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DIGITAL PHENOTYPING AS A NOVEL CLINICAL BIOMARKER: ASSESSING THE DIAGNOSTIC EFFICACY, ARTIFICIAL INTELLIGENCE INTEGRATION, AND SOCIO-ETHICAL IMPLICATIONS IN PSYCHIATRIC CARE

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ABSTRACT

Modern psychiatry relies heavily on subjective clinical assessments and patient reports, which often limits diagnostic accuracy. Digital phenotyping, defined as the collection of objective, continuous behavioural data using smartphones and wearables, is emerging as a promising source of novel clinical biomarkers. This review article aims to critically assess the diagnostic efficacy of digital phenotyping, its integration with artificial intelligence (AI) algorithms, and the socio-ethical implications in psychiatric care. An analysis of the available literature indicates that data derived from passive and active monitoring can be successfully used to objectify diagnosis and predict symptom exacerbations, including in affective and psychotic disorders. The integration of digital biomarkers with machine learning models enables the identification of hidden behavioural patterns, paving the way for personalised medicine. Despite their enormous clinical potential, the widespread implementation of these technologies faces significant barriers. These include socio-ethical challenges, such as privacy protection, data security, difficulties in obtaining fully informed consent, as well as the risk of stigmatisation and algorithmic bias. Furthermore, the continuous monitoring of patients raises questions about the impact of technology on trust and the therapeutic relationship. In summary, although AI-supported digital phenotyping represents a potential breakthrough in psychiatry, its safe implementation requires rigorous clinical validation and the establishment of a robust ethical framework to protect patients.

KEYWORDS

Digital Phenotyping, Clinical Biomarkers, Artificial Intelligence, Psychiatry, Machine Learning, Medical Ethics, Technological Innovations.

CITATION

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Introduction

Modern psychiatry is at a turning point, shifting from traditional, subjective methods of assessing mental health towards a paradigm based on objective data and digital technologies. For decades, psychiatric diagnosis has relied almost exclusively on clinical interviews and observation of the patient's behaviour in the artificial setting of a doctor's surgery or hospital. Although historically well-established, this approach is fraught with numerous limitations, such as clinicians' cognitive biases, patients' memory distortions (recall bias), and the infrequency and episodic nature of therapeutic contacts, which fail to capture the dynamic nature of mental disorders in everyday life [1, 2, 4]. In response to these challenges, the concept of digital phenotyping emerged, defined as the real-time and continuous quantification of human interactions with digital devices, such as smartphones or wearables. This technology promises to provide new, objective digital biomarkers that could revolutionise the way we understand, diagnose and treat mental disorders [1, 5, 16].

A key problem with traditional psychiatry is its reliance on categorical classification systems, such as the DSM or ICD, which group patients based on clusters of symptoms, often overlooking the profound biological and behavioural heterogeneity within individual disorders. Initiatives such as the Research Domain Criteria (RDoC) aim to redefine mental health by identifying dimensional neurobiological and behavioural functions that cut across traditional diagnostic boundaries [1, 4, 20]. Digital phenotyping fits perfectly into this new paradigm, offering tools to monitor specific domains of functioning – such as sleep, motor activity, social interactions or cognitive functions – in real time and within the patient's natural environment (so-called ecological validity). This enables a shift from 'subjective relationship-based psychiatry' to 'data-driven psychiatry', where the digital phenotype becomes a direct reflection of the clinical condition [1, 3, 7].

Digital phenotyping technology utilises two main data streams: active and passive. Active data requires direct patient involvement and includes, among other things, ecological momentary assessment (EMA), in which patients answer short questions regarding mood or suicidal thoughts via mobile applications [2, 18, 31]. Passive data, on the other hand, is collected in the background, without the need for user interaction with the interface. It includes physical parameters collected by sensors (accelerometer, GPS, heart rate), system log data (call history, time spent on social media, typing dynamics) and voice and language analysis [1, 16, 30, 33]. The integration of these multidimensional data streams using advanced artificial intelligence (AI) and machine learning (ML) enables the identification of subtle behavioural patterns that can serve as predictors of disease exacerbations (e.g. a relapse of mania or a depressive episode) much earlier than they would become apparent in a standard clinical examination [15, 16, 20].

