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Health Policy Analysis

The Early Experiences of Health Technology Assessment Bodies in the Implementation of the European Union Health Technology Assessment Regulation for High-Risk Medical Devices: A Qualitative Study

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ABSTRACT

Objectives: The EU Health Technology Assessment Regulation (HTAR) introduces joint clinical assessments (JCAs) to harmonize clinical evidence evaluation across Member States. JCAs are commencing in 2026 for high-risk medical devices (MD) and in vitro diagnostics (IVD), but little is known about how national health technology assessment (HTA) bodies are preparing for implementation. This study aims to explore how selected European Union (EU)/European Economic Area HTA bodies are planning for JCAs integration and HTAR implementation for high-risk MD/IVD.

Methods: Semistructured interviews were conducted with 15 participants from 11 different HTA bodies across 11 EU/European Economic Area Member States. Interviews were recorded and transcribed verbatim before being anonymized and coded using NVivo Software. Data were analyzed using thematic analysis.

Results: All participants recognized JCAs as a potential tool for improving evidence quality for high-risk devices and highlighted their willingness to use JCA-generated evidence in their clinical assessment. Some HTA bodies have initiated procedural or legislative adaptations; however, many remain in an observational position, waiting for further implementation documents. Key opportunities identified included work sharing, improved evidence standards, and capacity building, particularly in smaller HTA systems that might not have access to high-quality assessments without JCAs. However, substantial challenges were reported, including regulatory uncertainty, timing misalignments, and limited manufacturer preparedness for JCA evidence demands.

Conclusions: HTAR is viewed as an opportunity to strengthen HTA practices for high-risk MD/IVD. However, realizing its goals will require further collaboration, alignment of procedural timelines, and investment in national capacity. Further studies are needed after full HTAR implementation for high-risk MD/IVD to capture ongoing experiences.

Keywords: evidence generation, health technology assessment regulation, joint clinical assessment, medical devices, reimbursement.

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Highlights

- The plans for implementing the European Union (EU) Health Technology Assessment (HTA) Regulation (HTAR) for high-risk medical devices (MD) and in vitro diagnostics (IVD) vary significantly across EU/European Economic Area (EEA) member states. This study addresses a key evidence gap by exploring how national HTA bodies across 11 EU/EEA countries are preparing to implement HTAR for high-risk MD/IVD through semistructured interviews.
- Stakeholders expressed support for Joint Clinical Assessments but anticipated potential challenges that include regulatory uncertainty, resource constraints, potential timing and selection misalignment, and the process of contextualization of Joint Clinical Assessments within national reimbursement frameworks.
- To realize the full benefits of the HTAR, sustained coordination between member states, investment in HTA capacity, and alignment of EU and national processes are critical.

Introduction

Patient access to new health technologies often requires evidence that the technology provides positive patient-related and/or economic outcomes. This evidence is frequently assessed through a national health technology assessment (HTA) process.[1] In most European countries, HTA systems have been designed primarily around pharmaceuticals and have only been extended more recently to include medical devices (MD) and in vitro diagnostics (IVD).[2]

The Health Technology Assessment Regulation (HTAR) (EU 2021/2282),[3] which entered full application on January 12, 2025, standardizes the assessment of health technologies, including medicines and high-risk MD and IVD, across the 27 EU Member States. For high-risk MD/IVD, the HTAR complements the Medical Device Regulation (EU2017/745)[4] and the In Vitro Diagnostic Regulation (EU2017/746),[5] which were motivated by patient safety concerns and an ambition to improve evidence quality for MD/IVD. Starting in January 2026, the HTAR will be applied to a selection of

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high-risk MD/IVD, which represents a critical shift in how clinical evidence of these devices is assessed in Europe.[3,6]

The HTAR establishes a framework for joint clinical assessment (JCA), joint scientific consultation (JSC), horizon scanning, and voluntary collaboration between Member States, aiming to improve patient access to innovative health technologies with added benefits, support evidence generation, and reduce duplication of effort for health technology developers (HTDs) and national HTA bodies.[3]

JCA is one of the cornerstones of HTAR implementation, aiming to produce a single, EU-level clinical evidence report. JCAs are based on a dossier submitted by an HTD according to a predefined PICO (Population, Intervention, Comparison, and Outcome), which is subsequently appraised by HTA bodies in 2 Member States and must be used by all Member States when evaluating the relative efficacy and safety of health technologies, including high-risk MD/IVD. In parallel, the Regulation preserves Member States' autonomy in evaluating nonclinical domains, such as cost-effectiveness, budget impact, and broader health system considerations.[7]

Conformity with the HTAR requirements will support evidence-based decision making and safeguard patient outcomes. To date, most research has focused on the HTAR's design, its implications for medicinal products assessments, and the views of HTDs and European institutions.[6,8] However, questions remain about how national HTA bodies are preparing to adjust (or not, as the case may be) their systems to accommodate JCAs for high-risk MD/IVD, and how this will affect national funding decisions.

As previously reported, national HTA frameworks for high-risk MD/IVD differ widely across the European Union (EU) and European Economic Area (EEA).[9] Given this heterogeneity, the readiness of Member States to implement the HTAR for national decision making remains uncertain in the context of high-risk MD/IVD. This study explores how selected EU/EEA Member States plan to implement the HTAR for high-risk MD/IVD. Using semistructured interviews with representatives from national HTA bodies, it examines their views on the JCA, national adaptations to the Regulation (if any), and the challenges and opportunities of integrating EU-level evidence into national reimbursement systems.

