

Fostering an Innovation Culture to Reimagine Care Delivery



A collection of forward-thinking articles from NEJM Catalyst

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Catalyst Innovations in Care Delivery

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Dear Valued Reader,

The mission of NEJM Catalyst is to share real-life solutions to the most important and most difficult problems facing health care today. These solutions come from innovators at health care organizations around the world. This collection of previously published articles, case studies, and interviews exemplifies the breadth of innovations that we bring to subscribers every month.

An In-Depth article, "Vaccinating Health Care Supply Chains Against Market Failure: The Case of Civica Rx," details the creation of a new type of drug manufacturer and provides the first empirical evidence of improved access to commoditized generic drugs at reduced prices.

A case study, "The Digital Clinic: An Innovative Mental Health Care Delivery Model Utilizing Hybrid Synchronous and Asynchronous Treatment," describes Beth Israel Deaconess Medical Center's multimodal therapy approach that combines in-person sessions, a phone app, and a new care team member dubbed the Digital Navigator.

In "Addiction Medicine Clinician Shortages Require Innovative Treatment Approaches," members of the NEJM Catalyst Insights Council comment on how their organizations are addressing the many challenges of addiction medicine, including shortages of specialists and the complexity of care.

"The Whole Health Index: A Practical, Valid, and Reliable Tool to Measure Whole-Person Health and Manage Population Health" is an article by Elevance Health leaders on their new measure of true health, drawing on a broad range of data. Another article, "How Hospitals Improve Health Equity Through Community-Centered Innovation," pulls lessons from a broad range of efforts by health care organizations to improve their local communities.

In the coming months, NEJM Catalyst will publish a series of theme issues and hold related events on Innovating Health Care, to highlight outstanding examples of care delivery innovation, patientcentered innovation, digital technology innovation, and social innovation. We invite contributions and subscriptions from all those seeking to change care delivery for the better.

> The Editors, **NEJM** Catalyst

Fostering an Innovation Culture to Reimagine Care Delivery

TABLE OF CONTENTS

IN DEPTH Vaccinating Health Care Supply Chains Against Market Failure: The Case of Civica Rx	1
CASE STUDY The Digital Clinic: An Innovative Mental Health Care Delivery Model Utilizing Hybrid Synchronous and Asynchronous Treatment	21
INSIGHTS INTERVIEW Addiction Medicine Clinician Shortages Require Innovative Treatment Approaches	36
сомментаку The Whole Health Index: A Practical, Valid, and Reliable Tool to Measure Whole-Person Health and Manage Population Health	40
ARTICLE How Hospitals Improve Health Equity Through Community-Centered Innovation	57

IN DEPTH

Vaccinating Health Care Supply Chains Against Market Failure: The Case of Civica Rx



Carter Dredge, MHA, Stefan Scholtes, PhD Vol. 4 No. 10 | October 2023 DOI: 10.1056/CAT.23.0167

This article focuses on the value of introducing novel business models into health care to address market failures that are hurting people – delving deeply into learning from real-world examples within the generic drug supply chain and its failure to supply critical medicines reliably at a low cost. Some problems in health care are so complex that traditional private-sector or governmental interventions alone have not been able to solve the problems. In an original response to ongoing generic drug shortages, in 2018, seven U.S. health systems and three philanthropic organizations founded a novel not-for-profit drug manufacturer, Civica Rx, to address the issue. Civica is a new entrant in this supply chain and utilizes a new business model called a health care utility that prioritizes access over profit. The company has been scaled rapidly and now provides more than 75 critical medications that are most at risk for shortages to more than 55 health systems across the United States. This article provides the first empirical evidence of Civica's effect on security and cost of supply for one of its member health systems by utilizing internal supply chain, pharmacy, and external market data between 2016 and 2022. Results show that Civica was able to improve generic drug access above the wholesaler model. Using data related to 55 Civica orders of 20 distinct products between 2020 and 2022, the authors estimate Civica's fulfillment of its contractually guaranteed volume at 96% (95% confidence interval [CI] = 92%-100%), whereas data on 302 wholesale orders for the same products over the same period estimate the wholesaler order fulfillment rate at 86% (95% CI = 82%-90%); the difference between these rates is statistically significant



(P = 0.03). In addition, through its reserve supply of product, Civica offered a product access benefit of a further 43% above the Civica-guaranteed minimum viable volume floor. Wholesaler prices, at the order level, were estimated to be on average 46% above the Civica price for the same product in the same year (95% CI = 27%-64%, N = 302), with a *P* value of the difference of less than 0.001. However, through optimizing its wholesaler orders by buying more volume when prices were low from the 62 different non-Civica manufacturers, this closed the actual achieved cost-savings gap between the wholesalers and Civica to 2.7% in aggregate, with Civica still being the lower-cost option.

Introduction

Although competition increases quality and reduces the cost of goods and services across a wide spectrum of industries, health care seems intractably resistant to standard forms of competition — particularly in its hyperspecialized supply chains. Many access and cost problems in health care can be traced to the prevalence of oligopolies.¹ A specific case in point is the generic drug industry, where supply has been described as notoriously unreliable and concerns about price gouging or other pricing practices are common,²⁻⁵ particularly in the face of extreme cases of increasing prices by a factor of 50.⁶ These market failures make health care unnecessarily expensive and needlessly constrain access to critical medicines that are often decades old.^{7,8}

Since early 2018, the number of active drug shortages in the United States has exceeded 200 at the end of each quarter, topping 300 in the first two quarters of 2023.⁹ Shortages have ranged from <u>albuterol</u>, a critical bronchodilator used to treat respiratory emergencies (including Covid-19), to <u>vancomycin</u>, an essential antibiotic to treat serious infections. The problem also seems to be getting worse, not better. A U.S. Senate report states that new drug shortages increased by nearly 30% between 2021 and 2022, with a record 5-year high of 295 active drug shortages at the end of 2022. The report also noted that the average drug shortage lasts about 1.5 years, but more than a dozen critical drug products have been on shortage for more than a decade, which can contribute to adverse consequences for patients and health care providers, including care delivery delay or rationing.¹⁰

Historical approaches have not solved this problem. With generic pharmaceuticals, the solution is unlikely to come from progress in science or technology alone; although governmental interventions play an important role, engagement from the private sector is also crucial.

In 2018, three philanthropies (the Gary and Mary West Foundation, the Laura and John Arnold Foundation, and the Peterson Center on Healthcare) partnered with seven large U.S. health systems (Catholic Health Initiatives, now CommonSpirit Health; HCA Healthcare; Intermountain Healthcare; Mayo Clinic; Providence St. Joseph Health; SSM Health; and Trinity Health) that were exposed to drug shortages in their hospitals. To take matters into their own hands, they created a not-for-profit drug manufacturing company — Civica Rx (Civica) — to supply a significant

proportion of their demand for critical medications. The company was tasked not with the maximization of margins and profits for its owners, but instead with maximizing access to critical medicines at an affordable price. Civica delivered its first drugs to its member systems near the end of 2019 and has since been joined by more than 50 additional health systems, covering more than 1,500 hospitals accounting for approximately 225,000 hospital beds. Through July 2023, more than 56 million cumulative patient-doses of Civica medicines have been administered.

This rapid scaling success suggests that the injection of novel entities, such as Civica, into a health care supply chain is perceived by many health systems as an effective way of solving supply chain market failures, such as drug shortage problems. However, there is, to date, no publicly available quantitative evidence of the effect of Civica on drug shortages and drug costs for its member systems. This article provides the first such evidence on the basis of the first round of drugs produced by Civica.

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The Problem

The current players in the pharmaceutical industry make pricing decisions and shift resources to maximize profits. In the case of critical generic drugs, this creates two market dynamics that lead to access problems: prohibitively high prices and product shortages.

Problem #1: Prohibitively High Prices

For some generic drugs, barriers to entry in terms of manufacture and distribution cause the prices to be prohibitively high. Such has historically been the case with insulin, a drug used to manage diabetes. The average price for the uninsured for a box of five pen cartridges of insulin in 2022 was more than \$500,¹¹ with the price trend over the past 20-plus years experiencing a dramatic increase. The result is that 25% of Americans who rely on insulin have been forced to ration their medications because of cost.¹²

Three dominant firms produce insulin (Eli Lilly, Novo Nordisk, and Sanofi),¹¹ and three highly concentrated pharmacy benefit managers (PBMs) heavily influence its contracting and distribution (CVS/Caremark, UnitedHealth Group/Optum Rx, and Cigna/ExpressScripts); with 2020 estimated market shares of 32%, 24%, and 21%, respectively, those top three PBMs dominate the total equivalent prescription claims activity.¹³ The cost of developing and producing a new and lower-cost insulin as a complex biosimilar is a highly regulated, multiyear effort costing hundreds of millions of dollars. Few firms have been willing and/or able to pursue such a venture. As a result, the drug is available but not affordable.



Problem #2: Shortages

For other drugs, low barriers to entry cause the price of the drug to become prohibitively low, triggering a race to the bottom. Such is the case with lorazepam, a drug used to treat seizures. The drug typically sells for less than \$1.00 as the health system price. It is common to only have one available manufacturer of the drug at any given time. As a consequence, supplies for such drugs become highly unreliable. According to the American Society for Health-System Pharmacists (ASHP), lorazepam has been on active shortage since 2015. As a result, the drug is affordable but not available. A key factor influencing such lack of production is unsustainably low pricing that has driven aggressive offshoring and underinvestment in adequate supply redundancy,¹⁴ creating severe access problems.

Taken together, these problems present a paradox. Systemic problems in accessing affordable critical generic medicines are occurring because drugs are either too expensive or too cheap. Our current business structures are struggling to find a sustainable equilibrium. There is either not enough competition or not the right type of competition. Is there a middle-ground solution that could strike a more sustainable and equitable balance? One that could inject more competition while still sustainably ensuring stable, long-term access? That is the challenge that the founders of Civica sought to address.

C The novel business model that Civica uses is called a health care utility, which adopts the term utility and references other commonly shared basic services, such as water and electricity."

A Potential Solution: Health Care Utilities and the Premise of Reliable Supply at the Lowest Appropriate Cost

Creating another manufacturer along the same for-profit business model is unlikely to solve the problem. The founding health systems for Civica had to create a new type of manufacturer and inject it into the supply chain. The novel business model that Civica uses is called a health care utility (HCU),¹⁵ which adopts the term utility and references other commonly shared basic services, such as water and electricity; the HCU model also has applications beyond the generic drug industry.¹⁶

We define an HCU as a "self-sustaining nonstock corporation with a social mission, formed by health care institutions to provide critical products and services at the lowest sustainable cost, using a focused, transparent, and scalable business model."¹⁶ Figure 1 shows the key ingredients of the HCU model.

HCUs are access maximizers — in contrast with the prevalent price or margin maximizers — and are intensely focused on producing increased access and savings for essential goods and services that are well understood and can and should be commoditized. No one owns an HCU, and it cannot, therefore, be monetized for a profit. HCUs are membership organizations with

FIGURE 1

The Health Care Utility Model (Summarized)

The four key elements of the health care utility (HCU) model are related to its structure (it is not owned; rather, it is governed by stewards); its financing, which is provided by the stewards who also are the HCU's customers; its contracting, which is transparent and the same for all customers; and its market effect, which operating in the open market, translates scale into sustainable cost reductions rather than pricing premiums. The aim of the model is to minimize price while maximizing access to the product, which would be essential goods and services that are well understood and can and should be commoditized: in this case, critical medicines.



