COALITION FOR INNOVATION

HealthTech Blueprint for the Future

Coalition for Innovation, supported by LG NOVA

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The views and opinions expressed in the chapters and case studies that follow are those of the authors and do not necessarily reflect the views or positions of any entities they represent.

Senior Editor, Alfred Poor

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Preamble

The Coalition for Innovation is an initiative hosted by LG NOVA that creates the opportunity for innovators, entrepreneurs, and business leaders across sectors to come together to collaborate on important topics in technology to drive impact. The end goal: together we can leverage our collective knowledge to advance important work that drives positive impact in our communities and the world. The simple vision is that we can be stronger together and increase our individual and collective impact on the world through collaboration.

This "Blueprint for the Future" document (henceforth: "Blueprint") defines a vision for the future through which technology innovation can improve the lives of people, their communities, and the planet. The goal is to lay out a vision and potentially provide the framework to start taking action in the areas of interest for the members of the Coalition. The chapters in this Blueprint are intended to be a "Big Tent" in which many diverse perspectives and interests and different approaches to impact can come together. Hence, the structure of the Blueprint is intended to be as inclusive as possible in which different chapters of the Blueprint focus on different topic areas, written by different authors with individual perspectives that may be less widely supported by the group.

Participation in the Coalition at large and authorship of the overall Blueprint document does not imply endorsement of the ideas of any specific chapter but rather acknowledges a contribution to the discussion and general engagement in the Coalition process that led to the publication of this Blueprint.

All contributors will be listed as "Authors" of the Blueprint in alphabetical order. The Co-Chairs for each Coalition will be listed as "Editors" also in alphabetical order. Authorship will include each individual author's name along with optional title and optional organization at the author's discretion.

Each chapter will list only the subset of participants that meaningfully contributed to that chapter. Authorship for chapters will be in rank order based on contribution: the first author(s) will have contributed the most, second author(s) second most, and so on. Equal contributions at each level will be listed as "Co-Authors"; if two or more authors contributed the most and contributed equally, they will be noted with an asterisk as "Co-First Authors". If two authors contributed second-most and equally, they will be listed as "Co-Second Authors" and so on.

The Blueprint document itself, as the work of the group, is licensed under the Creative Commons Attribution 4.0 (aka "BY") International License: https://creativecommons.org/licenses/by/4.0/. Because of our commitment to openness, you are free to share and adapt the Blueprint with attribution (as more fully described in the CC BY 4.0 license).

The Coalition is intended to be a community-driven activity and where possible governance will be by majority vote of each domain group. Specifically, each Coalition will decide which topics are included as chapters by majority vote of the group. The approach is intended to be inclusive so we will ask that topics be included unless they are considered by the majority to be significantly out of scope.

We intend for the document to reach a broad, international audience, including:

- People involved in the three technology domains: CleanTech, AI, and HealthTech
- Researchers from academic and private institutions
- Investors
- Students
- Policy creators at the corporate level and all levels of government

Table of Contents

Chapter 1: Introduction

Author: Alfred Poor

"The only constant in life is change." *Heraclitus*

Change may be a fact of life, but the challenge is to create change that is a net positive for individuals and their communities. Thus, we focus on "innovation": the introduction of new ideas, methods, products, or services that result in improvement.

The story of health technology has been one of constant change and continuing innovation. But how can we encourage and guide that change? That was the charge when a group of volunteers answered the call to join the "Coalition for Innovation".

And those who chose to support the HealthTech group's efforts represent a broad and diverse set of backgrounds and expertise. After more than a year of discussions, brainstorming, organizing, and a whole lot of writing, we produced the document that you have in front of you now. The "HealthTech Blueprint" pulls together many different views about where we stand in the flow of change, where we would like to see it go, and how we think we might be able to encourage those new directions.

The Fundamentals

We distilled this challenge into a sequence of three factors:

Benefits: What are the potential benefits of various forms of innovation in healthtech? What problems do they solve?

Obstacles: What stands in the way of this progress? How can we identify the circumstances that can inhibit or even prevent innovation in healthtech?

Solutions: Once the obstacles have been identified, what strategies can be applied to get around them? What resources do we need to be successful in promoting change?

Blueprint Organization

One of our biggest challenges was to find a way to blend the rich collection of points of view and experience that each individual brought to the group's efforts. We have brought together the various contributions in a way that should make it easier for you to find the content that is of the most relevance to your interests.

This probably is not a document that you'll read straight through from start to finish. You can jump around between – and within – the chapters as you like. There are no spoilers revealed at the end (though I will tell you now that the butler did it).

Chapter 2: Challenges in Bringing Innovations to Market

Change might be inevitable, but it's difficult to bend it to your will. This chapter explores many of the challenges and strategies for creating successful innovation in healthtech.

As you might expect, artificial intelligence plays a significant role in much of this content, but you'll also find information and insights from a range of projects, including an innovative approach to fighting insect-borne tropical diseases.

Chapter 3: The Funding Landscape for HealthTech Startups

Innovation does not happen without resources, and one of the most critical resources is financial support. This chapter includes contributions by those who have been there and done that. It explores the many avenues to success – and failure – that follow different paths to financial stability.

This chapter covers the issues from "birth to earth", exploring different funding strategies for startups, and moving right through to potential exit strategies.

Chapter 4: Regulatory Challenges and Opportunities

Perhaps one of the greatest obstacles to innovation in healthtech – at least as perceived by some – is government regulation. These requirements can certainly inhibit change due to the time and money required to comply with many of them. But these same programs provide some assurance about the safety of healthtech products that will be used by healthcare professionals to treat patients.

In this chapter, you'll find interviews with experts who have had varying experience with a range of products and services, both with the FDA in the U.S. and with healthtech products on a global scaled. You'll also find insights into new ways of thinking about regulations and the information on which they should be based.

Chapter 5: AI and Regulatory Framework – Keeping Pace with Innovation

Throughout this entire Blueprint, you will find information about AI's role in healthtech, but this chapter dives deeper into many aspects of the subject.

AI is already having a significant impact on many aspects of healthcare, and its role will only increase rapidly. This raises important questions about the ethical use of AI, the safeguards that should be in place, and what does "responsible use" of AI in healthtech mean?

Our Authors

Many talented and experienced people contributed to the creation of this Blueprint. Some wrote or collaborated on the content of the chapters. Others made other contributions to the process. You can find them all listed at the end of the Blueprint, including contact information and a brief description of their backgrounds. We hope that this gives you a better understanding of the context that each one brings to this project.

Only the Start

This Blueprint is intended to be a living document that will continue to grow and evolve in time. As I write this, it's not entirely clear just how this will happen or what the next steps will be. But if you find this content to be valuable and would like to play a part in its continuing development, I hope that you will reach out and find a way to contribute to the process.

Author (In order of contribution)

Alfred Poor, **PhD, Keynote Speaker, The HealthTech Futurist**
Alfred Poor, the HealthTech Futurist, is a dynamic speaker and author with an international reputation in technology fields. He was the Editor of "HealthTech Insider," a website that covered wearable and mobile devices for health and medical applications. A graduate of Harvard College, he is the author or co-author of 15 books and is widely quoted in major media outlets. He brings energy and humor to his presentations and tailors his programs to match the technical levels and interests of his audience.

Part I
Challenges in Bringing Innovations to Market

Chapter 2:
The Innovation Gap: From Concept to Market

Author: John Hsu, MD

The "innovation gap" refers to the challenges and barriers that prevent a concept from reaching the market as a viable product or service. Bridging this gap involves navigating multiple stages—ideation, development, testing, and commercialization—while overcoming obstacles such as funding, technical feasibility, manufacturability, market fit, customer demand, and scalability. As an example, it currently takes 10-15 years of research and development and billions of dollars to bring a new medication to market. Commercial success is also not guaranteed; FDA regulatory compliance, the complicated world of drug reimbursement by insurance companies, adoption by the medical community, and patients' willingness to take the drug can sink a new product.

From my vantage point as a founder of two pharma companies and one medical device company, here are the key factors that contribute to the innovation gap, as well as some strategies that address those factors.

Challenges / Gaps & Potential Risks

Several challenges contribute to bringing an innovation to market. It is a road well-traveled by many successful entrepreneurs but there are many exits along the way before reaching the final desired destination.

1. The first exit is very obvious. It is the lack of funding and other resources. Innovators with early-stage ideas often lack sufficient capital for research, prototyping, or market entry so the idea remains stuck in the idea stage. To emerge, the innovator may try to secure a funding investment but that can be difficult without a proven track record or tangible product. Family and friends may assist but that source of funding often is not enough to support a real effort. Sometimes innovators will pool resources to attract and pitch to venture capital firms. These founders often struggle, however, because they often do not have a product or their idea is too niche or unproven. Investors prioritize quick, safe returns over long duration investments that present multiple risks for failure. Often 70% of digital transformation initiatives fail due to inadequate funding or resource allocation. https://businessmap.io/blog/why-digital-transformation-fails
2. Second, if they get past the funding and resources stage, founders must face technical and development challenges. Turning an idea into a functional product requires overcoming technical limitations, such as engineering complexities and lack of expertise. A novel medical device may face years of delays due to FDA regulatory requirements or difficulties in achieving consistent performance during testing. Continued iterations and constant prototyping quickly consumes scarce funding and resources and often leads to failure.
3. The third is lack of monetization strategy or reimbursement scheme. The best idea can be turned into a product but if it does not make money, it will fail. For example, Pear Therapeutics raised millions of venture funding and reached a billion

dollars in valuation but could not get insurance companies to pay for the services it offered. It could not service its financial obligations and declared bankruptcy. https://www.forbes.com/sites/katiejennings/2023/04/07/pear-therapeutics-files-for-bankruptcy-as-ceo-blames-shortfalls-on-insurers/

4. The fourth challenge is missing a market fit and gaining customer adoption. Even if a company produces a technically sound product, commercial success is far from assured. If the product doesn't meet customer needs or if the market isn't ready, the product will not have customer channels and fail. Many entrepreneurs build a product but misjudge demand or fail to communicate value propositions. 60% of new products fail to gain traction due to poor market fit. https://eximiusvc.com/blogs/why-startups-fail-top-10-reasons-failure-rate/#:~:text=The%20leading%20cause%20of%20startup,the%20market%20actually%20needs%20it
5. The fifth is underestimating the regulatory and compliance barriers to market entry. Many industries including healthcare, finance, and energy face stringent regulations that can delay market entry for years or even derail a product completely. Biotech innovations often require years of clinical trials and FDA approval, increasing costs and time-to-market.
6. The sixth is lack of scalability and ability for commercialization. Most startup founders do not have experience with supply and logistics. They have no experience in moving their product from a prototype to mass production. Widespread adoption requires a robust supply chain, distribution networks, and operational capacity, all of which must be created, nurtured, and financed. When promises are made but products are not delivered, orders stop, and the company goes out of business soon after. 45% of startups fail to scale due to operational inefficiencies.
7. The seventh is failure to perceive market change and corporatization. Startup entrepreneurs often have a vision that turns into a dream to disrupt the status quo. They see a new, better, and more efficient method to do something that has been done the same way for years. When the business grows, their continued focus

Example

The opioid epidemic costs the U.S. 100,000 lives and $2.7 trillion in added healthcare costs every year. The founders of a new company identified a specific need by a certain population of patients and created a medical device to address that need. It was designed to improve remote monitoring of patient adherence to medication treatment.

Cognizant of the difficulties in dealing with insurance reimbursement, the founders monetized their product by avoiding reliance on insurance reimbursement. Instead, they went to multiple customer channels that could reimburse for the device from opioid litigation settlement funds, revenue share programs with customers, and the government. In assessing market trends and customer needs, the company founders were able to identify multiple other customer channels providing multiple revenue streams.

A prototype medical device was produced and tested in the market and iterations were based on consumer feedback. Engaging an FDA consultant early allowed for quick FDA registration. The founders prepared to scale to meet the high potential demand for the device by partnering early with an industry leader in supply chain and logistics. The company is now well on its way to market launch with a potential of commercial success.

on innovation often leads them to engage corporate executives to operate the business who have preconceived ideas of how a business should operate based on their own previous experiences. Executives are risk-averse while entrepreneurs embrace risk. Within companies, resistance to change or risk-averse cultures can stifle innovation. Bureaucracy and siloed teams further widen the gap. Kodak failed to capitalize on digital photography due to internal resistance to disrupting their film business that was safe and financially sound, which ultimately led to the company's demise.

https://www.forbes.com/sites/chunkamui/2012/01/18/how-kodak-failed/

Mitigations

To make the road smoother, strategies can bridge the Innovation Gap. Early-stage companies can secure funding from alternative sources. They can leverage angel investors, crowdfunding, or government grants for initial capital by developing a compelling pitch with clear milestones that can attract capital.

To save money and build a better product, innovators should be agile in the development and prototyping of their products to test and refine concepts, reducing technical risks. To test market fit, they can use minimum viable products (MVPs) as a tool to gather valuable real-world feedback and customer validation. Robust market research tools include surveys, focus groups, beta testing, and analysis of competing products and market trends. In today's AI driven craze, AI-driven tools can quickly narrow the innovation gap by accelerating prototyping and aid with market analysis. AI tools can also mitigate the monetization risks by providing analysis of outcomes data, demonstrating high customer demand, and demonstrating positive healthcare economics which often leads to insurance reimbursement. To reduce the regulatory risk, it is best to proactively engage early with regulators and partner with legal or compliance experts to streamline the approval process. To reduce commercialization growing pains, establishing reliable supply chains and manufacturing partnerships early can often avoid complications later.

Next Steps

The innovation gap is a multifaceted challenge requiring strategic planning, resource allocation, and adaptability. By securing funding, iterating rapidly, validating market fit, navigating regulations, scaling efficiently, and fostering a supportive culture, innovators can increase their chances of success. Founders can also use tools such as AI-generated real-time market insights to bridge the gap.

The obstacles to launching and sustaining a successful healthtech product or service are real and significant, but with preparation and planning, founders can greatly increase their chances.

Author (In order of contribution)

John Hsu MD, Founder, CEO of iPill inc, CEO Quivivepharma
Dr. John Hsu practiced 32 years in anesthesia, chronic pain, and addiction medicine. He holds 8 granted patents in medical devices and drug development and was awarded a $1.9 NIDA/NIH grant. Dr. Hsu founded: iPill inc. a biometric secure pill dispenser to improve remote medication adherence; Quivivepharma a drug development company for an opioid-respiratory stimulant combination pill to make opioids safe and abuse deterrent; Fentavive a drug development company for a Narcan-respiratory stimulant combination injectable to address Narcan dosing ambiguity and is in the early stages of working with the DOD/DARPA; NAOMI systems, a practice management software company.

Chapter 3: The Impact of Artificial Intelligence on Healthcare

Author: Victor L. Brown

This section covers the impact of artificial intelligence (AI) on healthcare. The reader gains an understanding of what artificial intelligence is and how healthcare workers are using AI to enhance various applications. It will also discuss the outlook for how the evolution of AI and the adoption of healthcare will change the future by providing the author's opinion on what the trends and proverbial tea leaves are saying.

Overview of Artificial Intelligence

A foundational understanding AI will help you understand the key take-aways and themes of this chapter. For our purposes here, we define" artificial intelligence" as a computer algorithm that simulates the human ability to make decisions based on a collection of information.

For example, most people choose what to wear for the day based in part on a decision about how to dress for a warm day, moderate day, or cold day. A computer program could use artificial intelligence to make a decision on how to dress that day based on a number of factors with a goal of being comfortable. These systems take into consideration a large data set and draw their own conclusions. This contrasts with traditional computer programming that follows a defined decision tree based on if-then logic.

While choosing clothes represents a simple example, developers have created artificial intelligence capable of complex tasks using a variety of strategies and tools. Without diving deeply into the details of the different types of artificial intelligence, here is a brief summary of various types of AI characterized in different ways.

AI Categorized Based on Capabilities:

- **Narrow AI (Weak AI)**: Designed for specific tasks (e.g., virtual assistants such as Siri, chatbots, and recommendation algorithms)
- **General AI (Strong AI):** Hypothetical AI with human-like intelligence capable of reasoning and problem-solving across various domains
- **Super AI:** A theoretical AI that surpasses human intelligence in all aspects, including creativity, problem-solving, and decision-making

AI Categorized Based on Functionalities:

- **Reactive Machines:** Basic AI systems that respond to inputs but lack memory (e.g., IBM's Deep Blue chess-playing computer)
- **Limited Memory AI:** Can learn from past experiences to some extent (e.g., self-driving cars, fraud detection systems)
- **Theory of Mind AI:** Future AI with an understanding of emotions, beliefs, and human intentions
- **Self-Aware AI:** Hypothetical AI that possesses consciousness and self-awareness

AI Categorized Based on Learning Techniques:

- **Machine Learning (ML):** AI that learns from data to improve performance (e.g., predictive analytics, spam filtering)
    - **Supervised Learning:** Trained with labeled data (e.g., image recognition)
    - **Unsupervised Learning:** Finds patterns in unlabeled data (e.g., customer segmentation)
    - **Reinforcement Learning:** Learns by trial and error through rewards (e.g., game-playing AI)
- **Deep Learning:** A subset of ML using neural networks to process complex patterns (e.g., facial recognition, language translation)
- **Natural Language Processing (NLP):** AI focused on understanding and generating human language (e.g., ChatGPT, Google Translate)
- **Computer Vision:** AI that interprets visual data (e.g., medical imaging, facial recognition)
- **Expert Systems:** AI that mimics human expertise in a field (e.g., medical diagnosis, legal advisory AI)
- **Robotics AI:** AI combined with mechanical systems to perform physical tasks (e.g., autonomous drones, robotic arms in factories)

Characterization of Healthcare Industry

Research shows that the healthcare market is expected to grow to $25 trillion by 2040. This growth will be fueled by innovation just as the market has grown over the last 100 years due to innovation.

This amount of capital reflects transactions that impact most everyone on the planet. In the same sense, the oncoming adoption of AI within healthcare will have implications that will affect everyone. The million-dollar question is how exactly will AI have an impact. In an effort to answer this question, let's first look at how healthcare has historically handled adopting innovation and how that innovation has led to market growth to establish a baseline for predicting how AI will impact healthcare.

Historical Evolutions Within Healthcare

Over the course of the last hundred years, there have been many innovations in healthcare where those innovations have ultimately added value to the level of care individuals receive in healthcare and also added revenue to the overall healthcare market. Looking at these innovations, you could break down in ranges of years and for a good perspective of the changes within healthcare.

1920s–1940s: Foundational Advances - Market grew from approximately $20B to approximately $50B for 150% increase in size

Innovations in the 1920s through the 1940s included insulin, Penicillin, transfusions, vaccines, and the electrocardiogram. These innovations helped to fuel incredible growth over that time frame and further the advancement of overall health across the globe.

- **Insulin (1921):** First used to treat diabetes, saving countless lives
- **Penicillin (1928, mass use by 1940s):** The first true antibiotic, dramatically reducing deaths from bacterial infections
- **Blood transfusion & blood banks (1930s):** Enabled safe storage and widespread use during WWII
- **Vaccines:** Widespread immunization against diseases like diphtheria and tuberculosis
- **Electrocardiogram (ECG):** Became a standard diagnostic tool for heart conditions

1950s–1960s: Breakthroughs in Medicine and Technology - Market grew from approximately $150B to approximately $300B for 100% increase in size

The next phase of innovations included another critical vaccine – the Polio vaccine – along with the pacemaker, birth control, transplants, and medical imaging. Again, as one might expect, these innovations worked to help increase life expectancy and improve quality of life.

- **Polio vaccine (1955):** Mass immunization helped nearly eradicate the disease.
- **Cardiac pacemakers (1958):** Implanted to regulate abnormal heart rhythms
- **Birth control pill (1960):** Revolutionized reproductive health and women's autonomy
- **Organ transplantation:** First successful kidney (1954), liver (1963), and heart (1967) transplants
- **Medical imaging:** The development of ultrasound and improvements in X-rays transformed diagnostics.

1970s–1980s: Rise of High-Tech Healthcare - Market grew from $350B to $900B for a 157% increase in size

Over the next two decades, the rise of technology dominated healthcare evolution along with the HIV/AIDS growth which spurred a lot of research in an effort to combat the spread and treat the condition. Similar to past phases in the industry, humanity benefited worldwide.

- **Computed Tomography (CT scans, 1970s:** – Enabled cross-sectional imaging of the body
- **Magnetic Resonance Imaging (MRI, 1980s):** Non-invasive, detailed imaging of organs and tissues
- **Laparoscopic surgery:** Minimally invasive procedures reduced recovery time and risk
- **In vitro fertilization (IVF, 1978):** New paths to parenthood for infertile couples
- **HIV/AIDS identification and research (1980s):** Sparked global awareness and major research efforts

1990s–2000s: Digital and Genomic Era - Market grew from $1.8T to $4T for a 122% increase in size

In the 1990s through the 2000s, the promising innovation of mapping the human genome would lead to many health innovations. The innovation was accompanied by the evolution of technology and the start of digital health with early forms of telemedicine.

- **Human Genome Project (completed in 2003)** – Mapped human DNA, unlocking personalized medicine
- **Electronic Health Records (EHRs)** – Standardized digital documentation and data sharing
- **Telemedicine beginnings:** Early adoption in rural and military settings
- **Robotic surgery (e.g., da Vinci system):** Enhanced precision and patient outcomes
- **Targeted cancer therapies:** Designed to act on specific molecular targets in tumors

2010s–2020s: AI, Wearables, and Precision Health - Market grew from $7T to $10T for a 42% increase in size

Innovations across the next decades really started to lay the groundwork for incredible things yet to come due to the growth of data about health. Electronic records, connected devices, and wearables made it easier to collect and share with researchers and practitioners. New tools – including AI – improved the interpretation and understanding of this data. This period also saw growing acceptance that AI would be a dominating advancement in the future. All other innovations in some way could be improved using AI as a core part of the development and understanding of that new technology. Examples of some of these innovations include:

- **Wearable healthtech (Fitbit, Apple Watch):** Real-time monitoring of heart rate, sleep, ECG, etc.
- **Artificial Intelligence (AI):** Used in diagnostics (e.g., radiology, pathology), drug discovery, and patient triage
- **CRISPR gene editing (2012):** Pioneered gene therapy potential for diseases like sickle cell and cancer
- **mRNA vaccines (COVID-19, 2020):** A new vaccine platform rapidly deployed at scale
- **Telehealth boom (especially post-2020):** Video consultations and remote care became mainstream during the pandemic.

Research supports a continuing trend with great market growth; a big part of this growth will be driven by AI and AI-empowered solutions. There are a number of really cool innovations that are under the umbrellas of AI or AI-empowered. Digital twins, diagnostics, predictive analytics, personalized medicine, and regenerative medicine will all be a big part of what drives health innovation across the next couple of decades. However, AI will also be a very disruptive factor based on how it might be used and the impact that it will have in the industry. Here are just a few examples where AI will likely disrupt the industry as it operates today.

- **Digital twins:** Creating virtual models of patients for treatment simulations
- **AI-driven diagnostics:** Systems like IBM Watson and other AI tools for detecting diseases faster and more accurately than human doctors
- **Predictive health analytics:** Leveraging big data to forecast illness and optimize prevention
- **Personalized medicine:** Treatments tailored to individual genetics and lifestyle
- **Regenerative medicine:** Stem cells and 3D-printed organs hold promise for organ repair and replacement.

Historical Impact of Healthcare Innovation

When looking at the growth in market size and the innovation across the last 100 years, we can see that the life expectancy has risen, infant mortality rate has dropped, and overall management and control of illness have been enhanced. Those improvements have helped to advance our society and improve the quality of life for people in general. To a large extent, these innovations and the related growth has not been particularly disruptive for healthcare in general. At a high level, this improvement trend will continue powered by the advancement in AI and increased adoption of AI across a multitude of healthcare applications. This will likely lead to major disruptions in healthcare unlike what the industry has experienced over the last 100 years.

As a technology, AI is quite different from the other innovations that have been adopted within healthcare. Not since the dot com / Internet boom has industry been so impacted; AI is poised to be even more transformational and disruptive.

Outlook for AI's Impact on Healthcare

AI has combined with quantum computing to make the concept of a digital twin possible and signifies a leap forward in terms of the applications and impact within healthcare.

Imagine having a digital representation of yourself down to the exact genome, where you could then take a digital representation of a treatment and using AI and quantum computing simulate the outcome of that treatment. This could completely

revolutionize treatments in general and certainly be disruptive to the pharmaceutical industry. On one hand, effective treatments could be found faster, but on the other hand, perhaps natural cures might also be found faster which could make certain prescribed medications obsolete. Perhaps, it could even lead to a new revolution in performance enhancing designer drugs. The sky is the limit for this type of computing power leveraging AI.

CASE STUDY:

At Xcellent Life, we started working on Real-time Human Diagnostics (RtHD) which is the ability to describe human vitality in real time in a very accurate way. Because more data is becoming available, it is now much easier to evaluate vitality in a more holistic way. With AI, we can consistently examine a comprehensive data set using sophisticated predictive models. This will eventually give us the ability to identify the signatures of health risks long before those signatures result in symptoms or observable conditions.

At Xcellent Life we describe Real-time Human Diagnostics (RtHD) as being like an Onstar system for the human body. This innovation could take the industry from a reactive approach to a much more proactive approach which would also change revenue models.

It is not hard to imagine that with the pervasive access to data, sufficient computing power, and the ability to interpret that data, we will see personalized treatments start to play a more dominant role in treatment. In turn, people will start to expect this level of diagnosis and treatment. This should lead to much better outcomes, an increase in life expectancy, and lower healthcare costs overall. Of course, this sounds like an amazing advancement and it is, but now consider how AI is helping in the process of accelerating regenerating treatments.

Imagine having arthritis or bone-on-bone condition due to cartilage loss. Now imagine easily regrowing cartilage so that you no longer have a bone-on-bone condition. We are in the early phases of this now and the advancements in the field are going to accelerate due to AI.

Clearly, all these things sound very similar to things that have happened to healthcare over the last hundred years, which is to effectively improve care, lengthen life, and improve quality of life. How will AI be disruptive? What makes it different?

AI is different from any other technology that we have broadly adopted within healthcare. We have created tools, medicines, and treatments, as well as provided services that have been better over the years. However, “we” – as in human beings – have always been a required component of those solutions. Today, we have the capabilities using software and machines to diagnose, operate, and do many administrative tasks without any person really being needed. We are not totally operating like that today, which is a good thing, but the fact remains that we now have the technology that could in many cases perform better without human interaction to get a desired outcome.

What happens when it is broadly understood and trusted that we can get better outcomes, faster, more pervasively, and less costly using AI without so many humans in the equation?

It is an interesting question to ponder, and one likely outcome is the disruption of the healthcare industry. Revenue models will likely need to change; staffing will absolutely be different as well as the deployment of solutions. Given my time in the technology space – 30 years to be precise – I have not witnessed any technology that I believed to be more transformation than AI coupled with quantum computing.

Some incredible opportunities continue the trend of advancing health, lengthening life, and improving the quality of life for all, but there are also some incredible risks that AI practitioners and leaders will need to consider in the way this next wave of evolution impacts healthcare and the lives of everyone on the planet, if in fact we are to reap the benefits of this amazing technology vs realize the risks. As with any tool, AI can be used for good or bad. Hammers can build homes that provide shelter. They also can be used as a weapon that causes harm or even death. Metaphorically speaking, AI happens to be the biggest hammer we have seen in the last hundred years and thus we should choose to use it wisely.

Impact of AI in Healthcare Summary

We can expect to see incredible benefits from the growing adoption of AI within healthcare as it takes a foothold in helping with administrative tasks, operational tasks, and even in the act of providing analysis and treatments of illnesses. The industry will continue to grow, people will continue to get access to better care, which will lead to longer lives and higher quality of life. However, these things will likely happen in the context of disruption, which we will have to deal with as the industry works to get its arms around AI, which is a very big metaphorical hammer. We can be encouraged by the steps that industry leaders and AI practitioners are taking to ensure that AI is used to build society rather than tear it down.

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    - "The History of Medicine: A Very Short Introduction" by William Bynum
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Chapter 4:
The Ethical Use of AI in Healthcare

Authors: Ann M. Marcus, John Barton

The Rise of AI in Healthcare and Emerging Ethical Concerns

Artificial intelligence (AI) is rapidly transforming healthcare, bringing remarkable advances in diagnostic tools, personalized treatment plans, administrative efficiency, and remote patient monitoring. Yet with this progress comes a pressing ethical reckoning. As AI systems are increasingly trusted with decisions that directly impact human health, questions of equity, accountability, and privacy rise to the fore.

Concerns have emerged over how these technologies may unintentionally dehumanize care, erode patient trust, or worsen existing disparities. As AI assumes a more prominent role in decision-making – especially in sensitive contexts such as diagnosis and risk assessment – some patients and practitioners are growing uneasy over the transparency of its processes and the consequences of algorithmic errors. Moreover, reliance on biased or incomplete data sets threatens to replicate historical injustices within the healthcare system.

Who Is Affected? Identifying Stakeholders and Vulnerable Groups

The ethical landscape of AI in healthcare implicates a diverse group of stakeholders:

- **Patients** bear the brunt of AI decisions. From misdiagnoses to insurance denials, the consequences can be life-altering. Concerns over loss of autonomy, consent, and data security loom large, particularly when AI tools operate opaquely or without meaningful human oversight.
- **Healthcare professionals** face a shifting role as AI systems influence or even override clinical judgment. This dynamic can create tension between professional responsibility and technological authority.
- **Marginalized communities**—including people of color, low-income individuals, and non-native language speakers—are especially vulnerable. Underrepresented in medical datasets, they face higher risks of algorithmic misjudgment and reduced access to high-quality care.
- **Payers and policymakers** are grappling with the implications of AI in underwriting, pricing, and eligibility decisions, often without clear guidance on fairness or legal liability.

How AI Is Being Used, and by Whom

AI is no longer confined to back-office functions; it now plays a central role across the healthcare continuum:

- **Diagnosis and Treatment**: From radiology to dermatology, AI systems interpret scans, flag anomalies, and recommend therapies. While such tools can augment physician capabilities, their accuracy varies and often depends on how representative their training data is.
- **Home Testing and Observation**: Wearables and remote monitoring tools use AI to detect changes in vital signs or behaviors. While convenient, these technologies collect vast personal data, sometimes blurring boundaries between medical oversight and surveillance.

- **Administrative and Insurance Uses**: AI automates claims processing, fraud detection, and resource allocation. However, these efficiencies may come at the cost of human discretion, compassion, and fairness, especially for patients with complex or atypical profiles.

Who Is Getting Shortchanged? Equity and Justice

AI's promise of precision medicine is not evenly distributed. Access to advanced tools often correlates with institutional wealth and geographic location. Hospitals in underserved communities may lack the funding, staff, or infrastructure to adopt cutting-edge technologies, exacerbating existing care disparities.

Bias in algorithmic design and deployment further compounds the problem. If an AI system is trained on data that underrepresents certain populations, its decisions may systematically disadvantage those groups which can lead to missed diagnoses, inappropriate treatments, or denial of care.

Additionally, the communities most affected by AI systems often have the least influence over how those systems are designed and governed. This power imbalance challenges the democratic development of ethical, patient-centered technology.

Is AI for Diagnosis and Home Monitoring Responsible?

Responsible deployment of AI hinges on several principles:

- **Informed Consent**: Patients should be fully aware of when AI is being used, what data is being collected, and how decisions are made. They must retain the right to opt out.
- **Privacy and Surveillance Concerns**: Tools that monitor behavior or health at home can inadvertently collect non-medical information. Without updated regulatory protections – including reforms to HIPAA – such data could be exploited for commercial, disciplinary, or profiling purposes.
- **Transparency and Explainability**: Patients and clinicians must be able to understand and trust AI decisions. Black-box algorithms that offer no rationale undermine confidence and can erode the therapeutic relationship.

Insurance and Regulatory Challenges

AI is changing how insurers evaluate risk and make coverage decisions. While automation promises speed and efficiency, it also risks embedding structural biases into critical decisions about access to care. People with certain demographics, geographies, or social histories may be unfairly penalized.

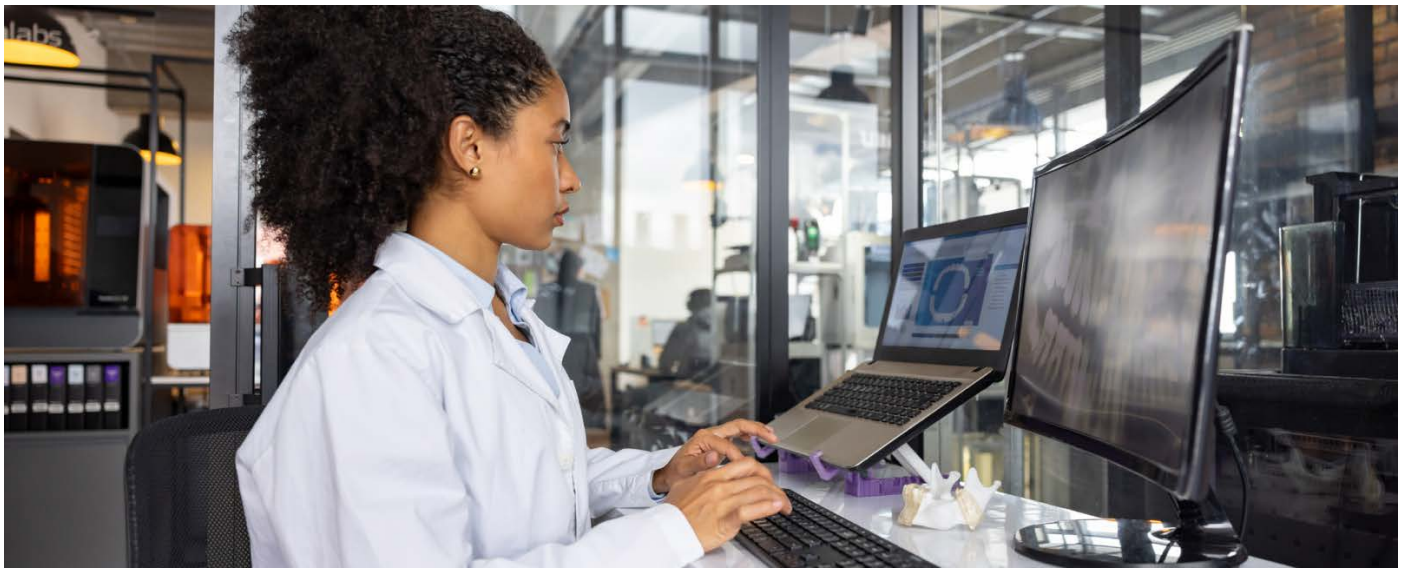
Determining legal responsibility for AI-driven errors remains murky. If a diagnostic tool recommends a harmful course of action, who is liable: the developer, the provider, or the system itself? Existing medical and legal frameworks are ill-equipped to answer these questions.

