

Through sustained partnerships between advocacy and industry, the US and Europe can overcome barriers to care.

As a source of human suffering, a barrier to workplace productivity, a burden on families and a driver of medical costs, mental illness amounts to an unparalleled public health crisis. Fortunately, there's an abundance of smart thinking on how to improve the lives of people who struggle with major depression, schizophrenia, bipolar disorder, and other serious conditions. In this report, in Ventiv Health has synthesized some of this analysis, with particular attention to the recommendations, strategies, and aspirations of patient advocacy groups. We have also collected insights from pharmaceutical companies, payers, and other key stakeholders. Amidst great uncertainty in the healthcare environments of the US and Europe, in Ventiv Health hopes to shine a light on unique challenges in mental health disorders and some possible solutions.



INTRODUCTION

One in five Americans will experience a mental health condition this year. In their most serious forms, these illnesses shorten patients' lives by 25 years, on average, yet more than half of the people affected receive no treatment at all. In rural areas, the percentage of untreated people is even higher, as are the percentages of veterans and children. Simply put, there are not enough services and mental health professionals to meet the need. Rising suicide rates tragically reflect these deficits in care, and the large-scale incarceration of people who could benefit from professional attention complicates and compounds the crisis.

Patients and advocacy groups in mental health say there's an urgent need for new treatments. Yet the past decade has witnessed an exodus of many large pharma companies from the psychiatric drug space and a contraction in related medical innovation. Languishing government research budgets contribute to a sense of second-class citizenship for mental health conditions when compared with therapeutic areas such as cancer, heart disease, autoimmune conditions, or diabetes.

In Europe, where 27% of adults have experienced a mental illness, the picture is similarly bleak. Patient organizations want to see parity in how societies handle mental illness compared with other health conditions. But that's still a distant dream at a time when budgets for healthcare services are under constant pressure. Protracted high unemployment in Europe increases stress levels, which can trigger depression. An influx of traumatized immigrants from war-torn nations to Greece, Germany, and other countries contributes to health system strains.

Despite this grim snapshot, there are also signs of progress in mental health in many advanced industrial countries. In the US, for example, landmark mental health parity legislation passed in 2008 has improved access to healthcare for patients with these conditions. And, in December 2016, a sweeping, bipartisan initiative called the 21st Century Cures Act sailed through the Senate and was signed by President Obama. In addition to funneling billions of dollars into brain research, 21st Century Cures consolidates authority for federal initiatives in mental health and shores up enforcement of mental health parity.

Yet, some of these milestones are vulnerable in a time of healthcare upheaval. In US policy circles relating to mental health, all eyes are on the expansion of Medicaid, a key provision of the Affordable Care Act. This provision is certain to be eliminated if Obamacare is repealed without a replacement on the table. That would be a disruptive blow. "For low income people with mental illness, nothing

matters more than the Medicaid expansion," says Charles Ingoglia, senior vice president of the National Council for Behavioral Health.

Whatever changes lie ahead, advocacy groups are hopeful a spirit of collaboration across the aisle will prevail. "There's bipartisan agreement that mental health is a high priority," says Andrew Sperling, director for federal legislative advocacy at the National Alliance on Mental Illness. Hoping to promote consensus, advocacy groups are fine-tuning their strategies for 2017 and beyond.

ABOUT THIS REPORT

What are the best ways to ensure progress in the mental health arena while repairing practices and policies that remain broken? In the second half of 2016, representatives of 10 leading mental health advocacy groups in the US and Europe shared ideas with executives at inVentiv Health, a global professional services organization that helps biopharma companies develop and market new treatments. inVentiv also collected insights from payers who make decisions on how to cover care, manufacturers who develop drugs to treat these conditions, and other mental health stakeholders.

While input from all perspectives is valuable, it's the firsthand experiences of patients and their families that best illuminate avenues for improving care. Their voices also apply upward pressure on quality standards at institutions that deliver and pay for treatment. Since the fall of 2014, inVentiv has conducted scores of interviews with advocacy groups in major areas of healthcare—including oncology and rare diseases—specifically to understand what these organizations seek from their pharma partners. The current report is the third publication from in Ventiv in this series. and it's our first report on mental health.

