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/).

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement N=825162.
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 Flow Diagram](image)

*Figure 1: PRISMA Flow Chart of the Literature Review Process*

The following themes were identified and discussed in detail:
Identified sandboxes were defined as ‘outcomes focused’ or ‘data focused’:

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

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
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.

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.
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**

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


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