Economic evaluation of nutrition interventions: Does one size fit all?

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Short title: "Economic Evaluation of Nutrition Interventions"

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Prècise: The paper analyses the features which make economic evaluation of nutrition interventions special and provides recommendations to modify the CHEERS check list.

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Abstract

Background: Nutrition interventions have specific features that might warrant modifications to the methods used for economic evaluations of healthcare interventions.

Aim: The aim of the article was to identify these features and when they challenge the use of cost-utility analysis.

Methods: A critical review of the literature was conducted and a 2 by 2 classification matrix for nutrition interventions was proposed based on 1) who the main party responsible for the implementation and funding of the intervention is; and 2) who the target recipient of the intervention is. The challenges of conducting economic evaluations for each group of nutrition interventions were then analysed according to four main aspects: attribution of effects, measuring and valuing outcomes, inter-sectoral costs and consequences and equity considerations.

Results and conclusions: Cost-utility analysis is appropriate for nutrition interventions when they are funded from the healthcare sector, have no (or modest) spill-overs to other sectors of the economy and have only (or mainly) health consequences. For other interventions, typically involving different government agencies, with cost implications for the private sector, with important wellbeing consequences outside health and with heterogeneous welfare effects across socio-economic groups, other economic evaluation methods need to be developed in order to offer valid guidance to policy making. For these interventions, checklists for critical appraisal of economic evaluations may require some substantial changes.

Highlights

Cost-utility analysis is a well-established approach to inform decision makers in the realm of health-care

There exist different types of nutrition interventions, each presenting special features that deserve attention for appropriate economic evaluations.

Depending on the type of nutrition intervention cost-utility analyses may be inadequate and additional methodological approaches may be required.

Introduction

Malnutrition ranks among the the most significant global health challenges, with one in three people directly affected by underweight, stunting, wasting, nutrient deficiencies; or overweight, obesity and diet-related non-communicable diseases (NCDs) (1,2). The double burden of malnutrition has been a top-level global priority for decades (3), and virtually all countries worldwide have enforced policies to address nutrition-related problems.

Governments are often responsible for, or involved in, the promotion, implementation, and monitoring of nutrition programmes. However, since public resources are limited, funding of nutrition interventions competes with other alternative prevention and public health services, personal health care interventions, as well as other non-health public programmes. In addition, government policies may introduce regulations or incentives/disincentives for producers and consumers aimed at promoting better nutrition.

Economic evaluation, is the preferred type of analysis to inform social choice on how to allocate scarce resources across competing programmes to improve health (4). Methods for the economic evaluation of healthcare interventions have existed for several decades, but these have mainly been applied to more narrowly defined 'clinical' interventions, such as drugs, devices and medical procedures (5). For these types of interventions, cost-utility analyses (CUAs) are standard. CUAs are usually undertaken from the narrower healthcare decision-maker perspective and focus on direct healthcare costs and consequences, with the latter often expressed in terms of Quality Adjusted Life Years (QALYs) gained. This article tries to answer to the following question: "Is a different approach needed for the economic evaluation of nutrition interventions, as compared with clinical interventions?'

In the field of nutrition, the closest analogy to clinical interventions more generally is medical nutrition. This encompasses a range of products and other interventions used as a nutritional therapy to manage disease- and condition-related nutritional needs (6). Medical nutrition is indicated in

clinical situations, such as for infants with special needs, disease-related malnutrition and other medical conditions in which there is an increased risk of malnutrition, including surgery and trauma.

Medical nutrition and regulation have been reviewed by the ISPOR Nutrition Special Interest Group (6). The group argues that the general principles of economic evaluation also apply to medical nutrition, but that special attention is required for certain aspects of the research methodology, such as study design, the study population (especially as underlying nutritional status can affect the impact of treatment), sample size, comparator and clinical outcomes (6). Indeed, in many circumstances, the impact of the nutrition intervention may be best reflected in the clinical outcomes of the associated medical therapy.

