The Use of the Sandbox Approach in the Context of HTA: A Literature Review

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BACKGROUND

A **"regulatory sandbox"** is an environment for testing new regulatory processes without compromising current regulation.

This literature review focuses on using **regulatory sandboxes in healthcare,** evaluate potential **use of this approach in HTA policy development** and inform **establishing a policy sandbox** within the Horizon-2020 HTx (Next Generation Health Technology Assessment) project.

More information about the HTx project can be found at the website **www.htx–h2020.eu/ (false://www.htx–h2020.eu/)**.

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METHODS

A **literature review** was undertaken to identify published papers and reports that described and/or assessed the use of sandboxes in the healthcare sector.

Searches were conducted in the databases Medline, Embase, Econlit, Social Policy and Practice, and Health Management Information Consortium. We also searched Google/Google Scholar. The search terms used focused around **"policy sandbox", "regulatory sandbox", "sandbox" and "healthcare"**.

The search was limited to articles published in English. We did not apply any publication date limits.

The records identified were then exported and checked for inclusion by, two reviewers (EL, DD) independently. The main inclusion criterion was that the **'article should focus on the definition or application of policy or regulatory sandboxes in healthcare'**.
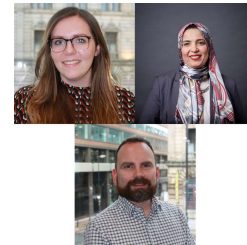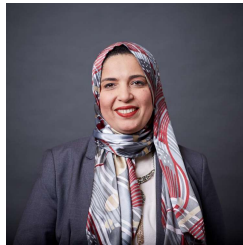
The themes extracted from the included articles were mapped by EL. These themes were then discussed with DD, and a final list was agreed by the three authors (EL, DD and PJ).

FINDINGS

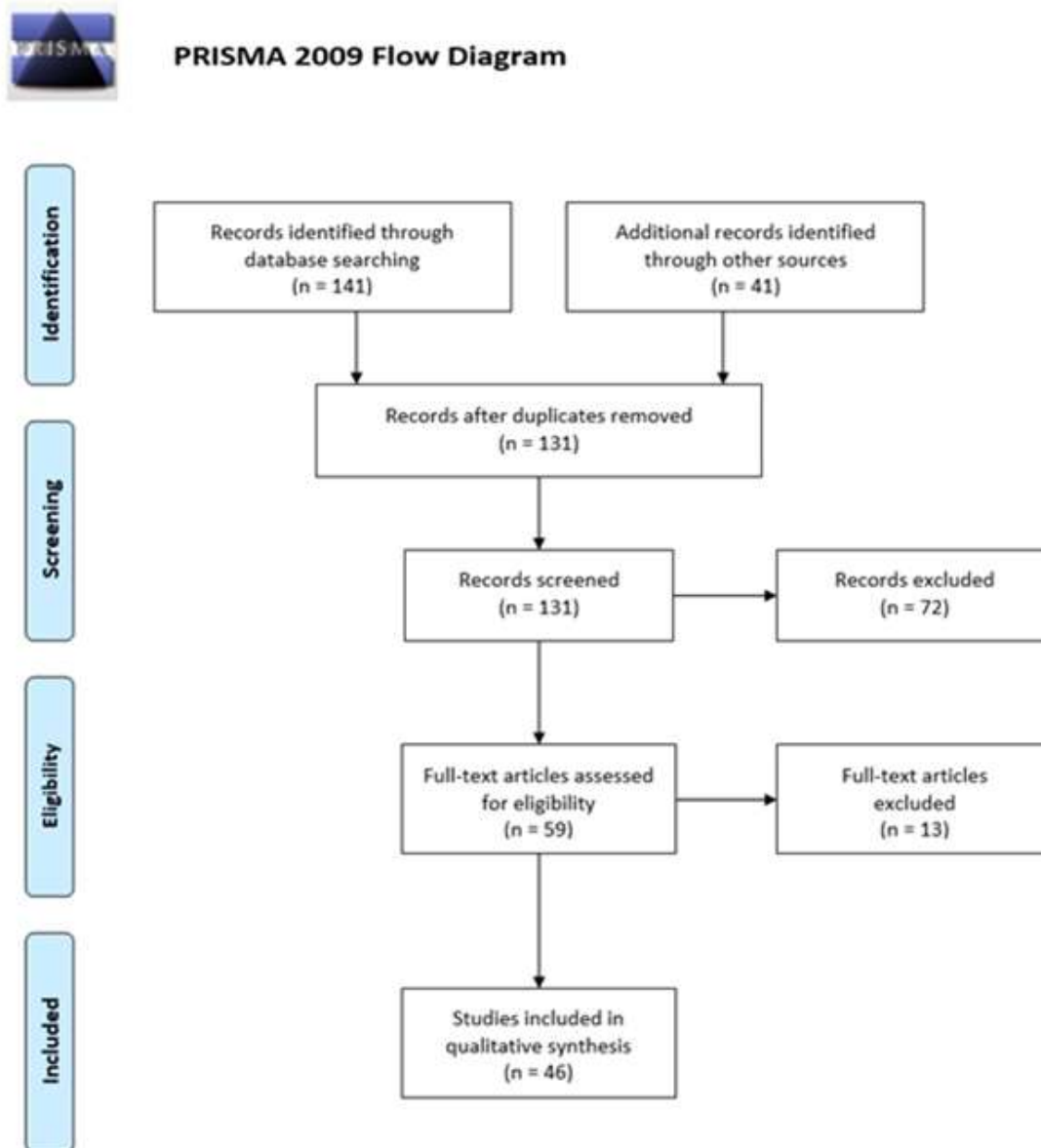Overall, a total of **46 articles and reports** were finally included.

