

pies are particularly suited to the research agenda of prescriptive algorithms for selecting specific intervention elements most likely to benefit an individual. Yet, user uptake, engagement and dropout are problematic, especially in routine clinical care settings. Since human support mitigates these concerns⁹, models that combine non-specialist providers with digital interventions have unique potential to expand reach, engagement and effectiveness.

Mechanistically targeted and personalized intervention elements that are matched to individual needs and adapted as needs change over time, delivered digitally or by clinicians, that can be scaled up through online tools and artificial intelligence technologies, offer a future in which delivery of evidence-based care will reduce the global disease burden of mental health by more than 40%. Challenges include the

enormous research agenda for developing mechanistically targeted interventions and their prescriptive matching to individuals.

Implementation will continue to be challenged by transportability of digital technologies into under-resourced areas, lack of resources for the most severely ill, and cultural adaptations to avoid simple exportation of Western constructs. Whether systems will choose to endorse evidence-based psychotherapies, in spite of the view that they are overly reductionistic or do not address complex refractory or comorbid cases, will most likely depend upon the success of that implementation.

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A path towards progress: lessons from the hard things about digital mental health

Discerning hype from hope in psychiatry remains challenging, as Stein et al¹ demonstrate in reviewing if promising perspectives and methods may launch a paradigm shift. Their conclusion that the path forward is incremental progress and iterative integration instead of a single transformative breakthrough is well argued. Perhaps nowhere else is this conclusion truer than for digital phenotyping and app-based digital mental health. Thus, focusing less on the well-known potential of these technologies, but instead on the current challenges can highlight the incremental and integrative advances Stein et al call for.

The current state of smartphone apps and digital mental health can be approached from many perspectives, but the paper published in this journal in 2019², promoting a consensus around evaluation, offers a very useful starting point. Briefly, the areas covered in that paper are: data privacy and safety, app effectiveness, user experience/adherence, and data integration. Considering selected examples of some of the actual hardest challenges in each of these areas can help highlight the real work to-

wards the progress of more equitable access, appropriate regulation, and quality assurance for digital health, as noted by Stein et al. This focus on negative examples is not to detract from the true potential, but rather to identify tangible targets for necessary next steps.

Focusing first on data privacy and safety, digital mental health continues to lack trust. In March 2022, the US-based Crisis Text Line was found to be sharing users' personal text messages with a for-profit company. Days later, the same concerns were raised about a UK-based crisis text line service, Shout, highlighting the global nature of this challenge. While academic research continues to uncover many technical risks around medical app security³, the cases of Crisis Text Line and Shout stand out, as they were legal under current regulation. They will both likely serve as the spark for regulatory changes, since patients, clinicians and the public have lost faith in self-regulation. Thus, the most important and necessary innovation for digital mental health may be identical to what it was half a decade ago – transpar-

ency and trust⁴. Legislation affording app users guaranteed protections for their data is not as flashy as cloud blockchain solutions for privacy, but it is the necessary and incremental work critical to improving the field.

The second incremental step involves proving app effectiveness. On the surface, this seems like an area of more progress compared to data privacy and safety. Today, terms such as digital therapeutics are commonly used, and regulatory agencies are granting approval or clearance to some apps. But looking beyond the hype reveals a different picture. Digital therapeutics is an industry-created term that has little grounding in either health care regulation or research. The term is actually confusing, as it is very hard to evaluate the entire evidence base for mental health apps. A 2022 systematic meta-review of 14 meta-analyses of randomized controlled trials for smartphone-based interventions failed to find convincing evidence in support of any mobile phone-based intervention on any outcome, because of the overall low quality of studies⁵. That is not to say that apps cannot

be effective, but that higher-quality studies are necessary. A case in point is the March 2022 study comparing a proposed digital therapeutic app to a control app which was little more than a count-down timer. While the use of the proposed digital therapeutic app was associated with improved symptoms, the study found the surprising result that the use of the count-down timer was equally effective⁶. Before creating new names, the field needs to do better science. Digital control groups may not make for an inspiring investor pitch, but they are the necessary and incremental work critical to improving the field.

Building off the first two steps, digital mental health must be engaging. Metrics of patient interest in mental health apps or the number of potential users as measured by smartphones are no longer useful. Instead, the question must be around digital literacy and whether people have the knowledge, skills and confidence to equitably benefit from innovation. This question is too rarely asked until it is too late. The complexity of engagement and its challenges are exemplified by the city of Reno, Nevada, and the contract they signed with the digital mental health company Talkspace to provide remote therapy during the height of COVID-19 pandemic. While details are not public, news reports suggest that the actual use of Talkspace was so low that the contract was not renewed⁷. A July 2021 interview with the founder of Talkspace suggests that, of the 55 million people who have access to the service, only ~0.1% (60,000) actively use

it⁸. This example serves to counter the notion that industry can solve health engagement challenges. The reality is that no one has solved this challenge and that it will require solutions beyond gamification or better design. The recent push for coaches to support digital mental technology is promising, but brings with it new risks that need to first be addressed under the first and second points of this framework (privacy/safety and evidence). Solutions such as task sharing suggested by Stein et al may also improve engagement, but the investment in such efforts only makes sense for tools that are truly effective and not, for example, digital clocks.

The last step, data integration, also only makes sense in terms of the other three. How can the digital health data be used to improve outcomes or the treatment integrated into a complete management plan? The point is moot if users do not trust the tool, the tool generates nothing of clinical value, or users do not engage with it at all. But, assuming progress in these steps, digital integration presents a new frontier for psychiatry. Vast amounts of new patient data generated by technology, combined with constant care through synchronous and asynchronous telehealth, require new clinical workflows, practices and training for true integration⁹. There is no artificial intelligence algorithm for retooling a field, but this investment in people expected to integrate and facilitate digital mental health may be the most valuable of all. While this step is often ignored with the assumption that high user engagement will make it un-

necessary, now in 2022 it should be apparent that ignoring any of the above four steps is perilous.

Just like Stein et al do not forecast any immediate paradigm shift but rather the need for incremental progress, digital mental health must follow the same route. Rather than a harbinger of a paradigm shift, there is an urgent need for iterative improvements around data privacy and safety, app effectiveness, user experience/adherence, and data integration. While this selective review took a purposely pessimistic view, focusing on harsh realities is necessary for a field where the hype is so amplified. These harsh realities also underscore how incremental progress can actually be transformational for digital health, and justify why we need to do the hard work instead of just the glamorous.

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Systems-based approaches to mental disorders are the only game in town

Stein et al's paper¹ provides an excellent overview of current directions in psychiatric diagnosis. The paper makes clear that, although there has been considerable work investigating novel approaches to psychiatric nosology, psychiatric diagnosis has in practice changed relatively little in recent decades. Mental disorders are defined and diagnosed today in pretty much the same way they have been for many

years: as sets of symptoms that tend to cluster in somewhat reliable ways. Hallucinations are often accompanied by delusions; sad mood by self-reproach; anxiety by avoidance. Thresholds based on such symptom clusters are typically used to operationally define mental disorders, and the presentation of symptoms in a person is phenomenologically matched to these definitions to arrive at a diagnosis that

guides treatment.

In recent years, much research operated under the assumption that, under the hood, psychiatric disorders are brain disorders², and that advances in neuroscience and genetics would reveal "what mental disorders really are". It is evident that no such breakthrough has materialized. It seems that most mental disorders simply lack central pathogenic pathways. Instead,