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Tenders for the Procurement of Medical Devices: Adapting Cost-Effectiveness Rules to the Requirements of the European Public Procurement Directive

Andrea Messori, PharmD, Sabrina Trippoli, PharmD, Erminia Caccese, PharmD, and Claudio Marinai, PharmD

Abstract
Background: In evaluating 3 or more comparators, pharmacoeconomic analyses can be improved by using the methodology of net monetary benefit (NMB) as opposed to incremental cost-effectiveness ratio (ICER). NMB is particularly suitable for managing competitive tenders that evaluate 3 or more devices in the same lot. For scientific purposes, the methodology of NMB is perfectly adequate. However, when tenders are managed in European countries, the Public Procurement Directive states that the tender score for price should be kept separate from that of clinical benefits. As a result, the traditional mathematical approach of NMB must be rearranged to comply with this administrative requirement. Methods: In this report, we describe how the classic equations of NMB should be modified to achieve this purpose. The mathematical principle of proportionality, which is typical of the ICER, must be replaced by the principle of mathematical additivity, which is typical of NMB. Furthermore, to rearrange the scale of benefits according to the NMB, an estimate is needed of the minimum acceptable benefit converted into monetary units, which is associated with 0 in the benefit scale. Results: A detailed example is presented to explain the practical application of these mathematical equations. These equations are widely applicable in the field of implantable devices. Conclusion: Since the expenditure for medical devices in European hospitals is close to that of hospital medicines, tenders for the in-hospital procurement of devices may represent a decisive tool to manage sustainability and ensure access to innovation. In this context, the methodology for managing clinical outcomes through tenders requires a specific mathematical approach that we have described in the present article.

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

Introduction
In times of increasing therapeutic innovations, sustainability is becoming more and more critical, particularly for hospital health care. In Europe, the in-hospital process of procurement and tendering of medical devices plays an important role to ensure sustainability. Public contracting authorities at different levels (eg, national, regional, hospital level) are directly involved in these activities. In recent years, the administrative scenario of medical devices has become more homogeneous across different European countries, but a value-based approach is still very rarely employed to manage the acquisition of devices.

One important point is that tendering in the field of devices would ideally require a comparative cost-effectiveness evaluation of 3 or more products aimed at the same disease condition. For this reason, the net monetary benefit (NMB) has several methodological advantages in comparison with the incremental cost-effectiveness ratio (ICER); in fact, this latter parameter is more suited to evaluating two comparators with one another.1-6

On the other hand, if we examine the current European regulation of tenders,1 managing cost-effectiveness through tenders, as recommended by the Public Procurement Directive,7,8 requires that, within the same lot, the price offers made by each manufacturer are managed separately from the other determinants of cost and effectiveness. Even though, in general, the NMB is more suitable than the ICER for application in tenders,2,7 no examples have been published wherein the

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calculations of NMB have been split into a first part that incorporates prices, and a second part that incorporates the remaining parameters.

In this article, we describe a modified mathematical pathway for calculating the NMB, in which the price offers for the device are kept separate from the other parameters of both cost and effectiveness. Although our contribution might seem to have a merely theoretical value, its practical implications are very relevant, particularly in countries like Italy where the hospital expenditure for devices tends to be as great as that for hospital medicines. Increasing the competition between manufacturers of medical devices is a recognized goal of many health care systems. On the one hand, the methods to achieve this goal currently remain outside any reasonable standardization, and essentially depend on local initiatives based on erratic methodologies; on the other hand, the main determinant of clinical value (ie, the magnitude of the clinical benefit) continues to play a minimal, or at best an unpredictable, role in the procurement process so that there is no guarantee the most cost-effective device among the various comparators is given priority.

Methods

Theoretical Background

Although the most common application of NMB incorporates into a single sum all pharmacoeconomic parameters (including the device price), the Public Procurement Directive\(^7\)\(^8\) states that the price offers made by the manufacturers should be managed in separate calculations. In particular, the scoring scale that handles quality (including clinical benefits) should be kept separate from the scoring scale that handles the price offered for individual devices.

In Italy, the scoring scale for quality/benefits typically ranges from 0 to 70, while the scoring scale for prices ranges from 0 to 30. Also, a "starting price" is set before running the tender so that all price offers should be equal to or less than this starting price. In more detail, if the offer is equal to the starting price, the price score for the device is 0; likewise, if the offer is less than the starting price, the score is \(\geq 0\) and \(\leq 30\). This unit of measurement (equal to 1/30th of the starting price) is used on the one hand for managing the price-related score, but on the other also for managing the information about quality/benefits. For this purpose, the above-mentioned unit of measurement has been referred herein as "virtual monetary unit" (VMU).

