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The value of innovation under value-based pricing

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Objectiv

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Method

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patent prices. The proposed CEA approach incorporates these two features to derive the total lifetime value of an innovative drug (i.e., the value of innovation).

Results

The conventional CEA approach tends to underestimate the value of innovative drugs by disregarding the benefit to future patients and savings from off-patent prices. As a result, innovative drugs are underpriced, only allowing manufacturers to capture approximately 15% of the total value of innovation during the patent protection period. In addition to including the incidence population and off-patent price, the alternative approach proposes pricing new drugs by first negotiating the share of value of innovation to be appropriated by the manufacturer (>15%?) and payer (<85%?), in order to then identify the drug price that satisfies this condition.

Conclusion

We argue for a modification to the conventional CEA approach that integrates the total lifetime value of innovative drugs into CEA, by taking into account off-patent pricing and future patients. The proposed approach derives a price that allows manufacturers to capture an agreed share of this value, thereby incentivizing innovation, while supporting health-care systems to pursue dynamic allocative efficiency. However, the long-term sustainability of health-care systems must be assessed before this proposal is adopt

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majority of health care in the UK. In order to ensure the long-term sustainability of the NHS, spending is allocated to technologies that maximize population health given the budget constraints. The challenge is identifying a method that allows health-care systems such as the NHS to incentivize innovation while supporting allocative efficiency.

Setting the price of a new pharmaceutical product is a complex part of this process. A commonly used approach is to price products according to their value for patients, commonly referred to as value-based pricing (VBP) (1). The principle of VBP is to align the incentives for conducting research with the needs of patients, thereby generating valuable innovation (2). In cost-effectiveness analysis (CEA) VBP is established in relation to a CEA threshold. However, CEA is incapable of capturing a number of dimensions associated with innovative technologies (3). For example, health gains from innovative technologies that address an unmet need are valued (and thus priced) equal to health gains from less innovative technologies that address an already satisfied need (e.g., me-too drugs) (4). This is the case because CEA only rewards gains in clinical benefit, regardless of whether the gains come from an innovative technology or not. The result is a pricing and reimbursement decision that fails to adequately reward valuable innovation (5, 6).

The key to successfully addressing the suboptimal financial incentives reflected in the current p y patented drugs. F cy makers must ag nology. Currentl el of innovati to value it quantita anslated into mor vious atten t an inflated meas osed to reflectin used for is in the ‘e ologies that are able er initiatives, such as between manufac

A major hurdle to reaching consensus around the measurement of innovation is the lack of a standardized definition of innovation itself (3, 7) (13). Here, we adopt the uncontroversial definition used by Claxton et al. (3), where innovation is restricted to new technologies that are claimed to offer benefits. The value of innovation is therefore defined here as the benefit that a new health technology brings to all patients (present and future) for as long it remains relevant for clinical practice.

Our objective in this article is to firstly identify the shortcomings of the conventional CEA approach to VBP in capturing the total lifetime value of innovative pharmaceutical drugs (hereafter named the value of innovation). Secondly, we propose modifications to the conventional CEA approach without advocating for a change to the CEA threshold. The proposed modifications aim to inform VBP by addressing the question of how the value of innovation is shared between the manufacturer and society (represented by a publicly funded health-care system). For illustration of a jurisdiction where the conventional CEA is used to inform drug prices, we use the National Institute for Health and Care Excellence (NICE), the reimbursement authority of the NHS in England and Wales. The proposal is illustrated through two hypothetical CEA case studies.

This paper focuses on patentable pharmaceutical drugs, but the findings are equally applicable to patentable medical devices such as diagnostics. It should be noted that there are other sources of innovation relevant to health-care providers, including new ways to patentable.

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fruits' of medical research have already been picked and the remaining unmet need requires an even larger research and financial effort. This current landscape leads manufacturers to raise concerns around the sustainability of medical research if 'sufficient' financial reward cannot be anticipated (15).

Allocation decisions based on comparing the incremental cost effectiveness ratio (ICER) of new technologies with a CEA threshold are intended to promote allocative efficiency of existent NHS resources. This has implications beyond the present day into future NHS efficiency because the adoption of new cost-effective technologies tends to displace less cost-effective technologies available in the NHS. In the long run, it is argued that this will improve NHS productivity, pulling down the CEA threshold even if the budget is kept constant over time (3).

