Title

Examining Direct-to-Consumer Healthcare Through Three Lenses: Consumer Trust, Industry Evolution, and Policy Uncertainty

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Publication Date

2024

Peer reviewed|Thesis/dissertation

UNIVERSITY OF CALIFORNIA

Los Angeles

Examining Direct-to-Consumer Healthcare Through Three Lenses: Consumer Trust, Industry Evolution, and Policy Uncertainty

A dissertation submitted in partial satisfaction of the

requirements for the degree Doctor of Philosophy

in Health Policy and Management

by

Ashwini Nagappan

2024

ABSTRACT OF THE DISSERTATION

Examining Direct-to-Consumer Healthcare Through Three Lenses:

Consumer Trust, Industry Evolution, and Policy Uncertainty

by

Ashwini Nagappan

Doctor of Philosophy in Health Policy and Management

University of California, Los Angeles, 2024

Professor Xi Zhu, Chair

This dissertation examines direct-to-consumer (DTC) healthcare by examining individual, organizational, and policy contexts. In the first study, I examined patterns of consumer willingness to share health data with various stakeholders (e.g., healthcare providers, technology companies) using latent class analysis. I identified three groups of consumers: 1) Wary (36.8%), who exhibited reluctance to share health data with any stakeholder; 2) Discerning (47.9%), who were more selective, willing to share data with particularly with family and healthcare-related entities; and 3) Permissive (15.3%), who showed a high willingness, with the exception of technology companies and government organizations. Across groups, the willingness to share data with physicians was notably high, indicating a persistent trust in these traditional healthcare entities. Findings also reveal significant heterogeneity in health data-sharing attitudes across groups of U.S. consumers, providing insights to inform the development

of data privacy policies. In the second study, I examined the landscape of U.S. DTC digital health companies to analyze their product and service offerings and estimated the effects of population and organizational characteristics on patterns of entry, exit, and achievement of success milestones. I show that since 2011, the number of DTC digital health companies has grown steadily, with a slight downturn in 2022. The organizational founding analysis supports density dependence theory, showing an inverted U-shaped relationship between density and founding rates. Companies employing telemedicine were associated with reaching success milestones faster in the time-to-event analysis, likely due to telemedicine's established legitimacy within traditional healthcare. In the third study, I used a qualitative study to understand how stakeholders perceive DTC telehealth companies prescribing controlled substances and how they perceive drug schedules in the development of permanent telehealth regulations for prescribing controlled substances. Findings indicate that the benefits of DTC telehealth companies prescribing controlled substances should be considered against risks cited by participants like lack of patient-provider relationships and conflicts of interest. Participants called for differentiated oversight tailored specifically to these companies. Additionally, the prominence of participant concerns about the current drug scheduling system suggests that an alternative foundation may better support the development of permanent telehealth regulations.

The dissertation of Ashwini Nagappan is approved.

Beth Ann Glenn-Mallouk

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Corrina Moucheraud

Anna Wexler

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University of California, Los Angeles

2024

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ACKNOWLEDGEMENTS

I am grateful to all the individuals who have provided support and encouragement throughout this journey.

First and foremost, I extend my heartfelt thanks to my committee chair, Dr. Xi Zhu, for recognizing the merit in my ideas, guiding my research, and providing invaluable mentorship in this process. Your support has been instrumental to my growth as a researcher. I am also profoundly thankful to the rest of my committee—Dr. Beth Glenn, for elevating my work, challenging me to become a stronger health services researcher, and encouraging me to think deeply about how everything fits together; Dr. Olivia Jung, for diving into the data with me, ensuring the rigor of my methods, and pushing me to consider the broader implications of my findings; Dr. Corrina Moucheraud, for your guidance as an advisor, your invaluable feedback, and your support in both my academic and professional development; Dr. Anna Wexler, for being an exceptional mentor over the past six years, for introducing me to the field of direct-to-consumer healthcare, and for shaping me into the researcher I am today.

A special thank you to Alexis Amano, for serving as a second qualitative coder for one of my studies, and to my friends at UCLA and beyond, who provided feedback, support, and encouragement.

To my family, thank you for your constant encouragement and unwavering support, both in my life and my academic endeavors.

I also would like to thank Rock Health for their support, which allowed me to use data from the Rock Health Digital Health Consumer Adoption Survey and the Rock Health Venture Funding Database.

Finally, I am deeply grateful for the research support which made this dissertation possible: the NIH/National Center for Advancing Translational Science (NCATS) UCLA CTSI, under grant number TL1TR001883; UCLA Graduate Division's Graduate Summer Research Mentorship Fellowship; UCLA Graduate Division's Graduate Research Mentorship Fellowship.

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5. **Nagappan, A.,** Krasniansky, A., Zweig, M., & Evans, B. (2022). "H1 2022 digital health funding: Two sides to every correction." *Rock Health*.

SELECT PRESENTATIONS (3 of 12)

1. **Nagappan, A**., Zhu, X. "Consumer Willingness to Share Health Data with Key Stakeholders." Oral presentation. AcademyHealth Annual Research Meeting, Baltimore, MD, June 29-July 2, 2024.
2. **Nagappan, A**., Zhu, X. "The Emergence of Direct-to-Consumer Digital Health Companies." Oral presentation. AcademyHealth Annual Research Meeting, Baltimore, MD, June 29-July 2, 2024.
3. **Nagappan, A**., Kalokairinou, L., & Wexler, A. "Ethical Issues in Direct-to-Consumer Healthcare: A Scoping Review." Poster presentation. AcademyHealth Annual Research Meeting, Seattle, WA, June 23-27, 2023.

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Chapter 1. Introduction

Background and Significance

In recent years, the unparalleled access to online health-related information and a growing array of consumer digital health technologies, from wearable devices to at-home diagnostic tools, has empowered individuals to take a more active role in their healthcare.[1,2] This trend, the "*consumerization of healthcare,*"[3–5] represents a shift towards a care delivery model wherein individuals can access healthcare on-demand, at one's fingertips, akin to an Amazon-like experience. The COVID-19 pandemic further propelled this paradigm shift by necessitating remote healthcare delivery.[6]

During this *consumerization of healthcare*, one healthcare delivery innovation that has been catalyzed is *direct-to-consumer (DTC) healthcare*.[7] In this provision model, companies offer health-related products and services that allow consumers to initiate their own care. The DTC model allows consumers to directly purchase healthcare products and services, typically out-of-pocket, without any significant involvement of a healthcare provider.[8] Examples of DTC products and services include at-home testing kits, wearables, and online prescription services.[7]

The growth of the DTC healthcare provision model may play a role in the transformation of health delivery. However, to date, there is a relative paucity of empirical research investigating the phenomenon. Recent bipartisan initiatives targeting the advertising practices of DTC healthcare companies,[9] as well as recent civil and criminal charges filed against DTC healthcare companies,[10,11] underscores the importance of timely research to inform policymaking in this rapidly evolving market.

DTC Healthcare

The DTC provision model confers benefits such as increased accessibility, convenience, and consumer autonomy. However, risks of DTC healthcare include questionable efficacy, physical and safety harms, and data privacy concerns.[12–14] Additionally, while DTC telehealth may improve access to care, it has also been associated with higher healthcare costs due to increased utilization[15] as well as due to requiring more follow-up visits compared to in-person care.[16] Secret shopper studies found a lack of standardized protocols in DTC companies offering certain treatments, [17] and another study found that some DTC companies fail to meet guideline-based criteria for clinical decisions.[18] Consumer experiences with specific DTC products and services have been studied, [19–23] providing insights into user satisfaction of the respective offering. Researchers have also found misleading marketing claims made by DTC companies.[24–26]

Notably, many DTC healthcare offerings have primarily focused on low-acuity medical needs,[27] which can disintermediate primary care journeys that traditionally begin with a physician, thereby leading to further fragmentation in the healthcare landscape. More intricate services—such as those related to chronic conditions—may require ongoing care management and in-person follow-ups, which DTC companies may not be best positioned to provide, despite efforts by some companies aiming to fill this gap.[28]

While DTC healthcare may effectively meet select low-acuity needs, DTC healthcare may create healthcare ephemeral "situationships" rather than meaningful long-term relationships between patients and providers. As public interest in DTC healthcare continues to grow,[29] it is essential to analyze the multilevel factors associated with this provision model.

Importantly, the scope of the DTC term’s application is continually expanding. For example, Amazon has Amazon Pharmacy, which offers prescription medications directly to

consumers.[30] Apple has integrated FDA-authorized health functionalities into consumer devices (e.g., AirPods as over-the-counter hearing aids, and the Apple Watch aiding in detecting signs of sleep apnea).[31,32] Dexcom recently launched an over-the-counter glucose monitor for consumer use.[33] Similarly, pharmaceutical companies, like Eli Lilly and Pfizer, have also entered the DTC space, partnering with third-party DTC telehealth companies to facilitate access, representing a subtle shift in how pharmaceutical companies engage with patients.[34]

A Note on the DTC Terminology

Prior to proceeding, it is important to note that there are various interpretations of the term "direct-to-consumer (DTC) healthcare," and to specify how it will be used in this dissertation. "DTC" can have different connotations depending on the context; thus, necessitates clarification to avoid confusion.

In the business world, "DTC" refers to a "go-to-market" strategy where companies sell products directly to consumers, bypassing traditional retail channels.[35] (Another example of a go-to-market strategy is business-to-business.) In healthcare, "DTC" has predominantly been used to describe direct-to-consumer advertising (DTCA) of pharmaceuticals. DTCA refers to the practice of *marketing* prescription drugs, from pharmaceutical companies directly to consumers, typically through advertising channels such as television ads, print, and social media.[36] However, this dissertation does not focus on this application of the DTC terminology.

Throughout this dissertation, the term "DTC" will be used to refer to health-related products or services defined by their mode of delivery rather than the inherent characteristics of the products or services,[8] similar to the business application of the term. However, in this case, the consumer independently initiates and manages their healthcare interactions directly with the provider of the healthcare product or service, often without traditional healthcare intermediaries

(i.e., healthcare providers). This modality of care delivery is typically facilitated by digital technologies, and it encompasses both prescription and non-prescription products, distinguishing it from over-the-counter (OTC) products.[22]

Overview of Dissertation

This dissertation seeks to provide a multilevel analysis of DTC healthcare by examining individual, organizational, and policy contexts. By addressing these distinct, yet interconnected, levels of analysis, the dissertation aims to offer a comprehensive understanding of DTC healthcare.

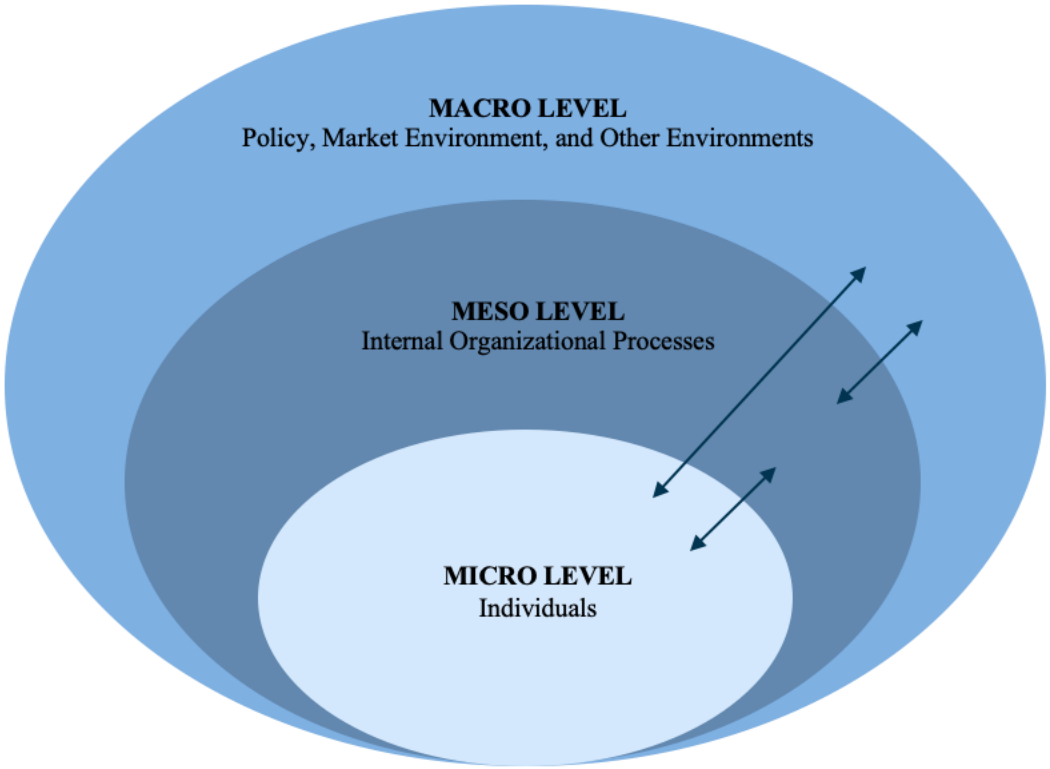
Conceptual Framework

A multilevel analytical framework serves as the conceptual framework that underpins the dissertation. It offers a systematic approach to examining DTC healthcare at three levels of analysis: micro (individuals), meso (internal organizational processes), and macro (policy and market environments) (**Figure 1.1**). This dissertation comprises three studies: one focusing on the micro-level and two on the macro-level, and each study has its own theoretical framework to guide its respective research questions (found within each chapter).

While each study is centered on a specific analytical level, it is important to recognize the interconnectedness of the three levels. For instance, policy changes at the macro-level may influence company/organizational strategies (also considered part of the macro-level) and consumer attitudes at the individual-level, and consumer attitudes (individual-level) could influence policy decisions (macro-level). Thus, there are potential interactions and feedback loops between the different levels which are not explicitly explored here but are important to

note. My goal with these interconnected studies is to gain an in-depth understanding of the factors associated with the DTC healthcare delivery model.

Figure 1.1 Multilevel analytical framework for investigating DTC healthcare.



Chapter 2

Study 1 focuses on the individual level, the micro-level. This study addresses consumer willingness to share health information with various stakeholders (e.g., physicians, tech companies, pharmacies). As consumers increasingly generate health data through connected devices and digital health tools, the issue of health data privacy becomes a concern. Latent class analysis (LCA) is employed to identify subgroups with similar data-sharing attitudes, and groups were compared based on sociodemographics, health status, and digital health utilization. If there are variations in consumer data-sharing preferences, then this can inform the development of privacy protections, both at the organizational-level as well as at the policy-level. The analysis

employs data from Rock Health's Digital Health Consumer Adoption Survey, from the years 2018, 2019, 2020, and 2022, and includes a sample of 23,994 US adults.

Aim 1.1: To identify subpopulations of consumers based on patterns of willingness to share their health data with different stakeholders (e.g., physicians, healthcare technology companies).

Aim 1.2: To determine if sociodemographic characteristics are associated with patterns of willingness to share health data.

Aim 1.3: To determine if adoption of digital health tools is associated with patterns of willingness to share health data.

Chapter 3

Study 2 addresses macro-level questions. Here, I examine the landscape of U.S. DTC digital health companies by using the Rock Health Venture Funding Database to characterize these companies. Negative binomial regression is used to analyze factors associated with founding rates of DTC digital health companies. Time-to-event analysis (i.e., Cox proportional hazards regression and Kaplan-Meier survival curves) are used to examine the factors associated with the failure and success of DTC digital health companies.

Aim 2.1: To explore the key characteristics and trends among DTC digital health companies in terms of their founding patterns, populations served, technological offerings, and health domains addressed.

Aim 2.2: To determine the factors that affect the founding rates of DTC digital health companies.

Aim 2.3: To determine the factors that affect the failure of DTC digital health companies and achievement of success milestones by DTC digital health companies.

Chapter 4

Study 3 investigates policy, at the macro-level. In this study, I explore the perspectives of key stakeholders—such as healthcare providers, healthcare executives, and policy experts—on the role of DTC telehealth companies in prescribing controlled substances, and their opinions about how drug schedules should be considered in the development of permanent telehealth regulations for prescribing controlled substances. This analysis is particularly timely, given the impending expiration of the temporary public health emergency policy that allowed for telehealth prescribing of controlled substances (Schedules II-V) without an initial in-person visit. Through semi-structured interviews with stakeholders, the study provides insights into the development of policy outcomes that impact the availability of DTC telehealth companies in prescribing controlled substances for consumers. It also explores how drug schedules should be considered in the development of permanent telehealth regulations.

Aim 3.1: To explore stakeholder perspectives on DTC telehealth companies prescribing controlled substances, and to gain insights to inform the development of permanent policies for such practices.

Aim 3.2: To explore stakeholder perspectives on how drug schedules should be considered in the development of permanent telehealth regulations for prescribing controlled substances.

Chapter 5

The final chapter of this dissertation synthesizes the principal findings across the studies, highlights the implications of the findings, and outlines my plans for future research in the field of DTC healthcare.

Chapter 2. Consumer Willingness to Share Health Data with Stakeholders: A Latent Class Analysis

Introduction

Consumers are increasingly generating health data outside of the traditional healthcare system through digital platforms, ranging from mobile apps and wearable devices to connected sensors.[37–40] While consumer-generated health data confers benefits to individuals, such as greater autonomy by enabling them to track and manage their own health information to make informed decisions, concerns arise regarding privacy and proper use of such data.[41,42] Regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act exist to protect the identifiable health information collected by covered entities (e.g., healthcare providers, payers) and their business associates;[43,44] however, a significant amount of consumer-generated health data falls outside the scope of these regulations.[37,45]

This regulatory gap, along with broader concerns over data privacy, has prompted various states, including California,[46] Connecticut,[47] and Virginia,[48] to enact a patchwork of laws that create privacy rights for consumers over their data. In addition to state-level regulations, the Federal Trade Commission (FTC) has taken action against companies that have shared sensitive health information with Big Tech companies and others without disclosure to consumers.[49–51] As of April 2024, the FTC updated its Health Breach Notification Rule to enhance privacy safeguards for users of health apps and devices not covered under HIPAA, thereby aiming to bridge gaps in existing privacy protections.[52]

Despite these protective measures and enforcement actions, vast amounts of consumer health data are still shared in ways that consumers may not fully understand. This is exemplified

by incidents where several direct-to-consumer (DTC) telehealth companies legally shared consumer health information with Big Tech companies without consumer consent,[53] and illegal health data breaches at digital health companies.[54] Such occurrences highlight the tradeoffs between the benefits of digital health data and the potential misuse of sensitive information.

The gaps in regulation surrounding digital health tools are concerning for several reasons. First, companies may make misleading claims or lack transparency in their privacy practices, leaving consumers at risk of being unaware of third-party data sharing;[13] this lack of clarity may impede consumers' ability to make informed decisions and lead them to erroneously believe their health data is protected when it is not.[55] Second, consumer misunderstanding of data protection practices is particularly troublesome because consumers often turn to these tools for privacy reasons, especially in cases where conditions bear a stigma, such as genital herpes and erectile dysfunction, and thus, prefer online services with minimal physician-patient interaction. Third, indiscriminate data sharing could cause harm to specific populations, such as menstruating individuals who use health apps to track menstruation or fertility following the Dobbs decision and members of the LGBTQ+ community who rely on digital tools to discreetly manage aspects of their identity.[50]

Previous research has extensively explored consumer attitudes towards health data privacy, focusing on demographics, the type of health data, and the recipients of this data, such as researchers and healthcare providers, as major influencing factors.[56–60] However, most studies tend to narrowly focus on data sharing with either traditional healthcare entities or non-traditional stakeholders, such as technology companies, without examining a range of stakeholders in the same study.[58,60–65] In the studies that include a breadth of stakeholders, there

remains a gap in understanding how these attitudes intersect with consumer utilization of digital health tools.[41,65–69]

Given the plethora of data generated digitally, the encroachment of tech companies in healthcare, and the ethical implications of non-consensual data sharing, this study examines consumer willingness to share health data across a diverse array of stakeholders, including technology companies, healthcare providers, and payers. This research aims to contribute to the ongoing discourse on digital health data privacy, attitudes toward data sharing with different stakeholders, and the ethical management of health data outside traditional healthcare settings.

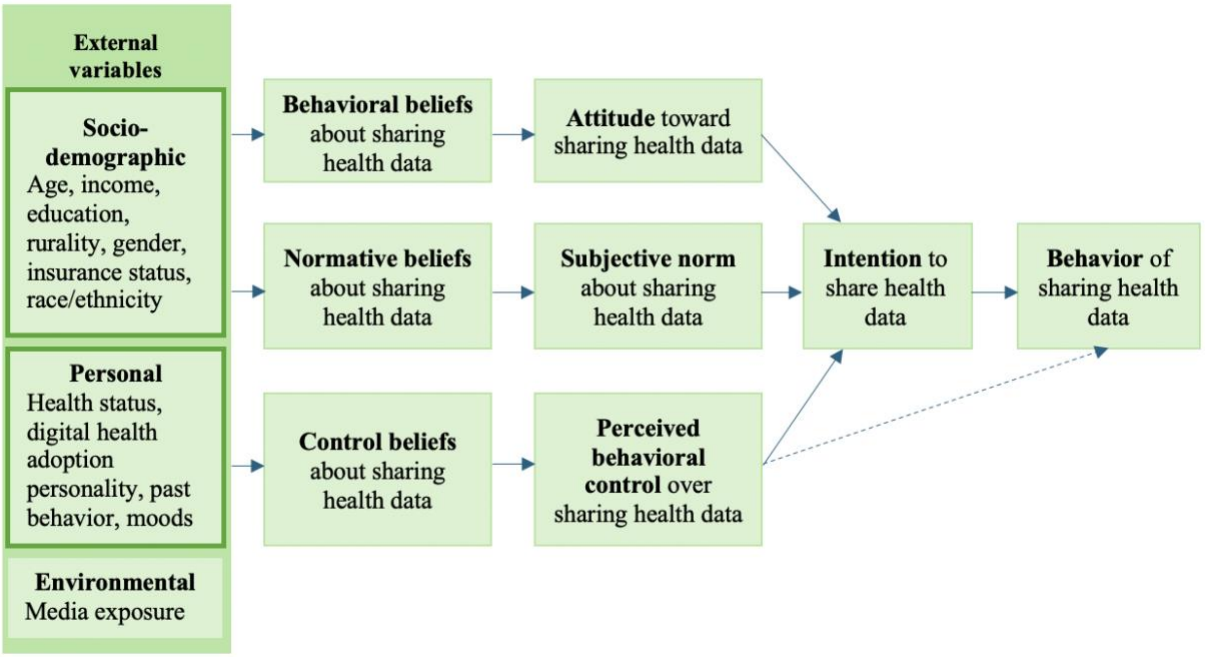
The objective of this study is twofold. First, this study aimed to identify distinct patterns in the willingness of consumers to share their health data with various stakeholders. Given that consumer attitudes toward health data sharing are multifaceted, understanding differences by stakeholder is crucial for developing policies that respond to distinct consumer preferences. To characterize these distinct consumer segments, I employed latent class analysis (LCA), a statistical technique used to identify unobserved groups of consumers within a population based on their responses across multiple variables, here, their willingness to share health data with different stakeholders.[70] LCA is well-suited for this study because it unveils hidden patterns that are not readily apparent in aggregate analyses. Second, following the identification of these latent classes, a further aim was to analyze the sociodemographic, health status, and digital health utilization differences across these groups. By understanding factors associated with the likelihood of being in different groups, this study sought to characterize the variation in consumer attitudes toward health data sharing with different stakeholders and inform the development of data privacy policies that are attuned to the diverse preferences of consumers.

Theoretical Framework

This study draws on the Theory of Planned Behavior (TPB) to explore consumer willingness to share health data. The TPB posits that an individual's behavior is driven by intentions; and intentions are influenced by three key components: (1) attitudes toward the behavior, (2) subjective norms, and (3) perceived behavioral control. This theory is rooted in social psychology[71] and has been used to measure the factors that influence the sharing of private information.[72–75]

Figure 2.1 illustrates the application of the TPB to the behavior of consumer willingness to share health data. There are three kinds of beliefs that guide behavior: behavioral, normative, and control. Each of these beliefs, respectively, leads to the formation of attitudes, subjective norms, and perceived behavioral control.

Figure 2.1 Theory of planned behavior applied to consumer health data sharing.



Behavioral Beliefs and Attitudes

Behavioral beliefs are the beliefs about the outcomes of a behavior, which produce either a positive or negative attitude toward that behavior. For example, if an individual believes that sharing health data—whether with technology companies, pharmaceutical companies, or healthcare providers—could lead to improved personalized healthcare recommendations or to better treatment outcomes, then positive attitudes are formed toward sharing health data. Conversely, if individuals believe that sharing their health data will lead to privacy breaches or data misuse, then negative attitudes are formed toward health data sharing. In this study, the purpose behind "health data sharing" was not defined, allowing respondents to interpret it based on their own understanding of sharing personal health information with various stakeholders. Therefore, it is hypothesized that subpopulations with positive beliefs of the outcomes of health data sharing, such as better healthcare outcomes or contributions to research, will exhibit a higher willingness to share their data.

Normative Beliefs and Subjective Norms

Normative beliefs are beliefs about the expectations of others, and subjective norms are perceived social pressures to perform (or not perform) a behavior. If an individual believes that their family and friends would express support to health data sharing, this perceived social support could strengthen the subjective norm to engage in data sharing. On the other hand, if an individual believes that their family and friends would discourage data sharing, then they may feel pressured to not share their health data. Beyond family and friends, if an individual believes that society at large views data sharing as a positive contribution or as a problematic behavior, then these broader social norms can shape an individual's subjective norms. Therefore, it is hypothesized that subpopulations influenced by positive subjective norms, such as support from family and friends, will be more willing to share their health data.

Control Beliefs and Perceived Behavioral Control

Control beliefs are beliefs about the existence of factors that impact the performance of a behavior, which influence perceived control over that behavior. For example, if an individual believes that the process of health data sharing is straightforward and that the entities with whom they share their data with has robust data security measures, then they might feel more in control of data sharing process. Therefore, subpopulations with high perceived behavioral control, such as confidence in data security and ease of sharing, will demonstrate a greater willingness to share their health data.

Existing literature suggests that sociodemographic variables influence behavioral intentions and actions. For example, one systematic review of public willingness to share personal health data found that: individuals with lower educational attainment are less willing to share health data, indicating that education correlates with greater perceived behavioral control due to a better understanding of data security measures; age plays a role, though the findings appear to be divided, with some finding that older individuals are less willing to share compared to younger individuals and vice-versa; individuals with a lower household income were less willing to share personal health data, suggesting that annual household income can also impact perceived behavioral control, as higher income levels may provide better access to technology and resources for secure data sharing; varying findings on whether women have higher privacy concerns than men; and that Black individuals are less willing to share their health data compared to White individuals, indicating that race and ethnicity may shape subjective norms and attitudes due to varied experiences with the healthcare system, including trust and perceived discrimination.[65] These sociodemographic factors, when considered alongside TPB components,

provide a more nuanced understanding of health data-sharing behaviors across different population groups.

In this study, latent class analysis (LCA; details to follow) is employed to uncover naturally occurring groups within the data based on patterns of willingness to share health data. LCA is a data-driven method that identifies subpopulations without preconceived notions. Analyzing factors associated with the group membership through the lens of the TPB will help us posit why individuals with certain characteristics exhibit a higher or lower probability of being classified into a specific latent class or group. This integration provides a nuanced understanding of the diverse factors influencing health data-sharing preferences and behaviors, allowing for the development of targeted policies that respect consumer preferences and address concerns.

The TPB is not without its limitations. The TPB primarily focuses on individual-level factors, potentially missing contextual factors that can shape behavior. In addition to not accounting for societal or environmental factors that can shape behavior, the TPB does not adequately account for other psychological variables, such as past experiences. Another limitation is that the theory assumes linear decision-making and does not consider that intentions can change over time. Other theories, such as the Social Exchange Theory or the Theory of Contextual Integrity, could provide additional insights, but TPB was chosen due to its specific strengths in explaining intention-driven behavior.

Research Questions

There are three research questions for this study.

1. Are there distinct subpopulations of consumers who can be identified based on patterns of willingness to share their health data with different stakeholders?

2. Are sociodemographic factors associated with patterns of willingness to share health data?
3. Is adoption of digital health tools (e.g., telemedicine) associated with patterns of willingness to share health data?

Building on the TPB, there are key theoretical relationships that I expect. First, I posit that sociodemographic factors, such as education and income, will be positively associated with patterns of willingness to share health data. I predict that non-Hispanic Black/African American individuals may demonstrate lower levels of willingness based on prior findings. Also, given previous findings, age and gender also will be associated with patterns of willingness, though the direction of association is not clear. Individuals' adoption of digital health tools, specifically telemedicine, digital health tracking, and online information seeking, will be positively associated with patterns of willingness to share health data.

Methods

Data

This study utilized data from Rock Health's Digital Health Consumer Adoption Survey. Rock Health, a digital health research and venture capital firm, conducts annual surveys targeting a U.S. Census-matched sample of adults aged 18 and older. The survey was collaboratively designed by Rock Health and Stanford's Center of Digital Health, and administered by Toluna, a third-party market research company that offers enterprises survey programming services. Toluna recruits survey participants from its network of 43 million consumers, who receive "points" redeemable for rewards such as gift cards for participating in surveys. Toluna's members were recruited through digital marketing channels. To ensure data quality, Toluna

performs validation checks at multiple stages, including before the panel (e.g., unique email identification), before the survey (e.g., IP validation), during the survey (e.g., speeding), and after the survey (e.g., remove extreme outlier responses). Rock Health requested that Toluna target respondents based on member profiles to obtain a sample representative of U.S. Census demographics (sample is Census-matched by gender, age, U.S. geographic region, race/ethnicity, and annual household income).

