Received: 29 July 2022 | Revised: 23 August 2022 | Accepted: 24 August 2022

DOI: 10.1002/hec.4600

SUPPLEMENT PAPER

Health Economics WILEY

Pushing the boundaries of evaluation, diffusion, and use of medical devices in Europe: Insights from the COMED project

Aleksandra Torbica[1] | **Rosanna Tarricone**[1] | **Jonas Schreyögg**[2] | **Mike Drummond**[3]

[1]Centre for Research on Health and Social Care Management (CERGAS), Bocconi University, Milano, Italy

[2]Hamburg Centre for Health Economics, University of Hamburg, Hamburg, Germany

[3]Centre for Health Economics, University of York, York, UK

Correspondence
Aleksandra Torbica, Centre for Research on Health and Social Care Management (CERGAS), Bocconi University, Milano, Italy.
Email: Aleksandra.torbica@unibocconi.it

Funding information
European Commission, Grant/Award Number: 779306

Abstract

The field of medical devices has attracted considerable interest from scholarly research in health economics in recent years. Medical devices are indispensable tools for quality health care delivery, but their assessment and appropriate use pose significant challenges to healthcare systems. More research is needed to overcome existing gaps associated with evaluation of digital technologies, address challenges in the use of real-world data in generating evidence for decision-making and to uncover drivers of variation in access to medical devices across countries. Furthermore, the translation of the results and recommendations stemming from research projects into health technology assessment practices needs to be strengthened. The European Union (EU) project COMED aimed to address these gaps by improving existing research and developing new research streams on the methods for evaluation and diffusion of medical devices. The project also intended to provide directly applicable policy advice and tools to inform decision-making, with the aim of impacting public health in the EU. This Health Economics Supplement, together with references of other published outputs of the project, is intended to be the main source for researchers and policy makers seeking information on the COMED project.

KEYWORDS
COMED, coverage with evidence development, health technology assessment, medical devices, real world evidence

1 | BACKGROUND TO THE COMED PROJECT

Health technologies defined broadly embrace a range of applications of organized knowledge and skills in the form of pharmaceuticals, medical devices, vaccines, medical and surgical procedures, and systems developed to improve health. Within this broad definition, medical devices include a wide-ranging and heterogeneous group of health technologies that are used to diagnose illness, to monitor treatments, to treat acute and chronic illnesses, and to assist disabled people. The European Union (EU) market has over 500,000 types of medical devices. With an estimated market size of roughly €100 billion, medical devices account for about 7.5% of healthcare expenditure in most publicly funded healthcare systems. These technologies are indispensable tools for quality health care delivery, but their assessment and appropriate use pose significant challenges to policy

[Correction added on 3 October 2022, after first online publication: The copyright line was changed.]

makers. The challenge is to adopt policies to allow access to safe and effective technologies while providing adequate incentives to the industry to invest in research and development of new products.

In the effort to properly address these challenges and overcome the gaps of the past, policy makers in Europe have for years discussed new rules for licensing and market access of medical devices in the EU market. These long discussions resulted in two important milestones with the potential to significantly change the evidence generation process for medical devices in the European context, especially for therapeutic, high-risk technologies.

First, in 2017, Medical Devices Regulation (MDR) 2017/745 initiated a series of important improvements to the past, with the intention to: improve the quality, safety and reliability of medical devices; strengthen transparency of information for consumers and practitioners; and enhance vigilance and market surveillance of devices in use. This MDR aimed to establish a modern and more robust regulatory framework to protect public health and patient safety. The MDR was fully endorsed by May 26, 2021, addressing the need for an increased availability of vitally important information on medical devices across the EU. While it is too early to assess the full impact of the MDR on the market, the new rules dramatically change the type, quantity, and quality of evidence to be generated by the manufacturers, especially of those producing high-risk technologies that are affected by the MDR. For the MDR to achieve desired results, it is essential to define what constitutes "appropriate evidence" and how this evidence should be generated to inform market approval of medical devices (Tarricone et al., 2020).

