# **Catalyst** Innovations in Care Delivery

#### CASE STUDY

## The Digital Clinic: An Innovative Mental Health Care Delivery Model Utilizing Hybrid Synchronous and Asynchronous Treatment

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As demand for mental health care rises, the limited supply of clinicians makes it difficult to meet the need for services. To increase supply, there must be innovation in both workforce capacity and digital solutions. But innovation must not come at the price of reduced quality of care because the need to balance access and quality requires more than offering self-help applications (apps) or coaching. Toward exploring one such solution, the authors describe the Digital Clinic, a model of hybrid synchronous and asynchronous mental health care led by a licensed clinician. (Although they developed a treatment manual to address mental health, the Digital Clinic care delivery model can be applied to other areas.) To increase access and quality, they integrated into treatment a smartphone application offering digital phenotyping and digital interventions, as well as a new care team member, the Digital Navigator, to collectively support engagement, digital equity, and clinic integration. In this Case Study, the authors outline the need, theory, and implementation of the Digital Clinic at a large academic medical center in the context of supporting referrals for depression and anxiety from primary care. Although the Digital Clinic – which began serving patients in January 2020 – continues to evolve, recent data suggest that rates of short-term remission achieved in 8 weeks are comparable to and greater than those in longer-term traditional treatment approaches.

- » Brief therapy treatments augmented by a Digital Navigator and a customizable smartphone application may yield improvements in depression and anxiety comparable to more traditional longer treatments.
- » Digital Navigators can help facilitate both patient engagement and clinician utilization of digital technology.
- » New treatment models, such as the Digital Clinic, are necessary to integrate digital phenotyping and smartphone data into care.

## The Challenge

Mental health outcomes, especially for young people, continue to decline.<sup>1</sup> Although telehealth visits make accessing mental health care more convenient, the technology does not, itself, increase access to care, which remains limited by a shortage of clinicians.<sup>2,3</sup> Asynchronous telehealth approaches, such as self-guided therapy programs and smartphone applications (apps), have become increasingly popular due to their ability to overcome the limitation of the number of available clinicians, allowing greater access to help for mental health problems.<sup>4</sup> But over the last decade, these digital approaches have failed to transform mental health outcomes, in part due to low patient engagement and the questionable efficacy of various digital therapeutics.<sup>5-7</sup>

As the acuity of mental health crises increases, evidenced by the rising rates of suicide deaths,<sup>8</sup> solutions that offer increased access to low-quality care must no longer be considered acceptable. Initial excitement about chatbots, mindfulness apps, text message-based therapy, and self-guided therapy programs has been replaced with the realization that the majority of patients do not engage with or adhere to these programs.<sup>9</sup> When they do engage, a new generation of higher-quality clinical studies suggests that many of these digital programs are no better than an active digital placebo — for example, playing Tetris or checking a countdown timer.<sup>10-12</sup>

The current landscape of digital mental health solutions is further complicated by ongoing challenges with trust and equity. The concerning lack of privacy for mental health data from various online companies has been well documented, not only in the academic literature, but also in the popular press.<sup>13</sup> In March 2023, the Federal Trade Commission fined one digital mental health company nearly \$8 million for patient privacy violations.<sup>14</sup> Less tangible, but equally insidious, is the *digital exclusion* concomitant with many of these new services, such as limited access to a digital device, an Internet connection, or the digital literacy sufficient to meaningfully engage.<sup>15</sup> Patients with such challenges are generally less able to benefit from digital mental health innovations.

Although digital approaches have the potential to improve access to mental health care, there is a need to rethink how these approaches are utilized. New approaches need to leverage the strengths of both traditional face-to-face care and digital therapeutics to maximize not just treatment access, but also its efficacy. The benefits of human rapport, the therapeutic alliance,<sup>16</sup>

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and a therapist's ability to tailor evidence-based therapeutic interventions to the needs of each client are tangible advantages of traditional care, whereas the scalability and accessibility of digital approaches confer clear advantages that should not be overlooked.