Methods

Study Design and Ethical Approval

This study is built upon a preceding scoping review conducted by the authors, which systematically mapped national HTA and reimbursement frameworks for high-risk MD/IVD across EU/EEA Member States. That review revealed substantial cross-country and intracountry variation in how HTA is structured and applied.[9]

This qualitative study explored whether and how national systems are adapting their evidence assessment and reimbursement processes for high-risk MD/IVD in anticipation of JCA through semistructured interviews with key stakeholders from HTA bodies. The study focused on representatives from national HTA bodies because these organizations are central to evidence generation, assessment, and interpretation under the HTAR through their involvement in the JCA process and are key contributors to the scientific and procedural components that inform reimbursement decisions. The reporting of this study was aligned with the consolidated criteria for reporting qualitative research (see Appendix Table 1 in Supplemental Materials).[10] The study received ethical approval from the Social Research Ethics Committee at University College Cork, Cork, Ireland (approval number: SREC 2024-206) and was conducted accordingly. The consent procedures aligned with the General Data Protection Regulation and the University's research ethics policies.

Identification of Participants, Study Settings and Data Collection

HTA bodies were first identified based on their engagement in a prior scoping review led by the authors,[9] which mapped national HTA and reimbursement frameworks for MD/IVD across all EU/EEA Member States and the UK. Of note, participants from the UK were excluded from the current qualitative study, given that the UK is not subject to the HTAR. Potential interview participants were identified by contacting national HTA bodies using publicly available information or the authors' network. The invitations to participate were sent to participants representing HTA bodies in the 30 EU/EEA Member States.

The semistructured interviews were conducted virtually via Microsoft Teams. Interviews were conducted by the first author (R.A.A.), an independent research pharmacist working in an academic setting and collaborating with an Irish HTA body in the conduct of the interviews (see Appendix Table 1 in Supplemental Materials). The interviews were conducted in English and followed a predeveloped topic guide presented in the Supplemental Materials. Participants provided written consent, and all interviews were video and/or audio recorded and transcribed verbatim. A pilot interview was conducted with one HTA body (the Health Information and Quality Authority, Ireland) to test the topic guide, but the data were excluded from the analysis.

Data Analysis

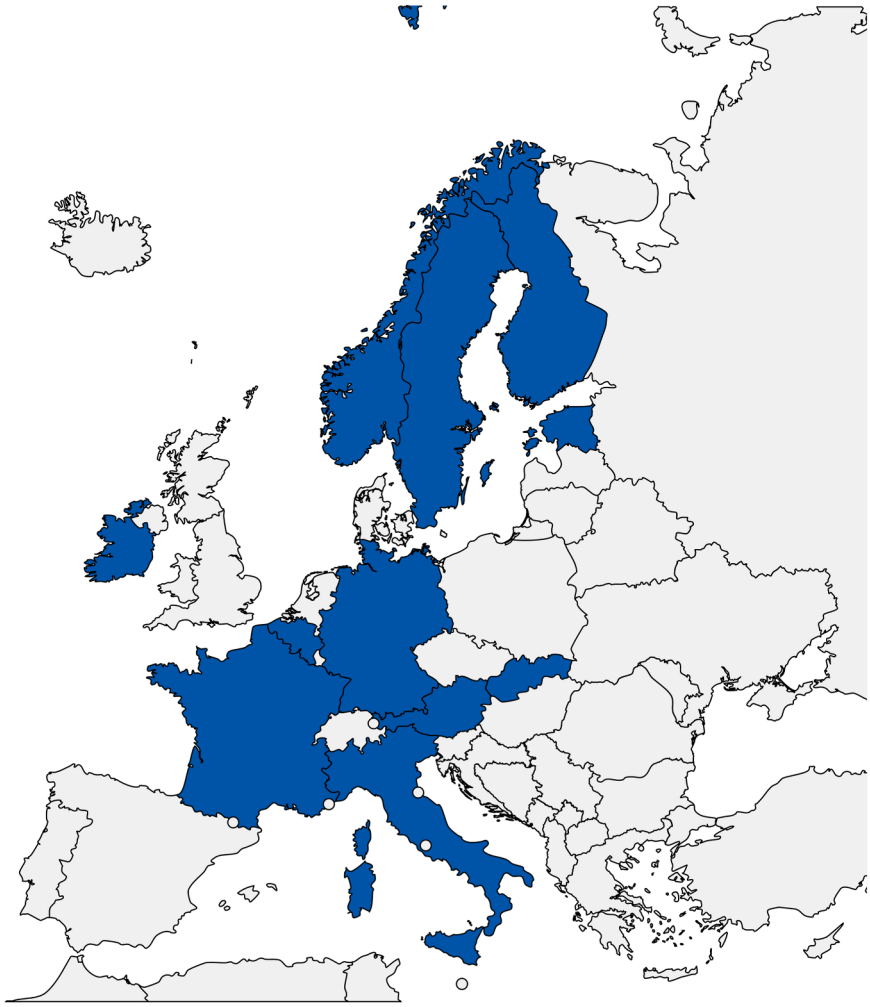
All transcripts were pseudonymized before analysis, all identifying information was deleted, and each interview was assigned a randomly generated identifier. Reflexive thematic analysis, as described by Braun and Clarke[11] was performed in a combined deductive-inductive manner. An initial coding framework based on the topic guide was refined iteratively as new themes emerged from the analysis. Three coded transcripts were independently reviewed by a second researcher with experience in qualitative methodologies (K.A.W.), and discrepancies were resolved through discussion and agreement. The coding was done with NVivo® software (Release 14.23.3).