It is therefore important to acknowledge that drug prices change over time and the effect such change has on NHS productivity. For example, the drop in drug prices due to generic entry represents a significant transfer of value from the industry to the NHS (16). The impact of this transfer of value is exemplified by statins, which, according to Claxton et al. (3), 'were cost-effective when introduced and improved the productivity of the NHS (tending to reduce the threshold). They then became much cheaper on generic entry dramatically increasing productivity (also tending to reduce the threshold further)'. Indeed, according to the latest published information, between 2004/2005 and 201 partially due to fa

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that off-patent prices bring to the NHS. Recently, these features have been successfully implemented in 'dynamic' CEA (18–22). The typical features of dynamic CEAs (above and beyond those from the conventional CEA) relate to time-dependent variations of the following:

- Drug prices (23): price erosion and off-patent price
- Size of the population treated (24): coverage level, market penetration and disease incidence

These features can be categorized as either exogenous or endogenous to the NHS, where endogenous refers to features under the control or influence of the NHS. Endogenous features include the periodic price cuts that cause price erosion during patent protection (18, 25), as well as the level of coverage and market penetration. Adjusting the ICER to account for historical trends in any endogenous features is of questionable value, because it could trigger an escalation in restrictions (e.g., an upsurge of price erosion). Hence, the approach proposed here excludes the endogenous features and incorporates the exogenous ones. Specifically, the proposed approach adds two features to the conventional CEA approach: incident patient population and a constant off-patent price from the time of patent expiry.

The conventional CEA approach makes the somewhat naïve assumption that drug prices re the predicta der to account d VBP approac ff-patent price, wh sed VBP approac -patent price ma he NHS. The dyna allocation of prese d future patients at makes the drug his conventi llocation of NHS res ent NHS resource

A different scale to the cost-effectiveness ratio is needed to quantify the total lifetime value of an innovative drug (value of innovation). The advantage of the incremental net health benefit (INHB) scale (27) is that it unifies the two CEA dimensions (health benefits and costs) into one (see Supplementary file) (27). The cumulative INHB (cINHB) function can be conceptualized as the net present value (NPV) function commonly used to forecast the profitability of an investment. The associated decision rule is to invest in the new technology if the cINHB≥0. The cINHB function captures the time-dependency of health benefits and costs, making it ideally suited for exploring the fluctuation in the value of a health technology over time (28). This allows the NHS to view the new technology as an investment and predict how long it will take to pay it off (2). That is, the NHS can predict the moment when the investment in a specific technology will break even (cINHB=0) to then start capitalizing the positive cINHB thereafter. From the NHS perspective, the sooner the 'break-even' occurs, the less risky the investment (2). The pattern of a typical cINHB function begins with negative values because the NHS accrues the drug costs before any health benefits are realized. The trend starts reversing with the realization of health benefits in the form of QALY gains. The break-even point (cINHB=0) occurs when the QALY gains fully offset the added costs. The cumulative INHB turns positive once the QALY gains exceed the added costs and, more importantly, it remains positive for as long the technology is relevant for clinical practice (2).

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implementation of the proposed VBP approach in a chronic disease setting, whereas the acute setting is illustrated in Fig. 3.

Fig. 1. Dashed line: cumulative incremental net health benefit (cINHB) along the patient time horizon under the conventional cost-effectiveness analysis (CEA) approach. Solid line: cINHB along the patient time horizon, adding incidence cohorts to the conventional CEA approach. Dotted line: cINHB extension of the solid line covering the drug lifetime (without accounting for the off-patent price).

