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Digital mental health: challenges and next steps

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ABSTRACT

Digital innovations in mental health offer great potential, but present unique challenges. Using a consensus development panel approach, an expert, international, cross-disciplinary panel met to provide a framework to conceptualise digital mental health innovations, research into mechanisms and effectiveness and approaches for clinical implementation. Key questions and outputs from the group were agreed by consensus, and are presented and discussed in the text and supported by case examples in an accompanying appendix. A number of key themes emerged. (1) Digital approaches may work best across traditional diagnostic systems: we do not have effective ontologies of mental illness and transdiagnostic/symptom-based approaches may be more fruitful. (2) Approaches in clinical implementation of digital tools/interventions need to be creative and require organisational change: not only do clinicians and patients need training and education to be more confident and skilled in using digital technologies to support shared care decision-making, but traditional roles need to be extended, with clinicians working alongside digital navigators and non-clinicians who are delivering protocolised treatments. (3) Designing appropriate studies to measure the effectiveness of implementation is also key: including digital data raises unique ethical issues, and measurement of potential harms is only just beginning. (4) Accessibility and codesign are needed to ensure innovations are long lasting. (5) Standardised guidelines for reporting would ensure effective synthesis of the evidence to inform clinical implementation. COVID-19 and the transition to virtual consultations have shown us the potential for digital innovations to improve access and quality of care in mental health: now is the ideal time to act.

INTRODUCTION: STATE OF THE ART AND BEYOND IN DIGITAL MENTAL HEALTH, AND CURRENT CHALLENGES

New innovations, such as digital phenotyping and apps as prevention and treatment interventions, hold tremendous potential in mental health.[1] However, emerging evidence suggests the need for high-quality validation, real-world clinical outcomes, implementation data and a clear vision to ensure such innovations have an ethical and transformative impact on patient outcomes.[2,3]

Psychiatry and psychology are constantly evolving fields, with COVID-19 forcing a rapid switch to virtual visits.[4,5] While this transition has had advantages, the projected benefits around increased access and better quality of care have generally not yet been realised for several reasons.[6] Virtual visits are a form of synchronous telehealth and thus access is still limited by the number of clinicians[1] and by digital divides between those who can meaningfully engage with virtual visits and those who cannot.[7] They also require clinician training and patient guidance for optimal benefit and this has been, and often continues to be, lacking.[6,8] In addition, virtual visits do not specifically focus on prevention, which is the only scalable means to reduce demand.[3]

By learning from the transition to virtual visits during the COVID-19 pandemic, we can see that now is the ideal time to prepare for the next generation of innovations which will advance the field. Additional and supplementary routes or methods to allow for a more flexible, 'just-in-time' and early intervention access to care include digital phenotyping, ecological momentary assessment (EMA), apps, real-time analysis, artificial intelligence (AI) approaches, virtual reality and blended decision-making, but each presents scientific, clinical, ethical and regulatory challenges. In addition, research into the feasibility and utility of integrating these digital techniques into a clinical setting is still just beginning.

The aim of this paper is to offer researchers, clinicians, patients and policy makers a framework to conceptualise the development of digital mental health beyond virtual consultations and its implementation in routine clinical care, to improve access and precision in treatments and outcomes. In providing a framework, we were aware that the scope is very broad and we could not include all advances in digital mental health. While this approach provides advantages in identifying some possible solutions across subspecialties, we acknowledge this has limitations and we do not attempt to cover every innovation in detail, but rather to highlight general principles which may be helpful for all approaches, with examples of case studies to illustrate these. With this broad focus, we aimed to explore and discuss core challenges in gathering and interpreting data and designing implementation strategies, key issues and themes that have emerged across the field in the last few years, and some potential solutions.

METHODS

We used a consensus development panel approach[9,10] following the methodology described and used by the US National Institutes of Health[11]

and WHO.[10 12] This method of consensus formation was chosen as it is most appropriate for identifying general areas of challenge and uncertainty, and formulating broad strategic plans. This is in contrast to the aim of achieving specific decision-making criteria or protocols, which are the focus of alternative approaches such as the Delphi technique or nominal group process.[13] Other advantages are that because the relevant literature and data are collected and circulated in advance of the meeting, the consensus development panel method is more evidence based (rather than on personal experience) and enables a multidisciplinary approach, which is critical in such a fast-moving and novel area.