Results

This study explored the perspectives of representatives from national HTA bodies in selected EU/EEA Member States regarding the implementation of the HTAR for high-risk MD/IVD in their national frameworks. A total of 11 HTA bodies from 11 Member States agreed to participate in the interviews. Representatives of 6 Member States declined to participate, and there was no response to the request for an interview from 13 states. The participating HTA bodies represented Member States with varying levels of HTA maturity for MD/IVD, with some having well-established HTA systems and others in which the HTA process is emerging or not yet fully integrated into reimbursement processes.[9]

The 11 interviews took place between January and April 2025, including the pilot interview, across 11 EU/EEA Member States: Austria, Belgium, Estonia, Finland, France, Germany, Ireland, Italy, Norway, Slovakia, and Sweden (Fig. 1). A total of 15 participants were interviewed (4 interviews included 2 participants), with an average of 12 years of experience in HTA and related fields. The demographic information for all participants is presented in Table 1.[9]

Figure 1. Geographic distribution of the 11 EU/EEA Member States that participated in the semistructured interviews (in blue).



EEA indicates European Economic Area; EU, European Union.

The interviewees' views and perspectives were analyzed using thematic analysis. Reflective themes were grouped into 4 overarching domains: (1) the current national structure and existing challenges of HTA and reimbursement for MD/IVD, (2) planned or expected adaptations to national structure in response to HTAR, (3) expected opportunities and benefits introduced by the HTAR, and (4) perceived challenges and barriers in adapting to HTAR requirements. The overarching domains identified and key themes and subthemes under each domain are presented in Figure 2. Furthermore, Figure 3 provides an expanded, detailed view of the 2 forward-looking domains (domain 3 and domain 4) with their themes and subthemes. Illustrative quotes are embedded within the text to highlight key insights from the participants within each domain; additional supporting quotations are presented in Table 2.

Domain 1: Current National Structure and Existing Challenges of HTA and Reimbursement for MD and IVD Across the EU/EEA

Generally, participants described variable levels of integration of HTA into high-risk MD/IVD reimbursement pathways in their Member States. All had at least 1 HTA-linked pathway, but its role ranged from being a formal requirement to an ad-hoc element, as was described previously.[9]

In 3 Member States, the participant highlighted that HTA for certain MD was mandatory with legally set timelines. Furthermore, the HTA scope varied: 3 countries did not routinely include economic assessment in the HTA, whereas participants from 8 countries mentioned that economic assessment is a core component of HTA for medical devices. Overall, participants noted that national HTA for MD/IVD was typically less standardized than HTA for medicinal products.

Emerging and Evolving National HTA Structures

Participants from member states with less developed HTA frameworks[9] described ongoing efforts to formalize HTA in reimbursement systems of high-risk MD/IVD and address longstanding issues with their national systems. These efforts aim to define criteria for device assessment, improve the translation of national assessments to local procurement decisions, and expand the HTA for MD. In these settings, HTA bodies had already begun revising internal procedures and building or expanding their HTA infrastructure, often starting

Table 1. Characteristics of the HTA bodies represented (n = 11) and interview participants (n = 15).

Characteristics of the HTA bodies represented (n = 11)	HTA bodies represented, n
HTA bodies from member States with a formal HTA component within reimbursement frameworks for high-risk MD/IVD.*	6
HTA bodies from member States with an optional HTA component within reimbursement frameworks for high-risk MD/IVD.	5
Characteristics of interview participants (n = 15)	Participants, n
Gender	
Female	12
Male	3
Other	0
Years of professional experience in HTA	
<10	6
10-19	5
≥20	4
Area of expertise (as described by participants)	
Health economics and related fields	6
Medical devices, non-pharmaceutical assessments, and related fields	7
HTA, HTA methods, and related fields	2
Familiar with national plans for HTAR implementation	
Yes	15
No	0

HTA indicates health technology assessment; IVD, in vitro diagnostics; MD, medical devices.
*Definitions of "formal" and "optional" HTA components were based on findings from a previous scoping review.[9]

from systems that had historically focused only on medicinal products.

> "But we do have work to try to have a more strict link between the national decision and the procurement." [Interview 2].

In these contexts, the risk class of MD is considered an important determinant of which MD could have a formal HTA component for reimbursement. However, these reforms are still in progress, with implementation challenged by multiple system deficiencies described in the following section (Table 2).

Current Challenges in National Processes for Assessment and Reimbursement of MD/IVD: A Space for HTAR-Driven Improvement

One of the most cited challenges for national MD/IVD assessment and reimbursement was the low quality of evidence available for decision making (Table 2). Participants noted that dossiers often lacked completeness or comparative data, especially from smaller companies. (Table 2). The lower quality of evidence for devices was linked to a lower evidentiary bar for MD compared with medicinal products, limiting national HTA agencies ability to produce high-quality assessments.

Furthermore, participants from 4 Member States described the link between HTA and reimbursement of high-risk devices as weak, where the procurement decisions are taken within decentralized or hospital-based systems, driven by clinical requests rather than national HTA review.

> "But linkage with decision maker is still lacking because there's no direct link between the assessment and the decision maker, because especially as you know, for the medical device, once the medical device has the CE mark … it can be used in the healthcare services." [Interview 11].

Participants also emphasized that the absence of clear incentives for HTDs of CE-marked devices to pursue national assessment often contributes to the disconnection between assessment and reimbursement (Table 2).

Domain 2: Planned or Expected Adaptations in National Structures in Response to HTAR

In general, all the interviewees expressed optimism for the HTAR implementation and described a variety of changes that have already happened, are underway, or are expected to happen in response to HTAR. These changes fell into 3 broad areas: (1) procedural adaptations of JCA, (2) structural and legal reforms, and (3) preparatory activities aimed at readiness and future alignment (Fig. 2).

Procedural Adaptations to Incorporate JCA Into National Workflows

Multiple participants indicated that their HTA bodies were beginning to review or adjust their national frameworks and decision-making processes to accommodate the integration of JCA outputs. Although the specific stage of preparedness varied, there was broad awareness that aligning with HTAR would require some procedural modifications at the national level. The general sentiment was positive, but participants expressed an intention to wait for further information, for example, finalization of the HTAR implementing acts, before initiating any change.

