Thank you for choosing to publish with us. This is your final opportunity to ensure your article will be accurate at publication. Please review your proof carefully and respond to the queries using the circled tools in the image below, which are available by clicking “Comment” from the right-side menu in Adobe Reader DC.*

Please use only the tools circled in the image, as edits via other tools/methods can be lost during file conversion. For comments, questions, or formatting requests, please use . Please do not use comment bubbles/sticky notes .

*If you do not see these tools, please ensure you have opened this file with Adobe Reader DC, available for free at https://get.adobe.com/reader or by going to Help > Check for Updates within other versions of Reader. For more detailed instructions, please see https://us.sagepub.com/ReaderXProofs.

<table>
<thead>
<tr>
<th>No.</th>
<th>Query</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Please note, only ORCID iDs validated prior to acceptance will be authorized for publication; we are unable to add or amend ORCID iDs at this stage.</td>
</tr>
<tr>
<td></td>
<td>Please confirm that all author information, including names, affiliations, sequence, and contact details, is correct.</td>
</tr>
<tr>
<td></td>
<td>Please review the entire document for typographical errors, mathematical errors, and any other necessary corrections; check headings, tables, and figures.</td>
</tr>
<tr>
<td></td>
<td>Please confirm that the Funding and Conflict of Interest statements are accurate.</td>
</tr>
<tr>
<td></td>
<td>Please confirm you have reviewed this proof to your satisfaction and understand this is your final opportunity for review prior to publication.</td>
</tr>
<tr>
<td>AQ: 1</td>
<td>Please supply date you last accessed the online source in reference 14.</td>
</tr>
</tbody>
</table>
Incremental Cost-Effectiveness Ratio and Net Monetary Benefit: Promoting the Application of Value-Based Pricing to Medical Devices—A European Perspective

Andrea Messori, PharmD¹, and Sabrina Trippoli, PharmD¹

Keywords
cost-effectiveness, medical devices, health economics, incremental cost-effectiveness ratio, net monetary benefit

In the in-hospital procurement of medical devices, the methodological advancements in cost-effectiveness and value-based pricing¹-³ have not been paralleled by an increased use of these methods in the real world. Differences in regulation and reimbursement of drugs and medical devices exist between different countries,⁴-⁷ but the need to take into account the clinical benefit is widely recognized, especially when the health care system is public.

Two pharmacoeconomic parameters represent the basic methodological tools to evaluate the cost-effectiveness of new treatments: the incremental cost-effectiveness ratio (ICER⁴,⁵) and the net monetary benefit (NMB⁸-¹²). These two indexes share an important feature because they both require the acceptance of quality-adjusted life-years (QALYs) as outcome measure, and refer to a pre-defined willingness-to-pay threshold (λ).

The ICER and the NMB are defined according to the following equations:⁸-¹²

\[
\begin{align*}
\text{ICER} &= \frac{\Delta C}{\Delta E} \\
\text{NMB} &= \Delta E \times \lambda - \Delta C
\end{align*}
\]

where ΔC is the incremental cost per patient and ΔE is the incremental effectiveness per patient (expressed in QALYs). In the case of a favorable pharmacoeconomic result for the new treatment, the (favorable) decision rule is when (ΔC/ΔE) < λ, if based on the ICER, or when (ΔE×λ – ΔC) > 0, if based on the NMB. Likewise, in the case of an unfavorable pharmacoeconomic result for the new treatment, the (unfavorable) decision rule is when (ΔC/ΔE) > λ or when (ΔE×λ – ΔC) < 0, respectively.

The ICER and the NMB differ under some important aspects. First of all, it should be recalled that value-based pricing has a practical importance particularly in countries where health care services are provided by public institutions, and value-based price negotiations are therefore mandatory for reimbursement approvals (eg, UK, France, Italy, Canada, and so on). At present, the value-based approach is applied much more frequently to drugs than to medical devices.⁵,⁹-¹⁴

One reason to explain this difference between drugs and devices is that price negotiations for drugs (a common practice outside the US) are traditionally conducted through a case-by-case approach; in other words, every negotiation of price, conducted by the regulatory agency, regards a single medicine, and so the reimbursement decisions are made one at a time. In contrast, in the field of devices, competitive tenders are the most common method of procurement, and furthermore, tenders are typically aimed at a class of devices (eg, drug-eluting stents, carotid artery stents, aortic valves, hip prostheses, knee prosthesis, and so on), not at a single product. This implies that price negotiations for devices are managed through the ICER (because 2 comparators only are considered, the new medicine and the standard of care), whereas price negotiations for devices within a given class (typically with 3 or more comparators) are managed through competitive tenders.

Recent reports, as well as simple theoretical considerations, have pointed out that the NMB facilitates the comparison of 3 or more comparators, whereas the ICER has a difficult application when the comparators are more than 2.⁸-¹⁰ Hence, the NMB appears to be more suitable than the ICER for evaluating multiple comparators among medical devices and for running competitive tenders on these products.

Quite surprisingly, the medical literature is very scanty concerning the use of cost-effectiveness methods for device procurement. In a PubMed query run on November 8, 2017 and based on the keywords “device* AND procurement AND cost-effectiveness,” only 12 items were identified from the whole database of more than 27 million articles. Apart from a pertinent paper written in Italian language,¹⁵ none of the

¹ HTA Unit, ESTAR, University of Florence, Regional Health System, Firenze, Italy

Submitted 12-Feb-2017; accepted 9-Mar-2018

Corresponding Author:
Andrea Messori, PharmD, HTA Unit, ESTAR, University of Florence, Regional Health System, Via di San Salvi 12, 50100 Firenze, Italy.
Email: andrea.messori.it@gmail.com
remaining 11 articles dealt with the application of value-based pricing to medical devices. The analyses reported in these articles were simply aimed at assessing the cost-effectiveness of a new therapeutic intervention but did not discuss the price of the devices or the opportunity to run a competitive tender.

Two papers published in the JAMA by Bach and Bach and Pearson have discussed the two main payment reforms proposed in the US (indication-specific pricing and value-based pricing). It should be noted that both indication-specific pricing and, to a greater extent, value-based pricing are aimed at linking the payment to the clinical benefit.

There is also a political issue on these topics; in fact, under the current US law concerning the price of pharmaceuticals, the Department of Health and Human Services is explicitly prohibited from negotiating directly with drug manufacturers on behalf of Medicare. Hence, if this regulation is not changed, value-based pricing in the United States would not be applicable to the drugs managed under Medicare, whereas its applicability could be more straightforward in the field of medical devices. On the other hand, the conceptual framework of the payment algorithms essentially affects the determination of prices, but does not strictly depend on whether the health care expenditure is funded by private insurances or by a public system.

In conclusion, we welcome the conduct of more economic studies focused on the application of value-based pricing to medical devices. In particular, real-world experiences are needed to describe value-based tenders that evaluate a specific device class. These studies are expected to maximise the clinical benefit derived from in-hospital funds allocated to devices.

Author Note
This paper was presented at the XIV HTAi Annual Meeting, Rome, June 17-21, 2017; abstract at http://www.xcdsystem.com/htai/files/HTAi_Rome_FullProgramme_DownloadVersion_20170606.pdf

Declaration of Conflicting Interests
No potential conflicts were declared.

Funding
No financial support of the research, authorship, and/or publication of this article was declared.

ORCID iD
Andrea Messori, PharmD http://orcid.org/0000-0002-5829-107X

References