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Access to innovation: Is there a difference in the use of expensive anticancer drugs between French hospitals?

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ABSTRACT

In DRG-based hospital payment systems, expensive drugs are often funded separately. In France, specific expensive drugs (including a large proportion of anticancer drugs) are fully reimbursed up to national reimbursement tariffs to ensure equity of access. Our objective was to analyse the use of expensive anticancer drugs in public and private hospitals, and between regions. We had access to sales per anticancer drug and per hospital in the year 2008. We used a multilevel model to study the variation in the mean expenditure of expensive anticancer drugs per course of chemotherapy and per hospital. The mean expenditure per course of chemotherapy was € 922 [95% CI: 890–954]. At the hospital level, specialisation in chemotherapies for breast cancers was associated with a higher expenditure of anticancer drugs per course for those hospitals with the highest proportion of cancers at this site. There were no differences in the use of expensive drugs between the private and the public hospital sector after controlling for case mix. There were no differences between the mean expenditures per region. The absence of disparities in the use of expensive anticancer drugs between hospitals and regions may indicate that exempting chemotherapies from DRG-based payments and providing additional reimbursement for these drugs has been successful at ensuring equal access to care.

1. Introduction

The question of how to pay for expensive drugs in hospitals in the context of a prospective payment scheme is relevant for many countries [1,2]. This is a major issue in the field of cancer where treatment costs have risen faster than in other disease areas. All healthcare systems have to face the question of access to innovation in cancer and the funding of expensive anticancer drugs [3–8]. In most countries, there are constraints on hospital drug budgets. However, major disparities in access to cancer drugs have been noted between countries [9] and in the mean expenditures of anticancer drugs per capita [10,11]. Recent studies demonstrated inequalities of access to drugs for cancer within some countries [12–16]. This could be due to differences in access policies between and within countries. In the United Kingdom, the availability of anticancer drugs in the National Health Service (NHS) is subject to the appraisal of NICE (National Institute for Health & Clinical Excellence). During the last decade, the proportion of negative decisions for the routine use of certain

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anticancer agents has increased [17]. In France, reimbursement decisions made by the French NHS for expensive anticancer drugs were markedly favourable and the level of expenditure for anticancer agents was two-fold the average in the rest of Europe [11].

Prior to 2004 and the implementation of prospective per case payment, French public hospitals were funded through a prospective global budget, covering all expenditures. As a consequence, drug budgets were capped, and access to expensive drugs was rationed. Paradoxically, this did not happen in the private sector, where hospitals were allowed to bill some expensive drugs and medical devices retrospectively. The list of these items was compiled incrementally through ad hoc negotiations with the sickness fund. Thus, access to expensive products was distorted between the two sectors, potentially creating differences in treatment. Moreover, within the public sector, access to high cost treatment was dependent on the relative financial situation of each establishment. Since the introduction of a prospective DRG-like payment scheme for both the public and the private sectors, a special mechanism was implemented in 2005 to facilitate access to innovation [18,19]. A list of expensive hospital drugs administered during hospital stays (so-called *liste en sus*) is funded separately from the case-based payments (article L162-22-7 of the Social Security code). Maximum reimbursement prices for drugs on the list were set by the *Comité Economique des Produits de Santé* (CEPS, Pricing Committee). Since then, hospitals are fully reimbursed, retrospectively, based on these prices if they comply with a "good usage contract" signed with the regional health authorities. This contract concerns the quality of the drug delivery process, as well as recommended prescription guidelines set at the national level. Hospitals which fail to meet a given target according to contract indicators may be penalised by a lower reimbursement rate, capped at 70%. During the first year when the *liste en sus* was implemented, the criterion used to transfer drugs to the list was only the acquisition cost of the drugs. In 2004, 177 specialties were transferred to the list in the public sector, while the private sector was left with its previous list. The growth of the list was due to new reimbursed products with high prices. Harmonisation of lists between sectors was implemented in 2005. In 2006, the list included a large proportion of anticancer drugs which accounted for nearly 80% of the expenditures [20]. Although no data are available to support the idea that there were disparities in access to expensive drugs due to the funding scheme before implementation of the *'liste en sus'*, inequalities were possible. The *liste en sus* was actually introduced to correct this distortion between the public and the private sector. In parallel with the implementation of the list of expensive hospital drugs, a specific public health programme for cancer (the 2003–2007 Cancer Plan, measure 46) placed emphasis on the diffusion of innovation and the reduction of inequalities [21]. The French health policy in the field of cancer resulted in a tremendous increase in anticancer drug expenditures which amounted to 1.7 billion Euros in 2010 for the whole hospital sector [22]. Expenditures for hospital anticancer drugs increased at a mean annual growth rate of 18% over the 1999–2009 decade [23]. According to an analysis we performed using the sales data at the hospital sector level from the *Groupement pour l'Elaboration et la Réalisation de Statistique* (GERS), the *'liste en sus'* has been the main growth driver of hospital drug expenditures since 2004, and amongst drugs on the list, oncology drugs have been the fastest growth segment. A special advisory board, the *Conseil de l'Hospitalisation*, composed of representatives from the main departments of the Ministry of Health and Social Affairs and from the National Sickness Fund, was entrusted with the job of defining and applying eligibility criteria for a drug to be listed. The innovativeness of the drug is now included among these criteria. It is appreciated by the ASMR (added clinical benefit that is appreciated by the *Commission de la transparence* and impacts the drug price). Since the end of 2010, only drugs with a ASMR I to III can expect to be on the list [24].

The issue concerning the cost of anticancer drugs emerged in the nineties when taxanes were commercialised [25]. These cancer therapies shown to be effective in reducing mortality caused by the most frequent cancers are considered as the first cancer blockbusters. A decade later, with the commercialisation of trastuzumab [26], a new class of agents, the so-called targeted therapies, was born. These anticancer agents have the particularity of being effective in patient subgroups with certain molecular characteristics [27,28]. As targeted therapies (mostly monoclonal antibodies and protein kinase inhibitors) are often developed in small specific populations of patients whose tumours carry specific mutations for which there are no effective alternative treatments, their acquisition cost can be several-fold higher than that of systemic chemotherapies [29,30]. Today, we are in the era of personalised medicine where each cancer patient could eventually be treated according the molecular profile of his/her tumour. However, the funding of these personalised therapies raises complex issues concerning affordability, sustainability and patient access to expensive cancer treatments [31].

2. Research objectives

One of the goals of health policy measures in cancer is to ensure equity of access to innovation [32]. We studied this issue empirically using the French context as the framework. To investigate access to innovation in cancer, the geographic allocation of healthcare resources and public/private health sector mix differences, we analysed the use of expensive anticancer drugs registered on the "liste en sus" in French public and private hospitals three years after the list of expensive hospital drugs was compiled. We wanted to determine whether differences existed between public and private hospitals and between regions. On the one hand, disparities between hospital sectors were to be expected because of major differences in size, case-mix, funding and sensitivity to financial incentives. On the other hand, geographical variation in the use of anticancer drugs and their expenditures could exist as a result of differences in cancer incidence, variations in cancer care services and of regulatory mechanisms at the regional level.