The second important milestone, recently achieved at the EU level, is the EU Regulation of Health Technology Assessment (HTAR). After years of discussions and considerable debate between member countries, HTAR was adopted by the EU on December 15, 2021 and entered into force on January 11, 2022 (Regulation (EU) 2021/2282). The new approach was adopted after years of voluntary coordination efforts between HTA bodies across Europe through the joint actions known as EUnetHTA (Drummond, Tarricone, & Torbica, 2022). The new HTAR aims to find the right balance between centralization and delegation of competencies to ensure efficient use of resources and strengthen the quality of HTA across the EU. In a nutshell, the HTAR focuses on the "clinical domain" of HTA, which includes the estimation of relative clinical effectiveness, as well as relative clinical safety of innovative health technologies, compared with adopted standards of care. Member States' HTA bodies are expected to conduct Joint Clinical Assessments of new medicines and certain high-risk medical devices. The results of these assessments should be used by member states in their decisions about the appropriate use of these technologies, although the evidence may be complemented to meet local needs. Other non-clinical domains of HTA, such as the assessment of cost-effectiveness, will remain the responsibility of individual member states (Drummond, Tarricone, & Torbica, 2022).

In parallel with these significant policy developments in the EU, the field of medical devices has attracted considerable interest from scholarly research in health economics. Faced with the challenge of providing appropriate evidence to inform policy making, health economists recognized that international guidelines for conducting HTA, in particular the economic evaluation component, have been written with the main focus on pharmaceuticals, thus disregarding the potential difficulties rising from evaluating medical devices and other more complex treatments and technologies (Drummond et al., 2009). An earlier EU funded research project, MedtecHTA, successfully investigated some of the particular features of therapeutic medical devices and provided a series of recommendations for improving the HTA, updating methods for their assessment and optimizing the diffusion of medical devices in the European context. More specifically, the MedtecHTA project suggested that: regulatory processes for medical devices should be more closely aligned; the HTA evaluative framework should be harmonized; processes for conditional coverage with evidence development (CED) should be used; the methods for HTA should consider medical devices as complex interventions; and high-quality registries should be established, using appropriate approaches for confounder adjustment to facilitate the assessment of comparative effectiveness. Finally, in order to optimize the diffusion of medical devices, a common classification should be developed across countries in order to facilitate international comparisons and investigate the reasons for variations in access within and across countries (Tarricone et al., 2017).

While the EU MedtecHTA project has successfully addressed some research needs of HTA bodies and improved our understanding of the diffusion drivers of medical devices in Europe, challenges in the assessment of medical devices persist. These include, among others, challenges associated with evaluation of digital technologies, increased use of available real-world data (RWD) to generate evidence on medical devices, use of surrogate outcomes in comparative effectiveness studies and new methodologies for health economic modeling early in the life cycle of medical devices. In addition, more research is still needed to understand the drivers of variation in access to medical devices across countries, and the translation of the results and recommendations stemming from research projects into HTA practices needs to be strengthened.

The EU funded project COMED aimed to fill these important gaps, advance scientific knowledge by improving existing and developing new research streams in the field and provide directly applicable policy advice and tools to inform decision-making on medical devices, with the aim of impacting public health in the EU and beyond.

2 | OBJECTIVES OF THE COMED PROJECT

The overarching scope of the COMED project was to push the boundaries of current scientific knowledge to: (1) improve the evaluation of medical devices; (2) investigate diffusion of medical devices across Europe; and (3) develop tools to foster the use of evidence in policymaking. Within these three broad research aims, COMED addressed the following objectives:

(i) to provide scientifically rigorous recommendations on what, when and how RWD/evidence sources can and should be used for assessment of medical devices, and which methods are available to produce unbiased evidence
(ii) to improve the decision-making process about medical devices whose evidence base is mainly supported by surrogate outcomes
(iii) to develop and apply methods for comprehensive assessment of health-related mobile applications (mHealth)
(iv) to improve methods for early health economic modeling to inform regulatory, coverage and reimbursement decisions
(v) to investigate the diffusion of medical devices across different geographical areas in the EU, exploring the reasons and justification for variation
(vi) to strengthen the use of clinical and economic evidence in policy making by exploring the most advanced policy tools (e.g., coverage with evidence development)
(vii) to develop methods to facilitate the transferability of economic evaluation of medical devices to countries with limited resources to conduct local studies within and beyond Europe

In the following sections, we describe the contributions of the COMED project by research aim and specific objectives. For each aim, we first briefly report on the existing literature including previously published papers stemming from the COMED project. Then, we highlight the novel contributions of the papers included in this *Health Economics Supplement.*

3 | RESEARCH AIM 1: IMPROVING THE EVALUATION OF MEDICAL DEVICES

As noted above, medical devices pose challenges for the traditional methods of economic evaluation in the context of HTA. The COMED project makes an important contribution toward the improvement of HTA methodologies for evaluation of medical devices by investigating issues underexplored in previous research. These include the use of real-world evidence (RWE), use of surrogate outcomes, evaluation of digital health solutions (mHealth apps) and methods for early health economic modeling of medical devices.

