



Using evidence-based management in practice: a case study on the pricing and reimbursements of medicines

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Introduction

In the last twenty-five years, there were several initiatives for European Member State (MS) collaboration for pricing and reimbursement. Initially, these were driven by the MSs, were voluntary, lacked coordination between them, and were not systematic (World Health Organisation [WHO] 2015).

Council Conclusions of different Presidencies of the Council of the European Union supported MS-driven voluntary cooperation on health technology assessment (HTA) (Council of the European Union, 2016; Council of the European Union, 2017). Pricing and reimbursement authorities of most MSs collaborated within the 'European Network for Health Technology Assessment' (EUnetHTA) (EUnetHTA, 2018); however, difficulties were experienced with implementation (European Commission, 2016). In 2018, the European Commission came up with a legislative proposal: 'Proposal

for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU' (European Commission, 2018). In parallel, initiatives for the development of 'regional co-operations' within groups of MSs had started, and Malta was signatory of the Valletta Declaration.

At that point, in 2017, experience showed that, in practice, collaboration for activities of pricing and reimbursement was difficult, challenging, and slow. There was lack of evidence on positive outcomes from collaboration, and



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tangible impact on access to medicines had not been proven. The researcher was involved at the policy level, as well as a practitioner. Conscious of the fact that her direct involvement may increase her level of bias and aware of the limited access to evidence, the researcher set to adopt an evidence-based approach to review the available evidence. It was considered that this evidence would strengthen the basis for decision making with respect to MS collaboration, with the objective of supporting ongoing initiatives and future developments. The researcher decided to carry out research to support this problem which was being faced in practice. The study needed to bridge practice with a valid academic approach.

This publication reflects the work done for a dissertation submitted in 2019 in partial fulfilment of the requirements of an MA in Management at the University of Malta, 'Attitudes, perceived impacts and motivational factors for European Member State collaboration for pricing and reimbursement of medicines: a review of the evidence' (Vella Bonanno, 2019). A publication in a scientific journal followed so that the evidence could be shared with academics and practitioners in the field (Vella Bonanno et al., 2021).

Methodology

The study of MS collaboration required a tradition of naturalism, whereby the researcher tries to understand the environment of the research and describes the setting, the interactions, and networks as they

are within the context of the study, the European pharmaceutical framework.

The study started with a review of the literature as a basis for the building of a theoretical framework, setting the research questions and adoption of the correct methodology. Information from the literature was used to build a 'logic model' of the system for pricing and reimbursement. As described in Barends and Rousseau (2018, p. 195-196), a logic model pictures the processes and is a "graphical representation" of the links between inputs (resources), activities and processes (what is done to inputs), outputs and outcomes (immediate results and long-term consequences). Collaboration is a challenging task, and three main concepts were identified: attitudes, measurement of perceived impacts, and study of motivational factors. Frameworks were built for these concepts based on organisational theories relevant to cooperation between MS regulatory organisations (Baldwin et al., 2012).

The research question required the collection of evidence about the topic. The model for evidence-based management from Barends and Rousseau (2018) described in Figure 1 was considered adequate to support the objectives of the study and was used to design of the research. This model shows that practitioners should base decisions on evidence obtained from four sources of evidence: scientific literature and empirical studies, organisation internal data, practitioners' professional expertise, and stakeholder values and concerns. The researcher identified four methods to get the best available evidence to cover these four sources: collection

of evidence from published scientific literature, collection of evidence from grey literature, evaluation of the ‘Study on impact analysis for policy options for strengthened EU cooperation on Health Technology Assessment, Final Report’ ‘the Study’ (European Commission, 2017), and a focus group with practitioners in the field.