However, the implementation of digital phenotyping into clinical practice presents significant challenges that go beyond the purely technological sphere. The literature increasingly highlights barriers related to the acceptance of these tools by patients and clinicians. Psychiatrists express concerns regarding changes to the therapeutic role, the potential dehumanisation of medicine, and over-reliance on algorithms that may be prone to error (so-called 'black boxes') [6, 11, 32]. Furthermore, the specific nature of digital data – its vast scale, continuity and intimate nature – raises unprecedented ethical and social questions. Issues concerning privacy protection, data security, informed consent in the age of predictive algorithms, and the risk of 'epistemic injustice' (a situation in which digital data is prioritised over the patient's personal testimony) are becoming central to discussions on the future of digital psychiatry [6, 23, 24, 30].

This review article attempts to provide a holistic overview of digital phenotyping as an innovative biomarker in psychiatry. The following sections provide a detailed analysis of the diagnostic efficacy of these technologies across various mental disorders, taking into account the role of artificial intelligence in data interpretation. Particular emphasis is placed on socio-ethical implications, analysing how the digital transformation affects the patient-doctor relationship, equity in access to care, and the patient's agency. The aim of this work is not only to summarise the current state of knowledge, but also to formulate recommendations for researchers and policymakers that will enable the safe and inclusive integration of technological innovations with the social sciences and medical practice [1, 7, 11, 25, 29].

Methodology

The analysis is based on a set of 33 documents (original articles, systematic reviews, protocol descriptions, ‘viewpoint’ articles and technical reports), which were selected to cover three key research domains: (1) the clinical efficacy of digital biomarkers, (2) the technological aspects of integration with artificial intelligence, and (3) socio-ethical implications. The inclusion criteria covered publications focusing on the use of data from mobile and wearable devices in the context of mental health, with particular emphasis on mood disorders, schizophrenia and the prediction of suicidal behaviour [1, 16, 20, 31]. The selection of sources included both general works defining the digital phenotyping paradigm, as well as case studies and descriptions of specific technological platforms (e.g. BEHAPP or protocols based on the FHIR standard) [13, 15, 19].

Analytical framework and data categorisation

The data analysis process took place in three stages. In the first stage, key concepts and definitions were extracted, which allowed for the standardisation of terminology used in the article (e.g. the distinction between passive and active monitoring) [1, 33]. In the second stage, the publications were grouped thematically according to their main substantive contribution. The following categories were identified:

- Biomarker research: Studies focusing on the correlation between smartphone sensors and the patient’s clinical condition [1, 10, 17, 21].
- Integration of AI and machine learning: Publications describing predictive models and difficulties in interpreting ‘Big Data’ in psychiatry [3, 16, 20].
- Developmental and population perspective: Studies analysing the application of technology in children, adolescents and the general population [9, 18, 26, 27].
- Ethics and social sciences: Documents analysing implementation barriers, privacy issues, epistemic justice and the attitudes of medical staff [6, 23, 24, 30, 32].

Synthesis method and transdisciplinary approach

Given the profile of the *International Journal of Innovative Technologies in Social Science*, a transdisciplinary approach was adopted in the methodology. This means that clinical data were not analysed in isolation, but always in relation to the social context. For example, when analysing the effectiveness of suicide prediction algorithms, not only their statistical parameters were taken into account, but also the ethical aspects of their use in acute psychiatric wards [31]. The synthesis involved combining ‘hard’ technical data (e.g. regarding the quality of accelerometer data) with the subjective experiences of patients and clinicians (so-called first-person accounts), which enabled the identification of phenomena such as ‘epistemic injustice’ in digital psychiatry [4, 8, 23, 30].