Furthermore, a number of studies have outlined the challenges around economic evaluations of public health interventions, which comprise an important sub-set of nutrition programs (5,7–11). First, the attribution of causal effects may be more difficult to ascertain because studies such as randomized controlled trials, that are usually considered as the gold standard in the hierarchy of evidence, are often too costly, poorly generalizable, or simply unfeasible in a public health context (5). Other studies have also stressed how the attribution of effects is complicated by public health interventions being multi-component, complex interventions that dynamically change with time and interact with the surrounding environment. One direct consequence is that the link between the intervention and the final health outcomes is influenced by different causal mechanisms that include a long chain of social, behavioral, as well as biological factors (8,11).

Another widely acknowledged issue is that the impact of public health interventions may go beyond the direct health effects on the targeted individuals, to include broader health and non-health consequences at the societal level. This aspect implies that measuring and valuing benefits using traditional quality adjusted life years (QALYs) may be too reductive for public health. Furthermore, public health interventions may generate interlinked costs and consequences between different

public sectors, the general public or the economy at large that may not be adequately represented within the narrower health-care sector perspective that is usually adopted when assessing clinical interventions. Lastly, equity considerations may be even more relevant for public health interventions, given their potential impact on the distribution of health across different population subgroups. In fact, in many cases, reducing inequalities in health is the primary objective *per se* of public health interventions. Equity considerations may be also relevant when inequalities in healthy behaviors are correlated to income inequalities, for example policies aimed at changing market prices (e.g., through taxation of unhealthy food) may be economically regressive, while progressive under the public health point of view.

Although some of these challenges certainly apply to nutrition interventions, they may not be relevant for all of them. In fact, nutrition interventions are highly heterogeneous in their objectives, design and funding mechanisms, to an extent that optimal conduction of economic studies requires a careful consideration of the intervention-specific characteristics. A review by Cobiac et al. concluded that, although there is an increasing body of evidence on the cost-effectiveness of nutrition interventions, lack of consistency in analytical methods and assumptions often limits the reliability and generalizability of the available studies (12). Another review of studies on interventions promoting low-fat diets showed that they do not adequately consider the non-health-related effects of nutrition on wellbeing, the private nature of food expenditure, the distributional effects of the interventions across population subgroups, and their overall impact on the economy at large (10). Not surprisingly, then, it has been argued that a critical overview of methods and guidelines for economic evaluation of nutrition interventions is warranted (13–15).

The aim of the article is to review the main methodological issues raised when conducting economic evaluations of nutrition interventions and to identify for which types of interventions they arise. In particular, a 2 by 2 matrix was constructed to characterize nutrition interventions and then

for each quadrant it is discussed whether standard cost-utility analysis is appropriate and, if it is not, what can be done to address its limitations.

In the following sections of the paper, the classification matrix of nutrition interventions is proposed and described. Then, four main methodological challenges for the economic evaluation of these interventions are presented and their relevance for each quadrant of the matrix discussed. The article closes with a discussion about when nutrition interventions require significant methodological developments and a partial adjustment of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (16).

Methods. A classification matrix of nutrition interventions

Nutrition interventions are defined as purposefully planned actions intended to positively change a nutrition-related behaviour, environmental condition, or aspect of health status for an individual, target group or the community at large (17). This definition encompasses a variety of programmes including the provision of nutritional products to manage disease- or condition-related dietary needs (i.e., medical nutrition) (6); interventions targeting specific nutrition-related conditions, such as undernutrition, overweight or nutrition-related diseases (e.g., provision of oral supplements, or individual counselling on eating behaviours); and more upstream interventions pursuing changes in the food and nutritional environment to improve population health outcomes (e.g., reformulation policies for processed foods, fiscal policies, like taxes or subsidies, to orient consumption habits, and public media campaigns).

Table 1 shows the proposed classification matrix of nutrition interventions. The matrix was developed in a full-day workshop attended by all authors of this article. The authors belong to different fields (health economics, health policy, statistics, food policy) and have specific research experience in the use of economic evaluation for nutrition interventions. The matrix is defined across two dimensions that are relevant to the purpose of informing methodological aspects of

economic evaluations. The first dimension concerns the question of who is the main party responsible for the implementation and funding of the intervention. In a first group (quadrants I and II), the interventions are mainly the responsibility of the healthcare sector, which is accountable for the programme costs and the outcomes in terms of population health gains. In the second group (quadrants III and IV), interventions are promoted, implemented and/or funded jointly by different parts of the public sector (for example the healthcare, education, agriculture, and social welfare sectors), or private individuals. Therefore, in this second group different partners commit scarce resources from their individual budgets and share a joint responsibility about the intervention. Included in this group there are also interventions such as regulatory initiatives enforced by the government, where the majority of costs fall on other parties having to conform to them. For example, the majority of the costs of mandatory reformulation policies or soda taxes will be borne by manufacturers or the consumers of these products, not by the government.

