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"Sailing the ship while building it": Sandbox regulation and the political economy of Israeli healthcare AI innovation

Aviad Raz [a,*], Liat Bela Lifshitz-Milwidsky [a], Yael Inbar [b]

[a] Department of Sociology and Anthropology, Ben-Gurion University, Israel
[b] Coller School of Management, Tel Aviv University, Israel

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1. Introduction

Healthcare AI is at the center of a global transformation invoking both prospects and perils. The unique advantages of AI in healthcare stir a global regulatory dilemma: while its adaptive capabilities offer promise for enhancing medical decision-making, global regulations rooted in risk-aversion constrain these very features (WHO, 2021; 2023). Regulatory challenges include how to integrate pre- and post-deployment adaptive regulation of AI systems, and how to regulate such lifecycle evaluations in diverse clinical settings with robust and real-time monitoring (Raz et al., 2025; Feng et al., 2022). The advantage of learning from real-world clinical experience provides a much-needed opportunity for deep learning AI algorithms to evolve and improve. Yet, it also constitutes a regulatory challenge, since such potential for learning may essentially change the algorithm and raise concerns about biases, explainability, accountability, and equity (Abulibdeh et al., 2025; Thomas et al., 2023). While the recent European Union Artificial Intelligence Act (EU AI Act) and similar U.S. Food and Drug Administration (FDA) frameworks are starting to grapple with this tension, their regulatory frameworks focus on pre-market approval and validation yet largely fail to provide a workable solution regarding the post-deployment need for continuous monitoring, re-training and re-validation of AI and especially machine learning (ML) models (Abulibdeh et al., 2025). The result is a regulatory environment prioritizing stability and predictability over the dynamic learning potential that makes AI particularly valuable in healthcare settings and elsewhere.

We examine how Israel, an early adopter of healthcare AI, is responding to this global tension through sandbox regulation—controlled experimental spaces designed to allow innovation within softened regulatory environments. We argue that sandboxes represent a national-level workaround to global policies, enabling local flexibility while maintaining alignment with international norms. However, this flexibility is neither neutral nor universally enabling. Drawing on qualitative data from interviews, policy documents, and observations, we explore how policy actors in Israel use regulatory boundary work to navigate these tensions. Our findings show that sandbox regulation is not only a technocratic fix but also a performative space where power is negotiated, expertise is reasserted, and health data is reimagined as a source of epistemic and economic value (Fiske et al., 2023).

By locating this analysis within the broader political economy of digital health, we argue that sandboxing serves both as a governance solution and a socio-technical assemblage for value extraction (Fischer & Rosenhak, 2023). Our study thus contributes to emerging debates on AI governance in healthcare, professional authority in health policy-making, and the social shaping of innovation in healthcare contexts. Specifically, we ask: How do policy actors in healthcare regulation use sandboxing in reaction to the uncertainty of promoting an early and innovative implementation of AI in healthcare? And what boundary work strategies emerge within such regulatory discourse on sandboxing?

* Corresponding author.
E-mail addresses: aviadraz@bgu.ac.il (A. Raz), liatmil@gmail.com (L.B. Lifshitz-Milwidsky), yinbar@tauex.tau.ac.il (Y. Inbar).

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1.1. Healthcare AI and sandbox regulation

The regulation of healthcare AI faces the challenge of matching such adaptive systems with an equally adaptive regulation. While arguably this is a common challenge for all AI categories, Large Language Models (LLMs) for example are not subject to a similar precautionary regulation as healthcare AI. According to the EU AI Act, healthcare AI falls under the "high-risk" category and requires oversight by deployers (European Union, 2024). Yet, clarification is needed regarding how exactly should deployers oversee such "adaptive" or "self-learning" systems (Abulibdeh et al., 2025; Raz et al., 2025). Scholars have warned that as AI models are exposed to new data in clinical settings, their performance may degrade or alter overtime, necessitating ongoing oversight (Feng et al., 2022). Recognizing this challenge, the FDA is in the process of shifting from the traditional medical device regulatory framework and has introduced the AI/ML-based software as a medical device action plan in 2021, employing a "total product lifecycle" approach to include post-market phases–covering data quality, algorithm transparency, and robust change management (US FDA, 2021). In 2024, the FDA further issued guidelines for an adaptive regulatory framework of AI/ML-enabled device software (US FDA, 2024; 2025), potentially letting developers address AI's continuous evolution without repeatedly seeking new FDA approvals. However, on-site post-deployment evaluations of AI in diverse clinical settings, requiring the implementation of robust, real-time monitoring mechanisms, remain inconsistent and underdeveloped (Thomas et al., 2023).

This often means that healthcare providers-cum-deployers must step in to develop local protocols for quality assurance and recalibration of AI systems. However, the significant financial and administrative requirements implied by such re-assessment often lead to avoiding system retraining, or re-validation, after deployment, which is then compensated by selective use patterns. An illustrative case is ChestLink, an X-ray imaging AI, which in 2022 was the first fully autonomous healthcare AI to receive the EU-CE mark certificate, including post-deployment AI retraining. The catch is that ChestLink is only allowed to autonomously produce reports for healthy patients (Díaz-Rodríguez et al., 2023). It does not autonomously analyze or report on chest X-rays with abnormalities.

Acknowledging the built-in tension of medical progress and restricting healthcare AI on-site learning (Van Kolfschooten & Van Oirschot, 2024), the EU AIA proposes the national implementation of "regulatory sandboxes," to be established by member states by 2026 (European Union, 2024). Regulatory sandbox approaches are becoming relevant in several rapidly evolving tech sectors like finance, health, and energy (Balyakin et al., 2022; Johnson, 2023; McCallum & Aziakpono, 2023; Truby et al., 2022). These controlled environments supposedly allow selected innovative projects to be tested under modified regulatory supervision, waving certain rules while maintaining essential safeguards. Regulatory sandboxes for AI are further advocated for their reactivity, "enabling regulators and market players to engage and interact directly … Benefits include avoiding possible regulator-market gaps that sometimes accompany hard law" (OECD, 2023, p. 12).