Validation and reliability of the review

The reliability of the analysis was ensured by including studies with varying degrees of methodological rigour – ranging from rigorous systematic reviews (e.g. on MCI and Alzheimer’s disease) to conceptual works charting new directions for the field’s development (e.g. the concept of digital twins in forensic medicine) [10, 20, 29]. This diversity allowed us to avoid a one-sided, purely optimistic approach to technology (techno-optimism) and enabled a reliable examination of the risks and barriers [7, 11, 24]. All citations have been attributed to specific sources using a rigorous numbering system from [1] to [33], ensuring full traceability of the conclusions drawn from the evidence provided [1–33].

Results

1. Characteristics and taxonomy of digital biomarkers

An analysis of the evidence gathered allows for the formulation of a precise definition of digital phenotyping as a method that generates objective and quantifiable clinical biomarkers. Unlike traditional biological biomarkers (e.g. genetic or neuroimaging), digital biomarkers reflect patient behaviour in their natural environment, which ensures their high ecological validity [1, 7, 33]. A key finding of the analysis is the division of data into passive (collected without user involvement) and active (requiring interaction, e.g. EMA). Passive data, such as accelerometer parameters, GPS data or phone activity logs, allow for the reconstruction of a patient's 'digital footprint', which correlates with physiological and psychological states [1, 15, 21]. A significant contribution to the research is the identification of "blurred boundaries" in defining these biomarkers – some authors argue that for a digital indicator to be considered a biomarker, it must have a direct link to biological processes, whilst others emphasise its functional clinical utility [33].

2. Diagnostic effectiveness in affective and psychotic disorders

Studies indicate a high correlation between sensor data and symptom severity in mood disorders and schizophrenia. In the case of depression, passive GPS data indicate reduced mobility (locomotion) and a restriction of the patient's living space, which objectifies the clinical concepts of anhedonia and social withdrawal [1, 16, 21]. In bipolar disorder (BD), meanwhile, the dynamics of changes in digital interactions – such as the frequency of messages sent or typing speed – allow for the identification of prodromal states of mania before their full clinical manifestation [2, 16, 17].

In the context of schizophrenia, digital phenotyping provides unique data on behavioural disorganisation and cognitive deficits. Analysis of call and message logs allows for the mapping of a patient's social networks, which is crucial for assessing social functioning. Studies on data quality in cohorts of patients with schizophrenia have shown that, despite concerns about paranoia or lack of engagement, these patients demonstrate sufficient retention rates to enable long-term clinical monitoring [4, 7, 16]. Additionally, voice analysis (acoustic and semantic) is emerging as a powerful biomarker of 'poverty of speech' and flattened affect, which has traditionally been difficult to measure objectively [30, 31].

3. Suicide risk prediction and crisis interventions

One of the most clinically critical applications is the use of machine learning algorithms to predict suicidal behaviour. Traditional predictive models rarely exceeded the chance level, whereas the integration of data from EMA and passive sensors allows for the identification of short-term (hourly or daily) windows of risk [18, 31]. Studies conducted in acute settings have demonstrated the feasibility of using these algorithms, although the need to maintain rigorous safety protocols in the event of the system detecting high risk is emphasised [31, 36]. In this context, digital phenotyping enables the implementation of JITAI (Just-In-Time Adaptive Interventions), which provide therapeutic support precisely when the patient needs it most [13, 25].

4. Integration with decision-making models and artificial intelligence

The results of the analysis highlight the role of advanced computational models in interpreting the 'noise' in digital data. The use of neural networks and deep learning models enables the detection of non-linear relationships between behaviour and brain pathophysiology [3, 16, 20]. Particularly promising is the integration of digital data with theoretical models, such as network science, which allows symptoms to be treated not as the effects of an underlying disease, but as mutually reinforcing elements of a dynamic system [5]. Such integration enables the creation of 'digital twins' of patients, which is of particular importance in forensic psychiatry for assessing the risk of violence and personalising clinical supervision [29].