**Definition of Net Monetary Benefit**

The NMB for each device is defined as follows:

\[
\text{NMB} = \frac{\text{clinical benefit of device converted into a monetary equivalent} - \text{[cost of device]}}{\text{[cost of other treatment - related costs]}}
\]

where

- the clinical benefit of the device (expressed in QALYs per patient) is converted into a monetary benefit (expressed in Euros) by using a predetermined cost-utility threshold; in the numerical example, we used €60,000 per QALY because, in our opinion, this value could be the most suitable for application to implantable medical devices;
- the cost of the device is expressed in Euros;
- the other treatment-related costs (OTRCs) are represented by a series of items that are qualitatively the same across all treatments under examination but are quantitatively different. These OTRCs do not include the cost of the device, but always include the other costs incurred in the short term (eg, accessories). In addition, depending on the specific disease condition and the type of economic information available, these OTRCs may also include the costs incurred by the patients in the long term.

In this paper, we have used the cost-utility threshold of €60,000 per QALY, but other values can be used as well. In the UK, the most common threshold is £30,000 per QALY; in the US, no cost-utility threshold is formally recognized, but values ranging from US$50,000 to US$200,000 have been reported in the medical literature.

To make the above NMB definition compliant with the Public Procurement Directive\(^7\)\(^8\), the term that incorporates the "cost of the device" should be left out from the equation and handled separately. In other words, the NMB must be split into two parts: the first corresponds to the device price while the second includes the remaining algebraic sum of monetary benefits and costs.

**Definition of Incremental Cost-Effectiveness Ratio (ICER)**

Using the same symbols and the same notations employed for the NMB, the ICER for device A compared with device B is defined as follows:

\[
\text{ICER}_{A\rightarrow B} = \frac{\text{[cost of device A] + [other treatment - related costs for device A]}}{\text{[QALYs per patient for device A]}} - \frac{\text{[cost of device B] + [other treatment - related costs for device B]}}{\text{[QALYs per patient for device B]}}
\]
The ICER is favorable when its value remains below the cost-effectiveness threshold, and is unfavorable when its value exceeds the threshold.

**Calculation of QALYs Per Patient**

Since this subject is covered by a wide literature, explaining how QALYs are calculated is beyond the purposes of the present paper. In general, QALYs represent the product of the duration of survival multiplied by the quality-of-life expressed on a 0-to-1 scale ("utility"). All the methods that handle these calculations are well standardized. In most cases, this calculation relies on a simulation model that, over the prespecified duration of survival, predicts the occurrence of some clinical events (namely, postoperative infections and hernia recurrence in the model described below). Each clinical event usually determines a change in utility and, in this way, influences the calculation of QALYs. The calculation of QALYs is based on well-standardized methods. No discounting of QALYs is employed in the calculations presented in this paper.

**Calculation of Costs Per Patient**

Also in this case, a simulation model predicts the occurrence of some clinical events (the same as before, i.e., postoperative infections and hernia recurrence, in the model described below). Each clinical event usually determines an increase in costs and, in this way, influences the calculation of NMB. No discounting of costs is employed in the calculations presented in this paper.

**Definition of VMU**

This parameter, expressed in Euros, is defined as follows:

\[
\text{NMB} = \frac{\text{[clinical benefit of device converted into a monetary equivalent]}}{\left(\text{[cost of device] + [other treatment - related costs]}\right)}
\]

\[
\text{VMU} = \frac{\text{[starting price of the tender]}}{30}
\]

where the starting price (in Euros) is the maximum cost of the device allowed by the tender. This implies that all price offers (prices) can be accepted upon the condition that prices should be less than or equal to the starting price.

**Calculation of the Minimum Acceptable Monetary Benefit**

This parameter (MAMB\textsubscript{VMU}) requires that a cut-off of the NMB is predeclared, which corresponds to a worst-case scenario identified according to the same model that calculates both QALYs and NMB. This worst-case scenario assumes a threshold rate for each clinical event on the side of worsened outcomes. For example, in the model described herein, the threshold rate is 30% for postoperative infections and is also 30% for hernia recurrence at 2 years.