The survey consisted of questions covering sociodemographics, health profiles, and consumer use of and attitudes towards digital health tools, such as telemedicine, wearables, health metrics tracking, and online information-seeking behaviors. The survey also asked respondents about their attitudes towards health data sharing and trust in various information sources (see **Appendix 2.1** for survey variables**)**.

For this study, datasets from 2018, 2019, 2020, and 2022 were analyzed, excluding 2021 due to a change in the survey methodology that only affected that year. The cumulative sample size for this repeated cross-sectional sample is 23,994, with the annual sample sizes as follows: 2018 (n=4,000), 2019 (n=4,000), 2020 (n=7,980), and 2022 (n=8,014). The survey methodology primarily samples new respondents each year. However, a small percentage of respondents have participated in previous surveys (**Appendix 2.2**). The overall response rate was 65%. All respondents provided informed consent for survey participation. Data collection and retention followed General Data Protection Regulation-compliant procedures, with personal information being erased within 6-12 months of collection and panelist data erased within three years of inactivity. The University of California, Los Angeles (UCLA) Institutional Review Board approved this study.

Study Variables

Willingness to Share Health Data

Respondents were asked the following question: "Please indicate which of the following individuals or organizations you would be willing to share your health information with (e.g., your medical records, test results, prescription drug history, genetic information, and physical activity data). Select all that apply." The nine stakeholders included: (1) a technology company, (2) a healthcare technology company, (3) the respondent's family members, (4) the respondent's health insurance company, (5) the respondent's pharmacy, (6) the respondent's doctor/clinician, (7) a research institution, (8) a government organization, or (9) a pharmaceutical company. The survey allowed respondents to select any stakeholders they were willing to share their health information with, including the option to opt for none; thus, a binary (yes/no) response was recorded for each stakeholder.

Covariates

All covariates and their measurement methodologies are summarized in **Appendix 2.1**. The survey's sociodemographic questions gathered information on age, annual household income, highest level of educational attainment, rurality, gender, health insurance coverage, and race/ethnicity. The race/ethnicity variable is represented by a series of non-mutually exclusive binary variables, allowing multiple selections to reflect complex identities. The survey asked participants to report their health status on a five-point scale and diagnosis of select chronic conditions. Additionally, this study incorporated variables related to digital health utilization. These include prior telemedicine utilization across various modalities, characterized by live video, live phone, picture or video, text messaging, email, or use of apps or websites; use of digital tools, such as wearables or digital journals, for tracking health metrics; and online health

information-seeking behavior, specifically regarding prescription drugs and/or side effects, medical diagnoses, or treatment options.

Statistical Analysis

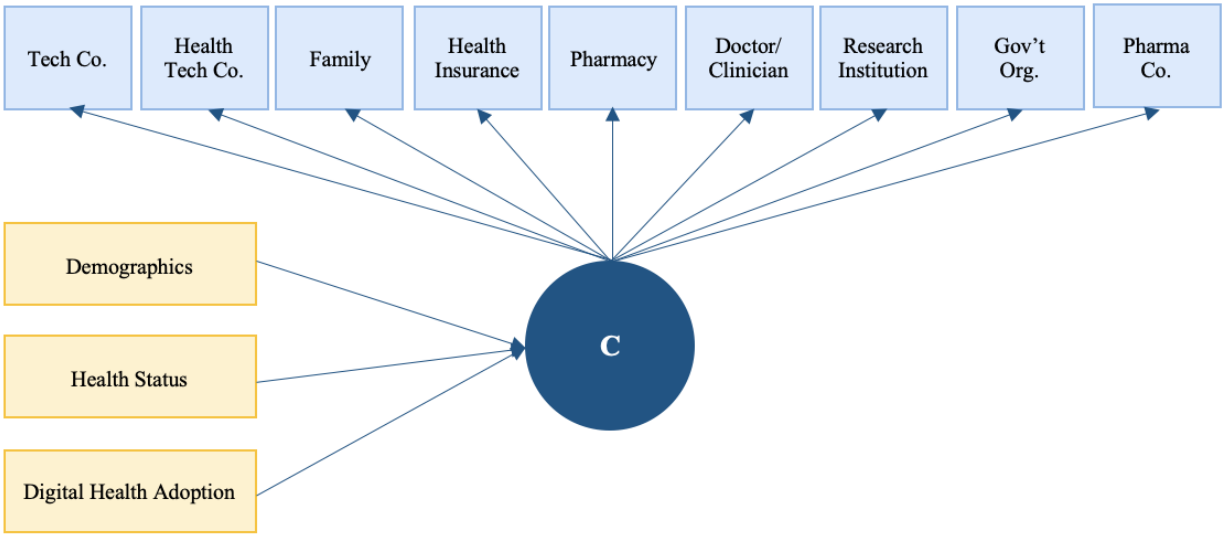
Latent class Analysis

Latent class analysis (LCA) was employed to identify distinct groups within the sample based on patterns of their willingness to share health information with the nine stakeholders. Latent class analysis (LCA) is an example of a finite mixture model, which express the overall distribution of one or more variables as a finite number of sub-distributions for each component.[70,76] Within this model, there are two types of variables: latent variables and indicator variables. Latent variables are not directly measured – they are unobserved or latent. Indicator variables (also referred to as manifest variables) are observed and are presumed to be influenced by the latent variable. There are two components to latent class models: the measurement model and the structural model. The measurement model relates the indicator variables to the underlying latent variables. The structural model defines the latent variable's distribution and the relationship between latent variables and between latent variables and observed predictor and outcome variables. Importantly, the measurement model serves as the basis for assigning latent classes.[70]

Compared to cluster analysis, which is not based on a statistical model, LCA is a probabilistic model, meaning that it uses probabilities to estimate the latent classes and provides information about the probability of respondents being in specific classes. Thus, the classes are data-driven as composed to being conceptually generated.[70,77] LCA was employed to identify distinct groups within the sample based on patterns of their willingness to share health data with various stakeholders (**Figure 2.2**). Beyond using multivariable logistic regression models to

estimate associations among respondent characteristics and willingness to share health data with stakeholders, LCA aims to uncover qualitatively different hidden clusters within the respondent pool.[78]

Figure 2.2 Path diagram of latent class analysis model with indicators.



Note: The circle with the C represents the classes that are formed.

Model Implementation and Data Analysis

A series of models were fitted,[38] starting with a single-class model and incrementally adding classes until the model fit ceased to improve. The optimal number of latent classes was determined through a review of statistical fit indices, including the Akaike information criterion (AIC) and Bayesian information criterion (BIC). Class membership probabilities were examined to understand the distribution of respondents across the identified latent classes.

For each latent class, I obtained descriptive statistics of covariates. Given the categorical nature of the variables, a chi-square test of equal proportions was used to compare sociodemographic, health status, and digital health utilization variables across the classes. Subsequently, multinomial logistic regression models were conducted to explore covariates

associated with class membership, with a focus on sociodemographic and digital health utilization variables. The selection of covariates, including sociodemographic characteristics and digital health utilization variables, is informed by the TPB to comprehensively capture the diverse factors associated with respondents' willingness to share their health information. All analyses were conducted using Stata version 16.1 (StataCorp).

Sensitivity Analyses

Several sensitivity analyses were conducted to compare latent classes derived from pre-pandemic and pandemic periods. First, LCA was performed using data from 2018 and 2019 to identify latent classes specific to the pre-pandemic era. This was also necessary due to the smaller sample size in 2018 and 2019 compared to other survey years. Then, LCA was performed using data from 2018, 2019, and 2020 to compare latent classes formed from pre-pandemic and the first pandemic year. While inclusion of the 2021 data, which provided added graduality (e.g., knowing the specific data being shared such as lab test results, prescriptions drug history, genetic information), was considered, exploratory analyses revealed that incorporating 2021 data would not be consistent with the data from the other years. Therefore, the 2021 data was excluded from further sensitivity analyses.

Results

Overall Sample Characteristics

The sample included 23,994 respondents, of which 19.8% were 65 or older, 50.7% were female, 11.5% identified as non-Hispanic Black, and 15.3% identified as Hispanic/Latino (**Table 2.1**).

Table 2.1 Respondent sociodemographic characteristics (N=23,994).

	n (%)
Age	
18-24	2,885 (12.0)
25-34	4,312 (18.0)
35-44	4,186 (17.5)
45-54	4,012 (16.7)
54-65	3,846 (16.0)
65+	4,753 (19.8)
Income	
<$25,000	4,998 (20.8)
$25,000-49,999	5,474 (22.8)
$50,000-74,999	4,115 (17.2)
$75,000-99,999	2,825 (11.8)
>$100,000	6,431 (26.8)
Prefer not to say	151 (0.6)
Education	
Less than high school	610 (2.5)
High school graduate (includes equivalency)	5,245 (21.9)
Some college/Associate's degree	7,839 (32.7)
Bachelor's degree	5,467 (22.8)
Advanced degree	4,750 (19.8)
Prefer not to say	83 (0.4)
Area Description	
Rural	4,647 (19.4)
Suburban	10,705 (44.6)
Urban	8,642 (36.0)
Gender	
Female	12,152 (50.7)
Male	11,727 (48.9)
Other	85 (0.4)
Prefer not to disclose	30 (0.1)
Health Insurance	
Commercial	11,537 (48.1)
Medicare	5,196 (21.7)
Medicaid	3,670 (15.3)
Other insurance	1,199 (5.0)
Uninsured	1,605 (6.7)
Don't know	787 (3.3)
Race/Ethnicity	
NH-White	15,786 (65.8)
NH-Black/African-American	2,759 (11.5)
NH-Native American or Alaska Native	153 (0.6)
NH-Asian / Pacific Islander	1,127 (4.7)
Hispanic/Latinx	3,669 (15.3)
NH-Multiracial	330 (1.4)
NH-Other	94 (0.4)
Prefer not to say	76 (0.3)

Latent Class Model Selection

The three-class LCA model was selected based on an assessment of goodness-of-fit statistics (**Table 2.2** and **Figure 2.3**). While AIC and BIC decreased from one to eight classes, indicating better fit with each additional class, improvement in fit plateaued after three classes, suggesting that the three-class model was the best model. There was also an issue of lack of convergence starting from the four-class model. Non-convergence indicates that the results of the model may not be interpretable, and estimating additional classes is usually stopped once convergence issues are encountered.[37]

Table 2.2 Latent class analysis goodness-of-fit statistics according to number of classes.

Number of Classes	G^2	AIC	BIC
1	35311.749	236186.047	236258.817
2	13309.655	214203.955	214357.580
3	3875.136	204789.435	205023.916
4	2681.320	203615.619	203930.956
5	1498.428	202448.728	202828.749
6	928.113	201900.412	202369.375
7	726.055	201718.355	202268.173
8	637.341	201649.640	202280.314

Note: G^2 = Likelihood Ratio statistic; AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion

Figure 2.3 Elbow plot of Bayesian information criteria (BIC).

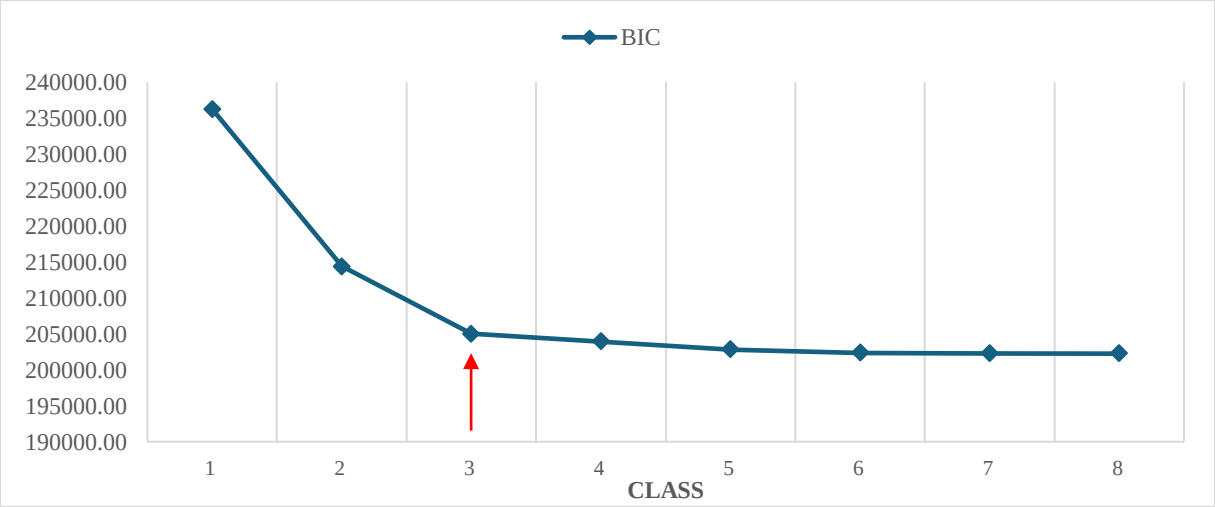
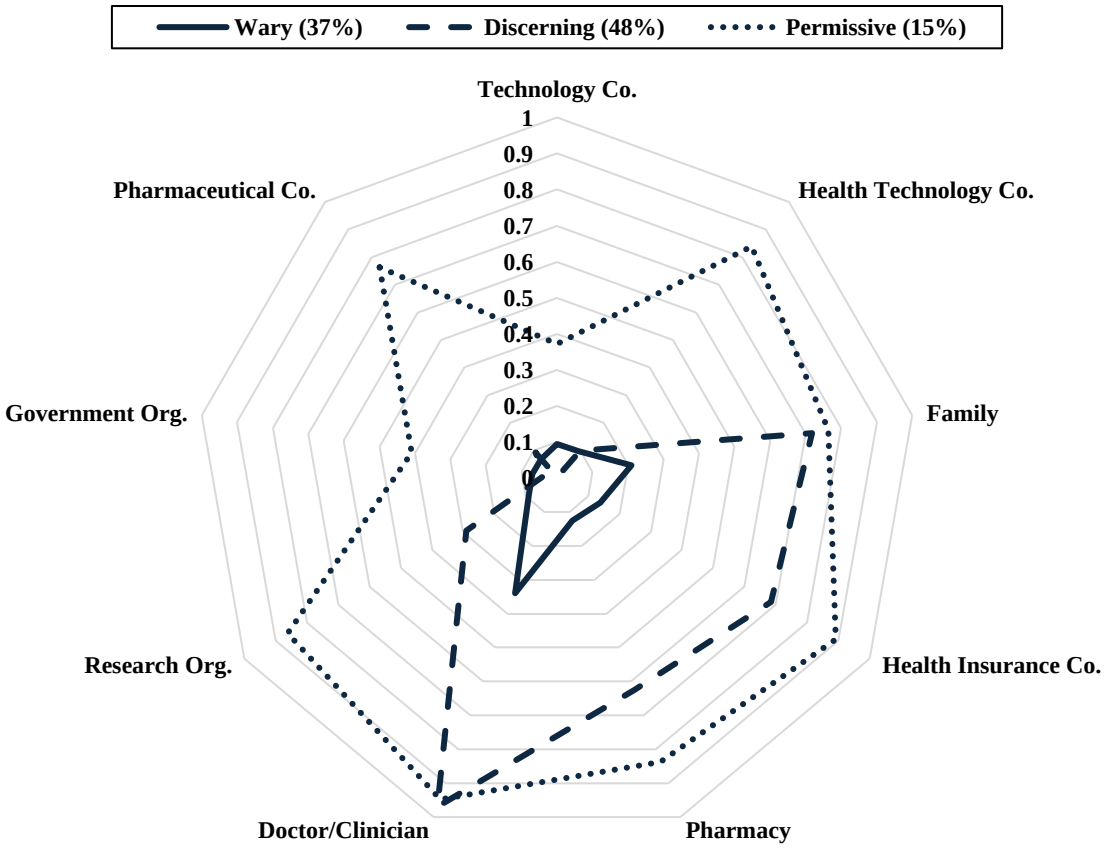


Figure 2.4 shows the predicted probabilities of willingness to share health information with each stakeholder by latent class (**Appendix 2.3**). Given the distinct patterns of willingness

to share health information by the three groups of respondents, they can be described as 1) the Wary group, 2) the Discerning group, and 3) the Permissive group. The Wary group, comprising 37% (n=8,823) of the respondents, demonstrated a low probability of being willing to share health data across all stakeholders. Individuals in this class were most willing to share their health information with physicians with a moderate predicted probability (Pr=0.34), followed by their family (Pr=0.21). Respondents in the Wary group were least willing to share their health information with pharmaceutical companies, government organizations, and research organizations (Pr ranges from 0.07 to 0.09). Within the Discerning group, which represents 48% (n=11,505) of respondents, a bifurcation in health data-sharing attitudes is evident. Members of this group showed high probabilities of willingness to share health data with physicians, family, health insurance companies, and pharmacies (Pr ranges from 0.62 to 0.97); however, they were very unwilling to share their health information with technology companies, government organizations, and pharmaceutical companies (Pr ranges from 0.00 to 0.09). The Permissive group (15%; n=3,666) generally exhibited a high willingness to share health data with most stakeholders. Though, the exceptions are technology companies (Pr=0.37) and government organizations (Pr=0.41), for which the probability of sharing is somewhat reduced but still relatively high compared to the two other latent groups. Across all latent groups, the highest willingness to share data was with physicians.

Figure 2.4 Predicted probabilities of willingness to share health data for each stakeholder by latent class.



Characteristics of Latent Classes

Sociodemographic variations exist across the three latent groups (**Table 2.3)**. The Wary group respondents, compared to the other two groups, reported greater percentages of being in younger age brackets (18-44) and living in urban areas. This group had a slightly higher percentage of uninsured individuals. In contrast, the Discerning group's respondents reported a higher percentage of being in older age brackets (55+), with a higher proportion being Medicare recipients. The Permissive group exhibited a balanced age distribution, with a nearly equal representation of females and males. Notably, the Permissive group had a slightly higher percentage of individuals on Medicaid.

Table 2.3 Sociodemographics of three groups (N=23,994).

	Wary	Discerning	Permissive	*p*-value

	n (%)	n (%)	n (%)	
Total respondents	8,823 (36.8)	11,505 (47.9)	3,666 (15.3)	
Age				<0.001
18-24	1,499 (17.0)	1,009 (8.8)	377 (10.3)	
25-34	2,113 (24.0)	1,497 (13.0)	702 (19.2)	
35-44	2,151 (24.4)	1,411 (12.3)	624 (17.0)	
45-54	1,427 (16.2)	1,941 (16.9)	644 (17.6)	
55-64	880 (10.0)	2,339 (20.3)	627 (17.1)	
65+	753 (8.5)	3,308 (28.8)	692 (18.9)	
Income				<0.001
<$25,000	1,954 (22.2)	2,368 (20.6)	676 (18.4)	
$25,000-49,999	1,874 (21.2)	2,731 (23.7)	869 (23.7)	
$50,000-74,999	1,224 (13.9)	2,197 (19.1)	694 (18.9)	
$75,000-99,999	953 (10.8)	1,412 (12.3)	460 (12.6)	
>$100,000	2,735 (31.0)	2,735 (23.8)	961 (26.2)	
Prefer not to say	83 (0.9)	62 (0.5)	6 (0.2)	
Education				<0.001
Less than high school	323 (3.7)	205 (1.8)	82 (2.2)	
High school graduate (includes equivalency)	2,059 (23.3)	2,480 (21.6)	706 (19.3)	
Some college/Associate's degree	2,428 (27.5)	4,083 (35.5)	1,328 (36.2)	
Bachelor's degree	1,728 (19.6)	2,857 (24.8)	882 (24.1)	
Advanced degree	2,228 (25.3)	1,859 (16.2)	663 (18.1)	
Prefer not to say	57 (0.7)	21 (0.2)	5 (0.1)	
Area Description				<0.001
Rural	1,378 (15.6)	2,519 (21.9)	750 (20.5)	
Suburban	3,377 (38.3)	5,628 (48.9)	1,700 (46.4)	
Urban	4,068 (46.1)	3,358 (29.2)	1,216 (33.2)	
Gender				<0.001
Female	3,951 (44.8)	6,374 (55.4)	1,827 (49.8)	
Male	4,817 (54.6)	5,085 (44.2)	1,825 (49.8)	
Other	32 (0.4)	39 (0.3)	14 (0.4)	
Prefer not to disclose	23 (0.3)	7 (0.1)	0 (0.0)	
Health Insurance				<0.001
Commercial	4,452 (50.5)	5,278 (45.9)	1,807 (49.3)	
Medicare	1,101 (12.5)	3,330 (28.9)	765 (20.9)	
Medicaid	1,438 (16.3)	1,598 (13.9)	634 (17.3)	
Other insurance	539 (6.1)	502 (4.4)	158 (4.3)	
Uninsured	731 (8.3)	626 (5.4)	248 (6.8)	
Don't know	562 (6.4)	171 (1.5)	54 (1.5)	
Race/Ethnicity				<0.001
NH-White	5,144 (58.3)	8,108 (70.5)	2,534 (69.1)	
NH-Black/African-American	1,420 (16.1)	1,050 (9.1)	289 (7.9)	
NH-Native American or Alaska Native	83 (0.9)	45 (0.4)	25 (0.7)	
NH-Asian/Pacific Islander	487 (5.5)	500 (4.4)	140 (3.8)	
Hispanic/Latinx	1,488 (16.9)	1,591 (13.8)	590 (16.1)	
NH-Multiracial	112 (1.3)	148 (1.3)	70 (1.9)	
NH-Other	33 (0.4)	49 (0.4)	12 (0.3)	
Prefer not to say	56 (0.6)	14 (0.1)	6 (0.2)	

Table 2.4 reveals varying health profiles across the three latent groups. Respondents in the Wary group mostly self-reported good or excellent health. The Discerning and Permissive groups showed a higher prevalence of having at least one chronic condition, which may be related to the older age of respondents in these groups.

Table 2.4 Health profile and digital health adoption of three groups (N=23,994).

	Wary n (%)	**Discerning n (%)**	**Permissive n (%)**	***p*-value**
Total respondents	8,823 (36.8)	11,505 (47.9)	3,666 (15.3)	
Health profile				
Self-rated health status				<0.001
Very Poor	81 (0.9)	82 (0.7)	45 (1.2)	
Poor	300 (3.4)	690 (6.0)	256 (7.0)	
Moderate	1,489 (16.9)	2,631 (22.9)	840 (22.9)	
Good	4,040 (45.8)	6,373 (55.4)	1,853 (50.6)	
Excellent	2,913 (33.0)	1,729 (15.0)	672 (18.3)	
Any chronic conditions				<0.001
No	3,973 (45.0)	3,980 (34.6)	1,184 (32.3)	
Yes	4,850 (55.0)	7,525 (65.4)	2,482 (67.7)	
Digital health adoption				
Telemedicine user				<0.001
No	1,979 (22.4)	3,153 (27.4)	818 (22.3)	
Yes	6,844 (77.6)	8,352 (72.6)	2,848 (77.7)	
Digital health tracker				<0.001
No	3,801 (43.1)	5,909 (51.4)	1,548 (42.2)	
Yes	5,022 (56.9)	5,596 (48.6)	2,118 (57.8)	
Online information seeker				<0.001
No	2,665 (30.2)	3,109 (27.0)	716 (19.5)	
Yes	6,158 (69.8)	8,396 (73.0)	2,950 (80.5)	

The three latent groups also demonstrated distinct digital health utilization patterns (**Table 2.4**). The Wary and Permissive groups exhibited higher adoption rates of telemedicine services, outpacing the Discerning group. Further, respondents in the Wary and Permissive groups were more likely to use digital health tools to track their health metrics. Conversely, individuals in the Permissive group were most likely to seek health information online, with 80.5% engaging in this behavior compared to 69.8% of Wary respondents and 73.0% of Discerning respondents.

Factors Associated with Latent Class Membership

Multinomial logistic regression was used to assess factors that are associated with membership in the latent classes, with the Wary group serving as the reference group and relative risk ratios (RRR) presented (**Table 2.5**).

Table 2.5 Multinomial logistic regression predicting class membership (N=23,834).

	Discerning vs. Wary		**Permissive vs. Wary**	
	RRR	**(95% CI)**	**RRR**	**(95% CI)**
Age (ref: 18-24)				
25-34	1.06	(0.95-1.18)	1.25**	(1.08-1.45)
35-44	1.05	(0.94-1.18)	1.08	(0.93-1.27)
45-54	1.88***	(1.68-2.11)	1.52***	(1.30-1.77)
55-64	3.33***	(2.95-3.76)	2.26***	(1.92-2.66)
Age 65 or older	5.64***	(4.97-6.40)	3.03***	(2.55-3.59)
Gender (ref: female)				
Male	0.73***	(0.68-0.77)	0.91*	(0.84-0.99)
Other	1.26	(0.75-2.11)	1.35	(0.70-2.63)
Education (ref: <high school)				
High school graduate	1.62***	(1.33-1.98)	1.23	(0.95-1.61)
Some college, no degree or Associate's degree	2.12***	(1.74-2.57)	1.80***	(1.39-2.34)
Bachelor's degree	2.32***	(1.90-2.84)	1.77***	(1.35-2.31)
Advanced degree	1.37**	(1.12-1.69)	1.07	(0.82-1.41)
Race/ethnicity (ref: NH-White)				
NH-Black/African American	0.62***	(0.57-0.69)	0.48***	(0.41-0.55)
NH- Native American/Alaska Native	0.50***	(0.34-0.73)	0.74	(0.46-1.17)
NH-Asian/Pacific Islander	0.91	(0.79-1.04)	0.71**	(0.58-0.87)
Hispanic/Latinx	0.97	(0.89-1.06)	0.94	(0.84-1.06)
NH-Multiracial	1.00	(0.77-1.31)	1.34	(0.98-1.84)
Other-only	0.92	(0.58-1.47)	0.71	(0.36-1.40)
Self-rated health status (ref: excellent)				
Very Poor	1.33	(0.95-1.88)	2.20***	(1.48-3.28)
Poor	2.21***	(1.88-2.60)	2.53***	(2.08-3.09)
Moderate	2.06***	(1.87-2.27)	1.99***	(1.75-2.27)
Good	1.92***	(1.78-2.07)	1.69***	(1.52-1.87)
Chronic condition status	1.05	(0.98-1.12)	1.20***	(1.09-1.31)
Telemedicine user	0.85***	(0.79-0.92)	0.90*	(0.81-1.00)
Digital health tracker	0.98	(0.92-1.05)	1.17***	(1.07-1.28)
Online information seeker	1.52***	(1.42-1.64)	1.97***	(1.78-2.18)

Reference group: Wary; *** p<0.001, ** p<0.01, * p<0.05

Respondents 65 or older were more likely to be in both the Discerning (RRR: 5.64) and Permissive (RRR: 3.03) groups compared to those aged 18-24. Males were less likely to be in

both the Discerning (RRR: 0.73) and Permissive (RRR: 0.91) groups compared to females. Higher education levels are associated with higher likelihoods of being in the Discerning group (RRRs: 1.62 to 2.32) and the Permissive group (RRRs: 1.07 to 1.80) compared to having less than a high school education. Respondents who identified as NH-Black/African American (Discerning RRR: 0.62; Permissive RRR = 0.48) or NH-Native American/Alaska Native (Discerning RRR = 0.50; Permissive RRR: 0.74) were less likely to be in both groups compared to those who identified as NH-White.

Respondents who rated their health as "Very Poor" were 1.33 times more likely to belong to the Discerning group and 2.20 times more likely to belong to the Permissive group, compared to the Wary group. In terms of digital health utilization, telemedicine users were less likely to be in the Discerning or Permissive groups, compared to the Wary group, with RRRs of 0.85 and 0.90, respectively. Conversely, online health information seekers were significantly more likely to be in the Discerning (RRR: 1.52) or Permissive (RRR: 1.97) groups relative to the Wary group. Digital health trackers were associated with a lower likelihood of belonging to the Discerning group (RRR: 0.98), but a higher likelihood of belonging to the Permissive group (RRR: 1.17), compared to the Wary group.

Sensitivity Analyses

Compared to the main analytical sample's LCA output, the sample in the first sensitivity analysis exhibited a similar class breakdown (**Appendix 2.4**). Including pandemic year data, the output remained largely consistent (**Appendix 2.4**). Thus, the differences in the classes were minimal, with the segmentation remaining the same. Examining the composition of the three groups across different years, Class 1 consistently remained Wary, Class 2 remained Discerning, and Class 3 remained Permissive.

Discussion

This study employed LCA to unearth patterns of consumer willingness to share health information with different stakeholders. The three groups–Wary, Discerning, and Permissive–highlight that consumer attitudes toward health data sharing are not uniform; rather, there is heterogeneity in sharing preferences.

The Wary group demonstrated a consistently conservative approach to data sharing, exhibiting a strong reluctance to share their health data across all stakeholders. Their willingness to share data with pharmaceutical companies, government organizations, and research institutions is particularly low, suggesting concerns about privacy or intentions behind data use.[65] This aligns with the TPB, where perceived behavioral control (concern over data use) and attitudes (negative perceptions) influence behavior (reluctance to share).

Conversely, the Discerning group was characterized by their selective sharing preferences, showing willingness to share health data with traditional healthcare actors—physicians, family, health insurance companies, and pharmacies–but hesitation about sharing with technology companies, government organizations, and pharmaceutical companies. This differentiation may stem from established relationships with traditional entities alongside skepticism about non-traditional healthcare entities' motivations or data security practices.[79] In TPB terms, their attitude toward sharing with traditional healthcare actors is positive, influenced by favorable subjective norms and perceived behavioral control regarding the security of their data with these entities. The Discerning group has moderate trust in research organizations, perhaps suggesting conditional acceptance of sharing data for research, influenced by both attitudes and perceived norms about the benefits of research.