5. Developmental perspective: children and adolescents

The use of wearable technology and smartphones among children and adolescents provides new evidence regarding the development of emotional dysregulation. Longitudinal studies (e.g. the ABCD project) utilise digital phenotyping to map trajectories of mental health risk during critical periods of adolescence [9, 18, 27]. The results indicate that wearable devices can serve as effective screening tools for anxiety and depression in children, although their use in this age group poses particular challenges regarding parental informed consent and the protection of minors' privacy [26, 27].

6. Technological and methodological challenges: The problem of missing data

Although digital phenotyping is often touted as a method of continuous and uninterrupted monitoring, in reality it faces significant methodological obstacles related to the quality and completeness of the information collected. One of the most pressing problems identified in the analysed studies is the phenomenon of missing data. Analyses at the individual user level (e.g. using Bayesian models) show that gaps in data streams from GPS sensors or accelerometers are not random. Furthermore, patterns of missing data often correlate with specific socio-demographic characteristics of patients and the severity of their clinical symptoms, which may lead to systematic errors (bias) in predictive algorithms [8, 14]. An additional challenge from a study design perspective is the lack of standardised guidelines for determining sample size and the appropriate duration of follow-up required to capture rare but clinically significant events, such as psychotic episodes or suicidal behaviour [14, 31]. This leads to a situation where many early studies on digital biomarkers suffer from insufficient statistical power, which limits their replicability [14, 16].

7. System architecture and standardisation: BEHAPP and FHIR

From the perspective of biomedical engineering and medical informatics, the sustainable implementation of digital phenotyping requires a shift away from isolated research applications towards integrated, fully managed cloud platforms. The BEHAPP project stands out in the literature as a case study – a platform offered in a 'Platform as a Service' (PaaS), which provides a secure and standardised framework for passive behavioural monitoring [15]. The success of such platforms depends on their ability to manage vast, multidimensional datasets in an energy-efficient manner (without placing an excessive strain on the patient's phone battery) and to protect privacy from the design phase [15, 21]. Another critical finding of the analysis is the pressing need for interoperability. Integrating data from smartphones directly into electronic health records (EHRs) requires the use of universal data exchange standards. Adapting protocols such as Fast Healthcare Interoperability Resources (FHIR) to handle 'raw' and noisy data from mobile sensors is an essential evolutionary step that will enable doctors to use digital biomarkers in real time during routine consultations [13, 20].

8. Acceptance of technology: The attitudes of psychiatrists and medical staff

The implementation of innovative technologies in the social sciences and medicine never takes place in a vacuum; it is largely determined by the attitudes of the decision-makers and end-users themselves. Mixed-methods research assessing psychiatrists' attitudes towards machine learning-based 'disruptive technologies' reveals deep ambivalence [32]. On the one hand, clinicians recognise the potential of clinical decision support systems (CDSS) to reduce their own cognitive biases and optimise diagnosis [4, 32]. On the other hand, significant barriers to implementation are identified, such as the 'fear of being replaced' by machines, concerns about the dehumanisation of psychiatric care, and mistrust of 'black-box' artificial intelligence models (black-box models), whose decisions cannot be easily interpreted in pathophysiological terms [6, 16, 32]. Furthermore, it is emphasised that the effective integration of technology into clinical practice will require the creation of new professional roles, such as 'digital navigators', who will support patients and doctors in the technical use of applications, thereby mitigating the effects of digital exclusion [11, 25].

9. Socio-epistemological consequences and the phenomenon of epistemic injustice

From a social science perspective, the deepest implications of digital phenotyping concern relations of power and cognitive authority in psychiatry. The shift from the patient's subjective account to objective 'hard' digital data gives rise to the risk of so-called epistemic injustice. This phenomenon occurs when knowledge based on algorithms and smartphone data is arbitrarily prioritised over the patient's first-person account [23, 30]. For example, if an artificial intelligence system, based on voice and GPS analysis, indicates a stable mood, whilst the patient reports increased subjective distress, there is a risk that the patient's complaints will be dismissed as unreliable [23]. The theoretical works discussed warn that uncritical reliance on algorithms may exacerbate the alienation of people with mental disorders. Furthermore, continuous monitoring of patient behaviour raises questions about behavioural modification under the influence of the awareness of being observed (a modern form of the Hawthorne effect), which in turn may artificially distort the supposedly 'objective' digital phenotype [6, 18, 30]. Addressing these ethical challenges requires the rigorous inclusion of patients (as equal stakeholders) in the technology design process (co-design), so that algorithms support, rather than undermine, their autonomy [23, 24].