This distinction is relevant since different criteria may be required to assess the value for money of new programs depending on whether interventions remain within the remit of the health care sector or involve a broader number of parties. Indeed, for health-care sector interventions cost-effectiveness should be judged by comparing the health gains generated by the new intervention with the health forgone due to the shadow price of the healthcare budget constraint (4). However, in presence of multiple partners, decision rules on cost-effectiveness should incorporate the shadow prices of all the budgets involved, and consider the maximization objectives for which each partner has been socially legitimized. This in turn will affect the perspective of the analysis, what type of costs and outcomes should be considered and how outcomes should be measured and valued.

The second dimension in the matrix relates to the target of the interventions. Individual-based interventions target specific individuals with a particular risk factor or nutrition-related condition, whereas population based interventions target broader groups that may consist of either restricted community settings such as schools or workplaces, or the population as a whole. In population-wide

interventions, the objective is to shift the whole distribution of the health risk by addressing the broader *conditions* that generate risky behaviors, rather than preventing or managing individual health risks. Example of population-wide interventions include those that aim to support more informed choices among individuals, such as social media campaigns, or those that aim to change the market environment, such as regulations on healthy and unhealthy foods.

This distinction is relevant because, for individual based interventions, many challenges related to the evaluation of public health interventions are likely to be less relevant or more easily addressed. For example, generation of evidence from randomized controlled trials is generally feasible for individual-based interventions, although some issues may remain, such as the need to extrapolate long-term relevant outcomes from intermediate endpoints, or to explain how social and behavioral factors impact on final outcomes.

Results. Main challenges in the economic evaluation of nutrition interventions

In order to discuss whether cost-utility analysis is appropriate for each of the four types of nutrition interventions presented above, the challenges identified by Weatherly et al. were used, since these are widely acknowledged by the majority of methodological studies (7). These challenges are as follows: 1) attribution of effects, 2) valuing and measuring outcomes, 3) intersectoral costs and consequences, and 4) equity considerations (5).

Attribution of effects

Theoretically, the causal effect of an intervention is given by the difference between the outcome measured on the subjects who have been exposed to the intervention, and the outcome for the same subjects when not exposed to the intervention. Given the impossibility of observing the same subject in both conditions (the well-known "Fundamental problem of causal inference" (18)), statisticians have devised methods aimed at producing an artificial counterfactual condition.

The most common approach to attribution of effects for healthcare interventions is the randomized controlled trial (RCT), where the impossibility of having both subjects in the treatment and control groups is overcome by relying on random samples of subjects extracted from the same population. While RCTs are often considered to be the gold standard, they are far from flawless when the objective is to capture the effectiveness of interventions and policies, especially when these depend on behavioural dimensions (19). Although the use of randomized social experiments to estimate the effects of nutrition and health interventions is gaining popularity (20–22), it is often difficult to achieve external validity and to move from efficacy in the experimental situation, to effectiveness in the context of population-based health interventions (23).

Given the complexities and challenges in designing internally and externally valid experiments to evaluate nutrition interventions, especially when they are implemented at the population level or on a large scale, natural experiments or observational studies appear the most appropriate option for interventions in quadrants II, III, and IV. For smaller-scale individual interventions, as those listed in quadrant I, RCTs might remain the most feasible and appropriate option, although a case-by-case assessment of internal and external validity is certainly needed.

Evaluations based on secondary (observational) data have the potential to overcome some of the key limitations of randomized studies. For example, they might be able to capture longer term effects by exploiting longitudinal data, while long-lasting randomized studies are an exception because of excessive costs. There are indeed notable exceptions of long-term cohort studies (e.g. the MRC National Survey for Health and Development in the UK, or the Framingham Study and the Harvard Adult Development Study in the US) (24,25), but because of their nature and the levels of attrition, they can hardly be treated as randomized experiments and end up in the same category of observational studies when the objective is to elicit the effect of health interventions.