Source: The authors

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institutional members — health systems in the case of Civica. The purpose of the HCU is to solve a collective supply problem for its members, who also are its customers. HCUs are incubated and scaled using long-term debt and philanthropic contributions provided directly by their governing member-customers. Once at scale, HCUs compete in the open market and are perpetuated over time through low and sustainable operating margins achieved by providing the same transparent prices for all members; this model is underpinned by long-term purchase commitments from these same members. HCUs exist exclusively to solve a focused, shared, large-scale problem that would otherwise be beyond the reach of any single member organization.¹⁶

Although Civica's HCU model started with a form of group purchasing, leveraging latent manufacturing capacity in the market, it is distinctly different from a group purchasing organization (GPO). A GPO will charge manufacturers fees to access the GPO's customers, but will give no commitment to purchase and does not actually buy or purchase the product. By contrast, Civica gives its contract manufacturers firm long-term commitments, buys the product,

oversees the quality of the product, puts its own brand and stamp of approval on the product with a unique FDA National Drug Code (NDC), and stores an average of 6 months of inventory in its warehouse to protect its members during shortages in the market. Civica is also currently building its own dedicated manufacturing facility to produce future products directly. Civica is designed as a fully fledged novel supplier that has been injected as an organizational antibody into the supply chain to ensure that other competitors in the market competitively compete in a transparent and sustainable way to avoid the aforementioned market failures of prohibitively high prices or shortages.

Data and Methodology

Data

This article provides the first evidence in answering two important questions. (1) Did Civica improve access to critical medicines that have historically been chronically experiencing shortages? (2) If so, at what cost?

To answer these questions, we accessed data from <u>SSM Health</u>, a 40,000-plus employee integrated health system located in the Midwest region of the United States that is one of Civica's original founders. SSM Health provided longitudinal purchasing history for the evaluated drug products and supported the study with clinical and operational expertise.

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Health care utilities are access maximizers — in contrast with the prevalent price or margin maximizers — and are intensely focused on producing increased access and savings for essential goods and services that are well understood and can and should be commoditized."

Data for this study were secured from internal hospital pharmacy operations systems, supply chain purchasing databases, wholesaler product availability and delivery information, the ASHP, and Civica itself. All data elements were aggregated annually and specified down to the level of the NDC, which is a unique identifier for each specific drug tracked by the FDA, to ensure accurate comparability.

Fourteen different Civica drugs, of a potential 22, were evaluated on the basis of the following selection criteria: (1) longitudinal data availability across multiple years of Civica supply to show the Civica effect over time, (2) material hospital purchasing volume to ensure operational relevance, and (3) variation in the types of medicines/clinical uses to ensure model robustness. All drug products were liquid medicines stored in vials, with a fixed strength. A detailed list of the medications evaluated, their clinical use, and shortage-related specifications is provided in Table 1.

Product Name	Medication Use	FDA Essential Medication	Shortage First Reported (ASHP)	Current** Shortage Status (ASHP)
Bivalirudin	Prevents blood clots during angioplasty	No	2019	Resolved 2020
Daptomycin	Antibiotic that treats infections, including complicated skin and skin structure infections and infections in the bloodstream	Yes	2018	Resolved 2022
Dexamethasone	A corticosteroid to reduce inflammation — used for multiple disease states — including as an adjunct to nausea and vomiting	Yes	2011	Ongoing
Fentanyl	A narcotic pain medicine to prevent or treat pain during and/or after surgery or other medical procedure	Yes	2017	Ongoing
Ketamine	Used to produce a loss of consciousness before surgery or a medical procedure; also used for rapid sequence intubation	Yes	2018	Ongoing
Labetalol	Treats severe hypertension (i.e., high blood pressure)	Yes	2017	Ongoing
Lidocaine	Local anesthetic that numbs an area of the body before and during surgery or other procedures	Lidocaine with epinephrine only	2015	Ongoing
Lorazepam	Treats seizures; also used for sedation, anxiety, and alcohol withdrawal syndrome	Yes	2015	Ongoing
Naloxone	Treats opioid overdose in an emergency situation	Yes	N/A	N/A
Neostigmine	An anesthesia reversal medication	No	N/A	N/A
Ondansetron	Prevents nausea and vomiting	Yes	2018	Ongoing
Rocuronium Bromide	A muscle paralysis medicine used for general anesthesia, rapid sequence intubation, and/or mechanical ventilation	Yes	2017	Ongoing
Sodium Bicarbonate	Used to treat cardiac arrest or metabolic acidosis	Yes	2017	Ongoing
Vancomycin	An antibiotic to treat bloodstream infections	Yes	2015	Ongoing

Table 1. List of 14 Evaluated Drugs*

* The drugs are listed in alphabetical order. ** The table was last updated on December 22, 2022. N/A = not applicable/never reported on a national shortage by ASHP. Source: The authors, with dates for drug shortage statuses being retrieved from the American Society for Health-System Pharmacists (ASHP): https://www.ashp.org/drug-shortages/current-shortages

The resulting longitudinal dataset comprises 784 observations, with an observation being defined as the year- and manufacturer-specific ordering and receiving volume and costs for each specific product at SSM Health. Throughout the rest of the article, we refer to these individual observations as orders. These orders accounted for 8.0 million vials received over 7 calendar years (January to December) of purchasing history between 2016 and 2022 inclusive. Data for the non-Civica medication wholesalers (wholesalers) were available for all 7 calendar years

2016-2022; data for Civica were available for calendar years 2020-2022. For more on the names and definitions of critical dataset variables, see the <u>Appendix</u>.

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Measures

Descriptive analysis is provided across numerous data-granularity levels; however, for the ultimate primary and secondary findings, we compare Civica and the health system's wholesaler (which is inclusive of all other health system purchases) on availability and cost at the product and unit level. We define a product as a specific drug with a specific strength and specific vial size (e.g., ketamine, 50 mg/ml, 10 units per vial). A unit is defined as the most granular level of detail for a medication's quantity. A definitional example of the drug, product, and unit distinction is provided in Table 2.

The analysis is performed at a product and unit level to ensure accurate comparability because some drugs have more than one strength and/or more than one vial size. Costs were measured as a standardized price per unit, which was calculated by dividing the order price by the Civica price paid for the product during the same year.

The wholesaler receives orders from the health system periodically depending on the inventory level of the drug in the health system. Therefore, we measure drug shortage pressure for the wholesaler on a given product as the proportion of wholesale orders, measured in units, that were unfulfilled.

In contrast to the wholesaler, Civica has a 5-year contract with its member health systems to provide a prespecified volume, typically 50% of the health system's projected demand for the drug, at a prespecified price. This annual volume is called the minimum viable volume (MVV). Therefore, we measure drug shortage pressure for Civica's supply by the proportion of its unfulfilled order up to the level of the product's MVV. (Of course, given the transparent pricing and member-customer governance, if there was a systemic reduction in demand across the nation for a product, the members can collectively agree to adjust terms as needed.)

Product (Drug + Strength + Vial Size)					
Drug	Strength, mg/ml	Form	Number of Units per Vial (i.e., Vial Size)	Number of Vials Purchased	Number of Units Purchased (i.e., Units per Vial × Vials Purchased)
Ketamine	50	Vial	10	20	200
Ketamine	100	Vial	5	25	125

Table 2. Example of Drug	, Product, and	Unit Distinctions
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Source: The authors

Although the Civica minimum viable volume contract serves as the floor of guaranteed access, it does not operate as a ceiling."

Findings

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The data contain order histories for 14 distinct drugs that can be categorized more granularly as 20 products on the basis of the following breakdown; three of the drugs had two different strengths, one drug had two different vial sizes, and one drug had three different vial sizes, yielding a total of 20 products. The 20 products were supplied by a total of 63 distinct suppliers (Civica plus 62 other manufacturers), with individual products being sourced from between 4 and 17 distinct suppliers. Of the 62 manufacturers supplying these products to SSM Health through the wholesaler, 32 supplied a single product, whereas 1 supplied 15 products. Civica supplied all 20 products to SSM Health. Three drugs (bivalirudin, lorazepam, and rocuronium bromide) were supplied by Civica from 2021 onward, and all others were supplied from 2020 onward. Demand at SSM Health for these 20 critical products rose steadily from 7.9 million units in 2016 to 8.8 million units in 2019, then jumped to 12.3 million units in 2020 because of the increased demand from the Covid-19 pandemic, and increased further to 15.5 million units in 2022 (Figure 2).

Across years when both Civica and the wholesaler were available as suppliers for a drug (2020–2022), we compared the wholesaler order fulfillment rates with those of Civica. Table 3 shows the fulfillments rate in aggregate at the product level.

Statistical Evidence

In addition, we provide statistical evidence by estimating confidence intervals (CIs) for fulfillment rates and standardized wholesale prices at the order level using a generalized linear model with a binomial distribution and a logit link function. We include observation year and product as two categorical predictor variables to reduce confounding by year-on-year and product-by-product variation. The model estimates Civica's fulfillment of its contractually guaranteed volume at 96% (95% CI = 92%–100%, N = 55) and the wholesaler order fulfillment rate at 86% (95% CI = 82%–90%, N = 302). The difference between these rates is statistically significant (P = 0.03). The data, therefore, provide statistically robust evidence that Civica outperforms the wholesaler model on reliability.

MVV Upside Potential

Although the Civica MVV contract serves as the floor of guaranteed access, it does not operate as a ceiling. When the standard supply chain struggles to supply critical medicines, Civica member health systems, such as SSM Health, will reach out to Civica to order above their MVV. This creates another positive benefit for health systems. Whenever possible, while still ensuring equitable access for all its members, Civica attempts to satisfy these over-and-above contracted

FIGURE 2

Demand for Evaluated Drugs

The demand for the 20 products selected for this study of Civica's health care utility model is shown over a 7-year purchasing history at SSM Health. Civica was created in 2018 and began its participation as a supplier of these medicines in 2020. The major increase in demand in 2020 was associated with the onset of the Covid-19 pandemic. The 20 products are listed in Table 3.



Total Demand at SSM Health for 20 Evaluated Products

Note: Demand is defined as quantity of units ordered (in millions) by SSM Health for the 20 evaluated products.

Source: The authors

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orders at its standard fixed price using its safety stock capacity when the shortage reason is well understood and it is determined that the inventory can appropriately be used as an intermediate buffer during a critical shortage.

What the empirical data strongly indicate is that it is not about comparing Civica's prices with the spot market on a given day but rather, with the longitudinal total mix of prices over time, accounting for longer-term stability and robustness of the supply."