The Permissive group's broad willingness to share data, notably more so with health technology companies than general technology companies, exemplifies the importance of the distinction for consumers in technology companies that are specialized in advancing healthcare, as opposed to technology companies at-large. This indicates a positive attitude and perceived behavioral control regarding health technology companies, likely influenced by the perceived benefits and social norms surrounding these entities. The acceptance of data sharing practices outside traditional healthcare settings by this group suggests a readiness to embrace innovations in health technology, in line with TPB's prediction that positive attitudes and perceived social norms drive willingness to share.

One notable finding is the relatively low willingness to share health data with technology companies and government organizations, even among the Discerning and Permissive groups, a result also supported by previous research.[65] Several potential reasons may explain this hesitation. Consumers may harbor concerns about data privacy, particularly around risks associated with data breaches involving technology companies and the possibility for misuse by these companies.[80,81] Also, it is possible that there may be a lack of transparency around how technology companies handle sensitive health data, which could erode consumer trust. In terms of government organizations, concerns about surveillance or unintended uses of health data (e.g., for law enforcement purposes) may also contribute to low willingness to share.

Importantly, across all groups, the high willingness to share health data with physicians signifies not only patients' enduring trust in traditional healthcare relationships but also a belief that data shared with physicians will be adequately protected. This consistent trust can be explained by positive attitudes, strong subjective norms favoring data sharing with physicians, and high perceived behavioral control. However, openness to sharing data with non-traditional

stakeholders like health technology companies by the Permissive group suggests acceptance of data sharing practices outside traditional healthcare settings by certain consumers, influenced by changing subjective norms and increased perceived behavioral control facilitated by advances in technology. It is reasonable to speculate that this permissiveness stems from a desire for convenience, where individuals may focus on the benefits of data sharing without fully considering the potential downsides, such as a lack of awareness that their data might not be stored solely on their devices but uploaded to a technology company's cloud system, which could pose privacy risks.

These findings mirror some previous research showing that consumer trust in health data sharing is not uniform but varies by stakeholder and context.[65,69] Prior studies have found higher trust and willingness to share with traditional healthcare entities like physicians, compared to non-traditional ones, such as technology companies,[65–67,69] which is consistent with results regarding the Wary and Discerning groups. However, in contrast to some of this earlier work finding broad skepticism toward technology companies, the identification of a Permissive group highlights the variability of consumer preferences.

Sociodemographic insights reveal that younger respondents predominate the Wary group, possibly reflecting greater awareness, and consequently, cautiousness toward data privacy issues. This group's higher proportion of respondents identifying as Black or African American, compared to the percentages observed in the other two groups, may reflect broader societal issues such as distrust in medical institutions and concerns about privacy and discrimination.[82] This is in accordance with TPB's concept of perceived behavioral control, where past experiences and awareness impact the willingness to share data.

Older adults were predominantly found in the Discerning group, reflecting a tendency to adhere to the most "traditional" data sharing practice—willing to share with traditional actors but more cautiously with the newer entrants. This aligns with the TPB, where traditional norms and perceived behavioral control with familiar entities influence their selective sharing behavior.

Female individuals were more represented in the Discerning and Permissive groups, compared to male individuals, perhaps reflecting their proactive engagement in health management. Their positive attitudes toward managing their health presumably influence their intentions to share data, demonstrating that perceived control and behavioral beliefs play a role in shaping this behavior.

Findings also suggest that individuals with poorer health conditions might be more inclined to share their health data, possibly in attempt to achieve better health management or treatment options. According to TPB, their positive attitude towards the perceived benefits of sharing for health management and supportive subjective norms could explain this behavior.

The study also uncovered some paradoxical insights regarding digital health utilization. Telemedicine users showed less propensity to belong to the Discerning or Permissive groups, suggesting that, while they may be less cautious about data sharing, they engage with telemedicine less than the Wary respondents. One possible explanation is that these individuals perceive telemedicine primarily as a means of accessing healthcare services, rather than as a technology involving significant data sharing. This highlights a potential incongruence between consumer attitudes and behaviors related to digital health. In contrast, respondents who actively sought online health information tended to be more discerning or permissive, indicating that individuals who actively seek health information might also be more comfortable with data sharing, perhaps viewing it as a valuable means to enhance their access to personalized health

insights and resources. Additionally, the permissive respondents showed a greater proclivity to being digital health trackers, suggesting that individuals appear to select technologies that match their data sharing preferences.

By employing LCA, we gain several insights. First, instead of quantifying the magnitude of willingness to share health data (e.g., low, medium, high), the findings evinced a spectrum of attitudes across different stakeholders. This highlights that a matrix of variables may influence decisions to share health data. Second, the findings revealed that willingness to share health data may depend on the nature of the relationship one has with each stakeholder. For example, respondents exhibited greater willingness to share with entities with whom they have a direct, tangible relationship, such as family members and physicians. Third, health status and utilization of digital health are predictors of latent class membership. The interplay of these variables likely impacts the degree of willingness to share health data.

Overall, the results of this study indicate varying public perspectives on health data sharing by stakeholder. The Wary group's absolutist stance against data sharing, irrespective of stakeholder, suggests an opportunity to further examine their concerns to inform privacy protections. However, it is also plausible that these individuals may not fully realize the benefits of health data sharing and may need to be better informed. In contrast, it would be informative to evaluate what benefits the Permissive group sees in data sharing, and the bright-line demarcation with technology companies and government organizations underscores that it would be wise for these entities to address privacy concerns and ensure transparency in data handling practices. For example, technology companies could implement clearer consent mechanisms, indicating how health data will be used and if it will be shared with third parties. For government organizations, policies that provide greater clarity on the purposes of data collection could help build trust. The

Discerning group took a bifurcated approach to health data sharing: openness with traditional actors in healthcare and reluctance with distal stakeholders in one's healthcare. Indeed, there may be a role for more trusted intermediaries, such as healthcare providers, to facilitate data sharing with non-traditional healthcare stakeholders.

Limitations

There are several limitations in the study due to some survey redesign. The sample size varied by year, with 4,000 respondents in 2018 and 2019, doubling in subsequent years to explore potential changes in digital health adoption following the start of the pandemic. The exclusion of 2021 data because of methodological differences limits the study's temporal consistency. Additionally, the question wording about sex and gender varied each year, and race and ethnicity were asked as a single question instead of as two separate questions. The lack of granularity on the specific types of health information consumers are willing to share (e.g., genetic information versus physical activity data) restricts deeper analyses into privacy preferences. Furthermore, the study did not define the specific purposes or intent behind data sharing, allowing for respondents to interpret what constitutes "data sharing," which may have led to varying perceptions of the potential benefits or tradeoffs associated with sharing this information. Also, the binary nature (yes/no) of the question on willingness to share limits the ability to capture fine-grained degrees of willingness. Potential sampling biases, such as respondents being more inclined to complete online surveys, must also be accounted for in the analysis.

Conclusion

Our analysis identified three distinct patterns of consumer willingness to share health information. The findings reveal variability in data sharing preferences, with higher willingness to share health information with traditional healthcare stakeholders, such as physicians, and more varied responses when it comes to non-traditional healthcare stakeholders like technology companies. It may be prudent for stakeholders to address areas of consumer concern to advance healthcare via data sharing.

Appendix 2.1 Study variables.

Category	Description	Type	Operationalization
Demographics	Age	Categorical	1 = 18 to 24 years 2 = 25 to 34 years 3 = 35 to 44 years 4 = 45 to 54 years 5 = 55 to 64 years 6 = Age 65 or older
	Income	Categorical	1 = Less than $25,000 2 = $25,000 to $49,999 3 = $50,000 to $74,999 4 = $75,000 to $99,999 5 = $100,000 or more . = Prefer not to say
	Education	Categorical	1 = Less than high school 2 = High school graduate (includes equivalency) 3 = Some college, no degree or Associate's degree 4 = Bachelor's degree 5 = Adv. degree (includes Master's degree, Ph.D., Graduate or professional degree (for example: MD, JD)) . = Prefer not to say
	Area description/rurality	Categorical	1 = Rural 2 = Suburban 3 = Urban
	Gender Identity	Categorical	1 = Female 2 = Male 3 = Other . = Prefer not to disclose
	Health Insurance	Categorical	1 = Commercial (Employer, Exchange, or private purchase) 2 = Medicare 3 = Medicaid, or other type of government assistance 4 = Other insurance (e.g., VA, IHS, Military) 5 = Uninsured . = Don't know
	Race/Ethnicity	Categorical	1 = NH-White 2 = NH-Black/African American 3 = NH- Native American or Alaska Native 4 = NH-Asian/Pacific Islander 5 = Hispanic/Latinx 6 = NH-Multiracial 7 = Other-only . = Prefer not to say
Health Status	Self-rated health status	Categorical	1 = "Very Poor" 2 = "Poor" 3 = "Moderate" 4 = "Good"

			5 = “Excellent”
	Any chronic condition	Binary	Yes = 1 No = 0
Digital Health Adoption	Telemedicine user	Binary	Yes = 1 No = 0
	Currently keeping track of health metrics (e.g., weight, health rate, blood pressure, medications, activity, food, sleep, other) digitally	Binary	Yes = 1 No = 0
	Online search for information about prescription drugs, for diagnosis, or for treatment options	Binary	Yes = 1 No = 0
Data Sharing Willingness with Stakeholders	Technology company	Binary	Yes = 1 No = 0
	Healthcare technology company	Binary	Yes = 1 No = 0
	Your family members	Binary	Yes = 1 No = 0
	Your health insurance company	Binary	Yes = 1 No = 0
	Your pharmacy	Binary	Yes = 1 No = 0
	Your doctor/clinician	Binary	Yes = 1 No = 0
	Research institution	Binary	Yes = 1 No = 0
	Government organization	Binary	Yes = 1 No = 0
	Pharmaceutical company	Binary	Yes = 1 No = 0

Appendix 2.2 Rock Health Digital Health Consumer Adoption Survey percentage of repeat respondents.

	Total Respondents	Repeat Respondents	% Repeat Respondents
2018	4,000	0	0%
2019	4,000	176	4.4%
2020	7,980	418	5.2%
2021	7,980	68	0.9%
2022	8,014	298	3.7%
Total (2018-2022)	31,974	784	3.3%

Appendix 2.3 Predicted probability results of latent class analysis for three classes.

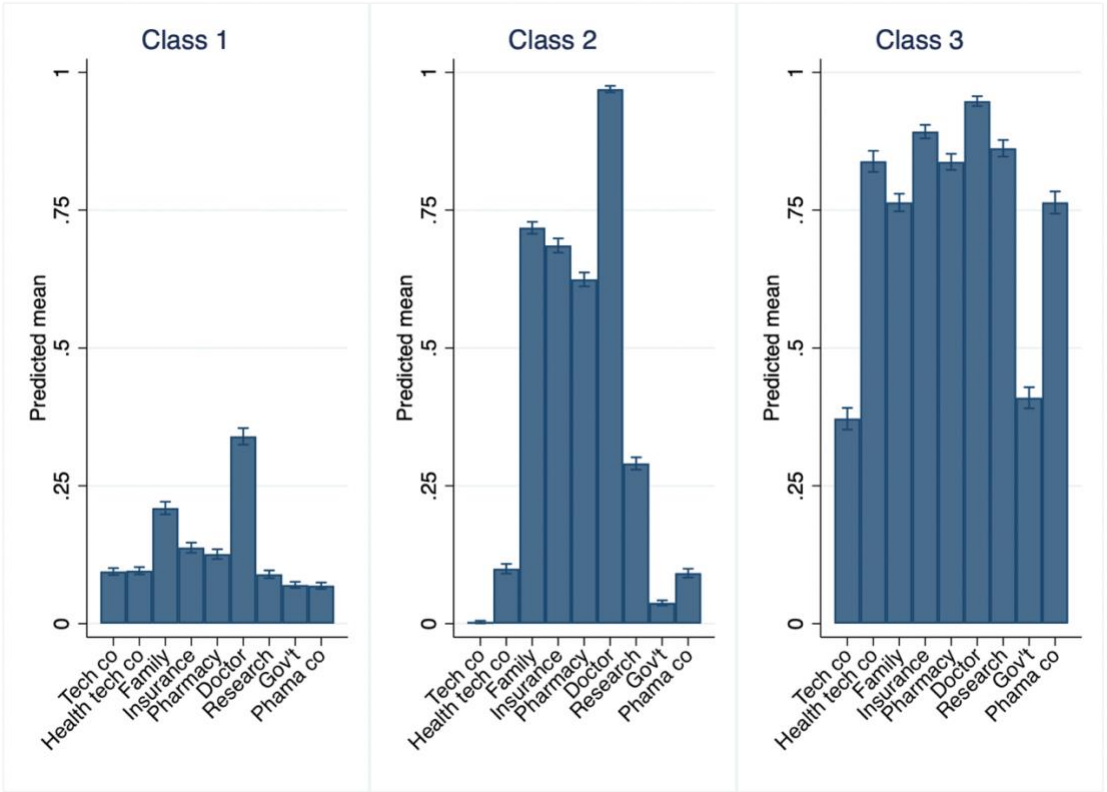
	Class 1	**Class 2**	**Class 3**
Pr(Class)	0.397967	0.451892	0.150141
Probability of…			
Technology company	0.0945322	0.0028932	0.3716768
Healthcare technology company	0.0959693	0.0996199	0.8384377
Family members	0.2096465	0.7180398	0.7638161
Health insurance company	0.1377626	0.6858198	0.8925491
Pharmacy	0.126183	0.6243628	0.8375679
Doctor/clinician	0.339519	0.9694729	0.9477609
Research institution	0.0894427	0.2905316	0.8621222
Government organization	0.0702221	0.0375197	0.4096194
Pharmaceutical company	0.0687718	0.0916139	0.7639086

Appendix 2.4 Sensitivity analyses.

For 2018-2019 data:

Summary results of latent class analysis for three classes (N=8,000).

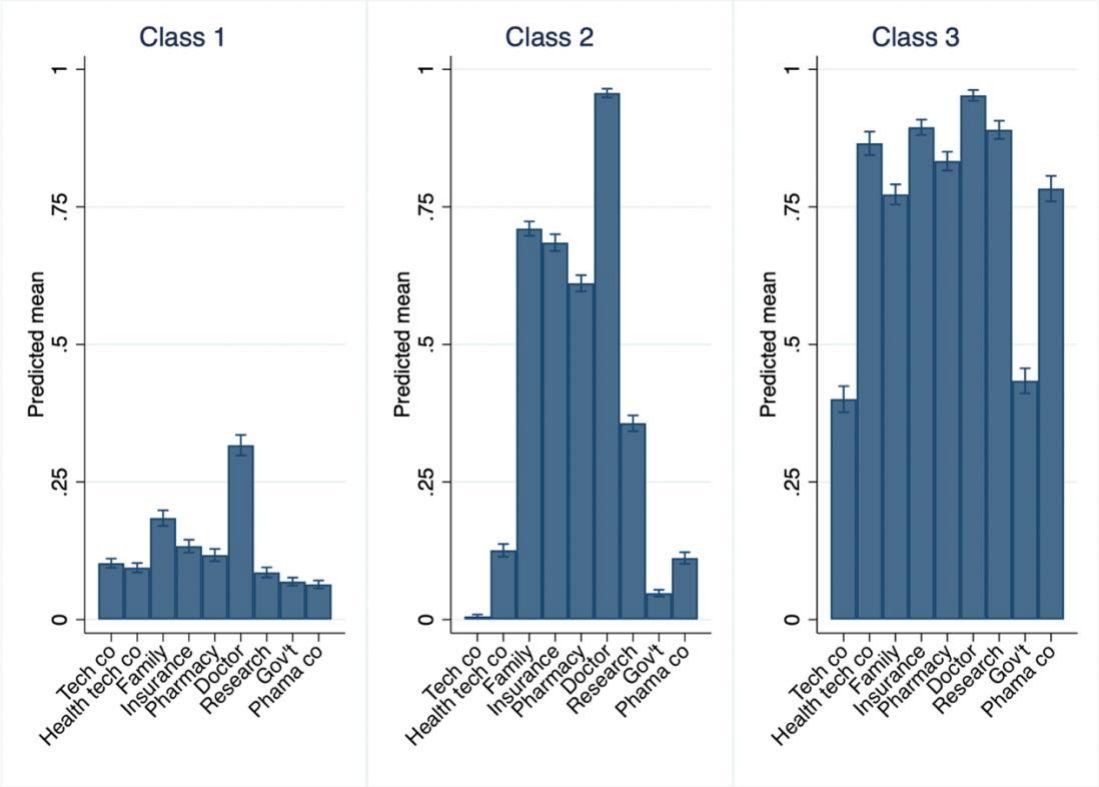
	Class 1	Class 2	Class 3
Pr(Class)	0.3697158	0.4867363	0.1435478
Technology company	0.0860218	0.0096238	0.46857
Healthcare technology company	0.0868764	0.1401804	0.8944719
Family members	0.1926731	0.7165628	0.7975638
Health insurance company	0.1216616	0.6871358	0.8991134
Pharmacy	0.1216724	0.6262342	0.8652504
Doctor/clinician	0.3302137	0.9524092	0.9559017
Research institution	0.088881	0.370301	0.9040562
Government organization	0.0627969	0.0547858	0.5006466
Pharmaceutical company	0.0682887	0.1161994	0.801608



For 2018-2020 data:

Summary results of latent class analysis for three classes (N=15,980).

	Class 1	Class 2	Class 3
Pr(Class)	0.3647649	0.4680572	0.1671778
Technology company	0.1024404	0.0056983	0.4006211
Healthcare technology company	0.0941568	0.1256805	0.8654797
Family members	0.1843566	0.710487	0.7727001
Health insurance company	0.1334208	0.6851102	0.8946199
Pharmacy	0.1171728	0.6111455	0.8332054
Doctor/clinician	0.3169212	0.9569654	0.9526512
Research institution	0.0855492	0.356738	0.8901724
Government organization	0.0689405	0.0478781	0.4338545
Pharmaceutical company	0.0637628	0.1117684	0.783212



Chapter 3. The Organizational Ecology of Direct-to-Consumer Digital Health

Introduction

In recent years, direct-to-consumer (DTC) digital health products and services—ranging from at-home diagnostic tests to on-demand prescription services—have garnered increasing attention.[7] These DTC digital health products and services include telehealth consultations, mental health apps, fertility tracking, genetic testing, health monitoring and tracking, and weight management platforms, among others. They are often promoted as products or solutions that promise greater access and convenience for consumers. The rise of DTC digital health products and services may be attributed to shifting consumer preferences, technological advances, and an influx of venture capital investment.[83,84] The COVID-19 pandemic also accelerated interest among entrepreneurs, investors, and consumers in remote, consumer-oriented, and consumer-driven solutions, further bolstering the DTC digital health market.[84,85]

Understanding the landscape of the DTC digital health market is important, as it has significant implications for consumers, healthcare systems, and policymakers. First, it is essential to identify which companies exist in the DTC digital health market as their presence suggests unmet and/or emerging needs that have not been fulfilled by the traditional healthcare system, raising questions of for whom and for what these companies are created. Second, understanding the pace at which these companies were founded is important, as founding patterns may indicate the conditions that stimulated their emergence. Third, examining the failure of new organizations is critical because this can reveal challenges or barriers that hampered DTC companies' survival.[86] Conversely, studying the success of these companies is equally vital, particularly as more enter the public market or undergo mergers and acquisitions. Their success may contribute to the transformation of the healthcare system, from traditional brick-and-mortar models to more

consumer-driven, tech-enabled, remote services. Furthermore, the success of DTC companies directly impacts consumer access to these products and services, potentially accelerating the broader adoption of digital health.

Given the increasing attention paid to DTC digital health, a growing body of research has examined healthcare costs,[15,16] consumer experiences, [19–23] marketing practices,[24–26] and the concomitant ethical issues associated with specific DTC products and services.[12] However, studies of the DTC digital health industry as a whole remain sparse, with few exceptions[87,88] and most insights coming from market reports and media coverage.[89] The literature lacks a comprehensive analyses of the DTC digital health ecosystem.

This study aims to fill this gap by 1) describing the growth of U.S. DTC digital health companies and the populations and health domains they serve, and 2) estimating the effects of population and organizational characteristics on patterns of entry, exit, and achievement of success milestones. This research offers timely analysis and insights on an emerging channel of healthcare delivery that has the potential to reshape access and equity in the US healthcare system. As new organizational forms emerge and contribute to the transformation of the landscape of the healthcare delivery, it is imperative to understand their dynamics to guide strategic decisions and policy development.

Theoretical Framework

This study employs organizational ecology as the theoretical framework to analyze the emergence of DTC digital health companies. Introduced by Hannan & Freeman in 1977,[90] organizational ecology, a sub-discipline of sociology, provides a unique perspective for elucidating the conditions by which organizations thrive or decline. This framework has been applied to a variety of industries, including U.S. labor unions,[91] newspapers,[92–94] wineries,[95–97]

the American brewing industry,[98,99] California restaurants,[100] the U.S. film industry,[101] the global fashion design industry,[102] biotech companies,[103] U.S. automobile manufacturers,[104] and the healthcare sector.[105]

In their 2000 book, "The Demography of Corporations and Industries," Carroll & Hannan expounded organizational ecology, describing it as the "scientific examination of [organizations'] vital rates of founding, growth/decline, and mortality."[106] This field studies the populations of organizations rather than individual companies.

Figure 3.1 Organizational ecology applied to direct-to-consumer digital health.

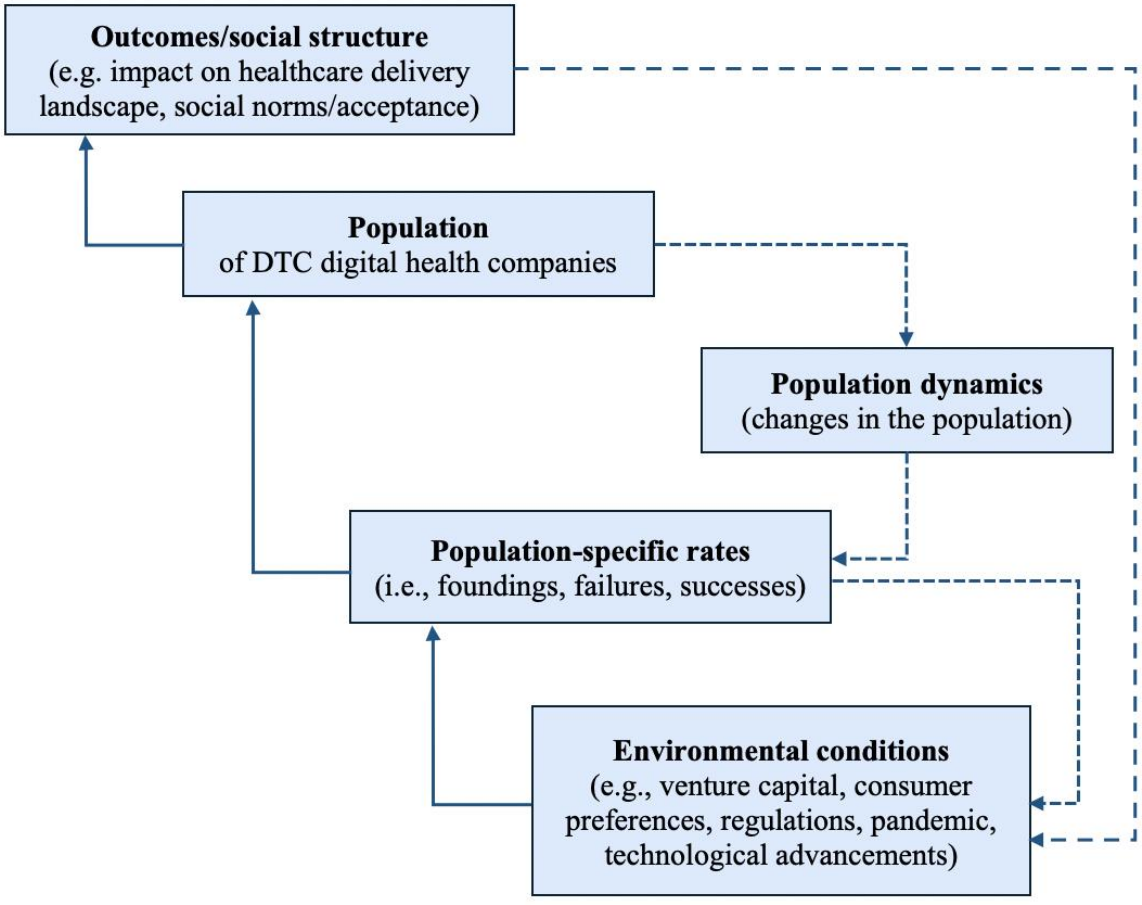


Figure 3.1 illustrates the application of organizational ecology to DTC digital health companies. This framework was chosen to provide insights into the trends and dynamics of this

industry, which are particularly salient given the nascent and rapidly evolving nature of the DTC digital health sector. By adopting an organizational ecology perspective, this research aims to provide a comprehensive understanding of the DTC digital health market, offering insights into how various factors influence the founding, failure, and success of these companies.

Key components of organizational ecology

Here, the *population* of interest is DTC digital health companies. These organizations are defined by certain shared characteristics, such as selling health-related products and services directly to consumers. Additionally, they rely on technologies as the foundation of their offerings—often paired with a service, but only when the technology remains the primary focus of the service provided. This study aims to understand how the population of DTC digital health companies has evolved over time.

Population dynamics refers to changes in the population over time, particularly in terms of the entry (founding) and exit (failure) of companies. This study applies two key processes from organizational ecology—*density dependence* and *niche width dynamics*—to understand how these population dynamics unfold in the population of DTC digital health companies.

Central to organizational ecology is the concept of natural selection due to competition between organizations for resources and legitimacy. The *density dependence* theory posits that the number of organizations within a population (density) affects founding and failure rates through *legitimation* and *competition effects*.[98,102,107,108] Legitimation refers to the process by which a new organizational form gains acceptance within its environment and reaches "taken-for-granted" status.[109] As density increases, it creates a *legitimacy effect,* by which a greater number of organizations in the same population signals acceptance within the environment, encouraging new entrants. Competition refers to the process by which organizations within the

same population vie for limited resources, such as funding and customers. As the population grows, a *competition effect* becomes more pronounced, reducing opportunities for new entrants and increasing the risk of failure due to limited resources. In the DTC digital health context, high organizational density can improve legitimation, leading to more foundings; but eventually, increased competition may increase failure rates. This study explores how density influences organizational founding.

Niche width dynamics refers to the breadth of an organization's target market or product offerings.[97,110,111] Generalists have a wider niche and serve a larger market segment, while specialists focus on narrow segments. Generalists may thrive in saturated markets given their adaptability and broader appeal. Specialists, in contrast, may succeed by serving underserved niches though they are more vulnerable to changes in market conditions or consumer preferences.[100] In the DTC digital health context, generalist companies may initially thrive by appealing to a wider market—such as those offering general wellness, primary care, or fitness services. Over time, however, specialists with a narrower niche, such as those focused on chronic conditions or population-specific needs like reproductive health, may find success by focusing on underserved, peripheral segments. This study examines how niche width influences organizational failure and success.

Population-specific rates refer to the birth (founding) and death (failure) rates of DTC digital health companies, driven by population dynamics. These vital rates are influenced by both environmental conditions and population dynamics. *Environmental conditions* refer to the external factors that impact the population of DTC digital health companies. This includes the availability of venture capital, macroeconomic conditions, consumer preferences, and technological innovation. Historical events, such as the COVID-19 pandemic, may also have

accelerated the adoption of remote solutions, and accompanying regulatory flexibilities may have facilitated growth of this population.

Outcomes/social structure refers to the broader impact of DTC digital health companies on healthcare delivery. Although not directly measured in this study, these outcomes are influenced by the underlying population dynamics, potentially affecting social norms if DTC digital health becomes ubiquitous.

Research Objective and Questions

This study seeks to investigate the characteristics and trajectories of DTC digital health companies, focusing on how population dynamics, funding, specialization, and technological differentiation influence their founding, failure, and achievement of success milestones. Specifically, this study aims to address the following questions:

1. What are the key characteristics and trends among DTC digital health companies' founding patterns, populations served, technological offerings, and health domains addressed?
2. How does the density of organizations within a population affect the founding rates of DTC digital health companies?
3. What factors influence the failure and success of DTC digital health companies?

I expect that as the density of DTC digital health companies within a population increases, the founding rates of new DTC digital health companies will follow a non-linear (inverted U-shaped relationship) pattern. According to the density dependence theory, early increases in density legitimize the organizational form and attract new entrants, but as density reaches a threshold, competition for resources intensifies, reducing founding rates. Lower

venture capital funding is positively correlated with the failure of DTC digital health companies. Greater funding is positively correlated with achieving success milestones. Greater funding provides the resources to meet market demands and investor expectations improving the likelihood of survival. Companies that fail to progress beyond early-stage funding are more likely to experience failure compared to those that advance to higher stages (e.g., Series B+). Companies that progress to a later funding stage are more likely to achieve success milestones (e.g., public offerings). Companies that advance through later funding stages indicate proven viability, making them more likely to succeed. DTC digital health companies that operate as specialists are more likely to fail compared to generalists. DTC digital health companies that operate as generalists are more likely to achieve success milestones compared to specialists. The niche width theory suggests that generalists, who serve a wider market, are more adaptable compared to specialists. The absence of differentiating technologies (e.g., telemedicine, wearables) is positively associated with the failure of DTC digital health companies. The use of differentiating technologies is positively associated with success milestones. These technologies allow companies to differentiate themselves and offer innovative solutions, improving likelihood of success.

