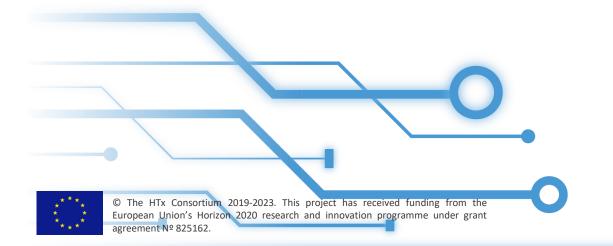


# Artificial intelligence (AI) driven scientific evidence in the HTA: barriers and recommendations to address them



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ISPOR Europe 2023 November 13, Copenhagen

## Al in HTA context



A data analytics tool supporting evidence generation for HTA

#### Machine learning:

 cohort selection, feature selection, causal inference, or developing economic models, etc.

#### Natural language processing:

 evidence synthesis from the literature, or extracting key parameters from textual notes (EMR), etc.

# Perspective and Aim



#### Central and Eastern European (CEE) countries

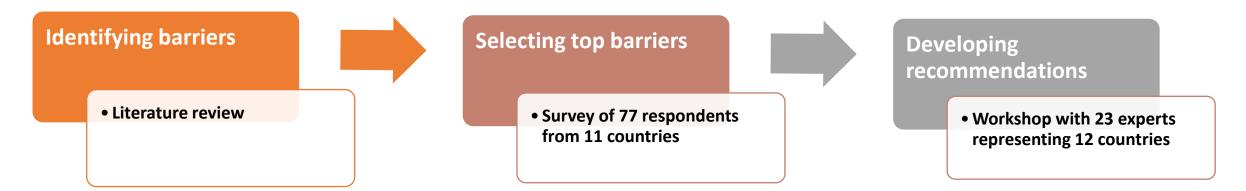
- lag behind Western Europe in HTA implementation
- have single-payer healthcare systems and large claims databases
- face substantial barriers to implementing AI-driven evidence generation in HTA

#### Aim

 to provide recommendations to support healthcare decision-makers in properly integrating AI into the HTA methodologies and processes

## Methods





ORIGINAL RESEARCH article

Volume 11 - 2023 | https://doi.org/10.3389/fpubh.2023.1088121

Recommendations to overcome barriers to the use of

artificial intelligence-driven evidence in health technology

Front. Public Health, 26 April 2023

Sec. Digital Public Health

assessment





## Barriers identified in the review<sup>3</sup>



	Next Generation Health Technology Assessment
	Systemic bias in the data (e.g. due to upcoding)
	Issues with reliability, validity and accuracy of data (e.g. due to the lack of quality assessment of data entry or self-reporting)
	Raw fragmented or unstructured data (e.g. electronic medical records, imaging reports), which are difficult to aggregate and analyze
	Data acquisition and cleansing is not feasible
	Analysis of multicenter data is limited due to the lack of interoperability across systems (e.g. electronic medical records of different service providers)
Data related barriers (11)	Lack of well-described patient level health databases
, ,	Multinational data collection and analysis is limited due to differences in coding system across countries, and the lack of mapping methods to
	standardize the vocabulary
	Data that are relevant for research purposes are missing from databases built for the healthcare financing or provision (e.g. important clinical endpoints)
	The database is incomplete to fully track patient pathways, leading to inconsistent, unreliable findings
	Sample size of the available databases are low (e.g. databases of health care providers are not linked)
	Potential bias of AI to favor some subgroups based on having more or better information
	Lack of transparency of protocols for data collection methods
Nathadalasiaal harriara (6)	Text mining and natural language processing algorithms cannot be applied due to the lack of standardized medical terms in the local language
Methodological barriers (6)	Limited reproducibility due to the complexity of the methods
	Lack of methodological transparency of deep learning models ("black box" phenomenon)
	Complexity of the diseases and co-morbidities
	Lack of capacity to build and maintain IT infrastructure to support AI process
Technological barriers (3)	High costs associated with securing and storing data for research purposes
	High cost of improving data validity (e. g. data abstracters to evaluate unstructured data)
	Regulatory compliance issues in the process of managing high volume of sensitive information
Regulatory and policy	Lack of awareness and openness on the part of decision-makers to rely on AI based real-world evidence
	Lack of political commitment (e.g. no health digitization strategy in the country to establish relevant databases)
related barriers (5)	Acceptance and consent by patients and medical professionals
	Lack of access to patient-level databases due to data protection regulations
	Lack of knowledge in data governance: data ownership and data stewardship
Human factor related	Lack of appropriate skills for applying AI methods (natural language processing, machine learning etc.) in outcomes research
barriers (5)	Lack of adequate education to generate AI driven scientific evidence
	Lack of decision-makers' expertise about the methods and use of AI driven scientific evidence

<sup>3</sup>Tachkov, et al. (2022). Barriers to use Artificial Intelligence methodologies in Health Technology Assessment in Central and East European countries. Frontiers in Public Health. doi: 10.3389/fpubh.2022.921226