3.1 | Real-world-data for evaluation of medical devices

Over the last few decades, digital innovation has permitted the generation, collection, and storage of a large volume of health-related data that can be employed to track patient health and to monitor health service delivery during all stages of the lifecycle of health technologies. Real-world data possess vast information potential in many areas: to significantly improve the outcomes and efficiency of healthcare delivery, unlock new research and innovation opportunities, and inform public health policy across Europe. The increasing availability of RWD has generated much attention in assessing whether, and to what extent, RWD can be used to generate RWE needed to inform HTA of health technologies.

Although not limited to this type of health technologies, RWD/RWE is particularly important for medical devices for the following reasons: (1) the effectiveness of a device in regular clinical practice is likely to differ largely from its efficacy in experimental settings due to use-specific effects, like the presence of a learning curve that impacts health outcomes; (2) the undertaking of an experimental study (such as a randomized controlled trial -(RCT) does not guarantee the elimination of biases because of the difficulties in maintaining blinding and challenges to effective randomization due to sample size issues (e.g., loss to follow-up, etc.); (3) the regulation process for the majority of medical devices does not require evidence from controlled clinical studies, which requires decision-makers to decide based on other evidence; and (4) medical devices are constantly developing while innovation is often incremental, which makes repeated RCTs simply unfeasible.

The COMED project offered new insights for addressing these challenges, providing novel empirical evidence on the actual and potential use of RWD and RWE in the HTA of medical devices. In reference to the actual use of RWD to inform HTA of medical devices, Klein and colleagues investigated the type and the quality of evidence used to assess the (cost) effectiveness of high-risk medical devices (Class III) by HTA agencies in Europe (Klein et al., 2022). Their results suggest that even though HTA agencies have paid increasing attention to the RWD and RWE, the quality of evidence included in HTA reports is generally of poor quality. The methodological rigor of the studies relying on RWD was found to be weak and not adequate to control

for confounding and biases intrinsic to observational data. Furthermore, meaningful analyses to test key assumptions were largely omitted. Although the analysis could not shed light on how much evidence impacted the final decision of the HTA agencies, Klein and colleagues argued that HTA agencies should increase the quality requirements for observational studies by adopting more rigorous methodologies that are widely available.

In addition to advancing methodological rigor in analyzing RWD, it is crucial to understand the availability and nature of the possible data sources for informing HTA decisions on medical devices. In an earlier study undertaken within the COMED project, Pongiglione and colleagues conducted a comprehensive assessment of possible sources of RWD on medical devices (MDs) in EU Countries (i.e., registries, administrative data, etc.) (Pongiglione et al., 2021). They mapped the existing RWD sources in Europe to assess their relevance for three case studies: hip and knee arthroplasty; transcatheter aortic valve implantation and mitral valve repair (TMVR); and robotic surgery procedures. The authors critically analyzed the appropriateness of these data sources for conducting HTA and concluded that existing sources RWD have a great potential to inform the HTA of medical devices. However, if RWD are to be considered an important source of evidence on the economic and health impact of MDs, there is a clear need to improve quality, quantity, and—especially—accessibility to these data sources. The authors shed light on excessive fragmentation and variation in RWD sources across EU countries and a lack of standardization of health and economic outcomes which prevent wider use of RWD for HTA purposes.

Pongiglione and Torbica go further in exploring the potential of RWD to inform HTA of MDs, by assessing the feasibility and applicability of using a health administrative database (Pongiglione & Torbica, 2022). Using a specific case study of drug-eluting-stents, they investigate the potential of administrative databases for estimating costs and health outcomes associated with the use of medical devices in real world conditions. They adopt different statistical methods in order to address the most important methodological challenges intrinsic to observational data (i.e., confounding and bias). The consistency of results across methods suggests internal validity of the study, while highlighting strengths and limitations of each model depending on the context. The authors shed light on the great potential of administrative data, but also show how crucial it is to understand their content in terms of endpoints, costs and possible controls in order to maximize the use of such existing data sources for HTA purposes. Their empirical analysis is aimed to provide a proof-of-concept case study on the opportunities and challenges of using administrative data for cost and outcome evaluation of MDs, leveraging routinely collected data that are readily accessible to decision makers.