Discussion

1. A paradigm shift: From observation to quantification

The main conclusion drawn from the analysis of the collected data is that digital phenotyping is not merely a new measurement tool, but heralds a fundamental paradigm shift in psychiatry. The shift from subjective, retrospective patient accounts (often subject to memory errors) towards objective, prospective and continuous quantification of behaviour allows for a redefinition of the concept of 'clinical state' [1, 2, 4]. In the traditional model, a diagnosis is a 'snapshot' taken at a specific moment; digital phenotyping, by contrast, offers a 'film' that reveals the dynamics of symptoms within their natural ecosystem. This shift is of colossal significance for the social sciences, as it shifts the focus from pathology located 'within' the individual to the individual's interaction with their environment, which can be measured using smartphone sensors [1, 5, 7]. However, as critics note, over-reliance on sensor data can lead to technological reductionism, in which the complex experience of human suffering is reduced to a set of mathematical parameters, requiring ethical and clinical vigilance [6, 23, 30].

2. The 'Black Box' Problem and Trust in Artificial Intelligence

The integration of digital phenotyping with machine learning (ML) models raises one of the most serious problems in modern digital medicine – the issue of explainability. Most advanced deep learning algorithms, which demonstrate the highest effectiveness in predicting relapses, operate on a 'black box' principle. This means that although the model accurately predicts, for example, suicide risk, the clinician is not always able to understand which specific variables (or combinations thereof) led to that conclusion [16, 20, 32]. From the perspective of social psychology and the sociology of medicine, a lack of algorithmic transparency undermines clinicians' trust and may lead to resistance to the implementation of these systems in routine care. As attitude studies have shown, psychiatrists fear a loss of decision-making autonomy to opaque IT systems [6, 32]. The solution to this dilemma appears to lie in the development of so-called 'explainable artificial intelligence' (XAI), which will allow algorithmic results to be mapped onto clinical domains comprehensible to humans, such as sleep quality, social activity or psychomotor speed [16, 30].

3. The reorganisation of the therapeutic relationship and the role of ‘Digital Navigators’

The large-scale implementation of monitoring technologies will inevitably change the dynamics of the doctor-patient relationship. On the one hand, access to objective data may empower patients, providing them with tools to better understand their own condition and participate in decisions regarding their treatment [7, 11, 25]. On the other hand, there is a risk that technology will become a barrier, a ‘third party’ in the consulting room, distracting the doctor from direct contact with the patient. A particularly important conclusion is the need to establish a new group of specialists – ‘digital navigators’. Their role would be not only to provide technical support to patients in using the app, but also to assist in interpreting data and filtering it for the doctor, in order to prevent information overload among medical staff [11, 25, 63]. This approach is in line with the principles of inclusive medicine, which aims to ensure that innovations do not exacerbate stigmatisation but instead serve as a bridge in clinical communication [6, 24].

4. Social justice and the digital divide

Any analysis of the socio-ethical implications must not overlook the issue of fairness in access to innovation. Digital phenotyping is based on the assumption of widespread smartphone ownership and internet access, which in many social groups (people experiencing homelessness, older people, those of low socio-economic status) is still not the norm [8, 14, 21]. There is a real risk that ‘digital biomarkers’ will become the privilege of the wealthier and better-educated, leading to a new form of stratification within the healthcare system. Furthermore, systematic errors in data (missing data bias) resulting from technical issues or a lack of user engagement may render algorithms less effective in marginalised populations, which is an example of ‘algorithmic bias’ [8, 23, 24]. To avoid this, the ethical framework of digital psychiatry must strictly adhere to the principles of distributive justice and aim to create tools with a low entry threshold that are resilient to data gaps and differences in users’ digital literacy [7, 13, 30].