Sandboxes may thus offer a solution to the difficulty of regulators in monitoring post-market, post-deployment AI performance. Regulatory sandboxes and standardization processes can feed and complement each other, especially as on-site post-deployment evaluations of AI in diverse clinical settings remain inconsistent and underdeveloped (Thomas et al., 2023). Data gathered from AI sandboxes, which provide a more manageable and contained pilot environment, could be used for evaluating safety, explainability, biases, and data privacy in the context of post-deployment adaptive learning (OECD, 2023). Indeed, such sandboxing can be seen as joining recent 'real-world evidence' methodologies supported for pharmaceuticals and medical device approval by both the US FDA and the European Medical Agency (EMA) (Flynn et al., 2022). Despite their growing popularity, the legal, methodological, and ethical challenges of implementing these experimental regulatory sandboxes warrant further research (Ranchordas, 2021). Arguably, such an approach embodies a built-in paradox. It purports to be a novel platform that expands field experiments or clinical trials, yet also potentially leading to what Eyal et al. (2024) describe as a constant 'flickering' between states of imagined control and acknowledged uncertainty.

Such regulatory sandboxes for healthcare AI thus need to be taken with a grain of salt. Their impact on healthcare AI's risks and affordances remains ambiguous and underexplored (Cahane & Shwartz Altshuler, 2023; Van Kolfschooten & Van Oirschot, 2024). Indeed, the EU AIA suggestion to establish national AI regulatory sandboxes was criticized for its shortcomings (Buocz et al., 2023; Elvidge et al., 2024). A recent study of fintech regulatory sandboxes concludes that such sandboxes are not simply regulators of fintech but are more fundamentally its facilitator. Through riskwashing, sandboxes facilitate the introduction of fintech into society (Brown & Piroska, 2021). Spain launched an AI regulatory sandbox in 2022 as the first pilot program to test the EU AI Act. As part of this initiative, 12 high-risk AI projects were selected across sectors such as healthcare, employment, credit, critical infrastructure, and biometrics; yet systematic reports on the outcomes and deliverables of this initiative are not yet available. Nevertheless, other healthcare sandboxes have reported success. The UK Care Quality Commission (CQC) whose pilot focused on the use of machine learning applications in diagnostic services, working with healthcare providers, technology suppliers and service users, to develop quality standards and identify areas where regulatory methods needed updating (CQC, 2020). Similar initiatives are being implemented by the California Department of Technology (Newsom, 2023). Israel, too, has opted for an enabling sandbox regulation of AI that would suit its national need for innovation (Paltieli, 2022), yet spurring a recent public debate led by non-governmental public stakeholders (Cahane & Shwartz Altshuler, 2023). We elaborate on the Israeli AI sandbox strategy as part of the findings.

1.2. Sandbox regulation, boundary work, and political economy

The concept of boundary work was developed by Thomas Gieryn (1983, 1999) to analyze how scientific disciplines and knowledge domains establish, maintain, and negotiate their boundaries. It later traveled to management, administrative and policy studies (Langley et al., 2019) where it has been discussed as a collection of strategies for tackling power dynamics, establishing legitimacy, and managing the complex relationships between different knowledge holders and expertise (Lamont & Fournier, 1992; Lamont & Molnár, 2002). Boundary work is particularly relevant in contexts of disruptive technologies and social risks, where the lines between scientific and regulatory knowledge become blurred (Zerubavel, 1993). In the context of healthcare AI, boundaries need to be worked out not only between safety and innovation, but also between the professional jurisdictions of human and machine expertise, as AI is expected not only to augment physicians and radiologists but also to replace (some of) them.

The notion of boundary work also problematizes boundaries by conceptualizing their creation, maintenance, blurring, and transformation as the target of purposeful action (Langley et al., 2019). This process is particularly relevant to sandboxing, where the task of combining safety and innovation to achieve a sense of control over healthcare AI is expected to breed ongoing boundary work. Different types of boundary work include competitive, collaborative and configurational work. In the first category, competitive boundary work, professionals raise boundaries around themselves to protect territory and control of resources. Such competitive boundary work has been extensively studied in social studies of science (Gieryn, 1983) and the sociology of professions (Abbott, 1988). The second category is collaborative work, where professionals realign the boundaries separating them to enable collaboration; and the third category is configurational boundary work, i.e. designing and expanding boundaries to

re-orient configurations of differentiation and integration among groups and knowledge fields (Langley et al., 2019).

We show that boundary work is not simply productive but acutely aware of its own limitations, a 'reflexive governance' (Beck, 1992) haunted by the recognition that regulation cannot fully tame AI's adaptive capacities. In such (arguably, largely configurational) boundary work actors are not only performing regulation but also recognizing its inherent contradictions and limitations, aware of their own instability or performativity. As regulatory responses are shaped by institutional efforts to manage dynamic technologies while preserving organizational legitimacy, they also manifest a political economy of health data (Fischer & Rosenhak, 2023; Fiske et al., 2023). Sandbox environments facilitate the transformation of health data into economic value, embedding datafication within capitalist logics. We argue that these perspectives converge in the sandbox as a socio-technical site where professionals perform reflexive boundary work, enacting governance not despite, but through, the recognition of its limitations.