PRISMA 2009 Flow Diagram

Figure 1: PRISMA Flow Chart of the Literature Review Process

The following themes were identified and discussed in detail:

Figure 2: Themes Identified from the Included Reports and Studies

Identified sandboxes were defined as **'outcomes focused'** or **'data focused'**:

	Location	Name	Organisation(s)	Aim
Outcomes focused	UK	HealthTech Regulatory Sandbox	ICO, Data Guardian, NICE	Cross sector collaboration for ensuring successful implementation into NHS
	UK	CQC Regulatory Sandbox	Care Quality Commission	Defining 'good care', and how to facilitate and deploy new innovations
	UK (Scotland)	Care Inspectorate Sandbox	Care Inspectorate	Focus on restructuring social care services to suit evolving care system
	UK	NHS Test Bed programme	NHS	Removing barriers to uptake of innovative technologies within the NHS; test and evaluate the impact of digital innovations in real-world settings
	Singapore	Licensing Experimentation and Adaptation Programme (LEAP)	Ministry of Health	Promote an effective way of supporting innovation while maintaining patient safety and welfare, through improved interaction between industry and regulators
	Japan	Regulatory Sandbox Framework	Government of Japan	Facilitate development of innovative technologies and business models in Japan
Data focused	UK	ICO Sandbox Programme	ICO	Delivering real benefit for the UK public through innovations in technology and use of data
	UK	Health Data Research UK sandbox	HDR UK	Virtual environment that offers access to large scale health data for the development of products, services or innovations that benefit the population
	UK	Kernow Health CIC Sandbox	Kernow Health CIC	Opportunity to sample and improve products in real-life NHS clinical environments
	Jersey	Digital Health Jersey Sandbox	Digital Jersey	Providing testbed environments to companies that are developing digital health solutions
	Europe	eIT Health Digital Sandbox	European Institute of Innovation and Technology	Improve access to registries, biobanks, and other digital health sources for SMEs
	America	Digital Health Sandbox Program	Massachusetts eHealth Institute	Support product development within digital health companies and promote the use of sandbox environments to a varied user base

Abbreviations: ICO: Information Commissioner's Office; NICE: National Institute for Health and Care Excellence; CQC: Care Quality Commission; NHS: National Health Service; HDR: Health Data Research; CIC: Community Interest Company; eIT: European Institute of Innovation and Technology