However, there was an overwhelming agreement between all the participants that the JCA, if available at the time of national assessment, will be used at the clinical evidence assessment stage of HTA, with comparative safety and effectiveness components already undertaken at the European level.

> "At this moment, we have plans that we use these assessments that are coming from the EU [the JCA], as the basic situation that we build our own assessment on." [Interview 3].

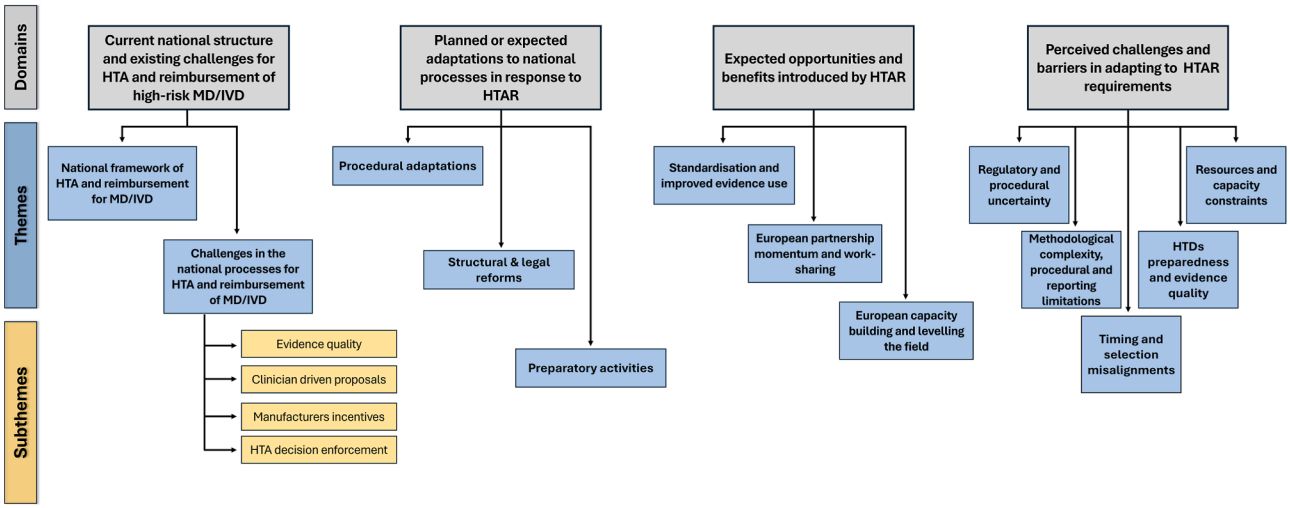
Implementing JCAs will require procedural restructuring in some Member States, including formalizing their use, adapting methodologies, and clarifying responsibilities between different bodies. These procedural changes are still being discussed, with potential adjustments expected in upcoming years (Table 2). However, most participants agreed that JCAs must be adapted to national contexts, requiring additional national analyses such as economic, organizational, legal, or ethical assessments and other country-specific criteria (Table 2).

Several participants suggested that it is unlikely that the publication of JCA alone will trigger a national assessment or reimbursement process for MD/IVD. Instead, the assessment and subsequent reimbursement will continue to be initiated based on existing national triggers (eg, HTDs' submissions or other currently defined initiators).

Structural and Legal Reforms to Strengthen HTA Capacity

Although the HTAR is directly applicable across all EU Member States, some degree of procedural or legal adaptation may still be necessary within national frameworks to ensure operational integration. Most participants described the lack of any

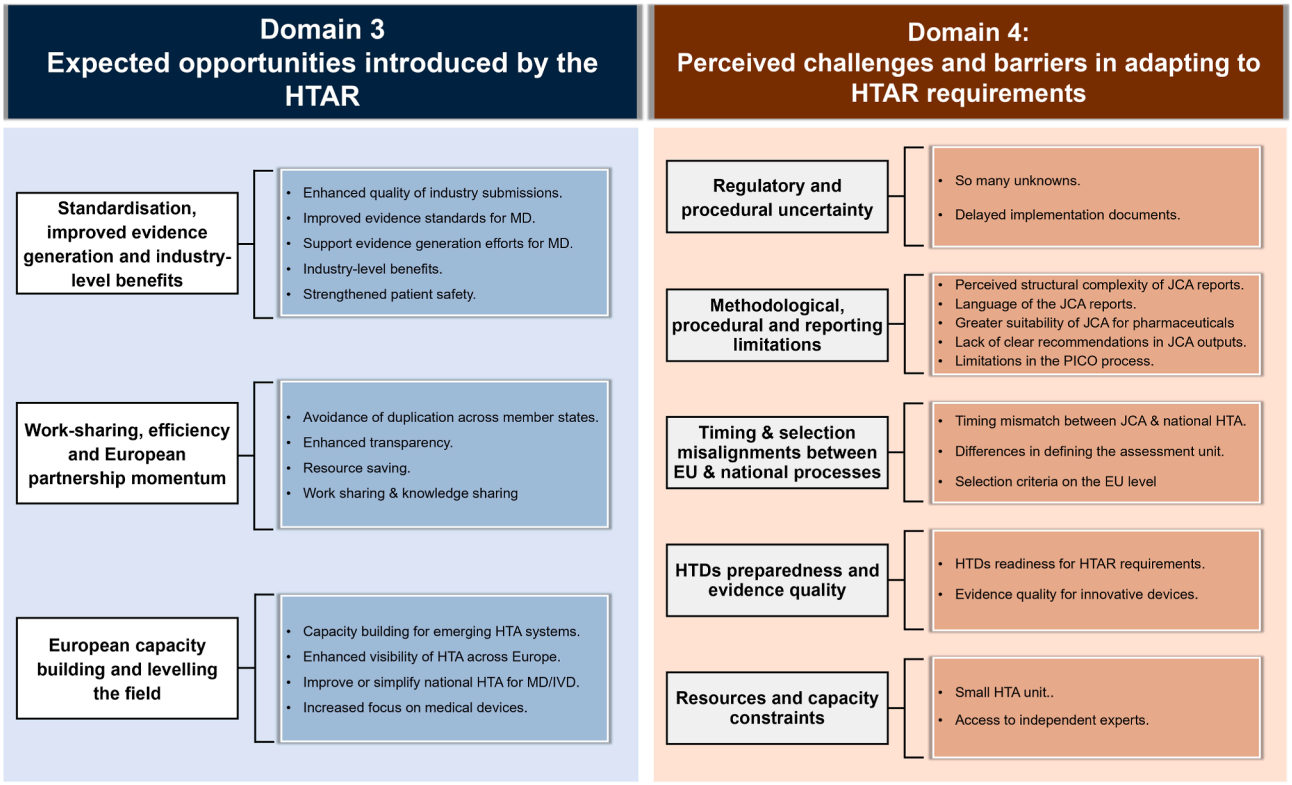
Figure 2. The thematic framework of findings from stakeholder interviews on the implementation of HTAR. Domains, themes, and subthemes were identified across the 10 EU/EEA Member States included in the analysis.