Evaluated Products (N = 20)	Wholesale Order Fulfillment (%)*	Civica Fulfillment of MVV-Guaranteed Volume (%)**	Civica Quantity Received Above MVV (as % of MVV) [#]
Bivalirudin, 250 mg, 250 units per vial	90	100	0
Daptomycin, 500 mg, 500 units per vial	78	100	44
Dexamethasone Sodium Phosphate, 10 mg/ml, 1 unit per vial	76	88	0
Dexamethasone Sodium Phosphate, 4 mg/ml, 1 unit per vial	69	100	38
Fentanyl Citrate, 50 mcg/ml, 2 units per vial	73	100	20
Fentanyl Citrate, 50 mcg/ml, 5 units per vial	70	100	4
Fentanyl Citrate, 50 mcg/ml, 50 units per vial	84	100	31
Ketamine, 100 mg/ml, 5 units per vial	94	100	94
Ketamine, 50 mg/ml, 10 units per vial	94	100	56
Labetalol, 5 mg/ml, 20 units per vial	53	100	337
Lidocaine, 1%, 5 units per vial	45	100	13
Lidocaine, 2%, 5 units per vial	65	100	21
Lorazepam, 2 mg/ml, 1 unit per vial	70	100	3
Naloxone, 0.4 mg/ml, 1 unit per vial	94	100	34
Neostigmine, 1 mg/ml, 10 units per vial	96	88	0
Ondansetron, 2 mg/ml, 2 units per vial	91	100	892
Rocuronium Bromide, 10 mg/ml, 10 units per vial	92	100	299
Rocuronium Bromide, 10 mg/ml, 5 units per vial	63	89	0
Sodium Bicarbonate, 8.4%, 50 units per vial	92	100	64
Vancomycin, 10g, 10 units per vial	42	96	0

Table 3. Fulfillment Rates by Product and Source

Product-specific results are for 2020–2022 when both the wholesaler and Civica were supplying these 20 products to SSM Health. Civica was unable to meet its guaranteed minimum viable volume (MVV) commitment on 4 of the 20 individual products, but was able to supply over and above its MVV commitment on 15 of the 20 products at SSM Health's request. The wholesaler was not able to meet the entire demand for SSM Health for any of the 20 products. *Wholesale volume received divided by wholesale volume ordered. **Civica volume received up to MVV divided by MVV volume. [#]Civica volume received above MVV divided by MVV volume. The authors

We quantified this upside benefit by dividing the total Civica units received by the total contracted MVV units (Table 3). During the 2020–2022 observation period, across all 20 products, SSM Health received an aggregated total of 43% more product units above its contracted MVV. This additional 43% accounted for 22% of SSM Health's non–MVV-guaranteed product volume from both Civica and the wholesaler. Additionally, as a further robustness check, given that three drugs had much larger additional MVV product percentages than the others (labetalol, ondansetron, and the 10-unit-per-vial rocuronium bromide), we evaluated the additional MVV product access benefit excluding these three products, and the effect was still significant at a total of 38% more product units above the contracted MVV. Figure 3 shows that this additional MVV product benefit has increased over time — providing a critical source of value during a time of overall demand increase.

FIGURE 3

Order Fulfillment Ratios over Time

During the study period, the wholesaler fell short in fulfilling the requested orders for all 20 products, and its fulfillment ratio also dropped from 0.90 in 2020 to 0.71 by 2022. The Civica data are relative to its contractual minimum viable volume (MVV) commitment, which for SSM Health, was approximately 50% of expected need; note that its fulfillment ratio improved over time, going from 1.19 in 2020 to 1.55 in 2022.



Order Fulfillment Rates over Time

Source: The authors

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Cost Findings

All Civica members purchase Civica medications at the same transparent price. Those prices are determined by Civica on the basis of the lowest appropriate cost necessary to sustainably provide the medicines over a 5-year period. Civica does not opportunistically change its price on the basis of the traditional spot-price market, and its products have the same stable price for each calendar year. For statistical analysis, we standardized costs at the product level by dividing the unit price of the wholesaler order by the Civica unit price in the same year during the time period between 2020 and 2022 when Civica was also delivering the same products (Figure 4).

Statistical Evidence

We estimate a CI for the standardized price of the wholesaler at the order level using a standard multivariate regression model, including similar to the previous analysis, year and product as

FIGURE 4

Standardized Wholesale Prices at the Order Level Relative to Civica Prices

This figure shows standardized wholesaler prices by order (blue squares) relative to Civica prices (orange line) during the years 2020–2022 inclusive, with the *y* axis depicting the wholesale order price as a proportion of the Civica price during the year and the *x* axis depicting the wholesale order's proportion of the total annual wholesale orders for the same product during the same year. The graph shows occurrences of both higher and lower wholesale order prices relative to Civica prices (with some extreme cases of the wholesale order prices being over 17 times higher than Civica prices and being more frequently higher than Civica prices at the lower total annual wholesale order proportions). This indicates that when wholesale prices are at their relatively highest levels, SSM Health attempted to minimize how much of its purchasing volume it consolidated at those high prices. However, even when wholesale prices were two to four times higher than Civica prices, the figure shows indications of distress purchases at SSM Health, which as a health system having to still provide essential care even while managing through difficult drug shortages on critical medicines, at times was desperate to source needed products for its patients, even when being required on multiple occasions to pay more than Civica prices.



Standardized Wholesale Prices at the Order Level Relative to Civica Prices

Received Volume as a Proportion of Total Annual Wholesale Volume of the Product Above the Civica MVV-Guaranteed Volume

MVV = minimum viable volume. Source: The authors

Source: The authors

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two categorical predictor variables to reduce confounding from year-on-year and product-byproduct variation. The model applied to wholesale orders when Civica was also present estimates wholesale prices to be, on average, 46% above the Civica price of the same product in the same year (95% CI = 27%-64%, N = 302). The difference is statistically highly significant (P < 0.001). We also reestimated the model with the two outliers in Figure 4 removed, resulting in an estimated wholesale price, on average, of 35% above the Civica price of the same product in the same year (95% CI = 24%-46%, N = 300). The difference remains highly statistically significant (P < 0.001).

Actual Cost Impacts to SSM Health of General Wholesaler Price Variation

Given the significant general wholesaler price variation, both higher and lower, it would be expected that the SSM Health pharmacy and supply chain teams would work diligently to buy more when prices are low and less when prices are high. Figure 4 suggests that this occurred. To further evaluate this, we performed a nonregression-based analysis that directly compares the annual aggregated costs on all products purchased from the wholesaler and from Civica (Figure 5).

Using this method, Civica products were still 2.7% lower in cost than the volume-weighted average annual wholesaler price during the period when both Civica and the wholesaler were delivering the products. This indicates that SSM Health optimized its orders by buying more volume when costs were low, which reduced the overall cost advantage of Civica to only 2.7% in total. It is noteworthy, however, that sourcing from a total of 62 non-Civica suppliers did not enable SSM Health's ordering teams to beat the Civica price on average. Furthermore, the purchasing costs alone did not include the time, effort, and opportunity costs of this order optimization process, which can be material at times during shortages.

Each health system also has a different internal cost structure. Therefore, results could vary between health systems on the basis of their specific product mix, cost, and rebate structures, and replicating similar studies across multiple other health systems is encouraged."

Collectively, the empirical results from the access and cost analyses show that by partnering with Civica, SSM Health achieved (1) favorable product stability above the wholesaler model, achieving an order fulfillment rate of 96% from Civica versus 86% from the wholesaler model, and (2) an aggregated additional product access beyond their expected MVV contract of 43% — at an overall lower product cost of 2.7%.

Discussion

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In terms of access improvement, for the hospital-based critical medicines studied, initial data suggest that the Civica model is superior to the wholesaler model with respect to well-understood

FIGURE 5

Total Cost per Unit over Time

Since Civica began supplying medicines to its members in 2020, the total cost per unit for 20 products purchased at SSM Health has remained stable, ranging between 18 and 19 cents. The unit price paid by SSM Health for the wholesaler products over the study period has varied, with a much wider range of minimum and maximum prices as can be seen by the dashed lines; the volume-weighted average wholesaler price trend decreased over time so that, in 2021 and 2022, it aligned closely with the Civica prices.



Product Cost per Unit over Time

Source: The authors NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

and commodifized products. Chronic drug shortages have been an extremely challenging problem and elusive to sustainable improvement in the past. This makes these early results highly promising.

Related to cost improvement, it is common in the health care industry for busy hospital pharmacy and supply chain teams at times to hyperfocus on the real-time spot prices of singular drugs, continuously iterating their purchasing patterns to try to optimize their cost structures on a drug-by-drug basis. This study indicates that this narrowly focused approach could be missing the bigger picture — if not contributing to the problem of instability itself. Of the drugs studied, there were multiple instances when the Civica price exceeded the lowest spot price. However, as shown, on the basis of volume-weighted averages, Civica's prices tracked below the average market prices compared with wholesalers; also, when examining price fluctuations as a

proportion of wholesale purchases across numerous different orders, Civica's prices were determined to be statistically lower than the wholesale prices. What the empirical data strongly indicate is that it is not about comparing Civica's prices with the spot market on a given day but rather, with the longitudinal total mix of prices over time, accounting for longer-term stability and robustness of the supply.

These findings could have material implications for multiple operational considerations. In terms of pharmacy and/or supply chain management, it is very common for pharmacy teams to be rewarded or penalized on the basis of the direct annual financial performance of their single departmental budget in a single year, and accountability of the overall stability of the supply chain is summarily determined to be beyond their scope and becomes "someone else's problem." Such a system frequently perpetuates the status quo. By focusing on broader systemic access- and stability-related problems, the need for more novel solutions becomes more apparent. When those access problems are determined to be oligopolistic in nature on well-established products or services beyond the reach of any single organization, a disruptive collaboration approach¹⁶ — which involves a large number of incumbent firms collaborating to collectively disrupt an entire subindustry — could be warranted and can be facilitated through the HCU model.

Limitations

Despite the favorable results, Civica's model is not shortage proof. If a drug shortage is acute enough for long enough, although Civica's model could provide intermediate relief, it would not be able to meet the entire market demand, nor could it continue to meet its members' needs once its safety stock was depleted.

Additionally, although the pricing and terms contained in an MVV contract between a health system and Civica are the same for all members, the contracts themselves are product specific. This allows each health system to have different pharmaceutical protocols and use patterns. Each health system also has a different internal cost structure. Therefore, results could vary between health systems on the basis of their specific product mix, cost, and rebate structures, and replicating similar studies across multiple other health systems is encouraged. Regarding rebates, for the types of long-standing, low-cost generic drugs, like the ones evaluated in this study, rebates are minimal. To test this assumption, a rebate and administration fee analysis was conducted by the SSM Health pharmacy team on the drugs in question, indicating that rebates and administration fees on these drugs would not be expected to be more than 1%–2% in aggregate.

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The innovation was structural — enabled by a business model that allowed institutional players who faced a common problem caused by a market failure to collaboratively disrupt the supply chain by injecting a new type of supplier into the market." There are also multiple potentially beneficial factors not included in the estimated Civica-related benefits: (1) reduced administrative costs from internal health system pharmacy staff now managing fewer acute drug shortages, (2) anticipated future lower Civica drug costs associated with the opening of its dedicated production facility,^{17,18} (3) increased high-quality product on the basis of only sourcing from reputable sources predominantly in North America and Europe, and (4) positive market externalities (halo effects) from Civica entering the market. Related to this last point, in March 2022, Civica announced plans to produce a new low-cost insulin for a price of \$30 per vial that represented a price reduction of 90% relative to the average wholesale price of reference products.¹⁹ A year later, on the basis of the combination of both governmental and private-sector pressures — including direct competition from Civica — the three largest manufacturers of insulin reduced their prices on several insulin products by over 70%.²⁰ This data point illustrates the potential of Civica's HCU model to vaccinate health care supply chains against market failures — not only through Civica operations directly, but also from the added value of increased and sustainable competition in the market more broadly.

Whether or not we could see similar effects on other pharmaceutical products or other services over time is still to be determined; quantifying and attributing such externalities are highly complex. However, Civica has begun to credibly establish itself as a new player in the pharmaceutical industry. It is different from other traditional models and appears to be working for generic pharmaceuticals. Further defining the boundary conditions more specifically of where and/or how this approach could be applied, or not, is an important strategic question for future research.