Since observational studies lack the experimental element, the estimation of intervention effects must address the likely biases due to the incomplete randomization in the assignment to treatment.

There are several powerful statistical tools to estimate treatment effects from non-experimental data (26) and their application to the evaluation of nutrition interventions is growing exponentially (27).

Five key methods are available to address the lack of randomization in non-experimental studies with micro-level (individual or household-level) data: (a) Difference-in-difference (28) (see e.g. Restrepo and Rieger, 2016 on the trans-fat ban from New York restaurants (28)); (b) Instrumental variables (see e.g. Zhang et al., 2017 on the effects of nutrition labels on sodium intake in the US (29)); (c) Propensity score matching (see e.g. Campbell et al., 2011 on the effects of the US National School Lunch Program (30)); (d) Regression discontinuity designs (see e.g. Capacci et al., 2018 on the effects of the French school vending machine ban (31)); (e) Model-based counterfactual (see e.g. Fletcher et al., 2010 on the effects of US soft drink taxes (32)).

The discussion of the technicalities behind these methods goes beyond the scopes of this review, but the rapid growth in their application to nutrition interventions requires a careful consideration of the assumptions they rely on, and the data characteristics they require, in order to provide unbiased and reliable estimates of the causal effects. There is a key element to be considered when adopting a counterfactual approach, which is that eating behaviours depend on a variety of factors other than the policy, and these may change across the groups and over time. This complication is amplified when considering nutrition outcomes beyond food consumption, such as anthropometric outcomes. For example, child stunting may be influenced by many factors other than food intake, such as sanitation. For this reason, the marginal effect of an intervention is not easily identifiable, unless one is able to control for these factors. Unfortunately, it is unlikely that a given study provides enough information to cover all potential covariates influencing the outcome, so that there will be unobserved covariates. These include any variable for which we have no data, but especially those important psychological and behavioural dimensions for which it is hard to get reliable measurements (knowledge, awareness, attitudes, tastes).

When all the relevant covariates are observed, or any unobserved factor is well proxied by the observed covariates, then plugging them into basic multiple regressions or propensity score matching algorithms should be adequate. Otherwise, there are counterfactual methods dealing with unobserved factors, but they rely on necessary assumptions (e.g. parallelism and linearity of pre-existing trends in difference-in-difference, exogeneity of instrumental variables, continuity of covariates at the cut-off point for regression discontinuity designs).

Ideally, researchers would undertake formal tests on these assumptions together with estimates of the treatment effects, but this is usually unfeasible, for the simple reason that they also refer to those variables that are not observed. Nevertheless, it is crucial that researchers provide enough evidence that their estimate of the treatment effect is credible. This can be achieved by performing a variety of robustness tests (including estimation of the treatment effect using different methods and assumptions), and creative falsification tests. These additional estimation efforts make evaluation studies longer and more complex to readers, but it is a necessary burden, and an insurance against "false positives" and publication biases (26,33).

Measuring and valuing outcomes

The most common approach to economic evaluation in health care, cost-utility analysis (CUA), implicitly assumes that the goal of interventions is to maximize health, therefore, the main measures used in the literature are Quality Adjusted Life Years (QALYs) and Disability-Adjusted Life Years (DALYs). Other types of benefits, including other domains of wellbeing, are neglected in CUAs. This appears justified for clinical interventions: they are delivered with the aim of improving health and it can thus be acceptable to limit the analysis of wellbeing effects to health outcomes. This also appears justified for nutrition interventions such as the administration of oral supplements, or other interventions in quadrant I of the matrix, where the aim is to treat a single individual at risk of or with a specific health condition. In these situations QALYs should reasonably capture the range of

the benefits derived from interventions where participation is voluntary and mainly motivated by expectation about health improvement.