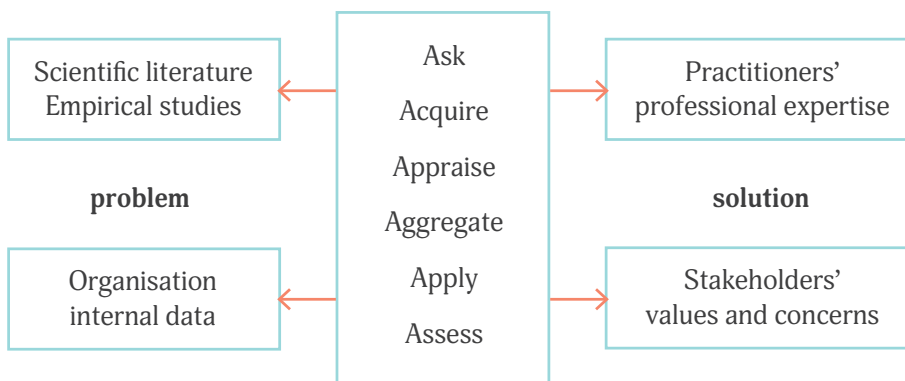


Figure 1. Model for the sources of evidence and for the steps for collection of evidence for evidence-based management decisions adopted from Barends and Rousseau (2018, p. 5)

Table 1 shows a mapping of the evidence collected from the different methods. Some of the methods produced evidence from more than one of the four sources of evidence. The evidence collected for this research was qualitative.



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Table 1. Mapping of the evidence collected through different methods from the four sources of evidence

Methods		Sources of evidence			
		Scientific literature & studies	Organisation internal data	Practitioner professional expertise	Stakeholder values and concerns
1. Analysis of published scientific literature		✓		✓	
2. Analysis of grey literature	Various documents and reports	✓	✓	✓	
	Websites and documents of collaborations		✓		
	Conference proceedings		✓	✓	✓
	Results of WHO interviews with members of the regional cooperations		✓	✓	
	Reports from stakeholder groups / organisations: patient organisation, industry				✓
	Media reports		✓		✓
3. Analysis of Study on impact analysis for Policy Options for strengthened EU cooperation on Health Technology Assessment Final Report					✓
4. Focus group with practitioners (primary data)			✓	✓	

The ‘Framework’ built was used to support the collation and presentation of the evidence in relation to the research questions of the project and to support the thematic analysis of the evidence. The evidence for each method was collated and analysed by thematic analysis. Thematic analysis entails presenting the evidence as it is “telling it like it is” (Bryman & Bell 2011, p. 572). This analysis was done as systematically as possible.

The collection of evidence and its presentation involved six definite steps: ask, acquire, appraise, aggregate, apply and assess (as represented in the middle of the model in Figure 1). These Steps were formulated into the process for this study as per Table 2.



Having evidence generated from different sources resulted in a much wider coverage of evidence and of perspectives of stakeholders.

Table 2. The process of the study

Step	Description
Step 1 Ask	<ul style="list-style-type: none">• Description of the situation and challenges with Member State collaboration (the problem)• Defining the scope of the study
	<ul style="list-style-type: none">• Presentation of the theoretical framework and relevant literature• Setting the research questions and the objectives of the study
Step 2 Acquire	<ul style="list-style-type: none">• Setting the process for the study (presented in this Table)• Building a logic model of the process for pricing and reimbursement• Building a 'Framework' for collection of the evidence for the concepts being studied: attitudes, perceived impacts (benefits and risks) and motivational factors (barriers and facilitators).• Using different methods to collect and present the evidence: scientific literature, grey literature, evaluation of 'the Study', focus group discussion
Step 3 Appraise	<ul style="list-style-type: none">• Appraising of the evidence - critical appraisal of the evidence from each method for its trustworthiness and relevance• Evaluation of the balance and coverage of the evidence
Step 4 Aggregate	<ul style="list-style-type: none">• Aggregation and presentation of the evidence from the different sources within the themes of the 'Framework'• Corroboration and evaluation of the evidence from the different sources to see if there were gaps or paradoxes in the evidence.
Step 5 Apply Step 6 Assess	<ul style="list-style-type: none">• Inferences for the use of evidence-based management in practice• Application of the evidence for collaboration between Member State authorities for pricing and reimbursement• Use of the evidence to assess ongoing initiatives for Member State collaboration for pricing and reimbursement• Implications of the evidence for future initiatives for MS collaboration for pricing and reimbursement

Results

Details of the results can be accessed from the published dissertation (Vella Bonanno 2019). The results of the different methods were presented separately. The evidence acquired from each of the four methods was appraised with respect to sourcing, trustworthiness, and relevance. Having evidence generated from different sources resulted in a much wider coverage of evidence and of perspectives of stakeholders.