Looking Ahead

The HCU model that Civica is based on is a new concept in health care, but its effects are growing rapidly. In the case of Civica, its medicines have already been used to help more than 50 million people. Additionally, CivicaScript, a Civica subsidiary company that focuses on retail generic medicines, has partnered with health insurance companies that cover more than 140 million Americans to lower the costs on high-cost specialty medications. CivicaScript's first product, abiraterone (a drug used to treat metastatic prostate cancer), expects to save some patients nearly \$3,000 a month.²¹

The problems we face in health care are daunting, but many of them are solvable with the right approach. In learning from Civica's experience, some of the most fundamental answers may already be at our fingertips. Civica's success did not come from a technological or scientific breakthrough. Its products were decades-old generic drugs — commodities. The innovation was structural — enabled by a business model that allowed institutional players who faced a common problem caused by a market failure to collaboratively disrupt the supply chain by injecting a new type of supplier into the market. This article provides the first empirical evidence that this approach is working.

Carter Dredge, MHA

Senior Vice President and Lead Futurist, SSM Health, St. Louis, Missouri, USA

Cofounder, Healthcare Utility Initiative, Judge Business School, Cambridge University, Cambridge, United Kingdom

Stefan Scholtes, PhD

Dennis Gillings Professor of Health Management, Judge Business School, Cambridge University, Cambridge, United Kingdom

Director of the Centre for Health Leadership & Enterprise, Judge Business School, Cambridge University, Cambridge, United Kingdom

Appendix

Name and Definition of Critical Dataset Variables

Disclosures: Carter Dredge serves on the boards of Civica Rx, CivicaScript, and Graphite Health. He receives no financial compensation for doing so. Stefan Scholtes has nothing to disclose.

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Catalyst Innovations in Care Delivery

CASE STUDY

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

Natalia Macrynikola, PhD, Nicolas Nguyen, MD, Erlend Lane, MPA, Shirley Yen, PhD, John Torous, MD, MBI Vol. 4 No. 9 | September 2023

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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.

KEY TAKEAWAYS_

- » 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.¹ 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.^{2,3} 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.⁴ 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.⁵⁻⁷

As the acuity of mental health crises increases, evidenced by the rising rates of suicide deaths,⁸ 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.⁹ 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.¹⁰⁻¹²

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.¹³ In March 2023, the Federal Trade Commission fined one digital mental health company nearly \$8 million for patient privacy violations.¹⁴ 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.¹⁵ 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,¹⁶

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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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."

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 care¹⁷ and transdiagnostic treatment approaches¹⁸ 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.¹⁹ Given that the majority of mental health needs are first identified by primary care and treated by primary care clinicians,^{20,21} 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 model²² 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.²³ 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;²⁴ 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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The benefits of human rapport, the therapeutic alliance, 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."

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 Disorders²⁵ (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 disorders²⁵ 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.

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 devices²⁷ — 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,²⁸ 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.²⁹ 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

Source: The authors

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;²⁹ 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

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 Data³⁰

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

FIGURE 2

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/depression.



Source: The authors NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society (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 (o-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 (o-4), mild (5-9), moderate (10-14), and severe (15-21).

"

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.³¹ 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%.³² 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.

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,²⁹ 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 Presented					
1	As a result of these sessions I a	m clearer as to how I might be ab	le to change.		
2	What I am doing in therapy give	What I am doing in therapy gives me new ways of looking at my problem.			
3	I believe my therapist likes me.				
4	My therapist and I collaborate on setting goals for my therapy.				
5	My therapist and I respect each other.				
6	My therapist and I are working toward mutually agreed upon goals.				
7	I feel that my therapist apprecia	tes me.			
8	My therapist and I agree on what	at is important for me to work on.			
9	I feel my therapist cares about r	ne even when I do things that the	v do not approve of.		
10	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 established a good understanding of the kind of changes that would be good for me.				
12	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

Natalia Macrynikola, PhD

Postdoctoral Research Fellow, Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA

Nicolas Nguyen, MD

Associate Chief Medical Officer Primary Care, Beth Israel Lahey Health, Brookline, Massachusetts, USA

Clinical Instructor in Medicine, Harvard Medical School, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts, USA

Erlend Lane, MPA

Clinical Research Assistant, Division of Digital Psychiatry, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA

Research Assistant, Harvard University, Cambridge, Massachusetts, USA

Shirley Yen, PhD

Associate Professor, Harvard Medical School, Boston, Massachusetts, USA

Director of Psychology Training, Massachusetts Mental Health Center, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA

John Torous, MD, MBI

Director, Digital Psychiatry Division, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA

Assistant Professor, Harvard Medical School, Boston, Massachusetts, USA

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Innovations in Care Delivery

INSIGHTS INTERVIEW

Addiction Medicine Clinician Shortages Require Innovative Treatment Approaches

Jonathan Bees Vol. 4 No. 8 | July 19, 2023 DOI: 10.1056/CAT.23.0217

Interviews from NEJM Catalyst Insights Council members on the challenges to addiction medicine and substance use disorder treatment.

Substance use disorder (SUD) is a serious problem throughout the world, say members of the NEJM Catalyst Insights Council. In an <u>April 2023 survey</u> of the Insights Council — composed of clinicians, clinical leaders, and executives at organizations around the world that are directly involved in care delivery — 82% of respondents report that addiction medicine specialist shortages are a moderate or serious problem within their organization (Figure 1), and nearly three-quarters (74%) say addiction medicine services within their community are not very sufficient or not at all sufficient to meet the needs of the patient population (Figure 2).

FIGURE 1 Addiction Medicine Specialist Shortages Are Problematic

How much of a problem are addiction medicine specialist shortages within your organization?



Statistically significant differences are noted in orange

Base: Global – 804; U.S. only – 464; Outside U.S. – 340 (may not total 100 due to rounding) NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

FIGURE 2

Addiction Medicine Services Largely Fall Short of Patient Needs

How sufficient are addiction medicine services (including addiction psychiatry) within your community to meet the needs of the patient population?



Statistically significant differences are noted in orange

Base: Global – 804; U.S. only – 464; Outside U.S. – 340 (may not total 100 due to rounding) NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Nalan Ward, MD, is board-certified in Adult and Addiction Psychiatry and is Chief Medical Officer of Beth Israel Lahey Health Behavioral Services in Massachusetts. She says that current shortages in addiction medicine specialists mean that health care providers of all types will have to play a bigger role in providing addiction care.

"Responsibility to care for patients with SUD typically falls on primary care and psychiatry," she says. "However, we're experiencing a workforce shortage crisis in health care right now and the overdose death rates are at their highest level. I think this responsibility needs to belong to all physicians. It is more important than ever that physicians screen patients for substance abuse and initiate treatment or refer them to other resources in the community." As an example of access challenges, Ward mentions opioid use disorder (OUD) treatment using methadone. "Methadone by itself is a very effective medication and has its advantages, but access can be very challenging in practice. Methadone treatment is provided under strict federal regulations, and historically its use has been very stigmatized. In many states, patients have to jump through hoops to get into a methadone clinic because there simply aren't enough of them. Patients also have to dose every day by physically going to the clinic, making it very inconvenient in a lot of ways. Relaxing some of the regulations would go a long way toward improving access."

Despite the current challenges to addiction medicine, Ward sees some signs of improvement. "There are a number of different initiatives in Massachusetts right now to increase the number of providers with training, including increases in residency slots and adding more addiction medicine programs for primary care providers. Over the past 10 years, medical school curricula have placed a greater emphasis on addiction training, and recent graduates are far better trained than previously."

Umberto Nizzoli, PhD, MPH, MCA, FAED, is a clinical psychologist, President of European Chapter of the Academy for Eating Disorders, and Professor at the University of Rome. He is also past President of the Italian Society for the Study of Eating Disorders (SISDCA), and former Director of the Mental Health and Addiction Program at the Local Health Authority of Reggio Emilia and former head of its Drug Abuse Unit. He says addiction medicine services are mostly sufficient in Italy.

"Italy's National Health Service (Servizio Sanitario Nazionale) is actually fairly decentralized and health care is delivered through 20 independent regions," he says. "While addiction services are generally good across the country there can be big differences between the regions, and the level of services can also vary depending on the substance being abused. For example, services for patients using psychostimulants can be very different between regions."

Nizzoli says opioid addiction is a serious problem in Italy, although regulations for methadone treatment are less strict than in the United States and patient access is better. "It can be prescribed freely through substance abuse rehabilitation organizations such as SerD (Servizio per le Dipendenze), which has over 560 facilities across the country. Because of this approach, patients are less stigmatized when using methadone and have a better chance of recovery."

Methadone is a controversial topic in Italy, he says. "There are competing views on methadone as a treatment. When drug treatment programs were first created here over 40 years ago, they were mainly driven by the Catholic Church, which was against its use. Today, there are many people who support methadone use, including many health care professionals, and every region supports its use to varying degrees."

Italy lacks an addiction medicine specialist certification, Nizzoli says. "Addiction medicine is not a formal specialization in Italy, and it's not a requirement in order to work at a substance use disorder unit. Typically, you need to have a degree in medicine or psychology and some training on addiction. But the challenge has been deciding who owns the practice. Is it internal medicine,

psychiatry, pharmacology, or toxicology? Because we've had difficulty reconciling these different disciplines, we haven't been able to create a specific specialization."

A.J. Reid Finlayson, MD, FASAM, is Professor of Clinical Psychiatry and Behavioral Sciences at Vanderbilt University Medical Center in Nashville, Tennessee, and Director of the Vanderbilt Comprehensive Assessment Program. He says that medical students are increasingly receiving addiction medicine training, but much more is needed.

"Students get some exposure to addiction medicine, but certainly not commensurate with the extent of the problem," says Finlayson. "This is especially true when you consider the substantial range of health impacts, including morbidity caused by tobacco, alcohol, opioids, and methamphetamine. At Vanderbilt, medical students are exposed to inpatient as well as outpatient addiction treatment, but we need to do more."

Along with specialist shortages, Finlayson says patients face problems with continuity of care. In fact, 69% of respondents in the NEJM Catalyst survey report that care transitions are not very sufficient or not at all sufficient for patients with addiction at their organization.

"A continuum of addiction management — like cancer management — systematically organized from diagnosis to satisfactory stabilization and recovery monitoring would help. Addiction care is fragmented in emergency rooms, psychiatric and detox units, and residential treatment facilities."

Finlayson says harm reduction initiatives suffer from similar drawbacks. "Harm reduction programs are insufficient without also providing an integrated system of care. Offering people syringes and safe injection sites and then standing by with naloxone appears to legitimize dangerously unsafe drug use. While it helps keep them alive, it needs to be paired with treatment."

Finlayson suggests that <u>Recovery Courts</u> and <u>Physician Health Programs</u> use coercion effectively and produce recovery outcomes far superior to treatment as usual. "Often drug victims have been resuscitated repeatedly prior to their fatal overdose. This indicates that involuntary commitment, which is legal but underutilized in many states, might be employed to initiate treatment."

Jonathan Bees

Contributing Writer, NEJM Catalyst

Disclosures: Jonathan Bees has nothing to disclose.



COMMENTARY

The Whole Health Index: A Practical, Valid, and Reliable Tool to Measure Whole-Person Health and Manage Population Health

Winnie C. Chi, PhD, MS, J. Marc Overhage, MD, PhD, Todd Sponholtz, PhD, MPH, Binh T. Nguyen, PhD, Peter Brady, MBA, April Falconi, PhD, MPH, MA, Martha Johnson, PhD, Amanda Price, MPH, Cory Silver, MPH, Kevin Bowman, MD, MPH, MBA, Samuel Simon, PhD, MA, Dmitriy Poznyak, PhD, Anita Somplasky, RN CHTS-CP, CHTS-PW, Shantanu Agrawal, MD, MPhil

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The Whole Health Index, developed by Elevance Health, is intended to serve its members but also to serve as a tool for others. The index combines multiple data sources and measure types, including publicly available and individual-level clinical and social data, claims data, and process and outcome measures designed to establish a valid and reliable measure of whole-person health that is useful not only for measuring and tracking health, but also for guiding actions to improve health both at individual and population levels.