EEA indicates European Economic Area; EU, European Union; HTD, health technology developer.

substantial legal or structural reforms in the current assessment and reimbursement frameworks and oversight structures involved for high-risk MD/IVD within their Member State. Although many interviewees perceive the HTAR as a stimulus for broader HTA reform and an opportunity to overcome system deficiencies, structural or legal changes in these Member States have not yet been planned and may potentially face some resistance.

Figure 3. Expanded visualization of domains 3 and 4 from Figure 2, highlighting participants' reported opportunities in adapting to the HTAR. The figure summarizes the main themes and subthemes under 2 key forward-looking domains identified through interviews: (left) the expected opportunities and long-term benefits of the HTAR (domain 3), and (right) the perceived challenges and barriers to its implementation (domain 4).



HTAR indicates Health Technology Assessment Regulation; HTD, health technology developer; IVD, in vitro diagnostics; MD, medical device.

Table 2. Key quotes from participants across the 4 overarching domains.

Overarching domain	Key quotes	Interview number
(1) The current national structure and existing challenges of HTA and reimbursement for MD/IVD.	"….trying to be more systematic and have more defined criteria on what should go through a national process of medical devices. But we haven't decided on the final criteria, but the risk class is definitely something that we are discussing"	Interview 2
	"Most of the time, the clinical data are quite limited, and the company asks for reimbursement anyway."	Interview 5
	"The evidence-based standards for medical devices are categorically lower [than] evidence standards in drugs."	Interview 6
	"The quality of the dossiers that are submitted [for MD] is very poor, and the data are very scarce."	Interview 7
	"We don't have clear incentives yet on why the companies should submit their product for HTA."	Interview 2
	"For medical devices, we don't have this same obligation. So it has been more or less, not random, but not a very systematic process for getting the medical devices through this national HTA system."	Interview 2
	"I don't know why, but from the beginning, it was like for MD, the quality of data should be less than for medicines, but that's not true; it should be as good as for medicines. I mean, it might be a bit more difficult sometimes to get randomized control trials, but we have to go there and to get there now."	Interview 7
(2) Planned or expected adaptations in national structure in response to HTAR	"Maybe something changes in 2026 or 2027. But at this moment, we don't know how it will go."	Interview 3
	"We're not starting with medical devices just yet. But, we are having a dialogue with the [relevant national bodies] on how they will handle the JCA reports when they start arriving."	Interview 4
	"I think we're still trying to figure out how we will incorporate it [the JCA] in our evaluation reports of the medical device …… But it comes with a lot of extra workloads just purely to make sure that we are legally covered because everything that has to change in our Regulation."	Interview 5
	"It will be very interesting to make this survey within one or two years when we will have the first assessment, the first JCA and the first JSC. I think it will be very interesting too."	Interview 7
	" I think we're still trying to figure out how we will incorporate it in our evaluation reports of the medical device, but yeah, it should be mentioned somewhere…. But, we're still trying to figure out how exactly that incorporation should be, but it's still in the step of evaluation for sure."	Interview 5
	"So in essence, these two processes [national assessments and JCA] are most likely to coexist and will only influence each other if possible without any real problems."	Interview 9
	"It [the JCA] has to be adapted in the law that covers our process, and that already is a long process, but we can't start it yet because we don't know what we should adapt."	Interview 5
	"We wrote the law, and we already knew the HTAR is on the way. So, the way the law was written already had this [the HTAR] in mind. So everything sort of was accounted for"	Interview 6
	"The question will be in which time frame the topics for the HTAR will be announced, because we cannot change the national process, so we can only try to fit in evidence that is generated by this joint assessment into the process, because it is an annual process by law.	Interview 10
	"Since a couple of months back, I started even more to prepare a bigger part of the [organization] for this. So, in the first years, we were just like a handful of people in the agency working with this, but now, as it's coming closer and closer, we're involving more people and spreading the knowledge."	Interview 4

