

# Hypothetical enrollment – an anticipatory situated method to assess the implementation of AI diagnostics in clinical settings

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## Abstract

**Purpose** – The paper aims to propose “hypothetical enrollment” as an anticipatory, situated and performative methodological approach to appreciate the organizational and epistemological consequences of adopting artificial intelligence (AI) diagnostics into clinical settings. This method provides a methodological contribution to move between the expectations about AI diagnostics and their integration into real-world, clinical settings.

**Design/methodology/approach** – The validity of this method was tested against an empirical case, the start-up Autism Scope (AS), which applies machine learning models for the early detection of autism spectrum disorder. As part of this pilot study, two interviews were conducted in person with designers from AS and three interviews with pediatric neuropsychiatrists.

**Findings** – Notwithstanding a generally positive attitude, several organizational and professional challenges emerged thanks to this method, such as the integration of the tool into hospital workflows and the potential effects for professional identity in neuropsychiatry.

**Research limitations/implications** – Other healthcare stakeholders, such as hospital managers or policy makers, were not interviewed.

**Originality/value** – The “hypothetical enrollment” interviews allowed comparing the expectations and implementation strategies devised by AS’ designers with the impediments and challenges highlighted by neuropsychiatrists, that is, potential users who have not been involved in development yet.

**Keywords** Hypothetical enrollment, AI diagnostics, Autism, Organization of work, Method

**Paper type** Research paper

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## 1. Introduction

Recent advancements in artificial intelligence (AI) systems applied to medicine are expected to transform the healthcare sector by promising to optimize, if not revolutionize, diagnostics and medical imaging (Shaheen, 2021; Joshi, 2024; Yu *et al.*, 2018). These expectations are justified not only by the accuracy of results achieved, but also by the relevance of medical imaging for multiple specialties, including radiology, ophthalmology, dermatology and pathology – fields that heavily rely on image-based diagnoses (Yu *et al.*, 2018). The substantial hype regarding the potential of AI (Shaheen, 2021) is underpinned by discourses framing AI either as an innovation able to raise standards of care (Koski and Murphy, 2021) or as a neutral “magic cure” for healthcare challenges (Strange, 2024). However, while research in labs and tech firms advances rapidly – so much so that “scarcely a week goes by without a research lab claiming that it has developed an approach to using AI or big data to diagnose and treat a disease with equal or greater accuracy than human clinicians” (Davenport and Kalakota 2019, p. 95) – the transition to widespread clinical adoption remains limited. In both literature and practice, relatively little attention has been paid to implementation as an important stage, besides design and production.

Despite AI’s promises and increasing accuracy, the implementation of AI-based diagnostic tools in actual healthcare settings lags behind, to the point that some scholars have talked of an “implementation gap” (Seneviratne *et al.*, 2020; Coiera, 2019; Cabitza *et al.*, 2020). A few recent studies suggest that this gap might be linked to the inability to envisage the epistemic consequences and clinical challenges of adopting these tools in specific, situated environments. Particularly, the adoption of AI diagnostic tools can reshape and transform organizational workflows, professional competencies and epistemic practices within the clinical settings where they are implemented (Carboni *et al.*, 2023; Williams *et al.*, 2024). Developing arenas and methods to assess the clinical and organizational challenges of AI would therefore become paramount to support the responsible and sustainable implementation of AI in healthcare settings, or its rejection.

As of today, there is a lack of research frameworks and methods that explicitly address the implementation of AI diagnostic tools into actual contexts (Williams *et al.*, 2024). Drawing on work done in Science and Technology Studies, we suggest that developing such frameworks and methods would require examining the particular “disease network” in which the new technology is to be adopted. In this paper we propose the notion of “disease network” to describe the set of human and non-human actors that are brought together to diagnose and cure a pathology. We argue that assessing the potential consequences of adopting a new technology requires involving in an exercise of imagination those actors who are expected to be part of the disease network and to provide them with space to reflect on the innovation prior to actual implementation. The goal would not be to normatively map out possible implementation pathways, but rather to prod actors to imagine potentialities and disruptions that might emerge during or after implementation. What we propose here as “hypothetical enrollment” is, therefore, an anticipatory, situated and performative method aimed to address the implementation gap in clinical settings. We tested the validity of our method against an empirical case, the start-up Autism Scope (AS), which applies machine learning models to fMRI for the early detection of autism-spectrum-disorder.

We structure the paper as follows. Section 2 reviews the expectations surrounding AI diagnostics and compares them with findings on their current state of implementation. Section 3 introduces our proposed approach, hypothetical enrollment. We then apply hypothetical enrollment to an empirical case: Section 4 details the data collection and analysis process, while Sections 5 and 6 present the results. Finally, Section 7 evaluates hypothetical enrollment by reflecting on the insights gained through its use.