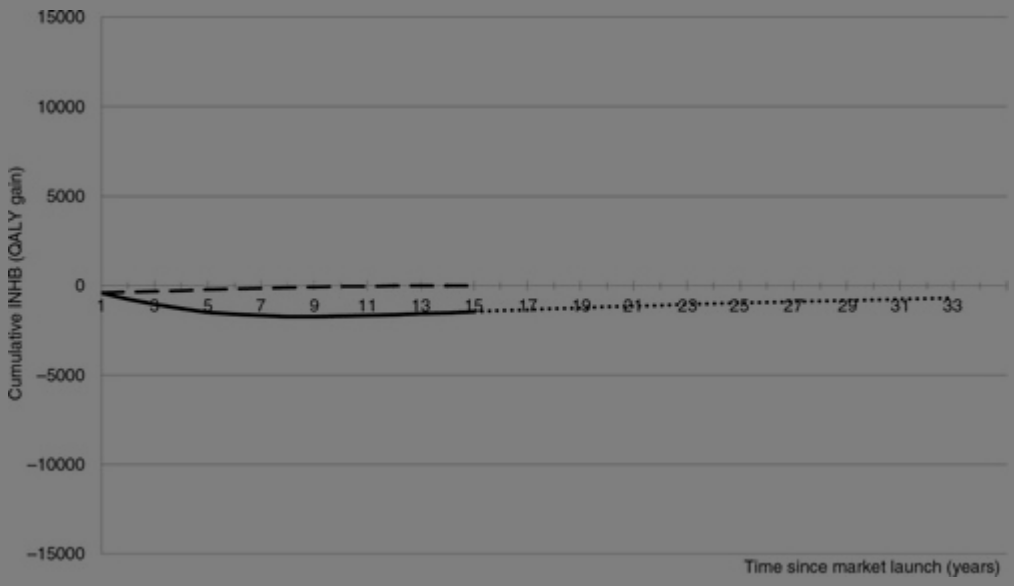

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Fig. 2. cINHB along the drug lifetime (in the chronic disease setting) accounting for the off-pater tted line: cINHB u thetical scenario during patent p

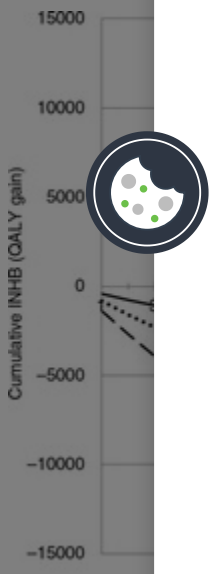

Fig. 3. cINHB along the drug lifetime (in the acute disease setting) accounting for the off-patent price. Solid line: cINHB under the conventional CEA approach. Dotted line: cINHB function under the proposed CEA approach. Dashed line: cINHB under a hypothetical scenario where the manufacturer captures 100% of the value of innovation during patent protection.

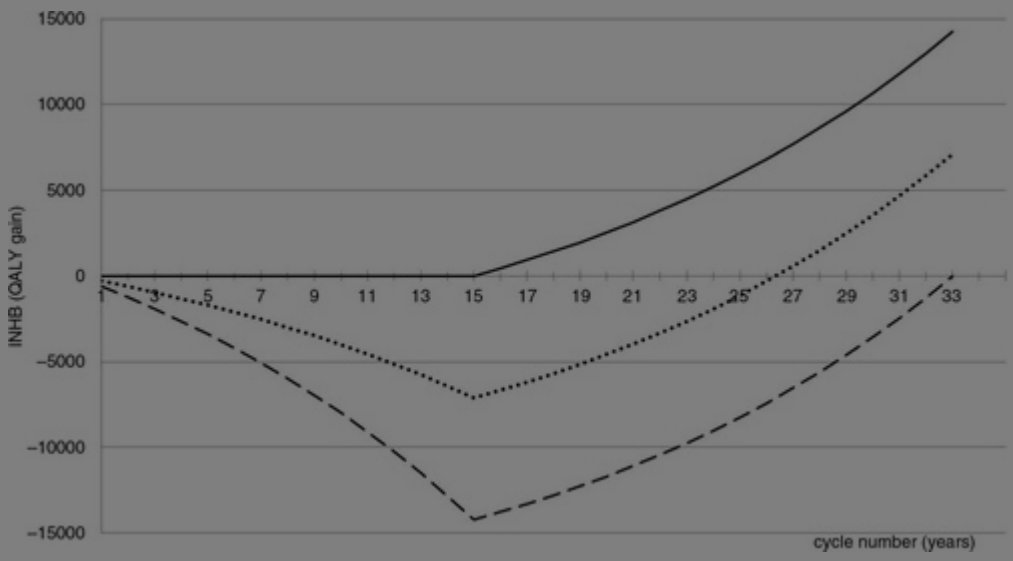

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Table 1. Description of two CEA case studies