An additional lens into regulatory boundary work is provided by Peter Haas' (1989, 1992) work on epistemic communities, which he defines as "a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge" (Haas, 1992, p. 3). Epistemic communities are powerful because they control the administrative/technical vocabulary through which problems are defined, actors included or excluded, and solutions legitimized. Furthermore, such science-industry-policy communities can also be driven by a shared sense of a 'community of hope' or 'community of promise' (Brown, 2003), where expectations structure and organize a whole network of obligations between innovators, investors, and regulators, as in the case of AI sandboxes. Examining such future-oriented, promissory boundary gatekeeping in AI sandboxing, we should ask what criteria were used to determine inclusion in the sandboxe? Which organizations and forms of expertise were certified as credible and relevant, and which actors (e.g., patient NGOs) were excluded?

Sandbox approaches, then, should be also understood within the broader political economy of healthcare data. Recent scholarship illuminates how digital health data, particularly when processed through AI systems, is increasingly constructed as an epistemic value-creating object (Fischer & Rosenhak, 2023; Hoeyer, 2023). In this perspective, health data, as well the forms of experimentality that produce real-world data (Petrynas, 2009, 2010) is reconceptualized as a form of capital that generates both scientific knowledge and economic value, transforming healthcare organizations into sites of data extraction and valorization (Birch, 2022; Birch et al., 2021; Birch & Muniesa, 2020). Literature on the political economy of AI has shown how hype cycles drive capital accumulation by creating periods of intense investment and expectation, leading to increased valuations, technology scaling, and assetization (Nayak & Walton, 2024). Case studies of the rise-and-fall of AI platform startups illustrated how the fetish of 'artificial intelligence' (for example posing chatbots for self-diagnosis as an intelligent 'doctor in your pocket') drives financial valorization by capitalizing on algorithmic systems and data as intangible assets linked to future-oriented prospecting (Kampman, 2024). Another stream of research showed how large AI platform firms changed governmental procurement conventions, for example regarding cloud computing, driving out previous large-scale contract relationships and producing proprietary legacy computer systems that will continue to shape public sector technologies (Margetts & Dunleavy, 2024; van Lier, 2025).

The regulatory sandbox serves as a crucial socio-technical assemblage that enables such value creation process. The sandbox model thus operates not merely as a 'neutral' technical solution to regulatory challenges but as an institutional arrangement that advances specific economic interests while reconfiguring power relations in healthcare governance, enabling value extraction and reinforcing institutional hierarchies under the guise of innovation. Sandboxes, in this perspective, are performative 'inscription devices' (Latour & Woolgar, 1986), inscribing through their discourse particular 'dreamscapes' (Jasanoff & Kim, 2015) of 'biotechnical embrace' (Delvecchio Good, 2001). A political economy perspective reveals how sandbox regulation simultaneously enables data capitalization while obscuring underlying value extraction processes, creating what appears to be a win-win scenario for innovation and regulation while often reinforcing existing power asymmetries between technology providers, healthcare organizations, and regulatory bodies (Brown & Piroska, 2021).

2. Methods

In the Israeli setting we have an "extreme" context enabling to observe tensions of early adoption in highly uncertain yet technologically advanced environment. We conducted 25 interviews with regulatory and policy actors in Israel between 2023 and 2025, alongside 38 h of observation (at relevant AI policy conferences, conferences of medical associations where AI was discussed, and governmental committee meetings concerning AI regulation), and analysis of 12 reports concerning AI strategy and regulation issued in the last 10 years by the Israeli government and public bodies.

Semi-structured interviews were conducted by the first and second authors in the native language (Hebrew) of the interviewers and interviewees. Policy actors whose work is related to healthcare AI were recruited through professional networks. Table 1 summarizes the distribution of interviews, with a majority (19/25) of male respondents from the public/governmental sector (that includes the health management organizations), and a diversity of academic fields of expertise dominated by data science. Interviews lasted 60–90 min and were transcribed verbatim. The interview guides were designed to explore the respondents' experiences with and attitudes toward AI sandboxing in healthcare, asking about the pros and cons of the sandbox approach and its effect on balancing safety and innovation. All interviewees signed an informed consent form, and the study received IRB approval from the ethics committee of <insert university name>.

Data were analyzed in two main ways. Firstly, we constructed a detailed policy timeline using the documents, exploring the interconnections between the global and local contexts at play. The documents, Committee protocols and reports were analyzed for examples of the politico-legal discursive performativity shaping sandbox regulation. We then coded the interviews and documents to enhance our understanding of the socio-political landscape surrounding sandbox regulation in the context of healthcare AI. Using a grounded theory approach (Charmaz, 2006; Gioia et al., 2013) interview transcripts were organized, coded, and analyzed thematically. In particular, the interviews allowed for a deeper exploration of the efforts required to balance safety and innovation in healthcare AI strategizing.

Our analytical process unfolded in four stages with several iterations in each stage. These iterations included discussing codes and themes in our meetings to prevent the bias of a single reader and ensure reliability and consistency. First, preliminary codes were identified based on a review of the literature. Second, we categorized interview and observation data according to patterns of respondents' views (Charmaz, 2006; Spradley, 2016; Strauss and Corbin, 1998), generating additional, emerging codes. The research team did the coding in parallel on the first

Table 1
Policy actors (n = 25) interviewed by sector, academic expertise and gender.

Sector	Academic Expertise	Gender
Public/governmental = 16 Private = 6 Health Management organizations = 3	Data science = 8 Social science = 6 Computational social science = 5 National security = 3 Computational medical science = 2 Medical science = 1	M = 19 F = 6

few interview transcripts, discussing the relevance of the codes and agreeing on needed modifications and reclassifications. Then, based on patterns that emerged from considering the first layer of codes within and across respondents, we matched these codes with second-order categories of boundary work, e.g., competitive, configurational and collaborative. Third, we further linked the codes and categories to the main theoretical themes identified in the literature review, such as the Israeli culture of innovation, its valorization of health data and the politico-legal aspects of sandboxing. Fourth, this systematic connection of reports, interviews and observational data (Gioia et al., 2013) allowed us to derive from our analysis general insights representing expert views on healthcare AI sandbox regulation. Data analysis was completed upon agreement by team members that thematic saturation was reached, i.e. no new topics emerged in subsequent interviews (Denzin & Lincoln, 1994). The quotes (translated by us to English) were selected to represent patterns and repeating categories in the policy papers, interviews and observational data. We refer to interviewees by a pseudonym, including their sector and academic expertise.

