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The European path to reimbursement for digital health solutions

The “fail fast and break things” approach that tech start-ups favor probably won’t work in healthcare. A slower, more deliberate route to market and reimbursement is required.

by Carola Brinkmann-Sass, Laura Richter, Tobias Silberzahn, and Adam Somauroo

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The digital revolution now gaining momentum in European healthcare is redefining how and which care is delivered. Especially in the era of COVID-19, the digital delivery of healthcare has been more important than ever. A survey McKinsey conducted among 213 European physicians suggests that 55 to 58 percent of them believe that telemedicine will play a significantly greater role in the future.

At the same time, thousands of digital health solutions are on the market and thousands more are being developed, mostly by start-ups and tech companies entering the sector for the first time rather than traditional healthcare companies. Naturally, many of the start-ups have set their sights on big rewards, but they are fast learning that these rewards can be hard to realize in such a complex sector, particularly when it comes to securing payment for a solution. Even companies that have attracted considerable initial funding to tackle significant health problems, such as nonadherence to medications or anxiety and depression, have struggled to commercialize their products.

There are five sources of payment for a digital health solution (see sidebar, "Who will pay?"). But because publicly funded health systems are the norm in Europe, reimbursement from one source—payers—tends to offer the greatest revenue potential and is the goal for the majority of companies developing digital health solutions. This is also, arguably, the most difficult path to reimbursement. A 2018 McKinsey survey of the CEOs of 30 healthcare-technology companies around the world showed that 55 percent had not yet been able to secure reimbursement from payers in a single country, while 30 percent had done so in just one. Moreover, of the companies that had secured reimbursement, 38 percent said this had been a hugely detailed process that had taken more than a year to complete.[1]

We looked at the key elements supporting the launch in Europe of digital health solutions that gain reimbursement from public payers. Our conclusion is that the "fail fast and break things" approach often favored by tech start-ups in other sectors is unlikely to work in healthcare, since the users of solutions will probably be patients, whose safety is paramount, and physicians. A slower, more deliberate route to market and reimbursement is more likely to succeed. Companies should take the time needed to understand fully each country's digital health environment and to build the high-quality medical and economic evidence that public payers require.

Know your market

Solution providers can craft a compelling value proposition if they thoroughly understand the healthcare system of the countries they are targeting. Healthcare systems can be extraordinarily complicated. Companies must therefore invest time to learn about the relevant reimbursement pathways and which stakeholders (apart from patients) have the most to gain from adopting their solutions.

Reimbursement pathways

Reimbursement pathways for digital health solutions are evolving at different speeds in different European markets. Germany, Sweden, and the United Kingdom are relatively mature markets where governments are promoting the digitization of care and have standardized reimbursement pathways. Elsewhere, pathways are either not yet established or far from clear. Spain, for example, has many highly autonomous regional payers, so the pathways and evidence requirements vary. It is thus a hard market to tackle.