One theme emerges forcefully from many hours of interviews. To serve patients with mental illness, key stakeholders—including families, pharma companies, and payers—must set aside blame for the profound deficiencies in the healthcare systems of both the US and Europe. Improved collaboration among all these groups is paramount. Organizations and individuals must create new forums for discourse. And in all these discussions, there should be a commitment to empathy, with shared social, medical, and humanitarian goals firmly in view.





People who experience mental illness or help loved ones with these conditions come to understand many facets of sorrow. The full emotional toll is never captured in statistics on emergency room visits, inpatient services, or numbers of suicide attempts, and grief itself is rarely factored into official estimates of mental illnesses' economic and social toll.

Advocacy groups believe progress would be swifter if nations could alter their shared perceptions of these conditions. How? By understanding that mental health is an integral part of overall health. Once society makes that leap, health systems might begin to screen for early warning signs of mental illness, exactly as we screen and monitor for other physical diseases. At that point, we can more effectively integrate treatment of behavioral health conditions into primary care.

The encouraging fact is, we can often prevent or remediate circumstances that shorten the lifespans of people living with mental illness. Yet, in America and Europe, we fail to monitor or act on warning flags for behavioral health conditions. "We already screen and monitor patients for cardiovascular disease and cancer," says Paul Gionfriddo, president and CEO of Mental Health America (MHA). "The patient with CV risk is taking a statin and is checked every six months."

Gionfriddo has 30 years of experience tackling mental health issues as a leader and consultant to government, private, and nonprofit initiatives. Like many patient advocates, his commitment wells from personal experience. Diagnosed with schizophrenia, his son, Tim, spiraled down a path of social isolation, homelessness, and incarceration. Gionfriddo chronicled his son's journey in an intimate and influential book titled Losing Tim (Columbia University Press, 2014).



6633

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> BRIAN DOW, EXTERNAL DIRECTOR OF **RETHINK MENTAL ILLNESS**

The comparison with oncology is telling (see sidebar). In the US health system, we regularly perform tests for tumors of the breast, colon, or prostate. Over time, technology improves, diagnostic screens grow more sophisticated, and treatments become more effective. Similar progress isn't the rule with mental illness. Apart from basic questionnaires for depression, no mental health testing is routinely included in annual health checkups.

Advocates acknowledge that screens for mental illness are not perfect, but the same is true for tests aimed at tumors of the breast and prostate. "Cancers can be aggressive or non-aggressive," says Gionfriddo. "You won't catch everything through testing or monitoring mental health, but you will catch a lot."

As a top priority, the medical community, including product innovators, must develop more sensitive and accurate screening tools, mental health advocates say. "There's a body of evidence that suggests if you can interview someone quickly when they develop an illness you can prevent them from falling off that cliff edge," says Brian Dow, external director of UK-based advocacy group Rethink Mental Illness. "That is good for them, for family, for friends, and for society at large." Payers, whether they're the national health plans of Europe or private plans in the US, should keep an eye on advances in mental health screening technology and cover the costs as new tests are adopted in primary care settings.

MENTAL HEALTH AND CANCER: AN IMPACT COMPARISON

The primary shackle on medical progress in mental health is a mindset akin to social stigma, some advocates say. It's a set of attitudes in professional circles that traps mental health in a lower-priority tier, dampens research fundraising efforts, and, ultimately, slows the pace of scientific innovation.

The annual budget of the National Institute of Mental Health (NIMH), the largest source of government funding in the US and in the world, speaks to the issue of status. Each year, the institute doles out roughly \$1.5 billion on research for all mental illnesses. By comparison, funding for the National Cancer Institute has an annual budget of \$5.1 billion, more than three times the size of the NIMH.

This disparity makes no sense, advocates say—either in terms of demographics or epidemiology. The American Cancer Society estimates there are 15.5 million cancer survivors in the US, and personal spending on cancer was \$122 billion in 2013, according to recent analysis in the journal Health Affairs. In contrast, about 43.6 million adults are living with mental illness in the US, nearly three times as many as those classified as cancer survivors. Personal spending on mental disorders—about \$201 billion in 2013—also far outstrips spending on cancer, according to Health Affiars.