There is a clear need for comprehensive policy updates that center on equity, patient rights, and algorithmic accountability.

Balancing Benefits and Challenges

AI can enhance healthcare delivery in powerful ways: reducing physician burnout, enabling earlier interventions, and tailoring treatments to individual biology. It holds particular promise for remote and underserved communities where it could close gaps in provider availability and diagnosis speed.

But these benefits must be weighed against real challenges. Without deliberate ethical oversight, AI could become another mechanism of exclusion. Data privacy, algorithmic bias, and the erosion of clinician-patient trust are not theoretical risks; they are already surfacing in practice.



Recommendations for Responsible AI Use

To guide the ethical use of AI in healthcare, we offer the following recommendations:

1. **Develop Inclusive AI Policies**: Engage stakeholders from diverse backgrounds to co-create fair and equitable systems.
2. **Enhance Transparency and Accountability**: Ensure AI decision-making is understandable and traceable. Assign liability clearly.
3. **Strengthen Data Privacy Protections**: Update laws and frameworks including HIPAA to address the scope and scale of modern data collection.
4. **Promote Public and Professional Education**: Equip clinicians, patients, and policymakers with the knowledge needed to understand both the promise and pitfalls of AI tools.
5. **Engage Diverse Stakeholders**: Prioritize participatory design processes that include the voices of those most at risk of harm.

Charting a Responsible Path Forward in Healthtech

The integration of AI into healthcare is not just a technological shift; it is a cultural, ethical, and systemic transformation. As these tools become more deeply embedded in diagnostics, treatment, monitoring, and administration, the stakes grow higher for every stakeholder involved.

For **healthcare practitioners**, AI should be a support, not a substitute to compensate for insufficient staffing or the lack of other resources. Clinical experience and human judgment remain irreplaceable, especially when navigating ambiguity or addressing patients' unique contexts. Practitioners must have access to transparent tools they can trust, along with the training to use them effectively and ethically.

Administrators and healthcare system leaders have a responsibility to ensure AI adoption aligns with institutional values of equity, quality, and accountability. Procurement decisions should consider not only performance metrics but also the representativeness of training data, explainability, and compliance with emerging standards in algorithmic fairness.

For **health technology developers**, innovation must go hand in hand with inclusion. This means

engaging early and often with diverse populations, clinicians, and ethicists; ensuring datasets reflect the full spectrum of humanity; and building systems that are interpretable, secure, and adaptable to local needs. Responsible AI is not a regulatory burden; it is a design imperative.

Patients and communities—especially those historically marginalized in healthcare—must be centered in the AI development and deployment process. They deserve transparency, consent, and the right to opt out. Most importantly, they must have a voice in shaping the systems that will increasingly shape their care.

Ultimately, AI in healthcare can be a force for tremendous good — unlocking efficiency, insight, and access. But without intentional safeguards and inclusive design, it risks becoming another mechanism of inequity and harm. The future of ethical healthtech depends on collaboration across domains, transparency at every level, and a steadfast commitment to human dignity.

Now is the time to reimagine not just what AI *can* do in healthcare, but what it *should* and *should NOT* do, and to or for whom.

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John Barton, Founder & Executive Director of the Spectrum Gaming Project, is an AI strategist and governance architect focused on building ethical systems for underserved markets. With a Master's in Counseling and decades in community education, he has delivered over 10,000 trainings in neurodiversity, education, and innovation. Based in Appalachia, his work has been recognized and adopted by the American Bar Association, the ACLU of West Virginia, AmeriCorps VISTA Leaders, and the WV Community Development Hub.

Chapter 5: Innovative Vector Control Technologies for Neglected Tropical Disease Eradication

Authors: Ricardo Machado, Nicholas Matias

Neglected tropical diseases (NTDs) affect millions globally, particularly in underdeveloped regions. Many of these diseases, including dengue fever, Zika, and sleeping sickness, are transmitted by insects – vectors – such as mosquitoes. Traditional vector control methods, while somewhat effective, often struggle with insecticide resistance, environmental concerns, and the sheer scale of the problem. A significant challenge exists; how do we sustainably and effectively reduce vector populations and, consequently, the burden of these debilitating diseases? One innovative approach gaining traction is the Sterile Insect Technique (SIT).

The Problem

Mosquito-borne diseases represent a pervasive and escalating global public health crisis, impacting millions annually and contributing significantly to morbidity and mortality rates. Mosquitoes, acting as highly efficient biological vectors, facilitate the transmission of a diverse array of pathogenic microorganisms, including viruses, parasites, and filarial worms. These pathogens are transmitted from infected human or animal reservoirs to susceptible healthy individuals. This intricate transmission cycle underpins the sustained prevalence of diseases such as dengue fever, malaria, Zika virus, chikungunya, West Nile virus, and lymphatic filariasis, particularly in tropical and subtropical regions where environmental conditions favor mosquito proliferation.

For decades, the primary strategy for managing these diseases has revolved around conventional vector control methods, predominantly centered on the widespread application of chemical insecticides. While initially effective in reducing mosquito populations and disease incidence, these methods are increasingly confronted with substantial and multifaceted drawbacks, which severely limit their long-term efficacy and sustainability:

Insecticide Resistance: A critical and growing challenge is the evolutionary adaptation of mosquito populations to chemical insecticides. Through natural selection, mosquitoes that possess genetic mutations conferring resistance to specific active ingredients are more likely to survive exposure and to reproduce, passing on these advantageous traits to their offspring. Over time, this leads to widespread insecticide resistance within mosquito populations, rendering previously effective compounds largely ineffective. This phenomenon necessitates the continuous development of new insecticide classes, which is a costly and time-consuming endeavor, often outpaced by the rapid evolution of resistance. The dwindling arsenal of effective insecticides poses a grave threat to global disease control efforts.

Environmental Damage: The broad-spectrum application of chemical insecticides has profound and often irreversible negative impacts on ecosystems. These compounds are rarely species-specific and can cause significant harm to non-target organisms, including beneficial insects (e.g., pollinators including bees), aquatic life, birds, and even mammals. Runoff from sprayed areas can contaminate water sources, leading to bioaccumulation in the food chain and disrupting delicate ecological balances, as was seen with the broad application of DDT in the past. Furthermore, persistent organic pollutants (POPs) derived from some insecticides can remain in the environment for extended periods, posing long-term health risks to both wildlife and human populations.

Logistical Challenges: Implementing conventional insecticide spraying programs on a large scale presents formidable logistical hurdles, particularly in geographically expansive or resource-constrained settings. These challenges include:

- **High Costs:** The procurement of large volumes of insecticides, specialized spraying equipment, fuel, and labor incurs substantial financial outlays, often prohibitive for the low-income countries where mosquito-borne diseases are most prevalent.
- **Infrastructure and Personnel:** Effective spraying campaigns require robust infrastructure for storage, distribution, and maintenance, alongside a well-trained workforce capable of safely and efficiently applying the chemicals. Such resources are frequently lacking in remote or underdeveloped areas.
- **Accessibility:** Reaching remote villages, densely populated urban slums, or inaccessible natural breeding sites can be extremely difficult, leaving significant gaps in coverage and allowing mosquito populations to thrive in untreated areas.
- **Community Acceptance:** Public concerns regarding the health and environmental impacts of chemical spraying can lead to resistance or non-compliance from local communities, undermining the effectiveness of control efforts.

These inherent limitations underscore an urgent and undeniable imperative for a paradigm shift in vector control strategies. There is a pressing need to move beyond sole reliance on chemical insecticides towards the development and deployment of alternative, more sustainable, environmentally benign, and precisely targeted methods. Such innovations are crucial for achieving effective and enduring control over mosquito-borne diseases, ultimately safeguarding global public health.

The Solution: Sterile Insect Technique (SIT)

The Sterile Insect Technique (SIT) stands as a highly effective and environmentally conscious approach to pest management. This innovative method hinges on the principle of introducing a significant population of sterile male insects into a target area. These sterile males then actively compete with their wild counterparts for mating opportunities with wild females. Crucially, any successful mating between a sterile male and a wild female will not result in viable offspring. Through repeated and consistent releases of these sterile males, the overall population of the target insect gradually diminishes over time. In the context of vector control, this translates directly to a reduction in the number of disease-carrying insects, thereby mitigating the spread of various illnesses.

The process of implementing SIT can be broken down into several distinct steps:

1. **Mass Rearing:** The initial phase involves the large-scale rearing of the specific insect species targeted for control (e.g., mosquitoes responsible for transmitting diseases such as dengue, malaria, or Zika). This is conducted in highly specialized facilities designed to optimize conditions for rapid and healthy insect development, ensuring the production of robust individuals.
2. **Sterilization:** Once reared, the male insects undergo a carefully controlled sterilization process. The most common and effective method involves exposure to precise doses of ionizing radiation, such as gamma rays or X-rays. This irradiation renders the males infertile, preventing them from producing viable offspring, but it is meticulously calibrated to ensure that their mating competitiveness and overall behavior remain largely unaffected. The goal is to make them unable to reproduce while still being attractive to wild females.
3. **Release:** Following sterilization, the sterile male insects are released into the designated target areas. This release is often conducted systematically, sometimes even using aerial dispersion methods, to ensure wide and uniform distribution within the wild insect population. The timing and frequency of these

releases are critical for maximizing their impact and outcompeting wild males.

4. **Population Decline:** The core mechanism of SIT comes into play here. When a wild female mates with a sterile male, the absence of viable offspring interrupts the natural reproductive cycle. As the proportion of sterile males in the environment increases with each release, the probability of wild females mating with fertile wild males decreases significantly. This repeated disruption of reproduction leads to a progressive and sustained decline in the overall wild insect population, ultimately reducing the vector's capacity to transmit diseases. This method offers a sustainable alternative to conventional pesticide applications, minimizing ecological disruption while effectively managing vector-borne diseases.

Benefits and Challenges of SIT

SIT presents a compelling strategy in the realm of pest and vector control, offering a unique blend of efficacy and environmental responsibility. However, like any sophisticated technological approach, its implementation is accompanied by a distinct set of benefits and challenges that warrant detailed examination.

Benefits of SIT

Species-Specific Targeting: A cornerstone of SIT's appeal lies in its unparalleled precision. Unlike broad-spectrum insecticides that indiscriminately affect a wide array of organisms, SIT targets only the specific insect species earmarked for control. This focused approach minimizes collateral damage to non-target insects, beneficial pollinators, and other ecologically vital organisms, thereby preserving biodiversity and ecological balance. This specificity stands in stark contrast to the often-disruptive impact of chemical pesticides on entire ecosystems.

Environmental Compatibility: The sterilization process at the heart of SIT—typically involving irradiation—is inherently clean and chemical-free. SIT represents an environmentally friendly alternative to conventional pest control methods that often rely on synthetic chemicals. By circumventing the use of insecticides, SIT eliminates concerns related to chemical residues in the environment, contamination of water sources, and potential harm to wildlife and human health. A critical advantage of SIT is its inherent safety regarding genetic integrity of vector and pathogen. Unlike other biotechnological approaches, SIT does not involve introducing genetic modifications into the target insect species or deliberately infecting wild populations with pathogens. This eliminates the risk of unintended or "runaway" genetic mutations impacting either the disease-causing agents or the vector itself, ensuring a contained and predictable intervention. This alignment with eco-conscious principles makes SIT a highly attractive option for sustainable pest management.

Mitigation of Insecticide Resistance: One of the most persistent and growing challenges in pest control is the development of insecticide resistance. As insects are repeatedly exposed to chemical treatments, their populations can evolve mechanisms to withstand these compounds, rendering the insecticides ineffective over time. SIT, by its very nature, sidesteps this critical issue entirely. Since no insecticides are involved in the process, there is no selective pressure for insects to develop resistance, ensuring the long-term viability and effectiveness of the technique.

Area-Wide Control and Accessibility: SIT possesses an inherent capacity for area-wide control, making it particularly effective in managing pest populations across vast geographical regions. The release of sterile insects, often by aerial means, allows for widespread dispersal, reaching even remote and hard-to-access locations that might be challenging or impractical for conventional chemical applications. This expansive coverage is crucial for controlling highly mobile pest species that can quickly re-infest treated areas.

Long-Term Sustainability: When carefully integrated into a broader, comprehensive vector control program, SIT offers the potential for sustainable, long-term population suppression. Unlike methods that require continuous reapplication, SIT aims to disrupt the reproductive cycle of the pest population, leading to a sustained decline in numbers. This approach can contribute to stable, enduring control of pest populations, reducing the ongoing need for intensive interventions and fostering a more resilient ecosystem.

Challenges of SIT

Complexities of Mass Rearing: The successful deployment of SIT hinges on the ability to rear and maintain astronomically large numbers of the target insect species in a controlled environment. This undertaking presents significant logistical and financial complexities. Program managers must maintain consistent quality, genetic diversity, and competitiveness of these mass-reared insects. Any deficiencies in the rearing process can compromise the insects' ability to compete with wild males for mating opportunities, thereby reducing the overall effectiveness of the program. The skilled care required for insect husbandry, including optimal feeding, temperature, and humidity, demands specialized expertise and substantial infrastructure.

Ecological Impact: Removing an entire species from an ecosystem can result in disruption of food chains and other dependencies for other species. While this is less of a factor when dealing with invasive species that don't belong naturally in the local ecosystem, it is still a concern. According to Dr. Clare Palmer of Texas A&M University, "Deliberate full extinction might occasionally be acceptable, but only extremely rarely."

Potential Sterilization Effects on Competitiveness: While extensive research and refinement have gone into optimizing the sterilization process, a delicate balance remains between achieving complete sterility and preserving the biological fitness of the released males. The irradiation process, though precise, can sometimes inadvertently affect the mating competitiveness, longevity, or overall survival of the sterile insects. Any reduction in their vigor or attractiveness to wild females can significantly diminish the effectiveness of the SIT program. Ongoing research aims to develop even more refined sterilization protocols that minimize these potential adverse effects.

Intricate Logistics of Release: The efficient and effective distribution of sterile insects over large and often diverse geographical areas is a monumental logistical challenge. Careful planning is essential to determine optimal release timings, densities, and methods to ensure widespread coverage and adequate dispersal of the sterile population. Factors such as prevailing winds, terrain, and the behavioral ecology of the target insect must be meticulously considered to maximize the chances of sterile males encountering and mating with wild females. This often necessitates the use of specialized aircraft or ground-based dispersal systems, adding to the operational complexity and cost.

Crucial Role of Public Perception and Acceptance: The success of SIT programs is inextricably linked to public understanding and acceptance. The concept of intentionally releasing insects, even sterile ones, can sometimes trigger public apprehension or misunderstanding. Addressing these concerns through robust public education and community engagement initiatives is absolutely vital. Transparent communication about the benefits of SIT, its safety, and its distinction from harmful pests can foster trust and garner community support, which is indispensable for the long-term success of any area-wide pest control program. This includes explaining that SIT does not rely on genetic modification, even though there is confusion about this with the public. Without strong community buy-in, even the most scientifically sound SIT projects can face significant hurdles.

Substantial Initial and Operational Costs: While SIT offers long-term sustainability benefits, its initial setup and operational costs can be considerably higher than some conventional chemical-based methods. Establishing and maintaining mass-rearing facilities, acquiring specialized equipment for sterilization and release, and funding ongoing research and monitoring programs represent significant investments. However, it is crucial to consider the broader economic and environmental benefits that SIT can deliver over the long term, including reduced reliance on costly insecticides, prevention of crop losses, and improved public health outcomes, which may ultimately outweigh the initial financial outlay.

Examples of SIT Implementation

Screwworm Eradication – A Historic Triumph: One of the most celebrated and pioneering applications of SIT was the eradication of the New World screwworm fly (*Cochliomyia hominivorax*) from North and Central America starting in the 1951 in the U.S. This devastating pest caused immense

economic losses to livestock industries by infesting wounds in warm-blooded animals, especially livestock. SIT played an absolutely pivotal role in eliminating this threat, demonstrating the technique's profound potential for area-wide pest eradication, and solidifying its place as a groundbreaking biological control method. The success of the screwworm program provided a powerful proof-of-concept for SIT on a grand scale.

Mosquito Control – Addressing Global Health Threats: SIT is at the forefront of innovative research and implementation efforts aimed at controlling mosquito populations, particularly *Aedes aegypti*. This notorious mosquito species is the primary vector for debilitating arboviral diseases such as dengue, Zika, and chikungunya, which pose significant global public health challenges. Numerous pilot projects and larger-scale initiatives have demonstrated promising results in reducing *Aedes aegypti* populations in various affected regions, offering a sustainable and environmentally sound approach to combating these widespread diseases. The ongoing work in this area holds immense promise for improving human health worldwide.

Fruit Fly Management – Protecting Agricultural Productivity: Beyond public health, SIT is also widely employed and extensively researched for managing agricultural pests, notably various species of fruit flies. These insects can cause significant damage to valuable fruit crops, leading to substantial economic losses for farmers. By releasing sterile fruit flies, SIT effectively disrupts their reproductive cycle, protecting horticultural industries and ensuring food security. This application highlights SIT's versatility and its critical role in integrated pest management strategies across different sectors.

Conclusion: The Transformative Potential of Sterile Insect Technique (SIT) in Neglected Tropical Disease Eradication

SIT is a highly promising and crucial tool in the global fight against neglected tropical diseases. Its significant advantages include unparalleled species-specificity, environmental compatibility, and effectiveness against insecticide resistance. Unlike broad-spectrum pesticides, SIT precisely targets disease-carrying vectors, minimizing harm to beneficial organisms and ecosystems, making it a refined and sustainable vector control solution. This technique's environmental friendliness is a key benefit, as it introduces no harmful chemicals, thereby protecting human health and natural resources. Furthermore, SIT's reliance on mating disruption, rather than chemical agents, allows it to bypass the pervasive problem of insecticide resistance, offering a vital and sustainable alternative where traditional methods fail and avoiding unknown risks from the introduction of genetic modifications or microorganism introduction to wild individuals.

Despite challenges in implementation, ongoing global efforts in research and innovation are continuously improving SIT's deployment. Advancements in automation, AI for insect sexing, and drone technology are streamlining the complex processes of mass-rearing, sterilization, and release. Continued research also focuses on optimizing rearing protocols, enhancing the fitness of sterile insects, and refining release strategies to maximize effectiveness. The development of robust monitoring and evaluation frameworks is also essential to ensure the optimal impact and adaptability of SIT programs. Ultimately, investing in and refining SIT is imperative for the global health community, as embracing this innovative and environmentally responsible technique can lead to more effective and sustainable vector control, significantly reducing the burden of NTDs and paving the way for a healthier future worldwide.

Case Study

The effective deployment of beneficial insects, such as sterile mosquito males, has long been a cornerstone of biological pest control. While the Sterile Insect Technique (SIT) has proven to be a safe and powerful tool over decades, a significant hurdle to its widespread adoption has been the challenge of efficient and scalable insect release. The advent of small, easy-to-operate drone technology has revolutionized this aspect, enabling the homogenous and highly efficient distribution of these insects across vast areas, even in remote or challenging terrains. This simplicity of operation also means that these vital interventions can be deployed locally where they are most needed, directly addressing Neglected Tropical Diseases (NTDs) in the developing countries that suffer the most from their impact.

Ricardo Machado and Nicholas Matias, authors of this section, co-founded BirdView in 2015 to address precisely this challenge. BirdView specializes in packaging and release technologies designed for beneficial insects, leveraging the capabilities of these small drones. The company has developed a modular packaging system that facilitates the decentralized release of adult beneficial insects. This innovation not only streamlines the logistical complexities of large-scale deployments but also contributes to reducing operational costs and enhancing the overall effectiveness of pest control programs, including those focused on vector-borne diseases.

The company's drones have flown more than 67,000 km during more than 12,000 flights, releasing beneficial insects not just to combat disease, but also for agricultural pest management.

BirdView's work demonstrates how integrating readily deployable drone technology with established biological control methods can overcome long-standing limitations, paving the way for more efficient, accessible, and sustainable vector management strategies in vulnerable communities.

Intended Audience and Call to Action

This section is primarily aimed at entrepreneurs, investors, and innovators within the HealthTech space, particularly those interested in novel approaches to global health challenges and sustainable development. We also intend to reach policymakers, public health officials, and non-profit organizations seeking scalable and environmentally responsible solutions for vector-borne diseases.

Our call to action is twofold:

1. **For HealthTech Entrepreneurs and Investors:** We urge you to consider the immense potential of SIT as a disruptive and impactful technology. This is an invitation to explore opportunities for R&D investment, partnership in mass-rearing technologies, development of efficient release mechanisms (e.g., drone integration), and scalable deployment strategies. The market for sustainable vector control is vast and growing, offering significant returns on investment in both financial and social capital.
2. **For Policymakers and Public Health Organizations:** We advocate for increased integration of SIT into national and international vector control programs. This requires supportive regulatory frameworks, dedicated funding, and collaborative initiatives to scale up implementation and overcome existing logistical hurdles. Embracing SIT represents a strategic shift towards more effective, environmentally sound, and long-term solutions for NTD eradication.

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Part II
The Funding Landscape for HealthTech Startups

Chapter 6: Introduction to HealthTech Funding

Authors: H. Timothy Hsiao, PhD, John Hsu, MD

Funding uncertainty coupled with the difficulties of insurance reimbursement, often determines success or failure for healthtech startups and the innovations they represent. A great idea that does not generate revenue is simply only a great idea. Many parts go into generating income including regulatory affairs, customer fit, manufacturing potential, IP protection, billing/collections, insurance regulations, medical device coding, provider acceptance, and workflow adoption. All of these factors play an essential role in future success.

For healthtech startups that engage in research, their early-stage funding sources typically rely on one or more of the following:

- Self/friends/family
- Crowdfunding
- Incubator/In-kind support (e.g., overhead/space benefits)
- Government (non-dilutive funding)
- Philanthropy (non-dilutive)
- Angel investors
- Venture capitals (VC)
- Mezzanine financing
- Private equity (PE)
- Corporate venture capitals
- Strategic alliances/partnerships and joint ventures
- Revenue-based financing
- Debt financing and loans

Among those potential sources, government funding has been historically considered one of the more desirable options because of its scale of budget, consistency, stability, and non-dilutive nature. As we observed the rise of uncertainty since the beginning of 2025, it is anticipated that the scale and processing time in government research funding in general will continue to be impacted negatively in the near future. However, in light of the current administration's pro-business sentiment, as well as the broadly bi-partisan support of the small business innovation research/small business technology transfer (SBIR/STTR) programs – branded as "America's Seed Fund" – it is plausible that small businesses can still leverage the government non-dilutive funding as one of the pillars of their fund-raising strategies.

On the other hand, increasing voices are calling the industry and philanthropy to step-up and fill in gaps of America's innovation funding landscape. For example, the CEO of Recursion Pharmaceuticals recently stated in February 2025 that "Publicly funded research built the biopharma industry. Now it needs our help" and a Harvard/Boston University team opined in March 2025 that "Philanthropy can help create a healthier biotech ecosystem".

One of the megatrends also provides hints on how the innovation funding landscape might shift. Through the "Great Wealth Transfer", an estimated $84 trillion in assets is expected to be transferred from the Baby Boomers to younger generations (Millennials and Gen X) and charitable/philanthropic organizations over the next two decades. In addition to their roles in philanthropy, wealthy Americans are also the key driving forces behind the retirement funds, angel investment, private equity, private lending, and in some cases, crowdfunding. With this trend in mind, it is possible that the innovation funding in America might become more "democratized" and more driven by asset owners' personal situations, convictions, and motivations.

As the domestic funding for the American innovation ecosystem might experience at least a temporary set-back in the near term, the competitions for VC/PE deals are anticipated to intensify and startup valuation to drop. As a logical next step for lower valuation, healthtech startup

equities in America might become more affordable by international investors, so foreign direct investments (FDIs) could become another source of funding on the rise. FDIs can be especially relevant for healthtech start-ups due to healthtech's typically shorter time-to-market (when compared to pharmaceuticals), which is typically favored by international investors as it allows for more nimble reallocation of assets when markets fluctuate.

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H. Timothy Hsiao is passionate about developing deep tech-solutions to address public health needs. His current focuses are radiological, quantum, and digital/AI technologies.

John Hsu MD, **Founder, CEO of iPill inc, CEO Quivivepharma**
Dr. John Hsu practiced 32 years in anesthesia, chronic pain, and addiction medicine. He holds 8 granted patents in medical devices and drug development and was awarded a $1.9 NIDA/NIH grant. Dr. Hsu founded: iPill inc. a biometric secure pill dispenser to improve remote medication adherence; Quivivepharma a drug development company for an opioid-respiratory stimulant combination pill to make opioids safe and abuse deterrent; Fentavive a drug development company for a Narcan-respiratory stimulant combination injectable to address Narcan dosing ambiguity and is in the early stages of working with the DOD/DARPA; NAOMI systems, a practice management software company.

Chapter 7:
Current Statistics on Funding

Author: Mark Wesson

Digital Health Investment Since 2024

High-Level Trends

The digital health sector in 2024 experienced a dynamic interplay of technological advancements, economic pressures, and regulatory challenges. While artificial intelligence (AI) emerged as a significant driver of investment, factors such as inflation, reduced exit opportunities, and regulatory bottlenecks influenced funding patterns. This report delves into the key trends that shaped digital health investments in 2024.

Global digital health funding approximated $25.1 billion in 2024 and the first quarter brought in about $3 billion, about 10% more than Q1 2024, marking a 3% year-over-year increase. The United States pushed out just over $10 billion to digital health companies in 2024, and spread it over nearly 500 deals, with early-stage funding seeing more deal volume and late-stage deals exhibiting lower volume but larger sizes.

The first two quarters of 2025, in the United States, showed many similar features. Investors put nearly $6.5 billion into U.S. digital health startups over about 245 deals. This was slightly up from the first half of 2024 year-over-year.

Despite availability of capital since 2024, substantial amounts of capital remain uninvested into early, growth-stage companies by and large. However, the surge in Artificial Intelligence progress and interest has served the Digital Health sector quite well. As the generation, documentation, analysis, alerting, and future re-incorporation into software and device uses apply heavily to Digital Health, many might see the arrival of mature, practical Artificial Intelligence to be the signal investors were awaiting to push the Digital Health age into very public view.

Economic, trade, inflation, and interest rate challenges present in 2024 persist and have increased the cost of capital, leading to more cautious investment strategies. Investors in Digital Health have correspondingly prioritized ventures with clear paths to profitability and tangible value propositions.

Shifts in Deal Dynamics: Fewer Deals, Larger Investments

Investment patterns since 2024 reflect strategic shifts in three notable areas:

- **Deal Volume**: There was only a slight decline in deal volume in 2024 compared to 2023, indicating some increased selectivity among investors. The deal count in the first half of 2025 was lower year-over-year at 245 (versus 273 in the first half of 2024). The first half of the year deployed more capital with fewer companies than the first half of 2025.
- **Deal Size**: In the first half of 2025, $6.4 billion was deployed, compared to $6.0 billion for that same period in 2024 ($6.2 in 2023). Average deal size by the end of the first half of 2025 ballooned to $26.1 million, a near 30% increase over the first half of 2024.
- **Late-Stage Funding**: Late-stage rounds saw a resurgence in 2025, likely driving the deal size figures reported.

This trend underscores a concentration of capital into ventures with proven models and scalability, often at the expense of early-stage startups.

Decline in Unicorns, IPOs, and Exits

The year-plus since 2024 has proven far less active in three key capital markets indicators for early-stage investment: significant reduction in unicorn formations and public exits.

- **Unicorns**: The pace of companies expected to experience explosive growth by frequently meeting previously unmet needs ("Unicorns"), has slowed considerably, with many startups delaying exits to strengthen financial positions amidst market volatility.
- **Initial Public Offerings**: IPOs, whereby a company offers its stock for public purchase on one or more stock markets, have remained noticeably below historical levels, as companies hesitate to go public in an uncertain economic environment.
- **Exits**: Transactions that distribute returns to prior investors, and set new share prices, often fueled by IPOs, substantial revenue growth, and forward momentum, have slowed for over a year. Mergers and acquisitions have seen an uptick in the 2024-forward period with most being venture-to-venture acquisitions.

The subdued exit landscape prompted many companies to seek alternative funding avenues, including follow-on rounds and secondary sales.

These challenges compelled companies to adjust strategies, often seeking bridge financing or exploring acquisition opportunities to sustain operations.

Valuation Pressures

Down-Rounds: An increasing number of startups seeking investment for growth faced the need to tighten up operational expenses, revisit market assumptions and strategies, and investor caution prompted many companies to experience lowered valuations and thus investment appeal. This, in turn, led to reductions in capital request amounts based on last year's economic landscape. Last year's advances versus declines recalibrated valuations in a more conservative investment climate. This has persisted through 2025 to date as of this writing.

Regulatory Challenges

FDA Delays: Regulatory bottlenecks, particularly at the FDA, impeded the approval process. Layoffs and restructuring within the FDA in early 2025 contributed to these delays, affecting companies reliant on timely approvals. Since December 2024, considerable guidance documents pertaining to drug and device development and approval for use in the United States have been issued by the FDA. All indications are that review processes have resumed and delays at present in mid-2025 have been considerably reduced.

Data Privacy and Approval Pathway Regulations: The news and enthusiasm for Artificial Intelligence in 2024 brought innovation but also quickly introduced challenges, including concerns about data privacy, algorithmic bias, and the need for robust validation to ensure clinical efficacy.

AI's Ascendancy Amidst Economic Pressures

AI-driven ventures dominated the funding landscape, capturing nearly 60% of total venture funding. Investments focused on medical diagnostics, health management solutions, and research tools.

AI's prominence continues to play a pivotal role in maintaining Digital Health's appeal to investors:

- **Investment Share**: AI-focused companies secured 62% of digital health funding in the first half of 2025. In the first half of 2025, AI-inside startups attracted 62% of all digital health venture funding.
- **Deal Size**: Early-stage AI deals have proven resilient and larger. AI-focused digital health companies commanded almost 55% more per average deal than those digital health companies not using AI in the first half of 2025. The first half of 2025

generated 11 “mega-rounds” (of more than $100 million each), on an annualized track to outsize 2024’s 17 deal sizes in this space.

These outsized rounds underscore strong investor confidence in Artificial Intelligence in health and healthcare.

Digital Health's share of venture funding remained robust, buoyed by AI's potential to revolutionize diagnostics, treatment planning, and patient engagement.

Conclusion

The digital health sector in 2024 navigated a complex landscape marked by technological innovation and economic headwinds. AI emerged as a double-edged sword, driving significant investment while introducing new challenges. As the sector moves forward, success will hinge on balancing innovation with regulatory compliance, ensuring that technological advancements translate into tangible health outcomes.

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Chapter 8: Monetization Strategies

Authors: John Hsu, MD, John Barton

Overview

There has not been a digital health blockbuster/unicorn yet because universal reimbursement has not been established. There are some unique success stories but each story has been a hard-fought battle with insurers and employers that has – in most cases – taken years and does not offer enough return on investment (ROI) to warrant further investment for growth. For this reason, the environment for raising capital has become very difficult in the last five years. Companies that survived on federal grants are folding. The investors who were willing to wait for profits to develop using grant funds are moving onto other more glamorous sectors like artificial intelligence (AI).

Stakeholders

- Employers
- Insurers
- Government agencies
- Industry

Challenges / Gaps

Because universal reimbursement has not been established, HealthTech monetization requires navigating the complex stakeholder ecosystem while ensuring value delivery. Key considerations include:

- Insurance reimbursement
- **Regulatory compliance**: HIPAA, GDPR, and FDA regulations shape pricing and data usage.
- **Value-based care**: Aligning revenue models with patient outcomes and cost savings
- **Scalability**: Balancing affordability with sustainable growth
- **Equity**: Ensuring access for underserved populations to avoid exacerbating healthcare disparities

Monetization strategies must prioritize trust, transparency, and measurable impact to succeed in this highly scrutinized sector.

Our New Vision

The traditional fee-for-service models are shifting to strategies that derive recurring, diversified, and value-based revenue streams. We used to be able to buy complete software programs to use for years which limited growth potential. Now software is sold as a monthly or yearly subscription. This change from traditional software has been driven by the growth of advanced analytics, AI, and interoperable technology to create an ecosystem of integrated digital solutions. No single software package is a complete solution. The shift has come about by the explosive growth of data coupled with massive computing power which can evaluate voluminous amounts of data quickly. As the evolution of the third cycle of machine learning (ML) artificial intelligence, we have developed a huge demand for real-time insights.

New key monetization strategies include:

Data as a Service (DaaS) and Insights-as-a-Service

How it works: Companies offer a subscription to access anonymized, aggregated, and AI-ready healthcare datasets through data marketplaces or exchange platforms. These data products can be

licensed to pharmaceutical companies for clinical trials, research institutions for medical advancements, or insurers for risk assessment.

Examples:

Examples of DaaS:

- Amazon Web Services (AWS) and Snowflake AI Cloud for cloud analytics of large datasets
- Streetlight Data and Similar web for GPS traffic data
- MongoDB Atlas for relational database analytics in the cloud

Examples of insights-as-a-service:

- Experian, TransUnion, Equifax for credit scores and financial data
- ZoomInfo and Enigma Technologies for marketing analysis
- Cognism for customer information regarding sales and social media

Benefits: Insights to data can provide businesses the data to improve efficiency and sales, healthcare the data to improve predictive diagnostics, finance companies the data prevent fraud and risk assessment, and retail companies the data to increase sales to satisfy consumer buying preferences.

Challenges: With greater data comes greater responsibility.

- Data privacy and security: Compliance and regulations usually follow far behind so there is a constant threat for data intrusion and illicit use of data.
- Constant evaluation of data quality and integrations: With different database platforms and legacy systems, data corruption occurs, complicating database integration and resulting in incorrect conclusions.
- Interpretability and trust: Conclusions from data analytics may conflict with human intuition and common sense, which may make decisions difficult.
- Talent shortage: Machine learning, database cloud analytics, and cybersecurity are evolving very quickly. It can be difficult to find qualified up-to-date employees.