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However, more consideration is needed to address how both traditional and digital mental health care can address each other's respective weaknesses. Measurement-based mental health care<sup>17</sup> and transdiagnostic treatment approaches<sup>18</sup> are two well-established approaches for increasing the quality of care, yet their implementation into traditional mental health care has been limited. Likewise, high rates of engagement with digital approaches are known to be associated with better outcomes, yet reliable digital solutions to engagement problems have remained elusive after decades of user-centered design, gamification, and related efforts.<sup>19</sup> Given that the majority of mental health needs are first identified by primary care and treated by primary care clinicians,<sup>20,21</sup> any new solution needs to be designed to serve the needs of this front line of care, with an emphasis on the clinician-patient dyad.

## The Goal

Our goal includes distinct components that involve the creation, evaluation, engagement, and piloting of an innovative care delivery model for mental health:

- to reimagine mental health treatment as both more accessible and more effective through the delivery of a hybrid model of care that integrates human support with digital therapeutics;
- to evaluate a model of providing rapid access to innovative and effective mental health care to a sample of patients from primary care and the community;
- to engage primary care clinicians in understanding and endorsing digital mental health as a robust pathway to address mental health needs; and
- to pilot this model of care in a manner that is completely replicable and reproducible so that others can adapt it to meet the needs of the populations they serve and expand upon it.

## The Execution

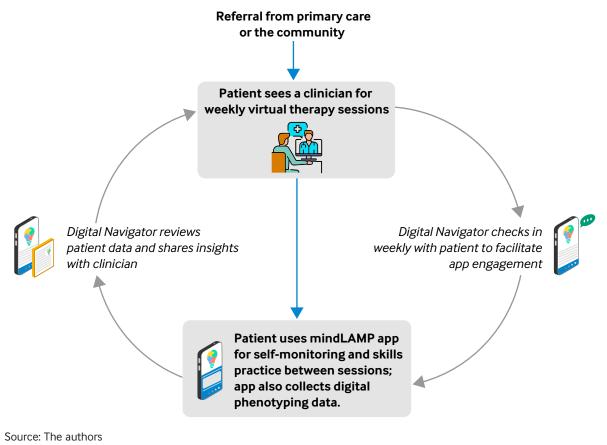
Beth Israel Deaconess Medical Center (BIDMC), an academic medical center located in Boston, Massachusetts, is a teaching affiliate of Harvard Medical School and is part of <u>Beth Israel Lahey</u> <u>Health</u>; it includes the <u>Division of Digital Psychiatry</u>, a collaborative research group comprising

mental health professionals with backgrounds in medicine, engineering, and clinical care. We work with hospitals, academic institutions, health care companies, federal organizations, and software developers to advance partnerships in technology and psychiatry aimed at improving the quality and accessibility of treatment for mental illness. Toward accomplishing these goals, we created the Digital Clinic, a hybrid mental health treatment model<sup>22</sup> supported by weekly therapy sessions, an app that is integrated into care, and the Digital Navigator (Figure 1).

FIGURE 1

## A Schematic of the Digital Clinic for Mental Health with the Digital Navigator

The Digital Clinic model involves four key components: (1) weekly virtual visits with a clinician, with the patient participating from any remote location; (2) the Digital Navigator, a new care team member who checks in with the patient on a weekly basis, first to help set up the mindLAMP application (app) and then to assist with and customize the patient's app engagement (with appropriate icons on the smartphone) between clinician visits; (3) the mindLAMP app itself, which involves passive and active between-visit functions, including data collection (digital phenotyping) and engagement by the patient (self-monitoring, skills practice, therapy exercises); and (4) the clinical integration of the data, facilitated in advance of the weekly patient–clinician sessions by the Digital Navigator, who reviews patient data and shares insights with the clinician, who can access that via an electronic tablet during the patient visit.



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Next, we detail each of the key components of this model.