In the following sections, we provide an overview of the results of this analysis. Starting with an analysis of the policy timeline, exploring the interconnections between the global and local contexts at play, the ensuing empirical sections demonstrate the socio-technical entanglement of Israel's attempt to align its healthcare AI sandbox with EU, US and local regulation. We focus on the boundary work efforts invoked by the sandbox discourse and how they are enacting frictions around 'safety', 'innovation', 'trust,' and 'valuable' health data. To conclude, we reflect on the social import of these performative value contestations for the future pathway of AI sandbox regulation, in healthcare and elsewhere.

3. Findings

3.1. Strategies for regulating and promoting AI: the national context

The Israeli healthcare system is based on a public insurance plan that provides universal coverage to its residents ("the basket of healthcare services") along with private health services (Filc, 2024). The Israeli National Health Insurance Law (1994) mandates that all Israeli residents are insured by one of the four licensed Health Management Organizations (HMOs), regulated by The Ministry of Health for the quality and standard of health services and for approving new medical technologies. Israel recognizes approvals from the FDA and EC, using them as a basis for its own registration processes.

While the term "sandbox" does not appear explicitly in all government reports related to AI regulation (e.g., Office of the Prime Minister, 2021), these reports use a similar concept of 'regulatory experimentation environments'. Fig. 1 illustrates the sandbox policy timeline as reflected in the documents.

Israel's early and rapid AI strategizing demonstrates how the tension between seeking clear boundaries and managing AI's dynamic nature has evolved over time from deliberations into policies. The first Israeli governmental Call for Information to industry regarding regulatory sandboxes was issued already in 2017 by The Ministry of Finances, in the field of fintech. Issues of cross-sectional regulation and AI ethics were not yet mentioned in this Call but were the focus of the Subcommittee of the Israeli National Intelligent Systems Project Report (2019). Israel's early reports advocated sandboxing as "test sites" that "enable rapid technological development that is not slowed down by existing and outdated regulation" (TELEM Forum, 2020, p. 63). The reports encourage self-regulation, stressing the responsibility of AI professionals within each organization to identify risks throughout the deployment process. Similar ad-hoc calls for regulatory experimentation were issued at the same time by the EU (CAHAI, 2021). In March 2022 The Ministry of Health's Innovation Committee held two roundtable discussions on implementing sandbox methodologies in healthcare (Ministry of Health, Innovation in Health Committee, 2022a,b). In December 2022, the Israeli Health Innovation Committee recommended creating regulatory testing environments (Health Innovation Committee, 2022). This was reinforced by the Israel Innovation Authority's annual report (2022) advocating regulatory sandboxes as prominent tools for addressing rapid technological innovation while reducing regulatory uncertainty.

These deliberations also highlight the unresolved challenges of operationalizing the outcomes of AI sandboxing: "Decision makers need to determine in advance what happens if the pilot is successful (or not), and how to continue with implementation. Every organization today tests each algorithm separately" (Ministry of Health, Innovation in Health Committee, 2022b, p. 3). The same ambiguity is echoed in the OECD (2025:5) report stating that sandboxes "typically involve a temporary regulatory waiver or flexibility".

In 2023 Britain's AI regulation white paper simultaneously endorsed regulatory sandboxes for AI governance and identified Israel as a key bilateral collaborator in this approach (UK Department for Science, Innovation & Technology, 2023). In its 2023 report, the Israeli Ministry of Innovation, Science and Technology proposed to establish a governmental "Knowledge Center" for AI sandboxing, which has not materialized so far. While all these reports and recommendations acknowledge the "limited and piecemeal" shortcomings of the sandbox, their language legitimizes its use as necessary for keeping up with the pace of technological innovation (Israel National AI Program, 2024; Ministry of Innovation, Science and Technology, 2024). At the end of 2024, the

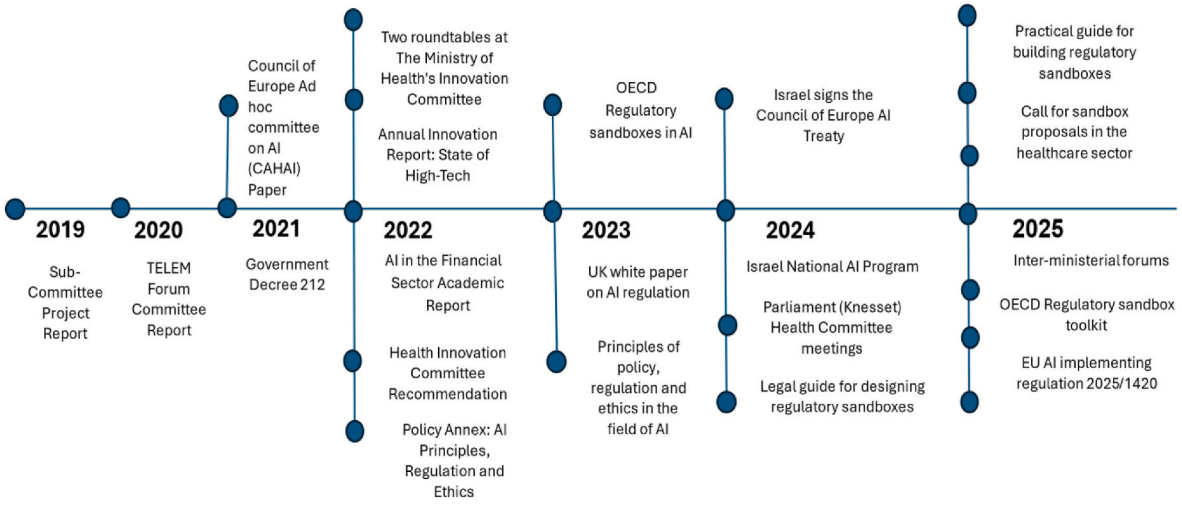


Fig. 1. The Israeli AI sandbox policy timeline. All activities are in Israel unless written otherwise.