3.2 | Surrogate outcomes for medical devices

In the drive toward faster patient access to innovative health technologies, HTA agencies and payers are increasingly faced with reliance on evidence based on surrogate endpoints, thereby increasing decision uncertainty. A surrogate endpoint is defined as a proxy outcome that can substitute for, and sometimes predict, a final patient-relevant outcome, such as mortality or health-related quality of life. The traditional focus of the use and application of surrogate endpoints has been in the licensing and coverage of drugs and biologics, with little application to other medical technologies, particularly MDs. Despite the development of a small number of evaluation frameworks, no consensus has been developed on the detailed methodology for handling surrogate endpoints in HTA practice. Furthermore, empirical evidence on their application or uptake by HTA agencies and payers is scarce.

The COMED project makes a significant contribution to the limited literature on the use of surrogate outcomes in HTA of medical devices. In this supplement, Ciani et al. provide an overview of the methods and findings of four empirical studies undertaken within the COMED project in the context of the wider contemporary body of methodological and policy-related literature on surrogate endpoints (Ciani et al., 2022). They also revisit the three-step framework and develop a web-based decision tool to support HTA agencies and payers when faced with surrogate endpoint evidence.

The first study reports the results of an international survey of HTA agencies on their current methodological guidance for use of surrogate endpoints (Grigore et al., 2020). In the second study, the authors investigate the current international practice of the application and validation of surrogate endpoints in HTA reports and the impact on coverage decisions (Ciani et al., 2021). The third study was an empirical investigation including a qualitative study exploring views of stakeholders on the issue of surrogacy in HTA decision-making. The fourth study presents a pilot choice experiment to better understand the trade-offs made by HTA stakeholders on their use of surrogate endpoints evidence as a basis for value determinations.

3.3 | Methods for evaluating digital health technologies (mHealth apps)

Digital health solutions have shown great promise in transforming health care, and they are expected to contribute to better patient-centered health care systems. However, assessing their added value to healthcare systems poses a number of challenges

of a methodological and technical nature. Indeed comprehensive evaluation frameworks for common evaluation approaches for digital health are lacking. The COMED project aimed to fill this gap by developing and testing methods for assessment of health-related mobile applications (mHealth).

Previously, Tarricone and colleagues outlined distinguishing features of mHealth apps and argued that these features should be considered in any assessment framework that aims to be comprehensive (Tarricone et al., 2021). In the follow-up paper, the same authors conducted a systematic review of randomized studies on mHealth apps for the management of high prevalence diseases (diabetes, cardiovascular diseases, chronic respiratory diseases and cancer) in order to uncover which features of mHealth apps are evaluated (Cucciniello et al., 2021). Their review reinforces the need for more robust development and appropriate study design to sustain evidence generation on mHealth apps.

In this supplement, Tarricone et al. analyzed current assessment frameworks for digital technologies and concluded that none is sufficiently complete as to encompass all relevant domains for regulatory, policymaking, HTA and coverage purposes (Tarricone et al., 2022). The authors identified 10 principles that would need to inspire assessment frameworks based on a life-cycle evidence generation approach for mHealth apps. The principles go beyond economic dimensions such as cost and economic evaluation to include mHealth development and update, classification and evidentiary requirements, performance and maintenance monitoring, usability testing, clinical evidence requirements, safety and security, equity considerations, organizational assessment, patient empowerment and environmental impact. The recommendations were developed based on systematic literature review and subsequent validation with key stakeholders.

3.4 | Early-stage health economic modeling for medical devices

The concept of early-stage health economic modeling has been discussed for more than 20 years, and most of the available literature has focused on exploring its benefits for technology developers. Early modeling aids investment decisions by estimating the expected costs and health benefits generated by an innovation, compared with current standards of care, in early stages of development. It can provide useful recommendations on how innovations should be further developed or implemented to enhance cost-effectiveness, including identifying the optimal indication and positioning of the innovation in the care pathway. While the benefits of early-stage modeling are rather straightforward for the R&D processes of the healthcare industry, less is known about the potential to inform early dialogs with regulatory bodies, payers and HTA agencies, especially in the field of MDs.