A core team of panellists (KAS, AC, JT) identified experts with expertise in a variety of specialist areas within digital mental health and invited them to join the process. The 12 panellists were chosen to be representative across different disciplines and professional backgrounds and offered expertise in many specialised and general fields of digital psychiatry, including: digital phenotyping and EMA, blended cognitive–behavioural therapy approaches, virtual consultations, clinical decision-making, AI approaches, ethics, methodology and placebo choice, lifestyle and physical interventions, evidence synthesis, special populations including adolescents, transdiagnostic approaches and codesign. The group composition was gender balanced and professional backgrounds included psychiatry, psychology, methodology, evidence synthesis and ethics. The panel of experts was international (including Belgium, the Netherlands, UK, France, Spain, USA, Denmark, Germany, Sweden).

In advance of the meeting the experts were asked to provide information on their specialised area of digital mental health (or more broadly) in the form of a short abstract supported by up to five references which they considered to be the key references in the last 2–3 years. This was supported by a literature review using PubMed to search for terms relevant to the main themes identified by the experts. This preliminary work identified the areas of recent development, uncertainties or challenges which formed the agenda for the questions to be addressed in the face-to-face meeting. The meeting was held in Rome over 2 days in December 2022. Each expert gave a brief presentation including shared slides, methodology, analysis of data and relevant citations, followed by whole group discussion of their particular topic. The meeting was facilitated by two panel members (JT and AC) and recorded and summarised by KAS. At the end of each day a summary was prepared in discussion with the whole group to agree to the key consensus points, areas of uncertainty and next challenges. The main themes identified were:

1. Challenges in techniques for gathering and analysing new data (eg, using digital phenotyping, EMA, transdiagnostic or machine learning approaches).
2. Challenges in designing interventions (including the choice of placebo, and preventative interventions, such as physical health interventions in those with mental illness).
3. Challenges in combining real-time assessments with intervention.
4. Challenges in implementation in the real-world clinical setting (including clinical decision-making, education and training and policies in organisations and healthcare systems).
5. Challenges in developing implementation studies (including reporting guidelines, accessibility and codesign, ethics and potential harms, specialised groups).

Just as important were the agreed decisions about what could not be included in the current consensus. It was also decided by the group that the output of the panel would be a coauthored consensus paper of the overarching challenges, with case studies of specific examples and solutions in the online supplemental appendix. Each panellist was asked to provide a case example illustrating a key challenge in their area.

The meeting was supported externally (by Angelini Pharma and Excerpta Medica). However, to avoid any potential conflict of interest, neither organisation had any input into the design of the meeting, the identification or selection of the experts, the agenda of the meeting, discussions, consensus or output.

We also performed a series of PubMed searches using keywords relevant to the themes and initial consensus areas identified by the group. Because of the broad scope of the themes addressed and the novelty of the field, consensus was not predefined by percentage. Instead, it was agreed in advance of the meeting that either full consensus would be achieved, or where there was disagreement, this would be reported.[14] An iterative process was then used to reach a consensus on the details of key themes. Question and answers were posed among the group with discussion on key messages. Case examples to illustrate each point were reviewed by the group before they were included in the online supplemental appendix. All experts participated in this process before finalising the consensus summarised here.

PRESENTATION
Theme 1: challenges in techniques for gathering new data
Assessments in daily life: digital phenotyping and EMA
Understanding patients' unique lived experience of their condition is critical to delivering the best care. Momentary real-life assessments such as digital phenotyping and EMA provide a rich source of data to complement information gathered from directly asking people how they feel (see online supplemental appendix table 1 for definitions and case examples). The real-time nature of these assessments promises to avoid several of the recall biases seen in other methods of symptom reporting,[15] and also the issue of 'back-filling', commonly seen with paper diaries.[16] When combined with digital phenotyping we can also access new data like environmental factors and mobility patterns (eg, how real-life urban green space exposure and amount of movement may impact mental health symptoms[17]).