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## 2. Intelligent machines for diagnosis: between expectations and implementation

A constellation of promises, expectations and attitudes surrounds the implementation of AI in the healthcare sector. The increasing production of health data combined with the development of machine learning and deep learning techniques are expected to significantly improve medical care and to advance several medical fields (Yu *et al.*, 2018; Rajkomar *et al.*, 2019; Davenport and Kalakota, 2019). As the sociology of expectation has amply illustrated, expectations have a performative nature, a collective dimension and a temporal pattern. As “real-time representations of future technological situations and capabilities” (Borup *et al.*, 2006, p. 286), technological expectations include statements, visions, promises and concerns which shape the development of technological innovations (Borup *et al.*, 2006; Pollock and Williams, 2010). They are not just descriptive statements about future development, but rather they contribute to the creation of interest and to the establishment of networks, obligations and alliances (Konrad *et al.*, 2016). Furthermore, expectations have a collective and public dimension (Konrad, 2006). They emerge as the result of the promises, concerns and attitudes of actors (scientists and engineers, users, publics, policy makers) and communities about new technologies and they are mediated throughout discursive activities (Brown *et al.*, 2020). Finally, expectations shape complex temporal dynamics. As future-oriented representations, they are often described through hype-patterns: initial promises, usually set by innovation actors and underpinned by deterministic accounts of technological change, can be followed by disappointment and failures (van Lente *et al.*, 2013; Bakker and Budde, 2012). All in all, expectations are the vehicles of different forms of anticipatory practices which attempt to intervene and to steer the governance of technological innovations (Lösch *et al.*, 2019). It is therefore paramount studying the types of expectations that steer the governance of a specific field.

Three main types of expectations about AI can be identified in healthcare, depending on the actors voicing them. First, medical researchers and health data scientists tend to voice their expectations in academic papers which emphasize the potentialities, opportunities and challenges of applying intelligent machines in several medical fields, including psychiatry (Bzdok and Meyer-Lindenberg, 2018; Graham, *et al.*, 2019; Abd-alrazaq *et al.*, 2022). In the field of mental health, AI promises to improve the understanding of mental disorders and to diagnose them earlier and more effectively (Abd-alrazaq *et al.*, 2022). The current diagnostic paradigm relies on evaluations formulated from expert clinicians on the basis of codifications from manuals such as the DSM-5 and the International Classification of Diseases-11 (Abd-alrazaq *et al.*, 2022). AI techniques would allow defining mental illnesses on the basis of biological markers “that achieve intrinsically valid and immediately useful clinical predictions” (Bzdok and Meyer-Lindenberg, 2018, p. 9). Such diagnostic methodology would therefore be allegedly more objective than the DSM-5 classification schema (Graham *et al.*, 2019).

Next to the expectations of medical researchers and health data scientists, a growing body of literature has started to enquire the attitudes of healthcare stakeholders (mostly physicians and patients) about the implementation of AI systems in clinical practices (Čartolovni *et al.*, 2023; Moy *et al.*, 2024; Scott *et al.*, 2021). While these studies do not specifically address AI systems for diagnosis, they provide an overview of the ambivalent hopes, fears and attitudes of stakeholders. On the one hand, AI systems are expected to improve the patient-physician relationship by alleviating physicians’ workload; on the other hand, there are fears that they might contribute to alienation and loss of empathy (Čartolovni *et al.*, 2023). According to a recent scoping review, patients have a generally positive attitude towards AI, as it would assure improved accessibility to and efficiency of care, decreased cost of diagnosis and treatment. Negative attitudes concern the lack of human supervision, accountability and trustworthiness, as well as the potential risk of job loss (Moy *et al.*, 2024). Empirical studies also enquired physicians’ perspectives about AI within specific medical fields. For instance,

Miele *et al.* (2024) explored doctors' and patients' narratives and imaginaries about the use of AI for the remote monitoring of people with Parkinson disease. They show how these narratives are informed by the dissatisfaction with the present (particularly with the monitoring process) and are oriented toward a prudent but effective cooperation (especially in terms of delegation of responsibility) between humans and AI tools.

A third type of scholarship focuses on healthcare decision makers, such as hospital managers, policy makers, members of regulatory agencies (Petersson *et al.*, 2022; Kusta *et al.*, 2024). Such emergent literature is now starting to identify expectations and challenges from the perspective of policy and executive actors, and it is still rather scant. Some literature stresses the hurdles that might affect AI introduction according to healthcare executives: the management of existing laws and policies, the systematic approach for implementing AI systems in practice, the transformation of professional roles and practices (Petersson *et al.*, 2022). Other policy makers tend to conceive of AI as a means for alleviating the increasing pressure on healthcare national systems and for providing better services to patients (Kusta *et al.*, 2024; Kannelønning, 2024). In this regard, governments can actively attempt to articulate the adoption of AI in the healthcare sector as a desirable and credible future by deploying multimodal tactics which both legitimize AI technologies and reassure healthcare professionals about the effects on their roles (Hoff, 2023).

Three main narratives and related expectations about AI diagnostics can be identified from this body of literature. First, medical researchers and health-data scientists highlight the new modalities of knowledge production stemming from machine learning algorithms, as well as the possibility to automatize and to make more efficient the clinical practices currently carried out by doctors. Medical professionals and patients tend to focus on the work-related implications of AI tools, particularly in terms of renewing and improving the relations between physicians and patient, mostly through the delegation of tasks and responsibility leading to expected reduced workload. In this respect, doctors also recognize that the adoption of AI diagnostics would transform their professional role and practices. Finally, hospital managers and policy makers perceive AI tools as a possibility for increasing efficiency and reducing heavy workloads, albeit they are cautiously weighting their implementation in terms of cost-benefit analysis and are concerned about the lack of regulatory and legal frameworks.