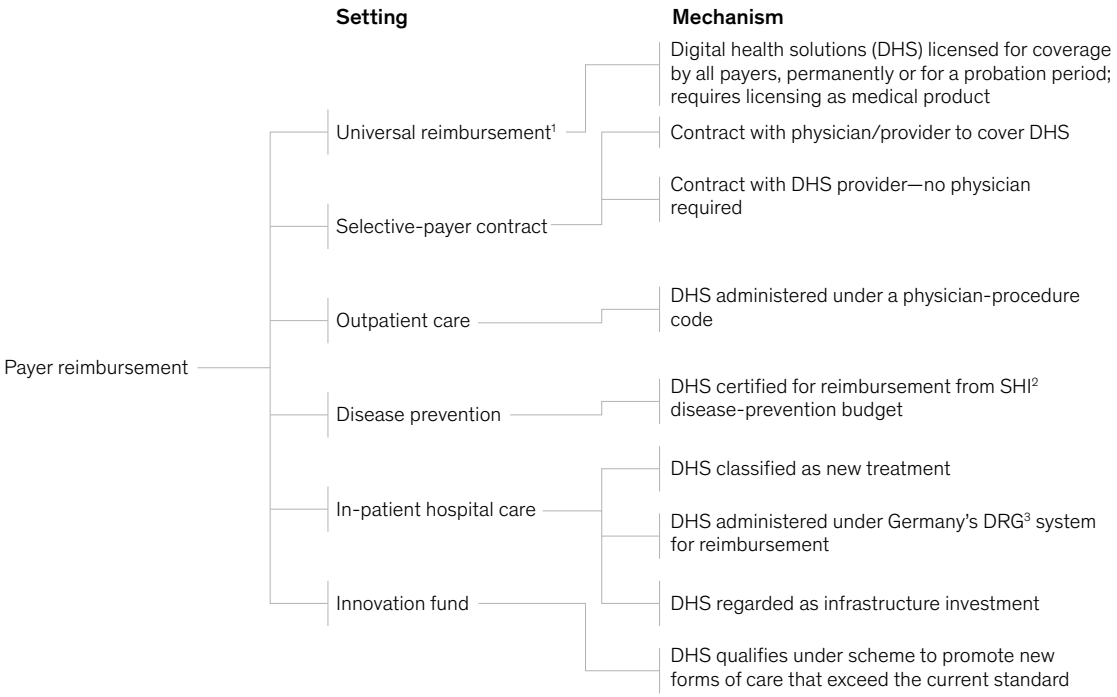
Even in less fragmented markets, the structure of public healthcare systems means that reimbursement mechanisms are likely to be complex. Take Germany, where there are multiple different reimbursement pathways, depending, for example, on whether a solution is for in- or outpatient hospital care, for preventative care, or for care that qualifies for reimbursement by the country's innovation fund, set up to promote new forms of care that improve

[1] A McKinsey policy survey of health-tech innovators, 2018.

Exhibit 1

Reimbursement mechanisms are complex: Germany offers multiple potential pathways for digital health solutions.

Pathways for digital health solutions in Germany



[1]New pathway under 2020 Digital Care Act.
[2]Statutory health insurance.
[3]Diagnosis-related groups.

on current standards (Exhibit 1). Bear in mind as well that funding mechanisms and the regulations that determine them change quickly. This year, a new law came into force in Germany that allows digital health solutions to be included in the nationwide reimbursement catalog as long as they meet certain safety, data-privacy, and efficacy conditions.

These different reimbursement pathways in different countries can make digital health products and services harder to scale than those in other industries. And though diseases don't discriminate between geographies, countries often set different clinical guidelines and patient pathways for treatments. This too increases the amount of detailed analysis any provider must conduct to embed a solution seamlessly into a healthcare system. There is no option but to proceed market by market.

Stakeholder incentives

Knowing the market means not only understanding the funding options but also uncovering which stakeholders will have incentives to adopt a solution. Even if its medical benefits have been proved and a strong case made for its economic advantages to the overall health system, certain stakeholders will probably have more to gain than others. These will be the ones to target.

Take as an example a solution that helps patients manage a chronic condition by offering remote counseling. The solution might reduce the number of visits patients make to see general practitioners (GPs). But that will be of little interest to German payers, since they grant GPs a set sum for each person the physician registers, regardless of the

Stringent criteria determine which traditional products and services public healthcare systems reimburse. The same high standards will apply to successful digital health solutions.

number of visits made. GPs would therefore be a better target for this solution because it could help them reduce the number of visits by patients but still receive the same level of funding. They might therefore be prepared to fund it from their own budgets, in effect circumventing the official reimbursement pathway.

Likewise, a UK company with a solution to reduce relapses and admissions for mental-health patients would do better to target secondary-care providers rather than payers. The reason is that the local payer—a health authority—negotiates a fee with providers for treating patients referred to them for certain mental-health conditions, no matter how much treatment patients receive. Providers under financial pressure as a result of the budget constraints of the National Health Service (NHS) therefore have an incentive to use the solution and keep any portion of the fee not spent.

Companies must understand these incentives before they can craft the value propositions of their digital health solutions.

Be market ready

Digital therapeutics that win public reimbursement must have solid proof of their efficacy. A market strategy that helps build that proof is therefore essential.