Office of Legal Counsel at the Ministry of Justice published a guide for designing regulatory sandboxes (Roitman et al., 2024). In January 2025, the Regulation Authority published a guide for building regulatory sandboxes, advocating moving from conceptual frameworks to implementation. However, no actual AI sandboxes have yet been established in Israel. As one of the authors of that guide, a senior AI policy manager at the Ministry of Innovation, Science and Technology, explained in a Knesset Health Committee deliberation: "we decided on modular development because we still don't fully understand the technology in this context" (Knesset Health Committee, 2025). In calling industry actors for sandbox proposals, Ministry of Health officials further explained the "stalling" by highlighting the economic valorization of AI in healthcare: "this is not some trivial sandbox for testing … this is a call for information gathering and we want to hear if there is real value in this for you and what value can be created" (Ministry of Health, 2025b). This process is still on-going. Several inter-ministerial forums that were convened in 2025 focused on stakeholder mapping rather than concrete deployment (Ministry of Innovation, Science and Technology, 2025a,b,c).

3.2. Views of policy actors

The main themes that emerged from the interviews interconnectedly regarded the sandbox as flexing the boundaries of regulation, embodying disruption and adaptiveness, and reflecting Israel's hybrid reconciliation of opposites. All these themes manifested a sense of ambiguity related to the sandbox as both a positive initiative and a significant challenge due to Israel's small market, which follows the US and EU, and the difficulties of strategizing AI as a rapidly evolving technology that changes during its lifecycle.

3.2.1. Flexing the boundaries

All respondents expressed an inherent ambiguity about the ability to regulate AI in general. As Mandy, an AI policy actor and activist in an NGO said: "The whole world of how these algorithms are used is not regulated. And here we feel much more, let's say, I won't say groping in the dark, it's, it's, but trying to navigate the way, in this forest." While policy actors expressed a variety of perils and prospects regarding healthcare AI regulation, the bottom line was that despite the risks, innovation must be promoted. For policy actors from the Innovation Authority, such as Patrick, this needed to be handled by reconfiguring the regulatory boundary between healthcare and national security:

> "We only regulate health, so now we fight about what's happening in health … it's crazy that we don't put any restrictions on the way people can be killed with AI, but we put a lot of restrictions on the way people can be saved by AI … In Israel, a lot of AI technologies are used to kill people before they are used to save people. So, Israel is always pushing for global regulation of AI to exclude the security field. Let's say, one of the most intuitive things people say is that they don't want robots to shoot. So, Israel is not so interested in that. Because, Iron Dome is, it's designed to shoot. I mean, it shoots autonomously."

The following quote from Joseph, a chief government advisor, demonstrates high tolerance for risk-taking with adaptive AI as part of pursuing national innovation:

> "Regulating AI is close to impossible … First, we try not to regulate too much, so as to keep innovation going […] Imagine the government will not let you have kids – another form of intelligent entities – unless you prove they cannot do harm … this is impossible. The same with AI. I cannot control how AI will change in the future according to the experience it collects. We can still make efforts to reduce the problem, but you cannot really solve it. We are in a stage where we need to agree on the ten commandments for AI regulation."

These policy actors thus see AI as a "known unknown," legitimating flexible spaces for innovation while still in a process of discussing its principles. As another policy actor noted at a policy conference on "Responsible AI: Innovation-Supporting Regulation" (December 18, 2024), implementing AI in healthcare while developing appropriate regulatory frameworks is like "sailing the ship while building it."

Respondents further addressed the risk of AI opacity. Moses, a policy officer at the Ministry of Innovation, Science and Technology, typically expresses this: "The additional risk is that we don't understand how—no, no, no—we won't always be able to understand how the system made the decision. So at least on the side of the information receivers, there should be some kind of mutual control." The recognition of black box AI (Pasquale, 2015) as a risk in healthcare also reflects EU and FDA calls for explainable AI. Collaborative boundary work is implied by the expressed need for cooperation ("a kind of mutual control") between AI policy actors and AI deployers (the information receivers).

Only one policy actor, Mandy, advocated a reconfiguration of the boundary in transparency, claiming that AI needs to be transparent to doctors as well as patients:

> "There isn't any policy [about transparency]. I think we need to learn from the past, from the secondary uses of health information. From approval processes, of technologies and of drugs … what didn't work back then, and how do we discontinue those gray areas and bad behaviors … health data is a huge asset that can be used. It's worth training machines on. It just needs to be done in a very supervised way, with more significant consideration of the rights of the patients, with greater transparency. Both towards the patients and towards the regulator."

Many respondents agreed that sandboxes were like conducting clinical trials, requiring collaborative boundary work between industry, government, and academic stakeholders: "Actually, a clinical trial or clinical research in many ways is a kind of sandbox … there's an alternative framework … in health … for purposes that allow controlled experimentation to understand effects and benefits" (Mandy). Bill, a regulation officer in the Ministry of Health, concurs: "The world of clinical trials is a world that in my eyes is a sandbox … but you should not forget it has many risks." Adapting existing frameworks like clinical trials to serve as de facto sandboxes for AI experimentation in healthcare expands the boundaries of experimentality and reconfigures them in a broader politico-industrial assemblage. Policy actors agreed about the importance of sustaining collaboration between government, industry and the medical system through expanding the boundaries of experimentality (Petryna, 2010). Medical data that are both digitalized and real-world, like those provided by sandboxes, were particularly seen as valuable: "In 2010 the State of Israel understood that its medical data, because it is digitalized, computerized and representative, is like a gold mine, or an oil field. Yes, it's worth a lot of money" (Mandy). This quote illustrates the commodification of health data and the economic valorization of AI in healthcare, that in the words of respondents like Mandy and Bill "could accommodate the needs of industry" and generate some "certainty in the market" regarding the value proposition of novel and yet unregulated forms of healthcare AI.