Admittedly, high rates of comorbidities blur the lines among illnesses and complicate comparison. Many cancer patients, for example, require treatment for depression as well. But this doesn't alter the realities of stigma, which causes private philanthropic initiatives to track closely with government budgets. In 2016 alone, a new cancer research institute at Johns Hopkins University received \$125 million from Michael Bloomberg and a second oncology initiative with a similar focus received \$250 million from former Facebook president Sean Parker.

"A lot of charities and wealthy organizations are very happy to fund research in cancer," says Henk Parmentier, director of the World Federation for Mental Health (WFMH) in the UK. "Call it a sexy topic—there's a lot of good feeling about it. But if you look at more complex challenges such as mental health research, they're at the end of the queue, and that's mainly due to stigma."

Indeed, the problem of stigma is so dire that even doctors are reluctant to disclose their own experiences with depression and other mental health conditions. This finding emerged in a recent survey of more than 2,000 female physicians in 50 states, published in the journal *General Hospital Psychiatry*.

ADVOCACY "WISH LIST" FOR PHARMA PARTNERS



Stay committed to the mental health space, developing new drugs in spite of the many technical and reimbursement challenges



Provide education on personalized treatment strategies, which may include combining medicines with talk therapy and other evidence-based options



Engage advocacy groups as partners early in the drug development process—and support the partnership after drugs reach the market



Defend corporate budgets for research into the causes of mental illness, and share knowledge with government and philanthropic programs



Develop more sophisticated screens for mental health conditions, including tests that can be used in pediatric settings



PRIORITIES FOR PROGRESS IN MENTAL HEALTH

Each category of stakeholder can promote reforms in different ways. Advocacy groups in the US and Europe recommend the following steps:

PHARMA CAN...



Extend length of clinical trials to ensure real-world relevance

Sponsor postmarketing surveillance studies of psychiatric drugs

Increase gender/ethnicity/ race representation in drug trials

Develop and test more products for pediatric and geriatric use

Seek clearance to test new drugs against the standard of care, not placebos

Develop more "multimorbidity" treatments to manage mental health conditions that are co-morbid with diabetes, cancer, and other conditions



Promote integrated primary care models that look at mental health issues as part of the "whole patient"

Reimburse for broader use of mental health screening in primary care settings

When making coverage decisions, pay closer attention to patient reported outcomes (PRO) data in Phase 3 and Phase 4 trial results

Establish new communication lines with advocacy groups and pharma companies so new drugs are more likely to meet criteria for coverage

Remove "fail first" policies that may place valuable products beyond the patient's reach

PROVIDERS CAN...



Implement system-wide efforts to integrate behavioral health into primary care and adopt more widespread screening

Persuade parents of teenagers or young adults that regular checkups are important even for physically healthy young people

Form teams of doctors. nurses, and community health volunteers to create "health homes" that support people with mental illnessespecially in rural or underserved communities

Help publicize clinical trials and explain benefits of participation

Support public service campaigns to break the mental health "taboo"



Provide financial support for advocacy organizations—as France's Ministry of Health does in the case of depression

Rebalance research allocations to channel more funds to mental health, reflecting demographics and economic impact of these diseases

Bring diverse stakeholders together to agree on what data are valuable in developing new drugs—on the model of Europe's "Adaptive Pathways" pilot program

Fund head-to-head and comparative effectiveness studies that are neutral and insulated from business agendas of insurers and manufacturers

GAPS IN RESEARCH

Over the past decade, government-funded research initiatives in advanced countries have lagged in the area of mental health (see "Mental Health and Cancer: An Impact Comparison"). Unfortunately, the private sector hasn't succeeded in filling the gaps.

It's no secret that there have been few breakthrough psychotherapeutic drugs since the arrival of SSRIs/SNRIs and atypical antipsychotics. Most psychiatric new drug approvals have been for derivatives or modifications of existing drugs. This is one reason payers have been reluctant to approve the use of newer, more expensive medicines.

In 2012, the journal Science Translational Medicine chronicled a surprising exodus by major pharma companies from the field of psychiatric drugs. The same year, in related news articles, experts struggled to explain the retreat, which amounted to a 70% contraction in drug research programs over a 10-year period, according to pharma newsletter NeuroPerspective.