continued on next page

Table 2. Continued

Overarching domain	Key quotes	Interview number
(3) Expected opportunities introduced by the HTAR	"But of course, work sharing, it's a new thing with the Regulation. There has been voluntary cooperation in Europe for years, but this is now in legislation that we collaborate on assessments on effectiveness, relative effectiveness and safety. That's something new!"	Interview 2
	"I work in this position for 15 years now, and I think in the last three or four, five years I have had much more contact with European partners than in the 10 years before."	Interview 9
	"This is the biggest experiment in HTA in the world … so many people have invested a lot into it, getting to where it is right now. "	Interview 6
	"I think we hope that it will increase the quality of the reimbursement demands. Because sometimes now, the evidence is not there or very, very weak."	Interview 5
	"It also makes HTA more visible and also visualizes what HTA is and what the requirements are for HTA compared to CE marking, for instance."	Interview 2
	"We will also gain power by using our joint forces, we will be able in the field of pharmaceuticals at least to have a joint pressure that can be exerted on manufacturers, and this helps transparency."	Interview 9
	"And also, you know, avoidance of duplication of work because we have a lot of examples where different countries have assessed exactly the same technology."	Interview 2
	"Because less experienced [countries] will get more experience, and I know some of the countries in Europe do not have HTA agencies or are about to start them. So I think, without the Regulation, it might have been more difficult."	Interview 2
	"In a few years with the JCA process or the JSC process, [health technology developers] will maybe grow in the way they see clinical evidence building and that will be a good thing at some point …"	Interview 5
	"Once the topic comes up in one or the other way, that we say, look, there is already an assessment so that we wouldn't duplicate the work."	Interview 10
	"Also that the industry starts thinking earlier about what are the needs of HTA bodies, what [are]the data sets because currently I have the feeling that it's more about how to get the marketing authorization, how to get the CE mark and then you know, then HTA bodies or payers start asking, OK, but what about comparison?, why did you do that kind of study? …. So I hope we are not asking them in a later stage, but those questions get more relevance in earlier stage, that companies understand that you have to start to provide the data."	Interview 8
	"…maybe a change in the way that the medical devices companies approach the clinical evidence that they would have to submit in order to get a reimbursement"	Interview 5
	"There should not be a link between the size of the manufacturers and the quality of the data …. We have a lot of work to convince the manufacturers that the world is changing."	Interview 7
	"So if I imagine the world ten years from now, when MDR is actually in place, and a category 2B and 3 does come with higher evidence standards. In this world, JCA on these medical devices will definitely be welcome and definitely useful. But as we get into that stage, I think there'll be loads of bumps on the way."	Interview 6
	"What will change is also that the industry starts thinking earlier about what are the needs of HTA bodies, and what are the data sets. Because currently I have the feeling that it's more about, how to get the marketing authorization, how to get the CE mark and then you know, the HTA bodies or payers start asking. OK, but what about comparison?"	Interview 8

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Table 2. Continued

Overarching domain	Key quotes	Interview number
(4) Perceived challenges and barriers in adapting to HTAR requirements	"I think that has been the biggest challenge, so many unknowns, … because the implementing act on joint clinical assessment for medical devices is still under development and also some of the guidance documents. So it's really hard to, you know, start to adjust the national processes and timelines because you don't know them at the EU level."	Interview 2
	"In the meantime, if you imagine this two-year gap, there might be a change in the PICO code that is so substantial that the JCA no longer applies. Therefore, this might trigger the need for a reassessment at the European level, but we're already tied by the timelines of our legal processes."	Interview 9
	"We didn't really get started properly [until] maybe autumn last year because we were waiting for all the guidance on all the implementing acts to be published"	Interview 2
	"I think it's that we have quite a small HTA process here and not so many HTA experts. So we have the problem of how we can be a part of this new assessment because we don't have so many people to do this job."	Interview 3
	"I think the biggest challenge for us during these years of preparations has been that we don't have the resources to do this work."	Interview 4
	"But at the same time, the joint scientific consultation for HTA, it's more complicated than the scientific advice that the developer can ask the EMA for the regulatory purpose…… I think I see a lot of challenge here, because there' s study design. There's going to be a lot of challenge because also the joint scientific consultation is not mandatory, it's on demand. So let's say, OK, why if I have CE mark and I can be sold directly or by registering in a list in your country. Why have to ask for a parallel advice?"	Interview 11
	"We fear that we won't have enough time to be able to get the required information to insert into this PICO"	Interview 5
	"…Which is, I guess, one of the big criticisms of JCA, as such that it doesn't really give you answers."	Interview 6
	"The hot topic always is the comparators which will be chosen at EU level, will those actually be those that make sense in our country?"	Interview 8
	I think that the most important challenge that we were thinking about from the very beginning was whether the medical device company would be able to submit enough evidence for JCA to be valuable? Because presently within [the] JCA process [it] is quite complex.	Interview 5
	"Joint clinical assessment is conducted by product, by single medical device, … we don't assess specific products, because [devices are] reimbursed by class, not by specific product.	Interview 11

HTA indicates health technology assessment; HTAR, Health Technology Assessment Regulation; HTD, health technology developer; IVD, in vitro diagnostics; JCA, joint clinical assessment; JSC, joint scientific consultation; MD, medical device.

(When asked if they would change anything in the legally defined process timelines to fit the JCA) "I'm not so sure because this process is so established and I think there will be a lot of resistance from many actors, they are very used to this process and it's working really well." (Interview 10).

On many occasions, participants from Member States further acknowledged that legal change might be required before JCAs could be formally embedded in national processes because their HTA body is legally bound to an annual reimbursement process with specified criteria (Table 2).

However, some Member States had already initiated significant structural and legislative adjustments to standardize the HTA process and support reimbursement decisions of high-risk MD/IVD. These adjustments were introduced with HTAR in mind and will support the integration of JCA into national decision making (Table 2).

Preparatory activities aimed at readiness and future alignment

Even where formal reforms had not yet begun, most participants described different readiness activities that were performed or underway to prepare for the availability of JCA reports. These included the formation of national working groups to navigate the HTAR implementation, the mapping of existing HTA workflows, and internal knowledge-sharing initiatives (Table 2).