Evidence

Stringent criteria determine which traditional products and services public healthcare systems reimburse. Payers generally want to see high-quality medical data that prove a solution's efficacy before they will even consider reimbursement. Increasingly, they also want some form of health economic modeling that shows the value at stake, any potential cost savings, and the improvement in outcomes for patients or adherence to treatment. The same high standards will apply to successful digital health solutions. In the United Kingdom, for example, health authorities have published guidelines governing the standards of evidence required to assess digital health technologies. Germany recently enshrined its standards in law.

Yet many companies, including some that enjoy high market valuations, fail to support the efficacy claims for their solutions with published, peer-reviewed evidence. A recent review of the research published by 47 healthcare "unicorns" found that only 8 to 11 percent of these papers were highly cited (referenced by at least 50 other academic papers). Some had published only a single peer-reviewed paper, and others none.[2]

Our own analysis tells a similar story. We used medical-focused search engines, such as Embase and PubMed, to determine the extent and nature of publishing on digital therapeutics. Over a three-

[2] Cristea et al, "Stealth research: Lack of peer-reviewed evidence from healthcare unicorns," *European Journal of Clinical Investigation*, January 2019.

year period, 21,725 relevant papers were published. About a quarter were classified as scientific (published in scientific journals). Of these, just 384 appeared in journals that conduct peer reviews, and less than half of this number included hard data (Exhibit 2).

If peer-reviewed papers are any measure of the quality of the data generated to substantiate claims of efficacy, the message is stark: despite high market expectations, many digital health solutions might not be eligible for reimbursement. Companies should therefore develop strategies for generating and publishing robust data. Such strategies will require a deep understanding of each market's reimbursement requirements, of the methodologies payers use to evaluate solutions (such as cost-effectiveness analyses), and of the most important concerns for each market. In Sweden, for example, outcomes dominate. In the United Kingdom, new technologies have to undergo particularly rigorous cost-effectiveness assessments.

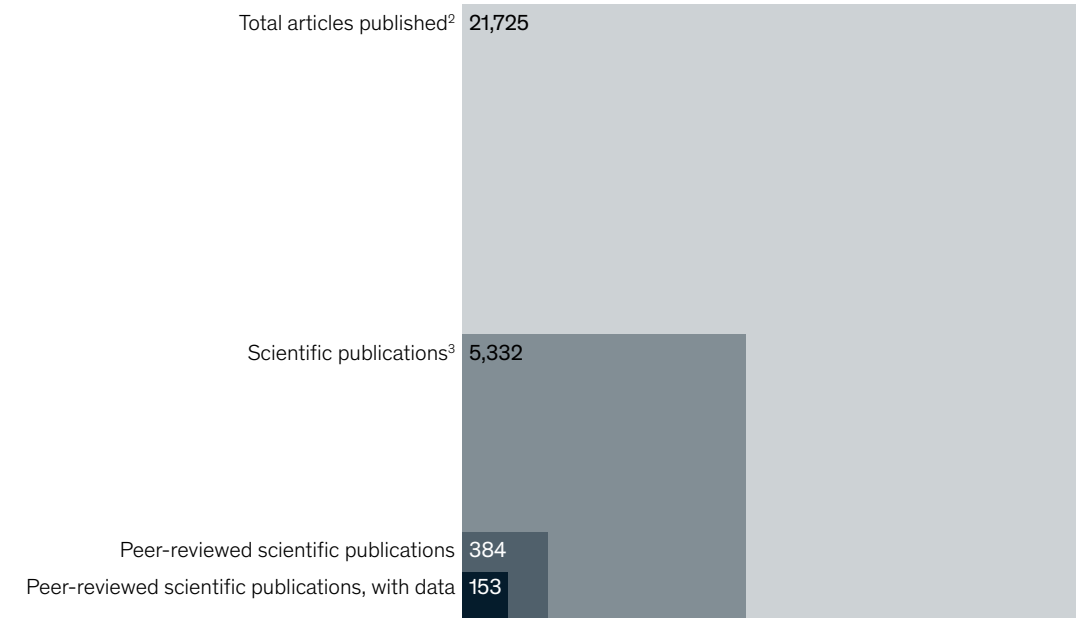
A four-step path

Given this high evidence bar, companies need to be realistic about their market readiness. In most cases, the route to reimbursement is likely to be slow as companies work to meet the requirements of public payers. Time and market experience are needed to collect sufficient evidence and sharpen the value

Exhibit 2

While plenty of research is published, little is peer-reviewed.