Digital phenotyping (in its broadest definition) is therefore a promising route to supplement clinical decision-making and reduce bias. From these data we have already learnt that momentary real-life patient data (eg, on alcohol use) may not match some of our assumptions about behaviour or traditional views of clinical symptoms over time.[18] Although this discrepancy might be expected, given that recall biases are avoided, systematic evidence that real-time models are more accurate than traditional clinical symptom assessment is still in progress. To date, studies of clinical validation have been scarce, as although digital phenotyping allows for an extensive and broad range of personal data, demonstrating its use and validity in the clinic is challenging especially when many outcomes are personalised. This is particularly so for passive data measures as, unlike standardised diagnostic interview or questionnaire-based measures which are used routinely in clinical trials and outcome management, agreed standards have not been defined for clinical validation of passive digital phenotyping.[19] In addition, standardised approaches have not been uniformly applied to assess how advanced analytical methods, including machine learning algorithms, could be used to reduce the complexity of active and passive phenotyping data to deliver clinically actionable predictive models.[20] For either focus, we need to be careful to avoid 'black box' machine learning models that do not explain 'why', as this explanation is necessary now for regulatory approval and clinical acceptance and uptake.

Transdiagnostic approaches

One solution to assessing clinical validity is to approach digital phenotyping in a more transdiagnostic manner. For example, in addition to searching for the digital marker of mania in bipolar disorder, markers of clinical transition across states (eg, stable to unstable) are also clinically important and can be followed in large population-based cohorts (see online supplemental appendix table 1 for examples). The digital phenotyping data could add new context and meaning to a core set of high-quality clinical assessments or more gold-standard measurements.

This combination is important as although digital phenotyping data may have high reliability, as noted its clinical validity has been sparingly investigated. The transdiagnostic approach may therefore address the challenge of trying to directly associate a new digital signal with a biological endpoint, as although in some areas the results are promising, there have also been examples of inconsistencies in associating particular metrics (such as sleep measures or screen time) with mental health disorders.[19] One approach would be new prospective studies, but an alternative or complementary strategy could also be to focus more urgently on developing and implementing agreed standards for measuring and reporting digital phenotyping.[2] This would allow data sets to be combined and results replicated and validated across illnesses.

A transdiagnostic approach is also particularly useful in patient populations where diagnostic boundaries are more fluid or in which the impact of development needs to be considered, such as the adolescent population or those with early psychosis (see online supplemental appendix table 2).

Machine learning approaches

In parallel with the rapid development of digital phenotyping technology, machine learning methods have emerged as powerful tools to explore high-dimensional, time-series data, such as electroencephalography, resting-state functional MRI or natural language. Machine learning (see online supplemental appendix table 3) can be used in this way to 'make sense' of digital phenotyping-based big data. However, there are challenges in translating this use to clinical settings,[20] often because the underlying data are not well understood, or the preprocessing steps have made bold assumptions that lack clinical nuance.

Theme 2: challenges in designing interventions

While digital phenotyping and EMA offer a new window into the lived experience of mental illness, using this and new digital modalities to deliver care and new interventions remain an area which needs increased focus. With thousands of health apps and new digital innovations gaining momentum, it is appropriate to consider broader issues around the assessment of their quality and efficacy. As health regulators around the world struggle to assess the 'true' effect of new treatments, the importance of placebo-controlled studies for interventions has expanded. Likewise, the focus on innovative digital software to deliver preventative interventions and complex therapies has also raised interest in gaining a better understanding of how interventions actually work.

Choice of placebo

The choice of a placebo is a key element in assessing the effectiveness of an intervention (see online supplemental appendix table 4 for further details), but there is often a lack of placebo literacy in digital health, with considerable variability in how placebos are designed or described.[21] In digital mental health

research contexts, investigators should decide in advance what they consider to be the locus of treatment. Rigorous placebos should then be designed that match factors such as the length and number of sessions of the active intervention, the aesthetic features of the interface, contextual features (such as interactivity), training and rationale, and assessing patients' views of whether they believe they are in the control or treatment group.[22] If necessary, so-called dismantling or additive studies, which incrementally examine the effectiveness of components of the active intervention,[22] could also be devised (see online supplemental appendix table 4). While designing placebos is methodologically challenging, this does not abnegate responsibility for due diligence: without adequate controls, researchers, and as a consequence, clinicians, risk overestimating the therapeutic effectiveness of digital mental health treatments.