Other participants highlighted the importance of active engagement at the European level, getting involved in pilot projects, participating in early PICO development exercises, monitoring the changes with medicinal products, and observing how JCAs would be received and operationalized before fully integrating them into national processes.

"We made the choice to be actively involved in the preparation, so for us, it's a way to get prepared. I mean to gain some experience and to get prepared." (Interview 7).

Finally, 1 participant further highlighted the need to develop a national protocol for disseminating JCA results to national stakeholders, including ministries, payers, and regional actors responsible for funding decisions.

"We have to establish a process of how to make all the actors in the system that are responsible for paying for, or making decisions, how to make them aware that these reports are available ……., so that even if there is an ongoing evaluation process of one of those devices, we will try to disseminate it to the ministry or to those who are generally involved in these processes." (Interview 1).

Domain 3: Expected Opportunities Introduced by the HTAR

All participants expressed strong optimism about the long-term potential of the HTAR to strengthen the existing HTA practices for high-risk MD/IVD. Despite recognized challenges (discussed in detail under domain 4), interviewees identified 3 overarching opportunity themes: (1) standardization and improved evidence generation for high-risk devices and industry-level benefits, (2) work sharing, efficiency, and European partnership momentum, and (3) system-wide capacity building and leveling (Fig. 3).

Standardization and Improved Evidence Generation for MD Including High-Risk Devices

Participants widely agreed that the HTAR, through JSC and JCA, could strengthen evidence generation and promote more consistent clinical data use in device assessments. They expected it to improve clinical trial design, and, in the long term, this will enhance the quality of dossiers submitted to support reimbursement applications for MD, not only those assessed at the EU level but also those submitted for national assessment (Table 2).

"I think all the companies will take it more seriously that they need to produce good evidence, because now it's at the European level and not just on the individual company, country or whatever level." [Interview 10].

Several interviewees also suggested that the HTAR might shift the attention of small and medium-sized enterprises to consider HTA requirements earlier during device development, aligning clinical trial design with payer needs rather than focusing solely on regulatory approval.

Interviewees also suggested this shift in generation and utilization of evidence for comparative safety and effectiveness for high-risk MD/IVD brought about by the HTAR would ultimately enhance patient safety by supporting more transparent, evidence-informed decision making across Member States (Fig. 3).

"These devices are selected for good reason …… these devices are not only high risk, they are usually high-priced devices, and you don't want to have these implanted in too many patients if the effects are not really well proven." (Interview 9).

Work Sharing, Efficiency, and European Partnership Momentum

Participants viewed the HTAR as a major step toward European work sharing and collaboration, promoting standardization, shared expertise, and trust in health decision making. Interviewees positively viewed the shift from voluntary collaboration under the European Network for Health Technology Assessment to legally mandated coordination as a milestone for European partnership and HTA of MD, symbolizing stronger European unity in HTA for high-risk devices.

"This is a huge step [the JCA]. It's a huge, huge achievement for the Member States.

We know each other, we see each other, there's a lot of collaboration." (Interview 11).

European Capacity Building and Leveling of the Field

Interviewees repeatedly emphasized that the Regulation could harmonize evidence use across Member States by strengthening capacity in those with weaker HTA systems. For countries with limited staff or infrastructure, JCAs were viewed as a valuable way to access high-quality assessments and bridge national capacity gaps (Table 2).

"But as a representative of [a small country], and we have really small teams…. So we wouldn't have that kind of workforce to do all the work ourselves, so I do hope that these reports will help us and support our work." (Interview 8).

Even for Member States with developed HTA systems for MD, participants noted that the HTAR would provide the opportunity to increase the number of devices assessed annually and improve or simplify national assessments. The HTAR was also seen as an opportunity to build institutional knowledge, enhance the visibility and recognition of HTA across Europe, and offer the chance to improve HTA methodologies for MD.

Domain 4: Perceived Challenges and Barriers in Adapting to HTAR Requirements

Although interviewees expressed strong enthusiasm for HTAR implementation, they also shared concerns about the implementation roadmap, which can be grouped under 5 core themes: (1) regulatory and procedural uncertainty, (2) methodological complexity and procedural and reporting limitations, (3) timing and selection misalignments between EU and national processes, (4) HTDs' preparedness and evidence quality, and (5) resources and capacity constraints (Fig. 3).

Regulatory and Procedural Uncertainty

Participants expressed concerns about the lack of procedural clarity for JCAs of high-risk MD/IVD. The absence of final guidance or implementing acts created uncertainty, leading many Member States to adopt a "wait-and-see" position. Many member states were reluctant to restructure national legislation or reimbursement pathways without clear knowledge of how JCA for high-risk MD/IVD would function (Table 2).

Methodological Complexity and Procedural and Reporting Limitations of the JCA Process

Another central theme among anticipated roadblocks was challenges related to the design of JCAs themselves. Participants highlighted concerns about the tight PICO collection timelines, potential conflicts of interest among consulted experts, and misalignment between consolidated JCAs and national contexts. Furthermore, participants from countries with later market access also worried that early-defined PICOs might be outdated by the time national reimbursement decisions occur.

> "Because in the meantime, if you imagine this two-year gap, there might be a change in the PICO code that is so substantial that …, the JCA done two years ahead [no longer] applies." (Interview 6).

Additional concerns included the complexity and language of JCA reports, especially in Member States where official documentation must be translated into national languages.

Timing and Selection Misalignments Between EU and National Processes

One of the most noted structural barriers was the potential mismatch between the timing of European JCA and fixed national HTA/reimbursement timelines and selection criteria. In several Member States, assessments must be completed within strict annual cycles, with deadlines set by law. If JCAs are not published in time to meet these cycles, they may be unusable because a decision will be made anyway. Participants noted that without better timing coordination, the JCA process might be too late for some Member States.