Rank	Barrier		Mean Likert score	Barrier group
1	Lack of decision-makers' expertise about the methods and use of AI driven scientific evidence		4.03	Н
2	Lack of appropriate skills for applying AI methods (natural language processing, machine learning etc.) in outcomes research	Top barriers:	3.90	Н
3	Lack of adequate education to generate AI driven scientific evidence		3.90	Н
4	Issues with reliability, validity and accuracy of data (e.g. due to the lack of quality assessment of data entry or self-reporting)	average score ≥3.5	3.88	D
5	Lack of awareness and openness on the part of decision-makers to rely on Al-based real-world evidence		3.85	R
6	Lack of political commitment (e.g. no health digitization strategy in the country to establish relevant databases)		3.81	R
7	Multinational data collection and analysis is limited due to differences in the coding system across countries, and the lack of mapping methods to standardize the vocabulary			D
8	Lack of resources to build and maintain IT infrastructure to support AI process			Т
9	Regulatory compliance issues in the process of managing a high volume of sensitive information			R
10	Analysis of multicentre data is limited due to differences in database structures across systems (e.g. electronic medical records database of different service providers)			D
11	Raw fragmented or unstructured data (e.g. electronic medical records, imaging reports), which are difficult to aggregate and analyse			D
12	High cost of improving data validity (e.g. data abstracters to evaluate unstructured data)			Т
13	Systemic bias in the data (e.g. due to upcoding)			D
14	Lack of well-described patient-level health databases			D
15	Data that are relevant for research purposes (e.g. important clinical endpoints) are missing from databases or are available only on paper.		3.54	D
16	The database is incomplete to fully track patient pathways, leading to inconsistent, unreliable findings			D
17	High costs associated with securing and storing data for research purposes		3.47	T
18	Data is not transferable across countries for multinational analyses		3.46	D
19	Lack of access to patient-level databases due to data protection regulations		3.42	R
20	Lack of knowledge in data governance: data ownership and data stewardship		3.42	Н
21	Lack of transparency of protocols for data collection methods		3.37	M
22	Data cleansing is not feasible		3.28	D
23	Lack of methodological transparency of deep learning models ("black box" phenomenon)		3.18	M
24	Potential bias of AI to favour some subgroups based on having more or better information		3.15	M
25	Sample size of the available databases are low (e.g. databases of health care providers are not linked)		3.13	D
26	Acceptance and consent by patients and medical professionals		3.13	R
27	Text mining and natural language processing algorithms cannot be applied due to the lack of standardized medical terms in the local language		3.12	M
28	The result of analysing complex diseases with AI is difficult to use in health economic models		3.10	M
29	Limited reproducibility due to the complexity of AI methods		3.06	М

# Selected barriers by groups

1 (very low importance) – 5 (very high importance)



Barrier group	Avg score	Selected
Human factor related barriers	3.8	3/4
Regulatory and policy-related barriers	3.6	3/5
Technological barriers	3.6	2/3
Data related barriers	3.5	7/11
Methodological barriers	3.2	0/6
Total	3.5	15/29

### Human factor related barriers



Limited AI expertise for decision-makers, lack of skills in methods like NLP and ML, and lack of education to generate AI-driven scientific evidence.

- More reliance on expertise in academic centers
- Ensuring diverse representation of WE and CEE countries in international collaborative projects (Horizon Europe, IHI) to facilitate knowledge transfer in AI methods or database developments
- Create or adopt a virtual platform for experience exchange between countries (e.g., Decide Health Decision Hub)
- Developing targeted (AI for HTA) educational material

## Regulatory and policy related barriers



Limited decision-maker awareness and openness to AI-based real-world evidence, insufficient political commitment for health digitization and data collection, and regulatory compliance challenges in handling sensitive information.

- Advocate more reliance on claims databases in health policy decisions, leading to better regulation of their use
- Join "federated network studies" to run analysis without the need to share or centralize datasets (e.g., EHDEN, DARWIN EU)
- Establish trusted research environments for the safe use of data in research

## Data related barriers



Interoperability issues, incl. coding system and database structure differences

Data incompleteness, unstructured data, reliability, validity and accuracy issues

- Standardization through common data models (e.g. OMOP CDM): structural and terminological mapping → allows for federated network studies
- Local coding systems to be harmonized with standards when updated
- Adapting data abstraction methods (e.g., RegExp) to retrieve key variables from texts
- Improve standardized and structured data entry in routine practice
- Link databases (e.g., claims with EHR)
- A chapter on limitations of the AI-based evidence (also in lay language) should be a standard part of the HTA report



## Technological barriers



Lack of resources to build and maintain IT infrastructure

- Develop infrastructure and human capacities for AI in centers
- Use technologies that are scaled to the needs of the analysis
- Sustainability plan to be presented for publicly funded database or Al-related project (e.g., Horizon Europe, IHI)

# Key takeaways



- AI can enhance HTA by providing data-driven insights, but it needs rigorous evaluation
- CEE countries have unique chances in AI due to (mostly) single-payer systems but face barriers
- Recommendations include enhancing expertise, international collaboration, regulatory enhancements, infrastructure development
- Data standardization is vital for AI-driven HTA, including common data models and harmonized coding systems. Participation in data initiatives is key for influencing EU-level decisions



# Thank you for your kind attention!

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