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Figure

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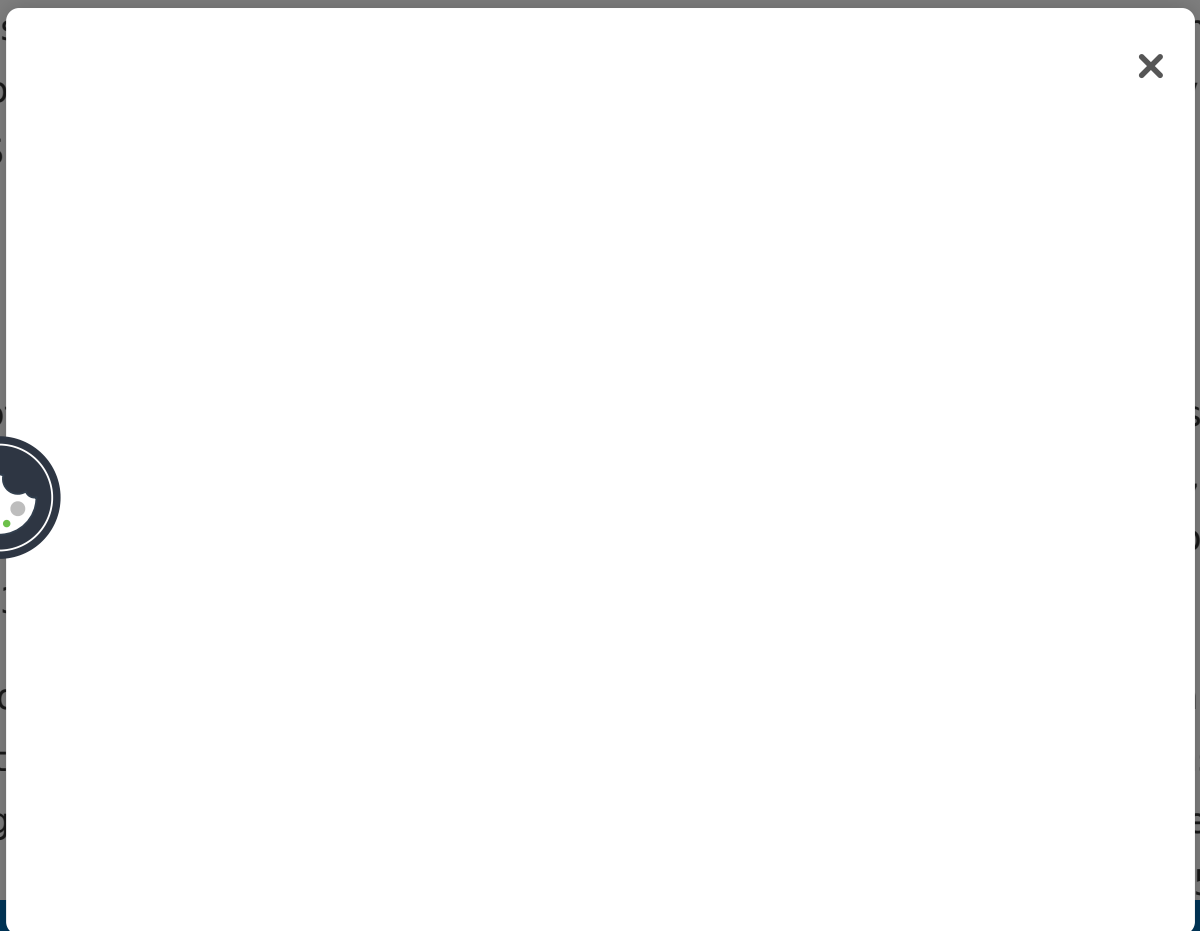
Figure 1 continuation: Adding incidence cohorts to the population modeled

The conventional CEA approach models an inception cohort without consideration to subsequent incidence cohorts. In line with other authors, we advocate modeling incidence cohorts because future patients will also benefit from the new drug (18, 32). Accounting for the entire patient population offers the additional advantage of internal consistency between the CEA and budget impact estimates, which is lacking under the conventional CEA approach (33).

The solid line in Fig. 1 includes the incidence cohorts. Fifteen years after market launch, this new drug is not a valuable investment for the NHS because it will have displaced more QALYs than it produces (cINHB<0).

Figure 1 continuation: The patient versus the technology-based time horizon

The time horizon for the technology is different to that of the patient. To capture the total value of an innovative technology requires consideration of the benefit it will bring to all patients during its entire market lifetime (dotted line). The total value of innovation is given by the cumulative INHB function at Year 33 (18) (i.e., the total lifetime value of innovation=−700 QALYs). The negative value of the dotted line indicates



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The denominator represents a hypothetical scenario wherethe manufacturer captures 100% of the total lifetime value of innovation during patent protection. Theoretically, this can be achieved if the manufacturer promises to sell the drug at a negligible price (e.g., production cost) after patent expiry, while constraining cINHB=0 at year 33. The dashed line represents this scenario, where the on-patent price of £57,500 per patient/year (=37,500+20,000) is set to capture 100% of the total lifetime value of innovation during patent protection.