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The amount of evidence about the different topics varied depending on the interest and perceived impacts of the topic and the power of the stakeholders involved/ affected.

The evidence was aggregated. The level of corroboration was evaluated and gaps in evidence were identified. The Logic Model depicting the system for pricing and reimbursement of medicines was prepared at different points in time to present the longitudinal data and record changes. The Logic Model at the end of the study was presented in Figure 2. The aggregated consolidated information on attitudes on collaboration, perceived impacts (benefits and risks) from collaboration and motivational factors (challenges/barriers) were also aggregated within the themes of the respective frameworks. Initiatives for collaboration between MSs were a relatively new concept, therefore there was limited experience with MS collaboration and few decisions were made as part of ongoing initiatives. The evidence

was applied to make inferences for the application of the evidence and to support future decisions in this regard.

The application of evidence–based management methodology in practice

This project was carried out as an academic research and needed to address the requirements of an academic dissertation. It also followed the specific methodology of evidence-based management from Barends and Rousseau (2018). The two complemented each other.

This dissertation showed that the methodology of evidence-based management as presented by Barends and Rousseau (2018) was robust and systematic and appropriate for management practice, particularly for practitioners of evidence-based management. This methodology is labour intensive and takes up time and resources. In practice, it would be recommendable



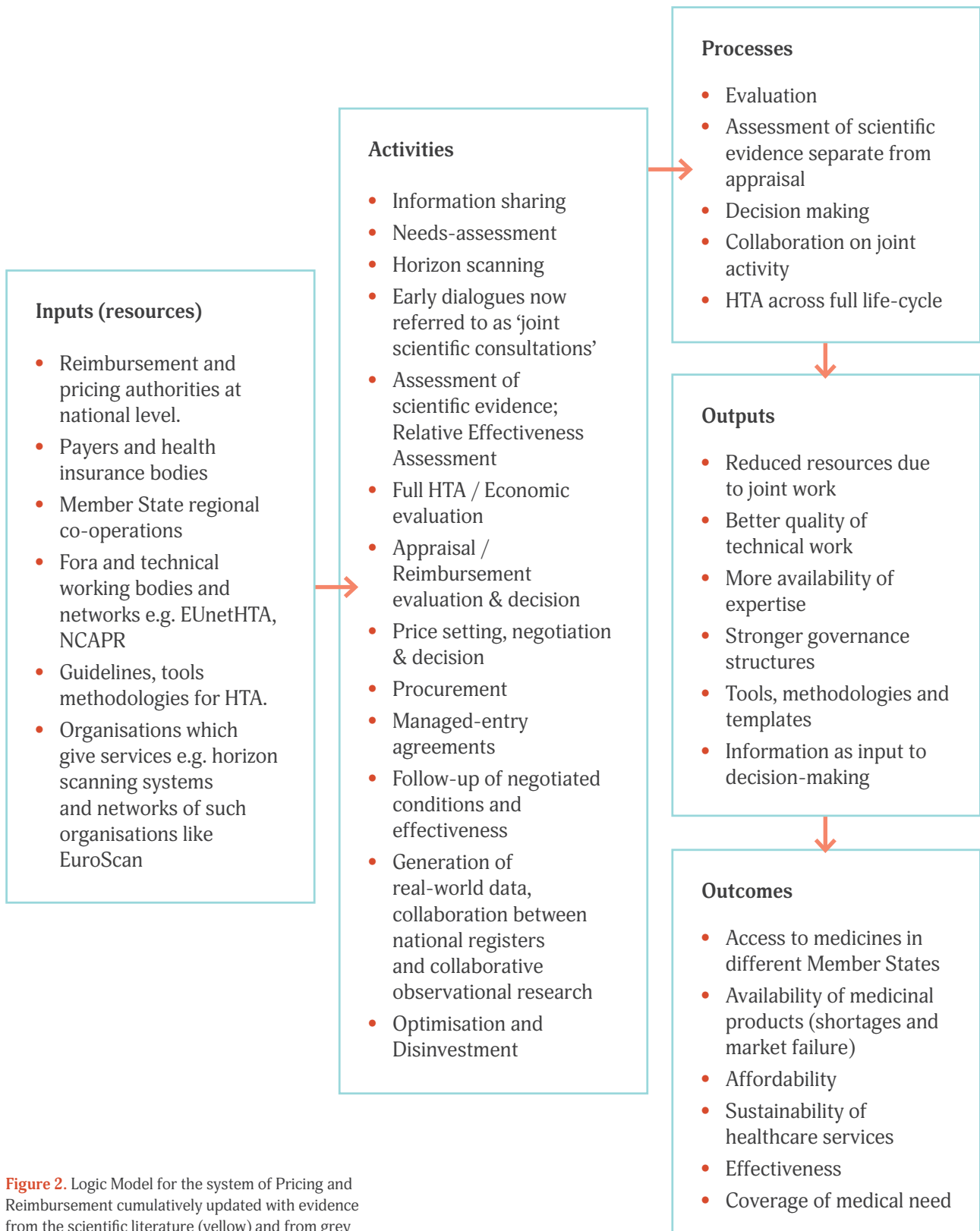


Figure 2. Logic Model for the system of Pricing and Reimbursement cumulatively updated with evidence from the scientific literature (yellow) and from grey literature (grey)



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to reserve this methodology to generate evidence for decisions which are of highest strategic importance.

Methods which are considered as weak sources of evidence in the pyramid for hierarchy of evidence, such as opinion papers and grey literature, were found to be strong sources when it came to studying concepts like attitudes, perceptions on impacts and motivational factors, particularly if the methods collected evidence from a comparatively representative sample of stakeholders. Thus, the choice of method depends on the best-available evidence for the concept being studied.

The aggregation of the evidence from the different methods, the corroboration of the evidence and the consideration of the appraisal of the different sources of evidence within the process enabled the building of a holistic and realistic picture. The approach by Denyer and Tranfield (2009, p. 19) for the “conscientious explicit and judicious use of the best available evidence” was highly applicable. The method of this study was ‘conscientious’, and great effort was dedicated to obtain what was considered the best-available evidence. The collection and aggregation of evidence was very time consuming, systematic, and laborious; and it