Methods

Data

This research utilizes the Rock Health Venture Funding Database. It is the most comprehensive database available for U.S. digital health companies. Rock Health, a digital health venture capital and advisory firm, maintains this proprietary database, which encompasses over 2,600 digital health startups.

This database includes companies that have received over $2 million in publicly disclosed funding between 2011 to 2023. Rock Health defines digital health companies as "health companies that build and sell technologies—sometimes paired with a service, but only when the technology is, in and of itself, the service."[112] This unique industry dataset captures various details about these companies, including founding date, total funding received from investors (e.g., venture capital, angel investors, private equity) , company status (e.g., active, defunct), differentiating technologies used (e.g., telemedicine, artificial intelligence (AI)/machine learning (ML)), clinical indications addressed, and target populations (e.g., women, older adults, LGBTQ). The database also contains information on the customers to whom the company sells its digital health product or service (see **Appendix 3.1** for study variables).

For this study, I extracted information about digital health companies that were exclusively pursuing a DTC go-to-market strategy—those selling products and services directly to individual consumers. Companies identified as selling exclusively to individual customers served as an indicator for a DTC model. Companies that sell to other customer segments either solely or in addition to consumers (e.g., payers or employers) were excluded from the analytic sample. This resulted in a final sample of 478 companies, out of 2,652 digital health companies in the database, identified as exclusively pursuing a DTC model as of December 31, 2023.

To ensure the accuracy and reliability of the data, I conducted a thorough review of all DTC digital health companies' websites and/or public records (n=478). This verification process involved cross-referencing the dataset with the websites/public records and resolving discrepancies or data entry errors. About half of the companies in the sample were not tagged with a clinical indication, as their product or service was not tied to a particular disease or

symptom but rather was related to fitness, nutrition, or another non-clinical area. The product or service could also relate to a specific group of people (e.g., helping older adults with fall detection, assistive robots, independent living). Thus, I created a new variable called “health domain” that was broader in scope than clinical indication and referred to an area of health or healthcare or people group that a company aimed to address through its product or service. A company’s health domain denoted the clinical indication, non-clinical indication (e.g., fitness), or people group served by the company’s product or service. Definitions of the health domains are provided in **Appendix 3.1**.

Study Sample

I focus on DTC digital health companies (N=478), as they represent a distinct organizational population within the digital health landscape. While these companies share the same "family" as those selling to providers or payers, they belong to a different "genus," as their business model and market approach are fundamentally different. DTC digital health companies offer products and services such as telehealth consultations, mental health apps, fertility tracking, genetic testing, health monitoring and tracking, and weight management platforms. The dataset encompasses companies that had publicly disclosed funding between 2011 and 2023, with some companies founded as early as 1998.

Study Variables

This study examines the dynamics of the DTC digital health population by analyzing key variables at both the population and organizational levels. At the population level, the focus is on how the density of companies within the population impacts founding rates. At the organizational level, funding, highest funding stage, specialization, and technology use is examined to determine whether companies face failure or achieve success milestones.

Outcome Variables

Three primary outcome variables are analyzed in this study:

1. Founding rate: This variable captures the number of new DTC digital health companies founded each year, measured at the population level.
2. Failure: Failure status refers to whether a DTC digital health company has ceased operations, resulting in defunct or "deadpool" status.[104] This is measured at the organizational level, indicating whether a company is no longer active as of the end of each year.
3. Success: Success milestone refers to whether a DTC digital health company has achieved a significant event, such as through an initial public offering (IPOs)/special purpose acquisition company (SPACs) or a merger and acquisition (M&A). While commonly referred to as a "successful exit," these companies remain active, meaning they are still operating in the DTC digital health market (unlike companies that failed). This is measured at the organizational level, indicating whether a company reached one of these milestones by the end of each year.

Independent Variables

Population-level covariates

1. Density: The number of active DTC companies in a given observational year.
2. Density-squared: This variable was included to capture any non-linear effects of population density on founding rates.

Organizational-level covariates

1. Total venture capital funding: The total venture capital funding received by each company through the end of 2023.

2. Highest funding stage: The most advanced funding round each company reached by the end of 2023, categorized as seed stage, bridge/debt/unlabeled, Series A, or Series B+. Companies progress through these funding stages during their life cycle, with each stage reflecting different expectations from investors for growth, revenue generation, and sustainability: at the seed stage (early-stage and conception), companies are typically pitching an idea; at Series A (early-stage and commercialization), companies are starting to commercialize a product/service; at Series B, C, D, and so on (mature stage and growth), companies are scaling their offerings to reach more customers. [113–116] Companies go through the stages consecutively, meaning a company must first go through seed funding before Series A funding, or Series A funding before Series B funding, etc. I consolidated bridge rounds (investments between two official rounds), debt financing (a loan from an investor), and unlabeled rounds (raising money without explicitly calling it a "stage"), given that all three are not official funding stages of a company's life cycle.
3. Niche specialization: This variable distinguishes between generalists and specialists, based on the health domains served (**Appendix 3.1** for niche definition).
4. Differentiating technology: This variable captures the technologies that set companies apart in the DTC digital health market. The three most prevalent technologies used by the population of companies—telemedicine, wearables, and AI/ML/deep learning—were included as binary covariates, indicating whether a company employed each specific technology. Telemedicine is defined by whether a company offers products or services that allow for remote healthcare, such as video consultations and asynchronous communication (e.g., messaging apps between patients and providers). Importantly, this

variable reflects not only the use of telemedicine as technology but also the provision of telemedicine as a service to consumers. The interpretation of findings will consider how telemedicine, as both a technology and a service, contributes to a company's differentiation in the market. Wearables refer to devices that provide continuous health monitoring. AI/ML/deep learning indicates whether advanced data analytics forms a core component of a company's product/service.

Statistical Analyses

Descriptive Analyses

Descriptive statistics provide an overview of the DTC digital health companies in the sample. This includes summary statistics for continuous variables such as total venture capital funding, as well as frequency distributions for company status, health domains, differentiating technologies, and target populations. Additionally, I plotted the founding and failure rates of DTC digital health companies over time.

Organizational Founding Rates

To analyze the founding rates of DTC digital health companies, I employed a negative binomial regression model, as the dependent variable (founding rate) is count data.[102] Density and density-squared were included as independent variables to account for the non-linear relationship between density and founding rates, an analytical approach originating from organizational ecology.[107] Sensitivity analyses were conducted to compare Poisson, negative binomial, and negative binomial models with robust standard errors to confirm model robustness. Additionally, separate analyses were performed for telemedicine and non-telemedicine companies to examine how density affects founding rates within these subpopulations.

Organizational Failure/Success

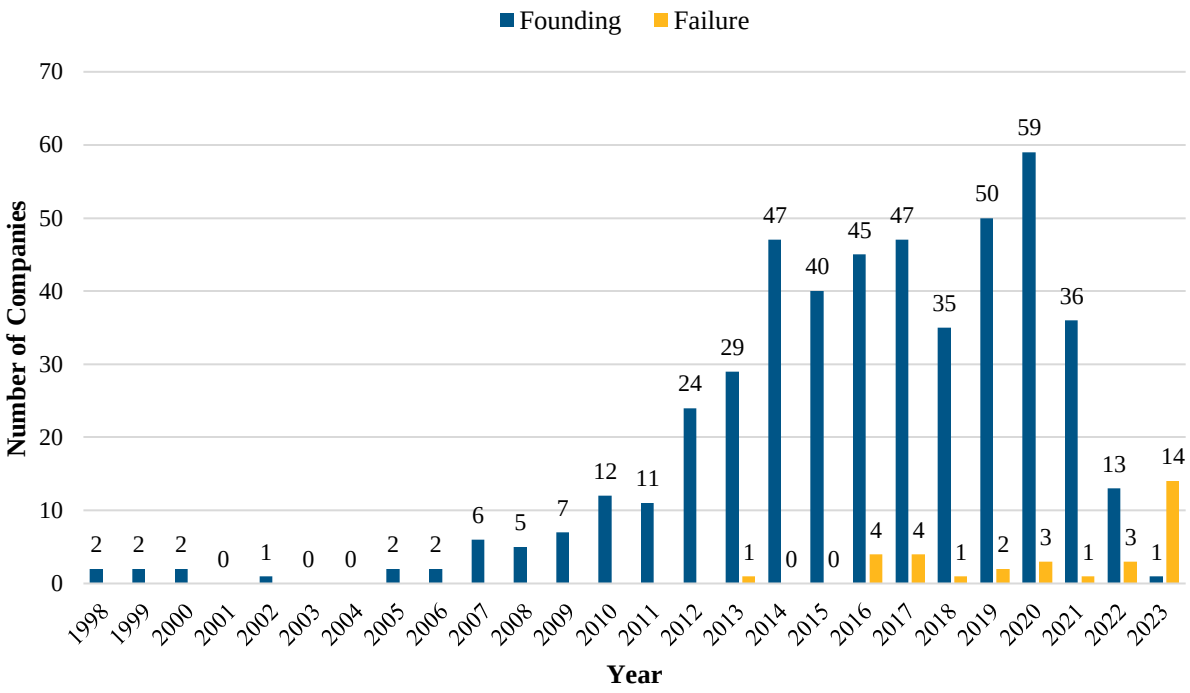
A time-to-event analysis was conducted to examine the factors associated with the failure and success of DTC digital health companies. First, summary statistics were obtained for total venture capital funding, and frequency distributions for highest funding stage, niche specialization, and technology use. Then, Cox proportional hazards regression was used to identify factors influencing the risk of company failure and success over time. Kaplan-Meier survival curves were generated to estimate and visualize survival functions. Covariates in this analysis included total funding, highest funding stage, niche specialization, and technology use (e.g., telemedicine, wearables, AI/ML/deep learning). In addition to the Cox models, logistic regression was employed to assess associations between the covariates and outcomes, independent of time effects.

Results

Descriptive Statistics

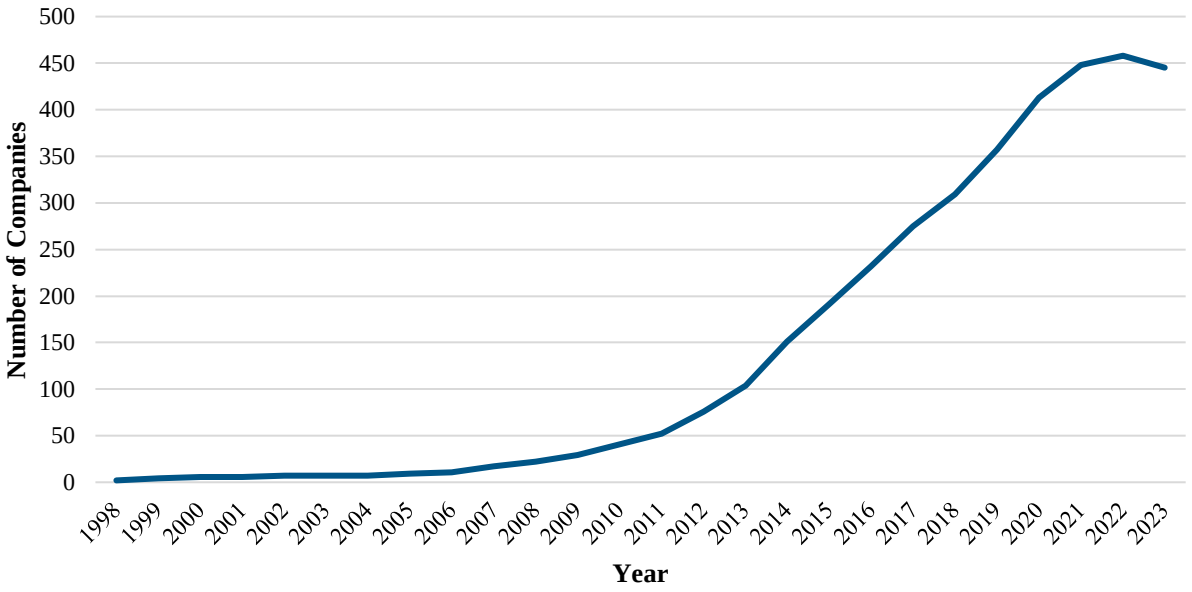
For DTC digital health companies (n=478), the rate of new company foundings surged in 2014, when 47 new companies were founded (**Figure 3.2**). This was followed by a secondary peak in 2020, which coincided with the increased demand for digital health solutions during the first year of COVID-19 pandemic. Approximately half of all companies were founded in 2017 or later. Failures began to appear in 2013, with the highest number of companies ceasing operations in 2023, when 14 companies shut down.

Figure 3.2 Founding and failure rates of direct-to-consumer digital health companies from 1998 to 2023 (N=478).



As of December 31, 2023, the majority of companies in the sample remain active, defined as continuing to operate in the DTC digital health sector in various ways, including as start-ups (n=375; 78.5%), acquired but still operating (11.5%), mixed (expanded to include brick-and-mortar locations; 1.9%), public enterprises (1.0%), and merged but still operating (0.2%). A subset of the population, 33 companies (6.9%), have ceased operations ("failure"). **Figure 3.3** shows the number of active companies per year as a density, with "active" conceptualized to include companies that were still in operation, have undergone M&A, expanded to in-person care, or gone public. The figure illustrates sustained growth in the number of active companies, peaking around 2022, but a slight downturn in 2023.

Figure 3.3 Density of direct-to-consumer digital health companies from 1998 to 2023 (N=478).



*Note: The density plot represents the number of all DTC digital health companies, excluding those that have ceased operations each year.

Women were the most frequently targeted customer population by DTC digital heath companies, with consistent growth over the years (**Appendix 3.2**). In 2023, 70 (14.6%) companies targeted women, 36 (7.53%) targeted pediatrics, 25 (5.23%) targeted older adults, 17 (3.56%) targeted men, 10 (2.09%) targeted underserved populations, and 5 (1.05%) targeted LGBTQ populations. The number of companies focusing on men saw slow but steady growth, particularly after 2016. Companies serving underserved and LGBTQ populations began to emerge, albeit in small numbers, around 2016, signaling a shift toward more inclusive solutions in the DTC space.

The average venture capital funding across all DTC digital health companies was $27.5 million (**Table 3.1**), with a standard deviation of $61.2 million, indicating a substantial variation in funding across companies, ranging from $2 million to $570 million. On average, LGBTQ-focused companies, though fewer in number, received the highest funding ($39.2 million).

However, the large standard deviation ($60.8 million) suggests notable variability within this group of companies. Women-focused companies, which represent the largest segment among the population-focused companies, had an average funding of $32.7 million. Companies targeting underserved populations received the lowest average funding ($10.6 million), highlighting disparities in investment across different target populations.

Table 3.1 Venture capital funding distribution by population-focus of direct-to-consumer digital health companies as of 2023.

	Number of companies	Mean funding (in millions)	SD	Min	Max
All DTC	478	27.5	61.2	2.0	570
Women	70	32.7	55.5	2.0	229.5
Pediatrics	36	21.8	27.4	2.2	129.7
Older adults	25	20.5	34.8	2.0	175.0
Men	17	35.1	63.4	2.0	202.3
Underserved	10	10.6	14.5	2.5	50.0
LGBTQ	5	39.2	60.8	3.0	144.0

There was a great diversity in the health domains addressed by DTC digital health companies, reflecting the wide range of health issues being tackled in this space (**Table 3.2**). Mental health was the most targeted health domain, with 16.7% of all DTC companies offering products or services for mental health conditions. Mental health was particularly prominent among pediatric-focused companies, with nearly 40% of these organizations addressing mental health.

Table 3.2 Direct-to-consumer digital health companies' health domain focus by target population.

	All (N=478)		Women (n=70)		Pediatrics (n=36)		Older adults (n=25)		Men (n=17)		Underserved (n=10)		LGBTQ (n=5)	
Mental health	80	16.7%	12	17.1%	14	38.9%	1	4.0%	3	17.6%	3	30.0%	1	20.0%
Reproductive and maternal health	71	14.9%	62	88.6%	7	19.4%	0	0.0%	16	94.1%	2	20.0%	3	60.0%

Fitness	68	14.2%	1	1.4%	0	0.0%	1	4.0%	0	0.0%	0	0.0%	0	0.0%
Weight management and obesity	42	8.8%	5	7.1%	0	0.0%	0	0.0%	1	5.9%	0	0.0%	0	0.0%
Primary care	40	8.4%	11	15.7%	3	8.3%	1	4.0%	5	29.4%	3	30.0%	0	0.0%
Cardiovascular disease	23	4.8%	4	5.7%	1	2.8%	0	0.0%	3	17.6%	0	0.0%	0	0.0%
Neurology	21	4.4%	1	1.4%	0	0.0%	3	12.0%	2	11.8%	0	0.0%	0	0.0%
Diabetes	20	4.2%	2	2.9%	0	0.0%	1	4.0%	1	5.9%	0	0.0%	0	0.0%
Elder care	18	3.8%	0	0.0%	0	0.0%	15	60.0%	0	0.0%	0	0.0%	0	0.0%
Musculoskeletal/ pain management	16	3.3%	2	2.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Gastrointestinal	15	3.1%	4	5.7%	1	2.8%	0	0.0%	3	17.6%	0	0.0%	0	0.0%
Substance use	15	3.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Developmental disorders	11	2.3%	0	0.0%	5	13.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dermatology	10	2.1%	7	10.0%	0	0.0%	0	0.0%	4	23.5%	0	0.0%	0	0.0%
Oncology	10	2.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Pediatrics	10	2.1%	0	0.0%	9	25.0%	0	0.0%	0	0.0%	1	10.0%	0	0.0%
Nutrition	6	1.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Allergy/ immunology	5	1.0%	1	1.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Pharmacy	5	1.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Pulmonary disorder	5	1.0%	2	2.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Audiology	4	0.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ophthalmology	4	0.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other	57	11.9%	1	1.4%	0	0.0%	3	12.0%	1	5.9%	1	10.0%	1	20.0%

Reproductive and maternal health was the second most common health domain across all groups (14.9%). This health domain was most prevalent among women-focused companies, with 88.6% addressing this area, and also among men-focused (94.1%) and the LGBTQ-focused (60.0%) companies. Examples of products and services in this category include platforms for menstrual health, fertility, pregnancy, hormonal wellness, and menopausal care. The third most common health domain was fitness (14%). This domain, similar to domains addressing nutrition, substance use, and oncology, was not linked to a specific target population. These findings

highlight the variability in population focus across health domains, with some health issues attracting more population-specific attention, while others remain more general in their scope.

Differentiating technologies employed by DTC digital health companies (**Table 3.3**), which are those that provide a competitive edge and are widely recognized in the market, were examined. Telemedicine was the most adopted technology among DTC digital health companies, with 108 (22.6%) companies utilizing it. This technology was particularly prevalent among companies targeting men (64.7%) and pediatrics (47.2%). The second most adopted technology was wearables and biosensors (19.5%), followed by AI/ML/deep learning technologies (13.2%).

Table 3.3 Differentiating technologies by population-focused direct-to-consumer digital health companies.

	All (N=478)		Women (n=70)		Pediatrics (n=36)		Older adults (n=25)		Men (n=17)		Underserved (n=10)		LGBTQ (n=5)	
Telemedicine	108	22.6%	26	37.1%	17	47.2%	6	24.0%	11	64.7%	4	40.0%	2	40.0%
Wearables and biosensors	93	19.5%	6	8.6%	5	13.9%	6	24.0%	0	0.0%	0	0.0%	0	0.0%
AI/ML/Deep learning	63	13.2%	4	5.7%	4	11.1%	5	20.0%	0	0.0%	0	0.0%	0	0.0%
Remote monitoring	28	5.9%	6	8.6%	1	2.8%	6	24.0%	1	5.9%	0	0.0%	0	0.0%
Genomics	27	5.6%	5	7.1%	1	2.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Nonmedical device hardware	26	5.4%	2	2.9%	3	8.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other	25	5.2%	2	2.9%	1	2.8%	0	0.0%	1	5.9%	0	0.0%	0	0.0%
Digital medical device	13	2.7%	5	7.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
AR/VR	6	1.3%	1	1.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
IoT	5	1.0%	1	1.4%	1	2.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Robotics	4	0.8%	0	0.0%	1	2.8%	1	4.0%	0	0.0%	0	0.0%	0	0.0%
Blockchain	2	0.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

None of the companies serving men, underserved populations, or the LGBTQ community utilize wearables or AI/ML/deep learning technologies. Additionally, none of the companies

focused on underserved populations use remote monitoring, which is surprising as it could improve access to care and health outcomes for low-income, rural communities. There was limited variability in the types of technologies used by companies targeting underserved and LGBTQ populations. AR/VR, IoT, robotics, and blockchain were the least adopted across the entire DTC digital health market.

The distribution of technologies across health domains shows how different technologies were being applied to address various health needs (**Appendix 3.3**). Telemedicine was primarily applied to reproductive and maternal health (27.8%). Wearables and biosensors were primarily used in fitness (25.8%), while AI/ML/deep learning was primarily applied to mental health (20.6%), fitness (20.6%), and gastrointestinal conditions (11.1%), and remote monitoring was most often used in mental health (17.9%) and elder care (17.9%).

Organizational Founding

Table 3.4 presents the results of a negative binomial regression analysis testing the effects of density on the founding of DTC digital health companies. Results indicate that density had a positive effect on the founding of DTC digital health companies, while density-squared had a negative effect, suggesting an inverted U-shaped relationship. Therefore, as density of companies increased, founding rates initially rose, but beyond a certain point, further increases in density led to a decline in foundings. Refer to **Appendix 3.4** for a figure illustrating the predicted founding rates by levels of density, calling to attention the point at which market saturation occurs and founding rates begin to decline.

Table 3.4 Models of organizational founding for direct-to-consumer digital health companies.

Outcome variable	(1) Founding of DTC digital health	(2) Founding of telemedicine DTC	(3) Founding of non-telemedicine DTC
DTC digital health density	.0261***		

	(.003)		
(DTC digital health density)^2	-.0000477*** (7.85e-06)		
Telemedicine density		.111*** (.016)	
(Telemedicine density)^2		-.001*** (.000)	
Non-telemedicine density			.032*** (.004)
(Non-telemedicine density)^2			-.000*** (.000)
Constant	.795** (.242)	1.474*** (.263)	.647** (.235)
Log likelihood	-83.121	-88.751	-76.159
Wald x^2	84.78	51.30	88.70
Number of observations	26	26	26

Note: Robust standard errors are in parentheses. Results of negative binomial regressions.
*p<.05; **p<.01; ***p<.001.

The same inverted U-shaped relationship holds true for sub-samples of telemedicine DTC digital health and non-telemedicine DTC digital health companies. See **Appendix 3.5** for observed founding rates of telemedicine DTC and non-telemedicine DTC companies.

Organizational Failure and Success

Table 3.5 summarizes overall sample and breakdown by failure and success. Of the 478 DTC digital health companies, 33 (6.9%) experienced failure, defined as the closing of operations. These failed companies had a mean total funding of $12.7 million (SD: $21.1 million), substantially lower than the overall sample's mean of $27.5 million (SD: $61.16 million). In terms of highest funding stage, many failed companies were in the seed stage (39.4%), while only 18.2% reached Series B+ funding. Specialists made up about two-thirds of the overall sample; they also made up approximately two-thirds of failed companies, as well as non-failed companies. Regarding technology, a greater proportion of failed companies employed wearables (27.3%) compared to non-failed companies (18.9%). Only one (3.0%) company that employed AI/ML/deep learning failed.

Sixty-one companies (12.8%) reached a success milestone, defined as going public via IPO, SPAC, or through an M&A. Companies that achieved a success milestone had a slightly lower mean total funding ($25.2 million; SD: $36.8) compared to those that did not ($27.9 million; SD: $64.0), but the difference was modest. Companies in seed stage made up 33.7% of the overall sample, with similar proportions among those that reached a success milestone (32.8%) and those that did not (33.8%). Notably, companies reaching Series B+ represented a larger proportion of those achieving a success milestone (34.4%) compared to those that did not (20.4%). There was a greater proportion of generalists among companies that reached a success milestone (41.0%) compared to those that did not (32.4%). Telemedicine was used by 22.6% of overall sample, with higher utilization among companies achieving a success milestone (31.2%). Wearables were employed by 19.5% of the overall sample, with no substantial difference between the two groups. AI/ML/deep learning technologies were less commonly employed overall (13.2%), with a smaller share of companies reaching a success milestone using them (6.6%).

Table 3.5 Sample characteristics for time-to-event analysis.

			Time-to-failure				***Time-to-success milestone***			
	All DTC (n=478)		**Failed (n=33)**		**Not Failed (n=445)**		**Reached Success Milestone (n=61)**		**Did Not Reach Success Milestone (n=417)**	
Total funding (in millions)										
Mean (SD)	27.53 (61.16)		12.74 (21.07)		28.63 (63.00)		25.21 (36.81)		27.87 (63.97)	
Highest funding stage										
Seed	161	33.68	13	39.39	148	33.26	20	32.79	141	33.81
Bridge/debt/unlabeled	43	9.00	2	6.06	41	9.21	3	4.92	40	9.59
A	168	35.15	12	36.36	156	33.26	17	27.87	151	36.21
B+	106	22.18	6	18.18	100	22.47	21	34.43	85	20.38
Niche										
Generalist	160	33.47	13	39.39	147	33.03	25	40.98	135	32.37

Specialist	318	66.53	20	60.61	298	66.97	36	59.02	282	67.63
Technology										
Telemedicine	108	22.59	8	24.24	100	22.47	19	31.15	89	21.34
Wearables	93	19.46	9	27.27	84	18.88	10	16.39	83	19.9
AI/ML/DL	63	13.18	1	3.03	62	13.93	4	6.56	59	14.15

The logistic regression and time-to-event analysis models in **Table 3.6** present factors associated with the failure of DTC digital health companies. In the logistic regression model, total funding was not a significant predictor of failure (OR=0.97; 95% CI: 0.95-1.00). The highest funding stage variables were also non-significant. Additionally, niche specialization was not significantly associated with failure. Although telemedicine companies had an odds ratio of 1.37 and wearables companies had an odds ratio of 1.98, the confidence intervals indicate no significant effect on failure. In the time-to-event analysis, neither total funding, highest funding stage categories, niche specialization, nor technology types had significant hazard ratios in predicting failure.

Table 3.6 Factors associated with the failure of direct-to-consumer digital health companies.

	Model 1		**Model 2**	
	Logistic regression		**Time-to-Event analysis**	
	OR	**95% CI**	**HR**	**95% CI**
Total funding	0.97	0.95-1.00	-0.02	-0.04-0.01
Highest funding stage (ref: Seed)				
Bridge/debt/unlabeled	0.54	0.12-2.55	-0.35	-1.84-1.15
A	1.00	0.42-2.37	-0.27	-1.08-0.55
B+	1.65	0.47-5.76	-0.23	-1.43-0.96
Niche (ref: Generalist)	0.64	0.30-1.37	-0.19	-0.92-0.55
Telemedicine (ref: non-telemedicine)	1.37	0.54-3.48	0.55	-0.34-1.44
Wearables (ref: non-wearables)	1.98	0.82-4.78	0.33	-0.51-1.16
AI/ML/DL (ref: non-AI/ML/DL)	0.17	0.2-1.31	-1.44	-3.44-0.56
Constant	0.13	0.06-0.29	--	--

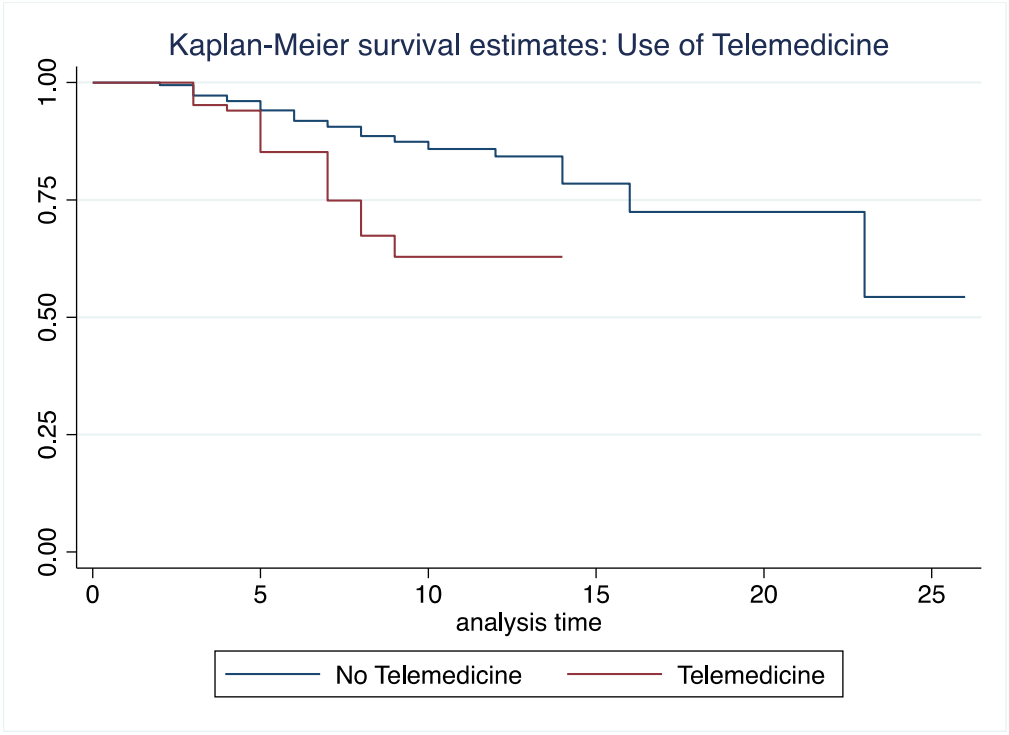
Note: OR=odds ratio; HR=hazard ratio
*p<.05; **p<.01; ***p<.001.

