



Equity of access to treatment on the Cancer Drugs Fund: A missed opportunity for cancer research?



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ABSTRACT

Using mixed-methods, we investigated the CDF in the South West of England (3193 cancer patients treated through the CDF, April 1st 2011–March 31st 2013) for evidence of: (1) equitable access across socioeconomic groups, age groups, sex, and Cancer Network; (2) time-to-treatment by socioeconomic group; and (3) the perception of the CDF as fair, using semi-structured interviews with oncology consultants.

There was no evidence of inequitable access to anti-cancer therapy for those in more deprived areas. For all cancer types, there was a lower proportion of women in the CDF cohort than in the Cancer Registry reference population (e.g., melanoma, CDF 36.8% female, reference population 48.7%; difference 11.9%, 95% CI 3.1–20.7%). There was a lower proportion of older patients in the CDF compared with the reference population (e.g., colorectal cancer, CDF 6.9% ≥ 80 years, reference population 30.1%; difference 23.2%, 95% CI 20.2–26.2%). Interviewed oncologists felt differences in performance status, not age, influenced referral to the CDF, with neither deprivation, nor gender contributing.

Our study suggests that the CDF has differential access by age and sex, but not by deprivation. The absence of high quality CDF data represents a missed opportunity to fully evaluate equity of access and the real-world costs and outcomes of novel anti-cancer drugs.

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1. Introduction

In 2011, the UK government introduced a £200 million Cancer Drugs Fund (CDF) to improve access to cancer drugs in England [1]. The CDF allowed access to: (a) drugs which were not recommended by the National Institute for Health and Care Excellence (NICE) because of poor or unproven cost-effectiveness; (b) drugs which had not yet been appraised by NICE; and (c) drugs used outside their marketing authorisation (off-label). In 2013, funding for the CDF was increased to £280 million annually and in 2014, a further budget increase (to £340 million) was coupled with the introduction of cost-effectiveness as a criteria for drug availability on the CDF. This was primarily due to a CDF overspend (£30.5 million in 2014) [2], but also reflects the rising number of high-cost cancer drugs, increasing cancer incidence [3], and the absence of a plan to disinvest from existing drugs to make way for new therapies. The opportunity cost of the CDF has been the subject of intense debate,

for example, about whether the money could be better spent on other cancer treatment modalities and/or other diseases [4].

Inequity of access to anti-cancer therapy in the UK, prior to the CDF, has been demonstrated by: age [5,6]; deprivation [7–9]; place of residence [10]; hospital involvement with clinical trials [11], and hospital processes for facilitating best patient care (such as Multi-Disciplinary Team meetings) [12]. The intent of the CDF is to provide all patients with better access to “cancer drugs their doctors think will help them” [1]. However, there is no peer-reviewed evidence on whether the CDF has reduced or exacerbated inequalities in access to anti-cancer therapy. Using mixed-methods, we assessed the strengths and weaknesses of the CDF for research and investigated (1) whether access to the CDF during 2011–2013 was distributed equally across socioeconomic groups, age groups, sex, and Cancer Network; (2) whether time to treatment on the CDF varied by socioeconomic group; and (3) whether the CDF was perceived by oncologists as being fair.

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2. Methods

2.1. CDF cohort

Anonymised patient-level CDF data for the period April 1st 2011–31st March 2013 for the south west (SW) region of England were obtained from NHS England South including age, sex, cancer type, cancer drug, general practitioner (GP) postcode, referring hospital trust, Cancer Network, CDF panel decision, treatment start, and end date and date of death. Cancer Networks (CN) were confederations of health organisations responsible for delivering the National Cancer Plan [13] in designated areas (now Strategic Clinical Networks (2013)) [14]. Data were not available after March 31st 2013 because regional CDF arrangements were transferred to a National Cohort List (a centrally agreed list of drugs available across England through the CDF). Out-of-region applications to the CDF (i.e., applications received in error and referred to another regional CDF) were excluded from the analysis, as were applications during the interim CDF period (October 1st 2010–March 31st 2011). Applications to the CDF which were not approved (3.0%) were not included in the analysis. Individuals who applied to the CDF more than once were identified by initials, GP postcode, diagnosis and age, and only the first application (93.8% of applications) was included in the analysis. Our primary analysis included SW patients resident in all six CNs (Avon Somerset and Wiltshire Cancer Services (ASWCS), Dorset, Peninsula, 3 Counties, Central South Coast, and Thames Valley) which were partially or wholly contained within the SW region. GP postcode data for all CDF participants (individual patient postcode data were not provided) were linked to lower super-output areas (LSOA) to obtain National Index of Multiple Deprivation (IMD 2010) quintiles [15]. Participants were grouped into nine diagnosis categories based on the cancer name recorded on the CDF application. International Classification of Diseases (ICD-10) diagnosis codes were very poorly recorded (49.0% missing or coded 'N/A') in the CDF. The diagnosis categories were: colorectal; prostate; breast; malignant melanoma; lung; gynaecological; upper gastro-intestinal; haematological; and other rare cancers. 'Gynaecological cancer' included uterine, ovarian and cervical; upper GI cancer included gastric, hepatic, pancreatic, and duodenal; and haematological cancer was made up of 84 different categories, including pre-cancerous conditions of myelofibrosis and amyloid. Other rare cancers were categorised based on being a member of the rare cancers list [16] and not being included in other named categories. Ethical approval was granted by the SW REC (REC reference 13/SW/0007 January 2013).