Some articles cited high failure rates in research—as much as 50%—because, for many psychiatric illnesses, pathogenesis is largely unknown and research tools are somewhat blunt. Scientists can't replicate the brain's distributed circuitry in a petri dish, as they can with tumor cells, and animal models for most psychiatric conditions are imperfect or nonexistent. What's more, for a variety of reasons, clinical trial recruitment in the US and Europe is more challenging than in other disease areas. And once the trial is underway, unusually high placebo effects can contribute to a high failure rate.

Advocacy groups understand the explanations for research shortcomings. But many organizations say industry has a responsibility to engage more in this disease area. "We desperately need continued investment and innovation," says Allen Doederlein, president of the Depression and

6633

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Bipolar Support Alliance. "We hope our colleagues in industry will agree that we have to take risks and press forward in research. Psychiatric conditions are a huge public health issue, and we must ask ourselves, at what point do the stakes of this issue outweigh the business imperatives?"

Though the single-payer health systems of Europe provide more effective safety nets than in the US, mental health advocates on the ground grapple with similar challenges. These include bias in the workplace, shortages of beds and psychiatric specialists, and a dearth of promising new drugs in the pipeline. The toll is significant in economic as well as human terms. Mental health conditions represent 22% of the EU's burden of disability, according to a 2016 EU report.

Many advocacy groups told in Ventiv Health they would like to see a greater number of innovative products coming through the drug pipeline—something larger government and corporate research budgets might help achieve. "I don't really see any meaningful improvement in the quality, range, and money that's going into mental health research," says Rethink's Brian Dow. His point is supported by a recent European market forecast for 2022 from consultants EvaluatePharma. The forecast includes sales projections for five R&D products likely to become blockbusters. Only one is a psychiatric treatment.





CLINICAL TRIALS: AN ADVOCACY AGENDA FOR REFORM

Thanks to their history of partnering with pharma companies, advocacy groups are candid when talking about the need for change. Near the top of their wish list is an agenda for improving clinical trials—beginning with recruitment. Pharma companies "are not making it clear to potential participants, especially in minority communities, that a clinical trial may not be harmful," says Susan Gurley, executive director of the Anxiety and Depression Association of America (ADAA). "It's potentially helpful to them and to their community."

Gurley would also like to see pharma companies encourage and support "peer-to-peer communities" that not only provide accurate information on trials, but enable participants to tell their stories, good or bad. "Some stories may be negative, which is okay, because that's the reality, too."

In two previous reports on patient advocacy, inVentiv Health described how advocacy groups seek expanded roles in shaping early clinical research. Mental health advocates desire this as well. "Patients' voices and experiences are critical to drug development," says John MacPhee, Executive Director and CEO of The Jed Foundation (JED), whose mission includes preventing suicide among teens and young adults. "Some companies developing drugs don't talk to the advocacy community at

6633

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all," he says. "It's a huge miss. People who are living with these conditions are an incredible source of information."

The Diagnostic and Statistical Manual for Mental Disorders (DSM) "creates bright lines between conditions, when in reality, the bright lines don't exist," says MacPhee. "It's closer to a Venn diagram in which the disorders share some features. Companies would benefit from looking at mental health conditions in this way." Talking to patients is the best way to gain an accurate picture, he says. "Science is starting to move past the current paradigm, but regulations that guide drug development will move more slowly and continue to look at the hard lines dividing mental health diagnoses."

Once psychiatric drug trials are underway, advocates would like to see pharma make better use of patient reported outcomes, so trial sponsors can understand what matters to the patient. In response to pressure from patient organizations, the 21st Century Cures Act endorses the use of PROs in psychiatric drug trials. Advocates say these relatively simple tools can reduce the danger that regulator-approved dosages will lead to over-treatment, which can cause side effects such as precipitous weight gain and other metabolic problems.

When a trial relies solely on input from clinicians, disease symptoms may be logged as more severe than what the patient actually experiences, or how they describe that experience. By skipping the PRO, the trial sponsor may miss the fact that the optimal dose of an experimental drug is lower than clinicians think.

Advocates raise a number of other issues with the way pharma companies perform clinical trials for psychiatric treatments. For example, most companies currently test new drugs for mental health conditions against a placebo, rather than giving patients in the control arm medications considered to be the current standard of care.

