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SUPPLEMENT ARTICLE

Implementation of coverage with evidence development schemes for medical devices: A decision tool for late technology adopter countries

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Abstract

Experiences with coverage with evidence development (CED) schemes are fairly limited in Central and Eastern European (CEE) countries, which are usually late adopters of new health technologies. Our aim was to put forward recommendations on how CEE health technology assessment bodies and payer organizations can apply CED to reduce decision uncertainty on reimbursement of medical devices, with a particular focus on transferring the structure and data from CED schemes in early technology adopter countries in Western Europe. Structured interviews on the practices and feasibility of transferring CED schemes were conducted and subsequently, a draft tool for the systematic classification of decision alternatives and recommendations was developed. The decision tool was reviewed in a focus group discussion and validated within a wider group of CEE experts in a virtual workshop. Transferability assessment is needed in case of (1) joint implementation of a CED scheme; (2) transferring

the structure of an existing CED scheme to a CEE country; (3) reimbursement decisions that are linked to outcomes of an ongoing CED scheme in another country and (4) real-world evidence transferred from completed CED schemes. Efficient use of available resources may be improved by adequately transferring evidence and policy tools from early technology adopter countries.

KEYWORDS
COMED, conditional reimbursement, coverage with evidence development, late technology adopter, managed entry agreement, medical devices

1 | INTRODUCTION

Decisions about the integration of new medical technologies into health care systems require scientific evidence of their benefits, safety, and costs. However, there is often limited information available on the efficacy, safety, costs, value for money and affordability of medical devices (MDs) that cause uncertainty in making decisions on their reimbursement or in selecting their priority indications and target populations (Reckers-Droog et al., 2020).

1.1 | Uncertainty in evidence of medical devices

Uncertainty about the clinical outcomes and cost-effectiveness of MDs is often greater than that of pharmaceuticals for several reasons. Contrary to pharmaceuticals, MDs often have multiple applications (Drummond et al., 2009), frequently undergo product modifications (Rothery et al., 2017) and during their product lifecycle, multiple incremental technological innovations take place affecting both clinical and economic consequences of their adoption into the clinical settings (Blüher et al., 2019; Gelijns et al., 2013; Rothery et al., 2017; Tarricone et al., 2017). In addition, their effectiveness usually depends not only on features of the device itself (e.g., reliability, accuracy), but also on features of their operators (e.g., on their skills and experience) and the institutional environment (e.g., size, availability of multidisciplinary teams) in which the device is used (Blüher et al., 2019; Drummond et al., 2009). A learning curve is often associated with operating an MD as health outcomes can be improved by gaining experiences with using the new technology (Blüher et al., 2019; Neugebauer et al., 2017; Rothery et al., 2017; Schnell-Inderst et al., 2015; Varabyova et al., 2017). The evidence base for demonstrating clinical effectiveness of MDs in the health technology assessment (HTA) process is generally less mature than that for pharmaceuticals (Beck et al., 2019; Ciani et al., 2015; Fuchs et al., 2017; Rothery et al., 2017; Schnell-Inderst et al., 2015; Tarricone et al., 2014), which can be explained by the less stringent regulatory requirements prior to product launch and the lack of confirmatory randomized controlled trials (RCTs) due to the difficulties in blinding and achieving randomization (Blüher et al., 2019). Additionally, suboptimal statistical power due to relatively small sample size and short follow-up in clinical trials are well described challenges for obtaining evidence on MDs (Gelijns et al., 2013; Sorenson et al., 2011). Moreover, MDs are often quickly introduced into clinical practice, especially in countries with high market potential, often even before clinical trials begin, which makes RCTs even less feasible or ethically justifiable to carry out in late adopter countries (Dreger et al., 2021).

1.2 | HTA of medical devices in late technology adopter countries

Western European (WE) countries have greater market potential, so newly developed MDs are introduced sooner than in less affluent Central and Eastern European (CEE) countries (World Health Organization, 2010). Due to relatively limited health care budgets and smaller market potential, CEE countries are typically late adopters of new MDs. This provides an opportunity for CEE countries to learn and make use of the experience of early technology adopter countries in WE. However, methodological challenges in the evaluation of MDs can be different for early and late technology adopter countries which has to be taken into consideration in the HTA process adequately. When comparing HTA processes between CEE and WE countries, the following differences in contextual factors are particularly important as they influence HTA and related decision-making processes: (1) financial resources for improving patients' health by utilization of

