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A Transparent and Consistent Approach to Assess US Outpatient Drug Costs for Use in Cost-Effectiveness Analyses

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ABSTRACT

Background: Assessment of drug costs for cost-effectiveness analyses (CEAs) in the United States is not straightforward because the prices paid for drugs are not publicly available and differ between payers. CEAs have relied on list prices that do not reflect the rebates and discounts known to be associated with these purchases. **Objectives:** To review available cost measures and propose a novel strategy that is transparent, consistent, and applicable to all CEAs taking a US health care sector perspective or a societal payer's perspective. **Methods:** We propose using the National Average Drug Acquisition Cost (NADAC), the Veterans Affairs Federal Supply Schedule (VAFSS), and their midpoint as the upper bound, lower bound, and base case, respectively, to estimate net drug prices for various payers. We compare this approach with wholesale acquisition cost (WAC), the most common measure observed in our literature review. The minimum WAC is used to provide the most conservative comparison. **Results:** Our sample consists of 1436 brand drugs and 1599 generic drugs. On average, the upper bound (NADAC) is 1% and 9.8% lower than the WAC for brand and generic drugs respectively, whereas the lower bound (VAFSS) is 48.3% and 54.2% lower than the WAC. The NADAC is less than the WAC in 89.6% of drug groups. The distributions of these relationships do not show a clear mode and have wide variation. **Conclusions:** Our study suggests that the WAC may be an overestimate for the base case because the minimum WAC is higher than the NADAC for most drugs. Our approach balances uncertainty and lack of data for the cost of pharmaceuticals with the need for a transparent and consistent approach for valid CEAs.

Keywords: cost-effectiveness analysis, drug cost, health economic methods, United States.

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Introduction

Prescription drug costs, which totaled more than $300 billion in the United States in 2015, are an essential input for cost-effectiveness analyses (CEAs) [1–5]. A lack of transparency in actual transacted amounts complicates the process of obtaining reasonable drug cost estimates for US-based CEAs [6,7]. Traditionally, the drug manufacturer's list price or the wholesale acquisition cost (WAC) of pharmaceuticals published in commercially available drug pricing compendia has been used in CEAs [8,9]. These list prices do not reflect the actual cost paid for drugs, because there are numerous discounts and rebates known to be granted to various entities throughout the drug supply chain [7,10,11]. Accounting for these rebates and discounts is necessary to reflect costs from any payer's perspective [8].

The goal of this work was to describe a consistent, transparent, and empirically based approach for estimating a plausible range of drug costs for US-based CEAs taking an all-payer's perspective such as the US health care sector perspective or the societal perspective. We then compare our approach with standard practice. Our approach relies on two publicly available price measures, the National Average Drug Acquisition Cost (NADAC) and the Department of Veterans Affairs Federal Supply Schedule (VAFSS), which are used to form the bounds of our drug cost parameter estimates. The range of net costs excludes pharmacy dispensing fees, which, although relevant for CEA, are not easily estimated. Our method does not incorporate dispensing fees, but does suggest assigning a separate parameter in the final analysis.

Our approach diverges from current practice that specifies a base case on the basis of either a list price or a prespecified fixed percent reduction from the list price, and then adds and subtracts a percent of the base case to cover the range of likely transaction costs for sensitivity analyses [12,13]. We focus instead on defining plausible extremes of the range and assign the base case as the midpoint of this interval. We compare our approach to using the WAC for more than 3000 drugs covered by Medicaid and examine subsets of highly used and costly drugs.

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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To provide some background, we review existing recommendations for best practices in assessing drug costs for CEAs, and then we conduct a systematic review of recent CEAs to understand whether, and how, the recommendations are being followed. Next, we summarize the drug supply chain and highlight vital features including the discounts available to pharmacies and rebates available to payers (health insurers or pharmacy benefit managers) that reduce the cost of pharmaceuticals compared with their list prices to motivate our approach.

Current Recommendations and Current Practice

To promote quality and uniformity in drug costing for CEA studies, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) published a series titled Good Research Practices for Measuring Drug Costs in Cost-Effectiveness Analyses [8,14–16]. ISPOR guidelines for costing drugs adopt the perspective of five different types of payers: societal, managed care organizations, US government, industry, and international. The guidelines state that "CEAs performed from a payer's perspective should use drug prices actually paid by the relevant payer net of all rebates, co-pays, or other adjustments [discounts]" [8]. The ISPOR guidelines provide limited guidance as to how to account for these discounts and rebates, but suggest a generic average discount by some percent of the list price. In the chapter on the managed care organization perspective, the guidelines suggest a range of 5% to 25% for the manufacturer's rebate [15]. This suggestion, however, is based only on a subset of highly used drugs from calendar year 2003 [11,17].