2.2. Cancer registry 'reference'

We used cancer registry (CR) data to identify a comparative group of patients with advanced cancer in the SW region who were potentially eligible for CDF drugs (the 'reference population'). The CR data, which includes information on cancer type, cancer stage, age, sex, and CN, were obtained from the public health England (PHE) Knowledge and Intelligence Team (SW). In our primary analysis of seven of the nine cancer types, CR patients were included in the reference population if they had the same cancer type, matched to the appropriate ICD-10 code, (Supplementary material) and were 'advanced' stage (IV). We selected only advanced stage tumors as this represents the subgroup of cancer patients most likely to be eligible for drugs prescribed on the CDF. In sensitivity analysis we expanded our inclusion criteria to include all stages. For malignant melanoma, where Tumour-Node-Metastases, based on Breslow staging, may be used more commonly clinically, and where stage IV cancers in the CR number less than those treated in the CDF, the reference population in the primary analysis included 'all' melanomas. For haematological cancers, where there is little

stage 0–IV information in the CR, 'all' haematological cancers were included in the reference population in the primary analysis. CR patients' postcodes were linked to IMD quintiles via LSOA.

2.3. Statistical analysis

2.3.1. Equity of access

Of 3530 CDF applications, 8 were out-of-region residents, 234 repeat applications for the same patient and 95 were not authorised by the CDF panel and were excluded from analysis, leaving 3193 (Fig. 1). Of these, 367 (11.5%) had missing or incomplete GP postcodes and could not be assigned an IMD designation. Other patient characteristics were missing in $\leq 2\%$ of CDF applications.

Chi-Squared, Ordinal Chi-squared, and Fisher's Exact tests were used to compare demographic characteristics of those treated on the CDF with the reference population.

2.3.2. Time-to-treatment

Time to receipt of treatment was calculated from the date of CDF panel authorisation to the date of treatment. Treatment start date was missing or incomplete for 1330 (41.7%) patients. Due to the large proportion of missing data, data were explored and found to be 'missing at random' for all observed variables apart from CN. A further 348 patients were excluded due to dates of authorisation occurring after treatment had started. Cancer types with fewer than 100 subjects were excluded from the regression analysis. The final model excluded missing data in IMD ($n=222$) age ($n=22$), and sex ($n=5$) resulting in a final time-to-treatment analysis of 899 patients. Cox regression was used to calculate multivariable adjusted hazard ratios for time-to-treatment, where a hazard ratio >1 indicates more prompt treatment. Potential confounders were identified a priori and assessed for inclusion using likelihood ratio tests to develop the final model (adjusted for age, sex, cancer type, CN) for the impact of deprivation on time-to-treatment. All statistical analyses were performed with Stata 13.1 (StataCorp).

2.4. Sensitivity analysis

In the absence of a unique patient identifier linking the CR to the CDF, or complete diagnostic (ICD-10) coding in the CDF, two sensitivity analyses were conducted to assess assumptions used in selecting the 'reference population' in the CR. Firstly, we included 'all stage' cancers of the same cancer type in the reference population to test the assumption that 'all' stages better reflected the population who were eligible to apply for the CDF than advanced CR cancers in the primary analysis. Secondly, the study population was restricted to those treated in the three CNs whose entire population was eligible for the SW CDF (ASWCS, Dorset, Peninsula). This addresses the possibility that equity of access to the SW CDF was being distorted by including CNs where some residents get care through other regional CDFs.

2.5. Interview study

As part of a wider qualitative study, all colorectal and urological oncology consultants in four hospitals in the SW region were identified through hospital switchboards and websites and invited to take part in semi-structured interviews. Thirteen email and postal invitations were distributed and ten interviews were conducted between April 1st and December 31st 2013. Interview topic guides were used and included questions about the criteria that influenced the oncologists' decision to refer a patient to the CDF, experiences of the CDF and its perceived impact on patients. Analysis used the technique of constant comparison to compare transcripts and elicit key themes [17]. The research was conducted iteratively, with

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