expensive innovative devices are relatively limited in CEE countries; (2) health status of the population is, on average, worse in CEE countries; consequently, the need for effective MDs could be higher; (3) the reliance on public financing and provision of health care is predominant in CEE; (4) the pricing rationale of new medical technologies, including pharmaceuticals and MDs, is driven by principles and requirements of influential WE countries with the highest market potential; and (5) human and financial resources for HTA is insufficient in the majority of CEE countries with the exception of Poland and Hungary (Kaló et al., 2016). A recent publication (Daubner-Bendes et al., 2020) has described several recommendations to CEE countries on how to address key challenges of HTA for MDs with special focus on the transferability of scientific evidence (see Table 1).

If evidence from RCTs is limited, real-world evidence (RWE) could extend the evidence base of MDs (Berger et al., 2017). In principle, RWE from early technology adopter countries may be transferred to CEE countries, however it is highly important to note, that RWE is more subject to local contextual factors compared with protocol-driven RCTs, partly because the benefit of MDs is dependent on the heterogeneity of patient pathways and capacity constraints, including follow-up care. Therefore, the feasibility of transferring RWE to late technology adopter countries needs to be explored.

1.3 | Coverage with evidence development

In areas with high unmet medical need, it may not always be possible or desirable for decision makers to delay the reimbursement or procurement decision until sufficient evidence is generated. Because of the uncertainty of the evidence, decision makers are confronted with the trade-off between delaying reimbursement of a potentially valuable MD and adopting an immature device that over time proves to be less safe, effective, or cost-effective than expected. In these situations, coverage with evidence development (CED) schemes offer an opportunity for reducing this uncertainty by allowing temporary reimbursement while additional data are collected and assessed. As such, CED schemes facilitate final reimbursement decisions at a later stage without delaying patient access to new MDs (Reckers-Droog et al., 2020; Rothery et al., 2017; Trueman et al., 2010). CED schemes aim to explore the performance of the MD in a specified patient population, tracked over a defined period of time and the level, or continuation of, reimbursement is based on the clinical and

TABLE 1 Recommendations on medical device HTA in late technology adopter countries (Daubner-Bendes et al., 2020)

Area	Summary of recommendations
Clinical value assessment	• Use relative effectiveness and safety assessment from joint EU work or use rigorous relative assessment from other jurisdictions • Rely on real-world evidence when evidence from explanatory randomized clinical trials is limited • Consider coverage with evidence development, when the scientific evidence from randomized clinical trials and real-world is premature • Explore the feasibility of transferring real-world evidence to late technology adopter countries in a stepwise approach • Reuse internationally validated surrogate endpoints with extensive sensitivity analyses • In the introductory period of medical devices consider inferior effectiveness and safety (1) based on learning curves from other countries (2) and by using Bayesian approach • Consider the relative effectiveness and safety of medical devices in large volume centers with licensed health care professionals
Economic value assessment	• HTA for medical devices should be considered primarily for national reimbursement decisions or centralized procurement by taking into account average expected payments (e.g., fee or charges) rather than actual costs • Adapt international economic models from early technology adopter countries after transferability assessment
HTA process	• HTA should not be performed for a particular version of a medical device, but for the group of devices with the same (or similar) characteristics • Full scope HTA may not be necessary in each potential indication, cost-effectiveness results in the most prevalent indications can be generalized to indications with similar expected health benefits

Abbreviation: HTA, health technology assessment.

economic outcomes achieved (Garrison et al., 2013). Currently CED schemes are either not applied in CEE countries, or they are used only for pharmaceutical therapies, which indicates that pricing and reimbursement decisions for MDs may be based on less objective and verifiable criteria. On the other hand, a wide group of CEE HTA and health policy experts recommended that CED schemes should also be applied for MDs due their limited evidence base compared with medicines (Daubner-Bendes et al., 2020). CED schemes from early technology adopter countries may be transferred to CEE countries, to take the opportunity to learn from the structure and results of CED schemes in other countries, which ultimately saves time, human and financial resources in the health system of the late technology adopter countries (Daubner-Bendes et al., 2020).

The aim of this study was to develop a decision tool with specific recommendations to CEE countries on how their HTA bodies and payer organizations can rely on CED in managing decision uncertainty for MDs. The tool describes alternative options in the form of a decision-tree for implementing CED schemes for MDs in CEE countries with a particular focus on transferability of the structure and data from currently operated schemes.