Conversely, a number of nutrition interventions are directed at populations or communities. They aim at modifying the environment in which decisions are taken, often stimulating changes in individual behaviour. For these interventions (typically those in quadrant IV of the matrix) health outcomes may not the only important consequences to take into consideration. Eating is a major health determinant; however, people do not demand and value eating mainly for its health impact. When people eat, they are seeking physical, emotional and psychological nourishment and pleasure (15,34). Food is a source of wellbeing much beyond its impact on health and thus individuals experience both the health effects of eating and its value in other respects. This suggests that QALYs or other measures related only to health benefits may not be fully adequate for economic evaluations of some nutrition interventions because they do not capture a larger set of mental and social outcomes (5).

In addition, most nutrition interventions require change in individual or population behaviours. The behaviour change is a process needed to achieve the desired outcome (11) and can cause loss of wellbeing (disutility) during the period in which it occurs. Furthermore, nutrition interventions require changes that interact with a variety of aspects of people's lives. Such interactions, that increase complexity and suggest the use of multi-component interventions, shape both the effectiveness of the interventions and their value as perceived by people. The valuation of an intervention that changes the way individuals behave (when, how and what they eat and drink) is likely to include the value of the outcome and the value of the intervention itself that in turn can be affected by the outcome (8). Those who change behaviour in response to a new policy (e.g., higher taxes on unhealthy food) may experience a loss during a first period (e.g., in the period of shifting consumption to healthier choices) but may eventually enjoy the new (healthy) food due to

adaptation mechanisms. In other words, the success of the intervention changes the value of the attributes of the intervention itself.

All these special features of nutrition interventions may challenge the use of QALYs and cost-utility analysis in general; methodological developments are thus needed to offer adequate economic evaluation techniques in the field of nutrition. Another form of economic evaluation, cost-benefit analysis (CBA), values costs as well as the range of benefits in monetary terms, making it possible to incorporate radically different outcomes in a single measure. Depending on how the evaluation is conducted, CBA can expand the evaluative space beyond health and can incorporate the wellbeing effects associated to the process involved in the delivery of nutrition interventions (e.g., the psychological costs of being on diet). In practice, however, its use for the evaluation of health interventions is rare (35) due to methodological difficulties and lack of public acceptability (11,36,37) In addition, the assumptions on which CBA are based, such as the possibility to aggregate individual Willingness-To-Pay (WTP) or the dependence of WTP on ability to pay, may be questionable and not fully consistent with decision makers' points of view.

Another strategy to cope with the need to develop evaluation methods that capture broader evaluative spaces would be to refer to Amartya Sen's capability approach to human wellbeing (38,39). The approach expands the evaluative space of QALYs so to include non-health outcomes like empowerment, social participation and self-esteem. The capability paradigm suggests to evaluate interventions on both opportunities and outcomes (38,39). For example, the adoption of this paradigm in the context of a food literacy program would propose that both the enhancement of the capability to make more informed decisions and the outcome in terms of health improvement should be evaluated. Although the operationalization of this approach is still in its infancy, a number of capability instruments have been recently developed. They include measures such as the Adult Social Care Outcomes Toolkit (ASCOT) for social care (40), OxCap-MH for mental health

(41) and the ICECAP (ICEpop CAPability) (42) that it is for a generic use in economic evaluation (43).

Given the lack of consolidated methods to measure and value the wide range of nutrition interventions, QALYs are likely to remain the dominant approach to measure and evaluate effects of interventions, especially for those in the upper row of the matrix (quadrant I and II) in which funding and service delivery are the responsibility of the healthcare system. However, there are different approaches to calculate QALYs (e.g., through EQ-5D, SF-6D or mapping from disease specific measures) and available evidence shows that no method is sensitive to all possible conditions (44). Therefore, in the evaluation of nutrition programmes it is important to investigate and report whether the tools employed to calculate QALYs are valid. In other terms, it should be verified that variations of quality of life are captured by the way QALYs are calculated.

Another approach that may be used to include process and non-health outcomes, is cost-consequences analysis (CCA) in which the evaluation of effects of interventions is multidimensional (11,45). Different effects (outcomes or processes) would be reviewed by decision makers so that they can be weighed informally and subjectively. As suggested by Weatherly (2009) (5), CCA should be performed prior to other approaches to valuation because it clarifies the set of different benefits expected to be included in an economic evaluation fully capturing all wellbeing effects. The inclusion of CCA makes users of the economic evaluation more aware of the complete array of effects of interventions, including those that are not captured by synthetic measures such as QALYs.