As ambivalent as they are, mapping such expectations could open new directions in studying a major issue in current AI development in healthcare: the so called "implementation gap" (Seneviratne *et al.*, 2020) or "the last mile of implementation" (Coiera, 2019; Cabitza *et al.*, 2020). This formulation refers to difficulties and challenges of moving AI tools from research setting to real-world implementation and clinical workflow. Despite their potentialities, the adoption of AI systems is a slow and troubled process, characterized by several challenges and barriers, sometimes linked to biases (Preti *et al.*, 2024; Seneviratne *et al.*, 2020; Coiera, 2019; Cabitza *et al.*, 2020). Challenges have been identified with data quality (Cabitza *et al.*, 2020), trust and explainability (Preti *et al.*, 2024), the need to embed the technologies within specific and local organizational network (Coiera, 2019).

In this regard, ethnographic studies have started to document the organizational, epistemic and professional consequences entailed by the implementation of AI systems into clinical settings. These studies tend to highlight the substantial misalignment between the narratives and expectations about AI diagnostic tools – as discussed above – and how they actually work in practice (Kusta *et al.*, 2024; Carboni *et al.*, 2023).

For example, rather than improving the speed and accuracy of the diagnosis, the introduction of AI systems may alter physicians' organizational workflow and cause epistemic uncertainty (Carboni *et al.*, 2023; Lebovitz *et al.*, 2022). In the case described by Carboni and colleagues

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(2023), epistemic uncertainty was caused by representationalist assumptions underpinning the AI-assisted diagnostic systems, which assumed the epistemic sameness of glass slides of tissue and digital samples. Other studies examined the implementation of AI systems by describing the processes of social learning (Williams *et al.*, 2024) and coevolution (Farič *et al.*, 2024) shaping their integration. Farič and colleagues (2024) observed that performances and uses of AI-based diagnostic decision support system depended on the different organizational, technological and demographic features of the radiological settings in which it was implemented. Williams and colleagues (2024) suggest that processes of domestication, social learning and experimentation characterize the procurement, implementation and clinical validation of AI diagnostic tools into real-world setting.

All in all, literature suggests a relationship between expectations and the implementation gap. On the one hand, expectations nurture a discourse about the promises and fears related to AI diagnostics. On the other hand, an actualized narrative describes the organizational, clinical and epistemic consequences of moving AI diagnostics into clinical settings. However, existent scholarship falls short in further qualifying such link, nor does it experiment with methods which mobilize the situated expectations of the diverse social actors participating in a “disease network”. The implementation gap reveals the need for research frameworks and methods which address and discuss expectations in specific situations to anticipate potential scenarios. Williams and colleagues (2024) indeed suggest that new conceptual frameworks and methodological strategies are needed to address the rapid evolution of AI tools as they move from research settings and are deployed in real-world across multiple locations. They thus call for longitudinal and biographical studies of AI tools, rather than snapshot approaches. While we share suspicion towards snapshot approaches, we also realize that longitudinal approaches can only be deployed with technologies which are already implemented. Therefore, it is not clear how they could be used to address the implementation gap. We therefore propose a more humble but reasonably feasible approach to link expectations with implementation in “disease networks”.

### 3. Hypothetical enrollment

We suggest that a novel direction to interpret the implementation gap could consider what we propose to name “disease network.” The implementation of a new healthcare technology “may be viewed as a new component added to an established network consisting of healthcare staff and existing objects (e.g. paper, medical instruments, other information systems)” (Cresswell *et al.*, 2010, p. 5). Such addition is expected to change the overall network of healthcare (Oudshoorn, 2011). We define “disease network” the established network of human and non-human actors that aggregate around the goal to diagnose, treat and cure a pathology [1]. The introduction of an innovation triggers the overall re-arrangement of the disease network: new actors may push to enter, while existing actors might need to realign. Neuropsychiatrists, behavioral tests, patients and medical guidelines, for example, participate in the established “mental health disease network”. The introduction of AI diagnostic tools would entail new actors to enter the network (e.g. data scientists, fMRI, radiologists) and established actors like neuropsychiatrists to acquire new knowledge and to develop new clinical practices. We suggest that the implementation gap reveals a transition between an existing disease network and a new network which could or could not come into existence.

To study this transition, methods that can align expectations of both new and established actors are needed. We propose “hypothetical enrollment” as an interview method that addresses the diverse stakeholders involved (or potentially involved) in a disease network. “Enrollment” is the third stage of translation described by Callon (1984), “problematization” and “interessement” being the first and second step, respectively. When an innovation is

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conceived by proponents, they imagine a set of actors, roles and interests that should be triggered to initiate the innovation process (“problematization”). Proponents then try to convince the actual actors that adhering to their innovation program is in their own advantage (“interessement”). If convinced, actual actors are “enrolled” in the network. Enrollment corresponds to the eventually successful involvement of actors whom the proponents of an innovation had initially identified as necessary to the overall endeavor. In the case of AI diagnostics not yet implemented, enrollment is (counter-intuitively) “hypothetical.” With this, we mean that enrollment is only hypothetical with respect to any future disease network in which AI systems might be introduced. Proponents like data scientists or industry are not yet enrolled in the existent disease network; physicians and patients are enrolled in the existing network, but their participation in a future one would require re-alignment (e.g. in terms of knowledge acquisition, trust, organizational roles). As an interview method, hypothetical enrollment is thus oriented to multiple stakeholders: not only those who are already part of established disease networks, but also those who could potentially be involved in new networks, such as proponents and new professional figures who might be needed.