2 | METHODS

The study was conducted as part of the European Commission funded Horizon 2020 Cost and Outcome analysis of Medical Technologies (COMED) (Pushing the boundaries of COMED) project that is aiming to push the boundaries of existing methods for cost and outcome analysis of MDs both within HTA and Health System Performance frameworks (COMED, 2018).

As part of the COMED project, structured interviews described in a separate manuscript (Federici et al., 2021) were conducted with 25 decision-makers or other stakeholders from 22 European countries to explore the characteristics of CED schemes for MDs and how challenges associated with operating the schemes were met. The current study built on the information obtained in relation to three questions on the practices and feasibility of transferring CED schemes for MDs: *(a) When designing your CED scheme, do you consider the structure of similar schemes in other countries? (b) Do you have mandate to publish the evidence generated through CED schemes? (c) Are the main characteristics of current and past CED schemes in your jurisdiction publicly available?* The information collected in the interviews was extracted in a spreadsheet and synthetized in a narrative description. The results of the survey served as a basis for determining whether it is desirable and feasible to transfer CED schemes from early adopter countries to CEE countries, and if so, how.

In four consecutive steps (see Figure 1), a decision tool to select the most appropriate approach for the implementation of CED schemes was developed in a decision-tree format. First, after the desirability of relying on CED schemes was confirmed by CEE HTA experts, a series of iterative meetings were held by the CEE partner of the COMED consortium (COMED, 2018) to identify barriers that are specifically relevant to CEE countries in conducting CED schemes and options for implementing CED schemes by utilizing international experiences. Hungary was the only country from CEE participating in the consortium, so the problem formulation and the initial recommendations were drafted by the Hungarian partner. The discussions were minuted and summarized in a report and subsequently approved by all participants.

Second, these options were summarized in a draft decision-tree, which was extensively discussed in a consortium meeting that was attended by all COMED team members in November 2019. The potential areas of transferability and ways to deal with implementation barriers in CEE countries were presented. Feedback from the COMED members were integrated into the decision tree.

The initial plan was to review and validate the draft decision tool and related recommendations in two consecutive meetings with multi-stakeholder CEE representatives. However, due to COVID-19 restrictions the face-to-face meetings had to be moved to a virtual platform. As a third step, therefore, a virtual focus group meeting was held in April 2020. In order to ensure diversity of viewpoints, the experts from CEE countries had different levels of experience with HTA and the use of conditional reimbursement.

During the meeting, COMED researchers presented options for implementing CED programmes in CEE countries and described possible areas for assessing transferability. Participants were asked to comment on the requirements for acceptability and feasibility of CED schemes in CEE countries based on their expertise. The entire discussion was audio recorded. The principal investigator (ZK) moderated the discussion and channeled the conclusions into recommendations. The audio recordings were summarized in a written report highlighting the key ideas from the focus group discussion. This report was shared with and commented on by the participants. The first, third and last author performed a thematic content analysis. Based on this analysis themes were extracted relating to decision options and recommendations from the participants in each focus group. These themes were discussed by all co-authors, including the focus group