Establishing a measure that holistically assesses health is foundational to improving not only health, but also health equity. Considering that health and its determinants are multidimensional, we think that an adequate measure of *whole-person health* (i.e., looking at the whole person — not just discrete components of the body)¹ should be (a) inclusive of social, clinical, behavioral, and physical factors, (b) valid and reliable, (c) systematically computable for a majority of individuals in a population, (d) sensitive in distinguishing differences in health status among individuals, even those without disease, and (e) available promptly.

Most measures and risk scores in population health management rely on diagnoses captured from administrative claims, such as the Charlson comorbidity index,²⁻⁴ the Elixhauser comorbidity index,⁵ and the Centers for Medicare & Medicaid's Diagnostic Cost Group Hierarchical Condition

Category.⁶ However, these measures don't differentiate health among those lacking access to health care. Other commonly used measures for comparing health across countries are based on mortality data, such as life expectancy, or disability-adjusted life years (DALY). However, those measures typically are not computable at the individual level, although recently there has been an effort to apply the DALY methods to individual members.⁷ Self-reported measures of health are valuable indicators of the individual's perception of their health. However, such indicators are costly to measure and may be subject to reporting bias and limited comparability. Another group of indices focuses exclusively on social factors, such as the University of Wisconsin's Area Deprivation Index (ADI) and the Centers for Disease Control and Prevention's Social Vulnerability Index (SVI).⁸⁻¹⁰ To the best of our knowledge, no index combines a comprehensive list of area-level and individual-level social and clinical risk factors, representing key determinants of health.

Elevance Health's approach to health begins by redefining health, reimagining the system, and strengthening our communities. As part of our efforts to redefine health, we sought to develop a single composite score that holistically measures an individual's health among the general population that we refer to as the *Whole Health Index*, starting in 2021. We adopted the National Academy of Medicine's Vital Signs framework to inform the domain and indicator selection for the Whole Health Index.¹¹ Additionally, we convened an expert panel consisting of clinicians, subject matters experts in clinical quality and social determinants of health, and population health researchers. The choice for domains and indicators was based on multiple considerations including (a) significance to health, (b) validity, (c) availability at large scale, (d) applicability to the broader population, and (e) timeliness. The result of this thought process is a numeric measure of health that can be used to track health longitudinally and to compare health across populations to inform meaningful action to improve health and health equity at both the individual and population level.

Methods

Data Sources

In November 2022, we combined Elevance Health enrollment and claims with publicly available data as the basis to compute the Whole Health Index for the 44.8 million Elevance Health members who had at least 1 day of medical plan eligibility from July 1, 2021, to June 30, 2022. These individuals were covered by multiple insurance types, including commercial plans, Medicaid, Medicare Advantage, and other supplemental health care plans. Global Health and Clinical Quality measures were drawn from enrollment and claims data. The Social Driver domain included individual-level and area-level measures for assessing social needs, including Z Codes from the International Classification of Diseases, Tenth Revision (ICD-10), Logical Observation Identifiers Names and Codes (LOINC), Census tract–level measures from the 2016–2020 5-year American Community Survey and the Environmental Protection Agency, and county-level measures from the 2021 County Health Rankings & Roadmaps.¹²⁻¹⁶ Health care affordability was calculated as total out-of-pocket spending (the sum of co-pay, coinsurance, and deductible amounts during the measurement period as recorded on claims data) divided by median household income at the census-tract level from the 2020 5-year American Community Survey.

C The Whole Health Index combines multiple data sources and measure types, including publicly available data, claims data, and process and outcome measures, at individual and area levels."

This study, conducted under the Research Exception provisions of Privacy Rule 45 CFR 164.514(e), was exempt from Institutional Board Review because researchers accessed a limited data set for analysis of the managed care organization's membership data for the purposes of health plan treatment, planning, and operations, was devoid of individual patient identifiers, and complied with all relevant provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Whole Health Index Scoring Method

We conceptualized the Whole Health Index as a formative composite measure in which three domains — Global Health, Clinical Quality, and Social Drivers — are intended to capture different conceptual aspects of whole-person health (Figure 1).



42

FIGURE 1

Whole Health Index: Three Domains of Whole-Person Health

The Whole Health Index score is calculated as the weighted sum (based on impact on wellbeing) of the three domain scores: Global Health, Clinical Quality, and Social Drivers. The Global Health domain score was calculated as the percentile ranking of Elevance Health members according to the DxCG score distribution, with higher percentiles indicating lower DxCG scores and better health. The Clinical Quality domain was based on 63 clinical quality process or outcome measures grouped into the six subdomains shown. The Social Drivers subdomain scores were calculated by combining individual and area-level data with equal weights (or solely area-level if individual data was not available).



Source: The authors NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Each domain comprises an array of indicators (Table 1, Table 2).

The three domains of the Whole Health Index were weighted as follows: Social Drivers, 50%; Global Health, 30%; Clinical Quality, 20% as informed by the National Academy of Medicine's Vital Signs framework.¹¹ The Whole Health Index score was calculated as the weighted sum of the three domain scores. The Whole Health Index was assessed by the Elevance Heath development team in partnership with a Mathematica Policy Research team for criterion validity, convergent validity, discriminant validity, and reliability. Assessment demonstrates that the Whole Health Index is a valid measure of whole-person health at both the individual level and several levels of geography, including at census tract-, 5-digit zip code-, and county-levels (Appendix).

The Global Health domain is designed to measure disease burden an individual experienced during the measurement period. We used the DxCG concurrent risk score (Cotiviti: South Jordan, Utah) as a summary measure. The DxCG concurrent risk score was developed to predict total health

Table 1. Elements	Included in Social	Driver Domain
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Individual-level	Neighborhood-level
Financial strain	
Z59.6: Low income or poverty	% Below Poverty
Z56.0-Z56.9: problems related to employment and unemployment	% Unemployed
	% No high school diploma
	Per-capita income
Neighborhood composition	
	% speaks English "less than well"
	% minority
	Residential segregation: nonwhite/white
Housing instability	
Z59.0: Homelessness	% multi-unit structures
Z59.1: Inadequate housing	% mobile homes
Z59.81: Housing instability	% group quarters
Z59.89: Other problems related to housing	% crowding
	% vacant housing units
Transportation barriers	
	% no vehicle
	EPA Walkability Index
Food insecurity	
LOINC: 87303-4 (Participant in WIC)	% population who lack adequate access to food
LOINC 88122-7: Worried about running out of food	% population living in a food desert
LOINC: 88123-5: Food didn't last	% of households in receipt of food stamps/SNAP
LOINC: 93031-3: Unable to get food	
LOINC: 9521-5: Ate less food because there wasn't enough money	
Z58.6, Z59, Z59.4: Lack of adequate food and safe drinking water	
Health care affordability	
Sum of co-pay, coinsurance, and deductible amount in the measurement period divided by median household income within home Census tract	

Notes: EPA = U.S. Environmental Protection Agency; WIC = Women, Infants, and Children; SNAP = Supplemental Nutrition Assistance Program. Source: The authors

care costs, including plan paid and patient paid amount, based upon demographic and clinical information reported in medical claims in a 12-month period.^{17,18} Higher scores indicate higher predicted total health care cost. We expect the total health care cost represents overall health care utilization more comprehensively, thus is a better proxy for disease burden, as opposed to plan paid cost. We are exploring exchanging DxCG with another disease burden measure in public domains. The Global Health domain score was calculated as the percentile ranking of Elevance Health members according to the DxCG score distribution in calendar year 2021 (as baseline year for benchmarking), with higher percentiles indicating lower DxCG scores and better health.

The Social Driver domain is constructed as the weighted summation of six subdomains: (1) financial strain, (2) health care affordability, (3) food insecurity, (4) transportation barriers, (5) housing insecurity, and (6) neighborhood composition. The subdomain scores were calculated by combining individual and area-level data with equal weights (50% and 50%). In the case where individuals did not have individual-level social driver data, the subdomain scores relied on area-level data alone. The Social Driver score was calculated by summing the percentiles of each subdomain multiplied by a weighting factor (Figure 1). Table 1 lists all the data elements included in the Social Driver domain.

C			Desitive (Nega			
domain			tive Indicators	Individual		
Level 1	Sub-domain Level 2	Measure Name	of Health	Weighting	Process	Outcome
Group 1	Access	Adults' Access to Preventive/Ambulatory Health Services (AAP)	¢	0.7143	x	
Group 1	Access	Annual Dental Visit (ADV) (NQF 1388)	↑	0.7143	x	
Group 1	Prevention/Screening	Chlamydia Screening in Women (CHL) (NQF 0033)	¢	0.7143	x	
Group 1	Prevention/Screening	Immunization for Adolescents - Combo 2 (IMA) (NOF 1407)	↑	0.7143	x	
Group 1	Prevention/Screening	Lead Screening in Children (LSC)	↑	0.7143	x	
Group 1	Prevention/Screening	Preventive - Breast Cancer Screening (BCS) (NQF 2372)	1	0.7143	x	
Group 1	Prevention/Screening	Preventive - Cervical Cancer Screening (CCS) (NQF 0032)	1	0.7143	x	
Group 1	Prevention/Screening	Preventive - Child and Adolescent Well- Care Visits (WCV)	Ť	0.7143	x	
Group 1	Prevention/Screening	Preventive - Childhood Immunization Status (CIS) (NQF 0038)	Ť	0.7143	х	
Group 1	Prevention/Screening	Preventive - Colorectal Cancer Screening	Ť	0.7143	x	
Group 1	Prevention/Screening	Preventive - Flu Vaccinations (NOF 0039)	<u>↑</u>	0.7143	x	
Group 1	Prevention/Screening	Preventive - Well-Child Visits in the First 15 Months of Life (W15)	↑	0.7143	x	
Group 1	Prevention/Screening	Weight Assessment and Counseling for Nutrition and Physical Activity for Chil- dren/Adolescents (WCC) (NOF 0024)	Ť	0.7143	x	
Group 1	Prevention/Screening	Well-Child Visits in the First 30 Months of Life - W30 (15-30 months) (2+ visits)	ŕ	0.7143	х	
Group 2	Acute	ACSC - PQI-12 Urinary Tract Infection Admission Rate	Ļ	-2.5		x
Group 2	Acute	Hospital Visits after Hospital Outpatient Surgery (NQF 2687)	t	-2.5		x
Group 2	Acute	Plan All-Cause Readmissions (PCR) (NQF 1768)	t	-2.5		x
Group 2	Care Coordination	Care for Older Adults (COA) - Medication Review (NQF 0553)	¢	0.8333	x	
Group 2	Care Coordination	Follow-Up After Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (FMC)	¢	0.8333	x	
Group 2	Care Coordination	Transitions of Care - Medication Reconcili- ation Post-Discharge (TRC)	Ť	0.8333	х	
					,	
Group 3	Overuse/Appropriate- ness	CC2_HEDIS_Opioid Use High Dosage_ HDO22 (HDO) (42730)	Ļ	-1.4286	x	
Group 3	Overuse/Appropriate- ness	Risk of Continued Opioid Use - 30 days (COU)	t	-1.4286	х	
Group 3	Overuse/Appropriate- ness	Use of High-Risk Medications in the Elder- ly (DAE) (NQF 0022)	Ļ	-1.4286	x	
Group 3	Overuse/Appropriate- ness	Use of Imaging Studies for Low Back Pain (LBP)	¢	1.4286	x	
Group 3	Overuse/Appropriate- ness	Use of Opioids from Multiple Prescribers and Pharmacies (UOP) - (Multi prescriber and Multi pharmacy)	Ļ	-1.4286	x	
Group 3	Safety	PSI-05 Retained Surgical Item or Unre- trieved Device Fragment Count	ţ	-4.2857		x
Group 3	Safety	PSI-07 Central Venous Catheter-Related Blood Stream Infection Rate	t	-4.2857		x
Group 3	Safety	PSI-08 In Hospital Fall with Hip Fracture Rate	Ļ	-4.2857		x