Leveraging advanced analytics and AI

How it works: Companies integrate analytics into internal operations to reduce costs and improve workflows through enhanced efficiencies and better patient outcomes. This indirect monetization strategy can lead to **revenue sharing of the savings.**

Examples:

- Predix is an AI driven platform that evaluates equipment to prevent downtime.
- Paypal uses an AI driven platform to analyze transactions to prevent fraud.
- Amazon uses an AI driven platform to follow purchase history and browser data to increase sales.
- IBM Watson Health uses an AI driven platform to evaluate treatment results to assist doctors in improving patient care.
- Walmart uses an AI driven platform to record purchase history, forecast demand, and manage inventory to reduce costs and meet customer demand.
- Tesla uses an AI driven platform to analyze real-time data from cameras to enable self-driving cars in traffic.

Benefits: The biggest advantage of data analytics within an AI environment is enhanced decision-making capabilities. Immediate improvements can be achieved in operational efficiency, risk mitigation, competitive advantage, predictions, and revenue growth because of greater data and accuracy of data.

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is a constant threat for data intrusion and illicit use of data.
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- Talent shortage. Machine learning, database cloud analytics, and cybersecurity are evolving very quickly. It can be difficult to find qualified up-to-date employees.

Integrated digital ecosystems

How it works: Medtech companies are moving beyond selling single products to offering integrated solutions. For instance, a subscription-based software ecosystem may combine hardware sales with analytics and developer access, creating multiple revenue streams.

Examples:

- Medtronic has Carelink, a platform to connect cardiac devices with AI driven analytics to promote remote patient monitoring.
- Stryker has Mako surgical systems to connect to Care.ai to make smart surgical suites and hospital wards.
- Siemens has AI-Rad Comparison to connect MRI and ultrasound systems to cloud based analytic and diagnostic systems to support radiologists.
- Johnson & Johnson has the Monarch robotic surgery platform for navigation and AI-Analytics to improve patient outcomes.
- BrightInsight has the BrightInsight Platform to integrate medical devices with digital health solutions to improve compliance.
- Benefits: Integrated solutions in the Healthtech/Medtech environment often leads to holistic care and operational efficiency. This data driven process can improve revenue growth, competitive advantages, patient care, and scalability; this is the future of medicine

Challenges:

- Integration complexity: Medical devices and software integration have been slow in adoption because of the lack of experience, secure and stable connectivity issues, computing power, and high development costs.
- Regulatory concerns: With the lack of data on use of combined hardware and software products, safety concerns loomed and resulted in a reluctance to grant approvals until data was produced.
- Adoption resistance: Doctors went to medical school, not engineering school. Their lack of knowledge and experience manifested as safety concerns and a reluctance to adopt new technology.
- Lack of data: Combining hardware and software into a new integrated system introduces new data that must be collected and evaluated. Inaccurate outcomes or unexpected results can undermine trust, adoption, and regulatory approvals.

Traditional Monetization Strategies

Subscription-Based Models

How It Works: Recurring fees (monthly or annual) for access to HealthTech platforms, tools, or services. Common in telehealth, remote monitoring, and wellness apps

Examples:

- Teladoc Health: Monthly or per-visit subscriptions for virtual consultations
- Headspace: Subscription for mental health and meditation content

Benefits:

- Predictable revenue stream

- Encourages user retention and long-term engagement
- Scalable across B2C and B2B markets

Challenges:

- High churn rates if perceived value diminishes
- Requires continuous feature updates to justify recurring costs
- Regulatory hurdles for data storage and sharing

Best For: Digital therapeutics, telehealth platforms, and patient engagement tools

Pay-Per-Use / Transactional Models

How It Works: Charges based on usage, such as per consultation, test, or data analysis. Often used in diagnostics or on-demand services

Examples:

- LabCorp OnDemand: Per-test fees for at-home lab kits
- Zocdoc: Per-booking fees for connecting patients with providers

Benefits:

- Low entry barrier for users hesitant to commit to subscriptions
- Aligns costs with actual usage
- Flexible for sporadic needs (e.g., one-off consultations)

Challenges:

- Revenue volatility due to inconsistent usage
- High competition in price-sensitive markets
- Complex billing systems increase operational costs

Best For: Diagnostic tools, appointment booking platforms, and episodic care services

Freemium Models

How It Works: Basic features are free, with premium features or services behind a paywall. Often used to build a large user base before upselling

Examples:

- MyFitnessPal: Free calorie tracking with premium nutrition coaching
- Fitbit: Free app with premium health insights via subscription

Benefits:

- Rapid user acquisition due to low entry cost
- Data collection from free users can inform product improvements
- Upsell opportunities for engaged users

Challenges:

- High cost of supporting free users
- Risk of low conversion rates to paid tiers
- Privacy concerns with data monetization

Best For: Wellness apps, fitness trackers, and patient education platforms

B2B Licensing and White-Labeling

How It Works: Selling or licensing technology to healthcare providers, insurers, or employers for integration into their systems. White labeling allows rebranding by the buyer

Examples:

- Cerner: Licenses electronic health records (EHR) software to hospitals
- Health Catalyst: Sells analytics platforms to health systems

Benefits:

- High-margin, scalable revenue from enterprise contracts
- Long-term partnerships reduce churn

- Aligns with B2B buyers' need for customized solutions

Challenges:

- Lengthy sales cycles and complex integration processes
- High upfront development and support costs
- Dependency on client renewals

Best For: EHRs, clinical decision support tools, and population health analytics

Value-Based Pricing

How It Works: Revenue tied to outcomes, such as reduced hospital readmissions or improved patient adherence. Often used in partnerships with payers or providers

Examples:

- Omada Health: Charges based on patient health improvements (e.g., diabetes management)
- Livongo: Revenue tied to cost savings for employers or insurers

Benefits:

- Aligns incentives with healthcare's shift to value-based care
- Builds trust with payers and providers
- Differentiates in competitive markets

Challenges:

- Requires robust data to prove outcomes
- Complex contracts and delayed revenue recognition
- Risk of non-payment if outcomes fall short

Best For: Chronic disease management, remote monitoring, and preventive care solutions

Data Monetization

How It Works: Aggregating and anonymizing health data to sell insights to researchers, pharma companies, or insurers. Must comply with strict privacy laws

Examples:

- Flatiron Health: Sells anonymized oncology data to researchers
- 23andMe: Monetizes genetic data for drug discovery partnerships

Benefits:

- High-margin revenue from existing data assets
- Supports innovation in drug development and public health
- Leverages data already collected for core services

Challenges:

- Stringent regulatory requirements (e.g., HIPAA, GDPR)
- Risk of consumer backlash over privacy concerns
- Requires significant investment in data infrastructure

Best For: Genomics, real-world evidence platforms, and large-scale health data aggregators

Hardware + Service Bundles

How It Works: Selling hardware (e.g., wearables, diagnostic devices) paired with software or service subscriptions for ongoing revenue

Examples:

- Apple Watch + HealthKit: Hardware sales paired with health app subscriptions
- Dexcom: Continuous glucose monitors with data analytics subscriptions

Benefits:

- Diversifies revenue across one-time and recurring streams

- Enhances user engagement through integrated ecosystems
- High margins on software/services post-hardware sale

Challenges:

- High upfront R&D and manufacturing costs
- Supply chain and regulatory complexities
- Competition from low-cost hardware providers

Best For: Wearables, medical devices, and home health monitoring systems

Employer-Sponsored Models

How It Works: Partnering with employers to offer HealthTech solutions as employee benefits, often funded or subsidized by the employer

Examples:

- Virgin Pulse: Wellness programs for corporate employees
- Castlight Health: Navigation tools to reduce employee healthcare costs

Benefits:

- Access to large, captive user bases
- Stable revenue through employer contracts
- Aligns with corporate focus on employee health and productivity

Challenges:

- Dependence on employer budgets and priorities
- Long sales cycles for enterprise deals
- Limited control over user engagement

Best For: Mental health platforms, wellness programs, and healthcare navigation tools

Hybrid Monetization Approaches

How It Works: Many HealthTech companies combine strategies to diversify revenue and mitigate risks. Hybrid models require careful alignment to avoid user confusion or perceived double-dipping.

Examples:

- Teladoc + Livongo: Combines subscription telehealth with value-based chronic care programs
- Fitbit: Freemium app, hardware sales, and premium subscriptions
- GoodRx: Transactional fees for prescriptions with data monetization for market insights. Hybrid models require careful alignment to avoid user confusion or perceived double-dipping.

Potential benefits (to providers, patients, self-help, insurance claims)

Overall benefits include improved better access for underserved regions, lowered risk of infection by avoiding clinics, enhanced chronic care management, faster submission, and more efficient reimbursement.

Specifically:

For providers: increased capacity, expanded reach, lower overhead, and improved workflow and care coordination, can improve documentation, patient management and practice revenues.

For patients: convenience, cost savings, access to specialists, improved chronic disease management, mental health support and continuity and engagement can lead to better outcomes for chronic care management

For insurers: streamlined processing, cost parity, fraud protection, lower overall costs, coverage

expansion, and simplified claims for covered services can lead to improved efficiency and lower operational costs.

Case Studies

Teladoc Health: Scaled through a mix of subscription and pay-per-use telehealth, with B2B contracts for employers and insurers.

Key lesson: Flexibility in pricing drives adoption across segments.

Flatiron Health: Monetizes anonymized oncology data while providing value to providers via analytics.

Key lesson: Ethical data use can unlock high-margin revenue.

Omada Health: Pioneered value-based pricing for diabetes prevention, aligning revenue with payer savings.

Key lesson: Outcome-based models require robust evidence.

Potential risks & mitigations

Monetizing digital health apps involves various strategies, each with potential risks and corresponding mitigations. Below is a concise overview of key risks and practical mitigations, focusing on privacy, user trust, regulatory compliance, and financial sustainability, tailored to the context of digital health apps.

Common Monetization Models and Specific Considerations

- **Subscriptions:** Risk of user churn if value isn't clear. Mitigate by offering flexible plans (monthly/annual) and free trials
- **In-App Purchases:** Risk of perceived "nickel-and-diming." Mitigate by bundling features into clear packages
- **Advertising:** Risk of privacy concerns or irrelevant ads. Mitigate by using contextual (non-personalized) ads and allowing ad-free upgrades
- **Data Licensing:** High privacy and ethical risks. Mitigate by limiting to anonymized datasets and securing user opt-in
- **B2B Partnerships:** Risk of misaligned incentives (e.g., insurers pushing cost-saving over care quality). Mitigate with strict partnership agreements and user-centric focus

Specific Security Risks and Mitigations

Privacy and Data Security Risks

Risk: Monetization models like data sharing or targeted advertising may involve collecting and processing sensitive health data, increasing the risk of breaches, unauthorized access, or misuse. Non-compliance with regulations like HIPAA (U.S.) or GDPR (EU) can lead to legal penalties and loss of user trust.

Mitigations:

- Implement robust encryption (e.g., AES-256) and secure data storage practices
- Obtain explicit user consent for data use, with clear, transparent privacy policies
- Anonymize or pseudonymize data before sharing with third parties
- Conduct regular security audits and vulnerability assessments
- Ensure compliance with HIPAA, GDPR, and other relevant regulations through legal consultation

User Trust and Engagement Risks

Risk: Aggressive monetization (e.g., excessive ads, paywalls for essential features) can alienate users, reduce engagement, or lead to app abandonment. Perceived exploitation of health

data may erode trust, especially in vulnerable populations.

Mitigations:

- Offer freemium models with core health features accessible for free, reserving premium features (e.g., advanced analytics, coaching) for paid tiers
- Use non-intrusive ads (e.g., opt-in or skippable) and avoid health-irrelevant promotions
- Communicate value clearly for paid features to justify costs (e.g., personalized health insights)
- Provide transparency about data usage and monetization practices via user-friendly dashboards or FAQs

Regulatory and Legal Risks

Risk: Monetization strategies may inadvertently violate health regulations, such as FDA rules for medical devices if the app provides diagnostic features, or advertising laws if claims are misleading. Partnerships with third parties (e.g., insurers, advertisers) may introduce liability risks.

Mitigations:

- Consult regulatory experts to classify the app (e.g., wellness vs. medical device) and ensure compliance with FDA, FTC, or equivalent bodies
- Vet third-party partners thoroughly, with clear contracts outlining data handling and liability
- Avoid exaggerated health claims in marketing; ensure all claims are evidence-based and substantiated
- Monitor regulatory updates, as digital health laws evolve rapidly (e.g., EU's Digital Health Data Space)

Financial and Market Risks

Risk: Over-reliance on a single monetization model (e.g., subscriptions) may fail if market demand shifts or competitors offer free alternatives. High development costs for compliance and features may strain finances if revenue is inconsistent.

Mitigations:

- Diversify revenue streams (e.g., subscriptions, in-app purchases, B2B partnerships with healthcare providers)
- Conduct market research to align pricing with user willingness to pay and regional economic differences
- Optimize development costs by prioritizing high-impact features and leveraging scalable cloud solutions
- Monitor competitor strategies and user feedback to adapt monetization models dynamically

Ethical and Equity Risks

Risk: Monetization may exclude low-income users if essential health features are paywalled, exacerbating health disparities. Sponsored content or biased algorithms (e.g., in mental health apps) may prioritize profit over user well-being.

Mitigations:

- Offer subsidized or free access for low-income users through partnerships with NGOs or government programs
- Ensure algorithms and content are vetted for bias and clinical accuracy by health professionals
- Prioritize ethical advertising, avoiding partnerships that conflict with health goals (e.g., promoting unhealthy products)
- Engage diverse user communities during development to ensure inclusivity

Next steps

Assess Your Monetization Strategy

Action: First identify the needs of the customer/patients. Without that information,

there's no way to tell if the product is a solution without a problem, determine which monetization strategy best fits your customer & market, or perform customer research.:

- Evaluate how or who would reimburse for the service or product
- Are there multiple potential customers to yield multiple revenue streams?
- Who are the competitors?

Action: Evaluate your current or planned monetization model (e.g., subscriptions, ads, data licensing, B2B partnerships) against identified risks (privacy, user trust, etc.).

- Create a risk-benefit matrix for each model, scoring factors like user retention, revenue potential, privacy impact, and regulatory complexity

Action: Conduct user surveys or analyze feedback (e.g., via app reviews, X posts) to understand user tolerance for costs and data-sharing

Timeline: 1–2 weeks.

Resources: Market research tools (e.g., SurveyMonkey), user analytics platforms (e.g., Mixpanel).

Strengthen Privacy and Security Measures

Action: Audit your app's data collection, storage, and sharing practices to ensure compliance with HIPAA (U.S.), GDPR (EU), or other relevant regulations.

- Engage a cybersecurity firm to perform penetration testing and vulnerability scans
- Update privacy policies to clearly explain data use in monetization (e.g., anonymized data for research)

Action: Implement or upgrade encryption (e.g., AES-256 for data at rest, TLS for transmission) and anonymization protocols

Timeline: 2–4 weeks for audit; ongoing for maintenance

Resources: Legal consultant specializing in health data, cybersecurity tools (e.g., OWASP ZAP)

Design a User-Centric Freemium Model

Action: Define core features to offer for free (e.g., basic health tracking, educational content) to ensure accessibility, reserving premium features (e.g., AI-driven insights, telehealth) for paid tiers

Action: Test pricing models with A/B testing to optimize conversion rates

Action: Develop non-intrusive ad options (e.g., opt-in, contextual ads) or an ad-free paid tier to balance revenue and user experience.

Timeline: 3–6 weeks for feature design and testing.

Resources: UX designers, A/B testing tools (e.g., Firebase).

Ensure Regulatory Compliance

Action: Consult a regulatory expert to classify your app (e.g., wellness vs. medical device) and align with FDA, FTC, or EU regulations

Action: If diagnostic features are monetized, prepare for potential FDA scrutiny by documenting clinical validation.

Action: Review marketing materials to ensure claims are evidence-based and avoid misleading health promises.

Timeline: 2–4 weeks for initial consultation; ongoing monitoring.

Resources: Health law firms, regulatory guidelines (e.g., FDA's Digital Health Center).

Build Ethical Partnerships

Financially, treatment is always going to be more profitable than cures. Getting beyond that mindset is either going to require a strong code of ethics, a customer base willing to pay for the best treatment available, or a major policy shift towards Universal Healthcare.

Action: Identify B2B partners (e.g., healthcare providers, insurers, research institutions) for monetization opportunities such as sponsored content or data licensing

- Draft contracts specifying data use, user consent, and liability to mitigate risks

Action: Avoid partnerships that conflict with user health goals (e.g., promoting unhealthy products).

Timeline: 4–8 weeks for partner outreach and agreements.

Resources: Legal team, industry networks (e.g., HIMSS conferences).

Enhance Transparency and Trust

Action: Create a user-facing dashboard or FAQ explaining how monetization works (e.g., "How we use your data" or "Why we charge for X")

Action: Launch a communication campaign (e.g., in-app notifications, email, X posts) to educate users on privacy protections and the value of paid features

Timeline: 2–4 weeks for content creation; ongoing for user engagement

Resources: Content writers, social media managers

Monitor and Adapt

Action: Set up key performance indicators (KPIs) to track monetization success (e.g., subscription retention, ad revenue, user churn) and user sentiment (e.g., NPS, app store ratings)

- Use analytics tools to monitor engagement and feedback in real-time.

Action: Regularly review competitor strategies (e.g., via X posts, web reports) and regulatory changes to stay agile

Timeline: Ongoing, with quarterly reviews

Resources: Analytics platforms (e.g., Google Analytics), competitor analysis tools (e.g., SimilarWeb)

Immediate Priorities

- Conduct a quick internal review of your app's data practices and monetization plans to identify glaring risks (e.g., non-compliant data sharing, aggressive paywalls)
- Draft a user survey to gauge preferences for monetization models and pricing
- Schedule a consultation with a healthtech legal expert to clarify regulatory requirements

Long-Term Considerations

- Explore grants or partnerships with public health organizations to subsidize access for low-income users, addressing equity concerns
- Invest in AI-driven personalization for premium features to increase perceived value, but ensure algorithms are transparent and bias-free

Conclusion

Finding the funding to launch any venture is hard enough, but health and medical products and services are particularly challenging. Within that space, digital health products are relatively new, making the task that much more difficult. And finally, the current investment climate is buffeted by economic uncertainty on a global scale, making funding that much harder to find.

But that does not mean that all development of new products and services will grind to a halt. A

good product that results in better outcomes, backed by solid science and a dependable business model will always have a chance for success. By careful consideration of the risks – and mitigations to reduce them – you can turn the odds in your favor.

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Chapter 9:
Exit Strategies and Market Opportunities

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Overview of Exit Strategies

For a healthtech venture, "exit" refers to the event in which the management and initial investors sell their ownership or equity in the company. Exit strategies for healthtech companies typically include:

Merger/Acquisition (M&A): This is probably the most common exit for successful medtech startups. Strategic buyers are often established healthcare companies seeking innovation.

Private Equity (PE) Transactions/Buyouts: This is a growing trend for mature medtech companies with stable revenue. PE firms are typically attracted to companies with established revenue streams and scaling potential. This path often involves company restructuring to optimize operations and can provide bridge financing before eventual strategic acquisition

Strategic Partnerships and Licensing: This path involves out-licensing technology or intellectual property (IP) to larger firms in exchange for upfront payments, milestone payments (depending on development/commercialization success), or royalties. Partnering and licensing allows monetization without full company sale.

Initial Public Offerings (IPOs): IPOs are typically viable for companies with proven market traction, substantial annual revenue ($50M+) and growth trajectory. This path requires substantial clinical validation and regulatory clearance. In addition, since the overall conditions of the stock markets can greatly sway the feasibility and outcome of IPOs, this pathway of exit, as compared to the other three approaches, is typically less under the control of the healthtech company management and initial investors.

The specific exit strategies for a healthtech venture will be highly dependent on not only its technology readiness levels and regulatory approval status. Market opportunities that its technologies and business model are anticipated to capture also play a major role, since such opportunities will be factored into the corporate (or technology) valuation when the venture leadership negotiates for any deals with the stakeholders that will pay in exchange for the venture's partial or full ownership.

Market Opportunities

Healthtech venture leadership needs to be aware that the most valuable assets of their will likely be its intellectual property and scientific/engineering talents. Potential investors may view the physical assets and operational/administrative components as irrelevant (except in the case of an IPO), since those parts of the companies are very likely to be stripped or reorganized in the case of M&A, PE, and technology licensing deals.

Nonetheless, whether a healthtech venture plans to pursue IPO directly or chooses to not operate in the late-stage, scaling, and maturing phases of the business, the venture leadership will always need to have a clear vision on how their products or services eventually will be adopted and disseminated into the market for revenue generation. Healthtech companies have a wide range of opportunities across seven different categories:

Care Delivery Transformation: This category includes opportunities in virtual care platforms, hybrid/telehealth solutions, hospital-at-home programs, and care navigation. Chronic disease management (e.g., diabetes care innovations, heart failure monitoring, and COPD/respiratory management) are also expected to offer growth opportunities.

Digital Health Integration Through Data Analytics and AI: This category includes opportunities in predictive analytics, clinical decision support, population health management, real-world data/evidence, AI/ML diagnostic and monitoring solutions, remote patient monitoring technologies, and digital therapeutics with clinical validation.

Consumer HealthTech: This category includes opportunities in wearable health monitors, digital therapeutics, health and wellness apps, and personal health records.

Infrastructure Modernization: This category includes opportunities in interoperability solutions, healthcare cybersecurity, cloud-based EHR platforms, and workflow automation.

Value-Based Healthcare Solutions: This category includes opportunities in hospital efficiency technologies, risk-sharing technology, quality measurement platforms, care gap identification, cost transparency tools, and preventative care technologies.

Minimally Invasive Technologies: This category includes opportunities in surgical robots and navigation systems, advanced imaging-guided procedures, and single-use instruments for infection control.

Personalized Medicine: This category includes opportunities in point-of-care (PoC) diagnostics, genetic testing and companion diagnostics, and custom implants and prosthetics.

Stakeholders and Potential Buyers

Before entering into any "exit" negotiations, the venture leadership must also acquire a clear understanding of the stakeholders that might become the buyers of their ventures or proprietary technologies. Relevant stakeholders for healthtech ventures may include:

- Large healthcare corporations (e.g., UnitedHealth Group, CVS Health, and Kaiser Permanente)
- Tech giants (e.g., Google, Microsoft, and Microsoft)
- Pharmaceutical companies (e.g., Eli Lilly, AstraZeneca, Sanofi, Novartis, Roche)
- Medical device manufacturers (e.g., Siemens Healthineers, Johnson & Johnson, Medtronic, Boston Scientific)
- PE firms
- Investment banks
- Partners/technology licensors.

Different stakeholders will have various reasons (business tactics and strategies) to buy healthtech ventures, and their capital standings will heavily impact the negotiations for pricing and terms.

Challenges for Healthtech Venture "Exits"

IPOs are typically considered the gold-standard or ultimate success of exit for technology investors. However, public markets nowadays are increasingly scrutinizing the validation of the path to profitability. Special Purpose Acquisition Company (SPAC) used to be considered as an accelerated pathway to IPOs, but recent statistics indicate that the financial performance of most SPAC deals are not impressive.

For strategic partnerships and licensing, revenue-sharing models with established healthcare providers might be difficult to build. Integration into larger health platforms can also be time-consuming and politically sensitive.

Our New Vision

As informed by history, the most successful exits typically occur for companies addressing significant unmet medical needs and market potential with solutions that demonstrate clear health benefits,

integration with the clinical workflow, interoperability with the electronic health record system, cost savings, existing or early reimbursement code approval, and strong intellectual property protection.

Therefore, our new vision points to the following best practices for healthtech business creation:

- Engage with health care systems, practitioners (the whole care team), and payors early, even starting at the stage of ideation.
- Co-create continuously with the key stakeholders throughout the product development journey and pivot quickly with frequent stakeholder feedback and market updates.
- Before investment is needed, begin to connect with and provide quarterly updates to build mutual trust and understanding with investors and potentially strategic partners.
- Monitor the policy environment of reimbursements. For example, bills such as the Health Tech Investment Act might create a new reimbursement pathway for AI-aided health care services.
- Evaluate the product's competitiveness frequently against the market landscape and be willing to abandon failing projects to adapt with agility.
- Prepare a backup/shadow pipeline of new development projects to minimize the impact of technology, market, regulatory, and competitive risks.
- Use strategic collaborations nimbly to capture synergies in complementary capabilities.

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Part III
Regulatory Challenges and Opportunities

Chapter 10: The Role of Regulation in HealthTech Innovation

Author: Alfred Poor

Introduction

Many people can look at the same scene, and each one will see something different. We see our realities through the lens of our own education, training, and experience.

We often can gain a better understanding of what a scene actually looks like by hearing the different points of view from various observers. This approach can be particularly helpful when considering complex settings that contain lots of different details.

And "complex" certainly describes the role of regulation in the healthtech industry. Different countries have different procedures. Within a single government, different products may face different requirements based on their intended use or how they are to be marketed. And within that, there can be multiple paths to approval; choosing the wrong path for your product can add years and millions of dollars to the project.

What does it take to bring a new healthtech product or service to market? What are the pitfalls to be avoided, and what strategic choices can a company — large or small — make in order to increase their chances of success?

Rather than address this issue from the viewpoint of one subject matter expert, I interviewed seven different experts who have different perspectives on the regulatory process. While there is naturally some overlap, each has their own piece of the puzzle to contribute.

Taken together, these interviews present valuable insights into the role that government regulation plays in the healthtech industry, and how companies can best navigate the complexities of the approval process.

[NOTE: These interviews were recorded and transcribed, then edited for length and clarity. The experts were given their edited interviews to review and offer corrections and edits. Those suggestions were included in this published version.]

Pathways to approval

Ashkon Rasooli, Principal Founder, EnGenius Solutions

Q: Tell me a little bit about your background, what's brought you into contact with FDA, I assume FDA clearance, and those kinds of issues.

Ashkon Rasooli: I've been in the medical device industry for about 15 years at this point, working with companies that had to interact with the FDA to get either clearance or approval of the product, or to make sure they stayed out of the zone where they needed clearance of a product, one way or another in that FDA-regulated space.

I've also had a few direct interactions with the FDA, in terms of the initiatives that the agency has had to develop for next stage regulatory frameworks.

Q: Can you say more about that?

Ashkon Rasooli: Back in 2018, I was engaged with the FDA's pre-certification initiative. I was part of one of the nine companies that they chose to pilot the program with. I was engaged in their mock audit; it was called an excellence assessment. They did not call it an audit.

Later on, I was part of a group sponsored by two public-private partnerships. We worked with the representatives from the FDA on coming up with what AI regulations might look like. The FDA doesn't currently have any official guidance or regulations on AI. They do have a good machine learning practices document, which is a set of principles.

When you look at the actual clearance reports of AI enabled devices, there is a heavy concentration in radiology. This typically looks like a back-end product that might have a web interface.

The products highlight certain details to assist radiologists in reading images to identify patterns. We call this CAD-X or CAD-E, which is “clinician-assisted diagnostics”.

So that's where the bulk of FDA-cleared devices are going. I believe you specifically mentioned LLMs in your original post, if I remember correctly.

Q: What sort of AI is being used. Is this based on LLMs, large language models?

Ashkon Rasooli: I think that it is important is we get our terminology right. AI as an umbrella term, that refers to a bunch of technical solutions. In theory, much of our standard software that we've had for the past 20 years could fit the definition of AI.

What most people talk about when they say “AI” is machine learning, which has been around for 10 or 15 years. For example, there’s Google's image processing that can identify a cat in an image. You start with a giant data set and learn from that data, then you can carry out the task.

But then a subset to that is now what ChatGPT brought to our attention in 2022, which is generative AI and LLMs.

Even though they're called large language models, for the most part, the industry has decided when we say “language”, we mean everything.

Q: It's not just text. It's images, video, and more.

Ashkon Rasooli: Right. The reason that I think the terminology is important is that the FDA has yet to clear anything with LLMs and generative AI.

When I talk about AI-enabled medical devices, they're really the classic machine learning kind of devices that are trained on a narrow task.

When I refer to classic machine learning, I’m talking about models that are trained for one particular task. We call those narrow models

Then there are foundation models that we call broad models. These can do a variety of tasks, within limitations. But the ones that are cleared by the FDA so far are only narrow machine learning models.

Q: It's easier to test the boundary conditions on those, I would think.

Ashkon Rasooli: Honestly, the idea of boundary conditions doesn't even mean anything in the machine learning world. The criteria depend simply on adequate quality assurance, and the FDA is just a little more comfortable with narrow models at this point.

Ultimately, the goal of the FDA is to ensure safety and effectiveness of devices. Their north star is safety and effectiveness.

Currently, the FDA is not comfortable with generative AI. I'm not either, to be honest. The entire industry is kind of uncomfortable and is unsure how you can validate an LLM? Nobody knows.

Q: You mentioned pre-cert. FDA also has the de novo clearance process and breakthrough designation. Have you dealt with either of those channels?

Ashkon Rasooli: I have not directly engaged with them, but I can tell you the feedback I've gotten from colleagues. The breakthrough pathway has been great, A, for publicity, but also B, for getting reimbursement. But if neither of those things are important in your business model, then the breakthrough pathways have been a little bit of a disadvantage for some companies. The idea with breakthrough designation is that we have identified your technology as worth accelerating the approval process, but we're not going to compromise safety and effectiveness, obviously.

The FDA will allocate additional resources to your project, and you're not going to be in the standard review process. You're going to get prioritized review.

Now, this also means that the company will have a lot more contact with the FDA to make sure that they get their buy-ins on the company strategy and other details.

It's kind of a pros and cons kind of a situation. And for some business models, it is definitely a way to go. For others, it's not.

Q: I've heard from some cases that a breakthrough designation is not necessarily a speedier path.

Ashkon Rasooli: Correct, but again it depends on your business model. It may not be the speedier path to market, but it may be the speedier path to reimbursement.

In medical device development, there's a thing we call "the Valley of Death". A lot of the medical devices get the FDA clearance and then they die.

And the reason they die is because they don't have reimbursement. The process of getting reimbursement is often far more arduous than the process of getting FDA clearance. This is why I say that you need to think about reimbursement early on.

I would say the same about the de novo pathway. A lot of companies are afraid of the de novo pathway. They try to position their products such that it fits within a standard traditional 510k pathway, so that it matches up with an already approved product. And that kind of ends up being their objective.

At the same time, while it is true that the de novo pathway is a longer pathway to market, sometimes it is the better decision for the business because it also becomes a moat around your castle.

You are creating a new regulation by the agency. You are given additional special controls. You become first to market under that regulation with that specific clearance. This means that your product is unique, the first of a kind. Anyone else who wants to compete with you on those exact same levels, on that exact same playfield, is going to have follow the example you set.

So again, is that of value to the business? Not all the time. Sometimes it is, sometimes the better approach is get to market fast.

Other times, I may choose to water down my technology and water down my claims in order to fit within a traditional 510K so that I can start making money sooner as a non-differentiated product.

Q: Maybe that's the better approach for the business, but I see products that are releasing a certain set of features now and shipping the product, but the roadmap is clear that they're planning to add more features in the future, you know, so rather than wait until they're ready. They

launch with the 510k features, and then they'll tack on the de novo features later when they're ready.

Ashkon Rasooli: And this is where the art of having a good regulatory strategist comes in. You need someone who understands the regulatory landscape comprehensively and can strategize around it so that you can build on that.

Q: Obviously, we're in a global economy. If you're coming out with a medical device, you've got CE, you've got Korea, you've got Japan, you've got the FDA: all these different agencies with their own hoops that you have to jump through.

How can companies strategize for an international product?

Ashkon Rasooli: I see two parts to that question. First, you have medical device-specific regulations, but then there's also non-medical device-specific regulations in general.

For example, if you've got AI in your product, the European Union passed the AI Act. It does not matter if it's a medical device application or not. You're going to have to comply with the AI Act. For that, you need to go beyond just a medical device regulatory quality management system framework.

For the medical device-specific items, though, what you're going to find is, yes, there are multiple agencies governing the introduction of medical devices to their markets.

However, there are initiatives working towards harmonizing these regulatory frameworks. One of the best-known ones is the MDSAP, the "single audit program" framework.

If you're a member of the MDSAP program, then instead of, you know, for example,

Brazil is a notable signatory to MDSAP. Classically, if you want to get into the Brazilian market, you must get ANVISA approval. And then you have regular audits every six months or so. But once you have MDSAP, countries including Brazil, Japan, and Canada will all recognize a single audit.

There are also committees such as the IMDRF that are focused on harmonizing the regulatory frameworks. But for many companies, by the time you've covered the U.S. and the E.U., the rest becomes marginal effort. That's been my experience.

Still, not all countries are created equal. Japan is notorious for being difficult. Brazil and China are also notorious for being difficult. They have their own specific requirements for certain things. This leads to a need for a case-by-case analysis.

Q: Is there anything that we didn't touch on that you think is important for companies entering the healthtech, med tech space?

Ashkon Rasooli: I think it's important to understand the intent behind the regulations. As expected, approval is slower and more reactive than for AI products for the consumer space. As a result, you're going to see the consumer market flooded with AI: especially generative AI and agentic AI.

On the regulatory side for medical devices, though, the potential failure of these models has far greater consequences and higher stakes. We're talking about actual misdiagnoses; we're talking about harm to patients; we're talking about fatalities. As a result, the adoption process understandably is going to be slow.

With that said, the application of AI in medical devices is going to be different from application of AI in the clinic in general. For example, we are already hearing about clinicians using LLMs such as ChatGPT to diagnose patients, which falls under the practice of medicine. It is scary, but it's happening. The hope is that you've got a trained clinician verifying everything that comes out of these systems. Ideally, it then becomes an assistant tool, but the current risks are real.

Q: I really appreciate your being so generous with your time. This has been very helpful.

Bringing a product to market

John Hsu, MD, CEO and Co-Founder, iPill Dispenser

Q: Please share a little about your background and what has brought you into contact – good or bad – with federal regulations for your products.

John Hsu: As an anesthesiologist and a chronic pain management addiction medicine physician, I'm supposed to make sure that patients take their medications as prescribed.

One day was actually late to my clinic and I saw my patients moving from car to car and I didn't know why. I asked one of them and they said, "You have a consent form for us for opioid use disorder treatment and pain treatment. Whenever our pill counts are incorrect, you kind of get angry and you always question us. So, from that point on, I stopped doing pill counts."

Later that day, I went to get something to eat and went to a bank ATM and couldn't get money out, so I opened my bank's mobile app, and that's when it hit me. Let's do a mobile app with a secure pill dispenser that we can send to patients' homes to reduce barriers to care.