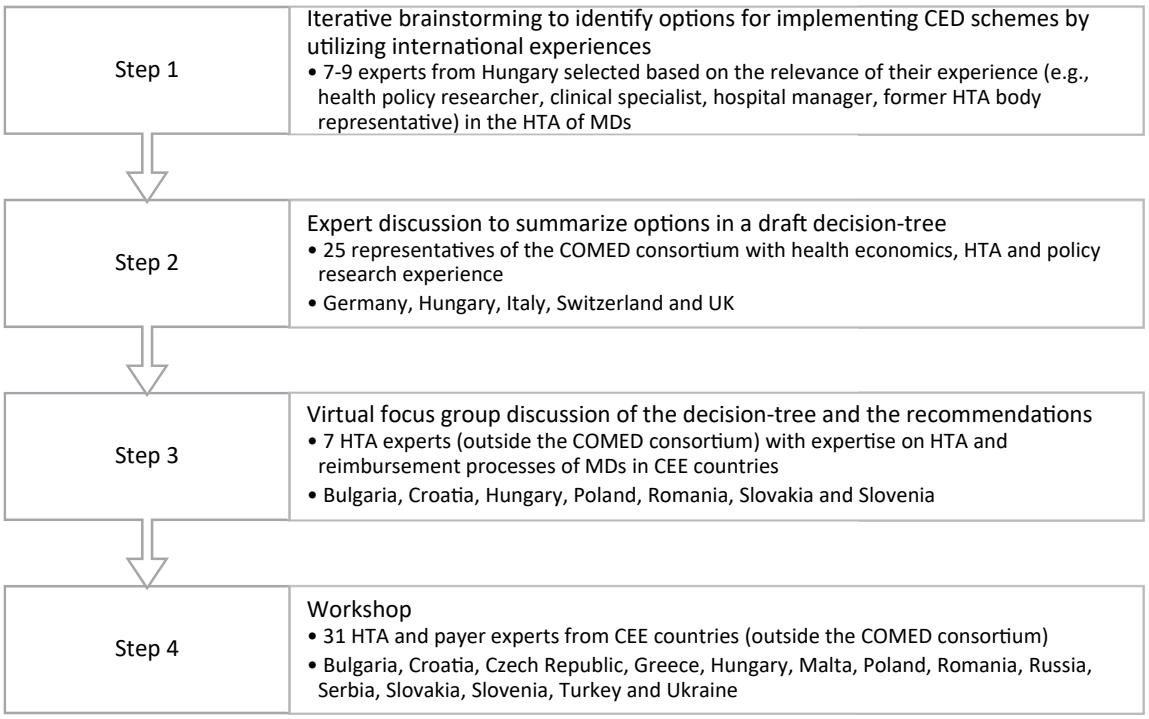

FIGURE 1 Process of developing the decision tool for late technology adopter countries on how to use coverage with evidence development (CED) schemes for medical devices (MDs)

participants. The analysis was carried out using an abductive (deductive and inductive) approach. We used a deductive (top-down) approach by deciding in advance to structure the process and our findings according to the decision tree presented to the focus groups. Furthermore, we used an inductive (bottom-up) approach to analyze and describe overlaps and differences between the different specific concepts that were discussed by participants, and where possible grouping them into more general concepts. The feedback from the co-authors and participants was then used to improve the description of the decision tool.

Finally, the decision-tree and the recommendations were reviewed and discussed by a wider group of experts, including HTA and reimbursement decision makers from CEE countries in online workshops held between May and June 2020 about the HTA of MDs in CEE countries. The participants in these virtual meetings were invited based on an iterative process in which the professional networks of the COMED partners were used. The main selection criteria were familiarity with HTA and policy decisions for MDs and balancing participants based on their geographical location. Overall, 31 experts from outside of the COMED consortium representing 14 late technology adopter European countries contributed to the validation process, which started with a webinar to present the issues and recommendations. After the webinar, participants were asked to provide written feedback on draft recommendations, which were then synthetized. Finally, a virtual interactive meeting was organized to deliberate on written feedback and facilitate consensus among participants.

3 | RESULTS

3.1 | Use and potential transferability of CED schemes to CEE countries

Out of the 22 country representatives participating in the interviews, 4 were from CEE countries (i.e., Bulgaria, Hungary, Poland, Slovakia). None of these countries currently use CED schemes for MDs; however, each of them has expressed the willingness to use CED schemes in the future and the interest in relying on information from CED schemes that are carried out in their own or other countries. In such cases, transferability assessment of CED schemes in earlier adopter countries is important. However, in WE countries where CED programmes exist (e.g., Germany, Belgium, the Netherlands), there is limited experience of adapting structure and experiences of ongoing CEDs from other jurisdictions and no formal processes are yet in place in Europe to facilitate joint implementation of such schemes by multiple countries.

Public information on CED scheme characteristics is available in some European countries (e.g., Belgium, England, France, Germany, the Netherlands), mostly after the scheme has reported its results, during the technology re-appraisals. Information available include the purpose of the scheme, key sources of uncertainty at initiation, design, duration, outcome measures, and reimbursement decision when the scheme is completed. However, it has been found that publicly available information on characteristics of CED schemes is scarce and is almost always published in the language of the country concerned, which poses a substantial challenge in facilitating the transfer of CED schemes (Federici et al., 2021).

Although CEE countries that participated in the interviews do not use CED for MDs, they have broad experience in implementing managed entry agreements, in which real-world data (RWD) are collected to reduce the uncertainty of pharmaceutical reimbursement decisions and to provide basis for the confidential price reduction. However, this RWE generated in such agreements is generally not made publicly available, which hinders the potential use of this information in other countries.