Table 2. Measure Weights in the Clinical Quality Domain

Sub- domain Level 1	Sub-domain Level 2	Measure Name	Positive/Nega- tive Indicators of Health	Individual Weighting	Process	Outcome
	1				r	,
Group 4	Cardiovascular	ACSC - PQI-07 Hypertension Admission Rate	Ļ	-2.5532		x
Group 4	Cardiovascular	ACSC - PQI-08 Heart Failure Admission Rate	Ļ	-2.5532		x
Group 4	Cardiovascular	Cardiovascular - Controlling High Blood Pressure (CPB)	¢	2.5532		x
Group 4	Cardiovascular	Cardiovascular - Statin Therapy for Pa- tients with Cardiovascular Disease (SPC) (Received)	¢	0.8511	x	
Group 4	Cardiovascular	Medication Adherence for Cholesterol (Statins) (NQF 0541)	¢	0.8511	x	
Group 4	Cardiovascular	Medication Adherence for Hypertension (RAS antagonists) (NOF 0541)	Ť	0.8511	x	
Group 4	Diabetes	ACSC - PQI-01 Diabetes Short-Term Com- plications Admission Rate	Ļ	-2.5532		x
Group 4	Diabetes	ACSC - PQI-03 Diabetes Long-Term Com- plications Admission Rate	Ļ	-2.5532		x
Group 4	Diabetes	ACSC - PQI-14 Uncontrolled Diabetes	Ļ	-2.5532		x
Group 4	Diabetes	ACSC - PQI-16 Lower-Extremity Amputa-	Ļ	-2.5532		x
Group 4	Diabetes	Diabetes - Comprehensive Diabetes Care	↑	2.5532		x
Group 4	Diabetes	Diabetes - Comprehensive Diabetes Care	↑	0.8511	x	
Group 4	Diabetes	Diabetes - Kidney Health Evaluation for	↑	0.8511	x	
Group 4	Diabetes	Patients with Diabetes (KED)				
Group 4	Diabetes	Diabetes (SPD) (Received)	↑ (0.8511	x	
Group 4	Diabetes	cations (NQF 0541)	1	0.8511	x	
Group 4	Oncology	30-Day Unplanned Readmissions for Can- cer Patients (NQF 3188)	Ļ	-2.5532		x
Group 4	Oncology	Oncology - Admission and Emergency De- partment (ED) Visits for Patients Receiving Outpatient Chemotherapy (NQF 3490)	Ļ	-2.5532		x
Group 4	Respiratory	ACSC - PQI-05 Chronic Obstructive Pulmo- nary Disease (COPD) or Asthma in Older Adults Admission Rate	t	-2.5532		x
Group 4	Respiratory	ACSC - PQI-11 Community-Acquired Pneu- monia Admission Rate	t	-2.5532		x
Group 4	Respiratory	Asthma Medication Ratio (AMR) (NQF 1800)	¢	0.8511	x	
Group 4	Respiratory	PQI-15 Asthma in Younger Adults Admis- sion Rate	t	-2.5532		x
						,
Group 5	Behavioral Health	Antidepressant Medication Management (AMM) - 12 Weeks (NQF 0105)	Ť	1.25	х	
Group 5	Behavioral Health	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (NQF 3175)	¢	1.25	x	
Group 5	Behavioral Health	Follow-Up after Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA) - 7 days (NQF 3488)	¢	1.25	x	
Group 5	Behavioral Health	Follow-Up after Emergency Department Visit for Mental Illness (FUM) - 7 days (NQF 3489)	1	1.25	x	
Group 5	Behavioral Health	Follow-Up After Hospitalization for Mental Illness (FUH) - 7 days (NOF 0576)	¢	1.25	х	
Group 5	Behavioral Health	Follow-Up Care for Children Prescribed ADHD Medication - 30 day (ADD)	Ť	1.25	x	

Sub- domain Level 1	Sub-domain Level 2	Measure Name	Positive/Nega- tive Indicators of Health	Individual Weighting	Process	Outcome
Group 5	Behavioral Health	Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treat- ment (IET) - 14 days (NQF 0004)	¢	1.25	x	
Group 5	Behavioral Health	Metabolic Monitoring for Children/Ado- lescents on Antipsychotics (APM) (NQF 2800)	1	1.25	х	
Group 6	Women's Health	Maternal - C-Section rate	Ļ	-2.5		х
Group 6	Women's Health	Maternal - Preterm birth	Ļ	-2.5		х
Group 6	Women's Health	Maternal - Severe Maternal Morbidity (SMM)	t	-2.5		x
Group 6	Women's Health	Osteoporosis Testing and Management in Older Women (OMW) (NQF 0037)	Ť	0.83	х	
Group 6	Women's Health	Prenatal and <i>Postpartum</i> Care (PPC)	1	0.83	х	
Group 6	Women's Health	Prenatal and Postpartum Care (PPC)	↑	0.83	х	

Source: The authors

We expect the total health care cost represents overall health care utilization more comprehensively, thus is a better proxy for disease burden, as opposed to plan paid cost."

The Clinical Quality domain was based on 63 clinical quality factors grouped into six subdomains: (1) access to care, prevention, and screening; (2) acute care and care coordination; (3) overuse, appropriateness, and safety; (4) cardiovascular conditions, diabetes, oncology, and respiratory conditions; (5) behavioral health; and (6) women's health. Subdomains were weighted such that those with more measures and more direct impact on well-being were given higher weights. Measures within each subdomain were identified as *process* or *outcome* measures, and a 1:3 process-to-outcome ratio was used to weight outcome measures more heavily. Table 2 lists the weighting for each quality measure. Individuals are only scored for the measures that they are qualified for. If an individual qualified for the denominator of a given measure and met the criteria for the numerator, they were given a weight specific to that measure. For example, if an individual is qualified for colorectal cancer screening and is compliant with the screening, then an individual would receive positive points of the measure weight (0.7143); however, if not compliant, an individual would receive negative points of the measure weight (-0.7143).

Results

The Whole Health Index has a theoretical range from 0 (worst health) to 100 (best health). In a sample of the nearly 45 million Elevance Health members, it ranged from 9.17 to 90.75 with an average of 53.08 and a median of 53.23 (IQR: 43.34, 62.95) with a standard deviation of 13.86 and an approximately bell-shaped distribution (Figure 2).

FIGURE 2

Elevance Health Members: Whole Health Index (2021 Baseline)

The Whole Health Index theoretically ranges from 0-100, (worst to best health). This figure represents the status of Elevance Health members, based on a sample of all 45 million members from the 12 months period (07/01/2021- 06/30/2022). The scores range from 9.17 to 90.75 with an average of 53.08 and a median of 53.23 (IQR: 43.34, 62.95) with a standard deviation of 13.86. Based on the probability vertical axis, the highest point shown (between 0.025 and 0.03) would represent about 27 in 1,000.



Source: The authors NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Figure 3 shows the average Whole Health Index of Elevance Health members by county in each of the 50 United States. We observed lower scores among states in the South region compared to states in the New England region.



FIGURE 3

Average County Whole Health Index: United States

The variation of health is evident in this map which displays the Whole Health Index based on county of residence among Elevance Health members. In addition to variation within individual states, the nation's southern states generally have lower index scores.



Key: Darkest red indicates lowest scores, darkest green indicates highest scores; gray indicates insufficient data due to fewer than 30 members; white indicates the mid-point between red and green shades.

Source: The authors

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We also observed that the Whole Health Index enabled us to identify counties associated with poor health outcomes. For example, Marion County, where Indianapolis, Indiana, is located, has a lower-than-average Whole Health Index score, whereas the adjacent counties of Boone (northwest) and Hamilton (north), have higher-than-the average Whole Health Index scores. These findings are consistent with results from the 2020 County Health Ranking report.¹⁵ The Whole Health Index has a moderate-to-strong correlation (0.64-0.81) with other known health indicators at county level (Figure 4).

FIGURE 4 Criterion Validity Assessment Results for the Whole Health Index

This figure shows Pearson correlation between the Whole Health Index and indicators that are commonly used in tracking population health. The Whole Health Index has positive correlation with indicators of good health (e.g., life expectancy) and negative correlation with indicators of bad health (e.g., mental distress). The correlation magnitude is between 0.6 and 0.8, which are considered moderate to strong correlation.



Source: The authors

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We observed that relatively socially vulnerable population subgroups — including older adults, women, those dually eligible for Medicare and Medicaid, rural residents, and Black, Hispanic, or Native American residents — have lower Whole Health Index scores. Individuals with more conditions have lower Whole Health Index scores compared to individuals with fewer conditions. Individuals with lower-acuity and more manageable conditions — such as diabetes, dyslipidemia, and depression — have higher Whole Health Index compared to individuals with the higher-acuity and less manageable conditions of COPD, lung cancer, stroke, chronic kidney disease, and heart failure.

Discussion

The development of the Whole Health Index represents a shift in how we view and measure health. It provides a comprehensive picture of whole-person health, combining 93 measures that are representative of social, physical, and behavioral factors of health, aligning with the World Health Organization's definition of health.¹⁹ The Whole Health Index is a practical tool for population health management, as it provides a numeric objective and comprehensive measure of population health at different geographic levels and by various population segments.

There is greater awareness among stakeholders in the health care ecosystem that we need to address social, physical, and clinical factors holistically to improve population health effectively. The first step in doing so is to measure whole-person health accurately, because we cannot improve what we do not measure. Several health plans and affiliated entities have published metrics publicly to report population health, yet the population health metrics reported are very different. Some collect self-reported metrics, such as the Centers for Disease Control and Prevention's Healthy Days Measures^{20,21} or self-perceived control of life.²² Others relied on administrative claims to report measures similar to disability adjusted life years.⁷ Some summarized publicly available population health metrics into a single score.²³ In addition to health plans, some provider groups have also developed measures incorporating social drivers of health to guide clinical decision-making.

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The Whole Health Index functions to triage members to the right solutions for their specific health and social needs."

Despite similarity in measure names, these measures appear to be quite different in terms of the exact concept being measured and elements included in the measures. In comparison, the Whole Health Index combines multiple data sources and measure types, including publicly available data, claims data, and process and outcome measures, at individual and area levels, aiming at creating a valid and reliable measure of whole-person health that is useful not only for measuring and tracking health, but also for guiding actions to improve health both at individual and population levels.