was ‘explicit’, particularly using a ‘Framework’ with clear themes and specific indicators for the themes. The judicious use of the evidence came through the appraisal and aggregation of the evidence.

Evidence-based decision making involves the intersection of evidence from the ‘four sources of evidence’. The prioritisation of the methods for collection of evidence and the adoption of a “fit for purpose” approach (Briner & Denyer, 2012, p. 328) for addressing the research questions and for comprehensive coverage of evidence from the four sources was found to be plausible for evidence-based management.

The ‘Framework’, which was built with the support of the literature was adequate to support the EU Pharmaceutical system and to study of the concepts of attitudes, perceived impacts and motivational factors. The ‘Framework’ supported the different steps of the study including collection of the evidence from the different methods and the aggregation of the evidence. The experience of using Logic Models for this research was very positive and the use of Logic Models to represent complex real life processes is commendable. The ‘Framework’ set by this research for measurement of attitudes, perceived impacts and motivational factors can be adapted to measure these concepts for other

research and practice questions. This research showed that it is important to consider the ‘external factors’ that impact the process, such as stakeholders, political influences, and so on.. It was very important to understand the different political positions and powers of the stakeholders concerned. Whenever a main strategic decision is to be taken, an exercise of influence / interest mapping should be done formally, using the best evidence, and incorporating the involvement of the different stakeholders concerned.

Conclusion

This project was a good case study for evidence-based management in health policy and regulation and showed the importance of evidence from different sources for decision making. The methodology for evidence-based management set by Barends and Rousseau (2018) which was adopted was found to be systematic, enabled balance of the evidence, filled gaps, and addressed biases. The evidence from this study can be used for future decisions on collaboration. The study supported the role of evidence-based management and can inform the use of evidence-based management methodology for policy and regulatory initiatives in different areas of public policy not just in healthcare.

Limitations of the study

The fact that the researcher is also a practitioner could introduce researcher bias. Care was taken to keep as objective as possible and to clearly state what was from the evidence and what was the opinion of the researcher.

Data Availability Statement

This study was conducted as a dissertation by Patricia Vella Bonanno. The full dissertation, including the raw data is published by the Library of the University of Malta (Vella Bonanno 2019). A paper was published from this dissertation (Vella Bonanno et al., 2021).

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