Articles published on digital therapeutics, 2015–18[1]



[1]Results from medical-focused search engines.
[2]Includes product descriptions, recommendations, and reviews; press releases and announcements; magazine articles; articles on WebMD.
[3]Includes study protocols and proposals; conference proceedings; opinion articles.
Source: Embase; Medline; PubMed; company websites and press releases

story. A gradual four-step path is therefore the one most likely to succeed (Exhibit 3).

The first step is the trial phase, in which a solution is piloted in a small patient pool to refine the technology and collect initial data proving efficacy. One option is to work with university hospitals and research institutes to establish high-quality methodologies. In the second phase, early adopters are enlisted with a view to collecting sufficient efficacy and safety data to qualify the solution for certification as a medical product. A health economic model is also developed at this stage to support reimbursement discussions with payers.

Next, the third step is to seek reimbursement. In Europe, public payers reimburse medical products and services in two main ways: a centralized approval process in which the full costs of qualifying treatments are reimbursed on a countrywide basis, or a decentralized one, in which payers or local healthcare authorities sign individual contracts with solution providers. The former, though attractive, is hard given the extra level of scrutiny and supporting data required when national budgets and large patient pools are in play. National payers might require standardized technical and efficacy data that meet specific criteria relating to the type and level of evidence. A digital health solution in the early stages of development would find such requirements hard to meet.

Moreover, since most European governments still have not defined a clear pathway stating the data required, the approval process could take a very long time. Therefore, step three is often to seek reimbursement contracts with individual payers. Over time, as the solution generates more real-world evidence and becomes a standard part of the care pathway in local markets, the solution provider can move on to step four: nationwide reimbursement in centralized markets.

Who will pay?

In addition to payers, four groups of individuals or organizations could potentially pay for digital health solutions.

Patients. Patients or health-conscious citizens can choose to pay for a digital health solution to manage their general health or a medical condition. But since public healthcare systems or healthcare payers cover the cost of medical treatment in most European countries, individuals are generally reluctant to pay for extras.

Providers. Healthcare providers can pay directly for a solution, but they too will be cautious. McKinsey surveyed 30 practitioners who treat multiple sclerosis, for example. Ninety percent said they would happily use technology that provided data on their patients' health and adherence to treatment. Yet only one-third said they would be willing to pay for such a solution—and then no more than $10 as a one-off payment. They might be more willing to pay if the solution delivered operational improvements, such as faster and more accurate diagnoses.

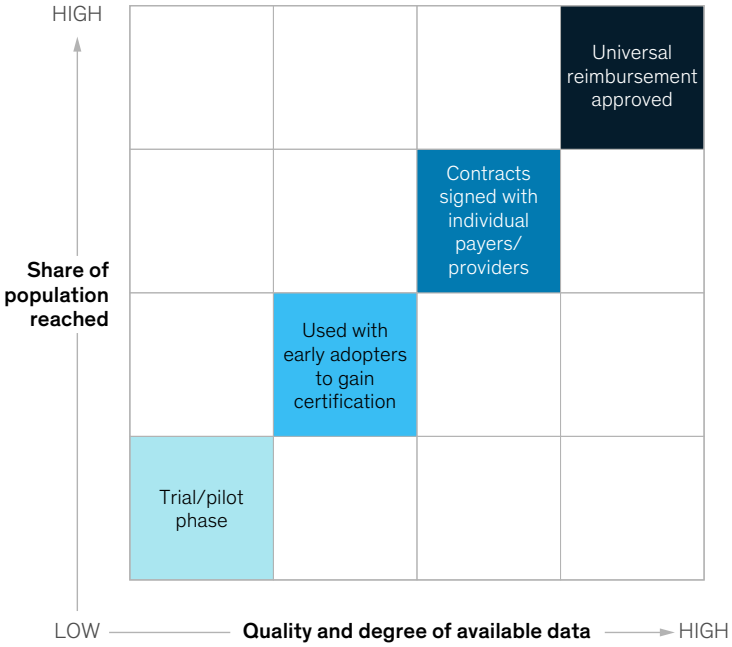
Employers. Employers might choose to pay for a digital health solution either to improve their employee value proposition or to reduce the level of sick leave. This can prove an attractive business model for solution providers because of the potential scale. (In Germany, employers who offer preventative-health advice and care or occupational therapy for employees even receive tax breaks.) Moreover, companies can pilot a solution with an employee and use feedback to improve it as they gather data for clinical evaluation.