Hypothetical enrollment is an anticipatory, situated and performative method to mobilize expectations in specific situations to anticipate potential scenarios. It is anticipatory as it aims to provide an opportunity to appreciate the potential uses of AI diagnostic tools not yet implemented by prodding actors’ expectations and the potential interactions, alliances and transformations. Originally drawing on the Collingridge dilemma (Collingridge, 1980), anticipatory practices have a long tradition in the sociology of expectations and science and technology studies. Depending on their differences, they aim at describing, criticizing or steering the process of co-construction between visions of the futures (expectations, promises, imaginaries) and the design and development of emerging technologies (Urueña, 2022). The anticipatory nature of hypothetical enrollment has a more humble goal, namely to identify and include in a yet-to-be- implemented AI-based network potential stakeholders [2] to understand how a technology might reshape professional competences and consequently organizational arrangements. In this regard, the focus of hypothetical enrollment as a methodological approach is not on the design and development of technologies *per se*. Rather, the goal of our method lies in understanding how technologies which are supposedly able to produce new forms of medical knowledge would transform doctors’ practices and reshape the organizational and professional boundaries characterizing a specific disease network.

Hypothetical enrollment as a method is situated because expectations and potential alliances are mapped and analyzed against the specific disease network in which the technology is to be adopted. In discussing predictive algorithms for child protection services, Ratner and Elmholtz (2023, p. 11) suggest that “algorithmic prediction, and their constructions of risk, needs to be studied contextually rather than in an abstract form”. A similar point can be made for AI diagnostic tools. These tools share some common elements (supporting human decision-making, discovering new patterns, increasing diagnostic accuracy) but the regulatory contexts, potential biases, organizational workflow in which they would be implemented, the temporal rationale underpinning their use, the possible practices of domestication or appropriation are strictly depending on the specific, contingent features of the disease network. In the case of mental illnesses in young children, the disease network is usually constituted by human actors such as parents, neuropsychiatrists, psychologists, but also by guidelines and protocols (diagnostics reports, DSM-5). Not all these figures are represented in the literature above discussed. Neuropsychiatrists, in

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particular, are distinctive figures of the children mental disease networks, but to our knowledge they have not yet been involved in studies on AI implementation.

Finally, hypothetical enrollment interviews have a performative nature as they prompt not-yet-involved parties to reflect on the possible implications of the innovation for their daily diagnostic tasks, to imagine further applications and hence to trigger reflection about new modalities of knowledge production. In this regard, hypothetical enrollment is also inclusive, since it allows to share knowledge with actors who, otherwise, could not have access to it, and hence to reflect about the potential organizational and epistemic consequences of innovation. As a consequence, the performative value of hypothetical enrollment is not limited to sharing knowledge about an innovation with actors, but it also includes participation in the form of production of new knowledge about the specific disease network.

#### 4. Data collection and method

We have tested the hypothetical enrolment interview method on the disease network of children with autism spectrum disorder (ASD). Children with ASD was chosen as it is a field in which AI diagnostic is expected to bring major improvements for two reasons. First, ASDs are neurodevelopmental conditions marked by highly complex and heterogeneous phenotypes, which make them particularly challenging to diagnose as they are believed to involve multiple and not yet fully understood etiologies (Newschaffer *et al.*, 2007). At present, the gold standard for ASD diagnosis involves two extensively used qualitative tools: the Autism Diagnostic Observation Schedule (ADOS), an observation-based behavioral assessment, and the Autism Diagnostic Interview-Revised (ADI-R), a structured interview conducted with individual's caregivers (Brentani *et al.*, 2013). While these methods are well-established, they are not without limitations, as broadly acknowledged within the field of psychiatry (Hus and Segal, 2021). A primary diagnostic challenge is the absence of definitive genetic or medical tests, as no biomarkers currently exist to confirm the disorder conclusively. This gap contributes to the ongoing evolution of diagnostic categories: the DSM-5 criteria are often perceived as vague, necessitating expert judgments about severity and diagnostic thresholds. This makes diagnoses reliant on neuropsychiatrists' interpretations, leading to variability and potential arbitrariness (Motttron and Bzdok, 2020). Second, these limitations are exacerbated when assessing young, pre-verbal children, where symptoms may be hard to detect or to report accurately, even though early ASD diagnosis is crucial. Because ASD often co-occurs with other disorders and medical comorbidities, its signs may be masked, increasing the risk of missed diagnosis and delayed treatment (Hus and Segal, 2021).

AS, the Italian start-up chosen as part of our study, proposes an alternative AI-based approach to address these challenges (see Section 5 for details). According to the developers, AS technology enhances the diagnosis of psychiatric and neurodevelopmental disorders through quantitative analysis and AI applied to brain imaging data. Specifically, the AS model operates on resting-state fMRI (rs-fMRI) scans to estimate the probability of an ASD diagnosis. The rs-fMRI brain scans are increasingly used to investigate psychiatric disorders and to identify biomarkers and, although testing them in clinical practice remains difficult, studies report acceptable overall accuracy for ASD diagnosis (Santana *et al.*, 2022). AS technology, not yet implemented or available for sale, is supposed to detect atypical brain activity patterns predictive of ASD, potentially enabling early diagnosis before the age of two. The model has been tested on the ABIDE data set (the largest existing international autism data set) and the results showed a diagnostic accuracy of 90%, with 89% sensitivity and 88% specificity.