Intersectoral costs and consequences

Economic evaluations of clinical interventions are often framed as a single objective (maximizing health) and single constraint (the limited healthcare budget) decision problem. Therefore consequences are uniquely expressed in terms of health effects (for example QALYs), whereas the only relevant costs, provided a healthcare viewpoint is adopted, are those falling on the health care

budget, and for which an opportunity cost exists (in terms of other treatments forgone due to the budget constraint) (4).

However, especially in public health, there may be an argument for including a wider range of non-health costs and benefits that are relevant for all stakeholders, since public health programmes may have multiple objectives and are more likely to affect other public budgets, individual consumption and the economy at large (7,46). When other public resources are involved that fall on different budgets (such as for example education, criminal justice or the agricultural sector) the shadow prices of each budget constraints should be appropriately taken into account. However, there is a need for methodological improvements on how to identify, measure and evaluate non-health effects in a way that is meaningful to decision makers. Again, CCAs reporting costs and consequences from the perspective of each sector, are often proposed, although it is not clear which decision rule should be used to make funding decisions given these multiple objective, multiple constraint decision problems. Claxton et al propose an extension of the social decision making approach, where the net benefits falling on different sectors are calculated (using appropriate cost-effectiveness thresholds) and funding decisions are made after a simple compensation test across sectors (47).

Nutrition interventions are different in terms of objectives, design and funding arrangements, so that the weight of non-health costs and consequences may also vary considerably. For interventions mainly funded by the healthcare sector (quadrants I and II in the matrix), it may be reasonable to assume that the perspective of the healthcare system adequately addresses most of the relevant costs and consequences. In fact, the main objective here is to improve health in the population (by treating or preventing nutrition related conditions), while resources used mainly fall on the single public health budget. However, an assessment on how such interventions will affect informal carers and private consumption may still be needed depending on the specific design of the intervention and the decision makers view on what is the purpose of public health. Also, especially for

population-based interventions, equity effects should be discussed as equity may be a further policy objective to be pursued (see Section below on equity considerations).

Conversely, for multi-sectorial interventions (quadrants III and IV), the adoption of a broader perspective may be crucial. For example, in wider nutrition interventions multiple public sectors may be involved, and nutrition related objectives will be part of a broader set of objectives such as supporting livelihoods, promoting income redistribution, improving environmental outcomes or individuals' empowerment. In this case, decisions are likely to be taken jointly across public decision makers so that all relevant information should be collected to allow informed decisions.

Lastly, there may be programmes that are not costly, or even revenue generating from a public sector perspective. Interventions such as fat taxes, labelling and mandatory reformulation policies (quadrant II in the matrix) will have costs mainly impacting on individual consumption and the society at large. By adopting a social decision making perspective and considering only costs falling on public budgets these interventions are likely to be viewed as being strongly cost-effective. Yet, neglecting non-health costs and equity considerations will impede fully-informed decision making.

Equity considerations

Systematic reviews of economic evaluation of health interventions, both medical and non-medical, show that distributional effects have been largely neglected (48). Studies generally report results averaging out health consequences and costs across different groups of beneficiaries, without providing information about the distribution of gains and losses and thus without any systematic assessment of equity considerations.

The lack of equity considerations in economic evaluation may be partly justified for clinical interventions as far as it is adopted in systems with collective funding. Resources come from the government budget (or other social institutions) so that differences in access across socio-economic groups are reduced, if not eliminated. In these contexts, economic evaluation replaces the market, and its dependence on ability to pay, for the allocation of resources. It is true that the maximization

of health for a given healthcare budget still incorporates important equity considerations, in that the assumption is made that QALYs are the same regardless of to whom they accrue, with no distinction across age, severity of disease or socio-economic status (49). . However, the fact that economic evaluation is designed to replace market mechanisms for the allocation of resources in systems with universal equality of access has contributed to keeping equity concerns on the back burner (50).

When nutrition interventions are similar to clinical interventions, as it is the case of individual counselling or medical nutrition, equity concerns are likely to be similar as well. If the costs of the intervention are completely borne by the public health sector or by any government agency (quadrant I and II in the matrix) equity concerns may still be created by non-financial barriers to access to services, but at least financial barriers are eliminated.