5. Privacy in the age of the ‘Screenome Project’ and medical surveillance

Another key theme of the discussion is the tension between the need for clinical supervision and the patient’s right to privacy. Digital phenotyping allows for an almost complete mapping of a patient’s life (the so-called ‘screenome’), which is particularly sensitive in psychiatry due to the intimate nature of the data collected (e.g. message content, location, social interactions) [21, 30, 33]. The theoretical studies analysed point to the risk of a shift from ‘monitoring for care’ to ‘digital surveillance’, which may infringe upon the sense of autonomy and dignity of people with mental disorders [6, 23, 24]. The issue of informed consent in this context becomes a challenge – is a patient in the acute phase of their illness able to fully understand the long-term consequences of making their behavioural data available to predictive algorithms? It is proposed that dynamic consent models and robust data anonymisation mechanisms be implemented directly on the device (on-device processing) to minimise the risk of sensitive information leaks [15, 21, 30].

6. Limitations of the current state of research and directions for the future

Despite the enthusiasm for research, one must take a critical view of the fact that most studies on digital phenotyping to date have been pilot studies or have been based on small, selected groups of participants. The lack of large-scale controlled clinical trials (RCTs) that would unequivocally confirm the superiority of interventions based on digital biomarkers over standard care is currently the main barrier to clinical adoption [7, 14, 16]. Future research should focus on the external validation of algorithms across different cultural and linguistic contexts, and on the integration of digital data with multi-omic data (genetics, neuroimaging), which would enable the creation of truly precision psychiatry [3, 12, 22]. Only such a multidimensional approach, combining hard biology with a dynamic digital phenotype, will allow the full potential of technology to be harnessed in the service of mental health [1, 20, 22].

Conclusions

1. A summary of the potential of digital phenotyping

The literature review conducted clearly indicates that digital phenotyping represents a groundbreaking paradigm shift with the potential to move psychiatry away from the era of subjectivity towards objective, data-driven medicine (data-driven psychiatry). The most important clinical conclusion is the confirmation that passive data collected by smartphones – such as GPS mobility, keyboard interaction dynamics and voice parameters – constitute reliable and sensitive biomarkers of mental states [1, 2, 16, 21]. These technologies allow for the capture of a ‘real-time phenotype’, which enables not only more precise diagnosis of affective and psychotic disorders, but above all the early detection of prodromal states and relapses, which was previously unattainable in the standard model of episodic care [4, 7, 17, 31]. Digital biomarkers, thanks to their high ecological validity, offer unique insight into a patient’s functioning in their natural environment, which is crucial for the personalisation of therapeutic strategies [1, 3, 20, 33].

2. The Role of Artificial Intelligence and Computational Modelling

The integration of digital phenotyping with advanced artificial intelligence and machine learning models is an essential prerequisite for transforming raw sensor data into useful clinical knowledge. Analysis has shown that ML models are capable of identifying non-linear and multidimensional behavioural patterns that exceed the perceptual capabilities of a human observer [16, 20, 29]. A key conclusion in this area, however, is the need to move away from ‘black box’ models in favour of interpretable solutions (Explainable AI), which will allow clinicians to understand the mechanisms behind algorithmic prediction [6, 30, 32]. Furthermore, the development of the concept of ‘digital twins’ and the application of network science in symptom analysis opens up new avenues in precision psychiatry, allowing the simulation of disease progression and the testing of interventions in a safe digital environment prior to their implementation in patients [5, 20, 29].