I went home and built a model in my garage, wrote the app, and began some market test information. I found that there was a great deal of interest because of the opioid epidemic. The FDA really liked it and we won a position in the FDA Innovation Challenge program.

Then we received a breakthrough designation, and then from then on, we have been focused on commercialization. We're just about ready to launch product with Foxconn, the makers of the iPhone, and we have a pharmacy license in all 50 states.

We're now mailing dispensers to patients' homes with the drugs already installed, so patients don't have to go to the doctor. We actually treat the whole person; we combine psychosocial support for the mind and physical support with medications to prevent relapse and accidental overdose deaths. Only about 10% of people get treatment for opioid abuse disorder and I think we can make a difference.

Q: How does this differ from some of the other automated pill dispensers that have been tried?

John Hsu: Currently, this device has just one pill for opioid use disorder medications. It is designed to hold almost any size and shape of pill.

The National Health Service in the UK has asked us for it. Some Caribbean countries want to use it for chronic heart failure and hypertensive drugs.

We're developing a lineup of products: one for multiple medications, one for solutions, and one for sublingual films.

Q: How are medications loaded into the device? Does it come with a preloaded cassette of some sort?

John Hsu: We actually preload the drugs in the machine itself. If someone tries to break into it or tamper with it, we actually dissolve the medications within 20 seconds. That prevents abuse, diversion, and accidental overdose.

Q: So, you have to send out a whole new unit each time?

John Hsu: Yes, but we recycle the returned units. We have to take out parts that need to be destroyed in order to comply with the Drug Supply Chain Securities Act. Parts such as the pill tank get incinerated, and the remainder is recycled.

Q: Tell me more about your breakthrough designation. Did that make it easier to deal with the FDA? Did it make faster to receive clearance for your product?

John Hsu: Breakthrough designation supposed to make it faster, but it doesn't. We started the process in 2018 and now it's 2025. Also, it doesn't come with any money. It just puts us on the top of the list. And that's about it. Also, it didn't help the process when COVID hit.

Q: Was there a 510k path even available when you started this? Was there an equivalent device?

John Hsu: There is a predicate device, so we just elected to pursue a Class 1 registration, which means that it's 510k exempt.

Now, we're going for a Class 2 clearance and working to make sure that everything is going pass muster with the FDA.

One of the reasons why we're doing that is because we're using photoplethysmography to capture vital signs without a blood pressure cuff or EKG contacts. You take a picture with your phone, and you get vital sign data.

We're also putting a transmitter in each individual pill so that when the pill hits the stomach, we can tell who's taking it where and when. This way we can distinguish between medication adherence and medication diversion or medication abuse.

Q: Does this system require that the user has a smartphone?

John Hsu: It does. 98% of the United States population has a smartphone, according to Pew Research. If you don't have a smartphone attached to this, there's no good way to remind people to take their pills.

Q: But you're also using the phone for identification and presumably for the pill tracking to confirm that the patient took it.

John Hsu: Correct. This technology can also help make the family, friends, and the caregiver a part of the team. When the patient forgets to take their drugs, their contacts can be notified via text or email or a phone call or a telehealth session. We use telehealth plus medications to really treat the body and the mind.

Q: What's your take on the future of telehealth? Currently in the U.S. many telehealth services rely on emergency regulations, not all of which have been renewed. It would seem to me that there's a fair amount of uncertainty about what the regulations are going to be around telehealth.

John Hsu: I think that the need for urgent care facilities is permanent, but there's also an important role for telehealth.

As a physician, a patient's history is the most important part of the exam, and I can get that in a telehealth session. But if I need to examine the patient, I need to see them in person.

The problem with opioid abuse is that pain is subjective. A physical exam is crucial because I actually need to look at and feel the patient. It's also part of the medical board requirement that I do a physical exam of some sort within 30 days.

Q: That seems reasonable. We're still a long way away from just being able to do it by phone call.

John Hsu: I think it's getting closer. And, you know, I'm a fan of technology. Elon Musk's Optimus and the DaVinci robotic operating system are giving us new tools for remote patient monitoring. Soon, we're going to get to a point where we can do telehealth and actually feel and be able to push on different parts of the body so that we more information for a diagnosis.

There's still something to be said about interacting with someone to see micro-expressions and so forth.

Q: Where does iPill stand in the FDA clearance process at this point?

John Hsu: We're FDA Class 1 registered. We're FDA Class 2 submitted. We think we will probably get a de novo approval for the Class 2 device. The contactless vital sign capture is already Class 2 approved. The small little transmitter on each pill is already approved.

But just because you get FDA clearance, that doesn't mean you can get reimbursement from the payers, such as Medicare or other insurers. If you don't have reimbursement structure, you do not have a company.

You have to go to Health and Human Services; a breakthrough designation is supposed to be helpful with that.

But one of the most intricate things and innovative things that we're doing with iPill is that we're not to going after insurance.

Instead, we're going after companies that will pay us ahead of time because they feel that our product can save lives and save money, which is way beyond getting insurance reimbursement.

Q: For a new company setting out to navigate these waters, any words of advice for people who think they've got a medical product?

John Hsu: Yes; you need to have a good engineer, a good attorney for IP, and a consultant for FDA.

You need to have a good fundraising consultant, or you need a lot of know-how of your own. Patience and perseverance are the two most important qualities.

Q: What about working with the FDA?

John Hsu: The easiest thing to do is to get to them first and see what needs to be done. Treat them as a collaborator, not as a competitor. That's the most important thing that I learned, even though I fought tooth and nail with them at times.

I think one problem is that the insurance companies haven't embraced some of the innovation that the FDA is pushing forward, and it's holding back patient care, honestly.

Q: Is there anything else that we didn't cover that you think is important?

John Hsu: Yes; as a founder, you need to have thick skin. You know how many pitches I gave before I raised money? Everyone was telling me that I was wasting my time, that no one's going to pay for the device, that no one's going to want you. They said that I was a doctor, and that no one's going to believe that I am going to be a good businessman, even though I had already created five successful companies.

You can't let that discourage you. Just focus on building relationships based on mutual respect. Learn from your mistakes and stay humble.

Q: That's sound advice. Thank you for being so generous with your time and knowledge.

Interacting with the FDA

Steven LeBeouf, CEO and Co-Founder of Quellios

Q: If you would, please share a little background about your experience with the FDA clearance process.

Dr. LeBouef: My first exposure to FDA clearance was in my past company, Valencell, and it was literally not through a Valencell product directly, but through partner products.

With Valencell, a large part of our business was B2B licensing of our technology. I'm not going to say the name because there still could be some confidentiality there, but we had a customer that was pursuing FDA clearance. We had to make sure that our manufacturing of the sensor modules – as well as the software that we provided them – met the FDA's criteria for compliance. As a result, we witnessed their battles and how they went through the FDA.

Ultimately, they had to take the de novo pathway because there was nothing substantially equivalent to what they were doing.

Now, when I look at what they went through, if they had known to take the de novo approach right away, that would have been better for them, even though the de novo approach does take longer. If you know that and you just plow through the process, the timelines can be reasonable.

Q: Are we talking years?

Dr. LeBouef: Yes, maybe two years, which sounds like a lot, right? But let's say that you went with the 510k approach. When you submit a 510k to the FDA, nine times out of nine, they're going to reject it.

I mean, there's a few times where they won't. Maybe somebody's on vacation and so the intern's there and the intern stamps it.

But the reality is that you're not going to get a 510k approved the first time around. So, you need a budget for that delay.

You're talking about a minimum of six months, and it's longer than that because you're going to have to make some changes in between submissions. So, in reality, it's nine months. So now you're already a year into the process, and you may not even get it this next time.

And you're constantly trying to force feed your solution into a predicate device that came before.

If I were going to launch a new cuffed blood pressure device, for example, I would definitely just take the 510k route. The science is already there, so there are no new tests required; you use the same tests as before. In three months, you get a result, and it should pass.

But if it's something new, you really need to consider the de novo approach. My next experience I had with the FDA was when Valencell decided it was going to make its own product in blood pressure device that was worn on the ear. It was not as accurate as a cuff, but it could track your blood pressure rather than infer it from some other data.

The first thing we tried to do was get a general wellness exemption, because the FDA has a 513g provision for general wellness products.

For example, the heart rate on your wearable device, the breathing rate on your wearable device. And to some extent, even some versions of SpO2 on your wearable device are considered to be general wellness solutions. This means that you don't need to get a 510k clearance from those from the FDA because the FDA said that those things are generally understood to be used in wellness situations that don't necessarily lead to a medical diagnosis.

Rather than just launching our device, we approached the FDA about getting a 513g classification. Their response was that if you use the words "blood" and "pressure" together, they view that as giving someone a diagnostic reading.

They still hold that position to this day, and frankly, I agree with them. Their argument is that if you tell someone their blood pressure, it's different than telling someone their heart rate.

If your heart rate is 180, you're just exercising maybe, and so you're just trying to stay within a heart rate zone. It doesn't necessarily mean that you're going to die. But if your blood pressure is 180 over 100, that's getting close to where you could probably die soon.

And many consumers know that; they know those numbers mean hypertension and there's no way to unknow that. It's not like 180 over 100 is ever good in any normal situation where you're going to measure blood pressure. But blood pressure can vary a lot in the moment, such as when you exercise strenuously, even though it will drop back down to normal range when you stop.

As a result, we had to pursue a clearance. Now, in hindsight, I think we would have been better off taking a de novo pathway, but we decided to pursue the 510k approach.

And in that approach, we would compare ourselves to the cuff. The challenge is that the FDA has special tests that they demand on devices that aren't exactly the cuff if you want to get a 510k.

Q: The device that you were creating is one that looked like a pulse ox clamp on the end of your finger.

Dr. LeBouef: Exactly. We decided that we would pursue what we call the fingertip BP device. It's a pulse oximetry type device, but rather than providing you blood oxygenation, it provides you your blood pressure reading as a spot check.

And that solution we developed, and we decided to pursue a 510k. The challenge, though, is that the tests that you have to go through are still pretty rigorous, in order to claim substantial equivalence to a cuff.

You are fully free to pursue a de novo pathway instead, and I do believe that more companies need to view that as a possibility for things that aren't just blood pressure.

For example, Apple was able to pull off a de novo clearance with atrial fibrillation monitoring at the wrist. That worked out really well for them, and since then other companies have gotten a 510k based off Apple's de novo. But had Apple tried to get a 510k, they could have gone years trying to do that.

So, you do need to balance it out which is best for you. But if your business model depends on a quick launch for your medical device, you might want to find another business.

Now, some companies have tried to make a decision as whether or not just to launch without the FDA, and I do advise that approach in some situations. If you have a wearable tech health product that does not make a medical claim, then don't pursue the FDA clearance. This means definitely no blood sugar and no blood pressure devices; those are the two hot spots. But there are so many other things you could do.

For example, one of Valencell's customers was a company named GoGoBan. They were actually detecting childhood in enuresis. If a child is about to wet the bed, it was able to detect that and wake the child.

They weren't making a medical claim. They were not diagnosing whether your child had enuresis. They were just simply indicating that your child might wet the bed. In that case, they didn't pursue 510k. They never got an FDA letter. They never were pursued in that particular way.

And so, I do advise companies to think about ways to launch a product if it's in healthtech where you don't have to make a medical claim.

Q: Going back to the Valencell fingertip blood pressure device, as I understand it, there was a lot of data collecting and machine learning because you were going for a non-calibrated device.

Dr. LeBouef: That's right. You didn't have to calibrate with a cuff.

Q: Machine learning and AI in general are playing increasing roles in healthtech. What are your views about how these large data sets can play a role in the development of this new healthtech? And what's the appropriate role of regulation to make sure that the conclusions that machine learning comes up with are valid?

Dr. LeBouef: The FDA has been proactive in trying to give people a paradigm for what they need to report in the machine learning.

And everything they're talking about makes sense. Now, what I do hate about it is, you never get anything from the FDA that is just, boom, a one-page of what you've got to do.

Instead, you get mounds and mounds of information, but to get to the roux of the gumbo, they want to make sure that you understand what your training sets are, and your testing sets are.

The training and testing sets must never, ever overlap. You have to identify and isolate all the co-founding situations that potentially could change the output. There are some other things that they have a lot of concern about there, but that's the most important.

Where people really get into trouble with machine learning is when they develop a model and they test it on the same data that they trained it on. The problem with this is that all you've done is create a filter that's perfect at characterizing your training set. If you train a model on 10,000 people and then test it on those 10,000 people, it's going to work perfectly.

On the other hand, if you train a model on 10,000 people and then apply it to a completely different set of 10,000 people and it still works, then you have something that works.

However, it is disconcerting when you train a model on 10,000 people, in reality it's not going to work on 10,000 people perfectly. It will always be less than perfect. But the question becomes, "Does it work good enough still to be useful?"

With things like blood pressure, the FDA has very well-defined ranges of what useful is. In other things, such as diagnosing childhood enuresis, there's not a device that has been cleared to do that today so there's nothing to compare it to. You have to set up your own parameters and then present that to the FDA.

That's part of the de novo process, but the provisions for that are clear before you start. Then if you train on 10,000 people and test on 10,000 separate ones, and it's good enough, then it's good enough.

Q: But doesn't the makeup of training and testing populations matter?

Dr. LeBouef: The FDA has a provision for this; your training and test sets need to be broad enough to include the market for intended its use.

For example, if you want to get your cuffless blood pressure device cleared and you narrow it down to just people of a certain weight, the FDA will let you do that.

But if you're using machine learning, you need to show that your training and testing sets had those people.

There's nothing egregious in this policy. It's basic, good housekeeping of machine learning.

Q: So, in developing a product, you can put guardrails up. I've seen products that say that if you've got atrial fibrillation, you can't use their product.

Dr. LeBouef: Yes, and there are companies that have clearances for blood pressure of people only in certain age ranges, such as only infants, or people of only certain wrist sizes because the wrist size is critical to how their technology works.

The folks at the FDA are not unreasonable at all. What is unreasonable is that I still feel that a lot of what the FDA communicates is not clear enough to the average entrepreneur.

You know, entrepreneurs are not idiots. We're pretty smart, but when we struggle to understand what the FDA is communicating, that's a real problem, and they need to figure out how to improve that.

Q: One of the things I've heard is that if you start with conversations with the FDA early in your product development, you're kind of stuck going through that channel. It's hard to unring that bell.

Dr. LeBouef: That's a great point. It's a blessing and a curse. If you want to launch your product in a reasonable timeframe, then you need to start conversations with the FDA soon.

At the same time, if you start conversations with the FDA and they take you in a certain direction, that's the direction you're going to go down.

This means that you're forced to find good consultants early on to help you with that strategy and realize that when you start executing that strategy, it's going to be a challenge to veer away from it.

We fell under this at Valencell. Looking back, we probably shouldn't have had to agree to some of the provisions, but we had taken that path, so we were committed to them. Forget about trying to go backwards.

Q: On balance. Would you say that the de novo pathway encourages innovation.

Dr. LeBouef: Yes. Your product doesn't have to do it the way we've always done it. But if you decide to go a de novo route, it's critical to find a consultant who has experience on that pathway.

In any case, anything new with the FDA is going to be a long road, and you need to be prepared for that.

Q: Thanks! This has been great information. I appreciate your sharing your time and experience to support this project.

The challenges of novel devices

Robert Rose, Chief Officer, MD Remote Connect

Q: Please share a little context about your history with regulation in the med tech space.

Robert Rose: Most recently, we started development of MedWAND in 2014. And we were to start FDA clearance by about 2017 or 2018.

The device has multiple sensors. It has a pulse oximeter, an ECG, a high-resolution imaging system, a digital stethoscope, and an IR non-contact thermometer. And while the stethoscope and the camera were exempt from FDA clearance from 510K, the others were not. So, I had three different devices and one handheld device that had to be cleared, but they also required us to clear the entire device for safety. This was like doing at least four devices in parallel, each of the three that required 510k plus the entire device itself.

Some of the requirements were appropriate, but some were silly and forced us to do some major redesign work along the way. It ended up being a five-year journey -- across a pandemic as well -- to clear the device.

Some of the hurdles were regulatory requirements. For example, the device is tethered by a USB port to a tablet, and the tablet's plugged into the wall. They want to be sure that if you're using the ECG in a thunderstorm and lightning strikes your house, and the lightning comes through all the safety things in your house to the power supply, into the tablet, out of the tablet, up the USB port, into the device that you don't get shocked while doing an ECG.

That sounds a bit like the of Hound of Baskervilles not barking; how do you prove that's not going to happen? Well, you can't. You have to design a failsafe to cause it not to happen.

So, we had to design an isolation board for the power supply side of the device, which we then had to fit inside, which meant we also had to retool because once we had the board, it had to be mounted.

And I mean, it was very arduous and expensive. That was just one of those examples of where regulatory can be over the top, I think, in that case.

Q: Time to market can make or break a project because you're aiming at a certain price point in a competitive field that is changing rapidly. I know from the display industry, if you missed by six months, your project was dead.

Robert Rose: In this case, it didn't so much cause the project to be dead, but it did cause us to transition from having our clearance.

It was being issued during the pandemic where we could have had some substantial impact by keeping people home and out of clinical settings. Telemedicine wasn't cool when we started even though it is now. The time to market impact was significant and these are things sometimes you can't project when you're in the FDA cycle and regulatory space.

There's also the issue of the IRBs, the review boards, the protocols for various FDA clearances. These protocols are approved by the IRB before you even begin the study.

Q: You mentioned the retooling, redesigning, coming up with new manufacturing, but also there is just the cost of the new testing. And this can cost millions, right? A lot of startups don't have that financial shock absorber to be able to survive that.

Robert Rose: If you're in the hardware design business and medical equipment, yes, you've got to have the funding depth to be able to absorb those kinds of things. And you really can't predict them. Depending on what you read, the average cost to bring a product to market regardless of the size of the company is around $30 million for a simple, single-clearance type of a product. This would be for a new pulse oximeter, for example.

Q: It seems that a lot of products are sold that do not appear to have FDA clearance.

Robert Rose: You can go on Amazon, and you can buy remote patient monitoring devices from China and everywhere else that are not FDA-cleared. They get around it by calling it a wellness device.

I think our medical community is savvy enough to know the difference. But for end users, not so much. If something isn't clinical grade, it can mislead you.

The regulatory process is important. I know that when we were testing ECG, we found some things that needed to be cleared up in our ECG traces because of the FDA requirements; it was appropriate.

It's important to recognize where the value is. In the clearance process, you're going to get hit with stuff that doesn't have a whole lot of value.

One of the more difficult things to navigate with FDA, and I suspect it would be true with any government agency today, is the inconsistency of people. Often, you're dealing with one person leading the project this week, and then you come back in three months after you've done what that guy asked for, and there's somebody else who has no idea what you're talking about and asked for something else.

That's been challenging and it's getting worse now under the current administration with the cutbacks; you don't have as many people to work with. It's important to maintain continuity in who is doing the reviews.

Q: Can you talk a little bit about the guidelines that you have to meet. As with blood pressure, there's a certain range of accuracy that the FDA requires. Is the difference significant or is that acceptable range too great or too small?

Robert Rose: It's funny you should bring up blood pressure because it's kind of a black art. But, you know, some devices are – by definition – more accurate than others and can be tested for more variables.

I'll use the IR thermometer as an example. As we were going through the testing process, we had to look at the interactions between ambient air temperature, relative humidity, and the skin color; you do a whole design of experiments around that, but within a range.

The FDA or the IRB protocols allow for a range of, let's say, ambient of 60 degrees to 105. If you go outside of that you're away from the plus and minus guardrails. That's okay, so long as your results are based on working inside of that prescribed range.

You have to know what the limitations are to the device. With blood pressure, there's a lot of variation in the results based on different factors: white coat syndrome, whether your legs are crossed, is it your left arm or your right arm, and are you upset about something.

Blood pressure is a bit of a black art, but it's also interesting because right now we're going through clearance on an optical blood pressure system that uses the camera on a cell phone or tablet. It does not require calibration. This is pure optical blood pressure, and it works, and it is CE cleared now.

It's actually got CE2 clearance which helps as we're bringing it to the United States. This is my new company doing this, as part of our MD Remote Connect platform.

But it's an app, and we have been cycling with FDA on this, and there's no way that we can go back through the normal blood pressure guidelines to get this cleared; it has to go through the de novo process.

Q: That's interesting. So please talk a little bit about 510k versus de novo.

Robert Rose: 510k implies a precedent. Let's say that I've got a great blood pressure cuff and monitor and I want to get it cleared; you pick a predicate product. I go out and I find an iHealth or a Tenovi or whoever has a similar device that's been cleared, and the predicate has met certain standards and certain guidelines.

As long as you fall inside of those guidelines, and you can show that you can perform as well as and as safely as that device, you can obtain clearance.

But with de novo, you're establishing the guidelines for a new class of product. This leads to a more rigorous IRB review to start with.

In the case of our optical blood pressure, we're not touching the patient. Other factors now come into play with an optical blood pressure system that weren't there for a traditional cuff, such as ambient lighting. So now we have to test to other variables.

And these are without guardrails. We kind of make it up and then hope that they approve it.

What you're doing is you're establishing the predicate device when you take the de novo pathway. And the next guy who comes along will have to meet your predicate.

Obviously, it's more expensive to go to de novo route because you have to convince FDA that some theoretical aspects are tangible.

Q: So, de novo does offer kind of a defined path for innovation. While 510k is really doing it like we've done it before.

Coming back to the focus on innovation, what I'm hearing is that, to a large extent, regulation is a good thing because it provides guardrails, ultimately for the end user's benefit. But is it a drag on innovation?

Robert Rose: I'd say that it's a necessary obstacle. In its purest form, it's there to protect the public from, you know, medical devices.

We want to return accurate readings. We want to be able to give a clinician reliable information about life and death decisions for a patient

Q: And talking about data, it's also who's going to be the consumer of the data. For example, new parents often aren't equipped to understand the data from their baby monitors.

Robert Rose: Right. Even doctors have a tendency to look at blood pressure as an indicator and they can panic.

If you have fairly normal blood pressure and you eat a high sodium meal such as a pepperoni pizza, your systolic blood pressure will spike to 180 or 190. Or you take your blood pressure after if you exercise a lot and it's 350 over 210, the immediate reaction is to panic and call an ambulance, right? But not really, because if you recover for a few minutes after the lift, you're going to be back to 120 over 80.

I participated on a panel a few years ago where everybody made the same statement; trend analysis is everything. But we tend to look at results from FDA-cleared remote patient monitoring devices as a point in time without applying context.

We have to apply common sense to what we're seeing from one of these devices. That means trend analysis, because you might be looking at an outlier. While you're trending in the right direction, why did this spike 30% today? Maybe it was an anomalous reading, so the clinician has to be very aware of what they're doing with the readings and not just reacting.

You also need predictive analytics, which leads to the cool thing about the recent advances in AI. Let's say you have a home blood pressure device, and even though there are outliers, when you look at the scatter plot you can put a linear trend line through it. With this, you can predict almost to the minute when a patient is going to cross a limit that is going to require further attention.

But without that, blood pressure is just a number. And all the clearance in the world doesn't change that.

All regulatory requirements are not bad, that's for sure. Sure, there may be some rocks to navigate in there, but, you know, for the most part, I would say I think we're better off with it than without it.

Q: And so, you know, you mentioned that you got CE clearance for your device. Does it help to have different standards with different countries?

Robert Rose: No, absolutely not. The FDA is robust. CE is fairly robust. I think that there are a lot of commonalities between the two. CE obviously covers the entire EU, except the UK, though it is still accepting CE right now.

So those two cover about 860 million people, which is a big portion of the global market. There are lots of places on earth that will look at FDA clearance and still require you to check all the other marks from an international commerce standpoint, and then they'll accept the FDA approval.

And then you have others that require you to go through the process again, while in some places there are no regulations at all, which in my opinion is just as bad.

Q: Yes, that's dangerous.

Robert Rose: So, it's still kind of the wild, wild west out there. I wish there was an international standard; it would make things a lot easier. But that's not the case currently, and I don't see any value in multiple regulatory authorities.

Q: Well, thank you so much for your time. I appreciate your perspective on these issues.

AI drives innovation

Nathan Buchbinder, Chief Strategy Officer and Co-Founder, Proscia

Q: Please start by sharing a bit about your background and how that relates to the topic of regulation.

Nathan Buchbinder: I was studying biomed engineering at Johns Hopkins when one of my other co-founders, David, and I were doing some research in a couple of cancer labs at the medical center.

We saw that pathology was woefully behind its other areas in terms of digitization, yet it had the biggest potential out of any medical field to take advantage of data-driven medicine and the shift towards a precision approach to drug development and drug delivery.

So that's where the concept of Proscia came to be. Proscia is a digital and computational pathology company. We are taking this very analog field of diagnostic medicine that has depended on 150-year-old technology: looking at a glass slide under the microscope and making an interpretation that influences 70% to 80% of downstream healthcare decision-making and spending.

We're taking that analog process and helping to transition it towards digital, towards the data-driven paradigm, where you can drive insights from digital images of these biopsy tissue specimens. You can then learn much more about the patient as well as develop new drugs that are targeted based on the patterns that are represented in histopathology.

Our platform, Concentric, is a software solution that serves as an operating system for these image-based workflows, both in the diagnostic world as well as in the research domain. Today, we serve 16 of the top 20 pharma companies, the two biggest clinical research organizations (CROs). Something like 80% of global clinical trials are supported by our customers.

And on the diagnostic side, we support somewhere around 8 million patient diagnoses every year, and that's more than doubling every year.

Q: Is this similar to what has happened with other medical imaging such as x-ray, CT, and MRI, and how digital imaging can have AI do some analysis to support the human doctors?

Nathan Buchbinder: It is very similar. The shift to digitized radiology happened about 20 to 30 years before the shift to digital pathology started. And I would say that radiology was a little bit more natural of a shift because the devices themselves that captured these images fit so smoothly into the workflow.

You went from a process that required physical image generation to something that required just purely digital image generation. In pathology, it's a little bit more challenging because you're introducing a new step in the process.

You still create the glass slide, but now instead of looking under the microscope, you have to take it and put it in a scanner and create these big images.

But I would say that the potential benefits are so much greater in pathology that other medical imaging. In radiology, your average image is dozens to maybe hundreds of megabytes in size. But there are a billion pixels — a gigabyte of information — stored in each and every one of these histopathology images, this data represents the patterns that underpin diseases such as cancer, which could reveal the specifics of who to treat and how to treat them with the treatments that are going to work best.

Q: I've seen how the digitization of medical data has led somewhat to democratization of health access. Is there a roadmap that takes this out of the wizard's hands in the basement to bring it out to the field where you can shorten the loop on analysis and diagnosis?

Nathan Buchbinder: Yes, absolutely. There are operational benefits of going digital that allow you to decouple the physical location of the pathologist and the specimen from each other.

What that means in practice is that if you have an expert pathologist in a particular subspecialty, say renal cancer, but they're based somewhere else in the world, you used to have to FedEx that glass slide for them to look at.

Q: And that's the one and only specimen, right?

Nathan Buchbinder: Exactly. Not only does shipping take days, there's a risk of the sample getting lost. You can't do anything meaningful while it's in transit, but with digital, you get instant access.

Once the image is generated, you can share it with that expert, and they can provide a review. The other thing that it does is it solves what I would say is an even bigger challenge in pathology, which is the deficit of pathologists.

The number of pathologists over the last 10 years has steadily declined by between 1% and 2% per year, while the number of cases that pathology is seeing has gone up by about 2% to 3% per year.

That imbalance means that an average pathologist today reads about 40% more cases than they had to 10 years ago to just keep pace.

That's not sustainable, and digitization allows you to address some of the geographic challenges that come up as a consequence. Sparsely populated regions such as much of Wyoming don't have a lot of healthcare resources. People all over need access to the best care, and digitization allows us to spread out that imbalance between where there's a big supply of cases and where you have the expert pathologists to review the images. You can give more immediate access in real time to the best experts around the world.

Q: This relies on a whole lot of novel technologies, which I think leads us directly into the government. What has your experience been with government regulation? Has it encouraged or has it inhibited new technologies such as yours?

Nathan Buchbinder: If you're using digitized images to drive the diagnosis for a patient, that's considered a medical device. The different components of that process are considered medical devices. The challenge for us is that this is a completely new domain.

It's something that the FDA had to create a new device category to support because there was no predicate. There wasn't a medical device that was already cleared that we could use for a 510k submission. So, the initial approval had to be done as a de novo application, and that took a lot of time.

The FDA had a lot of questions for us, such as how do you treat each of the components of this process?

The scanner that's creating the image, the software that you're viewing the image on, the monitor that you're actually looking at to make the diagnosis, the AI applications that come afterwards, is that just one device? Or are they multiple devices? Can they be separate so that I could pick and choose different components? And the FDA initially took a relatively conservative approach.

They defined an end-to-end pixel pipeline that included the scanner, the software for the digital pathology platform, and the monitor. They required us to go through the clearance process using these three specific items.

Everything's locked in. You have to prove that there's no disparity between the image quality and the composition of the image data.

As you substitute in or out different components, you have to do a lot of studies, sometimes clinical studies, to demonstrate that there's no difference in the diagnostic process when you're using different equipment.

AI has been a whole other behemoth. And I think this is true beyond pathology. What I will say is that on the one hand, candidly, the FDA might have been perceived as an inhibitor of digital pathology adoption early on. Before there was any clearance, it took a long time to get those clearances. There wasn't an enormous amount of clarity.

Recently, however, the FDA has engaged very dynamically with industry and with those that are using the medical community to better understand what's happening in practice, to adapt their approach, to develop mechanisms by which industry is able to innovate a bit more rapidly and allow for a bit more flexibility in how things get deployed.

A good example of are the predetermined change control plans: PCCPs. This is a mechanism that allows you to future-proof a regulatory submission. It allows you to define in advance the criteria that

must be met for you to then extend a regulatory filing or extend an approval to new software later on.

Q: So that could enable you to use a different monitor, for example, as long as makes it meets those criteria?

Nathan Buchbinder: Yes, it is now much easier to get approval to use those additional monitors as just one theoretical example. And we're seeing the FDA be very responsive to the changes in AI.

I'd say that from an FDA perspective, they're there for a reason. They're there to keep patients safe, to ensure that what's being brought to market is safe and efficacious, that no company is making claims that they can't back up.

On the other hand, I don't envy them the position that they're in. Technology is changing so quickly. The theoretical potential of all of this is so enormous.

But there's not necessarily a standardized way, if you look at this from the industry, from the medical and clinical community, and from a regulatory standpoint.

While I wouldn't say it's been a bottleneck to date on the AI front, I think we'll have more clarity in the next two to three years that'll help drive innovation.

Q: I think people are really, in all fields, but especially health and medical, are trying to wrap their head around just what AI is and how it applies to these kinds of products and services. For example, there's the whole question of what population you are using and data gathering procedures you are using for your training and testing data?

Nathan Buchbinder: Generally speaking, I see a lot more openness and a lot more effort being put into understanding where the technology is heading, and how to adapt regulations and standards and approaches towards that.

I'm not suggesting that any one person or group has the answer right now, but the mindset change has been noticeable. It's certainly encouraging that government can partner with industry and have solid awareness of where the industry and clinical practice of medicine are heading. The FDA is willing to adapt their approach to what the future looks like and to encourage that kind of innovation.

Q: Are you seeing a lot more de novo applications in recent years than traditionally?

Nathan Buchbinder: In our space, we're certainly seeing that same kind of thing, and we expect that to continue because, again, the types of things that technology is going to be able to do or that it can, in theory, do today are so different than what was possible even just two or three years ago.

You're going to start to tackle indications. You're going to start to tackle diseases and use cases in clinical practice today that would have been unimaginable two or three years ago.

In these cases, there will not always be a predicate. There's going to need to be new thought that's given into what the riskiness of a certain device is in a certain scenario.

What controls need to be put in place to ensure that you're safely delivering this in a way that benefits the patient and doesn't add new risks?

Q: From the outside, it seems to me that AI can handle complex factors such as comorbidities better than the individual healthcare professional working off their own experience.

Nathan Buchbinder: The promise of AI is enormous, but I want to be clear, there will always be a very critical role for the medical practitioner, for the pathologist, for the radiologist, for the oncologist, whoever it might be, to play in this process.

And it's not simply as a translator of AI results to the patient. AI is extremely adept at pattern recognition, it's able to catch subliminal hints of something that might be missed, it's a phenomenal second set of eyes. And it's an extremely rapid mechanism of interpretation. It will catch things sometimes that a pathologist or a radiologist might miss.

But there are always going to be those edge cases, situations where the human knows better or is aware of information that's not been pulled into the

AI application. I think that AI allows pathologists and other diagnosticians and medical practitioners to practice at the top of their license.

It's allowing them to avoid spending their time on the extremely mundane, on the extremely time-consuming manual aspects of their work, on the stuff that doesn't have anything to do with their training as a medical doctor and has more to do with the paperwork and the logistics and the mechanics and the very basic aspects of diagnostic or clinical medicine. AI technology puts those into the bucket of automatable tasks, so that the healthcare professionals can spend their time focusing on the most challenging and complex cases and armed with new tools that allow them to derive new insight from those cases.

I think this is where healthcare is heading, and we're seeing the changes happen very rapidly. And again, we've seen regulators recognize that that's the case.

We've seen CMS start to track some of this, to get a sense of where this is making an impact, who's using these types of technologies, who wants to use these types of technologies, and modify their own behavior as a consequence.

And at the end of the day, the one who benefits the most is the patient. The patient is the one who gets a faster diagnosis, faster turnaround. The patient is the one who gets more insight into what's going on with them and what treatment they should pursue.

The patient is the one who feels more confident. It's not quite the case in pathology today, but in radiology, for example, I don't need to tell you that it's not uncommon for a patient to receive their radiology results before their physician sees them.

Pathology is not that far away from that same type of behavior. And again, the patient is the one who gets the better outcome.

Q: So, have you been engaged in international? We've got CE, we've got FDA, Korea's got their own clearance requirements. There seem to be all these different hoops to jump through.

Nathan Buchbinder: We've obtained many of these regulatory certifications or clearances or approvals in, I think, over 30 countries at this point for our solutions.

What's interesting is that historically, I would have said that Europe and other geographies were ahead of the U.S. on the innovation curve. Five years ago, Europe had a much easier mechanism of driving innovation.

But that's starting to shift. We are seeing much more nimbleness from the FDA, with a forward-looking approach that is more dynamic and conversational and open This allows us and others in our space to make decisions with the confidence that there'll be an open-mindedness to the path that needs to be followed to get a novel, innovative solution to market.