The COMED project strived to fill in this gap with three studies. Blankart and colleagues investigated the perception of key stakeholders (competent authorities, HTA agencies and manufacturers) vis-à-vis different forms of early dialogs. It was argued that anticipating the discussions between stakeholders to early phases of technology development would improve evidence base at market entry of MDs. Awareness of evidentiary requirements, at an early stage in a product lifecycle, will assist manufacturers in identifying key evidentiary needs and potentially shortening the delay in patient access to life-saving MDs. Although promising, implementing early dialogue for MDs has numerous challenges, including lack of a clear legal mandate by the legislator and appropriate incentives for the manufacturers to engage in the process (Blankart et al., 2021).

In two other Supplement papers, COMED researchers investigated methodological aspects concerning early-stage health economic modeling. Federici and Peccchia focused on the methods to deal with uncertainty at early stages of a technology life-cycle, when evidence is still sparse (Federici & Pecchia, 2022). A cost-effectiveness model of a hypothetical total artificial heart was built using data from the literature and the (simulated) results of a pivotal study. Using a value of information analysis, the authors explore the misalignment on the value of further research between payers and manufacturers. They argue that value of information analysis could be used as an explicit framework for both payers and manufacturers to identify and resolve any potential conflict in the perceived value of evidence.

Iskandar and colleagues propose Probability Bound Analysis (PBA) as a new approach to characterize uncertainty when building early economic models of health technologies (Iskandar et al., 2022). Probability Bound Analysis needs fewer assumptions and shows the existing uncertainty more transparently than currently used methods; therefore, PBA is particularly suitable when evidence on some parameters in the model is lacking. This transparent representation of uncertainty shows the decision-maker exactly when and where a decision needs to be made. These methodological advances were applied to a case study on a total artificial heart for patients with late stage advanced heart failure.

4 | RESEARCH AIM 2: INVESTIGATING THE *DIFFUSION* OF MEDICAL DEVICES

Previous research recommended that, in order to better understand diffusion patterns of medical devices, it is necessary to leverage routinely collected data (administrative data), provided that the coding system allows for valid and reliable identification

of the technology. Moreover, it is important to endorse the use of a common classification for medical devices across countries to facilitate international comparisons. Following up on this recommendation, COMED project researchers developed an ad hoc database suited for investigating variations in the utilization of medical devices within and between European countries.

Rabbe and colleagues used a multilevel logistic regression at the patient, hospital, and regional levels to investigate (i) the levels to which variation could be attributed and (ii) the hospital and regional factors associated with treatment options (Rabbe et al., 2022). They used hospital discharge records for the years 2012–2016 in Germany and Italy and for 2014–2016 in the Netherlands, combined with hospital and regional characteristics, in nine clinical categorized into effective, preference-sensitive, and supply-sensitive care. Their results suggest that most variation in the treatment decision can be attributed to the hospital level, while only a minor part is explained by regional characteristics of the hospital location. Furthermore, they observed less variation for procedures in the effective-care category compared to the preference- and supply-sensitive categories.

These findings suggest that the impact of the regional level in variation of medical devices may be overestimated when data are not available at the patient level. It is thus important to gain a better understanding of the clinical, professional and organizational factors at the hospital level that encourage or discourage the use of the clinical procedures involving the use of medical devices. Thus, Möllenkamp and colleagues conducted additional country-specific analysis applying spatial econometric methods to test for spillover effects, through knowledge transfers or observational learning, between hospitals in Germany and Italy (Möllenkamp et al., 2022). The results of their study underline the importance of spillover effects among peers for the diffusion of MDs, even in the presence of a positive guideline recommendation. From a policy perspective, these findings suggest that regular communication and exchange between providers play an important role in the diffusion of MDs above and beyond the publication of medical guidelines and scientific evidence. Policymakers could use this point as an argument for developing and promoting various forms of exchange between hospital staff to accelerate the diffusion of appropriate technologies.

5 | RESEARCH AIM 3: STRENGTHENING THE USE OF ECONOMIC EVIDENCE IN DECISION MAKING ON MEDICAL DEVICES

The COMED project investigated innovative policy solutions that foster the use of economic evaluation in decision making. Furthermore, COMED tackles the issue of transferability of evidence across different jurisdictions including countries with limited resources for conducting local studies. The lack of transferability has been identified as one of the major barriers in the use of economic evaluation in policy making and is an important component of encouraging harmonization in the use of HTA across all EU member states.