Kaplan-Meier survival curves for DTC digital health companies based on their highest funding stage (**Appendix 3.6)** indicate that companies with Series B+ funding experienced a

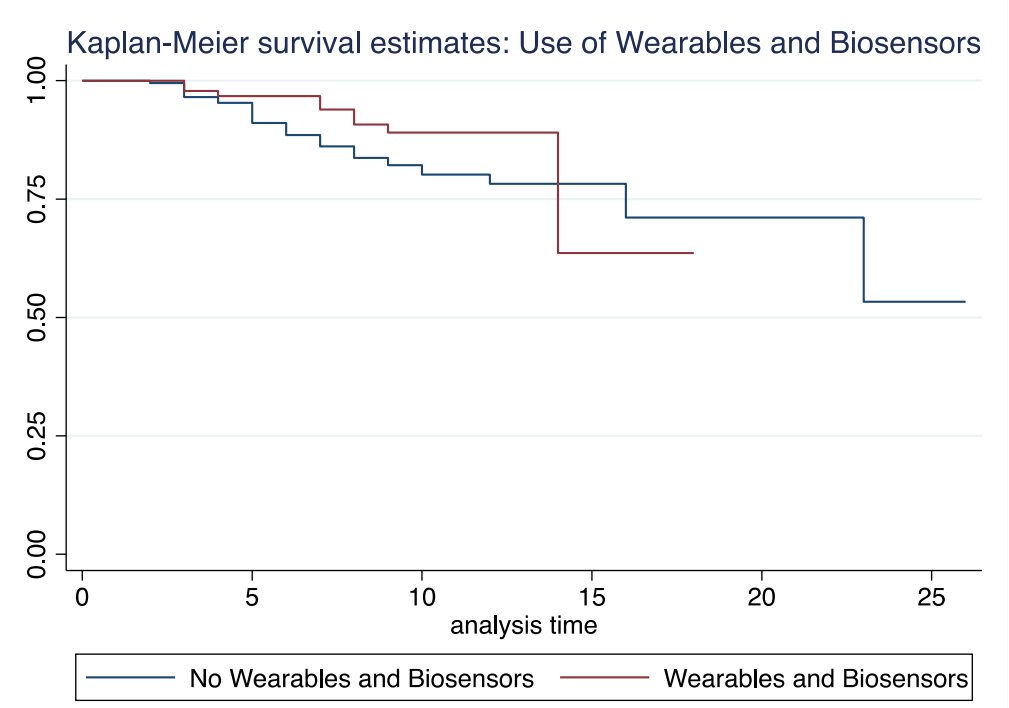
rapid achievement of success milestones after approximately five years; however, a log-rank test yielded a p-value of 0.4481, suggesting no significant difference in the time to reach a success milestone between companies at different funding stages. While generalists had a slight advantage in terms of achieving success milestones faster than specialists, this did not significantly affect the timing of success milestones, with a log-rank chi-square value of 0.4965.

Companies that use telemedicine achieve success milestones at a faster rate than non-telemedicine companies (**Figure 3.4**). They were more likely to reach success milestones than non-telemedicine companies throughout the analysis period (log-rank value is 0.0005). Companies that do not employ wearables show steady success over time, while companies using wearables more rapidly achieve success milestones between 10 and 15 years, indicating that they tend to reach success milestones around this period (log-rank value = 0.1521). AI/ML/deep learning companies take longer to achieve success milestones compared to non-AI/ML/deep learning companies, although this difference was not statistically significant (log-rank value = 0.2087).

Figure 3.4 Kaplan-Meier curve for success by technologies (A) telemedicine (B) wearables (C) AI/ML/deep learning.


Kaplan-Meier survival estimates: Use of Telemedicine
1.00
0.75
0.50
0.25
0.00
0
5
10
15
20
25
analysis time
No Telemedicine
Telemedicine

A)


Kaplan-Meier survival estimates: Use of Wearables and Biosensors
1.00
0.75
0.50
0.25
0.00
0
5
10
15
20
25
analysis time
No Wearables and Biosensors
Wearables and Biosensors

B)

C)

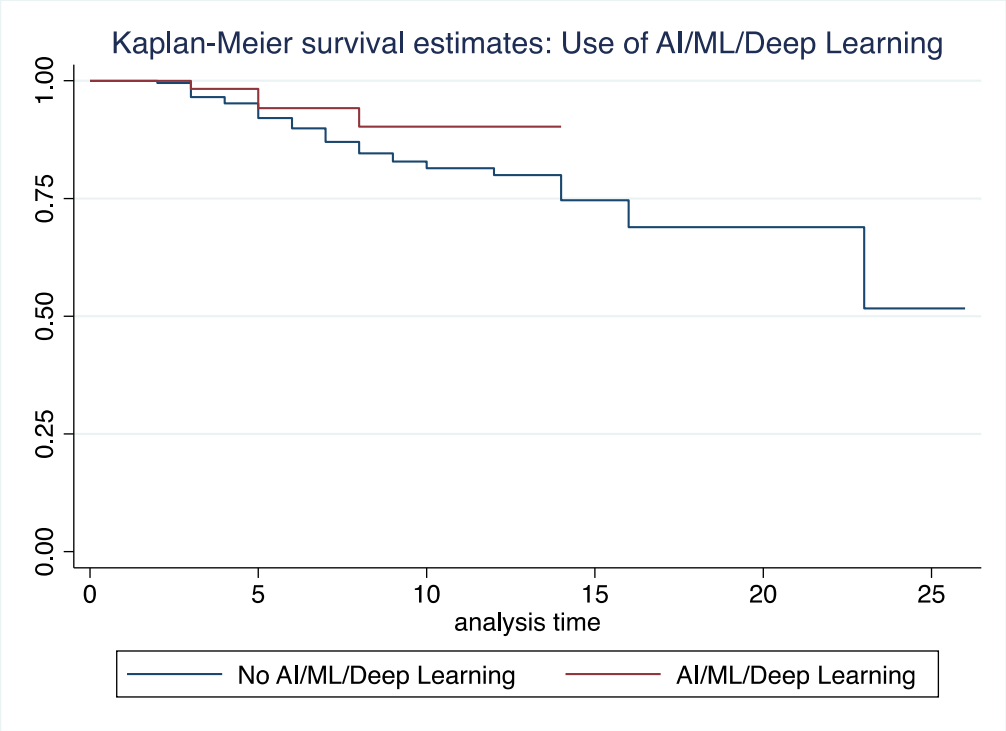


Table 3.7 presents results from two models analyzing factors associated with achieving success milestones for DTC digital health companies. Model 1 shows results from logistic regression, and Model 2 presents the time-to-event analysis results. In both models, total funding was not significantly associated with reaching a success milestone. Regarding highest funding stage, reaching neither bridge/debt/unlabeled nor Series A was a significant predictor of achieving a success milestone in either model. In the logistic regression, companies with Series B+ funding had significantly higher odds of reaching a success milestone (OR=2.59; 95% CI: 1.15–5.83) compared to seed stage. However, in the time-to-event analysis, funding stage had less impact on the time to reaching a success milestone. Specialist companies had a smaller odds ratio when it comes to reaching a success milestone compared to generalists, though this was not statistically significant. In Model 2, it appears that specialists might take longer to reach success milestones, but the result was not significant. Regarding technology, companies that employ

telemedicine showed a positive and significant association with reaching a success milestone in the time-to-event analysis; yet this was not statistically significant in Model 1. Employing wearables or AI/ML/deep learning did not show a significant association with reaching a success milestone in either model.

Table 3.7 Factors associated with success milestones of direct-to-consumer digital health companies.

	Model 1		**Model 2**	
	Logistic regression		**Time-to-Event analysis**	
	OR	**95% CI**	**HR**	**95% CI**
Total funding	0.99	0.99-1.00	-0.01	-0.02-0.00
Highest funding stage (ref: Seed)				
Bridge/debt/unlabeled	0.53	0.15-1.91	-0.59	-1.82-0.63
A	0.84	0.42-1.69	-0.38	-1.03-0.27
B+	2.59*	1.15-5.83	0.21	-0.51-0.94
Niche (ref: Generalist)	0.58	0.32-1.05	-0.36	-0.90-0.17
Telemedicine (ref: non-telemedicine)	1.89	0.97-3.68	0.91**	0.31-1.52
Wearables (ref: non-wearables)	0.95	0.44-2.05	-0.19	-0.91-0.53
AI/ML/DL (ref: non-AI/ML/DL)	0.48	0.17-1.41	-0.44	-1.47-0.60
Constant	0.19	0.10-0.36	--	--

Note: OR=odds ratio; HR=hazard ratio
*p<.05; **p<.01; ***p<.001.

Discussion

To my knowledge, this is the first study to comprehensively examine the U.S. DTC digital health landscape, providing critical insights into the market's growth, the populations it serves, the health areas it focuses on, and the technologies it leverages.

Since 2011, the DTC digital health population has grown steadily, with a small downturn seen in 2022. While companies targeting specific populations also grew, there was an uneven distribution of venture capital funding across population-focused DTC companies, with LGBTQ, men's health, and women's health companies receiving strong investor enthusiasm. In contrast, companies targeting underserved populations received significantly lower average funding, which could limit the availability of DTC solutions for those who stand to benefit the most from

improved healthcare access. Thus, the implications of these findings extend beyond mere market analysis; they raise fundamental questions related to who has access to these consumer-directed products and services and whether they are equitably distributed across different populations.

The range of health domains among population-focused DTC digital health companies is likely driven by the specific needs and demands of each population segment. From an organizational ecology perspective, this reflects niche differentiation, where companies are tailoring their offerings to meet the specific needs of populations that may have previously been peripheral and are now becoming the focus of specialized services. For instance, the prominence of mental health services among pediatric-focused companies indicates a responsiveness to the present-day youth mental health crisis.[117] Companies seem promising to satisfy children's and young adults' unmet needs. Though, this raises new questions about the level of requisite parental involvement for these services.

Notably, all technologies, other than telemedicine, were absent among companies serving underserved populations. Certain technologies, such as AI/ML/deep learning and remote monitoring, were more selectively applied. This suggests an opportunity for innovation, as technology can improve healthcare delivery and meeting the specific needs of low-income, rural populations.[118] Moreover, there is a growing recognition of the role that technology-enabled solutions can play in addressing health inequities.[119,120] For example, Pauly et al. (2024) illustrates the dramatic uptake of remote monitoring among Medicaid beneficiaries following the COVID-19 public health emergency, pointing to how these technologies need to be covered for these populations post-pandemic.[118]

These descriptive findings indicate that multiple stakeholders—including policymakers, providers, payers, and employers—need to be involved to ensure that these offerings are

delivered safely and equitably. Additionally, researchers need to evaluate whether and how DTC digital health addresses the needs of different populations. For entrepreneurs and investors, there is ongoing opportunity to innovate in both well-established and under-targeted areas of DTC digital health.

Founding

Findings from the organizational founding analysis support density dependence theory. The inverted U-shaped relationship between density and founding rates suggests that, initially, an increase in the number of DTC companies contributes to greater legitimation in the market, signaling social acceptance. However, as the density grows, competition for resources (e.g., such as funding and customers) intensifies, eventually leading to a decline in company foundings. This dynamic is observed in the overall DTC digital health market as well as in the sub-segments of telemedicine and non-telemedicine DTC companies.

Failure

The results of the time-to-failure analysis did not yield statistically significant findings, which may be due to the limited power of the model, as only 33 companies in the sample experienced failure. In addition, a large portion of the sample is censored—meaning that many companies have not yet reached the event of interest (in this case, failure)—so there is a great deal of uncertainty in estimating failure times. Given that this is a relatively nascent industry, future research could re-examine failure if the failure sample size increases with a longer observation period.

Success

This study also provides insights into the variables associated with achieving success milestones in DTC digital health companies. Contrary to my hypothesis, total funding was not

found to be a significant predictor of reaching a success milestone. While funding represents investor interest, it does not necessarily indicate business success. Investors may fund companies for a variety of reasons like perceived market potential or the prospect of future returns, rather than strictly basing their decisions off the viability of the product or service. In the DTC digital health context, total funding may be more reflective of investor sentiment, market perception, or "last ditch efforts" rather than the company's ability to sustain operations and reach a success milestone. High levels of funding can provide resources for growth, but this does not appear to guarantee the achievement of success milestones.

Reaching Series B+ shows significantly higher odds of achieving a success milestone, indicating that companies at this stage are better positioned for M&A or public offerings. These companies may have survived initial selection pressures and proven to be well-adapted to their environment. For DTC digital health innovators, these findings underscore the importance of building credibility and securing late-stage funding to improve long-term viability.

Organizational ecology's prediction that niche specialization confers a competitive advantage is only partially supported by this analysis, as generalists in this market appear to slightly outperform specialists in terms of quicker attainment of success milestones, albeit without statistical significance. This suggests that, in this market, generalists may not need to "shift gears" if the external conditions are relatively stable. Additionally, since specialists are performing almost similarly to generalists, this suggests that the niche or peripheral markets are stable enough to support specialists. Thus, specialists can address overlooked areas in healthcare, typically those that serve narrower markets. Future research could compare how generalist and specialist companies affect health outcomes.

Companies that employed telemedicine were associated with faster rates of reaching success milestones in the time-to-event analysis. This highlights that the DTC digital health market is more prepared to adopt telemedicine solutions, a tool that also became a healthcare necessity as a result of the pandemic, compared to wearables and AI/ML/deep learning. In contrast, companies using wearables and AI/ML/deep learning took longer to reach success milestones, though the results were not statistically significant. The more rapid success of companies that utilize telemedicine may be attributed to its role as both a technology and a service. From an organizational ecology perspective, telemedicine benefits from its established legitimacy in traditional healthcare settings. This pre-existing legitimacy likely provides companies that provide telemedicine an advantage, given that telemedicine is a well-accepted technology and service in healthcare. Thus, telemedicine's connection to traditional, established healthcare models likely signals its legitimacy, enabling DTC digital health companies that employ telemedicine to achieve success milestones more quickly.

Nevertheless, a question remains: does business success lead to improved healthcare outcomes? Future work should investigate if companies that reach success milestones positively impact health outcomes in order to evaluate the impact of DTC digital health on public health. As the DTC digital health market evolves, ensuring that business success translates into improvements in health outcomes should be a priority for entrepreneurs, investors, and regulators.

Limitations

This study has a number of limitations. First, it is limited to companies listed in the Rock Health Venture Funding database, which were restricted to those that have publicly disclosed investment deals of at least $2 million and meet Rock Health's definition of digital health. As a

result, the sample does not capture Big Tech players (e.g., Amazon, Apple) that have ventured into healthcare. Therefore, the sample is not representative of all U.S. direct-to-consumer health-related offerings. Second, the small number of failure events presented challenges in conducting the survival analysis, as the high level of censoring reduced statistical power, thereby increasing uncertainty in the results. Third, categorizing success milestones as IPOs/SPACs or M&As may not fully capture the nuances of these events–M&As, for instance, could be hostile takeovers and/or occur under unfavorable circumstances. Fourth, variables (e.g., founding, failure, funding) were collated at the annual-level, preventing more granular analyses within each observational year. Lastly, the organizational ecology theoretical framework focuses primarily on internal population dynamics and may underemphasize the influence of external factors, such as regulatory changes or technological advancements. For example, the relaxation of telehealth regulations during the COVID-19 pandemic may have spurred the founding of DTC digital health companies. Recent optimism around AI may have led to the funding of AI-enabled DTC digital health services. Shifts in consumer attitudes post-pandemic, such as a preference for convenient and accessible healthcare, may have influenced the success of DTC digital health companies.

Conclusion

This study provides an up-to-date analysis of the development of the U.S. DTC digital health ecosystem, examining the factors associated with organizational founding, failure, and achieving success milestones. As the DTC digital health industry evolves, they contribute to a transformation in healthcare delivery towards more consumer-driven models. Looking ahead, future research should explore whether business success generates value in healthcare.

Appendix 3.1 Study variables.

Category	Description	Type	Operationalization
General company details	Company	String	Company name
	Company description	String	Description
	Founded	Numerical	Year founded
	Company status	Categorical	1 = Active start-up 2 = Deadpool 3 = Public 4 = Merger 5 = Acquisition 6 = Mixed
	Year acq_dead_IPO	Numerical	Year of event
Investment-related details	Total funding ($M)	Numerical	Total amount of funding received in millions
	Highest deal stage	Categorical	1 = Seed 2 = Growth/debt/unlabeled 3 = Series A 4 = Series B+
Company product/service focus	Populations	Binary (for each)	1 = Yes 0 = No
	Differentiating technologies	Binary (for each)	1 = Yes 0 = No
	Health domains	Binary (for each)	1 = Yes 0 = No
	Niche	Binary	1 = specialist 0 = generalist

1. **Population =** Primary populations that the company seeks to address or serve, respectively (if any) [*categorizations are from Rock Health*]
    - **1.1. Older adults**
    - **1.2. Women**
    - **1.3. Men**
    - **1.4. Pediatrics**
    - **1.5. Underserved**
    - **1.6. LGBTQ**

2. **Differentiating technology =** Aspect of the technology that sets the company apart; usually top-of-mind in the market; subject to change based on new technologies introduced (if any) [*definitions below are from Rock Health*]
    - **2.1. AI/ML/deep learning =** The use of data, algorithms and machine learning techniques (e.g., designed with the ability to learn without explicit programming) to identify the likelihood of future outcomes based on historical data and /or perform tasks that normally require human intelligence.

      Companies in this category are a math-driven business that turns data into insight.

      Note: AI companies offerings may include (but are not limited to) visual perception, speech recognition, decision-making, and translation / natural language processing, artificial neural networks, and chatbots.
    - **2.2. Wearables and biosensors =** Wearable or accessory devices (not necessarily worn) that detect specific biometrics and are intended for consumers to track themselves
    - **2.3. Genomics and sequencing =** Hardware and software technologies that sequence, assemble, call variants, and otherwise analyze sequencing data (e.g., sequencing on a chip with data aggregation). Usually includes a data aggregation or marketplace aspects.
    - **2.4. Telemedicine =** Technologies that enable the delivery of healthcare services (synchronous or asynchronous) from a person (not a chat-bot, automated symptom checker, etc) when the

service provider is in a different physical location from the service recipient.

Note: Companies in this category may offer virtual visits via telephone, digital imaging, videoconferencing, and coaching.

2.5. **Remote monitoring =** Technologies that enable the tracking and monitoring (of one person by another/others) of information when a person is not in the presence of a caregiver or provider. Requires that the information is being transmitted to another person (not self-monitoring). Enables caregiving in lower cost site of care. Also enables non-medical monitoring (typically by family/caregivers in a non-medical setting).

2.6. **Augmented and virtual reality =** Technology that superimposes a computer-generated image on a user's view of the real world, thus providing a composite view or simulates an artificial environment that can be interacted with in a seemingly real or physical way by a person.

2.7. **IoT =** Connected sensors that measure the physical environment (not biometrics), creating a network of "things".

Note: Sensors that collect measures of human activity are tracked in the "Wearables / biosensors" category.

2.8. **Non medical device hardware =** Connected equipment or hardware designated for professional or at-home use, that does not require FDA approval.

Note: This category does NOT include Wearables and biosensors (which are included in the "Wearables / biosensors" category).

2.9. **Robotics =** Use of robots to deliver healthcare services

2.10. **Digital medical device =** Hardware, supplemented with digital capabilities, designed to diagnose, prevent, treat, mitigate, monitor or cure a disease or condition(s). Data aggregation component. Digital medical devices require FDA approval.

2.11. **Blockchain =** Use of an open, distributed ledger that can record transactions between peers efficiently and in a secured, verifiable, and permanent way

3. **Health domain =** Health domain refers to a specific area of healthcare that the company seeks to address or serve, with products or services that address medical or wellness needs.

3.1. **Allergy/immunology**

3.1.1. Companies focused on the diagnosis, treatment, and management of allergies and immunological conditions, offering products and services like food allergen sensors, personalized allergy medications, and at-home diagnostic tests

3.2. **Audiology**

3.2.1. Companies providing products and services related to hearing health, including personal sound amplifiers, AI-driven audio frequency adjustment devices, and wireless hearing improvement devices

3.3. **Cardiovascular disease**

3.3.1. Companies focused on cardiovascular health, offering products like heart rate monitoring smartwatches, virtual clinics for cardiometabolic chronic diseases, and health tracker phone cases.

3.4. **Dermatology**

3.4.1. Companies providing telemedicine and online platforms for dermatological care, including virtual consultations and prescription medication delivered to door

3.5. **Developmental disorders**

3.5.1. Companies offering services for developmental disorders such as ADHD and autism, including telehealth visits, prescription medication delivery, and personalized therapy platforms

3.6. **Diabetes**

3.6.1. Companies addressing diabetes care, offering services like on-demand care platforms, smart caps for insulin pens, and mobile apps for diabetes management

3.7. Fitness

3.7.1. Companies promoting physical fitness through personalized workout plans, fitness tracking devices, and fitness or personal trainer apps

3.8. Gastrointestinal

3.8.1. Companies focused on gastrointestinal health, providing services like digestive health diagnostics, probiotics for gut health, and personalized nutrition platforms for GI issues

3.9. Mental health

3.9.1. Companies addressing mental health through telehealth services, AI chatbots for mental health, sleep improvement, and virtual therapy sessions

3.10. Musculoskeletal / pain management

3.10.1. Companies addressing musculoskeletal health or pain management solutions, offering products like digital therapeutics and wearable technology for injury prevention

3.11. Neurology

3.11.1. Companies addressing neurological health (e.g., conditions such as stroke, dementia, Alzheimer's, MS, and traumatic brain injury, migraine), offering services like telemedicine for neurological conditions, devices for stroke and seizure detection, and virtual reality-based therapeutics

3.12. Nutrition

3.12.1. Companies that address nutritional health, such as apps that simplify nutrition labels, personalized nutrition advice based on urine, and nutritional coaching without specifying weight management

3.13. Older adults

3.13.1. Companies focused on addressing the needs of older adults, such as fall detection, assistive robots, and caregiver support

3.14. Oncology

3.14.1. Companies focused on cancer care, providing diagnostic and treatment services, telemedicine platforms, and care coordination

3.15. Ophthalmology

3.15.1. Companies offering eye health services, including vision correction devices, telemedicine for eye care, and AI-based diagnostic tools

3.16. Pediatrics

3.16.1. Companies that address pediatric needs, such as general pediatric health, child companion robots, smartphone connected baby monitors, and baby breathing video monitors

3.17. Pharmacy

3.17.1. Companies that are online pharmacies; note: this is different from companies that offer prescription services

3.18. Primary care

3.18.1. Companies offering comprehensive primary care services through telemedicine, AI-based health management platforms, and mobile health apps

3.19. Pulmonary disorder

3.19.1. Companies addressing pulmonary disorders, providing telehealth services and health tracking devices

3.20. Reproductive and maternal health

3.20.1. Companies focused on reproductive and maternal health, offering services like hormone-based wellness apps, personalized birth control solutions, and telemedicine for women's health; also includes male and female fertility testing, menopausal care, and maternal health

3.21. Substance use

3.21.1. Companies that offer therapy for substance use disorder

3.22. Weight management and obesity

3.22.1. Companies addressing weight management and obesity through personalized nutrition platforms, diabetes care services, wellness optimization apps, or offering GLP-1s

3.23. Other

3.23.1. Companies offering diverse health-related services that do not fit into the specific categories listed above, including emergency response connected health systems, longevity supplements, payment management apps, health benefits administration, healthy habit apps, personalized supplements, wellness trackers, and platforms that provide retirement benefit information

4. Niche

4.1. Generalist

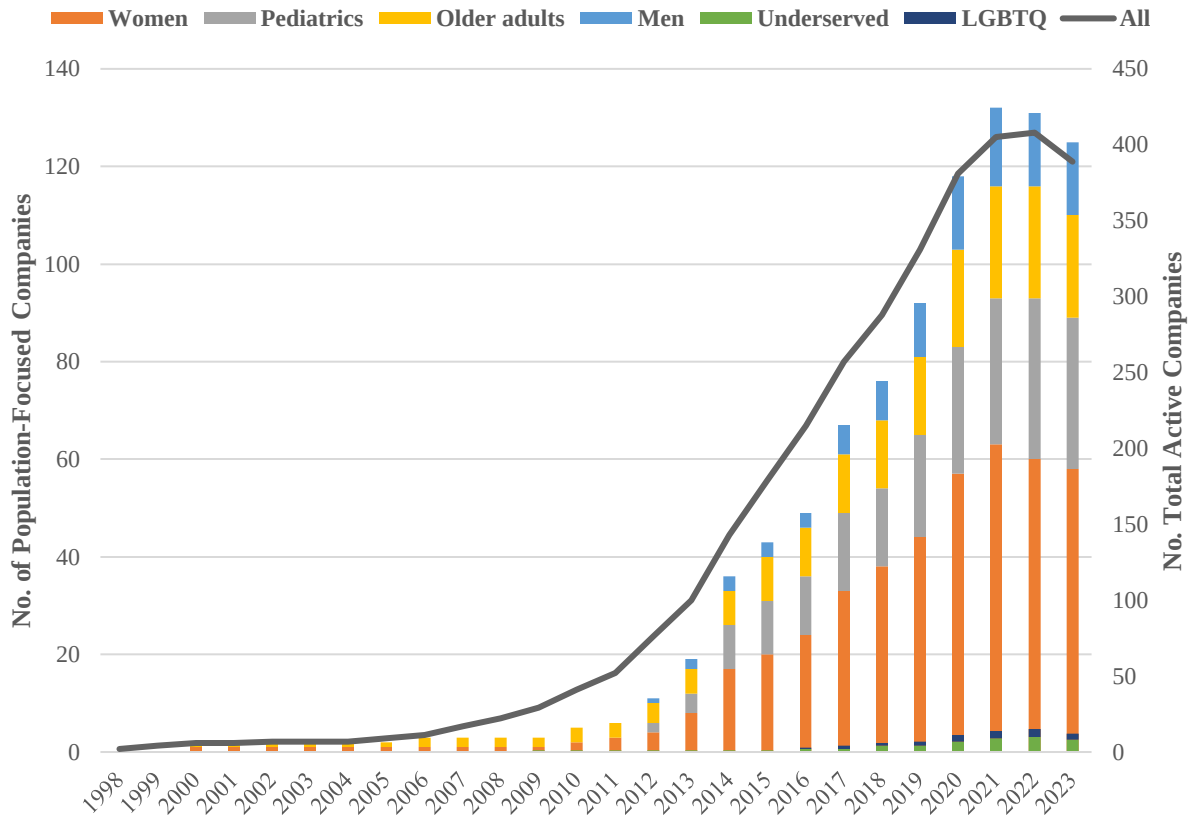
4.1.1. General health and wellness; combination of the following health domains: fitness, nutrition, pharmacy, primary care, other

4.2. Specialist

4.2.1. Chronic and specialized conditions; combination of the following health domains: allergy, audiology, cardiovascular, dermatology, diabetes, gastrointestinal, mental health, musculoskeletal/pain management, neurology ophthalmology, pulmonary disorders, substance use, weight management and obesity

4.2.2. Population-specific health; combination of the following health domains: developmental disorders, older adults, pediatrics, reproductive health

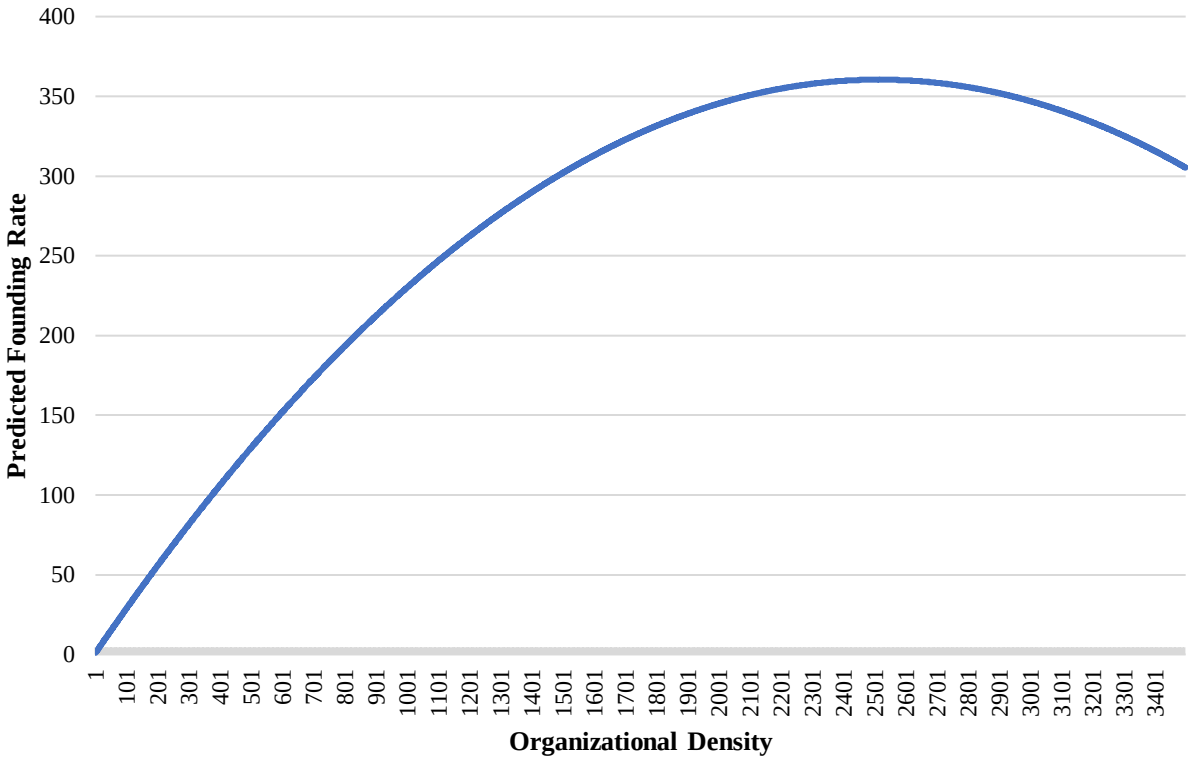
Appendix 3.2 Number of active direct-to-consumer digital health companies by target population.