Across the board, domestically in the U.S., as well as internationally in Europe, in Southeast Asia, in Japan, in China, we're seeing a big push towards the advance of medicine and the incorporation of novel technologies to make that happen.

Q: That's encouraging. Finally, is there any point that you want to make sure that we cover?

Nathan Buchbinder: This transition to a data-driven approach in diagnostic medicine is having a corresponding impact in drug discovery and drug development.

Big news was made this past year when AstraZeneca brought out a new Phase 2 clinical study that they were conducting, with an image-based AI-powered companion diagnostic.

Essentially, a precision diagnostic that indicated — or that will indicate when it gets approval — whether an individual patient is or isn't a good fit for a targeted therapy that has a very high response rate.

And we think that this is a sign of things to come. We think that this data-driven, data-rich transition that medicine has taken —and pathology in particular — is not just better for the clinician, for the pathologist who's trying to make sense of the patterns that they're trying to interpret on an individual patient level, but it's also opening up a whole new world of drug discovery and drug development to deliver precision therapies beyond

just delivering a new form, a new mode of insight, a new data modality.

It is also creating a new means of interpretation in diagnostic practice in a way that translates into decision-making about which therapies to provide.

It's driving access to patients through insights that are not localized to an individual pathologist, but that can be extracted and delivered in a standardized way, and that can help drug developers.

Let's bring these novel therapies to market faster and drive accessibility to these precision therapies and diagnostics to more patients. And so, this whole thing comes full circle.

Digitization and AI in the diagnostic world leads to obviously better diagnosis and treatment for an individual patient. It also accelerates drug discovery and the development of precision therapies that then transfer back into diagnostic practice and encourage more and more distinct avenues of digitization and AI in the clinical world.

So, it's a flywheel, and we think that it's starting to spin pretty rapidly.

Q: That's an exciting vision. Thank you for sharing your time and insights to support this project.

The value of outside advice

David Lennarz, Founder and President at Registrar Corp.

Q: Please tell me a bit about your company and your interaction with the FDA?

David Lennarz: Registrar Corp. is a 22-year-old business that helps companies regulated by the Food and Drug Administration comply with their various regulations. We work not just in the medical device sector, but also pharmaceuticals, cosmetics, and food and beverage as well. We focus on three main offerings: services, software, and training.

First, we have 30 to 40 different services that we provide to companies around the world. Most of our clients are foreign companies exporting products to the US or are involved in the supply chain somewhere.

We also have software products that we commercialize. The third focus is on training; we have an online, 100% online training platform with asynchronous learning courses that individuals can take, covering medical device regulations.

In the area of medical devices, I could call it med tech, but we handle everything from eyeglasses which are regulated as a Class One device by FDA, right on through to an artificial heart, for example.

We have a partner who handles the more technical or scientific oriented submissions, such as 510ks for products that are not exempt from requiring clearance. These are higher risk products that actually require an FDA review and are based on a predicate device that is already on the market.

There is also a pre-market approval process for products, and pathways as for novel products as well.

Q: That's helpful. In your view, how does regulation help or hinder innovation?

David Lennarz: Our perspective is shaped by our prospects, which includes literally everywhere in the world, including the U.S. They often come to us with an assumption that there's a very easy pathway to getting their products to market in the U.S. This includes prospects who are creating products here in the U.S.

Q: It sounds as though you work with a lot of founders of startups.

David Lennarz: Actually, there are a couple of types of prospects. Certainly, a percentage of them are startups.

But there's also a large percentage that have products that are already commercialized in another market. They might be in the EU, or Thailand, Taiwan, China, or India, for example. And they're actually producing this product and they're selling

it in their country and they're exporting it to other countries.

Typically, there is a sort of an initial surprise, even shock; they feel overwhelmed by what they need to do to be able to get their products onto the U.S. market.

These companies will come to us and say, “Here's my device. I've been commercialized this in Taiwan or wherever, and I've got a buyer in the U.S. that I'm going to export it to next month.” We have to tell them to slow down, and we explain what the process is.

Obviously, if it's a Class One device it’s exempt, and we do lots and lots of Class One devices. Still there is a registration requirement.

There's a product listing requirement. There's proper labeling. There are good manufacturing practices – GMPs – that have to be followed. But that's a fairly simple, quick process that takes of a matter of days to weeks to get through.

When it comes to products that are not exempt, know, step one is to determine how the product is classified. It takes a lot of time and money to obtain FDA clearance for a medical product. Once a company understands what the pathway is and the cost associated with that process, that can just close the door on their project.

All registered FDA products – whether they are exempt or not – pay an annual fee of about $11,000. This can be an expensive obstacle for something simple such as eyeglasses.

The fee is based on the actual costs of running the registration program at the FDA and can go up or down, but mostly it tends to go up.

Large companies can afford this fee with little difficulty, but it can be a significant obstacle for small companies and startups. I think these fees are one of the greatest reasons that we see the stifling of innovation.

And again, I’m not even talking about the fees to submit a 510k or a pre-market approval, which are even more.

Q: And then there’s the testing required to prove that the product does what you say it does and is safe and effective.

David Lennarz: Yes, there is all that other stuff that a company has to do for FDA clearance. This money doesn't go to FDA; it goes to independent companies to do the testing.

There is a Small Business Determination program where a company can qualify for a reduced FDA user fee, or have it waived entirely.

Q: But do you see this impacting the attitudes of the investors who might be more hesitant?

David Lennarz: If I were an investor in a med tech startup, I'd want to be darn sure that the inventor and small business owner who's doing this has clearly done their homework around their strategic pathway for being able to market this legally in the U.S. The last thing I'd want is to find out that, they need an additional $200,000 to get this through an approval process.

It's another thing for companies that have a product that is already being commercialized elsewhere in the world. And then they and then they say, hey, our strategy for next year is to enter the US and then they, you know, find out that, oh, my gosh, you know, this is this is going to be a couple hundred thousand dollars, and it's probably going to take six to 12 months or more.

Q: So, so one of the recurring themes I hear – and inferring it from what you're saying – is that you need a team of outside experts to handle all the different aspects of the clearance process. People don't know that they don't know. Right?

David Lennarz: Obviously I'm in this business, so yes, of course. But I look at it from the two perspectives of founders and of an existing company with an existing product.

Founders typically know their product. They know how to produce that product, but they don't understand the regulatory landscape unless they've done this before, which isn't generally the case.

I think their path of least resistance and path to most likely success is to have an outsider who has

the expertise and knowledge who can ultimately save them time and money.

The other perspective is from a foreign manufacturer of a product that's already being commercialized in a foreign market, and they want to export it here.

Typically, we see that if they have a regulatory person, depending on the size of the company, often that regulatory person is an expert in their home market, and they may have a cursory understanding of the U.S. requirements. But because of language barriers and other factors, they may lack understanding of what all the requirements are.

In the case of foreign firms, there's a lot of value to have an outside third party who can really walk them through the system for the same reasons as for startups: time and money. Being faster to market means being quicker to get revenue coming in.

Q: Do you see any progress, any hope for harmonization between the requirements of the different countries' regulatory agencies?

David Lennarz: No, I really don't. Everyone thinks that their way is the best. There are some similarities, some crossovers conceptually, and some recognized certifications or schemes, but generally, everyone is pretty different.

In food, it's interesting because there are some countries in Africa that have copied the FDA's food safety regulations.

But for the vast majority of FDA-regulated products, countries have their own processes and own requirements, and they can differ pretty dramatically, this can present a challenge if you're trying to commercialize something on a global basis.

Q: This has been great. We have covered a lot of ground, and your perspective is valuable. Thank you for your time.

Get help with regulatory strategies

Michael Kisch, Head of Global Healthcare Incubation, LG NOVA

Q: Clearly, you've had a lot of experience with products that get involved in FDA clearance or regulation. Can you share a bit of background about that?

Michael Kisch: I've been the Founder/CEO or just CEO for three different healthtech businesses, all of which required a regulatory strategy.

I've gone through the FDA process at least four times; three of those were for 510k, one for de novo.

In addition, the companies that I've led have also secured regulatory approvals in Europe, Canada, and Australia. I wouldn't consider myself an expert, but I have a good perspective.

Q: Can you contrast your experience with 510k and de novo routes to clearance?

Michael Kisch: 510k is the most common path for Class II medical devices. I would say that 95% of submissions to the FDA are for the 510k pathway where you're just trying to demonstrate substantial equivalence to an existing product that has already been cleared.

That can include both the accuracy of the product as well as its intended use; who will be allowed to use it? What benefits you might claim from its use?

The 510k path is not without its complexity, but you kind of have a North Star when you go through the process because you only need to be as good as the existing product.

Then we have the de novo path, which is taken by maybe 5% to 10% of submissions. It's a very underutilized pathway.

The primary reason for that is by its very name, you are the first. This means that you must define not only what is a "good enough" accuracy or the

performance characteristics of the product, you also have to define who it's for and what claims can be made about its use.

This requires a lot more work because you're the first and there's a lot more ambiguity and room for interpretation. This creates increased risk which ultimately leads to a lot more time and money required to get to your product approved. This is a challenge even for large companies, but especially for small startups.

But the more innovative products have to go with de novo because they are the first of their kind and a predicate device or substantial equivalent does not exist.

So, it is always ironic to me when people “We were super innovative, and we went down the 510k path” By its nature, that's not innovation. That's effectively imitation.

Q: What about a breakthrough designation? Does that have any impact on the process?

Michael Kisch: I think that breakthrough designation is a valuable program.

Through the lens of a startup, a breakthrough device designation builds credibility amongst investors and partners and customers in advance of a formal regulatory approval.

Breakthrough device designation also gives you more attention and focus from the FDA, which has always been difficult to get and will be given the recent cutbacks at the FDA. That extra help is very important.

And on the back end of breakthrough device designation, there can be an expedited pathway to reimbursement. The CMS can play a role as part of as one of the partners within the program, which brings a lot of value as well.

I do think that oftentimes it's quite hard to qualify for breakthrough device, however.

I think that some companies will alter their product to increase the likelihood that of getting a breakthrough device designation, but by doing that, they create other potential risks or limitations on what the product can do, and its potential commercial of focus.

As with all these things, there are advantages and disadvantages. There is no perfect pathway. You need to be knowledgeable about the pros and cons, then choose the one that is appropriate for you.

If you're a big company, you can take more risk because you have more resources. But if you're a smaller company, the determination of the FDA could be a life-or-death decision for your company. You must be very pragmatic about how you engage in a regulatory process.

You're not going to get everything you want the first time through. You need to start and then you need to have a strategy, a roadmap over time for successively going back to the agencies for improvements, such as expanding the intended patient population or the product claims.

A great example of this are the CGMs, continuous glucose monitors. They started out very focused on Type One diabetics who were using insulin and required daily calibration.

Today, these devices are now being used by pre-diabetics and non-diabetics. They're available over the counter direct to the consumer. And you may only have to calibrate once every two weeks, or possibly you don't have to calibrate at all, depending upon its intended use.

Companies such as Dexcom and Abbott have been in that business for the last 20 years, and they are good examples of a slow, steady incremental process that you have to go through if you want to find that balance of managing risk.

Q: You also mentioned all the countries that you've been involved with, with products. Is it a patchwork of regulations and different requirements and different processes and procedures you have to go through?

Michael Kisch: It certainly can be a challenge, but I think if you are thoughtful about how you're submitting in one region or country versus another, you may be able to look for some commonality. You build your application once, then use it twice. I

think you can make your life a little bit easier, but there are distinctions.

For instance, the U.S. FDA likes to see that if you're presenting clinical data, that it's run on a representative population of people within the U.S. But if you're going for CE mark through a notified body in Europe, they may not care as much about where the clinical trial was run.

You need to have a top-down overall regulatory strategy and be thinking about different regions, different regulators, in a broader context. What's the sequencing? What are the shared resources or assets or components that you'll be able to leverage multiple times with multiple regulatory bodies?

Q: Do you think there's any movement towards harmonization between the different regulatory bodies, or are they going to remain pretty provincial in their views?

Michael Kisch: I think that they look at each other and they do pay attention. I think they do leverage some of the same criteria and resources.

For instance, in areas like blood pressure monitoring, there's an ISO standard for blood pressure measurement that's relied upon by everyone. It doesn't matter if it's U.S., or if it's Europe, or if it's Japan, or the China FDA. But then they all have their unique process.

I don't think that you're going to see them move towards some type of global standard on how they evaluate new devices or new software, however. The best example of harmonization is obviously Europe, where you do have a single framework for the 27 EU nations, which is very, very powerful because navigating that once gives you the ability to sell into all the other member countries. That does make things simpler.

And what's even more powerful about that is that CE mark is recognized by a lot of other countries outside of Europe. It gives you an expedited pathway into Australia, New Zealand, South Africa, Brazil, and Canada: up to another 17 countries all over the world. They may do some additional review of your submission, but ultimately, it's an accelerated pathway because you got the CE mark.

Q: Working with LG NOVA, you must have contact with lots of startups. Are most founders equipped to deal with the registration process on a global basis? How important is it for them to get outside expertise as a consultant or some other sort of support in the med tech space?

Michael Kisch: If you don't have experience dealing with a regulatory body, you need to go find that experience. And if you are not in a place in your company's lifecycle where you can afford to hire a good person full time, then you need to find an advisor, of which there are many.

And you need to follow their direction, because they've been through this journey numerous times, and they'll help you kind of figure out the expedited, lowest risk path to getting your submission.

But to go in uninformed and ignorant to a regulatory process is just a massive red flag of poor decision-making as a CEO-founder; you're just taking on a really substantial risk. And if you're out trying to raise money, a regulatory denial or a poorly articulated regulatory strategy is one of the surefire ways to not get funding.

Q: My understanding is some accelerators provide access to that sort of expertise.

Michael Kisch: You should get this help wherever you can; you just want access to somebody that has the relevant experience.

Different types of products require different expertise. A new drug is different from surgical robot, which is different from an over-the-counter consumer device.

You want to find somebody that has taken products that are similar to yours successfully through the process. And if you have something that's truly novel, one of a kind, then you want to find a regulatory expert that's taken something truly novel through the process and has demonstrated a level of creativity in how they were able to get that done.

Q: I'd think that these consultants are very valuable and thus very expensive resources.

Michael Kisch: Many of them are already locked into later stage startups and very large companies.

It's not like you can throw a stone and hit two of them. And the difference between someone who's okay at regulatory versus a superstar is significant. A founder who doesn't really understand regulatory well can struggle to distinguish between the two.

Q: Can investors be a source of regulatory consultants?

Michael Kisch: If you're dealing with a venture firm that invests exclusively in medical devices, you might find that they have a roster of regulatory experts.

But a lot of investment in healthtech comes from non-traditional, non-healthcare investors. These groups have less sensitivity to regulatory requirements, and they have less of an activated network. As a result, they might be less inclined to pursue an investment because it's an unknown for them. And if they do invest without fully quantifying the risks, they often can be disappointed later.

Q: Is there anything that we didn't touch on that you think would be important either to founders or med tech projects in general?

Michael Kisch: The advice I give to most founders is that regulatory is one of those areas where you always want a second opinion. That's not to say that the first advisor you engage with isn't awesome; it's just they can't know everything.

This is such a great area of risk that you don't want to take unnecessary chances. And there is a level of creativity required, which most people don't think about when they think of regulatory. There's quite a lot of creativity and strategy that goes into this.

So, this is one of those areas that you want to get a couple of people's opinions. At almost all of my businesses, we had multiple regulatory experts that consulted with us. We always had a primary; they led the overall project and managed the submission and the interaction with the agency. But we always had a couple of other regulatory people who were reviewing and brainstorming with us about what our approach could be.

Now that carries more expense, but once again, I view regulatory for a lot of healthtech companies as an existential threat, and you cannot over-resource an existential threat.

If you really don't understand regulatory, if you haven't been in it before, then treat it like getting a diagnosis of a disease. You might trust your physician, but you want to verify that the diagnosis and prognosis are supported by others. Regulatory is a great area to exercise that same type of approach.

Q: That's great advice. Thank you so much for being so generous with your time and your insights.

Conclusion

As with many complex systems, there is room for differing opinions. Taken in aggregate, however, these interviews present a composite picture of what it's like to be in the trenches of the approval process, albeit from the perspective of different roles.

The main take-away is that we must be vigilant about recognizing that often we don't know what we don't know. The insightful founder or executive will find resources that help fill in these blind spots, to mitigate risks and increase chances of success. There are many paths to success, but there are even more paths to failure.

The other take-away is that government regulation of healthtech products exists to protect patients, and ultimately the companies that produce the products that patients rely on for their health. Yes, it can be a messy, inefficient, and inconsistent process at times, but the system exists for the greater good. We can find it helpful to keep in mind that those involved have the best of intentions.

By being informed and strategic about the regulatory process, we can all play a role in fostering innovation in healthcare. We can make healthcare more broadly available, with lower costs and better outcomes.

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Chapter 11:
The Role of Evidence Standards

Author: Mark Wesson

Overview

Digital healthcare involves the use of information and communication technologies (ICTs) to improve health management, disease prevention, diagnosis, and treatment. With the rise of user-generated health data and advanced technology, this information is now complementing traditional electronic health records. The shift toward patient-centered, value-based care increases the relevance of such data in clinical decision-making and Real-World Evidence (RWE) generation in the Age of Big Data.

Development of breakthrough technologies requires rigor in many areas: the steady accumulation of information that describes the technology, its intended uses, and convincingly studied and understood data. In health-related innovations, these data are intended to support not only regulatory approval from agencies such as the U.S. Food and Drug Administration (FDA), but also to ensure that the product is safe and effective as a diagnostic, monitoring, or treatment technology and achieves its best fit in the marketplace.

Most of us are familiar with the idea of the Age of Big Data. Many of us are increasingly interested in monitoring our own health, doubtless spurred onward by the COVID-19 pandemic's tectonic interruption to health services delivery across the globe. With sensors, wearables, and other forms of software and devices capturing more and more real-time data, the FDA continues to develop definitions and rules that only began to apply in the last few years.

The FDA defines digital health broadly to include tools such as wearables, telemedicine, mobile apps, health IT, and personalized medicine. In recent years, companies have developed health technologies under new forms of regulation such as the FDA's "Software as a Medical Device". These regulations have added higher bars for demonstrating safety and efficacy, as well as the incorporation of learnings back into the technology's updates. Ultimately, digital health aims to enable seamless, intelligent communication between patients, healthcare providers, and devices, supporting a more predictive, preventive, and customized approach to care.

The United States' FDA distinguishes between "Real-World Data" (RWD) and "Real-World Evidence" (RWE) as follows:

"**Real-world data** are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status."

"**Real-world evidence** is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD."

These forms of evidence can complement regulators' expectations of data describing the technology, its use, and how it performs. Real-World Evidence is the information that healthcare providers, administrators, insurers, and consumers can use to make everyday decisions while they deploy a new process or technology in what they do or want to know.

Many health technologies that collect data can themselves provide datasets that may be used or analyzed by other researchers and commercial partners. There are many reasons – beyond the opportunities in the data economy – to make the

generation, interpretation, and use of evidence a distinctive advantage in digital health innovation.

While the principle of evidence-based medicine is widely accepted, translating evidence into action is a human and organizational challenge. Lack of time, information overload, skepticism, misaligned incentives, and structural hurdles all contribute to the lag. Recognizing these barriers has led to a new focus on implementation science: the study of methods to promote the systematic uptake of research findings into routine practice. This field treats adoption as its own science, testing strategies (education, audit-and-feedback, workflow redesign, policy levers, etc.) to close the gap between "what we know" and "what we do." As one 2023 Journal of the American Medical Association article quipped, "It takes an average of 17 years for evidence to change practice; the burgeoning field of implementation science seeks to speed things up." Implementation research emphasizes that simply publishing evidence is not enough; one must also address the social and behavioral factors to achieve change in practice.

Most change in matters of health is slow, requires credible agents to facilitate, and may or may not contribute in a measurable and direct way to "better practice" by a provider or "better health outcomes" for the patient. However, the technologies we seek to make available for use by providers and patients need study for many reasons.

Challenges / Gaps: New Forms of Evidence

While randomized controlled trials (RCTs) have long been considered the gold standard in clinical research, the evolving landscape of healthcare innovation is prompting a broader and more flexible approach to generating evidence. Increasingly, real-world evidence (RWE) — derived from electronic health records, wearable devices, and patient-reported outcomes — is being recognized as a valuable complement to traditional trial data.

This shift is particularly relevant in the context of digital health technologies and therapeutics for rare or orphan diseases, where prospective observational studies and adaptive trial designs offer viable, efficient alternatives for generating timely insights. Moreover, the rise of medical devices and continuous learning systems driven by artificial intelligence (AI) demands an ongoing validation model, as these tools evolve and adapt post-deployment. Regulatory frameworks are beginning to accommodate this dynamism, acknowledging that evidence in the modern era must be both rigorous and responsive to technological advances. However, approaches and submission requirements vary considerably from one country to the next, and the recent explosion of data in the last 10 years or so has not yet produced a harmonized idea of what required or insightful evidence should be produced.

The advent of *in silico* studies (that are conducted entirely within computer simulations), powered by AI, has opened new frontiers in clinical research by enabling the simulation of molecular interactions and treatment effects on virtual patient models. These approaches allow researchers to rapidly explore multiple clinical scenarios with broad implications using fewer resources and greater flexibility than traditional methods.

Dosing guidelines could improve therapeutic outcomes compared to standard protocols, though the need to further refine and manage toxicity risks remains. Similarly, machine learning (ML) algorithms are now being used to personalize treatment strategies, such as predicting bleeding risk in patients with chronic kidney disease or organ rejection in transplant recipients. These innovations offer a more individualized and data-driven approach to care, potentially replacing expert opinion or case reports in some settings. However, to integrate these methods into routine practice, we must have robust implementation and validation frameworks to ensure their reliability, safety, and clinical utility.

Understanding One Form of Evidence Is Not Like the Other (i.e. Levels of Evidence, Scientific vs. Regulatory vs. Clinical vs. Consumer)

The trustworthiness and reliability of scientific evidence are foundational to safe, effective, and equitable healthcare. In clinical practice, high standards — often defined by formal "levels of evidence" — are essential for documenting, validating, and disseminating best practices. These standards ensure that innovations are not only effective in theory but also proven to work in the complexity of real-world care settings. In high-risk clinical environments, introducing a new intervention, form of patient or provider monitoring, quality measure, reimbursement change up or down, or innovation that replaces some form of labor performed by licensed human professionals requires a body of evidence that meets rigorous thresholds for reproducibility, safety, and impact. Sometimes, innovators may learn only prior to commercial launch that any or all of these features may apply to introducing what they have created into daily use by patients, providers, payers, families, and caregivers.

When a technology or therapeutic is truly cutting-edge, the burden of scientific responsibility becomes even greater. The introduction of novel tools must be approached with caution, transparency, and methodological rigor. Yet the path from innovation to clinical adoption is rarely linear. Innovators must navigate unclear regulatory and institutional contexts, market incentives that may not align with patient outcomes, and inherent human resistance to change. Often, this journey involves painstaking efforts to replicate and validate early findings before the broader medical community is willing to revise entrenched clinical norms.

Today, this landscape is being reshaped by rapid digital transformation in healthcare. The rise of AI, Big Data, and other emerging technologies is disrupting long-standing paradigms of how clinical evidence is generated, assessed, and adopted. Traditional models such as the evidence-based medicine (EBM) pyramid, which have guided research hierarchies for decades, are being re-evaluated in light of new methodologies. New models including real-world evidence, adaptive trials, and AI-powered decision tools challenge the assumptions of a static, one-size-fits-all approach.

A New Vision: Technology Tools and Opportunities to Apply Them

Bellini et al. (2023) suggest a thoughtful revision to the hierarchy of evidence that considers the addition of a number of factors to this pyramid that are increasingly important in an age of Value-Based Care. These considerations, termed a third dimension of the pyramid, reflect the effort and complexity required to advance to higher levels of scientific validation and the key legal, ethical, educational, and cost-effectiveness challenges that must be addressed to integrate the innovation into practice. The fourth dimension is also introduced: the volume of each step, symbolizing the real-world clinical impact associated with each level of evidence. This creates a more comprehensive, multidimensional model of evidence generation in the age of advanced technologies.

Digital health innovations must go beyond novelty; they should enable care anywhere, lower costs, improve quality, and leverage both real-time and longitudinal data. As information consumers in healthcare, we have long underutilized the vast data at our fingertips, hindered by fragmented systems and privacy silos. The shift from intermittent to continuous, multi-source data — from wearables to biobanks — demands new frameworks beyond traditional evidence-based medicine. AI-powered tools, including in silico research and adaptive decision support, offer unprecedented speed and precision, often outperforming static methods.

Ultimately, what matters most is not just methodological rigor, but real-world impact as measured through clinical relevance, usability, and tangible improvements in health outcomes.

Companies with Clear Evidence-to-Practice Strategy

Here are thumbnail descriptions of nine companies that are leading the way to apply RWE to healthcare issues.

Aetion (United States / Spain)

Aetion provides one of the leading software platforms for regulatory-grade RWE analytics. Its flagship Aetion Evidence Platform (AEP) enables rapid analysis of real-world clinical data to uncover causal relationships and comparative effectiveness. Pharma companies use AEP to answer questions for FDA submissions, optimize trial designs, and monitor post-market safety. Uniquely, Aetion has collaborated directly with the FDA. For example, the FDA has used RWE to study COVID-19 treatments and to address oncology care disparities. This focus on rigorous, "decision-grade" evidence and active work with regulators distinguishes Aetion in the digital health ecosystem.

Clarify Health (United States)

Clarify Health brings "Moneyball" analytics to healthcare by churning through billions of health records from over 300 million patient journeys. Its Atlas platform applies big-data and AI methods to longitudinal patient data (including medical, social, and behavioral factors) to predict outcomes and identify care improvements. For example, Clarify can model multi-year patient trajectories and assess the impact of social determinants of health on outcomes. Health systems and payers use Clarify's real-world insights to reduce costs and optimize quality, making Clarify stand out for its breadth of data and focus on predictive analytics in RWE.

Evidation Health (United States)

Evidation bridges everyday digital life and clinical research. Through its Achievement app (now MyEvidation), Evidation has recruited a network of over 5 million individuals who consent to share data from wearables, smartphones, and surveys in return for points and insights. Evidation's platform passively collects real-world health metrics – steps, heart rate, sleep, etc. – and actively engages users in research studies (e.g. prompting surveys or digital health interventions). The company specializes in analyzing these patient-generated data to validate digital health solutions and measure outcomes in the real world. By directly connecting participants with research (including collaborations with pharma, big tech, and government), Evidation creates "real-world evidence in everyday life," demonstrating how behaviors and digital markers translate into health outcomes. Evidation Health adds rigor to a source of data historically considered less structured and reliable as information generated by providers in a patient's record. Improved rigor, market receptivity, and reliable evidence standards have enabled their success.

Huma (United Kingdom)

Huma is a global digital health company enabling remote patient monitoring and decentralized clinical trials. Its platform can collect continuous real-world data from patients at home – symptoms, vital signs (via connected wearables), patient-reported outcomes – and aggregate these for research or care management. Huma's technology has been used in partnerships with national health systems (e.g. NHS's COVID-19 remote monitoring programs) and pharma companies. Notably, Huma emphasizes compliance with regulatory-grade evidence needs; it helps medtech and pharma partners generate RWE for device approvals and post-market studies by running virtual studies on its platform. The platform's ability to securely handle sensitive patient data in a distributed way (while meeting quality standards for Software as a Medical Device) sets it apart. Huma's work on federated data collection and analysis shows how real-world patient data can support new indications or regulatory submissions, essentially acting as a digital Chief Research Officer for the era of RWE.

Propeller Health (United States - now a ResMed company)

Propeller Health, a subsidiary of ResMed, produces FDA-cleared digital inhaler sensors and a platform for asthma and COPD management. Its sensors attach to patients' inhalers and passively track medication usage and environmental conditions. Real-world studies have shown Propeller's system can improve adherence and outcomes. For example, users experienced fewer asthma exacerbations and

better disease control by receiving personalized insights and alerts. Propeller's platform has been the subject of over 150 peer-reviewed studies and articles, demonstrating improved quality of life and clinical outcomes while lowering healthcare costs. Distinguishing features include integration with provider care (Propeller can share data to electronic health records – EHRs – for remote monitoring) and population-level analytics for public health. Propeller exemplifies how a medical device coupled with a digital app can yield RWE that not only validates the product's effectiveness but also actively guides patient care in everyday settings.

Tempus (United States)

Tempus is a precision medicine company applying AI to a massive real-world dataset of oncology patients. It has amassed over 70 petabytes (millions of gigabytes) of clinical and imaging data – matched with genomic sequencing results – by partnering with hundreds of medical centers. The Tempus Lens platform mines this trove of real-world data (RWD) to help clinicians personalize cancer treatment and to aid pharma in trial design and patient matching. Notably, Tempus's clinico-genomic approach – connecting EMRs, DNA/RNA profiles, and outcomes – distinguishes it from other services. The company collaborates with regulators and industry alliances to advance RWE use in approvals.

TriNetX (United States)

TriNetX operates a global health research network that connects hundreds of healthcare organizations and millions of de-identified patient records. Through its web-based platform, researchers can query aggregated EHR data in real time to perform cohort discovery, protocol feasibility, and outcomes analysis. The network's longitudinal clinical data and analytics tools allow creation of real-world evidence (e.g. synthetic control arms or epidemiological studies) from routine care data. A key differentiator is TriNetX's federated model – hospitals share data within a secure network – that enables collaboration between pharma and providers to accelerate trials and answer real-world clinical questions.

Verana Health (United States)

Verana operates a specialty data ecosystem by partnering with medical associations (ophthalmology, neurology, urology, etc.) to collect real-world clinical registry data. Through its AI-guided platform, Verana curates these EHR data pools to generate RWE for drug development, trial optimization, and even market insights (e.g. tracking treatment usage trends). This startup began with an eye-care app but pivoted to digital health. It has drawn major investments – including a $150 million round led by J&J's venture arm – underscoring its unique position in leveraging physician-sourced data networks for RWE.

Owkin (France/United States)

Owkin is an AI startup applying federated learning and real-world data to accelerate drug discovery and precision medicine. Instead of centralizing data, Owkin sends machine learning models to collaborate across many hospitals' datasets, which allows AI training on thousands of patient samples without pooling the data in one place. This privacy-preserving approach unlocks insights from diverse real-world sources (pathology images, genomics, clinical outcomes) that were previously siloed. Owkin's platform has been used to uncover novel disease biomarkers and optimize clinical trial designs (e.g. identifying high-risk cancer subgroups for targeted therapies). Major pharma companies have partnered with Owkin to leverage its AI on their data; Sanofi even invested $180 M. What distinguishes Owkin is this federated model and its focus on translational RWE: gleaning biological and clinical insights from real-world patient data while respecting data privacy. By improving trial design and drug targeting through RWE-driven AI, Owkin aims to reduce development time and increase success rates in the pharmaceutical pipeline.

Conclusion

As this transformation toward broader use of RWE accelerates, healthcare stakeholders must strike a delicate balance between embracing innovation and preserving the scientific rigor that underpins patient safety and trust. Only by evolving our standards of evidence — without compromising their integrity — can we ensure that new technologies genuinely

improve outcomes and are responsibly integrated into clinical practice.

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Chapter 12: The Future of Wellness & Diagnostics Testing

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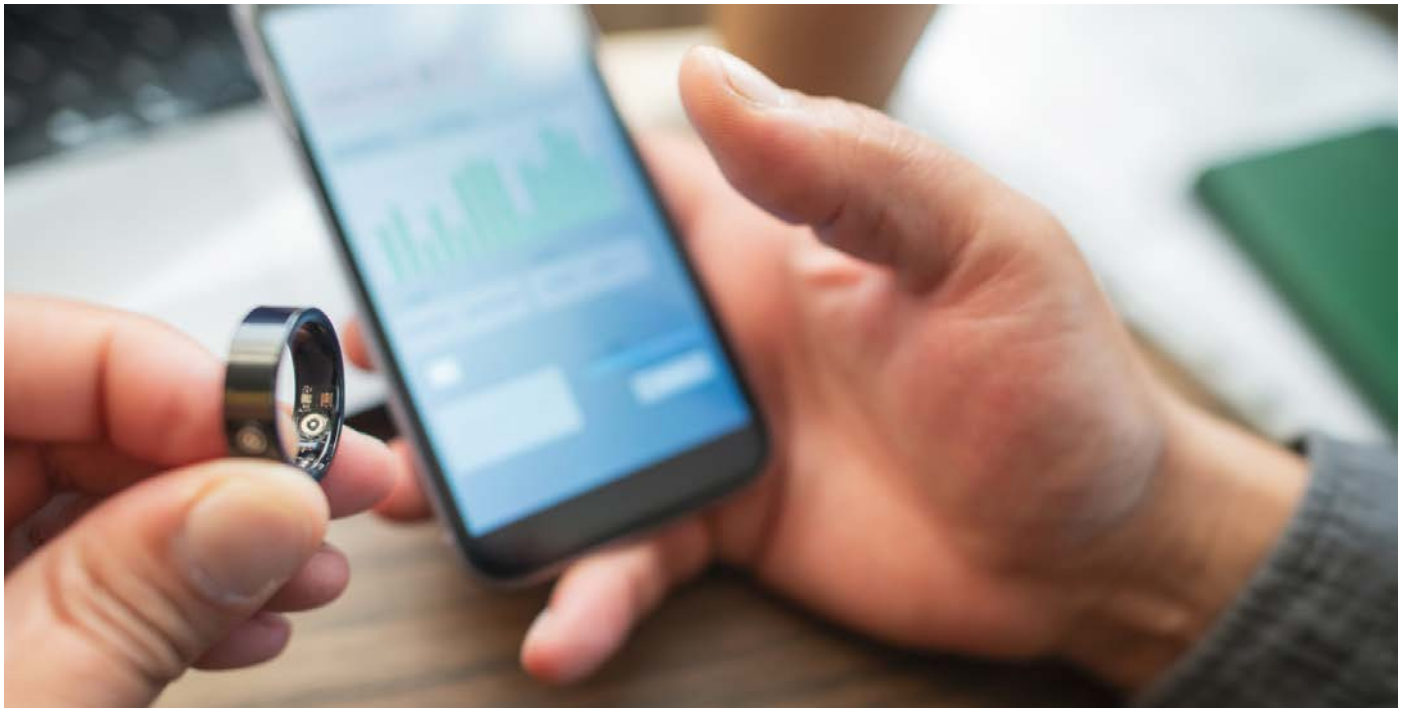

Introduction

The landscape of healthcare is undergoing a dramatic shift. Where once diagnostics were confined to sterile labs and wellness was relegated to annual checkups, today's innovations allow individuals to monitor and manage their health in real time, on their own terms. Powered by artificial intelligence, biosensors, and data interoperability, the future of wellness and diagnostic testing lies at the intersection of personal empowerment and institutional transformation. This chapter explores how emerging technologies are redefining the continuum of care: enabling early detection; fostering autonomy; and posing new ethical questions about the ownership, use, and protection of health data.