Among different policies that rely on the use of scientific evidence to inform decisions, Coverage with Evidence Development (CED) has been widely discussed in the domain of MDs, because regulatory evidence requirements are less demanding than for medicines. Therefore, once they are adopted in the clinical practice, the evidence base for estimating clinical and economic impact of medical devices is often limited. Based on this premise, the previous MedtecHTA project set out a conceptual framework for the assessment of policies for CED for medical devices (Rothery et al., 2017). Building on this work, the COMED project explored the actual implementation of such policies and the main practical issues in the conduct of CED, such as determining who should fund the research and how issues of study design are resolved. In short, the objective was to identify and describe the challenges that payers and manufacturers might face when applying CED schemes for medical devices and to develop a policy guide. The systematic review of 27 reviews and original articles on CEDs schemes for medical devices or health technologies more generally aimed to identify the main challenges relating to designing and implementing such schemes, and to collect information on existing conditional reimbursement programmes across Europe (Reckers-Droog et al., 2020). Subsequent study used both literature searches and interviews with policy makers, to explore further the importance of the various challenges and to document the key characteristics of schemes undertaken, or currently in progress, in Europe. It found that currently seven European countries had programs for conducting CED schemes for medical devices and the details of more than 70 individual schemes were documented. Based on these findings, authors make a number of recommendations for policy choices that should be considered, organized in terms of the steps in designing and implementing CED schemes, from assessing the desirability of a scheme, through to its evaluation (Federici et al., 2021).

Drummond and colleagues go beyond the prior literature to assess whether the actual practice of CED for medical devices in Europe meets the theoretical principles proposed by health economists and whether theory and practice can be more closely aligned (Drummond et al., 2022). They identify situations where practice departs from theory and explain why this might be the case. Then, based on examples from the schemes themselves, the authors discuss a series of proposals for good practice, based on theoretical principles, for assessing the desirability of, designing, implementing and evaluating schemes that are more closely aligned with the theoretical principles. They also develop six recommendations for how theory and practice could be even more closely aligned.

Because of their relatively limited resources for health care, Central and Eastern European (CEE) countries are typically late adopters of new medical technologies, including medical devices. This situation provides an opportunity to learn from the experience of early adopter countries in Western Europe, both in terms of HTAs conducted and CED schemes initiated. Methodological challenges in the evaluation of medical devices may be different for early and late technology adopter countries, as well as the potential HTA solutions for tackling them.

Daubner-Bendes and colleagues discuss the challenges of HTA for MDs in late-adopter countries, with special focus on the transferability of scientific evidence. Health technology assessment issues which pose a greater challenge, or require different solutions, in late technology adopter countries were selected based on a targeted literature review. Draft recommendations to address these issues were developed and then validated with a wider group of experts, including HTA and reimbursement decision makers from CEE countries. Then, a consolidated list of 11 recommendations were developed in three major areas (Daubner-Bendes et al., 2021).

Kovacs and colleagues explore how HTA bodies and payer organizations in CEE countries could rely on CED in managing decision uncertainty for MDs, with a focus on transferring the structure and data from CED schemes in early technology adopter countries (Kovács et al., 2022). Based on a series of structured interviews and focus group discussions, the authors propose a decision-making tool, describing decision alternatives and recommendations for implementation of CED in CEE countries. Four potential options are identified in which transferability assessment is needed: (1) joint implementation of CED scheme; (2) transferring the structure of an existing CED scheme to a CEE country; (3) reimbursement decisions that are linked to outcomes from an ongoing CED scheme in another country and (4) RWE transferred from completed CED schemes in another country.

6 | CONCLUSIONS

Recent changes in the regulatory landscape of medical devices, together with the remarkably fast pace of innovation that characterize MD industry, have put medical devices in the spotlight in both the policy and research arenas. The COMED project was an ambitious research initiative that aimed to tangibly improve scientific knowledge and decision-making processes on medical devices by providing a rigorous evidence base on the most pressing issues around the evaluation, diffusion, and use of medical devices in Europe. This *Health Economics Supplement*, together with references of other published outputs of the project, is intended to be the main source for researchers and policy makers seeking information on the COMED project.

Throughout almost 4 years of research endeavors, the COMED project made significant contributions in advancing knowledge on the methods for evaluation of medical devices and in improving our understanding of main drivers of diffusion of medical devices in Europe. This knowledge provides policy makers with evidence-based tools for making decisions that ultimately impact access to medical devices and, consequently, public health in the Europe. More specifically, we believe that findings from the project could substantially improve the decision making on collection and analysis of RWD for medical devices, evaluation of medical devices that depend on surrogate outcomes evidence and the assessment of mHealth technologies. In addition, the project sheds light on the potential of innovative policy tools to strengthen the use of evidence throughout the life cycle of medical devices from early assessment to CED schemes.

