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Commentary

Distributional Cost-Effectiveness Analysis of Health Technologies: Data Requirements and Challenges

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ABSTRACT

Governments and health technology assessment agencies are putting greater focus on and efforts in understanding and addressing health inequities. Cost-effectiveness analyses are used to evaluate the costs and health gains of different interventions to inform the decision-making process on funding of new treatments. Distributional cost-effectiveness analysis (DCEA) is an extension of cost-effectiveness analysis that quantifies the equity impact of funding new treatments. Key challenges for the routine and consistent implementation of DCEA are the lack of clearly defined equity concerns from decision makers and endorsed measures to define equity subgroups and the availability of evidence that allows analysis of differences in data inputs associated with the equity characteristics of interest. In this article, we detail the data gaps and challenges to build robust DCEA analysis routinely in health technology assessment and suggest actions to overcome these hurdles.

Keywords: distributional cost-effectiveness analysis, equity, health inequities.

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Introduction

Cost-effectiveness analysis (CEA) is a well-established method used by numerous health technology assessment (HTA) agencies to evaluate the costs and health gains of health interventions and to support funding decisions and allocation of resources.[1-4] The objective underlying CEA is typically maximizing total population health. Considering a healthcare system with limited resources, introducing a new health technology in the system benefits some patients, but funding displaces the opportunity to provide alternative technologies, leading to health losses for others, known as health opportunity cost.

Typically, CEA does not give any information on who benefits and who loses from the approval and reimbursement of new technologies—information that is of key interest to decision makers. The growing body of literature on equity in HTA demonstrates the increasing interest among government institutions in incorporating equity concerns in HTA in response to greater focus on health inequities[5-10]; this interest has been amplified during the COVID-19 pandemic. For example, the National Institute for Health and Care Excellence (NICE) in England made tackling health inequities 1 of its 6 challenges for the next 5 years. Frameworks have been developed to provide guidance on the consideration of equity in HTA.[6,11,12] A range of analytical methods have been proposed to incorporate equity concerns within economic evaluation, with each method having different requirements that affect their suitability for different decision problems and settings.[13] A recent review also highlights that equity concerns are increasingly incorporated into CEA.[14] The advancement of methods for distributional CEA (DCEA) facilitates a quantitative assessment of how health effects and costs are distributed between groups in a population (inequalities) and of any ensuing trade-offs between health maximization and equity. Value judgments about unfair differences in health are incorporated into the analysis via the choice of population subgroups and weighting of benefits in the different subgroups.[7,15] There have been calls to incorporate the evaluation of equity impacts in HTA decision making more formally,[16] and implementation of DCEA is currently being explored by NICE.[17] Applying a consistent approach to DCEA would allow the comparison of equity impacts across diseases and interventions. To date, most applications of DCEA have been based on public health interventions,[18-21] although one study has investigated the aggregate equity impact of NICE appraisals.[22]

A key challenge for the routine implementation of DCEA to health technologies is the availability of data to build robust analyses at the time of HTA.[23] The data requirements of DCEAs are greater because they ideally need to account for social variation in the per-person incremental health benefits and costs of a new technology, which are determined by variation in model

parameters. DCEAs also incorporate additional parameters to traditional CEA so that benefits and opportunity costs can be scaled up from the average patient to a population, such as disease prevalence and intervention uptake rates.

Defining and Operationalizing Health Equity Concerns

Many factors have been associated with health inequity concerns, including age, sex, race and ethnicity, geographic location, and a range of socioeconomic attributes that are commonly characterized as "social determinants of health" or social needs. Numerous studies have investigated the health inequities between population groups associated with individual diseases using such stratification attributes.[24-28] Some characteristics are objective and easily assessed (eg, age and sex), whereas others are more complex to define (eg, socioeconomic deprivation and race), and there can be measurement challenges because of the availability of accurate data and differences in definitions (eg, income). This often results in substantial variability in how the equity concern is operationalized, even for studies conducted in the same country, limiting the comparability of study results and conclusions across populations, diseases, and treatments. To support routine equity assessments and allow comparability between assessments and technologies, data consistency is crucial.