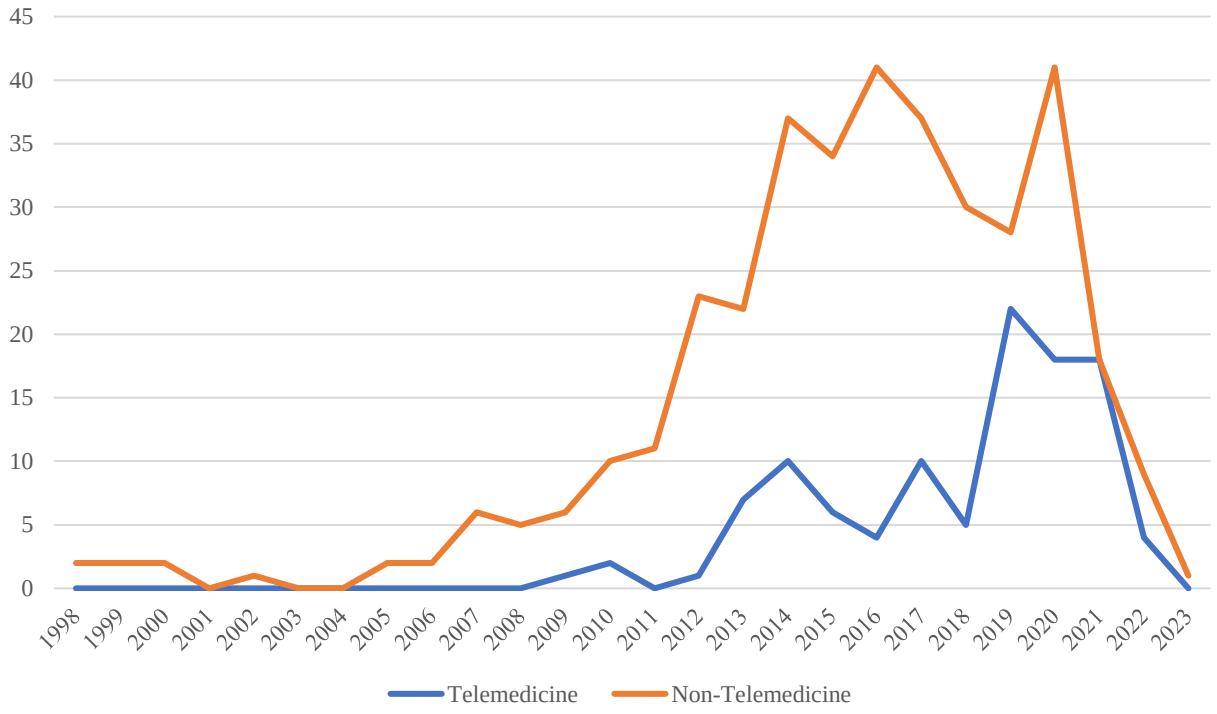
Appendix 3.3 Differentiating technologies across therapeutic areas of direct-to-consumer digital health companies.

	Total sample (n=478)	Tele-medicine (n=108)	Wearables and biosensors (n=93)	AI/ML/ Deep learning (n=63)	Remote monitoring (n=28)	Genomics (n=27)	Nonmedical device hardware (n=26)	Other (n=25)	Digital medical device (n=13)	AR/VR (n=6)	IoT (n=5)	Robotics (n=4)	Block-chain (n=2)
Mental health	16.7%	25.0%	12.9%	20.6%	17.9%	0.0%	11.5%	12.0%	7.7%	50.0%	0.0%	0.0%	0.0%
Reproductive and maternal health	14.9%	27.8%	5.4%	4.8%	10.7%	18.5%	7.7%	12.0%	30.8%	16.7%	20.0%	0.0%	0.0%
Fitness	14.2%	0.9%	25.8%	20.6%	10.7%	3.7%	46.2%	8.0%	0.0%	33.3%	20.0%	25.0%	0.0%
Other	11.9%	1.9%	4.3%	9.5%	3.6%	33.3%	3.8%	28.0%	0.0%	0.0%	20.0%	0.0%	100.0%
Weight management and obesity	8.8%	10.2%	14.0%	3.2%	3.6%	18.5%	3.8%	12.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Primary care	8.4%	18.5%	1.1%	6.3%	7.1%	0.0%	3.8%	4.0%	7.7%	0.0%	0.0%	0.0%	0.0%
Cardiovascular disease	4.8%	5.6%	11.8%	1.6%	7.1%	7.4%	0.0%	0.0%	7.7%	0.0%	20.0%	0.0%	0.0%
Neurology	4.4%	2.8%	8.6%	7.9%	10.7%	7.4%	3.8%	4.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diabetes	4.2%	5.6%	8.6%	3.2%	14.3%	7.4%	0.0%	0.0%	15.4%	0.0%	0.0%	0.0%	0.0%
Elder care	3.8%	2.8%	5.4%	3.2%	17.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	0.0%
Musculoskeletal/ pain management	3.3%	2.8%	2.2%	4.8%	3.6%	0.0%	3.8%	8.0%	7.7%	16.7%	0.0%	25.0%	0.0%
Gastrointestinal	3.1%	2.8%	1.1%	11.1%	0.0%	14.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Substance use	3.1%	9.3%	1.1%	1.6%	3.6%	0.0%	0.0%	8.0%	0.0%	16.7%	0.0%	0.0%	0.0%
Developmental disorders	2.3%	9.3%	1.1%	3.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dermatology	2.1%	7.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Oncology	2.1%	0.0%	1.1%	1.6%	0.0%	7.4%	0.0%	8.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pediatrics	2.1%	2.8%	3.2%	0.0%	0.0%	0.0%	7.7%	0.0%	0.0%	0.0%	20.0%	25.0%	0.0%
Nutrition	1.3%	0.0%	0.0%	0.0%	0.0%	3.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Allergy/ immunology	1.0%	0.9%	1.1%	0.0%	0.0%	0.0%	3.8%	4.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pharmacy	1.0%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Appendix 3.4 Predicted founding rates across organizational density for direct-to-consumer digital health companies.

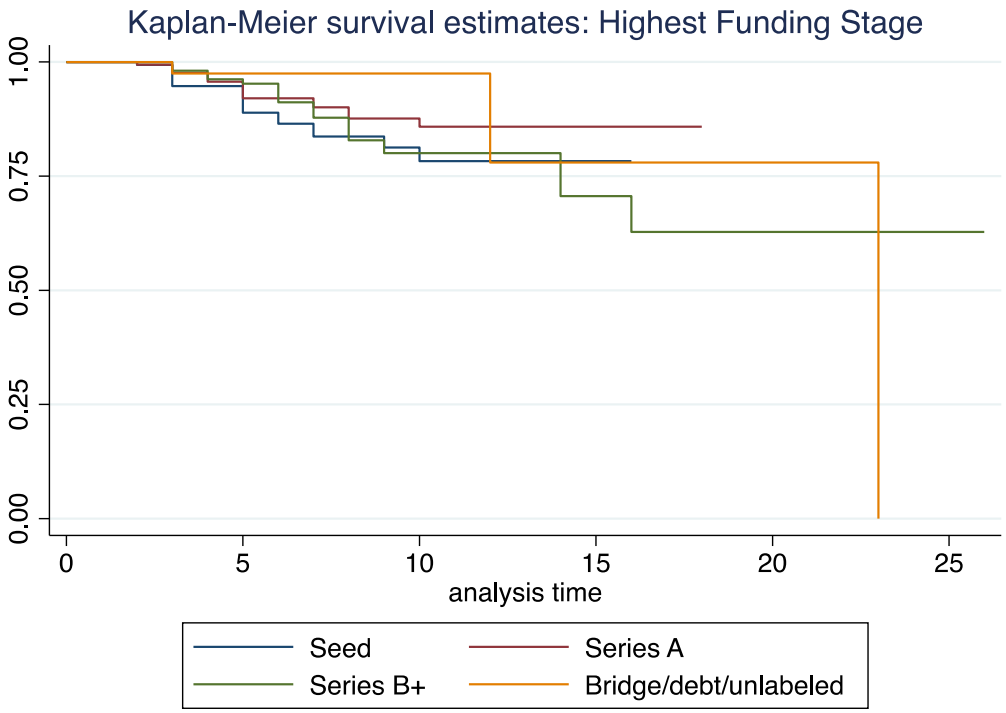


Appendix 3.5 Founding of telemedicine and non-telemedicine direct-to-consumer companies.

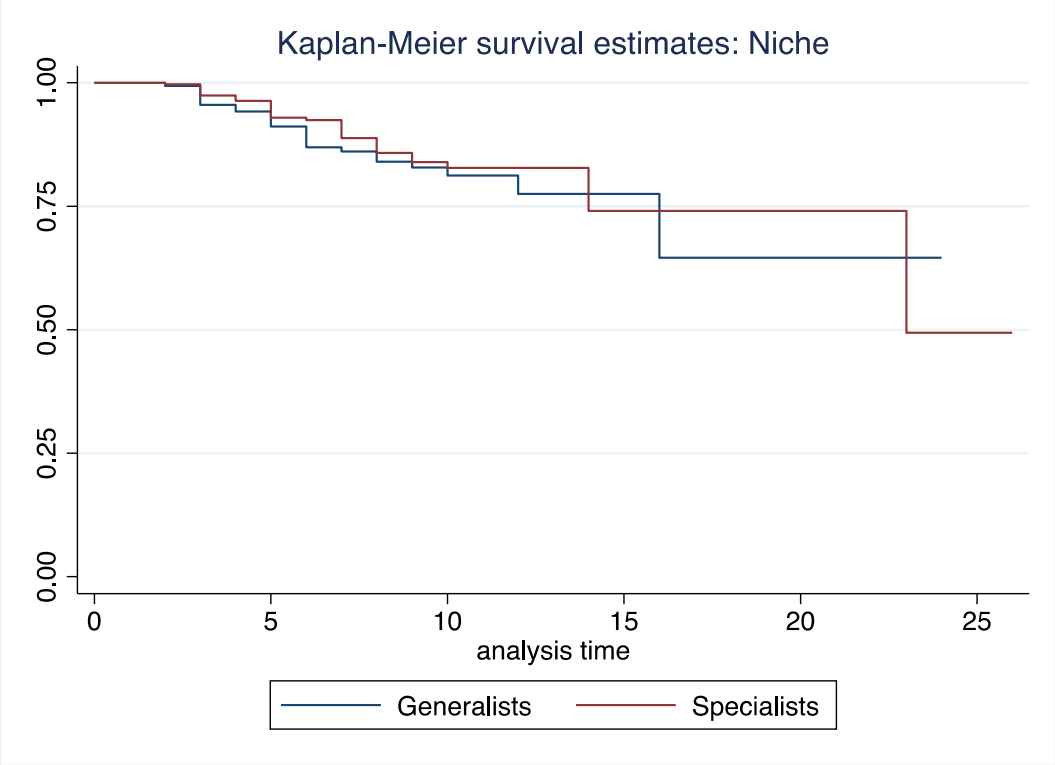


Appendix 3.6 Additional Kaplan-Meier curves.

Kaplan-Meier curves for success by highest funding stage.



Kaplan-Meier curve for success by niche specialization.



Chapter 4. Direct-to-Consumer Telehealth Prescribing of Controlled Substances and the Role of Drug Scheduling: Stakeholder Perspectives

Introduction

The COVID-19 pandemic catalyzed the adoption of virtual care, reshaping the landscape of healthcare delivery. In response to the urgent need for remote healthcare, policies were swiftly enacted to permit telehealth throughout the public health emergency (PHE).[121] One such policy considers controlled substances: drugs that are regulated by the government given their potential for abuse or addiction.[122] As established by the Controlled Substances Act (CSA), controlled substances are categorized into five schedules commensurate to their potential for abuse and accepted medical use, where Schedule I drugs are considered to have the highest risk and Schedule V drugs have the least.[122] In March 2020, the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) jointly implemented a temporary flexibility,[123] permitting healthcare providers to prescribe Schedule II-V controlled substances following a telemedicine visit. This was a departure from the status quo set forth by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008,[124] which required healthcare providers to conduct an in-person evaluation prior to any virtual prescription of controlled substances. While designed to be temporary, this flexibility has been extended repeatedly, most recently through the end of 2024. To date, a permanent policy has yet to be established.[125]

While the telehealth flexibility abridged the process of prescribing controlled substances for healthcare providers in traditional healthcare settings, it also opened the door for direct-to-consumer (DTC) telehealth companies to enter a space that had previously been tightly regulated.[126] DTC telehealth companies offer healthcare products and services directly to consumers, including prescription services.[27] Unlike providers in traditional healthcare settings

who may offer in-person evaluations when needed, DTC telehealth companies almost exclusively operate online. Amid the PHE, some DTC telehealth companies began offering controlled substances—such as stimulants, ketamine, and testosterone—for psychiatric conditions and hormone-replacement therapy.[127–130]

While DTC telehealth companies tout their potential to improve access and convenience, scholars have raised ethical concerns regarding their practices, including misleading advertising, potential conflicts of interest, and fragmentation of care.[12] Furthermore, several DTC telehealth companies faced highly publicized federal enforcement actions related to their practices. For example, the Department of Justice (DOJ) investigated Cerebral for possible violations of the CSA, such as inappropriate prescribing practices. [131] While not found to be in violation of the CSA, the DOJ and the Federal Trade Commission (FTC) ultimately sued Cerebral for several civil violations, including ones related to data privacy, data security, and marketing practices."[10] Additionally, in a first, the DOJ indicted two executives from Done Global for violating the CSA, specifically for their prescribing practices.[11] These cases underscore the need for heightened policy attention to the unique challenges posed by DTC telehealth models when controlled substances are involved.

Hence, given the ethical concerns and the legal actions taken against certain DTC telehealth companies, it is imperative for policymakers to consider the prescribing of controlled substances via these entities in the development of permanent policy. To date, little is known about DTC telehealth companies that operate outside of established institutions, leaving a significant gap in understanding the implications of these new models, particularly as they relate to the prescription of controlled substances. Much of the discourse around telehealth prescribing of controlled substances has focused on the impact of telehealth-based prescribing of controlled

substances via well-established healthcare institutions, such as hospitals and clinics.[132] Far less attention has been given to the DTC telehealth companies. Additionally, while previous studies have examined the impact of the temporary telehealth regulations—particularly the uptake of telehealth prescribing of controlled substances[132–137]—there has been limited exploration into how the scheduling system itself should inform permanent telehealth regulations.

Therefore, the present study sought to explore the perspectives of key stakeholders—including healthcare providers, healthcare executives, and policy experts—on the role of DTC telehealth companies prescribing controlled substances and how drug schedules should be considered in the development of permanent telehealth regulations for prescribing controlled substances. Developing a permanent, sustainable policy fitting for this unique landscape requires additional guidance from stakeholders. Through qualitative analysis, this research aimed to (1) provide insights into the interplay between evolving telehealth regulations and the role of DTC telehealth companies prescribing controlled substances and (2) provide an understanding of how drug scheduling functions as a framework for telehealth prescribing. These results can inform the development of permanent policies regarding such practice.

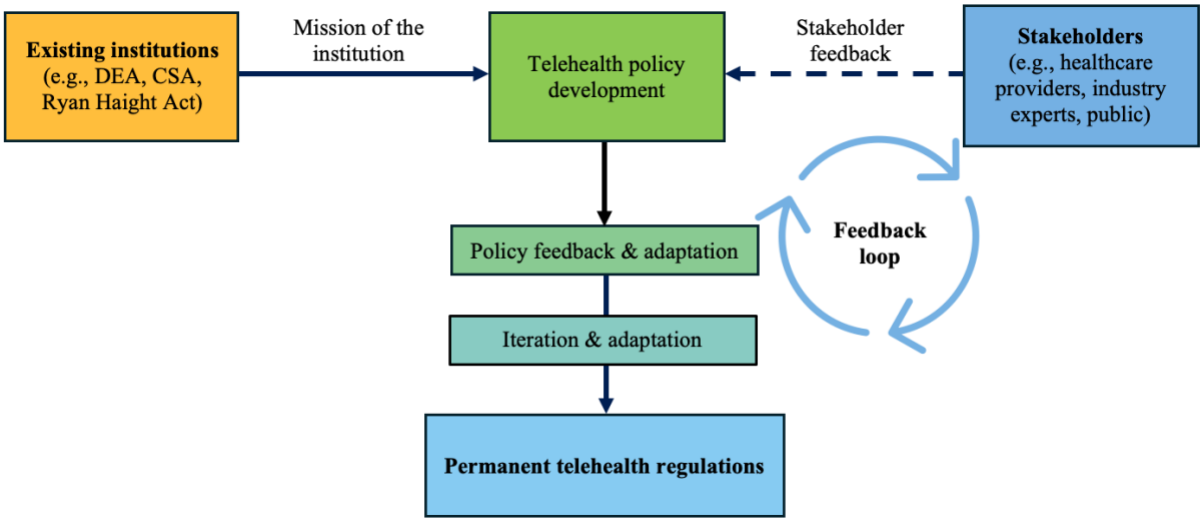
Theoretical Framework

Policy Feedback Theory, originating from political science, posits that policies are not passive or static but active and dynamic tools that actively reshape the political landscape. These policies set in motion new political dynamics that influence subsequent policymaking.[138] This feedback loop is integral to the evolution of regulations, in this case, those surrounding telehealth prescribing of controlled substances. The concept of "*policyscape*" refers to a landscape heavily shaped by past policies that have become entrenched institutions that exert enduring influence over present-day politics; there is no *tabula rasa* here but rather constraints are already in

place.[139] For example, the Controlled Substances Act (CSA) and the Ryan Haight Act—both enacted in a pre-telehealth era—continue to shape the policyscape for telehealth policy.

Informed by the Policy Feedback Theory, I describe the policyscape and feedback loop of telehealth regulation for controlled substances, focusing on how stakeholder perspectives may shape the regulatory approach to telehealth prescribing polices (**Figure 4.1)**.

Figure 4.1 Policy feedback theory applied to telehealth regulations for controlled substances.



Policyscape of Telehealth Regulation for Controlled Substances

Before the introduction of the temporary telehealth flexibilities during the COVID-19 pandemic, the policyscape surrounding telehealth prescriptions for controlled substances was already complex. For instance, the DEA's mission is focused on preventing drug diversion, and this goal has historically driven its regulatory approach. The CSA, enforced by the DEA, was intended to protect the public by controlling the distribution of drugs with the potential for abuse. Similarly, the Ryan Haight Act was created to prevent online prescriptions from illegitimate pharmacies by requiring an initial in-person visit before a controlled substance could be prescribed remotely.

However, the pandemic's demand for telehealth services required an urgent reevaluation of these past policies. The Ryan Haight Act was not designed for an era of healthcare that increasingly relies on telehealth. The temporary policy flexibilities introduced during the pandemic reshaped expectations around telehealth access and prescribing for providers and individuals, now necessitating a reassessment of the old policies that no longer fit the "new normal" created by the pandemic's ubiquity of telehealth.

Feedback Loop in the Rulemaking Process

Policy development for telehealth prescribing did not end with the introduction of these temporary measures. Central to the rulemaking process is the solicitation of public input. Federal agencies typically offer a public comment period when drafting new rules. In February 2023, the DEA and HHS proposed two rules intended to replace the temporary measure, followed by a public comment period that closed on March 31, 2023.[140] The rules would (1) allow the initial telehealth prescribing of a 30-day supply of non-narcotic Schedule III-V controlled substances ("General Telemedicine Rule") and (2) allow the initial telehealth prescribing of a 30-day supply of narcotic buprenorphine (Schedule III) for opioid use disorder ("Buprenorphine Rule"); an in-person visit would be required for any subsequent prescriptions.[126] Under these proposed rules, Schedule II controlled substances (e.g., stimulants) and narcotics (except for buprenorphine), cannot be prescribed via telehealth. These proposals reflect a continuation of the DEA's reliance on drug scheduling as the primary anchor for telehealth prescribing rules.

A total of 38,369 public comments were submitted. In response to the mammoth amount of feedback, the DEA and HHS extended the PHE-era flexibility for six months to November 11, 2023 ("First Temporary Rule").[141] Notably, in the First Temporary Rule, the DEA noted that it was only extending the flexibilities for six months "to disincentivize the creation of telemedicine

companies that may seek to engage in problematic prescribing practices"[142]—indicating the DEA's awareness of the DTC telehealth provision model.

In the interim, the DEA held a two-day public listening session on September 12-13, 2023,[143] further involving stakeholders such as healthcare providers and policy experts in the policy development process. Through this process, it became clear that the DEA needed more time to develop permanent telehealth regulations. After the public listening session, an additional extension ensued through December 31, 2024 ("Second Temporary Rule").[125]

Ongoing Policy Iteration and Adaptation

This ongoing process of policy development and adaptation exemplifies the iterative nature of policymaking shaped by institutional priorities and evolving stakeholder needs. The pandemic created a "new normal," in which there is now an expectation for the availability of telehealth services, particularly in relation to controlled substance prescribing. Stakeholders adapted to the temporary measures, and as a result, they are now advocating for their continuation post-PHE. For example, a September 10, 2024 petition from over 300 stakeholder organizations—representing a diversity of interests, including professional societies and telehealth providers—urged Congress to extend this telehealth flexibility for another two years,[144] further underscoring the importance for policymakers to consider stakeholder feedback.

In the days preceding the stakeholder petition, a DEA draft rule was leaked,[145] in which one of its stipulations was that providers could only do 50% of prescribing online and the other 50% must be in person. As of November 2024, the DEA has yet to issue permanent regulations for telehealth prescribing of controlled substances.

This study examines the feedback component of this iterative process, focusing on how stakeholder perspectives may shape the DEA's regulatory approach to telehealth prescribing of controlled substances regulations.

Research Questions

This study has two aims related to telehealth prescribing of controlled substances. The first aim focuses on the provision of controlled substances from DTC telehealth companies and how these companies should be considered in the development of permanent telehealth regulations. The second aim examines the prescribing of controlled substances via telehealth generally (without specifying the entity) and explores the role of the existing drug scheduling system in telehealth prescribing regulations. The study will address the following research questions:

1. How do stakeholders perceive DTC telehealth companies prescribing controlled substances, and what insights can inform the development of permanent policies for such practices?
2. How do stakeholders think drug schedules should be considered in the development of permanent telehealth regulations for prescribing controlled substances?

Methods

Participants and Recruitment

To answer these questions, I conducted a cross-sectional qualitative study with key informant interviews.[146] The initial participants were selected from those who took part in the DEA's telemedicine listening session held in September 2023, as the participant list and transcripts were publicly available on the DEA's website. The session featured 58 invited

commentators, comprising a diverse group of "healthcare practitioners, experts, advocates, patients, and other public members."[143] I selected this group as the initial pool of potential interviewees because they represented key stakeholders with direct knowledge of telehealth prescribing regulations for controlled substances, making these individuals uniquely qualified to provide insights on the evolving regulatory landscape. To broaden the study sample, I employed snowball sampling: at the end of each interview, I asked interviewees to recommend additional potential participants with relevant expertise. I chose this approach to capture insights from stakeholders who were not part of the formal DEA session but would add diverse perspectives on the regulatory and practical implications related to telehealth prescribing of controlled substances. Executives from DTC telehealth companies were excluded. All participants were invited via email to take part in the study.

Data Collection

I developed a semi-structed interview guide based on a thorough review of the literature related to DTC healthcare and telehealth policy as well as a review of the transcripts from the telemedicine listening session, identifying gaps and underexplored areas, such as DTC provision of controlled substances and scheduling-based proposals (**Appendix 4.1**). The interview guide addressed perceptions of DTC telehealth companies compared to traditional healthcare providers and the regulatory challenges unique to the prescribing of controlled substances via telehealth. Specific questions asked about participants' understanding of current telehealth prescribing policies; perceived benefits with the prescribing of controlled substances via DTC telehealth companies; considerations for drug schedules in developing permanent regulations; and recommendations for policymakers on telehealth regulation. The interview guide included both open- and closed-ended questions.

I conducted interviews over a four-month period from January to April 2024. Interviews lasted approximately 30 minutes on average, and I conducted all of the interviews via telephone or videoconference. All interviews were audio-recorded with verbal consent and subsequently transcribed by Research Transcriptions. Transcripts were deidentified and reviewed for accuracy prior to analysis.

Data Analysis

Data analysis was primarily inductive, where the interview guide provided the structure for organizing the data into overarching domains (e.g., benefits of DTC telehealth, accountability).[147] The initial codebook was developed collaboratively by two coders. Both coders independently applied this preliminary codebook to six transcripts (approximately 20% of the total sample), serving as the foundation for codebook development. During this process, inductive codes were added to the codebook as recurring patterns and nuances emerged from the data. For example, within the domain of "benefits of DTC telehealth," specific codes like "access as a benefit" were identified inductively. This process ensured that the codebook comprehensively captured the data. Once the codebook was finalized with the input from the two coders and a third researcher, both coders independently coded all transcripts in sequence using Dedoose (version 9.2.012). Then, consensus discussions were held for every transcript to ensure any discrepancies in coding were resolved.

Following coding, theme identification was conducted collaboratively. The primary researcher reviewed the excerpts associated with each code and developed preliminary themes based on recurring insights and themes in the data. The second coder reviewed the excerpts and assessed the preliminary themes, providing feedback on their accuracy, comprehensiveness, and

alignment with data. The two coders discussed the themes with a third researcher to finalize them.

The study protocol was reviewed and granted exemption by the University of California, Los Angeles (UCLA) Institutional Review Board.

Results

Of the 78 individuals contacted, 31 agreed to participate (**Appendix 4.2**). The participant cohort included a diverse range of stakeholders: eight were healthcare providers (e.g., psychiatrists, clinical psychologists); seven were representatives from professional societies and associations spanning health technology (e.g., telehealth), mental health, palliative care, and healthcare delivery systems (including community-based and hospital care). Five participants were executives from telehealth-only companies. Four participants were executives from hybrid healthcare organizations (e.g., organizations that had brick-and-mortar locations and provided telehealth). Additionally, 4 participants were policy experts (e.g., policy consultants, attorneys), 2 were pharmacists, and 1 was an academic researcher.

The results of this qualitative study are organized here into two sections, each addressing the primary research questions. The first section presents participants' perspectives on the role of DTC telehealth companies prescribing controlled substances (RQ1). The second section explores participants' views on using drug scheduling as a framework for telehealth prescribing of controlled substances (RQ2).

Perspectives on DTC Telehealth Companies Prescribing Controlled Substances

Participants shared perspectives on four key domains. First, they discussed the benefits and risks of DTC telehealth companies prescribing controlled substances. Second, participants

explored who should be held accountable in cases of inappropriate prescribing at DTC telehealth companies. Third, they offered suggestions on best practices for DTC telehealth companies. Fourth, they provided policy suggestions for regulators, offering guidance on how to effectively oversee DTC telehealth companies' practices of prescribing controlled substances.

Domain 1: Benefits and Risks of DTC Telehealth Companies Prescribing Controlled Substances

Participants were asked to reflect on the benefits and risks of DTC telehealth companies prescribing controlled substances, particularly in comparison to telehealth prescribing by providers in traditional healthcare settings (e.g., health systems).

Benefit: Improving Access. Participants highlighted one primary benefit of DTC telehealth companies improving access to care. This perspective surfaced across 18 participants, including healthcare providers (n=7), professional society/association representatives (n=4), policy experts (n=3), executives from hybrid healthcare organizations (n=2), a telehealth company executive (n=1), and an academic researcher (n=1).

These participants emphasized the role of these companies in improving access by addressing unmet needs. A professional society/association representative remarked that these companies were "fulfilling a really necessary need" (CS2), and an academic researcher highlighted how these companies serve consumers who have "no way of filling their needs locally" (CS1). One telehealth company executive noted: "Access to healthcare and behavioral healthcare is quite limited…if people have the financial ability to pay for that [DTC services], they're certainly allowed to do that" (CS15).

Improving access by overcoming barriers to care, particularly from geographic or sociodemographic circumstances, was highlighted. A policy expert noted that some individuals

face barriers to seeing a physician based on "where they happen to live…their circumstances, demographics, and other characteristics. At least if [they] go online this afternoon and approach one of these companies, [they] have some chance of getting a physician's attention." (CS23) One healthcare provider pointed to the potential for DTC telehealth companies to benefit underserved populations:

> If they [companies] can do it at scale, then prices are lower, which means that people who are often people of color, people of lower socioeconomic status, who live in rural areas, who don't have access to psychiatrists [can access care]. (CS29)

Another access-related benefit that emerged was the potential of DTC telehealth companies to reduce stigma associated with seeking mental health treatment. A professional society/association representative noted, "Mental health still has stigma…[which] alone creates a hesitancy for people to go forward" (CS28). One healthcare provider suggested that DTC services offer "anonymity in seeking care" (CS19). A hybrid healthcare organization executive connected reducing stigma to increasing accessibility for those who may be hesitant to engage with traditional healthcare settings:

> A lot of the conditions where a controlled substance is indicated as first-line treatment tend to be conditions where there's a lot of stigma attached to them. It will prevent individuals from wanting to physically go into a doctor's office and/or sometimes even walk into a pharmacy to pick up their medications out of fear of being judged and scrutinized for the type of care that they're seeking. It [DTC telehealth] provides a level of safety. (CS3)

A few healthcare providers cited the consumer-focused and retail-oriented approach of DTC platforms as an advantage in improving healthcare access. A healthcare provider noted: "Direct-to-consumer companies who are retail-focused and have a consumer in mind make it

much easier to get in and access somebody than the traditional healthcare system," especially for those who find it difficult to navigate the often "opaque" traditional healthcare system (CS21). Another healthcare provider also suggested that DTC telehealth companies are "business-first companies – they're experts in marketing and advertising and can probably reach people we [traditional healthcare] can't or have yet to reach" (CS17).