ACKNOWLEDGMENTS

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779306.

CONFLICT OF INTEREST

The author declares that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

This article provides an overview of research conducted within COMED project and introduces the papers published in the Supplement. Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

ORCID

Aleksandra Torbica https://orcid.org/0000-0001-8938-7608
Rosanna Tarricone https://orcid.org/0000-0002-2009-9357
Jonas Schreyögg https://orcid.org/0000-0001-8030-2161

REFERENCES

Blankart, C. R., Dams, F., Penton, H., Kaló, Z., Zemplényi, A., Shatrov, K., Iskandar, R., & Federici, C. (2021). Regulatory and HTA early dialogues in medical devices. *Health Policy*, *125*(10), 1322–1329. https://doi.org/10.1016/j.healthpol.2021.07.010

Ciani, O., Grigore, B., & Taylor, R. S. (2022). Development of a framework and decision tool for the evaluation of health technologies based on surrogate endpoint evidence. *Health Economics*. https://doi.org/10.1002/hec.4524

Ciani, O., Grigore, B., Blommestein, H., de Groot, S., Möllenkamp, M., Rabbe, S., Daubner-Bendes, R., & Taylor, R. S. (2021). Validity of surrogate endpoints and their impact on coverage recommendations: A retrospective analysis across international health technology assessment agencies. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, *41*(4), 439–452. https://doi.org/10.1177/0272989X21994553

Cucciniello, M., Petracca, F., Ciani, O., & Tarricone, R. (2021). Development features and study characteristics of mobile health apps in the management of chronic conditions: A systematic review of randomized trials. *NPJ Digital Medicine*, *4*(1), 144. https://doi.org/10.1038/s41746-021-00517-1

Daubner-Bendes, R., Kovács, S., Niewada, M., Huic, M., Drummond, M., Ciani, O., Blankart, C. R., Mandrik, O., Torbica, A., Yfantopoulos, J., Petrova, G., Holownia-Voloskova, M., Taylor, R. S., Al, M., Piniazhko, O., Lorenzovici, L., Tarricone, R., Zemplényi, A., & Kaló, Z. (2021). Quo Vadis HTA for medical devices in central and Eastern Europe? Recommendations to address methodological challenges. *Frontiers in Public Health*, *8*. https://doi.org/10.3389/fpubh.2020.612410. https://www.frontiersin.org/article/10.3389/fpubh.2020.612410

Drummond, M., Federici, C., Reckers-Droog, V., Torbica, A., Blankart, C. R., Ciani, O., Kaló, Z., Kovács, S., & Brouwer, W. (2022). Coverage with evidence development for medical devices in Europe: Can practice meet theory? *Health Economics*. https://doi.org/10.1002/hec.4478

Drummond, M., Griffin, A., & Tarricone, R. (2009). Economic evaluation for devices and drugs—Same or different? *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, *12*(4), 402–404. https://doi.org/10.1111/j.1524-4733.2008.00476_1.x

Drummond, M., Tarricone, R., & Torbica, A. (2022). European Union regulation of health technology assessment: What is required for it to succeed? *The European Journal of Health Economics*, *23*(6), 913–915. https://doi.org/10.1007/s10198-022-01458-6

Federici, C., & Pecchia, L. (2022). Exploring the misalignment on the value of further research between payers and manufacturers. A case study on a novel total artificial heart. *Health Economics*. https://doi.org/10.1002/hec.4520

Federici, C., Reckers-Droog, V., Ciani, O., Dams, F., Grigore, B., Kaló, Z., Kovács, S., Shatrov, K., Brouwer, W., & Drummond, M. (2021). Coverage with evidence development schemes for medical devices in Europe: Characteristics and challenges. *The European Journal of Health Economics*, *22*(8), 1253–1273. https://doi.org/10.1007/s10198-021-01334-9

Grigore, B., Ciani, O., Dams, F., Federici, C., de Groot, S., Möllenkamp, M., Rabbe, S., Shatrov, K., Zemplenyi, A., & Taylor, R. S. (2020). Surrogate endpoints in health technology assessment: An international review of methodological guidelines. *PharmacoEconomics*, *38*(10), 1055–1070. https://doi.org/10.1007/s40273-020-00935-1