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For this study, a total of five semi-structured, in-depth interviews were conducted: two in-person interviews with the data scientists who developed AS and who are currently trying to promote it as a software for medical diagnosis; three online interviews with pediatric neuropsychiatrists [3] based in different medical centers across Italy. Each participant was privately contacted and invited to voluntarily participate in the study. Ethical standards were maintained throughout the process: participants were provided with an informed consent drafted according to the *University of Bologna Ethical Committee* and permission was requested to record each interview. Two separate interview guides were designed, ensuring that the interview questions aligned with the particular focus of each group: one template tailored to the data scientists and the other to the neuropsychiatrists. During the in-person interviews with the designers, it was also possible to view a demo of the AS platform on one of the designer's computers, providing valuable context for the discussion.

Both the interviews with data scientists and those with neuropsychiatrists were part of the method. The discussion with the data scientists focused on understanding the actors who would need to be involved in the disease network reconfigured by AS, on exploring topics such as their business model, the initial implementation scenario, the primary intended users and the broader target audience for AS. The conversation then touched on topics intended to elicit, where possible, the designers' underlying assumptions, focusing on topics such as the skills required to use the technology and the specific needs of the various actors that AS is intended to address. The interview guide for the neuropsychiatrists was designed to invite them to imagine possible uses of the technology described at the beginning of the interview. It is important to clarify that the chosen neuropsychiatrists did not know about the technology being developed by AS – they were only hypothetically enrolled as the software's primary intended users. We described the functionalities of the AI diagnostics and explicitly invited them to reflect about the hypothetical implementation of the technology in their work. The interviews aimed to explore their perceptions of AS, which needs it could address, its potential usefulness in their practice and the advantages, disadvantages or alternative uses they might foresee beyond the intended purpose. For instance, we asked neuropsychiatrists if and how the introduction of AS would influence hospital workflow; how AS could change their medical research practices, how it would influence their relationships with caregivers.

The small number of interviews conducted represents a limitation to our study for two reasons. The first reason concerns the small sampling of people interviewed. However, the concept of theoretical saturation (Tracy, 2020) helps to contextualize this narrow empirical scope and to clarify the methodological assumption that guided the empirical investigation. Theoretical saturation refers to the point at which data collection and analysis yield little or no new information, and emerging findings and themes begin to stabilize. By the third interview with the neuropsychiatrists, we observed that a satisfactory level of saturation was reached, which justified the decision to conclude data collection for this category of respondents. The second reason has to do with the lack of interview with other healthcare stakeholders, such as hospital managers, policy makers and care-givers were not interviewed. This represents a significant limitation to our study, as we suggest that our interview methods can be productively apply to all the actors shaping a disease network. Due to this narrow empirical scope, our paper has to be considered as an exploratory pilot study. However, the core argument of our paper is methodological more than empirical. In this regard, the interviews carried out highlighted, despite their limited number, the potentialities and strength of our method. As we will illustrate in the next sections, our interviews prompted actors to reflect about the organizational, epistemic and professional consequences and challenges entailed by the potential integration of AS within clinical practices.

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## 5. Developers' expectations about AS

A number of expectations steered the developments at AS. First, early diagnosis is considered crucial in ASD. Most neuropsychiatrists now agree that the ideal age for autism diagnosis should fall before the age of two, as this is when interventions can have the greatest impact on improving a child's communicative and social skills due to the brain's neuroplasticity and synaptic pruning (i.e. the ability to form and reorganize neural connections) (Okoye *et al.*, 2023). Typically, the average age at which a child receives a reliable diagnosis of ASD is currently four (Elder *et al.*, 2017). The greatest potential of AS technology, according to its developers lies thus in enabling early diagnosis (by 18–24 months of age). AS's fMRI examination is expected to be fast and non-invasive, making it possible even for infants to undergo the diagnostic process. This opens the door to the benefits of early diagnosis, such as initiating treatment sooner.

Quantitative analysis of biological data constitutes a further expected value added of AS according to its developers. Traditional diagnostic methods offer limited insight into the neurobiology of individuals, relying heavily on a child's developmental history and observed behaviors. Diagnostic categories themselves are still evolving, as no clear biomarkers currently exist (Geschwind, 2011). A central aspect emphasized by the startup is its quantitative, brain scan-based diagnostic method, which is decoupled from purely behavior-based assessments. The company claims to have developed a diagnostic approach as effective as that of a neuropsychiatrist, but 'more objective'. The startup suggests that their algorithm may have uncovered an indirect measure of a complex biomarker for ASD:

AI will inevitably become an integral part of clinical practice because we have already discovered everything that can be identified using simple biomarkers [...] to make a diagnosis. Now, the remaining discoveries involve complex relationships between multiple variables, and effectively analyzing these is beyond human capacity. [4] (Promoter 2).

At the heart of this approach is the expectation of aligning psychiatry more closely with neurology, which is a discipline firmly grounded in biological mechanisms: bridging that gap serves as the start-up's first pillar. As each scan provides a data-driven, individualized profile, AS is expected to allow clinicians to better adjust treatments to each patient's needs and, ultimately, contribute to the evolution of current diagnostic categories. Finally, AS is expected to introduce time and cost savings, thus increasing diagnostic efficiency. The traditional diagnostic process carried out by neuropsychiatrists is often lengthy and expensive, involving follow-up appointments, consultations with additional specialists for comparison, extensive paperwork and sometimes repeating stages due to misdiagnoses or the need to rule out comorbidities (Wong *et al.*, 2017). In contrast, AS's platform claims to offer significant time and cost efficiencies, delivering results with a fMRI scan test that takes less than 2 min. Overall then, the expectations of AS's developers seem to match the expectations described above (section 2), especially in regard to neuropsychiatry: machine learning is expected to help identify indirect indicators of complex biological markers, thereby improving patient treatment.