3.2.2. Disruption and adaptiveness

Many policy actors expressed concerns about the trade-off between the flexibility and fragmentariness of the sandbox, stressing concerns about disrupted knowledge transfer in the context of the sandbox. Emma, a regulation officer in the Ministry of Health, said: "The sandbox gives the company a kind of grace period … to adapt itself … and it, I mean, that the regulator is not really learning anything from it." The concept of a "grace period" suggests phased implementation rather than a continuous one. Respondents saw the division between policy creation and practical adaptation in the sandbox as both setting a boundary and requiring reconfiguration and integration of the knowledge elicited by the sandbox. The concern that regulators "don't learn from the process"

indicates a concern regarding the lack of systematic information flow from companies to regulators.

Other respondents also mentioned the disruption in knowledge transfer caused by the absence of a clear mechanism connecting the sandbox "grace period" and the "real world." John, a regulation-compliance officer working in the private sector, stressed the lack of knowledge transfer, given the absence of an integrative regulatory body overseeing the sandboxes, arguing that while the sandbox idea is great in principle, "it doesn't happen in practice because there isn't really any proper Israeli regulation in this field." Neil, a policy actor at the National Digital Agency, explained the need for applying more central (horizontal rather than vertical/sectoral) oversight, which would apply to sandboxes too:

> "In the next two years there would have to be a horizontal law … When you're telling every regulator [in each sector] to handle it yourself, then you're saying I'm neglecting this issue horizontally … and part of this, also in health, is to monitor risk in AI. The OECD developed in the last year an AI incidents monitor. Regulators will have to pool resources, to create national monitoring systems, for all Israel, and look at, at, at things that happened badly … integrating a reporting obligation to the regulator that already exists in many sectors separately."

The close-knit nature of the Israeli government-industry nexus was described by many respondents as a double-edged sword, leading to lack of formal integration and knowledge transfer, as Noah, regulation officer in the Government, explained:

> "There aren't many countries where it's possible to create a loop with every relevant person, in the industry, academia or in government, within a day … In the United States if you want to build cooperation between agencies like that, good luck to you, it can take years. One of the disadvantages is that in the end, strategy is not for Israelis, it's, we're just not good at it."

Especially for policy actors from the Innovation Authority, such as Patrick, speed and agility were everything. The question is not the trade-off between disruption and adaptiveness, but rather reconciling both, since successful innovation of AI means being able to adapt to ongoing disruption:

> "I think what is very important to preserve is the spirit of Israeli innovation, the ability of Israelis to invent things, overcome obstacles, make attempts, make mistakes quickly, fix quickly, raise capital quickly. And it will determine if we will be a world leader in the AI revolution or if we end up as one of the guys that the revolution chews up and spits out … We must build a public sector where there is more patience for experiments, for mistakes, for things that don't work. In a world of innovation, you need to promote things quickly, make mistakes quickly, pivot quickly and move on to the next thing quickly" (Patrick).

This fast-paced, ideal reconciliation of adaptiveness and disruption is also echoed in the following theme.

3.2.3. Israel's hybrid reconciliation of opposites

Many respondents saw the sandbox positively as reflecting Israel's quest to reconcile its opposite features: a very small state striving for innovative independence while inevitably depending on the outside world. Even for the minority view that considered this critically, Israel's hybridity and even liminality was seen as a source of power. "We are simply a backyard when it comes to digital legislation" said James, a governmental regulation officer, "but many things were invented in the backyard or the garage." Mandy provided another angle: "We call it an island state, like we're, not belonging to the European Union, not part of the United States, we're an island state in our conduct, certainly from a regulatory perspective."

Laura, a policy officer at the Ministry of Health, typically explained how policy actors engage in an ongoing boundary work to reconfigure the in-between place of Israel in terms of healthcare regulation:

> "Look at European regulation and American regulation, you will see two completely different schemes. The Europeans are human rights and civil rights people … protecting privacy for example. The Americans look for economic profit, they look at the need for advancement, for innovation. Israel is a hybrid (*Sha'atnez,* in Hebrew, which carries a negative, profane connotation in Judaism). We prioritize the adaptation of technologies … the introduction of innovation … and we (regulators) need to actively come and say I want to see what the benefit is for the patient at the end."

This quote presents the view that by actively demanding to see what the benefit is for the patient, regulators mark the boundaries between which innovation is worth or not, protecting "the patient" from profit-driven healthcare prospecting. While Israel is inevitably dependent on US and EU regulation, as a "backyard" Israel can also position itself as an early adopter of less-regulated scientific innovations. Sustaining such an innovation hotspot is evidently also risky, and as Mandy frames it:

> "Despite all this … we haven't encountered a situation of irresponsibility to date – nothing that makes you say a health organization needs to be stopped. Often, we identify issues at earlier stages, drawing attention to things that need to be checked, but we haven't faced a situation where we had to say, 'Guys, take down this service.'"

Interestingly, this routinized disruption was seen by our respondents as an advantage. This quote illustrates how despite all the risks, the constant reconfiguration of boundaries has so far remained successful. Yet it may also manifest what Beck's (1995) termed as organized irresponsibility: a system where actors collectively produce and distribute risks but manage to avoid being held accountable for the negative consequences.