To assess the impact of the recommendations, we conducted a literature search of US-based CEAs published between 2011 and 2015 that explicitly estimated cost for at least one outpatient drug. Forty-four of 81 studies adopted a US health system or generic third-party payer's perspective, whereas 19 of 81 adopted the broader societal perspective.

Of the 81 studies, 43 used full nondiscounted WAC for the base case, 17 studies used nondiscounted average wholesale price (AWP), and 9 studies accounted for rebates/discounts by applying some discount to the AWP or the WAC. Twenty of the 81 studies used measures other than the AWP or the WAC for the base case, 19 studies used the VAFSS, and 1 study used the NADAC. Uncertainty of these estimates for sensitivity analyses was typically reflected by some percentage addition and subtraction, with a mode of ±25% (n = 19). Nevertheless, studies varied greatly, from as low as ±5% to as high as ±100%.

Key Transactions in the Drug Supply Chain

In a CEA, the relevant entities in the drug supply chain include drug manufacturers, drug wholesalers, pharmacies, and payers. Manufacturers produce drugs and sell these drugs to wholesalers, who, in turn, sell the drugs to pharmacies. Pharmacies dispense the drugs to patients and are usually paid by a health insurer or pharmacy benefit manager (herein "payer") [18]. The manufacturer's sale to the wholesaler is represented by the manufacturer's suggested list price known as the WAC. These purchases, however, are often made at less than the WAC, because manufacturers grant discounts to wholesalers [19].

The second transaction is the sale from the wholesaler to the pharmacy. In theory, this purchase is also represented by a manufacturer-reported number, the AWP. It is well documented that discounts are often available for this purchase, for larger quantity and prompt pay [1,7,20,21].

The third transaction is payer purchases of the drug from the pharmacy on behalf of the patient. This amount is negotiated between the pharmacy and the payer and is supposed to capture the amount the pharmacy paid to acquire the drug plus a dispensing fee. After the payer pays the pharmacy, the payer receives a rebate from the manufacturer independent of what they paid the pharmacy [22,23]. This rebate, the final key transaction, effectively lowers the price of the drug to the payer below what they paid the pharmacy. The details of the manufacturer rebate or final negotiated price for almost all payers are confidential and vary not only by different drugs and manufacturers but also by different payers and their market power to negotiate these rebates [7].

Cost Measures

Our method proposes two cost measures to represent the range of plausible net costs likely encountered by all payers. The NADAC defines the upper bound, whereas the VAFSS defines the lower bound. We describe these measures in sufficient detail to motivate why they can represent these respective bounds for CEA.

National Average Drug Acquisition Cost

The amount that fee-for-service Medicaid (distinct from Medicaid managed care) spends for a certain outpatient drug has two components—the payment to the pharmacy, which itself comprises ingredient costs and dispensing fee, and the rebates Medicaid eventually receives from the drug manufacturer [24]. The ingredient cost estimation varies by state, but is generally a fixed percent reduction or addition to the drug list price (either the AWP or the WAC) [25]. The second component comprises the rebates that are received by the state from the manufacturers after the drug has been dispensed and the pharmacy has been paid. The Medicaid Drug Rebate Program sets the amount and grants these rebates automatically, although the rebates can be larger if the state has negotiated an additional supplements rebate for individual drugs [24,26].

In 2012, in an effort to aid state Medicaid agencies in modernizing their reimbursement, to pharmacies, the Centers for Medicare & Medicaid Services conceived of the NADAC as a new price measure for use in fee-for-service Medicaid [19,27,28]. The goal of the NADAC is to estimate what pharmacies pay to acquire all outpatient pharmaceuticals reimbursed by Medicaid to better estimate their ingredient costs [27]. To compute the NADAC, an accounting firm contracted by the Centers for Medicare & Medicaid Services (CMS) conducts a monthly nationwide survey of a random sample of pharmacies to assess their drug acquisition cost for purchases using invoices from the last 30 days. A weighted average is computed using the number of times each product, by unique National Drug Code (NDC), is observed in the sample. NDCs are grouped into therapeutically equivalent "drug groups," that is, the same active ingredient, strength, and formulation. The survey yields a single weighted average cost for each drug group that may be used by states as the basis for reimbursement. Of the roughly 67,000 pharmacies in the United States, approximately 2000 to 2500 are sampled monthly [19,27,28].

We define the NADAC as an upper bound for sensitivity analyses, because it is an estimate of the net amount paid by payers before manufacturer rebates. We assume that the amount paid by the pharmacy to acquire the drug is the amount the payer will pay to acquire it, excluding the dispensing fee. The details of the NADAC are presented in Table 1.

Veterans Affairs Federal Supply Schedule

The US Department of Veterans Affairs (VA) Health Administration, an integrated care system with roughly 9 million enrollees, is able to negotiate the price of drugs with manufacturers. Unlike virtually all other US payers, these contract details, including the final negotiated prices, are publicly available [13,21,26,29]. The pricing process for the VA is complex, because the VA is charged

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