When used to measure population health at the geographic level, the Whole Health Index has a few notable advantages over publicly available health indices in the United States. First, because the Whole Health Index employs individual-level data, comparisons can be made across different states, as compared to ranking counties within a given state (which is the utility of the County Health Ranking). It also enables analyses on health disparities by population segments. Second, the Whole Health Index can be used to track progress over time because the Whole Health Index uses the baseline year as a benchmark to determine scores, as compared to using values from other counties or geographic units in the same years. For example, if all populations have improved health by the same amount in a given year, then the Whole Health Index will be able to represent the improvement of health, as indicated by higher scores for the given year, compared to the baseline year; whereas other publicly available rankings that are primarily based on peer comparisons in the same year may not show any changes in their scores. This feature allows the Whole Health Index to be used for tracking trends or improvement over time, which is not a common feature among publicly available health indices. Lastly, the Whole Health Index has more timely data, given that many of the indicators fed into the Index were drawn from claims and enrollment data, which are refreshed frequently.

In practical terms, the index can be used to support individual whole health and population health efforts through program planning and prioritization across diverse clinical and social care teams.

Program Planning

The Whole Health Index may be used to inform program planning. For example, Elevance Health used the Whole Health Index to identify members with high social and clinical needs in support of a campaign to improve influenza vaccination rates. The program reached out to members in the bottom 25th percentile of the Whole Health Index in several states. These members often have multiple physical, behavioral, and social conditions that put them at high risk for severe influenza symptoms; moreover, they are often harder to reach. Through this campaign, these members received additional outreach if they still were unvaccinated toward the end of the year. We also worked with community partners to ensure access to vaccines through transportation assistance and pop-up events.

Preliminary results show that these high-need members were vaccinated at 3%–18% higher rates than other members within the same insurance types. Additionally, the Whole Health Index has been used to inform the rollout of programs to prevent obesity and improve medication adherence in Medicaid populations; these programs were offered first in counties with lowest Whole Health Index scores. These examples demonstrate that the Whole Health Index allows health plans to provide comprehensive support to those who are most in need.

Cross-Sector Care Team Coordination to Offer Whole Health Solutions

The Whole Health Index also provides a comprehensive view of whole-person health in the social context that an individual lives in every day. This information allows health plans to partner effectively across multiple care teams to codevelop solutions to address an individual's most critical needs because it provides information that may not be readily available or observable to a single care team. For example, Elevance Health rolled out a program to enable cross-cutting partnerships across multiple care teams to streamline touch points and best support our members. Leveraging each domain score, care teams can quickly identify if there may be potential needs beyond their clinical program offering, and then work with corresponding internal care teams and external vendors to provide additional care solutions — such as meal delivery services, transportation support, or hearing aid consultation — to improve whole health. The Whole Health Index functions to triage members to the right solutions for their specific health and social needs.

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Assessment demonstrates that the Whole Health Index is a valid measure of whole-person health at both the individual level and several levels of geography."

Improving population health requires partnership and collaboration across multiple stakeholders. The Whole Health Index and its transparent scoring method can support stakeholders in efforts to work together in tracking progress in health improvement and identifying targeted population to achieve common goals. Therefore, we intend to make the Whole Health Index methodology transparent and easy to use in order to encourage wider adoption of the index across the health care ecosystem, given that the Whole Health Index provides an important and much needed perspective of measuring health. Organizations that have access to administrative claims, electronic health records, or comprehensive care history, including but not limited to government entities, public health departments, health plans, provider organizations, and integrated health care systems, will be able to compute the Whole Health Index for their populations based on our methodology.

Increasing availability for all-payer claims data in certain states and open claims data primarily sourced from clearing houses further expands the potential use of the Whole Health Index. We are also committed to making our Whole Health Index summary results available across the health care industry so that others with limited data access or resources will be able to use summary results from our experiences to help guide population health management efforts. Additionally, we will continue to evolve the Whole Health Index scoring methodology to address user feedback and simplify data inputs while ensuring the index is relevant, useable, and interpretable to stakeholders across the health care ecosystem.

Limitations

Despite the Whole Health Index incorporating individual-level social needs data when available, the collection of such data from health plans remains scarce. It is important to take into account the availability and quality of individual-level social needs data if one considers using the Whole Health Index as a measure of health for an individual. Broader efforts in collecting social needs data at the individual level are important to maximize the accuracy and precision of the Whole Health Index. Additionally, a number of elements in the Social Driver domain are drawn from publicly available data that are published annually. This limits the timeliness of social-needs information; however, despite the time lag in publicly available data release, the Whole Health Index has been found to be a valid and reliable measure of whole-person health.

Looking Ahead

The Whole Health Index is a practical, valid, and reliable tool to measure whole-person health and to improve population health management. As one of <u>Healthy People 2030</u>'s overarching goals is to achieve health equity, and because we believe that improving population health requires partnership and collaboration across multiple stakeholders, we make the Whole Health Index methodology and validation results transparent to allow wider adoption of the index across multiple stakeholders in the health care ecosystem.

Winnie C. Chi, PhD, MS

Research Director, Elevance Health Inc., Indianapolis, Indiana, USA

J. Marc Overhage, MD, PhD

Chief Health Informatics Officer, Elevance Health Inc., Indianapolis, Indiana, USA

Todd Sponholtz, PhD, MPH

Senior Researcher, Carelon Research, Wilmington, Delaware, USA

Binh T. Nguyen, PhD

Former Senior Researcher, Elevance Health Inc., Indianapolis, Indiana, USA

Peter Brady, MBA

Health Economics Director, Elevance Health Inc., Indianapolis, Indiana, USA

April Falconi, PhD, MPH, MA

Associate Research Director, Elevance Health Public Policy Institute, Washington, District of Columbia, USA

Martha Johnson, PhD Senior Researcher, Elevance Health Inc., Indianapolis, Indiana, USA

Amanda Price, MPH

Researcher, Elevance Health Inc., Indianapolis, Indiana, USA

Cory Silver, MPH

Researcher, Elevance Health Inc., Indianapolis, Indiana, USA

Kevin Bowman, MD, MPH, MBA

Staff Vice President, Enterprise Clinical Intervention and Analysis, Elevance Health Inc., Indianapolis, Indiana, USA

Samuel Simon, PhD, MA

Senior Director, Clinical Quality Measures, Mathematica Policy Research Inc. Princeton, New Jersey, USA

Dmitriy Poznyak, PhD Statistician, Mathematica Policy Research Inc., Princeton, New Jersey, USA

Anita Somplasky, RN CHTS-CP, CHTS-PW

Principal, Program Advisor, Mathematica Policy Research Inc., Princeton, New Jersey, USA

Shantanu Agrawal, MD, MPhil

Chief Health Officer, Elevance Health Inc., Washington, District of Columbia, USA Whole Health Index Process and Validation Results

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Catalyst Innovations in Care Delivery

ARTICLE

How Hospitals Improve Health Equity Through Community-Centered Innovation

Leonard L. Berry, PhD, MBA, Sunjay Letchuman, Joneigh Khaldun, MD, MPH, FACEP, Michael K. Hole, MD, MBA

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Hospitals that invest in community health equity – reducing and ultimately eliminating disparities in health and the determinants that adversely affect excluded or marginalized groups — can strengthen their financial performance, organizational culture, and reputation. By emphasizing health, not just health care, leaders of these hospitals help achieve a broader good for the community at large. By working with community stakeholders, these hospitals reduce barriers to good health (e.g., poverty, discrimination, inadequate housing, deficient education); welcome the community's input into hospital operations and programs; and extend the hospital's expertise, credibility, and financial resources into the community. The authors feature examples from hospital-based health systems that have successfully mitigated health inequities with primarily self-funded community initiatives while serving diverse geographic locations and populations. They conducted 30- to 60-minute semi-structured virtual interviews with 11 leaders at 5 hospitals between January and March 2022 and collected additional information through email. Interview questions centered on whether the hospital's community health equity investments make financial sense, how population health outcomes are measured for community interventions, how specific community programs were initiated, and the lessons other health systems can learn when investing in the community. From these interviews, as well as published reports and data, the authors show the positive impact that community-centered innovation can have for all stakeholders. They then offer specific leadership lessons for other institutions that aim to replicate these successes.

Small Investments, Big Impact

There are a number of approaches that care delivery organizations can take when addressing health equity, which can be summarized as efforts to reduce and eliminate disparities in both health and the determinants that adversely affect the health of excluded or marginalized groups.¹

Even modest community-centered investments by hospitals can improve patients' well-being. The <u>StreetCred</u> program of Boston Medical Center (BMC) helps low-income families file taxes and claim refunds during clinic and hospital visits. StreetCred partners with local nonprofits to recruit, train, and deploy volunteers — who are often college students or retired locals — into medical settings. Some volunteers help patients collect and upload tax-related documents to a secure online portal, while Internal Revenue Service (IRS)-certified volunteers use those documents to complete patients' tax returns. *Site coordinators* with advanced tax-preparation expertise oversee the process to ensure the accuracy of each tax return before helping the patient review, sign, and submit to the IRS. StreetCred is primarily funded by tax-deductible donations and grants to BMC; partner clinics pay each site coordinator \$8,000-\$10,000 per annual tax season. Since its 2016 launch, StreetCred has facilitated more than \$14 million in tax refunds (e.g., Earned Income Tax Credit and Child Tax Credit) to more than 6,000 low-income families at 9 clinics in 5 states.

To accelerate scale across the United States, StreetCred created an open-source toolkit and coalition of 24 health and financial services organizations in 10 states and the District of Columbia — sharing best practices on launching, growing, and sustaining financial services in medical settings. More than 90% of low-income families who receive extra funds — in particular, the monthly Child Tax Credits issued under the American Rescue Plan's credit expansion — use the money on food, clothing, shelter, and education.² In addition, evidence suggests that families receiving funds via financial services programs see improvements regarding infant birth weights, premature birth rates, maternal stress, employment rates among single mothers, and K-12 school performance.³ Some StreetCred sites also use trained volunteers to help families open and deposit money into a 529 college savings account, and StreetCred employs certified financial planners who offer free virtual sessions to patients to help create a budget, open a bank account, save money, build credit, and set financial goals. Having on-site financial service professionals can be advantageous for intervention efficiency and an opportunity to continuously tailor services to meet patients' needs.

Likewise, pooled money can increase purchasing power and the impact per dollar invested. <u>Be</u> <u>Well Fox Valley</u> — a financial and community partnership among 19 Wisconsin-based health systems (including ThedaCare from our sample), health departments, nonprofits, and philanthropy organizations, among others — tackles community health conditions, including diet and the consumption of high-fat foods. From grants and pooled money from health systems and other community partners, Be Well Fox Valley received approximately \$260,000 in 2022. Among many initiatives, the partnership enrolls patients with diabetes in a 13-week Eat Well for Life educational program⁴ that offers free, healthful meals. Between July 2021 and December 2022, four cohorts totaling around 200 people participated in the program. Postintervention analysis for the first cohort is complete, and the data show that average hemoglobin A_{1c} levels dropped from 9.6% before the program to 8.1% at 16 weeks after the program start date. In addition, over this same period, self-reported daily intake of fruits and vegetables increased from 3.0 to 5.7 servings. After the 13-week program is over, participants are enrolled in an alumni program, which connects them with healthy food through a community pantry partner; in addition, alumni events such as group walks and cooking classes are held periodically.