Companies do this in accordance with regulations and guidance from national health authorities. Currently, both in the US and the EU, rules governing the registration of new mental health drugs are based on the concept of absolute efficacy, as measured against a placebo, not an active comparator. Some mental health advocates say regulatory guidance should be revised so that the concept of absolute efficacy is replaced by one of added value. Evidence should show that the new drug is at least as safe as the current standard of care, and also more effective.

Guidance that insists on placebo controls also adds to the challenge of recruiting patients for trials—already a difficult hurdle. That's because many people with mental health conditions are anxious about being on a placebo for months at a stretch with no access to medications. that work. Researchers looked into the recruitment issue in 2011, with help from the NIMH. More than one third of patients they interviewed cited fear of being placed on a placebo as the primary reason for declining to participate in trials of psychiatric drugs.

Advocacy groups also note that placebo controls considered the gold standard by scientists—are not the general rule in areas such as oncology. For trials of most new cancer drugs, patients placed in the control arm are given anti-cancer medications with a proven track record, not placebos.

"We've looked at the issue of placebo versus standard of care," says DBSA's Doederlein, a prominent mental health advocate who talks openly about his personal experience of living with a mood disorder. "In cancer and other areas, the

control is often standard of care. Why not in mental health? It's hard to think of an explanation other than the subtle workings of stigma in this sector," he says.

The European Medicines Agency has wrestled with designing better clinical trials for illnesses such as schizophrenia. In 2013, it adopted a new guideline, aiming to assess both long-term and short-term efficacy of new schizophrenia drugs. Recognizing the strengths and weaknesses of competing trial strategies, the guideline recommended a hybrid approach. In effect, it minimizes the amount of time patients are exposed to placebo controls by folding a randomized "withdrawal" trial into a long-term parallel trial.

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WHAT PAYERS THINK

Mental health advocates in the US often lament that patients have trouble finding psychiatrists who accept insurance. A related grievance: people with mental health conditions sometimes must jump through hoops to ensure their health plans will cover promising new drugs.

No one familiar with the field would make light of these concerns. But in many cases, according to payers, the problems stem from larger deficiencies in how society cares for people with mental illness.

The private payer's perspective is an essential, but often neglected, element in discourse on mental illness. To fill the blanks, in the fall of 2016, in Ventiv Health conducted in-depth interviews with 13 executives responsible for reimbursement and formulary decisions at regional and national health plans representing more than 59 million lives. In wideranging discussions, we encountered consensus on some topics, and a surprising diversity of practices and opinions on others.

Most payers acknowledged there are shortages of in-network psychiatric professionals, especially in rural areas. But only one of 13 interviewees agreed with advocates' assumptions that raising reimbursement rates for services would "fix" the problem. Medical specialists are in short supply in gynecology, dermatology, hematology, and many other disciplines, payers noted.

"These are problems we must address at a societal level," one interviewee told us.

We pointed out that many patients are anxious about getting reimbursed for new and expensive medicines. Advocacy groups object to prior authorizations, as well as policies obliging patients to "fail first" on generic drugs or inexpensive oral medications before stepping up to costlier branded drugs and longeracting injectables. Yet these practices may be less widespread than advocacy groups think.

In fact, only two payers we spoke with required prior authorizations for the use of any psychiatric medication. Half of respondents did require patients to try generics before using branded drugs. All but three, however, said there were no "blocks" on branded products. In other words, patients and their physicians were free to find any drug that might work, though some may face high out-of-pocket costs.

To flesh out the picture, we asked payers if pharma companies—the most important stewards of treatment innovation—could help improve the coverage and reimbursement environment. All payers responding to this question believed longer clinical trials would yield better, more actionable data. "A six-week trial isn't helpful to us," one payer commented. Many mentioned the need for more postmarketing surveillance studies—the longer in duration, the

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PAYER RESPONDENT

better. Patients are on these drugs for decades, they explained. That means we must learn more about compliance rates, relapse rates, changes in efficacy/resistance, and other benefits and liabilities of long-term usage. None of the payers we interviewed was interested in seeing quality adjusted life years (QALYs) as a metric in benefit analysis. More than two-thirds said they were skeptical of health economic outcomes research (HEOR) conducted by pharma companies. And only two said they placed stock in patient reported outcomes (PROs) as part of a clinical dossier.