Preventative interventions: physical health interventions in those with mental illness

The delivery of preventative/behavioural health interventions in the general population is increasingly relying on digital technologies. People with severe mental illness (SMI) are known to be at higher risk of physical health problems, but the use of digital innovations to improve physical health in mental health populations has still not been widely considered.[23] Some examples of interventions are provided in online supplemental appendix table 5, and these could provide improvements in both the physical and mental health of people with SMI. However, evidence in this area is still nascent, and further research must be directed towards establishing the effectiveness of digital lifestyle intervention in mental illness, along with developing pathways for real-world implementation.

Theme 3: challenges in combining real-time assessments with intervention

Innovations in digital phenotyping and new digital interventions offer synergistic potential. Symptoms are often assessed as relatively slow-moving features, but in fact, they fluctuate frequently over time. Dynamic assessment of mood and behaviour using real-time analysis can be combined with intermittent, but more detailed information which is 'triggered' by a significant change. This can be used to assess 'response' to the change (eg, a move from one space to another) or to identify a change in behaviour (eg, increased phone calls in the days before a manic episode) which might predict relapse, and prompt a call from a clinician. Just-in-time adaptive interventions (JITAIs) show great potential, but as yet there is a scarcity of clinical examples in mental health.[24] Online supplemental appendix table 6 outlines this in more detail with some examples.

Theme 4: challenges in implementation in the real-world clinical setting

Clinical decision-making

While JITAIs are not ready for routine clinical use today, there are applications for novel digital technologies. One model is to use these new digital data to inform clinical decision-making and guide shared care decisions, for example, in medication monitoring. While digital data are not a replacement for clinical judgement, they can provide additional information and may help identify or confront bias[25] (see online supplemental appendix table 7 for further discussion and examples). There are several areas to consider for successful implementation; at the clinical level these include the importance of shared decision-making with the patient, speaking the same language and measuring

what patients see as important.[26] The decision when to use this, for example, as a population-level screening tool or a tool to confirm clinical suspicion of a condition, needs further data. Clinicians will need to work synergistically with new methods of measurement to inform diagnosis and also perhaps to inform predictions of illness in high-risk individuals. This synergy will also need to assess how the new measurements could effectively work in concert with biological measures such as neuroimaging, genetics or electroencephalography.

Education and training
At the fundamental level, this involves directly and continuously teaching and training clinicians. The lack of digital literacy and formal training among medical students and clinicians remains an ongoing but often overlooked concern.[27] A future challenge is to make better use of available technologies, as well as anticipating future innovations. Given the potential of asynchronous healthcare tools, this also means, for example, creating protocolised treatment manuals that allow non-clinicians to deliver aspects of the treatment in hybrid models of care. It is important to learn from hybrid and online care models that we need to continue to help people to be 'ready' for change and ensure there is some 'alliance' as active ingredients in any successful therapy.[5] Patients can also benefit from training programmes designed to teach them how to use digital health technologies and increase confidence in general digital skills.[1]

How clinicians combine and use digital tools remains a nascent area of exploration. It is unclear how these tools may influence biases or stereotypes held by clinicians, or how effectively digital data are incorporated into routine clinical practice to help mitigate these biases. However, it is generally accepted that clinicians' attitudes and lack of knowledge towards technology strongly influence its adoption in clinical practice, and so better knowledge and training are needed.[8 28] Knowledge and training can help increase a clinician's willingness to use technology by influencing known moderators like the expected effort or performance to make use of technology in clinical practice. However, the presence or absence of facilitating conditions such as infrastructure or organisational contexts can also have a significant impact.