### Weekly Therapy Sessions: Accessible, Evidence-Based, Transdiagnostic Treatment

The development of this model began in 2018 with careful consideration regarding the type of treatment offered.<sup>23</sup> Because our primary goal was to increase access to treatment, we implemented a brief 8-week treatment model that would allow clinicians to see more people and eliminate the need for a waitlist. (Patients are now seen in less than 2 weeks; however, for those with urgent needs, we can see patients immediately; the digital phenotyping data, although preferred, is not required for care, so app implementation can be delayed.) The traditional care model is often 12–20 weeks with a wait time that can exceed 3 months;<sup>24</sup> still, the 8-week Digital Clinic model, with little to no wait time, should not be considered a replacement for patients who need access to traditional, ongoing, or greater levels of care.

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Given that, in addition to expanded access, an equally important goal was to ensure the quality of brief treatment, we opted for an evidence-based approach: we chose the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders<sup>25</sup> (UP) to serve as the basis of treatment. The UP is a transdiagnostic, emotion-focused cognitive behavioral therapy (CBT) that targets emotion *reactivity* and *avoidance* as two mechanisms that perpetuate negative affect across various psychological disorders. The UP is supported by research demonstrating its efficacy for a range of psychiatric disorders<sup>25</sup> and has the additional advantage of simplifying clinician training because learning this one treatment enables a clinician to serve many patients with multiple and often comorbid disorders. We created a brief version of this treatment that integrates UP-based skills patients learn in sessions with smartphone-based exercises to help patients generalize these skills into their real-world contexts. Data from the patient's between-visit status and activity is recorded in the *mindLAMP* app and is then reviewed in session, where the clinician can troubleshoot skills and help the patient consolidate learning.

## Integrating an App into Care: Enabling Measurement-Based Care Through Digital Phenotyping

To facilitate measurement-based care and increase the impact of brief treatment, we integrated the custom smartphone app  $mindLAMP^{26}$  into care. The mindLAMP app — which is powered by the <u>LAMP</u> platform and represents an acronym for the key features of Learn, Assess, Manage, and Prevent — is available on phones that use either Android or iOS operating systems.

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The app augments care in three ways:

- 1. It enables patients to monitor their symptoms and behavioral patterns in real time, increasing insight into their own triggers and responses.
- 2. It facilitates skills practice so that patients can generalize the skills they learn in session into their own real-world contexts.
- 3. It allows for the collection of digital phenotyping data, which involves using smartphone sensors to capture health behavior data related to care.

In the Digital Clinic, data associated with *digital phenotyping* — which refers to the moment-bymoment quantification of the individual-level human phenotype in situ using data from smartphones and other personal digital devices<sup>27</sup> — is integrated with other data streams from mindLAMP and reviewed in session with the clinician; examples are provided in Table 1.

Essential to reducing the burden on clinicians who need to make sense of these data, however, is the role of the Digital Navigator,<sup>28</sup> a care team member who represents a third key component of our model.

## The Digital Navigator: Supporting App Engagement, Equity, and Treatment Impact

To address issues with a lack of sustained app engagement that tends to reduce the efficacy of many digital therapeutics — issues at times rooted in low digital literacy — we introduced a Digital Navigator role to our care team.<sup>29</sup> The Digital Navigator supports patients by offering them mindLAMP guidance (including homework and skills training related to the UP sessions that patients work on in the mindLAMP app) and troubleshooting in brief weekly check-ins (generally 5 minutes, with a range of 1–10 minutes), as well as initial clinic onboarding and app setup at the start of care (generally a range of 15–60 minutes). The Digital Navigator also spends between 5 and 10 minutes per patient per week monitoring weekly patient data collected by

Example of Digital Phenotyping Data, Type	Use/Function	Impact
Sleep	Identifying sleep duration, patterns, and disturbances in relation to symptoms and treatment goals	Sleep difficulty is a central symptom of mental illness and often overlooked in routine psychiatric care
Physical activity	Assessing levels and patterns of activity in relation to symptoms and treatment goals	Although physical activity can itself be a treatment strategy for some conditions, helping patients set goals and assess the impact of physical activity on their mental health can be important
Screen time (work, social)	Exploring smartphone use patterns in relation to symptoms and treatment goals	The impact of screen time can vary from person to person, but individual-level data can offer unique insights

Table 1. Uses and Impact of Common Digital Phenotyping Data	a
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Source: The authors

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the app, identifying relevant insights, and sharing them with the therapist in the form of brief bullet-point summaries that may be presented in person or electronically. This allows the therapist to enhance treatment by incorporating valuable information about the patient's progress and potential areas for further intervention. Digital Navigators receive training based on our published 10-hour curriculum;<sup>29</sup> their role on the care team is carefully detailed in a separate clinic manual that describes how they support patients, clinicians, and the use of the smartphone app.