Figure 2 continuation: The proposed VBP approach: sharing the value of innovation

The dashed line makes the unrealistic assumption that the health-care system is willing to let the manufacturer capture the whole value of innovation during the patent protection period. A more socially responsible proposal is to share it. In this case study, we apply a 50–50% split to illustrate the workings of the proposed approach. In addition, we assume an off-patent price of zero, representing a negligible cost of production after patent expiry. Note that the lower the off-patent price the higher the on-patent price.

The proposed VBP approach works by identifying the on-patent price (alongside the anticipated off-patent price) that guarantees that the manufacturer will capture 50% of the total

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Discussion

This article contributes to the much-needed debate about the role of CEA in incentivizing innovation. Specifically, the debate centers on the currently used conventional CEA for reimbursement decisions under a strict CEA threshold, and whether neglecting the value of innovation prevents VBP from capturing the inherent value of newly patented health technologies, leading to suboptimal incentives for future research.

The principle of VBP is intended to align the incentives for innovation with the needs of patients (2). However, as conventionally applied, VBP grants me-too drugs the same price as the originator if the two are clinically comparable (4), disincentivizing the development of truly innovative technologies (34). The integration of the value of innovation into VBP is intended to incentivize the development of truly innovative technologies by granting prices that better reflect their true lifetime value. Indeed, the proposed VBP approach will grant lower prices to me-too drugs compared to truly innovative medicines. This is possible because the dynamic CEA takes into account the cost savings generated by the earlier patent expiry of the originator.

Another important feature of the proposed VBP approach is that it accounts for the benefits
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dynamic perspective and helps minimize the up-front capitalization of benefits unrealized due to premature displacement. By accounting for the future off-patent price of the displaced drug, the price of the newer drug is pushed down. This is particularly impactful when the displaced drug is close to patent expiry and the price drop is expected to be substantial. Under such a scenario, the newer and better drug could be potentially priced lower that the older drug. Noticeably, this factor is not considered by the conventional approach; as a result, the newer and better drugs are always priced higher than older drugs, regardless of the time to patent expiry of the comparator. This questions the ability of the conventional approach to allocate future NHS resources efficiently.

The proposed VBP approach offers the opportunity to explicitly address the question of how innovation ought to be incentivized (38, 39). Specifically, price negotiations can benefit from a clear understanding on how the choice of price affects the share of value captured by manufacturers and health-care systems. Ultimately, the chosen (on-patent) price guarantees the appropriation by the manufacturer of the agreed share during the patent protection period. Our two case studies apply a 50–50% split for illustrative purposes. This compares to 15–85% (in favor of the health-care system) under the conventional VBP approach (38). Note that the larger the share captured by the manufacturer, the higher the drug price. To determine this split value, we recommend eliciting the share of value that society is willing to forgo in order to incentivize innovati

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by switching all prescribing to generics/biosimilars (assuming that the market is competitive) or by cutting the price of the originator. One provocative idea to help reduce uncertainty around the future off-patent price is to negotiate it at the time of market launch and to guarantee its sale for the same (inflation-adjusted) price for as long as the drug remains relevant for clinical practice. Under this scenario, a market access strategy devised to elude fierce competition after patent expiry is to accrue as much value as possible during the patent protection period. This can be achieved if the manufacturer offers an off-patent price equal to the production cost. The negotiation of off-patent prices at the time of market launch has three long-term consequences:

1. The progressive loss of viability of the generic/biosimilar industry, particularly as the off-patent prices of originators are negotiated downwards.

2. Assuming that the (financial) resources of the generic/biosimilar industry remain invested in health research, they will generate valuable innovation able to fulfill the still existing unmet medical need.

3. The industry as a whole is strongly incentivized to develop innovative technologies because there is limited revenue to be generated from off-patent products.

In line with Lundin and Ramsberg (40), we acknowledge that accounting for the value of innovation will increase spending on innovative technologies. However, the impact on health-c ess innovati prices of originato

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recommend its implementation as an additional scenario to the conventional CEA and then reporting the CEA findings comparing the results of each approach.

Conflict of interest and funding

This publication is independent research of the authors. This paper was conceived and originally drafted by SM in discussion with JR. SM is guarantor.

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Notes

To access the supplementary material for this article, please see Supplementary files under ‘Article Tools’.

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