Several participants (n=4), specifically hybrid healthcare organization executives (n=2), a telehealth company executive (n=1), and a pharmacist (n=1), explicitly stated that they did not see any benefits from DTC telehealth companies prescribing controlled substances.

Drawback: Access Compromising Standards of Care. Several participants across stakeholder types (n=6; three healthcare providers, one professional society/association representative, one hybrid healthcare organization executive, and one pharmacist) expressed concerns that increased accessibility might compromise the standard of care. One healthcare provider remarked, "Increasing access to care is not necessarily a good thing in and of itself" (CS4). Another healthcare provider highlighted the tradeoffs between accessibility and oversight:

> "It's more access versus more scrutiny over a situation. I don't think you could really have both. I think if you allow more access and more freedom, you're going to have more abuse of the system. The question is the magnitude of the abuse versus the good that it comes from it. And I don't quite know how that will be measured" (CS13).

A third healthcare provider expressed concerns about the quality of care provided despite the large customer base of companies: "With the millions of people that they [a DTC telehealth company] had access to, as a result, they're making a ton of money, but they weren't giving good care" (CS29). Additionally, a hybrid healthcare organization executive pointed to the risk of drug-seeking behavior facilitated by these companies, which could further compromise care:

“Anyone who tells you there's not drug seeking going on at these direct-to-consumer things, it's just not true” (CS5).

Drawback: Lack of Patient-Provider Relationship. The absence of a strong patient-provider relationship was another point of concern among 15 participants. Interestingly, this perspective was raised not only by healthcare providers (n=3), but also by representatives from professional societies/associations (n=3), executives from hybrid healthcare organizations (n=3), executives from telehealth organizations (n=2), pharmacists (n=2), and policy experts (n=2), reflecting its salience across stakeholder groups.

Participants highlighted concerns about the depth of the patient-provider relationship in DTC telehealth companies. One healthcare provider explained: “If you're [healthcare provider] doing an evaluation of somebody as a one-off…you're not really invested in whether or not the medication you send them is going to be helpful” (CS4). A policy expert emphasized continuity of care, stating that it was important to “have a relationship with a single doctor or a team of doctors” to “coordinate your care” for controlled substances (CS14).

Several participants expressed concerns about the transient nature of the clinical workforce in many DTC telehealth companies, which was perceived to be a barrier to fostering ongoing patient-provider relationships. A policy expert described the DTC model as having “an Uber-like” approach: “Most of these clinicians are [independent contractors] 1099 rather than [full-time employees] W2. This means that the end user, the patient, will oftentimes end up seeing more than one practitioner” (CS9). A hybrid healthcare organization executive similarly said, “There's been this explosion of mid-levels, especially nurse practitioners” who they felt, “have no idea who they're talking to…they have no idea whether or not it's [a medication] really necessary” (CS5). A professional society/association representative commented on the

impersonal nature of DTC services, noting that for consumers, “It's more difficult to figure out who you need to talk to when you are having an issue, and it's run more like a business than it is like a healthcare relationship” (CS25). Another professional society/association representative emphasized the importance of “a consistent provider” and “ongoing care” (CS31).

There were some worries about potential mismanagement of prescriptions and the absence of a healthcare provider to oversee follow-up care. A hybrid healthcare organization executive perceived that the DTC model prioritizes speed and convenience over proper care: “direct-to-consumer is often less than ideal…because they don't care about proper protocols. They don't want ongoing relationships with their patients. They want to get in, write the prescription, and leave” (CS30). One telehealth company executive suggested that consumers may exploit this system: “It’s people diagnosing themselves in those instances, and they know what to say in order to get the medication” (CS26). Another telehealth company executive viewed healthcare providers in more traditional settings as more likely to take a holistic view of patient care, rather than focusing on single diagnoses, as is common in the DTC model, noting:

> We don't often go to a healthcare provider for one specific condition alone…Direct-to-consumer doesn't seem to be oriented that way. It seems to be more targeting people with a specific diagnosis and offering to assess them for that diagnosis, treat for that one diagnosis…That's a different way of doing healthcare than having a relationship with a physician and addressing this condition as part of my overall health. (CS15)

Drawback: Conflict of Interest. Many participants (n=11), including healthcare providers (n=6), a professional society/association representative (n=1), a telehealth company executive (n=1), a hybrid healthcare organization executive (n=1), a policy expert (n=1), and a pharmacist (n=1), raised alarm about the perceived profit-driven nature of DTC telehealth companies. One healthcare provider summarized:

> If [the revenue model] is tied to the number of prescriptions you are sending out the door, or they are getting money based off of the prescription where that is a substantial portion of their margin, there is a non-negligible conflict of interest with that. (CS21)

This perspective highlighted the potential conflict of interest inherent in DTC telehealth companies whose revenue is tied to prescriptions filled, with one professional society/association representative stating, "The more medicine they [DTC companies] send you, the more money they make. That is a very serious perverse incentive" (CS27).

Another professional society/association representative noted: "We have a lot of both hard evidence and anecdotal evidence that when you have that private equity or business entity involvement, it really is run for efficiency rather than quality outcomes. That can be seriously deleterious to patient care" (CS25), suggesting these companies may prioritize financial gain over medical necessity. One hybrid healthcare organization executive called DTC telehealth "the worst care model ever," describing it as profit-focused at the expense of care: "They just want to be able to prescribe to everyone in their home anything that person would want and charge them on their credit card that amount of money every time" (CS30). A pharmacist said the practices of DTC telehealth companies put "margin completely over the mission" (CS11) and a policy expert stating, "They're all in it just to make money" (CS14).

These profit motivations were seen as contributing to concerning healthcare practices, such as rushed appointments and inappropriate prescribing. As one healthcare provider remarked: "It's the bad actors that are going to take advantage of whatever rules there are to try to maximize profit. And that's the risk here…fast appointments, poor diagnostics, lots of inappropriate prescribing of controlled substances." (CS17). Another healthcare provider connected this profit focus to diminishing the patient-provider relationship: "Companies want to

make money and the further they are away from the doctor/patient relationship or the prescriber/patient relationship, the less they feel connected to that…they're looking at the bottom line" (CS13). One telehealth company executive mentioned the risk of "errors of commission," (CS20), wherein actions taken at DTC telehealth companies, like prescribing medications, might not always align with the patient's best interests.

One healthcare provider even drew parallels to previous healthcare crises, such as the opioid epidemic, where "there was an incentive to fast appointments, to put everyone on, essentially, the most addictive opioids to maximize profit" (CS17). The possibility that DTC models could enable similar patterns of overprescription without appropriate safeguards was seen as a risk.

Perceived Equivalence in Risk Across Provision Models. A smaller subset of participants (n=5) from various stakeholder groups, including a healthcare provider (n=1), policy expert (n=1), professional society/association representative (n=1), a telehealth company executive (n=1), and an academic (n=1), did not perceive a stark difference in risks between telehealth prescribing delivered via DTC telehealth companies and that provided in traditional settings. One telehealth company executive (CS22) and one professional society/association representative (CS28) both viewed a DTC telehealth company as simply the "vehicle" of care delivery, and instead, what was more critical for them is how well providers engage with patients and uphold the clinical standard of care.

Domain 2: Who Should Be Held Accountable?

Participants were asked who should be held accountable if inappropriate prescribing of controlled substances occurs at a DTC telehealth company: the company itself or the providers within the company. There was an even split between those who firmly believed the

responsibility should rest with the provider (n=7) and those who believed the company should be held accountable (n=7). Twelve participants—nearly half of the total sample—advocated for a more nuanced, context-dependent approach that did not fall squarely within one of the two options, reflecting the complexity of the issue. Five participants either expressed uncertainty or provided other responses.

Provider Accountability. Participants who emphasized that providers should be held accountable came from a mix of perspectives, including pharmacists (n=2), policy experts (n=2), a telehealth company executive (n=1), a hybrid healthcare organization executive (n=1), and a professional society/association representative (n=1). Notably, no healthcare providers suggested that providers should be held accountable.

Proponents of provider accountability focused on the professional and legal responsibilities inherent in prescribing medications. This view was particularly evident in one policy expert's reflection on the autonomy of providers who articulated: “At the end of the day, they are a patient and not a consumer. You as a clinician are required to use your judgment in how to best care for them. That is a set standard” (CS9).

Similarly, a professional society/association representative noted that “the source of the prescription is ultimately the licensed medical professional interacting with the patient” (CS2). This perspective was echoed by a telehealth company executive who stressed that clinicians must "take ownership of every prescription they write” (CS15) regardless of the setting in which they practice. Pharmacists also remarked that it is “their [providers] license on the line” (CS11), with one noting that this applied “to all provider types regardless of their setting” (CS6).

A policy expert noted that clearer regulatory mechanisms exist to oversee and assign accountability to providers, as professional boards—such as those for medicine, psychology, or

nursing—can discipline individual licensees, but that "boards have no authority over corporations" (CS23); thus, reinforcing the view that accountability falls on the providers.

Company Accountability. Participants, consisting of healthcare providers (n=2), telehealth company executives (n=2), a policy expert (n=1), a hybrid healthcare organization executive (n=1), and a professional/society association representative (n=1), believed that the company should be held accountable if there is inappropriate prescribing of controlled substances. This perspective honed in on corporate practices.

A professional society/association representative characterized the approach of DTC telehealth companies akin to "an Uber of mental health," which they perceived to be the company "trying to minimize their level of accountability or responsibility by saying, 'We're just making the connection between the consumer and the provider'" (CS31). One healthcare provider asserted: "The company should be held responsible 100%...Ultimately, the company has told them [providers] what the job expectation is, and they're simply doing that" (CS7)—suggesting that the providers are merely following the company's directives.

Several participants emphasized that the role of the company is to establish operational standards. One telehealth company executive underscored the responsibility of the company to ensure "the patients are properly screened, and the providers are properly screened" (CS18). Another telehealth company executive pointed to the influence of corporate practices on provider behavior, noting that companies "create the incentives for action" (CS20).

A hybrid healthcare organization executive expressed skepticism about the level of training of mid-level providers working for these companies, which, in their view, further justifies holding the company accountable: "I just don't trust their [nurse practitioners] training… to me, it's the companies that have to be held responsible. I would expect to be responsible for

things that our providers do" (CS5). A policy expert drew parallels between the accountability of a company and that of a traditional medical practice: "I think the whole company should be held accountable, just like a medical practice that has a doctor who has malpractice. The whole practice is in trouble" (CS14).

Contextual Accountability. Many participants, representing different stakeholder groups, proposed a more nuanced, context-dependent approach to accountability. This group included healthcare providers (n=5), representatives from professional societies and associations (n=3), telehealth company executives (n=2), a policy expert (n=1), and a hybrid healthcare organization (n=1). These participants differentiated between isolated incidents and broader systemic issues, suggesting that if a practitioner violates the law, then they should be held accountable individually; however, in cases where the issue is related to practices like overprescribing, the company should face significant consequences. A professional society/association representative summarized:

> If it's something that is directly in conflict with the law, then [accountability falls on] that individual practitioner. But in terms of over-prescribing, which is something that is not necessarily legally proscribed, the outcomes are going to be on the company as a whole, who failed to do appropriate oversight of their internal systems and vetting of the practitioners that are on their payroll. (CS25)

Similarly, a hybrid healthcare organization executive said: "If I have a bad practitioner, of course that's on them and their license…but if it's happening on my watch, especially if it's happening a lot on my watch, I should be held just as accountable" (CS16).

Conducting an investigation emerged as an important step in determining accountability. A healthcare provider emphasized: "You would have to do an investigation to see: were the prescribers being pressured…or was just a few individual providers that were practicing outside

of those standards, or is it a combination of both in certain companies?" (CS19). Another healthcare provider elaborated that if prescribers knowingly engaged in illegal or unethical behavior, then they should be held accountable; however, if the company was involved in concealing such practices "unbeknownst to the prescribers," then the responsibility should primarily fall on the company (CS13). In this view, the question of who had knowledge of the inappropriate practices becomes a key determinant in assigning accountability.

A few participants indicated how company financial incentives might shift accountability. A policy expert described: "If the clinician is doing something that's not clinically appropriate, then they should be held accountable. But if the company is also incentivizing inappropriately, they should be held accountable" (CS12). This perspective suggests that if a clinician engages in inappropriate clinical practices, they should be held responsible for their actions, but if the company is encouraging such behavior—through inappropriate incentives like pay-per-prescription models where providers are only compensated if they prescribe, for example—then it too should be held accountable.

Telehealth company executives also highlighted how the level of corporate accountability would vary by context, with one noting that if there were "broad and gratuitous use of controlled substances inside of an entity instead of a specific provider, then they'd crack down on the entity" (CS22). Another telehealth company executive said in addition to the provider, the company should be held accountable "because you as a company, you're responsible for monitoring your employees" (CS26).

A few healthcare providers offered perspectives on provider accountability even within corporate structures. One provider perceived that while "providers will say, 'I operated within the guideline [of the company],'" they still maintained that "both" the provider and the company

should be held accountable (CS17). Another healthcare provider commented, “Individual clinicians also need to be held liable for the choices they have made with clients and need to face repercussions for practicing poor medicine” (CS21). Similarly, a professional society/association representative maintained that while this could be “corporate behavior and professional behavior…as the prescribing professional, I need to be exercising my best medical judgment free of any coercion or incentives that cause me to overprescribe or something else” (CS27).

Domain 3: Considerations for DTC Telehealth Companies

Participants were asked to identify specific safety measures or protocols that could improve prescribing practices at DTC telehealth companies.

Clinical Practice. Many participants (n=14), including representatives from professional societies/associations (n=5), healthcare providers (n=4), hybrid healthcare organization executives (n=2), two policy experts (n=2), and a pharmacist (n=1), suggested recommendations in regard to the clinical practices at DTC telehealth companies.

Several participants suggested implementing clinical controls or evaluation requirements at DTC telehealth companies. A hybrid healthcare organization executive suggested requiring “a biopsychosocial, a psychiatric evaluation” (CS16), and others proposed “in-person urine collection (CS5; hybrid healthcare organization executive) or “urine drug screens and medication contracts…depending on the situation” (CS27; professional society/association representative). A few healthcare providers suggested implementing “some kind of formal testing” (CS7) or “additional quality controls to ensure that you're appropriately routing patients to the right level of care” (CS8). One healthcare provider described the protocol they would implement:

> If I am one of these companies, I would absolutely require the initial evaluation, and that’s going to take a half an hour. You're going to fill out all this paperwork, and we're going to do the objective measures. And then, we're going to make a prescription. And

> then, a month or two later, we're going to follow up and we're going to do the same exact assessments to see if we're getting the treatment outcomes that we want. (CS29)

Participants also emphasized the importance of follow-up protocols. One professional society/association representative suggested, “there needs to be a structured assessment and professional diagnosis, and there needs to be adequate follow-up” (CS27). Two policy experts also echoed this sentiment stating “you’d have to put guardrails in… without follow-up care, there will never be another prescription…there’s checks and balances” (CS14) and requiring an “appropriate follow-up protocol” (CS9).

Several participants advocated for hybrid models where DTC telehealth companies partner with healthcare providers with physical locations or maintain a brick-and-mortar presence. Two professional society/association representatives suggested “mandating some kind of relationship to providers with physical locations” (CS31) or “coordinating with…some local physician” (CS24). One healthcare provider took a stronger stance that “no controlled substance should be offered direct-to-consumer” (CS17). They reflected:

> It’s too much of a slippery slope, it’s too dangerous. There should always be a hybrid model. I think the only way to protect against fraud or unethical practices is a hybrid model, where there is a brick-and-mortar office, and that a patient is required, initially–and at some frequency–some in-person appointments to protect against what we're talking about. (CS17)

However, one professional society/association representative raised an important counterpoint that implementing these measures might compromise the core strengths of the DTC model—"efficiency and the access”—explaining that “anything that you put in place to increase the safety or efficacy would just kind of end up turning them not into what they are” (CS25).

Operational Standards. Participants (n=11), from the perspectives of telehealth company executives (n=4), healthcare providers (n=2), policy experts (n=2), a hybrid healthcare organization executive (n=1), a professional society/association representative (n=1), and an academic researcher (n=1), emphasized the need for robust guardrails or standardized protocols to ensure the safe prescribing of controlled substances by DTC telehealth companies.

One academic researcher noted the importance of industry-wide standards: "as an industry, they either need to invite the government in, or they have to give the government a reason to recognize that they're not needed to be invited in because the industry is creating its own self-regulation" (CS1).

Several participants suggested formal and external oversight standards. A policy expert (CS12), a hybrid healthcare organization executive (CS3), and a professional society/association representative (CS24) all suggested an "accreditation" process. Both the policy expert (CS12) and hybrid healthcare organization executive (CS3) recommended the implementation of "third-party" certification, specifically referencing this could be similar to existing models like "LegitScript".[148]

Multiple participants focused on verifying prescriptions and record keeping. Telehealth company executives suggested ensuring that for the provider at the company, "I'm the person of record prescribing, and the identified patient is the person that I'm prescribing it to" (CS15), that providers should be able to "pull up your name and date of birth, and…see every medication you've had in the last two years instantly" (CS18). Another telehealth company executive noted, "It's about record keeping…require people to keep records. You can't track controlled substance without a continuity record" (CS22). A healthcare provider also reinforced the need for patient

identity verification, saying there needs to be "mechanisms in place to validate identity on the far side of who we are prescribing controlled substances to" (CS21).

Some participants highlighted operational changes. Recommendations from a healthcare provider included appointing a "Chief Medical Officer who is board certified, or fellowship trained in that area of medicine that's being practiced" to oversee clinical operations (CS17), while a policy expert suggested companies "employ their providers" (CS12) directly rather than using independent contractors. A hybrid healthcare organization executive noted: "If you're a founder who has never started a healthcare company, you may want to approach it very similarly to a non-healthcare company. That's where they unintentionally kind of get themselves into a little bit of trouble," (CS3) recommending that non-clinician founders thoroughly understand the unique challenges of the healthcare industry, distinguishing it from other technology/startup ventures.

Domain 4: Considerations for Policymakers on Regulating DTC Telehealth Companies

Participants were asked to provide guidance for policymakers, particularly the DEA, on how to consider DTC telehealth companies.

Differentiated Oversight for DTC Telehealth. Many participants (n=12) expressed that DTC telehealth companies should not be regulated in the same way as traditional healthcare providers offering telehealth, from the perspectives of healthcare providers (n=4), professional society/association representatives (n=3), telehealth company executives (n=2), a hybrid healthcare organization executive (n=1), a pharmacist (n=1), and a policy expert (n=1). Various participants described DTC telehealth companies as a "different beast" (CS26; telehealth company executive) or "its own beast" (CS31; professional society/association representative), not wanting them to "lump them in with everybody else" (CS27; professional society/association

representative) in regulations. One healthcare provider noted: “They probably do need to be handled differently. I just wish they didn’t” (CS29).

Several participants advocated for heightened scrutiny or different oversight mechanisms. One telehealth company executive noted, “I'd be having a whole lot closer eye on those companies. They'd be under a notably higher level of scrutiny…because I think your model has the potential to incentivize poor behavior” (CS22), and one healthcare provider proposed “there should be some different set of regulations, scrutiny, auditing” (CS17). A policy expert stated: “I'm not saying control substances can’t be done by direct-to-consumer but…I think there needs to be different regulations” (CS14).

However, some participants also acknowledged the delicate balance of crafting policy in response to “bad actors” while ensuring legitimate access to care remains unharmed. One professional society/association representative noted:

> This is a Rubik’s cube. My worry is that the DEA is only going to solve for one side of the cube, and they are willing for us to get scrambled…Health policy is all a Rubik’s cube. It is all about trying to align all your stakeholders and getting to the best possible stop to cover as many folks as you can. (CS28)

The same professional society/association representative mentioned: “They [the DEA] are law enforcement people. Get bad guys…That is what I worry about—the DEA making a decision without thinking about all these bigger pieces” (CS28). Some felt that overregulation could restrict access for patients with compliant providers, with one academic researcher preferring that “we don't have to overburden all of the good actors in the service of finding the bad actors” (CS1). One hybrid healthcare organization executive stated that policymakers should: “go get the bad guys… make those stop, not the rest of us” (CS16). One pharmacist

recommended that policymakers carefully consider long-term, "cascade effect" of regulatory changes, ensuring that rules do not unintentionally "impact others in ways that they may never truly anticipate" (CS6).

However, alternatively, a few participants (n=4; two healthcare providers, one professional society representative, and one telehealth company executive) cautioned that the DEA's focus should center on individual prescribers' qualifications and practices, rather than the type of company they work with, arguing that enforcement should be based on clinical behavior, not affiliations. One professional society/association representative summarized: "It's certainly not the position of the DEA…to determine who is a worthy prescriber…and who isn't…and certainly not based on the organization with whom they are partnering with" (CS2).

Expanding the Scope of Regulatory Oversight. Several participants (n=7) from a range of perspectives highlighted the need to expand the scope of regulatory oversight beyond the DEA, including professional society/association representatives (n=3), a hybrid healthcare organization executive (n=1), a telehealth company executive (n=1), a healthcare provider (n=1), and a policy expert (n=1).

One hybrid healthcare organization executive noted the limitations of the DEA's authority, stating that the agency's jurisdiction is confined to certain entities, such as physicians and pharmacies, but not the companies or organizations by which controlled substances are prescribed (CS30). This participant noted that, as a result, "the back door you're kind of seeing happening now is…the FTC [Federal Trade Commission] is trying to bootstrap" to regulate these companies. A professional society/association representative highlighted the "patchwork" of oversight and pointed out that this makes it difficult to adjudicate consistent guidelines at the federal level (CS25).

Several participants proposed a more collaborative approach between agencies, including but not limited to the Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Medicare & Medicaid Services (CMS), and Securities and Exchange Commission (SEC) for more effective oversight. One professional society/association representative emphasized the importance of distinguishing between clinical and diversion issues: "If they can split out the clinical versus the diversion issues, that would be the best. It has to be some kind of hybrid joint control" (CS24). Another professional society/association representative echoed this perspective, proposing that "It has to be some kind of hybrid joint control…where you can have different agencies sort of jointly overseeing and having equities in different regulations" (CS25). One telehealth company executive further suggested that: "It could be a combination of the DEA just for the prescribing practices alone, but it's also a fraud, waste, and abuse issue. There's a whole sector of CMS…that just does fraud, waste, and abuse" (CS26).

Further, a few participants commented that the DEA should not overstep clinical boundaries. One healthcare provider noted that: "the medical system should be the ones making the decisions about…the standard of care. The DEA then needs to just sort of put their stamp of approval on it, I suppose" (CS29). One policy expert advocated that regulatory responsibility should be shifted to "medical bodies" (CS14), and one professional society/association representative noted:

> When it comes to the idea of regulating the companies themselves as opposed to the licenses, they [DEA] have to be careful not to be making clinical judgments. Saying when an in-person is required is a clinical judgment. That is a standard of care judgment. They are painting with a really broad-brush things that are actually really complicated. (CS28)

Advertising Checks. Two participants (one policy expert and one professional society/association representative) perceived there to be a lack of regulatory oversight for DTC telehealth companies' advertising, especially on social media platforms like TikTok. The policy expert highlighted that "there is a role for oversight of [advertising], just the way that there is with the FDA oversees how pharmaceuticals can be advertised" (CS12), and the professional society/association representative suggested requiring them to provide a "warning or advisory" of the limitations of these services (CS31).

Implementation of PDMP and Special Registration. Participants (n=11), including professional society/association representatives (n=3), healthcare providers (n=3), policy experts (n=2), telehealth company executives (n=2), and a pharmacist (n=1), emphasized the need for more robust national prescription drug monitoring programs (PDMP/PMP) to track controlled substance prescriptions across state lines or the need for a special registration pathway. Importantly, these recommendations were not solely limited to DTC telehealth prescribing, but telehealth prescribing of controlled substances at-large.

A pharmacist noted that while state-level PDMPs exist, the absence of one national registry makes it difficult for providers to verify patient prescription histories, especially when patients receive care in multiple jurisdictions (CS11). A policy expert described this challenge:

> We have the Prescription Drug Monitoring Program that is state-based. That is a state-based tool…Some states share the information across state lines and some states do not…DEA absolutely needs to put in place some type of national prescription drug monitoring program to be able to track this. (CS9)

Several participants also called for a national system for prescription drug monitoring. Two healthcare providers suggested, "it would be helpful to have better, more systematic, and

transparent tracking of controlled substances through the prescription monitoring programs" (CS21), and "it would be really great if there were a national [prescription drug monitoring program" (CS13). Two telehealth company executives (CS18; CS20) and two professional society/association representatives also stressed that there needs to be a "national" PDMP (CS27; CS28).

Additionally, a few participants highlighted the need for a special registration pathway. A professional society/association representative "would like the DEA to pursue special registration process…[to] balance diversion with access" (CS2). A healthcare provider also wanted a "special registration process" (CS8).

Perspectives on Drug Scheduling as a Framework

Participants also offered perspectives on how drug schedules should be considered in the development of permanent telehealth regulations for controlled substances (RQ2). In response to a single open-ended question, the following themes emerged: (1) support for differentiated telehealth regulation by drug schedule, (2) concerns about the current scheduling system, (3) tension between policy and clinical practice, and (4) aligning telehealth and in-person prescribing regulations.

Theme 1: Support for Drug Schedule as Criterion for Telehealth Regulation

Participants from a diverse group of stakeholders—healthcare providers (n=3), representatives from professional societies/associations (n=3), policy experts (n=2), pharmacists (n=1), and telehealth company executives (n=1)—supported the notion that telehealth regulations for controlled substances should vary based on drug schedules (n=10). This perspective focused

on the inadequacy of a "one-size-fits-all" (CS13) regulatory approach, given the distinct characteristics of each drug schedule.

Several healthcare providers expressed objections to universal regulations. One healthcare provider remarked: "They're not all the same, so they shouldn't [be treated the same]—it's too simple and therefore wrong to give them all the same restrictions" (CS13). Similarly, another healthcare provider noted the importance of these regulatory classifications: "Controlled substances have different risks and benefits, and different issues with access" (CS19). This sentiment was echoed by a third healthcare provider who questioned the feasibility of uniform regulations: "I don't know that one set of rules is going to be appropriate for all five categories" (CS17). These comments reflect the perspective among several healthcare providers that telehealth rules should account for differences across drug schedules.

Similarly, a few professional society/association representatives also voiced concerns about universal regulations. One representative explained that there would be pitfalls: "Treating all controlled substances as if they are the same…would be hugely problematic" (CS28). Another professional society/association representative suggested tailored rules: "Schedule II versus Schedule III, maybe there's some heightened oversight or reporting responsibility" (CS31).

A few participants highlighted the logic of differentiating regulations based on schedules, which theoretically reflect the varying levels of risk and medical value. As one policy expert summarized:

> The point of the schedules is that as you go down from one to five in theory, the drugs in Schedule II are less risky and have greater potential therapeutic value than those in Schedule I…why would it not be logical to modify the restrictions commensurate with the changing risk picture? (CS23)

Thus, this viewpoint reflects a strong preference among these participants for telehealth regulations that mirror and align closely with drug schedules.

Theme 2: Concerns about the Current Scheduling System

A significant counternarrative that emerged among half of the participants (n=16) was skepticism about the current drug scheduling system. This perspective was shared by participants across stakeholder groups, including healthcare providers (n=6), telehealth company executives (n=4), representatives from professional societies/associations (n=3), policy experts (n=2), and an academic researcher (n=1). While participants were asked about the application of drug schedules to telehealth regulation, their responses frequently extended to broader critiques about the scheduling system in general (not necessarily its specific suitability for telehealth prescribing). Given the large presence of the perspective, this theme presents participant concerns about the validity of the current drug scheduling system, including perceived inconsistencies.

Several participants (n=7) expressed concerns centered on Schedule II and Schedule III substances, where participants from a range of perspectives (three telehealth company executives, one representative from a professional society/association, one policy expert, one healthcare provider, and one academic) felt that the distinctions seemed arbitrary. A professional society/association representative noted: “It’s quite arbitrary what ends up on Schedule II versus Schedule III. I’ve seen just as much harm come from Schedule III drugs as from Schedule II drugs” (CS27). Additionally, one policy expert speculated: “I’m willing to bet that one could fashion an argument…that drug X ought to be Schedule III and drug Y to be Scheduled II” (CS23). These perspectives indicate that current classifications may not reflect the risks of

substances, such that substances in lower schedules could pose equal or greater harm compared to those in higher schedules.

Additionally, a few participants extended this critique to highlight the risks posed by non-scheduled or over-the-counter medicines, arguing that despite their lack of classification, these drugs can still be "abused" (CS14; policy expert) or "misused" (CS13; healthcare provider). Another healthcare provider went further, suggesting that certain medications have been "mislabeled" as controlled substances; these misclassifications, they argued, have created barriers to access for those in need of these treatments (CS29).