Specifically, decision makers need to clearly define the health equity concerns (eg, socioeconomic deprivation) and recommend criteria or indices to identify equity subgroups and stratify the data. One commonly used indicator of relative socioeconomic deprivation in the United Kingdom is the index of multiple deprivation (IMD), which incorporates 7 dimensions of deprivation (income, employment, education, health, crime, housing, and living environment) and is estimated for small areas of roughly 1500 people.[29] IMD score (or quintile) can then be attributed to individuals based on their postal code. Similar composite indices of deprivation are available across many countries and could be used to understand equity effects.[30]

Data on Health Inequities: Gaps and Challenges

The specific data required for DCEA depend on the nature of the defined health equity concern (eg, socioeconomic deprivation). Once defined, the nature of the concern will determine the focus for data requirements, which could include epidemiologic data and data on relative treatment effectiveness, access to treatment, and adherence. These requirements raise significant challenges because consistency is needed in the definitions used across studies, and there is often a dearth of information on specific parameters.

Epidemiologic data stratified by an index of deprivation (or any other equity-relevant classification of interest) is required to define population subgroups in a DCEA. Data in the literature or published by government institutions that map to such indices are scarce or infrequently updated. For example, some statistics for common diseases (such as breast or lung cancer) are available in the United Kingdom, but there is a paucity for particular disease subtypes and rarer conditions, where the data are not collected or not reported. An example of this can be seen in a rare form of cancer (triple-negative breast cancer [TNBC]), which is more likely to be found in black women than white women and those in lower socioeconomic groups than higher ones.[31] Some of the present authors (A.M., L.L., S.K., S.R., and S.G.) investigated the impact of a treatment for TNBC on social deprivation using a DCEA approach for which data on incidence and stage at diagnosis based on deprivation were required from an English perspective. The available data on breast cancer incidence in England based on IMD were dated (published in 2009 based on 2006 cancer registrations) and incomplete.[31,32] Data on stage at diagnosis based on the income domain of the IMD are updated regularly, with the most up-to-date statistics based on 2019 registrations.[33] Nevertheless, in both cases, the data were not reported for subtypes of breast cancer such as TNBC. The only UK study investigating the risk of TNBC diagnosis by IMD dated from 2013 and was a small (N = 2417) retrospective study using a London registry,[26] therefore limiting the generalizability of the findings.

Assessments of the clinical effectiveness of interventions based on social determinants of health are rarely undertaken.[34] Observational studies can be used to better understand how health technologies might affect different populations; such studies, however, are currently limited. The treatment effect of a new intervention has the potential to differ between equity-relevant groups because of biological or behavioral factors, such as when a new mode of administration is developed that improves adherence. In these instances, consideration should be given to assessing equity impacts as part of clinical trials, given that it will often be the only data available at the point of HTA. There may be significant challenges in doing this, for example, different countries use different measures of socioeconomic deprivation or the population size recruited in a single country may be too small to conduct stratified analyses. Nonetheless, there is currently a lack of data collection on equity-relevant drivers and a lack of diversity in patient populations recruited to clinical trials.[35,36] For example, white patients represented 76% of participants in clinical trials that supported the US Food and Drug Administration approval of new drugs between 2015 and 2019 based on a 2020 analysis by the US Food and Drug Administration,[37] despite just 62% of the US population being white (based on the 2020 US population census).[38] Some of these challenges can potentially be overcome through trial design. Others are likely to need a more global change, such as developing common metrics as discussed above, and improving the diversity of clinical trial populations. These could also have benefits beyond DCEA such as improving the generalizability of clinical trials.

A range of factors in the treatment pathway beyond the direct impact of new innovations on patient subgroups—including health risks, uptake of services, adherence to treatment, and capacity of benefit—may lead different population subgroups to experience different outcomes. Understanding these factors and modeling them is key to estimating impacts on health inequities.[21,39] Indeed, a recent CEA of COVID-19 vaccines highlighted that the cost-effectiveness of vaccines depends on how well they are distributed and less on their clinical efficacy.[40] Nevertheless, data on uptake of screening programs, access to tests and treatment, or health status at diagnosis, for example, are seldom stratified by the equity-relevant attributes and may be poorly documented.

The parameters and the level of granularity required in a DCEA will vary depending on a range of factors such as the equity concern, disease area, type of healthcare system, and geography. DCEA can help understand which parameters drive outcomes and to design future evidence gathering tailored to a specific context and to better inform strategies for public health interventions.