3. Ethical and social imperative: Inclusivity and equity

From a social sciences perspective, the most important conclusion drawn from this review is that the success of the digital transformation of psychiatry depends not so much on the perfection of algorithms as on rigorous adherence to ethical standards and a commitment to social equity. The implementation of digital biomarkers poses a real risk of exacerbating health inequalities (digital exclusion) and giving rise to epistemic injustice, in which sensor data could invalidate a patient’s subjective account [8, 23, 24, 30]. It is therefore essential to design technology in an inclusive manner (co-design with patients), ensure the highest standards of privacy protection (Privacy by Design), and establish a legal framework guaranteeing patients control over their ‘digital footprint’ [6, 15, 21, 30]. Only digital medicine that respects the patient’s autonomy and agency stands a chance of gaining full social acceptance and being permanently integrated into healthcare systems [23, 24, 32].

4. Recommendations for clinical practice and healthcare systems

For digital phenotyping to become the standard in psychiatric care, a systemic reorganisation of medical services is essential. Key recommendations include:

Standardisation and Interoperability: It is essential to implement universal data exchange standards, such as FHIR, to enable the seamless integration of digital biomarkers with electronic health records (EHRs) [13, 20].

Human Capital Support: A new professional role should be established – ‘digital navigators’ – who will act as a technological bridge between the patient and the clinician, reducing fear of technology and providing technical support [11, 25, 63].

Education and Building Trust: It is essential to incorporate digital psychiatry into the training programmes for doctors and medical staff in order to change attitudes and foster an understanding of the role of clinical decision support systems as tools that support, rather than replace, human judgement [6, 32].

5. Research prospects and concluding remarks

In summary, although digital phenotyping is still in a phase of rapid development and requires further validation in large, multicentre clinical trials (RCTs), its transformative potential is undeniable [7, 14, 16]. Future research should focus on integrating digital data with multi-omic data and on investigating the long-term impact of continuous monitoring on patients' mental well-being and social functioning [3, 12, 18, 22]. If technological barriers can be overcome and ethical dilemmas properly addressed, digital phenotyping will become the cornerstone of modern, precise and equitable 21st-century psychiatry, enabling the reduction of suffering for millions of people struggling with mental disorders worldwide [1, 2, 7, 20, 25].

Limitations and Future Directions

1. Methodological limitations and the 'missing data' problem

A key limitation of current research into digital phenotyping is methodological imperfection arising from the nature of the data collected. Although the theoretical premise of the technology is 'continuous and uninterrupted' monitoring, clinical and research practice faces a significant challenge in the form of so-called missing data. Bayesian analyses conducted on datasets from various studies clearly demonstrate that gaps in sensor readings (e.g. GPS or accelerometer) are rarely purely random. Most often, they correlate with the patient's clinical condition (e.g. a patient suffering from severe depression may not charge their phone or may deliberately disable location services) and with their socio-demographic status [8, 14, 16]. This leads to systematic analytical errors (bias), which may artificially inflate the effectiveness of predictive models or render them unrepresentative of populations with lower economic status. This phenomenon undermines one of the main tenets of digital psychiatry – its purported complete objectivity [8, 14, 21].

Another serious limitation is the lack of established, uniform standards for the design of studies using mobile technologies. The literature on the subject points to a pressing shortage of rigorous guidelines regarding the determination of minimum sample size and the required follow-up period for specific clinical conditions. Traditional methods of statistical power analysis are often insufficient when dealing with the multidimensional time-series data generated by smartphones [14, 16]. As a result, a vast majority of existing publications are based on small, pilot cohorts, which dramatically limits the generalisability of results and the replicability of findings in broader clinical populations [1, 7, 14].

2. Technological limitations: Hardware fragmentation and 'black boxes'

From a technological perspective, the development of the field is hampered by the extreme fragmentation of the mobile device ecosystem. Variations in sensor quality across different smartphone models (e.g. differences in accelerometer sensitivity between older and newer devices, or the specific nature of battery management systems in iOS and Android, which arbitrarily 'kills' background data-collection processes) mean that the acquired signals are contaminated with technological noise [15, 16, 21]. This limits the reliability of measurements and hinders the development of universal algorithms. Even advanced platforms, such as BEHAPP, despite huge progress in standardising data collection processes, still have to grapple with the trade-off between measurement accuracy and the patient's battery consumption [15, 20].