The parameter MAMB\textsubscript{VMU} corresponds to the value of NMB calculated at the threshold rate for all clinical events divided by VMU. Hence,

\[
\text{MAMB}_{\text{VMU}} = \frac{\text{NMB at threshold rate for all clinical events}}{\text{VMU}}
\]

**Calculation of the Tender Score Regarding Price Offers**

This parameter, which is denoted as score\textsubscript{price}, is calculated from the following equation:

\[
\text{score}_{\text{price}} = 30 \times \left(1 - \frac{\text{price}_{\text{starting}}}{\text{price}}\right)
\]

where price\textsubscript{starting} is the starting price of the tender.

**Calculation of the Tender Score Regarding Quality**

This calculation is made according to the following equation:

\[
\text{score}_{\text{quality}} = \text{NMB}_{\text{VMU}} - \text{MAMB}_{\text{VMU}}
\]

where NMB\textsubscript{VMU} = NMB / VMU and MAMB\textsubscript{VMU} has previously been defined.

**Reparameterization**

If any of the calculated values of score\textsubscript{quality} exceeds the limit of 70 points, the following post-reparameterization must be applied.

Firstly, a correction factor (correction\textsubscript{factor}) is calculated as:

\[
\text{correction}_{\text{factor}} = \max\{\text{score}_{\text{quality}} - 70\}
\]

where max\{score\textsubscript{quality} (expressed in VMU) is reparameterized by the highest among all values of score\textsubscript{quality}.

Then, all the values of score\textsubscript{quality} are recomputed as:

\[
\text{score}_{\text{quality}_{\text{new}}} = \text{score}_{\text{quality}} - \text{correction}_{\text{factor}}
\]

The rationale for this reparameterization is as follows. If one adds or subtracts the same number to a series of different values of score\textsubscript{quality}, this introduces no change in the individual differences between these values; accordingly, although values of score\textsubscript{quality} greater than 70 make sense, the absolute post hoc reparameterization is employed in which the same number is subtracted from all values of score\textsubscript{quality} (so that all these values remain below 70). In our experience with our tender procedures, these cases are extremely infrequent.

**Detailed Presentation of a Numerical Example**

This example considers a series of different biological meshes employed for the repair of an incisional abdominal hernia. The clinical end-point evaluated in this analysis includes the rate of postoperative infection (within 30 days) and the rate of hernia recurrence (within 2 years).

The analysis employs the following two parameters with different values for the different devices under examination:
Table 1. Our Analysis Uses the Following 10 Parameters Set at the Same Value for All Devices.

1. COST\textsubscript{infection}: this parameter represents the extra cost for each case of infection occurring during the hospitalization (first 30 days) in which the mesh has been implanted; in the present model, COST\textsubscript{infection} has been calculated as the difference between the tariff of the DRG including a complication (€5962.25) and the tariff of the same DRG with no complications (€2340.01). Hence, COST\textsubscript{infection} = €5962.25 - €2340.01 = €3622.24. Clearly, the payer’s perspective is adopted, not the hospital one.

2. COST\textsubscript{recurrence}: this parameter represents the cost for each case of hernia recurrence occurring in the first 24 months after surgery; it is calculated as the average tariff (weighted for the number of patients) of DRGs 150, 151, 159, and 160; accordingly, COST\textsubscript{recurrence} = €3003.12.

3. Time horizon: 10 years (managed as 3650 days).

4. WTP (willingness to pay threshold): its value has been assumed to be €60,000.\textsuperscript{10}

5. Starting price of the tender: €2000 per mesh.

6. Virtual monetary unit (VMU): this parameter is defined as follows: VMU = (price\textsubscript{reimbursement} / 30) = 2000 / 30 = 66.67

7. Utility in the absence of complications such as infection or recurrence: its value has been assumed to be 0.70 (as an approximation of the values reported by Fischer et al\textsuperscript{11}), which ranged from 0.694 (page 649, second column, third paragraph\textsuperscript{11}) to 0.707 (page 653, Table 3\textsuperscript{12}).