In the research, we also heard anecdotes showing that mental illness has profoundly touched the personal lives of insurance industry workers, just as it has with drug company emplyees, doctors, regulators, politicians, and individuals in every other swath of society. "I live with a person who has mental illness," one insurance executive told us. "He's on all kinds of medications, and when side effects bother him, we try something else. This is true across our health plan. If the cost is high, it's unfortunate, but we cover it."

For payers, mental health is a deeply personal domain that can't be painted without a pallet of colors. To provide a fuller portrait, in Ventiv Health will publish a report about payer perspectives on mental health in February 2017.

CONCLUSION: A CALL FOR UNITY AND PURPOSE

In their search for guidelines to manage relations with industry, many advocacy groups emphasize consistent behavior. Once a drug reaches the market, pharma companies sometimes let their relationships with advocacy organizations languish, says Amelia Mustapha, a member and former executive director of the European Depression Association (EDA). Only a few "are doing long-term planning, trying to make the advocacy sector more robust and bringing patient groups together," she says.

Loyalty, advocates say, means sustained support on issues patients hold dear. That includes speaking out on behalf of people with mental illness in the wake of violent events that draw media glare. "You see this with schizophrenia, for example, where the rare, ultra-violent event is front-page news," says WFMH's Parmentier. "Patient organizations and their industry partners have a responsibility to tell the other side of the story—the good news as well as the bad. Some 50% of people with schizophrenia recover—and that is never in the news."

Carefully choosing her words, Mustapha points out that mental illness isn't the only sector struggling with stigma. In recent years, censure has enshrouded the pharmaceutical industry, often linked with drug pricing initiatives. Now, to a growing degree, the problem is entangling pharma's advocacy partners, Mustapha says. "We need the industry to stand up for itself because people feel distrust for pharma, and patient groups are pilloried if we take their money. But they are some of the only organizations offering resources, other than the government."

Fear, disdain, contempt. These are sentiments whose painful jabs the mental health community knows only too well. Patients and advocates who struggle to elevate the stature of mental health initiatives can't afford to see industry partners suffer a loss of social prestige. Everyone whose life has been touched by a mental health condition needs to be blameless on behalf of the shared challenge. With unity and purpose, Mustapha says, we can find a path forward.

INVENTIV HEALTH WOULD LIKE TO THANK THE FOLLOWING ORGANIZATIONS FOR SHARING THEIR TIME AND INSIGHTS:

National Alliance on Mental Illness	Depression and Bipolar Support Alliance
National Council for Behavioral Health	Anxiety and Depression Association of America
Mental Health America	The JED Foundation
Rethink Mental Illness	The Kennedy Forum
World Federation for Mental Health	European Depression Association

ABOUT INVENTIV HEALTH PUBLIC RELATIONS GROUP

The global public relations group of inVentiv Health helps launch brands and build the reputations of companies working to improve human health. Integration with the advertising and medical communications agencies within inVentiv Health creates complete communications solutions that build corporate and brand value and deliver on the bottom line.

inVentiv Health is a global professional services organization designed to help the biopharmaceutical industry accelerate the delivery of much-needed therapies to market.

Our Advocacy Patient Engagement Solutions

inVentiv Health PR Group's advocacy hub is centered in our Washington, D.C. office with a network of experts throughout the US and UK. Our team brings decades of experience in advocacy consulting for pharmaceutical, biotech and device companies, and patient and advocacy organizations. As a result, our experts are adept at bridging the gap between patients and companies to find mutual solutions and support new and existing treatments that improve patient care.

Traditionally, the patient voice has been limited to discrete points later in the product development lifecycle. in Ventiv Health helps clients infuse the patient voice throughout clinical development and commercialization with input mechanisms providing a continual feedback loop.

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 patient population/therapeutic
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- Patient Advisory Boards
- Behavioral Insights and Adherence Programs
- Patient and HCP Communications
- Comprehensive Patient Engagement Plans for how companies/franchises/brands should infuse the patient voice into the clinical pathway
- Social and Digital Activation



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