Figure 3: Examples of Sandboxes identified through the review

DISCUSSION

As a testing approach

Arntzen *et al.* (2019) categorised testing environments according to control within the environment, and when the approach is used during product development.
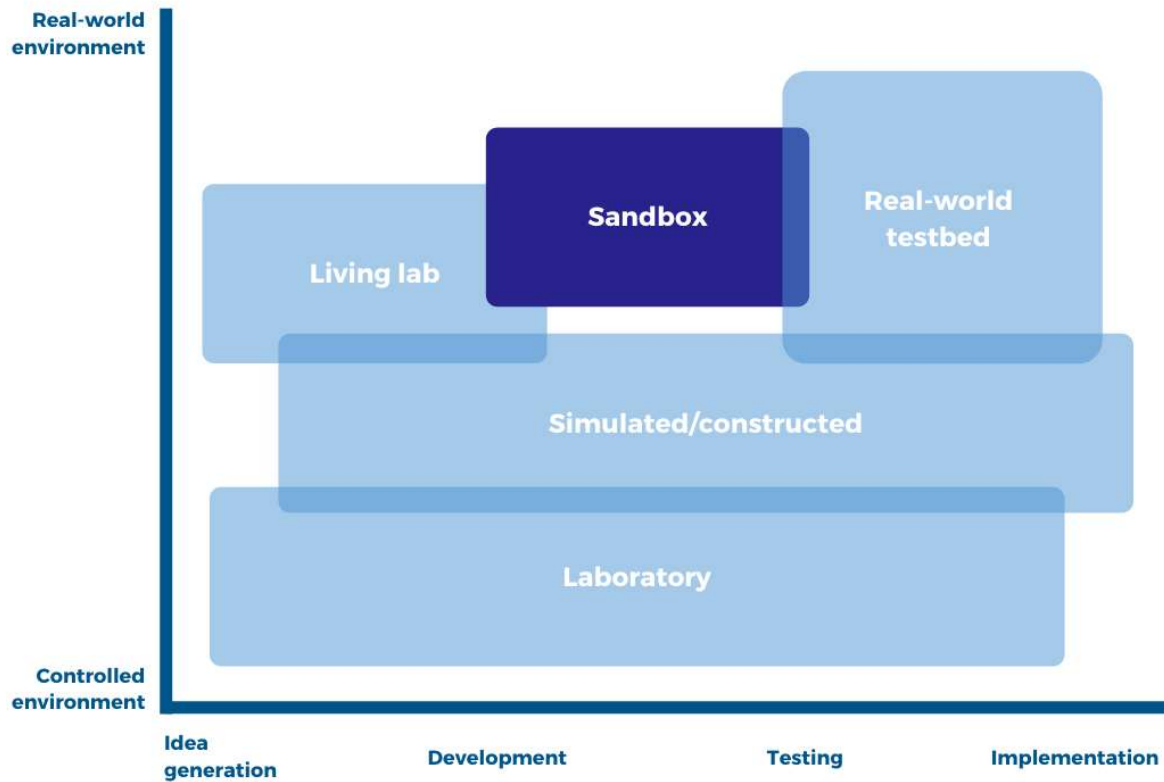

Figure 4: Types of testing environments used in product innovation (adapted from Arntzen et al., 2019)

As a regulatory approach

Armstrong & Rae (2017) described the sandbox approach as an example of anticipatory regulation, where regulation is seen a support tool rather than a barrier to innovation.
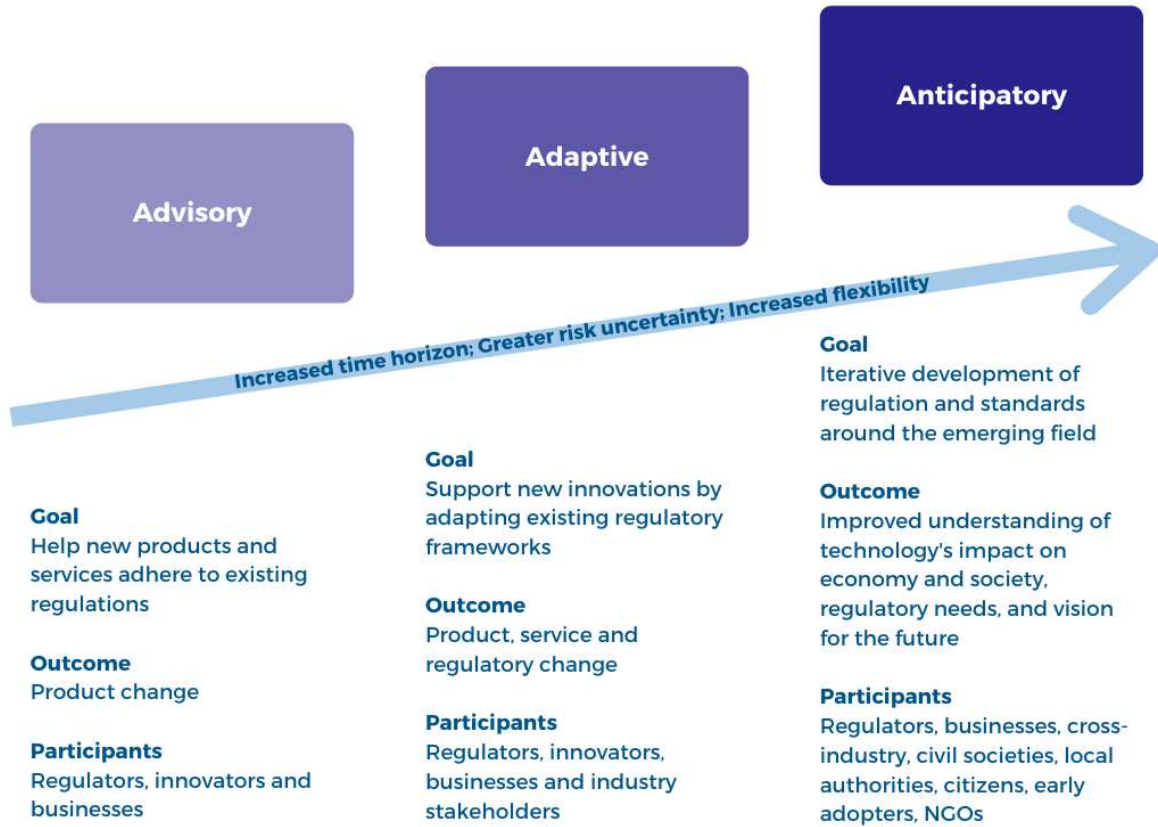
Figure 5: Levels of regulation used during product innovation (adapted from Armstrong & Rae, 2017)