### 5.1 Developers' expectations about users, and implementation strategies

To such expectations about the AI tool, AS proponents add expectations regarding the key actors within the ASD diagnostic network. As emerged from interviews, the developers are confident that neuropsychiatrists will be interested in the AS's potentialities described above, but initially they may exhibit polarized attitudes toward adopting this innovation:

We need to convince neuropsychiatrists because there are two kinds: those who are very enthusiastic about these systems and truly believe we should move in that direction and are already

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conducting research in this area, and then there are psychiatrists who say that diagnosis is already done through clinical practice and that there is no real need for AI and imaging. (Promoter 2).

Therefore, a central challenge for AS promoters lies in demonstrating that their system is both effective and genuinely useful in clinical practice. To address skepticism, they proposed a phased implementation strategy aimed at defining and stabilizing user roles. Initially, the platform is offered free to medical researchers to build epistemic credibility and gain preliminary validation from gatekeepers. Once established as a reliable diagnostic aid in research, the focus shifts to practicing neuropsychiatrists. This is modelled upon expectations about clinical neuropsychiatrists as users that first need validation from researchers as gatekeepers:

We do not want to collect data for training because the model has already been extensively trained, so this validation [from medical researchers] is not even necessary; it's something you do for [...] it's almost marketing, okay? You do it so doctors can look at a study, see that it's been tested, and say, 'Okay, this actually works'. (Promoter 1).

Yet promoters have also expectations concerning patients and their caregivers. They envision AS as a tool for democratizing early diagnosis and enabling broader screening of neurodevelopmental disorders. By reducing dependence on few highly specialized clinical experts, they anticipate that AS could facilitate more accessible diagnostic practices. From this perspective, patients and families are expected to find value in early diagnosis not only for clinical reasons but also for its potential to reduce the stigma associated with autism. By shifting the interpretive frame away from notions of individual will or behavioral conformity – and from viewing neurodevelopmental conditions as pathologies to be “cured” – the use of “objective”, measurable indicators such as radiological evidence is seen as a way to legitimize alternative understandings of autism and anchor diagnosis in more neutral, biomedical terms.

Several organizational challenges were acknowledged during the interviews. These include limited hospital resources, the high cost and scarcity of fMRI scanners, concerns over accountability, as liability for AI-related errors typically falls on clinicians, not developers. Secure data storage and the need for new regulations are also key issues. A major obstacle is adapting existing ASD diagnostic protocols—which currently do not include fMRI—to incorporate AS. Radiologists would need to take on a more proactive role, providing diagnostic input earlier in the process, whereas currently they are only involved to rule out other conditions.

## 6. The hypothetical enrollment of neuropsychiatrists

As we have defined it, hypothetical enrollment is an exercise in hypothesizing successful implementation to productively elicit indications from actors *as if* they were enrolled in the emergent AI-based network. In the context of the case study, hypothetically enrolling neuropsychiatrists meant that during the interviews, they were treated *as if* they were already part of (enrolled in) the potentially reshaped disease network. This approach aimed to reveal perspectives that might diverge from the implementation strategy envisioned by the promoters.

Overall, neuropsychiatrists expressed a generally positive attitude toward AS. They highlighted AS potential in supporting differential diagnosis and personalized treatment, particularly valuing its quantitative approach, which extends beyond traditional clinical and behavioral assessments. In contrast to current, mainly descriptive diagnostic practices, they all emphasized the need for tools capable of identifying biologically grounded subgroups:

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I find it frustrating to have to constantly reconfirm the same diagnostic category for children that I see as very different, but right now I don't have any alternatives [...] Do you see how little value something we use every day holds? It's too broad and we can't expect to standardise all patients within such a vast and varied range. (Neuropsychiatrist 1).

The promise of an etiological diagnosis grounded in radiological evidence is also expected to positively affect communication with families, offering a shared interpretive framework – or “common ground”, as one interviewee called it – for understanding and explaining the child's condition. More importantly, neuropsychiatrists recognized that the coexistence of multiple conditions under a single diagnostic label is not inherently problematic unless they complicate treatment. Treatment, often a trial-and-error process, is the critical and time-consuming aspect of care. Clinicians often struggle to understand why a particular drug works for one patient but not for another. In this context, the ability to tailor treatment, as envisioned by AS, becomes paramount.

The interviewees imagined several impediments to implementation. Among these, they mentioned the majority of those expected by the designers; more interestingly, however, they also brought up additional challenges. Neuropsychiatrists were concerned about the disruption of their current diagnostic practices and the potential for the technology to be used beyond its intended purpose. One major concern was that the technology could be relied upon as the sole diagnostic method or, even worse, as an autonomous system. This would imply that, despite AS not being designed as a substitute for neuropsychiatrists' expertise, it could foster a reductionist approach that overlooks the importance of diagnostic restitution, which should not be delegated lightly to a technician:

This tool should be integrated with the ones we already have. I think we're still quite a way from using AS exclusively. It's fine to use this tool to measure certain aspects, but the issue of its autonomy might also raise ethical concerns, as well as the claim of objective diagnosis. There should always be someone involved who can listen and observe; the tool should serve as support, not as a standalone solution. (Neuropsychiatrist 3).