For public health interventions, and thus for most interventions targeting nutrition, there is much more concern about inequality. First, reducing health inequality is typically a major objective of public health (5) as both health and its distribution across population groups matter in the public health agenda. Second, the design of public health interventions may strongly influence its effectiveness and the absorption of private resources across population groups. This is clearly relevant for nutrition interventions given that food expenses are an important component of household budgets, particularly for those with lower levels of income and wealth. The main issue is that some interventions targeting the population may have important implications on costs borne by individuals, notably when price increase is itself the route to promote healthier behaviours. In fact, when economic inequalities and health inequalities follow similar distributions, some interventions may be more burdensome on the poor under the economic perspective to lower health inequalities. For example, fiscal policies that discourage unhealthy food can pose a larger financial burden on lower income household if such burden is measured as food expenditure. The most salient example in this respect is the use of fiscal policies to modify market prices of products. Such policies have

raised equity concerns under the economic perspective because, other things being equal, higher prices for food result in a larger financial burden for low-income individuals. This is indeed the mechanism to promote healthier substitution, as low-income households are expected to be the most responsive to cost incentives and to substitute towards healthier options. However, a careful quantification of the economic loss/health gain trade-off becomes a priority, so that compensating interventions (e.g. price subsidies, or linking the value of food stamps to the nutritional quality of food purchases) may be planned.

Equity is affected by a number of characteristics of the interventions, including the elasticity of demand across socio-economic groups, characteristics of substitutes, the ex-ante and ex-post distribution of the health outcomes and the use of revenue generated by the fiscal policy (51). Equity analysis is thus very important in such interventions. CUA may present a very favourable cost-effectiveness ratio, typically because the costs of interventions are limited to the administrative costs to enforce the fiscal measure. However, the distributions of costs and benefits across socio-economic groups are likely to be very relevant and thus their investigation becomes an essential component of the economic evaluation study.

Equity concerns appear even stronger for interventions aimed at changing dietary behaviour. As eating is socially embedded, cultural and socio-economic characteristics tend to shape behaviours. Significant heterogeneity across population groups in life styles and in the response to interventions is largely expected. In addition, as some interventions require a major contribution of private human resources (monetary and cognitive) their unequal distribution in society may affect the degree of equity of interventions and of the costs associated to their implementation. For example, food labelling might have different effects across education levels due to the intellectual resources required for its interpretation, or public health campaigns that recommend eating fish and vegetables might have different impacts across income groups because of their higher prices compared to the less healthy alternatives. Compared to medical care, nutrition interventions may

face greater trade-offs between effectiveness and equity so that the quantification of health benefits across socio-economic groups becomes central.

Therefore, reporting equity considerations is essential for the economic evaluations of nutrition interventions, particularly when they are population-based and multi-sectoral (quadrant IV of the matrix). These considerations should examine possible sub-groups of individuals/populations targeted by the intervention according to a number of criteria, including socio-economic status, area of living, gender, ethnicity and age.

Different approaches have been suggested for incorporating equity considerations in economic evaluation studies. A useful first step to investigate equity implications would be to perform a narrative review in which equity is addressed by presenting qualitative evidence and background information (52,53). A more demanding strategy, named health impact assessment, consists in estimating economic evaluation measures (e.g., cost per QALY) across sub-groups of the population (e.g., across education level or ethnicity). Such an approach requires to plan the collection of additional data and to anticipate which equity dimensions deserve to be investigated.

In a recent paper Cookson and colleagues (54) have developed two more structured approaches to deal with equity concerns. Both approaches assume the use of CUA and integrate them with measures of equity. The Health Equity Trade-Off analysis considers the opportunity cost of the best use of resources to improve health in terms of equity. Intuitively, the idea is that decision makers might be ready to give up some level of health in order to improve its distribution across population sub-groups. Therefore, interventions should be evaluated by a mix of the two criteria (maximization of health and equal distribution). Some interventions may produce positive effects on both the effectiveness and equity criteria but others may present trade-offs. Some successful interventions may improve average outcomes, but may exacerbate existing inequalities by benefitting privileged groups more than disadvantaged groups (55). In such situations, there are two policy objectives conflicting and decision making needs to count the cost of fairer but less cost-effective options in

terms of health forgone. A second approach is based on assigning weights to population groups in order to calculate an aggregated metric that reflects equity concerns (e.g., that gives higher weight to groups with a lower initial health level (56).