Within individual schedules, several participants noted inconsistencies. This issue was particularly evident for Schedule II non-opioids—particularly stimulants. One healthcare provider remarked: "To treat [Adderall and oxycontin] similarly in the same class is doing a disservice to the actual clinical situation at hand" (CS21). Another healthcare provider felt that "there are fewer guardrails needed for stimulants than opioids" (CS17). Additionally, one healthcare provider suggested carving out exemptions for certain medications:

> If the concern of the DEA is fentanyl, oxycodone, and opioid overdose—not that there isn't diversion of ADHD medications—but if that's the main concern to be so restrictive, then why not just carve out those medications specifically? (CS8)

A smaller group of participants (n=5; one academic, one healthcare provider, one telehealth company executive, one policy expert, and one representative from a professional society/association) expressed concerns about the classification of Schedule I substances, particularly in relation to marijuana and psychedelics, albeit these issues were discussed less prominently. Although this discussion on Schedule I was not directly tied to telehealth

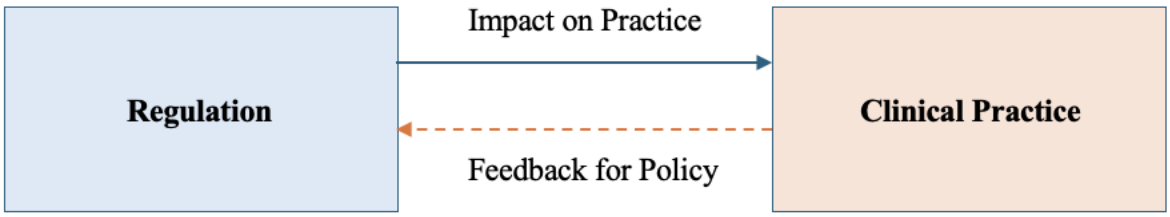
regulations, there was a call to revisit the scheduling of these drugs that aligns with contemporary scientific evidence and patient needs.

Some participants offered recommendations for improving the current scheduling system. Opinions varied on whether there should be more or fewer schedules, with some advocating for more classifications (CS29; healthcare provider) and others suggesting a more simplified approach—"scheduled or non-scheduled"—to streamline day-to-day practices (CS7; healthcare provider). However, calls for re-scheduling substances were tempered by an acknowledgment of the challenges involved in updating this system, such as the DEA not having "the bandwidth or human power to do that right now" (CS15; telehealth company executive). The slow pace and complexity of rescheduling drugs were highlighted—such as ongoing "national debates about marijuana" (a Schedule I drug)—serving as emblematic of the difficulties involved in changing the schedule of a drug (CS12; policy expert).

Theme 3: Tension Between Regulation and Clinical Practice

Eight participants (2 telehealth company executives, 2 hybrid healthcare organization executives, 2 health providers, and 2 professional society/association representatives) put forth a two-way relationship between regulatory policies and clinical practice (**Figure 4.2**) wherein regulations shape clinical practice, while clinical practice has the potential to provide real-world feedback that guide regulators in iterating policy.

Figure 4.2 Interplay between regulation and clinical practice.



These participants noted that regulations may not always align with the realities of clinical practice. One professional society/association representative explained the rigidity of policy:

> The problem with public policy is that we try to say it should be like this: "you should be seen in-person on this schedule at least once a year or before this can happen" …I think in medicine we try to have some cadence: "maybe once a year you have to do this." (CS28)

Similarly, a telehealth company executive raised a broader philosophical question about the role of clinical evidence versus regulation in guiding practice: "Should the scheduling drive the clinical practice, or should the evidence of patient benefit drive the scheduling? In either setting, there's some harm done and there's some benefit done" (CS20). A few healthcare providers cautioned against the creation of "blanket rules" that fail to account for the nuances of patient care (CS13), with one stating: "I make a decision on whether to prescribe that based on a patient's needs and symptoms, not based on what the DEA has decided to rule it as" (CS7). These perspectives reflect the tension between regulation and clinical judgment.

Several participants stressed that the patient-provider relationship should guide prescribing decisions. A professional society/association representative explained: "The clinician who knows the patient, has a relationship with the patient, is able to make that call" (CS31). Concerns were voiced that overly rigid regulations could undermine the clinician's ability to deliver personalized care. As another professional society/association representative noted, controlled substances are essential tools in the therapeutic arsenal:

> They [controlled substances] should all be tools in the toolbox for providers caring for patients. If a provider believes and deems it to be clinically necessary for the treatment of a patient…they should…not have it be second guessed…that would be unnecessarily

> undercutting the patient-provider relationship, unnecessarily plying the hands of the provider in the best interest of the patient, which we believe would not be clinically appropriate, and, it would be unfortunately erecting barriers. (CS2)

Theme 4: Aligning Telehealth and In-Person Prescribing Regulations

A small number of participants (n=4) discussed whether the prescribing of controlled substances via telehealth should follow the same requirements as in-person prescribing or if distinct telehealth regulations are warranted. Perspectives varied: both support for uniformity and an argument for more differentiated approaches by modality.

Two professional society/association representatives advocated for consistency in regulations across telehealth and in-person modalities. One noted: “I think the in-person and the virtual should probably have the same requirements. I don't think they should be regulated differently” (CS24), advocating for uniformity in regulations, regardless of the modality through which care is provided. One policy expert explained that issues of inappropriate prescribing predate telehealth prescribing: “Opportunities of abuse…[have] come way before telehealth” (CS9). This view suggests that prescribing concerns are not exclusive to the virtual model, further supporting the case for aligning regulations across settings.

In contrast, a pharmacist suggested that the standards for record-keeping and tracking should be more stringent than those currently applied to traditional, in-person models:

> If we are going to go to a strictly telehealth model or allow a strictly telehealth model, then I think you almost have to make the record keeping and the tracking far more strict than you would even with the traditional models. (CS6)

Discussion

The discussion is presented in two parts: the first part focuses on the policy considerations specific to DTC telehealth companies prescribing controlled substances, and the second part focuses on policy considerations related to drug scheduling in telehealth regulations for controlled substances.

Perspectives on DTC Telehealth Companies Prescribing Controlled Substances

The primary aim of this qualitative study was to examine diverse stakeholder perspectives on DTC telehealth companies' prescribing of controlled substances. On the one hand, stakeholders recognized the potential of DTC telehealth companies to improve access to care, particularly for those in rural areas. On the other hand, they also expressed concerns, such as the lack of patient-provider relationships and potential conflicts of interest within the DTC model. This accords with prior work, which also found these benefits and drawbacks of DTC healthcare more broadly.[12] However, the fact that some participants were concerned about the access conferred by DTC telehealth potentially compromising standards of care is a rather novel finding, particularly regarding controlled substances. This reveals a need to carefully consider the tradeoffs between quantity and quality of care, as well as to differentiate between controlled substances prescribed via DTC telehealth services and telehealth from traditional healthcare settings. To address these concerns, stakeholders offered a variety of suggestions for DTC telehealth companies, such as adopting hybrid models of care (to foster patient-provider relationships) and seeking third-party accreditation (to assuage conflict of interest concerns).

As policymakers contemplate permanent regulations for telehealth prescribing, the findings suggest that DTC telehealth companies prescribing controlled substances may require a separate mechanism of oversight. The DEA's drafted rules[145] have already raised worries among companies about the potential impact, ranging from closures to contriving a plan to see patients

in-person.[149] Though, given the inherent differences of this model, many stakeholders felt it should not fall under the same purview as rules that govern telehealth prescribing of controlled substances offered via traditional healthcare settings. At the policy level, the interviews suggest that policymakers should consider creating separate policies for the potential "bad actors" in the crowd, rather than considering these companies in rulemaking as previously done by the DEA.[142] At the same time, it would behoove DTC telehealth companies prescribing controlled substances to carefully consider stakeholder suggestions put forth here to maintain standards of care.

The points above support the development of proactive telehealth regulations. However, if inappropriate prescribing of controlled substances were to occur in DTC telehealth companies, that accountability is often reactively assigned. Stakeholder perspectives considerably varied on who should be held accountable, with some recommended holding providers accountable, citing the professional obligations that come with licensure; others believed that DTC telehealth companies should be held accountable given their role in creating prescribing incentives and environments that may prioritize profit over consumer safety. A third, more nuanced approach suggested a context-dependent model, wherein accountability lies on a spectrum where context moves the needle as to whom accountability should fall on. The recent criminal prosecution involving Done Global illustrates this context-dependent approach, where an investigation of the context led to the arrest of two executives for systemic inappropriate prescribing practices of controlled substances.[11] However, the findings also point the importance of carefully considering provider accountability, even in the face of systemic issues like pay-per-prescription incentives, and still maintain independent medical judgment.

This harkens back to the importance of establishing a patient-provider relationship as a foundation for clinical practice at DTC telehealth companies.

Importantly, whether it is proactive or retroactive, several participants recommended expanding regulatory oversight to include collaborative efforts across multiple agencies. Given the limitations of the DEA's authority, stakeholders highlighted a need for other agencies, such as SAMHSA and CMS, to fill gaps in oversight. Participants emphasized that while the DEA plays a crucial role, regulatory solutions will require collaboration across multiple agencies and careful consideration to avoid unintended consequences that could restrict legitimate care.

Future work should evaluate the prescribing practices at DTC telehealth companies and investigate consumer experiences of these services given that little is known about the actual benefits or harms experienced by these users beyond media investigations.[127,150] Additionally, as a few stakeholders noted, there is need for greater scrutiny of advertising practices by DTC telehealth companies, especially on social media, suggesting that while the U.S. permits DTC advertising of pharmaceuticals, the marketing strategies used by DTC telehealth companies warrant additional consideration—which notably aligns with a recent bipartisan bill addressing this recommendation.[151]

The development of permanent telehealth policies for controlled substances is, of course, complicated. However, the findings highlight that DTC telehealth companies are perceived by stakeholders to be different from traditional telehealth, and thus, may require different considerations. So it would perhaps be in the DEA's best interest to develop separate policies for each respective modality of telehealth (DTC and traditional). At present, drafted rules appear to exercise an overabundance of caution to the extent that compliant providers are being prevented from providing safe and necessary care to individuals. As such, the DEA needs its policies to reflect modern expectations—including the access of controlled substances through telehealth. In regard to potential bad actors, the DEA should explore alternative measures to discourage the

inappropriate prescribing of controlled substances, including but not limited to working more closely with other federal agencies and state medical licensing boards.

Perspectives on Drug Scheduling as a Framework

The secondary aim of this study was to explore how regulations regarding controlled substances for telehealth should be structured. Four major themes emerged from the analysis: support for using drug schedule as a criterion for telehealth regulation, concerns about the scheduling system itself, tension between regulation and clinical practice, and differing views on aligning telehealth and in-person prescribing regulations.

Many participants across stakeholder groups favored differentiating telehealth regulations based on drug schedules, citing the level of risk associated with each drug schedule. This is in accordance with the DEA's current approach, with its initial proposed rule allowing a 30-day supply of telehealth prescriptions for Schedule III-V non-narcotic substances, excluding Schedule II substances.

However, some participants raised significant concerns about the current drug scheduling system, focusing on arbitrary distinctions between schedules and inconsistencies within individual schedules. These critiques raise an important point: if the foundational classifications are flawed, then any policy built upon them may be inherently unstable. Given participant perspectives suggesting a need for a broader reassessment of the drug scheduling system itself as well as the ongoing debate about drug scheduling,[152,153] the findings draw attention to the importance of considering alternative foundations to base telehealth policy—rather than the DEA’s scheduling-based approach to policy development. For instance, the DEA's proposed rule

to allow prescribing buprenorphine, a Schedule III substance, via telehealth highlights the need for exceptions based on clinical utility.

The timing of this discussion is particularly salient, as it coincides with current policy discussions and petitions to reschedule marijuana and testosterone.[154,155] For instance, the DEA's support for HHS's recommendation to move marijuana to Schedule III is a notable development.[154] However, the present-day controversy surrounding this reclassification among various professional societies, for example, highlights the challenges with reaching a consensus on such changes[156]—a consideration also elucidated by several participants.

The tension between regulations and clinical practice identified underscores the importance of policy to be informed by clinical practice. Notably, this issue resonated across different stakeholder groups, with both healthcare providers and non-healthcare providers expressing a preference for prioritizing clinical judgment over rigid regulations. This suggests that a policy that relies heavily on categorical distinctions may inadvertently fail to capture the nuances of clinical practice. Indeed, greater involvement of clinicians in shaping regulations for controlled substances may help, as those directly involved in patient care are best equipped to understand the practical implications of such policies. For instance, the DEA's categorical exclusion of all Schedule II substances from telehealth prescribing may be a barrier to care and unnecessarily constrain clinical decision-making.

The DEA's commissioner comparison of ketamine abuse to the early stages of the opioid epidemic[157] suggests that lessons from past public health crises may inform current regulatory decisions and foster a more rigid, law enforcement-driven approach to regulation. However, singling out drugs like ketamine for stricter regulation could lead to barriers for patients who benefit from it, especially in telehealth contexts where in-person access is limited.

A few participants favored uniform regulations across both modalities (telehealth and in-person) to maintain consistency across settings, suggesting that policymakers should standardize regulations across settings. Thus, it may be prudent for the DEA to align telehealth and in-person regulations and to determine other ways to prevent drug diversion. Overly strict telehealth-specific regulations, like those seen in the leaked DEA rule from September 2024,[145] which proposed limiting online prescribing to 50%, could impose unnecessary barriers and limit the potential of telehealth to expand access to essential treatments.

Future research should examine the potential risks of diversion associated with increased telehealth prescribing flexibility as well as assess the positive impact to outcomes, such as improved access to care and treatment adherence.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, although a diverse range of perspectives were captured, the sampling strategy—particularly the use of snowball sampling—may have introduced bias, as it likely attracted individuals who are particularly invested in or familiar with the space. The use of snowball sampling, while helpful for identifying knowledgeable and hard-to-reach participants, may have limited the diversity of perspectives by concentrating the sample within certain professional networks. This could reduce the generalizability of the findings beyond those who are most engaged with these regulatory issues. Additionally, the exclusion of individuals who declined to participate initially may have introduced selection bias. Second, the absence of participants from DTC telehealth companies limits the inclusion of the industry's perspective. Future research should address this gap to gain a more comprehensive understanding of the role DTC telehealth companies play in this evolving regulatory landscape. Third, the interview questions were posed

in a broad sense to prescribing of controlled substances rather than to specific medications such as stimulants, ketamine, or testosterone. This is an important area for future research, as it could yield more granular insights into stakeholders' views on the permissibility of the DTC model by medication. Finally, the interviews primarily centered on the DEA's role in the telehealth flexibility, which may have narrowed the scope of the discussion. While the DEA plays a significant role in regulating controlled substances, the FDA also shares responsibility for scheduling (and rescheduling) these substances. Also, other entities, such as Congress, can initiate the rescheduling process, meaning the focus on the DEA may overlook broader regulatory dynamics.

Conclusion

As the temporary policy is nearing expiration, the DEA has a complicated task of developing a permanent policy that meets the needs of consumers while preventing drug diversion. It may be wise for the DEA to create separate policies that monitor the practices of potential bad actors rather than relying on broad telehealth policy to govern these entities. Additionally, stakeholder perspectives emphasize a desire for prescribing decisions to be guided by more clinical judgment—such that the DEA might wish to consider avoiding different regulations for Schedule II drugs.

Appendix 4.1 Semi-structured interview guide

Introductions

Thank you for talking the time to speak with me today. As I mentioned in my initial email and the informed consent document I sent you, the purpose of this interview is to understand your perspective on the prescribing of controlled substances from direct-to-consumer telehealth companies.

Your participation in this interview is voluntary, and the interview will be audio-recorded to aid data analysis. Do you voluntarily agree to participate in this study? (yes or no)

Background

1. To start, I'm wondering what benefits you see in telehealth prescribing of controlled substances?
    a. What are some specific scenarios or examples where telehealth prescribing has been particularly beneficial?

Current understanding of policy

1. What is your understanding of the DEA's temporary policy related to the prescribing of controlled substances via telehealth?
    a. Are there specific aspects to the proposed rules that you find most impactful or concerning?
2. What are your thoughts on the DEA extending the temporary policies until December 31, 2024?

Current understanding of DTC companies

So, as I mentioned, I am specifically curious about direct-to-consumer telehealth companies offering controlled substances online.

3. I'm wondering if you have heard about DTC companies selling these prescriptions online?

Risks and benefits

4. What are some benefits, if any, that you see with DTC telehealth companies offering this service?
5. Do you feel there are adequate safety measures and protocols in place currently to prevent misuse of controlled substance prescriptions from DTC/telehealth companies? Are there any specific safety measures or protocols you think are necessary or effective?
6. I'm curious to know how you view the risks and benefits of DTC companies offering these prescriptions versus traditional healthcare actors.

Recommendations for policy

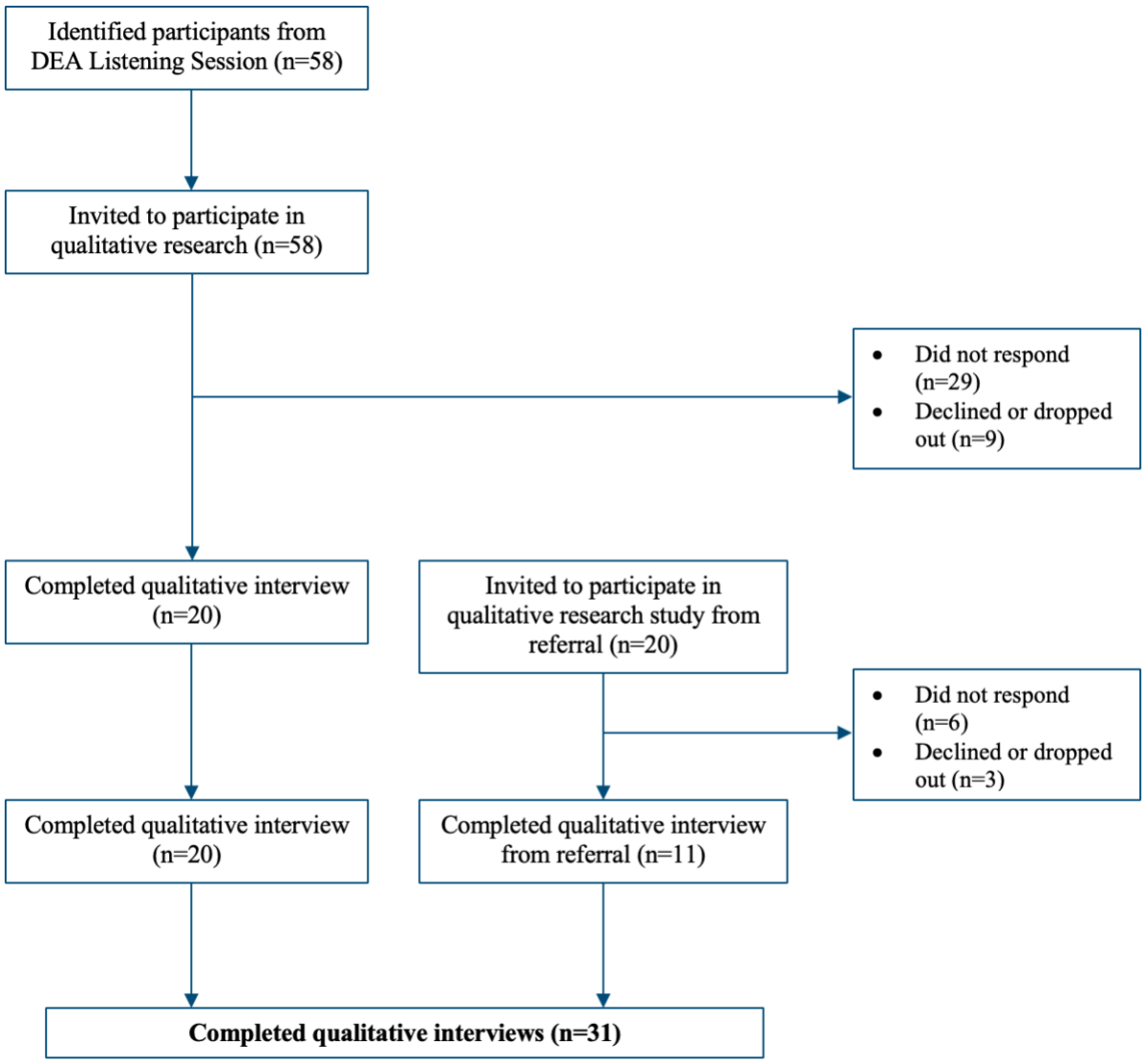
7. In the May 2023 extension, the DEA said it was only extending the flexibilities for 6 months to disincentivize the creation of telemedicine companies that may seek to engage in problematic prescribing practices. Do you think this was a good strategy?
    a. How do you think the extension through 2024 would impact DTC companies?
    b. How do you think the extension through 2024 would impact the customers of DTC companies?

8. How do you think telehealth prescribing of controlled substances <u>should</u> be regulated?
    a. Do you think there should be different telehealth regulations based on what schedule a drug falls into? (Note: Adderall is schedule II and ketamine is schedule III – should they have the same regulations?)
9. How do you think controlled substances <u>will</u> be regulated by the DEA?
10. Is there anything else you would like policymakers to consider regarding prescribing controlled substances through DTC telehealth companies?

Closing

11. Are there any other questions on this topic I didn't ask, but should have?
12. Are there other stakeholders whose insights would be important for this research? If so and you think they might be interested in sharing, could you please ask them to email me?

Appendix 4.2 Flowchart for recruitment



Chapter 5. Conclusion

The care delivery landscape in the U.S. is rapidly moving toward technology-enabled, consumer-centered care, and DTC healthcare is a piece of this transformation. The findings from this dissertation contribute to understanding three facets of DTC healthcare: (1) consumer preferences, (2) industry evolution, and (3) telehealth regulations—at the individual, organizational, and policy levels.

Consumer Preferences

Chapter 2 examined consumer willingness to share their health data with nine stakeholders (e.g., physicians, technology companies). Using data from four years of Rock Health's Digital Health Consumer Adoption Survey (2018, 2019, 2020, 2022), I conducted a latent class analysis to identify groups of respondents with similar health data-sharing attitudes. Three groups emerged: Wary (36.8%), Discerning (47.9%), and Permissive (15.3%), indicating heterogeneity in health-data sharing attitudes among U.S. consumers. Findings highlight a persistent trust in traditional healthcare providers. However, the varying willingness to share with non-traditional stakeholders suggests that while some consumers are open to sharing, others remain hesitant and selective. Data privacy policies and practices need to recognize and respond to multifaceted and stakeholder-specific attitudes.

Industry Emergence and Evolution

In Chapter 3, I applied organizational ecology to examine the U.S. DTC digital health landscape. Using time-to-event analysis and the Rock Health Venture Funding Database, I identified factors linked to successful exits (e.g., IPOs, mergers). Telemedicine emerged as a predictor of success, and companies at later funding stages (Series B and beyond) had higher odds of achieving these milestones. However, disparities in funding for companies targeting

underserved communities raise questions about equity in this sector. Findings suggest that entrepreneurs and investors may wish to support companies that target underserved populations to ensure that innovations solve equity. It is important for future research to evaluate the effectiveness of DTC digital health offerings to determine if they lower costs, improve outcomes, and maintain high-quality care, essentially evidence-based evaluations of these solutions.

Telehealth Regulation

In Chapter 4, I conducted semi-structured interviews with a breadth of stakeholders—including healthcare providers, policy experts, and healthcare executives—to explore perspectives on how policymakers should formulate future telehealth regulations, particularly with DTC telehealth companies in mind. Stakeholders advocated for balanced policies that maintain access while mitigating risks, such as drug diversion. Findings highlight that DTC telehealth companies are perceived by stakeholders to be different from traditional telehealth, and thus, may require different considerations. Participants also called for a broader reassessment of the drug scheduling system and stressed the importance of clinical judgment in telehealth to avoid undermining the patient-provider relationship.

Multilevel Analysis

As aforementioned in the Introduction, while each study of this dissertation centered on a specific analytical level, the implications of each study extend to the other levels.

Individual, Micro-Level

At the individual (micro) level, I examined the consumer attitudes toward health data-sharing with various stakeholders in Chapter 2, and the diversity of DTC digital health companies available to U.S. consumers in Chapter 3. I found that certain consumer segments,

such as women, have more targeted solutions, whereas others, like low-income or rural populations, have fewer options catering to their needs. This suggests that there is an opportunity for innovation at the macro-level to better serve these underserved consumer segments. Future work should evaluate whether DTC digital health companies generate value (e.g., improving healthcare outcomes) for individuals, and continue to investigate which consumers opt for these products and services. In Chapter 4, I examined a telehealth flexibility that allowed consumers to access certain controlled substances via telehealth without requiring an initial in-person visit. Moving forward, depending on what permanent policies are put in place, consumers may or may not have abridged access to controlled substances. A key finding from the interviews in this chapters is that DTC telehealth companies improve access for consumers, especially those living in rural areas or facing other barriers to in-person care. Together, these studies provide insights into consumer preferences, the types of DTC options they might seek, and the policy factors shaping their access to DTC products and services.

Market Environment, Macro-Level

At the macro-level, Chapter 2's LCA results revealed a varying willingness to share with non-traditional stakeholders. This suggests that entities that have yet to garner consumer trust may need to prioritize communication of their data privacy protection measures to alleviate concerns. While the study did not directly examine the reasons behind willingness to share health data, it may be valuable for newer entrants in healthcare to focus on developing robust privacy protections. In Chapter 3, I examined the landscape of U.S. DTC digital health companies. One significant finding of this study was that telemedicine and reaching Series B+ funding improved the time to reach a success milestone. Chapter 4 illustrates how policy can impact the viability of DTC healthcare companies, as a telehealth flexibility allowed them to enter a space that was

tightly regulated. If permanent regulations were to restrict telehealth prescribing of controlled substances to require an initial in-person visit, then many of these DTC telehealth companies may need to shutter operations or pivot to other offerings. These studies, in conjunction, highlight organizational changes that can foster consumer trust, the characteristics that drive success for DTC digital health companies, and the role of policy on company operations.

Policy, Macro-Level

Chapter 2's findings highlight a need to revisit data privacy policies, particularly to enhance protections for health data shared to non-traditional healthcare stakeholders. The examination of the DTC digital health landscape in Chapter 3 underscores the importance of ongoing regulatory oversight to monitor this burgeoning industry. While some DTC telehealth companies have faced federal legal action, this chapter provides insight into the range of products and services offered and the consumer segments they aim to serve. At the policy level, it sheds light on a burgeoning industry that typically falls through the cracks when it comes to proactive monitoring; though there are instances of post-reprimanding. In Chapter 4, I analyzed the in-flux telehealth policy landscape. Collectively, these studies indicate a need for policies that better protect consumer data, ongoing regulatory monitoring of DTC digital health companies, and an awareness of how policy shapes the presence of DTC healthcare.

Future Research

Looking ahead, I envisage several avenues for future work. More research is needed to examine novel and innovative models that are reshaping the provision of healthcare services. The convergence of technology and healthcare is disrupting traditional healthcare delivery, making it crucial to understand these changes as they emerge. For example, pharmaceutical companies are

increasingly adopting DTC approaches, which represents a significant transformation in the delivery of medications, potentially increasing access but also raising new regulatory and ethical questions. Questions arise regarding cost, marketing practices, conflicts of interest, and anticompetitive practices. For instance, a content analysis of the websites of DTC telehealth companies and DTC pharmaceutical platforms could compare the presentation of medication information, privacy policies, and the framing of benefits, offering insights into differences in marketing strategies. Additionally, a secret shopper study could compare the provision models between pharmaceutical companies using DTC approaches and DTC telehealth companies offering prescription services via compounding pharmacies, evaluating factors such as the length of questionnaires/consultations, depth of consumer screening, level of healthcare provider involvement, and overall cost to the consumer. Given that it is currently emerging and unfolding, it is relatively unexplored.

Evaluating the DTC offerings of technology companies would be another fruitful area for further work. Big Tech companies have entered healthcare, including ventures like Apple's integration of FDA-authorized health functionalities into consumer devices. For example, one study could evaluate the adequacy of current data privacy laws to protect the sensitive health data generated by these devices, identifying whether additional protections are needed to safeguard data. Another study could analyze the regulations that govern these devices to examine their effectiveness in addressing devices with consumer and clinical applications. By investigating what is being offered, by whom, and under what regulatory frameworks, future work can inform policies that support innovation while ensuring patient safety and maintaining ethical standards.

Considerably more work will need to be done to contribute to the development of ethical guidelines and policies that protect consumer interests, promote transparency, and encourage responsible innovation in the DTC healthcare industry. For example, research could comprehensively analyze the legal and regulatory frameworks governing DTC healthcare, focusing on the roles of the FDA and FTC, as well as examine enforcement actions and regulatory responses to innovation. This is particularly crucial as medications, such as for psychiatric conditions and weight loss, are increasingly promoted through DTC telehealth companies. On the consumer-end, more mixed-methods research is needed to better understand consumer preferences for tech-enabled alternatives. Such studies could explore factors influencing consumer adoption, such as affordability and trust. Additionally, future studies should investigate how DTC products and services are marketed and whether consumers fully understand what is being sold to them—including data collection practices.

Conclusion

In sum, as healthcare becomes more digital and consumer-oriented, it will be important to ensure these innovations are both ethically sound and beneficial to society. This dissertation has laid the groundwork for an ongoing research agenda designed to guide policy recommendations that help regulate and monitor a burgeoning digital health industry with significant implications for consumer health.

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