As this quote suggests, neuropsychiatrists were concerned that the diagnostic outcome produced by the AS would replace the holistic nature of traditional methods. Clinical interviews are considered essential for building a trusting relationship between doctor and patient, which contributes to both the diagnostic and therapeutic process. They stressed that technology should augment – not replace – the bio-psycho-social model of care, cautioning against a narrow biological focus.

The adoption of AS could also disrupt other two current clinical practices. The first is the training of what a neuropsychiatrist refers to as a “refined eye,” i.e. the embodied, phenomenological understanding that an experienced clinician has of a patient's lived experience. According to a neuropsychiatrist, some specialists do not even use ADOS or ADI; they interact with the child once and then they are able to make an accurate diagnosis. AIs cannot inherently replicate this. While AS can study aspects beyond human understanding, humans also explore areas that AI cannot investigate. The more children a specialist assesses, the sharper their diagnostic acuity becomes; however, this requires time and experience, which AS could potentially deskill. The second clinical practice potentially disrupted is the pursuit of diagnostic goals beyond accuracy, such as the practice of the “forced diagnosis” – the pressure to assign a more severe diagnosis to enable caregivers to access specific forms of financial support:

A child with autism often has associated comorbidities, such as anxiety or ADHD, or disabilities: you might need to undertake many different approaches in treatment. Autism may be classified into levels 1, 2, and 3 – so just saying “autism” doesn't resolve much. Maybe I would label it as

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level 3 and force the diagnosis solely to ensure the child gets the necessary support. (Neuropsychiatrist 3).

While not widespread, this practice uses diagnosis as a means to an end, rather than as a reflection of a quantifiable medical condition. In these cases, the broadness of diagnostic categories is leveraged for a beneficial purpose: ensuring access to treatment. If AS becomes part of diagnostic protocols, these real-world practices could clash with the more rigid framework that it imposes.

This ties into a broader concern raised by neuropsychiatrists: the challenge of interpreting results expressed as numerical values and statistical probabilities. While AS may support differential diagnoses, it raises challenges in handling cases that fall on the borderline – such as individuals currently diagnosed with autism who might not meet stricter criteria under this system. Managing these intermediate cases will require new guidelines, due to the interpretability challenges of these types of AI models:

We need to be cautious because autism isn't necessarily limited to those brain regions [identified by AS] where these genes are expressed. [...] I mean, I wouldn't want only a certain type of individual to be classified as autistic. [...] I tend to be a bit skeptical of systems that seem overly simplistic and linear for diagnostic purposes. [...] Autism is a very complex and fundamentally behavioral issue [...] it is such a complicated task to accurately align all the key elements for a diagnosis. (Neuropsychiatrist 2).

These scenarios introduce a level of clinical interpretation for which neuropsychiatrists have not yet been trained, and even promoters cannot fully address. Overall then, despite a positive attitude, neuropsychiatrists identified several epistemic challenges which might be caused by the integration of AS within their clinical practices. Particularly, they stressed how the knowledge produced by AS and expressed in terms of numbers and probabilities might conflict either with diagnostic practices which, despite their limitations, are still considered as highly valuable, or with other clinical practices, such as “forced diagnosis”, in which socio-economic factors are prioritized over the purely medical ones.

On another level, neuropsychiatrists also highlighted the potential challenges posed by the integration of AS within their workflow. A first issue is represented by the administrative steps and permissions which would be required to deploy AS:

[The use of] AS should not entail an excessive expenditure of time for those who have to use it, because we are overwhelmed by bureaucracy. If using it meant preparing it in a certain way, filling out two hundred forms, requesting three thousand things, doing procedures beforehand, I think someone could, let's say, put the use of this [tool] in second place. (Neuropsychiatrists 1).

Excessive bureaucratic demands could overshadow the potential benefits, leading practitioners to prioritize simpler alternatives over the technology. A second point concerns the enrollment of radiologists within the new disease network. Even in hospitals where MRI machines are available, securing time slots for these specific diagnostic procedures can be a hurdle, as radiology departments must authorize their use. Despite the brief duration of advanced MRI exams gaining approval for these specialized slots may still present challenges. Addressing these logistical and administrative barriers means convincing these departments to dedicate their resources to such psychiatric diagnostic purposes. A last issue exceeds the organizational boundaries of the hospital to reflect upon how the deployment of AS would also require to be supported by the healthcare national systems, especially in respect to the target population:

The main problem would be to identify the population to which to subject this software. If the idea is that the earlier the diagnosis, the better the treatment, ideally you should use it for all infants, so

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one of the most difficult things would be to identify which children you think should be subjected to this software. Would the choice be left to the clinician? (Neuropsychiatrists 1).

The integration of AS within the healthcare system would entail the creation of new guidelines and policies needed to define specific criteria for selecting candidates. Moreover, the effects of the increase in early diagnosis on the healthcare system would represent a crucial factor. Currently, the Italian healthcare system already struggles to keep up with the growing number of cases, and hence to provide adequate follow-up and treatment. Early diagnosis could place additional pressure on the healthcare system, affecting both the availability and quality of treatment. Notwithstanding its potential benefits, the adoption of AS would then pose several implementation issues, which include epistemic, professional and organizational challenges. In the next section we discuss these points and conclude the paper by evaluating the merits of our proposed methodology.

