The effect of the drug life cycle price on cost-effectiveness results: A real-world data analysis

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Objectives

Cost-effectiveness analyses (CEA) generally assume constant drug prices throughout the model time horizon.

Yet, drug prices are not constant over time. In particular, these prices often decrease significantly after loss of exclusivity (LOE).[1,2]

Previous research highlighted the consequences of price decreases for CEA through algebraic models, assumptions or combined cohort-price impacts.[3,4,5,6] Yet, none of them included real-world price data and subsequently isolated its effect.

The aim of this study was to explore the isolated impact of using drug-specific historical dynamic prices on the incremental cost-effectiveness ratio (ICER).

Methods

The influence of drug life cycle price development is illustrated using exemplary drug case-studies.

The criteria for the case-study selection were:

- availability of drug specific historical data for dynamic pricing;[2]
- the selected cases should represent the characteristics of a wide variety of drugs; and
- the published CEAs should be reproduceable.

Notably, drugs for which patents expired between 2008 and 2013, were selected from an initial dataset of 250 drugs.

For the selected drugs, published CEA models were identified, replicated and lastly modified by applying historical Dutch price data. Prescription data as well as (list-) prices were extracted for the selected drugs and included in the replicated single-cohort CEA models. The timing of first generic entry was used as a proxy for LOE.

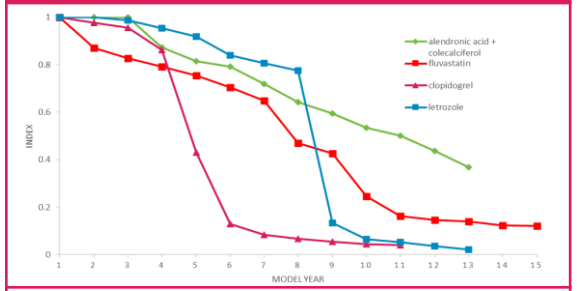
In real-life, successive patient cohorts periodically start using a drug after an initial (single-)cohort, at a point in time with potentially lower drug prices. Thus, additionally a multi-cohort analysis was performed to examine the effect of this multi-cohort dynamics on the cost-effectiveness results.

Lastly, ICERs of a drug in both single- and multi-cohort analyses were compared with the outcome of the replicated original model for which the Dutch historical price was kept constant at the cost year reported in the published CEA.

Results

The following four drug case-studies were selected: i. alendronic acid + colecalciferol (osteoporosis)[7]; ii. fluvastatin (elevated cholesterol)[8]; clopidogrel (myocardial infarction)[9]; and letrozole (oncology)[10]. Figure 1 shows the price development over time.

Figure 1. Annual price development for all four drugs compared to price in first model year.



Model year 1 is representing the cost year in the orig. study.

A summary of important drug-specific details and model characteristics, time horizon, drug utilization, cost year and year of generic entry, is listed in Table 1.

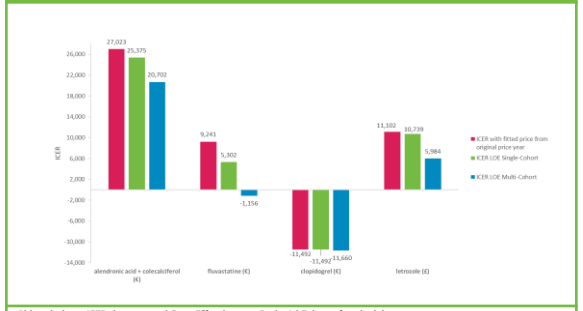
Incorporating drug life-cycle price compared to the application of a constant price, reduced the ICER in a single-cohort setting by up to 43%.

Notably, the difference in magnitude of the impact between drugs/models was dependent on: i. the length of the drug prescription period relative to model time horizon; ii. Proportion of drug cost relative to overall incorporated treatment costs; and iii. timing of LOE.

Results (continued)

Applying multi-cohort analyses, resulted in a reduction of the ICERs up to 113% (Figure 2), with the most substantial impact occurring in case-examples with relatively short treatment duration.

Figure 2. ICERs (cost per QALY) per analytic approach for all drugs compared to original price.



Abbreviations: ICER; incremental Cost-Effectiveness Ratio, LOE; loss of exclusivity

More specifically, multi-cohort ICERs of most drugs improved significantly over the successive cohorts, clearly showing the increasing effect of LOE on the cohort specific ICERs over time (Figure 3).

"Including real-world drug price development in CEAs gives a more precise estimate of cost-effectiveness"

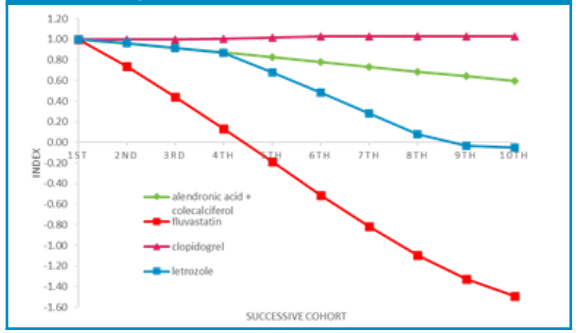
Table 1. Model characteristics of the analysed drugs as derived from original publication (except when indicated otherwise).

Model	Time horizon	Drug Utilization	Cost year original model	Year generic entry*
alendronic acid + colecalciferol	10 years	maximum 5 cycles	2004	2013
fluvastatin	10 years	health state dependent	2002	2008
letrozole	40 years	health state dependent	2004	2011
clopidogrel	1 year	first cycle	2006	2009

*Year of generic entry derived from van der Schans et al.[2]

Results (continued)

Figure 3. ICERs per drug and cohort reported as ratio relative to ICER of starting cohort.



Conclusion

Assuming constant drug prices leads to inaccuracies when estimating ICERs to inform healthcare decisions. Inclusion of real-world drug price development in CEA more precisely estimates cost-effectiveness of drugs, which could be of importance for health-care decision making.

Future research should focus on predicting life cycle price development of drugs, on how to standardise incorporation of dynamic pricing data in CEA, on how to facilitate such a incorporation (e.g. online tool) and on the interaction of LOE and international reference pricing mechanism.

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