4. Discussion

Our findings highlight the sandbox as a political economy space of boundary work where policy actors are simultaneously aware of their limitations and engage in maintaining legitimacy. This aligns with recent work (e.g., Van Hoyweghen, 2024) on the performative contradictions of risk governance. Rather than resolving the tension between innovation and regulation, sandboxing manages it through strategic ambiguity and selective boundary-making. However, without standards of operation and evaluation, sandboxes for AI can become, in a similar way to fintech sandboxes (Brown & Piroska, 2021), riskwashing facilitators of the penetration of AI into the healthcare market. Fig. 2 provides an overview of the relationship between sandboxing, regulation, and types of boundary work.

We found that policy actors are not a monolithic group. While policy actors shared an overall ambiguous view of sandboxing that tended to be nevertheless positive, they had a variety of views reflecting their different agendas and positions. Policy actors from the National Innovation Authority, for example, were adamantly in favor of pushing innovation at all costs, while policy actors from NGOs were more critical of the costs of innovation. The Ministry of Health policy actors were, in turn, more attentive to the balancing of safety and innovation. Overall, most policy actors regarded sandbox regulation positively, yet challenging, mainly because of the small Israeli market that follows the US and the EU, and the difficulty to strategize a fast-moving target like AI which may change during implementation. To cope with these uncertainties and tensions, policy actors respond to AI sandboxing in dynamic boundary work that manifests itself in the themes found: flexing the boundaries, adapting to disruption, and routinizing a hybrid reconciliation of opposites. The sandbox was constructed as an apt metaphor (if not a reality) for such goals. Notably, we found little or no competitive boundary work, probably because policy actors saw the

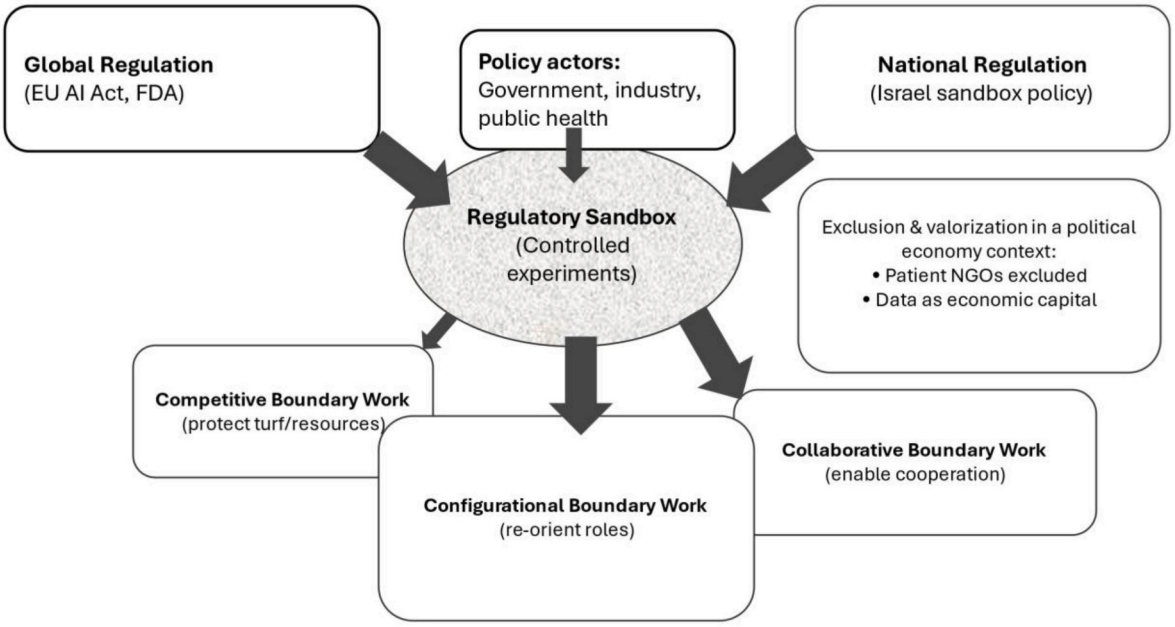


Fig. 2. The relationship between sandboxing, regulation, and boundary work.

sandbox as an opportunity rather than a threat. Unlike traditional boundary work that seeks to establish stable demarcations (for example between professions or scientific fields), the boundary work manifested by the sandbox discourse operates with the understanding that we are drawing moveable lines in shifting sands. Technological change will inevitably require additional socio-organizational changes and reconfigurations. Such a descriptive summary of the findings depicts the challenges and opportunities in the AI sandbox approach, and illustrates the various boundary works involved in strategizing this approach while devising a policy for deploying AI.

It is also important to move beyond a descriptive analysis of boundary work to its normative assessment. If we subscribe to the idea that AI regulation should pay explicit attention to whether a specific instance of data use is in the public interest, we need to actively monitor AI sandboxes for indicators of medical as well as socio-economic value that data creates, and for whom (Fiske et al., 2023). While regulatory sandboxes present opportunities for innovation, the findings also present challenges such as regulatory readiness, which remain significant barriers to their effective implementation (Fuad et al., 2023). The too-easy acceptance of the sandbox trope despite its shortcomings points to a significant gap.

Drawing on Haas' (1989, 1992) work on regulatory boundary work in epistemic communities, our findings demonstrate a network of government-public health-industry professionals posing authoritative claims to policy-relevant knowledge. Their administrative/technical vocabulary, through which problems are defined, emphasized moving forward by legitimizing flexible spaces for innovation. These actors addressed the risk of AI opacity, for example, reflecting EU and FDA calls for explainable AI. However, while this language emphasized that successful innovation of AI means being able to adapt to ongoing disruption, it did not include clear guidelines and metrics, such as training models on diverse populations, evaluating how AI makes decisions, or recognizing how test accuracy can change when diseases are rare. Furthermore, facing this challenge was framed as requiring cooperation ("a kind of mutual control") between government and public health AI policy actors and industry AI developers/vendors. While certain actors were included and a specific solution was legitimized, other actors and problems were excluded. There was, for example, a wide neglect of advocating AI transparency to doctors as well as to patients, and patient NGOs as well as other civil organizations were excluded from the sandbox discourse. Also, while the long and on-going path from deliberations to policy was delayed by government actors in order to more clearly define the value proposition of novel and yet unregulated forms of healthcare AI, similar concerns were not raised about equity, public benefit, or civil representation.