Policies in organisations and healthcare systems
In order to fully leverage the benefits of digital mental health, organisations are looking at ways to adapt their workforce and processes. Digital mental health has the potential to provide ongoing support and guidance for both patients and clinicians, and the creation of positions such as digital navigators[1] can help facilitate their use, in the same manner as radiology and pathology technicians play a key role in their respective fields. Hybrid clinics provide an example of a new model of care where a clinician works with a team of digital navigators flexibly combining synchronous and asynchronous digital tools as well as traditional face-to-face assessment. These digital approaches need to be manualised and further research is needed on key parameters such as the duration of treatment, 'dose', and exposure as well as effectiveness and cost efficiency. However, with more human involvement, issues around low engagement and missing data may become less acute. While we do not want to ignore chatbots and similar technologies that remove the human, the lack of high-quality data on engagement or outcomes at this time does not make these a viable clinical option yet.[29]

Policy makers need also to consider factors outside the clinic in order to integrate these technologies more fully into the mental healthcare system. These include providing proper reimbursement for their use and the costs of staffing and infrastructure, in order to ensure successful implementation and continued use.[1 30]

Theme 5: challenges in developing implementation studies
Having identified some of the challenges, the immediate priorities are now to address the potential barriers to the implementation of digital mental health interventions in the real-world clinical setting. First, there are particular questions which need to be considered in the design, reporting and analysis of implementation studies, such as standardisation of outcomes, methods and conceptual frameworks.

Reporting guidelines
Questions such as the design, dose and intensity of an intervention, or the exact type of data collected may be poorly described or lacking in studies of digital observation and intervention, although reporting guidelines have been proposed.[15 31] In addition, information on fidelity to interventions, and updates or technical issues of the digital tools may not be well described. This makes it difficult to compare outcomes across studies: implementation of agreed guidelines for reporting would standardise approaches and allow reliable synthesis of the data to inform clinical practice.

In addition, we lack effective ontologies of mental illnesses, so mapping new data onto current ontologies may not be productive. Ontologies are standard representations of the subject matter of a domain that allow clarity in what is being referred to through provision of unambiguous definitions. They offer a comprehensive computable semantic framework complete with labels and synonyms, definitions and examples, relationships between entities and other meaningful logical axioms. Semantic frameworks broadly interpreted, including ontologies and other kinds of semantic resources such as controlled vocabularies, are not new to the mental health domain and encompass widely used tools such as the Diagnostic and Statistical Manual of Mental Disorders. However, these have so far been developed in isolation to represent distinct perspectives and are not inter-related, thus are not suitable for use in comprehensive and integrative evidence synthesis efforts. Integrative, cross-disciplinary ontologies are therefore essential to enhance the discoverability and interoperability of evidence and reduce fragmentation, as well as driving cost-saving automation. An agreed ontological framework for reporting outcomes in digital mental health would also help focus on the core features to be measured and provide a common language for reporting studies. There is already an established literature on how to develop an ontological framework which could be applicable here.[32]

Accessibility and codesign
As a first step for any clinical implementation (and the research studies associated with this), innovations need to be truly accessible for the populations they are aiming to reach. In the context of mental health, it is therefore critical to ensure that innovations are designed to be clear, usable and engaging for those living with mental disorder.[1] This will involve considering aspects of these conditions which may hinder engagement with digital interventions (such as amotivation and cognitive impairments),[33] and working with diverse patient populations during the processes of design and implementation, to ensure patient perspectives and preferences, treatment targets and outcomes are fully integrated.[34] Digital literacy and codesign of tools by stakeholders is also key so that they can direct treatment targets

and use cases in an equitable manner (see online supplemental appendix table 8).

Ethics and potential harms

A variety of ethical concerns can arise with digital mental health interventions (see online supplemental appendix table 9). Issues such as ensuring that digital interventions are based on high-quality evidence from diverse populations, are predictively valid and support accurate diagnoses and prognoses and do not themselves cause harm are key elements to consider and address. In addition, key areas such as patient privacy and confidentiality need to be explained. Patients need to be fully aware and consent to how their data are collected, managed and used, and this is critical to preserving their trust in clinicians. In addition, it is important to address the issue of potential silo formation or fragmentation of data when using specific digital tools. Patients can be disadvantaged if they no longer have access to their data or a digital intervention after a study finishes.

The possibility of harm or potential negative effects from digital mental health interventions, especially for vulnerable populations, is an essential area to consider, but research is scarce.[35] Preliminary data suggest that male gender, lower educational level and comorbid anxiety symptoms increase the risk of dropping out,[36] but further focus and research is needed to identify which aspects are unique to digital health, and which are most amenable to targeted solutions.