The Rise of Personal Health Technologies

One of the most profound developments in modern healthcare is the advent of devices that track biometric and behavioral data continuously. Whether worn on the wrist, embedded in clothing, or integrated into the bathroom, these tools offer unprecedented insights into day-to-day health. Devices such as the Oura Ring and Apple Watch not

only track steps or heart rate; they signal when something is wrong.

For instance, take the story of a nurse practitioner whose Oura Ring alerted her to unusual physiological patterns, prompting her to seek medical attention. That vigilance led to the early diagnosis of Hodgkin lymphoma. “If I didn't have the Oura ring, I'm sure I would have figured it out eventually. But having this information… made me take it more seriously," after alerts from her Oura Ring prompted her cancer diagnosis and early treatment interventions, noted Nurse Practitioner Nikki Gooding in a March 2025 article on People Magazine’s website.

Healthcare practitioners are recognizing the value of continuous wearable sensing and AI health tools to data to generate greater self-awareness and enable earlier detection and more informed care by medical providers. “As physicians, we often only get a snapshot of what's happening for a patient,” observed Dr. Sandeep Kishore, MD, PhD, an associate professor of Medicine at University of California, San Francisco (UCSF) who is part of a joint UCSF and UC Berkeley team preparing to pilot wearable devices to help treat some people with diabetes and high blood pressure (UCSF June 2025 online news article). He noted that wearables, such as electronic blood pressure cuffs or other electronic devices, could record a patients’ measurements daily and provide their physician with a new window into their health over time. Kishore added, “Artificial intelligence has the potential to sift through the firehose of data to detect new patterns in diseases.”

Similar innovations are emerging in women’s health. A wearable ultrasound bra, pioneered by Canan Dağdeviren at MIT, offers daily scans for breast cancer detection, dramatically increasing monitoring frequency and early detection rates. Another bra, the Eva, was invented by Julian Rios Cantu, an 18-year-old Mexican student, who was inspired by his mother’s experience with breast cancer. It features 200 sensors that can track temperature and texture changes as a method for detecting early breast cancer development for which he earned the top prize at the Global Student Entrepreneur Awards in Frankfurt, Germany.

The lesson from these examples is clear; continuous, user-initiated monitoring has the power to surface health anomalies that may otherwise go undetected. These tools are democratizing diagnostics, bringing clinical-grade insight to everyday users, and enabling earlier detection and treatment for better outcomes and a reduction in healthcare costs.

Data Sovereignty and Empowerment

While healthcare providers and researchers can certainly benefit from having the additional data that these devices provide, the digitization of health information introduces critical questions about data ownership, privacy, and consent. Individuals today increasingly expect not just to access but to control their personal health data: a movement known as data sovereignty. It is the idea that individuals and organizations have the right to control their own data and determine how it is collected, stored, used, and shared as a way to assist them in accessing services.

An innovative concept that permits this type of control is a personal data wallet. One thoughtful example of a personal data wallet is the Personal Access System for Services (PASS), under development by Open Commons in Portland, Oregon. PASS is an open-source application designed for housing-insecure individuals to give them secure, user-controlled data exchange across housing and health services while maintaining privacy and revocability. It allows them to store and share essential documents, including medical histories.

PASS additionally aims to assist caseworkers with processing and providing documents needed to complete the housing-assistance application process. It allows data and associated documents to be easily shared with case workers and with anyone else the user designates. In addition, it allows users to grant access to personal data, revoke previously granted access, and prevents unauthorized access. PASS makes data interoperable across health management information systems (HMIS) throughout the United States. A trial release of the application will be available for testing in the field soon.

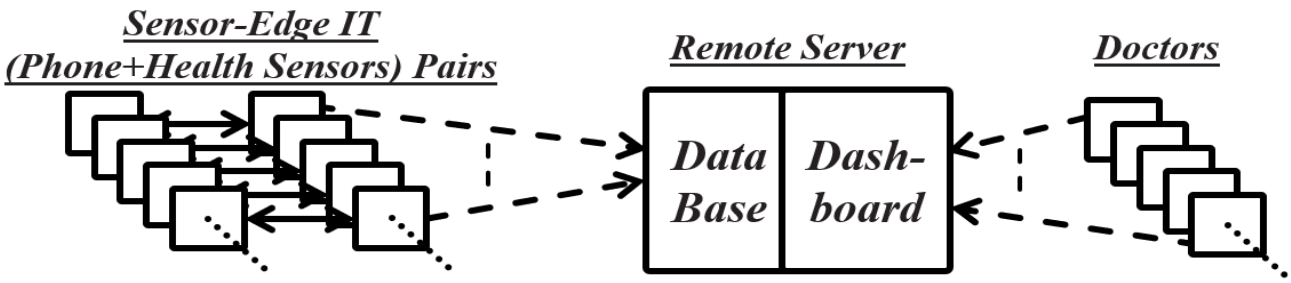

Figure 1: End-to-End System Architecture for Data Sharing and Analysis of Private Health Records.

Once users control their information, they can pre-populate forms, apply for services more easily, and selectively grant access to providers or researchers. This level of control is especially critical for transient or marginalized populations often excluded from traditional health systems.

Similar projects include My Digital Data Locker Baltimore, Kiip, and OpenWallet Foundation; these demonstrate a shift toward user agency in health data ecosystems. Much more can be done to mature this space.

Easier Research Access to Aggregated Health Data

The challenge of effectively monitoring patients remotely began in the early 1920s using telephone and radio waves. Globally, countries such as Germany recently approved nationwide efforts in digitizing health records, thus joining a long list of countries that already support electronic form storage of health data (including the U.S.). Systems that combine state-of-the art biosensors enhanced with edge AI (aka AutoML) and comprehensive data security allow users to transmit health data to physicians and researchers.

An example of a system that can aggregate user data on a centralized remote server – allowing queries across a vast array of patients – is depicted in Figure 1.

A plethora of devices – introduced for data collection to allow for early detection and better research – have been on the market for some time including such hallmark devices as the Dexcom continuous glucose monitor (CGM) first released in 2006; the Fitbit first released in 2009 that can detect respiratory issues, early COVID-19 symptoms before diagnosis, and heart rate variability; the Apple Watch, first released in 2015, that can detect falls and atrial fibrillation, tachycardia, and other heart conditions (ECG added in 2018); and a Smart Toilet first introduced in 2023 by Stanford University that could detect bladder / kidney disease and digestive biomarkers…to name just a few.

More recently a host of new health detection devices have been introduced that are embedded in clothing or textiles.

Device / Platform	Format	Monitors:
Hexoskin Smart Shirt	Shirt / Vest	ECG, HR, HRV, breathing, activity
Siren Diabetic Socks	Socks	Foot temperature
Sensoria Socks / Nadi X Pants	Socks / Yoga Pants	Gait biomechanics, posture feedback
Cambridge Smart Pajamas	Pajamas	Breathing, sleep states, apnea
Acoustic Smart Textile (Wang et al., 2025)	Fabric	Pressure, humidity, sound, strain
3D E-Textile Maternal & Sport System	Garment	ECG, EMG, maternal health signals
Nanowear SimpleSense	Smart Shirt	ECG, respiration, activity

Table 1: Health detection devices embedded in clothing or textiles

From the research perspective, the value of aggregated, anonymized health data is immense. These datasets enable longitudinal studies, support remote patient monitoring, and offer a foundation for epidemiological insights. Yet ethical collection and usage practices are vital.

Recent national efforts such as Germany's health record digitization initiative and the U.S. federal investment in interoperability standards highlight growing recognition of the need for the ability to connect data to multiple systems. During the COVID-19 pandemic, the limitations of disconnected health data became painfully obvious, underscoring the value of real-time, population-level health monitoring.

Researchers now advocate for systems that balance privacy with utility: models that use edge computing and federated learning to protect individual identities while still drawing insight from mass data. Refined architectures like the one in Figure 1 illustrate how biosensors can feed into secure, centralized systems for physician analysis, forming an ethical backbone for real-time diagnostics.

AI in Predictive Diagnostics: A New Frontier

Perhaps the most transformative advancement in healthtech is AI's role in predicting illness before symptoms arise. Tools once used to assess chronological age are now being used to calculate biological age: a more meaningful indicator of health and longevity.

Research on "biological age" has accelerated in the past three years, powered by large biobanks, multi-omics assays, and ever-larger AI models. Instead of counting the candles on your birthday cake, scientists are now reading molecular and physiological "fingerprints" that reveal how fast (or slow) your body and brain are really aging. Those same measurements are beginning to flag early disease, guide drug trials and — most relevant for everyday life — spot reversible risk factors years before symptoms appear. Artificial intelligence is being combined with new physiological analyses, such as testing for brain plaque to signal Alzheimer's, protein tests to identify heart disease risks early, and other new science to help identify ways to stay healthy longer.

Bryan Johnson's "Don't Die" initiative exemplifies this new frontier. His self-experimentation and publication of protocols have ignited interest in personalized aging clocks and holistic metrics that track vitality. These technologies assess everything from epigenetic tags and protein levels to electrical heart signals and stress biomarkers.

These tools not only predict disease risk but also inform lifestyle interventions. An elevated heart-age score from an Apple Watch might prompt dietary changes; a sleep tracker showing chronic insomnia could lead a patient to cognitive behavioral therapy.

Cultural and Public Trust Challenges

Yet the power of these technologies is tempered by public skepticism. Concerns over trust, transparency, and misuse remain at the forefront. Core trust drivers include system reliability, perceived fairness, privacy protections, and human oversight.

Additionally, cultural norms shape trust differently. In the U.S., where privacy and autonomy are deeply valued, AI-driven diagnostic systems often face more scrutiny than in collectivist societies that emphasize communal benefit over individual data control.

Trust gaps can be exacerbated by poor communication. When users don't understand how an AI reaches its conclusions, they may reject even highly accurate insights. To build trust, systems must be explainable and interactive: not just accurate.

AI for Caregivers and Decision Support

Another critical, emerging domain is the use of AI to support caregivers: both professional and family based. A 2024 article in the journal JMIR Aging explores how AI-based support tools can reduce

caregiver burden, offering guidance, symptom monitoring, and emotional validation.

These tools help caregivers triage priorities, track patient health changes, and know when to seek professional help. In environments such as elder care or dementia support, AI can monitor agitation patterns, remind patients to take medication, and even flag emerging health crises.

However, such support systems must be deployed ethically. Caregivers must remain in control, and AI should complement, not replace, human empathy and judgment. Misplaced reliance on chatbots or unvetted apps can result in reduced quality of care or privacy breaches.

Navigating Public vs. Private Interests

The commercialization of health data is perhaps one of the most contested ethical frontiers. Many systems collect personal health data under the guise of self-improvement, only to repurpose it for profit-driven motives: pharmaceutical targeting, insurance pricing, or political micro-targeting.

Consider the case of 23andMe, whose genetic data partnerships raised concerns about secondary use beyond user consent. Or Sam Altman's iris-scanning "WorldCoin" project, which paid individuals to submit biometric data that would later train identity verification systems.

Distinguishing between public-good applications — including early pandemic detection or nutrition alerts — and commercial exploitation is vital. Transparency in data usage, user opt-in mechanisms, and enforceable accountability structures are key components of a responsible data ecosystem.

With care, clarity, and collaboration, we can ensure that tomorrow's diagnostic breakthroughs lead to greater levels of wellbeing for everyone, not just those who can afford them.

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Ann M. Marcus is a Sonoma-raised, Portland-based communications strategist and ethical technology analyst focused on smart cities, community resilience, and public-interest innovation. She leads the Marcus Consulting Group and serves as director of ethical technology and communications at WeAccel.io, a public-good venture advancing mobility, communications, and energy solutions for communities. Ann has advised public and private organizations—including Cisco, the City of San Leandro, Nikon, AT&T, and InfoWorld—on trust-based data exchange, digital public infrastructure, resilience strategy, AI and more. Her current projects include a California senior evacuation program, a Portland robotics hub, and digital energy resource initiatives with utilities in Portland and the Bay Area.

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Part IV
AI and Regulatory Framework: Keeping Pace with Innovation

Chapter 13: The Impact of AI on Caregiving, Personalized Care, and Health Coaching

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Introduction

Artificial intelligence is no longer confined to research labs or specialized clinics; it is rapidly becoming a practical tool for addressing some of the most pressing challenges in healthcare. Two areas stand out as particularly ripe for transformation: the hidden labor of caregiving and the growing demand for personalized health coaching. Family caregivers represent an invisible workforce whose unpaid contributions sustain millions of patients, yet often at the cost of their own well-being and economic stability. At the same time, patients themselves are seeking tailored guidance that fits their individual health profiles, habits, and life circumstances.

AI offers a powerful bridge between these realities. On one side, it can help caregivers manage complex care tasks, reduce stress, and prevent burnout. On the other, it enables highly personalized health coaching that empowers individuals to take proactive control of their health. Together, these developments point toward a more integrated, patient- and caregiver-centered model of healthcare. The sections that follow explore both dimensions: first, the potential of AI to support caregivers, and second, its role in advancing personalized care and coaching.

Why AI for Caregivers Is the Missing Link in U.S. Healthcare

An invisible workforce contributes $600 billion dollars in value to the U.S. economy each year. These unpaid employees are informal and family caregivers, working an average of 26 hours per week in addition to their paid full-time or part-time jobs. Many of these patient supporters do not think that assisting a loved one with errands, giving rides to appointments, completing online medical tasks, handling prescription management and taking the reins of patient navigation as caregiving. However, the impact of these irreplaceable healthcare workers is clear, and the task of taking on this additional workload is having far reaching consequences.

Harvard Business School's white paper, "The Caring Company", determined that 73% of all employees are serving in some form of a caregiving capacity. A sizable fraction of these caregiving employees are a part of the approximately 53 million Americans juggling the responsibilities of "caring for a spouse, elderly parent or relative, or special-needs child." It has created $33 billion in yearly lost workplace productivity, due to absences, reduced hours, rearranged work schedules and declined promotions. Moreover, this extra workload has caused an estimated $13.4 billion in increased health care costs annually for employers.

Between the growth of the aging population and demands placed upon working caregivers, our society could reach a breaking point without the

intervention of digital innovation by way of AI. According to the 2023 Profile of Older Americans Report, the overall percentage of older Americans relative to the population has been growing since Baby Boomers started turning 65 in 2011. Helpr's 2025 Blueprint for Better Care Benefits Report estimates that the number of adults aged 65 or older will grow to 20% of the population by 2030. It's important to note that, due to increased longevity among older Americans, "the 85 and older population is projected to more than double from 6.5 million in 2022 to 13.7 million in 2040 (a 111% increase)." Sandwich Generation caregivers, those who care for their children and elders simultaneously, are expected to be 25% of the workforce by this same period. In the past families and healthcare systems have been able to rely on immigrants for home health and long-term care support. Comprising 30% of personal care staff and 40% of home health aides, these needed employees are part of a shrinking workforce due to the federal administration's push to strip them of their work authorizations.

Challenges to Personalized Care

Unfortunately, the desire for offloading responsibilities is at odds with the realities of caregivers, the current healthcare landscape, and traditional medical protocols. The constant flow of caregiving responsibilities prevents overwhelmed caregivers from having the time, attention, and financial outlay to put towards finding, using, and adopting tailored care and health coaching resources. Helpr's 2025 Blueprint for Better Care Benefits Report highlights that caregivers who are women, frontline workers, low-income employees, or from families with special care needs face systemic barriers to care resources.

According to Deloitte's 2025 Global Health Care Outlook, 81% of surveyed hospital leaders acknowledge Gen AI is a trend that will have a moderate or serious impact on health care this year. Many shared that their hospital systems are exploring or planning to explore use cases in 2025, and 40% revealed that they are seeing a significant-to-moderate return on their Gen AI investments. However in Forbes article "Accelerating Healthcare With AI: Reducing Administrative Burdens", "healthcare workers are facing burnout as they struggle to meet the needs of the expanding patient population." Research published in the American Public Health Association's Official Journal of the Medical Care determined that the average primary care visit lasts 18 minutes, leaving a small window of opportunity for caregivers to learn, process, and ask follow-up questions about their loved one's current health condition.

Lastly, although there have been great strides made with digitizing medical records, integration across health systems, and implementing national efforts to improve continuity of care, a recent Mathematica article on fragmented care "suggests initiatives seeking to improve continuity, coordination, and comprehensive care more broadly may have to focus on a broader array of providers beyond the primary care setting if they are going to have an impact."

For example, my mother's medication protocol involved a process of switching from infusion treatments to an at home injectable. The approval plan for her to receive the medication with patient assistance from the manufacturer entailed my completion of an online application on behalf of my mother, a faxed form to her specialist from the manufacturer's representative, and a faxed completed form from her specialist's office. What should have been a day long, one-time process was stretched to a month long back and forth of constant phone calls to the manufacturer's customer service to find out why they had not received the faxed form from the physician's office, frustration on behalf of the healthcare professional that their multiple faxes were not being received and logged by the manufacturer's customer service center, and our worry about the effectiveness of a delayed treatment for her condition.

For already burdened caregivers, fragmentation adds additional stress, work, and increased possibility for negative health outcomes for their loved ones. The introduction of AI tools can create a layer of support that makes every day experiences such as the one above more efficient.

There is an overlooked and untapped opportunity to create AI tools to help this volunteer workforce tackle their invisible labor duties. Currently, caregivers must resort to sourcing suggestions from Reddit threads and news articles when it comes to AI tools for meal planning. ChatGPT has a directory of Custom GPTs for this task. One example is Meal Planner, Diet Advisor, and Private Nutritionist (by OG), which bills itself as a private professional nutritionist that will create structured meal plans with detailed recipes and provide dietary advice. Additionally, there are AI apps like ChefBot which touts itself as "an artificially intelligent cooking companion" that will generate unique recipes based on entering ingredients, dietary restrictions and preferred cooking style.

Case Study: The Primary Caregiver AI Toolbox

One day I blinked, and I was a caregiver. As with millions of Americans, this overnight promotion was the result of my mother's health collapse. She had been neglecting her own personal care at the expense of serving as the primary caregiver for her 95-year-old mother and 94-year-old father. After three months apart, my mother was soon rushed to the hospital, and my caregiving journey began. That was seven years ago.

Every caregiver's story is similar in different ways; my experience mirrors the reality of over 53 million unpaid caregivers. They are thrust into a job that requires them to shoulder invisible healthcare responsibilities, often without resources, training, or time. It is a tall order to juggle complex decisions that impact a loved one's health alongside one's own productivity, mental wellbeing, and finances. In a 2024 Otsuka study conducted by Columbia University Mailman School of Public Health, research found that caregiving-induced declines in health contribute an estimated $28.3 billion annually to healthcare costs, highlighting the profound economic impact of deteriorating caregiver well-being.

To ease the burden of invisible labor on caregivers, I created the Primary Caregiver AI ecosystem. The system currently contains six vertical AI agents that can do the heavy lifting for caregivers in the following areas:

- **Ready to Care** – Provides personalized, step-by-step caregiving guides.
- **RxWiz** – Gives simplified, reliable medication insights.
- **Ask the Doc** – Creates tailored questions for upcoming doctor visits.
- **Next Option** – Helps you discover breaking research & clinical trials
- **Out of Pocket** – Offers affordable, local healthcare service suggestions.
- **Conditional Eating** – Outlines meal plans and localized menu options for special diets

For example, a working mother caring for an aging parent with diabetes uses "Ask the Doc" for visit prep and "Conditional Eating" to find meals that align with her parent's dietary restrictions while they are out shopping for groceries.

Currently, The Primary Caregiver Toolbox offers a direct-to-consumer collection of AI tools with at-home and on-the-go support for a broad cross section of invisible labor tasks. Learn more by visiting the website: theprimarycaregiver.com

Outside of providing meal prep support for caregivers, TCARE.ai is "a digital platform that utilizes AI to assess the risks of caregiver burnout algorithmically." After an initial assessment, the algorithm will provide a care plan with interventions to best support the caregiver. This service is offered through managed care programs, insurance providers and employers.

AI's Role in Streamlining Healthcare Interactions

In the Future Healthcare Journal article "Artificial Intelligence in Healthcare: Transforming the Practice of Medicine," the authors wrote that "AI could significantly reduce inefficiency in healthcare, improve patient flow and experience, and enhance caregiver experience and patient safety through the care pathway.

For example, an AI tool to provide hyperlocal insights for members of the Infusion Access Foundation community would be an invaluable resource" noted Executive Director Alicia Barron. She recalls how – as a national resource provider – something as simple as securing transportation for a patient in the Houston area can be a complex endeavor due to the county borders and areas served by their transport partners. She remarked, "I was thinking how it would be great to have an AI tool to help with this, but I'm just not exactly sure how to go about it."

From easing the burden on healthcare stakeholders such as the Infusion Access Foundation to reducing healthcare costs, AI tools can serve as a 24-hour information resource and line of defense that yields better health outcomes. AI agents, for instance, can highlight overlooked prescription side effects (such as sunlight sensitivity or avoiding grapefruit) that patients or their caregivers might overlook. Bringing attention to these important medication details could result in preventable ER visits for adverse reactions.

Challenges to AI Adoption for Caregivers

The journey from developing AI tools that address caregiver needs to mass adoption has a number of barriers. Some statistics featured in athenahealth's "Patient Engagement in the Age of AI" white paper point to how digital literacy, privacy, ethics, and demographics can pose challenges for digital adoption. Older populations are not as tech savvy as younger generations. Women are more engaged than men. Rural patients lag behind those living in metropolitan areas. Moreover, there is higher usage of the tools by White and Asian users as opposed to Black and Latino users.

A necessary foundation to equitable access to these AI tools is broadband access. Considered a "super-determinant of health," it influences many of the socio-economic factors mentioned above that serve as barriers to AI adoption. As it stands, the current federal administration is pausing and dismantling a popular broadband grant program, which would prevent the awareness and adoption of these AI tools.

Additionally, AI tools need stringent guardrails to ensure that they do not misuse confidential health data, misinterpret caregiver inquiries, and provide responses that are outside of their scope. Deloitte's 2025 Global Health Care Outlook mentions that skepticism around AI tool effectiveness can halt or slow the adoption of these resources. There are concerns about blind spots, such as biased or unbalanced data used to train AI models, as well as documented instances of Gen AI technology "hallucinations" that produce false information.

Fortunately, programs such as Mayo Clinic's Platform Solutions Studio can provide an opportunity for AI-driven health tools to be "trained, tested, and deployed in a streamlined and accelerated manner." Innovators have access to high quality, de-identified data to train their tools and a comprehensive evaluation from teams of world-class physicians, data scientists, and AI experts.

Pioneering AI for the Caregiving Economy

For personalized care to be effective, digital innovation is needed to support caregivers. AI tools have the potential to aid in this revolutionary step towards more efficient, integrated care. With comprehensive vetting and strategic partnership among hospital systems, employers, insurance

companies, foundations, and other stakeholders, we can achieve mass adoption and ease burdens, improve healthcare interactions, and create sustainable, personalized patient support.

AI-driven personalized coaching and care is likely to have a significant impact on the roles and expectations of caregivers. While caregiving and health coaching may appear to be distinct aspects of healthcare, they are deeply interconnected. Family caregivers shoulder the burden of coordinating treatments, managing medications, and navigating fragmented systems, often without formal support. As described in the previous section, AI tools can ease these invisible responsibilities by streamlining logistics and offering decision support. Building on this foundation, let's look at how AI's ability to personalize care — through predictive analytics, adaptive coaching, and real-time monitoring — extends beyond caregivers to the patients themselves. Together, these two perspectives demonstrate how AI can simultaneously lighten the load for caregivers and empower individuals to actively shape their own health journeys.

AI in Personalized Care and Health Coaching

Personalized Care: How AI Is Transforming the Experience

Artificial intelligence (AI) is changing healthcare at a fundamental level by enabling a more personalized, proactive, and continuous model of support for patients and caregivers. By harnessing vast amounts of health data, AI technologies can improve the precision of diagnosis, tailor interventions to the needs of individual patients, and extend care beyond the clinic into daily life.

AI enhances the delivery of personalized care by analyzing data drawn from electronic health records (EHRs), wearable devices, and even genetic profiles. Predictive analytics makes it possible to forecast conditions such as diabetes, cardiovascular disease, and mental health deterioration with far greater accuracy and speed than traditional methods. For example, algorithms can adjust dietary, medication, and activity recommendations in real time, providing truly individualized treatment plans.

Virtual health assistants such as Babylon Health and Ada Health are already offering 24/7 support, enabling patients to check symptoms, receive health advice, and schedule follow-ups. These tools extend clinical care into the everyday lives of patients, easing the burden on medical professionals while improving access for users. A pioneering example is IBM Watson for Oncology, which was originally deployed to match cancer patients with the most effective treatments based on individual characteristics and current clinical literature.

AI in Health Coaching: A More Responsive and Scalable Model

Beyond direct clinical support, AI is also reshaping the field of health coaching. By recognizing behavioral patterns, AI can detect user-specific triggers — such as missed medication, poor sleep, or sedentary behavior — and provide tailored interventions. These tools dynamically adjust goals in real time, ensuring that coaching remains relevant and motivating as patients progress or encounter challenges.

AI-driven coaching platforms use multiple modes of engagement, from text messages and voice prompts to video consultations, to deliver nudges and positive reinforcement. Examples include Noom, which integrates psychology with real-time tracking to support weight loss, and Lark Health, which offers AI-powered coaching for diabetes, hypertension, and behavioral health. These platforms illustrate how AI can scale individualized support to millions of users simultaneously.

Challenges and Risks

Despite the promise of AI in personalized care and coaching, challenges remain. Protecting sensitive health data is paramount, requiring strict compliance with regulations such as HIPAA in the

U.S. and GDPR in Europe. Another concern is bias: when AI systems are trained on non-representative datasets, their recommendations may be less accurate or even harmful for certain populations, reinforcing health inequities.

There is also the risk of over-reliance on automation, which could reduce human oversight in critical areas of care. Finally, AI's rapid evolution often outpaces regulatory frameworks, leaving uncertainty about standards, liability, and accountability.

Emerging Trends and Future Directions

Several innovations point to the future of AI in health coaching and personalized care. Digital twins — virtual models of individual patients — are beginning to be used to test interventions before they are applied in real life, potentially reducing risks and improving outcomes. Conversational AI systems are becoming more emotionally intelligent, providing not only medical guidance but also mental and emotional wellness support.

Meanwhile, federated learning allows AI models to be trained across decentralized data sources, enhancing privacy by keeping sensitive data local while still improving accuracy. The fusion of wearables with AI, such as the Apple Watch or Oura Ring, enables real-time health monitoring and analysis, delivering insights that can support continuous care outside of clinical settings.

Key Considerations for Implementation

For AI to reach its potential in healthcare, ethical and practical considerations must guide implementation. Transparency and explainability are critical to building trust among patients and providers. Inclusivity in data sourcing will help ensure that AI recommendations are equitable and representative of diverse populations. AI should be integrated with, not replace, human professionals to ensure empathy and oversight remain central to healthcare delivery. Finally, alignment with evolving regulations and deliberate efforts to build public trust will determine whether AI's promise translates into lasting improvements in health outcomes.

Conclusion

Caregiving and personalized health coaching are often seen as separate domains, yet this chapter has shown how deeply they intersect. Both rely on continuous support, tailored information, and timely decision-making: areas where AI offers unprecedented potential. For caregivers, AI can streamline complex care coordination, reduce burnout, and provide much-needed decision support. For individuals, AI-powered health coaching extends those same principles into daily life, enabling proactive management of chronic conditions, healthier behaviors, and more personalized care pathways.

Several themes cut across both areas: the need for trustworthy and explainable AI, the importance of equitable data sourcing to avoid bias, and the opportunity to integrate human expertise with digital tools rather than replace it. These common challenges also highlight shared opportunities: developing AI systems that are interoperable across health platforms, accessible to diverse communities, and adaptable to the dynamic needs of both caregivers and patients.

Looking forward, there is ample room for further study. Research into the economic impact of AI-driven caregiving tools, long-term outcomes of AI-enabled health coaching, and the intersection of broadband equity with health access will provide a deeper understanding of AI's role in reshaping healthcare. Those interested in the most innovative developments should look to collaborations at the intersection of healthcare providers, AI startups, and academic research institutions: particularly initiatives emerging from digital health accelerators, medical AI research hubs, and partnerships between hospitals and technology companies. These frontiers are where we will see the most promising advances, not only in reducing costs and improving efficiency, but also in creating a more compassionate,

personalized, and resilient healthcare system for both caregivers and patients.

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Qiana Martin is a nationally recognized family caregiver advocate and creator of The Primary Caregiver ecosystem — a suite of AI-powered tools, physical resources, and corporate wellness talks designed to support caregivers balancing paid work and unpaid care. Her work addresses the intersection of healthcare, public health, and workplace burnout.

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Chapter 14:
The Impact of AI on Wellness Coaching

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AI Innovation Is Affecting Wellness Coaching

Artificial intelligence (AI) is rapidly transforming wellness coaching by making it more personalized, data-driven, accessible, and scalable. Through advancements in machine learning, real-time analytics, and behavioral modeling, AI is enabling coaches and organizations to move beyond one-size-fits-all approaches. Today's AI systems can provide continuous support, analyze health metrics, and deliver personalized advice that aligns with each individual's unique needs. As a 30-year technology professional, I am astonished by the advancement of AI and the way it will reshape wellness coaching in the future. What does the wellness coaching market look like today and how does this serve as a point of reference for the potential impact of this area of innovation?

To start, let's break down this market into three categories: the total market, the digital health coaching market, and the AI-empowered digital health coaching market.

Global Health & Wellness Coaching

The global value for the market in 2025 was valued at USD 20.1 billion in 2025, expected to reach USD 17.4 billion in 2025 and jump to USD 26.6 billion by 2029, growing at a CAGR of 7.3% (2025–2029). A report by Market.us Media indicates that global health coach market (including offline) was USD 16.1 billion in 2023, projected to grow to USD 32.3 billion by 2033, with a CAGR of 7.2%. The overall theme and trend is very clear and shows that there is fast and steady growth globally for wellness coaching as an industry. This begs the question, "What portion of this will be a digital-based solution and in particular in the United States?"

Digital Health Coaching

Horizon Grandview Research shows that the U.S. market reached USD 3.14 billion in 2024, forecast to hit USD 5.56 billion by 2030, growing at a 10.3% CAGR . This is clearly a significant opportunity and highlights a fast-moving trend in the United States.

That research further shows that in North America, overall digital health coaching was valued at USD 4.14 billion in 2024, and projected to expand to USD 7.72 billion by 2030, with an 11.2% CAGR. These forecasts predict broad adoption of digital health coaching services.

AI Wellness Segment

Research shows that AI-enhanced health coaching markets (e.g. wearables, chatbots, nutrition apps) are expected to grow at a CAGR of between 10% - 15% (2024 - 2034)

https://www.thebusinessresearchcompany.com/report/health-coaching-apps-global-market-report

https://www.globenewswire.com/news-release/2025/3/20/3046609/0/en/Digital-Health-Coaching-Market-Report-2025-2030-with-Profiles-of-Atlantis-Health-Naluri-Therapeutics-Noom-Lark-Technologies-Omada-Health-Avidon-Health-Quartet-Health-Lyra-Health-mo.html

https://www.insightaceanalytic.com/report/digital-health-coaching-market/2934

Case Study: Xcellent Life and Patent US 10,671,707 B2

As an innovator and advocate for greater health, it is important to me that great healthcare become more accessible to everyone, so it is exciting to see that technological innovation is opening up so many opportunities for communities who have historically been undeserved.

One innovation is Xcellent Life's patented AI wellness system (US 10,671,707 B2). This technology dynamically manages communication between coaches and clients based on the client's activity data. For instance, if a trainee hasn't met their workout threshold, the system can limit messaging while displaying motivational feedback. Once the client meets their goals, they're rewarded with more access to coaching or other perks.

This model:

- Reduces unnecessary message volume.
- Encourages consistent engagement in healthy behaviors.
- Promotes self-motivation while ensuring scalability for wellness providers.

This growth is outpacing the growth of the general wellness coaching market and thus shows that the adoption of AI technology within healthcare will gradually cannibalize more traditional wellness coaching opportunities.

The market for AI-empowered wellness presents a tremendous opportunity for innovators in the healthcare industry and those that can adapt and leverage AI as a core component to their offering will likely fare much better than any who do not embrace AI.

Wellness Coaching Applications Empowered by AI Today

AI is already playing an important role in digital health coaching. Here are just some of the areas where AI is helping with wellness coaching.:

- **Behavioral Nudging**: AI delivers timely prompts to encourage healthy habits, including exercise, hydration, sleep hygiene, and mindfulness. An example of this would be sitting at your desk too long without moving and an AI Chatbot telling you that it is time to move and get active.
- **Data-Driven Personalization**: Through integration with wearables and mobile apps, AI tailors coaching plans using real-time data such as heart rate, sleep cycles, and stress levels.
- **Mental Health Monitoring**: Emotional wellness platforms use AI to analyze mood patterns and suggest interventions or support systems.
- **Administrative Automation**: AI helps coaches by handling scheduling, client messaging, progress tracking, and insight generation.

Benefits

The current benefits of AI-driven wellness coaching include:

- **Accessibility**: AI reduces costs, offering high-quality wellness coaching through apps and devices to people who may not afford human coaches.
- **Consistency**: Digital coaches are always available, reducing gaps in support between in-person sessions. Digital coaches are chat bots that perform the same role as a wellness / health coach.

- **Scalability**: Organizations can support thousands of users with minimal increase in human labor.
- **Motivation and Retention**: Gamification and behavior tracking maintain user engagement and progress. The gamification and consistent interaction has been shown by many studies to drive behavior change.

In a pilot of Xcellent Life's software, we looked across a population of 500 users where we measured against baselines and documented measurable differences including a 80% increase in healthy behaviors and a 45% increase reduction in avoidable health incidents.

Future Applications: Xcellent Life's Lifeforce Metric and AI Coach

Looking ahead, Xcellent Life plans to deploy an AI-powered virtual wellness coach that delivers **real-time guidance** based on its proprietary **Lifeforce Metric**—a novel measurement designed to reflect a person's true physiological vitality. Unlike static or single-point biometrics, the Lifeforce Metric dynamically synthesizes multiple biological signals to deliver an accurate picture of human health in real time.