8. Utility with infection: its value is 0.451 according to Fischer et al\textsuperscript{11} with a duration of 14 d.

9. Utility with recurrence: its value is 0.528 according to Fischer et al\textsuperscript{11} with a duration of 90 d.

10. Minimum acceptable monetary benefit (MAMB); this parameter (expressed in VMU) is calculated from the value of NMB\textsubscript{VMU} estimated at the threshold rates of the two clinical parameters (threshold rates: 30% for both rate\textsubscript{infection} and rate\textsubscript{recurrence}). Under these conditions, MAMB\textsubscript{VMU} = 6255.98 (see Table 2).

\[
\text{rate}_{\text{infection}} = \text{percentage of infections observed over 30 days after surgery}
\]

\[
\text{rate}_{\text{recurrence}} = \text{percentage of hernia recurrences observed over 24 months after surgery}
\]

These two parameters are device specific. In addition, our analysis uses 10 parameters set at the same value for all devices (Table 1).

It should be noted that since the tender assumes a starting price of €2000 per mesh, a monetary unit ("virtual monetary unit," VMU) is implicitly declared in this definition according to the 0-to-30 scale. The range from 0 to 30 points corresponds to €0 to €2000; hence, in the score defined as score\textsubscript{quality}, the value of each point is 1/30th of €2000, that is, €66.67. In addition, to make the units of score\textsubscript{quality} identical to the (pre-defined) units of score\textsubscript{price}, VMU has been adopted as the common units for both scores. In more detail, the value of NMB initially expressed in € has been converted into a value expressed in VMU. As an example, if one considers device A, the price of which (€1036.62) is €36.62 more than the price of device B (€1000), and device B, these two devices will receive the same overall score (score\textsubscript{overall} = score\textsubscript{quality} + score\textsubscript{price}) if the infections observed with A are 1 percentage point less than the infections observed with device B. In fact, reducing the rate of infections by 1% (in absolute terms) can be assigned a monetary value equal to the extra cost of an infection (€3662.24) divided by 100 (ie, €36.62).

Another mathematical observation is that in the scale of quality (maximum value = 70), the property of mathematical additivity applies, but not that of direct proportionality.

This article does not contain any studies with human or animal subjects performed by any of the authors.

Results

Table 2 shows, step by step, how the mathematical calculations proceed with reference to a hypothetical example. In the example, the sum of score\textsubscript{quality} (8.79 points) and score\textsubscript{price} (15 points) generates the overall tender score (23.79 points).

Table 3 shows the evaluation of different abdominal meshes characterized by a different effectiveness, and how these differences have impacted on the device-specific values of NMB. In this example, the most costly mesh ranks first in the tender because of its superiority in the two clinical outcomes. The final conversion into tender points of quality and tender points of price is not shown because the sum of these two kinds of points by definition must reflect the qualitative ranking that can be estimated from the values of NMB (excluding price) minus the values of price.

Discussion

The present study was designed as a development of our previous work published on this topic\textsuperscript{7,8} because we adjusted our tendering model to make it compliant with a specific requirement of the Public Procurement Directive.\textsuperscript{7,8} This requirement separates the 0-to-30 scale of prices from the 0-to-70 scale (that, in the framework of the NMB model, includes the remaining costs and benefit with benefits converted into their monetary equivalent). Separating these two scales does not introduce any mathematical bias in the model because our tendering methodology ensures that the same unit of measurement (ie, the virtual monetary unit) is employed in the two above-mentioned scales. In this way, although the mathematical complexity of the model increases to the same extent, the advantage is that tenders remain "connected" to the theory of cost-effectiveness modeling. Another advantage is that this approach allows us to keep the price offers confidential as long as the other parameters of the tender (including device-specific clinical benefits) are being evaluated.

All in all, our revised model permits to apply the principle of cost-effectiveness to the procurement of devices in all cases where tenders are used to identify the device with the best cost-effectiveness profile. As a result, the least expensive device is not necessarily preferred if another
1) Initial assumptions

