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Health Policy Analysis

A Tale of Two Thresholds: A Framework for Prioritization within the Cancer Drugs Fund

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ABSTRACT

Backgound: The Cancer Drugs Fund (CDF) has been the subject of controversy since its inception, with critics arguing that it creates a "backdoor" to the National Health Service (NHS), circumventing the National Institute for Health and Care Excellence and its health technology assessment program. Nonetheless, with its creation comes a new decision problem, how to best allocate resources among cancer drugs. **Objectives:** Our objective was to estimate CDF's willingness and ability to pay for cancer drugs, providing guidance regarding where CDF funds are best spent, and determining the number of NHS quality-adjusted life-years (QALYs) displaced through the existence of the fund. **Methods:** Using CDF utilization figures, cost-per-QALY, and treatment episode costs from National Institute for Health and Care Excellence health technology assessment reports, the league-table approach was applied to determine appropriate cost-effectiveness thresholds to inform the CDF's decision making. **Results:** The CDF exhibits a willingness-to-pay value of £223,627 per QALY, with 74% and 33% of expenditure for drugs with incremental cost-effectiveness ratios of more than £50,000 and more than £90,000, respectively. During 2013-2014, CDF expenditure generated 4,677 QALYs, compared with a potential 13,485 if the same funds were used as part of routine NHS commissioning, displacing 8,808 QALYs. By ring fencing 10%, 25%, and 50% of the CDF budget for the provision of unevaluated drugs, cost-effectiveness thresholds of £149,000, £111,400, and £68,600 were calculated, respectively. **Conclusions:** Adopting the proposed framework for CDF prioritization would result in disinvestment from a number of highly cost-ineffective drugs applicable for CDF reimbursement. The present lack of a formal economic evaluation not only results in net health losses but also compromises a founding principle of the NHS, that of "equal access for equal need."

Keywords: Cancer Drugs Fund, health economics, prioritization.

Introduction

National Health Service (NHS) England's Cancer Drugs Fund (CDF) has been the subject of controversy since its inception, with many critics arguing that it creates a "backdoor" to the NHS, which circumvents National Institute for Health and Care Excellence (NICE) and its health technology assessment (HTA) program [1–4], imposing opportunity costs in terms of population health. Although the debate surrounding the existence of the fund has been lively, to date, very little attention has been paid to resource allocation within the fund.

NICE applies a universal decision rule in which the incremental cost-effectiveness ratio (ICER) of an intervention must, at least in theory, be below a predefined cost-effectiveness threshold in order to be considered a good use of scarce NHS resources. The exact value this threshold should take has been the subject of much debate, with arguments for higher [5–7], lower [8,9], varying [10], and flexible [11] thresholds throughout the literature. Of particular relevance to the CDF is the move away from NICE's default position that "a QALY is a QALY is a QALY," the emergence of "value-based assessment," and the growing support for reforming HTA to allow for the inclusion of "wider health benefits." These include the continuing debate around the "super-QALY" [12–14], disease severity [15–18], and "end-of-life" weightings [19–21], all of which are of significant relevance to the CDF.

However, perhaps the greatest barrier to such reform is not ideological or philosophical but technical. Although we are aware that funding one intervention necessitates imposing opportunity costs on others, we cannot be certain where these opportunity costs are borne. Comparing "known" and "unknown" means we cannot rationally attach an "equity weight" to an intervention under evaluation, unless we are able to identify and apply the correct weight to the unknown bearer of the opportunity cost and its corresponding patient group.

Although the wider NHS decision problem encounters efficiency-limiting information constraints [22] and issues surrounding disinvestment [23,24], the CDF does not. Because the CDF is exclusively meant for the funding of drugs and exclusively for

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the therapeutic area of cancer, the technical problem of searching for an accurate cost-effectiveness threshold becomes much simpler. In contrast to the NHS budget, in which opportunity costs are borne somewhere within a vast array of interventions across numerous therapeutic areas, we need only consider a much narrower range of health technologies, 74 at the time of writing, making the adoption and disinvestment of cancer drugs and services an issue of mathematical programming. Moreover, we need not concern ourselves with whether a cancer quality-adjusted life-year (QALY) ought to be valued more highly than a non-cancer QALY because all QALYs are accrued to cancer patients.