Some data inputs required for DCEA are not yet collected routinely. Nevertheless, in some instances, the data may exist (eg, epidemiology data) but be scattered across multiple sources or limited by missingness, requiring database linkage and imputation techniques. This creates a barrier to analysis because it is resource intensive and time consuming to generate the data in a format aligned with equity concerns. In addition, steps to link data may result in notable loss of sample, which can affect

representativeness and generalizability. Assumptions and scenario analyses may be required to overcome data gaps, with potential consequences for the robustness of findings of the DCEA.

Recommendations for Future Research

DCEA is a useful tool to quantify health equity impacts and equity/efficiency trade-offs, which facilitate an explicit consideration of equity impacts when formulating reimbursement decisions about new health technologies. Insights generated from DCEAs can have broader implications for the design of health system and public health initiatives through the ability to identity (1) current key data gaps for equity-relevant subgroups and (2) critical issues in the patient care pathway that may be exacerbating current inequities. Nevertheless, for many interventions and disease areas, the data required to build robust analyses are either not collected, not reported, or not stratified based on the equity characteristics of interest. We suggest some key actions to address the challenges highlighted in the previous sections.

First, decision makers interested in explicit quantitative assessment of health inequities must be clear about the equity concerns of interest to them and specific about how they define those concerns (eg, the measure of social deprivation if that is the concern) This would provide a steer to researchers regarding what types of evidence are most useful to inform decision making.

Second, there is a need for public investment to collect, process, and report the data stratified based on the equity factors of interest to high-quality standards. There are many existing initiatives that could be used to address this if the data collection, analysis, and reporting were adapted to provide data aligned with the equity concerns and with more granularity, such as addressing disease subtypes. Existing data sources can be enriched or linked to ensure that equity-relevant drivers of health outcomes are being captured, reducing the resource burden on analysts. Consistent with calls for greater availability and accessibility of health data, the European Commission is working to create a European Health Data Space.[41,42] The objective is to ensure the continuity of care for patients and support research, policy making, and regulation of health technologies by unlocking health data such as health records, genomics data, and disease registries. Collection of equity-relevant characteristics should be incorporated into such initiatives to improve the evidence base for DCEA and other forms of equity-informative CEA. Public trust regarding the security and confidentiality of data collection, storage, and sharing will be vital to the success of such projects, as demonstrated by the failure of the care data program in the United Kingdom[43] and the delays to the Health Data Hub project in France.[44]

Third, echoing calls by the research community over the past few decades,[45] we encourage manufacturers to be as inclusive as possible in the selection of patient populations when generating new clinical evidence. Finally, efforts should be made to build the equity component into analyses earlier by designing equity-relevant clinical trials following guidelines and frameworks proposed in the literature.[46,47] We acknowledge, however, that clinical trials have limitations, and they may not be powered to assess equity impacts. Therefore, we recommend also using real-world data, such as registries and observational studies, to provide insight on current health inequities at the time of HTA review and conduct postlaunch studies to assess heterogeneity in treatment effectiveness according to equity-relevant attributes. Governments, HTA bodies, and manufacturers need to collaborate to ensure the quality of the data, the alignment of the data with the equity concerns, and the sufficiency of the data for meeting HTA requirements.

Finally, the data collected will have applications beyond DCEA and can be analyzed longitudinally to evaluate trends in health inequities over time as already done for certain metrics (eg, life expectancy) in a range of countries.[48,49]

Conclusions

DCEA offers a useful tool to embed equity assessments in HTA in response to growing concerns about unfair differences in health across populations. Nevertheless, the routine implementation of DCEA for the evaluation of health technologies is hampered by a lack of consistency in the equity characteristics used and how the data are collected or reported. Therefore, governments and HTA agencies must be explicit about which equity concerns are of most interest, such as differences in health by neighborhood deprivation, and recommend or develop generic indices that best capture them. The evidence base for informing DCEAs can be improved in numerous ways to pursue the important policy objective of reducing unfair differences in health. Database linkage, enrichment of existing registries to collect information on equity-relevant attributes, and stratified analyses of both trial and observational studies would alleviate the burden on analysts and greatly improve the quantity and quality of DCEAs.

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