3.2 | Decision tree for the implementation of CED schemes in CEE countries

The first step in implementing CED schemes is to decide about the desirability of schemes. The criteria used by different countries to decide on a scheme and the decision rules and algorithms that have been proposed in the literature were explored in another study of the COMED project (Federici et al., 2021). The second step is to assess feasibility of a scheme and its ability to collect relevant and timely data for decision making. In some countries, there may be limited interest in improving the transparency and evidence base of reimbursement or procurement decisions or it is not feasible to apply conditional reimbursement. If the national HTA body concludes that the evidence base of an MD in priority areas is insufficient, and RWD collection in CED schemes is needed and feasible, CEE countries have the option to develop a new scheme from the start or transfer the design of existing schemes from other jurisdictions. Countries might be willing to rely on CED schemes, but the feasibility of generating additional evidence in a local CED scheme may still be limited. The most obvious limitations raised during the development of the decision-tree for these countries were that the patient population and thus the sample size may be small and the cost of implementing CED schemes relatively high, the relevant data sources (such as patient registries, electronic health records, administrative databases) are missing or not accessible for research purposes. CEE countries with relatively small patient populations and limited resources may increase the sample size and reduce the human and financial burden of CED by implementing a joint scheme with other countries. Moreover, these countries usually have limited trained personnel and financial resources for implementing such schemes. If the feasibility of applying local schemes or joining other countries is limited, the policy decision can still rely on the existing evidence base developed in early adopter countries. Alternatively, decision-makers may take into account ongoing schemes and link their conditional reimbursement decisions to CED schemes running in other countries, or they might consider evidence generated in completed schemes in other jurisdictions for local reimbursement decisions.

The decision tree describing abovementioned options is depicted in Figure 2. The next section provides a broader description as well as recommendations relating to the four potential options with necessary transferability assessment, including (1) joint design and implementation of CED scheme, (2) transferring the structure of an existing CED scheme and adjusting it to local context, (3) reimbursement decision is linked to outcomes from an ongoing CED scheme in another country and (4) RWE from completed CED schemes in another country. Recommendations are summarized in Table 2.

3.2.1 | Joint implementation of CED schemes

Especially in cases where recruitment of patients in the scheme is expected to be difficult in a single country, it makes sense that a country seeks to join an ongoing CED scheme or start a new one in collaboration with other countries. In this case, participant countries should seek to agree on a common set of clinical and economic endpoints that are relevant to all participating countries and determine the (quality of) data to be collected. Participating countries are responsible for financing their part of the data collection. National decision-making is based on aggregated health outcomes data collected in a joint CED scheme in participating countries, which is stored and accessible in a shared database. The data analysis can either be organized on a supranational or national level. The scheme's decision rule can be formulated in line with local standards, requirements and constraints. As such, the decision about reimbursement can vary from country to country.