> "If you just add up the legally specified timelines, the European HTA process for medical devices will be too late for the national HTA." (Interview 9).

Another barrier is the unit of assessment for JCA of high-risk MD/IVD; although the EU process assesses a single device, representatives from different Member States expressed that they essentially assess a procedure (in which a device is being used) or a class of devices (device category).

HTDs' Preparedness and the Quality of Available Evidence

Several interviewees voiced concerns about the capacity of medical device HTDs, particularly small and medium-sized developers to meet the evidence standards and trial design expected in JCAs.

> "…. the level of readiness from the health technology developers for medical devices, which are probably less ready than the [Medicinal products] ones. As we said earlier, it's mostly small companies or small to medium-sized companies, and even bigger companies, that might not be completely ready for the HTAR." (Interview 7).

Participants also expressed concerns about the usability of JCAs when clinical evidence is limited (eg, highly innovative devices) that might have limited value for national systems, forcing them either to reject technologies or seek additional data that may not be available (Table 2).

Resources and Capacity Constraints

Resource limitations emerged as a significant challenge for participants from multiple Member States, particularly among smaller HTA bodies. Interviewees described being overstretched with current work, lacking staff dedicated to HTAR planning, or not having access to enough independent experts for PICO development or expert consultation. Some also noted that contributing to JCA production would divert resources from national priorities, particularly in systems with small teams.

Clinician engagement was also identified as a potential bottleneck. Participants from smaller Member States could see potential difficulty in recruiting expert advisors free from conflicts of interest, especially in specialized fields, such as diagnostics or surgical technologies.

> "As a small country, we do not have so many experts, clinician experts who have no conflict of interest. That's also a challenge." (Interview 3).

Discussion

In this qualitative study, we examined how selected EU/EEA HTA bodies perceive the transition in response to HTAR and the challenges and opportunities they face during the process. Although HTA bodies may not directly control national reimbursement processes, they play a key role in engaging stakeholders, informing procedural discussions, and preparing for potential national adaptations ahead of HTAR implementation.[12] These findings offer a ground-level view of how the Regulation is being integrated into national systems at the early stage of implementation, building on earlier legal and policy analyses of HTAR implementation challenges.[8,13-15]

Member States are required to give due consideration to the JCA outputs,[7] to reduce duplication of effort; however, they retain independence of the national reimbursement decisions.[13] The interviewed participants expressed enthusiasm for JCA outputs for high-risk MD/IVD, a field with a historically low bar for evidence quality in Europe.[2] Participants expressed optimism about the HTAR's potential to strengthen evidence standards for high-risk MD/IVD, promote work sharing, improve transparency, and enhance equity by supporting smaller HTA systems.[16]

Some Member States are already updating their legislation and reimbursement systems for HTAR, whereas others are waiting because of procedural uncertainty and pending implementation documents. A key barrier to effective HTAR adaptation was the misalignment between EU and national timelines, a concern that was raised by previous stakeholders.[6] This prompts the call to initiate dialog around aligning timelines and clarifying the role and applicability of JCAs in systems with differing legal and procedural structures.

Interviewees raised concerns about conflicts of interest in PICO development, especially in smaller Member States with limited experts, and about the national relevance of consolidated European PICO for each JCA, a concern repeatedly voiced by other stakeholders in a previous study.[17] They stressed the need for greater dialog to ensure final PICOs are meaningful across all countries.

Another recurrent challenge was the uncertainty surrounding HTD preparedness, noting that many small and medium-sized device developers lack experience with comparative trials and structured HTA submission, a concern reported as a barrier in previous studies examining national HTA submissions by HTD stakeholders.[18] This concern echoes broader commentary on the need to improve the quality of evidence for high-risk MD/IVD across Europe.[2]

The weaknesses in HTD-submitted evidence were seen as a challenge and a key area for reform in which the HTAR can catalyze higher standards (especially when combined with JSC), better alignment with regulatory pathways, and ultimately safer, more transparent decision making for high-risk MD/IVD across Europe.

Strengths and Limitations

To our knowledge, this study offers one of the first empirical studies of the views of HTA bodies across Member States on HTAR implementation for high-risk MD/IVD. Although the sample size might be considered small, it is important to note that qualitative studies can reach "data saturation" within 12 to 13 interviews, particularly those with relatively homogenous study populations and narrowly defined objectives.[19]

In addition, the interviews were conducted before the full implementation of HTAR, meaning that views may evolve as JCAs are operationalized. Therefore, continued monitoring will be important to capture changes over time. Also, 1 potential limitation is that all interviews were conducted in English, which was not the first language for most participants and could therefore

have possibly influenced the depth of some responses. Finally, as with all qualitative research, findings are shaped by the interviewees' perspectives and may not fully capture institutional dynamics not discussed during interviews.

Conclusions

Interviews with HTA stakeholders from 11 Member States revealed wide differences in readiness, expectations, and views on JCA feasibility. Overall, the HTAR was seen as an opportunity to harmonize clinical assessments, minimize duplication, and build capacity for evaluating high-risk MD/IVD, ultimately improving patient outcomes across Europe. However, participants raised concerns that are responsible for a "wait-and-see" position that multiple Member States held.

Meaningful HTAR implementation for high-risk MD/IVD will require ongoing coordination, consultation, capacity building, and a sustained commitment by all relevant stakeholders to balance EU-wide integration with the realities of national HTA and reimbursement systems of all Member States. Our findings suggest HTAR success for MD/IVD will depend not only on the technical quality of JCAs but also on how effectively they align with diverse national decision-making frameworks.

Author Disclosures

Author disclosure forms can be accessed below in the Supplemental Material section.

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