Conclusions

The call for government interventions to fight malnutrition in its various forms requires appropriate methods to measure their impact. Economic evaluation methods developed for health care interventions, and in particular cost-utility analysis, are appropriate for nutrition interventions when they are funded from the healthcare sector, have no (or modest) spill-overs to other sectors of the economy and have only (or mainly) health consequences. This is likely to be the case for interventions such as counselling, education and nutritional care. For other interventions, typically involving different government agencies, with cost implications for the private sector, with important wellbeing effects outside health and with heterogeneous welfare effects across socio-economic groups, cost-utility analysis is likely to be inappropriate and other economic evaluation methods need to be developed in order to offer valid guidance to policy making. To help researchers in this respect we propose the use of a matrix to classify interventions according to (i) whether they are led by the healthcare sector or not and (ii) whether they target individuals or population groups. Moving from the first quadrant (healthcare-led interventions targeting individuals) to the other quadrants is likely to challenge the use of cost-utility analysis concerning i) how to design studies that can identify treatment effects, ii) how to measure and value outcomes, iii) the variety of effects (cost and consequences) that should be included in the analysis and iv) equity implications. These major challenges to conduct economic evaluation studies in the field of nutrition suggest the importance of further development of methods through theoretical work, experimentation and testing.

Checklists have been widely used to judge the quality of economic evaluations. Some, such as the CHEERS checklist (16), concentrate on the quality of reporting. Others, such as those developed by

the BMJ Working Party (57), Drummond et al. (4) and Evers et al (58), judge both aspects of methods and reporting. However, existing checklist may not reflect all the methodological implications that derive from the characteristics of nutrition interventions discussed above. It is thus useful to adapt existing quality standards to the specificities of the nutrition field.

Taking the CHEERS checklist (reproduced in table 2) as an illustrative example the following points should be emphasized when reporting economic evaluation of nutrition interventions:

(a) In Item 4 (Target Population and Subgroups) the characteristics reported should include social, socio-economic and behavioural factors, since these can be important influences on the take-up and/or effectiveness of nutrition interventions.

(b) In Item 7 (Comparators) there should be discussion of the likely causal steps linking the intervention(s) with their costs and consequences, since these may be less obvious than in the case of clinical interventions.

(c) In Item 10 (Health Outcomes) there should be a presentation of non-health outcomes attributable to the intervention, if relevant.

(d) In Item 19 (Incremental costs and consequences) specific emphasis needs to be placed on the distribution of costs between the health sector, other public and private institutions, and private individuals themselves, since it is less likely that the health care sector will bear the majority of costs. Therefore, understanding the relative cost burdens can be important when considering how best to implement interventions.

(e) In Item 22 (Study findings, limitations, generalizability and current knowledge) the discussion should include consideration of whether the particular setting or environment in which the study was conducted influenced the costs and consequences of the interventions and whether such interactions would limit the generalizability of the findings.

Lastly, given the particular relevance of equity considerations when evaluating nutrition interventions, more emphasis should be placed on reporting what are the distributional consequences of the interventions across different socio-economic subgroups. Therefore, it is suggested that one additional item is added to the results section in the checklist to appropriately characterize equity effects and to discuss whether the intervention will ultimately increase or reduce unwarranted differences in population health. In some cases, when the interventions are expected to affect private expenditures and wealth, such as for example the introduction of a new indirect tax on sugar-sweetened drinks, it is recommended that both the health and financial consequences on population sub-groups are described and discussed.

In conclusion, cost-utility analysis is the starting reference method for the economic evaluation of nutrition interventions. It is likely to be appropriate for individual interventions funded from the healthcare budget. It is also likely to be appropriate, provided that a societal perspective is adopted, when the public sector at large is involved. On the contrary, for population-based interventions having consequences beyond health and to the society at large cost-utility analysis may miss to capture important costs and consequences and thus may not be recommended.

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