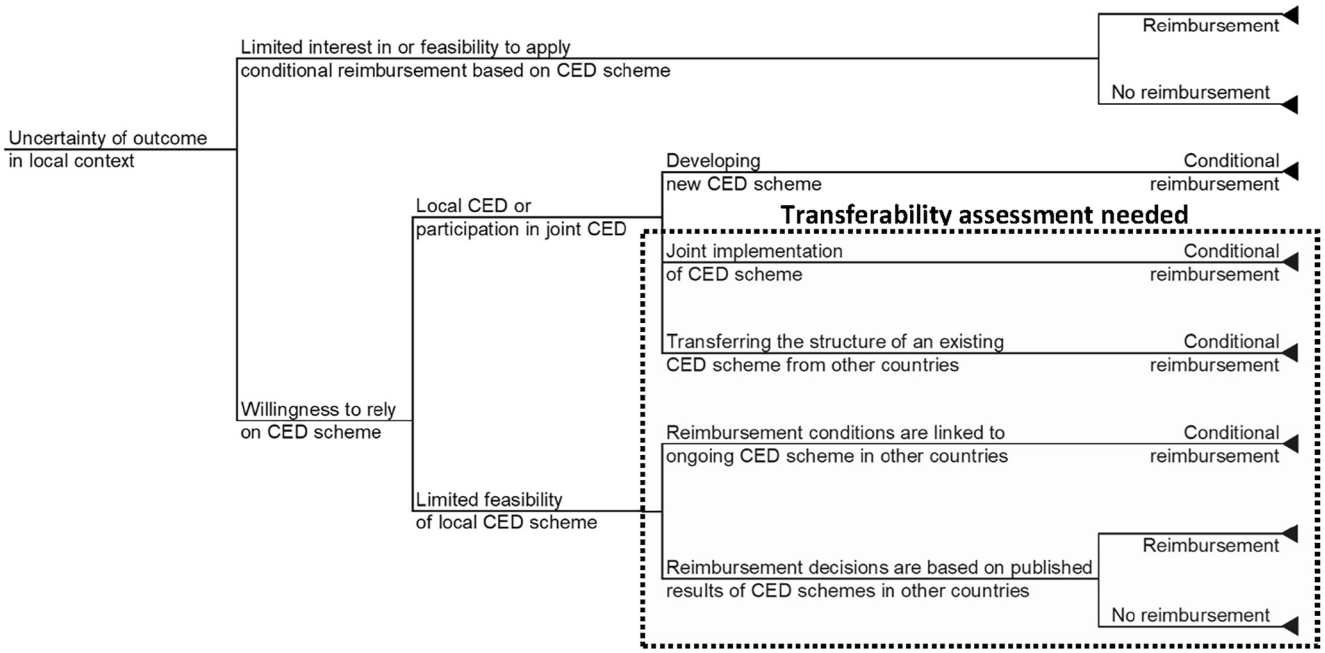

FIGURE 2 Decision tree for the implementation of coverage with evidence development (CED) schemes in Central and Eastern European (CEE) countries

TABLE 2 Main recommendations on the decision options that require transferability assessment

Option	Recommendations
Joint implementation of CED schemes	• Collaboration of multiple centers in multiple countries and adherence to similar protocols for patient care need to be organized • Participating countries should agree on a set of common outcomes and data collection methods, complemented by local economic data • Use of shared database and joint analysis of data is advised, while decision-making should remain at the national level
Transferring the structure of an existing CED scheme and adjusting it to local context	• The transferability of a scheme, that is, the relevance of collected outcomes, the decision rule, the length of the CED scheme, the stopping rule and the feasibility of data collection should be assessed and adapted to the local context
Reimbursement decision is linked to outcomes from an ongoing CED scheme in another country	• The appropriateness of the design and timing of the scheme, and the accessibility of detailed data for applying it to conditional reimbursement locally, needs to be assessed • If patient level data are not directly accessible, the relevance of the outcome measure(s) collected and the decision rule in the local context must be assessed • Locally relevant decision rules need to be developed and additional effect modifying factors need to be considered (differences in learning curve, patient population and organizational background)
Real-world evidence from completed CED schemes in another country	• The feasibility of transferring real-world evidence from early technology adopter countries need to be explored using a stepwise approach

Abbreviation: CED, coverage with evidence development.

Recommendation for the implementation

In the case of jointly operated CED schemes, requirements regarding the similarity of patient care should be defined and actively be enforced, since a high level of variability in comparators, clinical guidelines and patient pathways may hamper the aggregation of data from multiple countries. Additional collection of resource use data (e.g., by means of registries) within the local context provides opportunity to reassess the economic value of MDs in the real world after the CED is completed. It is important to involve stakeholders from healthcare providers to obtain agreement on the relevant outcomes and the procedure for data collection. Such schemes require adequate governance and administrative structure to efficiently organize the cooperation of multiple centers across several countries.

3.2.2 | Transferring the structure of an existing CED scheme and adjusting it to local context

If the decision maker is willing to apply conditional reimbursement and intends to generate additional evidence based on local data collection it can save time and effort to transfer a CED scheme that was designed and used in an early adopter country. It is important to examine the factors that may contribute to the success of transferring and applying a scheme in the local context. There are a few online databases and websites providing information on existing schemes, however, it should be noted that detailed information on the data collection protocol, outcomes, decision rules etc. might be limited. When opportunities arise to adopt a CED scheme that is or was operated in another country, it is necessary to investigate the structure and the potential implementation barriers of the scheme from the local perspective. The results of the CED will add new data that can be considered along with all the existing data in HTA assessments.