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Social Innovation, Financial Savings

Social innovation investments can generate financial savings for hospitals and payers by focusing on specific patient groups. For example, a housing-first program⁵ based in Seattle, Washington, called <u>1811 Eastlake</u>, identifies and houses individuals experiencing homelessness who have chronic issues with alcohol and use a high level of local crisis services. A study of the program from November 2005 to March 2007 measured the use and cost of community and state services including hospital-based medical services, emergency medical services, detoxification services, and shelter use, among others — between 95 individuals in the program and 39 control individuals on the program waiting list. In addition to housing, case managers were also present to guide program participants through their substance abuse. After accounting for housing and other costs, average per-month total costs for program participants were \$2,449 lower per person compared with the control group at 6 months' postintervention.⁶

The promise of programs such as 1811 Eastlake is reinforced in a 2014 report concluding that a person experiencing chronic homelessness costs taxpayers approximately \$35,500 annually; this amount is nearly halved when housing is provided, to \$17,611. After counting the cost of supportive housing at about \$12,000, the net savings are about 13%, or \$4,800 — resulting from decreased usage of jail services, emergency medical services, and hospitalizations.⁷ Savings are best realized when housing is supplemented by other services, including substance use programs and job training, which can lower the risk of incarceration and need for emergency medical care.⁸ A holistic approach becomes even more essential given the housing supply shortages and rising costs in many markets.

Investing boldly in environmental sustainability can improve community health and save institutions money. Approximately one-fourth of global health care greenhouse emissions come from the United States;⁹ America's hospitals produce thousands of tons of solid waste daily and 10% of national smog annually.¹⁰ In 2014, <u>Gundersen Health</u> in La Crosse, Wisconsin, became energy-independent by producing more energy than it consumed. It saves more than \$3 million annually by partnering with the county's public works department to generate electricity and heat from methane produced

by the local landfill, designing its buildings and facilities for energy efficiency, and investing in nearly every form of renewable energy — including erecting two wind farms, operating a biomass boiler, installing solar panels on its dialysis center to help power its water-heating system, and building an underground geothermal heat pump to improve heating, ventilation, and air conditioning efficiency.

Community Focus, Greater Trust

Partnering with community stakeholders to identify and understand problems, cocreate and implement solutions, and define and measure success helps hospitals earn trust, a precious asset in health care.¹¹ Effective partnership involves focused, ongoing, needs-centered investments that address root causes of community ills. Memorial Hermann Health System, for instance, invests in increasing physical activity among children in its Houston, Texas, community. One of Memorial Hermann's school-based health center nurse practitioners noticed a growing number of students presenting with acanthosis nigricans, which is often associated with diabetes and obesity.¹² The health center nurse practitioner teamed up with the school nurse to discuss with parents why kids had inadequate physical activity. Highlighting perceived safety issues in accessing nearby Clark Park, parents sought safer routes to the park as well as organized activities there for children and adults. In response, Memorial Hermann built a 1.1-mile sidewalk from the local middle school to the park, improved lighting throughout the grounds, rebuilt the basketball court, revamped the soccer field, and created the Soccer for Success organized-sports program for children.¹³

Among the 262 children who have participated in the soccer program, the hospital reports 85% of them improved their scores on the Progressive Aerobic Cardiovascular Endurance Run test, an endurance examination in which students run for as long as possible while keeping a specified pace that gets faster each minute.¹³ In addition, 75% of the children reduced their body mass index. Soccer seasons run for just less than 4 months, with two 60-minute practices each week.

Sanford Health, which is headquartered in Sioux Falls, South Dakota, and operates 46 medical centers in the upper Midwest, has worked with leaders of Tribal Nations for over 20 years to strengthen their relationships with Native American communities across the Dakotas. Sanford leaders say this and other efforts to build trust with the Native American community have made a positive difference. For example, a points-based health hygiene program at Sanford Health in Chamberlain, South Dakota, provides diapers, bedding sets, nursing pillows, infant swings, bathtubs, and other items to pregnant low-income women to incentivize and support them in making healthy choices about nutrition, prenatal care, drinking, and smoking. Between January 2019 and December 2022, a total of 325 women participated in the program, 173 of whom are Native American. This suggests an overrepresentation of Native Americans using the program, as they make up about 11% of the Brule County population.¹⁴

Leadership Lessons

Leaders of these organizations have learned key, replicable lessons from their health equity investments.

When possible, hospitals should partner with local nonprofits and businesses, other hospitals, and government agencies with relevant expertise to address health inequity; the BMC initiative with local hospitals and government-sponsored tax programs is an example. Proactively screening patients for resource insecurities, connecting patients to community resources, and following up to ensure receipt is an important collaborative health equity opportunity. Since August 2017, BMC screens approximately 70% of new primary care patients with an internally developed tool called *Thrive*, which identifies patients' resource needs and creates a printout of referral information for relevant services located within the hospital and community.¹⁵ Between August 2017 and January 2018, this involved screening 1,696 of 2,420 new patients, of whom 445 responded positively to at least one social need. The most prevalent issues involved employment, food, and medication affordability.¹⁵

Organizing teams that focus on the social drivers of health, such as poverty and homelessness, can enhance implementation success through resource sharing and cross-functional expertise. ThedaCare organizes *community health action teams* of local leaders from government, health care, business, and education who participate in daylong excursions (called *plunges*) into local communities to see and hear patients' unvarnished stories. This approach led to the January 2021 launch of ThedaCare's <u>Rural Health Initiative</u>, which brings at-home health care to Wisconsin farm families, including health coaching, referrals, and monitoring of blood glucose, cholesterol, hemoglobin A_{1c} , and other metrics. More than one-half of these screenings detect issues that can be addressed proactively, before they become urgent or emergent concerns.¹⁶ In 2022, the rural health initiative team served 596 residents, 222 of whom are Latino workers at large dairy farms. The team detected 74 acute conditions — such as high blood pressure, blood sugar, or cholesterol — requiring medical attention. In addition, 154 individuals were referred to see a primary care clinician.

Activating community stakeholders and earning their trust requires listening, asking for participation, truly involving participants in the endeavor, and needs-based framing of the ask. Jeff Thompson, MD, retired Chief Executive Officer of Gundersen Health who championed its sustainability initiative, regularly engaged *external* groups with this message: "Health care costs too much. We want to charge less. And we want to figure out ways we can work with the community to improve health and lower costs."

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ThedaCare organizes community health action teams of local leaders from government, health care, business, and education who participate in daylong excursions (called plunges) into local communities to see and hear patients' unvarnished stories."

Empower Employees to Advocate for Patients

A workforce that embodies cultural humility — which involves an awareness of self and the realities of others — is also critical to advancing health equity.¹⁷ Well-managed hospitals empower employees to listen to, partner with, and advocate for patients. Employees' trust in the leadership's commitment

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to patient-centeredness is essential to them feeling psychologically safe in finding creative ways to help patients when creativity is needed. Hospital employees at Sanford Health advocated for patients lacking access to essential items such as blood pressure cuffs, scales, walkers, canes, or diabetic shoes, resulting in the Providing Needed Assistance to Patients Locally fund, known colloquially as the *Pineapple Fund*. Staff can now purchase low-cost items through the fund.

When strict infection-control rules dictated patients' stays at the height of the Covid-19 pandemic, ICU staff at North Carolina's Novant Health Rowan Medical Center felt empowered to bend the rules to place a couple — both nearing death from Covid-19 — in the same room together. Originally in separate rooms, the couple was moved into one room, and the staff clasped the couple's hands for their last moments. The couple's son recounted the staff saying they would have "moved mountains" to bring his parents together. The staff felt confident that leadership would support their creativity in serving patients with the utmost empathy.¹¹

Employees' trust in the leadership's commitment to patient-centeredness is essential to them feeling psychologically safe in finding creative ways to help patients when creativity is needed."

Measure Outputs and Outcomes; End Unsuccessful Programs

Rigorously evaluating programs' effects on community health optimizes execution and measures success. StreetCred tracks patient demographic characteristics (e.g., race, income) and program outputs (e.g., clients served, dollars returned), reporting to partner clinics' leadership and funders. Given StreetCred's relatively fixed cost per site, the organization has closed sites serving lower volumes of low-income patients to focus on optimizing operations at sites serving higher volumes. Moving forward, research must compare programs' effects on outcomes, not just outputs, to better understand how allocating funds might affect health equity. For example, numerous studies have shown the Earned Income Tax Credit's beneficial impact on infant and maternal health, employment rates, and school performance, among other outcomes;³ StreetCred is studying its impact on similar outcomes with the aim of directing resources to its sites that most positively effect such outcomes and advance health equity.

Refocus from "Charity Care" to "Equity Care"

In exchange for their tax-exempt status, nonprofit hospitals must meet the community benefit standard set by the IRS. The standard can be met, in part, by providing significant charity care, which may not address health inequities.¹⁸ Although charity care can fulfill the immediate medical needs of individual patients, it is unlikely to address the underlying systemic cause of disease. Although it may be generous and well intentioned, charity care may not offer enduring community benefit. To share one example from leaders at BMC, a \$1 million charity care investment for 10 open-heart surgeries has a different impact than a \$1 million equity care investment for 10,000

prenatal visits with low-income women: 10 surgeries affect 10 patients and their loved ones; 10,000 prenatal visits lift entire communities.

Commit to Acting on Survey Results

Many communities facing disparities are frequently the focus of research studies by academic institutions and hospitals, with little or no follow-up and no perceived benefit to participants. This inaction further erodes community trust. Not only do hospitals need to be conducting community-based health equity research as best practice, but they also need to follow through on sharing results and action plans with community members.¹⁹

Moving forward, research must compare programs' effects on outcomes, not just outputs, to better understand how allocating funds might affect health equity."

Tailor Investments to Specific Community Disparities

In 2021, Sanford committed \$350 million to a <u>virtual care center</u> (VCC) for people in rural areas (where two-thirds of Sanford patients live) in the Dakotas, Minnesota, and Iowa. Upon its expected completion in 2024, the VCC will include a flagship command center that will offer a direct connection to satellite clinics, giving patients the option to get the care they need in person, with additional resources and expertise available virtually. Rural communities continue to experience higher rates of poverty, food insecurity, and chronic disease, thereby worsening health outcomes.²⁰ The virtual care initiative targets health disparities and barriers to access for underserved communities by providing the right care, at the right time, in the right place — no matter where patients live or what challenges they face.

Hospitals have an opportunity to work strategically and intentionally, both *in* and *with* communities, to advance health equity. The U.S. Centers for Medicare & Medicaid Services, in 2023, is incorporating health equity measures into the <u>Hospital Inpatient Quality Reporting</u> program, including hospitals' collection and analysis of health-related social needs data.²¹ The social innovation investments presented in the current article can contribute to the expansion and continued development of health equity initiatives that can build trust, boost institutions' reputations, save money, benefit cross-sector stakeholders, and improve health. Other hospitals can follow their example, tailored to each institution's abilities and each community's needs.

Leonard L. Berry, PhD, MBA

University Distinguished Professor of Marketing, Texas A&M University Mays Business School, College Station, Texas, USA

Senior Fellow, Institute for Healthcare Improvement, Boston, Massachusetts, USA

Sunjay Letchuman

Medical Student, Icahn School of Medicine at Mount Sinai, New York, New York, USA

Joneigh Khaldun, MD, MPH, FACEP

Vice President and Chief Health Equity Officer, CVS Health Corporation, Woonsocket, Rhode Island, USA

Practicing Emergency Medicine Physician, Henry Ford Hospital, Detroit, Michigan, USA

Michael K. Hole, MD, MBA

Assistant Professor, Dell Medical School, The University of Texas at Austin, Austin, Texas, USA

Assistant Professor, Lyndon B. Johnson School of Public Affairs, The University of Texas at Austin, Austin, Texas, USA

Executive Director, The Impact Factory, The University of Texas at Austin, Austin, Texas, USA

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