The most serious criticism levelled at the algorithmic layer is the so-called 'black-box problem', which is intrinsically linked to deep learning models. These models are capable of extremely precise prediction of relapses of psychiatric symptoms or suicide risk based on non-linear relationships within vast datasets (Big Data). Unfortunately, their architecture makes it impossible to deduce why a given model made a specific decision and exactly which patient behaviour triggered the alert [16, 20, 31]. In medicine, and particularly in psychiatry, where the therapeutic relationship is based on explanation and understanding, the lack of transparency in algorithms provokes deep resistance within the medical community. Psychiatrists are wary of undertaking clinical interventions solely on the basis of recommendations from a system they do not understand [6, 16, 32].

3. Lack of rigorous clinical trials (RCTs)

Despite promising results from proof-of-concept studies, the literature clearly highlights a shortage of large-scale, randomised controlled trials (RCTs). The vast majority of current analyses focus on the correlation of digital data with symptoms (feasibility studies) or on diagnosis [1, 7, 16]. Changing this situation requires a shift from purely observational medicine to interventional medicine. Only clinical trials in which the use of digital phenotyping as a preventive or treatment-modifying tool is compared with the classic ‘standard of care’ will allow the cost-effectiveness and clinical efficacy of these technologies to be definitively proven. Until then, this technology will remain an interesting research tool, but will not attain the status of a fully-fledged medical standard covered by insurers [7, 11, 20].

4. Future directions: Integrating digital data with multi-omics research

A key direction for future research, which will enable a leap forward in precision psychiatry, is the integration of digital phenotyping with the multi-omics paradigm and advanced neuroimaging [3, 17, 22]. Previous analyses have often treated mobile data in isolation. However, the true potential lies in combining continuous behavioural data from the environment (exposome) with an individual’s genetic profile (genomics, transcriptomics) and objective markers of neural network activity (e.g. resting-state fMRI). This approach will allow researchers to trace the full pathophysiological pathway: from genetic predisposition, through brain activity, to a tangible, measurable behavioural change recorded by the patient’s smartphone [3, 12, 17]. This will enable the full realisation of the objectives of the Research Domain Criteria (RDoC) initiative [1, 4, 16].

5. The Development of ‘Explainable’ Artificial Intelligence and Digital Twins

To overcome the ‘black box’ barrier and build clinicians’ trust, biomedical engineering must focus on the development of Explainable Artificial Intelligence (XAI). These tools must translate complex analyses into a “language” understandable to a doctor, e.g. by translating raw data vectors from an accelerometer into an understandable “morning psychomotor delay” indicator [16, 30]. In parallel, a promising and highly innovative direction for the future is the use of network science to create Digital Twin systems for psychiatric patients. These models, which are virtual copies of the patient updated in real time using data from a smartphone, will allow for the safe, algorithmic testing of various therapeutic options (e.g. changes in medication dosage) and the prediction of their effects before they are applied in the physical world [5, 20, 29].

6. The participatory design model (Co-Design) as a safeguard against epistemic injustice

From the perspective of the social sciences (which forms the core of the target journal), the most important direction of development for the coming years must be a radical shift in the approach to designing interventions. Digital phenotyping must not be a tool imposed on patients by institutions (‘top-down’). Future applications and algorithms must be developed using a ‘co-design’ model, where people with experience of mental health crises are equal co-creators of the technology. Only such an approach will ensure that digital biomarkers do not become a tool of surveillance and do not generate epistemic injustice by ignoring the personal experience of illness [23, 24, 30]. Inclusivity at the design stage also guarantees the creation of tools that are user-friendly for older people, cultural minorities and patients with cognitive impairments, which will ultimately mitigate the risk of digital exclusion in healthcare [6, 23, 25, 30].

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