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The 8-week Digital Clinic model, with little to no wait time, should not be considered a replacement for patients who need access to traditional, ongoing, or greater levels of care."

The role of the Digital Navigator is one that can be staffed in a number of ways, although we recommend that the staff member remains within the organization rather than outsourced, given the close and integrated role with the care team, working directly with patients and clinicians. There is no particular educational prerequisite, because this position could serve as an entry-level role for a tech-smart individual who can work well with teams (including patients), or it could be taken on as an add-on skill by existing clinical staff. The position could be full time or part time, working on site, remotely, or through a hybrid arrangement.

## Hurdles

Establishing the Digital Clinic was feasible, but it required careful attention to implementation considerations and, at times, innovative solutions to increase the impact of this model.

## Training Clinicians to Deliver Brief, Data-Driven Care

This model of care is new to many clinicians and requires additional support. To solve this problem, we created a manual with careful guidance on delivering not just a brief version of the UP, but also a technology-enhanced version. As a teaching hospital, we also offer weekly personal and group supervision for clinicians to support fidelity to the treatment and provide a forum for clinicians to receive additional support. The model is not mandatory; of the five clinicians, all have opted in to use the Digital Clinic model for most of their patients.

## Personalizing Brief Treatment

The Digital Clinic model is also an opt-in choice for patients; the primary care physician discusses the option with the patients and only refers those who agree to the model. The primary care physicians have shared, anecdotally, that most patients have welcomed the opportunity and agreed to opt in. In addition, although the UP helps patients understand how aversion and avoidance perpetuate negative affect and provides the rationale for CBT-based interventions, some patients will benefit from different approaches. To maintain the quality of treatment while nevertheless staying flexible to meet patient needs, we decided to keep the UP

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as our basis but introduce adjunctive modules drawn from other evidence-based therapies as needed. This approach allowed us to continue to provide evidence-based interventions while still tailoring treatment to the unique needs of each patient.

## Refining the Use and Visualization of Digital Phenotyping Data<sup>30</sup>

It was necessary to give special consideration to digital phenotyping data visualization and data sharing to increase interest in and utility of the data. Our Digital Navigators were key members in this process and innovated substantially to design engaging graphics that could be shared by the patients. This and their valuable role in extracting insights from patient data has allowed therapists to integrate data insights and visuals into evidence-based treatment in a more seamless way. Examples are shown in Figure 2.

## The Team

To develop the Digital Clinic, we benefited from an interdisciplinary team. To ensure this model met stakeholders' needs, we obtained input from primary care doctors (on patient needs), a patient with lived experience of mental illness (to ensure the care model and technology use was patient-centric), the authors of this article (on implementing emotion-focused and evidence-based treatment, digital phenotyping, and digital therapeutics), and a host of Digital Navigators (on data integration into the clinic).

Regarding the care team itself, we have five part-time clinicians, who collectively see about 20 patients per week, about the same as 0.35 full-time equivalent (FTE) clinicians. We also have six part-time individuals performing the Digital Navigator role, collectively handling about one-half of an FTE position, or about 20 hours per week combined as they work with patients; this work includes clerical duties such as appointment scheduling, assisting eligible patients in accessing the U.S. Federal Communication Commission's <u>Affordable Connectivity Program</u>, digital literacy training for patients and clinicians, and the weekly check-ins with patients.