Industry partners. Other companies—typically in the medical-device or pharmaceutical industries—might pay for a solution if it gives them access to data or complements their own products or therapies. Roche, for example, has bought MySugr, a digital health solution for managing diabetes. The attraction of this business model for solution providers is the funding and resources that an industry partner can bring.

Exhibit 3

The path to reimbursement is often a highly detailed process.

Path to reimbursement



- Collect data to prove efficacy and safety
- Refine solution to meet stakeholder needs

Stakeholders to engage
- AMCs[1] and medical-research organizations

- Collect additional data on safety and efficacy for medical-device certification
- Collect data to build initial health-economic case/do pilot studies (with small population)

Stakeholders to engage
- AMCs and medical-research organizations
- Health economists
- Key opinion leaders
- Early-adopter patients (willing to pay out of pocket)

- Collect data (eg, in a clinical trial) to meet requirements for potential universal reimbursement
- Establish product as standard therapy in market
- Increase awareness with providers and payers

Stakeholders to engage
- Individual payers
- HTA[2] bodies
- Certification agencies
- AMCs (as clinical-study partners)

- Build awareness at scale of availability of solution

Stakeholders to engage
- Physician associations
- Patient associations

[1]Academic medical centers.
[2]Health technology assessment.

One company that has successfully taken this approach is Germany's Kaia Health, which developed a solution to treat back pain. Kaia initially partnered with AOK Bayern and the Technical University of Munich on a large research project to assess how a digital therapy like Kaia's could be included in standard care for back pain. This work led to the publication of a study demonstrating the feasibility of Kaia's digital tool, which incorporates general education about back pain, mindfulness practices, and physical exercises. Kaia Health used this study and data from a growing user base to establish partnerships with several German insurers that pay for the therapy in the same way they do for conventional treatments. That in turn helped establish the technology in the existing

patient pathway. More recently, Kaia published the results of its first randomized control trial in a small patient population. The trial demonstrated that Kaia's technology was more efficacious than physiotherapy and online education, the current standard of care.

In the United Kingdom, the digital health company Oviva designed a solution to help diabetics manage their condition through better diets and lifestyles. The company has worked hard to back its claims with data. Oviva built a health economic model that compared real-world data from users of its platform with outcomes from existing pharmaceutical therapies, creating a compelling case for the efficacy of its product. To demonstrate cost savings, it then supplemented these data by comparing the cost-effectiveness of its platform with that of current diabetes therapies and face-to-face diabetes-support programs. The company now has multiple agreements and partnerships with regional NHS payers and hospitals for elements of its offering.

As governments wake up to the potential health and financial benefits of digital therapeutics, they are likely to become increasingly keen to promote and accelerate their adoption. In Germany, for example, the new law previously mentioned will allow physicians to prescribe digital technologies in the first year after the solution provider applies for approval, even if it has only trial evidence of clinical benefits to patients, if that evidence meets certain criteria. In the United Kingdom, a range of digital health accelerators seek to speed the adoption of digital technologies within the NHS, and the European Union's Digital Health Europe initiative has a program to help companies integrate digital technologies into healthcare systems across the continent.

Nevertheless, shortcuts to universal reimbursement remain the exception rather than the rule, and companies would be unwise to bet on finding one. The four-step pathway is sounder.

Digital health solutions are indisputably disrupting the sector, but not as quickly as their developers might like. In this respect, they have something in common with traditional pharmaceutical companies seeking reimbursement from public payers. The diversity of health-system structures, funding models, and regulations—as well as increasing scrutiny from payers, providers, and physicians—means that to have any chance of reimbursement at scale, companies will need to invest considerable time and effort in demonstrating the need for and efficacy of new treatments. While the current COVID-19 pandemic might speed up the development and adoption of some digital health solutions (such as remote monitoring or telemedicine), cutting corners in pursuit of a faster route to market could lead to a dead end. Sure and steady will probably win the day.

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