Specialised groups

While there are many targeted clinical uses for digital mental health interventions, adolescent populations may be the ideal given the opportunity for early detection, prevention and, if necessary, intervention. With access to youth mental health services limited across the world and now nearly 50% of youth reporting they are online 'constantly', innovations like digital phenotyping are a good match (see online supplemental appendix table 10). Other groups such as the elderly, people with physical disabilities and those with learning disabilities are also important populations for further study (online supplemental appendix table 10).

DISCUSSION

In this clinical review, we have summarised some of the key areas of challenge in digital mental health, with illustrative case studies. We are aware of some limitations in our approach, which is a narrative rather than a systematic review of the literature and was reached by expert consensus. We did not address some important approaches that have been tested in digital mental health, such as mobile apps, internet-based interventions (including internet-based cognitive therapy and internet-based self-help interventions) and virtual reality[37]; however, we aim to cover these in future projects. In addition, while the consensus development panel enabled international and multidisciplinary expert discussion, we are aware that we were not able to include patient and public representation, and rather than using a separate panel—given the novelty and the complexity of the field—we used the whole expert group for consensus. While there have been many calls for consensus guidelines in areas of digital mental health, particularly in the area of mental health apps[38 39] and in the new ethical issues and safety issues raised (eg, in digital monitoring studies in at-risk populations),[40 41] to the best of our knowledge this is the first attempt at consensus recommendations across the broader area of digital mental health. As an expert international and cross-disciplinary consensus panel and on the basis of

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Box 1   Consensus points for future plans in digital mental health

We list here the agreed consensus points for measuring and implementing digital innovations in the real-world clinical setting.

⇒ Definitions and reporting of interventions vary. This creates confusion and prevents consistent reporting, which makes the systematic synthesis of data much more difficult. Agreed definitions are needed to ensure replicable and incremental science.

⇒ We lack an agreed ontology for mental illness; an agreed framework would also improve reporting, but a transdiagnostic approach focused on symptoms rather than diagnosis may also be a helpful route for validation of digital biomarkers.

⇒ Research on perfecting digital measurements is a good start, but will only be helpful if it correlates with real-world clinical symptoms and functional outcomes.

⇒ Digital interventions are often best used as an *addition* to enrich face-to-face or virtual care, they are not necessarily a replacement. Sustained engagement with digital interventions needs human interaction as well. Hybrid approaches in the clinic would combine the advantages of each approach. They could also increase the efficiency of delivery of care, especially if provided by a range of clinicians and support workers (eg, digital navigators) with a combination of standard clinical care and protocolised treatment.

⇒ Digital interventions are most useful when implemented in the real-world clinical setting. Clinicians need to be familiar with digital interventions and apply them as stand-alone interventions or combine them flexibly within the standard clinical assessment. Teaching and training for clinicians will be essential to facilitate this.

⇒ Ensuring patients are engaged is just as important. Patients and carers will use a technology if they feel it is relevant to their needs, and so codesign is critical. Teaching and training for patients will also be key to ensure equitable access to the technology and care.

⇒ Ethics and potential harms are present in all research studies. As well as common challenges (such as the choice of an appropriate placebo, and placebo/nocebo effects) because of the nature of the data collected, digital intervention studies also carry concerns about privacy, confidentiality and information governance. These need to be carefully addressed to ensure that trust is maintained between patients and clinicians.

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non-biased discussion, we have attempted to identify the current state of knowledge and bring together the immediate challenges throughout the field of digital psychiatry and mental health. By taking this broad approach we have been able to identify themes and challenges relevant across all subspecialised fields, as well as addressing potential solutions through the case studies in the online supplemental appendix.

In conclusion, the international consensus meeting identified a number of key areas and potential solutions (box 1). Given careful consideration and a clear vision to implement these changes in a challenging landscape, these measures can ensure that we start to harness the huge potential of digital innovations

in the real-world clinical setting and ensure improved outcomes for patients and carers, and via preventative measures aimed at at-risk groups, at a wider population level.

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