the type of economic evaluation conducted (CMA, CCA, CEA, or CUA), a variety of different outcomes may be used. It is not always essential for there to be a significant difference in outcomes, as costs may differ between groups. For CEAs, it is generally preferable that the outcome for the economic evaluation is the same as the primary trial outcome measure, such as stillbirth or cesarean delivery, in order to be confident of sufficient power to detect differences. Furthermore, outcomes such as these are often chosen because they are of the most importance to women or decision-makers, and thus it may be relevant to present the cost effectiveness in these terms to facilitate decision-making (for example, if policymakers are seeking options to reduce stillbirth, then presenting the cost-effectiveness results as cost per stillbirth avoided may be desirable). Outcomes should also ideally be unrelated to costs.

For CUA, outcomes will be measured in QALYs, which will require additional data collection as a part of the trial using a Health-Related Quality-of-Life (HRQoL) instrument. HRQoL instruments describe a range of health states and are frequently used as outcome measures in research as they enable interventions, services, and programs to be evaluated using a common unit of measurement.[35] The most common HRQoL measures used in maternity care are the EQ-5D, SF-36, SF-12, and the World Health Organization's Quality of Life Scale-BREF (WHOQoL-BREF)—all of which are generic measures.[36] Currently, no maternity-specific QoL measures are in widespread used, and there have been calls for further work in this area as it is considered that current measures may not be adequate for measuring QoL in maternity care.[36,37] In addition to the instrument to be used, the researcher also needs to specify the time points at which the instrument will be used, which should be designed to reflect the likely time points at which quality of life will be affected.

3.9 | CHEERs Item 12: valuation of outcomes (if applicable)

If a cost utility analysis is being undertaken, health states will need to be valued in terms of QALYs. Utility values are applied to each woman's reported health state using a HRQoL survey instrument to identify quality of life. These utilities are then multiplied by the amount of time spent in that state to obtain a QALY value. Utilities should be a reflection of a given population's preference for different health states.[38] They are measured on a cardinal scale between 0 and 1, where 0 represents death and 1 represents full health; utilities less than 0 represent health states worse than death (e.g., permanent brain damage).[38] Consequently, more desirable or preferred health states are weighted more than less desirable/preferred health states. Health state utilities enable the calculation of QALYs by multiplication of the health state utility and the duration of time spent in that health state (see formula below).[38]

$$\text{QALY} = \text{Health state utility} \times \text{time}$$

The length of time in each state is assumed to be from the time of data collection until the mid-point with the next data measure point.

3.10 | CHEERS Item 14: Measurement and valuation of resources and costs

Here, researchers must consider the direct resources involved in operationalizing the intervention (which may include educational materials, resource development, drug purchase, staff time, or staff travel) and which are ultimately tailored to each intervention and to what is relevant. Background health service use should also be captured for intervention and control groups, to capture any changes in resources use as a direct or indirect result of the intervention. Background health service use is generally collected either through health service use surveys, data linkage, or both. The collection of health service use data through self-report such as questionnaires or patient diaries is common and may be an accurate means of collecting health service used data in the absence of formal health and medical records.[39,40] The timing of a health service use survey will often be determined by trial data collection time points. The time points covered by costs

should be the same as the time points covered by the health outcome measures.

Unit costs for the resources involved in operationalising the intervention are often recorded as part of the trial data, as these are generally funded directly by trial budgets. Unit costs for health service utilisation are often applied at the activity level using activity coding such as diagnosis-related groups (DRGs) or healthcare resource groups (HRGs) to assign costs based upon publicly reported or government costing reported (for example, in Australia the Independent Hospital Pricing Authorities National Hospital Cost Data Collection, or in UK, the Hospital Episodes Statistics and the National Schedule of Reference Costs).

3.11 | CHEERs Item 15: Currency, price date, and conversion

Costs need to be presented in a common currency and for a common year. Often the unit costs for resources are based upon historic prices, which will need to be inflated to this common year. If costs are identified from different countries, they need to be converted using Purchasing Power Parities (PPP).

3.12 | CHEERs Item 16: Rationale and description of the model (if applicable)

If using modeling, the researcher should describe the model structure, with the design capturing the relevant health states/pathways effected by the intervention in terms of both costs and outcomes. This will vary based upon the intervention type, but for maternity care, it may include different types of antenatal services accessed, intrapartum events such as induction of labor, mode of birth, and length of in-patient stay. Other events such as neonatal admission to special or intensive care should also be considered. Consideration should explicitly be given to how the outcomes and costs of the woman and the child are considered. This is a key and unique challenge for maternity care, as most other areas of health care include only one subject, whereas maternity care will involve at least two subjects (woman and child/children). The model structure should be described, along with the data used to populate the model.

3.13 | Conclusions

The ultimate goal of clinical research related to perinatal health care is to improve healthcare practice, through the introduction of effective interventions, the maintenance of current care, or the disinvestment of current practice.[41] To facilitate uptake of new practice, it is essential to be able to provide decision-makers with evidence of costs and cost-effectiveness. Although there is evidence that the use of economic evaluation in maternal health care is increasing,[11] there is concern over the quality and content of evaluation, providing opportunity for improvement in economic evaluation quality.

The guidance we outline can be used for designing economic evaluations to be conducted as part of clinical trials. Whilst generic guidelines do exist[35] and should be followed, these are the first recent guidelines aimed directly at maternity care. Without these guidelines, the study design of economic evaluations may not be of high quality due to lack of appropriate data from clinical trials. Hence, this paper is aimed at a noneconomist audience to ensure appropriate data collection by trialists.

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CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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