Our findings may also be interpreted in the broader context of the Israeli start-up culture, which has been characterized by high tolerance for uncertainty (Hofstede & Usunier, 2003). Rather than leading to a systematic and cautious approach, Israel's regulatory sandbox policy for AI favors risk-taking, but requires more formalization in designing and implementing mechanisms of risk-assessment and monitoring. Israel's commitment to scientific and technological innovation (Prainsack & Firestine, 2006), combined with a historical narrative of existential risk and a need for agility, has shaped its approach to AI strategy (Paltieli, 2022). In line with research on the 'neo-developmental state,' our study demonstrates the key role of state agencies in the promotion of innovative high-tech economic sectors (Maggor, 2020). The sandbox discourse illustrates the fundamental cultural work invested by State agencies and policy actors in communicating that imaginary. The findings indicate the need for regulatory innovation to keep pace with technological advancements, and a balancing of regulatory agility with the desire for market stability and sense of certainty. Specifically, in the healthcare sector, where AI autonomy raises ethical and medicolegal concerns regarding responsibility, the lack or vagueness of regulations may cause substantial harm and liability.

Adriana Petryna's (2009, 2010) critical concept of "experimentality" describes a shift in how governance, particularly in the context of globalized clinical trials, operates through the growing framework of real-world health data collection. She argues that "experimentality" isn't simply about hypothesis testing, but a distinct way of operating where experiments become the primary means of addressing issues and distributing resources, especially in public health crises (such as COVID-19). The healthcare AI sandbox can be seen as conducive to such experimentality and as constituted by it. Unregulated experimentality, just like healthcare AI sandboxing, can lead to the overlooking of ethical protocols, especially in the context of vulnerable populations in developing countries. Our findings reveal how sandboxing is not neutral but has political-economic stakes. It facilitates the construction of health data as a value-creating object—a site where economic, political, medical and regulatory interests intersect.

5. Conclusions

The Israeli case illustrates how sandbox regulation functions as a workaround to globally imposed constraints and drives, enabling national-level flexibility. However, this flexibility is not merely technical. It involves ongoing boundary work by regulatory policy actors who are reflexively aware of the limitations of their role. These practices not only shape the governance of healthcare AI but also embed digital health data within circuits of value creation.

We argue that sandbox regulation should be understood as a dual strategy: one that enables controlled innovation while reinforcing economic interests. As such, it reflects broader dynamics in the global governance of digital technologies (Sharon, 2018). Medical progress in clinical AI requires parallel evolution of regulatory frameworks and clinical practice workflows. The precautionary nature of the regulation of AI in healthcare creates an experimental space where healthcare regulators and deployers/users engage in configuring a useable framework for AI during an early adoption phase. Our recommendations address two major topics: monitoring and NGO inclusion.

First, to become a sustainable approach, the sandbox cannot be left unmonitored and unevaluated. Regulation should address adaptive AI by requiring deployers to monitor and evaluate sandbox performance and outcomes using standard metrics. Future research should explore how similar dynamics unfold in other national contexts and examine the implications of sandboxing not just in terms of technological, medical and economic performance but also in ethically-related issues such as health equity, data justice, and public trust in digital health systems. This requires, for example, built-in sandbox monitoring mechanisms such as training models on diverse populations, evaluating how AI makes decisions, or recognizing how test accuracy can change when diseases are rare. Second, patient NGOs and civil organizations should be included in regulatory sandboxes. Rather than participating directly, they can be incorporated through mechanisms like advisory boards or stakeholder consultations (Brown & Piroska, 2021). Such engagement should ensure a focus on the impact of sandbox innovations on citizens and civil society and how to address the needs of vulnerable populations.

In conclusion, the sandbox reflects both the unique characteristics of Israel's innovation ecosystem and the universal challenges of regulating rapidly evolving AI technologies. The findings highlight the need for continued exploration of innovative regulatory approaches that can effectively bridge the gap between technological advancement and regulatory oversight in the healthcare sector. Our findings' practical implications for policymaking highlight an urgent need to promote three steps. First, to provide policy actors leading regulation with critical AI expertise. For example, they should be reflexive not only of the opacity of healthcare AI for healthcare providers/deployers, but also for patients. Regulation is urgently needed regarding the transparent disclosure to patients concerning the use of AI in their healthcare, and this could be (but is presently not) monitored as part of healthcare AI sandboxing. Second, setting up more explicit, exploratory and participatory formats of sandboxing AI where policy actors, AI vendors and healthcare providers-cum-deployers come together to explore such AI tools as objects of regulatory inspection, monitoring and evaluation (Reshef Kera et al., 2024). Such monitoring mechanisms that evaluate sandbox outcomes at designated milestones can act as "regulators of non-regulated" environments, providing a framework that is guiding rather than limiting for the experimental process. Third, bringing in more social actors that would oversee the sandbox and its outcomes. The sandbox approach should incorporate input and monitoring from constituency groups and NGOs, especially in relation to vulnerable populations (such as patient groups), as well as third party monitoring bodies and academics.

CRediT authorship contribution statement

Aviad Raz: Writing – review & editing, Writing – original draft, Supervision, Project administration, Formal analysis. **Liat Bela Lifshitz-Milwidsky:** Writing – review & editing, Project administration, Investigation, Formal analysis. **Yael Inbar:** Writing – review & editing, Formal analysis.

Data availability statement

The original contributions presented in this study are included in this article/supplementary material, further inquiries can be directed to the corresponding author.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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