Despite the increased simplicity of cancer-specific threshold determination, it should be noted that the CDF's purpose implies two potentially competing objectives, making this process more challenging. The first is to offer an extended willingness to pay for cancer drugs beyond that of the NICE cost-effectiveness threshold. The second, similar to the European Medicines Agency's "adaptive pathways approach" [25], is to speed up and increase access to cancer drugs that are yet to be assessed by NICE, currently under evaluation, or have had their assessments suspended or terminated, henceforth referred to as "unevaluated" treatment indications. Because the relative importance of these two CDF objectives has not been made explicit, any threshold necessarily becomes a function of how resources are to be allocated between the two, and can only apply to the former case, in which cost-effectiveness is known. Given that we do not know the precise objective function of the CDF, but do know the likely arguments within, in an attempt to formalize this process we propose a series of funding splits for the provision of known (NICE evaluated) and unknown (unevaluated) cancer drugs. Using historical CDF utilization data and NICE HTA and evidence review group (ERG) reports, this article determines each drug's impact on CDF's ability to pay for drugs and the subsequent potential for QALY generation, calculating corresponding candidate thresholds for treatments of known cost-effectiveness for each of these funding splits.

Methods

An analysis was undertaken to identify the cost-effectiveness and affordability of all treatments currently subject to reimbursement under the CDF, enabling the estimation of a range of suitable cost-effectiveness thresholds that may be used to inform CDF decision making, dependent on a range of potential funding allocations between evaluated (known) and unevaluated (unknown) treatment indications.

Data Sources and Extraction

We conducted a search of the NHS UK Cancer Drugs Fund Web site [26] to reveal all drugs subject to reimbursement under the most recent edition of the "CDF-approved list" at the time of writing. Because the treatment duration, clinical effectiveness, and cost-effectiveness of these drugs differ with respect to the form of cancer they are indicated to treat, every therapeutic indication for each of these drugs was identified. Following the identification of all relevant treatment options reimbursed by the CDF, a literature search was conducted with the sole purpose of identifying evidence concerning cost-effectiveness and drug acquisition costs. For the purpose of data collection and synthesis, no systematic search criteria or date restrictions were applied. The selective literature search was initially confined to the NICE database, to limit our results to those solely from an NHS perspective.

For each intervention, where available, full copies were obtained of the NICE technology appraisal resulting in the initial rejection or "optimized" recommendation for funding under routine NHS care. Data were extracted concerning total drug acquisition costs per indication and the estimated ICERs versus the next best standard of care, expressed in terms of the incremental cost per QALY. Because NICE HTA reports often contain multiple estimates of ICERs, contingent on numerous assumptions and conditions being met, the ICERs used were those identified as "most plausible" by the ERGs. Furthermore, because the remit of the CDF only permits the reimbursement of "drugs," and not the associated nursing and chemotherapeutic costs, every effort was made to ensure that the costs reported were in fact those solely associated with drug acquisition.

The expected utilization of each CDF intervention was obtained from historical CDF audit reports [26]. For indications for which NICE technology assessments were not available, this information was obtained using a range of resources including the NICE Web site, ERG reports, notices of HTA suspension and/or termination, and final appraisal determinations. If data were still unavailable, either due to HTA suspension and/or termination or simply having not yet undergone NICE HTA, these treatment indications were labeled as unevaluated due to being in use but having ultimately unknown cost-effectiveness or budget impact. In cases in which evidence obtained from NICE was incomplete, that is, information were available concerning the estimated cost per QALY but not the estimated cost per treatment episode, these were estimated using recommended dosing regimens contained within the HTA. If this information were also not available, treatment costs were sourced from the literature, converted to pounds sterling, and inflated to represent their net present value as appropriate.

Threshold Search: League-Table Approach

This model makes use of the league-table search approach to threshold determination and applies it to the CDF. First proposed by Gafni and Birch [27,28], and the subject of much debate within the health economics literature [9,29], the league-table approach is a well-validated method for cost-effectiveness threshold elicitation, both in theory and in practice. Although excessive informational requirements render this approach infeasible for informing NHS-level questions of resource allocation [23,24,29], this approach has been successfully applied to more modest NHS decision problems, including the estimation of "local" cost-effectiveness thresholds at the primary care trust level [24]. As such, given the highly bounded nature of our hypothesis, a resource allocation problem considering just 74 treatment options within a single therapeutic area, we deemed this method to be the most accurate, flexible, and practical means of determining a CDF-specific threshold to inform future resource allocation. Under this approach, interventions are ranked in order of decreasing cost-effectiveness (increasing ICERs), expressed in terms of the cost per QALY gained, and adopted sequentially until the budget is exhausted. As presented in Table 1, adapted from Appleby et al. [24], the relevant threshold theoretically lies between indications *X* and *Y*, the point between the ICER of the last (least cost-effective) or marginal intervention funded (CDF indication *X*) and that of most cost-effective service not currently funded (CDF indication *Y*). To adopt interventions beyond this threshold (e.g., CDF intervention *N*) necessitates disinvestment from others of greater cost-effectiveness that produce greater health gains for every pound spent, resulting in an unambiguous loss in population health. In the event that the CDF budget exceeded the costs of satisfying demand for every treatment indication, the benchmark interventions approach [30] was applied to estimate the threshold on the basis of the maximum willingness to pay demonstrated when funding previous CDF interventions.