### Metrics

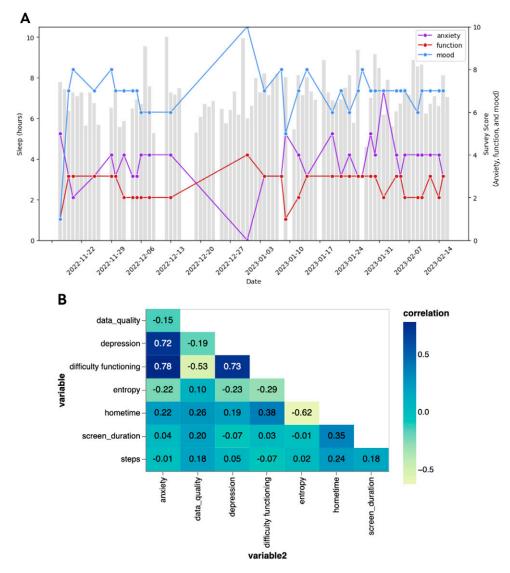
We accepted referrals from primary care for this wave of the pilot for about 1 year, through March 2023. In that time, we have received more than 300 referrals from primary care physicians, and 150 patients have received treatment in the Digital Clinic. Exclusion is based on patient acuity and a clinical assessment that the patient would not benefit from a short-term, digital model, that is, the patient already has a therapist and has tried but not benefited from short-term therapy.

Implementation has been an iterative process, with the Digital Clinic constantly refining its process, including the clinical protocol, clinician training, Digital Navigator support, mindLAMP interventions, and integration of digital phenotyping data into treatment. We thus examine clinic outcomes in cohorts. Here, we share data from a cohort from the latest wave of the model (active between October 2022 and January 2023), which consists of 40 adults, ages 20 to 72 years

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## A Sample of Two Data Visualization Presentations in Support of the Digital Clinic

To aid patients and clinicians in understanding the effects and trends associated with the mix of digital phenotyping data collected via the mindLAMP application (app), visual presentations are used. Two examples are shared here. In Panel A, we see information on the hours of sleep per day as well as the patient's self-reported survey scores (0–10, with 10 being optimal) for mood, function, and anxiety. Some days have no gray bar sleep metric, perhaps because the patient's smartphone was not active, and we also see that the patient did not provide data for each day, only those with dots. In Panel B, we see the positive or negative correlation associated with eight distinct variables. In this example, the greatest correlation (dark blue, value >0.7) is associated with depression/anxiety, difficulty functioning/anxiety, and difficulty functioning/depression.



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(mean = 40, standard deviation [SD] = 13.99), who identified as cisgender female (60%) or cisgender male (40%). The racial and ethnic composition of the sample was 78% white, 8% Black or African American, 5% East Asian, 5% Middle Eastern or North African, and 4% Hispanic (2% Hispanic nonwhite and 2% Hispanic white).

Targeted outcomes for these 40 patients, which reflected the focus of treatment in each case, were based on scores from the Patient Health Questionnaire-9 (PHQ-9), a self-administered patient health questionnaire to assess depression severity (n = 31), and the Generalized Anxiety Disorder-7 (GAD-7) assessment, a self-administered patient survey to address anxiety severity (n = 24). The average baseline PHQ-9 score was 13.19 (SD = 5.24), dropping to 7.87 (SD = 5.86) at the end of treatment; levels of depression are scored as none/minimal (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), and severe (20–27). The average baseline GAD-7 score was 11.96 (SD = 4.79), dropping to 7.67 at the end of treatment (SD = 5.35); levels of anxiety severity are scored as minimal (0–4), mild (5–9), moderate (10–14), and severe (15–21).

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These outcomes meet and exceed outcomes from longer-term treatment. A recent meta-analysis of CBT outcome trials found an overall remission rate of 51% for anxiety disorders. Another recent meta-analysis of primarily evidence-based treatments (mostly CBT and third-wave therapies) found the remission rate for depression to be roughly 33%."