Recommendation for the implementation

It is important to determine the factors that should be considered when deciding whether the existing CED scheme in another country is relevant to the local environment. For example, the original research questions may not be relevant to the new setting (e.g., due to different HTA processes and decision criteria) and although they relate to the technology in question, the research protocol needs to be changed. It can be useful to reach out to HTA agencies who ran the CED schemes and learn from their experiences. This way information that may be relevant but has not been published can be shared and incorporated into local adaptation of the scheme. In order to implement a CED scheme that has already been used elsewhere, the national HTA body should investigate the feasibility of data collection (e.g., registration, testing) and make the necessary adjustments. The relevance of collected outcome measures should be assessed and adapted to the local context as well as the length of the CED scheme and the stopping rule to be applied. Additionally, the probable difference in the length and shape of local learning curves compared with the country where the original CED scheme was implemented should also be considered when selecting the appropriate centers and planning the length of data collection. If a scheme is deemed transferable, obtaining consensus on the CED scheme across multiple stakeholders (e.g., payers, manufacturers, hospitals, clinical opinion leaders, and patient organizations) is recommended to ensure successful implementation and maintain proper engagement among participants throughout the scheme. Pre-set decision rules that are specific to the scheme (e.g., a minimum clinical threshold to be reached to confirm reimbursement) should be adjusted to local requirements.

3.2.3 | Reimbursement decision is linked to outcomes from an ongoing CED scheme in another country

Linking the reimbursement decision to results of an ongoing CED scheme in another country can be a feasible solution for those CEE countries that do not have sufficient resources, legal framework or sample size to implement a local CED scheme, while decision-makers have the willingness to rely on evidence and conclusions from an international CED scheme. In this case, the CED schemes run independently from the country where the results will be used for reimbursement decision, so this scenario is only applicable if the collected data is relevant and outcomes are transferable to local context. As data analysis is carried out in the country where the CED is running, access to detailed data may be limited and decision-makers need to rely mainly on the results. However, the decision rule may vary according to local circumstances and may lead to different reimbursement decisions.

Recommendation for the implementation

In this scenario, it needs to be carefully considered whether the design and timing of the scheme is appropriate for applying it to conditional reimbursement locally. It needs to be explored if detailed data is available, and whether the adopting country can have access to analyze it. If not, the assessment of relevance of collected outcome measure(s) and decision rule in the local context is still required. If necessary, a locally relevant decision rule need to be developed and additional effect modifying factors, like differences in learning curve, patient population and organizational background need to be considered. Transparency and a multi-stakeholder consensus on the decision rule of the CED scheme among payers, manufacturers and patient organizations may contribute to the acceptance of final decision in case of rejection of the MD.

3.2.4 | Real-world evidence from completed CED schemes in another country

Finally, if evidence is already available from a completed CED scheme, transferability assessment of (the relevance and quality of) RWE is required.

Recommendation for the implementation

In order to overcome decision uncertainty and potentially heterogeneous quality of evidence, a stepwise approach is recommended to explore the feasibility of transferring RWE, regardless of whether the data were collected in a CED scheme or not. The first step should be the systematic search and collection of relevant RWEs, followed by an evaluation of the equivalence of MD presented in the study of origin and local context. In the next step, assessment of the quality of evidence should be completed by using quality assessment tools for grading RWE studies and including only studies of good quality. As a last step to ensure usability of evidence in the local context, application of a "transferability checklist" (e.g. (EUnetHTA, 2011)) is recommended to evaluate the variation in learning curve, patient population, medical practice and health systems (Daubner-Bendes et al., 2020).

4 | DISCUSSION

In CEE the life expectancy at birth is, on average, five to 10 years lower than in WE (European Commission, 2013). CEE countries suffer from scarcity of financial resources available within the healthcare systems as well. It is therefore even more important to strive for efficient allocation of the limited health budget while ensuring the clinical and economic benefits of the implementation of new innovative health technologies.

As CEE countries are typically late adopters of MDs (World Health Organization, 2010), there is an opportunity to shorten the time to the implementation of the innovation by limiting the decision making uncertainty with the transfer of the structure and data used for CED schemes elsewhere. Duplication of efforts can be reduced and hence the available resources can be used more efficiently by utilizing the experiences of early technology adopter countries with CED schemes. This requires the appropriate assessment of transferability.

Across the group of CEE experts participating in this research, there was unanimous interest in transferring the knowledge about CED schemes from early technology adopter countries to improve access to new MDs for patients. Although different jurisdictions may have the same ultimate goal to reduce decision uncertainty, it has to be considered that CED schemes may have additional setting specific objectives to be reflected in the structure of the particular national reimbursement program as well. For example, Germany and the Netherlands tend to collect evidence on relative effectiveness, whereas post-registration studies in France and Spain are targeted more into collecting non-comparative data about the MD performance in the real world (Federici et al [Under review, expected publication 2021]). Nevertheless, the CED schemes implementation across different jurisdictions may always provide important insights for others as they involve the same or similar MDs.