## 7. Discussion and conclusion

The hypothetical enrollment interviews allowed us to compare the expectations and implementation strategies devised by AS' promotors with the impediments and challenges highlighted by neuropsychiatrists as if they were enrolled in an implemented AI-supported disease network. The interviews with neuropsychiatrists, based on their imagined and potential use of and interactions with AS, enable to bridge the discursive level of expectations with the actualized level of implementation. The thematic issues emerged from the interviews provide the ground for discussing the possible consequences entailed by the adoption of AS within the ASD disease network. First, neuropsychiatrists pointed out the professional and organizational effects of AS. The integration of AS may lead to the emergence of a new professional identity for neuropsychiatrists altering their competencies and duties, as well as impact on hospitals' organization by fitting into and simultaneously shaping existing workflows. The first shift would be driven by several transformations, including the evolving role of radiologists in diagnostic practices and the adoption of new decision-making frameworks by neuropsychiatrists. Furthermore, beyond transforming clinical workflows and redefining professional identities, AS would also reshape the broader organizational landscape. Particularly, the deployment of AS would require extensive preparatory steps (filling in multiple forms, undergoing multiple procedures) and developing rigorous criteria to effectively target the patient population. Additionally, integrating radiology departments into psychiatric diagnostics requires administrative management, including how to engage and convince these departments to allocate resources for such purposes. On a broader scale, the implications of a potential increase in early ASD diagnoses remain uncertain. The healthcare system is already struggling to meet existing demand, and a surge in early identification could further strain resources, compromising both the availability and quality of care. This may lead to delays and difficulties in accessing the very interventions that early diagnosis is meant to enable.

Second, our interviews highlighted how the potential epistemic consequences caused by the implementation of AS would modify both neuropsychiatrists' approach to ASD and caregivers' expectations. While enquiring how AS might change the definition of ASD is beyond the goal of this paper, it is worth to note that the AI model of AS would not be limited to diagnosing ASD; but it would also participate in enacting both the disease and the patient accordingly. ASD is not a singular, uniform condition, but one that is enacted differently across medical practices and settings; as these practices evolve, so too does the very definition of the disorder (Mol, 2002). Including AS in the diagnostic process would not merely offer a more precise specification of the same underlying disorder currently defined by the DSM-5 as "ASD"; rather, it would

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contribute to the shaping of a new diagnostic entity, co-produced with the AI system itself. AS might then steer neuropsychiatry toward a more quantitative and data-driven approach, introducing new challenges as well as associated reductionist risks. Yet using AI systems based on machine learning raises questions about the explainability and interpretability of the model. In this respect, the adoption of AS as a diagnostic system could contribute to the widespread diffusion of an “objectivity” rhetoric commonly associated with AI systems and explicitly emphasized by its designers. This narrative – already critically challenged from various philosophical perspectives (Daston and Gailson, 2007; Hacking, 2015) – nonetheless carries significant real-world implications. It may shape caregivers’ expectations, encouraging the perception of AS as a “truth-speaking” system. In turn, neuropsychiatrists may be required to actively manage these expectations, ensuring that families understand the interpretive nature of diagnostic results.

In this paper we suggested hypothetical enrolment as a method for moving between expectations and implementation of AI diagnostics. We began our analysis by acknowledging a significant gap between expectation about AI diagnostics and their adoption in clinical settings. This gap is also reflected in the lack of methodologies for studying the transition of these systems from research settings to real-world settings. To address this issue, we proposed hypothetical enrolment as an exercise of imagination for potential stakeholders. Specifically, it is a method for eliciting potential stakeholders to imagine and to speculate about how an innovation would affect, transform and re-organize the disease network in which it would be implemented. Testing our method with the case of AS allowed both to identify several analytical issues and also to produce new knowledge and learning experiences for the stakeholders interviewed. First, our method allowed to distinguish between the current disease network and how such network would change if AS was implemented. Importantly, this distinction enabled to assess the epistemic, organizational and professional challenges which would shape the new disease network. Second, the hypothetical enrolment interviews had a significant performative element: by including potential stakeholders who did not know about the technology, our interviews allowed to produce and circulate new knowledge about an innovation and they prompt them to reflect about how such innovation would transform their working practices. Our method hence offers a possibility, both for stakeholders and for scholars, to appreciate and to assess the potential consequences and challenges entailed by the integration of a technological innovation within a specific and situated working environment.

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### Notes

- [1.] The concept of “disease network” draws from actor-network theory (ANT) and the sociology of translation (Latour 2005). Moreover, the concept was inspired by the work of Cresswell and colleagues (2010) about the theoretical and practical values of applying ANT for studying the implementation of information technology in healthcare. However, whereas Cresswell and colleagues discuss electronic health records, we focus on and foreground the associations established among human and non-human actors for the diagnosis and cure of a specific disease.

- [2.] With its goal of identifying potential stakeholders at an early stage of technological development, hypothetical enrollment can be seen as indebted to the Constructive Technology Assessment (CTA) approach (see among others [Rip 2018](#)).
- [3.] In what follows, we will refer to these professionals simply as ‘neuropsychiatrists’, both for the sake of readability and because in Italian, the term “neuropsichiatra” (i.e. “neuropsychiatrist”) refers to what English-speaking contexts would call a “child psychiatrist” or “pediatric neuropsychiatrist”.
- [4.] All quotations from Italian sources have been translated into English by the authors, with careful attention to preserving the original meaning.

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