Approaches for developing a policy sandbox

Overall, there is limited sandbox activity that relates directly to HTA. Therefore, a sandbox that focuses on policy issues, rather than solely regulatory challenges, is required to drive forward advances in this area.
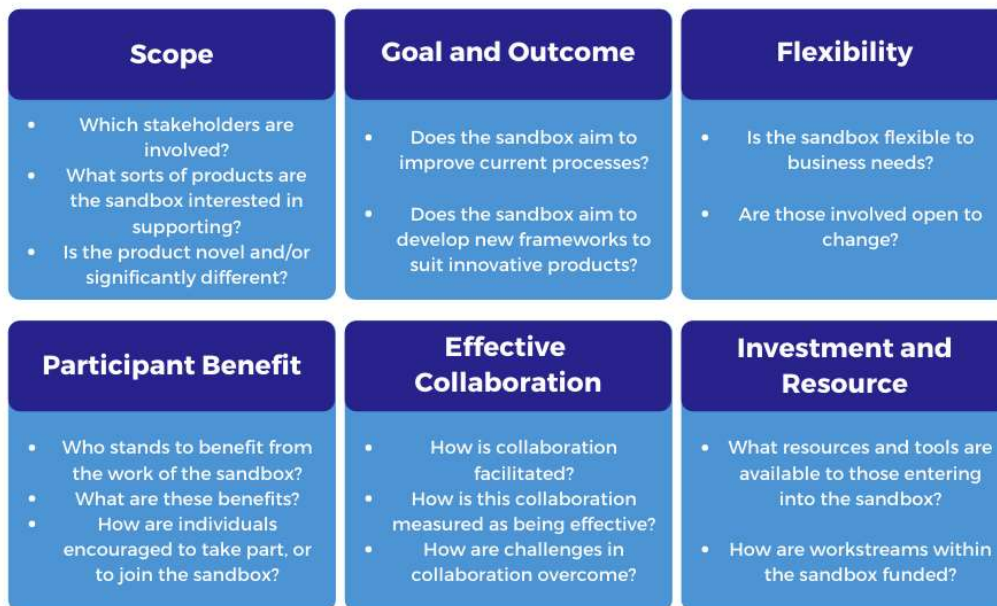
References

- Arntzen, S., Wilcox, Z., Lee, N. & Hadfield, C., 2019. Testing innovation in the real world: real-world testbeds.

- Armstrong, H. & Rae, J., 2017. A working model for anticipatory regulation.

AUTHOR INFORMATION

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ABSTRACT

OBJECTIVES: A "regulatory sandbox" is an environment for testing new regulatory processes without compromising current regulation. This research aims to review the literature on using regulatory sandboxes in healthcare, evaluate potential use of this approach in health policy development and inform establishing a policy sandbox within the Horizon-2020 HTx (Next Generation Health Technology Assessment) project.

METHODS: A literature review was undertaken to identify published papers and reports that described and/or assessed the use of sandboxes in the healthcare sector. Searches were conducted in Medline, Embase, Econlit, Social Policy and Practice, and Health Management Information Consortium. Google search was also conducted to identify the relevant grey literature. Only papers and reports discussing or evaluating the use of sandboxes in healthcare settings and published in English were included.

RESULTS: Overall, 45 papers and reports were included. Findings show that the use of regulatory sandboxes in healthcare is relatively new. The first was launched by the UK Care Quality Commission in 2019 to develop regulatory clarity for deployment of innovative healthcare technologies including digital triage and machine learning. Several regulatory sandboxes have emerged since to support the development and implementation of new medical technologies, particularly those related to e-health. Different models of "policy sandboxes" can be established to aid in the development of methods for the assessment of innovative health technologies for widespread adoption and use. Transferability to low- and middle-income countries' settings will need to be assessed.

CONCLUSIONS: The use of sandboxes as controlled environments for testing new innovations and regulatory developments is increasingly seen within healthcare. This approach has not yet been used in HTA policy and methodological developments, despite its potential. Research projects working on methodological developments, similar to HTx, should consider establishing policy sandboxes to assess the potential use of this approach in informing real-life decision-making.

REFERENCES

- Arntzen, S., Wilcox, Z., Lee, N. & Hadfield, C., 2019. Testing innovation in the real world: real-world testbeds.
- Armstrong, H. & Rae, J., 2017. A working model for anticipatory regulation.

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