When defined as a minimum of 25% (50%) symptom reduction, the overall response rate to the treatment among the 40 patients was 73% (49%). The proportion of total outcomes (n = 55) reflecting clinically significant improvement — defined as dropping by at least one level of severity from baseline to the end of treatment (e.g., *severe* to *moderate*, *moderate* to *mild*) — was 67% (n = 37), whereas just 4% (n = 2) saw a rise in severity level (in one instance to *moderate depression* from *mild depression* and in another to *moderately severe depression* from *moderate depression*. Notably, 76% of scores that were severe at baseline and 71% that were moderate at baseline reflected clinically significant improvement at the end of treatment. Finally, the overall remission rate was 64%. Remission was defined as an end-of-treatment score of <10 (i.e., mild, minimal, or no symptoms) when the corresponding baseline score was moderate or severe and <5 (minimal/no symptoms) when it was mild. For those with baseline scores in the severe (n = 17) and moderate (n = 21) range, the remission rate was 65% and 71%, respectively.

Notably, these outcomes meet and exceed outcomes from longer-term treatment. A recent meta-analysis of CBT outcome trials found an overall remission rate of 51% for anxiety disorders.<sup>31</sup> Another recent meta-analysis of primarily evidence-based treatments (mostly CBT and third-wave therapies) found the remission rate for depression to be roughly 33%.<sup>32</sup> These findings are encouraging and suggest that when we target depression and anxiety with brief technology-enhanced, evidence-based treatment, our patients tend to obtain meaningful gains.

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Furthermore, feedback from this cohort of 40 patients through the Working Alliance Inventory – Short Revised assessment tool suggests a beneficial impact over the course of the Digital Clinic experience with mean scores improving from 46.59 in Session 1 to 51.55 in Session 6, with a possible range of 12–60 (Table 2).

### Where to Start

The Digital Clinic model is a hybrid approach involving therapy, Digital Navigator support, and mindLAMP digital phenotyping and interventions. The mindLAMP app is available as open-source software for others to compile themselves or work with BIDMC to help host. The Digital Navigator curriculum has been published,<sup>29</sup> and the clinician treatment manual can be shared upon request after a larger, more definitive study.

	WAI-SR Session 1	WAI-SR Session 3	WAI-SR Session 6		
Count	27	29	30		
Mean (SD)	46.59 (SD = 8.43)	49.67 (SD = 5.80)	51.55 (SD = 7.26)		
Minimum	31	41	34		
Maximum	60	60	60		
The 12 Statements Prese	ented				
1	As a result of these sessions I	As a result of these sessions I am clearer as to how I might be able to change.			
2	What I am doing in therapy gi	What I am doing in therapy gives me new ways of looking at my problem.			
3	I believe my therapist likes me	I believe my therapist likes me.			
4	My therapist and I collaborate	My therapist and I collaborate on setting goals for my therapy.			
5	My therapist and I respect eac	My therapist and I respect each other.			
6	My therapist and I are working	My therapist and I are working toward mutually agreed upon goals.			
7	I feel that my therapist appreci	I feel that my therapist appreciates me.			
8	My therapist and I agree on w	My therapist and I agree on what is important for me to work on.			
9	I feel my therapist cares about	I feel my therapist cares about me even when I do things that they do not approve of.			
10	I feel that the things I do in th	I feel that the things I do in therapy will help me to accomplish the changes that I want.			
11	My therapist and I have establ good for me.	My therapist and I have established a good understanding of the kind of changes that would be good for me.			
12	I believe the way we are workir	I believe the way we are working with my problem is correct.			

Table 2. Patient Assessment of the Digital Clinic's Therapeutic Alliance

During the 8-week program, six clinical sessions between the patient and therapist occur in weeks 3–8. The Working Alliance Inventory – Short Revised (WAI-SR) assessment tool measures key aspects of the therapeutic alliance through the patient's response to 12 statements. Patients received the survey through the mindLAMP application, along with weekly reminders to complete the survey to rate their agreement with each statement based on a scale of 1 (Seldom) to 5 (Always), with a combined score ranging from 12 to 60. Total scores improved from 46.59 in Session 1 to 51.55 in Session 6. Note: The weekly subtotals do not necessarily represent the same patients, because participation was not required. SD = standard deviation. Source: The authors

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