rate\_infection = 13.8%,
rate\_recurrence = 31.8%,
price\_starting = €2000

2) Calculation of quality-related tender score (score\_quality)
   a) Calculation of QALD (without including the disutility resulting from infections and recurrences):
      QALD = 3650 × 0.70 = 2555
   b) Calculation of infection-related disutility loss (DELTA\_infection) with reference to utility\_baseline:
      DELTA\_infection = 14 × (0.70 – 0.451) = 3.4860
   c) Calculation of recurrence-related disutility loss (DELTA\_recurrence) with reference to utility\_baseline:
      DELTA\_recurrence = 90 × (0.70 – 0.528) = 15.48
   d) Subtraction from QALD of disutility losses for infections and recurrences:
      QALD = 2555 – (DELTA\_infection × rate\_infection/100) – (DELTA\_recurrence × rate\_recurrence/100) = 2549.593
   e) Conversion of QALD into their monetary equivalent based on WTP:
      NMB\_partial = 60,000 × QALD/365 = 4,191,117.22
   f) Subtraction from NMB\_partial of infection-related costs and recurrence-related costs:
      NMB\_excluding device \( \approx \) NMB\_partial – (COST\_infection × rate\_infection/100) – (COST\_recurrence × rate\_recurrence/100) = 417651.41
   g) Conversion of NMB from € to VMU:
      NMB\_VMU = NMB / VMU = 417,651.41/66.667 = 6264.77
   h) Calculation of MAMB\_nom:
      MAMB\_nom = NMB (assuming rate\_infection = 30% and rate\_recurrence = 30%) / VMU = 417,065.19/66.7 = 6255.98
   i) Calculation of quality-based tender score (score\_quality):
      score\_quality = NMB\_VMU – MAMB\_nom = 6264.77 – 6255.98 = 8.79

3) Calculation of price-related tender score
   score\_price = 30% × (1 – offer\_2000/100) = 15

   where 2000 is price\_starting expressed in € and offer\_2000 is the offer made by the manufacturer expressed in €; in this example, offer\_2000 = €1,000.

4) Calculation of overall tender score
   The overall tender score is the sum of quality-related score and price-related score:
   score\_overall = score\_quality + score\_price = 8.79 + 15 = 23.79

*The series of calculations presented in this table should be repeated as many times as the number of price offers received in the tender. In this example, no reparameterization of score\_quality was needed. Disutility is defined as 1 – utility; utility is expressed as quality-adjusted life days (QALD).

Table 3. Comparison of 4 Different Meshes.*

<table>
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<tr>
<th>Mesh</th>
<th>Infections at 30 d (%)</th>
<th>Recurrences at 24 mo (%)</th>
<th>NMB_€ (Column A)</th>
<th>Improvement in NMB Compared With the Hypothetical Mesh Corresponding to MAMB (€)</th>
<th>Price Offer (€)</th>
<th>Final Result (€)*</th>
<th>Final Ranking</th>
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<td>Mesh A</td>
<td>41% 19/44</td>
<td>54.2% 30</td>
<td>415,257</td>
<td>Excluded because its NMB is less than MAMB 0</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
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<td>Hypothetical mesh with 30% infections and 30% recurrences</td>
<td>30% (hypothetical) 30% (hypothetical) 417,065 assumed as MAMB</td>
<td></td>
<td></td>
<td></td>
<td>1,000</td>
<td>416,065</td>
<td>Last (ie, third)</td>
</tr>
<tr>
<td>Mesh B</td>
<td>29% 19/59</td>
<td>26.4% 30</td>
<td>417,307</td>
<td>242</td>
<td>1,200</td>
<td>416,107</td>
<td>Second</td>
</tr>
<tr>
<td>Mesh C</td>
<td>21% 17/85</td>
<td>28.0% 30</td>
<td>417,557</td>
<td>492</td>
<td>1,400</td>
<td>416,157</td>
<td>First</td>
</tr>
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</table>

*It should be noted that the tender is awarded to Mesh C, which is the most costly but also the most effective.

*Data extracted from Craciun.12

*All values of NMB in this table should be intended as incorporating all parameters of our equation except price.

*All of these values are hypothetical.

*Calculated as [column A] – [column B].
device determines an increase in effectiveness with a “reasonable” increase in its price.

In the European context, the Legislative Decree n. 50/2016 and subsequent amendments (in particular Legislative Decree n. 56/2017) are the current reference for this topic.1 Hence, the mathematical calculations involved in competitive tenders on implantable medical devices should conform not only to value-based methods and cost-effectiveness principles but also to the administrative requirements regarding the scores for quality and price. Since the application of value-based methods is still scarce in Europe,13 and has a limited frequency also in the US,14 the computational advancement described herein is hopefully a useful step forward.

In conclusion, the current practice of tendering in Europe is becoming more and more homogeneous in the field of medical devices, but there is still a long way to go. Although, by law, the two components of quality and price must now be systematically considered in all tenders, this is not equivalent to performing a cost-effectiveness evaluation. Cost-effectiveness is becoming more popular for the selection of the technologies, but is still very rarely used in public procurement of medical devices.1,13

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