Impact in Today's Wellness Coaching Industry

AI is democratizing wellness, giving more people access to the tools they need to lead healthier lives. Businesses are also seeing improved workforce health, leading to increased productivity and reduced healthcare costs. AI's influence extends from individuals to institutions, reshaping how health and vitality are monitored, supported, and improved. When applied the right way and with good purpose, AI will truly serve to advance society through many innovations, including in the area of wellness coaching.

How AI Innovation Will Affect Wellness Coaching in the Future

Future capabilities of AI-empowered systems will include:

- **Predictive Analytics**: Forecasting potential health issues before symptoms appear
- **Biometric-Driven Recommendations**: Continuous optimization of wellness plans based on fluctuating reading from biometric vitals and internal conditions
- **Emotional Intelligence**: AI with empathy models responding to emotional tone and stress indicators
- **Immersive Experiences**: Integration with VR/AR for guided meditations, workouts, or recovery sessions

Examples

- **Neurofit** is using neuroscience and AI to tackle chronic stress through personalized somatic exercises.
- **CloudFit** offers enterprise-grade wellness platforms that integrate AI-based coaching across nutrition, sleep, stress, and physical activity.

Benefits

- **Hyper-Personalization**: Health recommendations tailored down to genetic, lifestyle, and moment-to-moment emotional data
- **Preventive Care**: Interventions initiated before illness begins, helping extend healthy life years
- **Greater Inclusion**: AI that adapts across cultures, languages, and communities—expanding global access to care
- **Human + Machine Synergy**: Coaches enhanced with AI providing deeper emotional and contextual support

Impact

AI is set to help shift the paradigm from reactive to proactive wellness, empowering individuals to become stewards of their own vitality. The convergence of real-time data, intelligent algorithms, and ethical design could create a society where health coaching is not only a luxury but a ubiquitous support system. Given this reality, how should people position themselves to best benefit from this innovation?

How Should You Prepare?

Embrace Technological Evolution

Change can be intimidating, but those who lean into innovation stand to benefit the most. Begin by familiarizing yourself with AI-powered wellness tools; try wearable integrations, health apps, and virtual coaching systems to experience how they work.

Understand How to Leverage Innovation to Empower Yourself and Family

Look for platforms that provide transparency, evidence-based guidance, and personalization. Teach your family to use these tools to monitor health proactively, set goals, and make smarter lifestyle choices. AI can be a family's wellness assistant, guiding everyone toward better health.

Become an Innovator and Be a Part of Shaping Our Society

Whether you're a wellness professional, tech enthusiast, or simply a concerned citizen, you can play a role in shaping how AI serves society. Advocate for ethical use, contribute feedback to developers, or even develop solutions that prioritize health equity, empathy, and empowerment.

Conclusion

AI-empowered wellness coaching is no longer niche; it's a booming multi-billion-dollar market with digital and AI facets growing at mid-teens to low-20s percent annually. As AI's adoption deepens, expect both investment and consumer uptake to surge. If you're considering launching or joining an AI wellness initiative today, you're entering a market set for explosive growth.

Moreover, AI is not just changing wellness coaching—it's reinventing it. We are entering an era where health support is predictive, personalized, and profoundly empowering. The future of wellness coaching is here, and it's digital, data-driven, and deeply human at heart. The question is: will you be a passive recipient... or an active participant in the next health revolution?

Author (In order of contribution)

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Victor L. Brown is a seasoned leader with extensive experience within both large global companies and start-ups where he has spent decades driving technology innovations across global markets.; Victor has driven business success as a leader and as a hands-on practitioner of best-practice approaches across engineering, marketing, business development & sales. Victor now cherishes the opportunity to explore ways to utilize AI to advance society.

Chapter 15: Observability, Transparency, and Responsible AI Use

Authors: Sylwana Kaźmierska, Ann M. Marcus

Observability, Transparency, and Responsible AI Use

In today's rapidly evolving healthcare landscape, AI systems are becoming integral to improving diagnostics, treatment planning, and patient management. However, with these benefits come responsibilities. Terms such as **observability**, **transparency**, and **responsible AI use** are often tossed around, but what do they really mean in practice? And importantly, how can these principles be implemented by AI practitioners, machine learning engineers, clinicians, and healthcare administrators alike?

While these concepts are interrelated, they serve different roles in managing and deploying AI systems effectively:

- **Observability** is the technical foundation that lets us peer into an AI system's inner workings.
- **Transparency** builds on observability by making those internal processes understandable to everyone, from developers to patients.
- **Responsible AI Use** is the overarching principle ensuring that AI not only performs the intended task well but does so ethically and safely.

Together, they form a comprehensive framework that ensures AI is efficient, trustworthy, and aligned with ethical standards in any application – but especially in medical settings.

Let's examine these three principles in more depth.

Observability: Understanding the Inner Workings

Observability is all about understanding the internal state of an AI system through its monitoring and data analysis. In practice, this involves:

Monitoring and Logging: Capturing operational data such as performance metrics and error logs to track how the system behaves over time. For instance, imagine a diagnostic tool that constantly logs its prediction errors; this data can be invaluable for pinpointing when and why a mistake might have occurred.

So, for example, AI models are built around systems that can shift over time due to a variety of factors. These include evolving consumer profiles in the healthcare sector, generational shifts in workplace behavior, and the emergence of new diseases. So, a model that was initially accurate may degrade over time in unpredictable ways. If this is due to "data drift" – when societal changes make the original datasets inaccurate – it is essential to monitor the model's performance to quickly identify any erroneous trends. This allows for timely regeneration of the model or a reevaluation of its foundational principles.

Metrics and Tracing: Establishing quantitative measures (including latency, throughput, and resource usage) and detailed process traces helps identify performance bottlenecks or anomalies. Think of it as the "black box" in an aircraft; it records everything so that if something goes wrong, engineers can diagnose the cause of the problem quickly.

However, the challenge lies in balancing technical depth with user-friendliness. Too much information might overwhelm non-experts, yet the data must be precise enough to account for user variation and foster trust. Healthcare institutions, therefore, need clear protocols for post-deployment audits, real-time alerts for unusual behavior, and safe rollback procedures for models that aren't performing as expected.

Transparency: Making AI Understandable

Transparency in AI means making the processes, assumptions, decisions, and data handling practices clear and accessible to all stakeholders, including developers, clinicians, insurers, regulators, and patients. This concept is especially crucial in healthcare, where trust and accountability are paramount.

Explainability: At its core, transparency involves offering understandable explanations for AI decision-making. For example, consider a diagnostic tool: clinicians should be able to see which factors influenced a particular decision. This not only helps in verifying the accuracy of the diagnosis but also allows healthcare providers to assess whether the AI's reasoning aligns with clinical expertise.

One such tool for understanding data models is a heatmap. It pinpoints the areas that contributed the most to a model's decision process and outcome(s). Decision trees and regression algorithms implement a set of "feature importance" metrics – that should be transparently established by developers, practitioners, and patients – as well indicate which inputs to the model are the ones that most strongly influenced the decision.

One such example of the limitations in AI decision making is the case of skin tone bias in melanoma detection AI. A study published in the professional journal *Dermis* (April 2025) found that melanoma detection models underperform on darker-skinned patients because training datasets lacked diversity. AI carries the risk of reinforcing existing biases in healthcare, largely stemming from the underlying data rather than the AI algorithms themselves. Because AI models are trained on datasets influenced by human decisions and existing inequities, they may inadvertently perpetuate these biases

Education and Training: To fully leverage transparency, non-technical stakeholders may require training. Integrating AI literacy into medical and nursing school curricula will ensure future healthcare providers understand AI's limitations, inherent biases, and the reasoning behind its decisions–though this is a moving target as AI algorithms are constantly being updated. A well-informed workforce is also less likely to blindly trust AI outputs and more likely to critically assess AI-driven decisions–as they should.

By making AI systems more transparent, we not only build trust but also empower all users — especially those directly responsible for patient care — to make informed decisions about integrating AI into their practices and help patients better understand those decisions and even influence the decision-making process and its assumptions.

Responsible AI Use: Ethics, Accountability, and Compliance

The goal of responsible AI use is to ensure that AI models operate safely, ethically, and effectively. In healthcare, this means that AI models must be validated across diverse populations, clinical settings, and geographic regions to prevent biased or unsafe recommendations. Insufficient testing that relies on a limited population has produced unintended results.

Data Provenance and Quality: AI developers must define a framework that outlines where the data comes from, how its quality is ensured, and what measures are in place to detect bias. Without such a framework, AI models may inadvertently amplify existing disparities in healthcare outcomes. For example, an AI system trained predominantly on data from one demographic might not perform as well for another demographic,

One example, albeit from seven years ago (an eternity in AI development) is this **automatic soap dispenser located that did not recognize black hands**, as shown in this video.

A more recent example is this large-scale study published by the National Institute of Health in April 2025 revealed that LLM-based clinical assistants consistently provided less aggressive diagnostic testing recommendations for low-income patients, despite identical clinical details to high-income counterparts. This bias meant wealthy patients were more likely to receive advanced tests like MRIs or CT scans, reflecting systemic healthcare inequities and raising ethical alarms about fairness in triage delivery based on AI decision support.

Accountability: When AI systems make errors — be it a faulty diagnosis or a biased treatment recommendation — we must have clear accountability frameworks. Whether through internal governance, liability laws, or disclaimers accompanying AI-assisted decisions, assigning responsibility helps avoid ethical and legal dilemmas.

A case in point was reported by Verge in August 2025: Google's Med-Gemini model published a research paper in 2024 introducing a serious hallucination in a section on head CT scans in which it created a part of the brain that didn't exist by conflating two terms –"basal ganglia" and "basilar artery"-- into "basilar ganglia." A blog post also reflected the erroneous term. Nobody at Google caught it, in either that paper or a blog post. The error persisted despite review by dozens of experts until a board-certified neurologist / researcher with expertise in AI flagged the mistake. The blog post was quietly edited with no public acknowledgement, but the paper remained unchanged. Google called the incident "a simple misspelling of 'basal ganglia'," but some medical professionals say it's a dangerous error and an example of the limitations of healthcare AI without real-time monitoring or human-in-the-loop checks.

Regulatory Compliance: The landscape of AI regulation is complex and global. AI systems must comply with laws such as HIPAA, GDPR, and emerging local AI regulations while also adhering to ethical standards. A coordinated, cross-disciplinary regulatory approach is needed to avoid fragmented compliance that could hinder innovation and patient safety.

As an example, General Data Protection Regulation (GDPR) requires that healthcare organizations in the European Union (EU), including the National Health Service (NHS) in the UK, comply with AI-centered companies to incorporate advanced tools for data safety. This has led to the introduction of a federated approach in which machine-learning models are trained on data that remains distributed across multiple locations without the need for the system to "see" the data directly. This approach addresses privacy concerns and data security regulations by keeping sensitive data within its original location while still enabling training for the integrated model.

Embracing Standards as Enablers, Not Barriers

It might seem that all these principles — observability, transparency, and responsible AI use — are cumbersome requirements for engineers and healthcare practitioners to follow. But they are there for protection. Consider again the standards in healthcare such as HIPAA (Health Insurance Portability and Accountability Act), which ensure the confidentiality, integrity, and availability of protected health information and facilitates secure electronic data exchange, safeguarding patient privacy. In the same way, unified standards for AI can simplify development and ensure compatibility and trust across various platforms and institutions.

By establishing common ground rules, AI practitioners can focus more on innovation and less on wheel reinvention. Standards not only streamline the development process but also provide a clear roadmap for integrating AI responsibly into healthcare settings. Ultimately, when every stakeholder — from machine-learning engineers to medical professionals — speaks the same language, the path to safer, more effective AI use becomes much clearer.

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Chapter 16: From SDOH to Solutions: Leveraging AI to Address Health Inequities in Rural Communities at Home & Abroad

Author: John Barton

Overview

Community health is the foundation of economic resilience, civic stability, and durable change. However, not all communities are equally protected or supported. Where people live — and what they are exposed to — is shaped by decades of structural decisions: Who gets clean water? Who lives near polluting industries? Who benefits from public investment… and who is burdened by its absence? These inequities are not accidental. They reflect policy choices, land use decisions, and systems of exclusion designed to concentrate harm in some communities while shielding others.

Repair requires more than acknowledgment. It requires alignment. Communities, policymakers, and investors each hold part of the solution, but too often they're working in parallel, cut off by siloed systems, conflicting timelines, and incompatible tools. What's missing is not intent, but alignment.

Communities want more than aid; they want justice. They want to see systems change, not just services delivered. Policymakers want measurable results. Investors want to know their capital is building something real. The approach outlined here bridges those needs. It translates deeply rooted drivers of health — Social Determinants of Health — into actionable, measurable outcomes. By giving each stakeholder the tools to act on what matters most to them, it advances a shared commitment to structural change.

What Are Social Determinants of Health?

Social Determinants of Health (SDOH) are the structural conditions that shape whether people can live long, healthy lives or face preventable harm. (CDC, 2023) These forces include economic exclusion, legal discrimination, environmental exposure, under-resourced infrastructure, and systemic disconnection from civic power. (Healthy People 2030, 2023) From redlining and labor exploitation to environmental dumping and educational segregation, these inequities are designed outcomes… and they can be dismantled. (Harvard T.H. Chan School, 2019)

Health outcomes are not determined solely by personal choices or genetics. They are produced through decades of policy decisions: how budgets are set, where housing is built, who has access to care, and who holds power. Neighborhoods with economic instability, failing infrastructure, and unsafe conditions often have life expectancies that are 10 to 20 years shorter than more affluent areas nearby. (CityHealth Dashboard, 2023) These disparities are not natural; they are manufactured. (Braveman et al., 2022) And they come at a cost: illness, instability, wasted investments, and systemic failure.

To target these root causes, SDOH are grouped into five core domains that define the terrain of structural health inequality:

- **Economic Stability**: Income, employment, cost of living, and financial stress
- **Education Access and Quality**: Literacy, school quality, language access, and opportunity gaps
- **Health Care Access and Quality**: Coverage, proximity, provider capacity, and cultural competency
- **Neighborhood and Built Environment**: Housing, transit, pollution, green space, and safety
- **Social and Community Context**: Social support, civic life, discrimination, and trauma exposure

These domains shape everything from maternal mortality to asthma rates to chronic illness burden. For example, economic instability drives chronic stress; poor housing conditions contribute to respiratory illness; and limited education reduces long-term health literacy. When harm accumulates across these dimensions, the result is a system where outcomes are structurally unequal. (NIH, 2023) Advancing equity requires focusing on these domains, because they define where harm is distributed, and where repair is possible.

Why Traditional Responses Fall Short

Traditional responses to health disparities often fail because they focus on managing downstream symptoms rather than addressing upstream causes. (Braveman & Gottlieb, 2014) These interventions — whether in the form of temporary funding, isolated programs, or reactive public health campaigns — treat visible outcomes while leaving the structural sources of harm intact.

They are often:

- **Short-term**: Limited to election cycles or grant timelines
- **Fragmented**: Disconnected across sectors and systems
- **Technocratic**: Centered on metrics and outputs rather than root causes
- **Top-down**: Designed without the insight or consent of affected communities

Despite this, dominant health policies continue to center individual behavior through education campaigns, behavioral incentives such as smoking cessation, and clinical interventions that treat symptoms rather than causes. These models prioritize personal responsibility while ignoring structural barriers including food deserts, unsafe housing, racialized policing, or economic precarity. They seek efficiency without equity, and results without repair. Without a structural lens, even well-intentioned efforts risk reinforcing the very systems that create harm in the first place.

Frontline communities have long insisted — and research confirms — that structural conditions, not personal failure, drive health disparities. Ignoring these forces is not just ineffective. It is unjust.

The Need for a Structural Lens and Systemic Tools

To achieve equity, we must move beyond treating symptoms. We must name and address the systems that produce harm. (Braveman & Gottlieb, 2014) This includes recognizing historical injustice, exposing how it continues to shape outcomes, and building tools for repair. A structural lens allows us to:

- Identify upstream drivers and legacy harms,
- Forecast preventable risk before it escalates,
- Align cross-sector action without requiring centralization, and
- Link governance to community-defined accountability.

Technology alone cannot fix structural violence, but a framework enabled by artificial intelligence (AI) can strengthen a community's ability to see, respond to, and reshape the systems that perpetuate harm. When designed with equity at its core, AI can help trace structural root causes, identify where disparities are emerging, and support coordinated, data-informed interventions. Rather than dictating solutions, it amplifies local insight, links prevention to accountability, and transforms analysis into action.

The following framework is designed to put equity into practice through structure, foresight, and

shared accountability. It links data to decision-making, communities to governance, and power to responsibility. By making the invisible visible — and the structural actionable — it offers a path forward: not just to manage harm, but to transform the systems that cause it.

Stakeholders

This framework operates across a distributed network of stakeholders; each one is positioned to identify structural harm, shape resource flows, implement interventions, and hold systems accountable for repair. Rather than treating participation as symbolic, the framework embeds stakeholder roles directly into its causal model, governance design, and feedback architecture. This section defines how each group engages at key stages, what tools they use, what decisions they shape, and where authority or access gaps persist. It maps the infrastructure of equity — not just in theory, but in practice — through operational roles that enable systems to counter harm, not just understand or sustain it.

By explicitly mapping the roles, causal stages, tools, decision control, and access gaps for each group, this section supports traceable, auditable alignment across the entire framework. Stakeholders are not passive recipients; they are positioned as operational actors in a shared learning system. Bridged by AI-enabled insight and guided by structural equity principles, this network can adapt in real time to emergent harm and opportunity, if authority, access, and governance thresholds are honored system-wide.

1. Community Members and Local Advocates

- **Role:** Ground truth the framework, provide experiential insight, co-author definitions of harm and impact
- **Needs:** Tools that validate lived experience, support participatory governance, and make data usable and accessible
- **Engagement Point:** Co-design workshops, community data collection, dashboard transparency
- **Tools Used:** Community feedback-to-action interface, equity tracking dashboard
- **Causal Stage:** Foundational Forces → Adaptive Feedback → AI Diagnosis
- **Decision Control:** Participatory input only; cannot trigger resource shifts
- **Access Gap:** Often excluded from authority over system-level decision making despite being primary data producers

2. Community-Based Organizations (CBOs) and Nonprofits

- **Role:** Deliver frontline services, connect structural barriers to individual outcomes, pilot interventions, and act as trusted intermediaries between systemic structures and lived experience
- **Needs:** Translation and modeling tools that articulate frontline work in structural terms, enable impact mapping, and support alignment with system-wide logic models
- **Engagement Point:** Narrative builders, logic model support, structural impact mapping
- **Tools Used:** Structural impact mapping tools, intervention/prevention matching matrix, logic model builder
- **Causal Stage:** Foundational Forces → SDOH Domains → Matched Interventions
- **Decision Control:** Provide applied insight; typically excluded from funding decisions
- **Access Gap:** Limited access to forecasting tools and outcome evaluation dashboards

3. Public Health Agencies and Systems Planners

- **Role:** Coordinate resources, respond to community health trends, forecast demand and impact
- **Needs:** Real-time data integration, forecasting tools, prioritization models
- **Engagement Point:** SDOH diagnostics, intervention matching, equity dashboards
- **Tools Used:** SDOH diagnostic template, structural equity scenario comparator

- **Causal Stage:** Foundational Forces → Indicators → AI Diagnosis → Matched Interventions
- **Decision Control:** High operational authority; responsible for tool implementation and oversight
- **Access Gap:** May lack upstream community insight without structured participatory input

4. Local and State Governments

- **Role:** Allocate funding, shape infrastructure and policy, set equity goals, and enforce cross-sector alignment with structural equity goals
- **Needs:** Decision-support tools that integrate structural forecasting, policy alignment, and adaptive planning responsive to equity thresholds
- **Engagement Point:** Investment forecasting tools, adaptive planning interfaces
- **Tools Used:** Equity tracking dashboard, structural equity scenario comparator, adaptive planning interface
- **Causal Stage:** Foundational Forces → Matched Interventions → Adaptive Feedback
- **Decision Control:** Policy and budget-setting authority
- **Access Gap:** May operate without grounded definitions of structural harm or lack access to equity-triggered adaptation mechanisms

5. Funders and Philanthropic Advisors

- **Role:** Invest resources, shape grant criteria, evaluate impact at scale
- **Needs:** Strategic filters for grantmaking, tools to forecast structural impact, and mechanisms to prioritize preventive investment
- **Engagement Point:** Proposal evaluation engine, causal alignment reviews, and predictive funding guidance tools
- **Tools Used:** Proposal evaluation engine, structural equity scenario comparator
- **Causal Stage:** Foundational Forces → Forecasting → Proposal Review → Matched Interventions
- **Decision Control:** High leverage in shaping structural priorities via funding alignment
- **Access Gap:** May lack mechanisms for upstream accountability to equity goals

6. Researchers & Data Analysts

- **Role:** Validate models, generate insight, and assess effectiveness as validators within the feedback system
- **Needs:** Transparent data flows, auditability, and alignment between data and theory
- **Engagement Point:** API access, model interpretation tools, longitudinal data archives
- **Tools Used:** Equity tracking dashboard, AI adaptation and evaluation module
- **Causal Stage:** Foundational Forces → AI Diagnosis → Adaptive Feedback
- **Decision Control:** Indirect; influence through validation and feedback loops
- **Access Gap:** Limited control over intervention adoption or prioritization

7. Technology Partners

- **Role:** Build, integrate, and maintain the systems that enable adaptive AI and user interface layers, and translate governance specifications into technical architectures that shape system behavior and inclusion
- **Needs:** Operational specifications, equity-aligned design protocols, and structured access to feedback loops for evaluating long-term equity performance
- **Engagement Point:** Open-source governance standards, user feedback channels, sandbox environments
- **Tools Used:** Participatory simulation module, user interface frameworks, structural translation engine, sandbox environments
- **Causal Stage:** Infrastructure layer across all stages
- **Decision Control:** Implementation authority; dependent on specification from other stakeholders

- **Access Gap:** Often lack long-term visibility into system impact or feedback on harm reproduction, limiting ability to course-correct or uphold equity goals

8. Educators and Policy Co-Designers

- **Role:** Teach, translate, and embed the framework into public knowledge and policy structures, and influence long-term civic understanding and upstream governance capacity
- **Needs:** Culturally grounded curricula, participatory toolkits, and frameworks for translating governance logic into civic understanding
- **Engagement Point:** Civic education modules, participatory design training, policy lab integration
- **Tools Used:** Participatory simulation module, feedback-to-action interfaces, governance design toolkits
- **Causal Stage:** Foundational Forces → Feedback → Diagnosis → Design
- **Decision Control:** Influence policy literacy and adoption; not empowered to control system response
- **Access Gap:** Often siloed from development timelines, limiting their ability to shape tool design, curriculum relevance, or civic integration at key points

9. Oversight & Equity Governance Bodies

- **Role:** Enforce equity thresholds, audit foundational harm, and oversee system-wide alignment
- **Needs:** Transparent metrics, participatory escalation mechanisms, structural impact triggers
- **Engagement Point:** Public audits, equity review boards, governance alignment protocols
- **Tools Used:** Foundational force accountability module, equity tracking dashboard
- **Causal Stage:** Foundational Forces → Governance → Feedback
- **Decision Control:** Regulatory and oversight authority
- **Access Gap:** May lack timely insight or tools for intervention unless explicitly embedded in feedback loops

Stakeholder Alignment Insights

- **No single group controls the system**. Collaboration across roles is not optional; it's infrastructural.
- **Community stakeholders produce the most insight-rich data** yet remain the least empowered. Closing this gap is a governance imperative.
- **Governments and technologists must be structurally accountable**, not just efficient. Without grounded equity checks, they risk harm reproduction.
- Oversight only works if embedded early and with authority, not as a post-hoc safeguard.
- **Funders, educators, and analysts serve as translation engines**, shaping what counts as insight, investment, and governance literacy.
- Access gaps are not neutral; they reflect legacy systems of exclusion. This framework tracks them as design failures to be corrected.
- Participation is not symbolic; it is embedded through tools, feedback loops, and role-specific entry points.

Challenges and Gaps

Social Determinants of Health (SDOH) are the conditions under which people live, work, and play; they drive the majority of health outcomes. Yet despite their predictive power, most systems treat SDOH as background context rather than as levers for action. The challenges below reveal how structural misalignments, broken feedback loops, and governance gaps prevent communities from addressing harm upstream. Each barrier disrupts the causal chain that would otherwise translate insight into equitable action.

Core System Barriers

A. Structural Misalignment

Problem: SDOH are often treated as descriptive instead of actionable.
Example: Mapping food deserts without funding mobile grocery programs or land-use reform: Existing interventions lack alignment with structural causes. Interventions often target symptoms (e.g., ER overuse) without addressing root causes such as housing exclusion, transit deserts, or policy inaccessibility.

Key Stakeholders Affected:

- Community-Based Organizations (CBOs) & Nonprofits
- Community Members & Local Advocates
- Public Health Agencies & Systems Planners
- Local & State Governments

Unmet Needs:

- [TOOLS] Translation tools to reframe local work as structural
- [TOOLS] Tools that validate lived experience
- [MODELS] Prioritization models for structural intervention
- [TOOLS, MODELS] Evidence-based investment tools

B. Equity Failures

Problem: - Persistent health disparities across racial, geographic, and economic lines
These disparities remain entrenched, particularly in rural communities, disinvested urban areas, and regions with limited public infrastructure.

Unmet Needs:

- [METRICS] Community-defined equity metrics
- [TOOLS, PROCESSES] Curriculum and tools to embed equity in governance
- [PROCESSES, METRICS] Grantmaking filters based on structural need

C. Technological Risks

Problem: AI systems risk reproducing harm through biased data, limited access, and top-down implementation.
Predictive tools can reflect existing inequalities if not locally governed or audited. Centralized systems often ignore regional context or community expertise.

Unmet Needs:

- [PROCESSES, AUTHORITY] Equity design principles and local co-creation mandates
- [MODELS, ACCESS] Transparent and auditable data models
- [PROCESSES, AUTHORITY] Participatory governance controls

D. Systemic Inflexibility

Problem: Most public health systems lack dynamic feedback or preventive forecasting capacity. Many systems can track outcomes but not adapt in real time to early warnings or shifting structural conditions.

Misaligned metrics prioritize volume or efficiency over equity. Programs are evaluated by throughput or cost-saving rather than structural repair, upstream prevention, or community-defined success.

Unmet Needs:

- [TOOLS] Real-time adaptation tools and dashboards
- [PROCESSES, METRICS] Feedback loops integrated with equity metrics
- [MODELS] Prevention ROI modeling

E. Funding Misalignment

Problem: Funding misalignment due to lack of predictive data
Without the ability to forecast structural outcomes, funding often flows to high-visibility symptoms rather than high-leverage prevention. Communities with the greatest long-term need may be overlooked due to data blind spots or reactive budget planning.

Most public health systems lack dynamic feedback or preventive forecasting capacity. Misaligned metrics prioritize volume or efficiency over equity
Programs are evaluated by throughput or cost-saving rather than structural repair, upstream prevention, or community-defined success.

Unmet Needs:

- [TOOLS, MODELS] Forecasting and prioritization tools for structural ROI
- [MODELS, PROCESSES] Logic model support to justify impact
- [TOOLS, ACCESS] Adaptive planning interfaces for policy

Summary

Each challenge reveals where the current system breaks its causal chain, whether between diagnosis and intervention, prevention and funding, or insight and adaptation. These breakdowns are not simply technical; they are governance failures, measurement failures, and authority gaps. This new framework responds by assigning tools, feedback loops, and predictive models directly to the actors most affected, enabling upstream repair at the point of disconnection.

Together, these challenges expose a fundamental disconnect: health systems often capture "what" is happening without investing in "why", or enabling communities to act on what they already know. This framework is designed to bridge that gap.

By mapping these systemic barriers to specific stakeholder roles, causal stages, and tool-based needs, the framework reveals not just what is broken, but where and how to repair it with precision and accountability. Each challenge corresponds to concrete gaps in stakeholder tools, authority, or data access. Aligning the system to support these groups — from grassroots advocates to state planners and technology partners — is essential for shifting from reactive responses to proactive, equity-driven design.

A New Framework for Structural Health Equity

Overview

This framework equips communities, policymakers, funders, and public health actors with a durable system for translating structural harm into coordinated, preventive, and equitable action. It is built to address a persistent challenge: how to move from understanding the root causes of health disparities — what we call the Social Determinants of Health (SDOH) — to real-time interventions that shift outcomes at scale.

Unlike traditional health efforts that react to downstream symptoms or operate in fragmented silos, this AI-powered framework is designed to align efforts across systems. It connects community insight to decision-making authority, governance to accountability, and data to impact, without requiring centralization or consensus. Each actor works within their own domain but toward a shared outcome: systems that are structurally aligned, equity-centered, and participatory by design.

At the core is a structural translation engine. This engine interprets deep patterns of harm (e.g., eviction data, environmental hazards, access barriers) and translates them into predictive insights and recommended actions. It builds feedback loops that adjust in real time, enabling stakeholders to learn, adapt, and remain accountable to measurable equity benchmarks.

Whether identifying a transit gap that leads to missed prenatal visits or mapping housing instability against asthma hospitalizations, the framework doesn't just describe disparities; it acts on them.

What the Framework Does

Key shifts enabled by the framework:

- From disconnected efforts → aligned, role-specific contributions
- From one-time interventions → continuous feedback and improvement

- From intention → traceable structural impact
- From community input → community ownership

This is not a single intervention. It is a continuously learning and role-responsive system: modular, self-correcting, and structured around equity enforcement mechanisms. It builds coherence across differences, allowing community leaders, funders, technologists, and agencies to act in complementary ways.

The system's design is anchored in five guiding principles:

- **Equity** as a structural precondition, not an aspirational value
- **Prevention** as a measurable investment
- **Participation** as an infrastructure requirement
- **Trust** built through transparency and feedback
- **Alignment** across governance, data, and impact

Core System Capabilities

Each core function targets a common failure in current systems and replaces it with a mechanism for insight, foresight, and coordinated change. Together, they form a toolchain for system-wide transformation:

1. Forecast Health Outcomes from Funding Decisions

Helps funders and governments model the long-term impact of investments — housing, transit, broadband, mobile health — on public health and equity. Forecasts guide budget prioritization and trigger review when predicted outcomes diverge from reality.

2. Evaluate Proposals by Health & Equity Impact

Screens funding and policy proposals for root-cause alignment. Flags short-term fixes that ignore upstream drivers and supports smarter investment through structural risk and impact scoring.

3. Translate Local Programs into Structural Language

Helps community coalitions and nonprofits communicate their value to systems. Converts lived experience into logic models and impact narratives that resonate with planners and funders.

4. Identify High-Impact Prevention & Intervention Opportunities

Uses AI to map structural risks and disparities in real time. Hotspot mapping and scenario models identify where early intervention is most needed and most effective.

5. Support Adaptive Feedback & Real-Time Adjustment

Builds performance dashboards, equity alerts, and public feedback loops into implementation. Tracks what's working, where gaps are emerging, and how systems can adapt responsively.

6. Enable Participatory Design & Community Ownership

Centers communities in decision-making, not just feedback. Participatory governance tools, veto gates, and simulation modules ensure affected populations can shape and redirect high-impact decisions.

Linking Capabilities to System Stages

The core capabilities outlined above describe what each group of stakeholders can *do*: forecast, evaluate, translate, intervene, adapt, and govern. But capabilities don't operate in a vacuum. They engage with the system's causal structure: a sequence of interlocking stages that describe how structural harm translates into health outcomes, and how those outcomes can be shifted.

Capabilities are not mapped one-to-one with these stages. Instead, they act as intervention levers across them. For example, forecasting tools influence both early investment decisions and late-stage feedback triggers. Translation tools convert lived experience into actionable data that feeds diagnosis, intervention selection, and evaluation.

In this way, the capabilities empower stakeholders to disrupt harmful causal flows, reinforce equity-positive ones, and align efforts across the system. The stages are where structural harm plays out. The capabilities are how we intervene to change that trajectory.

How the System Operates

The framework moves through seven interlocking stages that connect structural harm to health outcomes. These are not linear steps, but iterative loops; each one refines and reinforces the next:

- **Barriers** → Systemic obstacles such as exclusionary zoning, underfunded infrastructure, or discriminatory enforcement policies
- **SDOH Domains** → Core life areas where these barriers manifest: housing, education, transportation, employment, environment
- **Indicators** → Quantifiable signals such as eviction rates, asthma prevalence, or school dropout rates that reveal pressure points in the system
- **Health Impacts** → The downstream results of these conditions, including ER visits, maternal mortality, and chronic illness
- **AI Diagnosis** → Pattern recognition across time and geography that detects causal clusters and emergent disparities using structured and unstructured data
- **Matched Interventions/Prevention** → Tailored responses selected from a catalog of context-sensitive solutions, ranging from legal aid to broadband expansion to mobile health
- **Adaptive Feedback** → Monitoring, evaluation, and real-time adjustment based on structural equity benchmarks and community-led governance triggers

Each stage is supported by real tools, each mapped to a specific causal function and stakeholder group:

- **SDOH Diagnostic Template**: Identifies barriers and indicators across SDOH domains *(Stakeholders: Public Health Agencies, Researchers | Stage: Barriers → Indicators)*
- **Equity Tracking Dashboard**: Monitors disparities in access, uptake, and outcomes (Stakeholders: Local Government, Community Advocates | Stage: Indicators → Health Impacts)
- **Structural Equity Scenario Comparator**: Forecasts outcomes of proposed strategies by structural alignment and impact *(Stakeholders: Funders, Planners | Stage: Diagnosis → Prevention)*
- **Intervention/Prevention Matching Matrix**: Connects structural risks to tailored interventions *(Stakeholders: CBOs, Public Health Agencies | Stage: Diagnosis → Matched Interventions)*
- **AI-Assisted Adaptation & Evaluation Module**: Assesses intervention effectiveness and recommends adjustments *(Stakeholders: Researchers, Systems Planners | Stage: Feedback)*
- **Community Feedback-to-Action Interface:** Enables residents to flag harms, contribute data, and verify influence *(Stakeholders: Community Members, Local Governments | Stage: Feedback → Diagnosis)*
- **Participatory Simulation Module:** Allows communities to model policy scenarios and project impacts before implementation *(Stakeholders: Policy Designers, Technologists | Stage: Diagnosis → Prevention)*
- **Proposal Evaluation Engine**: Evaluates funding proposals through a structural equity lens *(Stakeholders: Funders, Governments | Stage: Prevention → Feedback)*

Every feedback loop is governed by thresholds. Communities, for example, can trigger adaptive responses when equity deltas breach agreed limits. Escalation is not top-down; it's built into the governance fabric.