Iskandar, R., Federici, C., Berns, C., & Blankart, C. R. (2022). An approach to quantify parameter uncertainty in early assessment of novel health technologies. *Health Economics*. https://doi.org/10.1002/hec.4525

Klein, P., Blommestein, H., Al, M., Pongiglione, B., Torbica, A., & de Groot, S. (2022). Real-world evidence in health technology assessment of high-risk medical devices: Fit for purpose? *Health Economics*. https://doi.org/10.1002/hec.4575

Kovács, S., Kaló, Z., Daubner-Bendes, R., Kolasa, K., Hren, R., Tesar, T., Reckers-Droog, V., Brouwer, W., Federici, C., Drummond, M., & Zemplényi, A. T. (2022). Implementation of coverage with evidence development schemes for medical devices: A decision tool for late technology adopter countries. *Health Economics*. https://doi.org/10.1002/hec.4504

Möllenkamp, M., Pongiglione, B., Rabbe, S., Torbica, A., & Schreyögg, J. (2022). Spillover effects and other determinants of medical device uptake in the presence of a medical guideline: An analysis of drug-eluting stents in Germany and Italy. *Health Economics*. https://doi.org/10.1002/hec.4587

Pongiglione, B., & Torbica, A. (2022). How real can we get in generating real world evidence? Exploring the opportunities of routinely collected administrative data for evaluation of medical devices. *Health Economics*. https://doi.org/10.1002/hec.4562

Pongiglione, B., Torbica, A., Blommestein, H., de Groot, S., Ciani, O., Walker, S., Dams, F., Blankart, R., Mollenkamp, M., Kovács, S., Tarricone, R., & Drummond, M. (2021). Do existing real-world data sources generate suitable evidence for the HTA of medical devices in Europe? Mapping and critical appraisal. *International Journal of Technology Assessment in Health Care*, *37*(1), e62. https://doi.org/10.1017/S0266462321000301

Rabbe, S., Möllenkamp, M., Pongiglione, B., Blommestein, H., Wetzelaer, P., Heine, R., & Schreyögg, J. (2022). Variation in the utilization of medical devices across Germany, Italy, and the Netherlands: A multilevel approach. *Health Economics*. https://doi.org/10.1002/hec.4492

Reckers-Droog, V., Federici, C., Brouwer, W., & Drummond, M. (2020). Challenges with coverage with evidence development schemes for medical devices: A systematic review. *Health Policy and Technology*, *9*(2), 146–156. https://doi.org/10.1016/j.hlpt.2020.02.006

Rothery, C., Claxton, K., Palmer, S., Epstein, D., Tarricone, R., & Sculpher, M. (2017). Characterising uncertainty in the assessment of medical devices and determining future research needs. *Health Economics*, *26*(S1), 109–123. https://doi.org/10.1002/hec.3467

Tarricone, R., Ciani, O., Torbica, A., Brouwer, W., Chaloutsos, G., Drummond, M. F., Martelli, N., Persson, U., Leidl, R., Levin, L., Sampietro-Colom, L., & Taylor, R. S. (2020). Lifecycle evidence requirements for high-risk implantable medical devices: A European perspective. *Expert Review of Medical Devices*, *17*(10), 993–1006. https://doi.org/10.1080/17434440.2020.1825074

Tarricone, R., Petracca, F., Ciani, O., & Cucciniello, M. (2021). Distinguishing features in the assessment of mHealth apps. *Expert Review of Pharmacoeconomics & Outcomes Research*, *21*(4), 521–526. https://doi.org/10.1080/14737167.2021.1891883

Tarricone, R., Petracca, F., Cucciniello, M., & Ciani, O. (2022). Recommendations for developing a lifecycle, multidimensional assessment framework for mobile medical apps. *Health Economics*. https://doi.org/10.1002/hec.4505

Tarricone, R., Torbica, A., & Drummond, M., & Group, for the M. P. (2017). Key recommendations from the MedtecHTA project. *Health Economics*, *26*(S1), 145–152. https://doi.org/10.1002/hec.3468

How to cite this article: Torbica, A., Tarricone, R., Schreyögg, J., & Drummond, M. (2022). Pushing the boundaries of evaluation, diffusion, and use of medical devices in Europe: Insights from the COMED project. *Health Economics*, *31*(S1), 1–9. https://doi.org/10.1002/hec.4600