A substantial barrier to transferability is however the so far limited accessibility of information on the structure and data from CED schemes. In some countries the process of developing a scheme is very centralized (e.g., Germany, England), so selection of the MD for CED and the protocol is decided by national public bodies, whereas in other countries the studies are mainly a responsibility of manufacturers or health care providers. In the former group, sharing of ex-ante information on the study design (i.e., before the scheme initiation) is more likely (e.g., details are published in

the authorizing decree from the relevant health authority; Federici et al., 2021). In general, in countries where there is a more established and transparent HTA system, it is more likely to find relevant information.

The report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force suggests that information about what works in the clinical practice is a public good regardless of whether it is generated by public or private entities (Garrison et al., 2013). As CED schemes are designed to collect data with the objective of reducing uncertainty concerning the clinical outcomes or cost-effectiveness of a health technology, the authorities who utilize data from CED schemes in their own decisions should put the RWE in the public domain. The RWE generated in CED schemes through public health care financing must be a global public good that provides valuable evidence base not only to local decisions, but also for patients and health care professionals seeking for reliable information all over the world. Some countries encourage the involvement of academic groups in CED schemes, as an independent party in the collection and analysis of data (Federici et al., 2021). This might increase the chances of the data from schemes being published.

Another import factor influencing the transferability of results from early technology adopter countries is the study design used for data collection. In some countries the focus is on observational studies which can be very specific to the local practice (as the primary objective is to understand how the device performs in that specific setting). This requires the transferability assessment of RWE (Daubner-Bendes et al., 2020). In others, the focus is more on RCTs, which can provide evidence with more internal validity, although with less external validity.

International HTA networks, such as EUnetHTA or The International Network of Agencies for Health Technology Assessment can play an important role in promoting cooperation and information exchange among HTA bodies (e.g., post launch evidence generation activities of EUnetHTA). Such organized cooperation between European countries and a development of a repository of CED schemes could also facilitate the exchange of information and the joint work between countries, especially at the regional level (Baran-Kooiker et al., 2019).

The decision-tree and recommendations described in this report may provide support for policymakers to judge which implementation strategy of CED schemes is feasible and is the best approach to manage decision uncertainty concerning MDs. It is our hope that applying this decision tool can foster the use of CED schemes in late technology adopter countries and ultimately contribute to strengthening the timely and evidence-based decision making of MDs.

Our study mainly focused on CEE, and hence on less affluent European countries. Nonetheless, the decision-tree and recommendations can also be applied in other lower-middle income countries, which due to their limited market potential, may also adopt MDs relatively late and have limited human and financial resources to collect sufficient data for evidence-informed decision making. To improve the use of CED schemes in resource-constrained countries, it is important that decision makers have insight into factors of transferability and address the challenges associated with this task. We therefore expect that the need for transferability assessment studies will be greater in countries with limited scientific capacities and financial resources.

The decision-tree and recommendations described in this paper are based primarily on the opinion of a relatively small group of experts, which is the main limitation of our study. To ameliorate this limitation at least partially, the recommendations were discussed with a wider group of experts in the field of HTA and MD market access in the EU. The strength of the paper is that it describes several ways in which knowledge about CED schemes can be transferred and that the CEE countries can judge for themselves which methodology works best for them. The recommendations were not only based on information from the interviews, but were also supplemented by a systematic review carried out as part of the COMED project (Reckers-Droog et al., 2020), which contributed to the comprehensiveness of this study. The aim of constructing the tool in decision-tree format, as described in this document, is to raise awareness of the benefits of using CED schemes, since CEE countries do not have substantial experience with such form of performance-based risk sharing agreements. Future research on (i) identifying characteristics which would make a CED scheme from an early technology adopter country successful in a CEE country, (ii) the development of a quantitative tool for objective assessment (e.g., a scorecard format) and, (iii) the demonstration of relevant case-studies could further improve the transferability assessment of CED schemes.

5 | CONCLUSION

New MDs are usually launched earlier in higher income countries. The delay in adopting potentially cost-effective technologies to countries with more limited resources can be reduced by adequately transferring evidence and policy tools aiming to accelerate the decision process, including transferring the structure of an existing CED schemes from other

jurisdictions, linking conditional reimbursement to ongoing CED schemes in other countries and reducing decision uncertainty based on recent evidence generated in CED schemes elsewhere.

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CONFLICT OF INTEREST

The author reports no conflicts of interest (financial or otherwise) and no competing interests.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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