What Makes This Framework Different

- **Causal structure orientation**: Tackles root causes, not symptoms
- **Integrated toolchain**: Modular ecosystem that supports iterative change
- **Stakeholder-centered governance**: Entry points tailored to community leaders, funders, and policy designers
- **Real-time equity feedback**: Adjusts to shifting risk, rather than locking in static benchmarks
- **Public system focus**: Built to reshape how governments interpret harm and invest in resilience

Conventional wisdom says prevention is hard to fund because it's hard to prove. This system disproves that. It offers predictive insight, measurable outcomes, and structural traceability, making it not just easier to justify prevention, but harder to ignore it.

Outcome: A Structurally Aligned Public System

The result of activating this framework is more than improved performance; it's structural coherence. Roles remain distinct, but impact becomes shared. Each stakeholder has the tools to act, the data to improve, and the governance mechanisms to participate meaningfully in long-term system change.

This alignment produces a public health system that is:

- **Preventative**: Anticipates and reduces harm through early structural intervention
- **Participatory**: Centers communities in problem definition, design, and oversight
- **Transparent**: Makes power, trade-offs, and outcomes visible and traceable
- **Just**: Redistributes authority and accountability in ways responsive to history and context

This framework is not a future proposal—it's an operational model ready for integration. Whether through pilot activation, stakeholder training, or systems alignment, the path forward is clear: structural harm can be transformed, not just managed.

Proof of Concept Use Cases

The following cases are presented as proof-of-concept demonstrations of AI-driven interventions across diverse health and equity contexts. While they are not direct applications of our framework system, they illuminate key challenges — such as data access, stakeholder authority, and auditability — that the proposed framework is designed to address.

Each example illustrates core causal elements, stakeholder collaboration, and the strategic use of AI and diagnostic tools. The final note on "Unresolved Shortfalls" identifies areas where structural gaps persist, highlighting precisely the kinds of system weaknesses the framework seeks to resolve. Each shortfall can be mapped to a specific risk identified in the Risks section, such as Digital Exclusion, Tech-Centric Rollout, or Misaligned Metrics; these can be addressed by corresponding safeguards like participatory co-design, adaptive governance thresholds, or structural feedback triggers embedded in the framework.

To reinforce alignment with the Vision and Stakeholder architecture, examples include references to core system tools where applicable.

(Future versions of this section will expand to include additional use cases, stakeholder roles, and improve geographic and demographic balance.)

1. Los Angeles, CA: AI-Optimized Peer Networks for HIV Prevention

Causal Stages: Indicators → AI Diagnosis → Matched Interventions → Adaptive Feedback
Vision Capabilities: Prevention, Structural Translation
Stakeholders: Public Health Agencies, CBOs, Researchers
Function: Prevention & Intervention

Stakeholders Engaged: Public Health Agencies, Youth Advocates, CBOs, Researchers
Tools Used: AI social network analysis for peer leader identification (linked to: Structural Impact Mapping, Feedback-to-Action Interface) (Framework Tools: Structural Impact Mapping, Feedback-to-Action Interface)

Problem Identified: Youth experiencing homelessness faced high HIV exposure due to unstable housing, trauma, and disconnection from services.
Insight or Diagnosis: AI analyzed social networks to identify the most influential peer connectors to deliver health information, outperforming human guesswork.
Intervention Chosen: AI-selected peer leaders were trained to disseminate preventive behaviors.
Outcome Achieved: Youth reached through AI-supported peer outreach showed significant reduction in HIV risk behaviors versus control groups.
Unresolved Shortfalls: Governance of AI outputs and decision pathways remained institutional rather than community-based. These could be mitigated by implementing a Participatory Simulation Module or Co-Governance Review.
Study: JMIR Formative Research | AJPH Article

2. Mumbai, India: Predicting Dropout in Maternal Health Programs

Causal Stages: Indicators → AI Diagnosis → Matched Interventions → Adaptive Feedback
Vision Capabilities: Forecasting, Feedback Loops
Stakeholders: NGOs, Community Health Workers, Data Scientists
Function: Forecasting & Feedback
Stakeholders Engaged: ARMMAN (NGO), Data Scientists, Community Health Workers
Tools Used: AI dropout prediction model using demographic + call log data (linked to: AI Diagnostic Engine, Equity Tracking Dashboard) (Framework Tools: AI Diagnostic Engine, Equity Tracking Dashboard)

Problem Identified: A program experienced high dropout rates among low-income pregnant women who were receiving maternal care info via mobile phones.
Insight or Diagnosis: AI models predicted individual risk of program dropout weeks in advance based on behavioral and demographic patterns.
Intervention Chosen: Targeted outreach and support were provided for at-risk individuals before dropout occurred.
Outcome Achieved: Improved engagement and behavioral adherence; validated predictive outreach in low-resource settings
Unresolved Shortfalls: Data modeling remained externally controlled, with no evidence of frontline worker or patient ownership of insight generation. This could be addressed by implementing a Community Feedback-to-Action Interface and Veto Gate mechanisms.
Study: arXiv Preprint

3. Sub-Saharan Africa: Offline AI for Mobile Diagnostics

Causal Stages: Barriers → SDOH Domains → Indicators → Matched Interventions
Vision Capabilities: Access Expansion, Translation
Stakeholders: Tech Developers, Clinics, Global NGOs
Function: Access & Translation
Stakeholders Engaged: Global Health NGOs, Local Clinics, Tech Developers
Tools Used: Mobile AI diagnostic app operable without internet (Framework Tools: Offline-Capable Diagnostic Engine, Intervention Matching Matrix)

Problem Identified: People in underserved, disconnected regions lacked access to healthcare infrastructure.
Insight or Diagnosis: Offline-capable AI enabled disease screening via mobile phones even in areas without connectivity or lab capacity.
Intervention Chosen: Mobile diagnostic tools (e.g., monkeypox screening) were deployed using AI-enabled clinics-on-wheels.
Outcome Achieved: Demonstrated functional diagnostics in low-bandwidth regions with successful deployment in remote pilot zones
Unresolved Shortfalls: While access improved, local stakeholders lacked input into tool design or diagnostic criteria. Mapped to Risk: Digital Exclusion. This could be mitigated through

implementation of Co-Design Protocols and Equity Threshold Alerts for tool deployment.
Study: arXiv Use Case

4. United States: Predicting Health-Related Quality of Life from SDOH

Causal Stages: Indicators → Health Impacts → AI Diagnosis → Prevention Targeting
Vision Capabilities: Structural Diagnosis, Impact Modeling
Stakeholders: NIH, Researchers, Health Planners
Function: Structural Diagnosis & Impact Modeling
Stakeholders Engaged: NIH All of Us, Public Health Planners, Researchers
Tools Used: ML models trained on longitudinal survey + SDOH data (Framework Tools: Structural Equity Scenario Comparator, AI Diagnostic Engine)

Problem Identified: Lack of integration between SDOH and planning for population-level well-being
Insight or Diagnosis: AI demonstrated strong predictive ability using housing, economic stress, emotional wellness, and access indicators.
Intervention Chosen: The program used findings to inform upstream resource targeting and prevention efforts.
Outcome Achieved: Validation of quality-of-life predictions from structural inputs; supports equity-aligned population health strategy
Unresolved Shortfalls: Predictive success did not necessarily translate into equitable governance. Mapped to Risk: Misaligned Metrics. Recommended safeguard: Feedback-to-Action Loop and Community Governance Escalation Trigger. The intervention pathway lacked community-defined thresholds or public oversight for resource targeting.
Study: MDPI Biomedical Engineering Paper

5. Global South (Multi-site): Ethical AI for Health Equity

Causal Stages: Barriers → SDOH Domains → Participatory Diagnosis → Intervention Design → Adaptive Feedback
Vision Capabilities: Governance, Localization, Ethical AI
Stakeholders: Local Researchers, Ministries of Health, Community Leaders
Function: Participatory Governance & Localization
Stakeholders Engaged: Local Researchers, Ministries of Health, NGOs, Community Leaders
Tools Used: Locally co-designed AI tools, context-specific interventions (Framework Tools: Participatory Simulation Module, Structural Impact Mapping Toolkit)

Problem Identified: Risk of imported, top-down AI systems failing in local health contexts
Insight or Diagnosis: Participatory methods and ethical frameworks were used to ensure that AI design reflected cultural context and community priorities.
Intervention Chosen: Locally led AI development for infectious disease management, maternal health, and triage systems
Outcome Achieved: Strengthened capacity, legitimacy, and relevance of AI tools; lessons published across 12 case studies
Unresolved Shortfalls: No visible process for community challenge or appeals when proposals are deprioritized by algorithmic filters. Mapped to Risk: Tokenistic Participation. Mitigation: Add Participatory Governance Layer and Shared Decision Audit Mechanism.
Study: Equity Assessment Tools Report

6. Ontario, Canada: Equity Assessment for Health Funding

Causal Stages: Indicators → Proposal Review → Matched Interventions
Vision Capabilities: Equity-Focused Grantmaking, Governance Integration
Stakeholders: Provincial Health Ministry, NGOs, Public Health Analysts
Function: Proposal Evaluation & Governance
Stakeholders Engaged: Provincial Health Ministry, Public Health Ontario, Local NGOs
Tools Used: Equity Impact Assessment (EIA) tool & AI filters (Framework Tools: Proposal Evaluation Engine, Equity Tracking Dashboard)

Problem Identified: Funding was directed to high-volume services without assessing equity impact, leaving marginalized populations underserved.

Insight or Diagnosis: EIA tools flagged proposals that lacked co-design and structural targeting. **Intervention Chosen:** AI-integrated evaluation filters prioritized equity-aligned proposals. **Outcome Achieved:** Improved grant distribution to communities facing structural exclusion **Unresolved Shortfalls:** No visible process for community challenge or appeals when proposals are deprioritized by algorithmic filters **Study:** Equity Assessment Tools Report

7. Appalachian Virginia: Health Wagon Mobile Clinics

Causal Stages: Barriers → SDOH Domains → Indicators → Matched Interventions → Adaptive Feedback
Vision Capabilities: Access Planning, Real-Time Adaptation
Stakeholders: Community Nurses, Rural Nonprofits, Advocates
Function: Access & Adaptive Feedback
Stakeholders Engaged: Rural Nonprofits, Community Nurses, Local Health Advocates
Tools Used: Mobile scheduling, service tracking dashboard (Framework Tools: Adaptive Planning Interface, Equity Feedback Dashboard)

Problem Identified: Residents in rural Appalachia lacked access to basic preventive care. **Insight or Diagnosis:** Route optimization and feedback dashboards showed peak need areas and service gaps. **Intervention Chosen:** Scheduled mobile health outreach with real-time adaptation **Outcome Achieved:** Expanded reach, improved follow-up, and added counties served **Unresolved Shortfalls:** Service delivery was effective but relied on nonprofit leadership without structural decision authority or systemic budget guarantees. Mapped to Risk: Failure to Scale Equity. Mitigation: Tie operational funding to Equity Dashboard metrics and introduce community-triggered resource escalators **Study:** Health Wagon Wiki

8. U.S. Rural Hospitals: Predictive Budget Allocation

Causal Stages: Indicators → Forecasting → Structural Prevention
Vision Capabilities: Predictive Budgeting, System Sustainability
Stakeholders: Medicaid Offices, Economists, Rural Health Leaders
Function: Forecasting & Structural Prevention
Stakeholders Engaged: Medicaid Offices, Health Economists, Hospital Coalitions
Tools Used: AI-based closure risk forecasting, Medicaid policy integration (Framework Tools: Structural Equity Scenario Comparator, Funding Forecast Module)

Problem Identified: Hospital closures in rural communities due to reactive funding and underutilization
Insight or Diagnosis: Models predicted closures based on demographic and payer mix trends. **Intervention Chosen:** Budget targeting and Medicaid policy waivers to stabilize services **Outcome Achieved:** Preemptive investment averted closures in forecast-identified counties. **Unresolved Shortfalls:** Budget decisions were centralized, with no evidence of local or community validation of forecasting models. Mapped to Risk: Local Political Capture. Safeguard: Public Review Gate and Structural Equity Scenario Comparator embedded in funding protocols **Study:** KFF Rural Hospital Brief

9. United States (EPA): EJScreen for Environmental Health Equity

Causal Stages: Barriers → Indicators → Matched Interventions → Funding Targeting
Vision Capabilities: Structural Equity Mapping, Environmental Health Prioritization
Stakeholders: EPA, Health Departments, Environmental Advocates
Function: Structural Diagnosis & Funding Prioritization
Stakeholders Engaged: EPA, Local Health Departments, Community Advocates

Tools Used: EJScreen environmental justice indicators dashboard (Framework Tools: Environmental Risk Mapping Tool, Equity Prioritization Engine)

Problem Identified: Health and environmental remediation funds often missed the most burdened communities.
Insight or Diagnosis: EJScreen visualized the overlap of demographic vulnerability and environmental hazard.
Intervention Chosen: Targeted grant support and program design in identified high-risk zones
Outcome Achieved: Shifted federal funding to communities with compounding risk
Unresolved Shortfalls: While prioritization improved, decision pathways remained federal; community governance was consultative, not directive. Mapped to Risk: Surveillance Harms. Mitigation: Enforce transparency protocols and embed participatory Veto Gate for tool activation
Study: EJScreen Overview

Summary

These proof-of-concept examples demonstrate the powerful role AI can play in diagnosing disparities, optimizing interventions, and improving public health outcomes. However, each case also highlights structural gaps — particularly around decision-making authority, data ownership, and participatory governance — that limit their long-term equity impact.

By explicitly calling out these "Unresolved Shortfalls," this section underscores the essential argument for a more accountable, inclusive, and auditable system. The proposed framework was designed to address exactly these missing pieces—transforming promising but isolated interventions into sustainable, community-aligned systems of action.

(Future versions of this section will expand to include additional examples, incorporate underrepresented stakeholder groups, and improve geographic and demographic balance across cases.)

Potential Benefits: Systemic and Operational Outcomes

The following outcomes represent the structural, measurable results that systems can expect when this framework is implemented as designed. They are not abstract goals or idealistic aspirations; instead, they are operational consequences produced through the framework's use of threshold-based governance, participatory tools, and alignment with equity-focused causal logic.

Each outcome is grounded in a specific function of the system; mapped to a causal stage; supported by technical tools; and governed by defined decision protocols. Together, they form the operational spine of the framework's equity model, turning SDOH theory and AI capability into enforceable change.

These systemic and operational outcomes are what allow public systems to shift from fragmented, reactive services to coordinated, adaptive, and equity-driven governance.

Ensure Equitable Access and Usability of Tools

The framework will ensure all tools — including dashboards, diagnostics, and planning interfaces — are accessible across geographic, linguistic, and connectivity barriers. Offline compatibility, low-bandwidth modes, and multilingual interfaces will be prioritized.

This guarantees that communities most at risk of digital exclusion are not further marginalized by the very systems meant to serve them.

Tools: Offline-compatible diagnostics, multilingual interfaces, adaptive UI modules
Stakeholders: Rural users, linguistically diverse communities, low-connectivity regions
Causal Stage: Implementation → Feedback
Governance Trigger: Access gap alerts, tool use disparity thresholds
Risk if Unmet: Digital exclusion, intervention failure in underserved zones
Mitigation Tool: Conditional deployment freezes,

equity-triggered redistribution of access investment
Measurement: Tool access parity, usage rates across marginalized regions

Enable Causal Diagnosis of Health Disparities

The framework will move beyond symptom tracking by identifying structural barriers across SDOH domains. It will equip public health teams and analysts with tools like the SDOH diagnostic template and indicator mapping to trace upstream causes, such as housing instability or broadband exclusion.

By identifying root causes rather than symptoms, the system will enable earlier, more targeted action that will reduce long-term health inequities and improve resource targeting.

Tools: SDOH diagnostic template, indicator mapping
Stakeholders: Public health teams, data analysts
Causal Stage: Diagnosis
Governance Trigger: Threshold indicators from upstream data
Risk if Unmet: Misdiagnosis, ineffective intervention
Mitigation Tool: Audit-triggered review system
Measurement: Reduction in preventable health disparities

Deliver Precision Interventions Informed by Local Conditions

The framework will align interventions with place-specific barriers and opportunities. The intervention/prevention matching matrix will enable governments, CBOs, and funders to deploy tailored, context-aware solutions grounded in local realities.

This will improve intervention success rates, ensure cultural and geographic fit, and avoid wasteful deployment of one-size-fits-all programs.

Tools: Matching matrix, local needs assessment
Stakeholders: CBOs, funders, local government
Causal Stage: Intervention
Governance Trigger: Geographic or demographic threshold mapping
Risk if Unmet: Misaligned programs, wasted funding
Mitigation Tool: Scenario validator in AI planning suite
Measurement: ROI increase, population reach by region

Support Early-Warning and Preventive Action

The framework will enable forecasting of health and equity impacts before crises emerge. Predictive modeling — via the AI diagnostic engine — will help funders and policy planners allocate resources proactively, reducing preventable harm like ER overuse or maternal mortality.

This will lead to earlier interventions, reduce preventable harm, and lower long-term system burden through proactive rather than reactive health measures.

Tools: Predictive modeling, AI diagnostic engine
Stakeholders: Funders, policy planners
Causal Stage: Forecasting → Prevention
Governance Trigger: Model-forecast thresholds
Risk if Unmet: Crisis escalation, system overload
Mitigation Tool: Real-time dashboard alerts
Measurement: Crisis avoidance rate, ER trend decline

Build Public Trust Through Co-Design and Shared Governance

This includes enforcing participatory thresholds, shared decision audits, and transparency gates that allow communities to escalate concerns when trust is broken.

Stronger community trust will increase engagement, compliance, and the long-term sustainability of programs designed to address local needs.

Tools: Equity dashboards, data transparency protocols
Stakeholders: Community leaders, public boards

Causal Stage: Problem Framing → Adaptation
Governance Trigger: Community input thresholds
Risk if Unmet: Loss of legitimacy, public resistance
Mitigation Tool: Feedback sessions and dashboard comment logs
Measurement: Community engagement rate, feedback volume

Improve Grantmaking and Resource Allocation

This will ensure that limited funding is directed toward interventions with the greatest structural impact, increasing ROI and equity outcomes.

It also ensures community accountability is embedded in funding logic, aligning grant cycles with structural harm forecasts and equity-based eligibility scoring.

Tools: Logic models, forecasting tools, equity dashboards
Stakeholders: Funders, public agencies
Causal Stage: Resource Allocation
Governance Trigger: Equity-impact forecasting score
Risk if Unmet: Structural inequities remain underfunded
Mitigation Tool: Equity prioritization rules in review portals
Measurement: ROI of high-priority investments

Enable Rapid, Real-Time Learning and Adjustment

The framework will use feedback systems to detect early signs of program underperformance or disparity. The AI-assisted adaptation module and equity dashboard feedback loops will support responsive corrections, critical for pilot phases and scaling efforts.

Improved responsiveness will reduce harm, support adaptive management, and protect vulnerable populations from prolonged policy or program failure.

Tools: AI adaptation engine, equity dashboards
Stakeholders: Program evaluators, technologists
Causal Stage: Feedback → Adaptation
Governance Trigger: Real-time performance flag
Risk if Unmet: Delayed corrections, prolonged inequity
Mitigation Tool: Escalation logic tied to dashboard feedback
Measurement: Time to correction, outcome recovery speed

Reduce Waste by Aligning Spending to Structural Need

The framework will minimize inefficiencies by directing resources to structural causes, not symptoms. Funding will flow toward documented equity gaps rather than political priorities or surface-level metrics.

As a result, public funds will be used more effectively, reaching underserved populations and closing structural gaps that fuel long-term disparities.

Tools: Equity gap maps, structural prioritization filters
Stakeholders: Funders, budget planners
Causal Stage: Diagnosis → Resource Allocation
Governance Trigger: Verified structural inequity
Risk if Unmet: Funds diverted to low-impact areas
Mitigation Tool: Spending threshold alerts by SDOH domain
Measurement: % funds redirected to structural causes

Shift AI from Extractive to Reparative Use in Public Systems

The framework will repurpose AI to support structural repair, equity forecasting, and culturally grounded measurement of success, instead of optimizing for surveillance or efficiency alone.

This will reorient AI toward community benefit, producing insights that will directly serve impacted populations and guide ethical intervention design.

Tools: Reparative AI metrics, ethical impact models
Stakeholders: Technologists, ethics reviewers,

CBOs

Causal Stage: Tool Development → Intervention Design
Governance Trigger: AI tool audit and community approval
Risk if Unmet: Perpetuation of extractive or biased systems
Mitigation Tool: Reparative feedback loop, external review gate
Measurement: Bias reduction, equity score per deployment

Strengthen Multi-Sector Coordination and Governance Readiness

The framework will create a shared infrastructure of language, logic models, and toolkits that will enable sustained collaboration among health departments, funders, community leaders, technologists, and analysts.

This will reduce siloed efforts, increase system-level alignment, and support the kind of cross-domain coordination required for structural change.

Tools: Shared dashboards, logic models, common protocols
Stakeholders: Health departments, technologists, funders
Causal Stage: Implementation → Governance
Governance Trigger: Joint approval or coordination milestones
Risk if Unmet: Fragmentation, conflicting actions
Mitigation Tool: Multi-party coordination engine
Measurement: Cross-agency alignment score, joint initiative count

Build Institutional Capacity for Equity Stewardship

The framework will ensure that equity knowledge, tools, and practices persist across leadership transitions. Modular systems and shared dashboards will embed institutional memory, helping systems retain lessons, scale learning, and maintain momentum beyond any single initiative.

This will ensure continuity and embed equity frameworks into standard practice, improving long-term effectiveness and resilience across policy cycles.

Tools: Shared dashboards, equity training modules, knowledge repositories
Stakeholders: Government agencies, funders, researchers
Causal Stage: Capacity Building → System Resilience
Governance Trigger: Leadership turnover, system review triggers
Risk if Unmet: Equity erosion over time, knowledge loss
Mitigation Tool: Equity continuity protocol
Measurement: Equity retention score post-transition, documentation reuse rate

Conclusion

These systemic and operational outcomes demonstrate how the framework translates principles into practice. Each outcome is the result of deliberate design: activated by causal logic, governed by enforceable triggers, and aligned with tools that equip systems to act with purpose and precision.

By embedding equity into structure, measurement, and adaptation, the framework enables public systems to evolve beyond fragmented services and crisis response. Instead, it supports a coordinated model of governance: one capable of diagnosing root causes, forecasting harm, elevating community voice, and delivering reparative outcomes at scale.

This is how systems move from intention to integrity, from promising equity to building it.

Risks and Mitigations

The responsible deployment of AI-supported systems depends not only on what these systems aim to achieve, but on what they are structurally designed to prevent. This section identifies nine systemic risks that threaten to undermine equity, legitimacy, and effectiveness across the framework's life cycle. These risks span every layer — from data sourcing to policy deployment — and reflect deep

points of vulnerability where inequity can be reproduced or amplified.

Each risk is presented with its corresponding mitigation strategy, a clearly defined success state, governance logic, and real-world illustration. These risks are not theoretical; they reflect recurring patterns observed in public systems when equity is not embedded from the outset. By mapping each risk to a causal stage, stakeholder group, and benefit dependency, this section supports proactive design and accountable implementation.

The purpose of the framework is to build adaptive, trust-centered systems that reinforce structural equity. To do so, it must be capable of detecting, responding to, and correcting for these known points of failure before harm occurs.

Risk 1: Biased or Non-Representative Data

Risk: Bias is baked into many of the datasets used in public systems. Structural inequities are often reflected, magnified, or rendered invisible through data collection methods that prioritize scale over nuance or exclude marginalized communities. Without active intervention, this bias is carried into predictive models and policy tools.

Mitigation: Embed community-led data collection and third-party model audits to ensure inclusive, context-aware inputs for diagnosis and forecasting

Causal Stage(s): Diagnosis, Evaluation

Success State: The system continuously reflects lived realities, prioritizing inclusivity in predictive analytics and program design.

Trigger Logic: Disparities detected in predictive outputs or flagged community mismatches in model results

Governance Actor: Independent model audit board + community data stewards

Escalation Mechanism: Mandatory audit trigger; halt on model deployment until bias threshold addressed

Impacted Stakeholders: Analysts, Implementation Teams, Funders

Examples: Mumbai, US HRQoL, Global South, Riverbend

If Unmitigated, Undermines: Causal diagnosis of disparities and equitable predictive design. Related Benefits: Enable Causal Diagnosis, Improve Grantmaking. Feedback Trigger: Equity breach detection in upstream model outputs

Risk 2: Digital Exclusion

Risk: Many of the communities most affected by health and infrastructure failures are also digitally excluded, whether due to geography, poverty, or systemic underinvestment. If digital access is assumed, these communities will be further marginalized by tools meant to serve them.

Mitigation: Design low-bandwidth, offline-compatible, and multilingual tools to support accessibility in underserved and rural areas.

Causal Stage(s): Implementation, Feedback

Success State: All user groups, regardless of location or device, are able to access tools and receive timely interventions.

Trigger Logic: Detection of geographic or demographic gaps in tool access or response rates

Governance Actor: Local implementation teams + digital equity monitors

Escalation Mechanism: Conditional deployment freeze or reallocation of funding until access parity is confirmed

Impacted Stakeholders: Community Coalitions, Public Health Teams

Examples: Sub-Saharan Africa, Appalachian VA, Mumbai, Riverbend

If Unmitigated, Undermines: Equitable access and timely intervention for all communities. Related Benefits: Ensure Access Equity, Deliver Precision

Interventions. Feedback Trigger: Tool access gaps or usage disparity

Risk 3: Surveillance Harms

Risk: Without strong protections, AI systems meant for public health can become tools of surveillance. Communities already over-policed may be targeted through predictive profiling or data misuse, further undermining trust in institutions.

Mitigation: Implement community-owned governance and privacy safeguards to limit misuse of AI for monitoring or profiling

Causal Stage(s): Design, Implementation, Feedback

Success State: Data collection and system use are community-approved, with clear, enforceable limits and consent protocols.

Trigger Logic: Unauthorized data usage or profiling detected; feedback from communities or watchdog groups

Governance Actor: Privacy oversight board + co-governance body

Escalation Mechanism: Immediate rollback of implicated system features; public audit disclosure

Impacted Stakeholders: Community Members, Data Stewards, Technologists

Examples: Global South, EPA, Riverbend

If Unmitigated, Undermines: Trust, consent-based governance, and ethical data use. Related Benefits: Build Public Trust, Shift AI from Extractive Use. Feedback Trigger: Privacy dashboard alerts, unauthorized data audit log

Risk 4: Tech-Centric Rollout

Risk: When systems are developed without the people they affect, they fail. Tech-driven solutions risk irrelevance — or harm — when they don't reflect community knowledge, context, or cultural logic.

Mitigation: Require co-design processes and local trust scaffolding to prevent disconnection from lived realities and social context

Causal Stage(s): Design, Implementation

Success State: System design and rollout reflect real community needs and are co-owned by those most affected

Trigger Logic: Community disconnect signals—e.g., tool rejection, low engagement, or formal complaints

Governance Actor: Community review councils + project implementers

Escalation Mechanism: Halt deployment; require redesign with co-design documentation and approval

Impacted Stakeholders: Implementation Teams, Educators, Local Leaders

Examples: Ontario, Global South, Riverbend

If Unmitigated, Undermines: Community-aligned design and locally responsive implementation. Related Benefits: Build Public Trust, Enable Rapid Adjustment. Feedback Trigger: Community rejection metrics, trust dashboard signal

Risk 5: Failure to Scale Equity

Risk: Even well-designed pilots can lose their equity focus as they scale. Without safeguards, programs drift toward efficiency, replicability, or political expedience, leaving the most impacted behind.

Mitigation: Use equity dashboards and structural alignment metrics to evaluate and iterate on system performance

Causal Stage(s): Evaluation, Adaptation

Success State: Equity remains a central evaluation metric from pilot to national deployment.

Trigger Logic: Divergence in equity metrics during pilot-to-scale transition (e.g., reduced reach to priority groups)

Governance Actor: Structural equity review board + funder advisory group

Escalation Mechanism: Performance-based funding tied to equity indicators; intervention plans required

Impacted Stakeholders: Public Health Agencies, Policy Designers, Data Analysts

Examples: Ontario, Mumbai, Riverbend

If Unmitigated, Undermines: Continuity of structural equity during program scale and replication. Related Benefits: Build Institutional Capacity, Enable Rapid Adjustment. Feedback Trigger: Divergence in equity dashboard signals post-scaling

Risk 6: Misaligned Metrics

Risk: What we measure defines what we value. If success is defined by speed or cost-efficiency, equity will always lose. Tools must be designed to reward systems-level improvement, not surface-level throughput.

Mitigation: Integrate structural indicators into success criteria using equity dashboards, prioritizing outcomes linked to repair, not throughput

Causal Stage(s): Evaluation, Feedback

Success State: Evaluation tools prioritize structural change and community impact over speed or scale alone.

Trigger Logic: KPIs deviate from equity outcomes; tools prioritize throughput over structural change.

Governance Actor: Evaluation standards committee + civic accountability office.

Escalation Mechanism: Metric reset protocols; program redesign until structural indicators are restored

Impacted Stakeholders: Evaluation Teams, Funders, Civic Auditors

Examples: EPA, Ontario, US HRQoL, Riverbend

If Unmitigated, Undermines: Meaningful equity evaluation and feedback-driven improvement. Related Benefits: Enable Rapid Adjustment, Improve Evaluation Accuracy. Feedback Trigger: Structural indicators drift from equity benchmarks

Risk 7: Tokenistic Participation

Risk: Community engagement is not enough if it lacks power. Many systems invite participation but fail to act on it. This creates disillusionment and deepens mistrust, especially in communities already excluded.

Mitigation: Require shared decision-making roles and feedback-to-action audits to ensure community input shapes design and deployment

Causal Stage(s): Design, Feedback

Success State: Community voice is embedded in decision-making, with visible impact on system direction and outcomes.

Trigger Logic: Feedback loops ignored; participation tracked without decision influence

Governance Actor: Co-governance council + participation auditor.

Escalation Mechanism: Participation audit score triggers corrective action; eligibility for continuation depends on meeting shared decision-making standards.

Impacted Stakeholders: Community Coalitions, Co-Governance Bodies

Examples: Global South, Riverbend

If Unmitigated, Undermines: Shared power, community legitimacy, and participatory accountability. Related Benefits: Build Public Trust, Strengthen Governance Readiness. Feedback Trigger: Participation audit score drop or engagement loss signal

Risk 8: Local Political Capture

Risk: In some settings, tools and data may be co-opted by dominant political actors to reinforce power or punish dissent. If equity tools are not protected, they can become weapons of inequity.

Mitigation: Build protections through open governance standards, transparency protocols, and third-party evaluations to preserve framework integrity

Causal Stage(s): Design, Adaptation

Success State: Decision-making structures are transparent, and checks prevent consolidation of control.

Trigger Logic: Evidence of biased use of tools by dominant actors; bypass of transparency mechanisms

Governance Actor: Independent ethics committee + civic oversight body

Escalation Mechanism: Emergency intervention clause; freeze access to tools/data until third-party review completed

Impacted Stakeholders: Civil Society Advocates, Oversight Bodies, Local Government

Examples: EPA, Ontario, Riverbend

If Unmitigated, Undermines: Integrity of open governance and protection from misuse of tools. Related Benefits: Ensure Governance Readiness, Build Public Trust. Feedback Trigger: Public audit threshold breach, transparency veto activation

Risk 9: Vendor Lock-In / IP Dependency

Risk: Public systems should not be dependent on private contracts to function or adapt. Overreliance on proprietary tech creates fragility, cost escalations, and an inability to evolve tools over time.

Mitigation: Prioritize open-source, auditable tools and local technical capacity building to reduce dependency on proprietary systems

Causal Stage(s): Implementation, Adaptation

Success State: Communities and public agencies retain long-term control, customization rights, and continuity beyond vendors.

Trigger Logic: Tool failures tied to proprietary limitations or inability to adapt without vendor

Governance Actor: Procurement oversight board + public agency CTO

Escalation Mechanism: Triggered shift to open-source replacement plan; vendor contracts renegotiated with exit clauses

Impacted Stakeholders: Government IT, Implementation Teams, Technologists

Examples: Sub-Saharan Africa, Global South

If Unmitigated, Undermines: Public sector autonomy, long-term continuity, and adaptive capacity. Related Benefits: Build Institutional Capacity, Shift AI from Extractive Use. Feedback Trigger: Contract lock alert or system customization barrier breach

Summary

These risks are not isolated technical oversights; they are persistent structural patterns that emerge when equity is not embedded into the logic of systems. Whether through data collection practices, digital access gaps, design failures, or governance breakdowns, these risks reflect the recurring ways that AI-supported public systems can reinforce the very disparities they aim to resolve.

To counter these risks, each safeguard reflects a proactive step to reduce harm, increase legitimacy, and ensure the system remains accountable to the communities it serves. By embedding mitigation strategies at every causal stage, the framework aims to prevent extractive outcomes and uphold structural equity from the outset. This ensures that tools, decisions, and stakeholders are all aligned

toward the same goal: protecting community trust, redistributing institutional power, and delivering measurable improvements in equity outcomes.

Taken together, the risk section operates as both a diagnostic map and a governance blueprint. When viewed in parallel with the benefits section, each reinforces the other: every benefit the framework seeks to deliver has a risk that could undermine it, and every risk is paired with mechanisms for early detection, escalation, and repair.

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Chapter 17: Conclusion

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This Blueprint is the result of hundreds of hours of discussions, writing, and production. Our hope is that it will be a valuable resource for you in several ways.

Information: This document is rich with details based on actual experience with attempts to encourage innovation in healthtech. It also contains insights that can inform many aspects of creating change through new products and services.

Sparking discussion: You may find many of the concepts and insights contained in this Blueprint to be thought provoking. We encourage you to act on that reaction and start discussions with friends and colleagues about how these might apply to your projects.

Inspiration: Perhaps most of all, we hope that this content serves to trigger new ideas for healthtech innovation. Much can be done to make healthcare more available, more efficient, and more effective, and new approaches to healthtech will lead the way.

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For more information about the Coalition for Innovation,
including how you can get involved, please visit coalitionforinnovation.com.